

“ASPICon 2023”

1st Annual
Conference of
Academic Society
of Pharmacologist of IGIMS



SOUVENIR
cum
Abstract Book

THEME: “Precision Clinical Pharmacology: Future of Rational Therapeutics”

17th - 19th
August, 2023

Supported by:



Department of Pharmacology

Indira Gandhi Institute of Medical Sciences, Patna, Bihar-800014

Under aegis of : Indian Pharmacological Society Bihar State Branch



Welcome all Delegate

to

1st

Annual Conference of

Academic Society of Pharmacologist of IGIMS

“ASPICon 2023”

18th - 19th

August, 2023

**& Pre-Conference Workshop
On 17th August, 2023**

THEME: “Precision Clinical Pharmacology : Future of Rational Therapeutics”

Organized By :

Department of Pharmacology

Indira Gandhi Institute of Medical Sciences, Patna, Bihar-800014

Under aegis of : Indian Pharmacological Society Bihar State Branch



“ASPICon 2023”

Messages



Rajendra Vishwanath Arlekar
Honourable Governor of Bihar
Raj Bhavan, Patna-800022



It is a matter of great pleasure that the Department of Pharmacology, IGIMS, Patna is organizing 1st Annual Conference of Pharmacologist of IGIMS (ASPICon2023) on 18th & 19th August, 2023. The conference is preceded by two pre-conference workshops on Animal Handling and Experimental Pharmacology and Analytical Biochemical Assays in Experimental Pharmacology on 17th August 2023.

The theme of the conference "Precision Clinical Pharmacology: Future of Rational Therapeutics" is very meaningful for the doctors and researchers to understand and predict which treatments are more likely to work for a patient.

I congratulate the organizers for organizing this national conference as well as the workshops which will highlight the important areas of the medical sciences.

I extend my best wishes for the grand success of the scientific events.

Rajendra Vishwanath Arlekar



बिहार सरकार

Tejashwi Prasad Yadav
Honourable Deputy Chief Minister
cum Health Minister of Bihar
Secretariat,
Patna - 800 022



I am pleased to know that the Department of Pharmacology, Indira Gandhi Institute of Medical Sciences, Patna is organizing the first Annual Conference of Pharmacologists at IGIMS on 18th & 19th August, 2023.

The theme of the conference 'Precision Clinical Pharmacology: Future of Rational Therapeutics' is extremely important for updating the knowledge and skills of the medical professionals and budding young scientists.

I hope the conference would provide an ideal platform for all the healthcare professionals, esteemed delegates and experts to interact with each other and extend the frontiers of the discipline of Pharmacology.

I extend my warm greetings to the organizing committee members and wish the conference a grand success.

Tejashwi Prasad Yadav



Prof. Bindey Kumar
Director-cum- Vice Chancellor
Indira Gandhi Institute of Medical Sciences,
Sheikhpura, Bailey Road,
Patna - 800014.

Message

With immense pleasure and joy I extend my best wishes to the organisers of 1st Annual Conference of Academic Society of Pharmacologists of IGIMS (ASPICon2023).

The deliberations, presentations and interactions will definitely bring new information to the participants of this conference. The pre-conference workshop on "Precision Clinical Pharmacology: Future of Rational Therapeutics" and Animal Handling & Experimental Pharmacology will also be useful to the researchers and doing basic works on different pharmaceutical agents.

Recent developments in artificial intelligence, quantum computing and other mathematical models like super computers will be discussed in this conference and this will open, a new vista in the field of research.

Thanking you

Prof. Bindey Kumar



Dr. Manish Mandal

Dy. Director (Admn.)-cum-
Medical Superintendent-1
Indira Gandhi Institute of Medical Sciences,
Sheikhpura, Bailey Road,
Patna - 800014.

Message

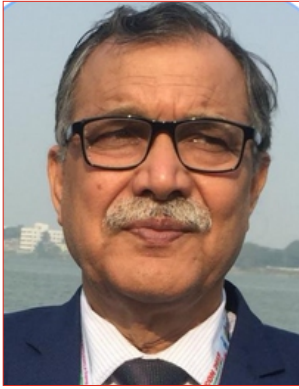
It gives me immense pleasure and joy to welcome all distinguished delegates, invitees and participants in the 15 Annual Conference of Academic Society of Pharmacologist of IGIMS (ASPICon2023), organized by Department of Pharmacology, Indira Gandhi Institute of Medical Sciences (IGIMS), Patna. The conference intends to explore the role of personalized medicine in modern era.

The adoption of PM practices in hospitals requires the interaction of different medical disciplines including Clinical Pharmacology. Clinical Pharmacology tells about the promotions of rational use of medications in humans by studying their restorative effect to amplify the effect of drugs and reduce their side effects. Clinical Pharmacology follows the optimal use of drugs by applying the provisions of personalized Pharmacotherapy, taking into consideration the factors that have an influence on the inter-individual variation of drug response. Personalized medicine has created a dynamic opportunity for Pharmaceutical companies developing molecular-targeted therapeutics, but also through the optimised use and repurposing of existing drugs and combination therapies.

Personalized medicine has potential to offer improved medication selection and targeted therapy reduce adverse effects, increase patient compliance, shift the goal of medicine from reaction to prevention, improve cost effectiveness and increase patient confidence post-marketing by approving novel therapeutic strategies and altering the perception of medicine in the healthcare system.

I extend my wishes for success of the conference, which will have a larger impact on doctors/healthcare worker/ officers at large.

Dr. Manish Mandal



Prof. (Dr.) Harihar Dikshit
Chairman, ASPICon2023
President, ASPI
Secretary, IPS Bihar Chapter,
Prof. & Head, Dept. of Pharmacology,
Assoc. Dean (Academic), IGIMS, Patna.

Message

It is great privilege and honour for me to welcome you all to the 1st Annual Conference of Academic Society of Pharmacologist of IGIMS (ASPICon2023). The theme of the Conference is "Precision Clinical Pharmacology: Future of Rational Therapeutics". I am happy that an extensive and comprehensive programme has been planned to discuss the theme, recent trends, prospects, and future directions of clinical pharmacology in precision medicine for ensuring rational prescribing.

As the president and founder of ASPI, I extend my gratitude to members of the society for successfully organizing the conference as the initial and great step in achieving its primary goal of promoting departmental research, education and training in clinical pharmacology research, pre-clinical studies and allied subjects.

There are two preconference workshops on "Animal Handling and Experimental Pharmacology" & "Analytical Biochemical Assays in Experimental Pharmacology". We are grateful to NIPER, Hajipur for collaborating with us in successfully organizing the workshop on "Analytical Biochemical Assays in Experimental Pharmacology" for the goal of making students and researches acquainted with basic knowledge and skills in pre-clinical research.

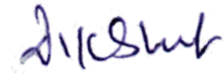
We are grateful to the Indian Pharmacological Society for reposing full faith in us to make this event a reality. The Organizing Committee has strived really hard to put up a wonderful scientific programme for all of you.

An academic feast is going to be served by renowned and learned speakers on most of the relevant and important topics such as artificial intelligence in pharmacovigilance, pharmacogenetics and treatment optimization in psychiatry, oncology, and diabetes; adaptive clinical trial; antibiotic stewardship program in hospital setting etc. Hope, these discussions will set trends, prospects and future directions of clinical pharmacology in precision medicine and research for ensuring rational prescribing.

The organising committee has tried their best to ensure comfortable stay, delicious food and rich academic feast. I also extend my gratitude to the Director Prof. (Dr.) Bindey Kumar, Dean (Academic) Prof. (Dr.) V. M. Dayal, Deputy Director Prof. (Dr.) Manish Mandal, Principal Prof. (Dr.) Ranjit Guha, all faculties, DM student, SRs, and MD students of department of Pharmacology and faculties, resident doctors and all

employee of IGIMS, sponsors, delegates, my local organising committee members, and student volunteers for their active participation in making this conference a successful scientific event, a step towards Rational Pharmacotherapeutics.

Once again, I extend a warm welcome to all of you at an event that promises to be exciting as well as enriching. May you have a pleasant stay here with lots of smart memories to carry back home.



Prof. (Dr.) Harihar Dikshit



Prof. (Dr.) Lalit Mohan
Organizing Secretary,
ASPICon2023
Assoc. Dean-I (Exam.)
IGIMS, Patna

Message

It gives me immense pleasure and honour to welcome you all delegates to the 1st Annual Conference of Academic Society of Pharmacologist of IGIMS (ASPICon2023) at Indira Gandhi Institute of Medical Sciences, an Institute of excellence, Patna. The conference will run on the theme “Precision Clinical Pharmacology: Future of Rational Therapeutics” with the goal of sharing knowledge and skills on optimal and safe use of drugs by applying the provisions of personalized pharmacotherapy.

We are grateful to the Indian Pharmacological Society and Academic Society of Pharmacologist of IGIMS for reposing full faith in us to make this ASPICon2023, a reality. The organizing committee has strived really hard to put up a wonderful scientific programme for all of you under the dynamic leadership of Prof. (Dr.) Bindey Kumar, Director-cum Vice Chancellor, IGIMS, Prof. (Dr.) N.R. Biswas, Ex-Director-cum Vice Chancellor, IGIMS, Prof. (Dr.) Ashutosh Biswas, Ex-Director-cum Vice Chancellor, IGIMS, Prof. (Dr.) V. M. Dayal, Dean (Acad), Prof. (Dr.) Manish Mandal, Dy. Director (Admn.) cum MS- 1, Prof. (Dr.) Om Kumar, Dean (Exam), Prof. (Dr.) Rajesh Kumar, Dean (Research), Prof. (Dr.) Ranjit Guha, Principal, Prof. (Dr.) Aman Kumar, MS-2, Prof. (Dr.) Avanish Kumar, Faculty-In-Charge Finance, Prof. (Dr.) Naresh Kumar, Prof. (Dr.) Indu Sinha, Dr. Keshav Kumar Sinha, Dr. Hitesh Mishra, Dr. Manish Kumar, Dr. Sukalyan Saha Roy, Dr. Adil Ali Shakur, Dr. Md. Margoob Ahmad, Dr. Pankaj Prabhakar, Dr. Noor Husain, Dr. Purnendu Arya, Dr. Raushan Kumar Ranjan, Dr. Rinki Thakur, Dr. Chakrapani Kumar, Dr. Saajid Hameed, Khushboo, Ritika Raj, Dr. Mukesh Kumar, Dr. Amrendra Kumar Arya, Dr. Ravi Roushan, Dr. Rajeev Kumar Neeraj, Dr. Nitu Pandey, Dr. Chandani Prakash, Ms. Suchitra Kumari, Mr. Prem Nath Sharma, Mr. Pradeep Kumar Singh, Mr. Rabindra Kumar Singh & Md. Shakil Ahmad to name a few.

I extend my gratitude to our esteemed Organizing Chairman Prof. (Dr.) Harihar Dikshit, Head, Dept. of Pharmacology, & Assoc. Dean (Academic), IGIMS, Patna for his consistent guidance and inspiration.

There are two preconference workshops on (i) “Animal Handling and Experimental Pharmacology” in collaboration with PGIMER, Chandigarh & Kasturba Medical College, Manipal and (ii) “Analytical Biochemical Assays in Experimental Pharmacology in collaboration with NIPER, Hajipur” to promote knowledge and skills of

healthcare researchers. We are thankful to the our collaborators Prof. (Dr.) Bikash Medhi, Prof. (Dr.) Smita Shenoy, Dr. Meena Kumari K, Dr. Debabrata Mandal, Dr. Vipin Kumar Parihar, Dr. P. Ramalingam, Dr. Krishna Murti, Dr. Nitesh Kumar, Dr Rahul, Dr Anupam and all team members for their constant support.

A high quality and informative scientific program is planned, which will strike a balance between various stakeholders in the academia, industries and regulatory of India and abroad. It will be an excellent opportunity to exchange knowledge & strike friendship. Members of Indian Pharmacological Society understand that health and science are global issues that require scientists from many different countries to work together. In order to accomplish this collaborative effort, students and career scientists come to the city of Patna to share their knowledge, participate in scientific conferences in the search for solutions ever growing advent of precision medicine for treatment of the diseases. Academic exchange in such medical subject is by its very nature based on bilateral exchange.

The organizing Committee has tried their best to ensure comfortable stay, delicious food, and rich academic exercise. I am especially thankful to all our invited faculties, chairpersons, and delegates coming from different parts of India.

I also extend my gratitude to all government employees, trade representatives, delegates, my organizing committee members, and student volunteers for their active participation in the conference.



Prof. (Dr.) Lalit Mohan



Dr. Hitesh Mishra
Editorial Team, IGIMS,
Patna



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Editorial Team, IGIMS,
Patna



Dr. Noor Husain
Editorial Team, IGIMS,
Patna



Dr. Saajid Hameed
Editorial Team, IGIMS,
Patna

Message

It is a proud privilege and pleasure to note down august gathering of eminent health care professionals, academicians and scientists from across the India. We accept the responsibility to release Souvenir and scientific abstracts from our distinguished contributors in the 1st Annual Conference of Academic Society of Pharmacologist of IGIMS (ASPICon2023), organized by Department of Pharmacology, Indira Gandhi Institute of Medical Sciences (IGIMS), Patna.

The central theme across this Souvenir is to bring all scientific proceedings and new developments together, in chronological orders, which are to happen in the 1st Annual Conference of Academic Society of Pharmacologist of IGIMS (ASPICon2023). It is a collective effort to make you familiar with the grand function to follow.

I as an editor and we as a team have tried our best to fasten all facts of the conference so that they find true recognition in our grand scientific forum.

I feel indebted to the entire organizing committee and the conference secretariat at Department of Pharmacology, Indira Gandhi Institute of Medical Sciences (IGIMS), Patna for their meaningful suggestions, complete involvement enormous help and support in the publication of this Souvenir and abstract.

I ask all of you who have contributed in the different ways to accept my apologies if my edits carry errors. We acknowledge the financial support extended to our project.

With warm regards.

Dr. Hitesh Mishra
Dr. Pankaj Prabhakar
Dr. Noor Husain
Dr. Saajid Hameed



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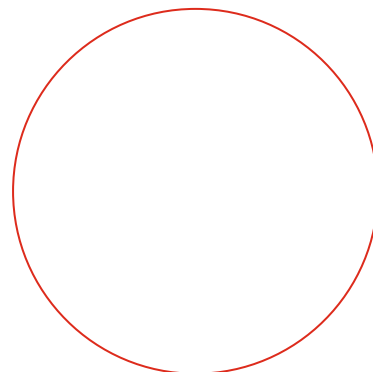
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“ASPICon 2023”

Programme



Programme Schedule

ASPICon2023

VENUE

Conference: K. K. Sharma Hall

Paper Presentation Sessions: Ranjit Roy Chaudhary Hall & Mohib Ahmad Hall

Poster Presentation Sessions: Auditorium Gallery

Day 1 (18th August 2023)

Time (Hours)	Topic for Symposium	Speaker
08:30–09:00	Registration and Breakfast	
09:00–09:05	Welcome Note	
09:05–09:45	<p>Prof. G. Achari Inaugural Oration of ASPI (Conference Theme Lecture): Precision Clinical Pharmacology: Future of Rational Therapeutics</p>	<p>Orator: Prof. (Dr.) Shantanu K. Tripathi Chairperson: Prof. (Dr.) N. R. Biswas, Prof. (Dr.) R. N. Sharma, Prof. (Dr.) Vijay Achari</p>
<p>Symposium-1: Patient Safety Chairpersons: Dr. Keshav Kumar Sinha, Dr. Vipin Kumar Parihar</p>		
9:45 - 10:00	Materiovigilance: Issues and Way Out	Dr. V. Kalaiselvan
10:00 – 10:20	Artificial Intelligence in Pharmacovigilance	Prof. (Dr.) Mira Desai
10:20 – 10:45	Drug Disposal and Environmental Health Concerns	Prof. Syed Ziaur Rahman
10:45-11:00	Evidence based drug information for medication safety	Mr. Ihtimam Hossain
11:00-13:00	<p>Parallel Sessions: Paper Presentation Session/ Poster Presentation Session / Symposia 2 & 3</p>	
<p>Symposium-2: Neuropsychopharmacology Chairpersons: Prof. (Dr.) Rajesh Kumar, Dr. Nupur Niharika, Dr. Manish Kumar</p>		
11:00 - 11:20	Pharmacogenetics and Treatment Optimization in Psychiatry	Dr. Vinay Kumar
11:21 – 11:40	Pharmacotherapy in Seizure Disorders with Co-Morbidities	Dr. Gunjan Kumar
11:41 – 12:00	Drug Therapy of Parkinsonism – Challenges and Strategies	Prof. (Dr.) Ashok Kumar
<p>Symposium-3: Pharmacotherapy of Diabetes Chairpersons: Prof. (Dr.) Sudhir Kumar, Prof. (Dr.) Asish k. Biswas, Dr. Rajiva Ranjan</p>		
12:01 - 12:20	Dealing with Cardiac Autonomic Neuropathy in Diabetes	Dr. Nirav Kumar
12:21 – 12:40	Pharmacotherapy of Diabetes – Focus on Reversal and Remission	Dr. Ajay Kumar
12:41 – 13:00	Challenges in Insulin Therapy – Focus on Access	Dr. Ved Prakash
13:00-14:00	LUNCH	



Programme Schedule

ASPICon2023



VENUE

Conference: K. K. Sharma Hall

Paper Presentation Sessions: Ranjit Roy Chaudhary Hall & Mohib Ahmad Hall

Poster Presentation Sessions: Auditorium Gallery

Time (Hours)	Topic for Symposium	Speaker
14:00-14:30	Guest Lecture: Electrophysiological Intervention in Arrhythmia	Dr. Ashutosh Kumar Chairpersons: Prof. (Dr.) Rajiv Kr Singh, Dr. Ravi Vishnu, Dr. Birendra Kr. Singh
14:30-15:00	Prof. R. A. Shakur Inaugural Oration of ASPI: Access to Affordable Medicines and Promotion of Rational Pharmacotherapy	Orator: Prof. (Dr.) N. R. Biswas Chairpersons: Prof (Dr.) Harihar Dikshit, Prof. (Dr.) Rani Indira Sinha, Prof. (Dr.) Naresh Kumar
15:00-17:00	Parallel Sessions: Free Paper Presentation Session/ Poster Presentation Session / Symposia 4 & 5	
Symposium-4: Reforms in Postgraduate Education in Pharmacology Chairpersons: Prof. (Dr.) Shantanu K. Tripathi, Prof. (Dr.) Bikash Medhi, Prof. (Dr.) Mira Desai		
15:00 – 15:15	Enabling factors for successful implementation of competency based UG and PG medical curriculum	Prof. (Dr.) Ranjit Guha
15:16 – 15:30	Post Graduate Curriculum – Planning for Self-Directed Learning	Prof. (Dr.) Nirmala Rege
15:31 – 15:45	Postgraduate Training – Focus on Formative Assessment	Prof. (Dr.) Dinesh Badyal
Symposium-5: Clinical Pharmacology Chairpersons: Prof. (Dr.) N. R. Biswas, Prof. (Dr.) Debasish Hota, Prof. (Dr.) S. M. Naser		
15:45 – 16:05	Organisation and conduct of Phase-1 Clinical Trial in India- Challenges and Regulations	Dr. Shubhadeep Sinha
16:06 – 16:25	Adaptive Clinical Trial	Dr. Anand Srinivasan
16:26 – 16:45	Clinical Trial Data Management	Prof. (Dr.) Bikash Medhi
16:46 – 17:00	TEA	
17:00-18:30	INAUGURATION	
18:30 onwards	Gala Dinner	



Programme Schedule

ASPICon2023



VENUE

Conference: K. K. Sharma Hall

Paper Presentation Sessions: Ranjit Roy Chaudhary Hall & Mohib Ahmad Hall

Poster Presentation Sessions: Auditorium Gallery

Day-2 (19th August 2023: Saturday)

08:30-09:00

Breakfast

Time (Hours)

Topic for Symposium

Speaker

Symposium-6: Antimicrobial Resistance

Chairpersons: Prof. (Dr.) S.K. Shahi, Prof. (Dr.) Namrata Kumari, Prof. (Dr.) Manish Shankar

09:00–09:20

Antibiotic Stewardship Program in Hospital setting vis-a-vis in the Community - Challenges and How to Overcome

Prof. (Dr.) Ashutosh Biswas

09:21–09:40

Preparation of Hospital Antibiotic Policy: Technical Guidance for Step-by-Step Workflow

Dr. Saibal Das

09:41–10:00

Choice of Appropriate Antimicrobials

Dr. Vikash Maharshi

10:00-10:30

Prof. SB Pandey Inaugural Oration of ASPI:
Neutraceuticals – Current Status and Future Perspectives in
India

Orator: Dr. B. Dinesh Kumar.
Chairperson:
Prof. (Dr.) Indu Sinha,
Prof. (Dr.) Deepak Kumar,
Dr. Asha Singh

10:30-11:30

Parallel Sessions: Free Paper Presentation Session/ Poster Presentation Session / Symposia 7

Symposium-7: Immunotherapeutics in Cancer

Chairpersons: Padma Shri Dr. Jitendra K. Singh, Prof. (Dr.) Rajeev Ranjan, Prof. (Dr.) Rajesh Kumar Singh

10:30-10:50

Immune Checkpoint Inhibitors: Challenges and Cautions

Dr. Alok Ranjan

10:51-11:10

Small Molecule Inhibitors in Haemato-Oncology

Dr. Avinash Kumar

11:11-11:30

Vaccines and Vaccination in Cancer Patients

Dr. Sanjeev Kumar

11:30-12:00

Prof. SNP Sinha Inaugural Oration of ASPI:
Drug Discovery – Historical Contributions by Indian Scientists

Orator: Prof. (Dr.) R.N. Sharma
Chairpersons:
Prof. (Dr.) Ranjit Guha,
Prof. (Dr.) Lalit Mohan,
Dr. Keshav Kr. Sinha

12:00-01:00

Valedictory Function, Prize Distribution & Felicitation

01:00 onwards

LUNCH & DISPERSAL



“ASPICon 2023”

Keynote Address

Dr. Santanu Kumar Tripathi

*Principal & Professor of Pharmacology
Netaji Subhas Medical College,
Bihta, Patna*



The discipline of medical therapeutics follows the norms and guidelines for the 'average patient'. This 'one-size-fits-all' approach seems a little too simplistic. It not really help all patients. The concept and approach of precision medicine concept are aimed at bridging this gap. Precision medicine is 'an innovative approach to tailoring disease prevention and treatment that takes into account differences in people's genes, environments, and lifestyles' (1). The goal is to target the the 3 R's - the right treatments to the right patients at the right time. And when we talk of disease prevention and treatment, we have to consider about drugs and pharmacotherapy. We ought to consider if the index drug treatment gels with the person in her/his context. To achieve this, we must think holistically and not in silo.

It is imperative that the disciplines of precision medicine and clinical pharmacology are very closely interdependent, sharing the same ecosystem (2) that accommodates areas like drug development clinical trials, drug regulatory affairs, health technology assessment, medication errors, off label use of drugs, repositioning of drugs, biomarkers, diagnostics, and above all rational therapeutics. This refers to emergence of the sub-discipline of precision clinical pharmacology that assures realization of the goal of rational therapeutics.

With the advent of pharmacogenomics, and emphasis on precision medicine, the concept of precision clinical pharmacology is evolving. The fullest application of clinical pharmacology principles in the context of precision medicine assures achievement of the goal of rational therapeutics. Of course cost is a major constraint at present. But with time it is hoped, the fruits of precision clinical pharmacology shall be more affordable. The future thus looks bright for the practice of precision medicine.

Dr. Mira K. Desai

*Dr. Mira Desai, MBBS, M.D
Clinical Pharmacologist,
Member, Signal Review Panel, PvPI
Former Professor & Head,
Pharmacology & Coordinator of RTC,
B. J. Medical College, Ahmedabad.*



Artificial Intelligence is a dawn of new era. It has already become an integral part of our personal lives from home to street and the technology is now pervading scientific research, health care system and pharmacovigilance.

Artificial Intelligence (AI) is a branch of computer science, statistics and engineering that uses algorithm to make intelligent machines that replicate intelligent human behavior. The machines acquire human intelligence by learning and training using huge volume of robust datasets, just like a child learns from teaching and training from the environment and becomes an intelligent human being. AI encompasses a variety of techniques such as machine learning, deep learning and natural language processing. Deep learning comprises of neural networks (like neurons in human brain) and teaches computers to process data in a way like human brain to solve a given problem that requires human understanding and reasoning.

Considering the ever-increasing drug safety reports in the database and other sources, implementation of AI based PV system offers opportunities to enhance and facilitate processing of ADR reports in a sophisticated and seamless way. AI technology promises of reducing the burden of manual, repetitive task of data entry and negate the need for routine reviews of single cases and manual identification and validation of signals. However, implementation of AI technology faces challenges such as accessibility, digitization and integration of health records, standardization of terminologies, quality and quantity of data, regulatory guidelines for data safety and privacy, ethical issues and financial support to establish and sustain PV systems etc.

Additionally, it also raises questions whether the qualitative assessment by AI technology to determine causal relationship and safety signals will be as good as PV experts? Can it completely replace the clinical experience of subject experts? The technology needs to be validated to prove whether it can complement or substitute human expertise and adds value to the existing system. We look forward for the next decade to provide more insight and evidence for implementation and practical impact of routine use of AI algorithm.

Syed Ziaur Rahman

*Prof. Syed Ziaur Rahman
Professor, Department of Pharmacology
Jawaharlal Nehru Medical College,
Aligarh Muslim University,
Aligarh 202002 (UP)*



A wide spectrum of forces underlies the generation of drug disposal for both used and leftover drugs, ranging from certain practices of manufacturers, distributors, prescribers, and dispensers, to patients themselves. Much of the need for drug disposal could be eliminated by focusing corrective actions on these forces. If new approaches to medical care were developed that could minimize or eliminate drug disposal, the consequent environmental residues of APIs would be eliminated, therapeutic outcomes might improve, health care expenses could go down, and human morbidity and mortality (due to addictive usage and poisonings from diverted, leftover drugs) would decline. Reducing, minimizing, or eliminating drug disposal via an active Pharmaco-Environmentology program represents a very significant opportunity to improve both ecological and human health.

Study material:

1. An Introduction to Environmental Pharmacology (ISBN 978-81-906070-4-9). Ibn Sina Academy, Aligarh, India, 2008 (Eds: SZ Rahman, M Shahid and V Gupta)

2. Syed Ziaur Rahman and Ahmad Zee Fahem, Environmental Pharmacovigilance (Chapter 1). In: Environmental Pharmacology of NSAIDs 2020: 1-33. Ed. Eugenia Yiannakopoulou (ISBN: 978-1-53617-466-3), Nova Science Publishers, New York, USA

3. S Z Rahman & R A Khan, Environmental Pharmacology - A New Discipline, Indian J Pharmacol 2006; 38 (4): 1-2

Mr. Ihtimam Hossain

*Clinical Drug Information Specialist,
Wolters Kluwer,
Singapore*



Medication safety is a pressing issue in healthcare systems around the World, including India

Multiple factors are implicated in poor medication safety practices, e.g. lack of knowledge and information, work culture, lack of manpower

Manufacturers' labelled information may be unable to address the needs of safe medication use in clinical practice

Healthcare professionals (pharmacologists, clinical pharmacists, nurses) need:

Reliable evidence-based drug information to make safe medication decisions in practice

Robust drug information skills to find and evaluate information to apply in complex clinical situations”

Dr. Gunjan Kumar

*Assistant Prof.
Department of Neurology, PMCH, Patna
Consultant Neurologist-BNDC*



Then last 3 decades have seen an exponential increase in the availability of Anti-epileptic drugs (AED). There are more than 30 AEDs in the market with their own metabolism, site of action, indications and contra-indications. No single AED is perfect, and it has become even more important to choose the AED according to the patient. Many of the patients have associated comorbidities with their own set of drugs further complicating the picture. The type of comorbidity is important in deciding the most suitable treatment, including that for acute epileptic seizure and chronic therapy.

Comorbidities may have a direct association with epilepsy or a complex association or be unrelated to epilepsy. The primary goal of therapy is seizure freedom with optimal therapy taking into consideration of potential side-effects and interactions. For example in patients with underlying cardiovascular diseases intravenous phenytoin can lead to arrhythmias with valproate or levetiracetam safer option. Many of the older drugs are enzyme inducing affecting levels of various blood thinners.

The level of scientific evidence is low in treatment of epilepsy with comorbidities and a rationale and informed decision has to be taken based on the best available evidence and clinical acumen.

Dr. Ashok Kumar

*MBBS, MD (Medicine), DM (Neurology).
Professor & Head of Neurology Dept
Indira Gandhi Institute of Medical Sciences,
Patna, Bihar*



Among the various forms of Parkinsonism, Parkinson's disease is most responsive to treatment. The treatment currently still focuses on replacing the levels of dopamine. Challenges exist in the management ranging from search of therapy to halt or slow the progression of disease to the pitfalls in the current therapy.

Current drugs for parkinsonism:

- Dopamine precursors: Levodopa
- Peripheral dopa decarboxylase inhibitors: Carbidopa
- Dopamine receptor agonists: Ropinirole, Pramipexole, Rotigotine, Apomorphine
- MAO B inhibitors: Rasagiline, Selegiline, Safinamide, Zonisamide
- COMT inhibitors: Entacapone, Tolcapone
- Amantadine
- Central anticholinergics: Trihexphenidyl, Procyclidine, Bzotropine

Challenges in current therapy:

Treatment of motor symptoms: Levodopa was previously avoided for treatment of early Parkinson's disease so that it can be used in the later part of illness when symptoms worsen. However, PD-MED trial found that patients treated with levodopa initially had persistent mobility benefits after 7 years as compared to patients started initially with dopamine agonists or MAO-B inhibitors¹. The patients had less likelihood of discontinuing levodopa as compared to dopamine agonists or MAO-B inhibitors due to adverse effects. But the incidence of levodopa induced dyskinesias was slightly higher in the Levodopa group.

National Institute of Health and Care Excellence (NICE) recommendations for initiating therapy:

- Consider Levodopa in patients with prominent motor symptoms affecting quality of life for early Parkinson's disease
- Levodopa/dopamine agonist/MAO-B inhibitors in patients with motor symptoms not affecting quality of life

Wearing off phenomenon: As the disease progresses, more frequent dosing of levodopa is required to minimise symptoms. Dopamine agonists, MAO B inhibitors or COMT inhibitors can be used adjunctly to reduce the frequency of levodopa dosing. MAO-B and COMT inhibitors degrade enzymes that block dopamine thus prolonging the action of Levodopa. Dopamine agonists should be used with caution as they are associated with impulse control disorders in up to 40% of individuals. In severe off periods and delayed onset of subsequent dosing, subcutaneous apomorphine and inhaled levodopa can be used.

On period dyskinesias: Dyskinesias occur during the peak action of Levodopa or other dopaminergic drugs as the therapeutic window narrows with disease progression. They can be managed by reducing frequency of Levodopa and adding MAO-B/COMT inhibitors/dopamine agonists. Amantadine is approved for drug induced dyskinesias in Parkinson's disease. Other options include deep brain stimulation and levodopa/carbidopa enteral suspension.

Drug therapy of Parkinsonism: Strategies and challenges

- **Deep brain stimulation:** It involves surgical placement of unilateral or bilateral leads in subthalamic nucleus or globus pallidus interna. It is used to treat the effects of wearing off and dyskinesias. It was found to improve on medication and off medication scores as compared to best medical therapy. However, levodopa unresponsive symptoms, age > 75 years and associated cognitive impairment are associated with worse outcome.
- **Levodopa/carbidopa enteral suspension.** It is useful for treatment of motor fluctuations and dyskinesias. Levodopa gel is administered continuously via a pump through a percutaneous endoscopic transgastric jejunostomy. It provides more continuous plasma levodopa levels than oral dosing. It reduces off times (- 1.19 hours per day) and increases time when symptoms are well-controlled without troublesome dyskinesias

Treatment of non motor symptoms: non motor symptoms of Parkinson's disease are difficult to manage as they do not respond to dopaminergic treatment. Treatment of these symptoms is similar to treatment of non motor symptoms in general population. Evidence for these treatments specifically in people with Parkinson disease is variable.

- **Parkinson's disease dementia:** For Parkinson disease dementia, the International Parkinson and Movement Disorder Society designates rivastigmine as clinically useful. Based on a double-blind clinical trial participants receiving rivastigmine had a mean improvement of 2.1 points on the 70-point Alzheimer Disease Assessment Scale vs a 0.7-point decline in the placebo group ($P < .001$)². Donepezil and galantamine are designated as possibly useful because of limited evidence to support their efficacy in Parkinson disease. There is no evidence to support use of memantine or treatment of mild cognitive impairment.

- **Depression:** Selective serotonin reuptake inhibitors, selective serotonin norepinephrine reuptake inhibitors, and tricyclic antidepressants may all be useful for treating depression in Parkinson disease. Pramipexole, a dopamine agonist, is useful for depression in some individuals.

Psychosis: initially, weaning potentially contributing medications, such as anticholinergics, amantadine, dopamine agonists, MAO-B inhibitors, and sometimes levodopa may be helpful. Occasionally weaning is limited by bothersome reemergence of previously controlled Parkinson disease symptoms. If psychosis persists and requires treatment, there are 3 main options: pimavanserin, clozapine, and quetiapine³. Other antipsychotic medications should be avoided given adverse event risks including worsening parkinsonism and death. Nonpharmacologic approaches such as cognitive-behavioral therapy and repetitive transcranial magnetic stimulation may also be useful. Pimavanserin, a selective inverse serotonin 5-HT_{2A} receptor agonist, is the only FDA-approved medication for Parkinson disease psychosis, but safety data beyond 6 weeks are lacking². Multiple randomized clinical trials show that clozapine improves Parkinson disease psychosis. Quetiapine is the most convenient of the antipsychotic drugs to prescribe, so it is commonly used in clinical practice despite the absence of observed benefit in clinical trials.

- **REM sleep behaviour disorder:** Rapid eye movement sleep behavior disorder is treated with melatonin (6- 15 mg) as a first-line agent. Clonazepam (0.5- 1.0mg) can be used if needed, but high-quality evidence is lacking.
- **Autonomic manifestations:** Fludrocortisone, midodrine, and droxidopa are all

- possibly useful for orthostatic hypotension. Probiotics and prebiotic fiber, macrogol, and lubiprostone have limited evidence for treating constipation in Parkinson disease. Various prokinetics and laxatives are commonly used⁴. Sildenafil is useful for treating sexual dysfunction. Botulinum toxin injections have the most evidence for treating sialorrhea in Parkinson disease, but glycopyrrolate and sublingual atropine are also prescribed.

- Impulse control disorders: they are seen commonly with use of dopamine agonists. Lowering its dose may be helpful. Cognitive behavioural therapy has been found to be useful. Naltrexone was investigated but had insufficient evidence for efficacy

Emerging therapies

There is a plethora of evidence suggesting that alpha-synuclein aggregation plays a central role in the pathogenesis of PD. Thus, therapeutic approaches have been developed aiming to:

- reduce α -synuclein production
- inhibit α -synuclein aggregation
- increase intracellular and extracellular degradation of α -synuclein aggregates
- reduce uptake of extracellular α -synuclein by neighboring cells

Various drugs targeting these mechanisms under trials:

- Anle 138b: Phase II trial, inhibits formation of alpha synuclein oligomers
- CLR01: Phase I trial, reduces alpha synuclein proteasomal inhibition
- Nilotinib: Phase II trial

Exenatide: Phase III trial

Impulse control disorders: they are seen commonly with use of dopamine agonists. Lowering its dose may be helpful. Cognitive behavioural therapy has been found to be useful. Naltrexone was investigated but had insufficient evidence for efficacy.

Pharmacotherapy of Diabetes- Focus on Reversal and Remission

Dr. Ajay Kumar

*MD, MRCP (U K), FRCP (Edin)
Consultant Physician & Diabetologist
Director, Diabetes Care & Research Centre,
Patna, India*



Reversal of diabetes could be a myth as much as reality. Recent advances in the understanding of pathophysiological mechanisms of type 2 diabetes have provided insights into possible strategies to reverse clinical diabetes. Intensive dietary management and myriad newer molecules targeting hepatic and pancreatic fat beyond generalised fat accumulation have generated sufficient data to initiate discussion regarding diabetes reversal. However, these strategies are likely to be effective only if instituted early in the natural history of the disease and with realistic expectations.

Dr. Ashutosh Kumar

*Senior Interventional Cardiologist
Clinical Director & Cardiac
Electrophysiology
CARE Hospital*



Cardiac arrhythmias refer to abnormal heart rhythms that can present with palpitations, giddiness and syncope. They are responsible sudden death in athletes and young adults who are otherwise relatively asymptomatic. They can also lead to heart failure if persistent (tachycardiomyopathy) and stroke in atrial fibrillation.

Electrophysiological interventions are procedures used to diagnose and treat cardiac arrhythmias by targeting the electrical conduction system of the heart.

Electrophysiological interventions for cardiac arrhythmia two type of interventions-one are catheter ablation and other are device implants also called CIED (cardiovascular implantable electronic device) which includes pacemakers, ILR (implantable loop recorder), Cardiac defibrillator and cardiac resynchronization therapy.

Catheter ablation is a minimally invasive procedure that uses a catheter to deliver radiofrequency energy or cryotherapy to ablate the abnormal electrical pathways in the heart. This technique has proven to be highly effective in treating certain types of arrhythmias, such as atrial fibrillation and supraventricular tachycardia and VT.

Implantable devices, such as pacemakers and implantable cardioverter-defibrillators (ICDs), are also used in electrophysiological interventions. Pacemakers are commonly used for patients with bradycardia (slow heart rate), while ICDs are used for patients at risk of life-threatening arrhythmias. These devices work by monitoring the heart's electrical activity and delivering electrical impulses or shocks to regulate the heart rhythm.

Cardiac resynchronization therapy (CRT) is another implantable device offered to the patients with heart failure and electrical conduction abnormalities (LBBB). This therapy involves the implantation of a special pacemaker that coordinates the contractions of the heart's ventricles, improving the heart's pumping efficiency.

Electrophysiological interventions have revolutionized the management of cardiac arrhythmias, providing effective and less invasive treatment options for cardiac arrhythmias.

While electrophysiological interventions have shown significant success rates, they are not without risks. Complications can include bleeding, infection, damage to the heart or blood vessels, and adverse reactions to anaesthesia or medication. However, the benefits of these interventions in terms of improved quality of life, reduced risk of stroke, and decreased mortality rates outweigh the potential risks for most patients.

Prof. (Dr.) Nihar Ranjan Biswas

*VICE CHANCELLOR, SRI BALAJI VIDYAPITH
Former Director & Vice Chancellor
Indira Gandhi Institute of Medical Sciences,
Patna , Bihar
Former Director ,Mahavir Vaatsalya Asptal*



Rational Drug therapy is the use of drugs which are effective , safe , low cost and easy to administer. It plays a vital role in avoiding preventable adverse effects maximizing therapeutic outcomes with minimum Cost of drug therapy. It needs strong ecosystem in health care and patient's co-operation like strict adherence to prescribed medicines. Rational Drug prescription includes first determining the patient's problem and treatment, then verification of P-treatment, its onset, dose, duration, instruction properly with precautions.

Equitable access to essential medicines and other medical technologies depends on affordable pricing and effective financing, promoting fair prices and cost effective intervention is central to the achievement of universal health coverage. Strategies for measuring, monitoring and managing prices are essential for promoting access to medicines.

WHO works with member states and partners to promote programs and policies that make medicines affordable and accessible to all people. WHO develops guidelines in this respect and also convenes biennial Fair Pricing Forum to bring stakeholders together to discuss issues of medicines affordability, innovations and price transparency in improving access to essential medicines to everyone.

The WHO essential medicine price and availability monitoring mobile application (WHO EMP Medmon) allow users to Monitor Medicines'prices and availability. Clinical Pharmacologists should play a major role in it by advising Govt. Policy makers, facilitating rational use of medicines, choosing optimum number of drugs with correct dose and duration preferably generic drugs and for conducting therapeutic drug monitoring for drugs with narrow therapeutic indices.

Enabling Factors for Successful Implementation of Competency based UG and PG Medical Curriculum.

Dr. Ranjit Guha

*Principal
Professor of Anatomy
Indira Gandhi Institute of Medical Sciences,
Sheikhpura, Patna*



The medical education system all over the world is witnessing a paradigm shift from traditional methods of teaching to competency-based medical education (CBME) which is gaining momentum across the globe. CBME has been acknowledged as the need of the hour owing to the multiple benefits associated with it over traditional curriculum. CBME approach is organized around competencies, or predefined abilities, as outcomes of the curriculum. This approach encourages learners to take responsibility for their progress towards competence, and hence is termed learner-led approach with teachers serving the role of facilitator. It allows a learner to acquire the desired skills at his/her own pace. Though the driving force for the CBME process is a learner, the responsibility also lies with the teachers. The teachers need to work closely with the learners and do hand holding whenever needed. In CBME, the objective is to prepare students for clinical practice. Hence, the focus is on knowledge application and not on knowledge gain. To achieve this, the learning has to be made contextual. The teachers have to create appropriate educational opportunities for the learners, provide access to resources and give effective feedback during practice through formative assessment. In fact, the competencies in CBME are so designed to bridge the gap between theoretical aspects with practical/ clinical skills, tempered with compassion and empathy to become a health professional guided by a value system having sound ethical principles. COVID-19 pandemic has posed an uphill struggle on medical educators to understand, apply and eradicate the challenges in effectively implementing the newer elements of CBME curriculum namely Foundation Course, Early Clinical Exposure, Electives, Integration and Learner Doctor Method of clinical clerkship. Health profession educators in India are now in a position to answer the queries that tickle the minds on how to implement and address the anticipated challenges and where to look for solutions or to put it in other way how to identify the enabling factors. The need of the hour is to allay the apprehensions and address the key issues that are hindering the implementation of CBME and to convert the disabling factors into enabling ones.

Post Graduate Curriculum – Planning for Self-Directed Learning

Dr. Nirmala N. Rege

*Professor Emeritus, Department of Pharmacology
& KEM Hospital, Parel, Mumbai 400012 and
Professor, Pharmacology, Era's Lucknow Medical
College & Hospital, Lucknow*



In the context of changing global dynamics, including the explosion of knowledge and increasing globalization, there is a growing imperative for both learners and educators to embrace self-directed learning (SDL). SDL, as defined by Knowles in 1973, is a proactive process wherein individuals identify their learning needs, set goals, locate resources, choose learning strategies, and evaluate outcomes. Rather than being a specific technique, SDL reflects the capacity of adults for critical self-reflection and transformative life changes. This approach fosters critical thinking, problem-solving skills, and supports lifelong learning, a concept articulated by Cohen in 1975 as continuous, flexible, and accessible learning throughout one's life. The present talk explores the importance of SDL in the context of a postgraduate pharmacology curriculum, highlighting its benefits, challenges, and effective strategies for implementation.

In the realm of postgraduate pharmacology, where constant emergence of new drugs, technologies, and regulatory requirements prevails, the mastery of SDL becomes vital. This empowers students to stay at the forefront of pharmacological knowledge, continuously improving and adapting throughout their careers. By taking ownership of their learning, students enhance their ability to critically analyze information, synthesize diverse sources, and apply their knowledge to novel challenges, thereby deepening their understanding of pharmacological principles and contributing significantly to the field's research and practice.

However, implementing SDL within a postgraduate pharmacology curriculum presents challenges. Students often face difficulty discerning reliable information amidst an overwhelming sea of data. Additionally, maintaining motivation and discipline without traditional classroom structures can prove demanding. Some students, especially those not exposed to SDL concepts and accustomed to passive learning methods, may struggle with the elements of SDL. Moreover, SDL necessitates skills like information gathering, analysis, interpretation, and effective communication of findings. Lower-achieving students may find SDL particularly challenging, making it imperative for teachers to share the responsibility of planning SDL activities rather than leaving it entirely to students.

Teachers play a significant role in nurturing SDL among students, particularly in the initial stages. A more active approach, involving the development of a "learning partnership" with students, is essential. Assessing students' readiness for SDL is crucial, and the subsequent learning methods should be tailored based on the learner's stage (dependent, interested, involved, or self-directed), with the objective of progressing towards independent learning and personal responsibility for learning. As students mature, their readiness for self-directed learning evolves, influenced by previous learning experiences and growing confidence in controlling the learning process. Since students joining postgraduate programme hail from diverse backgrounds with varying capabilities, no 'one-size-fits-all' method exists. However, the chosen method should align with mutually agreed-upon goals between teachers and students, with a focus on enhancing SDL skills.

Effective strategies for implementing SDL within a postgraduate pharmacology curriculum may draw from Knowles's six-step process, emphasizing a supportive learning environment, identifying learning needs, providing diverse resources, executing learning activities, evaluating progress, and identifying future needs. Oswalt's comprehensive model, integrating numerous SDL components, offers valuable insights into implementation. Collaborative platforms, such as online forums and discussion groups, can facilitate peer-to-peer learning and enhance student engagement. Appropriate assessment tools, employed longitudinally, to ensure the development of SDL abilities, and timely feedback are crucial for the postgraduate students as they embark on their lifelong learning journey.

Organisation and conduct of Phase-1 Clinical Trial in India- Challenges and Regulations

Dr. Shubhadeep Sinha

*MBBS(GSMC&KEMH), MD(Pharmacology, TNMC&BYLNairCH.Hospital),
FCGP (IMA-CGP), F.Diab(RLA, UK),
PGDiplInfect.Diseases(UNSW, Aus), MBA
Hosp.Management, BITS, PILANI*



Early phase studies are exploratory, first-in-man studies that are conducted most often (but not always) in healthy volunteers and are critical to the development of a potential new drug. The objective of these studies is to establish proof of safety of the new molecule, as well as its pharmacokinetics in healthy volunteers and often other special study populations, before proceeding on to clinical trials with patients. These studies are an essential step before taking a 'go/no-go' decision for further development.

India as a hub for phase-1 clinical trials

Several midsize to small pharma companies abroad, viewed India as a potential area for the conduct of these studies at a faster rate, greater and more cost-effective availability of healthy and patient subjects, bring new compounds early and efficiently to the patients. Expertise and experience in this area is limited in India even today, among regulatory, biopharmaceuticals, contract research organisations (CRD). 1

Indian Regulatory changes and Challenges

Until 2005, Indian regulations under schedule Y did not allow first-in-man dosing studies of foreign molecules to be conducted in Indian populations. However, Phase 1 trials could be conducted for drugs developed in India. This resulted in a "Phase lag", which was time and cost-consuming for pharmaceutical companies. CDSCO subsequently amended in 2005, Schedule Y of the Drug and Cosmetic Rules of 1945, which provided a collection of clinical trial guidelines. The guidelines on Indian Good Clinical Practice (CDSCO, 2005; ICMR guidelines, 2006) also got released. This new amendment removed the Phase lag, described the responsibilities of sponsors and investigators, and the required notification of protocol changes.

59th and 66th Parliamentary report of April 2013 led to various regulatory amendments for clinical trials, introduced by the CDSCO giving the highest importance to the protection of trial subjects in all phases of trials. In the past, the New Drug Advisory Committee (NDAC), Medical Device Advisory Committee or Investigational New Drug (IND) Committee reviewed clinical trial applications for various subtypes of products. Their recommendations then were reviewed by the Technical Review Committee (TRC), and then finally approved by the Apex Committee. These NDACs have been superseded by Subject Expert Committee (CDSCO, 2014) including those for INDs and phase-1 clinical trials⁴. First, applications are reviewed by the SEC, and then their recommendations are assessed by the TRC. Finally, the CDSCO confers approval of clinical trials based on the assessment of the TRC (CDSCO, 2014). It is mandatory to obtain prior approval from the respective ethics committee, to register the phase-1 and other phase trials with clinical trials registry of India (CTRI), and to submit an annual study report to the DCGI (MHFW, 2013).

The infrastructure requirements for phase-1 and early phase studies

A fully equipped, multi-bedded emergency handling unit whose staff understand the special requirements of these studies and are also well trained in advanced emergency resuscitative measures. Several bioequivalence centers with extensive experience with

Organisation and conduct of Phase-1 Clinical Trial in India- Challenges and Regulations

healthy volunteer studies have since upgraded some of their infrastructure and facilities to meet the needs of early phase studies, some even have started a separate phase-1 units, revamping existing bioequivalence study units. But these are too few in numbers. There is also a great deal of difference in the risk assessment and risk management in bioequivalence vs first-in-man studies. Designating an appropriately qualified 'Principal Investigator' for early phase studies is still something that many CROs find difficult to implement because there is a lack of clear understanding and consensus on what constitutes 'appropriately qualified' and there is a dearth of such investigators. 1

Phase-1 Trials conduct

The goals of Phase I trials include: (1) exploring the safety of the investigational compound carefully and progressively through gradually increasing doses and durations of exposure; (2) determining the absorption/bioavailability, pharmacokinetics, metabolism, and excretion of the compound; and (3) delineating the pharmacodynamic actions of the investigational compound, first in normal volunteers, and later in patients with the target indication.

a) Healthy volunteers as these trials focus primarily on safety and the distribution of the investigational drug, not on potential therapeutic actions, therefore, the participants in early Phase I trials are usually normal volunteers.

b) Dedicated trial centres as explained above

c) Accurate First in human dose determination and increment dosing-

Ø For calculation of maximum recommended safe starting dose, after the NOAELs in the relevant animal studies have been determined, they are converted to human equivalent doses (HEDs). A decision should be made regarding the most appropriate method for extrapolating the animal dose to the equivalent human dose.

Ø Doses are gradually increased until some evidence of dose-limiting intolerance is detected. Single dose pharmacokinetic blood sampling is done on at least a portion of participating subjects.

Repeated Dosing- Dosing intervals are determined based on pharmacokinetic data and the duration of pharmacodynamic effects from the single-dose studies. Repeated-dose studies are usually done for 10-14 days. Pharmacokinetic data are obtained during repeated-dose studies in participating subjects, monitored closely for 4-5 times elimination half-life ($t_{1/2}$) after the last dose of investigational drug was received, and again 30 days after the last dose.

Phase-1 Trials conduct

The goals of Phase I trials include: (1) exploring the safety of the investigational compound carefully and progressively through gradually increasing doses and durations of exposure; (2) determining the absorption/bioavailability, pharmacokinetics, metabolism, and excretion of the compound; and (3) delineating the pharmacodynamic actions of the investigational compound, first in normal volunteers, and later in patients with the target indication.

a) Healthy volunteers as these trials focus primarily on safety and the distribution of the investigational drug, not on potential therapeutic actions, therefore, the participants in early Phase I trials are usually normal volunteers.

b) Dedicated trial centres as explained above

c) Accurate First in human dose determination and increment dosing-

• For calculation of maximum recommended safe starting dose, after the NOAELs in the relevant animal studies have been determined, they are converted to human

Organisation and conduct of Phase-1 Clinical Trial in India- Challenges and Regulations

∅ equivalent doses (HEDs). A decision should be made regarding the most appropriate method for extrapolating the animal dose to the equivalent human dose.

∅ Doses are gradually increased until some evidence of dose-limiting intolerance is detected. Single dose pharmacokinetic blood sampling is done on at least a portion of participating subjects.

∅ Repeated Dosing- Dosing intervals are determined based on pharmacokinetic data and the duration of pharmacodynamic effects from the single-dose studies. Repeated-dose studies are usually done for 10-14 days. Pharmacokinetic data are obtained during repeated-dose studies in participating subjects, monitored closely for 4-5 times elimination half-life ($t_{1/2}$) after the last dose of investigational drug was received, and again 30 days after the last dose.

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Dr. Anand Srinivasan

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Adaptive clinical trials aim at refining the efficiency and ethical rigor of clinical research. Unlike traditional fixed-design trials, adaptive trials permit modifications to study parameters based on interim data analyses, promoting real-time adjustments that optimize the trial design.

Various adaptive trial designs, including group sequential, sample size re-estimation, and Bayesian methods, empower researchers to make data-driven decisions. These modifications may involve adjusting treatment arms, sample sizes, or endpoints, fostering efficient utilization of resources, and expediting drug development. However, maintaining trial integrity and controlling the risk of false positives remains paramount in adaptive designs, demanding meticulous statistical planning.

Ethical considerations are embedded within the framework of adaptive trials. Complexities arise in preserving blinding and controlling type I error rates, necessitating transparency and vigilance to prevent potential biases.

In summation, adaptive clinical trials offer an innovative pathway to efficient drug development. While their dynamic designs enhance adaptability, ethical considerations remain essential. By meticulously integrating methodological innovation with ethical oversight, adaptive trials hold promise in revolutionizing clinical research.

Dr. Saibal Das

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Antimicrobial resistance (AMR) has emerged as a major public health problem all over the world. Optimizing the use of antibiotics is critical to effectively treat infections, protect patients from harm caused by unnecessary antibiotic use, and combat AMR. One of the approaches is to have an evidence-based antibiotic usage policy in hospitals and standard treatment guidelines for common infectious diseases. The primary aim of the hospital antimicrobial policy is to minimize the morbidity and mortality due to antimicrobial-resistant infection and to preserve the effectiveness of antimicrobial agents in the treatment and prevention of communicable diseases. The hospital antibiotic policy shall be based upon: the spectrum of antibiotic activity; pharmacokinetics/pharmacodynamics of these medicines; adverse effects; potential to select resistance; cost; and special needs of individual patient groups. This presentation focuses on the ground mechanism to develop a practical hospital antibiotic policy and standard treatment guidelines. It contains information on various effective strategies for the preparation and implementation of hospital antibiotic policy (step-by-step workflow), surveillance of AMR, cumulative antibiogram, standard treatment guidelines, promotion of rational antibiotic prescribing, and antimicrobial stewardship program.

Dr. Vikas Maharshi

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The selection of appropriate antimicrobials is a critical aspect of modern healthcare, particularly in the context of increasing antimicrobial resistance. Antimicrobial resistance poses a significant threat to public health, making it imperative to make informed decisions when choosing antimicrobial agents for treatment.

Effective antimicrobial selection requires a rational approach that considers several key factors. First and foremost, understanding antimicrobial resistance and its mechanisms is essential. This knowledge helps us grasp the urgency of appropriate selection and underscores the need to preserve the effectiveness of these life-saving drugs.

Rational antimicrobial therapy involves tailoring treatment to specific infections based on various factors. This includes considering local epidemiology and understanding the susceptibility and resistance patterns of pathogens. Surveillance data is crucial in informing empirical therapy and ensuring that chosen antimicrobials are effective against prevalent pathogens in a given region.

Moreover, patient-specific factors play a crucial role in antimicrobial selection. Age, immune status, comorbidities, and previous antimicrobial exposure should all be considered. By taking these factors into account, healthcare professionals can better identify the most appropriate antimicrobials for individual patients, optimizing therapeutic outcomes.

Understanding the pharmacokinetics and pharmacodynamics of antimicrobials is also vital. This knowledge allows healthcare providers to optimize dosing regimens, ensuring that the antimicrobial agent reaches effective concentrations at the site of infection. Matching the drug's properties with the specific requirements of the infection is key to achieving successful treatment outcomes.

Furthermore, antimicrobial stewardship programs are crucial in promoting appropriate antimicrobial selection and usage. These programs encourage interdisciplinary collaboration, education, and adherence to guidelines, all aimed at ensuring judicious antimicrobial prescribing practices.

In summary, the selection of appropriate antimicrobials requires a comprehensive understanding of antimicrobial resistance, local susceptibility patterns, patient-specific factors, and pharmacokinetics/pharmacodynamics. By integrating evidence-based guidelines and promoting antimicrobial stewardship, we can make informed decisions that improve treatment outcomes while combatting the emergence and spread of antimicrobial resistance.

Immune Checkpoint Inhibitors: Challenges and Cautions

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Immune checkpoint inhibitors have revolutionized the field of oncology, offering new hope to patients with various types of cancers. These drugs, which unleash the power of the immune system to fight cancer, have seen extraordinary success in some cases. However, their use is not without challenges and cautions. Before Administration of Immunotherapy- Proper biomarker identification/diagnosis and PDL 1 status needed. During Administration- Anaphylaxis, Cutaneous reaction may occur. After Administration - Drug monitoring and adverse events occurs. Immune Related Adverse Events (IRAEs) occurs in about >50% of patients. Onset is often delayed by several months. Colitis, Endocrinopathy, Nephritis, Liver toxicity, Skin, rash, or pruritus, Pneumonitis are common adverse events. Most side-effects of these drugs revolve by Withholding ICI and by steroids. Pseudo-progression is an initial flare up followed by tumour shrinkage after starting a new treatment. Hyper-progression is a rapid increase in tumour growth rate after starting a new treatment Hyper-progression seems more frequent than pseudo-progression with use of immunotherapy. Patients with autoimmune disease at higher risk of immune-related adverse events, but frequently manageable. Many patients need steroids before, at starting, during or even after ICI treatment due to comorbidities, for treatment or toxicity management. There is Controversial evidence on the (less) benefit of ICI with steroids. Immunotherapy resistance are new challenges .Factors influencing the immunotherapy resistance are tumor heterogeneity, genomic factors etc. It may be Primary or Acquired.

Dr Avinash Kumar Singh

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Therapy for hemato oncology has evolved from palliation, blood transfusion, chemotherapy, targeted therapy, immuno therapy to HCT. Decades of experience with chemotherapy has saved millions of lives but side effects or post chemotherapy complications due to non specific mechanism of action has led to enormous morbidity as well as mortality. Small molecule inhibitors are introduced as they are more targeted leading to better efficacy and less side effects. In 2001 imatinib was approved by FDA for CML and since then about 89 small molecule inhibitors has been approved for various indications. Problem with them are reduced efficacy and development of resistance.

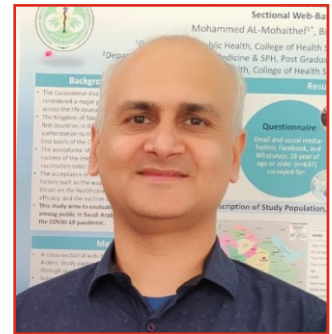
There are different types of small molecule inhibitors, some of them are-

1. Receptor TKI
2. Non-receptor TKI
3. Serine/Threonine Kinase inhibitors
4. Epigenetic Inhibitors
5. Bcl2 inhibitors
6. HEDGEHOG pathway inhibitors
7. Proteasome inhibitors
8. PARP inhibitors

With an in-depth understanding of tumor pathology and the evolution of new drug research and development technology, we believe that more new small-molecule anti-cancer drugs that target novel genes or the mechanism of action will be developed in the near future.

Dr. Sanjeev Kumar

Additional Professor, Department of Community & Family Medicine, AIIMS Bhopal



Patients with cancer are at higher risk of serious infections due to immunosuppression emanating from the underlying malignancy or the immunosuppressive anticancer treatments. This can be modified by selective and focused vaccination. There is limited knowledge available on recommendations for vaccination among cancer survivors.

Guidelines for vaccination of cancer patients:

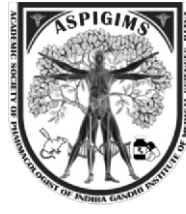
Vaccine guidelines have been recommended by the Infectious Diseases Society of America (IDSA) and the United States Advisory Committee on Immunization Practices (ACIP). There are no readily available guidelines on vaccination for cancer patients in India. There are documents by SAGE WHO, the Association of Physicians of India, and MoHFW for adult vaccination. For children, as we all know, MoHFW and IAP guidelines are there. Vaccines can be given to prevent infections or as an adjuvant in therapeutic efforts among cancer patients. They can be administered before chemotherapy, immunosuppressive drug prescription, radiation, or splenectomy. Preventive vaccines can be classified into inactivated, recombinant, and live vaccines. Inactivated and live vaccines must be given at least two weeks and four weeks before chemotherapy. If given during chemotherapy, inactivated vaccines are less effective, while live vaccines may result in vaccine-derived infections. Some special precautions are required. For example, patients who have received anti-B cell antibodies such as Rituximab, Alemtuzumab, etc., or immunosuppressive drugs such as Fludarabine should receive the vaccines not before six months of these medications. Vaccines should be given at least one month after stopping corticosteroids. All patients who underwent a hematopoietic cell transplant should be revaccinated with most of the routine vaccines. Influenza, pneumococcal, Hepatitis A & B, Covid-19, HPV, Td/Tdap, Meningococcal Hib, Poliomyelitis, etc are examples of inactivated vaccines. RZV Zoster vaccine and Hepatitis B are recombinant vaccines. MMR (Measles, Mumps, Rubella), and Varicella are examples of live vaccines. Examples of therapeutic vaccines are Sipuleucel-T, Talimogene Laherparepvec (T-VEC), and BCG, respectively, in prostate, melanoma, and urinary bladder cancers.

Challenges in vaccination:

Common barriers to vaccination in cancer patients in India are lack of access and concerns about safety among both patients and providers. A cross-sectional study reported that the uptake of routine immunization with Influenza and Pneumococcal vaccines among elderly patients in India was less than 1%. However, the high coverage of >80% for Covid-19 vaccination among the elderly (which might include cancer patients, too) is a ray of hope.

Conclusion:

New vaccines are developing to prevent these specific and common infections in immunocompromised hosts. Many of the infections in cancer patients can be prevented by vaccination. Practitioners should be strongly encouraged to discuss vaccinations and other aspects of preventive medicine with their patients. Accountability of the vaccine administered and its side effects need to be maintained.



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ABSTRACT

THEME: “Precision Clinical Pharmacology : Future of Rational Therapeutics”

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POSTER PRESENTATION



Imeglimin: Current Development and Future Potential in Type 2 Diabetes

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Background : Imeglimin is the first of the new class of medications known as "glimins," which was created to treat type 2 diabetes mellitus (T2DM). This review emphasises its mode of action and its setting within the realm of T2DM therapy. Numerous rodent models used in preclinical research have revealed important impacts on mitochondria, most notably enhanced mitochondrial bioenergetics. Included in these are adjustments that favour complex II and complex III metabolism, which may act as a catalyst for improved fatty acid oxidation and the reduction in hepatic lipid buildup seen in these animals. Both in vitro and in vivo studies on imeglimin revealed that it increased muscle glucose absorption while lowering hepatic glucose synthesis.

Although studies have also demonstrated that imeglimin considerably increases insulin secretion and decreases β -cell death, it is still unknown if imeglimin's physiological actions are only insulin-dependent. Early preclinical investigations have demonstrated improvements in cardiac and renal function in rats with metabolic syndrome—effects that are not provided by the majority of T2DM medications presently on the market.

Imeglimin has boosted insulin secretion and lowered fasting plasma glucose and glycated haemoglobin in human clinical investigations. Its reported effectiveness was on par with that of the drugs metformin and sitagliptin, which are presently on the market, and it improved when administered in conjunction with either drug. Imeglimin has genuine promise to offer a unique strategy for treating T2DM, with prospective use in a bigger, more diverse patient group, when taken into account alongside its favourable safety profile found in individuals with chronic renal disease.

Keywords : mechanism, imeglimin, sitagliptin, T2DM drugs

Detection of hemoglobin variants during HPLC evaluation of HbA1c

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Glycated HemoglobinA1c (HbA1c) is used for diagnosis of Diabetes mellitus and to monitor glycemic control in diabetic patients. Detection of HbA1c by cation exchange-high performance liquid chromatography (CE-HPLC) interpretation done by chromatogram in which abnormal hemoglobin variants can be traced. Some of these interfere with HbA1c values affecting clinical management. Various hemoglobin variants found in different parts of India. A prospective analysis done over 8 months, of the hemoglobin variants detected during all the HbA1c runs. The HbA1c was performed on Bio-Rad D10 dual HbA2/F/A1c platform, which uses the CE-HPLC method. Each and every chromatogram was carefully studied to look for unknown peaks. The samples showing unknown peaks >15% were re-run in extended HbA2/F mode to categorize the hemoglobin variants. We had 8526 HbA1c samples, of which 60 cases showed a variant window. There were 40 males and 20 females, age ranging from 28 to 66 years. The different hemoglobin variants detected were HbD, HbE and HbS in heterozygous state, high HbF (with a differential diagnosis of Hereditary persistent of foetal hemoglobin heterozygous and delta-beta thalassemia heterozygous), HbE homozygous, HbQ heterozygous and HbJ heterozygous. The present study concludes that in the process of monitoring glycemic control using HbA1c, hemoglobin variants can be diagnosed. Hence, it is essential to review HbA1c graphs, so that the diagnosis of hemoglobin variants is not missed and the HbA1c reported is reliable.

Keywords: Chromatograms, Glycated hemoglobin (HbA1c), Serendipity, Hemoglobinopathy, Thalassemia

Vascular function and exercise capacity in diabetes mellitus

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Background: Diabetes mellitus is a chronic metabolic disorder characterized by elevated blood glucose levels, which can lead to various complications, including cardiovascular diseases. Vascular dysfunction is a key factor contributing to these complications. Exercise is known to have beneficial effects on vascular function and overall exercise capacity. However, the relationship between vascular function and exercise capacity in individuals with diabetes mellitus remains unclear.

Methods: In this study, we investigated the association between vascular function and exercise capacity in patients with diabetes mellitus. Study conducted in the department of Pharmacology at Darbhanga Medical College & Hospital during the period January 2023 to June 2023. A total of 150 participants were enrolled in the study, including 75 patients diagnosed with type 2 diabetes mellitus and 75 age and sex-matched healthy controls. Vascular function was assessed using non-invasive measures, including flow-mediated dilation (FMD) and pulse wave velocity (PWV). Exercise capacity was evaluated using a graded exercise test on a treadmill, and peak oxygen consumption (VO₂peak) was measured as an indicator of aerobic fitness.

Results: Our findings revealed that individuals with diabetes mellitus exhibited significantly impaired vascular function compared to healthy controls, as evidenced by lower FMD and higher PWV values ($p < 0.001$). Furthermore, the diabetic group demonstrated reduced exercise capacity with a significantly lower VO₂peak compared to the control group ($p < 0.001$). Importantly, a significant negative correlation was observed between vascular function (FMD and PWV) and exercise capacity (VO₂peak) in the diabetic cohort ($r = -0.45$, $p < 0.001$), suggesting that impaired vascular function may be associated with decreased exercise capacity in diabetes mellitus.

Conclusion: Our study highlights the presence of impaired vascular function and reduced exercise capacity in individuals with diabetes mellitus. Moreover, the negative correlation between vascular function and exercise capacity in this population suggests that vascular dysfunction may contribute to the decreased exercise capacity observed in diabetes mellitus. These findings underscore the importance of addressing vascular health as a potential target to improve exercise capacity and overall cardiovascular health in patients with diabetes mellitus.

Keywords: Diabetes mellitus, Endothelial dysfunction, Exercise capacity, Arterial stiffness, Flow-mediated dilation, Pulse wave velocity

Severe asthma: Advances in current management and future therapy

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Severe asthma remains a challenge as some patients' symptoms are not well controlled despite maximum inhaled therapy. Poor adherence to controller therapy can contribute to poorly controlled asthma symptoms. Combination inhalers containing corticosteroids and long-acting β_2 -agonists as reliever therapy in addition to maintenance treatment can improve adherence and symptom control. New bronchodilators with longer durations of action are being developed and show promise in managing severe asthma. Studies have demonstrated the benefits of adding a long-acting anticholinergic bronchodilator to β_2 -agonists in patients with severe asthma. Anti-IgE therapy can be effective for selected patients with severe asthma. Clinical trials are underway for blockers of specific mediators, such as prostaglandin D₂, IL-5, IL-9, and IL-13, which may benefit patients with different subtypes of severe asthma. Broad-spectrum anti-inflammatory therapies targeting neutrophilic inflammation are being developed but might require inhaled delivery to minimize adverse effects. Macrolides, although not consistently effective, may have benefits for patients with atypical bacterial infections, particularly those with neutrophilic asthma. Corticosteroid resistance is a significant problem in severe asthma, and research is exploring novel therapeutic approaches to reverse this resistance, such as theophylline and nortriptyline. Bronchial thermoplasty, while potentially beneficial for selected patients with severe asthma, has shown mixed results in clinical studies. Recognizing different subtypes of severe asthma

highlights the importance of finding biomarkers that can predict responses to specific therapies in the future.

Clinical characteristics and early outcome of Bedaquiline-containing regimens for the treatment of Multidrug-Resistant Tuberculosis (MDR-TB)

Rajnish kumar

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Objective:

To assess the clinical characteristics and early treatment outcomes of patients with multidrug-resistant tuberculosis (MDR-TB) receiving regimens containing bedaquiline.

Methods:

This retrospective study included 50 patients diagnosed with MDR-TB who were initiated on bedaquiline-containing regimens at a designated treatment at SKMCH, Muzaffarpur . Data on demographics, comorbidities, treatment duration, sputum culture conversion, adverse events, and treatment outcomes were collected and analyzed.

Results:

The mean age of the patients was 38 years, with a range of 22-55 years. Among the study population, 60% were male and 40% were female. Comorbidities such as diabetes mellitus and HIV infection were observed in 25% and 12% of patients, respectively. The median duration of the bedaquiline-containing treatment regimen was 9 months. Sputum culture conversion was achieved in 76% of patients within the first 3 months of treatment. Adverse events were reported in 32% of patients, with the most common being gastrointestinal disturbances (20%) and QT interval prolongation (10%). However, 16% had an unfavorable outcome, experiencing persistent positive sputum cultures despite treatment, and 16% experienced treatment failure or death.

Conclusion:

In these study patients with MDR-TB receiving bedaquiline-containing regimens, a high rate of sputum culture conversion and favorable treatment outcomes were observed. However, it is important to note the occurrence of adverse events, particularly gastrointestinal disturbances and QT interval prolongation, which necessitate careful monitoring and management during the course of treatment.

Key words: bedaquiline, MDR-TB, gastrointestinal disturbances, QT interval prolongation, diabetes mellitus

A Comparison of lornoxicam and diclofenac's efficacy and safety as post-operative analgesics after mastoidectomy surgery

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Introduction :

The surgical trauma that happens during the manipulation of tissues causes postoperative discomfort. As a nonselective NSAID with analgesic and anti-inflammatory characteristics, lornoxicam has a quicker start of action than other oxicams and a shorter half-life. Cyclooxygenase inhibitor diclofenac sodium has been used for many years to treat postoperative pain. It builds up in the inflamed tissue, and its active metabolite, which acts as an analgesic, keeps the plasma concentration higher for several hours. The purpose of the current study is to compare Lornoxicam and Diclofenac for the management of postoperative pain after mastoidectomy surgery in order to assess their effectiveness and safety.

Materials And Methods : 20 patients who underwent mastoidectomy surgery and were randomly assigned to two parallel groups participated in this prospective single-blinded trial. For three days in a row, group A received an intramuscular injection of lornoxicam 8 mg, while group B received an injection of diclofenac 75 mg. Using the Visual Analogue Scale and Wong Bakers Scale, the postoperative pain was the main measure. Intramuscular injection of paracetamol 300 mg was the rescue drug employed. The patients in each research group's use of and duration of use of rescue medicine are the secondary parameters. Adverse events that the patient reported or that the doctor saw during each follow-up appointment were noted.

Results : The key effectiveness measure consistently shown a substantial decrease in postoperative pain in

the lornoxicam group compared to the diclofenac group (p value 0.05). In the lornoxicam group, 3 patients (7.5%) and 11 (27.5%) patients, respectively, required rescue medicine. The diclofenac group had a significantly higher rate of patients who needed rescue medicine than the lornoxicam group. When using rescue medicine, the average time was 7.33 2.21 hours for the lornoxicam group and 7.09 3.36 hours for the diclofenac group. The preoperative & postoperative values of renal & liver function markers did not significantly differ from one another. In the two groups, there were no significant adverse events.

Conclusion :Based on the findings of our study, we draw the conclusion that intramuscular injection lornoxicam 8 mg is a more effective and tolerable analgesic than intramuscular injection diclofenac 75 mg for the treatment of postoperative pain after mastoidectomy surgery.

Keywords :Postoperative pain, Lornoxicam, Diclofenac, Mastoidectomy surgery

Estimation of Nicotine in Tobacco Extract Using C8 Column in High Performance Liquid Chromatography

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Background: Nicotine is the most used toxic substance in spite of mass media awareness. Column used in the estimation of nicotine is found to be the inhibiting factor for its estimation.

Objective: To develop a method for nicotine estimation on C8 column in HPLC.

Methods: The method involved a model Waters 1515 binary HPLC Pump system interfaced with a 2489 Waters UV/VIS detector, a 4.6 X 250mm, 5 μ m beads Symmetry C8 column at 37°C, and an isocratic mobile phase containing 60%: 40% v/ v mixture of 10mM sodium acetate (pH 5.5) and methanol at a flow rate of 1.0ml/min at 256 nm. The method was validated for specificity, linearity, precision, accuracy, the Limit of Detection (LOD), the Limit of Quantitation (LOQ) and system suitability.

Results: The HPLC Nicotine peak with average retention time of 3.415 minutes was observed on chromatogram with RSD<0.5%; linearity was greater than 0.99 with acceptable precision (within USP limits of <2.0% RSD) and USP tailing less than 2. LOD was found to be 0.200 μ g/ml and Limit of Quantitation (LOQ) was found to be 0.609 μ g/ml of nicotine. The average yield of the nicotine extracted by acid base extraction method from tobacco was 1.68% (range: 1.34–2.22%).

Conclusion: A HPLC method based on C8column for analysis of Nicotine was developed and validated successfully.

Assessment of quality of life among patients with adverse drug reactions using the WHOQOL-BREF questionnaire: A cross-sectional study

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Department of Pharmacology, Indira Gandhi Institute of Medical Sciences (IGIMS), Patna.

Objective: This study was aimed to assess the quality of life (QoL) among patients experiencing adverse drug reactions (ADRs) using the WHOQOL-BREF questionnaire. The study contributes to the existing literature on ADRs and QoL, providing a comprehensive assessment of patients' lived experiences and guiding healthcare professionals in optimising patient-centred care.

Methods: A cross-sectional study was conducted among patients admitted with ADRs, who completed the WHOQOL-BREF questionnaire. The questionnaire assesses QoL across four domains: physical health, psychological well-being, social relationships, and environmental factors. Descriptive statistics were used to summarize the sociodemographic of the participants. Inferential statistics like independent t-test and ANOVA were used to assess the differences between the groups. Statistical analyses were performed using SPSS version 25.

Results: The study included a sample of 300 patients with ADRs. The demographic characteristics of the participants were as follows: 36.7% belonged to the 31-50 age group, 52.7% were female, 74.7% were married, 64% resided in rural areas, 35.3% had completed secondary education, 28.7% were homemakers, and 55% had an income less than 2.5 lakhs. Furthermore, 67.7% of the ADRs reported by the participants

were categorized as moderately severe. Females had significantly lower QoL scores compared to males ($p < 0.05$) additionally, residents of rural areas had significantly ($p < 0.05$) lower QoL scores compared to those from urban areas. The results of the one-way ANOVA revealed significant associations ($p < 0.05$) between education, income, severity of ADRs, and QoL scores.

Conclusion: The results demonstrated the impact of ADRs on various aspects of patient's QoL. The findings revealed the varying levels of QoL across different domains, indicating the specific areas affected by ADRs. This information is vital for healthcare providers in understanding the impact of ADRs on patients' well-being and tailoring interventions accordingly.

Evaluation of prescription pattern of high-end antibiotics among inpatients at a tertiary care hospital

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Introduction: The United Nations declared antimicrobial resistance to be 'the greatest and most urgent global risk' in 2016. Antibiotic overuse and misuse drives antimicrobial resistance. In India, rates of infections caused by antibiotic-resistant bacteria are high and increasing. Hospital antimicrobial stewardship programs (ASPs) aim to promote judicious use of antimicrobials to combat antimicrobial resistance.

Objective of the Study: The purpose of this study was to evaluate the use of high end antibiotics in hospital.

Methodology: An observational cross sectional study was carried in in-patient departments at a tertiary care hospital IGIMS, Patna. Patients prescribed on high end antibiotics such as carbapenems, vancomycin, colistin, linezolid and capsosfungin were included in the study and their prescriptions were evaluated. Data of patients were extracted using pre designed Performa from medical data sheets, medication chart and laboratory investigations. The collected data were summarized using descriptive statistics as appropriate. Statistical analysis were performed using SPSS version 25

Result: The number of patients included in study was 100. The demographic characteristic of patients was as follow: 55% were male followed by 45% female. The common antibiotics prescribed were Meropenem (45%) followed by Vancomycin (23%) followed by Colistin (10%) and Imipenem (7%). The commonest diagnosis/indication that led to high end prescription was Respiratory infection (35%) followed by surgery related (20%) and bone (22%).

Conclusion: This study focused more on limiting the use of high end antibiotics. It has been found that most of the most of the antibiotics treatment regimens were given without doing culture sensitivity which may lead to irrational prescribing.

Hypercholesterolemia associated mood and memory deficit

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Alzheimer's disease (AD) is a progressive and fatal neurological illness that is the most frequent form of dementia among the aged population led by one of the hypotheses of cholesterol metabolism. Cholesterol influences the metabolism and clearance of A β plaque and tau protein, inflammation and immune system involvement, stimulates oxidative stress and mitochondrial dysfunction, and favours autophagy. As a result, we hypothesized that an increase in cholesterol in the peripheral circulation may lead to extracellular matrix degradation, mitochondrial histopathological changes. The aim of our study is to explore the potential effect of hydroalcoholic extract NHP021, for its potent lipid-lowering property that can suppress the formation of amyloid β plaque, hence it has excellent antioxidant and anti-inflammatory properties & restores the integrity of extracellular matrix in mice model of hypercholesterolemia. We proposed another hypothesis that our extract has a positive pharmacological response in reversing the symptoms associated with hypercholesterolemia and induces a neurocognitive deficit.

To evaluate the protective efficacy of NHP021 against hypercholesterolemia-induced extracellular

matrix damage and eventually associated with AD like symptoms. The 4 months old C57BL6/J mice were fed with high cholesterol diet (HCD) for 60 days, and a parallel control with normal chow diet was maintained. Data generated from the behavioral study showed the mice received HCD exhibited hippocampus and prefrontal cortex-dependent mood and memory deficits, which was evidence by reduced novelty preference in NOR and OiP test. Further, biochemical analysis confirmed that diet manipulation significantly elevated the level of blood cholesterol and deteriorate the extracellular matrix components like collagen IV, reelin. Moreover, the mice fed with HCD showed the enhanced expression of neuroinflammation which was evidence by elevated level of TNF- α , HMGB1 and GSK3 β .

However, NHP021 treatment showed a significant decrease in these parameters and a protective effect in hypercholesterolemia-induced neurodegeneration and extracellular matrix damage. Hence, the present study provides first time evidence that treatment with NHP021 promotes functional recovery of extracellular matrix as well as ameliorate HCD-induced mood and memory deficits.

Role of NHP001 in alleviating Diabetic Nephropathy

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Diabetes mellitus is the condition defines as the higher blood glucose level that negatively influence on quality of life, increasing disability and mortality among susceptible individuals. Diabetic patients have an increased risk of developing nephropathy due to various complications for instance hypertension in diabetes contributes to diabetic nephropathy. This study aims to explore whether our novel compound (NHP001 synthesized at NIPER Hajipur) can reverse the inflammation, epigenetic alteration and promote cell proliferations in high fat diet (HFD) and Streptozotocin (two concurrent low dose of STZ-30mg/kg) induced Diabetic mice. Our proteomics results reveal the potency of NHP001 to reverse expression of proteins involved in epigenetic alteration, and promote podocyte expression, renal regeneration & cell proliferation. Furthermore, IHC data revealed that NHP001 treatment for a period of two weeks notably produced anti inflammatory response through reduced expression CD200+ cells. Moreover, quantification of number of newly born cells (Ki67+ cells) revealed that NHP001 enhanced cell proliferation in diabetic mice model. Further this treatment reversed diabetes induced epigenetic alteration evidenced by the reduced level of methylated DNA and enhanced expression of TET-1 enzyme in NHP001 treated diabetic mice. Moreover, RT-PCR analysis indicates that our novel compound produces beneficial response towards the podocyte regeneration as well as promoting stem cell proliferation in diabetic nephropathy.

Therefore, NHP001 treatment has shown promising results in reducing inflammation and promoting proliferative and nephroprotective activity, hence providing remarkable benefits against diabetes associated nephropathy.

Molecular insight into neurobehavioral changes associated with Fluoride exposure in Wistar rats

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Summary: This study highlights the potential neurotoxic and behavioural effects associated with high fluoride concentrations in drinking water.

Purpose: Fluoride is known to cause neurotoxicity evinced by lower IQ levels in children from high-fluoride regions compared to those in low-fluoride regions. Thus, the present study was designed to investigate the the molecular mechanism behind the neurological and behavioural changes rats induced by sodium fluoride in Wistar rats.

Material and Methods: A total of 24 female Wistar rats, aged six weeks and weighing approximately 150-250g, were randomly divided into three groups: Group I (control) received reverse osmosis (RO) water, Group II received Sodium Fluoride (NaF) at 10 ppm, and Group III received NaF at 50 ppm in their drinking water for 180 days. The animals underwent behavioural tests including the Forced Swim Test (FST), Open

Field Test (OFT), and Novel Object Recognition Test (NORT) to assess any alterations in behaviour. After 180 days, the animals were euthanized, and their blood and brain samples were analysed to evaluate biochemical changes, Western Blot/ IHC analysis of BAX, Bcl2, LC3B, TLR4, PARP1, p53, Caspase, α -Synuclein, PARKIN and NeuN for assessing molecular pathways for toxicity.

Results: The results demonstrated that exposure to fluoride for 180 days led to impaired locomotion, memory impairment, and behaviour resembling depression in the animals, as evidenced by reduced mobility index in the FST, discrimination index in the NORT, and open field test results. Additionally, alterations in antioxidant and oxidative stress parameters were observed in the brain. The expression levels of various apoptotic and inflammatory biomarkers (BAX, Bcl2, TLR4, PARP1, p53, and Caspase) were analysed via Western Blotting to further comprehend the role of fluoride in neurotoxicity within the Wistar rat brain tissue. Also, confocal studies were performed for increased expression of inflammatory (α -Synuclein, PARKIN), apoptotic (LC3B, BAX, p53) and mitochondrial dysfunction (NeuN) marker in fluoride treated animals.

Conclusion: Fluoride at 10 ppm showed potent neuronal toxicity evidenced by various molecular markers.

Synthesis, characterization and biological activity of allantoin-mannose carbon dots against breast cancer cells

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Breast cancer is a significant global health concern, necessitating the development of novel therapeutic approaches. In this project, we focused on the synthesis, characterization, and assessment of the biological activity of Allantoin-Mannose Carbon Dots (CQD) against MCF-7, a breast cancer cell line. The Allantoin-Mannose CQDs were prepared using a facile and cost-effective synthesis method, and their physicochemical properties were thoroughly characterized using various analytical techniques, including spectroscopy, microscopy, and particle size analysis. The synthesized CQDs exhibited favourable properties such as small particle size, high stability, and efficient fluorescence properties. To evaluate their potential as an anticancer agent, we conducted biological assays (MTT, ROS and RNS) using MCF-7 cells. The results revealed significant cytotoxic effects of the Allantoin-Mannose CQDs on MCF-7 cells, demonstrated by reduced cell viability and increased Necrotic cell death. Overall, our findings suggest that Allantoin-Mannose CQDs hold promise as a novel therapeutic agent against breast cancer, warranting further investigation and optimization for potential clinical applications.

Synthesis, Characterization, and Efficacy Evaluation of Hemoglobin Amphotericin-B Nanoparticle Against Leishmania donovani

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The protozoan parasite *Leishmania donovani* is still a major cause of leishmaniasis. public health is a major concern, especially in developing nations. The ineffectiveness of standard antileishmanial drugs, their severe toxicity, and the development of drug resistance The investigation of cutting-edge therapeutic modalities is necessary for therapies. Our goal was to create and assess the effectiveness of hemoglobin-amphotericin B (Hb-AmB) nanoparticles against *L. donovani* in this investigation. Hb-AmB nanoparticles were created using a modified desolvation process, and their physicochemical properties were determined using a variety of methods, including dynamic scattering of light and Fourier-transform infrared spectroscopy. The encapsulation and release kinetics of AmB within the Hb nanoparticles were also assessed using a UV spectrophotometer, and an in vitro drug release investigation was performed using HPLC. The efficacy of Hb-AmB nanoparticles against *L. donovani* was tested in vitro and in vivo. Further antileishmanial activity was assessed using *L. donovani* promastigote and intracellular amastigote forms. Mammalian cell lines were used to test the cytotoxicity of Hb-AmB nanoparticles. The outcomes showed that the average size of the Hb-AmB nanoparticles, which had a limited size distribution, was 408 nm. The effective encapsulation of AmB within the Hb nanoparticles was confirmed by FTIR spectroscopy. Strong antileishmanial activity of Hb-AmB nanoparticles was

discovered through in vitro research, considerably lowering the parasite burden in both promastigote and amastigote forms of *L. donovani*. Additionally, Hb-AmB nanoparticles showed a good safety profile with no cytotoxicity toward mammalian cells.

To Evaluate the Adverse Events for the selected Cardiac and Radiotherapy Medical Devices

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This study aimed to evaluate the adverse events (AEs) associated with the use of cardiac and radiotherapy medical devices. A prospective observational study was conducted over a period of one year and included 160 patients. The AEs were monitored using a standardized reporting form as per MVPI-IPC and were classified as either true positives (TP), false positives (FP), or false negatives (FN). The results of the study showed that there were 50 AEs reported, of which 32 were TP, 30 were FP, and 10 were FN. The most common AEs were skin reactions (30%), followed by oral cavity dysfunction including Dysphagia, altered salivation, altered taste (20%), and nausea and vomiting (10%). Most of the AEs were mild or moderate in severity, and no serious AEs were reported. The study found that the false positive rate for AE reporting was 30%, and the false negative rate was 10%. This suggests that there is a need for improved training and education for healthcare professionals on the proper reporting of AEs. The findings of this study have important implications for the safety of patients who use cardiac and radiotherapy medical devices. The high rate of false positive reporting suggests that healthcare professionals may be over-reporting AEs, which can lead to unnecessary anxiety and stress for patients. The high rate of false negative reporting suggests that some AEs may be going unreported, which can put patients at risk. The results of this study highlight the importance of accurate AE reporting. Healthcare professionals should be properly trained and educated on the proper reporting of AEs, and patients should be encouraged to report any AEs that they experience.

Teneligliptin induced Bullous Pemphigoid in Type 2 Diabetes mellitus: A Rare Case Report

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Introduction: Teneligliptin is a recently developed oral dipeptidyl peptidase 4 inhibitor indicated for the management of Type 2 Diabetes mellitus as monotherapy or in combinations with other drugs in adults along with diet and exercise.

Bullous pemphigoid (BP) is an autoimmune sub-epithelial disease characterised by pruritus followed by urticarial plaques and finally bullae on skin and mucosa. Autoantibodies targeting 2 main structural proteins of the dermal-epidermal junction, BP antigen 1 (BPAG1 or BP230 antigen) and BPAG2 (BP180 antigen), are involved in the pathogenesis of BP. Drug-associated bullous pemphigoid (DABP) is a term used to describe instances of bullous pemphigoid demonstrating clinical, histological or immune-pathological features similar to those of idiopathic form of bullous pemphigoid associated with topical application or systemic ingestion of particular drugs. There are so many drugs are associated with DABP and the strongest evidence for DABP is seen with gliptins, loop diuretics and penicillin and their derivatives etc.

Case report: We describe the case of male of 55 years old with known case of Type 2 Diabetes mellitus and on mono-therapy with teneligliptine 20 mg. He was apparently normal before but recently he reported with white patch over buccal mucosa which initially appeared as multiple vesicular eruption of small size that burst and coalesced into larger ulcer that later appeared as white slough. Initially it started in oral mucosa and after it appeared on skin. Immediate withdrawal of causative drug together with supportive care with steroid was given which led to satisfactory outcome of the case within a month.

Conclusion: Our case report emphasizes the clinician to identify the cases of DABP earlier and cease the offending medication to prevent the lethal complication and to educate the patient about earlier recognition of DABP to decrease the incidence of avoidable serious drug reactions.

Key words: Bullous Pemphigoid, Teneligliptin, Adverse reaction

A review study on role of clinical pharmacology in monitoring tacrolimus level in organ transplant

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Biochemistry, IGIMS, Patna

Background : As medication experts, pharmacists play a fundamental role on the transplant team. By participating in these activities, pharmacists help reduce the risk of graft rejection by addressing pharmacological, nonpharmacological factors and potential barriers to the best therapeutic outcomes. Non-pharmacologic factors are also taken into consideration to identify patients that may be at an increased risk of organ rejection due to nonadherent behaviours and socioeconomic or communication barriers post-transplant.

Aim: To identify the role of clinical pharmacology in monitoring tacrolimus levels on patients in kidney transplant.

Objectives: 1. To identify the role of pharmacist in monitoring the level of tacrolimus in transplant patients. 2. To understand if pharmacist assessment and education positively will impact on therapeutic tacrolimus levels in patients pre and post organ transplant.

Method: Review study is based on data collected from various research articles to understand the role of pharmacology in therapeutic drug monitoring and maintaining tacrolimus level before and after organ transplantation in patients.

Results: Data collected from various review articles, for analysis included goal tacrolimus level, number of sub and suprathreshold tacrolimus trough serum concentrations before and after pharmacist post-transplant visit, and the number of therapeutic tacrolimus trough serum concentrations before and after pharmacist post-transplant visit.

Conclusions: Based on various review studies it was concluded that including a clinical pharmacology consultation in patients before and after in renal transplant, and monitoring of tacrolimus levels by pharmacologists can decrease percentage of graft rejection and can increase the survival rate of patients undergoing organ transplant.

Comparison of efficacy and safety of empagliflozin versus dapagliflozin as add on to metformin in type 2 diabetic patients

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Pharmacology, DMCH, Darbhanga

Background: SGLT-2 (sodium-glucose cotransporter-2) inhibitors are a novel class of oral hypoglycemic agents for the management of type 2 diabetes mellitus (T2DM). Herein, we aimed to assess the efficacy and safety profile of empagliflozin versus dapagliflozin in type 2 diabetic patients.

Methods: In this randomized controlled trial, type 2 diabetic patients with inadequate glycaemic control HbA1c 7.5-11% with different first line anti diabetic medications were randomly divided into two groups. Group A were given tablet Empagliflozin 25 mg while Group B were given tablet Dapagliflozin 10mg over a period of 12 weeks. The primary end point was to measure efficacy profile in terms of changes in body weight, BMI, fasting blood sugar and HbA1c. The secondary end point was to determine safety and tolerability profile.

Results: After 12 weeks of treatment body weight was reduced significantly in both groups empagliflozin – 2.9±6.4 kg (p=0.002) versus dapagliflozin -1.7±2.4 (p=0.007). However, comparison between two groups was non-significant (p=0.032). FBS was reduced in both study groups empagliflozin – 75.6±43.5 mg/dl versus dapagliflozin -63.5 ± 60.5 mg/dl with p<0.01. However, empagliflozin caused a significant reduction in fasting blood sugar as compared to dapagliflozin (p=0.001). HbA1c was also significantly reduced in both groups empagliflozin -1.7±0.9% versus dapagliflozin -1.2±1.4% with p <0.01. However, empagliflozin caused a more significant reduction in HbA1c as compared to dapagliflozin (p=0.002). The tolerability profile of both drugs was quite good and no major adverse effects were reported in both study groups. However minor adverse effects were observed in both study groups. There was low risk of urinary and genital infection with empagliflozin (2.34% & 3.1%) as compared to dapagliflozin (7.08% and 8.66%) with p-value 0.003 and 0.005 respectively.

Conclusions: Both empagliflozin and dapagliflozin has excellent efficacy and safety profile. They can be used as add on therapy in type 2 diabetic patients.

Critical appraisal of World Health Organization guideline based information in addition to various claims laid in drug promotional literatures

Dipti Singh

Pharmacology, NMCH, Jamuhar, Sasaram

Background: Drug promotional literature (DPL) is utilized as an important door visit tool by pharmaceutical companies and healthcare organizations in the form of printed or digital materials to promote and provide information about their medications.

Aim & Objective: The study aimed to evaluate for the accuracy of the drug promotional literatures (DPLs) and to evaluate various supportive claims made by DPLs.

Methods: This observational, cross-sectional study was conducted in the Department of Pharmacology, NMCH, Sasaram, Bihar. The DPLs in leaflet form were collected from various departments outdoor in June 2023. Total 184 DPLs were evaluated on 14 checkpoints based on WHO guidelines. The claims in addition, were also analyzed.

Results: A total of 184 DPLs followed 49.38% of the WHO criteria only. Medicines were advertised by generic names in 184 (100%) and brand names in 180 (97.8%) leaflets. Dosage form 152 (82.6%), but dosage schedule was mentioned in only 36 (19.6%) DPLs. Amount of active ingredient per dose 140 (76.1%), indications 160 (87%), adverse effects 16 (8.7%), precautions 16 (8.7%), drug interactions 12 (6.5%) and contraindications 12 (6.5%) were listed in DPLs. Manufacturer's names were mentioned in 152 (82.6%), but their addresses were mentioned in 88 (47.8%). References were cited only in 92 (50%) leaflets. Among drugs classes, respiratory system drugs 36 (18.4%), followed by cardiovascular drugs 28 (14.3%) and antidiabetic drugs 24 (12.2%) were promoted the most. Single drug was promoted in 104 (56.5%) more than fixed dose combination of two drugs in 68 (36.9%) and multiple drugs 56 (30.4%) in leaflets. Majority of references were cited from research articles 19 (33.9%) and no references were found in 50% leaflets. Over-emotional and impressive claims in 64 (45.7%), efficacy 48 (26.1%), followed by safety and pharmacokinetic features 44 (23.9%) were promoted.

Conclusion: The study concluded that DPLs were seldom aligned to WHO guidelines. Brand names were hugely highlighted than their generic names. Promotion of exaggerated emotional and impressive claims overwhelmed purposive learning. Though, promotion literatures enable clinicians to upgrade their existing knowledge, it may yield in irrational prescription if clinicians adopt inappropriate claims. Therefore, DPLs adhered to proper guidelines, need to be designed to improve therapeutic approach and to encourage practicing evidence-based medicine.

Keywords: Drug promotional literatures, WHO guidelines, impressive claims, irrational prescription.

Expired medicine storage and Disposal: A descriptive cross sectional, questionnaire-based study to assess Knowledge, Attitude and Practice among medical and nursing students of Bankura Sammilani Medical College Hospital

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Background: Expired medicines are a source of environmental hazards leading to public health problems if not disposed according to guideline. It is expected from future healthcare professionals that they could give the leadership to other parts of the society in managing the issue more sensitively. This study among medical & nursing students will help to estimate the base line understanding for further course of actions.

Aim / objectives: To assess Knowledge, attitude and practices of storage and disposal of expired medicine, among medical & nursing students of Bankura Sammilani Medical College Hospital.

Methods: A descriptive cross-sectional study was conducted among 200 medical and nursing students of Bankura Sammilani Medical College hospital in West Bengal. Out of 200 only 122 had given the consent for taking part in the study. They were provided a pre validated structured questionnaire set in Google Form to assess their knowledge, Attitude and Practices regarding expired and leftover medicine with 4 days window to respond. Data collection, tabulation and analysis and report generation took one month to complete. (May-

June'2023).The data were entered and analysed in excel sheet using Descriptive statistics and results were presented in the form of percentage using bar & pie diagram with statements.

Results: 87.9% cases, students responded in favour of having adequate knowledge about expired medicine. 82 students (68%) responded that there is no "Medicine take back System' in place in their city. 71.22% cases students had shown right attitude about expired medicine. 109 students (90%) said they use to store 'Over the counter' drug prior hand. 75.37% cases, students affirmed right practice about expired medicine.85 students (70%) responded that they would like to return back expired medicine to the pharmacy if opportunity exist.

Conclusion: The major study participants dispose expired medicine with household waste against recommended. Though adequate knowledge is there, deficit seen in practices and in attitude.

Keywords: Leftover expired medicine, Environmental pollution, pharmaceutical waste, Knowledge, Attitude, Practice, medical and Nursing student.

Adverse drug reaction of bullous pemphigoid associated with teneligliptin monotherapy adjunct for type 2 diabetes mellitus: A Case Report

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Background: Type 2 diabetes mellitus is a chronic metabolic disorder characterized by insulin resistance and impaired glucose regulation. Management typically involves lifestyle modifications, including diet and exercise, as well as pharmacological interventions. Teneligliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, is commonly used as a monotherapy adjunct for glycemic control in patients with type 2 diabetes. However, adverse drug reactions have been reported with its use, including bullous pemphigoid.

Objective: To present a case of bullous pemphigoid as an adverse drug reaction in a patient with type 2 diabetes mellitus receiving teneligliptin as a monotherapy adjunct to diet and exercise.

Method: A comprehensive review of the patient's medical records, including laboratory results, medication history, and clinical examination findings, was conducted. The patient's demographic information and relevant clinical data were analyzed.

Result / Case description: A 62-year-old female with a history of type 2 diabetes mellitus, managed with diet and exercise, presented with tense blisters and erosions on the upper extremities and trunk in SKIN and VD OPD, D.M.C.H , Laheriasarai. Skin biopsy revealed findings consistent with bullous pemphigoid. The patient had been taking teneligliptin as a monotherapy adjunct for the past six months, with no other significant changes in medications or exposures reported. Lesions regressed within a month of stopping DPP4 inhibitors lesions remitted in the patient and did not recur.

Conclusion: This case report highlights the occurrence of bullous pemphigoid as an adverse drug reaction associated with teneligliptin monotherapy adjunct for type 2 diabetes mellitus. While the exact pathophysiological mechanism remains unclear. There is potential association when prescribing DPP-4 inhibitors. Early recognition and appropriate management of bullous pemphigoid are crucial to ensure optimal patient outcomes in individuals with diabetes. Prompt identification, discontinuation of the suspected medication, and initiation of appropriate treatment are essential for favorable patient outcomes.

Keywords: Type 2 diabetes mellitus, bullous pemphigoid, adverse drug reaction, teneligliptin, monotherapy, diet, exercise.

NOOTROPIC EFFECTS OF ETHANOLIC EXTRACT OF TERMINALIA CHEBULA

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Objective: The present study investigates the effect of *Terminalia Chebula*, a well known medhyarasyana in Indian system of Medicine, on scopolamine induced amnesia in rats.

Materials and methods: Amnesia was induced by scopolamine (1 mg/kg s.c) in Charles foster Albino rats. Nootropic Effect of T.Chebula on amnesia was evaluated via passive avoidance, elevated plus maze and water maze test.

Results: Scopolamine induced amnesia accompanied by deficits in learning were attenuated with T.Chebula pre-treatment (100 mg/kg sc for 14 days) .

Conclusion: The results suggest that *T. chebula* might be useful in neurodegenerative conditions as a nootropic drug.

Pharmacovigilance monitoring and treatment adherence in patients on antihypertensive drugs

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Introduction: The study aims to evaluate medication adherence and pharmacovigilance monitoring in hypertensive patients

Materials and methods: A descriptive, cross sectional study was done on 124 patients who attended the outpatient department of medicine. The descriptive tools were MMA (Morisky medication adherence) scale, and WHO causality scales for adverse drug reactions

Result: The mean MMA score was 5.20 ± 1.29 . Among the demographic profile age, gender, co morbidities and duration of disease was significantly associated with mean MMA scores. Sixty three patients experienced drug reactions due to medications. Most common ADR was oedema (19.4%).

Conclusion: our study suggest that patients were poorly adherent to their medications. Effective interventions should be taken into considerations, to improve adherence in patients. Monitoring for ADRs can lead to improved patient outcomes, while interventions to improve adherence can lead to better blood pressure control and reduced risk of cardiovascular events

Key words: Hypertension, MMA scale, Adverse drug reaction, medications

LC method development for isolation of degradation products of losartan potassium and olmesartan medoxomil and their genotoxicity assessment by COMET assay

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Pharmaceutical industries are currently experiencing challenges in controlling potential genotoxic impurities in drug products, despite the availability of guidelines on managing such impurities. Since, sartans, including losartan and olmesartan are being widely used for long- term treatment of hypertension, the presence of toxic impurities such as azide and nitrosamine raises concerns about potential side effect. In this study, the genotoxicity of the degraded impurities of losartan potassium and olmesartan medoxomil was assessed using chromatographic analysis, mass spectrometric and in vitro genotoxicity studies. The separation was carried out on Porosil gold C8 (5 μ m, 10mm, 250mm) column of RP-HPLC. The degradation of sartan was carried by acid, base and peroxide. The samples were allowed to degrade to its maximum and the degraded samples were injected in FP ECOFLEX C18 4g column of Flash chromatography for separation and collection of impurity fractions. The collected impurities were characterised by LC-HRMS using ESI mode. Out of 7 impurities, 3 impurities of molecular weight 446.51 g/mol, 254.23 g/mol and 460.54 g/mol were found to be known in the literature. The genotoxicity was evaluated using *in silico* model (ProTox-II) and *in vitro* comet assay. All the 3 known impurities were found to be class 3/4 by *in silico* model. *In vitro* comet assay was performed using HEK cells. The cell suspension was exposed to the impurities (at 1.5 μ g/ml) for 4 hrs, followed by applying gel electrophoresis technique. The extent of cell damage was analysed by the imaging software Comet Assay IV. It revealed that almost all isolated impurities are probable of being genotoxic at concentration of 1.5 μ g/ml.

In silico screening of effective nutraceutical for inhibition of PRC-2 complex to target epigenetically mediated cancer resistance

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The use of nutraceuticals is seen to have great promise in the fight against cancer because the allopathic way of cancer treatment shows some unwanted side effects as well as resistance which is ultimately responsible for the therapeutic failure. The polycomb repressor complex PRC2 contains the histone methyltransferase enhancer of zeste homolog 2 (EZH2), this enzyme responsible for cancer resistance in pancreatic, prostate, glioblastoma, and colorectal cancers. Among, histone methyltransferases, EZH2 has emerged as a molecule whose overexpression and functional modifications have been implicated in various types of cancer. In this study, 50 nutraceuticals have been screened on 4 subunit proteins and further on 4 ligand interaction sites of the PRC-2 complex. The proteins are (PDB id) 4MI5, 2QXV, 4WAK, and 5WG6). The standard ligand used were GSK-126, GSK-343, and tesmetostat. The *in-silico* docking was conducted using Maestro, and Schrodinger by standard flexible docking. The glide energy, binding energy, and amino acid residue interactions were compared to suggest the potential inhibitor for further studies. Out of all the compounds anthocyanin, phloretin, hesperidin, davidiin, betanin, rosmarinic acid, and emodin showed a higher docking score and comparable binding interaction as reference ligand/drug.

Neohesperidine suppresses the progression of lung cancer by promoting the mitochondria mediated xIAP apoptotic signalling pathway

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Lung cancer is one of the major causes of death in humans worldwide. However, the results of current treatment options are still unsatisfactory. Also, the currently identified chemically synthesised compounds functioning as xIAP inhibitors have been found to exhibit adverse effects, thereby posing challenges in the context of chemotherapy treatment. Thus, the study explores low-toxic natural substances that release caspases and trigger apoptosis. Neohesperidine (NHP, a hesperidine derivative) is a flavonoid, which exhibits anticancer activity against some tumours. However, the precise molecular mechanism of NHP is still poorly known. In the current work, through *in-silico* and *in vitro* screening, we discovered that NHP significantly reduces the levels of x-linked inhibitor of apoptosis (xIAP) expression, leading to apoptotic cell death in lung cancer cells. Furthermore, NHP promoted the production of the second mitochondria-derived activator of caspase (SMAC) in lung cancer cells. It has also been observed that NHP treatment seems to trigger mitochondrial dysfunction in lung cancerous cells. Furthermore, NHP induces apoptosis as well as necrosis in lung cancer. This mechanism is regulated by mitochondria-mediated (p53, Bax, and Bcl-2-dependent) caspase-dependent apoptotic and ROS mediated pathway which also increases SMAC expression along with lowering xIAP level. Therefore, this study indicates that NHP is a potential therapeutic agent to mitigate and control the proliferation of lung cancer and might act as a SMAC mimetic agent.

Effects of Elaeocarpus Ganitrus on deoxycorticosterone acetate salt-induced hypertension and associated vascular dementia in rats

Mahesh Ahire, Abhishek Tiwari, Sanjiv Singh, V. Ravichandiran

Oxidative stress is the major cause of neuronal cell degeneration observed in neurodegenerative diseases including vascular dementia (VaD), and hypertension has been found to increase the probability of VaD. Here, we investigated the effects of *Elaeocarpus Ganitrus* (EG) in deoxycorticosterone acetate (DOCA)-salt-induced hypertensive rats (DHRs). The systolic blood pressure of rats treated with low- (10 mg per kg body weight) and high-dose (20 mg per kg body weight) EG for 4 weeks was lower than that of the control group by 12.18 and 17.48% in a dose-dependent manner, respectively ($p < 0.05$), which was regulated by inhibiting angiotensin-converting enzyme (ACE) activity and increasing the nitric oxide (NO) production. *Elaeocarpus Ganitrus*-treated DHRs showed a significant decrease in both the swimming distance and time

required to reach the escape platform (78.20 to 82.56%, $p < 0.05$). In addition, the probe trial session and working memory test indicated that *Elaeocarpus Ganitrus* improved the long- and short-term memory of the rats. Moreover, the brain antioxidant activity was increased by elevating the activities of superoxide dismutase (SOD), catalase (CAT) and glutathione peroxidase (GPx) levels, and the malondialdehyde (MDA) content and acetylcholinesterase (AChE) activity were decreased, indicating that *Elaeocarpus Ganitrus* suppressed oxidative stress. In conclusion, we demonstrated that *Elaeocarpus Ganitrus* exhibited comparable blood pressure (BP)-lowering and VaD-improving effects with the clinically used drug, lisinopril in DHRs while there was a positive correlation between the doses. Therefore, this bioactive compound may be useful for developing functional foods, thereby extending the application of *Elaeocarpus Ganitrus* -containing crops.

Anti-atherosclerotic effect of plant extract of *Musa balbisiana* in high-fat diet-induced atherosclerosis in mice.

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Atherosclerosis is a complex inflammatory disease characterized by the accumulation of lipids, cholesterol, and inflammatory cells within arterial walls. Several natural compounds have shown promising effects in combating atherosclerosis, including plant extracts with potential anti-inflammatory and lipid-lowering properties. In this study, we investigated the potential anti-atherosclerotic effect of *Musa balbisiana* plant extract in a high-fat diet-induced atherosclerosis mouse model. After 12 weeks of dietary intervention, the mice were euthanized, and their aortas were collected for histological analysis. Serum lipid profiles, inflammatory markers, and oxidative stress parameters were measured. Our results demonstrated that mice in the HFD group developed significant atherosclerotic lesions in the aortic walls, characterized by increased lipid deposition and foam cell formation compared to the control group. However, mice in the HFD+MB group showed a marked reduction in atherosclerotic lesion development, suggesting a potential protective effect of *Musa balbisiana* extract against atherosclerosis. In conclusion, our findings indicate that *Musa balbisiana* plant extract exerts an anti-atherosclerotic effect in high-fat diet-induced atherosclerosis in mice. The observed improvement in lipid profiles, inhibition of atherosclerotic lesion development, and attenuation of inflammation and oxidative stress suggest that *Musa balbisiana* extract may hold promise as a natural therapeutic agent in the prevention and treatment of atherosclerosis.

Promoting tissue repair and regeneration in the mouse model of type II diabetes mellitus

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Diabetes mellitus (DM) is the most prevalent chronic metabolic disorder, characterized by inappropriately elevated blood glucose levels that result from the body's inability to produce insulin or resistance to insulin action, or both. Approximately 537 million adults (20-79 years) are living with diabetes. World Health Organization (WHO) reckons DM is an epidemic because 10% of the world's population is at high risk of diabetes or diabetic. Unresolved wounds are the major problem associated with DM. About 20% of diabetic patients are suffering from chronic wounds worldwide. Compromised recruitment of endothelial progenitor cells, impaired collagen synthesis, and infiltration of inflammatory cytokines such as interleukin 1 β (IL-1 β) and tumor necrosis factor α (TNF α) is the key reason behind impaired tissue regeneration. We investigate the potency of morin hydrate topical films for promoting tissue restoration and regeneration of chronic wounds in diabetic rodents. C57Bl/6J mice have been selected for the study, and Type II DM was induced by using the high-fat diet and streptozotocin. The topical film was characterized by drug content, tensile strength, mechanical properties, swelling, erosion, pH, and *in-vitro* drug release. The drug content per film was 6mg whereas 40% of the drug was successfully released from the film. On day 70 a biopsy punch having 176.6 mm² area was used to create 2 full-thickness dorsal excised wounds 3-4 mm apart from each other. The wound has been allowed to form a scab for 24 hrs. After scab formation morin films were applied to the wounded area, and wounds were checked for contraction, and images of wounds were captured on a regular basis for the conformation of wound healing in animals. Animals were successfully sacrificed on days 9 and 13, and tissue was preserved for molecular studies like western blot, immunofluorescence, collagen synthesis, etc. Morin showed significant wound contraction on day 9 as compared to the control with mean closure of 61.44 \pm 11 % in the excision wound model.

Targeting adenosine receptor signaling in mitigating accelerated brain ageing

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Stress has been one of the major culprits for deteriorating human's physical, mental, social and spiritual health. However, the exact cause of stress induced neuronal inflammation, accelerated brain ageing, mood and memory deficits is not completely known. In this study, we aimed to explore the effects of chronic unpredictable mild stress (CUMS) on the brain structure and function. Chronic exposure to stress associates with subsequent age-related cognitive decline, reductions in neurogenesis, alterations in neuronal structure and cognitive integrity, cellular senescence, increased inflammation, oxidative stress, and DNA damage. As such, therapeutic strategies to reverse this CUMS-induced neurological disorders represent an unmet medical need.

Cordycepin (CP), a bioactive compound derived from the fungus *Cordyceps militaris*, and a purported adenosine receptor signalling activator known to facilitate adult neurogenesis and synaptic plasticity, may help to ameliorate stress-induced CNS impairments. To test this hypothesis, numerous neurobehavioral modalities were used to evaluate the efficacy of CP to ameliorate stress-induced learning and memory deficits along with disruptions in mood, upon repeated exposure to stressors for 4 weeks.

Our findings demonstrated that acute CP treatments (20 mg/kg orally) effectively alleviated cognitive and mood dysfunction in stressed mice. The beneficial effects of CP were exemplified by improved hippocampal and cortical-dependent memory function on the novel object recognition (NOR), object in place (OIP), and temporal order (TO) tasks, while similar benefits on mood were shown by reductions in depressive- and anxiety-like behaviours on the forced swim test (FST) and elevated plus maze test (EPMT) respectively.

The foregoing neurocognitive benefits were associated with significant increases in newly born (doublecortin+) neurons, hippocampal neurogenesis (NeuN+mature neurons), restored neuroplasticity (netrin+ neurons), and reduced expression of the inflammatory mediators (HMGB1, CD11b) in the hippocampus of stressed mice. CP also preserved telomere length (a marker for cellular ageing), attenuated cellular senescence (P16INK4a), mitigated DNA damage (8OHdG levels), and astrocytic activation (GFAP expression).

Collectively, these findings strongly indicate that CP decelerates the effects of clinically relevant stress wherein overall neurological benefits in memory and mood, coincided with increased hippocampal cell proliferation, neurogenesis, reduced expression of pro-inflammatory signatures, and preserved cellular ageing.

Naringin Increases Temozolomide Sensitivity by Affecting DNA Repair Pathway and Causes Apoptosis in T98G Glioblastoma Cells

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Glioblastoma is the most prevalent and fatal kind of primary invasive brain tumor, affecting a huge number of patients each year and having an average total survival time of roughly 14.6 months after diagnosis. Patients with Glioblastoma have a 5% 5-year survival rate, and virtually all of them experience recurrence following extensive therapy. Currently, the three principal clinical treatment techniques are surgery, radiation, and chemotherapy with temozolomide (TMZ). However, TMZ resistance frequently limits the ability to treat patients adequately. PARP inhibitors have recently been investigated as sensitizing drugs to increase TMZ efficacy. Naringin, a PARP-1 inhibitor, has been a hot candidate in the therapeutics arena. We found that when naringin and TMZ were given in combination, there was a significant decrease in percentage viability, showing the chemosensitization of TMZ in TMZ resistance cells (T98G). Further, in a protein expression study, it is revealed that naringin + TMZ inhibit DNA repair enzymes (PARP-1, MGMT) which cause chemosensitization proven by reducing expression of resistance markers (nestin, S100A4, CD70, CD15, CD44, and CD133) and ultimately cause apoptosis shown by western blot and ICC study that expression of apoptotic markers (p53, cytochrome c) increases after naringin + TMZ treatment. In conclusion, we can say

that naringin in combination with TMZ causes chemosensitization of TMZ towards glioblastoma cells and causes apoptosis in tumor cells.

Pharmacodynamic interaction profile of apigenin with diclofenac in an experimental model of inflammation in rat

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Objective: To evaluate pharmacodynamic interaction of apigenin with diclofenac by paw edema model in Wistar albino rats

Methods: The present study investigates the interaction of Apigenin, A plant flavonoid with NSAID in Wistar rats. In the study, Inflammation was induced using Carrageenan and Diclofenac was given per orally in therapeutic dose, sub-therapeutic doses, most effective dose of Apigenin(20mg/kg), subtherapeutic dose & maximal dose of Apigenin 1hr. before Carrageenan administration. Most effective dose of Apigenin was co-administered with sub-therapeutic dose of Diclofenac. Percentage Protection of paw edema was calculated.

Results: Standard drug with proven anti-inflammatory property (Diclofenac-100mg/kg) showing maximum protection (66.66%) against carrageenan induced rat paw edema in all the time interval (+1hr., +2hr., +3hr., +4hr., +5hr., +6hr.). Among all three doses of apigenin most effective anti-inflammatory dose of apigenin(20mg/kg) showing maximal percentage of protection ($P<0.001$) i.e., 47.65% against carrageenan induced rat paw edema at +3hr. Standard drug with proven anti-inflammatory property (Diclofenac-100mg/kg) showing maximum protection effect at +3hr. includes 55.70% ($P<0.001$) in comparison with control treated group. Sub-therapeutic dose of Diclofenac-50mg/kg individually showing less protection effect (21.47%) than maximal dose of apigenin (Ap-40mg/kg=28.18%). While we combined most effective anti-inflammatory dose of Apigenin(20mg/kg) with sub-therapeutic dose of standard drug (Diclofenac-50mg/kg) showing near about 50% of protection rate which can compete the anti-inflammatory efficacy of standard dose of diclofenac(100mg/kg) alone.

Conclusion: - Present study demonstrate the pharmacodynamic interaction of Apigenin as it potentiates the anti-inflammatory activity of subtherapeutic dose of Diclofenac in rat.

Role of NHP051 attenuating radiation induced Mood & memory deficits, Cognitive dysfunction & CNS complications in mice

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Despite improvements in the radio therapeutics management of brain tumors, the majority of survivors still experience persistent cognitive dysfunctions as one of the after effect. It has been difficult to pinpoint the exact causes of normal tissue toxicity, but preclinical rodent models have provided evidence that decreased neurogenesis and microvascular integrity, impaired synaptic plasticity, increased inflammation, and changes in neuronal structure are contributory, if not causal, factors. Along with previous mentioned factor, we also explored towards a novelty that radiotherapy also have potency to altered energy source of brain. To explore this hypothesis four treatment paradigm were used to evaluate the efficacy of our NHP051 to reverse radiation induced altered cells in brain as well as its correlation with learning and memory, mood disturbance and depression in cranial irradiated mice. Result demonstrated that two weeks treatment of NHP051 effectively alleviated cognitive and mood dysfunction in cranially irradiated mice. The significant effects of NHP051 were exemplified by improved hippocampal- and cortical-dependent memory function on the novel object recognition and object in place tasks, while similar benefits on mood were demonstrated by reductions in depressive-like behaviors on the forced swim test. Additionally, data confirmed that NHP051 enhanced the cognitive flexibility and extinction of spatial learning in Water Maze test. Furthermore, western blotting analysis revealed that our compound has potency to increase the population of newlyborn and mature neurons in the hippocampal region of the brain, in addition it also attenuates inflammation by inhibiting the expression of HMGB1 and CD200 proteins in the cranial irradiated brain of mice.

Further, it also helps to advance a variety of efforts toward understanding and modulating the cognitive process and exploring molecular and cellular therapeutic targets for radiation induced mood and memory alteration and neurodegeneration.

An exploratory study of the relationship between serum uric acid levels and renal function in chronically ill patients

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Background: Renal failure is frequently brought on by chronic illness, which presents a serious healthcare burden. In certain populations, serum uric acid (SUA) levels have been proposed as a possible biomarker for renal function. In order to determine if SUA could be useful as a marker for renal impairment in this population, this exploratory study sets out to examine the connection between SUA levels and renal function in a sample of 100 patients with chronic illnesses.

Aims and objective: -The aim of this exploratory study was to investigate the relationship between SUA levels and renal function in a sample of 100 chronically sick patients, with an emphasis on the relationship between SUA and estimated glomerular filtration rate (eGFR). The study also sought to pinpoint other determinants of this association, including comorbid conditions, age, and medication use.

Materials and methods: 100 patients with chronic illnesses were used as a sample in a cross-sectional study. To quantify SUA levels and evaluate renal function by eGFR calculations using pre-established methods, blood samples were taken. Statistical analyses, including correlation tests and multivariate regression models, were performed to examine the relationship between SUA levels and eGFR, while controlling for potential confounders.

Results: In the sample of 100 patients with chronic illnesses, the study discovered a statistically significant negative connection ($r = -0.37$, $p 0.001$) between SUA levels and eGFR. Even after accounting for age, sex, comorbidities, and medication use, this link was still significant (coefficient = -0.24 , $p 0.001$). Results from subgroup analysis were consistent across various age groups and comorbidity profiles. Furthermore, lower eGFR ($60 \text{ mL/min/1.73m}^2$) revealed a higher incidence of renal impairment in the presence of elevated SUA levels.

Conclusion: This small, 100-patient exploratory investigation shows a strong correlation between higher SUA levels and impaired renal function. The findings suggest that higher SUA levels may be indicative of reduced renal function in this population. As a result, SUA may be used as a possible biomarker to track renal health and identify people with chronic illnesses who are at risk of developing renal impairment. In order to confirm these results and assess the clinical use of SUA as a predictive marker in maintaining renal function in chronically sick patients, additional research with bigger sample sizes and longitudinal studies are required.

Dapagliflozin-Induced Pancreatitis: A Case Report

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Introduction: Recently developed sodium-glucose cotransporter-2 (SGLT2) inhibitors have become a great insulin-independent approach for type 2 diabetic management. Acute pancreatitis is characterized by a recent inflammatory reaction within pancreatic tissue. Numerous etiologies have been identified, with gallstones and chronic alcohol consumption representing the two most common.

Case Presentation: A 60 year old female diagnosed with type 2 diabetes mellitus since 5 years, was prescribed with metformin 1000 mg and dapagliflozin 25 mg once daily. After 1 month of pharmacotherapy, she reported to emergency department with sudden onset, sharp left upper quadrant abdominal pain associated with multiple episodes of nausea and vomiting. Abdominal CT was concerning for ileus and severe pancreatitis. The patient was treated in the traditional manner, including bowel rest, intravenous fluids, antibiotics, and pain management. The patient was able to advance to clear liquid diet five days later, followed by persistent daily advancements in diet until discharge. Dapagliflozin was stopped and vildagliptin 100 mg was added.

Conclusions: With a growing body of case reports, it is imperative physicians and related healthcare providers remain vigilant for adverse drug reactions in the setting of dapagliflozin initiation. Care should be put into adequate patient education so that patients can be active participants in symptom surveillance. A lower threshold for dapagliflozin discontinuation may be prudent.

Keywords: Dapagliflozin, Acute Pancreatitis, Type 2 Diabetes

Prevalence of elevated serum total Immunoglobulin E(IgE) in patient of chronic spontaneous urticarial (CSU)

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Background: Immunoglobulin E (IgE) and its receptor, FcεRI, importantly contribute to the pathophysiology of chronic spontaneous urticaria (CSU). Recent findings point to a possible role of total IgE as a marker of CSU disease activity, endotypes, and responses to treatment. The evidence in support of total IgE included in the diagnostic workup of patients with CSU has not yet been reviewed. Chronic urticaria is a frequent disease with a broad spectrum of different clinical presentations.

Objective of study:

To study the prevalence of elevated serum IgE in patient of CSU.

Materials and methods:

A total of 50 patients with chronic spontaneous urticaria from Department of Skin & V.D as well as 50 healthy control were enrolled in this study. Serum levels of total IgE, was measured in CSU patients as well as healthy controls.

Results:

In the chronic urticaria patients, 4 (8%) were classified as mild, whereas 17 (34%) were classified as having moderate and 29 (58%) as having severe chronic urticaria. Total IgE levels were elevated, above 175 U/ml, in 17/50 (34%) of patients, compared with 4/50 (8%) of healthy controls ($p < 0.001$). A significant association between increased total IgE and chronic urticaria severity was found. Whereas 92% of patients with increased level of total IgE suffered from moderate-to-severe chronic urticaria.

Conclusion: Total serum IgE levels are frequently elevated in patients with chronic urticaria and these are associated with disease severity. The results suggest that total IgE is a valuable marker for CSU.

Correlation of liver enzymes in type 2 diabetes mellitus

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Background: The prevalence of raised liver enzymes common in Type 2 diabetes mellitus (T2DM). A study in Type 2 diabetes patients were analysed alanine aminotransferase, aspartate aminotransferase (ALT, AST) and alkaline phosphatase (ALP) elevated enzymes along with Fasting blood glucose (FBG) and glycosylated hemoglobin (HbA1c) along with total protein (TP) in T2DM.

Material and Method: This was a cross-sectional descriptive study clinic-based study in patients with T2DM. A total of 140 participants (70 healthy controls and 70 T2DM) were recruited. Activity of liver enzymes including alanine and aspartate aminotransferase (ALT, AST) along with alkaline phosphatase (ALP) was measured. FBG and HbA1c along with TP were also measured.

Quantitative variables were expressed as mean \pm SD, while qualitative variables as frequencies (%). A P-value of $< .05$ was set as statistically significant.

Results: The study was conducted on 70 T2DM patients as case and 70 healthy people, out of 70 T2DM patients, 28 were male and 42 were female. The mean age of the T2DM patients was 46.4 ± 13.6 years, while healthy individuals have mean age of 39.2 ± 12.0 years. It was observed that the activity of AST in T2DM is comparable with the healthy persons ($P = .060$). While the level of ALT, total bilirubin and ALP in T2DM is significantly higher compared to healthy control ($P < .000$). On average, 62.53% of T2DM subjects and 32% of participants of healthy subjects had abnormal liver enzymes activity.

Conclusion: The present study has revealed widely co-existent derangements in liver function tests (LFTs) in the diabetic population. A detailed workup in such patients may be helpful in timely diagnosis and treatment. Moreover, early detection and management of abnormal liver parameters in T2DM would help minimize liver-related morbidity and mortality.

Pharmacovigilance among geriatric patients: Report from Katihar Medical College & Hospital, Bihar

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Introduction: According to Census 2021, 8.14% of Indian population has crossed 60 years of life or geriatric age group. This age group calls for a diversity of physiological and pathological changes that influence pharmacokinetic and pharmacodynamic aspects of a drug. Moreover, polypharmacy among these individuals is not very uncommon, due to multisystem involvement. This poses them at risk of variety of drug interactions and Adverse Drug Reactions (ADRs), as well. The current pharmacovigilance study in Geriatric patients done at a tertiary care hospital of Bihar to assess the spectrum, cause, severity and preventability of ADRs.

Materials and Methods: With this background, an observational study was conducted by the Department of Pharmacology, Katihar Medical College & Hospital, Bihar. All patients who were aged ≥ 60 years and diagnosed with ADR during the span of 6 months (January 2023 to June 2023) were included in the study. Informed consent forms were obtained from each participant. Suspected ADR reporting forms were used to obtain information in ADR along with its characteristics. WHO-UMC system was used to assess the prevalence and profile of ADRs. Data was entered and analyzed using Microsoft Excel.

Results: A total of 52 suspected cases of ADR among geriatric population were taken into consideration over the study period. The most common form of ADRs were cutaneous (48.1%), followed by metabolic (32.7%) and gastrointestinal involvement (7.7%). Out of all cases, 61.5% ADRs were possible, 71.2% were moderate in intensity and 75% ADRs were probably preventable.

Conclusion: Most common form of ADR reported was cutaneous form followed by metabolic manifestation. Majority cases were of moderate intensity and majority of the cases were probably preventable as well.

Keywords: ADR, Pharmacovigilance, Geriatric population

Covishield Induced Allergic Asthma: A Case Report

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Introduction: We are describing a case of a 32 years female with no comorbid illness who developed episodes of asthmatic symptoms after taking 1st dose of covishield vaccine for COVID-19. She had frequently visited the outpatient department and emergency department for her symptoms. This is the rare adverse reaction related with covishield vaccine.

SYMPTOMS & SIGNS:

1. Runny nose
2. Recurrent coughing
3. Shortness of breath (increasing over time in an episode)
4. Rhonchi and wheeze on auscultation

After considering these symptoms and signs, patient had been diagnosed with a case of Allergic Asthma. Giving formoterol 6 mcg and budesonide 200 mcg in outpatient department, symptoms got relieved. Nebulizing with levosalbutamol 0.63mg & ipratropium 500mcg along with iv hydrocort 100mg in emergency setup, patient got relieved with her symptoms. Her symptoms were more than 3 episodes in a week, so she had been advised to take "foracort 200 rotacap" with rotahaler 12 hrly and follow up after regular interval or as advised by treating doctor.

Apart from the allergic reactions described above, Covishield vaccine must be closely monitored in order to detect any additional adverse reactions. Both healthcare professionals and patients should report promptly any unexpected or serious adverse reactions. This is vital because it will aid in their prevention and treatment. Careful vaccine-safety surveillance over time will contribute to the development of a safe vaccine strategy.

Super Vasmol hair dye induced progressive chemical vitiligo: A Case Report

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Introduction-A rare adverse reaction related to super vasmol hair dye. In this case we describe a case of 40yrs old female with no previous complication. After applying two to three episodes of super vasmol hair dye, she developed white decoloration of skin adjoining hairline at the nape of neck, which was progressively increasing with itching.

Signs and symptoms-

1. Development of whitish discoloration of skin of nape of neck adjacent to hairline.
2. Itching at border.

O/E whitish discoloration spreads above hairline, below back, and in front of chest.

With these signs and symptoms and after having slit lamp examination, patient was diagnosed as contact dermatitis (Progressive chemical vitiligo).

Treatment was started with PUVA therapy, psoralen, sunscreen lotion having SPF50%, lactocalamine lotion. Within 1 to 2 months vitiligo spreads to adjacent area with some depletion of depigmented area. Again, the treatment changed to Tacrolimus 0.1% ointment apply to affected area with precaution, twice daily & 0.1% clobetasone propionate ointment twice daily.

Progression of disease slowed as well as cure started but at slower rate. Oral corticosteroid 25mg added once daily. Treatment continued to one and half to two years. Depigmented area of neck vanishes, but white area in scalp is still there, so now she is taking corticosteroid thrice a week. She is advised to visit if any sign and symptoms appear.

Apart from the allergic reactions described above, every hair dye including Super Vasmol hair dye should be

Analysis of the prevalence and practice of self-medication among outpatients in a tertiary care hospital of Patna, Bihar, India

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Background – self medication practised globally is an important public health problem. Inappropriate self-medication results in ADR, disease masking, drug interaction antibiotic resistance and wastage of health resources.

Aims/Objective – To estimate prevalence and practice of self medication in the study group.

Method – Questionnaire based cross sectional study was done between Feb to April 2023 in 100 randomly selected outpatients of NMCH. Self medication for this study was the use of medicine in 3 months without prescription of medical practitioner.

Descriptive data analysis was done and reported in frequency percentage. The study revealed high prevalence of self medication with 17% of subjects practicing it frequently and 56% occasionally.

Results – Most of the patients practicing self medication were male. 72% in age group 31-60 yrs old. Most common conditions were headache, fever, cold. Most of the patients practicing SM were either illiterate or high school drop out. Also the general health condition of patient was one important factor. SM being more common in patient with chronic illness.

Conclusion – Self medication practices are quite frequent in India. Fever, cold, headache were most common illnesses. Pharmacist were source of information. Irrational use of antibiotics 18% without considering its dose and prolonging the course of treatment was observed.

Keywords: Self medication, Antibiotic, Drug, Diagnosis.

Guggul based therapy as an adjuvant to conventional dilzem among patients of stable angina attending a tertiary care centre of Bihar

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Background: Cardiovascular disease (CVD) is the number one cause of death globally. Dyslipidaemia is a well-known risk factor for the development of cardiovascular disease, a leading cause of morbidity and mortality in developed countries. As a consequence, the medical community has been dealing with this problem for decades, and traditional statin therapy remains the cornerstone therapeutic approach. Guggul based therapy is one such approach.

Objective: To evaluate the role of guggul based agent in comparison with dilzem among patients of stable angina attending medical OPD of Katihar Medical College, Bihar.

Methodology: A double blinded randomized trial was conducted by Department of Pharmacology. Sixty clinically diagnosed cases of stable angina attending the medical OPD during the span of 1 year (July 2022 to June 2023) were enrolled in the study. Patients were divided in 3 equal groups. Group A was given tab Dilzem 30 mg TDS for 45 days, group B received Lasunadi Guggulu Vati 2 grams TDS for 45 days and group C was given both. Lipid profile was used for assessment. Dietary and lifestyle modifications were introduced. Statistical analysis was done using Microsoft Excel. Paired t-test was done to evaluate effectiveness of the intervention.

Results: The mean age of the patients was 52.6 with SD of 11.2 years. There was a male dominance. Majority had positive family history of IHD, followed non-vegetarian diet and had sedentary lifestyle. All the three groups were comparable based on these background characteristics. The mean difference in serum cholesterol, triglycerides, HDL, LDL and VLDL was 32.5, 37.5, -5.1, 20.8 and 8.1 mg/dl, respectively, in group B. In group C, the mean difference in serum cholesterol, triglycerides, HDL, LDL and VLDL was 30.2, 48.9, -5.9, 32.2 and 9.1 mg/dl, respectively. However, only serum triglycerides showed significant changes in group A patients. This showed good dyslipidemia correction and cardioprotective action of guggul.

Conclusion: Guggul based therapy has shown encouraging results in correcting dyslipidemia among patients of stable angina and has cardioprotective action.

Keywords: Guggul based therapy, Dilzem, Dyslipidemia

Comparative study of Metformin and Sitagliptin/Metformin in treatment of Type 2 Diabetes Mellitus

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Background: Type 2 Diabetes mellitus is a chronic metabolic disorder in which prevalence has been increasing steadily all over the world. Sitagliptin is a dipeptidyl - peptidase inhibitor that has recently approved for the therapy of Type 2 Diabetes mellitus. Like other DPP -IV inhibitor Sitagliptin's action is also mediated by increasing level of incretin hormones glucagon-like-peptide -1 (GLP-1) and gastric inhibitory polypeptide (GIP). Metformin is a biguanide drug that reduces blood glucose level by decreasing glucose production in the liver, decreasing intestinal absorption, and increasing insulin sensitivity. Metformin decreases both basal and PPBS. Metformin is recommended with dietary changes and exercise for better results. Sitagliptin is effective in lowering Glycosylated hemoglobin (HbA1c) and fasting blood sugar (FBS).

Aims and Objectives: To compare the efficacy and safety of Metformin monotherapy and Metformin/Sitagliptin combination therapy.

Methods: A prospective study was done on 40 patients selected from NMCH, Patna from February 2023 to May 2023. Patients divided into two groups: Metformin 500 mg monotherapy group and combination of Sitagliptin (100mg)/Metformin (500 mg). The primary and secondary end points were any changes in baseline HbA1c and Fasting Blood Glucose after 12 weeks of treatment in both groups.

Results: After study of 12 weeks, reduction in HbA1c was found in greater proportion of patients receiving Sitagliptin /Metformin combination had HbA1c level below 7% or below 6.5% compared with those receiving metformin monotherapy (49.2% VS 34.2% and 31.8% VS 16%, P<0.001). Improvement in FBS were also significantly greater in the combination group (-68.5 mg/dl vs -54mg/dl, P<0.001) respectively. Hypoglycemic episodes were less pronounced in combination therapy as compared to monotherapy.

Reduction in body weight and lipid levels were similar among treatment groups.

Conclusion: Among patients with Type 2 DM, study shown that there was more reduction in HbA1c and FBS in combination therapy of Sitagliptin/Metformin as compared to Metformin Monotherapy. Addition of sitagliptin to metformin was well tolerated and gastrointestinal side effects and hypoglycemic episodes were not increased.

Keywords: Type 2 DM, Sitagliptin, Metformin

A comparative study of low dose isotretinoin in daily and alternate day regimen in treatment of acne vulgaris

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Background: Acne vulgaris is a very common skin disorder which can present with inflammatory and non-inflammatory lesions of pilosebaceous unit, mainly involving the face but can also occur on the upper arm, trunk & back. Oral isotretinoin is highly effective in all forms and grades of acne, even in lower dosages (<0.5 mg/kg/day).

Aim and Objectives: To assess and compare the efficacy and tolerability of two lowdose oral isotretinoin treatment regimens (20 mg daily and 20 mg alternate days) in moderate to severe acne vulgaris.

Materials and Methods: A prospective randomized comparative study was performed in 120 patients selected from NMCH from February 2023 to May 2023 with moderate to severe acne vulgaris into two groups and treated with a fixed dose of 20 mg of isotretinoin (Group A daily and Group B alternate days) for 16 weeks. Treatment response was also evaluated according to response criteria, which is as follows:

1+ = Poor response (<30% reduction)

2+ = Fair response (30%–60% reduction)

3+ = Good response (60%–90% reduction)

4+ = Excellent response (>90% reduction)

Results:

According to severity of acne, in cases of severe acne a statistically significant difference in response rate was noted between both groups (Group A better than Group B) during the study period (P value < 0.005) whereas in cases of moderate acne statistically significant difference between both groups (Group A better than Group B) was observed only up to 12 weeks (P value < 0.02).

At 16 weeks the excellent response in treatment groups A and B was seen in 98.3% and 93.96% patients, respectively (P= 0.166).

Conclusion: We conclude that fixed low-dose regimen of oral isotretinoin should be encouraged because of excellent response in moderate-to-severe acne with the advantage of lesser adverse effects, patients compliance, and cost effectiveness. In moderate acne 20 mg alternate day regimen can be preferred, but for severe acne 20 mg daily regimen is a better choice in the terms of response.

Keywords: Acne Vulgaris, Isotretinoin, low dose

A comparative study of efficacy and safety of timolol versus latanoprost in the treatment of primary open angle glaucoma at Sri Krishna Medical College, Muzaffarpur

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Objective: Primary open-angle glaucoma (POAG) is a chronic eye disease characterized by progressive optic nerve damage, often resulting in vision loss. Timely and effective management of POAG is essential in preserving visual function. This study aimed to compare the efficacy and safety of timolol and latanoprost, two commonly used medications for POAG.

Methods: An observational study was conducted in the department of Ophthalmology with collaboration in the department of Pharmacology, patients diagnosed with POAG who received either timolol or latanoprost as monotherapy, between January 2023 to May 2023. The primary outcome measures were intraocular pressure (IOP) reduction and maintenance of visual field function. Secondary outcome measures included the occurrence of adverse events and patient adherence to treatment regimens.

Results: A total of 30 patients were included in the study, with half (15 patients) receiving timolol and the other half (15 patients) receiving latanoprost. After 6 months of follow-up, both medications showed

significant reductions in IOP levels from baseline ($p < 0.05$). However, latanoprost demonstrated a greater mean reduction in IOP compared to timolol ($p < 0.001$). Moreover, latanoprost exhibited a higher rate of achieving target IOP levels compared to timolol ($p < 0.05$). There were no significant differences in the preservation of visual field function between the two groups ($p > 0.05$). Adverse events were minimal and comparable between the two medications, with the most common being ocular irritation.

Conclusion: In this comparative study, latanoprost demonstrated superior efficacy in reducing IOP levels and achieving target IOP compared to timolol in patients with POAG. Both medications showed comparable safety profiles with minimal adverse events reported. These findings suggest that latanoprost may be considered as a preferred first-line treatment option for POAG. However, further prospective studies are warranted to validate these results and evaluate long-term efficacy and safety outcomes.

Keywords: Primary open-angle glaucoma, timolol, latanoprost, intraocular pressure, visual field, efficacy, safety, comparative study, tertiary care hospital.

The pattern of drug usage in pregnant women of the obstetrics and gynaecology department at a tertiary care hospital

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Background: Drug usage during pregnancy requires careful consideration due to the potential impact on both maternal health and fetal development. Understanding the patterns of drug usage among pregnant women is crucial for optimizing maternal and neonatal outcomes. This study aimed to investigate the pattern of drug usage in pregnant women attending the Obstetrics and Gynecology Department at Sri Krishna Medical College Muzaffarpur.

Methods: A prospective analysis was conducted pregnant women who received antenatal care at the Obstetrics and Gynecology Department at Sri Krishna Medical College & Hospital. During the period of 6 months. Information regarding drug usage, including medication type, dosage, duration, and indication, was extracted in the department of Pharmacology. The collected data were analyzed to identify the most commonly used medications, their therapeutic categories, and the prevalence of drug usage in different trimesters.

Results: First Trimester: 40% ($n = 40$) of pregnant women used medications during this period. The most commonly prescribed medications in the first trimester were folic acid (30%), prenatal vitamins (25%), and progesterone (10%). Second Trimester: 60% ($n = 60$) of pregnant women used medications during this period. The most commonly prescribed medications in the second trimester were prenatal vitamins (55%), iron supplements (30%), and antihypertensive medications (10%). Third Trimester: 50% ($n = 50$) of pregnant women used medications during this period. The most commonly prescribed medications in the third trimester were prenatal vitamins (40%), calcium supplements (25%), and progesterone (15%).

Conclusion: The findings highlight the prevalence of drug usage, with 72% of pregnant women receiving medications. The study identifies the most commonly prescribed medication categories and specific medications, including prenatal vitamins and supplements, antenatal medications for specific conditions, antibiotics, analgesics, and antiemetics. This information can aid healthcare providers in optimizing the management of drug usage during pregnancy, ensuring the well-being of both mother and child. Further research is needed to evaluate the safety and efficacy of specific medications used during pregnancy to improve clinical practice guidelines and promote optimal maternal and neonatal outcomes.

Keywords: Drug usage, pregnant women, folic acid, iron supplements, calcium supplements.

Fixed Drug Eruption Following Azithromycin administration: A Case Report

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Background: Fixed drug eruptions is an adverse drug reaction that occur at same site everytime the offending drug is taken. It occur when a person is exposed to a particular medication, resulting in the development of distinct patches on the skin. These patches can be single or multiple, with well-defined boundaries, and they typically have a round to oval shape. FDE present within 30 min to 10 hours after taking drug. Clinically it presents with well-defined lesion, round or oval in shape, can be single or multiple. They appear oedematous and red, ranging in colour from pink to dark red to brown. Skin and mucosal surface are commonly involves.

Objective : To report a fixed drug eruption (FDE) that occurred following the administration of Azithromycin administration.

Case Report:

A 35-year-old male came to skin and vd opd D.M.C.H, Laheriasarai with complain of bullous lesion over right ankle and painful oral erosions . Detailed history of patient was taken and cutaneous examination was done. He reveals that he had been prescribed Azithromycin for grade 2 acne vulgaris . 4 to 5 hour following drug administration he developed these lesion. He has revealed he had similar lesion in past when he used to take medicine for Common cold. The patient was educated about FDE and the importance of drug avoidance. Follow-up visits were scheduled to monitor the resolution of lesions and ensure patient compliance.

Conclusion:

This case report emphasizes the importance of considering FDE as a possible adverse reaction to Azithromycin . Physicians should be vigilant in recognizing the characteristic clinical features and obtaining a detailed drug history.. Management involves discontinuation of the offending medication and symptomatic treatment. Patient education regarding drug avoidance is essential to prevent future episodes and minimize potential complications associated with FDE.

Keywords: fixed drug eruption, Azithromycin, adverse drug reaction.

Pattern of use of anti-hypertensive drugs amongst hypertensive patients at Bmims Pawapuri, Nalanda

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Background:- Hypertension is one of the primary modifiable risk factor for cardiac and renal disease and is single most important risk factor for stroke.Despite different guidelines for management of hypertension like JNC,BHS,NICE there are still the clouds of controversy.

Aims & Objective:

To evaluate the prescribing pattern of antihypertensive drugs among the patients attending medicine outpatient at Bhagwan Mahavir Institute of Medical Sciences in Pawapuri, Nalanda, Bihar.

Methods:

A Cross-sectional, observational study was conducted in our hospital over a period of six months. Relevant information was collected from medical records of 206 hypertensive patients fulfilling inclusion criteria. The collected data were sorted and analysed.

Results:

Out of 206 patients , maximum were of age group of 45-64 years(55%).112(55%) were male and 94(45%) were female.Diabetes mellitus(24.4%) was the most common associated disease with hypertension.most of the patients had received single hypertensive drugs(90.9%).Among the monotherapy category calcium channel blocker (CCB)(82.77%) was the most commonly prescribed antihypertensive drugs class followed by Angiotensin converting enzyme inhibitor (29.66%).Amlodipine(81.8%)was the most common among CCBs.The most frequent two drug combination prescribed consisted of Amlodipine and Atenolol.Most of the drugs were prescribed in generic name.

Conclusion:

By addressing these findings ,The treatment pattern in general, confirmed to standard treatment guidelines.

Key words: - Hypertension, Amlodipine, Generic.

ADR reporting of suspected drug-induced Steven John's Syndrome: A Case Study

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Introduction

Pharmacovigilance (PV) is a very significant and inevitable part of drug discovery and development, which requires a comprehensive documentation process and severe monitoring at every phase of drug development including risk management and pre & post-authorization safety studies. This necessitates an utmost requirement for effective regulations of the drug approval process and conscious pre- and post-approval vigilance of the undesired effects, especially in India. PV helps the patients get well and to manage optimally or ideally, avoid illness is a collective responsibility of industry, drug regulators, clinicians, and healthcare professionals to enhance their contribution to public health.

Case Presentation

This case was considered as serious (Hospitalization). The initial spontaneous report was received from a healthcare professional regarding a 21-year-old female patient, who experienced Drug-Induced Erythematous Stevens-John Syndrome while on treatment with Monocef SB 1 gm for the treatment of fever. The patient's medical history includes delivered a baby by LSCS 2 months back and 3 units of blood transfusion were done. The patient was hospitalized due to ADR, Fever, itching, and red patches all over the body and discharged after three days. On discharge, patient was advised to take Monocef 1gm twice a for 3 days, Amikacin 500 Mg BD for 3 days, and Tab Paracetamol 650 mg SOS for 3 days and few days after discharge from the hospital she again got a fever and the advised treatment was started by the patient. The patient is recovering from the event but pedal edema, Low hemoglobin, and fever are still persistent. The action taken with the suspected drug was withdrawn. The patient has been recovering from the event and the treatment is under process. The reporter suspected that the adverse event was possibly related to the suspected drugs (as per the WHO UMC scale).

Discussion

A rare but serious ADR reported at an overall rate of less than 1% of the entire patient population, may seem less significant than it truly is to the individual patient. Case reports are especially valuable in identifying rare ADRs not previously seen or evaluated by the FDA or CDSCO. A causality assessment was done for the case and concluded that the ADR was probably / likely related to the suspected medicine, that is Ceftriaxone (as per the WHO-UMC scale).

Conclusion

The patient was admitted to Prabha nursing home, Gaya on 14.08.21 for ADR fever, red patches on the skin, and itching. She was discharged on 17th aug 2021 after recovering from mild ADR. During discharge, the patient was advised Monocef 1 mg, Amikacin, Pan 40, and Dolo. Few days later, she was brought to IGIMS emergency medicine and experienced SJS, Drug-Induced Erythromatus rashes, peeling of the skin, and burning sensation all over the body. And it was suspected that Patients experienced severe Adverse Reactions due to the suspected medication Ceftriaxone. It also comes under medication error.

Analyzed comprehensively, a signature of LncRNA-mRNA integration reveals the functional role of a Linc RNA in triple negative breast cancer

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Background: Triple negative cancer (TNBC) represents a highly aggressive subtype of breast cancer. The mechanism through which long non coding RNAs (lncRNA) regulates TNBC tumorigenesis remain elusive. IN this research, we investigated the roles and regulatory aspects of lncRNAs in TNBC, both prior to and following treatment, by comparing them to healthy controls.

Methods: Here, we compared the expression profiles of mRNAs, lncRNAs and between treated and non-treated sample utilizing RNA-Seq Data from The Cancer Genome Atlas (TCGA). Gene Ontology and KEGG pathway enrichment analyses were executed to investigate the principal functions of the significantly dysregulated mRNAs and lncRNA.

Results: A total of 245 lncRNA, 345 mRNA were found to be differentially expressed in TNBC blood sample pre-treated compared with healthy controls. 269 lncRNA, 345 mRNA were found in post treated vs control. Functional analysis revealed that 19 mRNAs in the ceRNA network were enriched in 17 cancer related pathways.

Conclusion: Taken together, we identified novel lncRNAs/miRNAs which may serve as potential biomarkers to predict the survival and therapeutic targets for TNBC patients based on a large-scale sample. More importantly, we constructed the ceRNA network of TNBC, which provides valuable information to further explore the molecular mechanism underlying tumorigenesis and development of TNBC.

Rational Use of Drugs and Drugs Hazards: A Review

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Background The rational use of drugs is a fundamental principle in healthcare systems worldwide, aimed at optimizing patient outcomes while minimizing drug-related risks. The concept of rational drug use and

highlights the potential hazards associated with drug administration.

Aims & Objective:

The objective of this study was to assess the rational use of drugs and identify potential drug hazards among patients receiving healthcare services at BhagwanMahavir Institute of Medical Sciences in Pawapuri, Nalanda, Bihar.

Methods:

A Cross-sectional analysis was conducted at BhagwanMahavir Institute of Medical Sciences, Pawapuri, Nalanda (Bihar) from March 2023 to May 2023, A total 50 patients were enrolled for the study, The study focused on evaluating drug prescription patterns, adherence to treatment guidelines, and the occurrence of drug-related hazards such as adverse drug reactions (ADRs), medication errors, and drug interactions. Data were collected, coded, and analyzed using appropriate statistical methods.

Results:

The study included a total of 50 patients, with 10 patients in the age group below 18 years, 30 patients in the age group of 18-65 years, and 10 patients above 65 years. there were 25 male patients and 25 female patients. 80% of the patients were prescribed multiple medications, with analgesics being the most commonly prescribed drug class (60%), followed by antibiotics (50%) and antihypertensives (40%). A total of 20% of patients experienced documented adverse drug reactions (ADRs), with gastrointestinal reactions being the most common (10%), followed by allergic reactions and central nervous system effects (both at 5%). The severity of ADRs varied, with 10% categorized as mild, 5% as moderate, and 5% as severe.

Conclusion:

By addressing these findings and implementing appropriate interventions, Bhagwan Mahavir Institute of Medical Sciences can enhance the rational use of drugs, reduce drug-related risks, and improve patient safety and healthcare quality. Continuous monitoring, evaluation, and improvement of prescribing practices and medication safety protocols are essential for ensuring optimal patient outcomes and the overall well-being of the patients served by the institute.

Key words: Hazards of drugs, rational use of drugs.

Fixed Drug Eruption Following Doxycycline administration: A Case Report

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Background: Fixed drug eruption (FDE) is a distinct type of adverse reaction to drugs affecting the skin and mucous membranes. It is characterized by its tendency to reoccur at the same site on the skin or mucosa whenever the offending drug is administered, thus earning the term "fixed." FDEs occur with common causative drugs including analgesics, sulfonamides, and tetracyclines, among others. Typically, it presents as a solitary, well-defined, round or oval patch or plaque with a violaceous or dusky erythematous background, often accompanied by itching or burning sensations. In some cases, localized vesicles or bullae may form, leading to the condition being referred to as localized bullous FDE.

Objective : To report a fixed drug eruption (FDE) that occurred following the administration of Doxycycline

Case Report: A 30-year-old man visited skin and vopd, DMCH Laheriasarai with a recent 4-day history of multiple red, itchy, and painful patches on his skin. These patches had varying sizes and were accompanied by blisters and fluid-filled sacs (bullae) scattered all over his body. Additionally, the patient had ulcerations in his mouth and genital area. He mentioned that these skin lesions appeared suddenly about 3 hours after taking a single dose of doxycycline (100 mg), which was prescribed by a physician to treat a skin infection. Interestingly, the patient disclosed that a similar outbreak occurred in the same areas two years ago following the use of the same medication. However, during that previous episode, the lesions were fewer and less extensive, eventually healing and leaving behind darkened spots on the skin (residual hyperpigmented macules). He denied taking any other drugs that could be responsible for the condition. Doxycycline was stopped, and the patient was managed conservatively along with a short course of oral corticosteroid (prednisolone - 1 mg/kg/day) for 10 days. The lesions resolved with residual post inflammatory hyperpigmentation. The patient was advised to strictly avoid doxycycline and other related drugs in the future

Conclusion: This case report highlights the significance of recognizing Fixed Drug Eruption (FDE) as a potential adverse reaction to Doxycycline. Physicians should exercise caution and attentiveness in identifying the characteristic signs of FDE and obtaining a comprehensive history of the patient's medication intake. When FDE is suspected, the immediate action is to discontinue the use of the triggering drug and

initiate appropriate treatment to alleviate symptoms. Educating the patient about avoiding the offending drug in the future is crucial to prevent further episodes and minimize the risk of complications associated with FDE

Keywords: fixed drug eruption, Doxycycline, adverse drug reaction.

Adverse Drug Reactions of Latanoprost: A Case Report

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Background: Primary open-angle glaucoma (POAG) is the prevailing type of glaucoma, and elevated intraocular pressure (IOP) is a major risk factor associated with it. Studies have demonstrated that lowering IOP can effectively slow down the progression of the disease. Latanoprost, a prostaglandin analog used in the treatment of glaucoma, has known adverse drug reactions (ADRs).

Objective: To report a case of Latanoprost-associated adverse drug reactions in a patient with primary open-angle glaucoma.

Methods: A 62-year-old male patient came to eye OPD D.M.C.H, Darbhanga with complain of ocular discomfort, mild blurring of vision, burning sensation, conjunctival hyperemia, and changes in iris and eyelash pigmentation after three weeks of Latanoprost therapy. Detailed history of patient was taken and ocular examination was done and management plan were documented. Follow-up visits were scheduled to monitor the resolution of drug reaction and ensure patient compliance.

Results: The patient's examination findings were consistent with the known ADRs of Latanoprost, including conjunctival hyperemia, increased iris and eyelash pigmentation. The patient's ocular discomfort and mild blurring of vision were considered transient and related to the drug's initial effects. Symptomatic relief was provided with lubricating eye drops, and the patient was educated about the expected side effects and reassured about their harmlessness. The patient expressed satisfaction with the management plan and was scheduled for follow-up in three months.

Conclusion: This case highlights the importance of recognizing and managing ADRs associated with Latanoprost. Healthcare providers should be aware of potential ocular symptoms, such as burning sensation, conjunctival hyperemia, and changes in iris and eyelash pigmentation and obtaining a detailed drug history. Educating patients about expected side effects and providing symptomatic relief can enhance treatment adherence and patient satisfaction.

Keywords: Latanoprost, glaucoma, adverse drug reactions.

COVID-19 Awareness among Undergraduate Medical Students

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Background: These features of COVID-19 bear resemblance with the infections caused by previously known Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) coronaviruses. India could suffer from outbreak of new strain of COVID-19 or similar pandemic. Lessons learned from the SARS outbreak in 2003 suggest that knowledge and attitudes towards infectious diseases are associated with level of panic emotion among the population, which can further complicate attempts to prevent the spread of the disease. In the society MBBS students can play a major role in spreading awareness in their society, relations and friend circle.

Aim: To assess the level of awareness and attitude of medical students towards this disease.

Materials and Method: A structured and validated questionnaire on COVID-19 disease and its related infection control practices will be sent to the students through Google form link. The self-administered questionnaire consisting of socio-demographic questions, and 15 questions based on knowledge and infection control practices related to COVID-19 disease in the healthcare setting had been adapted from the current interim guidance and information for healthcare workers published by the CDC, updated on March 7, 2020. Intra-class correlation coefficient (ICC) had been used to assess the reliability of the questionnaire and ICC value was found to be 0.89.

Results: 300 students attempted the questionnaire. More than 70% of the students had knowledge about COVID-19 disease, its causative agent and mode of transmission. However, more than 50% of the students did not know about definition of close contact. 54 students (18.00 %) had answered all the 14 questions

correctly. 169 students (53%) had answered 10 to 13 answer correctly.

Conclusion: More efforts should be directed at younger medical students generally. Health Care Authorities should be more involved in the process of education about the pandemic. The lesson learnt from the pandemic should be implemented in any future outbreaks.

Keywords: COVID-19, Awareness, Knowledge, Attitude, Awareness, Medical Students, Pandemics

Fixed Drug Eruption Following Ofloxacin Tinidazole drug combination: A Case Report

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Background: Fixed drug eruptions is an adverse drug reaction that occur at same site everytime the offending drug is taken. It occur when a person is exposed to a particular medication, resulting in the development of distinct patches on the skin. These patches can be single or multiple, with well-defined boundaries, and they typically have a round to oval shape. FDE present within 30 min to 10 hours after taking drug. Clinically it presents with well-defined lesion, round or oval in shape, can be single or multiple. They appear oedematous and red, ranging in colour from pink to dark red to brown. Skin and mucosal surface are commonly involves. Drug commonly causing FDE includes NSAIDs, Antipsychotics, Tetracycline, CCB, Azoles.

Objective : To report a fixed drug eruption (FDE) that occurred following the administration of Ofloxacin Tinidazole drug combination

Case Report: A 42-year-old male came to skin and vdo D.M.C.H, Laheriasarai with complain of painful oral erosions and raw area over glans penis. Detailed history of patient was taken and cutaneous examination was done. He reveals that he had loose motion for past two days for which he took ofloxacin tinidazole combination group drug and 4 to 5 hour following drug administration he developed these lesion. He has revealed he had similar lesion in past when he used to take medicine for loose stools. The patient was educated about FDE and the importance of drug avoidance. Follow-up visits were scheduled to monitor the resolution of lesions and ensure patient compliance.

Conclusion: This case report emphasizes the importance of considering FDE as a possible adverse reaction to Ofloxacin Tinidazole drug combination. Physicians should be vigilant in recognizing the characteristic clinical features and obtaining a detailed drug history.. Management involves discontinuation of the offending medication and symptomatic treatment. Patient education regarding drug avoidance is essential to prevent future episodes and minimize potential complications associated with FDE.

Keywords: Fixed drug eruption, Ofloxacin Tinidazole drug combination, adverse drug reaction.

Critical evaluation of outpatient prescribing trends and rational medicinal use based on WHO indicators in tertiary care centre teaching hospital of South west Bihar

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INTRODUCTION: A prescription audit is a quality improvement process of prescription writing that seeks to improve patient care and outcomes through a systematic review of care against explicit criteria and the implementation of change.

AIM: The study aimed to evaluate for the accuracy of the prescriptions and rationality of prescribing medicines.

METHODS: This descriptive, observational, cross-sectional study was conducted in the Department of Pharmacology, NMCH, Sasaram, Bihar. Total 360 prescriptions were collected from various departments outdoor in June 2023 and were evaluated on 25 eligible checkpoints based on World Health Organization (WHO) guideline. Rationality of the prescribed medicines was also analyzed based on WHO indicators.

RESULTS: The study showed that 65.78% of total criteria were adhered to WHO guidelines, but less than 1% prescriptions completely followed all criteria. Per prescription 4.89 medicines and 0.84 antibiotics were advised. 67.78% of prescribed medicines followed the essential medicine list. Oral drugs were 88.61% whereas 11.39 % of medicines were injectable preparations. Clinician mostly habituated in writing medicines by using small letters (78.89%) and very few medicines were written by generic names, 4.72 % of total prescriptions. Vitamins, Tonics or Enzymes prescribed in 38.89 % of prescriptions. But, few criteria like inscription by brand names, inappropriate antibiotic use and over-utilization of medicines enhanced the

prescribing error.

CONCLUSION: The study concluded that prescriptions were moderately aligned. Adequate adherence was noticed because patient's information was almost fully mentioned by well organized computerized system for data entry. Some criteria were also followed strictly as per hospital management. This suggested that the autonomous set of this hospital, adopted targeted sell strategy from own pharmacy. Also, urgent requirement and poor local availability of medicines oblige patients to acquire it from hospital pharmacy. Prescribing trends in this hospital poorly adopt proper treatment duration and follow up advices. Practising flexible treatment protocol and compulsive or habitual writing of medicines in running letters are frequently observed in prescribing behaviour of clinicians. Therefore, prescription audit should be adopted in routine process to minimize medication error.

Keywords: Prescription audit, Essential medicine list, WHO guideline, WHO indicators, Medication error

Amlodipine-induced gingival enlargement: A case report

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Introduction: Local or systemic diseases can be responsible of gingival enlargements and determining the aetiology is essential for appropriate management. Health practitioners must first exclude haematological malignancies and squamous cell carcinoma as any delay in the diagnosis could have dramatic consequences. Other aetiologies are represented by periodontal diseases, genetic diseases and iatrogeny. Gingival enlargements (GEs) can be caused by local, systemic diseases or drugs. Three molecules can be responsible of GEs: ciclosporin, phenytoin and calcium channel blockers (CCBs).

Case Presentation: We report the case of a 42-year-old female treated by Amlodipine, a CCB, for hypertension for many years and who recently developed a severe GE affecting both mandibular and maxillary arches inducing dental malposition. The histological examination showed non-specific inflammation with a predominance of lymphocytes. Amlodipine was suspected and suspended in agreement with his physician. One month later, the enlargement significantly reduced but GE was so severe and dental malposition so marked that all the teeth but the canines were extracted. No recurrence was noted one year later.

Conclusion: This exceptional case should encourage every practitioner to be vigilant with patient treated with CCBs and their potential side effects and consequences.

Keywords: Amlodipine; Calcium channel blocker; Gingival enlargement; Iatrogeny.

Nimesulide Induced Toxic Epidermal Necrolysis; Still an Occurrence? – A Case Report

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Introduction: Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) are rare but potentially life-threatening muco-cutaneous reactions with an annual incidence of 1-6 and 0.4-1.2 per million people and mortality rates being 1-5% and 30%, respectively.

Nimesulide is an NSAID with antipyretic and analgesic properties. The drug was banned in several countries like USA, Spain, Switzerland, etc. in the year 2000. In India, it was banned in 2011, that too for paediatric use only and continues to be available for adult use. Several case reports of Nimesulide induced SJS/TEN have surfaced in the past; this is one recent report depicting the hazard of self-medication with this drug given its free availability and unregulated marketing.

Case Presentation: Here, we report a case of TEN in a 25-year-female patient following ingestion of Nimesulide tablets for fever without consultation with any physician. She presented with complaints of generalized rash with denudation of skin involving all four limbs, chest, abdomen, back and genitalia for three days; there was oral involvement with ulceration and crusting of lips also. Nimesulide is a Non-Steroidal Anti-inflammatory Drug (NSAID) with antipyretic and analgesic properties. Aggressive management with parenteral corticosteroids (Dexamethasone), antibiotics (Meropenem), emollients and supportive care was done. The patient showed gradual improvement with fading of rash and healing of mucosal lesions.

Conclusion: The drug Nimesulide has been a cause of concern for long for its continued use in India despite

being banned in most of the developed nations. Though the government of India has banned the drug for paediatric use, it is still available easily over-the-counter. Regulatory Authorities, should thus take necessary steps to limit the availability of such drugs that have indications with much safer options. Also, there is need to raise awareness in public regarding the consequences of self-medication with such drugs.

Keywords: Nimesulide, Toxic Epidermal Necrolysis, Over-the-counter, Self-medication

Sumatriptan in Trigeminal Neuralgia: a case report

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Introduction: Treatment-resistant trigeminal neuralgia is a distressing condition, for both the patient and the treating doctor. To our knowledge, there are no reported cases of trigeminal neuralgia successfully treated with oral sumatriptan in the literature.

Case presentation: A 51-year-old Caucasian woman was prescribed opiate analgesia for management of her treatment-resistant trigeminal neuralgia. Given the possible harmful effects of initiating such a course of treatment, a speculative therapeutic trial with oral sumatriptan was initiated with a successful outcome.

Conclusion: This case raises the hypothesis that oral sumatriptan may be an effective drug in the treatment of trigeminal neuralgia. Further research is required to test this theory.

Non animal methods relevant in drug testing – an overview

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Background: Every year, millions of experimental animals are used all over the world. The pain, distress and death have been a debating issue for a long time. Besides the major concern of ethics, there are few more disadvantages of animal experimentation like requirement of skilled manpower, time consuming protocols, high cost and results from animals cannot always be extrapolated to humans. The limitations of traditional animal testing have prompted researchers to explore alternative methods that better capture the complexities of human biology and predict human response. FDA modernization Act 2.0 on December 29, 2023 removes the mandate for animal tests for development of new drug. An amendment to the New Drugs and Clinical Trial Rules (2023) recently passed by Government of India, authorises researchers to instead use non animal and human relevant methods, including technologies like 3D organoids, organs on chip and advanced computational methods, to test the safety and efficacy of new drug.

Aims/Objectives: An overview of alternatives or animal substitutes in drug testing.

Methods: The overview was taken from Research articles, Journals and Latest Government guidelines.

Results: Human Stem cells has 93% sensitivity at detecting substances known to cause developmental problem whereas Animal testing detect only 60%. Computational methods have also given better results. Moreover the trials are ongoing and better results are awaited.

Conclusions: Many alternatives to animal testing methods aim to overcome translational barriers toward developing urgently needed treatments for unmet medical needs. As a result, using non animal models for research could save the lives of more humans and animals, time and money. And without sacrificing quality and safety, alternatives to animal testing could improve the quality of society while improving health outcomes.

Keywords: Alternatives, organ-on-chips, organoids.

Comparative study of propranolol and topiramate for prevention of chronic migraine

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Background: Oral preventive treatment for chronic migraine lacks credible evidence except for topiramate.

Aims and Objectives: The main aim is to compare the efficacy and safety of propranolol to topiramate for the prevention of chronic migraine.

Methods: Chronic migraine patients who are above 18 but under 65, are chosen for study. Study was done in

NMCH, Patna on October 2022 to March 2023. Patients are given either topiramate (100 mg/day) or propranolol (160 mg/day).

The primary efficacy outcome was the mean change in migraine days per 28 days at the end of 24 weeks from baseline. A mean difference of 1.5 days per 4 weeks was chosen at the cut-off delta value. Secondary efficacy outcomes and treatment adverse effects are multiple & were also assessed.

Results: Total participants are 95. 46 patients were on topiramate and 49 patients were on propranolol. The mean change in migraine days was -5.3 ± 1.2 vs -7.3 ± 1.1 days ($p=0.226$) for topiramate and propranolol groups respectively. Propranolol was found to be non-inferior and non superior to topiramate (point estimate of -1.99 with a 95% confidence interval of -5.23 to 1.25 days). The secondary outcomes were numerous and showed no difference between the two groups. Also, the two groups had no significant difference in adverse events.

Conclusion : This study found that no significant differences in terms of efficacy between the topiramate and propranolol when used as a preventive treatment for chronic migraine.

Keywords : Chronic migraine, Topiramate and Propranolol.

The efficacy and adverse drug profile of risperidone versus olanzapine in the treatment of patients with bipolar affective disorder on combination therapy

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Bipolar affective disorder is a complex psychiatric condition that requires a combination of therapies to effectively manage symptoms.

Objectives: To compare the efficacy and adverse drug profile of risperidone and olanzapine in patients with bipolar affective disorder who are on combination therapy.

Methods: A randomized controlled trials comparing risperidone and olanzapine in patients with bipolar affective disorder on combination therapy. The study conducted in the department of Pharmacology during the period from January 2023 to June 2023, Efficacy outcomes, including symptom reduction, response rates, and relapse rates, were assessed. Adverse drug profiles were evaluated based on discontinuation rates, weight gain, sedation, extrapyramidal symptoms, and metabolic effects.

Results: A total of 100 patients were included in the analysis. The analysis revealed that risperidone was significantly more effective than olanzapine in terms of overall symptom reduction ($p=0.02$), response rates ($p=0.01$), and lower relapse rates ($p < 0.0001$). Additionally, risperidone showed a lower incidence of extrapyramidal symptoms compared to olanzapine ($p < 0.01$). Olanzapine was associated with a higher risk of weight gain ($p < 0.01$) and metabolic effects ($p < 0.05$) compared to risperidone. No significant differences were found in sedation or discontinuation rates between the two drugs.

Conclusion: In patients with bipolar affective disorder on combination therapy, risperidone demonstrated superior efficacy compared to olanzapine in terms of symptom reduction, response rates, and relapse prevention. Risperidone also exhibited a lower risk of extrapyramidal symptoms, while olanzapine was associated with greater weight gain and metabolic effects. These findings suggest that risperidone may be a preferred choice for patients with bipolar affective disorder on combination therapy, although individual patient characteristics and preferences should also be considered.

Keywords: Bipolar affective disorder, risperidone, olanzapine, combination therapy, efficacy, adverse drug profile.

Antitubercular drug induced hepatitis: A Case Report

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Introduction: Isoniazid, Rifampin and pyrizinamide are first line antitubercular medication. Among them isoniazid and Pyrizinamide inhibit mycolic acid synthesis and rifampicin inhibit RNA polymerase. They are potent hepatotoxic. These drugs are metabolized in liver by CYP450 enzyme. The drug toxicity is different in different individual because in some individuals drug is metabolize by different pathway. Apart from hepatotoxicity there are some reported cases of anti tubercular drug induced cutaneous reaction and gastrointestinal disturbances.

Case Description: A 31 years old female patient came to emergency department of Jawahar Lal Nehru medical college and hospital, Bhagalpur, with chief complain of breathlessness, chest pain, abdominal pain, weight loss and loss of appetite. She was diagnosed with tuberculosis two months. For that she was put on HRZE regimen. Her laboratory data suggest she had hepatitis. After stopping potent hepatotoxic medication her laboratory data started to normalize and symptoms relieved. For tuberculosis she was shifted to alternate regiment.

Discussion: The exact mechanism of drug induced hepatitis is poorly known. Drug induced liver injury may be dose dependent. Injurious free radical causes hepatocytes necrosis in zone farther from hepatic arterioles, where metabolism is greatest and antioxidant detoxifying capacity is at least. Release of TNF- alpha, IL-12 and IF- gamma promotes apoptosis of hepatocytes.

Conclusion: The antituberculosis medication has many adverse effect , hepatotoxicity is most common and serious one . To prevent adverse drug reaction close monitoring of patient and therapy is required.

Medical Error

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Medical errors encompass a wide range of preventable adverse events, including diagnostic errors, medication mistakes, surgical errors, and communication failures. Contributing factors to these errors can be categorized into several domains: individual factors (such as lack of knowledge or fatigue), systemic factors (such as inadequate staffing or flawed processes), and contextual factors (such as poor communication or complex healthcare environments).

The consequences of medical errors can be severe, ranging from patient harm and prolonged hospital stays to death. Moreover, these errors have significant financial implications, as they contribute to increased healthcare costs through readmissions, longer hospital stays, and legal settlements. Furthermore, medical errors can give rise to ethical concerns, as they breach the obligation of healthcare providers to provide high-quality, safe care.

To address these issues, several strategies have been proposed to prevent and mitigate medical errors. These strategies include the use of technology, such as electronic health records and computerized physician order entry systems, which can help minimize medication errors and enhance communication. Additionally, improving teamwork and communication among healthcare providers through training programs and effective communication protocols can decrease errors resulting from miscommunication.

Furthermore, establishing a culture of safety within healthcare organizations is crucial in preventing medical errors. This involves promoting open reporting of errors, analyzing root causes, and implementing appropriate changes to prevent similar errors in the future. Additionally, implementing standardized protocols and guidelines, as well as continuous quality improvement initiatives, can help improve patient safety and reduce errors.

In conclusion, medical errors are a significant concern in healthcare systems, leading to patient harm, increased healthcare costs, and ethical implications. Understanding the contributing factors and implementing various strategies, such as technology integration, teamwork enhancement, and safety culture promotion, can aid in preventing and mitigating medical errors, ultimately improving patient safety and healthcare quality.

Evaluating the Prebiotic efficacy of *Mucuna pruriens* hydroalcoholic extract in various strains of probiotics

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Gut microbiota dysbiosis has been considered as a contributing factor in inflammatory neurodegenerative diseases. Prebiotics, medicinal herbs, probiotics, and synbiotics have shown promising results in preclinical and human clinical trials for treating and modulating health, ageing, and neurodegeneration. It is proven that prebiotics modulate the inflammatory process, counteract with oxidative stress, and modify gut microbiota. One such prebiotic plant is *Mucuna pruriens* belongs to the Fabaceae family and is

ordinarily known as velvet bean with anticholesterolemic, anti-Parkinson, antioxidant, antidiabetic, anti-inflammatory, antimicrobial that makes it an excellent component in pharmaceutical and therapeutic applications. Apart from high protein and starch content, the seeds contain L-Dopa, Ursolic acid (UA) and Betulinic acid (BA). This study evaluated potential prebiotic effect of MPE which is widely used in. An overall CFU was recorded with various Probiotic strains like *Lactobacillus rhamnosus GG*, *Lactobacillus fermentum K78*, *Lactobacillus, L. plantarum K90*, *L. fermentum K100*, and *L. acidophilus* at 12 and 24 hours of bacterial incubation, an overall CFU abundance of 8.726 ± 0.015 at 12h and 8.824 ± 0.015 at 24h was found. As per the results we have observed significant increases in the growth rate for *L. acidophilus* in comparison with other strains with higher acetate production. This summarizes the medicinal importance of MPE enhancing and put forward the potential targets where it can act for therapeutic interventions.

N-Acetyl Cysteine versus Metformin in Poly Cystic Ovarian Syndrome: Report from a tertiary

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Background: Poly cystic ovarian syndrome (PCOS) is an ovarian dysfunction syndrome that is considered to be the most prevalent endocrinopathy resulting from anovulation and affects 5%–10% of women. Metformin, an insulin sensitizer, is being used for long in the treatment of PCOS. But it comes with an array of side effects. NAC (N-acetyl-cysteine) along with glutathione have been postulated to have similar role with multiple mechanism.

Objective: The current study was done to compare the efficacy of Metformin and NAC among PCOS patients.

Methodology: A prospective study with 100 PCOS patient was done by Department of Pharmacology, Katihar Medical College. Patients were equally divided in two groups, M and N, based on type of chemotherapy given. Base line parameters were obtained. Demographic characteristics, clinical features, biochemical and hormonal tests on day 2 of menstrual cycle and TVS was done. Each patient received the treatment for 3 month, after that they were evaluated again for all the parameters. Data analysis was done in by Microsoft Excel. Appropriate tests of association was applied to compare various parameters between the groups. A p value of $p < 0.05$ was considered significant.

Results: Mean age in group M was 25.6 years while in the group N, it was 23.4 years. Mean BMI was 26.6 kg/m^2 and 28.3 kg/m^2 in group M and N, respectively. Groups were similar in biochemical and hormonal profile. Ultrasonographic features of PCO showed no changes post treatment. But clinically patients improved in terms of weight management, and hirsutism in group N. Fasting blood sugar level improved from 86.3 mg/dl to 84.4 mg/dl in group M and 86.6 mg/dl and 82.6 mg/dl in group N. Fasting Insulin level as well as the fasting glucose/fasting Insulin ratio also had a significant decrease in group N ($p < 0.05$).

Conclusion: NAC improves the long-term health status of women with PCOS through inhibition of oxidative stress and improvement of peripheral insulin. Due to lack of adverse effects, NAC can be regarded as an appropriate substitute for insulin reducing medications in the treatment of PCOS patients.

Keywords: PCOS, NAC, Metformin

A case of Oxcarbazepine induced hyponatremia in a patient of seizure disorder

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Background: Adverse drug reactions (ADRs) are one of the prime causes of morbidity and mortality, increase in hospital stay and socioeconomic burden on the patients. Periodic monitoring aids in formulating methods for safe usage of medicines in hospitals. Identification of ADRs and their reporting pattern can provide useful information for their prevention. Oxcarbazepine is a well known and effective anticonvulsant used for patient with underlying seizure disorder. It is structural analogue of carbamazepine, it follows a different metabolic pathway in which it is converted to a different active metabolite. Side effect associated with this medication are vast and this include dose related neurotoxicity eg- sedation, ataxia, diplopia and hypersensitivity reaction eg- rashes, photosensitivity, hepatitis, lupus like syndrome rarely agranulocytosis and aplastic anaemia. In this case report, we will throw light on the renal adverse effects i.e. syndrome of inappropriate anti diuretic hormone secretion (SIADH) is a condition which results in too much water

absorption and causes Hyponatremia with neurologic sequelae. Here we are reporting a case of ADR Oxycarbazepine induced hyponatremia in Patna Medical College and Hospital, Patna.

Case-report: Here is a case of 45 years old female patient of history of seizure disorder for 2 years who was prescribed oxycarbazepine 300 mg BD for last 6 months, now she had presented to OPD with complaint of irrelevant talking, insomnia, extreme fatigue for last 7- 10 days. On investigation serum sodium was 126 mEq/L which was diagnosed as hyponatremia secondary to having SIADH, an ADR associated with Oxycarbazepine use.

Discussion: The causality of Oxycarbazepine in this case was “probable” with score 7 as per Naranjo scale. The patient was managed by discontinuing the Oxycarbazepine. Patient was admitted and electrolyte imbalance was corrected and other conservative methods were applied.

Conclusion: Anti-epileptic drugs are vital in controlling the seizure attack in epileptic patients. Thus, it is important for the clinicians to be familiar with anti-epileptic drugs associated with these adverse drug reactions.

Keywords: Oxycarbazepine, hyponatremia, adverse drug reaction.

Andrographolide attenuates endothelial dysfunction in LPS-induced rats by reducing oxidative stress and chronic inflammation

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Context: Mostly in pathogenesis of heart disease, oxidative stress, inflammatory, as well as vascular dysfunction were interconnected components. Andrographolide, a strong antioxidant, may be able to reverse LPS-induced endothelial dysfunction by lowering oxidative stress and inflammation.

Objective: The goal of the current investigation was to determine how andrographolide could reduce oxidative stress, inflammation, and vascular dysfunction in rats that had received LPS.

Methods: Lipopolysaccharide (LPS) was injected into a rat's tail vein once a week for six weeks in order to establish chronic vascular inflammation and oxidative stress. The study examined the effects of orally administered Andro (50 mg/kg/day) on these conditions. Nitric oxide (NO) thresholds, superoxide dismutase (SOD) activity, constitutive NOS (cNOS) activity, and inducible NOS (iNOS) activity were measured, along with physicochemical markers. In order to determine endothelial dysfunction, endothelium-dependent and endothelium-independent vasorelaxation was assessed in aortas.

Results: Endothelial activity was considerably reduced in LPS group animals when compared to normal control, as well as the reduced endothelial performance was dependently improved by andro therapy. Interleukin-1 β (IL-1 β) and tumour necrosis factor (TNF-) levels in the aorta decreased in a dose-dependent manner after exogenous andro delivery to LPS-induced rats. However, aortic SOD activity, NO levels, and cNOS activity increased, whereas aortic MDA levels and iNOS activity decreased.

Conclusion: Prolonged andro therapy might act as a modifier on endothelial dysfunction in LPS-induced mice by lowering oxidative stress and inflammation. These findings suggest that long-term andro therapy may help avoid cardiovascular challenges posed on by endothelial dysfunction.

Keywords: Andrographolide, Antioxidant, Endothelial dysfunction, Cardiovascular complications, Nitric oxide

Ceftriaxone-Induced Adverse Reactions: A Comprehensive Case Series Analysis

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Purpose: Adverse drug reaction is most often avoidable cause of significant morbidity and mortality. This case series provides a comprehensive analysis of three distinct adverse drug reactions (ADRs) associated with the administration of Ceftriaxone, a commonly used antibiotic. The study highlights the critical significance of vigilant monitoring, early detection, and individualized therapeutic interventions in effectively managing Ceftriaxone-related ADRs underlying pathophysiological mechanisms and guiding optimal patient management.

Method: The study systematically evaluates three distinct cases encompassing hepatic dysfunction and

cutaneous reactions following Ceftriaxone administration.

Results/Interpretation: The cases under scrutiny manifest distinct clinical presentations. In one instance, a young female patient developed cutaneous lesions and hepatic impairment after Ceftriaxone exposure. Prompt cessation of the antibiotic regimen, in conjunction with adjunctive medication, resulted in the patient's clinical amelioration. Another case highlights a paediatric patient who experienced Stevens-Johnson Syndrome following Ceftriaxone administration. Discontinuation of the drug and judicious combination of supportive care and corticosteroids contributed to eventual resolution. Lastly, an elderly patient exhibited cellulitis and cutaneous eruptions following Ceftriaxone therapy. A comprehensive therapeutic regimen, involving antibiotic discontinuation and targeted wound management, facilitated resolution.

Discussion underscores the integral interplay between clinical acumen and pharmacovigilance in achieving prompt diagnosis and informed therapeutic decisions. Synthesizing clinical observations with laboratory insights and timely removing the offending drug affords a comprehensive understanding of the diverse clinical spectrum associated with Ceftriaxone-related ADRs.

This study significantly enriches our experience of Ceftriaxone-induced ADRs, offering indispensable insights into optimizing patient care and safety. Ultimately, it underscores the imperativeness of proactive clinical monitoring and timely intervention during Ceftriaxone therapy, culminating in a harmonious confluence of patient well-being, safety, and favourable clinical outcomes.

Key words: Ceftriaxone, Severe Adverse Drug Reaction, ADR, Pharmacovigilance.

Drug-Related Problems and Their Preventability among Admitted Patients in Paediatrics Department of a Tertiary Care Institute from Eastern India - A Prospective Study

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Introduction: Patients with different manifestations and different diagnoses are admitted in Paediatric department. In admitted cases, drug therapy usually consists of multiple drugs including antibiotics, anticoagulants, glucocorticoids, antihypertensive, anti-diabetics, etc. Due to the prescription of multiple drugs, the chance of drug interactions is high. Early detection of DRP can help prevent any harm to patients. It is therefore possible to thoroughly evaluate various drug-related problems and prevent some of them in the paediatric inpatient department.

Aims & Objectives: The aim was to find out the drug-related problems during management of patients under paediatric department, to find out the magnitude and preventability. In addition, we hoped to provide insights into the DRPs encountered among hospitalized paediatric patients that can help in finding the appropriate solutions. All children's medical records were identified, collected and analyzed by trained clinical pharmacologists to identify DRP according to the well recognized and appropriate criteria system established by the Pharmaceutical Care Network Europe (PCNE). For standardization, patient demographics (age, gender, location and diagnosis) were recorded using WHO ICD version. Drugs were grouped into different categories using the Anatomic Therapeutic Chemical (ATC) classification (WHO-ATC). Descriptive analysis was done to summarize the findings of this study.

Results: Of 534 patients, 193 patients (36.1%, 193/534) had at least one DRP. A total of 262 DRPs were identified in 193 patients, of which 230 DRPs (87.8%, 230/262) were considered preventable. The vast majority of DRPs were related to dose selection (74.78%, 172/230). The second most common cause was related to drug choice (23.04%, 53/230) and drug use (2.5%, 5/280). We found that an increase in the number of drugs also increases the chances of having DRP by 1.31 times (95% CI, 0.89 to 1.81, P=0.00005).

Conclusion: There is high incidence of preventable drug related problems which is generally ignored if not thoroughly investigated. Most of the DRPs are associated with dosing and drug choice problems.

Keywords: Paediatric, Prescription, Drug Related Problem, Medication Error, Adverse Drug Reaction.

Cost variation analysis of different brands of commonly prescribed drugs used in Indian market for the management of angina pectoris

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Introduction:

Coronary artery disease (CAD) is one of the most common causes of cardiovascular mortality and morbidity in developing countries like India. Initial management includes use of many anti-anginal drugs. If angina pectoris not managed adequately results in significant morbidity and mortality too due to the complications. Anti-anginal drugs are used for lifelong. Therefore, analysis of the price of different drugs used in ischemic heart disease will help to improve patient compliance.

Objective: (1) To assess the cost variation of different drugs available as antianginal agents in India. (2) To assess the cost ratio and percentage price variation of different formulations.

Method:

The maximum and minimum price of each brand of the drugs given in Indian rupees (INR) was noted by using 'Drug Today' (Jan 2023 – April 2023, volume I). The cost range, cost ratio, and the percentage cost variation for individual drug brands were calculated. The cost of tablets/capsule was calculated, and the cost ratio and percentage cost variation of various brands was compared.

Results:

The costs of a total of 11 anti-anginal drugs available in 14 different formulations were analyzed and a substantial variation in cost was observed. Out of 14 drug formulations studied, the percentage cost variation of 12 drug formulations was more than 100% out of which 3 drug formulations had more than 400%. The cost ratio was also observed to be very high, and 12 drug formulations had this ratio of more than 2. After calculation of cost ratio and percentage cost variation for each brand of anti-anginal drugs, tab Diltiazem (60 mg) had a maximum percentage cost variation of 459.76% and a cost ratio of 5.59 while tab GTN (6.4 mg) had a minimum percentage cost variation of 76.19% and cost ratio of 1.76.

Conclusions:

There is a wide variation in the price of different brands of anti-anginal drugs available in India. The clinicians prescribing these drugs should be aware of these variations to reduce the financial burden of drug therapy and improve compliance.

Key Words:

Anti-anginal drugs, Cost ratio, Percent cost variation, Angina Pectoris, Drug Today, Cost Range

Pharmacogenomics or PDL1 expression responsible for low dose NIVOLUMAB in R/M SCCH&N cancer

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Background: - Squamous cell cancer of head & neck region is the most common tobacco-induced cancer of Hindi-speaking areas of India and 70% patients presented in advanced stage. Recurrent & metastatic cancer of head & neck form the major bulk. We have very limited treatment options for R/M Squamous cell cancer and immunotherapy [Nivolumab] is the new armament. Although its efficacy in higher dose (3mg/kg) is established in western world but in India, low dose (fixed 20mg) in R/M SCCH&N is gaining recognition. We are doing similar study of low dose Nivolumab 20mg with either OMTC or Physician-choice metronomic chemotherapy and want to find out what is the reason that low dose is quite effective in Indian patients – whether high expression of PDL1 or Pharmacogenomics is responsible for it.

Objective: - To collate whether PDL1 overexpression or Pharmacogenomics is responsible for the low dose Nivolumab in R/M SCCH&N with metronomic chemotherapy

Methods: - Till date, number of patients of R/M SCCH&N enrolled is 26 [must accrue 50 patients] and we have been doing PDL1 testing & single-nucleotide polymorphisms (SNPs) on all patients. This study was conducted under the aegis of Declaration of Helsinki and approval of institution ethics committee was taken before initiating the study. PDL1 expression is expressed in more than 50% in one sub-group and more than 1% (1-49%) in another sub-group.

Results: - Likely to publish at the end of December 2023.

Keywords :- Recurrent/ Metastatic Squamous cell cancer of Head & Neck, Immunotherapy, PDL1, SNP, Metronomic Chemotherapy (Oral OMTC)

Serum Parathyroid Hormone Levels after Thyroidectomy as a Predictor of Post-Operative Hypocalcemia

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Hypocalcemia after thyroidectomy is a common complication with significant morbidity, and it has been proven to increase hospital stay and readmission rates. The assessment of serum parathyroid hormone (PTH) levels following thyroidectomy is a reliable approach for predicting post-thyroidectomy hypocalcemia, but it is rarely employed. This study looks at serum PTH levels 3 hours after thyroidectomy as a predictor of hypocalcemia. We enrolled 121 patients aged 23 to 73 years who were eligible for complete thyroidectomy and had multinodular goiter, a suspicious nodule on cytological examination, Graves' disease, or toxic multinodular goiter. 53 individuals (43.8%) had a decrease in serum PTH three hours following complete thyroidectomy. 75.5% of these patients developed hypocalcemia within 24 hours of surgery, and 100% were hypocalcemic within 48 hours ($p < 0.001$). There was no substantial difference due to the various thyroid illnesses or the patients' ages. PTH levels three hours after complete thyroidectomy accurately predict post-operative hypocalcemia. Early diagnosis of patients at risk of developing post-operative hypocalcemia allows for rapid calcium and vitamin D administration to prevent symptoms and safe and timely discharge.

Personal formulary for gonorrhoea developed by residents of pharmacology

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Introduction: Incorporating P-drug concept in pharmacology curriculum can assist the students to learn principles of rational evaluation of available therapeutic options and form a well informed and rational decision concerning drug treatment for an individual patient. This study was designed to develop a personal formulary by senior residents and postgraduate students for the treatment of gonorrhoea according to P-drug concept of Joshi and Jayawickramarajah.

Materials and Methods: Senior residents and junior residents (post graduate students) were taught about how to analyze and give score (α) to drugs used for gonorrhoea available in market with the help of various standard text books & journals available in the library, by internet and Current Index of Medical Specialties (CIMS). Scores were given to each four parameters (efficacy, safety, cost and convenience) from 1 to 10 for each drug. Each parameter had given a fractional numerical rating (β) according to the importance i.e. 0.4 for efficacy, 0.3 for safety, 0.2 for cost and 0.1 for convenience. Score (α) was multiplied by fractional numerical rating (β) to get total score ($\gamma = \alpha \times \beta$). The drug with the highest score became the personal drug.

Results: Cephalosporin group had highest score (8.4). Treatment cost of Cefixime was lowest (₹ 24.9) with respect to Ceftriaxone (₹30.55) and Cefotaxime (₹ 30.62) but the overall score was better for Ceftriaxone (score 7.2) so it was chosen as Personal drug for gonorrhoea. Further personal formulary was developed for the P-drug ceftriaxone as a practical elaboration of the P-drug concept.

Conclusions: Teaching of P-drug concept to residents will be helpful in acquiring proper skills in the development of personal formulary and also helpful in promoting rational use of medicines.

Keywords: P-drug, Personal formulary, Rational uses of drugs, Prescription writing



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ORAL

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ORAL PRESENTATION



Prescribing pattern and use of non-steroidal anti-inflammatory drugs among orthopedic outpatients in a Teaching Hospital of Bhagalpur

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BACKGROUND: Rational prescribing is required to prevent the unfavorable outcomes of irrational prescribing like paucity of therapeutic resources, undue increase in the cost of treatment and adverse clinical consequences of therapy. So, this real-world study was conducted to evaluate the Prescribing pattern and use of non-steroidal anti-inflammatory drugs among orthopedic outpatients in a Teaching Hospital of Bhagalpur.

AIMS & OBJECTIVES: To assess Rational prescribing pattern and polypharmacy among outpatient department of orthopedic patients.

METHODS: A cross sectional descriptive study was conducted in the Jawaharlal Nehru medical college and hospital, Bhagalpur. Only outpatient department registered orthopedic patients were selectively approached for their prescriptions on a specific day of each week at the hospital pharmacy in between February 2023 to April 2023. The data has been obtained by this method from 206 different prescriptions belonging to same number of patients.

RESULTS: In 206 patients, age less than or equal to 80 years, 733 drugs were prescribed in which NSAIDs 242, Anti peptic ulcer drugs 190, multivitamins and multimineral 190, Antibiotics 58, Anti-gouts 11, Anti-rheumatics 13 and Hematinic 29. The maximum number of NSAID was prescribed for 5-15 days. Polypharmacy and fixed dose combination drugs was present mostly in bone fracture cases. Whatever be the reason, approximately one fourth prescription had branded drug also.

CONCLUSION: This study revealed various problems in prescribing habits. Important problems were polypharmacy, non-adherence with national formulary and inclination of prescribers for branded and fixed dose combination drugs. Duration of administration were comparatively longer and not mentioned in a significant proportion of cases for NSAIDs. Institution of hospital formulary and educational interventions aimed at rational prescribing particularly for interns are needed to rectify the prescribing habits.

Keywords: NSAIDs, Orthopedic outpatients, Prescribing pattern, Teaching Hospital.

Drug utilization study of antidiabetic drugs in hypertensive patients of rural tertiary care center of Uttar Pradesh

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Introduction- From 108 million cases in 1980 to 463 million cases in 2023, diabetes is become more common. The clarification of current knowledge regarding the pattern of anti-diabetic medicine usage in the population is crucial in order to concentrate and treat these diseases properly. Hence the present study is conducted to assess the drug utilization study of antidiabetic drugs in hypertensive patients of rural tertiary care center of Uttar Pradesh.

Material & methods- The prospective study was conducted among 100 patients who visited the outpatients department of a tertiary care centre in rural area of Uttar Pradesh. In a prepared performa, all of the medications that the study patient's doctor had prescribed for her were listed along with their class, dosage, frequency, and duration. Results were analyzed using SPSS version 23.0.

Results – Males (60%) were more as compared to females (40%). The maximum subjects belong to age group of 61 to 70 years. Two drug combinations was most widely used method to control diabetes. 77.96% of drug- drug interactions were found to be monitor closely interactions.

Conclusion – Metformin was the highly utilized individual antidiabetic drug in the study. Prescriptions evaluation revealed that prescription were rational and were in accordance with the treatment guidelines.

Keywords- Antidiabetic drug, hypertension, drug interaction, type II diabetes mellitus.

Drug-Drug Interactions and Prescription Appropriateness in COVID-19 ICU Patients in a Tertiary Care Hospital

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Introduction: Severe Coronavirus disease 2019 (COVID-19) management has been challenging due to varying treatment protocol. Additionally, co-morbidities and older age group receiving polypharmacy increases the risk for drug-drug interactions (DDIs). With limited DDI research studies in Indian setup, we aimed to assess the frequency and severity of potential DDIs in COVID-19 ICU patients.

Materials and Method: This was a retrospective, observational study conducted in a tertiary care hospital, Karnataka, India. Case record of all patients aged ≥ 18 years with COVID-19 disease admitted to the COVID-19 ICU during March 2021 to July 2021 and treated with two drugs at least were included. A total of one hundred ninety one medical records of COVID-19 patients confirmed by RTPCR were reviewed from medical record department. DDIs were assessed by validated INTERCheck[®] web system which classifies DDIs as Class A, Class B, Class C, and Class D; and prescription appropriateness was evaluated by updated Beers criteria.

Statistical methods: The results were analysed by using statistical software SPSS software version 17.0. Descriptive statistics was used for the categorical variables and were reported as frequencies and percentages. Mean with standard deviation was expressed for continuous variables. Analysis for qualitative variables was performed by Chi square test and Fischer's exact test. A p-value of ≤ 0.05 was considered statistically significant.

Results: Among 191 COVID-19 treated patients, a total of 1049 pDDIs were recorded. Thirty nine percent of the total interactions were classified as potentially severe (class C + class D). Severe pDDIs increased significantly (140 to 274; $p < 0.001$) during hospitalization. Consistently, a significant increase in drug interactions trend was observed during hospitalization (432 to 617; $p < 0.001$).

Conclusions: This study concludes that the severe pDDIs increased significantly during hospitalization and consistent increase in overall (Class A, B, C D) drug interactions trend was observed during hospitalization largely because of the drugs managed to treat comorbidities. Therefore, web based system with multidisciplinary team of expertise may be adopted in hospitals for regulating the dosage of interacting drugs and selecting substitute for over all optimizing the therapy.

Adverse drug reactions due to gabapentin-nortriptyline in patients with neuropathic pain in a tertiary care teaching hospital

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Introduction: Gabapentin and Nortriptyline are used to treat neuropathic pain. Gabapentin belongs to a group of drugs called anti-convulsant and Nortriptyline belongs to tricyclic antidepressant. Gabapentin acts by binding to the specific site on voltage-gated calcium channels. This helps in relieving nerve pain and lowers the risk of seizure. Nortriptyline works by preventing the released chemical messenger in brain (serotonin and norepinephrine) from being reabsorbed back into the nerve cells. As a result, it prolongs the effect of serotonin and norepinephrine in the brain and over time, this helps to relieve depression and lighten the mood.

Case- Series: We are reporting a case series including 3 patients having neuropathic pain and taking tablet gabapentin-nortriptyline developing adverse drug reactions in department of neurology, Patna medical college and hospital, Patna developed some adverse drug reactions.

Discussion: Causality assessment was done in each case by Naranjo scale. Each case was filled properly in ADR (adverse drug reaction) reporting form and was sent to nearby adverse drug reaction monitoring centre (AMC). During the posting for pharmacovigilance in neurology department of Patna medical college and hospital, Patna from 01/07/2022 to 30/09/2022 we got three adverse drug reactions due to gabapentin-nortriptyline. Two of them were due to Gabapentin and one was due to nortriptyline.

Conclusion: Gabapentin-nortriptyline is one of the most commonly used drugs in neurology department. It causes some frequent as well as some rare adverse drug reactions which are required to be assessed and finally reported to the nearby AMC.

Keywords: Gabapentin, Nortriptyline, Neuropathic pain, Adverse drug reaction

Prescription pattern and drug utilization study of anti-hypertensive drugs at Katihar Medical College & Hospital, Bihar

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Background: Hypertension is one of the leading causes of cardiovascular morbidity and mortality. It has been established as a major public health challenge globally as well as in our country. Prevalence of hypertension in India varies from 12-17% in rural areas and as high as 20-40% among urban population. Although many antihypertensive drug regimens are available, many a times the treatment remain untreated or inadequately treated. Hence, studies on prescription pattern are needed to optimize and control the drug treatment.

Objective: The current study was conducted to study the prescription pattern of antihypertensive drugs among diagnosed cases attending medical OPD of Katihar Medical College and hospital, Bihar.

Materials and Methods: A secondary data analysis was conducted by Department of Pharmacology where case records of patients diagnosed with hypertension between the time period of last 1 year, were collected. The demographic information and prescription pattern were obtained from hospital record and evaluated. Drug utilization (DU) frequency was assessed using WHO indicator of Defined Daily Doses in terms of DDD/1000 inhabitant/day. The data collected were analyzed using Microsoft Excel software.

Results: Of 232 cases studied, the male to female ratio was 1.33. The age of the patients in the study ranged from 28 to 92 years, with a mean age of 42.7 years. Combination therapy was preferred over single drug regimen. The most common combination used were drugs from classes ARB, CCB and diuretics. Upon consideration of overall DU frequency, CCBs were the most preferred drugs with a utilization percentage as high as 89.7% followed by ARB at 74.6% and diuretics at 66.9%. The DDD/1000 inhabitant/day of amlodipine was the highest. Among associated co-morbidity, diabetes mellitus was the most frequently encountered. Among these patients, ARB with CCB was used. The prescriptions were specific to age and comorbidity. Generic drugs were preferred by physicians.

Conclusion: Overall, the prescriptions seemed to be in accordance with national and international guidelines including the Indian Guidelines on Hypertension. Further studies on adherence of patients to prescription needs to be done.

Keywords: Hypertension; Drug Utilization Study; Defined Daily Dose

Assessment of Adverse Drug Reaction In Patients Admitted In A Tertiary Care Teaching Hospital of Sikkim

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Background

Adverse Drug Reactions pose a significant problem in healthcare and have a major impact on patients' morbidity and mortality. There is a need for implementation of a robust system for reporting and analysis of adverse drug reactions, which in turn is expected to promote the safe use of drugs.

Aims/Objective

The study was conducted to observe and analyse adverse drug reactions reported in hospitalized patients of a teaching hospital in Sikkim.

Methods

This hospital based observational study was conducted over a period of 18 months (March 2021 to September 2022), in the Department of Pharmacology, SMIMS and CRH Gangtok. A predesigned case record form was employed to collect patient and drug related data. Causality assessment was done using the WHO-UMC scale. Severity of reactions was assessed using modified Hartwig Scale and preventability of adverse drug reactions (ADRs) was assessed using the Schumock and Thronton Scale.

Results

A total of 54 suspected adverse drug reactions were reported during the study period. ADRs were more frequently reported in females (n=37; 68%) as compared to males (n=17; 32%). ADRs were most commonly observed in the 18-29 years age group (n=24; 44.4%) followed by the 30-49 year age group (n=18; 33.3%). Anti-microbial class of drugs were most frequently associated with ADRs. Cephalosporins (20.4%) and Fluoroquinolones (13%) were the most commonly implicated antimicrobials. The

most common system involved was Dermatological(n=34;63%) followed by gastrointestinal(n=10;18.5%). A total of 18 (34.4%) ADRs were categorized as “Possible”, whereas 36 (65.6%) were “Probable” on causality analysis of the reactions. Analysis of the reactions for severity using modified Hartwig Scale indicated most reactions to be “Mild”(n=30;55.2%) which was followed by “Moderate”(n=22;39.7%) and “Severe” reactions(n=2;5.2%) were the least. Preventability analysis indicated 48(89.7%) of the reactions to be “not preventable” and 6 (10.3%) reactions were “probably preventable”.

Conclusion

Antimicrobials in general and cephalosporins in particular were most commonly associated with adverse reactions in our hospital. Reported ADRs were more common in Females and the 18-49 age group.

Keywords

Adverse Drug Reaction, ADR-Reporting, Pharmacovigilance, Drug-Safety.

Drug usage pattern of anti-hypertensives in diabetic patients - a cross-sectional opd-based study in a tertiary care set-up

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Objective:

To analyse the usage pattern of several classes of antihypertensive medicines among diabetic patients admitted to a tertiary care hospital.

Materials & Methods:

It was Institution-based cross-sectional study; the current study was carried out at Sri Krishna Medical College Muzaffarpur, in the Department of Medicine and analysed in the department of Pharmacology. This study included 100 Diabetes Mellitus patients with hypertensive disorders who presented to the Department of Medicine at Sri Krishna Medical College Muzaffarpur, during the study period.(July 2022 to January 2023).

Results:

While analysing the prescribing pattern of anti diabetic drugs we found Metformin was most common (80%) followed by Sulfonylureas (65%), DPP4 inhibitors (56%), SGLT2 inhibitors (13%) and Alpha Glucosidase Inhibitors (10%), a total of 5 classes of antihypertensive drugs were used. The most common type of anti hypertensive drug was ARB (46%) followed by CCBs (35%), β -Blockers (22.%) and Diuretics (12.%).

Conclusion:

This study found that Angiotensin receptor blockers (ARBs) were the most commonly used class of antihypertensive drugs in diabetic patients in the tertiary care hospital, followed by Calcium channel blockers (CCBs), beta blockers, and diuretics. The preference for monotherapy over combination therapy was also observed, with telmisartan being the most frequently prescribed medication, either as monotherapy or in combination. These findings provide insight into the current practices for managing hypertension in diabetic patients in this hospital and could inform future treatment decisions.

Keywords: Metformin, DPP4 inhibitors, angiotensin receptor blockers, Calcium channel blockers

Practice of self-medication and household storage of drug: A habit among the patients attending Out Patient Department of Katihar Medical College, Bihar

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Background: WHO has defined self-medication as the selection and use of medicines by individuals to treat self-recognized illnesses or symptoms. This practice is associated with household storage of drugs. It poses potential risks to the population due to inappropriate storage conditions and irrational use of medication without medical consultation may result in serious health problems. Global data has seen a tremendous hike in rate of self-medication, this has not only led to wastage of resources but also serious side effects.

Objective: This study was conducted to assess the practice of self-medication and household storage of drugs among the patients attending Medical OPD of Katihar Medical College, Bihar.

Materials and Methods: An observational study with cross-sectional design was conducted by the Department of Pharmacology from January 2023 to June 2023. A total of 500 individuals visiting the

Medical OPD were interviewed using a pre-designed questionnaire. Basic demographic data, information on various aspects pertaining to drug storage and self medication were obtained. Data was entered and analyzed using Microsoft Excel.

Results: Among 500 individuals, 315 came from urban background. A little more than half of them were illiterate. Around three-fourth of the study population had self-administered any oral drug in last 1 year. Storage of drugs at household level was seen among 88% of the patients. Among the most common drugs stored at household level were PPI, multivitamins, analgesics, paracetamol and antibiotics. Among antibiotics, most commonly named azithromycin, levofloxacin, metronidazole. A designed box for medicines was present in almost all houses. Refrigerator for storage was used in less than 1% of cases. Only a few had any of the injectable drug at home. None of them had faced an accidental intake of stored drug by children at home.

Conclusion: The study showed that large and variety of drugs were being stored at household levels. There is a need for change in the practice of self medication or household level storage of drugs.

Keywords: Self-medication, drug storage

Study of prescription pattern of anti-epileptic agents in a tertiary care hospital

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Background: Epilepsy is a chronic neurological disorder characterized by recurrent seizures, affecting millions of people worldwide. The appropriate selection and utilization of anti-epileptic agents (AEAs) play a crucial role in the management of epilepsy. However, there is limited research on the prescription patterns of AEAs in tertiary care hospitals. This study aimed to assess the current prescription patterns of AEAs in Sri Krishna Medical College, Muzaffarpur.

Methods: A cross-sectional study was conducted, in the department of Pharmacology at Sri Krishna Medical College, Muzaffarpur. Patients diagnosed with epilepsy who visited the outpatient department between January 2023, to June 2023. Data related to patient demographics, seizure types, duration of epilepsy, and prescription details of AEAs were collected and analyzed.

Results: A total of 100 patients with epilepsy were included in the study. The mean age of the patients was 34 years, with a slight male preponderance (52%). The most common type of epilepsy was generalized tonic-clonic seizures (62%), followed by focal seizures (28%) and absence seizures (10%). Monotherapy was prescribed for the majority of patients (78%), with polytherapy being the second most common approach (22%). Among the prescribed anti-epileptic agents, carbamazepine (48%) was the most frequently prescribed medication, followed by valproic acid (38%) and lamotrigine (14%). The analysis revealed that adherence to established treatment guidelines varied among healthcare providers. Approximately 65% of the prescriptions adhered to the recommended dosage regimens, while 35% showed deviations. In terms of monotherapy selection, approximately 80% of the prescriptions followed the guidelines, while 20% deviated from the recommended medications.

Conclusion: The majority of prescriptions adhered to treatment guidelines, a significant proportion showed deviations in dosage regimens and medication selection. These findings highlight the need for continuous medical education and awareness among healthcare providers to improve adherence to treatment guidelines and optimize the management of epilepsy. Further studies are warranted to explore the reasons for non-adherence and evaluate the impact of adherence on treatment outcomes.

Keywords: AEAs, carbamazepine, valproic acid, lamotrigine

Knowledge, attitude, and practice among interns and postgraduate students from clinical and para clinical departments about pharmacovigilance and adverse drug reaction (ADR)

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Background- Pharmacovigilance plays an important role in the health and care sector, in terms of health and economic burden. As we know, pharmacovigilance and filling out the adverse drug reaction form is necessary to know any drug's new and serious side effects. Studies on interns/PG students are limited and are an aspect that requires further study.

Aim-To assess the knowledge attitude and practice of pharmacovigilance awareness among interns/PG students from clinical and paraclinical departments of government teaching hospitals i.e., JLN MCH, BHAGALPUR.

Also, to study the reasons for underreporting of ADR.

Material And Method-The study is going on in JLN MCH, Bhagalpur, Bihar from 28th May to 15th June tentatively. The method is a questionnaire-based cross-sectional study.

The answered questionnaire was statistically analyzed by using a Microsoft Excel worksheet.

RESULTS- Till now 26 PG students from different departments and 9 interns participated.

There were 8 female and 18 male PG students with an average age (of 30-53 years) and 4 females and 5 male interns average age (of 25-30 yrs).

Almost 90% of them come across ADR cases during their ward duty. However, among them only 20% reported. The majority of them know about ADR, less than 30% didn't see the form, and 50% didn't know about the presence of an ADR monitoring center in the institute.

Conclusion- Interns and PG students are upcoming doctors so attention must be paid to their lack of knowledge about pharmacovigilance, improving the clinical management and rational use of drugs.

As the study is going on so the percentage of KAP among students can vary.

Keywords- Pharmacovigilance, Adverse drug reaction, knowledge, attitude, practice, interns, PG students.

The knowledge, attitude and the perception of prescribers on the rational use of antibiotics – A cross sectional survey at BMIMS Pawapuri Nalanda Tertiary Care Hospital

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Background: Antibiotics are prescribed frequently and there is always an overuse with a risk of resistance and increasing costs. Rational drug prescribing is essential for minimizing the health care costs and for reducing the resistance. The implementation of a strict antibiotic policy by all the health care institutes is being made mandatory nowadays. An improving awareness among the prescribers which can be created through educational interventions, can promote the rational use of antibiotics. **Aims & Objectives-** To study the knowledge, attitude and the perception of the practitioners towards a rational antibiotic use.

Methods: All the registered practitioners who were working in the hospital setting and were willing to give written informed consents, were enrolled in the study. All the participants who were enrolled in the study during a one month period, had to fill up a predesigned, structured and validated questionnaire which was used to assess the knowledge, attitude and the Perception among towards the rational use of antibiotic.

Results: About 65% of the participants who provided complete information in the questionnaire, were included in analysis. Among them, more than 50 % agreed on the existence of an essential drug list, on the knowledge about new antibiotics and on prescribing antibiotics rationally and on the interpretation of the culture and the sensitivity results. A majority strongly agreed that they ensured that their patients completed the course, that they provided counseling and that they took special interest in the proper use of antibiotics. There was a consensus on the overuse, issues of resistance, and on the input from fellow colleagues.

Conclusion: The participants in our study had knowledge about the rational use of antibiotics, an attitude to prescribe drugs as per the essential drug list and a perception that antibiotics were being overused and that rational drug prescribing had an important role in the antibiotic resistance.

Key words:- Antibiotic policy, Rational drug use, Drug resistance

Drug Utilization Study and Monitoring of Adverse Events of Anti-cancer Drugs in a Tertiary Care Hospital of Bihar

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Introduction: Chemotherapy is one of the integral components in the management of carcinomas. Significant variation in the response rate of individual anticancer drugs, availability of different regimens, and intolerability of combination regimens necessitate observation and evaluation of cancer chemotherapy. It has been found that the ADR profile of cancer chemotherapeutics is very less reported and the situation is even worse in India.

Aims & Objectives: Present study was conducted to delineate the various drugs used in carcinomas to find discrepancies, if any, between the actual and the ideal prescribing pattern of psychotropic drugs, to assess prevalence of various carcinomas and to assess adverse events. This was an observational and prospective study in which chemotherapy prescriptions and data regarding adverse event (patients complain, clinician report, laboratory data) were collected from out-patient department of Medical Oncology. Their prescriptions were collected and they were screened for adverse events of grade 1-4 of CTC version 5. Descriptive analysis was done to analyse and compare the results.

Results: Most of the patients were of age group 46-60 (39.08). Gall bladder cancer was mostly found in age group 61-70. Hodgkin's lymphoma and germ cell tumour were mostly found in younger patient. Cisplatin (15.13%), Gemcitabine (13.38%) and Carboplatin (11.40%) were mostly prescribed drugs. 20.56% of all adverse event were haematological. Most of the grade 3 adverse events were haematological.

Conclusion: More recent developments in the availability of anticancer drugs which include molecular-targeted therapy such as targeting the proteins with abnormal expression inside the cancer cells should be utilized judiciously. Nevertheless, an early detection of these ADRs may help in minimizing the damage by either modifying the dose or changing the offending agent.

Keywords: Cancer, Chemotherapy, Drug utilization study, Adverse events, Prescriptions.

A randomized controlled study comparing the efficacy of 75 mg versus 150 mg aspirin for the prevention of preeclampsia in high- risk pregnant women

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Background: Preeclampsia is a major factor in both maternal and fetal morbidity and mortality. The most widely investigated preeclampsia prevention medication is low dose Aspirin. However, guidelines differ considerably regarding the prophylactic dose of Aspirin for preeclampsia.

Objective: The objective is to compare the efficacy of 150mg versus 75mg Aspirin for the prevention of preeclampsia in pregnant women at high risk of preeclampsia.

Methodology: This was a parallel, open-label, randomized control trial carried over a period of one year and three months at a tertiary care center of Eastern India. Block randomization was done and block sizes of 2 and 4 were used to ensure balanced distributions within the study arms. Primary outcome was the development of preeclampsia and secondary outcomes were fetomaternal complications in both groups.

Results: The present clinical trial was conducted on 116 pregnant women with a risk factor of preeclampsia and they were randomly assigned to receive either 150mg or 75mg of Aspirin daily at bedtime beginning from 12 to 16 weeks of gestation till 36 weeks' gestation. A significantly greater number of pregnant females who received Aspirin 75mg (33.92%) developed preeclampsia in contrast to those who received Aspirin 150mg (8.77%), $p=0.001$. There were five times greater odds of preeclampsia in those who received Aspirin 75mg in comparison to 150mg (cOR = 5.341, 95% CI = 1.829-15.594). There was an insignificant difference in fetomaternal outcome among both the groups of women.

Conclusion: Among women who are at high risk of developing preeclampsia, Aspirin 150 mg once a day at bedtime is more effective than Aspirin 75 mg once a day at bedtime in preventing preeclampsia with similar fetomaternal outcomes (NICU admission, IUGR, neonatal death, still birth, eclampsia, HELLP syndrome, placental abruption and pulmonary edema).

Keywords: Fetomaternal outcome, Low dose aspirin, Primary outcome, Preeclampsia prevention, Randomized control trial

A Comparative study of Topiroxostat and allopurinol in chronic Heart failure patient with hyperuricemia

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Background: The benefit of xanthine oxidase inhibitors to chronic heart failure patients is controversial. The beneficial effects of Topiroxostat, a novel xanthine oxidoreductase inhibitor, in patients with CHF and Hyperuricemia is compared to allopurinol.

Aims and Objectives: To investigate Topiroxostat as a safe and effective alternative to allopurinol for chronic heart failure patients complicated by hyperuricemia.

Methods: A prospective study was performed in patients aged (> 20 years to < 85 years) with CHF (BNP level ≥ 40 pg/ml & Hyperuricemia (S. Uric acid level ≥ 7 mg/dl) in NMCH. Patna from December 2022 to May 2023. Patients were given either Topiroxostat or allopurinol to achieve target Uric acid level ≤ 6.0 mg/dl.

Primary and secondary endpoint analyses performed in the full analysis set included all Participants.

Results: According to the protocol, 100 patients were followed up for 24 weeks. Percent change in (N-terminal-proB-type natriuretic peptide) at week 24 (primary endpoint) was comparable between topiroxostat and allopurinol groups (1.8 ± 8.7 versus $-0.5 \pm 8.52\%$; $P = 0.19$). In the limited number of patients with heart failure with reduced ejection fraction (left ventricle ejection fraction $< 45\%$), ratio of peak early diastolic flow velocity at mitral valve leaflet to early diastolic mitral annular motion velocity (E/e') decreased in topiroxostat group, but not in allopurinol group. Urinary 8-hydroxy-2'-deoxyguanosine and L-type fatty acid-binding protein levels increased and osmolality decreased significantly in allopurinol group, while these changes were less or absent in topiroxostat group. Allopurinol raises urinary marker levels and lowers creatinine levels in HFrEF patients, but doesn't affect clearance. Topiroxostat doesn't cause these changes.

Conclusion : Topiroxostat is a safe and effective alternative to allopurinol for chronic heart failure patients with hyperuricemia. It may also have additional benefits such as reducing left ventricular end-diastolic pressure and providing renoprotection for HFrEF patients.

Keywords: Topiroxostat, allopurinol, Chronic Heart failure, NT-Pro BNP Level

Management of acute low back pain with Aceclofenac and Etoricoxib: A comparative study

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Background: The aim of management of acute low back pain is to alleviate the pain quickly and improve functional ability. Non-steroidal anti-inflammatory drugs are the first line of treatment. The challenge lies in deciding which NSAIDs will provide greater symptomatic relief, while also being cost-effective.

Objective: To compare the effectiveness of aceclofenac and etoricoxib in the management of acute low back pain.

Methods: This prospective, open label, observational study was conducted at Jawaharlal Nehru medical college and hospital Bhagalpur. Patients over 18 years of age and presenting with low back pain of less than 6 weeks duration were enrolled in the study. Fifty patients with non-specific low back pain were randomized into two groups: Group A received aceclofenac (2 mg/kg) twice a day and Group B received etoricoxib (1 mg/kg) twice a day for 1 week

Results: The decrease in pain intensity in Group A was 52.27%, while in Group B it was 62.53%. However, the decrease in pain scores between the groups was not statistically significant ($p = .3795$). Improvement in functional ability in Group A and Group B was 57.01% and 61.48%, respectively. However, this improvement between the groups was not statistically significant ($p > .999$) at the end of 1 week. The average cost-effectiveness ratio indicated that etoricoxib was the dominant treatment over aceclofenac. Therefore, etoricoxib was found to be the cost-effective option for short-term pain relief in acute low back pain for 1 week.

Conclusion: Both aceclofenac and etoricoxib were clinically effective in reducing the pain intensity and in improving functional ability. However, etoricoxib was found to be the cost-effective intervention.

A comparative study of the clinical efficacy and safety of topical retapamulin and mupirocin in the treatment of acute bacterial skin infections

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Objective: Acute bacterial skin infections (ABSI) are a common condition worldwide, requiring effective and safe topical treatments. This study aimed to compare the clinical efficacy and safety of topical retapamulin and mupirocin in the treatment of ABSIs.

Methods: A randomized, single-blind, parallel-group trial was conducted in the department of Dermatology with collaboration in the department of Pharmacology, involving adult patients with ABSIs. Participants were randomly assigned to receive either topical retapamulin or mupirocin for the period of 6 months

December 2022 to May 2023. The primary outcome measure was the clinical cure rate, assessed by complete resolution of infection signs and symptoms at the end of treatment. Secondary outcome measures included time to resolution, microbial eradication rates, and safety profiles of the treatments.

Results: A total of 40 patients were enrolled in the study, with half (20 patients - retapamulin group & 20 patients- mupirocin group) assigned to each treatment group. The clinical cure rate in the retapamulin group was comparable to that in the mupirocin group, with no statistically significant difference observed ($p > 0.05$). Time to resolution and microbial eradication rates were similar between the two treatment groups. Both retapamulin and mupirocin demonstrated favorable safety profiles, with no severe adverse events reported. The most common adverse reactions were mild local skin reactions at the application site, which were transient and self-resolving.

Conclusion: This comparative study suggests that topical retapamulin and mupirocin are equally effective in the treatment of ABSIs, exhibiting similar clinical cure rates, time to resolution, and microbial eradication rates. Both treatments were well-tolerated, with a low incidence of adverse events. These findings support the use of retapamulin as a potential alternative to mupirocin for the management of ABSIs, providing clinicians with additional therapeutic options.

Keywords: acute bacterial skin infections, retapamulin, mupirocin, clinical efficacy, safety.

Comparison of clinical efficacy of topical clindamycin with adapalene and adapalene alone in treatment of mild to moderate facial acne vulgaris-a prospective study

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Background: Acne vulgaris is the most common disease worldwide among adolescents and adults with 80% prevalence. With the goal to develop topical treatments for acne that are effective against both inflammatory and noninflammatory lesions to avoid the development of antibiotic resistance, antibiotics are often have to be combined with other substances. Retinoids and associated therapies also have anti-inflammatory effects and limit the development of microcomedones.

Objectives: To compare and evaluate the clinical efficacy of topical clindamycin with adapalene and adapalene gel in mild to moderate facial acne vulgaris.

Methods : The prospective, randomised, open-label, comparative-efficacy study was conducted at the Darbhanga Medical College Hospital, Laheriasarai. The effectiveness and tolerability of clindamycin plus adapalene gel 0.1% and adapalene 0.1% alone for the treatment of mild to moderate acne vulgaris were examined in the study. There were 60 patients altogether, split into two groups. The directions that were given for one group (30 patients) were to apply clindamycin 1% lotion and adapalene 0.1% twice daily, while the directions for the second group (30 patients) were to use adapalene 0.1% gel once daily for 12 weeks.

Results : The clindamycin 1% plus adapalene 0.1% group showed a significantly reduced level of total (P.001), inflammatory (P.004), and non-inflammatory lesions (P.001) than the adapalene 0.1% treated group. These significant treatment improvements for both non-inflammatory and total lesion counts were seen as early as week 4. Both treatment plans were accepted successfully. . In terms of total lesions, the mean percentage reductions were 46.45% versus 25.28%, inflammatory lesions were 55.1% versus 44.51%, and non-inflammatory lesions were 42.8% versus 17.06%.

Conclusions: The complimentary as well as distinct modes of action of antibiotics and adapalene result in a considerably superior and more rapid decrease of acne lesions, suggesting that this therapeutic regimen may be effective at the beginning of therapy to get an improved clinical response.

Key words- Inflammatory lesions, Non inflammatory lesions, Microcomedo, Clindamycin, Adapalene, Clinical efficacy, Total lesions

A comparative study of the effect of losartan and enalapril in the management of HTN in patients with T2DM

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Introduction: Diabetic nephropathy (DN), the world's most common cause of end-stage renal disease (ESRD) in individuals with Type 2 diabetes mellitus (T2DM) and hypertension, is thought to cause ESRD in

about 20% of type 2 diabetics throughout the course of their lifetimes.

Methodology: A prospective, open-label, randomised, comparative study was carried out on 60 T2DM patients, including 10% dropouts, who had mild hypertension and Grade I DN. The patients were randomly divided into two groups of 30 each, with each group consisting of patients between the ages of 18 and 69 and of either sex, attending medicine outpatient department or admitted in medicine wards. One group was given 5-10 mg/day of enalapril maleate, whereas the other was given 40-80 mg/day of losartan, and they were followed up on once a month for 6 months.

Results: Mean urinary albumin excretion (UAE) decreased significantly ($P < 0.001$) in patients treated with losartan from 64.1 to 41.5 $\mu\text{g}/\text{min}$ and in those treated with enalapril from 73.9 to 33.5 $\mu\text{g}/\text{min}$ after 25 weeks of therapy. A significant relationship ($P < 0.05$) between changes in systolic and diastolic BP and the decrease in UAE at 25 weeks was seen in both groups. Reduction of BP was greater with losartan (systolic BP/diastolic BP (DBP): $P < 0.001$). There was also reduction in, Fasting blood sugar, Post lunch blood sugar, HbA1C, Total cholesterol, low density lipoprotein, very low density lipoprotein, high density lipoprotein and triglycerides.

Conclusion: Our results indicate that a six month course of antihypertensive therapy with either losartan or enalapril significantly reduces UAE in hypertensive type 2 diabetic patients with early nephropathy. The reduction in UAE with each treatment is similarly related to decrements in ABP. In addition, the rate of decline in GFR is similar in both treatment groups.

Key Words: T2DM, DN, Hypertension; Microalbuminuria; Enalapril Maleate; losartan

A comparative study of Etoricoxib and Indometacin in Acute gout

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Background: Acute gout is a common medical condition that most commonly presents with pain which can be treated by simple NSAIDs. Indometacin and Etoricoxib are two such drugs. This study compares safety and efficacy of Etoricoxib with Indometacin in treatment of acute gout.

Aim and Objectives: Our objective in this study was to compare the safety and efficacy of Etoricoxib and Indometacin in treatment of acute gout.

Materials and Methods: A Prospective open randomized comparative study was done in patients selected from NMCH from February 2023 to May 2023. The patients were divided into two groups. Group A were given 120 mg Etoricoxib and group B were given 50 mg Indometacin over 4 days. Treatment response was evaluated based on the 3 point blast scale change. Run score: 0, 1 & 2 and Corresponding to Pain: No pain, Pain state & Pain state + Patient withdraws his limb respectively.

Results: We analyzed 100 patients. No significant differences were obtained in pain score change tenderness, or swelling between Etoricoxib and Indometacin; the mean differences were -0.05 (95% CI, -0.20 to 0.10), and -0.04 (95% CI, -0.18 to 0.09) [$P > 0.05$] over 4 days. Adverse events were more with Indometacin as compared to Etoricoxib $P < 0.05$.

Conclusion: We conclude that both Etoricoxib and Indometacin have equal efficacy in terms of pain relief in Acute gout, But Indometacin is associated with more adverse effects.

Keywords: Gout, Etoricoxib, Indometacin

Efficacy and safety of Carbetocin compared to Oxytocin in prevention of Post-partum haemorrhage : a randomized controlled trial

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Background: PPH is a major issue for maternal morbidity and mortality after vaginal delivery and caesarean section. Carbetocin and Oxytocin is used for prevention of PPH after VD and CS.

Aims and Objectives: To know the efficacy and safety of Carbetocin compared to Oxytocin after VD and CS.

Materials and Methods: A prospective study was performed in 50 patients selected from NMCH from November 2022 to May 2023. Participants divided into two groups: Group A and Group B. Group A received Carbetocin (a bolus of $100\mu\text{g}$ IV) and Group B received Oxytocin (1000ml of 0.9% NaCl solution IV @ $150\text{ml}/\text{hr}$). The primary outcome of the study was evaluation of early haemodynamic effects of Carbetocin

and Oxytocin in terms of effect on BP, evaluation of significant difference in blood loss ≥ 500 ml in women undergoing VD and CS in both group participants. The Secondary outcome of the study was to evaluate the significant difference in blood loss ≥ 1000 ml in women undergoing VD and CS as well as need of blood transfusion, use of additional uterotonic drugs, haemoglobin level, diuresis effect in both group study participants.

Results: After study of both groups A and B. The primary outcome had no statistically significant difference between Carbetocin and Oxytocin in blood loss ≥ 500 ml (RR, 0.52; 95% CI, 0.24-1.15, P= 0.11). BP in group B (Oxytocin) was lower as compared to group A (Carbetocin) after 5 minutes of drug administration. (P<0.01). The secondary outcome had also no statistically significant difference in blood loss ≥ 1000 ml (RR, 1.04; 95% CI, 0.86-1.26; P= 0.67). Blood transfusion (RR-1.13, 95% CI, 0.94-1.37; P=0.19). Group B needed additional uterotonic agents in comparison to group A participants (23.5% vs 0%, P=<0.01), though there was no significant difference in haemoglobin levels (P>0.05). Carbetocin had high diuretic effect than Oxytocin (1300 ml \pm 450 ml vs 1100 ml \pm 250 ml, P=0.01)

Conclusion : After study we conclude that there was no statistically significant difference in blood loss was seen. There was no need of additional uterotonic drug in Carbetocin group. Carbetocin group had less drop in blood pressure as compared to Oxytocin group.

Keywords : Carbetocin, Oxytocin, PPH

Efficacy and safety of once weekly semaglutide vs once daily sitagliptin as add on to metformin in the patients with type 2 diabetes mellitus

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Background: Type 2 diabetes in a complex multifactorial disease. Semaglutide is a novel glucagon-like peptide-1 (GLP-1) receptor agonist, suitable for once-weekly subcutaneous administration, in development for treatment of type 2 diabetes. We assessed the efficacy and safety of semaglutide versus the dipeptidyl peptidase-4 (DPP-4) inhibitor sitagliptin in patients with type 2 diabetes inadequately controlled on metformin.

Aim and Objectives: To evaluate the efficacy and safety of once weekly semaglutide vs once daily sitagliptin as add on to metformin in patients with type 2 DM.

Materials and Methods: A prospective study was performed at NMCH, Patna BIHAR from Jan 23 to June 23 on the patient of age > 18 years with Type 2 DM poorly controlled on metformin (HbA1c 7-10.5%). 100 Patients were divided in 2 groups, GROUP A has given METFORMIN 500mg twice a day with 1mg SEMAGLUTIDE once weekly while GROUP B has given METFORMIN 500 mg twice a day with 100 mg SITAGLIPTIN once daily to achieve target HbA1c < 7%.

The primary end point was change in HbA1c from baseline to HbA1c after 24 week. Secondary end point was significant reduction in body weight after 24 weeks.

Results: The primary focus of the study revolved around evaluating changes in HbA1C and body weight. The findings revealed that once-weekly Semaglutide showed substantially improved HbA1C (WMD: -0.98; 95% CI: -1.28, -0.69, p-value: < 0.0001), and body weight (WMD: -3.17; 95% CI: -3.84, -2.49, p-value: <0.00001%) compared to once-daily Sitagliptin. Regarding secondary outcomes, there was an elevated risk of total adverse events and premature treatment discontinuation with Semaglutide.

Conclusions: The administration of once-weekly Semaglutide exhibited a substantial reduction in HbA1c, and body weight as opposed to the once-daily administration of Sitagliptin.

Keywords: Sitagliptin, Semaglutide, once weekly, once daily

Report on efficacy and safety of Dapagliflozin: An observational study from a tertiary care hospital of Northern district of Bihar

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Background: Type 2 diabetes mellitus is a multi-dimensional health condition affecting a huge proportion of population. The age old treatment has seen scientific innovations time and again. One very recent addition is dapagliflozin, a sodium glucose co-transporter 2 inhibitor under investigation. This is proposed as an add-on

therapy for better glycemic control in patients inadequately controlled with metformin.

Objective: The current study was done to assess the renal safety of dapagliflozin among patients attending medical OPD of Katihar Medical College, Bihar

Methodology: The study was conducted by Department of Pharmacology. It included 100 diagnosed cases of T2DM who were on metformin @ 1.5–2.5 g/day. They were randomly divided in 2 equal groups. Group A was given dapagliflozin @ 10mg/day. Group B was given any additional hypoglycemic agent apart from these two drugs. The endpoint was change from baseline in HbA1c at 6 and 12 months as well as changes in BMI and lipid parameters at 12 months. Renal function was assessed by the change in blood creatinine levels at 6 and 12 months, as well as urine microalbumin levels at 12 months. Statistical analyses were performed using SPSS Statistics version 20.

Results: The result showed that there was a significant reduction in HbA1c levels (8.1% to 7.2%) after 12 months of treatment with dapagliflozin. Creatinine levels for patients of group A reduced from 74.9 to 70.2 mg/dl while in group B, the mean creatinine reduced from 76.3 to 74.4 mg/dl. Moreover, microalbumin levels reduced by 24.1 units in patients of group A. The drug also had a significant impact on weight reduction. The mean BMI in group A reduced from 31.3 to 30.1 kg/m².

Conclusion: Dapagliflozin, a SGLT2 inhibitors promises to have better glycemic control when used as an adjuvant with metformin with least renal hazard and good weight reduction.

Keywords: SGLT2 inhibitor; dapagliflozin; efficacy; renal safety; type 2 diabetes mellitus

A comparative study of glimepiride and dapagliflozin in the treatment of type 2 diabetes mellitus

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Background: The management of T2DM includes various pharmacological interventions, and two commonly prescribed medications are glimepiride, a sulfonylurea, and dapagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor. While both drugs have demonstrated efficacy in lowering blood glucose levels, there is limited evidence directly comparing their therapeutic effects and safety profiles. Therefore, this study aims to compare the effectiveness and tolerability of glimepiride and dapagliflozin as monotherapy in patients with T2DM.

Methods: This was a prospective, randomized, open-label, parallel-group study conducted over a duration of 6 months. Study conducted in the department of Pharmacology with collaboration of department of Medicine at BhagwanMahavir Institute of Medical Sciences Hospital, Pawapuri, Nalanda, Bihar. A total of 200 participants diagnosed with T2DM, aged between 30 to 70 years, were randomly assigned to receive either glimepiride (2 mg to 4 mg once daily) or dapagliflozin (5 mg to 10 mg once daily). Primary outcomes measured were changes in HbA1c levels, fasting plasma glucose (FPG), and postprandial plasma glucose (PPG) from baseline.

Results: The study included 100 patients in each treatment arm. Both glimepiride and dapagliflozin significantly reduced HbA1c levels from baseline ($p < 0.001$). However, dapagliflozin showed a greater reduction in HbA1c compared to glimepiride (mean reduction of 1.6% vs. 1.2%, respectively). Dapagliflozin also demonstrated superior reductions in FPG and PPG levels compared to glimepiride ($p < 0.05$). While those on glimepiride exhibited a slight increase in body weight and no significant change in blood pressure. Both treatments were generally well-tolerated, but hypoglycemic events were more frequent in the glimepiride group, while genital infections were more common in the dapagliflozin group.

Conclusion: In this comparative study, dapagliflozin showed superior glycemic control, as evidenced by greater reductions in HbA1c, FPG, and PPG levels compared to glimepiride. Furthermore, dapagliflozin provided additional benefits of weight reduction and blood pressure lowering, while glimepiride was associated with a higher risk of hypoglycemic events. These findings suggest that dapagliflozin may be a more effective and well-tolerated option for the management of T2DM in selected patients.

Keywords: Glimepiride, Dapagliflozin, Type 2 Diabetes Mellitus, HbA1c, Glycemic Control, Adverse Events.

A Comparative Study on Latanoprost and Travoprost, in reducing intraocular pressure in patients with Primary open angle glaucoma

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Background : Glaucoma is a disease characterized by a progressive form of optic nerve damage resulting in blindness and elevated (Intra ocular pressure) IOP is the major risk factor for glaucoma development. Increased IOP results from impaired drainage of aqueous humour which is produced by the ciliary epithelium in the posterior chamber of the eye. Serial IOP measurements are required for glaucoma diagnosis and medication response monitoring. Prostaglandins analogues (PGAs) are the first line therapy for POAG because of their ability to reduce IOP. So, in my study I compared Latanoprost and Travoprost in reducing IOP in patients with POAG.

Methods: In this clinical trial 60 patients were diagnosed with POAG were taken including 10% dropout. Who were OPD patients of Ophthalmology dept. DMCH, Laheriasarai Then they were divided in two group 30 each. In group A I had given Latanoprost 0.005% and in group B Travoprost 0.004%. Patient were examined at baseline and at 12th week. In both the group IOP was measured using goldman applanation tonometer.

Results: The study groups were distributed in terms of age and gender with participants having a mean age of 51.78 ± 15.63 years. At the start of the study the mean IOP in group A and B was 23.42 ± 1.19 mmHg and 23.81 ± 1.53 mmHg respectively and there was no significant difference found at the baseline ($p=0.100$). After 12 week of treatment with latanoprost and travoprost in group A and B respectively the mean IOP in group A was 19.20 mmHg ± 1.03 mmHg and and group B was 19.50 mmHg ± 1.12 mmHg further we found that the inter group comparison was non significant ($p=0.120$). Statistic used: unpaired T-test.

Conclusion: The efficacy of Latanoprost and Travoprost are almost equal and no one is superior among both drugs.

Keywords : IOP , open-angle glaucoma, Latanoprost, Travoprost.

Biomarkers as a Drug Development Tool: Enabling Targeted Therapies and Treatment Monitoring

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Background: This narrative review explores the growing significance of biomarkers in modern drug development and their potential to revolutionize personalized medicine. The traditional drug development process faces challenges in achieving optimal treatment outcomes due to individual variations in response to therapies. Biomarkers offer promising solutions by identifying drug targets, predicting therapeutic efficacy, and stratifying patient populations for precision medicine.

Aims/Objectives: 1. To examine the various types of biomarkers utilized in drug development, including genetic, epigenetic, protein, metabolomic, and imaging biomarkers. 2. To explore the impact of biomarkers in clinical trial design and execution, enhancing patient selection and treatment response prediction. 3. To discuss the challenges associated with biomarker development, including standardization, data reproducibility, and ethical considerations.

Methods: This narrative review is based on a comprehensive analysis of published literature, scientific journals, and relevant databases. The search terms included "biomarkers," "drug development," "precision medicine," and "clinical trials." Studies were selected based on their relevance to the topic and applicability to the objectives of this review.

Results: The review highlights the significance of biomarkers as pivotal tools in drug development. Various biomarker types are explored, with genomic and proteomic technologies playing essential roles in their identification and validation. The integration of biomarkers in clinical trial design is shown to enhance patient stratification, resulting in improved treatment responses. Nevertheless, challenges related to standardization, data reproducibility, and ethical considerations remain crucial concerns in biomarker development.

Conclusion: Biomarkers hold tremendous promise as a crucial tool in modern drug development, paving the way for personalized medicine. Their utilization facilitates the identification of potential drug targets, prediction of treatment efficacy, and patient stratification for optimized therapeutic outcomes. However, addressing challenges associated with biomarker development is vital to realizing their full potential and

accelerating the progress of precision medicine.

Keywords: Biomarkers, Drug development, Precision medicine, Clinical trials, Personalized medicine, Therapeutic efficacy, Patient stratification

Targeting time, the new era and future of precision clinical pharmacology: Aiming clock gene molecular machinery in breast cancer management

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Introduction: In the next 20 years, the burden of breast cancer is estimated to increase by 40% to 3 million new cases per year and the number of deaths by 50% to 1 million per year. Emerging evidence has shown that circadian rhythms, regulating more than 80% of the transcriptome have a significant role in breast cancer pathogenesis. The association between time of intervention and outcome has paved the way for personalizing therapy with the patient's circadian rhythm and developing novel agents targeting circadian genes.

Aims and objectives: In this review, we aim to highlight the mechanisms that link circadian genes with breast cancer pathogenesis and the role of precision drugs targeting these proteins along with proposing areas where more studies are needed to venture into this era of preventative medicine in breast cancer.

Material and methods: A systematic literature search was performed using PubMed, Scopus, Google Scholar and Web of science. 96 articles met the inclusion criteria and offered relevant insight into the topic

Conclusion: The relevance of circadian clock health in cancer prevention should not be underestimated, and in the long term the perspective of our research and therapeutic efforts should focus on prevention rather than intervention. Lessons learned from studies on the circadian clock molecular mechanism on breast cancers should guide traditional radio- and chemotherapeutic techniques, usage of target-specific medications, and treatments utilizing pharmaceuticals customized for a breast tumor-type-specific or even a patient-specific cancer molecular signature. Chronotherapy is top priority in future research due to the drift of enhancing the outcomes for licensed medications, evidence for improved survival and lesser side effects in various cancer types, and conceivable path for finding novel molecular targets.

We will quantum leap precision medicine in breast cancer as we take into account the time of sample collection and patients' daily sleep-wake behaviours, altered circadian molecular machinery and scope of chronotherapy in an individual.

Empowering drug discovery and development with artificial intelligence

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Background: Traditional drug discovery process is time-consuming, costly and often yields low success rates. Artificial intelligence (AI) has emerged as a promising approach to address these challenges by analysing large datasets and make predictions in drug discovery and development.

Aims/Objectives: This review aims to provide overview of the role of AI in drug discovery and development and focusing on its applications, limitations, and potential impact. The objectives are to explore how AI can accelerate the identification of potential drug candidates and predict toxicity.

Methods: To achieve these objectives, literature review from relevant research articles, reviews related to AI in drug discovery was conducted. Multiple databases, including PubMed, Scopus, EMBASE, and MEDLINE, were searched using specific keywords.

Result : The results of the study indicate that AI has been successfully applied in various areas of drug discovery, including de novo drug design, predictive toxicology, and drug repurposing. AI-driven target identification and validation have also shown promising results. However, challenges such as data quality, interpretability of AI models, and ethical considerations remain.

Conclusion: The findings of this study highlight the transformative potential of AI in drug discovery and development process. Collaborative efforts between AI and researchers are important for utilizing the full potential of AI in drug discovery and development but it should be used in conjunction with human expertise

and in compliance with ethics. Continued advancements in AI technologies hold promise for improving the drug discovery process.

Keywords: Artificial intelligence, drug discovery, drug development, de novo drug design

Evaluation of serum human epididymis protein 4 and its role in differentiating between benign and malignant breast diseases: A cross sectional study

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Background: Human Epididymis Protein (HE4) is expressed in many epithelial tissues and its increased expression has been shown in many gynecological and gastrointestinal neoplasms but its expression level and diagnostic potential in breast cancer has not been elucidated.

Aim and Objective: To evaluate the diagnostic power of HE4 in breast carcinoma and its importance in differentiating benign and malignant breast cancer

Material and Method: It was a cross sectional study which involves 90 female subjects 30 breast cancer; 30 benign breast tumor and 30 healthy subjects. Serum level of HE4, CEA and CA 125 were estimated by CLIA method. Statistical analysis was done by SPSS 16.0. One way ANOVA was used to determine statistical significance between three groups. Receiver Operating Curve (ROC) was applied for determination of diagnostic power of HE4.

Results: Mean level of HE4 was significantly higher in malignant breast cancer vs benign breast cancer and age matched control. (266 ± 33.6 vs 48.81 ± 1.74 , 26 ± 1.74 pmol/L, $p < 0.001$) Compared to CEA and CA125, HE4 has superior diagnostic ability (AUC 0.832) with sensitivity 82.4% and specificity 79.6%.

Conclusion: HE4 is a sensitive non invasive diagnostic tool. As it is not elevated in benign breast cancer, so it may be an important diagnostic biomarker for evaluation of breast cancer.

Electrophoresis patterns and effect of antituberculous drugs on serum proteins in patients of pulmonary tuberculosis

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Introduction: India has the highest cases of tuberculosis worldwide. According to WHO (2022) incidence of Tuberculosis in India is 210 per 100,000 population. There incidence of new positive smear cases is 75 per 100,000 population per year. Patients mainly presents with anorexia, weight loss, general malaise, and weakness, fever and sweating at night. In Tuberculosis disease, the level of albumin decrease while globulin increase leading to low Albumin to Globulin (A/G) ratio, and Electrophoresis of serum proteins are good diagnostic approach and provides important information for monitoring treatment outcome.

Materials and Methods

The present study includes 50 cases of pulmonary tuberculosis and 50 age sex matched healthy controls. Initially serum proteins estimation and serum protein electrophoresis was performed in both newly diagnosed patients and controls. All drugs were given as RNTCP guidelines and blood samples were collected on 2 month, 4 month and 6 month interval and different serum protein fractions are compared and analysed.

Results: The total serum protein was significantly lower in the cases than in the controls; 6.12 ± 0.61 vs. 7.02 ± 0.56 g/dL ($p < 0.0020$, t -value=3.12) Similarly, the mean serum albumin was also significantly lower in the cases compared to the controls; 1.65 ± 0.69 vs. 3.87 ± 0.47 g/dL ($p < 0.0001$, t -value=10.98). The $\alpha 1$ globulin stated to rise after 4 months treatment and at 6 months level is 0.262 ± 0.32 g/dl. The level of Y globulin continuously decreases after antituberculous treatment to 1.56 ± 0.67 gm/dl at 6 months.

Conclusion: The nutritional status of pulmonary tuberculosis patients are poor as compared to healthy individuals. The present study shows that level of Total proteins, Albumin and $\alpha 1$ globulin are decreased in patients of pulmonary tuberculosis and gamma globulins levels are elevated. The cause of decrease in total protein and albumin may be due to malnutrition or low cellular immunity. Serum proteins should be done as routine tests in pulmonary tuberculosis patients. Further studies on larger population is required whether albumin and globulin could be predictor of more strong measures of success of treatment like as non

relapse diseases and insignificant death related to tuberculosis.

Keywords: Tuberculosis, Serum protein Electrophoresis, Antituberculosis Drugs

Study of serum cc16 level in patient of chronic obstructive pulmonary disease and its correlation with level of dyspnoea (by MMRC)

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Introduction: Chronic obstructive pulmonary disease (COPD) is a respiratory disease characterized by airway inflammation and reversible airflow limitations. According to WHO COPD is the third leading cause of death worldwide, causing 3.23 million deaths in 2019. CC16 plays a protective role in oxidative stress and inflammation. Recurrent environmental exposure, like cigarette smoking, leads to decreased club cell numbers and serum CC16 levels. Lower levels in blood and airways are associated with COPD prevalence and severity.

Aims and Objective: To investigate possible correlation between serum CC16 level and level of dyspnoea (by MMRC).

Material and Method: A cross-sectional study was performed on 30 COPD patients who visited the pulmonary consultation. Diagnosis was based on clinical presentation according to the GOLD criteria and pulmonary function test. Serum CC16 concentration is determined by sandwich ELISA (Enzyme Linked Immunosorbent Assay).

Results: The serum concentration of CC16 was down-regulated in stable COPD patients compared with healthy control group ($p < 0.05$). The decreased serum CC16 was negatively related to smoking ($p < 0.05$), GOLD grading ($p < 0.005$), MMRC score ($p < 0.05$) and medical history ($p < 0.05$) of patients, but positively correlated with pulmonary function ($p < 0.05$). The smoking, FEV1/FVC values, COPD grading and MMRC scores all affected the concentration of CC16 ($p < 0.05$). The decreased CC16 was an independent risk factor in the process of deterioration of lung function. The sensitivity and specificity of serum CC16 for identifying COPD reached to 65.3% and 75%.

Conclusion: There is a correlation between decreased serum CC16 concentrations and the progression of COPD, suggesting it may contribute to the diagnosis and assessment of the disease.

Correlation between parathyroid hormone and serum creatinine levels in end stage renal disease (ESRD) patients

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Background: Chronic kidney disease (CKD) is a pathophysiological process with multiple etiologies, resulting in the inexorable attrition of nephron number and function and frequently leading to end-stage renal disease (ESRD). ESRD represents a clinical state or condition in which there has been an irreversible loss of endogenous renal function. Diabetic and hypertensive nephropathy are the leading underlying etiologies of both CKD and ESRD. As a result of an accelerated degeneration of glomerular filtration rate (GFR), the kidney becomes dysfunctional. There is a complication associated with chronic kidney disease (CKD) is hyperparathyroidism. Diabetic and hypertensive nephropathy are the leading cause of CKD and ESRD.

Objective of the study: The study design is a cross-sectional focusing on the correlation between parathyroid hormone (PTH) levels and serum creatinine in patients with end stage renal disease.

Materials and methods: the study included 100 subject diagnosed case of ESRD. Study was conducted at department of biochemistry in collaboration with department of nephrology at IGIMS Patna. Measurements of eGFR by CKD-EPI creatinine equation 2021. Measurement of serum creatinine by Jaffe's method was on Beckman Coulter Autoanalyzer AU5800 and iPTH on Abbot Architect i-2000SR Autoanalyzer after QC check. the reports of above parameters were released.

Results: There was a statistically significant positive correlation found between PTH and serum creatinine ($p \leq 0.001$, $r=0.596$) whereas statistically significant negative correlation found between PTH and eGFR ($p \leq 0.001$, $r=-0.525$).

Conclusion: Hyperparathyroidism is one of the earliest manifestations of impaired renal function. Monitoring trends is important for the detection and treatment of Chronic Kidney Disease.

The relationship between leptin and insulin resistance in type 2 diabetes mellitus

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Background: Diabetes mellitus type 2 (T2DM) is a major cause of mortality and morbidity worldwide, whose incidence is increasing rapidly in India. There is a relationship between insulin resistance (IR) and relative insulin deficiency that causes T2DM. Leptin, an adipokine with the primary function of regulating energy balance, is found to mediate insulin secretion and sensitivity in peripheral tissues. Hence, we aimed to determine the role of leptin in the development of IR in newly diagnosed T2DM patients.

Aims and objective: -1. to measure serum leptin and insulin level in diabetes mellitus type 2, 2. to assess relationship between leptin and insulin resistance.

Materials and methods: This is a cross-sectional study done in diabetic patients, attending medicine department in I.G.I.M.S. hospital. The present study will be conducted in 50 adult patients of type 2 diabetes mellitus. Serum leptin is measured with ELISA method, Insulin is assayed by CMIA. Insulin resistance is calculated by HOMA score.

Results: Leptin and HOMA-IR levels were significantly high in T2DM patients ($P < 0.001$) when compared with reference values. Body mass index showed a significant positive correlation with insulin ($r = 0.40$, $P < 0.01$), HOMA-IR ($r = 0.37$, $P < 0.01$), and leptin levels ($r = 0.90$, $P < 0.01$). Leptin levels showed significant positive correlations with plasma insulin ($r = 0.35$, $P < 0.01$) and HOMA-IR levels ($r = 0.31$, $P < 0.05$). The correlation between leptin and HOMA-IR levels was more pronounced and significant among the obese T2DM subjects ($r = 0.82$, $P = 0.01$).

Conclusion: Leptin can act as a marker of insulin resistance in diabetes mellitus type 2. The development of IR in T2DM patients is strongly linked to hyperleptinemia, making leptin a potential biomarker.

Transcriptome Profile Analysis of Triple-Negative Breast Cancer before and after treatment by Next generation sequencing for target prediction

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Background: Human cancers are now divided into various subtypes with different disease development and therapeutic response due to the ability to investigate illness at the most fundamental molecular level. Breast cancer is an extremely heterogeneous illness with wide variations in its histologic and biochemical characteristics, much like the majority of solid tumours. Human epidermal growth factor receptor 2 is not amplified or overexpressed in triple-negative breast cancer (TNBC), a subtype of breast cancer in which neither the oestrogen receptor nor the progesterone receptor is expressed.

Materials & Methods: The aim of the present study was to elucidate the pathogenesis of breast cancer and investigate novel potential diagnostic and therapeutic targets. Blood samples were collected for RNA sequencing (RNA-Seq), and the differentially expressed genes were analysed by RNA sequencing Illumina Nova Seq 6000. The RNA-Seq data of breast cancer were further analysed using bioinformatics. The sequenced reads were quantified and qualified in accordance with the analysis demands.

Results: The transcriptomes of the breast cancer blood sample pre-treated, post treated and healthy controls were analysed, 121 upregulated and 224 downregulated genes were identified in pre-treated vs controls, 436 upregulated and 146 downregulated in post treated vs control. Gene Ontology analysis uncovered a significant enrichment in the terms associated with extracellular matrix (ECM) organization, cell adhesion and collagen catabolic processes. Kyoto Encyclopedia of Genes and Genomes analysis demonstrated that these differentially expressed genes were mainly enriched in the focal adhesion pathway, ECM-receptor interaction pathway, phosphoinositide 3-kinase (PI3K)-Akt pathway, and cell adhesion molecules. Comprehensive analyses of the gene tree and pathway network revealed that the majority of cell cycle genes were upregulated, while the majority of the genes associated with intracellular response, cell adhesion and cell differentiation were downregulated. ECM-receptor interaction, focal adhesion kinase (FAK) and GABA receptor kinase pathways were closely associated with one another and held key positions in differential signalling pathways. **Conclusion:** The ECM-receptor MHC II and complement component C3b binding pathways were found to synergistically promote breast cancer occurrence and progression, and may serve as potential diagnostic and therapeutic targets for this type of cancer.

Expression and Purification of Nup88 Complex Associated with Disease and Investigating its Role in Pathogenesis

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Background: The nuclear pore complex is present in the inner and outer membranes of the nuclear envelope. There a few structural studies have been done in lower eukaryotes, however, in higher eukaryotes, it is still a challenge for protein purification and there is a significant difference observed in the NPC architecture of lower vs higher eukaryotes. Although, the absence of a high-resolution structure of the mammalian Nup88 complex, it becomes important to study these protein complexes to understand the puzzle of NPC assembly, architecture, and function. These findings may shed light on the molecular mechanisms underlying cytoplasmic transport and its relevance to cellular processes and disease states.

Methodology: Cloning of Nups of Nup88 complex –PCR amplification of the truncated Nup88⁵⁹⁻⁷⁴², full-length Nup88 and Nup214. Cloning of these genes into the bacterial expression vector and the truncated Nup88⁵⁹⁻⁷⁴² into the mammalian expression vector. Expression and purification optimization –Purify the β -propeller domain of Nup88 and Nup214 alone and then Nup88Nup214 complex. Biophysical characterization of the Complex –The purified alone Nups and complex will be used for the SEC and SEC-MALS analysis and Crystallization of the protein.

Result: Full-length Nup88 was successfully cloned into the mammalian expression system and ready for expression and purification. Optimization of the β -propeller domain of the Nup88⁵⁹⁻⁴⁹⁸ with SEC and SEC-MALS analysis showed that it exists in the monomeric state in the solution; crystalized Nup88⁵⁹⁻⁴⁹⁸ was confirmed by UV [microscopy](#) analysis. It was found that the β -propeller domain of the Nup214¹⁻⁴⁰⁷ was soluble during purification and reconstituted the stable Nup88⁵⁹⁻⁴⁹⁸Nup214¹⁻⁴⁰⁷ complex.

Conclusion: Detailed in solution behavior and structural analysis of the full-length Nups and its domain of the Nup88 complex are not yet reported from the mammalian complex. And there is no structural information available on the Nup88⁵⁹⁻⁴⁹⁸Nup214¹⁻⁴⁰⁷ complex, which is very crucial for the export and remodeling of the mRNA molecules at the cytoplasmic side of the NPC. We reconstituted the stable Nup88⁵⁹⁻⁴⁹⁸Nup214¹⁻⁴⁰⁷ complex and further we will employ cellular or animal models to investigate the impact of Nup88 dysregulation on disease pathogenesis.

Mitochondrial Targeted Antioxidants MC1 and MC2 Novel Compounds with Potential Therapeutic Efficacy in Cardiovascular Pathologies

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Cardiovascular diseases (CVDs) remain a leading cause of morbidity and mortality worldwide. Endothelial dysfunction, macrophage infiltration of the vessel wall, and proliferation and migration of smooth muscle cells are well-established contributors to the pathogenesis of CVDs, involving various types of reactive oxygen species (ROS) produced by different vessel wall components. Although antioxidant therapies have been explored as potential interventions, clinical trials with conventional antioxidant compounds have yielded disappointing outcomes, indicating the need for improved strategies and a deeper understanding of ROS's role in cardiovascular physiology and pathology.

To address these challenges, we investigated a novel set of compounds, the mitochondrial-targeted antioxidants MC1 and MC2, to assess their efficacy in mitigating oxidative stress-induced cell death and pathological effects associated with CVDs. Our research aimed to compare the effectiveness of these compounds against their parent antioxidant compounds. Initial studies revealed promising results with the mitochondrial-targeted compounds, with MC2 showing particularly positive outcomes.

Furthermore, when evaluating cell protection, a synergistic effect was observed when using a combination of both MC1 and MC2. This result can be attributed to the involvement of cytosolic sources of ROS production, such as NADPH oxidase, xanthine oxidase, and cytochrome P450 reductases, suggesting that ROS generation occurs in both mitochondrial and extra-mitochondrial subcellular compartments.

Nonetheless, a comprehensive understanding of the mechanisms governing enzymatic ROS generation, the importance of subcellular ROS compartmentalization, and the molecular impacts of ROS on cell cycle regulation remains imperative. Further investigations are needed to elucidate these intricate processes to pave the way for the development of more effective antioxidant therapies targeting CVDs.

In conclusion, our study highlights the potential of mitochondrial-targeted antioxidants, particularly Mc2,

as promising compounds for attenuating oxidative stress-induced cell damage and other pathological effects related to CVDs. These findings underscore the significance of continued research efforts to deepen our understanding of ROS in cardiovascular physiology and identify innovative antioxidant strategies to combat cardiovascular pathologies effectively.

A Study on nebulized Salbutamol versus Adrenaline in the treatment of wheeze associated respiratory tract infection

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Background: Infancy and the early years of childhood are frequent times for wheezing caused by respiratory illnesses. These infections are severe enough to need hospitalization in 1-3% of all babies. The majority of wheezing attacks in infancy are viral in nature and include a diverse group with various results. The goals of this study were to evaluate the effectiveness of bronchodilators in treating respiratory infections associated with wheezing and to compare the effectiveness of a nebulized beta-2 specific agonist salbutamol with a nebulized nonspecific adrenergic agonist -1 adrenaline.

Methods: The study was conducted in children reporting to the Pharmacology Department DMCH, Darbhanga. The study period was 6 months from January to June 2023. Children between the ages of two months to two years attending the hospital with the clinical diagnosis of bronchiolitis were enrolled.

Results: There were 30 kids enrolled. 8 (26.7%) people in the age range of 1-2 years and 22 (73.3%) people in the age range of 2 months to 1 year. The reduction in respiratory rates, wheezing, and retractions in one group compared to the other had no extra benefit.

Conclusions: It can be concluded that bronchodilators, including salbutamol and nebulized adrenalin, are effective in symptom relief and oxygenation improvement in wheezy newborns with clinical diagnoses of WRTI. No medication is claimed to be superior to another.

Keywords: Respiratory tract infection, Nebulization, Epinephrine, Wheezing

Effect of vildagliptin & linagliptin on glycaemic control, or renal function, liver function, and lipid profile in patients with type 2 diabetes inadequately controlled with combination of metformin & glimepiride

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Background: Type 2 diabetes mellitus (T2DM) is a prevalent chronic condition associated with impaired glycaemic control and an increased risk of complications affecting various organ systems. In patients with inadequate glycaemic control despite receiving a combination of metformin and glimepiride, additional therapeutic approaches are warranted. This study aimed to investigate the effects of two dipeptidyl peptidase-4 (DPP-4) inhibitors, vildagliptin and linagliptin, on glycaemic control, renal function, liver function, and lipid profile in this specific patient population.

Methods: A prospective, randomized, double-blind, placebo-controlled trial was conducted in the department of pharmacology collaboration in the department of Medicine at Darbhanga Medical college & Hospital, during the period of December 2022 to June 2023, A total 234 adult patients diagnosed with T2DM and showing inadequate glycaemic control with metformin and glimepiride therapy. Participants were randomly assigned to one of three groups: vildagliptin, linagliptin, or placebo, administered orally in addition to their existing treatment regimen. The primary endpoint was the change in HbA1c levels from baseline to the end of the study (12 weeks). Secondary endpoints included changes in renal function, liver function, and lipid profile.

Results: Both vildagliptin and linagliptin demonstrated significant improvements in glycaemic control compared to the placebo group. The mean reduction in HbA1c levels from baseline to the end of the study was 1.2% in the vildagliptin group and 1.0% in the linagliptin group, while the placebo group showed a minimal reduction of 0.2%. These reductions were statistically significant ($p < 0.05$) in both intervention groups. No cases of acute kidney injury or significant changes in urine albumin-to-creatinine ratio, No cases of drug-induced liver injury or hepatic adverse events there were no instances of severe dyslipidemia or significant lipid-related adverse effects during the study.

Conclusion: The results of this study suggest that the addition of vildagliptin or linagliptin to the existing

combination therapy of metformin and glimepiride is effective in improving glycemic control in patients with inadequately controlled T2DM. Furthermore, both DPP-4 inhibitors were well-tolerated and did not adversely affect renal function, liver function, or lipid profile.

Keywords: Type 2 diabetes, vildagliptin, linagliptin, glycemic control, HbA1c, renal function, liver function, lipid profile, metformin, glimepiride.

An observation of association between steroid treated COVID-19 patients and mucormycosis

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Introduction: Mucormycosis is a severe fungal infection characterized by angio-invasion, predominantly observed in patients with uncontrolled diabetes mellitus and compromised immune systems. This rapidly progressive and destructive infection poses a life-threatening risk.

Aim: Our study aims to investigate whether the use of systemic steroid therapy contributes to the development of mucormycosis in COVID-19 patients.

Methods: We examined 25 patients admitted to the mucormycosis ward at Rajendra Institute of Medical Sciences in Ranchi. Patient data, including age, gender, history of COVID-19 infection, diabetes mellitus status, duration of DM, and details of systemic steroid therapy during COVID-19 infection (type and dosage of steroids administered, duration of treatment), as well as blood sugar levels and HbA1C, were included in the study.

Results: All 25 patients in our study had a confirmed COVID-19 infection. Of these, 23(92%) were male and 2(8%) were female. The most affected age group was between 41-50 years, comprising 12 patients (44%). Among the patients, 14(56%) had a known history of type 2 DM, 9(36%) were newly diagnosed with diabetes, and 2(8%) were non-diabetic. Among the 23 diabetic patients, 17 (74%) exhibited poor glycemic control. Systemic corticosteroid therapy was administered to 21 (84%) out of 25 patients as part of standard treatment for COVID-19 infection. The most commonly used steroid in our study was dexamethasone, administered intravenously at an average daily dose of 12.3 mg in 18(86%) patients. Methylprednisolone was prescribed for 4 (20%) patients at a dosage of 0.5-1 mg/kg/day orally. The duration of steroid therapy was less than 10 days for 6(29%) patients, 10-19 days for 11(52%) patients, and over 20 days for 4(19%) patients.

Conclusion: The immune dysregulation and hyperglycemic state resulting from COVID-19 infection, DM, and systemic steroid therapy contributed to the epidemic outbreak of mucormycosis cases. To address this alarming situation, glucocorticoids should be administered at the lowest possible dose for the shortest duration on alternate days, while ensuring proper glycemic control in COVID-19 patients undergoing systemic steroid therapy.

A comparative study of efficacy and safety of intravenous ondansetron and granisetron in management of intra-operative hypotension induced nausea and vomiting in patients undergoing caesarean section under spinal anaesthesia

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Introduction: One of the cutting-edge therapeutic strategies being used to combat the well-known hemodynamic side effects of spinal anaesthesia namely bradycardia and hypotension, is the use of 5HT₃ receptor antagonists. Two such widely used 5HT₃ receptor antagonists are the antiemetic medications ondansetron and granisetron. It is important for anaesthesiologists to choose correct drug at right dose and right time to prevent haemodynamic instability after spinal anaesthesia.

Aims/ objective: To compare the efficacy of granisetron and ondansetron in caesarean section patients in reducing the hemodynamic reaction to spinal anaesthesia.

Materials and Method: Pregnant women of group O and group G were given ondansetron 4 mg and granisetron 3 mg through intravenous route as constituent of their pre-anaesthetic medication before giving spinal anaesthesia. Presence of (defined as heart rate exceeding 20% below baseline) and hypotension

(defined as SBP less than 20% below baseline) was noted.⁷ To manage every case of bradycardia and hypotension, 0.5 mg of the drug atropine and 500 mcg of phenylephrine were given intravenously. For each patient, the total number of dosages utilised was recorded, and the total dose was computed.

Results: Both the drugs were effective in reducing intraoperative nausea and vomiting with no significant difference between two groups. There was appreciable decline in systolic blood pressure soon after spinal anaesthesia was given but it became stable after 10 minutes in both the groups. There was significantly lower incidence of hypotension in patients who were given granisetron before spinal anaesthesia as compared to patients who were given ondansetron ($p < 0.05$). There was also less incidence of bradycardia in granisetron group but the difference was not significant ($p > 0.05$).

Conclusion: Both drugs were effective in counteracting hypotension bradycardia but could not control early fall in blood pressure heart rate. High dose granisetron proved to be superior to low dose ondansetron in reducing incidence of hypotensive episodes caused by spinal anaesthesia.

Keywords: Granisetron, Ondansetron, Spinal Anaesthesia, Haemodynamic Instability, Hypotension, Bradycardia.

Comparative study of renal effect of Telmisartan and Ramipril in patient with diabetic Nephropathy

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Background: Diabetic nephropathy, also called diabetic kidney disease, is characterized by excessive albumin excretion, glomerular lesions, and declining GFR in individuals with diabetes. Type 2 Diabetes patients are at risk of hypertension and kidney protein leakage (microalbuminuria/macroalbuminuria). Renin-Angiotensin System (RAS) targeting medications like ACE inhibitors and ARBs are effective in preventing renal function decline, overt diabetic nephropathy, and End Stage Renal Disease. These renoprotective drugs play a crucial role in managing hypertension and safeguarding the kidneys from diabetes-related damage, thereby preventing life-threatening conditions associated with diabetic nephropathy.

Objectives: To compare study of renal effect of telmisartan and Ramipril in patient of hypertension with type 2 diabetic mellitus

Method: A total of 100 patients were recruited into two groups of 50 each. Group A: Telmisartan 40 mg once daily and Group B: Ramipril 2.5 mg once daily. The study was carried out in 20 weeks. All the parameters like blood urea, serum creatinine and 24hr urinary albumin were analysed at two visits of the study i.e. 0 week & after 20 weeks. The study was conducted at medicine department, Darbhanga Medical College Hospital, Laheriasarai.

Analysis of Data: Mean and standard deviation of parameters were calculated and analysed. Within group comparison of parameters were performed by using Paired t-test. Comparing parameters of both groups were performed by using unpaired t test.

Results & discussion: The study included 100 patients divided into Group A (Telmisartan, $n=50$) and Group B (Ramipril, $n=50$). Mean duration of diabetes mellitus in group A (Telmisartan) is 8.26 ± 3.95 and in group B (Ramipril) 7.76 ± 3.32 . P value was 0.5107. Baseline parameters at 0 weeks for group A were (Creatinine = 1.07 ± 0.21 , urea = 29.2 ± 7.64) and Baseline parameters at 0 weeks for group B (creatinine = 1.09 ± 0.26 , Urea = 29 ± 7.63). After 20 weeks in Group A Parameters were (Blood urea = 28.98 ± 7.25 , S.creatinine = 1.14 ± 0.32) and for Group B (Blood urea = 28.58 ± 7.37 , S.creatinine = 1.06 ± 0.19). After 20 weeks, both drugs showed similar effects on renal function and reducing urinary albumin excretion rate, with no significant differences observed ($P > 0.05$). Both Drugs significantly change Blood Urea and Serum Creatinine after 20 weeks study period but these effects were almost equal when comparing both groups. Group B had a higher incidence of cough (8 cases) compared to Group A (2 cases). Mean age and diabetes duration did not significantly differ between the groups ($P = 0.84$, $P > 0.05$).

Conclusions: Telmisartan and Ramipril have almost equal renal effect in terms of Urinary Albumin Excretion Rate, Blood Urea and Serum Creatinine. Telmisartan was better tolerated than Ramipril.

Keywords: Ramipril, Telmisartan, Hypertension, Type 2 diabetes mellitus, Renal function

Comparative study of efficacy and safety of empagliflozin vs linagliptin as add on therapy to insulin in patients of type 2 diabetes mellitus and chronic kidney disease in tertiary care centre of eastern India

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Introduction: It is essential to find a pharmacotherapy that is fast acting and effective in achieving proper glycaemic control and thus delaying the onset and progression of chronic kidney disease. The options of drugs for glycaemic control in patients with eGFR<60 ml/min is limited and insulin therapy has low compliance as limiting factor. Empagliflozin decreases the reabsorption of filtered glucose leading to high excretion of urinary glucose and decrease in fasting and postprandial blood glucose level with a reduced risk of hypoglycaemia.

Aims/ objective: To compare the efficacy and safety of empagliflozin and linagliptin as add on therapy to insulin in patients of T2DM and CKD. The primary objective was to assess and compare change in HbA1c from baseline to 1 year in empagliflozin and linagliptin group while secondary objectives were to assess changes in eGFR, albuminuria and incidence of hypoglycaemia and other adverse event after therapy.

Materials and Method: Prescriptions, laboratory reports and interview were taken from patients at baseline, 3 months, 6 months, and 12 months of follow-up to collect data regarding primary outcome measure that was HbA1c and secondary outcome measures that were Fasting blood sugar (FBS), eGFR, Urine Protein-Creatinine ratio (UPCR), Hypoglycaemia and other adverse events. Comparison between two group was done using unpaired t test and comparison with group at different follow-up was done using repeated measure ANOVA.

Results: Both the groups showed significant decline in HbA1c values from baseline to end of trial. At 6 months and 12 months of follow-up, glycaemic control as HbA1c values was significantly better in empagliflozin group ($p<0.05$). As per FBS values, glycaemic control was better achieved with addition of empagliflozin to previous insulin therapy. At 6 month and end of trial, addition of empagliflozin to previous insulin therapy had significantly better control on albuminuria as per mean UPCR values ($p<0.05$).

Conclusion: Addition to empagliflozin to background insulin therapy was found more effective than addition of linagliptin. Better glycaemic control can help in halting the progression of chronic kidney disease and albumin.

A study of low dose continuous versus low dose intermittent oral isotretinoin therapy in moderate to severe acne vulgaris

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Background: The use of oral isotretinoin is suggested for individuals with moderate to severe acne vulgaris who have not had satisfactory results with standard treatments. The recommended dosage is 1-2 mg/kg/day. However, the medication is known to have several side effects. Limited information is available regarding intermittent isotretinoin therapy. Our objective was to evaluate and compare two different isotretinoin treatment schedules in order to decrease the occurrence of side effects, enhance clinical effectiveness, and improve cost-effectiveness for patients.

Objectives: To determine the efficacy of the oral isotretinoin in low dose continuous and intermittent treatment of moderate to severe acne vulgaris. To determine the various side effects with oral isotretinoin in low dose continuous and intermittent treatment of moderate to severe acne vulgaris.

Materials & Methods: This prospective randomized open labeled comparative efficacy & safety study carried out at outpatient department in the Department of Dermatology in D.M.C.H, Darbhanga. Two treatment regimens (low dose continuous and low dose intermittent) were randomly assigned to patients with moderate to severe acne. Group A received 20mg oral isotretinoin daily for 4 months, while Group B received the same dose for 1 week out of every 4 weeks. Each group had 50 patients, with a total drug administration duration of 16 weeks for Group A and 4 weeks for Group B.

Results: There was a significant statistical difference in the GAGS score between Group A and Group B ($p<0.005$). The low dose continuous isotretinoin regimen showed significant clinical improvement compared to the low dose intermittent regimen. Side effects were more frequent in the low dose continuous group compared to the low dose intermittent group. Both groups experienced muco-cutaneous dryness as the main side effect. There was a statistically significant increase in LDL levels ($p<0.001$) with the low dose continuous isotretinoin regimen. Acne flaring was more common with the low dose intermittent isotretinoin regimen.

Conclusions: According to the study, the findings suggest that for patients with moderate to severe acne vulgaris, low

dose continuous treatment is the most appropriate in terms of clinical effectiveness.

key words: Acne vulgaris, oral isotretinoin

Efficacy of Meropenem- EDTA combination compared to Meropenem alone for Carbapenem-sensitive strains in patients under Intensive care

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Background: Meropenem, of the class Carbapenems, is a frequently used drug in ICU. EDTA (ethylenediaminetetraacetic acid) composition are also being developed and employed for reducing biofilms in intravenous and urinary catheter and therefore represent as antibiotic agent which can significantly help to reduce catheter related blood stream infections. EDTA has been utilised for control of microorganisms and biofilms often by being combined with other actives that include alcohol, antibiotic, silver iodine, surfactant and other antiseptic.

Aim/ Objective: The objectives of this study were to understand the outcomes of patient with various agents in the treatment of ESBL-producing bacteremia and to evaluate the efficacy of meropenem and EDTA combination against ESBLs.

Methodology:

Study design: This was an observational and prospective study conducted for a period of 3 months, from February 1, 2023 to April 30, 2023 on 90 patients in the ICU of Patna Medical College, Patna.

Inclusion- exclusion criteria: Medical and surgical patients aging from 18 to 80 years in the ICU were included in the study, and patients who were immune compromised, pregnant, HIV positive, and having bone marrow transplantation were excluded from the study.

Sample size: This study was conducted on 90 patients admitted in ICU fulfilling the inclusion and exclusion criteria.

During these 3 months, blood, urine, and sputum (including endotracheal and tracheostomy tube) samples were collected and sent to microbiology laboratory for routine and culture-sensitivity pattern.

Statistical analysis: Cultures showed 51 isolates in total, which were ESBL-producing bacteria. Further, E-strips were applied to check for in vitro sensitivity to meropenem and combination of meropenem and Ca-EDTA, of which, 14 were meropenem-resistant isolates and showed sensitivity to meropenem-EDTA.

Result: Efficacy of Meropenem-EDTA was more than that of Meropenem in sensitive isolates. The MIC value of combination for meropenem-EDTA was reported to be 50% less than that of meropenem in sensitive isolates and intermediate sensitive isolates, $P < 0.005$.

Conclusion: Meropenem in unification with EDTA can exhibit more potent antimicrobial activity against ESBL producing pathogens than just Meropenem or EDTA alone.

Keywords: Antimicrobial resistance, Combination therapy, Gram-negative pathogens.

Evaluation of suspected adverse drug reactions of psychotropic drugs in a tertiary care hospital of east india

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Introduction: Mentally ill patients need lifelong treatment with psychotropic drugs that predetermine the ADR network. The common adverse effects associated with psychotropic drugs are weight gain, somnolence, tremors, and tardive dyskinesia. These adverse effects tend to deteriorate the mental and physical well-being of the patient and thus lead to patient's non-adherence to therapy. Setting standards and assessing the safety of care through performance review should become part of everyday clinical practice.

Aims & objectives: Keeping this in mind, present study was conducted to highlight pattern of Adverse Drug Reactions with use of oral anti-diabetic drugs. All suspected Adverse Drug Reaction Reporting form having any psychotropic drug as suspected cause of ADR was analyzed. Patient on psychotropic drug were screened for suspected ADRs and were reported to AMC (Adverse drug reaction

Monitoring Centre), Department of Pharmacology. The reported ADRs on the notification forms, after being confirmed by the physician-in-charge, were assessed for causality using WHO-UMC Causality Categories, and preventability using Modified-Schumock and Thornton scale. Descriptive analysis was done for comparative analysis of data using numbered analysis.

Results: Majority of ADRs were found in female (56.6%). Majority of ADRs were observed in 31-40 years of age group (40.41%). Most commonly reported ADR was weight gain (17.11%) followed by sedation (12.39%), Diarrhoea (12.39%) and insomnia (11.80%). Most cases of weight gain were reported by patients receiving atypical antipsychotics (42 out of 58). Causality assessment according to WHO-UMC criteria showed 59% ADRs had probable causality while 40.12% had possible causality and only 0.88% had certain causality.

Conclusions: The study results strongly suggest the need for healthcare professionals to focus more on assessment and reporting of suspected ADRs for generating more evidences for clinician to plan accordingly to reduce the cases of preventable ADRs. There is a need for evidence-based psychiatry which integrates with day-to-day clinical care. There is a need to integrate newer trends which are evidence based and have the potential to improve outcome and overall treatment results.

Keywords: Adverse Drug Reaction, Psychotropic Drugs, Mental illness, Pharmacovigilance

Retrospective study of ADR due to cancer chemotherapy in a rural tertiary care hospital

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Introduction – Use of anticancer medications is associated with a variety of adverse drug reactions. But by changing dosages or treatment plans as soon as an ADR is identified, adverse effects may be minimised. Hence the present study is done to retrospectively to find out the adverse drug reactions due to cancer chemotherapy in a tertiary care hospital.

Material & methods- A retrospective, study was conducted in a tertiary care centre on the patients who developed ADRs due to anticancer drugs during the study period of six months. These ADRs were assessed on the basis of different criteria. The data was analyzed using Statistical Package for the Social Sciences (SPSS) version 23.0 and frequencies and percentages were determined for each variable.

Results – Total 65% females developed ADRs and age group of 51-60 years (32%) were affected the most. Bronchogenic carcinoma (22%) was found to be the most common cancer. Most common ADRs observed were alopecia (16%) followed by anorexia and anaemia. Carboplatin (25%) followed by Cisplatin, Paclitaxel, Docetaxel were the most common drugs causing different ADRs.

Conclusion – Anticancer medication use is linked to a number of adverse side effects. Early ADR discovery, however, can make it possible to reduce side effects by altering dosages or treatment regimens.

Keywords – drug reaction, cancer, chemotherapy, pharmacovigilance, world health organization

Vitamin B12 status in long-term metformin monotherapy for type 2 diabetes

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Objective: This study aimed to assess the vitamin B12 levels in individuals with type 2 diabetes (T2DM) who were undergoing long-term treatment with metformin as monotherapy for more than six months.

Methods: A cross-sectional observational study was conducted at SKMCH, Muzaffarpur, Bihar, in collaboration with the Departments of Pharmacology, Medicine, and Biochemistry. The study included 50 consecutive cases of T2DM patients on metformin monotherapy from the Department of Medicine, along with 50 age and sex-matched healthy controls. The duration and dosage history of metformin therapy were determined through medical record review and confirmed verbally by the patients. Additionally, the use of other anti-diabetic agents during the period from December 2022 to June 2023 was recorded.

Results: The mean age of the metformin group was 64.320 ± 11.95 , while the control group had a mean age of 63.840. Among the patients in the metformin group, 22 (44%) had been diagnosed with diabetes for over 10 years, 18 (36%) for 6-10 years, and only 10 (20%) for 1-5 years. Regarding metformin usage, 19 (38%) patients had been taking it for 1-5 years, 13 (26%) for over 10 years, and 18 (36%) for 6-10 years. In the metformin group, 15 (30%) patients had normal vitamin B12 levels (>220), 14 (28%) had possible

deficiency (151-220), and 21 (42%) had deficient levels (≤ 150). Among the healthy control group, 33 (66%) patients had normal vitamin B12 levels, 9 (18%) were possibly deficient, and only 8 (16%) were deficient out of the total 50 individuals.

Conclusion: This study demonstrates that metformin monotherapy increases the risk of low vitamin B12 levels in patients with type 2 diabetes. Currently, there are no guidelines recommending regular monitoring of vitamin B12 levels or preventive measures to mitigate the drop in B12 levels caused by metformin usage.

Key words: vitamin b12, metformin, diabetes mellitus

Metronidazole induced neurotoxicity: a case report

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Introduction: Metronidazole is a well-known antimicrobial agent, used for the treatment of anaerobic bacterial and protozoal infections. It is generally well tolerated with common side effects like nausea, dizziness, headache and metallic taste in the mouth. But prolonged use of metronidazole can cause neurotoxicity like ataxic gait, dysarthria, seizures and encephalopathy.

Case Report: Here, we are reporting a case of a 60 years old male patient who was a chronic alcoholic with liver abscess and he developed acute ataxia and dysarthria after four weeks use of metronidazole.

Discussion: The causality of metronidazole in this case was "probable" with score 7 as per Naranjo scale. The patient was managed by discontinuing the metronidazole and there was considerable improvement in his gait and speech after that. The case was recorded properly in adverse drug reaction reporting form and was sent to nearby adverse drug reaction (ADR) monitoring centre.

Conclusion: Metronidazole induced neurotoxicity or encephalopathy should be considered in any patient who presents with seizure, cerebellar features, altered sensorium, and is receiving prolonged therapy of metronidazole. Metronidazole should be immediately discontinued in these conditions. Increased awareness among physicians may enable early recognition of potentially reversible neurotoxicity and unwarranted prescription of such medicines.

Keywords: Metronidazole, Neurotoxicity, Adverse drug reaction

Impending Corneal Perforation due to Inappropriate Self-Medication in a Patient with Recurrent Herpes Simplex Keratitis – A Case Report

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Introduction: WHO defines Self-medication as 'selection and use of medicines by individuals to treat self-recognized illnesses or symptoms' and promotes inappropriate use of medicines. The global prevalence of self-medication with ophthalmic drugs ranges from 23.3% to 73.6%. Of the various drugs, corticosteroids are one of the most commonly used. Even though these drugs are highly effective, given the multitude of adverse effects they can cause, inappropriate use of these drugs should be avoided.

Case Presentation: Here, we present a case of a 48-year-old male patient with recurrent Herpetic Keratitis with Epithelial Thinning and Impending Perforation due to self-medication with Topical Corticosteroid who could have lost his sight without timely diagnosis and management.

Conclusion: Our report highlights the issue of self-medication and over-the-counter availability of such drugs as topical corticosteroids, which in this case could have led to loss of sight in this patient. Improving the quality and availability of eye-related healthcare services and continuous awareness raising programs will therefore play a very important role in order to minimize self-medication in ophthalmology.

Vildagliptin-Induced Arthralgias: A Case Report

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Introduction: Since 2005, additional novel add-on therapies have been introduced, including glucose-like peptide 1 (GLP-1) receptor agonists, sodium–glucose transporter 2 (SGLT2) inhibitors, and DPP-4 inhibitors. Agents are selected based on many factors, including cardiovascular comorbidities, hypoglycemia risk, and impact on weight, risk of side effects, cost, and patient preference. It is generally believed that incretin-based therapies are effective in patients possessing certain levels of preserved β -cell function. This case highlights a rare adverse effect seen with the use of the DPP-4 inhibitor Vildagliptin.

Case Presentation: A 52-year-old female patient diagnosed with type 2 diabetes mellitus since 5 years was prescribed with metformin 1000 mg sustained release tablet once daily in morning and vildagliptin 100 mg once daily in evening. After 3 weeks of pharmacotherapy, she began experiencing bad and worsening joint pain, light-headedness, and constipation. She reported that it caused her to miss work and that she was just not feeling like herself. She discontinued the vildagliptin on her own because of this adverse effect. After 1 week, she visited OPD of endocrinology and vildagliptin was stopped and changed to empagliflozin 25 mg. She did not report any further joint pain since discontinuing the vildagliptin. She said she was tolerating her medications well and only reported increased urination and a little nausea.

Conclusion: Our case report suggests further long-term studies to evaluate the risk of arthralgia with DPP-4 inhibitors. Pharmacogenetic association should also be investigated. DPP-4 inhibitors should be used cautiously in patients with joint disorders.

Keywords: Vildagliptin, Arthralgia, Type 2 Diabetes Mellitus.

Amiodarone-Induced Neuropathy: A Case Report

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Introduction: Amiodarone hydrochloride is a class III anti-arrhythmic drug usually used for atrial fibrillation. It has several clinically significant toxic effects, comprising visual disturbances, thyroid dysfunction, pneumonitis, hepatotoxicity, and neurological complications. Long-term administration of amiodarone may have various neurological complications and systemic involvement.

Case Presentation: Herein, we report a 46-year-old male patient who was admitted as a result of paresthesia and progressive four-limb weakness started six months before. Spiral chest CT scan showed bilateral hyperdense consolidations predominately seen in peripheral and lower lobes. We checked the serum level of amiodarone that was 3.1 mg/L (therapeutic range: 1.5 and 2.5 μ g/mL). According to the characteristic pulmonary findings in lung CT scan, demyelinating polyneuropathy, and lack of response to treatment, with the suspicion of amiodarone toxicity, CT-guided percutaneous core needle biopsy was performed. The pathological assessment revealed chronic interstitial inflammation and fibrosis, and exudation of macrophages with finely cytoplasmic vacuolization associated with hyperplasia of type II pneumocytes in alveoli with necrosis. These findings are consistent with amiodarone-induced pulmonary toxicity.

Conclusion: Chronic use of amiodarone may present as a CIDP-like presentation, which may be overlooked if clinical suspicion is not high upon presentation.

Keywords: Amiodarone neurotoxicity, chronic inflammatory demyelinating poly-radicleuropathy, chronic inflammatory demyelinating polyneuropathy

Impact of Beta Vulgaris Root Extract on the Hyperglycemic Mice (*Mus musculus*)

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Background: Insulin resistance or inadequate insulin production causes diabetes mellitus, a chronic metabolic condition. Its rising frequency and complications make it a global health issue. Diabetes management includes exploring naturally occurring medicinal molecules. Beta vulgaris, or beetroot, may

treat diabetes and other diseases. Beetroot's anti-diabetic effects in albino mice haven't been fully studied. Beets contain nitrates, antioxidants, and bioactive substances. These components can lower diabetes by altering glucose levels and insulin sensitivity.

Aim: The aim of the investigation was to evaluate the impact of *Beta vulgaris* root extract on the altered blood Glucose profile of hyperglycemic mice.

Method: Male albino mice were selected for the study. Hyperglycemia was induced using an intraperitoneal injection of alloxan of 140mg/dl to albino mice weighing 25 ± 5 g. The mice were monitored for fasting blood glucose levels, and only those with elevated glucose levels of 150mg/dl and above were considered as hyperglycemic. The hyperglycemic mice were randomly divided into groups: a control group, and experimental groups receiving doses of *Beta vulgaris* root extract. Blood samples were collected from the mice after an overnight fast, and glucose concentrations were measured.

Result: During the experiment, mice with hyperglycemia were provided with a diet consisting of standard animal food supplemented with *B. vulgaris* extract at a concentration of 140 mg/dl/BW for a duration of eight days. The administration of root extract of *B. vulgaris* to experimental mice resulted in a significant decrease in glucose levels, reducing them from an initial average of 184 ± 22 (mg/dL) to a final average of 90.5 ± 17 (mg/dL). A positive correlation exists between control mice and treated mice.

Conclusion: The findings of this study suggest that the presence of high amount of antioxidant of *B. vulgaris* root extract resulted in enhanced glucose tolerance in cellular models.

Keyword-*Beta Vulgaris*, Alloxan, Glucose, Hyperglycemia

Effect of fat rich diet on serum and liver cholesterol in *Mus musculus*

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Background: In this modern era people are habituated of having Junk Food which contains too much Fat. Fat is deposited in the adipose tissue as triglyceride. One fat cell can store 1.2 μ g of triglyceride and once these cells are full, they increase their number to store excess energy. In this way, obesity is maintained by increasing the number of adipocytes. Fat deposition in liver causes insulin resistance, Insulin is the key hormone for the effective metabolism of fats and availability to the cell. The consumption of Fat Rich Diet leads to metabolic disorder such as obesity and metabolic syndrome and high blood pressure. High blood sugar gives the additional load to the individual organs that lead to abnormal cholesterol level, increases the risk of cardiovascular diseases and hormonal imbalances etc.

Objectives: The aim of this study was to investigate the Effect of Fat Rich Diet on , serum cholesterol and liver cholesterol in *Mus musculus*.

Methods: Fat Rich diet was prepared by Edible Coconut oil and Vanaspati ghee in the ratio 2:3 and It was administrated at the dose of 10ml/kg body weight with normal Chow diet for 30 days. Blood sample and liver collected after 24 hours of last administration to estimate serum cholesterol and liver cholesterol.

Results: Serum Cholesterol level in control group was 103 ± 4.63 mg/ml and in Fat Rich diet group was 303.65 ± 40.09 mg/ml. Liver Cholesterol level in control group was 0.7 ± 0.097 mg/100mg of tissue and in Fat Rich Diet group was 1.99 ± 0.113 mg/100mg of tissue. Both the result were significant at $P < 0.01$ value.

Conclusion: It is evident from the study that Coconut oil and Vanaspati Ghee Contain high proportion of saturated fat and Trans Fat which increases the level of LDL Cholesterol.

Keywords: Fat Rich Diet, Serum Cholesterol, Liver Cholesterol, LDL Cholesterol.

Alpha-Lipoic acid alleviates Imidacloprid-induced neuro-behavioral deficits and Alzheimer's disease like pathology in rats via modulating Nrf2/HO-1/Smo/Shh pathway

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Abstract: Imidacloprid (IMI) is a neurotoxic pesticide commonly used in agriculture. However, it has also been identified as a potential food contaminant. The present study was conducted to assess the neurotoxic effects of IMI exposure and the potential protective role of alpha-lipoic acid (ALA) in rats. ALA, a naturally produced and dietary antioxidant, has been studied for its potential benefits in managing oxidative stress, and promoting healthy nerve function. In this study, twenty eight rats were divided evenly into four groups and

administered oral treatments of vehicle (corn oil), IMI, IMI + ALA, and ALA, respectively for 40 days. The results of the study indicated that rats exposed to IMI exhibited significant neurobehavioral impairments as analyzed by various behavioral tests, reduced expression of adult neurogenesis markers Smo/Shh and antioxidant proteins HO-1/Nrf2, and increased levels of A β 1-42 as analyzed by western blot and immunohistochemistry and elevated expression of IL-6 and TNF- α in their hippocampal tissues. Furthermore, histopathological analysis of the brain tissues, specifically cortex and hippocampus, from the IMI-treated group revealed varying degrees of neuronal degeneration. In contrast, rats co-administered ALA alongside IMI showed noticeable improvements in all the assessed toxicological parameters. In conclusion, the simultaneous administration of ALA with IMI was found to provide protection against IMI-induced neurotoxicity, potentially through the activation of the Nrf2/HO-1/Smo/Shh pathway and lowering A β 1-42 level. This is for the first time we have shown, imidacloprid as a possible causative agent of Alzheimer's disease like pathology which can be mitigated by the administration of ALA.

Keywords: Imidacloprid, Neurotoxicity, Alpha-lipoic acid, Nrf-2, HO-1, A β 1-42

Promoting hippocampal neurogenesis and alleviating neuronal inflammation in diabetic brain

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Uncontrolled chronic hyperglycaemia impairs life expectancy and increases the risk of disability and death. Diabetes causes major health issues that impact several organs in which brain is one of the major organs affected by the higher level of glucose in blood. The aims of this study are to explore the effect of our novel compound NHP001 (synthesized at NIPER Hajipur) in diabetes associated CNS complications includes learning, mood and memory, depression and neurodegeneration. Our findings determine that high fat diet affecting the learning and memory via decreasing the population of newly born and mature neurons in hippocampus, promoting neuronal inflammation and it also alters the healthy expression of genes and proteins in brains. Additionally, we determined that NHP001 treatment for two weeks (50 mg/kg/oral) significantly improved the hippocampus, prefrontal and entorhinal cortex-dependent object and perirhinal cortex- dependent reactivity in diabetic mice. Interestingly, transcriptomics and proteomics data reveals that NHP001 have significant positive effect at gene levels by regulating the expression of genes and proteins which was reconfirmed by western blotting analysis. Furthermore, quantification of newly born neuron (NeuN+ neurons), number of newly born cells (Ki67+ cells) in the hippocampus revealed that our drug enhances neurogenesis and cell proliferation in diabetic mice ($p < 0.05$ compared to vehicle treated diabetic group). Moreover, NHP001 also attenuates cellular and neurovascular inflammation, as evidenced by reduced expression of HMGB1 & CD200 in medial frontal cortex. Further, our findings indicates that NHP001 also regulates the level of dopamine and GABA in diabetic brain. Therefore, NHP001 treatment enhances learning ability, memory retention, reverses neuronal inflammation and promotes neurogenesis and cell proliferation in neurogenic regions, promoting the population of mature neurons as well as regulating the expression of genes and proteins in brain, hence providing neurocognitive benefit in diabetic mice.

The toxic impact of different concentrations of lambda-cyhalothrin on blood glucose and blood serum cholesterol level of *Anabas testudineus*

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Background: We now live in a technological age when advancements in technology have made life simpler. Pesticides became the crop's knightly armor during the Green Revolution in the 1960s, particularly in India. Numerous pesticides, including insecticides, herbicides, fungicides, and others, are used heavily in agriculture, which has led to a number of health issues as a result of their indiscriminate usage. Nearly all environmental systems, but notably aquatic ecosystems, are impacted by these substances. Fish are one of the aquatic life forms that are most negatively impacted by pesticide residues that enter the water through surface runoff. Lambda-cyhalothrin is one of a new class of synthetic insecticides called pyrethroids. They frequently outperform organophosphates and organochlorines because of their propensity for

hyper-ingestion and contact toxicity to a variety of insect pests, as well as because of their greater potencies.

Objective: The purpose of this study was to determine the impact of lambda-cyhalothrin exposure on blood serum cholesterol and glucose levels in *Anabas testudineus*.

Methods: Commercial-grade pesticide lambda-cyhalothrin was purchased from the local market and the dose was prepared as 0.01mg/ml, 0.12mg/ml, and 0.014mg/ml.

Results: The serum cholesterol level in the control group was 232.72±12.05 mg/ml and the blood glucose level of the control group was 47±4.25mg/dl. After exposure to lambda-cyhalothrin in concentration 0.014mg/ml, the serum cholesterol level was 339.99±29.40mg/ml and the blood glucose level was 158.2±21.94mg/dl. Both the result were significant at p<0.05 value.

Conclusion: According to the study pesticide lambda-cyhalothrin showed harmful effects which increase blood glucose levels and blood serum cholesterol levels, and negative effects on the pancreas and liver.

Keywords: Pesticides, Lambda-cyhalothrin, Cholesterol, Blood glucose.

Fisetin potentiates 5-fluorouracil anticancer response via targeting the TSC-2/AKT/PI3k/IL-6 pathways in-vitro human colon cancer Caco-2 cell lines and DMH induced colon cancer wistar rats experimental models.

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Background: 5-fluorouracil (5-FU) is the most widely used chemotherapeutic drug in treating colorectal cancer. However, its high dose can cause toxicity to normal tissues and tumour resistance which is the main hurdle in cancer treatment. Signalling and inflammatory alterations especially AKT/PI3k/TSC-2/IL-6 promotes the proliferation of colon cancer cells. The present study was conducted to examine whether Fisetin (F) combined with 5-FU improves the anti-proliferative effect of 5-FU on Caco-2 cell lines and decreases the nodules size and progression of colon cancer through detection of the AKT/PI3k/TSC-2/IL-6 signalling pathway in animal model.

Methods: Cell viability in Caco-2 cell lines following Fisetin and 5-FU treatment alone and in combination for 48 hours was determined using the MTT assay. *In-Vivo* and *In-Vitro* anticancer activity evaluated through immunohistological, histological, immunoassays and biochemical parameters in colon cancer condition.

Results: Our study revealed that the potent antitumor effect of Fisetin and 5-FU by induction of apoptosis, inhibition of inflammation, cytokines signalling cascades, oxidative stress, proliferation, invasion, migration, and improvement of the therapeutic efficacy of 5-FU with fisetin against Caco-2 cells and DMH induced animal experimental model. It also increased inhibition of tumour progression and decreases the size of crypt foci via Akt/PI3k/TSC-2 and IL-6 expression.

Conclusions: Fisetin as a potential chemotherapeutic agent combined with 5-FU can enhance and potentiate the anticancer response against colon cancer.

Keywords: Colon cancer; Fisetin; 5-fluorouracil; IL-6/AKT/PI3k/TSC-2.

Effect of Momordica charantia seed on blood glucose levels in normal and alloxan-diabetic mice (Mus musculus)

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Background: Momordica charantia, sometimes known as bitter melon, is a tropical fruit with long-recognized potential therapeutic effects on a variety of metabolic illnesses, including diabetes.

Aim: The purpose of this study was to examine the impact of M.charantia seed on blood glucose levels in normal and alloxan-diabetic mice.

Method: Male Swiss albino mice were placed into four groups for this experiment: normal control, normal treated, diabetic control, and diabetic treatment. Alloxan administration caused diabetes in the mice. The treated groups received an oral dose of 100 mg/kg body weight of M.charantia seed extract for 21 consecutive days, whereas the control groups received an equivalent volume of vehicle. Blood glucose levels were measured at regular intervals throughout the study using o-toluidine method and glucometer. Statistical analysis was done by SPSS 16.0.

Result: This study indicated that treatment with M.charantia seed extract effectively decreased blood

glucose levels in both normal and alloxan-diabetic mice relative to their respective control groups. There is significant decrease of glucose of diabetic control from 224.90 ± 9.49 to 127.50 ± 18.68 .

Conclusion: These results imply that the seed extract of *M. charantia* has antihyperglycemic properties and could be a possible treatment for diabetes.

Keywords: *Momordica charantia*, alloxan, glucose, diabetic, Swiss albino mice

A study on concept of P- drug selection among general practitioners in rural area of Patna district

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Background: The objective of the study was to assess the awareness of P- drug selection among rural general practitioner's (GP) for common medical conditions.

Methods: Eighty general practitioners in Patna district, Bihar were provided the proformas for selection of P- drugs for mild to moderate hypertension, diabetes mellitus, upper respiratory tract infections and acid peptic disease based on safety, affordability, need, and efficacy (SANE criteria).

Results: Seventy two GP's responded by completing the proformas. Thirty five of them were aware of the concept of P- drug selection. In hypertension, Diuretics followed by Angiotensin Converting Enzyme (ACE) inhibitors were most commonly preferred. In diabetes, Metformin followed by sulfonylureas were preferred as oral hypoglycemic agents. Amox-clav, cefexime, azithromycin and Ciprofloxacin were the commonly used oral antibiotics; but Inj. Ceftriaxone, Inj.cefotaxime and Inj. ceftazidime were prescribed among parenteral formulation for upper respiratory tract infections. Omeprazole followed by Rabeprazole per oral were preferred for acid peptic disease. Affordability followed by efficacy was the deciding criteria for P- drug selection.

Conclusions: There is lack of awareness of P- drug selection among many GP's. Therefore, there is necessity to create awareness about P- drug selection through continued medical education for rational use of drugs which ultimately improve patient compliance and decrease economic burden.

Keywords: General practitioner's, P- drug, Proforma, Rational use of drugs, SANE criteria

Efficacy and Safety of Linagliptin and Insulin in Patients of Type 2 Diabetes Mellitus with Grade 3-5 Chronic Kidney Disease in a Tertiary Care Hospital

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Introduction: Insulin therapy is preferred as safest for glycaemic control in patients with elevated serum urea/creatinine level. Management of diabetes in grade 3-5 Chronic Kidney Disease (CKD) with oral hypoglycaemic is very challenging because most of them cause renal impairment and thus dose adjustment is needed in renal disease. Linagliptin, a DPP-4 (dipeptidyl peptidase-4) inhibitor has only 5% renal excretion; hence its dose adjustment is not needed in patients with CKD.

Aim: To compare the efficacy and safety of linagliptin with insulin in patients of Type 2 Diabetes Mellitus (T2DM) with CKD.

Materials and Methods: The present study was a longitudinal study, in which a total of 101 patients of grade 3-5 CKD with T2DM were divided into two groups, insulin group (n=54) and linagliptin group (n=47), based on their drug therapy. All the cases were tested for HbA1c (Glycated Haemoglobin), Random Blood Sugar (RBS), Creatinine clearance, Urine Protein-Creatinine Ratio (UPCR) and different adverse drug events at their first visit (baseline) and then during follow-up at 1st, 3rd, 6th and 12th month. Statistical analysis was done through GraphPad Instat by unpaired t-test for group comparison and Analysis of Variance (ANOVA) for intragroup comparison.

Results: At the end of study, mean difference of RBS, Creatinine clearance and UPCR in both the groups were not significant. But mean HbA1c level was less in linagliptin group (6.62 ± 0.10) as compared to insulin group (6.82 ± 0.23) on long term therapy and the difference was statistically significant. Hypoglycaemia (33 vs 24), urinary tract infection (6 vs 5) and respiratory tract infection (5 vs 4) were more frequent in insulin group versus linagliptin group.

Conclusion: Linagliptin for glycaemic control provides clinically meaningful improvements in long term glycaemic control without unacceptable side effects in CKD like vulnerable group of patients.

Keywords: Creatinine clearance, Glycaemic control, Glycated haemoglobin, Hypoglycaemia, Urinary tract infection, Urine protein-creatinine ratio

Comparative study of Efficacy and Safety of Alfuzosin and Tamsulosin in Benign Prostatic Hyperplasia in Tertiary Care Hospital in Patna (Bihar)

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Background: Benign Prostatic Hyperplasia is one of the most common conditions affecting elderly males. The prevalence of BPH increases with increase in age. With increase in life expectancy, number of aged men are increasing. This led to substantial increase in cases of BPH in the society. The BPH may cause symptoms of Lower Urinary Tract Symptoms (LUTS), which affect the quality of life of elderly males. The long-term untreated disease can lead to many complications like retention of urine, bladder stone and urosepsis. The Alpha receptor blockers are 1st line medical treatment of uncomplicated BPH. Alfuzosin and Tamsulosin are commonly used alpha receptor blockers in BPH. Both differs in their receptor selectivity and pharmacokinetic parameters.

This study compares the reduction in International Prostate Symptom Score (IPSS), rate of urine flow (UFM), and postvoid residual urine (PVRU) with Alfuzosin (10mg) and Tamsulosin (0.4mg).

Methods: Prospective, randomized, open label study was conducted in 60 patients of BPH. One group received Tab Alfuzosin (10mg) and other Tamsulosin (0.4mg). IPSS, PVRU and UFM were measured at baseline and follow-up visits at 1 month and 3 months. Results were compared and analysed using Student T test. P value < 0.05 was considered significant.

Results: Significant reduction in all parameters were seen in both groups from baseline. The difference between both groups were statistically not significant as p value was >0.05. The Alfuzosin group reported more side effects which were self-limiting. There was no drop out in study participants.

Conclusion: Both drugs are equally effective in treatment of BPH, though Alfuzosin has slightly more side effect which are self-limiting and mild.

Keywords: BPH, Benign Prostatic Hyperplasia, Alfuzosin, Tamsulosin

A rare case of methotrexate toxicity and myelosuppression in case of elderly female

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Introduction: Although the occurrence of high dose methotrexate toxicity is common in clinical setting but acute toxicity with low dose methotrexate related myelosuppression is rare side effect of methotrexate which responds to folic acid supplementation.

Case description: A 70 years old lady presented with chief complains of: high grade fever for 5 days and unable to eat/drink for same duration along with skin rash for 2 days and bilateral symmetrical small and large joint inflammatory poly arthritis. In general physical examination oral mucosal ulceration and thrush along with multiple patchiae, echymosis were present. Pallor and bilateral pedal pitting edema were present. Pulse was 96 beats per minute, BP- 110/60mm/Hg and spo2 was 96% on room air, Chest and CVS examination were normal. Abdomen was soft and nontender. CBC shows Hb 7.2gm/dl, TLC 570/cumm, N-7%L-58%, E-38% plat count-11k with normal INR. BUN was 36.6mg/dl, s. creatinine was 1.1 mg/dl, s. albumin-2.5, s alk phos-148, sr Na-138, sr K-3.0TSH-1.93, Retic count-0.31, ferritin-898.79 and sr methotrexate level of <0.30 (normal->0.5 after 48 hours of intake).

The patient was managed conservatively with empirical broad spectrum antibiotic coverage along with antifungal, along with leucovorin rescue. The cbc picture further deteriorated with plt count of 10k and hb drop to 6.6gm/dl along with multiple new echymotic patches. She was given 1 unit prbc and 4 units of platelets in subsequent days. She was given a single dose of Filgrastim sc. In view of febrile severe

neutropenia.

Discussion: Low dose MTX in RA rarely produces toxicity, and most of such cases occur due to failure to adhere to the recommended guidelines. The risk of toxicity is greater if additional methotrexate is administered sooner than the usual scheduled weekly dose. Self-administration of the higher, consecutive dose which acted as precipitating factor. The probable cause of myelosuppression the patient could be advanced age, concomitant use of NSAID, and in advertent use of MTX dose.

An assessment of prescribing pattern and rationality of fixed dose combinations used in patients of hypertension at a tertiary care hospital

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Background: Hypertension is a prevalent health concern, often managed using fixed dose combinations (FDCs) of antihypertensive drugs. Presently many FDCs are present in market without being assessed for safety efficacy and rationality, therefore evaluating the rationality of FDC usage is crucial for ensuring effective treatment and patient safety.

Objective: This study aims to assess the rational use of fixed dose combinations in hypertension management at a tertiary care hospital.

Methods: A prospective observational study was conducted between March 2023 to July 2023. In this study a total of 93 outpatients were evaluated for prescribing pattern and rationality of Antihypertensive FDCs. Rationality was assessed using seven-point criteria. Data on patient demographics, prescribed FDCs, safety, efficacy, dosing convenience, and cost-effectiveness were collected and analysed.

Results: In this study 10 different Fixed dose combination antihypertensive agents were observed in the prescription of patients. Out of the total 93 patients, 56% received dual combination therapy, among this the most commonly used dual combination therapy was Telmisartan + Hydrochlorothiazide (17%), followed by Telmisartan + Chlorthalidone (14%). Among the 10 different FDCs analysed it was seen that 30% of them were irrational and 70% of them were rational.

Conclusion: The study highlighted the utilization pattern of fixed dose combinations in hypertension management in a tertiary care hospital. Dual combination therapies, with Telmisartan as a common component, were frequently prescribed. Although FDCs were rational in most cases but irrational FDCs were also prescribed. The findings emphasized the importance of adherence to evidence-based guidelines to ensure rational and effective hypertension management.

Comparison of the Effectiveness and Safety of Bilastine 20 mg versus Fexofenadine 180 mg for treatment of Perennial Allergic Rhinitis; Randomized Controlled Study

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Introduction: Antihistamines has always remained the mainstay drug treatment for allergic rhinitis. Bilastine is a novel, non-sedative antihistamine with a super-selective H1 receptor antagonist property. Both Bilastine and fexofenadine are second generation antihistamine drugs commonly used to manage allergic rhinitis and chronic urticaria. Autologous Serum Skin Test (ASST) is a practical test for basophil histamine release in chronic autoimmune urticaria. These tests have been also studied in Allergic Rhinitis Patients.

Methodology: 114 patients diagnosed with perennial allergic rhinitis were recruited and divided into groups of 57 each. One group was started on Bilastine 20 mg OD and fexofenadine 180 mg OD. TNSS was calculated based on symptom severity at presentation and 2 weeks of antihistamine therapy. ASST was hypothesized to be the test for allergic rhinitis at the time of presentation and at 2 weeks. Intergroup and intragroup assessment of TNSS, ASST and its variables were done using unpaired and paired T-test.

Results: Patients showed reduction in symptoms of AR with both drugs. TNSS and sneezing, rhinorrhoea showed significant improvement in fexofenadine group as compared to Bilastine. ASST showed significant reduction in both groups. Adverse drug reactions were mild in both the groups.

Conclusion: Both Bilastine and fexofenadine were found to be effective in reducing symptoms in patients. Bilastine was more effective than fexofenadine in overall symptom control and specifically in

controlling sneezing and rhinorrhoea after 2 weeks of therapy.

Key words: Bilastine, fexofenadiene, ASST, TNSS

Evaluation of anxiolytic effect of combination of Tramadol with Gabapentin and Pregabalin in wistar rats

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Introduction: Anxiety is a widespread disorder that approximately 18% of the population experience at some stage in their lives. Pain is a common stimulus that induces anxiety in both Animals and human beings. We have undertaken this study to evaluate the anxiolytic activity of combination of Gabapentin with Tramadol, Pregabalin with Tramadol compared to fluoxetine, in Elevated-plus maze & Light-dark arena models of anxiety in Wistar rats. If the combination drugs show a good anti-anxiety effect, this can be used for the treatment of chronic pain, pain induced anxiety, post-operative and procedure related pain and anxiety.

Materials and methods: 24 Male or female wistar rats from Central Animal House MRMC Kalaburagi. Fluoxetine 10mg/kg, Gabapentin 30mg/kg, Tramadol 30mg/kg, Pregabalin 30mg/kg were used. Elevated plus maze and Dark and light arena models were used to study the effect of drugs in reducing the pain and anxiety.

Results:

The study showed reduction in anxiety after drug administration, in fluoxetine and G&T group, the percentage of **entry into the light chamber or open arm** at-least once or more during the time period of 5 minutes (300 sec) has increased > 75% when compared to those rats after exposure to hot plate. Whereas in P&T group, it was observed that 25% increase in entry of rats into open arm at-least once during the time period of 5 minutes (300 sec) and 25% decrease in entry of rats into light chamber as compared to those rats after exposure to hot plate. Results from the present study show that exposure to hot plate induces pain, creates anxiety, reduces locomotor and explorative activity among the rats when exposed to hot plate compared to baseline reading.

Conclusion: Our study has demonstrated that tramadol, pregabalin and gabapentin have got analgesic as well as anti-anxiety effects in rats when given in combination. All these experimental data, together with previous experimental studies and the results reported in this work, suggest combination of these drugs could be more effective in treating anxiety related disorders like chronic pain, pain induced anxiety, post-operative and procedure related pain and anxiety with minimal side effects. Further dose ranging studies and models might be necessary to better understand the effects of these drugs in combination.

Keywords: Anxiety, Gabapentin, Tramadol, Pregabalin, fluoxetine.

Comparative efficacy-safety of conventional versus newer antiepileptics in epileptic patients in a tertiary care hospital, India

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Background: As initial monotherapy, individuals with epilepsy are treated with both conventional and newer antiepileptic drugs (AEDs). The differences in their relative efficacy and safety as a group, however, have not been thoroughly studied.

Objective: To evaluate and compare the efficacy and safety of conventional and newer anti-epileptic drugs in epileptic patients.

Methods: A prospective comparative study was done in 126 epileptic patients. Patients divided into two groups Group A and B of 63 each received conventional and newer antiepileptic drugs respectively. Patients were allocated the AED based on type of epilepsy, patient characteristics and drug characteristics by the treating physician. Patients maintained a seizure diary which they filled weekly and this seizure diary was evaluated at 6 weeks and 12 weeks of follow up. Patients were assessed for adverse drug reactions (ADRs) at 0, 6 and 12 weeks of follow up and also for spontaneous reported ADRs at any time during the study.

Results: In both group A and group B, our study demonstrated that seizure freedom, seizure severity, and time before first seizure did not differ significantly ($p > 0.5$). Except for cognitive dysfunction, impaired memory, and swollen gums, which were more frequent in the conventional anti-epileptics group, the ADR

profiles of both group of medications were similar. Phenytoin was found to cause gum swelling and cognitive impairment. No subject experienced a serious adverse event.

Conclusion: Newer Antiepileptics as monotherapy are equally efficacious as conventional antiepileptics but may offer a better safety profile to epileptic patients.

Key words: Newer, conventional, antiepileptic drugs, efficacy, safety

Key Message: Newer Antiepileptics as monotherapy offer a better safety profile to epileptic patients.

Influence of CYP2C9*2 and CYP2C9*3 polymorphisms on valproate associated ADRs in persons living with epilepsy – A case control study

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Epilepsy is a chronic noncommunicable neurological disorder characterized by repeated seizure activity. Pharmacotherapy still remains the most common modality in the treatment of epilepsy. Valproate being one of the most commonly used anti-epileptic drug shows large inter-individual variation in pharmacokinetics and dynamics. In the era of personalized therapy evaluation of factors determining drug response is vital.

Aim: To find the influence of CYP2C9*2 and CYP2C9*3 Polymorphisms on sodium valproate associated adverse drug reactions and plasma valproic acid levels (VPA).

Methods: We recruited 79 cases and 79 controls from epilepsy clinic, steady state plasma valproic acid levels were measured and genotyping done.

Results: The presence of mutant genotype showed an odds ratio (OR) of 2.82 (95% CI = 1.10 – 7.24) $p = 0.027$, the adjusted OR was 5.39 (95% CI = 1.69 – 17.16) $p = 0.004$. There was no significant difference in steady state plasma VPA concentration between genotypes.

Conclusion: The presence of mutant CYP2C9 genotype possesses 5 times the risk of developing ADRs to sodium valproate.

Assessment of adherence to medication in patients with type II diabetes mellitus

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Adherence is the extent to which individuals follow the instructions they are given for prescribed treatments. The present study was conducted to assess the adherence level of patients with type II DM.

Materials & Methods: The present study was conducted on 148 patients which included 88 males and 60 females. All underwent fasting and random blood glucose level examination. All were provided with Morisky 8-item medication questionnaire which included information related to adherence to medication. It was recorded as low, medium and high. Awareness about disease and reasons were evaluated.

Results: 120 males were aware of medicines taken, 90 aware about dose and route of medicine, 102 were aware about frequency of administration, 84 were aware about precautions to be taken while taking medicines, 72 were aware that not taking medication would affect in any way, 30 stopped taking any medicines prescribed by doctor and 45 stopped any medicine due to adverse effects. The difference was significant ($P < 0.05$). Adherence level was high (5%), medium (30%) and low (65%). The difference was significant ($P < 0.05$). Reasons for non adherence was forgetfulness (23%), high cost (18%), not aware of need (31%) and little perception (28%). The difference was non-significant ($P > 0.05$).

Conclusion: Patients with type II DM are usually on multiple medications. We found 65% showed low adherence level. The most common reason was not aware about the need.

Key words: Adherence, Awareness, Diabetes mellitus

An Analysis of Prescription Pattern of Antiepileptic Drugs in a Pediatric Population of Tertiary Care Teaching Hospital

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Background: Prescription pattern of drugs plays an important role in helping the health care system to

understand, interpret and improve the prescribing administration and using medications. Without the knowledge of how drugs are being prescribed and used in children with epilepsy, it is difficult to initiate discussion on rationale drug use and to suggest measures to change prescribing habits for the better management.

Aims and Objectives: To study prescribing patterns of antiepileptic drugs (AEDs) in pediatric patients along with the assessment of effectiveness, compliance and safety profile of AEDs in tertiary care teaching hospital.

Methodology: This was a prospective, observational, single center study conducted at Pediatrics department of tertiary care teaching hospital. Prescriptions of patients attending pediatric outpatient and inpatients department were collected prospectively. The particulars of the participants were collected at the time of enrollment comprised of baseline demographics data, type(s) of seizures, characteristics of the disease, existing drug therapy (dose and duration), and any other concurrent medications during the study. All data were recorded on case record forms and analyzed using descriptive statistics.

Result: A total of 86 prescriptions were collected, male female ratio being 1.6:1. Most common pediatric age group diagnosed with epilepsy was less than 5 years of age. Duration of epilepsy was between 1 to 5 years in approximately 63% of patients. In the pediatric patients of above 3 years age group, schooling was compromised because of epileptic disease. EEG was advised to approximately 17% of patients and MRI to around 3% of patients. Generalized epilepsy was the most common type of epilepsy observed followed by focal Epilepsy. Most common AED prescribed was sodium valproate and carbamazepine. Average number of drugs prescribed per patient was 1.56. Sodium valproate in generalized seizure patients and carbamazepine in focal epilepsy patients most commonly prescribed AEDs.

Conclusion: Generalized tonic clonic seizure was the most commonly observed type of seizure and sodium valproate was the most frequently prescribed drug to them followed by focal seizure. Most common drug prescribed to patients with focal seizure is carbamazepine. Majority of patients were given monotherapy to achieve seizure control. Reduction in seizure episodes was noted with all the drugs and doses but highest seizure free patients were observed with lowest doses of AEDs.

Comparative Efficacy of Metformin and Resveratrol in the management of Diabetes associated complications: A Systematic review

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Background: Food-derived bioactive compounds such as resveratrol are increasingly explored for their protective effects against metabolic complications. Evidence supports the strong antioxidant properties and therapeutic effects of resveratrol in managing diabetes and its associated complications. However, evidence informing on the comparative or combination effects of this natural compound with an accomplished and well-characterised antidiabetic agent like metformin has not been revised. In particular, both compounds showed strong ameliorative effects against hyperglycemia, dyslipidemia, insulin resistance, a pro-inflammatory response, and lipid peroxidation in various experimental models of diabetes.

Objective: This systematic review is to provide a comprehensive synthesis of preclinical studies assessing the comparative effects of metformin with resveratrol against diabetes-associated complications.

Methods: A total of 153 records were acquired through the combined systematic search of the literature. Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) guidelines were followed to prepare the current systematic review. The primary search encompassed all experimental studies reporting on the impact of metformin, in comparison or when combined with resveratrol, against diabetes or its related complications.

Results: The median score range of all included studies was 15 (10–19) out of a possible score of 20. The introduction domain had a median score of 4 (4-4) out of the possible score of 4 (overall agreement 100%, kappa = 1) whilst the methods domain had a median score of 6 (2-9) out of a possible score of 9 (overall agreement 88.89%, kappa = 0.76).

Conclusion: It concluded that widely used interventions like metformin can control diabetes mellitus-related complications, the escalating prevalence of the metabolic syndrome warrants further investigation into alternative beneficial therapies. Otherwise, some preclinical studies summarized in this review that resveratrol has comparative effects in controlling diabetes-related complications as metformin.

Keywords: Metformin, resveratrol, combination therapy, diabetes mellitus.

Linagliptin-induced Liver Toxicity: A Case Report from a Tertiary Care Hospital

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Background: Linagliptin is an oral anti-diabetic medication belonging to the class of dipeptidyl peptidase-4 (DPP-4) inhibitors. While generally well-tolerated, rare instances of liver toxicity associated with linagliptin have been reported. This case report aims to present a patient who developed liver toxicity following the initiation of linagliptin therapy.

Aims & Objective: To describe the clinical presentation, management and outcome of a patient who experienced liver toxicity after starting linagliptin treatment.

Methods: We conducted a retrospective analysis of medical records of a patient admitted to our tertiary care hospital with a diagnosis of linagliptin-induced liver toxicity. Demographic information, medical history, laboratory investigations, imaging studies and management strategies were collected and analyzed.


Results: A 64-year old male with type 2 diabetes mellitus was admitted to our hospital with complaints of jaundice, malaise and abdominal discomfort two weeks after initiation of linagliptin 5 mg daily. His liver function tests revealed elevated liver enzymes including alanine transaminase (ALT) and aspartate transaminase (AST). Other liver function parameters such as bilirubin and alkaline phosphatase were also significantly elevated. An extensive evaluation for other causes of liver injury such as viral hepatitis and autoimmune disorders was negative. Linagliptin-induced liver toxicity was suspected and the medication was immediately discontinued. The patient was closely monitored and supportive measures were provided. Over the course of two weeks, his liver function gradually improved and all liver enzyme levels returned to normal ranges. The patient's symptoms resolved and he was discharged in stable condition.


Conclusion: This case report highlights the potential risk of linagliptin-induced liver toxicity which should be considered in patients presenting with unexplained liver dysfunction shortly after starting linagliptin therapy. Timely recognition and prompt discontinuation of the drug can lead to successful resolution of liver injury and prevent serious complications. Healthcare professionals should be vigilant about monitoring liver function in patients initiated on linagliptin therapy to ensure early detection of any adverse hepatic effects.

Keywords: Linagliptin, liver toxicity, DPP-4 inhibitors, case report, diabetes mellitus.

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