Journal of Pharmacovigilance and Drug Safety

An Official Publication of Society of Pharmacovigilance, India.

Abstracts

'SoPICON 2022' & International Conference on Safety of Medicines', 17th to 23rd September 2022

INVITED SPEAKERS

Pharmacovigilance of Biosimilars

Sunita Singh

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Abstract:

Biologicals play a major role in the treatment of autoimmune diseases like rheumatoid arthritis, inflammatory arthritis, diabetes, Cancer, Alzheimers disease and hepatitis etc.

In past few years, a number of biopharmaceuticals patents have expired or lost intellectual property rights including Granulocyte- CSF, erythropoietin, interferons and human growth hormones. It creates an opportunity for various biopharmaceuticals to produce similar biologics or biosimilars which costs less.

Biosimilar drugs are very similar to Food and Drug Administration (FDA) approved biolological products known as a reference product. They are synonymously also called Subsequent Entry Biologics (SEB), and Follow-on Biologics.

They are being produced by biopharmaceuticals as cheap alternatives to biologicals. Biosimilars provide better access to patients and reduce overall cost of treatment.

Biosimilars are large sized molecules, produced in living organisms. It is difficult to make exact copies of their reference protein. India approved its first biosimilar in 2000 for hepatitis B.

They are derived proteins having immunogenic reactions and risk of adverse events. Both biological and biosimilars are proteins, both have tendency of immunogenic potential. However, biosimilars have more adverse reaction episodes of immunogenic reactions as they do not go through the exact same regulatory approval when compared to reference drugs. Due to Insufficient analytical testing system prediction of certain activities or safety reactions in patients are lacking. Timely reporting adverse events is important. Extensive Pharmacovigilance program with standard and validated methods for detection of immunogenic reactions is needed.

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DOI: 10.21276/jpds.2020.19.02.06	

SAFE USE OF DRUGS IN PATIENTS WITH LIVER CIRRHOSIS

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Abstract

Introduction: Liver cirrhosis changes the pharmacokinetics of a large number of drugs, and there are also changes in the receptor systems of many tissues, so the effects of the drugs also change, and rate of adverse drug reactions increase for 30%.

Objective: To underline main principles of safe drug use in patients with liver cirrhosis.

Material and methods: Narrative review based on literature search from Medline database using the following key words: liver cirrhosis; drug dose adjustment; drug-drug interactions; adverse drug reactions.

Results/observation: Cirrhosis affects metabolism of drugs with both high and low hepatic extraction ratio (E_H), increasing the concentration of free drug in plasma and slowing elimination. Cirrhosis of the liver reduces the activity of the cytochrome isoforms CYP3A4 and CYP1A2, and medicines that are metabolized through these isoforms achieve a significantly higher concentration in plasma.

During cirrhosis of the liver, there is a gradual deterioration of the kidneys, primarily through a decrease in the number of functional nephrons. The Child-Pugh score correlates better with liver function than the MELD score, and it should be used to assess liver function when adjusting drug doses in patients with liver cirrhosis.

There is a correlation between the size of the total daily dose of the drug and the probability of toxic effects on liver cells.

Drugs whose total daily dose does not exceed 10 milligrams are far less likely to cause damage to liver cells.

Conclusions: In order to achieve safe use of drugs in patients with liver fibrosis, it is necessary to adjust their dosing regimens to the degree of liver disfunction.

Vaccine Vigilance

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Abstract

Pharmacovigilance of vaccines or Vaccine vigilance is a science and system to evaluate the safety of vaccines in preclinical, clinical and post marketing settings throughout the life cycle -whereby analysis of adverse events can be used to minimize risk to the subjects. Information on adverse reactions can help the health care providers (HCPs) and patients to make an informed choice about the use of the product and its benefit-risk ratio. The global vaccine market was predicted to touch USD 48 billion in 2025, however it has already reached USD187 billion in 2021 with Covid-19 vaccines contributing USD 137 billion and it is predicted to grow at a CAGR of 10.8 % in the future in North America and Asia pacific regions dominantly. The Covid-19 pandemic has triggered a public health emergency, where-by newer technologies like m-RNA have advanced rapid development of vaccines and antibody cocktails approved for emergency use authorization (EUA) by regulators globally. Newer adapted vaccines with Omicron variants have been approved without clinical trials based on previous trial data. As of July 2021, about 108 covid -19 vaccines were under clinical development, 184 in the preclinical phase and 21 vaccines were WHO approved! This has further reinforced the need for stringent Vaccine vigilance by sponsors and regulatory agencies globally, requiring large sample size trials (N=3000) and more post-licensure studies in extremes of age or special patient groups. Vaccines differ from drugs as they are preventive, while drugs are curative. Vaccine related adverse events are immunologic, while drug reactions are undesirable and organ related. The immunization inequity gap and vaccine vigilance gap needs to be addressed globally, as 50% of the 20.8 million unvaccinated children are from South Asia and Africa with poor PV facilities. A child receives 37 shots or more from birth through 6 years of age and vaccine safety has a very narrow margin for error. Higher valency vaccines like HPV (9 valent) and newer Pneumococcal conjugate vaccines (15 &20 valent) are licensed while (24&25 valent) are being developed to increase strain coverage with support from Gates Foundation, UNICEF, WHO and GAVI. These innovations will further bring about a increase in adult immunization and demand a complete vaccine -vigilance system and risk mitigation. The author discusses methods for vaccine adverse events detection, international agencies, important case reports and some real time case reports to bacterial, viral and pandemic vaccines across the globe.

Pharmacovigilance and Undergraduate Medical Education

Misbahuddin

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Abstract:

Adverse drug reactions (ADRs) are one of the leading causes of mortality and morbidity worldwide, and responsible for increased healthcare burden. Pharmacovigilance (PV) as defined by the WHO is the “science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem”.

To minimize the incidence of ADRs, the importance of incorporating some elements of PV in undergraduate curriculum is being increasingly recognized. Medicine and clinical pharmacy graduates are expected to face complex challenges related to prescription and treatment monitoring, especially with the swift arrival of newer medications on a regular basis and repurposing of older medicines for newer indications.

Though PV training modules are available with some organizations and societies like EMA, UMC, FDA, MHRA, TGA, Eu2P, ISoP and so on, but most of these courses are for professionals working in the field of clinical research and PV. The reception of these courses in undergraduate medical pedagogy is still unconvincing.

Nonetheless, some acquaintance to PV is given in undergraduate curriculum, but it is mostly ‘academic’ with less emphasis on practical aspects. In addition, the credit hours allotted are very less. There are reports that most of the medication and prescription errors are in initial career stage after graduation, and a supplementation of PV component during the final years of undergraduate curriculum helped them in rational prescribing.

Hence, there is a high need to formulate a credit-based core PV curriculum during undergraduate training, and it should be customized according to the country's needs depending on its own medication safety issues and PV program. Furthermore, it becomes extremely prudent in low resource setting, and countries with a poorly regulated drug market.

Keywords: Side effects; Monitoring; Hospitalization; Disability; Curriculum; Teaching

PHARMACOVIGILANCE PROGRAM OF INDIA

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Abstract

Introduction: A standardised and effective pharmacovigilance and drug safety monitoring programme for the country is essential in a large country like India with a population of over 1.2 billion people, with different disease prevalence patterns, the practice of different systems of medicine, and a wide range of socioeconomic status, ethnic diversity.

Aim – To ensure that the benefits of the use of medicine outweigh the risks and thus safeguard the health of the Indian population. Objectives –

- To monitor Adverse drug reactions (ADRs) in the Indian population
- To create awareness amongst health care professionals about the importance of ADR reporting in India. • To monitor the risk-benefit profile of medicines.
- To generate independent, evidence-based recommendations on the safety of medicines.
- Support the CDSCO in formulating safety-related regulatory decisions for medicines.
- Create a national centre of excellence at par with global drug safety monitoring standards
- To work together with other national centres for the exchange of information and data management. • To offer other national pharmacovigilance centres throughout the world training and consulting help. • Communicating findings with all key stakeholders

Material and Methods –

- Active Surveillance
- Passive Surveillance
- Ad hoc studies

Conclusions:

- Systems for pharmacovigilance are required to protect the public's health.
- Pharmacovigilance techniques must be able to identify the patients who are most at risk when taking a medicine.
- If medications are to be used responsibly, a well-functioning Pharmacovigilance system is essential.
- Monitoring medications for risk will be beneficial for medical practitioners, regulatory bodies, pharmaceutical businesses, and consumers.

Implementation and evaluation of the effectiveness of Jigsaw method in enhancing students' knowledge and communication skills among Phase 2 MBBS students: An educational Interventional study

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Abstract

Background:

Indian Medical Graduates (IMGs) are self-directed and lifelong learners. Teaching learning methods transform them from dependent learners to active independent learners. There has been a shift in teaching methods from teacher centric to student centric approach. In Cooperative learning students work together as a team, interact to achieve common goal. Jigsaw is one of the methods which teach to work in small groups as a team. This method enhances independent learning, confidence and communication.

Aims & Objectives of the study:

1. To implement jigsaw classroom teaching method for teaching Pharmacology to phase II students.
2. To assess the knowledge acquired by students using the Jigsaw learning method
3. To obtain the faculty and students perception toward cooperative group activities.

Methodology: After Institutional Ethical Committee permission a departmental meeting was conducted to sensitize the faculty. Test and feedback Questionnaire were prepared. Students were divided into two groups. An interventional crossover of teaching learning method in which one group was taught using jigsaw teaching method and another with the conventional way of teaching, the study was conducted in 2 batches of 30 students each and the data was analyzed. The crossover was done to avoid deprivation of the students from any of the teaching methods. Cognitive domain was assessed by MCQs.

Results: There was improvement in knowledge of students as shown from results of post test. More than 86% faculty and more than 80% students rated JIGSAW methodology >3 at Likert scale.

Conclusion:

• Learning of the students was enhanced by JIGSAW method.

•Students found it more enjoyable, interactive, comprehensible and easy to retain.

Key words: Cooperative learning, Jigsaw, Indian Medical Graduate (IMG)

Effect of Fenofibrate and Gemfibrozil in Sodium Nitrite Induced Anterograde Amnesia in Male Wistar Rats

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Abstract

Objective: The present study was planned to study the effect of fenofibrate and gemfibrozil on Sodium nitrite induced anterograde amnesia in male Wistar rats.

Methods: Anterograde amnesia was induced by 75mg/kg of sodium nitrite in six groups (8 in each group) of male Wistar rats (150-180 grams). Fenofibrate (21mg/kg and 18mg/kg) and Gemfibrozil (108mg/kg and 21mg/kg) were used as test drugs. The paradigm used was

Morris water maze, where a hidden platform was kept for the rat to escape from the water. Rats were trained to locate a hidden platform by releasing them into water for four times a day for four consecutive days. The acquisition of this task was measured by noting the time taken to escape to the platform. On the sixth day of the study, retrieval of this learnt task was measured by noting the time taken to search for the missing hidden platform. The time taken by the rats during the acquisition and retrieval tasks in fenofibrate and gemfibrozil treated groups were measured and compared with disease control group. On the 6th day (Retrieval trial) only vehicle (distilled water oral) was administered to the groups.

Results: Fenofibrate and gemfibrozil completely ameliorated the anterograde amnesia. The mean escape latency time of both Fenofibrate and gemfibrozil administered rats was significantly reduced with respect to sodium nitrite group while, retrieval time increased significantly. However, the same group of rats showed significant retrieval of task memory. At the end of the study, we did not observe any abnormal behaviour or movement of rats, which may indicate that the drugs have been safe during the study. Also, no single mortality was recorded during the study

Conclusion: In the present study, fenofibrate and gemfibrozil ameliorated chemical hypoxia induced anterograde amnesia. Both can potentially inhibit oxidative stress induced neurodegeneration at the commonly prescribed clinical doses. In addition to their hypolipidemic effect they can also prevent modifiable risk factors of chronic neurodegenerative disorders. Further studies are needed to substantiate these findings.

Keywords: Anterograde amnesia, fenofibrate, gemfibrozil, sodium nitrite, Morris water maze.

Prescribing pattern of neutraceuticals in Oncology: An observational study

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Abstract

Introduction: Nutraceuticals are products found in foods and fruits that are also used as medicines besides used for nutrition. They provide physiological benefits and protection against chronic diseases. They include minerals, vitamins, amino acids, essential fatty acids, medicinal herbs or other dietary substances used as supplements eg. polyphenols, quercetin, co-enzyme Q and genistein are in use because of their chemopreventive potential.

Aim of study: To examine prescribing pattern of neutraceuticals in cancer patients.

Materials and Methods: The present cross-sectional, observational study was conducted in OPD of Oncology of GMC Jammu after getting approval from institutional ethics committee. Patients of either gender, diagnosed of carcinoma attending oncology OPD were included in the study. Fifty prescription slips were evaluated for the prescribing pattern of neutraceuticals. The data was analysed in percentages.

Results: Most of the patients were prescribed more than one neutraceuticals. Most commonly prescribed neutraceuticals were Vitamins (44%) which included Vitamin A, B complex, C, D followed by Minerals (36%), Essential amino acids (12%), Beta carotene (8%), Coenzyme Q (6%), Lycopene (6%), Curcumin (4%), Wheat grass (2%).

Conclusion: Neutraceuticals are being increasingly prescribed in cancer patients. In our study, vitamins were most commonly prescribed. Most of them have antioxidant potential. Neutraceutical use may increase in future because of their safety and therapeutic effects.

Title: Prescribing pattern in Oncology OPD in a tertiary care teaching hospital

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Introduction: Cancer is one of the leading cause of mortality. Drug utilization studies are important as they provide insight into issues like polypharmacy.

Aim: To examine the prescribing pattern in an oncology OPD.

Materials and methods: The present observational, cross sectional study was conducted in department of oncology, Government Medical College Jammu after obtaining approval from institutional ethics committee. Patients diagnosed of carcinoma, of either sex, age 18 years & above, on anticancer drugs attending oncology OPD were included in the study. The prescriptions were analysed for demographic profile, type of cancer, anti-cancer and other drugs prescribed, average number of drugs per prescription. The data was analysed in percentages.

Results: 60 patients (33 males, 27 females) were included in study. Most patients were of age >50 years (59%). Lung carcinoma (25%) was most common type of cancer followed by breast and gall bladder (15% each), cervix (10%), thyroid (10%), leukaemia (5%) and others carcinomas.

Total number of drugs prescribed were 253 (average 4.2 per prescription). Alkylating agents were commonly prescribed (16 %) followed by platinum compounds (12%), antimetabolites (10%), antibiotics (8%) and others. The adjuvant drugs prescribed were antiemetics (34%), analgesics were prescribed (32%), steroids (22%), proton pump inhibitors (28%), H2 blockers (14%), magnesium sulphate (12%), and cytoprotective agents (leucovorin, filgrastim, pegfilgrastim, mesna) (12%). Vitamins (30%),

antianxiety drugs (6%) and antibiotics (10%) were also prescribed.

Conclusion: Most of the patients were males and above fifty years of age. Cancer of lungs and breast were common types. Average number of drugs per prescription was 4.2. Alkylating drugs, platinum compounds and antimetabolites were frequently anticancer drugs used. Adjuvant drugs included antiemetics, analgesics, steroids and PPIs/ H2 blockers.

Urticaria and Contact dermatitis from Curcumin

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Abstract

Introduction

TURMERIC is a spice derived from the dried rhizome of the plant Curcuma longa, which is cultivated in India and Southeast Asia. As a spice, it gives a food such as curry its strong flavor and color. Turmeric has been purported to treat many medical conditions ranging from liver and stomach ailments to dyspepsia, diarrhea, and many inflammatory conditions. Curcumin is the component of turmeric that gives the spice its unique taste and yellow color and is thought to be responsible for turmeric's biologic activities. Rare cases of allergic contact dermatitis from curcumin have been reported among workers who dye animal furs, in a worker at a pasta factory, in an Indian spice miller, and from use of the Chinese herbal cream Chuu-ou-kou. In one patient's case, curcumin was noted to co-react during patch testing with ginger, cinnamic aldehyde, and cinnamic alcohol—spices with chemical structures similar to that of curcumin. In this paper we explore the adverse effects of curcumin, an active component of Curcuma longa on the skin.

Material And Methods: Databases including PubMed, Google Scholar, scopus were searched from 2000 to 2022 using the terms Curcuma longa, curcumin, together with skin allergy, urticaria, atopic dermatitis. The inclusion criteria were case reports, case studies, with special focus on contact dermatitis.

Results: Two categories of contact urticaria have been noted: (1) immunologic, which is IgE mediated, and (2) nonimmunologic, which is likely mediated by other inflammatory mediators, such as histamine, prostaglandins, leukotrienes, and substance P. The immunologic variant, as do other IgE-mediated responses, typically causes systemic symptoms and extends beyond the area of contact (eg, reaction to latex). The nonimmunologic variant typically does not cause extracutaneous reactions and stays confined to the area of contact. This nonimmunologic type may develop into chronic dermatitis

Conclusion: Contact urticaria from spices is relatively common. The immunologic variant is IgE mediated and is treated with avoidance and antihistamines. The mechanism of the nonimmunologic variant is not well understood; this variant can sometimes present as a combined eczematous and urticarial reaction. Causative agents usually produce an initial wheal and flare reaction followed by eczematous changes after repeated exposure. A few cases of allergic contact dermatitis (type IV hypersensitivity) have been reported. With the increasing use of this spice, we anticipate a rise in the cases of allergy to curcumin.

Keywords: Turmeric, Curcuma longa, curumin, contact dermatitis

National Pharmacovigilance Centre, Govt. Tibbi College Patna- an analytical evaluation of the scheme

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Abstract

The government of India is promoting AYUSH as equivalent to mainstream allopathic medicine for decades. Quality drugs with fair and equitable access to appropriate and the mass population are the ultimate goal of the department of AYUSH.

Ministry of AYUSH has recently introduced a central sector scheme of pharmacovigilance of Ayurveda, Sidha, Unani, and Homeopathy Drugs. There are 15 peripheral pharmacovigilance Centers of Unani in various Unani institutions all over the India under direct monitoring of the Intermediary Pharmacovigilance center (IPvC) at the National Institute of Unani Medicine, Bangalore, Karnataka. Basically, three-tier network of National Pharmaovigilance centre (NPvCC), Intermediary Pharmacovigilance Centers (IPvCC), and Peripheral Pharmacovigilance Centres (PPvCC) are designed to evaluate the medicines of ASU. NPvCC is obliged to report adverse drug reactions, misleading advertisements, and regular coordination with the higher center.

Although ADR reporting is quite slow but is necessary to evaluate the drugs being dispensed, and the quality of consultation being provided at hospital, Govt. Tibbi College, Patna. We are sure that within a few upcoming years this scheme will surely add to the quality evaluation of the Unani Drugs. Here at PPvC, Govt. Tibbi College, Patna we have reported hundreds of Misleading advertisements but only a few ADRs yet. Compounds of Asrol (*Rauwolfia serpentina*) and Dhatura (*Datura stramonium*) have been identified in a patient that causes noticeable ADR and was quite prominent. Other compound drugs like *Jawarish Jalinoos, Majoon Jograj Gogul, Safooof Hazim, Safoof chobchini, Qurse Mulayyin, Majoon Falasfa, Majoon Suranjan, Roghane*

Surkh, Khamira Abresham Sada, Habbe Shifa, and *Dawaus Shifa* has been reported for ADR. If allowed a detailed analytical presentation/ paper shall be presented.

Keywords: Pharmacovigilance; Unani Medicine; AYUSH; Ayurveda; Sidhha; Homeopathy

Evaluation of antibacterial utilization using WHO indicators at a tertiary care hospital in Nuh, Haryana

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Abstract

INTRODUCTION: Appropriate use of antibacterials has brought a revolutionary change in management of infectious diseases. Nowadays, inappropriate use leads to several problems including increased antibacterial resistance, adverse drug reactions, infection severity, increased cost of treatment and increased health care burden. Antibacterials drug utilization studies are valuable in overcoming the inappropriate and in promoting the appropriate use of antibacterials.

OBJECTIVES: Present study was done to estimate the pattern of antibacterial drugs utilization by using WHO (World Health Organization) indicators and to estimate the suspected ADRs (Adverse drug reactions) associated with antibacterial drug utilization.

MATERIAL AND METHODS: A Non-interventional, Prospective Crosssectional study was conducted among 200 OPD patients of SHKM, GMC, Nuh, Haryana for a period of 6 months. Simple random sampling technique was employed to select prescriptions during data collection. Data processing and analyzing was done using SPSS version 20.

RESULTS: 526 patients were screened and based on inclusion criteria 200 patients were included in the study, among them 96 were males and 104 females. There were 4.19 drugs prescribed per patient, of which 1.37 were antibacterials. Percentage of encounters with at least one antibacterial was 38% and percentage of antibacterials prescribed by generic name were 35%. A total of 0% of antibacterials were prescribed in injection form and 92% were prescribed from essential drugs list. Among 200 patients 5 ADRs were reported.

Conclusion: Use of antibacterials was not high but more efforts are needed to enhance the rational use of antibacterial drugs.

Keywords: Antibacterial Drug Utilization, WHO indicators, ADR.

Safety Parameters of Unani Herbal Medicines According to WHO: A Review

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Abstract

INTRODUCTION

Herbal medicines are used for the treatment as pharmaceuticals and food source as nutraceuticals till date. About 80% of population worldwide depend on herbal medicines for some aspects of their primary health care. Consumption of herbal medicines worldwide is an urge to determine the efficacy, adverse effect and safety of medicines. The herbal medicinal products are widely considered to be of lower risk compared with synthetic drugs; they are not completely free from the possibility of toxicity or adverse effects.

OBJECTIVE: To discuss the safety parameters of Unani medicines, in order to prevent and protect from adverse effects.

MATERIAL AND METHOD: Classical manuscripts of Unani medicine and scientific research papers.

DISCUSSION: There are a number of causes of adverse events to herbal medicines, which can be intrinsic and extrinsic toxicity. As the extrinsic toxicity associated with herbal medicines may result from contamination of products with toxic metals, misidentification, adulteration or substitution of herbal drug, or improperly processed or prepared products. WHO has made compulsory to do safety study of herbal drugs and food items before performing any research or experiments as per their guidelines. This includes determination of heavy metals, aflatoxin, pesticidal residue and microbial load.

CONCLUSION: Determination of efficacy, adverse effects and safety parameters of Unani medicines may help in diagnosis, treatment and prevention of various diseases in this era where there are a spectrum of diseases occur.

KEYWORDS: Safety study, Unani medicines, WHO

Environmental Pharmacovigilance

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ABSTRACT

We are living in an environment that is polluted not only by heavy metals, pesticides, and emissions from gasoline engines, but also with pharmaceutical chemicals. Some drugs lead double lives! Once APIs in administered medications have completed their intended purposes, they can take on renewed lives in environment. These pharmaceuticals enter into environment through various

routes causing harmful effects. Moreover, there is little concern and research to find adverse effects on environment, of particular drugs given at therapeutic doses. A number of regulatory bodies like FDA and European Union have set some cut-off limit for environmental concentration of drugs. In Clinical Trials, where many limitations like that of limited size, narrow population, narrow indications and short duration are observed, we also found evaluation of drugs on environment is practiced very minimally. The Risk Assessment procedure for new active pharmaceutical substances, their metabolites, and also excipients, is to be done. The issue of potential impact of pharmaceuticals on environmental, is emerging one, but not new. The US-FDA has regulated pharmaceuticals in environment since 1977 through environmental review process for NDA. In Europe, guidelines for ERAs have been available in draft since 1996, with most recent draft issued in June 2006 including recommendations for appropriate precautionary and safety measures to limit product's environmental impact. As a part of Good CT, studies on impact of particular drugs on environment should too be incorporated. The existing term 'Ecopharmacology' is too broad and not even defined in a clear manner. The term 'Pharmacoenvironmentology' seeks to deal with environmental impact of drugs given to humans and animals at therapeutic doses. Some concerns that need to be taken up under Pharmacoenvironmentology are that of drugs and their exact concentration in different components of environment including deterrent measures such as Ecofriendly techniques like bioremediation. In the present, we will try to explain the concept and definition with examples.

Keywords: Pharmacovigilance, Pharmacoenvironmentology, Ecopharmacology

Current status of ADR reporting by Government AMCs & Non- Government AMCs

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Abstract

Introduction: Adverse drug reactions (ADRs) have been reported to be among the leading causes of morbidity and mortality. Adverse drug reactions (ADRs) are unwanted drug effects that have considerable economic as well as clinical costs as they often lead to hospital admission, prolongation of hospital stay and emergency department visits. A standardized and effective pharmacovigilance and drug safety monitoring programme for the country is essential in a large country like India with a population of over 1.2 billion people, with different disease prevalence patterns, the practice of different systems of medicine, and a wide range of socioeconomic status, ethnic diversity.

Aim –To evaluate the current status of ADR reporting by Government/ Semi Government and Private Sector in India.

Objectives –

• To measure the frequency of ADR reporting by Government/Semi-Government AMCs in the year 2022.

• To measure the frequency of ADR reporting by NON-Government AMCs in the year 2022

Material and Methods –We visited the Indian Pharmacopoeia commission site where we searched for the ADR reporting status of AMCs in the year 2022.The data was obtained from the Indian Pharmacopoeia commission site and then entered into an excel sheet and the percentage was calculated.

Result: During this current year total of 43,449 ADRs were reported; of which 59% of ADRs were reported in Government/Semi-Government AMCs and 41% of ADRs were reported Non-Government AMCs.

Conclusions: • To improve the efficacy of the pharmacovigilance program in India there is more need for ADR reporting from non-government AMCs.

An Ayurvedic literature review on drug safety: Pharmacovigilance on ASU&H Drugs

Domin.GS

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Abstract

Introduction

"India is my country and I am proud of it's rich and varied heritage". India has its own Medical System known as Ayurveda and Siddha that has been practiced by our ancestors for the cure and prevention of diseases but there is a misconception that all drugs of natural origin assures both safety and efficacy. Ayurvedic literatures also highlighted that right drug at the right dose by the right route at the right time for the right person ensure the safety of the patient.

Objective: To review the pharmacovigilance concepts mentioned in the Ayurvedic literature and to combine the knowledge on drug safety mentioned in classical Ayurvedic books in a reader friendly manner

Materials and methods

This literature review was done by referring authentic Ayurvedic textbooks A Drug or Poison?

"All substances are poisons there is none which is not a poison. The right dose differentiates poison from a remedy" -Paracelsus, The father of Modern Toxicology. The same was said by Acharya charaka believed to be between 100 BCE and 200 CE. Acharya Charaka in his book Charaka Samhita Sutra Sthana first chapter 126th slokahas mentioned that a potent poison can become a best medicine on its proper administration whereas even the best medicine becomes

poison if used incorrectly. Pharmacovigilance in Rasaoushadhis (Mineral drugs) Ayurveda uses even toxic minerals like arsenic Mercury lead etc as medicines at proper administration where dose is minimal. There is a common notion among the publicthat Ayurvedic mineral drugs are responsible for all vital organ failures but the truth is that all these consequences persist only due to administration of substandard drugs (improper drug preparation), Prescribing over dose and lack of textual knowledge. Ayurvedic literatures have mentioned a proper diet plan while administering rasaoushadhis Individualistic Treatment
Ayurvedic literature has mentioned a unique concept of Prakriti (human constitution) and there is a mode of individualistic treatment where analyzing and assessing the constitution of each human is important before prescription of medication. Persons belonging to different Prakriti will have a different way of drug metabolism. In ayurvedic literature we can find contraindicated drugs in specific human constitution. Alll this textual knowledge should be considered to avoid adverse drug reactions. Incompatible food and drugs Drug interactions are one of the causes mentioned in ADR. In ayurvedic literatures there is a concept mentioned as Viruddhaahara and aushadha (incompatible food and drugs) and also about Apatyasevana (unwholesome diet plan). Various examples for the types of drug interactions like herb herb interactions, herb food interaction, herb animal drug interaction, drug exercise interaction, drug disease interaction where mentioned. All this knowledge should be considered while prescribing medicine to avoid ADR. Pharmacovigilance in Panchakarma
ADR also includes any unintended response from materials used to diagnose or treat. Thus, ADR in Panchakarma therapeutic procedures can also be included. In Panchakarma procedures Ayurvedic literature have mentioned certain consequences like inadequate, excess administration of therapy, contraindication and complication while treating patients by means of Panchakarma. These includes
The flaws in the materials used that is Bastiyantradoshas Iatrogenic events, Patients related like lack of observance, following improper diet etc

Results and Observations: Ayurvedic literatures highlighted on safe treatment hence to prevent ADR. All Ayurvedic physician is responsible to use the source of knowledge while prescribing for better
therapeutic success and for minimum drug induced toxicity. Ministry of Ayush has initiated pharmacovigilance program for ASU&H drugs for reporting and analysing the reported drug events from ASU&H Drugs.

Conclusion: Pharmacovigilance is very important in ayurvedic stream of medicine as it makes the patient to trust the drug safety of Ayurveda. ADR can be prevented or reduced by use of medicines prepared by following various guidelines mentioned in ayurvedic literature and also by following the drug administration procedures. A rich literature knowledge is necessary to minimise the occurrence of ADR. Research should be carried out to find out the reasonings behind the literature drug safety concepts. Reporting of ADR related to Ayurveda treatment as also very important.

Hypersensitivity Reaction After Covid Vaccination

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Abstract

Introduction: Covishield, a vaccine for Covid-19, is being universally used for last two years. But long-term manifestations of this are yet to be studied in detail.

Objectives: To study adverse drug events/adverse drug reaction following Covid-19 vaccination.

Material and method: A 33 years old male health care worker was injected with Ist dose of Covishield vaccine (Serum institute of India, Batch no- 4120Z012, expiry date-02/05/2021) by im route, left arm on 22/01/2021. 2nd dose of Covishield vaccine (Serum institute of India, batch no. 4120Z014, expiry date-05/05/2021) was injected on 19/02/2021.

Observation: 12 hours after Ist dose, patient developed fever with myalgia, for which he took single tab paracetamol 650 mg. His symptoms subsided. Three days later, patient developed swelling on his face, eyes and penis, for which patient went to skin OPD and he was prescribed tab Montair LC. Two days after taking the same treatment his symptoms resolved completely. Within 24 hours of 2nd dose of covishield, patient developed swelling on his face, lips and penis along with rashes all over the body, for which he took Montair LC. His symptoms decreased except penile swelling which remained on and off for 5 months. It was not associated with pain. Patient had no difficulty in sexual intercourse. Patient was given steroids for the same after 2 months (tab Dexamethasone 8 mg for 2 days, tab prednisolone 20 mg for 1 week and later tapered off, along with continuous administration of tab Montair LC). His complaints of penile swelling finally resolved after 5 months.

Conclusion: Hypersensitivity reactions can be one of the rare manifestations of Covishield vaccination.

Distribution of Adverse Drug Reactions at the Inpatients Department of Medicine in B.R.D. Medical College, Gorakhpur (Uttar Pradesh)

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Abstract

INTRODUCTION: Adverse drug reactions are a great cause of concern to all the stakeholders in the health care system including but not limited to the patients, healthcare givers and the authorities. ADR monitoring is most commonly conducted by two modalities: spontaneous reporting and active surveillance. The ADRs in such patients can correlated with polypharmacy (5 or more medications) and comorbities (diabetes and hypertension).

OBJECTIVE: To investigate the distribution of ADRs, demographic, characteristics (age, gender, polypharmacy, ATC (Anatomical Therapeutical Chemical Classification) , patient characteristics and polypharmacy and to find out the correlation of ADRs with co-morbidities

MATERIALS AND METHODS: - Adverse drug reactions were evaluated by causality assessment by Naranjo (14).Their severity was evaluated by Hartwig scale.

RESULTS/ OBSERVATIONS: The mean + - SD value of age was 47.32 + - 17.76 (years).-TOTAL 57 (38.0%) patients belonged to the Gorakhpur district, 93 (62.0) patients belonged to places other than Gorakhpur. The number of patients with ADRs, according to gender was female n=58 was 61.33% and male n=92 was 38.67%.- pts with ADRs , subjected to polypharmacy (pts with >5 medications).

CONCLUSIONS: -The factors like age, gender, polypharmacy, and class of causative agents (drugs) were not statistical significant for either the occurrence or severity of ADRs.- A positive correlation between severity of ADRs and co-morbidities was statistically significant established by Karl-Pearson's correlation co-efficient i.e an increase in ADR severity on co-occurrence with co-morbidities.- A positive correlation between severity of ADRs and drug-drug interactions was statistically significant i.e an increase in ADR severity with concomitant drug-drug interactions.

Keywords: ADRs, demography, poypharmacy, comorbidities, ATC.

An Overview on the Importance of Safety Profile of Herbal Unani Drugs

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ABSTRACT

Introduction: Traditional herbal remedies that are acknowledged as safe in view of long standing traditional use as proof of their safety and are expected to be exempted from a comprehensive toxicological study but in recent years they have been proved hepatotoxic and even carcinogenic due to contamination by toxins from fungus like Aflatoxins and presence of heavy metals like lead and arsenic etc.. So, WHO international drug monitoring program has advised a pharmacovigilance system for herbal/natural drugs also so that their safety can be checked.

Objective: Keeping in mind the above points in the present paper, the importance of the safety profile/study in Unani drugs will be discussed in brief along with the parameters and methods to be adopted for this purpose.

Material and methods: The study will provide the information/data used in Unani classical literature and modern pharmaceutical texts. Besides these relevant research papers from electronic data bases will also be used as the reference material.

Results and discussion: The Safety profile of herbal Unani drugs is obtained by estimation of microbial load, heavy metal content, Aflatoxin estimation and pesticidal residue determination. safety study has been made mandatory by WHO as there are some plant parts which are used as drug as well as food component like spices, dry fruits and essential oil etc . If they are contaminated with any of the factors, they become toxic and unfit for consumption leading to various types of diseases and abnormalities.

Conclusion: The safety profile of every unani herbal drug should be produced and they must be below the permissible limit, so that the quality, Safety, efficacy and toxicity of the drug can be ascertained leading to Consumer Confidence as there is no second quality in drugs.

Ofloxacin and Ornidazole-Induced Fixed Drug Eruption

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Abstract

Background: Approximately in 2 percent of patients taking medications cutaneous skin reactions occur. Fixed drug eruption (FDE) is a distinctive type of cutaneous drug reaction that characteristically recurs at the same site after re-exposure to a particular drug. Drugs inducing FDE are usually those taken intermittently. Most common drugs causing fixed drug eruptions are antibiotics and analgesics. Here, we report a case of FDE to ofloxacin and ornidazole combination which was used in empirical treatment of diarrhoea.

Observation: A 28-year old lady presented with the history of 4 episodes of diarrhea, was prescribed ofloxacin 200 mg twice daily and ornidazole 500 mg twice daily for 5 days. Later, the patient presented with the complaints of itching, swelling and numbness over left upper lip, left angle of mouth and perioral area 1 day after oral administration of the drug. The event was sudden in onset and gradual in progression. The drug was stopped on the same day. 2 days later the area developed hyperpigmentation and crusting. The reaction resolved on its own with skin peeling after one week of the stoppage of drug.

Keywords: Adverse drug reaction, ofloxacin, ornidazole, fixed drug eruption

Extraction and Quantification of Fumaric acid from *Fumaria parviflora* L. plant

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Abstract

Introduction: *Fumaria parviflora* L. is a species of flowering plant known by the common name Shahtara , Family-Fumariaceae. *Fumaria parviflora* L. is a valuable medicinal herb and also used in the Unani system of medicine for the treatment of various ailments such as skin disease etc.

Aim: To extraction and quantification of Fumaric acid from *Fumaria parviflora* L. plant.

Method: Extraction of Fumaric acid from *Fumaria parviflora* L. plant was done by different methods like maceration, reflux, soxhlation and ultrasound assisted extraction (UAE). Quantitative analysis of Fumaric acid in each extract was done by UV-Spectrophotometry method.

Results: Our study indicated that out of all extraction methods employed, UAE was found to be the best method for Fumaric acid extraction. Moreover, methanol stood out to be the most effective solvent for Fumaric acid extraction.

Conclusion: It was concluded that modern extraction techniques (non-thermal) are a better choice for Fumaric acid extraction from *Fumaria parviflora* L. plant.

Keywords: *Fumaria parviflora* L., Fumaric acid, extraction methods, UV-Spectrophotometry method

Doxorubicin and cardiotoxicity – systematic review with a special focus on its Mechanism

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Abstract

Introduction

Cardiomyopathy is a myocardial disorder that affects the structural as well as the functional integrity of myocardium. As stated by the World Health Organization (WHO), cardiomyopathy affects normal electrical rhythm and thus the ability to pump blood is reduced. Progresses to the development of heart failure or arrhythmias (Sisakian, 2014).

Chemotherapeutic medicines are used to treat various malignancies and types of cancer. Clinical adverse effects on heart restrict their use. One of the anthracycline antibiotics (doxorubicin) is used for cancer treatment. It is associated with the apoptosis of cardiomyocyte, fibrosis of myocardium, cardiomyopathy, arrhythmias and congestive heart failure (CHF)

Material and Methods:

PubMed, ScienceDirect, Google, Google Scholar databases were searched from 1996 to 2021 using the terms *Doxorubicin* together with cardiotoxicity, oxidative stress, endothelial dysfunction, heart failure and myocardial dysfunction. The inclusion criteria were *in vitro*, animal, and clinical cardiovascular pharmacological studies conducted on Doxorubicin and full-text accessibility.

Results:

An application of anthracycline doxorubicin (DOX), a known stress factor, can induce chronic pathological changes in myocardium. DOX is used in treatment of various cancers such as solid tumours, leukaemia, lymphomas and soft tissue sarcoma; however, its clinical utility has been hampered by its adverse cardiac effects. The mechanisms of its cardiotoxicity may be multifactorial, including the impairment of mitochondrial energetics by increase in the mitochondrial calcium and reactive oxygen species (ROS) leading to oxidative stress, cell necrosis and induction of pro-apoptotic signaling pathways. An application of DOX was also found to influence sensitivity of hearts to ischemic injury. A recent study demonstrated that acute administration of DOX upon induction of ischemia significantly increased the infarct size. On the other hand, a prolonged exposure of rats to DOX induced adaptive responses of myocardium associated with modulation of myocardial resistance to acute ischemic insult. Nrf2 a master regulator of the oxidative stress signaling. It is a transcription factor that controls basal and inducible expression of antioxidant genes and other cytoprotective phase II detoxifying enzymes that are ubiquitously expressed in the cardiovascular system. Some recent shreds of evidence have revealed that cardiovascular homeostasis is regulated by Nrf2 via suppression of oxidative stress.

Conclusion:

The mechanisms of its cardiotoxicity may be multifactorial. DOXO derived metabolite induces cardiac injury via reactive oxygen species (ROS) generation leads to oxidative stress, further leading to mitochondrial damage, breaks in DNA strands, sarcomere structural alteration, and altered gene expression. Also, it is found that Nuclear factor erythroid-derived 2 -like 2 (Nrf2) is a prominent central regulator of cellular impenetrable to oxidants whose activation may lead to oxidative stress induced cardiac injury.

Understanding The Various Elements Determining the Susceptibility to Adverse Drug Reactions: A Review

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Abstract

INTRODUCTION: There are 2 separate varieties of adverse drug reactions (ADRs): those that will affect all patients but happen at different dosages in different patients (dose-related ADRs) and those that will only harm some patients, regardless of how high a dose is given (non-dose related ADRs). Few individuals are more likely than others to suffer adverse effects at any given dose and some adverse effects can happen at far lower levels than therapeutic doses. Those who experience such reactions are hypersusceptible. Hence, we should try to understand the factors causing the susceptibility.

AIM & OBJECTIVES

The aim of this review poster is to develop a better understanding of multifactorial interactions leading to ADRs. The objective is to determine the elements in susceptibility of various individuals to ADRs.

METHODS

We searched in PubMed using the terms like “adverse drug reactions” and “nondose related adverse drug reactions”.

RESULTS & CONCLUSIONS

Dose, Time, and Susceptibility (DoTS), are important factors determining the occurrence of ADRs. The elements that alter an individual's susceptibility include Immunological factors, Genetic factors, Age, Sex, Physiological changes, Exogenous factors (drug interactions), and Disease; that is, I GASPED. These factors interact, and the interactions depend on the drug dose, which helps to explain why some patients experience severe adverse events while others are unaffected.

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 and safety of Vildagliptin-Metformin treatment & compared to Glimepiride-Metformin treatment for type 2 diabetic patient.

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 Glimepiride (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 event.

Result: HbA1C reduction less than 7% at week 24 was 52% in the Vildagliptin group and 48% in the Glimepiride group (B) was examined. Lower incidence of hypoglycemia was observed in Vildagliptin group (A). Vildagliptin- Metformin treatment are providing a good efficacy of blood glucose control and also in the term of safety, Subject of this group were facing lower risk of hypoglycemia, weight gain. Flatulence, Abdominal bloating/discomfort & Giddiness.

Conclusion: Vildagliptin offer a superior benefit 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.

To assess the treatment satisfaction between Vildagliptin versus Glimepiride added to Metformin in patient with type 2 diabetes mellitus (T2DM).

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Abstract

Introduction: Metformin is a most common drug for starting treatment in type 2 diabetes mellitus but sometime according to the medical situation patients need additional drug to control Blood glucos level.

Objective: The objective of the present study is to assess the treatment satisfaction between Vildagliptin versus Glimepride added to Metformin in patient with type 2 diabetes mellitus (T2DM).

Material & Methods: This is a prospective study of 300 subjects were divided into two groups: In group A 150 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. Patient satisfaction was assessed by Diabetes Treatment Satisfaction Questionnaire.

Result: Treatment satisfaction as reflected in DTSQ, The result suggests that patient satisfaction was better for all six parameters [1,2,4-8] in Vildagliptin group. The overall mean treatment satisfaction score (1,4,5,6,7&8) for Vildagliptin was significantly greater than glimepiride group. Similarly perceived hyperglycaemia and hypoglycaemia score were lower, indicating good adverse effect profile, in Vildagliptin group. Treatment with Vildagliptin was associated with less incidence of hypoglycaemia compared to glimepiride and

with weight loss whereas weight gain was observed in glimepirde group.

Conclusion: Questionnaire scores were higher for Vildagliptin indicating better treatment satisfaction compared to glimepiride.

To observe the adverse effect of Covishield vaccine.

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Abstract

Background: Covishield vaccine is a recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. Following administration of Covishield, the genetic material of part of corona virus is expressed which stimulates an immune response. Clinical trials began to show the efficacy and safety of vaccine.

Objective: To observe the adverse effect of Covishield vaccine.

Materials and methods: This was an observational prospective study carried out between January 2021 to June 2021 in BPS GMC for women, which is a tertiary care institute in Khanpur kalan, Sonepat. We assessed the incidence, pattern and severity of adverse events following immunization among the health care workers. According to the guidelines, two doses of vaccine were recommended at an interval of 4 weeks. The vaccine was administered intramuscularly into deltoid muscle. Total of 2952 health workers were vaccinated during the study period. Health workers were observed for 30 minutes and followed up after 72 hours for enquiring the adverse effects post-vaccination.

Results: Among 2952, only 74 health workers experienced adverse effects. Out of 74 health workers, 71 experienced adverse effects after 1st dose and the remaining 3 after the second dose. There were 4 health workers who experienced adverse effect following both the doses. Most common side effect observed was fever with chills (52.7%), headache/dizziness (45.9%), myalgia (13.5%), nausea/vomiting (8.1%), itching (6.7%), rashes (6.7%), throat irritation (5.4%), penile swelling (1.3%).

Conclusion: Covishield is observed to be safe based on our findings as majority of AEFIs were self- limiting. None of the side effects were severe.

Adverse drug reaction monitoring at a tertiary care teaching hospital in Nuh, Haryana

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Abstract

Introduction: Adverse drug reactions (ADRs) poses an unforeseeable risk associated with all the prescribed medicines. They contrast in severity and duration in any population. Thus, ADRs are monitored and assessed on a large scale in our country by the Pharmacovigilance Programme of India through adverse drug reaction monitoring centres (AMCS).

Objectives: This study was done to assess the pattern of ADRs reported in a tertiary care teaching hospital in Haryana by applying various aspects of ADR monitoring such as clinical presentation, causality and severity assessment in various Inpatient departments at SHKM GMC.

Material and Methods: A Prospective, Observational study was conducted in all the inpatient clinical departments of SHKM Govt. Medical College, Haryana for a duration of 12 months. ADRs were recorded in pre-designed proforma along with ADR reporting form "Version 1.3". Processing & analyzation of data was done using SPSS version 20

Results: A total of 187 ADRs were reported during the study period. Females were affected more than males. Maximum ADRs were reported in the age group of 19-60 years. Medicine department had maximum number of ADRs. Antibacterials implicated for major number of ADRs. GI tract was the most affected organ system. Of the total ADRs, 50.9% were probable. Regarding the severity, 3% ADRs were severe, while 60% were mild. On applying preventability scale, 90% of ADRs were not preventable. Polypharmacy was present in 33% of patients having ADRs.

Conclusion: By keeping a careful and timely watch majority of ADRs can be prevented by early intervention. This will be a step towards improving patient safety.

Role of nitric oxide (NO) and NO-based neurotherapeutic agents in postraumatic stress disorder

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Abstract

Post-traumatic stress disorder (PTSD) is a traumatic stress disorder and though complex neurochemical pathways are proposed for its genesis, treatment strategies with psychotropic agents are inconsistent and have major safety concerns. Nitric oxide (NO) is a ubiquitous, gas transmitter signaling molecule with neurotherapeutic potential, but its role in PTSD is not clearly defined. In the present study, the

effects of NO modulators were evaluated on PTSD-induced neurobehavioral and brain biochemical changes in rats. Time dependent sensitization (stress + re-stress, TDS) was used as the experimental model for PTSD. Following TDS, neurobehavioral assessment was done by the elevated plus maze test (EPM), and brain homogenates were assayed spectrophotometrically for oxidative stress markers. . Our results showed that, TDS induced anxiogenesis in the EPM test as evidenced by reduced open arm entries (OAE) in the EPM as compared to controls. Pretreatment with the NO precursor, L-Arginine reversed the TDS-induced anxiogenic effects towards anxiolysis, with marked increases in both OAE and OAT – which were comparable with the standard psychotherapeutic agent, fluoxetine. On the other hand, L-NAME, the NO depletor, did not show any such effect. Assay of brain homogenates showed that levels of MDA (a marker for lipid peroxidation) and (to a lesser extent) NOx (stable NO metabolites) were elevated, with changes in MDA being most marked. These alterations in brain MDA and NOx levels were differentially influenced by L-arginine and L-NAME, with the former drug showing clearcut attenuating effects. These results suggest that NO could play a crucial role in the pathogenesis of PTSD and that NO-based therapeutic agents like L-arginine could be potentially effective and safer neurotherapeutic agents against this unique stress disorder.

Role of *Gymnema Sylvestre* (Gurmar) in Type 2 Diabetes Mellitus & Obesity. (Literature Review)

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Introduction: -

Gymnema Sylvestre, locally called "gurmar", renders glucose lowering activity and Anti-obesity activity due to the presence of phytochemicals, such as gurmarin, gymnemic acid and gymnema saponins which are classified as oleanane saponins and occur naturally in the leaves of the plant.

It has insulin secretagogue and α-glucosidase inhibitory activity. Also, antagonistic effect on somatotropin, corticosteroid and adrenaline that induces hyperglycaemia with increased insulin sensitivity.

Methods: - Relevant data was obtained from databases like PubMed, Google Scholar, Scopus and Elsevier using the keywords – Gymnema sylvestre, diabetes mellitus, gymnemic acid and Obesity.

Gymnema Sylvestre in T2DM and Obesity: - There are three extracts prepared from its leaves - Ethanol extract reduces glucose level by 46%, aqueous extract by 26% and methanol extract by 12%.

All forms of extract cause increase in β cell mass and reduce the dose of drugs like glyburide or tolbutamide.

Gymnemic acid IV given at a dose of 3.4/13.4 mg/kg administered for 6 hours decreased blood glucose levels by 13.5/60.0% as compared to glibenclamide.

Also, it increased plasma insulin levels in STZ-diabetic mice at a concentration of 13.4 mg/kg.

Gymnema sylvestre leaves extract significantly inhibited lipase with low concentration was 30.20% while the higher concentration was 84.11% as compared about orlistat as standard drug.

Conclusion: - Gymnema Sylvestre targets several etiological factors connected with diabetes, including chronic inflammation, obesity, enzymatic defects and pancreatic cell function. No single oral hypoglycaemic drug presently exerts such a diverse range of effects. It suggests that Gymnema may be useful in the management of diabetes and the prevention of associated pathological changes

To study hypersensitivity reaction to sublingual misoprostol- A case report

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Abstract

Introduction: Misoprostol, a PGE_1 analogue has been used frequently for treatment and prevention of PPH, cervical priming and dilatation. Although rare, hypersensitivity reaction to misoprostol has been reported in past.

Objectives: To study hypersensitivity reaction to sublingual misoprostol.

Material and method: A primigravida female, with no previous history of allergic reaction to any drug, was admitted in Obs. & Gynae department of BPS GMC, Khanpur Kalan, Sonipat on 28/11/2021 after having labour pains after 38+3 weeks of gestation. Her labour was augmented using I.V. infusion of injection Oxytocin. She delivered a full term, live female neonate after vaginal delivery around 8:30 pm. She was given i.m. Inj. Oxytocin 10 mg followed by single dose of 400 µg of misoprostol for prevention of PPH.

Observation: At around 10:00 pm, she complained of uncontrollable shivering and shortness of breath. Her Blood pressure was found to be 80/40 mm of Hg and her pulse rate was 168 bpm and she was febrile to touch. She was given 1 ampoule of avil (Chlorphaeniramine), inj. Dexamethasone 8 mg and injection hydrocortisone along with 2 units of normal saline. For maintenance of BP & Pulse pressure, noradrenaline was started at rate of 30 drops/min. At around 10:15 PM her BP was 86/46, her pulse rate was 180 bpm and her temperature was found to be 104 F. For fever, she was

injected with 1 ampoule of PCM. Her SPO_2 on room air was 90% and she was intubated and kept on ambulatory ventilator at 8 litre/min. At around 12:30 AM, she was maintaining SPO_2 at 4 litre/min. She was extubated after re-examination and having no fresh complaints. She was discharged from hospital after two days of observation.

Conclusion: although rare but hypersensitivity reaction to misoprostol has been reported in past. This is case of anaphylactoid reaction to sublingual misoprostol.

To observe the cardiac adverse effects of Bupivacaine: A Case report

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Abstract

Background: Bupivacaine is a lipophilic and potent long-acting amide-linked local anesthetic, which is used for infiltration, nerve block, epidural and spinal anesthesia of long duration which blocks nerve conduction by decreasing the entry of Na+ ions during upstroke of action potential (AP).

Objective: To observe the cardiac adverse effects of bupivacaine.

Material and methods: 31 years old male was admitted to the orthopedics ward with the complaint of pain in the right knee with a history of RTA 5 months back. On MRI, tear was found on ACL and PCL. During surgery inj Bupivacaine 0.5%-3mL was injected in the epidural space, after which patient started complaining of intense itching in the lower back and gluteal region and lancinating discomfort radiating to limb. Observing the patient condition, general anesthesia was administered.

Observation: After 2.5 hrs. patient developed arrythmia with pulse rate of 140-160 bpm, BP 148/82 mmHg. Ventricular tachycardia was suspected. Fio2 100%, inj lignocaine 4ml iv was given immediately. After the interventions BP was maintained and sinus rhythm was restored. After 1hr similar episode was repeated. Inj amiodarone slow iv was given along with inj thiopentone and inj morphine. Ventricular tachycardia persisted, and shock of 200J was delivered but ventricular tachycardia persisted, Patient was shifted to SICU. After 12hrs ventricular tachycardia reverted to sinus rhythm. Bupivacaine caused ventricular tachycardia and ST-segment elevation observed on ECG.

Conclusion: Bupivacaine may cause cardiac toxicity like ventricular tachycardia and should be used cautiously.

Pharmacovigilance: - An Ignored Domain

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Abstract

INTRODUCTION: -

• Pharmacovigilance, also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring and prevention of adverse effect with pharmaceutical products. {1}

• WHO defines pharmacovigilance as the pharmacological science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems.{2}

• ADVERSE DRUG REACTION -At a normal dose sometimes the given medications may harm the patients which are called Adverse Drug Reactions (ADR). Adverse drug reaction is different from side effect. The evaluation of ADRs is most critical in the field of pharmacovigilance.{3}

• These adverse drugs reactions (ADRs) not only add to suffering of patients but also increase morbidity and mortality along with a financial burden on society. The overall incidence of ADRs 0.32% (0.1-0.85%).{4}

AIMS OF PHARMACOVIGILANCE PROGRAME: -

• To monitor ADRs in the Indian population.
• To create awareness among HCPs about the importance of ADR reporting in India.
• To generate evidence-based data on the safe use of drugs
• To support the CDSCO in formulating safety related regulatory decisions of medicines
• To monitor benefit risk profile of drugs and communicate information to all key stakeholders
• To create a national centre of excellence at par with global drug safety monitoring standards
• To collaborate with other national centers for the exchange of information on adverse drug reports.
• To promote rational use of medicine.{5}

NEED OF PHARMACOVIGILANCE: - • Drug trials in animals and humans (phase I–III) do not provide detailed information on adverse reactions to drugs faced by practitioners.

• Rare/ serious ADRs/drug interactions/chronic toxicity and use in special populations (e.g., pregnant women, geriatrics, and pediatrics) are not available from the drug information literature, such as package inserts, drug manuals, phase III clinical trials, etc. Thus, pharmacovigilance helps in evaluating effectiveness, tolerability, and safety of drugs while prescribing treatment to patients.

• This helps to identify and control severe adverse reactions seen with individual drugs and hence promotes a comprehensive assessment of the benefit/risk profile of drugs as they are utilized by the patients.{6}

ROLE OF PHARMACOVIGILANCE: -

• Pharmacovigilance (PV) plays a key role in the healthcare system through assessment, monitoring and discovery of interactions amongst drugs and their effects in human.
• Pharmaceutical and biotechnological medicines are designed to cure, prevent or treat diseases.{7}
PHARMACOVIGILANCE IN INDIA: - • India has more than half a million qualified doctors and 15,000 hospitals having a bed strength of 6,24,000. It is the fourth largest producer of pharmaceuticals in the world.
It is emerging as an important trial hub in the world. Many new drugs are introduced in our country. Therefore, there is a need for a vibrant pharmacovigilance system in the country to protect the population from the potential harm that may be caused by some of these new drugs.
• Clearly aware of the enormity of task the Central Drugs Standard Control Organization (CDSCO) has initiated a well-structured and highly participative National pharmacovigilance program.
• It is largely based on the recommendations the WHO document titled "safety monitoring of medicinal products-Guidelines for setting up and running a pharmacovigilance centre "{8}

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9. It can be concluded that pharmacovigilance is an important tool in ensuring patient safety as by reporting the ADRs, the patient morbidity and mortality can be reduced.
10. This also enhances the knowledge of prescribers about drug related events, and thus appropriate modification in the treatment can be done to benefit the patient

Comparison of conventional small group teaching with skill-based teaching in proper use of drug delivery system in Phase II MBBS students of NDMC Medical College

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Abstract

Introduction: Under Curriculum Based Medical Education (CBME), National Medical Council has introduced new method of small group teaching (skill-based teaching) of Phase II MBBS students for drug delivery system which comprises of skill training and communication training for the use of drug delivery system in addition to the knowledge aspect of the same

Objective: To compare the conventional method of small group teaching with skill-based teaching in learning the proper use of drug delivery system in Phase II MBBS students

Materials & Methods: Students were first given a questionnaire (pe-test) followed by didactic lecture on Drug Delivery System. After that, they were randomly divided into 2 groups. Group A was taught by skill-based teaching and Group B by conventional teaching forinsulin pen, and were crossed over for Metered Dose Inhaler. Students were again given the same questionnaire (post-test). All the students were assessed randomly for skill of using device and its communication.

Results: Significant improvement was seen in the questionnaire score between pre-test and post-test ($p<0.0001$). There was significant improvement in student's performance in skill of using MDI ($p<0.05$) and in communication of insulin pen ($p=0.0001$) in groups taught by skill-based teaching. Similar results were seen in skill of using insulin pen and communication aspect of MDI in both groups.

Conclusions: Skill-based teaching encourages student's involvement and better interaction with the faculty as compared to conventional teaching methods leading to similar or better performance in terms of skill and communication of drug delivery system

Understanding and Attitude of health care professionals of the tertiary health care system in Delhi towards Covid vaccination.

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Background: For the COVID infection chain to be broken, knowledge and a supportive attitude toward the COVID

vaccine are crucial. Inappropriate COVID protocol procedures directly raise the risk of infection. Knowing vaccine knowledge, attitudes, and practices (KAPs) and potential risk factors aid in predicting how planned behavior would turn out.

Objective: To assess the knowledge, awareness, and attitudes of medical and paramedical students towards the recently discovered coronavirus vaccine.

Material & methods: This was a cross-sectional study conducted on medical and paramedical students at North DMC Medical College and Hindu Rao Hospital, Delhi. A questionnaire containing demographic information, 14 knowledge items, and 6 attitude questions was completed by 124 participants.

Results: Overall, >85% of people were aware of the vaccines, route of administration, possible side effects, and doses of vaccine. However, very few of them knew about the in-depth details. The knowledge score revealed that 90% of participants had sufficient knowledge about the coronavirus vaccine. MBBS students had significantly better knowledge in comparison with nursing students. In terms of attitude, > 64.2% of students showed a positive attitude.

Conclusion: The medical & paramedical students of North DMC Medical College and Hindu Rao Hospital, Delhi showed a satisfactory level of awareness and attitudes towards the COVID vaccine, with an obvious difference in disciplines. Further educational interventions with periodic assessment of such interventions are the need of the hour in the current scenario of this COVID pandemic.

Keywords: Awareness, Attitude, Medical students, Covid vaccine

Implementation and assessment of simulation-based learning in medical students at Hindu Rao Hospital and North DMC Medical College, Delhi

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Abstract

Aim & objective - Examine the impact of simulation-based learning on second-year medical students.

Background: After the implementation of competency-based medical education, simulation-based learning has the potential to assist Indian medical graduates with their medical goals. Simulation-based learning provides a chance to improve all three learning domains.

Material & Method- A simulation-based learning method is implemented for the demonstration of routes of administration among a class of second professional 50 students. Students were divided into 2 teams, with 25 in each. The pre-test was taken containing questions related to routes of administration. once the pre-test is completed one cluster is instructed with the normal teaching technique and another with simulation-based learning topics was intramuscular injection and cross-over is completed with intravenous injection demonstration. once the teaching each strategy, a post-test was taken. For the assessment of their attitude and perception evaluations, demonstration and feedback from students on the implementation of simulation-based learning was taken.

Statistical analysis: Was performed mistreatment Microsoft 365 surpass. All participants gave their consent before participation in the study

Result: Knowledge domain-The modification in mean score count from pre-test to post-test, was a lot of in simulation-based learning is 5.45 to 7.79 compared to didactic teaching 5.45 to 6.75 statistically this distinction was vital (p-value: .004)The attitude and perception domains were evaluated with the assistance of feedback and demonstration by students, Students provided positive feedback for Simulation-based learning, and their performance was higher than traditional teaching team performance.

Conclusion: • Learning of the students was enhanced by the simulation-based learning method.

•Students like it because it was a hand on experience, participatory, understandable, and easy to remember.

Keywords: Simulation-based learning, Clinical skills; medical education

Safety of Ayurvedic metal origin Bhasma (Dhatu Varga) through subacute Toxicity Studies– A review

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Abstract

Introduction

Bhasma possesses broad-spectrum therapeutic utility but is blamed due to frequently raising toxicity concerns. Although their safety has been evident with the practice since ancient times, scientifically proven through toxicity studies, clinical safety, still comprehensive conclusive documentation is needed.

Methods Materials

Online published research articles on in vivo, oral single dose, subacute toxicity studies on Bhasma of Dhatu Varga were searched through search engines and observations on behavioural, ponderal, autopsy, maximum tolerated dose (MTD), LD 50 and safety were summarized.

Conclusion- Bhasma of Loha, Tamra, Yashada, Naga and Vanga are safe at behavioural and some at ponderal, autopsy level through per oral single dose, in vivo acute toxicity studies in rat and mice at 4160, 2000, 300, and 4160 mg/kg body weight of animals which are up to 100 times of TED. Bhasma of Loha, Tamra, and Naga are safe at behavioural and some at ponderal, autopsy level through per oral single dose, in vivo subacute toxicity studies in the rat at 20.8, 27.5 20 mg /kg body weight of animals which are up to 5 times of TED. Bhasma of Swarna is safe at behavioural physiological, biochemical, haematological, histopathological parameters and at, autopsy level through per oral single dose, in vivo subacute toxicity study at13.5) mg per kg body weight along with diluted honey up to 10 times of TED. However, in subacute toxicity of Yashada Bhasma is safe at 300mg/kg body weight of animals which are up to 100 times of TED.

Keyword- Safety, Ayurveda, Bhasma, Subacute toxicities.

Aflatoxins: A Global Threat to the Safety of Herbal Unani Drugs

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Abstract

Introduction

In Unani system of medicine drugs of natural origin are used to cure various diseases No doubt, many herbs are found to be of miraculous cure for several diseases but biological contamination (bacterial, fungal and insect) of herbal medicines is a serious concern. When certain types of fungus grow on herbs they produce toxins, known as mycotoxins. Aflatoxins are the most potent and lethal toxin substances produced by the *Aspergillus flavus* and *Aspergillus parasiticus* that occur naturally. WHO has made the determination of aflatoxins in Unani herbal drugs as mandatory to ascertain their safety.

Objective

The aflatoxins with respect to their occurrence, structure, properties and effects on health along with the analytical methods for their determination are summarized. Some measures to prevent their contamination are also suggested to improve the efficacy and safety of Unani herbal drugs.

Material and Methods

This study was conducted using various electronic databases like Scopus, PubMed, Web of science etc along with some other relevant articles.

Result and Discussion

Aflatoxins are human carcinogens so the prevention or reduction of all the conditions that are conducive to aflatoxin production in herbal products could have a significant effect on public health especially in low-income countries and deserves significant attention.

Conclusion

To manage mycotoxins contamination, decrease health risks and economic costs is to instruct herbal drug producers and handlers on how to minimize aflatoxin contamination These actions would minimize the risks throughout the production, handling, and processing chain and can complement product.

Cabenuva – A Novel Long Acting Injectable for Treatment Of HIV-1

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Abstract

Introduction: Human immunodeficiency virus (HIV) is a single stranded RNA virus that attacks immune system, resulting the host to opportunistic infections and malignancies. If not properly treated HIV can progress to Acquired Immunodeficiency Syndrome (AIDS). The mainstay of current treatment consists of two nucleoside reverse transcriptase inhibitors (NRTIs) combined with a third ARV medication from one of the following classes: non-nucleoside reverse transcriptase inhibitor (NNRTI) ,a protease inhibitor(PI), or integrase strand transfer inhibitor(INSTI).

Approved by the food and drug administration (FDA) in January 2021, cabotegravir/rilipivirine CABENUVA is the first extended -release injectable indicted for the treatment of HIV-1. This promising new ARV regimen consists of INSTI (cabotegravir) and a NNRTI (rilipivirine) and is intended to replace current therapy in adult patients who are virologically suppressed with no history of treatment failure /resistance to either component of the combination drug.

Based on results of ATLAS and FLAIR trials the regimen has US FDA approval and recently used in Canada.

The poster summarizes the milestones on development of co-packaged cabotegravir and rilpivirine, drug indications, dosage and administration, limitations and ADRs, advantages over oral tablets .

A questionnaire based cross-sectional study to assess knowledge, attitude and practice of pharmacovigilance and adverse drug reaction reporting among postgraduate medical students in a Tertiary Care Teaching Hospital of South India

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ABSTRACT

BACKGROUND: Spontaneous reporting of adverse drug reactions (ADRs) is one of the common methods to obtain

safety data. .Lack of awareness is a major reason for under reporting. Hence, this study was undertaken to evaluate the knowledge, attitude and practices (KAP) of the postgraduates about pharmacovigilance and ADR reporting in a tertiary care teaching hospital.

MATERIALS AND METHODS:

A cross-sectional questionnaire-based survey was conducted among postgraduate students in a tertiary care teaching hospital in South India to evaluate the participants' knowledge, attitude, and practice (KAP) on ADRs and Pharmacovigilance. A pre-designed and validated questionnaire containing 14 questions was used to assess knowledge, attitude and practice. The filled KAP questionnaires were analyzed and their percentage value was calculated by using Microsoft Excel spreadsheet.

RESULTS:

A total of 120 postgraduate students participated in the study. Around 81% of participants agreed that reporting of ADRs is a professional obligation and all ADRs should be reported. They did not have adequate knowledge regarding the purpose of monitoring ADRs and 22.5% of study participants were unclear as to where and how to report ADRs. Unfortunately, only 12.5% of participants actually reported ADRs due to lack of proper sensitization and knowledge of pharmacovigilance and ADR.

CONCLUSION:

This study indicated that the postgraduate students have a good attitude towards ADR reporting. However, they lack knowledge and the actual practice of ADR reporting is still lacking among them. There is a need to create awareness among the health care professionals about ADR reporting and pharmacovigilance. Educational interventions targeting the medical fraternity should be implemented to help improve spontaneous reporting and knowledge of pharmacovigilance and ADR.

KEYWORDS: Knowledge, Attitude, Practice, Adverse drug reporting, pharmacovigilance

A Comparative Study to Evaluate the Efficacy and Safety of Rupatadine 10 Mg And Olapatadine 10mg in Chronic Spontaneous Urticaria

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Abstract

INTRODUCTION

Definition of chronic spontaneous urticaria(CSU): persistent symptoms of urticaria (hives, redness, itching & angioedema) last for ≥ 6 weeks

The global prevalence is around 8.8%. Urticaria occurs frequently with a lifetime prevalence of around 20%. Anti-histamines are widely used for chronic urticaria.

This study focuses on efficiency of Olopatadine with Rupatadine in CSU

Objective:

To compare efficacy and safety of rupatadine 10 mg versus olopatadine 10 mg in patients of chronic spontaneous urticaria.

Materials and methods:

A 6-week, parallel group prospective comparative clinical study was conducted on patients with chronic spontaneous urticarial at department of dermatology at osmania general hospital . Following inclusion and exclusion criteria, 60 patients were recruited and randomly allocated to two treatment groups and received the respective drugs for 6 weeks. parameters assessed at follow up were mean total symptom score (MTSS) calculated by adding the mean number of wheals (MNW) and the mean pruritus score (MPS),absolute eosinophil count(AEC) and serum IgE levels .to assess safety adverse effect in each group were compared.

Results:

Both the drugs significantly reduced the MTSS, number of wheals, size of wheal, total symptoms score, absolute eosinophil count, serum IgE but olopatadine was found to be superior. In olopatadine group, there was significantly higher reduction in MTSS ($p = 0.0127$), and change in eosinopils count ($p = 0.012$) than that of rupatadine. Serum IgE levels in two groups mean difference was significant ,significant reduction of IgE in olapatadine than rupatidine ($p=0.001$). Incidence of adverse effects was found to be less in olopatadine group when compared with rupatadine group..

Conclusions:

Olopatadine is a better choice in chronic spontaneous urticaria in comparison to rupatadine due to its better efficacy and safety.

To compare therapeutic efficacy of topical luliconazole versus topical ketoconazole in the treatment of pityriasis versicolor.

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Abstract

Introduction- Pityriasis versicolor is a mild , persistent benign superficial fungal skin infection caused by Malessezia yeasts. The patients presents with both hypo and hyperpigmented scaly macules.

Aim: To compare the efficacy of topical luliconazole versus topical ketoconazole in the treatment of pityriasis versicolor.

Objective: To compare the clinical condition in two groups of pityriasis versicolor patients at baseline , 2nd week and end of 4th week of treatment with topical luliconazole and ketoconazole .

Materials and methods : A 4 week prospective comparative clinical study was conducted on patients with pityriasis

versicolor at the department of dermatology at Osmania general hospital. Following inclusion and exclusion criteria 100 patients were recruited and randomly allocated to two treatment groups and received the respective drugs for 4 weeks.

Results: At 1st follow-up after 2 weeks, 81% patients were negative in the treated Luliconazole group and approx 70% were negative in the treated Ketoconazole group.

At 2nd follow-up after 4 weeks, 95% patients were negative in the treated Luliconazole group while around 74% were negative in the treated Ketoconazole group.

Conclusion: Both topical Luliconazole and topical Ketoconazole were effective in treating pityriasis versicolor, but topical Luliconazole was found to be more effective than topical Ketoconazole

Keywords: Pityriasis versicolor, Luliconazole and Ketoconazole

Nutraceuticals in the Management of Lifestyle Diseases

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Abstract

INTRODUCTION: Lifestyle diseases are rapidly becoming the leading cause of mortality and morbidity globally. Unhealthy dietary habits, physical inactivity, inadequate nutrition, and non-communicable diseases are closely linked. Herbs having medicinal values along with significant nutritional value can be beneficial in maintaining the health of a normal person. Hippocrates stated that "*let your food be your medicine, and medicine be your food"*. In the Unani system of medicine, many modified diets act as nutraceuticals. These nutraceuticals are known to be used for the treatment and prevention of various lifestyle diseases, such as Ma-ul-jubn, mainly used in melancholia (depression), Ma-ul-Asl, Ma-ul-Fawakah, Ma-ul-Laham, Ma-ul-shaeer, Ma-ul-Buqool, hasramia, laboob, Maibah, Hareera, Kavameekh, Nabeez, Mazeera, Vinegar, Aabkama, Halwa, Murabba and Gulqand etc.

METHODOLOGY: A retrospective screening using classical literature of Unani system of medicine and published original articles was performed with special emphasis on nutraceuticals used in lifestyle diseases.

CONCLUSION: Nutraceuticals can be used alone or as an adjuvant to pharmacotherapy to effectively manage a number of lifestyle diseases, including hypertension, stroke, dyslipidemia, diabetes, obesity, cancer, arthritis, mental disorders, anemia, malnutrition, and vitamin deficiencies. Many of our nutritional demands are met by nutraceuticals without the risk of adverse effects that are associated with the intake of pure medications. Therefore, if used wisely, herbs could be better alternatives to be formulated as nutraceuticals for both prevention and treatment of such health hazardous disorders. This would significantly lessen human suffering**.**

KEYWORDS: Lifestyle diseases, Nutraceuticals, Ma-ul-jubn, Ma-ul-Asl

Concept of Tadbeer-E-Advia (Detoxification) in Unani System of Medicine: An Overview

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Abstract

INTRODUCTION

Most of the Unani drugs are believed to be safe, but as per the data reveals, many unani drugs and their formulations produce harmful effects, owing to their side effects Unani physicians have already suggested large number of processes to cope up with these untoward and undesirable effects. This review aims to

explore the concept, aims and objectives of *tadbeer-advia* (rectification/purification of drugs) in Unani system of medicine

MATERIALS AND METHOHDS

A through literature survey was undertaken using the various online bibliographic databases like Pub Med, Google Scholar, Science Direct, Web of Science and Scopus. Classical Unani literature books were used for Unani references. The keywords used for the search included "*Tadbeer-e-Advia*", "*Islah-e-advia", Mudabbar process,* detoxification and purification of drug.

RESULTS

The ancient Unani physicians were well aware of toxicity of the drugs and have divided drugs into four degrees (1°, 2°, 3° and 4°) according to the *Mizaj* (temperament) of drugs. The fourth-degree drugs produce so strong effects that the physiological functions of the body get disturbed; such drugs are also considered to be poisonous drugs. Different methods of purification have been mentioned for drugs belonging to the third- and fourth-degree temperament and always recommended their use after subjecting them to certain *Tadbeer* (rectification/purification). Otherwise, these drugs may destroy the physiological function of the body. After purification process the drugs become physically and chemically pure, therapeutically more effective and less toxic. Very few pharmacological and toxicity studies have been conducted.

CONCLUSION

Third- and fourth-degree drugs and their formulations have been claimed by Unani scholars to be useful in the management of various diseases of the body. After

purification toxicity has been reduced in comparison crude drug. However, further comprehensive studies are required to validate such claims.

Omidenepag Isopropyl Ophthalmic Solution 0.002% for the treatment of glaucoma and ocular hypertension (CDSCO approved new drug)

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Abstract

Glaucoma is a second most common cause of irreversible blindness worldwide. In India, glaucoma is leading cause of irreversible blindness with atleast 12 million people affected and 1.2 million people blind from the disease. Currently, the first line medications in the management of glaucoma and ocular hypertension are prostaglandin analogues(FP receptor agonists)like latanoprost, bimatoprost, travoprost .OMIDENEPAG isopropyl is a novel topical ocular hypotensive agent that is approved in India on 12-3-2021 for the treatment of glaucoma and ocular hypertension. After topical instillation and during corneal penetration, Omidenepag isopropyl is converted to active metabolite omidenepag which is a selective E prostanoid subtype 2 (EP2) receptor agonist. Omidenepag isopropyl reduces intraocular pressure by enhancing both conventional trabecular outflow and uveoscleral outflow without complications of prostaglandin associated orbitopathy seen with FP receptor agonists .Multicenter studies were conducted in United States and Japan where Omidenepag isopropyl demonstrated stable IOP lowering effects and was well tolerated. The poster summarizes the development of Novel drug Omidenepag, indications, dosage, safety and tolerability profile and advantages over FP receptor agonists.

Keywords: EP 2 receptor,FP receptor,intraocular pressure, glaucoma ,ocular hypertension,Omidenepag isopropyl.

Tools and Techniques of Pharmacovigilance in USM

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Abstract

Introduction: Pharmacovigilance in medicine is aimed to reduce the adverse effects caused by a drug. Recently it has been observed that adverse effect by a drug is one of the leading cause of raised percentage of mortality in developing as well as developed countries. W.H.O. has made strict guidelines to make a check-list to any drug 'to be prescribed on the counter'. Such ADR are also reported by drugs of traditional system of medicine. But it is most often observed that, when traditional medicine is prescribed in compliance of its principles, then those adverse effects are minimized to a larger extent.

Objective: To identify the tools used in USM which are helpful in reducing ADR

Materials and method: A detailed review from classical Unani literature was collected based on our objective.

Result: Unani concept from *Kulliyat-e-advia* reveals many instances in classical literature where every physician has elaborated the therapeutic effects as well as adverse effect by any Unani drug. Therefore, Unani scholars has given the concept of line of treatment *Usool e Ilaaj* in which drug therapy was kept on third number. Similarly, when they allowed the use of a natural drug too, the concept of temperament of a drug along with its degree is detailed. Thus whenever a Unani drug is prescribed it is done as per its opposite temperament *Ilaaj bil zid*. Along with this dosage of the drug and substitute of the drug is mentioned with every available drug in texts. An important concept of detoxification *tadabeer-e-advia* also helped to a greater extent in reducing ADR.

Conclusion: Drugs are as much harmful as they are of any therapeutic value, this basic concept helps in establishing the Unani principles. Present study will highlight all those Unani principles or concepts which are helpful in reducing various side effects or reduce the ADR of unani drugs. A default mechanism of pharmacovigilance in USM helps in promoting their efficacy and reducing ADRs.

KEYWORDS: Adverse Drug reactions, Pharmacovigilance, Tadabeer-e-advia.

Importance of Pharmacovigilance in Unani System of Medicine: A Review

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ABSTRACT

Introduction: Pharmacovigilance is defined as the activities related to detection, assessment, understanding and prevention of adverse effects or any other drug related problem that is intended to be used for the benefit of the recipients. This is of the prime importance for the patient care to identify the risk or side effects of the herbal drugs so that harm can be minimized earlier. In Unani medicine, there is concept of Temperament *(Mizaj-e-Advia)* in which drugs are prescribed according to their potency having 4 degrees means that higher the degree more potent the effect. Moreover, Correctives *(Muslehat)* are used since long period of time to avoid or lower the toxic effects. Inspite of fact that herbal medicines have no side effects, some drugs

are toxic in their crude form so they are processed or purified before the use *(Mudabbar or Tadbir).*

Objective: To discuss the concept of Pharmacovigilance and its importance in Unani System of Medicine.

Materials and method: Collect the data from classical Unani literature, relevant research papers and electronic databases.

Observation: As there is myth about herbal drugs that they are completely safe but fact is that like other healing system of medicine, Unani drugs are obtained from plant, animal and mineral origin are having some side effects too. But there are certain processes and techniques in unani system which are used to detoxify the drug *(Islah-e-Advia)* resulting in minimizing their harmful effects.

Conclusion: This review will provide the information about the Pharmacovigilance and its use to analyse the drug adverse effects if any and its management how to overcome from and to improve the quality and efficacy of the drug so as to promote the effectiveness of the Unani Medicine.

KEYWORDS: Pharmacovigilance, unani, mudabbar, herbal, adverse effect

Safety of SGLT2 Inhibitors in Diabetes: A Review

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Abstract

Introduction

Sodium-glucose cotransporter type 2 inhibitors (SGLT2is) are recommended after metformin for a large spectrum of patients with type 2 diabetes, because of a favorable benefit/risk profile despite a variety of adverse events

Aim

To review the safety profile of SGLT2 inhibitors

Material and Methods

Information collection from literatures available in Pubmed

Result

SGLT2 inhibitors significantly increased the risks of diabetic ketoacidosis genital infection and volume depletion and showed the increased trends in the risks of fracture, amputation and urinary tract infection. SGLT2 inhibitors reduced the risk of acute kidney injury and showed the reduced trend in the risk of severe hypoglycemia.

Conclusion

SGLT2 inhibitors is associated with certain adverse effects, but it have less risk of Hypoglycaemia and acute kidney injury. These findings will guide that specific adverse events are monitored when SGLT2 inhibitors are used in clinical practice.

Keywords: SGLT2 inhibitor, safety, ADE, Side effects

Fosfomycin in UTI- A Breakthrough or Setback? A Review of Literature and Analyses of Adverse Effects of Fosfomycin

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Abstract

INTRODUCTION: Fosfomycin is a broad-spectrum antibiotic. The commercial forms of Fosfomycin include calcium or trometamol salts for oral administration and disodium salt for intravenous delivery. It is currently the first-line treatment for uncomplicated UTIs, especially in women, in several nations.

Current recommendations propose reserving Fosfomycin for patients for whom the typical first-line medications are not an option; to reduce resistance and prolong efficacy. Interest in the pharmacovigilance of Fosfomycin has grown as a result of emerging antimicrobial resistance.

OBJECTIVE: For the detection, assessment, understanding, and prevention of adverse effects of Fosfomycin.

MATERIALS AND METHODOLOGY: Literature review of clinical trials and research papers on public databases like PubMed, Google Scholar, etc.

In total, 23 studies involving the parenteral administration of Fosfomycin to 1242 individuals were chosen for the literature evaluation, comprising 8 comparative and 15 non-comparative studies. Only prospective comparative studies (n = 28) including 2743 individuals were included for oral Fosfomycin.

DISCUSSION: In general, Fosfomycin is well tolerated. In instances of known hypersensitivity, it's contraindicated. Fosfomycin is classified as pregnancy category B2. It's not advised for lactating mothers. Due to the lack of accessible data, it's not recommended for children under the age of 12. There are a few other unfavourable drug interactions, like- lower serum and urine concentrations when co-administered with metoclopramide.

RESULT: Rash, peripheral phlebitis, hypokalaemia, and gastrointestinal issues were the most typical AEs linked to parenteral Fosfomycin. Rarely were serious AEs such as aplastic anaemia, anaphylaxis, and liver toxicity recorded.

The most frequent AEs linked to oral Fosfomycin were gastrointestinal illnesses.

CONCLUSION: The reported adverse events (AEs) were in line with Fosfomycin's safety profile. There were no newly discovered safety warnings for either parenteral or oral Fosfomycin.

KEYWORDS: ADR, Adverse effects, Fosfomycin, Pharmacovigilance, UTI

Methods of processing of Lac (Laccifer lacca Kerr) described in Unani system of Medicine

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ABSTRACT

Objective: Discussing various methods of processing of Lac (*Lacca laccifer)* mentioned in unani system of medicine.

Material and method: Classical manuscrips of unani medicine and scientific research papers.

Discussion: Processing of crude drugs is done since ages in unani system of medicine for various purposes like to increase the potency, to decrease the toxicity, to maximize its penetration and absorption, to free it from unnecessary bulk and other unwanted parts of the plants. Similarly, Lac is processed for mainly two reasons firstly to remove impurity i.e., unwanted insect parts and other contamination and to increase its penetration power. Specific methods are mentioned in unani literature for the processing of crude lac is being discussed in this paper

Conclusion: Processed lac differs physically from unprocessed lac although these differences are not distinguishable in ordinary chemical tests, they are nevertheless obvious and it is found by experience have particular applications to which they are best adapted. Suggested that the processing method has got a role in more efficacious drug action of lac. The claim of classical literature that the processing by Izkhar and Rewand chini increases the penetration effect or enhances absorption may be suggested as mechanism of this effect.

Keywords: Lac, *Lacca laccifer*, rewand chini, izkhar.

Adverse Drug Reporting using an active surveillance method: Trigger Tool Method (TTM)

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Abstract

Aims and Objectives

To compare the efficacy of most commonly used spontaneous method of adr reporting and an upcoming novel active surveillance method: trigger tool method (TTM) of adr reporting

INTRODUCTION

Adverse drug reactions (ADRs) are a major cause of hospital admissions, and consequently an economic and financial burden on the healthcare system.

Underreporting with spontaneous reporting system of ADRs is a major drawback for Pharmacovigilance (PV) system for various reasons (i) causality relationship (ii) complacency (iii) indifference (iv) ignorance (v) problems with the usual workload and lack of time.

Active surveillance or TTM is defined to report an "occurrence, prompt or flag, found on review of the medical record that "triggers" further investigation to determine the presence or absence of an adverse event."

Materials and Methods

We performed a computer aided search of PubMed, national and international databases of suspected ADRs reports in order to identify previous published case reports, spontaneous reports and implementation of TTM active surveillance in hospital setting about the ADRs using keywords pharmacovigilance, ADRs, case reports, trigger tool method.

RESULTS

The active surveillance method of ADRs reporting overcomes the issues of spontaneous method of adr reporting.

CONCLUSIONS

TTM is an effective method of ADR monitoring in the clinical setting. An awareness of TTM helps in better detection of ADRs.

Key Words

Pharmacovigilance, ADRs, active surveillance, spontaneous reporting, voluntary reporting.