Abstracts

'SoPICON 2023' & Medication Safety in an Era Of Evidence-Based Medicine held at AIIMS Rishikesh 11th – 12th May 2023

A Cost Variation Analysis Study of Antihypertensive Drugs Available In Indian Market

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Abstract

INTRODUCTION

Hypertension is the most common chronic medical problem prompting visits to primary health care providers. Drug cost has become a significant obstacle in the treatment of hypertension, along with patient compliance, which makes it challenging for doctors to select the least expensive medication because these patients often have polypharmacy. Patients' compliance and adherence are worsened by rising antihypertensive medicine costs. A useful method for determining the cost differences between several brands is percentage price variation.

AIMS AND OBJECTIVES

- To evaluate the Cost of different branded drugs and Generic antihypertensive drugs.
- To evaluate the difference in the Cost of different brands for the same active drug by calculating percentage variation of cost and P-value.

METHODOLOGY

Offline sources : latest issues of CIMS : Jan- April 2022 and IDR (Issue 2)

1. Percentage cost variation = Maximum Price – Minimum Price X 100 /Minimum Price
2. Paired t-test is applied for calculating the P-value

RESULTS

Maximum cost variation seen in telmisartan+ hydrochlorthiazide 40mg+12.5mg is 640% & minimum in glyceryl nitrates is 50%. The p-value calculated is 0.00000045, i.e highly significant.

CONCLUSION

Our study demonstrated that there is a significant price difference between brands of oral antihypertensive medications. Given that hypertension is a chronic condition, the cost of the medication has a significant impact on how well patients follow their treatment plans. It is important to raise awareness about this vast range in prices so that drug costs can be decreased and made more accessible to the average person.

The safety profile of dexamethasone versus prednisolone in induction-phase chemotherapy for paediatric and adolescent ALL patients: A Randomized Controlled Trial.

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Abstract:

Background: Acute lymphoblastic leukaemia (ALL) is the most common childhood cancer with OSR > 85% after adoption of MRD-based intensive treatment regimens. Previous studies that compared dexamethasone versus prednisolone regimens have shown superior response & decreased relapse rate along with increased toxicity with dexamethasone.

Objective: To compare the safety profile of dexamethasone and prednisolone in phase 1A, induction therapy of ALL as per modified BFM 2009 protocol.

Methodology: A single-centre, randomized, parallel-group trial that enrolled 75 newly diagnosed ALL patients of 1-25 years of age between January 2022 to March 2023 after IEC approval. The study participants were randomized in 1:1 ratio to receive either dexamethasone 10 mg/m2/day intravenously for 14 days or prednisolone 60 mg/m2/day orally for 28 days during phase 1A induction therapy. The AEs of any grade and grade 3-4 (SAE) as per CTCAE version-5 were recorded and compared between both groups.
Result: The overall incidence of mortality was 12% [Dexa: 14.6%; Pred: 8.8%; p value: 0.44]. The steroid-related AEs observed were gastritis, proximal myopathy, febrile neutropenia, hypokalaemia, invasive fungal infections, septic shock, hypertension, hyperglycaemia, and osteonecrosis. All these AEs were observed similarly in both groups except for more incidence of hyperglycaemia & hypertension in prednisolone group and neutropenia in dexamethasone group (p value: < 0.001). The incidence of other haematological and non-haematological AEs was similar in both groups.
Conclusions: The study results conclude that safety profile of dexamethasone and prednisolone were similar with no statistically significant increase in incidence of steroid related AEs among dexamethasone group.
CTRI registration number: CTRI/2022/01/039113.
Keywords: Dexamethasone, Prednisolone, Paediatric ALL, Adolescent ALL.

Medication Safety Strategies and Interventions: A Review and Future Directions

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Abstract

Introduction: Medication safety risks are the most important preventable factors jeopardizing patient safety. A global concern toward medication errors and medication safety has forced the healthcare settings to review its existing patient safety strategies. There have been constant efforts to devise strategies toward effective medication error prevention at global level. In light of this, the present study attempts to reviews the existing literature on strategies/interventions toward prevention of medication errors in healthcare settings.
Methodology: A review of research articles was performed from databases using the keywords: medication errors, medication safety, pharmacovigilance and patient safety. Reference lists of included studies were also searched. The relevant studies published between 2010-2022 were considered for the present study.
Results: The search resulted 214 studies to be screened and 12 studies met the inclusion criteria of the study. All these studies primarily concentrated on prevention of medication error. Major strategies/interventions found from the review were: education programmes, medication information services, pharmacist role, training and system designs, computer automation and double checking.
Conclusion: Education and training and system designs were found to be the most important elements of the interventions to reduce the medication errors but still the concern exists on the effectiveness of these measures, as many studies concluded to adopt the multifaceted approach in providing medication safety in the healthcare settings.

Safety profile of anti-epileptic drugs: a pharmacovigilance perspective

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Abstract

Background: Epilepsy accounts for 0.70-1% of global burden of disease. Antiepileptic drugs have a narrow therapeutic index & their long term use has significant safety implications. CDSCO Drug safety alerts were recently issued regarding antiepileptic drugs (AEDs).
Objective: To analyse Adverse Drug Reactions (ADRs) of Antiepileptic drug reported to the adverse drug monitoring centre at tertiary Care Hospital.
Methods: The study site was ADR monitoring centre, Department of Pharmacology, Pt. B.D. Sharma, PGIMS, Rohtak. It was a retrospective study done by analysing ADR forms from July 2019 to December 2022. Total 4200 ADRs were screened, out of which 100 ADRs were of AEDs. Causality assessment was done using a WHO-UMC scale.
Results: Out of 100 ADRs assessed, the percentage of ADRs from male and female patients were 61% and 39% respectively. 76% of ADRs were in possible category, 24% in probable category while none of the ADR was in certain and unlikely category. The majority of ADRs were due to Sodium valproate (48%) followed by Carbamazepine (16%) & Phenytoin (16%). The most common ADRs were related to CNS disorders e.g. sleep disorder (20%), dizziness (5%), drowsiness (3%), tremors (3%), decreased memory (2%) etc. Other ADRs were related to GIT disturbances (13%), weight gain (12%), weight loss (3%). Stevenson-Johnson syndrome was reported in 3% & DRESS syndrome in 1% of patients.
Conclusion: Extensive pharmacovigilance is further needed for AEDs e.g. Sodium valproate, Carbamazepine & Phenytoin to guide physicians for better clinical outcome & prevent irrational prescribing of these drugs.
Keywords: Adverse drug reaction monitoring, Pharmacovigilance program, Anti-epileptic drugs.

Comparison Between Two Recommendations to Conduct and Report Systematic Reviews on Drug's Safety.

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Abstract

Background:
Several recommendations are available to conduct and report a systematic review of adverse drug reactions. This study is aimed at identifying and comparing the methodologies of the

two most commonly used recommendations to conduct and report systematic reviews on drug's safety.

Methods:

Two systematic reviews were conducted following the recommendations "Cochrane Handbook for Systematic Reviews of Interventions" and "Systematic Reviews' Centre for Reviews and Dissemination guidance for undertaking reviews in healthcare." The methods of each recommendation were characterized, and the results and the discussion of each systematic review were also evaluated.

Results:

The methodologies of both recommendations are similar. The review question was structured. Both recommendations suggest including pre- and post-marketing data. The recommended data sources differed and, consequently, the results of the systematic reviews (37 vs. 35 studies). Other aspects of search literature were identical. Different tools are suggested to evaluate the methodological quality of the included studies. For case reports, both recommendations only report some questions that may be helpful to assess risk of bias. The reporting of the results and discussion is also identical for both recommendations.

Conclusions:

Few methodological differences were observed between the analyzed recommendations to conduct a systematic review on drug's safety. Combining their methods into a single and recognized recommendation could be of great value.

Direct patient Reporting (DPR) of suspected adverse drug reactions: a new step in signal detection in pharmacovigilance

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Abstract

Introduction: The current system of pharmacovigilance encourages reporting of adverse drug reactions (ADRs) mainly from health care professionals. Underreporting is a major problem more so in developing countries than in the developed world. Very less reports are added to WHO databases from developing countries In this regard, consumers have also been empowered to report any ADRs directly to the regulatory agencies to strengthen this system. The objective of the present study is to analyze the pros and cons of direct patient/consumer reporting of ADRs.

Methodology: PubMed, EMBASE, and the Cochrane Library were searched for clinical trial reports and reviews on direct patient reporting of suspected adverse drug effects.

Results: Consumer reporting can detect early signals and ADRs and thus can overcome under-reporting. It can also promote consumer rights. However, consumer reporting may lack medical confirmation and user awareness.

Conclusion: Consumer reporting can play a crucial role in pharmacovigilance. Possible solutions to improve consumer reporting include easy-to-access reporting methods and a smartphone application. Further research is needed to address the limitations of consumer reporting and to maximize its benefits in ADR detection and management. Indian pharmacopeia commission has launched an ADR reporting form for consumers along with a patient-centric helpline number to enable reporting of ADRs directly.

Keywords: Adverse drug effect; adverse drug reaction; direct patient reporting; Indian pharmacopeia; side effect.

Knowledge, Attitude, And Practice Of Materiovigilance Among Medical Post Graduate Students

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Abstract

INTRODUCTION:

"Materiovigilance" is the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices and protection of patient's health by preventing its recurrences.[1] Post-Graduate medical students play a key role in reporting adverse events associated with medical devices in patients. Therefore, this study was conducted to identify the lacuna regarding Materiovigilance among the residents and to create awareness about the difference that they can make by ADR reporting.

METHODOLOGY:

Study design – Cross-sectional questionnaire-based

Study population – Post graduate students of a tertiary care government institute of Southern Rajasthan

Inclusion criteria – All PG students

Exclusion criteria – Those not willing to be a part of study

Study tool - A questionnaire comprising of 18 questions pertaining to knowledge, attitude, and practice of Materiovigilance and ADR reporting, was developed using Google forms

Data collection – The pre-validated questionnaire was shared with PG residents through social media that contained three sections.

1. Informed consent and questions to evaluate knowledge,
2. To assess attitude
3. To note practice towards Materiovigilance and ADR reporting.

Ethical clearance obtained from the IEC

RESULTS:

Out of 110 participants 81% knew about Materiovigilance, 67% have been trained about MV while 85% consider reporting its ADR necessary, however, 35% have reported ADRs caused by devices.

CONCLUSION:

Most PG students are aware of the term Materiovigilance and know about what should be done but the attitude is inert and regular practice of reporting needs to be developed.

Educational interventional programmes are required to promote Materiovigilance and ADR reporting in regular practice and it should be a part of the UG curriculum so that the residents are familiar to this concept while working during residency.

Keywords: Adverse events, adverse reactions, materiovigilance, medical devices

A Review on Safety Monitoring of Digital Therapeutics

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Objective: As Digital Therapeutics become more prevalent in clinical practice, it is important to implement effective post-marketing surveillance to quickly identify any potential safety issues and establish a strong safety profile for these technologies.

Study Design and Setting: To explore the topic of safety monitoring for Digital Therapeutics, we conducted a comprehensive literature search on PubMed & Google Scholar and narrowed down our findings to five relevant articles.

Results: Digital Therapeutics have a number of benefits, including direct patient access, lower treatment costs, and the potential to replace or supplement traditional treatments. Additionally, in countries where there is a shortage of doctors to patients, adopting technology to collect patient data can give prescribers more time to focus on finding effective solutions to patient problems.

Conclusion: Digital Therapeutics are becoming increasingly important in treating chronic and other hard-to-treat conditions, and are expected to significantly impact healthcare delivery. While regulations for Digital Therapeutics are still evolving, it is important to remember that soft skills will be essential in creating effective regulatory changes in this field.

Study on medication errors and reporting among nursing students

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Abstract

Introduction- The provision and improvement of human health is nurse's primary professional duty. Administration of medications is main responsibility of nurses in our hospitals. One of the most frequent sorts of medical mistakes that might endanger patient's health is medication error (ME). It is estimated that ME account for 100,000 hospitalizations annually. Such errors are viewed as widespread issue that raises mortality rates, hospital stays and associated expenditures. The primary objective of this research was to assess nursing student's knowledge, attitude and practices regarding drug mistakes and reporting.

Methodology: A cross-sectional study was conducted in which 197 nursing students were enrolled randomly. They were asked to fill out a pre-developed and pre-validated KAP questionnaire, including 10 items on demographic characteristics and 7 items about medication errors. Data were analyzed using descriptive and inferential statistics in SPSS software.

Results: Seventy-two percent of nursing students lacked understanding about reporting ME. The improper dosage, missed doses and infusion rate were most often reported error types. The most common causes were using abbreviations instead of full names of drugs and similar names of drugs. Lack of pharmacological understanding and being chronically overworked were two main contributors to ME.

Conclusion: The reporting of ME has to be improved because they constitute significant concern among nursing students. By analysing present practices, creating interventions to change them, and measuring impact of these initiatives, ME can be reduced. Medication education programs are need of the hour and CMEs should be regularly conducted to improve understanding and influence their attitudes and practice patterns.

PHARMACOVIGILANCE

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Abstract

INTRODUCTION:

Pharmacovigilance has been defined by WHO as the 'science and activities relating to the detection, assessment, understanding and related Problems. The information generated by Pharmacovigilance is useful in educating doctors about ADRs and in official regulation of drug Use. Its main purpose is to Reduce the risk of drug-related harm to Patients.

METHODOLOGY:

The questionnaire-based study was conducted in a medical Hospital. The study instrument is a questionnaire which is Prepared by the Department of Pharmacology.

RESULT :

It is based on the knowledge, awareness Practice of Pharmacovigilance among doctors.

CONCLUSIONS :

Educational intervention(CME) on pharmacovigilance improves knowledge, awareness & practices. It will minimize the risk to the patient's health and improve the patient's health.

AN INTRODUCTION TO ADVERSE DRUG REACTION REPORTING SYSTEMS

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Abstract

Objective

To review adverse drug reaction (ADR) reporting schemes, with emphasis on identifying community pharmacists' roles in ADR reporting.

Method

Review of published articles on ADR reporting by pharmacists. Health and medical sciences databases including International Pharmaceutical Abstracts, MEDLINE and ProQuest were searched for relevant publications. Websites specific to ADR reporting schemes in the selected countries were also searched.

Key findings

ADRs impact significantly on a nation's healthcare costs. Voluntary reporting by health professionals is currently considered the cornerstone to the detection and management of ADRs and makes a valuable contribution to the safe use of medicines. ADR reporting systems are managed by national ADR or pharmacovigilance reporting centres, and differ internationally. In general, medication-related problems are reported more commonly in hospitals than in the community. Physicians are the main contributors. Time pressure, no remuneration for reporting, and confusion about what to report were identified as some of the main deterrents for reporting by pharmacists.

Conclusion

Most reporting systems for ADRs are either hospital based, or physician based. The opportunity therefore exists to further develop reporting systems that are accessible by community pharmacists, as they are in an ideal situation to detect and report ADRs through contact with patients.

PIROXICAM INDUCED STEVENS JOHNSON SYNDROME – A CASE REPORT

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Abstract

INTRODUCTION

Stevens johnson syndrome is a rare and severe adverse reaction to medication or infection that typically begins with fever and rash. It can progress rapidly , involving skin and mucous membrane, eyes, mouth and throat. It leads to painful rash and blisters , that spread causing the skin to peel off. Piroxicam is a non steroidal anti-inflammatory drug used to relieve pain and inflammation . This case report describes a patient who developed STEVENS JOHNSON SYNDROME after taking intravenous PIROXICAM for his neck and shoulder pain. The patient initially developed fever and rash over chest and back and then severe mucosal involvement includes lips and mouth. Then patient was admitted in hospital. Treatment included discontinuation of PIROXICAM, supportive care and systemic corticosteroid. The patient's condition gradually improved over the next few weeks.

METHODOLOGY

This case has been collected from the medicine department of Tertiary Care Hospital of Jharkhand. Additional details are collected from patient by visiting Medicine ward. Causality assessment done by WHO – UMC causality criteria.

RESULT

As per WHO UMC causality criteria, the association of adverse reaction to suspected drug PIROXICAM is probable.

CONCLUSION

This case highlights the potential for STEVENS JONSHON SYNDROME to occur as a rare but serious adverse reaction to NSAIDS, PIROXICAM

ASSESSMENT OF ADVERSE DRUG REACTIONS REPORTED THROUGH VARIOUS REPORTING TOOLS UNDER PHARMACOVIGILANCE PROGRAMME OF INDIA

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Abstract

Background – Adverse Drug Reaction (ADR) is a response which is noxious and unintended, and occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for modifying the physiological function. To enhance the numbers of ADRs reported under Pharmacovigilance Programme of India (PvPI), NCC-PvPI, IPC has developed several tools for ADR reporting like ADR reporting forms, Toll-free Helpline, Voluntary Reporting by Non-ADR Monitoring Centres (AMCs) & Mobile Application.

Objectives – To assess the number of Adverse Drug Reactions (ADRs) reported at ADR Monitoring Centre (AMC) through various ADR reporting tools.

Methodology – It is a retrospective, observational study in which ADRs reported at AMC of a tertiary teaching hospital were assessed for the specific tool by which it was reported from January to December, 2022. Further, data was segregated into 4 categories, namely, ADR reporting forms, Tollfree Helpline, Voluntary Reporting by Non-AMCs &

Mobile Application. Data was presented as percentage value using MS Excel 2.70.1.

Result - In total, 188 ADRs were reported through various tools from January-December, 2022. 166 (88.3%) were reported through ADR reporting forms, 9 each were reported through both toll-free number and e-mail (4.79%) and 4 (2.13%) were reported via mobile application.

Conclusions – Maximum number of ADRs were reported through ADR reporting forms, (88.3%) and least by mobile application (2.13%). Awareness regarding these various tools especially mobile application for reporting ADRs, should be propagated as it can bring a revolutionary change in increasing the ADR reporting since, mobiles are now available with every strata of society.

PATTERN OF ADVERSE DRUG REACTIONS REPORTED AT A TERTIARY CARE HOSPITAL UNDER PHARMACOVIGILANCE PROGRAMME OF INDIA

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Abstract

Background- Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem. Adverse Drug Reaction (ADR) reporting is done under the Pharmacovigilance Programme of India (PvPI) for patient safety and is also beneficial to the society in long term. **Objective-** To assess the pattern of ADRs reported at a tertiary care teaching hospital under the Pharmacovigilance Programme of India. **Methodology-** It is retrospective observational study for assessing the ADRs reported at Adverse Drug Reaction Monitoring center (AMC) of tertiary care teaching hospital from January-December 2022. These ADRs were analysed for the type of reactions & its severity, suspected drugs causing it and its causality assessment. Result- Total 188 ADRs were reported during year of 2022. Skin reactions like redness, rashes and itching were most commonly (42%) observed. Majority of ADRs belongs to type B, among them (86.3%) were found to be nonserious and (13.7%) serious. The common causative drugs for ADRs were antimicrobials (26.2%), anticancer (24.5%) & contrast media/dye (24.1%). As per WHO-UMC causality assessment scale highest number of ADRs were probable (74.5%), followed by possible (24.5%) and unlikely (1.5%).

Conclusion-Awareness regarding Pharmacovigilance & ADRs reporting among healthcare professionals and patients/consumer are the potential approaches for proper functioning of PvPI for patients' safety. The major limitation was under-reporting of ADRs which can be overcome by sensitisation and awareness sessions and promoting the culture of ADRs reporting in the society.

RELAPSE CASE OF CORTICOSTEROID-INDUCED MYOPATHY DUE TO NON-FLUORINATED CORTICOSTEROID- A CASE REPORT

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Abstract

Introduction:

Corticosteroid-induced myopathy is a part of the constellation of symptoms constituting Cushing syndrome. It is defined as a toxic non-inflammatory myopathy associated with prolonged use of intravenous or oral intake of steroids and is more incident with the use of fluorinated corticosteroids. The report in discussion is a suspected relapse case of Corticosteroid-induced myopathy with the use of non-fluorinated corticosteroid which first appeared after 12 months of oral Methylprednisolone therapy in a patient receiving treatment for diagnosed Sarcoidosis. After the discontinuation of Methylprednisolone, the symptoms resolved but reappeared after 3 weeks of oral Hydrocortisone therapy, another non-fluorinated corticosteroid which was initiated as a replacement. However, this too resolved within 1 week of stopping off Hydrocortisone. The objective of the study is to perform a critical evaluation of the causality assessment of the reported adverse drug reaction.

Methodology:

The initial and the follow-up cases were received from the treating physician. The patient was contacted over the phone for additional details which were uploaded as Individual case safety reports (ICSRs) in the VigiFlow software. Causality assessment was done by WHO-UMC causality criteria.

Result:

As per the WHO-UMC causality criteria, the association of adverse reaction to suspected oral Methylprednisolone is Probable whereas the association to Hydrocortisone is Possible.

Conclusion:

Corticosteroid-induced myopathy can manifest as an isolated reaction and its temporal relationship to the initiation of corticosteroid therapy remains variable. Pharmacovigilance of corticosteroid use is hence essential to strengthen data on its incidence and promote efficient use of corticosteroids in practice.

IMPACT OF SENSITIZATION AND TRAINING SESSIONS ON PHARMACOVIGILANCE AND ADR REPORTING IN A TERTIARY CARE TEACHING HOSPITAL

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Abstract

Background: Health Care Professionals (HCPs) are the pillar of healthcare system and are most important target for the successful implementation of Pharmacovigilance programme.To encourage (Adverse Drug Reaction) ADR reporting culture and to ensure patient safety Pharmacovigilance programme of India (PvPI) was implemented.Presently there are more than 701 established ADR Monitoring Centres (AMCs) in the country.The problem of under reporting still exists which needs to be addressed for smooth and proper functioning of this programme.

Objective: To assess the impact of sensitization and training sessions on Pharmacovigilance and ADR reporting in a tertiary care teaching hospital

Methodology: Pharmacovigilance week was celebrated from 17th to 23rd September 2022 at our AMC of tertiary care teaching hospital.Data was collected and compared before and after 6 months duration of Pharmacovigilance week using MS Excel 2.70.1.Medical and paramedical students,HCPs including doctors,nurses and other paramedicals were sensitized and trained regarding PvPI and reporting ADRs.After that the data was analysed for the impact of sensitization and training programme on ADR reporting data at our AMC.

Result: Data was compared and analyzed. Before 6 months duration of sensitization and training sessions held during Pharmacovigilance week,103 ADRs were reported and after 6 months duration,140 ADRs were reported at our AMC.

Conclusions: Sensitization and training sessions held at our AMC had an impact on ADR reporting.Thus, to promote awareness towards Pharmacovigilance and ADR reporting,training sessions should be conducted at frequent and regular intervals.

PATTERN OF ADVERSE DRUG REACTIONS REPORTED WITH CONTARST MEDIA IN A TERTIARY CARE TEACHING HOSPITAL

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Abstract

Background-Computer tomography (CT) and Magnetic resonance imaging (MRI) in some cases require the use of contrast media to enhance visibility of specific structures.The two main groups of contrast media are Iodine-based and Gadolinium-based compounds. Iodine compounds like Iomeprol, Iopromide, Iodixanol, Iohexol are used in CT imaging while Gadobutrol, Gadobenic acid, Gadoteridol are used in MRI.

Objective-To describe the pattern of Adverse drug reaction (ADR) reported with the use of different contrast media in a tertiary care teaching hospital

Methodology-This is a retrospective observational study in which all the ADR reported with the use of contrast media to the ADR Monitoring Centre of Dr.RMLIMS, Lucknow between January 2022 to December 2022 were analysed .

Result-A total of 51 ADRs were reported with the use of contrast media to the ADR Monitoring Centre of Dr.RMLIMS, Lucknow between January 2022 to December 2022. Itching (41%) was the most common ADR reported with the use of contrast media followed by Rashes (31%), Chills (10%), Swelling of face (8%), Vomiting (4%), Tongue dry (4%) and Fever (2%)

Conclusion-Itching and Rashes are the most common ADR reported with the use of contrast media and Iodixanol is the most common contrast media causing ADR

EFFICACY AND SAFETY OF VITAMIN D AS A SUPPLEMENTARY TREATMENT FOR ANAEMIA IN PATIENTS WITH ULCERATIVE COLITIS

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Abstract

Introduction- Ulcerative colitis (UC) is an inflammatory bowel disease. Anaemia is a common complication of UC, resulting from chronic inflammation and blood loss. This study was aimed to assess the effectiveness and safety of Vitamin D supplementation as an adjunct to standard therapy in UC patients with anaemia, by comparing changes in haemoglobin levels, disease activity and adverse events with standard therapy alone.

Methodology- Initially, 78 patients with diagnosed UC and anaemia were screened and those meeting the inclusion criteria were enrolled in the study. Group I received standard therapy for 12 weeks, Group II received standard therapy plus oral vitamin D3 4000 IU OD for the same duration. The primary endpoint was the change in haemoglobin levels from

baseline to week 12, while the secondary endpoints included changes in disease activity and adverse events.

Results- At the end of 12 weeks, the mean haemoglobin levels was significantly higher in the group II compared to group I ($p< 0.05$). The vitamin D group also had a significantly greater improvement in disease activity, as measured by the Mayo score ($p <0.02$). No serious adverse events were reported in either group.

Conclusion- Vitamin D supplementation as an adjunct to standard therapy can be beneficial in improving haemoglobin levels and disease activity in UC patients with anaemia. These effects may be due to the anti-inflammatory and immunomodulatory effects of vitamin D. Additionally, the safety profile of the adjunct treatment is comparable to that of standard therapy alone. However, further research is necessary to confirm these findings.

A CASE REPORT OF DAPSONE INDUCED METHAEMOGLOBINEMIA

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Abstract

Objective: To report a case of methemoglobinemia in patient receiving dapsone for treatment of generalized bullous pemphigoid.

Case summary: A 64-year-old female patient diagnosed with generalized bullous pemphigoid was admitted in dermatology ward. She was prescribed Tab. Dapsone for 19 days. On 19th day she complained of sudden onset of breathlessness. Her oxygen saturation was 88% on room air, laboratory investigation showed Hb- 7 gm/dl, methaemoglobin level - 3.4 %, ABG: pH-7.48, pCO2-34.5mmHg, pO2-131mmHg, SO2- 99.2%, Hct-55%, HCO3-25.4mmol/L. Patient was diagnosed with methemoglobinemia and managed with high flow oxygen support, two units of PCV, vitamin E and vitamin C.

Discussion: Drug-induced methaemoglobinaemia is the commonest cause of acquired methaemoglobinaemia. Here we present a case of methemoglobinemia in patient receiving therapeutic dose of dapsone.

Conclusions: Methaemoglobinaemia is uncommon and potentially life-threatening complication of dapsone. Hence, it is important that clinicians are aware of the presentation, diagnostic criteria, and treatment options. Thus, early diagnosis and treatment will decrease complications of drug induced adverse event.

A CASE REPORT OF ETHAMBUTOL INDUCED OPTIC NEUROPATHY

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Rationale:
Ethambutol-induced optic neuropathy (EON) is a well-known complication that results from the use of ethambutol. The ocular manifestations of EON include painless loss of central vision and cecocentral scotomas in the visual field.

Patient concerns: A 33-year-old man suffered from this rare ocular disorder because he took ethambutol for about 8 months. Patient had past history of HIV and he is on antiretroviral therapy (Tenofovir, Dolutegravir and Lamivudine) since 2017.

Diagnosis: He was diagnosed as EON based on series of ophthalmic examinations performed.

Interventions: The physician stopped the ethambutol and prescribed tablet Zinc to him.

Outcomes: The patient did not come for next visit but, by telephonic conversation patient's vision improvement by 50% after 3 months.

CONCLUSION: Because of optic neuropathy is an uncommon, can be permanent and dose and duration related. The ocular toxicity is monitored closely among the tuberculosis patients that take ethambutol. It is important that clinicians are aware of the presentation, diagnostic criteria, and treatment options.

A KNOWLEDGE, ATTITUDE AND PRACTICE (KAP) STUDY OF PHARMACOVIGILANCE AMONGST HEALTHCARE PROFESSIONALS AND MEDICAL STUDENTS OF A TERTIARY CARE HOSPITAL ATTACHED WITH MEDICAL COLLEGE, GUJARAT, INDIA

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Abstract

Introduction: Adverse drug reactions (ADRs) are a global issue, can lead to serious health issues. Healthcare professionals are essential for successful pharmacovigilance programmes, as they are responsible for identifying and reporting ADRs to monitor drug safety. Knowledge, Attitude and practice (KAP) towards pharmacovigilance and ADRs were evaluated among medicos and paramedics.

Methodology: A cross-sectional survey was conducted to evaluate the KAP of healthcare professionals and medical students regarding ADRs and pharmacovigilance, with 21 questions peer-reviewed by experts. The results were analysed using Microsoft Excel.

Result: We have enrolled a total of 100 participants in this study. We included medicos (n = 70) and paramedics (n = 30) from different clinical departments. An average of 62.65% of medicos and 51.42% of paramedics have correct knowledge about ADRs and pharmacovigilance, and an average of 85.70% of medicos and 96.60% of paramedics agreed that reporting ADRs is necessary. Only 34.28% of medics and 40.00% of paramedics reported ADRs at the ADR reporting centre. While 34.28% of medics and 53.30% of paramedics

don't know where to report ADRs. Additionally, we discovered that, at every year, six-month, and monthly intervals, respectively, 58.30%, 30.70%, and 05.00% of all participants expressed interest in the pharmacovigilance awareness programme.

Conclusion: We concluded that medicos and paramedics have a better attitude towards reporting ADRs but lack knowledge and poor practises, due to excessive workload. The majority of medics and paramedics felt ADR reporting and monitoring were very important, but few had ever reported ADRs because of a lack of sensitization and knowledge of pharmacovigilance and ADRs.

RESPIRATORY FAILURE AS SERIOUS ADVERSE EVENT FOLLOWING DEXTROMETHORPHAN USE IN CHILDREN; A SERIES OF CASES REPORTED FROM A TERTIARY CARE TEACHING HOSPITAL IN UTTARAKHAND.

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Abstract

Background: Dextromethorphan, an NMDA Antagonist, is an over-the-counter medication usually available in combination for non-productive cough and common cold. Though it has low abuse potential, it is frequently associated with numerous side effects like blurred vision, hallucination, drowsiness, difficulty in breathing, and seizures. Many cases of death and respiratory depression in children have also been reported. The safety and efficacy of Dextromethorphan in children is not well established and its use is not approved in children below 2 years by CDSCO.

Case Series:4 paediatric patients, aged 1 year 8 months to 7 years presented with altered sensorium, respiratory failure, decreased Glasgow Coma Scale (GCS) and a history of intake of dextromethorphan containing cough syrup within a short span of 6 months in Emergency. Out of 4 cases 3 required intubation and mechanical ventilation in ICU care. All responded well to Naloxone, with prompt improvement in their GCS, respiration, and general condition. All were also found positive for urinary opiates.

Conclusion: Acute respiratory failure is a serious consequence after consumption of Dextromethorphan containing OTC cough syrup in children. Easy availability, OTC use with variable doses and varied formulations, lack of quality control with laxity in regulations being subjugated to State regulatory authorities are some of the reasons for such serious adverse events. Keeping OTC dosage uncertainty in mind, Dextromethorphan should not be used in children due to its safety concerns, doubtful efficacy, poor quality control keeping in mind the availability of better pharmacological and non-pharmacological alternatives.

ZOLENDRONIC ACID INDUCED LICHENOID DRUG ERUPTIONS (LDE)

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Abstract

Introduction: Lichenoid eruptions are uncommon skin rashes that can be induced by many environmental agents or medications. LDE can look much the same as Idiopathic lichen planus. The differentiating features of LDE include-

- ✓ The rash may be scaly, resembling Eczema or Psoriasis, extensively distributed over the trunk and limbs predominantly in areas exposed to Sun.
- ✓ Wickham striae are usually absent.
- ✓ Nail and mucous membrane involvement is uncommon.
- ✓ More likely to leave pigmentation after rash has cleared.

Objective: To report the case of Zolendronic Acid induced LDE.

Case: 58 years old lady with previous H/O Modified Radical Mastectomy done for Right Breast Carcinoma, was on chemotherapy for bone metastasis; Six cycles of chemotherapy with Paclitaxel 240 mg & Zolendronic acid 4 mg, and seventh cycle of Zolendronic acid 4 mg (alone) completed without ADR. But, three days after eighth cycle of chemotherapy with Zolendronic acid (alone), patient developed purplish erythematous plaque with itching; all over the body.

Treatment: For this, patient was referred to Dermatology department of tertiary care hospital, where she was diagnosed for LDE and was prescribed Tablet Chlorpheniramine, Tablet Montelukast, Tablet Levocetirizine, Ointment Betamethasone and liquid Paraffin. After few weeks, lesions subsided leaving scars.

Result: A total of 33 cases of LDE has been reported through VigiAccess to WHO. According to WHO Uppsala Monitoring Criteria, it was a 'Probable' reaction. The reaction was reported by me to ADR monitoring center on 24/09/2022, with AMC report no. RMC/Oct-2022/01 & Worldwide Unique no. IN-IPC-300691031 and uploaded through Vigiflow.

Conclusion: It is very important to report any ADR to AMC for continuous improvement of drug treatment.

A REVIEW ON OVER-THE-COUNTER DRUGS PRACTICES AMONG THE ADOLESCENT POPULATION

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Abstract

Introduction (Background & Objective)

Self-Medication, defined as the use of medication by a patient on his own initiation or on the advice of a pharmacist or a layperson instead of consulting a medical practitioner, has became an everyday practice. Although over the counter (OTC) drugs are believed to be relatively safe, their inappropriate use could have serious implications. The aim of reviewing these studies is to assess the practices of self-medication, prevalence of risky practice of its associated factors.

Methodology

Comprehensive search was conducted on Research databases like PubMed, ResearchGate, Google Scholar using keywords such as "Over the Counter Drugs", "Self-Medication", "Adolescent" separately and in combination.

Inclusion Criteria: Articles containing data on Self-Medication uses among the Adolescent Population.

Results

The prevalence of self-medication is found to be high. Mostly used OTCs are antipyretics, antitussives, medications used for pain relief, respiratory conditions, allergic conditions, dermatological conditions, nutritional supplements & vitamins, gastrointestinal products, antidandruff products, hair products. Most common sources of information on medicines were parents. Other associated factors being type of family, father's education, mother's education, distance from a nearest medical store.

Discussion (Conclusions)

It has been seen that even after the years, the prevalence of self-medication is high among adolescents & most of them had taken it without consulting a doctor, so it is important to create awareness among adolescents regarding self-medications.

A REVIEW ON ADVERSE EVENTS FOLLOWING IMMUNISATION AND VACCINE SAFETY AMONG INFANTS UNDER 1 YEAR OF AGE

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Abstract

Introduction (Background & Objective)

As one of the most cost-effective healthcare interventions, vaccines have a major effect on reducing the burden of infectious diseases & their associated mortality, especially in children. But immunization safety has become as important as the efficacy of vaccination programs. Adverse Events Following Immunization is defined as 'Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the use of the vaccine'. The objective of reviewing these studies is to assess about Adverse Events Following Immunization (AEFI) among infants under 1 year of age.

Methodology

Comprehensive search was conducted on Research databases like PubMed, ResearchGate, Google Scholar using keywords such as "Vaccination", "Adverse Events Following Immunization", "AEFI", "Infants", "Vaccine Safety" separately and in combination.

Inclusion Criteria: Articles containing data on Adverse Events Following Immunization & Vaccine Safety among infants under 1 year of age.

Results

The most frequent AEFI were high fever, persistent crying, diarrhea, mild local reaction, swelling and pain. The majorly implicated vaccines for AEFI were Pentavalent vaccine, BCG vaccine, Oral Poliovirus vaccine. Consistent causal association to immunization was observed with high number of cases.

Discussion (Conclusions)

Immunization is a fundamental public health policy for controlling vaccine preventable infectious diseases. A high incidence rate of AEFI was observed while reviewing these studies. AEFI surveillance studies help to detect changes in the frequency of adverse events, which may be an alert to consider vaccine quality or identify a specific risk among the local population.

A CASE SERIES ANALYSIS OF MEDICATION ERRORS OF METHOTREXATE

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Abstract

Background

Methotrexate (MTX) is an antimetabolite primarily used at lower doses as a therapeutic agent for rheumatoid arthritis. Drug toxicity is an avoidable state, if patient education and medication reconciliation become a routine part of patient care. We report three common and preventable clinical scenarios of drug toxicity that leave us with a valuable lesson in patient care.

Objectives: To monitor methotrexate levels with identification and analysis of factors related to methotrexate toxicity.

Methods: This is a single centre case series from a tertiary care hospital that included all the patients admitted through emergency with suspicion of methotrexate toxicity during six

months period (August 2022 to Feb 2023).The study was observational and descriptive research.

Results: Patient's education status, comorbidities, polypharmacy, lack of patient education, prescription errors were identified as important factors contributing to methotrexate toxicity. Inadvertent consumption of toxic dose of MTX due to the unawareness of dosing schedule, wrong prescription and low medication literacy are preventable medication errors.

Conclusion: Medication errors that lead to preventable drug toxicity can be avoided with easy but effective tools like medication reconciliation and patient education.

Key-words: Methotrexate, case series, patient education, medication reconciliation

Reporting Culture of Medical Devices Adverse Events in a Tertiary Care Hospital

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Abstract

Background

In recent years, like pharmacological agents, the safety of medical devices has got an immersion among the healthcare professionals, scientists, biomedical engineers and researchers throughout the world. The under-reporting of medical devices adverse events (MDAEs) because of the lack of awareness, even after more than 7 years of the Materiovigilance Programme of India (MvPI) implementation by the IPC, leads to a miserable situation and an alarming signal for people's health in India.

Objective: Our aim is to know the reporting culture of the MDAEs in a tertiary care hospital located at Aligarh particularly in the field of cardiovascular system.

Methodology: The consultants and physicians were asked to cooperate in reporting medical device related adverse events. They were made aware about the reporting process and informed that the reporting of MDAEs was generally done by a healthcare professional, biomedical engineers, manufacturers, and/or patients to any MvPI's Monitoring Centre (MDMC). They were also informed that the MDAEs can be reported using different modes such as through the online system of ADRMS-IPC, through the MvPI's toll free number, or by e/mailing a dully filled editable MDAE's form to a respective MDMC.

Observation: We found 90% of the consultants and physicians from the Department of Cardiology and Cardiothoracic Surgery were unaware of the MvPI, which was the main reason of under-reporting to the local MDMC. However, they showed keen interest in cooperating and reporting medical device related adverse events.

Conclusion: Physicians and consultants were not aware about the actual reporting methodology of MDAEs. This presentation is an eye opener and would ease all healthcare professionals in reporting the adverse effects of medical devices in India. The MDAE form needs to be available in all OPDs which has the following sections: General details, Device details, Manufacturer/Importer/Distributor (MID) details, Healthcare centre details, Event details, Patient details (Baseline study), Causality assessment (Investigation action taken), and Signal detection (Root causes).

A STUDY TO ANALYSE ADVERSE EFFECTS OF HYPNOTICS ON MEMORY AND PSYCHOMOTOR FUNCTIONS IN INSOMNIA PATIENTS

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Abstract

Introduction: The present study was done to analyse the adverse effects of hypnotics, which are widely used for insomnia, on memory and psychomotor functions.

Methodology: This prospective, observational study was carried out at Psychiatry OPD in adults with Insomnia who were prescribed hypnotics for at least 28 days and who gave written informed consent. A detailed history of patients, memory (PGI memory scale) and psychomotor functions were assessed at baseline, 2 week, and 4 week. Data was analysed by using repeated measures ANOVA (p value <0.05 statistically significant).

Results: Total 28 patients were included in the study out of them 9 were prescribed clonazepam (0.5 mg), 9 lorazepam (2 mg) and 10 patients zolpidem (5 mg). The mean age of study population was 39.75 ± 11.190 years, amongst them 2 patients had transient insomnia, 21 acute insomnia and 5 chronic insomnia. In this study, attention and concentration, delayed recall, immediate recall, recognition and total scores significantly worsened at 2 weeks and 4 weeks as compared to baseline (p <0.05). All other parameters like remote memory, recent memory, mental balance, visual retention, verbal retention of similar and dissimilar pairs of PGI memory scale worsened but statistically insignificant. In Psychomotor functions single letter cancellation and hand steadiness were significantly worsened at 2 weeks and 4 weeks as compared to baseline (p <0.05), while digit letter substitution, audio-

visual choice reaction time, critical flicker fusion were worsened but statistically insignificant.

Conclusion: Hypnotics have short term and long term adverse effect on some aspects of memory and psychomotor functions.

Fixed Drug Eruption due to Ceftriaxone: A case report

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Abstract

Introduction: Fixed drug eruption (FDE) is an unusual type of cutaneous adverse drug reaction that is characterized by recurrent site-specific lesions each time the drug responsible is taken. Ceftriaxone, broad-spectrum third-generation cephalosporin, appeared to be a safe and effective therapy in greater than 90% of infections including cellulitis, abscesses and necrotizing ulcers of the skin and subcutaneous tissues. FDE from cephalosporins has been rarely reported.

Material & Method: Suspected Adverse Drug Reaction (ADR) due to Ceftriaxone were reported from Chest and TB Dept. The ADR was filled in Suspected ADR reporting form and as per WHO-UMC causality assessment scale causality was assessment was done and ADR was reported through vigiflow to Indian Pharmacopeia commission, Ghaziabad.

Result: A 85 year old male presented to Chest and TB Department with complaints of recurrent pulmonary tuberculosis with COPD, Diabetes Mellitus, BPH, CKD and CAD. Patient was started on iv antibiotics and on Day 4 of treatment patient complained of Bluish patch on left forearm and near left knee. In view of this fixed drug eruption, injection ceftriaxone was stopped immediately and supportive measures were taken.

Conclusion: Fixed drug eruption (FDE) represents the most common cutaneous adverse drug reaction attributed to antibiotics. It is mainly characterized by skin lesions that recur at the same anatomic sites upon repeated exposures to an offending agent. A proper diagnosis and management of such fixed drug eruption should be done immediately to avoid serious complications.

Keywords: Ceftriaxone, Fixed drug eruption, ADR

WHAT FUTURE HEALTHCARE PROFESSIONALS NEED TO KNOW ABOUT PHARMACOVIGILANCE :INTRODUCTION OF THE WHO PV CORE CURRICULUM FOR UNIVERSITY TEACHING WITH FOCUS ON CLINICAL ASPECTS

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Abstract

Background- Healthcare professionals play a crucial role in the pharmacovigilance system. They require considerable knowledge and expertise in the field of medication safety which will successfully contribute to this area through early recognition, management and reporting of the medicine safety issues.

Objective-To build knowledge of and raise awareness about ADRs among healthcare professional.

Methodology-Since time and resources for PV education are limited, either this can be integrated into existing courses such as pharmacology and pharmacotherapy, or used as a stand-alone course.

Result-It is expected that PV competencies for students are vital for their contribution to safe use of medicines in the future.

Conclusion-By developing PV competencies at universities, we may take the very first step in this journey of change.

THE IMPACT OF ACTIVE SURVEILLANCE IN ADR MONITORING- INSTITUTIONAL OBSERVATION.

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Abstract:

An active surveillance system in pharmacovigilance has been defined by the World Health Organization as the collection of case safety information as a continuous pre-organized process. The Council for International Organizations Of Medical Sciences (CIOMS) cumulative glossary version 1.1 released in 2021 distinguished three types of active surveillance: (1) drug based, (2) setting based: identifying adverse events in health care settings, (3) event based: identifying adverse events associated with medical products. In the period between April 2022 to March 2023, total 191 ADRs reported were, of which 165 were between April to September and only 26 were reported between October to march. This decline in number of ADR reporting was due to resignation of the pharmacovigilance Associate (PvA). This highlights the fact that ADR reporting at present is dependent on PvA. Sensitization of heath care professionals to spontaneously report ADRs has not yielded the desired outcome. So, there is need for active surveillance by other approaches. Although spontaneous reporting remains a cornerstone of pharmacovigilance, and is indispensable for signal detection, distinctive additional approaches can be

adopted like 1) sensitizing the general public through mass media regularly and repeatedly, 2) Installing large hoardings in local language within hospital premises that ADRs can occur due to any drug and must be reported at the given toll free number functional 24x7, 3) A specific room must be allotted in the hospital near the pharmacy for ADR reporting, 4) lastly the reporting of ADRs must be incentivized to ensure pharmacovigilance delivers its full benefits.

TO KNOW THE VIEWS OF FACULTIES ON AWARENESS, PREPAREDNESS AND LIMITATIONS IN IMPLEMENTATION OF CBME BASED UNDERGRADUATE CURRICULUM –A QUESTIONNAIRE BASED STUDY

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Abstract

Introduction: In India, MCI/NMC has implemented the Competency based medical education in 2019. Embracing of CBME would change the current method to medical undergraduate teaching. The faculty members of medical colleges are consider as a prime movers for implementation of CBME.

Methodology: We conducted a questionnaire based study to assess the interpretation and preparedness of the faculties on competency-based curriculum and its implementation. Responses of the faculties were collected and data were analysed in the form of percentage.

Result: Most of the faculties appreciate the new curriculum which shows their alertness and willingness for its implementation. They think that traditional text books are not sufficient enough for the students. Therefore, there is need of change in traditional text books accordingly.

Conclusion: We concluded that most of the faculties appreciate the new curriculum which shows their willingness for its implementation with few changes, but they need more training and guidance at institute level.

Health Related Quality of Life and its Determinants among Patients encountering Adverse Drug Reactions in an Indian Set-Up

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Abstract

Introduction: Conventional system of monitoring adverse drug reactions (ADRs) typically concentrates on the clinical outcomes of a reaction, significantly neglecting the humanistic aspect. ADRs not only entails huge clinical and economic burden, but also affect a patient's health-related quality of life (HRQoL). The present study estimated the HRQoL indices in patients experiencing ADRs and further explored the determinants of lower HRQoL.

Methods: A hospital-based prospective, observational study conducted for three years including all cases who were admitted with a suspected ADR or encountered one or more ADR(s) during the hospital stay. All patients were interviewed for some basic ADR related information and HRQoL measures using WHO-QoL-BREF and EQ5D. Pharmacovigilance workup included assessing the ADR severity, causality and preventability. Data was statistically analyzed. Multivariate linear logistic regression analysis was done to find predictors for the HRQoL score.

Results: The study included a total of 519 cases. The mean EQVAS was 72.56 (6.64) and overall mean WHO-QoL score was 60.93 (7.78) at baseline. On post discharge follow-up, the mean scores were 85.90 (3.70) and 72.89 (6.26) respectively. Multivariate linear regression analysis showed that both WHO-Qol BREF Score and EQVAS in patients experiencing ADRs was negatively affected by ADR severity (β = -5.588, p=0.000 and β = -3.372, p=0.000).

Conclusion: Patients with low education, higher age and more severe ADRs reported with lower HRQoL scores. ADR Severity was a strong predictor of lower HRQoL considering all domains of physical health, psychological health, social health, environmental health, mobility, self-care, usual activities, pain/discomfort and anxiety/depression.

Self-Medication pattern among undergraduate medical students in a teaching institute in North India: A cross sectional study

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Abstract

Introduction: Self-medication can result in irrational drug use. The medical undergraduates have easy access to information and hence easily tend to self-diagnose and self-medicate. The present study was undertaken to identify the patterns of self-medication among medical students.

Material and methods: This was a questionnaire based observational study using Google form filled by medical

undergraduates under various courses i.e. MBBS, BDS, Nursing and Pharmacy. The study was approved by ethics committee. The inclusion criteria were age >17 years, either gender and willing to give informed consent. The study endpoints were socio-demography, common illness in which self-medication done, commonly used self-medications and any consequences with self-medication. Data was anonymized and analysed.

Results: Out of 647 participants who gave their consent to fill the form 56.9% were MBBS, 26.3 % were Nursing, 14.2% were BDS and 2.6% were Pharmacy UGs. 4.8% among them were suffering with chronic illness. 76.6% have used self-medication. The most frequently used medicines were antibiotics (69.1%) followed by antipyretics and analgesics (51%). The ailments for which self-medications used were fever (76%), headache (70%) and common cold (50.5%). Majority (58.1%) prefer to stop medicine once symptoms get relieved. In case ailment not relieved, 92.7% preferred to consult physician. Around 14.5% experienced adverse events after self-medication use.

Conclusion: Self Medication is prevalent among medical undergraduates but majority preferred consulting physician if not relieved of symptoms. They were not complaint with full course of treatment for which, they were guided appropriately.

Comparative study of Efficacy and Safety of Ramelteon vs Zolpidem in patients of Insomnia in Tertiary Care Centre of East India

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ABSTRACT

Introduction: Insomnia is a sleep disorder which is associated with difficulty in falling sleep(sleep latency) or staying asleep(sleep maintenance). This may leads to anxiety disorders, major depression, substance use disorders, suicidality, diabetes, and hypertension. Because of the unintended, harmful effects such as drowsiness, headache, dizziness attributed to the use non-benzodiazepine agonist of benzodiazepine receptor like Zolpidem, alternative dugs like supplementation with melatonin and agonists of melatonin receptor have been investigated for insomnia.

The aim/objective of the study is to compare the efficacy and safety of ramelteon to zolpidem for improvement in sleep in patients of chronic primary insomnia.

Materials and Method: Random allocation of 50 patients was done into group ramelteon and group zolpidem with 25 patients in each group. Patients in ramelteon group were advised to take ramelteon 8 mg at bedtime and in zolpidem group zolpidem 10 mg at bedtime for 14 days. The primary efficacy outcome measure was to measure the change in sleep latency from baseline to day 14. Secondary efficacy outcome measures include duration of sleep, number of awakenings, quality of sleep based on self-assessment of patients and frequency of rebound insomnia using questionnaire.

Results: A significant reduction in subjective sleep latency in patients taking ramelteon (reduced from 63.04 ± 34.51 minutes at baseline to 30.93 ± 21.65 minutes; $p < 0.05$) and also in patients taking zolpidem (reduced from 61.96 ± 44.73 minutes at baseline to 31.24 ± 26.17 minutes; $p < 0.05$)was observed at the end of therapy. More incidence of headache, dizziness and anxiety was observed in zolpidem group as compared to ramelteon group. There was no significant difference between ramelteon and zolpidem pharmacotherapy with respect to adverse events ($p<0.05$).

Conclusion: Ramelteon was proved to be as efficacious as zolpidem with respect to sleep latency, duration, and quality. In addition, there is low risk of adverse drug reactions like withdrawal and rebound symptoms, impairment in learning and memory, impairment in motor co-ordination, and it has less abuse potential.

Keywords: Ramelteon, Zolpidem, Insomnia, Sleep Latency, Sleep Duration, Sleep Quality.

Title: Study of adverse drug reactions reported from rural tertiary care teaching hospital-an observational descriptive study.

Name of the authors:

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Department: Department of Pharmacology

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Introduction: Adverse drug reactions (ADRs) represent a major cause of iatrogenic morbidity and mortality in patient care. Good pharmacovigilance practice helps to minimise or prevent ADRs through early detection and effective communication, which ultimately help each patient receive optimum therapy. The present study aims to identify the incidence of ADRs in the various departments of rural tertiary care teaching centre.

Methodology: An observational study of all the reported cases of Adverse Drug Reactions that occurred in both outpatients and in patients at Dr PSIMS & RF in a period of 1 year (April 2022 to April 2023) was included in the study. The causality assessment was done based on the WHO-UMC causality scale. The reports were analysed as per the standard guidelines fixed by the Pharmacovigilance Programme of India.

Results: There were total of 140 ADRs reported. Majority of the ADR occurred in females (61.42%). Commonest route is oral (85%). Frequent manifestations were rash (24.28%), sedation (19.28%), vomiting (5%) followed by galactorrhoea (2.4%) etc. Most of the ADRs reported were from Psychiatry (44.3%), Dermatology (15.9%) followed by Pulmonology

(15%). Among 140 ADRs, maximum cases were mild, 9 ADRs led to hospitalization and 1 ADR was life threatening. Based on WHO-UMC causality scale majority graded as probable (82.80%).

Discussion & conclusion: In 2022, Dr. PSIMS&RF is recognised as an ADR monitoring centre. The present study findings have certain limitations in the form of incompleteness of the ADR forms which can be overcome by reemphasizing on ADR reporting & its importance.

Title: Analysis of cutaneous adverse drug reactions reported at ADR monitoring centre of a tertiary care teaching institute.

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Abstract

Background

A cutaneous adverse drug reaction (cADRs) is an undesirable change in the structure or function of the skin, its appendages or mucous membranes due to drugs. cADRs are the most frequent of all manifestations of drug sensitivity. These reactions range `from mild erythematous skin lesions to life-threatening cADRs. Knowledge about pattern of cADR in local population is helpful in the management and predicting outcomes.

Objectives

To analyze cADR according to demographic profile, morphological pattern, causative drugs, severity and outcome in patients.

Methodology

Retrospective data analysis was done from a spontaneous ADR reporting form submitted to ADR monitoring centre (AMC) between February 2020 and September 2022 after getting approval from ethics committee. Casualty assessment was done according to WHO-UMC scale. Severity was assessed as per modified Hartwig and Seigel scale.

Result

Out of 176 ADR forms analysed, 78 forms reported cADR. 34(44%)females and 44 (56%) male were suffered from cADR. Most common age group affected by cADR was 19-40 years (44%). Maculopapular rash(33.33%) was the most common presentation followed by itching (28.2%). Antimicrobials were responsible for 58.92% of cADR. As per WHO-UMC causality assessment criteria, 4 ADR belongs to probable and 74 as possible. At the time of reporting, 42 cADR were resolved while 36 cADR were in the stage of recovery.

Conclusion

The most common cADR observed in the study was maculopapular rash and most common drug category responsible for cADR was antimicrobials.

Training program on Patient safety and Pharmacovigilance for Nurses

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Abstract

Introduction: Adverse Drug Reactions (ADRs) are the major cause of hospital admissions and in-hospital morbidity accounting for up to 5% of hospital admissions, 28 % of emergency visits and 5 % of hospital deaths with associated costs of economic burden. Nurses play an important role in ADR reporting, because they are in close contact with patients for a longer duration and have good knowledge of health management.

Methodology: Using convenient sampling approach, nurses from various inpatient and intensive care units in our tertiary care hospital were approached. Approximately 90 nurses were enrolled in this training program. A written informed consent was obtained from all participants prior to their inclusion in the training. Preceding commencement of the educational-cum-sensitization program, they were administered a questionnaire aiming to assess their baseline knowledge, attitudes and beliefs towards Pharmacovigilance. Similarly, Post-test questionnaire was also administered after completion of the training session. The questionnaire comprised of 20 items based on knowledge with regards to Pharmacovigilance, attitude and beliefs regarding nurses' role in reporting of ADR.

Results: Pre-test and post-test responses of 90 nurses were recorded. Only 20% of the total participants had knowledge about Pharmacovigilance in pre-test and 5% of the participants were reporting ADRs before attending the training program. There was significant improvement in the knowledge and beliefs among nurses after the end of training session when compared to pretest.

Conclusion: Imparting adequate knowledge regarding Pharmacovigilance to nurses is very important. We must encourage them to contribute in collection and reporting of ADRs.

Knowledge, Attitude and Practice of general public about Drug safety

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Abstract

Background- Drug safety is a critical concern for public health, as it directly impacts the well being of patient who are

on medication to treat their illnesses and improve their quality of life. While drugs can offer many benefits, they also come with potential risk and side effects that should be carefully monitored to ensure patient safety.
Objective- To assess the knowledge, attitude and practice of general public about Drug safety, and to create awareness about the potential risks and side effects of medication so they can make informed decision about their healthcare.
Methodology- A cross sectional study was conducted using a validated well- structured questionnaire. Total of 609 drug consumers of different age group participated in the study.
Result- More than 94% of the patients believed that drugs can have both good as well as harmful effect, only 3.2% were aware about the ADR form, have filled it and submitted it to the ADR center,0.8% only knew about the toll free helpline number,83.4% believed that it is the duty of everyone to report ADR. 86% said that they would stop consuming the drug causing the adverse effect, on asking what would be done on occurrence of ADR 67 % reported that they would 1st stop the drug before consulting physician.
Conclusion-Pharmacovigilance plays a critical role in promoting drug safety, therefore it is the duty of healthcare professional to conduct pharmacovigilance programmes and teach the general public about ADRs, its form filling and reporting.

PHARMACOVIGILLANCE IN CHILDREN

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Abstract
Ensuring medicine safety in children is challenging. Routine electronic healthcare information increasingly contributes to health protection practice.
Objectives
This systematic literature review explores the use of routine healthcare data to:
Support the identification of adverse drug reactions through signal detection using routinely collectedhealthcare data
Demonstrate that routine healthcare data sets can be used to provide population cohorts for pharmacovigilance
Methods
MEDLINE and EMBASE databases were searched from 1999 to 2009 using MESH and text words. Two observers independently reviewed titles/abstracts for the review?s inclusion criteria: paediatric population, adverse drug reaction(s) and routinely collected electronic healthcare data. Two observers independently carried out full text review and data extraction of the eligible articles.
Studies were quality assessed using appropriate assessment tools to assist in identification and methodological strengths and weaknesses.
Results
The most commonly reported reactions were: Mental and Behavioural Disorders
Symptoms, laboratory findings not elsewhere classified
Medicines most commonly associated with reactions were vaccines and central nervous system drugs.
Conclusions
The review highlighted that electronic healthcare records can be used to signal adverse reactions to medicines and to provide cohorts for retrospective pharmacovigilance. Reactions are nevertheless relatively rare and require an all Scotland approach and advantage should be taken of the increasing healthcare datasets available in Scotland for this purpose.

SAFETY PROFILE OF DRUGS PRESCRIBED IN COVID-
A PHARMACOVIGILANCE PRESPECTIVE

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Introduction
Post-marketing assessment of medicines is needed to look for drugs safety profile in real-world setting and filling the evidence gap of pre-marketing studies. COVID-19 pandemic highlighted relevance of pharmacovigilance and proper risk communication during public health emergency as there was accelerated approvals of drugs and vaccines to tackle the COVID-19 pandemic. Advanced methodologies including machine learning techniques, artificial intelligence and electronic healthcare data help in calculating drug benefit-risk profile evaluation in real world setting.
Methodology
After thorough literature search through search engines including Pubmed, Cochrane, Embase, Medline, various drugs repurposed in COVID-19 were compiled and detailed analysis was done.
Results
Various database network was used to monitor the post-marketing safety of vaccines, medicines and biological drugs to generate real-world evidence to support decision-making. Hydroxychloroquine, ivermectin and azithromycin have been off-label used for the treatment of COVID-19 patients, even though scientific evidence on benefits was of low quality and mostly based in vitro studies. Azithromycin depicted proarrhythmogenic activity which was exacerbated when used in combination with hydroxychloroquine for the treatment of COVID-19 patients. It led regulatory agencies to issue warnings against the use of this drug, unless in case of bacterial superinfection occurrence. Hydroxychloroquine despite its efficacy was not proven, it was promoted by Donald J Trump, US President which led to inappropriate drug use and increased risk of serious adverse drug reactions.
Conclusion
As accelerated approvals of drugs and vaccines to treat the COVID-19 pandemic led to severe adverse drug reactions, it

emphasizes that it is mandatory to do extensive post-marketing surveillance in cases of drugs which get accelerated approvals to ensure patients' safety.

Abstract

"Adverse Reaction Monitoring following Corona Virus Disease (COVID-19) Immunization among Health Care Workers of a Tertiary Care Hospital"

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Introduction

Background & Objectives: With unprecedented and devastating impact of Corona Virus Disease (COVID-19) pandemic on public health, the roll out of vaccination strategy against COVID-19 disease was carried out to overcome this catastrophe as early as January 2021 in India. Since there is a dearth in research studies about the adverse event following immunization (AEFI) associated with COVID-19 vaccination, the present study was aimed to determine the incidence and types of adverse events (AEs) following COVID-19 vaccination among healthcare workers (HCWs).

Methodology: It was a prospective, observational study conducted among the HCWs of a tertiary care hospital who received the first dose of the ChAdOx1 nCoV-19 vaccine between January-March 2021. Systemic and local AEs experienced up to first 24 hours of vaccination were surveyed using Google form. Descriptive statistics was used for the categorical variables and Chi square test was for qualitative variables.

Results: Of total 1045 HCWs who were vaccinated, 666 HCWs responded completely to the Google form. Majority (79.3%) of the participants were in the 18-30 years age group. The most commonly reported AEFI were pain at the injection site (68.8%), fatigue (40.1%), myalgia (35.4%) and malaise (35%). Among the systemic AEs, the incidence of fatigue and among local AEs, incidence of pain at injection site was considerably greater in the 18-30 years age group than in the other HCWs group ($p < 0.001$). However, severity of most AEFI was mild-to-moderate in nature.

Conclusion: AEFI associated with the ChAdOx1 nCoV-19 vaccine after single dose were safe and tolerable. Maximum participants experienced AEFI, which were accepted by them owing to the fact that minor reactions would be common and treatable.

TO EVALUATE THE SAFETY OF INTRAVENOUS IRON FERRIC CARBOXY MALTOSE (FCM) IN THE MANAGEMENT OF SEVERE IRON DEFICIENCY ANEMIA(IDA) IN A TERTIARY CARE HOSPITAL.

AUTHORS: -

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ABSTRACT

INTRODUCTION: - BACKGROUND

Nutritional iron deficiency anaemia (IDA) is the most common nutritional deficiency disorder in both the developed and developing world.

In 2022, global anaemia prevalence was 16.4% in women of reproductive age.

OBJECTIVE: The present study is to Study the safety of ferric carboxy maltose (FCM) in the treatment of Severe Iron deficiency anaemia.

MATERIALS AND METHODS: -

It is an open-label, prospective, observational study.

Duration February 2023 to April 2023. Total of 25 patients were included in the study.

After exclusion ,10 Pregnant women attending for antenatal check-up between 16- and 36-weeks period of gestation, 5 Patients with Hb > 6 g/dL and 10 patients <10 g/dL due to menstrual blood loss were enrolled for the study. After Calculating total iron deficit, patients were administered IV FCM.

RESULTS: -

1– Ferric carboxy maltose significantly increased haemoglobin in women with moderate, and severe iron deficiency anaemia at 3–6-week post-infusion.

2- No serious adverse events were recorded in this study.

3- Moderate reaction with shortness of breath for intermittent days is recorded in 1 patient due to fast infusion rate. This can be avoided by gradually slow infusion rate.

4- Minor temporary side effects like Skin discoloration (including local skin irritation, nausea, and headache) occurred in 15pts.

CONCLUSIONS: -

FCM is a safe intravenous agent in pregnancy and severe anaemia in reproductive age group due to menstrual blood loss.

The management of iron infusions requires meticulous observation, and, in the event of an adverse reaction, prompt recognition and severity-related interventions must be done by well-trained medical and nursing staff.

DOLUTEGRAVIR INDUCED SUPRAVENTRICULAR TACHYCARDIA

Authors: Dr. Bakul Naik1, Dr. Neha Kadhe2, Dr. Swati Patil3, Dr. Sudhir Pawar4

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Dolutegravir (DTG) is integrase inhibitor commonly used as first line drug for the treatment of HIV infection. Its mechanism is blocking of catalytic activity of the HIV-encoded integrase of HIV-1 and HIV-2, preventing integration of viral DNA into the host chromosome.

Common adverse effects of DTG are diarrhoea, nausea, headache, and nasopharyngitis as noted in DTG trials. But CVS related ADR are not known. Only a single case of cardiomyopathy after treatment with DTG was reported in the FLAMINGO trial.

In this study are 3 case reports of Supraventricular tachycardia (SVT) that were reported to ADR Monitoring Centre of a tertiary care hospital. The causality in one case was evaluated as 'Possible' and two other reactions were evaluated as 'Probable' according to WHO-UMC Scale. All of the reactions were evaluated as 'serious' and none of them were 'Preventable' according to Modified Schumock and Thornton scale. The mechanism of DTG induced SVT is not completely clear. The possible mechanism could be due to direct toxicity to myocyte Alternative theory is due to increased amounts of retroelements that can stimulate the innate immune syndrome. It is evident that a subset of HIV-infected patients is prone to the development of severe, potentially fatal drug-related toxicities after initiation of DTG. The aim for presentation is to make physicians aware of drug related toxicities. And as DTG is used in first line regimens, occurrence of such reaction raises a question of further use of the drug and looking for alternative regimen.

Hypersensitivity Reaction due to Lignocaine Hydrochloride : A case series

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ABSTRACT

Introduction: Lignocaine Hydrochloride is the preferred anaesthetic agent used in surgical procedures. Hypersensitivity reactions are exaggerated immunologic reaction occurring in response to exogenous and endogenous substances.TRIPLE RESPONSE is an immediate type Hypersensitivity reaction having cutaneous response due to release of histamine which is a dibasic vasoactive amine located in skin and other body tissues

Material & Method: Suspected ADRs due to Lignocaine Hydrochloride were reported from Obstetrics and Gynaecology Dept. The ADRs were filled in Suspected ADR reporting form and as per WHO-UMC causality assessment scale causality was assessment was done and ADRs were reported through vigiflow to Indian Pharmacopeia commission, Ghaziabad.

Result: A case series of hypersensitivity reaction due Lignocaine Hydrochloride is presented. First one is 40-year-old-female admitted for Vaginal hysterectomy with perineal floor repair under surface anaesthesia. Second one is 24 -year- old female admitted for Tubal Ligation under surface anaesthesia and third one is 21 -year- old female admitted for resuturing of incision site under surface anaesthesia. All these patients experienced triple response after the injection was given.

Conclusion: It is important for practitioners to be aware that allergic reactions though very rare, can occur after after injection of lignocaine intradermally for allergy testing. A proper diagnosis and management of such allergic reaction is very essential to avoid undesired consequences. `

Keywords: Hypersensitivity, Lignocaine Hydrochloride, Triple Response.

Title: **Fluoxetine induced hepatomegaly- A case Report**

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2. Dr. Jarnail Singh- Professor, Department of Pharmacology, PGIMS, Rohtak
3. Dr. Suneel Kumar- Assistant Professor, Department of Pharmacology, PGIMS, Rohtak

Introduction- SSRI's precipitate drug induced liver injury, especially in patients with pre-known liver dysfunction which is much less than other antidepressants, fluoxetine with only 0.02%. In this case fluoxetine causes marked hepatomegaly without any previous history of liver dysfunction.

Case- Patient named Harjeet Kaur 37 years old female resident of Manna (Punjab) had complaints of headache, generalized weakness, sad mood, decreased appetite and insomnia after a febrile illness which last for 7 days. Patients was prescribed with capsule Fluoxetine (Fludac) 20 mg HS. Along with this only PCM 650 was given twice a day for 5 days. After approximately 2 months of taking Fluoxetine patients started complaining of pain abdomen right side which was radiating to back. Patient is known case of renal stones, so doctor prescribed her with ultrasound whole abdomen with other significant blood tests.

Result- On ultrasound report marked hepatomegaly (enlarged liver measuring 17.3cm) was found accidentally

with normal echo texture of liver. Right renal calculi were also seen as patient is known case of renal stones. No significant other finding was there on examination and investigation which can rule out the other cause of hepatomegaly.

Conclusion- This is case of fluoxetine induced hepatomegaly within 2 months of intake of drug with no other findings to rule out other cause of hepatomegaly.

PROPOFOL INDUCED FEVER

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Abstract:

Propofol, an intravenous anaesthetic, is commonly used for procedural sedation and as an induction agent for general anaesthesia. Use of propofol is often accompanied by febrile episodes which are often self- limiting and can be attributed to a variety of causes.

This case series was made encompassing 18 cases of fever reported over 7 years (2014-2020) to the ADR Monitoring Centre of a tertiary care hospital. Mass adverse drug reactions were seen among paediatric patients posted for MRI, each of which had received propofol among other drugs. The causality, seriousness and outcomes of each case was determined.

All the patients had fever as a common symptom while convulsions, flushing over face, chills, dyspnoea, hypotension, etc were also seen. The causality in all cases was evaluated as 'Possible' and all reactions were classified as 'Serious'. 17 patients recovered while 1 patient had a fatal outcome.

Propofol, prepared in a medium of containing egg lecithin and glycerol, is a good culture medium for bacteria and hence, in absence of aseptic precautions, this drug is prone to bacterial contamination resulting in adverse events on administration.

The occurrence of these reactions did raise the question if fever was a result of vial contamination and has promoted certain changes in practices such as aseptic precautions during handling and storage of drug, using smaller vials for single use, limiting the time of propofol infusion and avoiding use of open vials that have faced prolonged environmental exposure.

ANTI SNAKE VENOM INDUCED ANAPHYLACTIC REACTION: A CASE REPORT

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ABSTRACT

Introduction: Adverse reactions to snake antivenom are widespread in many places of the world where snakebite is common .Mortality due to snakebites and

serious adverse reactions to anti-snake venom (ASV) are both underreported in India. Antivenom is an immunoglobulin usually pepsin refined F(ab)2 fragments of IgG purified from the serum or the plasma of a horse or sheep that has been immunized with the venom of one or more species of snakes which is given to prevent snake venom from binding to tissues causing serious blood, tissue, or nervous system problems. In India only polyvalent ASV is available. Benom vial of 0.0021gm powder is a polyvalent ASV.

Material & Method: Suspected ADRs due to anti-snake venom were reported from the emergency department .The ADRs were filled in Suspected ADR reporting form and as per WHO-UMC causality assessment scale, causality was assessment was done and ADRs were reported through vigiflow to Indian Pharmacopoeia commission, Ghaziabad.

Result: A case report of anaphylactic reaction due to anti-snake venom was presented. A 12-year old male with history of snake bite presented with neurological symptoms such as pupil mydriasis, ptosis and treated symptomatically with Antisnake venom but after half an hour anaphylaxis reaction occurred due to Antisnake venom. Symptomatic treatment was given and patient was recovered.

Conclusion: Snake bite is a medical emergency faced mainly by rural populations. Anaphylaxis reactions are rare and are dependent on the patient's inherent characteristics which cannot be modified. As a clinician, it is our responsibility to report these reactions to ensure treatment at right time to right patient with right drugs and doses.

Keywords: Adverse reaction, anti-snake venom, Anaphylaxis

Covid 19 and it's long term detrimental effects

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Introduction

Coronavirus disease 2019 (Covid-19) pandemic has affected the lives of millions of people globally in one way or the other. It manifests itself with presentation ranging from asymptomatic or mild to life-threatening and fatal disease.

During this period of three years, the main target of healthcare system has been to address acute phase of disease and to save the population. However, the long term health consequences of COVID-19 have been observed consistently, with multi-organ system impacts which need attention. This chronic illness has been described as 'Long-Haul COVID-19'. The primary objective of the present review was to study the long term complications of Covid 19.

Methodology

Databases including PubMed (MEDLINE), Scopus, the World Health Organization Global Literature on Coronavirus Disease were searched from January 2020 to October 2022.

Results

Long term effects of covid 19 involve multiple organ systems. Many long term effects of Covid-19 were reported including skin disorders, gastrointestinal, renal, haematological, pulmonary cardiovascular, neurological, psycho-social and other miscellaneous effects, with symptoms ranging from fatigue, breathing difficulty, pain, sleep disturbances, loss of taste and/or smell, cognitive changes and decreased quality of life, depression to serious organ dysfunctions including pulmonary fibrosis, myocarditis and renal failure.

Conclusion

The present study indicates that clinical management of post-acute and chronic consequences of COVID-19 require multidisciplinary clinics under one roof. These should include specialists from pulmonary medicine, cardiology, neurology, neuropsychiatry and also general physicians. The involvement of physiotherapists, dieticians, occupational therapists and experts from other allied fields also may be required along with the clinicians.

Key words: Long term Covid 19, multidisciplinary approach.

A case report of Metoprolol induced Fixed Drug Eruption

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Rationale:

Metoprolol induced fixed drug eruption is a very rare case. Only 7 incidences of FDE due to Metoprolol reported till now on VigiAccess.

Patient concern (Case summary):

A 48 years old male patient diagnosed first time with hypertension and was prescribed Tab.Metoprolol 25mg twice daily. On the 5th day of intake of oral metoprolol patient developed single skin lesion over left hand with itching. Apart from Metoprolol, no any concomitant drug was started.

Diagnosis:

This reaction was diagnosed as Fixed Drug Eruption(FDE) based on clinical picture and drug history.

Interventions:

He was advised to stop taking Tab.Metoprolol and prescribed him Tab.CPM 4mg twice a day and Betamethasone & framycetin cream for local application twice a daily for 5days.

Outcome:

After stopping of metoprolol and with interventions, patient was recovered after two days.

Conclusion:

- We are presenting a very rare case of fixed drug eruption caused by Metoprolol, which is commonly use for many cardiac conditions.
- Therefore, reporting of such events is utmost necessary, efficient pharmacovigilance holds the key in this regard.
- Clinicians should be aware of the presentation, diagnostic criteria, and treatment options for this kind of rare adverse drug reactions.

Title: Assessment of Knowledge, Attitude, and Practice (KAP) on Over-the-Counter (OTC) Drugs Among Medical & Nursing Students: A Cross-Sectional Study

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Co-Authors – Dr. Harshal Pise
Presenter: Dr. Divya Raj
Designation: Junior Resident 2
Department: Pharmacology
Name of College: Government Medical College, Nagpur
Name of PG Guide: Dr. Harshal Pise

Introduction:

Context :Many types of antibiotics, mild-analgesics, and many of the anti-inflammatory drugs are all available OTC. Self-medication assumes a special significance among nursing ,pharmacy and medical students as they are the future health care practitioners and have a potential role in counselling their patients about the advantages and disadvantages of self-medication.

Objective : Assess the knowledge, attitude, and practice of medical and nursing students towards OTC medication use . To know why they self medicate and what influences their choice for the same

Settings and Design: A cross-sectional study is done online through Google forms for a period of 2 months from feb to march 2023

Materials and Methods: A structured questionnaire containing a five-point Likert scale was sent to medical & nursing students across Maharashtra by sharing link. Descriptive statistical analysis was carried out

Results: A total of 161 students (61% mbbs and 34% nursing) took part in the study. Around 84.4% students responded that they frequently self medicate.Most common illness for which they self medicate include fever & headache(56.4%) followed by cough & common cold(27.5%),dysmennorhea,dyspepsia,abdomen cramps.Unwillingness to wait outside the OPD for minor illness (64.5%) are some of the main reasons to self medicate

Conclusion: In this study lack of knowledge regarding storage of OTC medication, it's expiry & doubling the dosage of medications. Measures should be implemented for the safe use of OTC drugs in order to avoid events associated with the lack of knowledge related to usage.

PARACETAMOL AND MEFENAMIC ACID INDUCED STEVEN JOHNSON SYNDROME

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Introduction: Steven Johnson Syndrome (SJS) is an immune hypersensitivity complex that typically involves skin and mucous membrane. It is a minor form of toxic epidermal necrolysis with less then 10% percent body surface area involvement.

Aim &Objective: To report the case of SJS with paracetamol and mefenamic acid.

Case Report: We present a 8-year-old female child who developed SJS after being administered paracetamol and mefenamic acid syrup for a short period. Given the patient's past profile, she went to local doctor for fever and was under treatment with paracetamol and mefenamic acid. Irrespective of any symptoms of SJS in the past, she started developing symptoms soon after being treated with this syrup giving us a clue about paracetamol and mefenamic acid induced SJS.

Results: This is a case report of Paracetamol and mefenamic acid induced skin reactions like SJS.Causality assessment of this event with Naranjo' scale suggests Probable .

Summary: Steven Johnson syndrome is a rare mucocutaneous disorder. The drugs inducing SJS are mainly antibiotics, such as ampicillin, Vancomycin.Other drugs involved are non-steroidal anti-inflammatory drugs, such as Paracetamol, mefenamic acid and ibuprofen. There are 9 cases reported in vigi-access for SJS for fixed drug combination of paracetamol and mefenamic acid.

Conclusion: NSAID group, like Paracetamol and mefenamic acid, is a commonly prescribed drugs in developing countries due to efficacy and cost-effectiveness. Physicians must be careful of the consequences while advising patients, and tell them to visit the hospital with even slightest cutaneous manifestations.

Key Words: Paracetamol, Steven Johnson syndrome, Mefenamic acid.

Aceclofenac-Paracetamol Induced Erythema Multiforme: A Case Report

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ABSTRACT

Introduction: Aceclofenac and Paracetamol belong to a group of medicines known as nonsteroidal anti-inflammatory drugs (NSAIDs). Aceclofenac mainly acts as an anti-inflammatory drug whereas Paracetamol has primary antipyretic action. The widespread use of NSAIDs lead to an increase in the number of adverse effects. Presently, the major adverse effects of NSAIDs are GI complications, renal disturbances and CV events. Various drugs like antibiotics, antiepileptics and antitubercular drugs are known to cause skin reaction whereas Nonsteroidal anti-inflammatory drugs causing serious complications are very rare and only few case reports are published.

Methods: We report a case of Aceclofenac-Paracetamol induced Erythema Multiforme after single dose administration of this combination.

Results: On examination, multiple well defined erythematous papules and plaques with central necrosis (target lesions) were present over the back, chest and limbs. Few erythematous papules present over palms and soles. In the oral cavity, Erythematous plaque was present over the tip of tongue. Hence, it was diagnosed as Erythema Multiforme by the above findings.

Conclusion: Our findings in the present case highlight a potential adverse effect of Aceclofenac-Paracetamol. Such reactions, although rare, can drastically impact patient's health. So, the health care professionals should be vigilant while prescribing the drug.

Key words: Aceclofenac, Paracetamol, NSAIDs, Erythema Multiforme, Adverse effects.

ABSTRACT

TITLE: A Comparative study of fixed dose Combination of Vildagliptin and Glimepride with Metformin in type 2 Diabetes Mellitus Patients.

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Introduction: In Present study investigated the efficacy, safety and treatment satisfaction. **Material & Methods :** This is a prospective study of 300 subjects were divided into two groups: A and B, In group A 150 subjects (Patients) received a fixed dose combination of (Vildagliptin 50 mg+Metformin 500 mg) and 150 subjects in group B received a fixed dose combination of Glimepride (2 mg+Metformin500 mg) for 6 months. Fasting blood glucose, postprandial glucose, HbA1C were evaluated within the interval of every 3 months.Two parameter safety and efficacy were evaluated by reporting adverse events.Patient satisfaction was assessed by Diabetes Treatment Satisfaction Questionnaire and assessment of diabetes-dependent quality of life (ADDQoL). **Result & Conclusion:** HbA1C reduction less than 7% at week 24 was 52% in the Vildagliptin group (A) and 48% in the Glimepiride group (B) was examined. Lower incidence of hypoglycemia was observed in Vildagliptin group (A).Subject of this group were facing lower risk of hypoglycemia,weight gain, flatulence, Abdominal bloating/discomfort &

Giddiness.Vildagliptin offer a superior benefit and better score over Glimepiride in the management of Type 2 Diabetes Mellitus.There was a significant reduction seen in groups (p value - Group I <0.0001, 99.9%, Group II < 0.005, (95.0%). Significance was assessed at 4% level of significance.

Excipients- Are they safe?

A case series of cutaneous adverse drug reactions.

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Background

Tuberculosis is a very common disease in India and is treated with multiple drugs in fixed dose combination in a single tablet, which has an active drug component and an excipient component, so adverse drug reactions due to these can be caused by either the active drug component or the excipient component.

Objective

To understand that even excipients like colouring agents, titanium dioxide and red oxide of iron added to fixed dose combination could provoke adverse reactions.

Methodology

This is a case series study of four cases which presented with cutaneous adverse drug reaction on taking fixed drug combination. Fixed drug combination was stopped and individual drugs were rechallenged.

Result

On rechallenging with individual drugs, no adverse drug reactions were seen. The patients tolerated individual drugs and the course of antitubercular therapy was completed successfully.

Conclusion

Fixed drug combination of antitubercular therapy developed cutaneous adverse drug reaction in all four patients but these patients had no adverse reaction on rechallenging with individual drugs. So its concluded that excipients are the probable cause of cutaneous adverse drug reactions.

TITLE- Hypothalamus-pituitary-adrenal axis (HPA axis) suppression with inappropriate use of steroids in recalcitrant dermatophytosis- A cross-sectional study

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ABSTRACT:

INTRODUCTION

Improper use of OTC (over the counter) steroid medication may lead to recalcitrant dermatophytosis and HPA axis suppression. This study aims to determine the prevalence and pattern of inappropriate steroid use in dermatological practice and its effects on HPA axis suppression in adults with recalcitrant dermatophytosis.

METHODOLOGY

This cross-sectional study of 2 months included 103 patients of recalcitrant dermatophytosis with history of OTC corticosteroid use. Clinico-demographic details and basal serum cortisol levels were recorded in all the patients.

RESULT

Of 103 patients, 61 (59.22%) were males and mean duration of steroid abuse was 17.78 months. Among 103 subjects, 50 (48.54%), 4 (3.88%) and 49 (47.57%) patients reported the use of topical steroids, oral steroids, and both oral and topical steroids, respectively. Among all the topical (n=99) and oral(n=53) steroids users, clobetasol propionate (48.48%) and prednisolone (45.28%) were most commonly used agents, respectively. The morning serum cortisol levels (8-9 am) were found to be decreased in 44 (42.7%), elevated in 6 (5.8%), and within the normal range in 53 (51.5%) patients. The mean ± SD serum cortisol level was 12.46 ± 4.38µg/dl, 1.29 ± 1.04µg/dl, and 44.28 ± 17.34µg/dl in patients having normal, decreased, and increased levels, respectively. 51.51% and 35.35% of the total topical steroid group used ultra-high and high potency topical steroids, respectively. Among oral steroid consumers, long and intermediate-acting steroids amounted to 43.39% and 71.69%, respectively.

CONCLUSIONS

Significant proportion of the patients had below-normal serum cortisol levels, which is suggestive of HPA axis suppression.

Toxic effect predictions of polyphenol rich methanolic extract of aerial parts of *Pedilanthus tithymaloides* (L.) using acute and sub-acute toxicity in rats and ADMET modeling.

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Abstract

Background & Objectives: *Pedilanthus tithymaloides* (L.) Poit of family Euphorbiacea, is latex producing low tropical and subtropical shrub originated from North America (Mexico), Central America and south Asia. Traditionally *Pedilanthus tithymaloides* is used to treat wound healing, skin cancer, and also exhibits anti-inflammatory, antipyretic, antioxidant, antiviral, antitumor, antibacterial properties etc. The present study evaluated the potential toxicity of methanolic extract of *Pedilanthus tithymaloides* (PTME) and active constituents using acute and sub-acute oral toxicity and ADMET modeling approaches.

Methodology: Male rats were orally given PTME at single doses of 100, 500, 1000, and 2000 mg/kg during an acute toxicity investigation in accordance with OECD Guidelines

425. Wistar rats were given daily doses of PTME for 28 days in order to study its sub-acute toxicity. In this study, the targets of bioactive constituents of *Pedilanthus tithymaloides* and their toxicities were also screened using an ADMET investigation.

Results: At the tested doses, the acute toxicity research found no behavioural indicators of toxicity and no lethal consequences, indicating that the LD_{50} is higher than 2000 mg/kg. A substantial decrease in body weight ($p<0.05$) was seen in the sub-acute study. Lymphocytes, platelet counts, AST, and ALT all showed a substantial ($p<0.05$) rise. Male rats given 2000 mg/kg of PTME showed minor hepatic cell deformation. The ADMET studies revealed the toxicity profile of active phytoconstituents.

Conclusion: PTME found safe upto 2000mg/kg of dose based on acute and subacute toxicity studies. The ADMET attributes of a therapeutic molecule includes absorption, distribution, metabolism, excretion, and toxicity parameters. With the help of ADMET Approaches, possible toxicities predicted at the early stages of the drug discovery.

Keywords: *Pedilanthus tithymaloides* (L.), Toxicity predictions, ADMET modeling, acute toxicity, sub-acute toxicity.

LYELL'S SYNDROME INDUCED BY PHENYTOIN COMPLICATED BY RTA

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INTRODUCTION: Even after approval of the drug and coming to the market, there are many tragedies reported due to drug resulting in withdrawal of drug from the market for that particular indication. Eg: Thalidomide tragedy. In order to monitor this, there should be vigilant people who should identify the adverse reaction of the drug and to report in an expedited way to the authorities concerned.

CASE: A 18 Year old patient had a history of road traffic accident (RTA) followed by seizures. He was admitted in the hospital and prescribed Inj. Phenytoin 900 mg IV stat followed by Tab. Phenytoin 100 mg. Following the oral administration, patient developed fever and bullous lesions all over the body with oropharyngeal ulcer and eye infection. On examination, patient was found to have multiple vesicles over chest, abdomen, bilateral upper extremities, crusted erosion over lips and conjuctival congestion. Patient was stopped T. Phenytoin in suspect of phenytoin induced Lyell's syndrome. Patient was treated with pulse therapy of Dexamethasone (80 ml in 250 ml of 5% dextrose), Azithromycin, Paracetamol infusion, Tobramycin eye drops and ointment. For the seizure complaint, the patient was started on Inj. Levetiracetam infusion.

CONCLUSION: Phenytoin should be stopped at the onset of development of rash and genetic cause (HLA-B*1502 and HLA-A*3101) should also be borne in mind as the suspectibility increases with genetic etiology. Preventive measures should be educated to the patient as RTA also increases the risk of seizures.

ATT induced Cutaneous Adverse Drug Reaction-A Case Report

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ABSTRACT

Introduction: Tuberculosis is a major global health problem and has been the major cause of mortality and morbidity worldwide. Antitubercular therapy(ATT) has been associated with various adverse effects like hepatitis, flu-like symptoms, arthralgia and Cutaneous adverse drug reactions(CADR) which may range from mild rash to life threatening Toxic Epidermonecrolysis(TEN). Despite the high effectiveness of ATT, serious adverse reactions induced by these drugs are the reason for the discontinuation of ATT in most patients.

Methods: We report a case of ATT induced Cutaneous adverse drug reaction in a tertiary care hospital.

Results: On examination, diffuse erythematous blanchable maculopapular rash were present over trunk, bilateral extremities. Palms and soles were also involved. Erosions with crusting was observed on the lips. It was diagnosed as ATT induced Cutaneous Adverse Drug Reaction.

Conclusion: Cutaneous adverse effects are a late manifestation of ATT regimen. Although rare, they are a cause for concern as it decreases compliance and requires modified ATT regimen. The condition can be improved by discontinuing ATT and starting systemic corticosteroids. Safer alternative ATT therapy should be opted and monitored for any further CADR. Hence, Physicians must be judicious while prescribing ATT.

Key words: Tuberculosis, ATT, Cutaneous Adverse Drug Reaction, Adverse effects.

Title: Knowledge, Awareness and Attitude of Pharmacovigilance among interns, residents and faculty of Tertiary care hospital of South Asia.

Authors:

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Abstract:

Introduction: Pharmacovigilance (PV) aims to ensure the safety of drugs and vaccines establishing the drug's efficacy. The study aims to evaluate the level of knowledge, attitude,

and perception of adverse drug reporting (ADR) and PV among interns, postgraduate residents, and the faculty in Tertiary Medical Hospital.

Methods: A questionnaire-based, cross-sectional study was conducted among 150 participants directed to assess knowledge, attitude, and perception. Descriptive statistics were applied to analyze the data using SPSS version 24.0.

Results: Based on the pre-specified criteria, just 2% of the participants were well aware of PV. 20.67 were moderately aware and 77.3% were less aware. 82% of participants had encountered ADR in their practice. While only 44% knew how to report and 62% had known where to report. 81.3% believed ADR reporting is an essential task. However, 48.6% of participants had not reported any ADR form and 39.3% of participants were unaware of the reporting procedure. 58% preferred to report an ADR if encountered in the future.

Conclusion: This study documents perceptions of PV among various study participants and the need to report ADR. The study highlights the low awareness and the gap in the knowledge regarding PV necessitating training among healthcare workers.

Adverse drug reactions of Spesolimab: A systematic review of case reports

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Absract

Background - Spesolimab, a humanized anti-IL-36 receptor monoclonal antibody is the first targeted treatment for the various immune-mediated disorders. Currently, approved for the treatment of generalized pustular psoriasis flares in adults. The data regarding ADRs of Spesolimab are limited.

Objectives - This study aims to review case reports and case series on adverse drug reactions (ADRs) of Spesolimab.

Methods - The search was made using PubMed, Embase, MEDLINE, and Scopus databases. Articles reporting the adverse drug reactions, safety and efficacy data of intravenous (IV) Spesolimab in genralised pusular psoriasis published between October 2022 and April 2023 were retrieved and included in the study. Researches that used in-vitro and in-vivo animal studies, as well as reviews were excluded.

Results - The study identified various cases of Spesolimab associated ADRs in patients of genralised pustular psoriasis. The most frequent drug-related ADRs spesolimab vs placebo were skin rash (5.4%; 0%) followed by acne (4.1%; 0%), nasopharyngitis (13.3%; 0%) and headache was reported in one patient. The frequencies of infections and infestations in spesolimab was minimal. These data suggest that spesolimab does not lead to a risk of serious infection, even in immunosuppressed patients with GPP.

Conclusion - Spesolimab was also generally well tolerated in patients with GPP. Skin rashes, nasopharyngitis and acne were the more frequently reported adverse drug reaction associated with Spesolimab. These data are consistent with studies in other inflammatory disease.

Keywords - Spesolimab, Generalised pustular psoriasis

Title: Ciprofloxacin-induced peripheral neuropathy in a diabetic patient – A case report with possible exploration of its mechanism of action

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Abstract:

Introduction: Peripheral neuropathy is a rare and serious adverse drug reaction to fluoroquinolones. However, its mechanism of action is not clearly known.

Methodology: In this case report, we tried to explain the various scientific perspectives related to the pathogenesis of ciprofloxacin-induced peripheral neuropathy, particularly in a diabetic patient.

Results: After receipt of a few cases of individual case safety reports (ICSRs) on Ciprofloxacin-induced peripheral neuropathy in a diabetic patient, we tried to assess the causative factors and mechanism of action of the reaction. The case reports derived from the designated ADR reporting forms are based on the findings we received at AMC, a program being run under the aegis of Indian Pharmacopoeia Commission (IPC) which is known as 'Pharmacovigilance Programme of India (PvPI).

Conclusion: In our opinion, there are multifactorial causes that synergistically aggravate the ciprofloxacin-induced peripheral neuropathy condition in a diabetic patient.

Keywords: Ciprofloxacin, Diabetes, Peripheral Neuropathy

Zavegepant nasal spray-Novel treatment for acute migraine

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Abstract

Introduction: Migraine is a complex neurological illness. It often has a pulsating or throbbing sensation, lasts 4–72 hours, and is accompanied by neurologic, gastrointestinal, and autonomic symptoms. According to the Global Burden of Disease Survey 2019, it can be a very disabling condition and is the second highest cause of years lived with disability among women under 50.

Background: Earlier migraine was thought to be a vascular condition but now we know that it is the result of neurogenic activation and inflammation It has been proposed that a neuropeptide called calcitonin gene-related peptide (CGRP) plays a role in the pathophysiology of migraine by dysfunctionally activating the trigeminovascular nociceptive system. Zavegepant is a novel CGRP antagonist which is being studied for treatment of migraine.

Objectives: To study the adverse effects and safety profile of zavegepant nasal spray.

Methods: The literature search was done on Pubmed, Medline and Google scholar; original research articles, review articles and clinical trials were included. The search was done on CGRP antagonists and zavegepant.

Results: The adverse effects were mild to moderate, dysgeusia (13.5% to 16.1%) followed by nausea nausea (2.6% to 4.1%) and nasal discomfort (1.3% to 5.2%).

Conclusion: Single doses of 10 or 20 mg Zavegepant nasal spray, was effective for the acute treatment of migraine, with a favorable safety profile,though more research is needed to establish its safety.