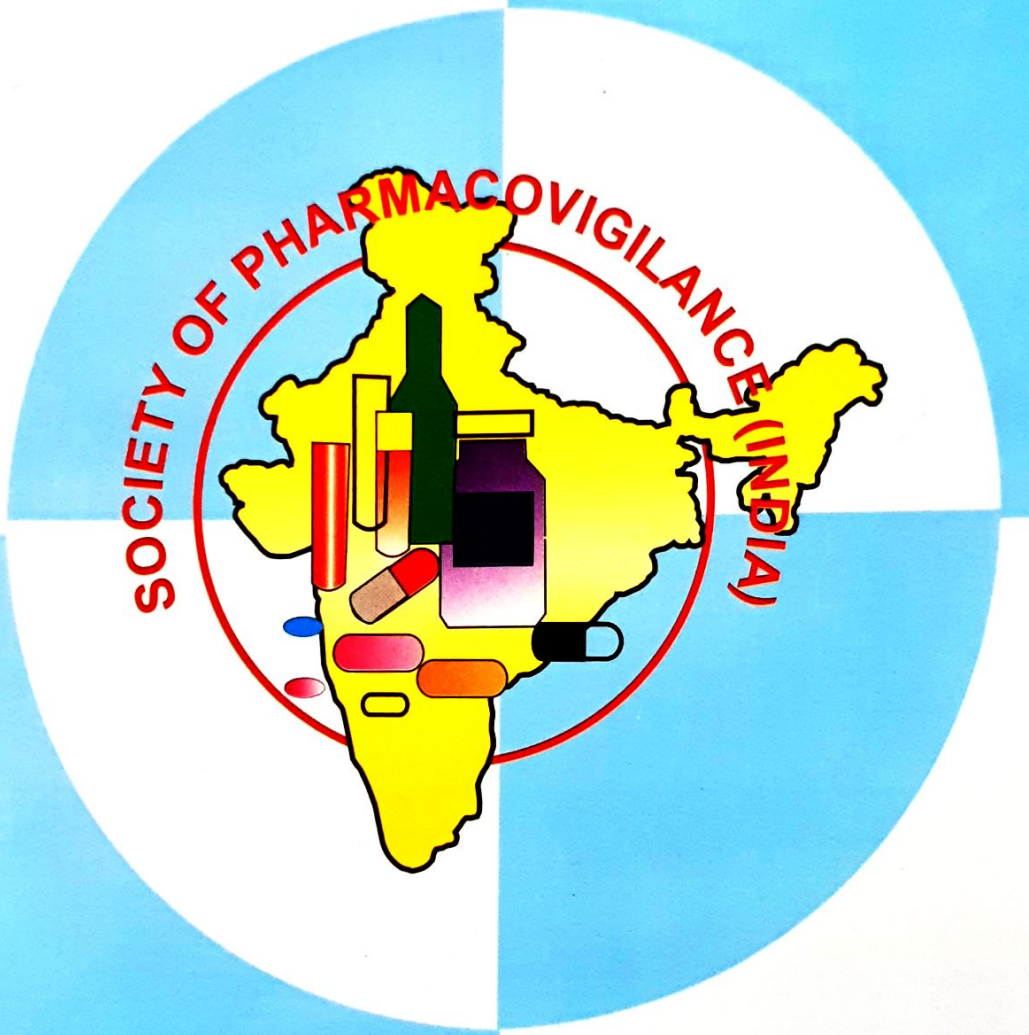
Journal of Pharmacovigilance & Drug Safety

VOLUME 9 NUMBER 4 OCTOBER-DECEMBER, 2012



ISSN 0972 -8899

Official Publication of
Society of Pharmacovigilance, India

Editor-in-Chief
Dr. Anurag Tomar

Journal of Pharmacovigilance & Drug Safety

(Official Publication of Society of Pharmacovigilance, India)

Volume 9, No 4, 2012

Journal of Pharmacovigilance & Drug Safety (ISSN 0972-8899) is published by the Society of Pharmacovigilance, India (SOPI). Journal is provided free of charge to Life members. For institutional library annual subscription is Rs. 2000/- and for individuals Rs. 500/- per annum. Loose issues will not be sold. Manuscripts and illustration for publication should be sent to Dr. Anurag Tomar, Editor-in Chief, Journal of Pharmacovigilance & Drug Safety, NIMS City Centre, 4 Govind Marg, Jaipur - 302004 India. Email sopijaipur@gmail.com Please refer to instruction for Authors, for additional information concerning preparation of manuscripts for publication.

FROM THE DESK OF EDITOR

It is my proud privilege to extend a very warm welcome to the delegates and scientists attending 12th Annual Conference of Society of Pharmacovigilance, India and International symposium on pharmacotherapeutics and biomedical approaches in health & diseases from 23rd- 25th November 2012 at NIMS University, Jaipur.

Pharmacovigilance is important and integral part of medical science, it defined as the process of identifying and responding to drug safety issues and has grown considerably as a discipline over the past 10 to 15 years. The conference special issue of the journal has evaluated the Pharmacovigilance report in current years and its growing importance as a science critical to effective clinical practice and public health science. It contains research works from the different parts of the country and abroad showing of importance of Pharmacovigilance in public health and clinical practice.

The commonest myth regarding self medicines or by prescription is that medicines are completely safe, and can therefore be safely consumed by the patient on his/her own, without a physician's prescription. This belief has led to large-scale self-medication by people all over the world, often leading to disappointing end-results, side-effects, or unwanted after-effects. The discipline needs to develop further to meet public expectations and the demands of modern public health. The purpose of this conference is to develop method and tools for the detection, assessment and understanding of the prescription of drugs by clinicians and pharmacists and developing newer approaches in prescription of drugs in disease states.

I am hopeful that this conference will provide an ideal environment to exchange of knowledge and network amongst the clinicians, pharmacists, scientists and general public and pave the way for future Pharmacovigilance practice and research in the related domains.

I thank all the member of the organizing committee and editorial board who helped me in reviewing and drafting the scientific material to make the Conference issue of the Journal special.

Dr. Anurag Tomar
MBBS, MD (Pediatrics)
Editor in Chief
sopijaipur@gmail.com

Journal of Pharmacovigilance & Drug Safety

October-December, 2012 Volume 9 : Number 4

Contents.....

K.C. SINGHAL ORATION

Adverse Reactions to Oral Contraceptives

PROF. NICHOLAS R DUNN (U. K.)
Faculty of Medicine, University of Southampton, UK

Oral contraceptives ("the pill") are an important form of birth control in the world generally, more particularly in Europe and the North America. There are published estimates that there are well over a hundred million users in the world overall. India has an enormous population of 1.2 billion and although oral contraceptives appear not to be used by a large proportion of the women in India, we can still make a rough estimate that around 1 million women are using the pill at any one time.

The pill is has risks and benefits, just like any other medication. One of the more serious risks is an increase incidence of venous thromboembolism. It has been shown, from very early on,(1960s), that the risk is higher in users of the pill than non-users, and it has been shown more recently that so-called third-generation pills, with modern progesterone, are more risky than second-generation pills, with more tried and tested progesterone types. The epidemiological work behind studies which showed this increased risk is controversial and there is still room for argument on the degree of risk posed by third-generation pills. Equally, the new progesterone, drospirenone, seems to confer an increased risk of venous thromboembolism compared to the older pills.

There can be little doubt that, overall, the risks of taking the oral contraceptive are outweighed by the benefits, and it is important that women taking the pill understand this. They are certainly protected against certain types of cancer, for example, by taking the pill. The market for the pill in India could be huge, of course, and it is better that, from the start, women are well-informed about the risks and benefits that might be conferred on them by this highly effective contraception.This talk will examine the pharmacoepidemiology work behind the controversy on venous thromboembolism and the pill, particularly with reference to the 1995 scare in the UK, but also bringing in more modern studies on the same theme. I shall relate this to the situation in India, where the absolute numbers of potential pill users is high enough to warrant our attention. Use of the pill will almost certainly increase in India as literacy rates, and standard of living, increase as well.

INVITED LECTURES

IL-01
Adverse Reaction and Patient Safety Issues in Medical Practice

K.C. SINGHAL
NIMS University, Jaipur India

IL-02
Pharmacovigilance System in United Kingdom

NICHOLAS R DUNN
Faculty of Medicine, University of Southampton, UK

IL-03
Introduction to Adverse Drug Reaction

B.R. MADAN
Former Professor 0f Pharmacology, Jaipur

IL-04
Safety Issues of Drugs in Pediatric Practice

ALOK PUROHIT
Department of Pediatrics
NIMS University, Jaipur

IL-05
Medical Problems in ICU

NARENDRA RUNGTA
Critical Care and Trauma Hospital, Jagatpura,
Jaipur

IL-06
Practice of Pharmacovigilance in Cardiovascular Disease

ATUL KASLIWAL
Santoba Durlabhji Hospital, Jaipur

IL-07
Drug Induced Ophthalmic Reactions

SWATI TOMAR
Department of Ophthalmology, NIMS Medical College, NIMS University, Jaipur

IL-08
How Drugs are Safe in Pregnancy

PADMA NAGPAL
Department of Gynecology, NIMS Medical College, NIMS University, Jaipur

Half of the pregnancies in India are unplanned and 86% women take medications during pregnancy. Despite this high rate of medication intake, most drugs are not labeled for in pregnancy. This presentation sumerizes the Pharmacovigilance to be done for drugs intake in embryogenesis and organogenesis; throughout pregnancy and lactation.

IL-09
Associated Problems with Use of Plastics in Clinical Practice

D.K. KASLIWAL
Department of Surgery
NIMS Medical College, NIMS University, Jaipur

IL-10
Types of Adverse Drug Reactions

UMA ADVANI
Department of Pharmacology
NIMS Medical College & Hospital, Jaipur,

An adverse drug reaction (ADR) is a response to a medicine which is noxious, undesirable and unintended, and which occurs at doses normally used in human for diagnosis, prophylaxis and treatment. Adverse Clinical Events (ACEs) areany new health problem or worsening of an old complaint since commencing the new medication. All suspected ADRs are ACEs while few ACEs are ADRs. Rawlin and Thompson (1991) classified ADRs into six types. *Type A* are most common (80%), dose-related, pharmacologically predictable, causing high morbidity and low mortality.It can be side effects, toxic effect or secondary effects. *Type B are* non-dose related, bizarre and unpredictable causing low morbidity and high mortality. It can be immune related such as hypersensitivity (Allergic) reactions, non-immune reactions (idiosyncratic reaction) or genetically determined. *Type C*aredose-related and time-related &associated with long-term (Chronic) drug therapy. *Type D reactions* refer to carcinogenic and teratogenic effects. These reactions are delayed in onset.*Type E are* end of dose (Withdrawal) reaction. *Type F*occurs withunexpected failure of therapy & may be caused by drug interactions. The W.H.O recommends standardization of descriptions of frequency of ADR as *very common* (>1/10 patients), *common* (>1/100), *uncommon* (>1/1000), *rare* (>1/10,000) &*very rare* (<1/100,000). According to severity into *Minor, Moderate, Severe&Lethal.*Risk factors for developing an ADR are multiple drug therapy, very young & very old age, pregnancy, co-morbidity/chronic diseases & hereditary factors. *ADRs impact* Quality of Life, increase costs, prolong hospital stay & increase risk of death.

IL-11
Off Label Use of Medicines and Safety

BARNA GANGULY
Department of Pharmacology, P.S. Medical College, Karamsad, Gujarat

When a medicine is used in a different way from that described in the FDA-approved medicine label, it is said to be an "off-label", also called "non-approved" or "unapproved" use. This means that the medicine is either used for a different disease or medical condition or administered by a different route or given in a different dose than in the approved label. Off-label prescribing is common as it is found to be beneficial but, it is often done in the absence of adequate supporting data. It is not restricted by law for doctors to use drugs off label but it is not legal for drug companies to market their medicine for off-label uses. Studies have reported that use of drugs in an off label manner to treat children is widespread. About half of the chemotherapeutic agents are used in conditions not listed on the FDA-approved drug label. Off-label use can vary greatly from one doctor to another as it depends on the doctor's preferences, knowledge, and past patient experiences. Advantages of use of such appear to be some innovative approach in clinical practice, particularly when approved treatments have failed, offers patients and physicians earlier access to potentially valuable medications and allows physicians to adopt new practices based on emerging experience. This can also provide some available treatments for "orphan" conditions. At the same time, off-label use has potentially negative consequences. All drugs have side effects and lack of information on off-label drug use and outcomes may increase a higher risk for medication errors, side effects, and unwanted drug reactions. As of now, there is no standard guideline or regulation on off label use of medicines in our country though in western countries it is legal. Recently FDA has passed a rule which allows manufacturers to promote the off-label use of their drugs directly to doctors. In this way it can save millions of dollars by avoiding the requisite application to the FDA with the documentation (clinical studies) needed to prove that a drug is safe and effective for another condition. A lot of arguments and discussion are going on this issue.

IL-12
Medical Error and their Prevention

SANDEEP AGARWAL
Agra

IL-13
Skin susceptibility in Adverse Drug Reaction

SANJAY KANODIA
Department of Dermatology, NIMS Medical College, NIMS University, Jaipur

Drug eruptions are probably the most frequent of all manifestations of drug sensitivity—the incidence of which varies from 24% - 29%. It can be manifested in form of immunological and nonimmunologiacl pathways. Drug reactions may arise as a result of immunological allergy directed against the drug itself, a reactive metabolite or some contaminant of the drug or, more commonly, by non-immunological mechanisms, such as pseudoallergic reactions caused by nonimmune-mediated degranulation of mast cells and basophils. Autoimmune reactions, in which the drug elicits an immune reaction to autologous structures, may also occur. About 80% of drug reactions are predictable, usually dose-related, are a function of the known pharmacological actions of the drug and occur in otherwise normal individuals. The clinical presentation of drug eruptions is highly variable, in part explicable by involvement of a variety of cytokines, inflamatory cells and regulatory mechanisms, and ranges from common transient and benign erythema occurring 6–9 days after the introduction of a new drug in up to 3% of users, to the most severe forms which affect fewer than 1/10 000 users. It is important for clinicians to recognize these severe cutaneous adverse reactions: anaphylaxis; drug reaction with eosinophilia and systemic symptoms (dress) syndrome (previously termed drug hypersensitivity syndrome) (mortality 10%); acute generalized exanthematous pustulosis (AGEP) (mortality 5%); bullous fixed drug eruptions; serum sickness syndrome; vasculitis; Stevens–Johnson syndrome and toxic epidermal necrolysis (TEN) (mortality 25 to 30%).

IL-14
Principles and Methodology for Causality Assessment

DINESH K. BADYAL
Department of Pharmacology, Christian Medical College, Ludhiana, India

The assessment of cause-effect relationship between drug and adverse drug event is essential link to label an adverse drug event (ADE) as adverse drug reaction (ADR). ADE is any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this

treatment e.g. road accidents, falling from roof. The conversion of ADE to ADR follows principles of causality assessment. The principles mainly focuses on exclusion of all other causes, concomitant drugs, natural progression of disease, withdrawing the suspected drug (de-challenge) and re-challenge with same drug to evaluate reoccurrence of event. The methods can be subjective or objective. The various method used include; Naranjo Probability Scale, WHO-UMC Criteria (used in CDSCO form), Kramer Scale, Jones Scale and Karch and Lasgna Scale. The commonly used methods are Naranjo scale and WHO criteria. Both have been used in various studies and there is no definite advantage of one over other. The Naranjo scale converts the responses to scores and based on the scores, the relationship between drug and ADE can be highly probable, probable, possible or doubtful. The WHO criteria give a set of assessment criteria and based on these criteria the relationship can be certain, probable, possible, unlikely, conditional or unassessable. After an ADE is reported, the concerned person from pharmacology or pharmacovigilance cell, contacts the reporting physician and verifies the questions/points based the scale used. Then he applies these scales to the responses and gets a relationship/causality assessment.

IL-15
Regulatory Compliance in Safety Monitoring in Clinical Trials

ATUL JAIN
Department of Pharmacology, Nims Medical College, NIMS University, Jaipur

IL-16
Post Marketing Surveillance

MANISH VERMA
Eli-Lilly, Mumbai

IL-17
Ethics in Clinical Trial

BARNA GANGULY
Department of Pharmacology, P.S.Medical College, Karamsad, Gujarat

Clinical trial is a systematic study involving human participants intended to generate data to find out the safety and efficacy of medications, devices, diagnostic products, herbal remedies and vaccines etc. Clinical trial is necessary because it aims at progressing the well-being and treatment, prevention and diagnosis of ill health (WHO definition). There are certain risks for the participants either healthy volunteers or patients in such trials. The inhuman experiments by German physicians on prisoners during the Second World War (1939-1945) generated worldwide concerns and intense reactions. The deliberation of the world war trial courts led to formulation of the Nuremberg Code (1947), which highlighted the element of essentiality of voluntariness in the informed consent. This was followed by the UDHR (Universal Declaration of Human Rights, United Nations General Assembly, 1948), Helsinki Declaration (1964), International Covenant on Civil and Political Rights (ICCPR, 1966) etc. Thus certain guidelines have been framed to protect the research participants from any avoidable risks, to guide researchers for making trial protocols and to facilitate Ethics Committees to review and approve the studies. In India, we have ICMR guidelines (2000), updated in 2006, taking into consideration the changing ethical perspectives around the world. For the purpose of research, three ethical principles are to be followed: respect for persons, beneficence and justice. While conducting clinical trials, the Investigator should adhere to four basic ethical principles: autonomy or respect for the participants, beneficence, non-maleficence and justice. The investigator should ensure the protection of the rights, safety and well-being of the trial participants. S/he should conduct the trial strictly abiding by Indian GCP guidelines and ICH-GCP Guidelines if the requirement is by USFDA or EU regulatory agencies.

IL-18
Unani Medicine and Medical Ethics in Reference to Pharmacovigilance

ABDUL LATIF, SUMBUL REHMAN
Department of Ilmul Advia (Unani Pharmacology & Pharmaceutical Sciences)
Faculty of Unani Medicine; Aligarh Muslim University, Aligarh

Unani medicine has its roots of origin since 1500 B.C, in Egypt then it developed in Greek and Arabs. Father of Medicine, the Greek philosopher-physician *Hippocrates*kept the very basis of Unani Medicine (UM) and there were basic pillars set for Tibb-e-Unani on which it still stands today. He believed that every possible medicine should be gentle and safe. UM treat disease as well as patient. This is the main objective of UM. There are various Arabic giant Unani physicians known to medical world like Ibn Sina (*Avicenna*), Al-Razi (*Rhazes*), and Zohravi (*Abulcasus*).

Usually it is said about UM, that these drugs are not harmful and that is why, people are more intended towards its use. It is because of the adverse effect of the Allopathic drugs as compared to Unani drugs which does not cause such harms, so it is popularised.

Medical Ethics (*Tibbi Aqhlaqhiyat*) is based upon its three basic principles: *Respect, Benefit* and *Justice* to patient. And Unani Medicine is following the Medical Ethics properly.

Father of Medicine *Hippocrates* had described in respect of the treatment that it should be first started by following Restrictions and dietary management before use of drugs.

This almost clears the point that he was aware of the facts that Unani drugs may be harmful to patients. And for the treatment Unani physician should always use drug which should produce benefit at its maximum and harm as minimum as possible.

Unani physicians have laid greater emphasis on basic regulations and principles for the line of treatment and use the drugs accordingly, so that harmful effect of the drugs must be minimized or neutralized. The naturally occurring drugs are used in this system usually free from any side effects while Unani drugs are also toxic but these are mandatory to be processed / detoxified and purified in many ways before the use of these drugs to the patients so as to make them free from any kind of side effects / toxic effects. That is based on special technology of detoxification, four degrees of potentiality of drugs, substitution, compounding of formulations, prescribing of specific drugs for specific temperament of patient; theses all for minimizing the toxic/side effects of Unani drugs while Allopathic Medicine don't follow any procedures and principles, and that is why allopathic drugs are harmful / producing ADR.

Thus Unani Medicine follows the Medical Ethics and pharmacovigilance as they modify the drugs with some special procedures & a unique technology to minimize the harmful effect before prescribing it to the patient.

How this happens, what are its guidelines, what are the procedures used for preparation of safe Unani drugs; these all will be discussed in full length paper.

IL-19

Fluoride in Medicine: Biomedical Consequence in Health and Diseases

ANURAG TOMAR[1], DUSHYANT SINGH CHAUHAN[2], VIVEK PRATAP SINGH[2], SANDEEP TRIPATHI[2]

National Referral Centre for fluoride poisoning in India, [1]Department of Pediatrics, NIMS Medical college and [2]Department of Biotechnology, NIMS University, Jaipur

The relation between fluoride and human health has been extensively studied for over 100 years. Small amount of fluoride can prevent dental carries and strengthen bones, but there are a number of adverse affects including dental fluorosis, skeletal fluorosis, decreased birth rates, increased rate of rolithiasis, impaired neurological and thyroid function, reduced sperm quality and lower intelligence score in children. Fluorinated chemicals are of growing importance, with applications in medicine. Fluorine-containing drugs are used in medicine as anesthetics, antibiotics, anti-cancer and anti-inflammatory agents, psychopharmaceuticals, and in many other applications. Fluorine substitution has profound effects on the properties of organic compounds. The very high electronegativity of fluorine can modify electron distribution in the molecule, affecting its absorption, distribution and metabolism. The generation of ROS and lipid peroxidation has been considered to play an important role in the pathogenesis of hronic fluoride toxicity and reduced enzymatic and non enzymatic antioxidant. Fluoride (F) crosses the blood brain barrier and increase the possibility of Fluoride accumulation in central nervous system and alteration in its structure and functioning of the CNS. Therefore, the potential contribution of fluorinating pharmaceuticals and health related problems should be considered. However, further in depth studies is required for the understanding of pathophysiology of fluorosis.

IL-20

Biochemical Dysregulation in the Treatment of Schizophrenia

GORA DADHEECH

Department of Biochemistry, NIMS Medical College and Hospital, Shobha Nagar, Jaipur

Background: Schizophrenia is a psychotic disorder with a complex pathophysiology and requires treatment that includes long term administration of antipsychotics. Although all the drugs used are highly effective and have become cornerstones for the treatment of schizophrenia yet, recently in various researches, administration of these antipsychotics has also been found to be associated to the metabolic and CV risk factors. Aim: This study was designed to evaluate the effect of different typical and atypical antipsychotics on various biochemical and anthropometric parameters that are responsible for the induction of metabolic syndrome in schizophrenic patients. Method: Schizophrenics were recruited for the study after their proper classification by the ICD-10 diagnostic criteria and divided into groups, each group given a different antipsychotic drug for 16 weeks after washout along with the prescribed line of treatment. Measurement of biochemical and anthropometric parameters was done to find their dysregulation Result: Final comparison of the metabolic parameters showed Olanzapine is the drug that has maximum potential to cause metabolic dysregulation followed by clozapine. Aripriazole and amisulphride are relatively safer drugs. Since, antipsychotic drugs cause metabolic abnormalities it is recommended that regular monitoring of metabolic and cardiovascular risk factors is a must, especially when they are required to be administered for a long time period.

IL-21
Altered Metabolism of Drugs - Role of Cytochrome P-450

R.C. GUPTA
Department of Biochemistry, NIMS Medical College, Jaipur

All drugs are foreign compounds which are strangers to our body (xenobiotics). If they are not metabolized, they will accumulate in our body causing toxicity. During the course of evolution, we have developed mechanisms to metabolize and excrete drugs. Cytochrome P-450 (CYP), a conjugated protein, is involved in the metabolism of majority of drugs. There are more than 200 isoforms of CYP, divided into a number of families and subfamilies. Each isoform is encoded by a specific gene.

CYP isoforms are subject to induction and inhibition. Some isoforms may be genetically deficient. Some have overlapping specificities. This may lead to altered metabolism of drugs when two or more drugs are given simultaneously. These features of CYP necessitate knowledge of drug metabolism by CYP, and alertness on the part of the physician while prescribing a combination of drugs.

IL-22
Adverse Effects of Aluminum in Medications: A Pharmacovigilance Study

SANDEEP TRIPATHI, MANISHA CHOUDHARY, DEVESH KUMAR JOSHI
Department of Biotechnology, NIET, NIMS University, Jaipur

Aluminum (Al) is the most widely distributed in the environment and is extensively used in medications and diet in modern daily life. Aluminum hydroxide comes as a capsule, a tablet, and an oral liquid and suspension. The consumption of large oral doses of aluminum-containing phosphate binders or antacids is the major cause of aluminum overload through medication. It is extensively used in dialysis buffer which further leads to dialysis dementia. It has also been reported that Aluminum is responsible for Alzheimer's disease. Aluminum is a well-known contaminant of intravenous solutions found that aluminum concentration in the enteral nutrition formulas and the parenteral solutions. There is no known physiological role for aluminum within the body and hence this metal may produce adverse physiological effects. The mechanism of action is poorly understood. The possible mechanisms of toxicity include inhibition of enzyme activity and protein synthesis, alterations in nucleic acid function, changes in cell membrane permeability and oxidative stress. No known physiologic need exists for aluminum; however, because of its atomic size and electric charge, it is sometimes a competitive inhibitor of several essential elements of similar characteristics, such as magnesium, calcium, iron, copper and Zinc. Our previous study demonstrated that Aluminum responsible for early aging evident by the large accumulation of aging pigment lipofuscin. We suggest that, aluminum should be replaced by alternative compound.

IL-23
Indian System of Medicine; Concepts of Drug Therapy in Ayurveda

AJAY KUMAR SHARMA
National Institute of Ayurveda, Jaipur

IL-24
Concepts of Drug Therapy in Ayurveda

PARIMI SURESH
National Institute of Ayurveda, Jaipur

IL-25
National Programme for Monitoring ASU Drugs

RABINARAYAN ACHARYA
Gujrat Ayurved University, Jamnagar, Gujrat

IL-26
Safety of Heavy Metals Used in ISM

GALIB
Gujrat Ayurved University, Jamnagar, Gujrat

Ayurveda, the first systematic science ever evolved in the universe focuses on maintenance of positive health in healthy and eradication of diseases in diseased. To fulfill these two, seers have tried a number of laudable measures and found that the drugs of different sources (herbal, animal, mineral or marine in origin) are the most suitable media to achieve them. Screening through the classical literature proves that, the seers emphasized on the quality and safety aspects of the drugs, which are the most essential aspects for their acceptance.

During the past few decades, *Ayurvedic* drugs are continuously under screening and concerns are being raised over the safety aspects. Few recent publications conclude that, *Ayurvedic* medicines contain considerable levels of heavy metals like lead, mercury, arsenic and cadmium etc. and are harmful to be consumed. Such reports are giving a big blow over the reputation of age old *Ayurvedic* system of medicine.

A drug can be panacea or poison. A drug fulfilling the criterion of quality standards will always become panacea provided, if it is used properly. On the other hand, a poorly prepared or manufactured drug however used skillfully, will always prove to be a poison. *Ayurvedic* classics do mention the hazards of drugs, which are not properly manufactured. Such references clearly show that the seers were fully aware about the possible hazards or adverse

effects with drug administration. Based on this knowledge, they have prescribed specific processing techniques to remove the hazardous properties (if any) from the drugs. They have also prescribed testing methods, which will tell the manufacturer whether the drug has attained a form, which does not have hazardous properties when used properly by a physician. In such circumstances, statements like "*Ayurvedic* drugs are toxic, as they contain heavy metals" is nothing but ignorance about the *Ayurvedic* science. Mere presence of metallic fractions doesn't have any relation with the toxicity of metallic preparations. Different manufacturing techniques to which the metals or minerals subjected ensures that, a number of changes will take place in their structure and the final form after reaction with various organic and inorganic materials during these procedures is finally responsible for the specified therapeutic action.

In recent past, many studies have been carried-out at different universities of India, which proven safety aspects of various metallic and mineral preparations, based on the observations, it can be said that, *Ayurvedic* preparations are not poison, but can serve the ailing humanity as panacea.

YOUNG SCIENTIST ORAL PRESENTATIONS

YS-01

Trigger Tools for Monitoring and Reporting of Adrs: A Scientific Tool for Efficient Reporting

ATUL AGGARWAL, TARUN WADHWA, M S GANACHARI, TARANG SHAH

Department of Pharmacy Practice, KLEU's College of Pharmacy, Belgaum, Karnataka

Adverse drug reactions (ADRs) are the leading cause of morbidity, mortality and increased healthcare cost. A new scientific tool has been developed to monitor and report ADRs. Trigger tool is one of the active data collection process which triggers to identify the ADR in a quicker fashion. The objective of our research was to study and assess the trigger tools for detection and analysis of ADRs. This prospective study was conducted in internal medicine department of a tertiary care hospital for duration of 3 months. Patients aged ≥ 18 years of either gender admitted were included. Subjects treated on OPD basis, emergency cases, and ICU cases were excluded. Patients and their medical records were reviewed for trigger tools (if any) to monitor and further report ADRs. A total of 220 subjects were enrolled into the study. Out of them, 40 subjects experienced 93ADRs. Eighty three trigger tools were identified in 40 subjects. Out of which, 63 trigger tools were utilized to report 80 (86.02%) ADRs. The incidence of ADRs was found to be 18.1%. Male 132 (62.85%) preponderance was observed over females 88 (41.90%). Polypharmacy (67.74%) was one of the most prominent predisposing factor reported. Majority of ADRs were found to be of probable 47 (50.5%) in nature. On severity analysis, 27 (29.03%) ADRs were of moderate (Level3) severity and 59 (63.44%) were probably preventable. Our results showed incidence of 18.1%. Trigger tools proved to be one of the best scientific tool in identification and reporting of ADRs in our study. Scientific validation of trigger tools is required to further utilize in large scale studies.

YS-02

Inadvertant Use of Eye Drops Causing Ocular Drug Toxicity

ALAKA PRIYADARSINI DASH, SWATI TOMAR

Department of Opthalmology, Nims Medical College, Nims University, Jaipur India

Long term use of topical eye drugs has clearly been shown to induce toxic immunopathological changes in ocular surface. Lacunae exist in regards to respective role of active compounds and their preservatives.

Topical ophthalmic medications sometimes may cause toxic or allergic reactions resulting in iatrogenic ocular disease. Toxic reactions relate to the direct chemical irritation of tissue whereas allergic reactions imply sensitization and induction of ocular inflammatory processes by the patient's immune system.These adverse external ocular effects of ophthalmic therapy are due to the topically applied drug, or the excipients present in the preparation. Preservatives are among the excipients currently used in ophthalmic preparations.

Drug induced ocular toxicity is a matter of concern.Toxicity is dose dependent & concentration dependent & generally varies according to overall health of the eye. The inadvertent use of a variety of eye drop preparations in rural population has led to a dramatic rise in the number of serious cases of ocular toxicity from eye drops. This article review serious ocular toxicity which have been described with the use ofTopical natamycin, acyclovir, sulfa drugs, ciprofloxacin, timolol, latanoprost, brimonidine, corticosteroids, tear substitutes, gentamycin, antihistaminic and chloramphenicol etc in rural population. So there should be a rational in use of eye drops & inadvertent use of drugs should be minimised as much as possible & should be aware of its toxicity in eye before instillation.

YS-03

A Prospective Randomized Open Label Study Comparing Efficacy and Tolerability of Amlodipine and Ramipril in Patients of Stage-I Hypertension

BALBIR KAUR, RANI WALIA, B K AGRAWAL, SHAFIQA ASLAM

Department of Pharmacology, Maharishi Markandeshwar Institute of Medical Sciences and Research (MMIMSR), Mullana, Ambala

Objective: To compare the efficacy and tolerability of Amlodipine versus Ramipril in patients of stage I hypertension.

Material and Methods: A 12 week prospective, randomized, open, parallel group study including 50 patients with stage I hypertension was conducted in the department of pharmacology association with medicine department at MMIMSR, Mullana. Patients giving the informed consent and fulfilling the eligibility criteria were randomized to group 1, n=25 (Amlodipine 5-10 mg/day) and group 2, n=25 (Ramipril 2.5-10 mg/day). At baseline, 1 week, 2 weeks, 3 weeks, 4 weeks, 6 weeks, 8 weeks and

12 weeks B.P was recorded. Any adverse drug reactions were inquired, analyzed and recorded at each visit. The difference in B.P reduction in two treatment groups from baseline to 12 weeks was the main outcome measure.
Results: Mean supine systolic blood pressure was reduced from 153.04±4.8 to 131.28±5.7 mmHg (amlodipine) and 154.48±3.7 to 133.36±5.7 mmHg (ramipril) after 12 weeks treatment (percentage difference was 14.2%, 13.6%). Mean supine diastolic blood pressure was reduced from 93.68±4.1 to 80.0±1.7 mmHg (amlodipine) and 95.28±3.5 to 80.24±3.8 mmHg (ramipril) after 12 weeks treatment (percentage difference was 14.6%, 15.7%). Both the drugs were well tolerated. The adverse events occurring most frequently in amlodipine group were headache (2) and ankle edema(1).The adverse events occurring most frequently in ramipril group were headache(1), nausea(1), mild dry cough(1) and hypotension(1).
Conclusion: Amlodipine and ramipril had similar effects on B.P reduction but ramipril was better tolerated except for mild dry cough and hypotension than amlodipine.

YS-04

Comparison of Prophylactic Ketamine, Clonidine and Tramadol for the Control of Shivering Under Spinal Anaesthesia

HARPREET SINGH, B.L. GUPTA
Department of Anesthesia, Nims Medical College, NIMS University, Jaipur

Background: Shivering is a common problem during spinal anaesthesia. Spinal anaesthesia impair thermoregulatory control and up to a 56.7% incidence of shivering has been reported.
Aim: To evaluate the effectiveness of prophylactic use of intravenous ketamine, clonidine and tramadol in control of shivering and to note any side-effects of the drugs used.
Setting and Design: Randomised double-blind study.
Methods: This study was conducted in 80 ASA grade I &2 patients. Neuraxial block was performed with 3 mL of 0.5% bupivacaine heavy in all patients. The patients were randomly allocated into four groups of 20 each to receive saline as placebo (group P), ketamine 0.5 mg/kg (group K), Clonidine 75 mcg (group C) and Tramadol 0.5 mg/kg (group T). Temperature and hemodynamic parameters were recorded at every 5-min interval. Shivering was graded from 0 to 4 grades and, if grade 3 shivering occurred, the study drug was considered as ineffective.
Statistical Analysis: Data among groups was compared using one-way ANOVA. The incidence of shivering and side-effects were compared using the chi-square test.
Results: The incidence of grade 3 shivering showed a statistically significant difference in group P (12/20) as compared with the other groups (group K=3/20, group C=1/20, group T=2/20. No major hemodynamic changes were seen with prophylactic use of test drugs; however, sedation score was significantly higher in group K as compared with the other groups.
Conclusion: The prophylactic use of ketamine, clonidine and tramadol were effective in preventing shivering during spinal anaesthesia without causing any major untoward side-effects.

YS-05

The Association of Chronic Therapeutic Use of Diclofenac with Reversible Cholestasis

KAMLESH M. PALANDURKAR, KIRAN GIRI[1]
Department of Biochemistry Gujarat Adani Institute of Medical Sciences, Bhuj Kutch, Gujarat; [1]Department of Pharmacology Jawaharlal Nehru Medical College, DattaMeghe Institute of Medical Sciences University, Sawangi (Meghe), Wardha

Background: Many patients of chronic inflammatory orthopedic conditions shown haphazard results of Liver function tests profiles on their hospital admission.
Introduction: Diclofenac is one of the many NSAIDs given commonly to the patients with inflammatory conditions. Diclofenac is approved for use in rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, dysmenorrhea, and topically for the treatment of ocular inflammation and actinic keratosis. Diclofenac exhibits approximately equal selectivity for COX-1 and COX-2. The most common adverse reactions are GI disturbances and headache. A reversible elevation of serum transaminases occurs in 15% of patients. Reversible cholestasis is one of the hepatocellular damaging effects of many NSAIDs. But this type of effect has not been mentioned for Diclofenac.
Objective: To establish reversible cholestatic effect of Diclofenac.
Methods: A group of 10 patients who were taking diclofenac more than 3 months daily for various diseases were under study. All those patients on admission were shifted from diclofenac to oral opioid analgesic, Tramadol for better analgesic control. Serum Alkaline phosphatase (an enzyme marker of cholestasis) values were measured in these patients preadmission and post admission. Post admission Serum Alkaline phosphatase values were measured on 04^{th}, 07^{th} and 10^{th} day.
Results: Serum Alkaline phosphatase values showed significant changes in the groups when preadmission group values was compared with 04^{th} and 07^{th} day groups ($P< 0.005$) and also between 04^{th} and 07^{th} day groups ($P< 0.005$) but no difference was shown in the values of 07^{th} day and 10^{th} day values.
Conclusion: Reversible cholestatic effect of Diclofenac is clearly established by this pilot study.

YS-06

Drug Utilization Study in Pediatric Neurology Outpatients Department at a Tertiary Care Teaching Hospital

KRUTIKA BHATT, SUPRIYA MALHOTRA, KAMLESH PATEL, VARSHA PATEL
Department of Pharmacology, Smt. NHL Municipal Medical College, Ellisbridge, Ahmedabad

Background: Neurological disorders are a significant cause of morbidity, mortality and adversely affect quality of life amongst pediatric patients. Most of these disorders being multifactorial in origin cannot be prevented. In India, more than 30% population is under 20 years of age, many of whom are presented late during the course of illness due to negligence. Hence it is important to study the common neurological disorders and the drugs prescribed.

Aims & Objectives: To study drug use pattern in patients attending outpatient department of pediatric neurology at a tertiary care teaching hospital.

Methodology: Prescriptions of patients attending the neurology outpatient department were collected. They were analyzed for morbidity pattern, WHO core prescribing indicators, cost of drug therapy and potential for drug interactions.

Result: A total of 100 prescriptions were collected. The male female ratio was 2:1. Epilepsy was the most common condition diagnosed (74%) followed by migraine, breath holding spells and developmental delay. Partial seizure was the most common type of epilepsy (48.64%). Average no. of drugs prescribed per patient was 1.57. Most commonly prescribed drug was sodium valproate (27.21%) followed by carbamazepine (9.49%), oxcarbazepine (6.96%) and phenytoin (6.32%). About 8% patients received newer antiepileptics. More than 50% of the drugs were prescribed from WHO essential drug list. Average cost of drug treatment per patient per month was Rs.166.33. Ninteen percent prescriptions showed potential for drug interactions.

Conclusion: Epilepsy is the most common neurological disease and sodium valproate is the most commonly prescribed drug. However, further studies would be required in this direction.

YS-07

A Qualitative, Drug Focused, and Prospective Study of Oral Contraceptive Pills in Gynaecology OPD & Family Welfare Centre at HAH Centenary Hospital

HANAE AHMED, MANJU SHARMA, POONAM SAITH[1], GUNJAN SHARMA[2], YASMIN SULTANA[3]
Department of Pharmacology, [1]Family Welfare Centre HAH Centenary Hospital, [3]Department of Pharmaceutics, Jamia Hamdard, New Delhi [2]Amity University, NOIDA

Oral contraceptives are the most popular reversible hormonal contraceptive methods used. Combined hormonal contraceptives administered through any delivery route are popular forms of reversible contraception and, when correctly used, are over 99% effective. Correct and consistent use of oral contraceptive pills is associated with unintended pregnancy rates of as low as 0.3% during the first year. Women often make the decision to discontinue pill use without knowledge of the seriousness of their symptoms and may decide to substitute a less reliable contraceptive method or no method at all, which exposes them to a greater risk of unintended pregnancy and the associated inherent health risksTheoretical and ''typical use'' failure rates differ because COC effectiveness relies on correct patient use. Women taking oral combined contraceptive pills have higher risk of developing deep vein thrombosis (DVT), usually in the legs, which may lead to pulmonary embolism. However, the advent of oral contraceptives (OC) has offered women a variety of benefits that can positively affect quality-of life and long-term health.

The study aimed at performing a drug utilization study (DUS) of oral contraceptives, studying the prescription pattern and adverse drug reactions (ADRs) of oral contraceptive pills. This study examines the behavior and attitude towards OCs use, and investigates the parameters of its discontinuation which majorly include side effects, compliance, and socio-demographic status. The importance of taking the pill at the same time everyday was emphasized by the clinical pharmacist to ensure perfect use of oral contraceptives and prevent pregnancy. Proper counseling was given to each individual patient especially to patients living in the rural areas.

YS-08

Drug Utilization in Emergency Medicine Department of a Tertiary Care Teaching Hospital – A Prospective Study

PREKSHA BAROT, SUPRIYA MALHOTRA, KAMLESH PATEL, VARSHA PATEL.
Department of Pharmacology, Smt. NHL Municipal Medical College, Ellisbridge, Ahmedabad

Introduction: The practice of emergency medicine has the primary mission of evaluating, managing and providing treatment to those patients with unexpected injury or illness. Drug therapy in emergency medicine requires updated knowledge and skill. It reflects the clinical judgment and behaviour of the physicians. Instituting appropriate therapy is imperative for safety of the patient and to decrease mortality and morbidity.

Aims and Objectives: To study the drug utilization pattern in patients of all age groups admitted to emergency medicine department of a tertiary care teaching hospital.

Methods: Prescriptions of all patients admitted to emergency medicine ward were collected and followed up

the next 48 hrs. They were analysed for morbidity pattern, drug use pattern, cost of therapy of initial hospitalization and potential for drug interactions. Result: A total of 100patients were included. Most common diagnosis was acute coronary syndrome (21%) followed by encephalitis (10%). Number of drugs prescribed per patient was 9.99(range 4-16). Ondansetron (86%) was most frequently prescribeddrug followed by pantoprazole (84%). Amongst antimicrobials most commonly prescribed drug was metronidazole (36%) followed by ceftriaxone (29%). Amongst cardiovascular drugs most common drug used was furosemide (45%) followed by aspirin (33%) and atorvastatin (33%). About 84.7% drugs belong to National list of essential medicines India 2011. Potential for drug interaction was observed in 93% patients. Average cost of treatment /patient for the first 48 hours wasRs 4194.57. Conclusion: This field is new in our country; hence focusing on drug therapy in emergency medicine would be helpful to physicians in improving prescribing policies.

YS-09

Self-Medication Practice among Engineering Students in NIMS Institute of Engineering and Technology, Jaipur, Rajasthan

RAHUL PARAKH, SAURABH KOHLI, SHOBHA KULSHRESHTHA, ATUL JAIN, UMA ADVANI, PANKAJ MODI, RAJEEV SINHA
Department of Pharmacology, NIMS Medical College, Jaipur

Aims: This study was undertaken to determine the knowledge, attitude & practice of self medication among engineering students of NIMS College of Engineering and Technology, Jaipur, Rajasthan.
Methods: This was an anonymous, questionnaire-based, descriptive study in which a self-developed, pre-validated questionnaire was used. Data was expressed as counts and percentages and evaluated using the Chi-square test.
Results: After exclusion, 346 students were included in the study of which 70.5% were male & 29.4% females. Out of these, 73.4% students had taken self medication with 77.86% being males and 22.13% being females ($p<0.01$). The commonest indications for self-medication were fever (67.1%) and cough/common cold (39.69%). Guardians were the main source of information for self-medication (54.9%), while the main reason for self-medication was that that they didn't feel the need to consult a doctor (37.4%). Analgesics-Antipyretics were the commonest drugs used (56.56%) with Paracetamol (37.5%) commonest among them followed by antimicrobials (15.62%) with Beta lactams (35.2%) being the most common; but only 52.5% students completed the recommended course of antimicrobials. Self-medication was considered harmful by 46.56% students. Adverse drug reactions were reported by 29.77% of students with sedation being the commonest (16.79%). Conclusion: In our study the practice of self-medication in students is common and often inappropriate. The high prevalence and high percentage of students not completing the course of antibiotics is a cause of great concern. Education, proper information and strict control on the sale of antibiotics may go a long way in promoting safe and responsible self medication.

YS-10

Ameliorative Effect of Docosahexaenoic Acid and Gama Linolenic Acid on Gamma – Amino Butyric Acid Levels in Lead Induced Swiss Albino Mice Pups

SACHDEV YADAV, VEENA SHARMA[1]
Departments of Pharmacy and [1]Biosciences and Biotecnology, Banasthali University, Rajasthan

Introduction: Lead is ubiquitous in our environment but has no physiologic role in biological systems. The brain is exceptionally sensitive to the effects of lead and gamma-aminobutyric acid levels play an important role in the pathogenesis of several neuropsychiatric disorders. The present study highlights ameliorative effect of docosahexaenoic acid and gamma-linolenic acid on gamma-aminobutyric acid levels in lead induced Swiss albino mice pups. Method: Sexually mature male and females weighing 25-30gm were put in breeding cages in the ratio of 1:1 (6 female: 6 male) and were provided standard diet and water ad libitum. The cages were checked every day in the morning and females showing vaginal plug were isolated. An animal model of lead poisoning was developed in which suckling mice were exposed to lead nitrate and lead acetate trihydrate from birth indirectly through their mothers and then directly after weaning. Comparable litters that received normal standard diet and water ad libitum were studied concurrently as controls. Estimation of gamma-aminobutyric acid content in mice offspring was measured between 150 to 180 days of age. All the experimental work was approved by the Institutional Animal Ethics Committee (Ref. No. IAEC/257) and as per CPCSEA guidelines. Treated and control animals were given docosahexaenoic acid and gamma-linolenic acid used in the treatment of minimal brain dysfunction hyperactivity in children. Result: Lead produces not only clinically defined encephalopathies and neuropathies, but also various behavioral changes indicative of cerebral dysfunction. Lead-treated hyperactive mice responded well with the above said treatment and brain dysfunction hyperactivity was significantly suppressed. Conclusion: Docosahexaenoic acid and gamma-linolenic acid shows putative ameliorative effect in lead induced Swiss albino mice pups.

YS-11

Antiepileptic Drug Therapy in Pediatric Patients Visiting Rural Teaching Hospital of Central India: A Pharmacovigilance Study

SACHIN B. KHOND, VAIBHAV K. GUPTA, SOHIN A. THAIM, MUZAMMIL PATHAN
Department of Pharmacology, Jawaharlal Nehru Medical College Sawangi (Meghe), Wardha, Maharashtra, India.

Objective: To assess and interpret the ADR profile of antiepileptic drug therapy in pediatric age group in rural teaching hospital of Central India. Materials and Methods: Pediatric patients both indoor and outdoor on antiepileptic drug therapy were included. History was interpreted in questionnaire format. They were assessed on different demographic and clinical parameters for 4 months duration. Results were analyzed with Naranjo's scale. Therapeutic Drug Monitoring was done.
Results: Total 48 patients were included in this study,in which 31 (64.6%) are males and 17 (35.4%) are females. Commonly prescribed drugs were Sodium valproate, Phenytoin, Phenobarbitone and Carbamazepine. Incidence of ADR was high i.e 39.6% (19 out of 48 patients). Out of 19 patients, Sodium Valproate (6), Phenytoin (4), Phenobarbitone (5), Carbamazepine (2), Diazepam (2). Total ADR observed were 34 as one drug causes more than one ADR. Naranjo's algorithm showed 20 (58.82%) ADRs as probable and 14 (41.18%) ADRs of possible category. All body systems were involved, with CNS (12), GIT (8), cognitive (4), skin (3), eye (2), hematological (1) and others (4). TDM results correlate with toxic ADRs of drugs.
Conclusion: The high incidence of ADR can be due to small sample size. Sodium valproate appears to be most toxic of all. Although sedation was a common ADR which disappeared later due to tolerance. The role of TDM and Surveillance is more emphasize with this kind of results.

YS-12

Comparison of the Efficacy of Pioglitazone with Metformin on Clinical Parameters in Symptomatic Cases of Polycystic Ovary Syndrome (According to Androgen Excess Society Criteria 2006)

SUMITA TANWAR, G.D KHILNANI[1], REKHA THADANNEE[2], RAKESH KARNANI[3], RAMESH SHARMA
S.P.Medical College Bikaner Rajasthan, Departments of [1]Pharmacology, [2] Paediatrics, Gujarat Medical Education and Research Society (GMERS) Medical College, Dharpur, Patan, Gujarat; [3]Department of Pharmacology Jhalawar Medical College Jhalawar, Rajasthan

Introduction: Polycystic Ovarian Syndrome (PCOS) is one of the most common metabolic abnormalities (occurring 6%-10% globally) in reproductive age women. The Clinical features of PCOS are persistent weight gain of 10-15 pounds per year, hirsutism, acne, menstrual irregularity, infertility and obstructive sleep apnoea. The occurrence of obesity and infertility in conjunction with skin and hair manifestations of the syndrome has a negative effect on self esteem and self image of the women. Because insulin resistance is a cardinal feature of PCOS, one therapeutic approach is to use insulin sensitizing agents as therapy for the treatment of PCOS. In our study we have compared the efficacy of Metformin a well establishedbiguanide and pioglitazone which is a thiazolidinedione on clinical feature of PCOS in married and unmarried women.
Methodology: - It was a prospective, parallel group comparative trial comprising of 40 proven cases of PCOS (According to Androgen Excess Society criteria 2006) of age between 18-38 years, divided into two groups, Gp-1 married infertile women and Gp-2 Unmarried women with menstrual/endocrine abnormality. Each group was subdivided in subgroups and metformin 500mg TDS Pioglitazone 45mg OD was prescribed to the patients for 6 months to each subgroup The measurements included weight, height (Anthropometry), BMI (Quetelets index), Waist hip ratio-WHR- (WHO criteria 2003) and hirsutism (F-G score) was taken at day 1 and follow up was done once in every two months for six months. All results were evaluated statistically.
Results:-We found that all women were overweight (Mean weight-80.22$\pm$3.34Kg), had WHR more than 0.80 (0.81to 0.93), BMI $\geq$28kg/m^2, F-G Score more than 8 (hirsutism present). After 6 months of treatment with metformin a significant decrease in BMI (Mean reduction of 1.11$\pm$0.60), WHR (Mean reduction of 0.014$\pm$0.008)and F-G Scores (Mean reduction of 6.44$\pm$1.58) were obtained where as Pioglitazone increased BMI (Mean gain of 1.33$\pm$0.5) and WHR (Mean gain of 0.033$\pm$0.0133) and F-G Score decreased with both the drugs. Both drugs were well tolerated but Pioglitazone caused swelling of feet in three patients and muscle soreness in two of them. Post meal fullness and gaseousness were more with Metformin (11 cases) than with Pioglitazone cases.
Conclusion:-Both drugs improve hirsutism significantly by decreasing F-G Score. But Pioglitazone treatment resulted in slight weight gain. It may be due to it fluid retention property and redistribution of fat, so metformin is more effective and better tolerated drug than pioglitazone for the symptomatic treatment of PCOS.

YS-13

Status of ADR Reporting in a Tertiary Care Hospital: Need for Vigilant Monitoring

TARANG S SHAH, TARUN WADHWA, M S GANACHARI
Department of Pharmacy Practice, KLEU's College of Pharmacy, Belgaum, Karnataka

Drug safety is considered as an important aspect for optimal clinical outcome. Pharmacovigilance network has been strongly built up across the world to vigilantly monitor adverse drug reactions but still in developing countries it is slowly progressing. [1]Creating awareness about adverse drug reaction (ADR) reporting means to make it easy and convenient may aid in improving spontaneous reporting. The main objective of the study was to assess the knowledge and attitude of healthcare professionals towards monitoring and reporting of ADRs. This study was conducted at South Indian tertiary care teaching hospital for duration of one month. A pre-validated questionnaire was administered to health care professionals (Physicians, Post graduate students, Medical interns and Nursing staff) and responses were collected. A total of 91 health care professionals completed the questionnaire with response rate of 79.13 %. The response rate of medical interns was found to be low (50%). Among 91 responders, 87 (95.60%) agreed that ADR reporting could have significant impact on patient care but 41 (45.05%) were not aware of different methods of reporting ADR. Lack of sufficient information was reported as one of the reason of underreporting by medical interns (58.33%) followed by nursing staff (55.55%), physicians (42%) and post graduates (25%). Our results showed increased level of under reporting which could mislead in estimating the true incidence of ADRs. To overcome this problem, we need to create awareness on ADR reporting and highlight the importance of Pharmacovigilance.

YS-14

Monitoring and Evaluation of the Fixed Drug Eruptions in Patients Receiving Treatment from Rural Teaching Hospital of Eastern Maharashtra

VAIBHAV K. GUPTA, SACHIN B. KHOND, SOHIN A. THAIM, MUZAMMIL KHAN A. PATHAN
Department of Pharmacology, Jawaharlal Nehru Medical College Sawangi (Meghe), Wardha, Maharashtra, India

Objective: To evaluate the occurrence of Fixed Drug Eruptions (FDE s) to different drugs. Materials and Methods: This study was conducted by Department of Pharmacology, Jawaharlal Nehru Medical College from May 2012 to August 2012. During this period the details of patients manifesting with FDE and drugs causing them were collected from both in and out patients. The data was analyzed for age, gender, site of reaction, drugs implicated and their outcome.
Results: A total of 36 adverse drug reactions were collected of which 7 were diagnosed as FDE. Among them 4 were males and 3 females aged between 2- 60 years. 5 FDEs were due to NSAIDs (diclofenac, nimesulide, paracetamol, piroxicam) and 2 due to antimicrobials (ciprofloxacin, norfloxacin). The site of lesion in all cases was over the extremities, and 4 cases also had it over the lips and 1 case on genital and oral mucous membrane respectively. Conclusion: Literature shows around 16-21% of FDEs and in our study we have observed 19.44%, of which 71.43 % were due to NSAIDs and 28.57 % were due to antimicrobials. All of them recovered. Over the counter availability of NSAIDs could be the probable reason for higher occurrence.

YS-15

Use of Potentially Inappropriate Medicines (PIMS) in Elderly – A Prospective Study in a Tertiary Care Teaching Hospital

RUSHI PANDYA, TAUFIK MOMIN, ROHAN CHRISTIAN, DEVANG RANA, VARSHA PATEL
Department of Pharmacology, Smt. NHL Municipal Medical College, Ellisbridge, Ahmedabad

Background: The use of Potentially Inappropriate Medicines (PIMs) is highly prevalent among the geriatric patients and a major safety concern because of high incidence of adverse drug reactions (ADRs) associated with it. These patients already have an altered physiology because of advanced age which may be superimposed by associated comorbidity. Hence, it is important to study the prevalence of PIM use in elderly patients using appropriate criteria.
Aims and Objectives: To study the prevalence and pattern of use of PIMs in hospitalized elderly in medicine department of V.S. General Hospital using Beers 2012 criteria.
Methods: Prescriptions of the elderly patients aged 65 years and above were collected from the medicine ward and analyzed. PIMs were identified with help of Beers 2012 criteria.
Results: A total of 181 prescriptions were analyzed and it was found that 72 (39.77%) elderly patients received at least one PIM out of which 20 (27.7%) received multiple PIMs. The total number of drugs prescribed was 1702 of which 94 (5.52%) drugs were prescribed inappropriately. The most commonly prescribed PIM was mineral oil (29, 16%) followed by spironolactone (24, 13.2%), digoxin (15, 8.3%) and benzodiazepines (11, 6%). There was a significant association between the number of drugs prescribed and use of PIMs ($p<0.001$).
Conclusion: The study shows that there is high prevalence of prescribing potentially inappropriate medicines in hospitalized elderly patients which eventually increases the

chances of ADRs. There is accompanying increase in morbidity, mortality and the cost of treatment. Hence a conscious effort should be made to avoid the use of these PIMs.

YS-16

Adverse Drug Reaction Monitoring in Patients Receiving Non-Steroidal Anti-Inflammatory Drugs

ALPA GOR, B.K.SHAH[1]
Department of Pharmacolgy, Pramukhswami Medical College, Karamsad; [1]Department of Pharmacolgy, College of Dental Sciences & Research Center, Ahmedabad Gujarat

A prospective monitoring of adverse drug reactions in patients receiving Non-Steroidal Anti-inflammatory Drugs (NSAIDs) was carried out in tertiary care teaching hospital. Total 1000 patients were enrolled in the study, among them 900 were included from Outdoor and Indoor departments of Orthopedic,Medicine and paediatrics and 100 patients were from the general practitioners clinic of Anand district. All the patients were followed up for one month at the interval of 3rdday, 7th day and 1 month prospectively. WHO probability scale and Naranjo's algorithm were applied to assess the causality of the reported ADRs. Modified Hartwig and Seigel scale was applied to assess severity and modified Shumock and Thortan scale was applied to assess the preventability. After analysing the data, 192 ADRs were observed. Out of 192 ADRs, 150 were associated with single formulation of NSAIDs and 42 ADRs were associated with the fixed dose of combination (FDCs) of NSAIDs. In 183 ADRs history of over the counter use of NSAIDs was present. It was found that 21.87% ADRs were due to FDCs, 18.75% ADRs were observed with Diclofenac, 17.18% with Ibuprofen, 15.10% with Paracetamol 10.41% with Piroxicam 6.77% with Etoricoxib, 5.72% with Nimesulide and 3.64% with Indomethacin. Only 1 ADR was found with Aceclofenac. Among all ADRs 71% of ADRs were possible and 21% were probable in nature by WHO scale. In severity level 88% ADRs were mild, 20 ADRs were found definitely preventable, 170 were probably preventable and 2 ADRs were not preventable.

YS-17

Comparative Evaluation of Metoprolol and Telmisartan in Terms of Antihypertensive Efficacy, Safety Profile and Effects on Metabolic Parameters

AMRIT AGARWAL, RANI WALIA, P.D. GUPTA, SHAFIQA ASLAM
Department of Pharmacology, MMIMSR, Mullana, Ambala

BACKGROUND: Meticulous control of blood pressure is required in patients with hypertension to ensure a reduction in the total risk for cardiovascular morbidity and mortality. Metoprolol is a cardioselective (beta 1 selective) beta-blocker widely used in clinical practice. Telmisartan causes inhibition of angiotensin II by competitive antagonism of the angiotensin II receptors, which attributes to reduced adverse effects and improved clinical efficacy among the antihypertensives.
MATERIAL & METHODS: A prospective, randomized, open, parallel study was carried out in 40 patients attending OPD of Medicine department MMIMSR Mullana (Ambala) with Grade I Hypertension according to JNC VII. The patients were randomly divided into two groups to receive tablet Metoprolol-SR 50 mg (Group A, n=20) and Telmisartan 40 mg (Group B, n=20) once a day, for a total period of 12 weeks with regular follow-up at every 2 weeks from the baseline. At each visit heart rate, BP and adverse effects were evaluated. Lab Investigations were carried out at baseline and at end of study period. P <0.05 was considered statistically significant
RESULTS: Metoprolol and Telmisartan both significantly reduce BP and heart rate.Telmisartan being more efficacious in reducing BP. Telmisartan significantly improves metabolic parameters. There were no serious adverse events requiring drug discontinuation among patients receiving active therapy in both the study groups.
CONCLUSION: Telmisartan is a better choice for Grade I hypertension between the two drugs as it leads to greater reduction in BP with beneficial effects on metabolic parameters.

YS-18

Oral Contraceptive in Women with Polycystic Ovary Syndrome: Influence on Behavioural Changes

ARCHANA AGGARWAL, VIJAYSHREE MAHASANI, SURABHI TOMAR
Department of Obstetrics & Gynecology, NIMS Medical College & Hospital, NIMS University, Jaipur (Rajasthan)

BACKGROUND: Women with polycysticovarysyndrome (PCOS) have gynecologic, psychological, reproductive and metabolic co-morbidities that span their entire lifespan. Women with PCOS have higher depression scores and a higher risk of depression independent of BMI.
OBJECTIVE: The aim of this study was to determine the impact of an oral contraceptive (OC) treatment on health-related quality of life (HRQOL), behavioural changes in polycystic ovary syndrome (PCOS).
DESIGN: Prospective observational study. Changes in the variables and the scores of questionnaires were evaluated after 6 months of treatment with EE/DRSP (3 mg/30 µg).
METHOD: This study was undertaken at Department of Obstetrics & Gynecology, National Institute of Medical Sciences, Jaipur.42 patients with PCOS without a previous

psychiatric diagnosis. Category I includes Oral contraceptive users in PCOS. Category II includes Non Contraceptive users in PCOS.
RESULTS: The main complaints of the patients were hirsutism and irregular menses. Accordingly, menstrual and hirsutism problems were the most serious concerns followed by emotional problems on the PCOSQ. Eight patients had clinical depression scores. After treatment, regular menstrual cycles were attained. Hirsutism and emotion domains of the PCOSQ improved at 6 months. Overall, depression, anxiety mean scores and depression rates did not show a significant change.
CONCLUSION: OC therapy in PCOS improves hirsutism and menstrual disturbances, along with HRQOL. This improvement is not associated with any change in the prevalence of depressive and anxiety symptoms.

YS-19

Cutaneous Adverse Drug Reactions Profile in Eastern Maharashtra: A Prospective Cross Sectional Study

MUZAMMIL KHAN A. PATHAN, SOHIN A. THAIM, VAIBHAV K. GUPTA, SACHIN B. KHOND
Department of Pharmacology, Jawaharlal Nehru Medical College Sawangi (Meghe), Wardha, Maharashtra, India

Objectives: To evaluate the incidence and to establish a causal link between Drugs and Cutaneous Adverse Drug Reactions (CADRs) in a tertiary care hospital.
Methods: A Prospective observational study was conducted in Dermatology OPD in patients presenting with cutaneous manifestations after drug intake. Adverse drug reaction history, medication history and all relevant details were gathered in the format adopted by National Pharmacovigilance Programme. The data was analyzed after grading of CADRs as per causality assessment scale of WHO.
Results: A total of 64 CADRs were recorded over a period of six months. Of the total 53.13% were males and 46.87% were females. The age group 21-40 yrs showed the maximum number of cases (46.87%). Antibiotics (57.81%) were main drugs implicated followed by NSAIDS (20.31%) and steroids (9.37%). Maculopapular rash (40.62%) followed by fixed drug eruption (15.62%) and urticaria (12.5%) were the most commonly reported CADRs. The common drugs causing CADRs were co-trimoxazole (18.75%), ibuprofen (7.81%), ampicillin (6.25%), diclofenac (4.68%) and betamethasone (3.12%). WHO scale showed 4.69% as certain, 60.94% probable and 34.37% possible. 20 required hospital administration of which 1 required Intensive Care management.
Conclusion: Antibiotics and NSAIDS lead maximum number of CADRs and strict precautions must be taken while using them especially in cases of patients with history of CADRs.

YS-20

A Study of Adverse Drug Reactions in Patients Admitted to General Surgical Wards of a Tertiary Care Teaching Rural Hospital

NIRAV PATEL, SAGUN DESAI
Department of Pharmacology, S.B.K.S. Medical Institute and Research Centre, Piparia, Vadodara, Gujarat

Introduction: Adverse drug reaction (ADR) is one of the major problems associated with pharmacotherapy. The aim of the present study was to find out the incidence rate of ADR and investigate its various aspects in surgical patients admitted to a tertiary care teaching rural hospital.
Material & Methods: A prospective-observational study, involving 800 patients over one and half year, was carried out to find the incidence rate of ADR, and its various aspects like types, grades, drugs causing them, organs/systems involved, onset and duration and management strategy with outcome. Structured and pre-tested format was used for compiling the data.
Results: Thirty one of the 800 patients developed ADR which yielded an incidence rate of 3.87%. Neither the age nor sex of the patients influenced incidence rate. Twenty six (83.87%) ADR were Type A (Augmented) reactions. Causality assessment, using WHO-UMC method revealed that 58.06% and 41.93% ADR were of "probable" and "possible" grades respectively. Certainty assessment, using Naranjo's score method, showed that 70.96% and 29.03% ADR were of "probable" and "possible grades respectively. As the number of drugs increased, the incidence of ADR also increased. Majority of ADR (77.42%) occurred due to antimicrobial drugs, followed by NSAIDs. Seventy one percent of ADR involved the gastrointestinal system. None of the ADR was fatal. Suspected drug/s was/were discontinued in 64.51% patients and 96.77% patients had fully recovered at the time of discharge.
Conclusion: The incidence rate (3.87%) of ADR amongst surgical patients appears to be much lower than the reported rate (10%-25%).

YS-21

Changes Induced in Behavioral Profile of Mice in the Elevated Plus – Maze Test for Anxiety by Valeriana Officinalis Ethanolic Extract

PARUL SINGH, DEVANG PARIKH, S.K.DATE
Department of Pharmacology, S.B.K.S.MI & RC, Piparia, Dist.Vadodara

Introduction: Valerian, derived from the Valeriana officinalis plant, is one of the most popular herbs for the treatment of anxiety and insomnia.
Aim of this study: The present study was done to evaluate the anxiolytic effects of Valeriana officinalis on the

elevated plus-maze (EPM), an animal model of anxiety evaluation.
Materials and methods: Male swiss albino mice were either treated orally with the Valeriana officinalis extract at doses of 300 and 600 mg/kg or with positive control normal saline, one hour before behavioral evaluation in the EPM. A video-tracking system (All Maze) installed on an Hp computer with a USB 2.0 megapixel digital video camera was used to automatically collect and analyze behavioral data for 5 minutes for each mice.
Results: It was observed that, mice treated with extract of V. Officinalis 300 mg/kg ($p<0.0001$) and 600 mg/kg of the same extract ($p<0.0001$) have shown significant increase in open arm entries when compared to control mice. Both the groups have also shown highly significant increase in total time spent in open arms ($p<0.0001$).
Discussion: There was increase in open arm entries and total time spent, in mice treated with both 300 mg/kg and 600 mg/kg of V. officinalis. This could be related to increased brain GABA levels and neurotransmission by stimulating glutamic acid decarboxylase (GAD) in mice brains by V. officinalis.
Conclusion: The evidence supports Valeriana officinalis as a potentially safe and better alternative to the traditional anxiolytic as measured by the elevated plus maze.

YS-22
Pharmacist Driven Scientific Tool for Monitoring, Detection, Analysis and Reporting of Adverse Drug Events in Psychiatric Patients- results from interim analysis (ILLUSION study)

DISHA A KHODA, TARUN WADHWA, M S GANACHARI
Department of Pharmacy Practice, KLEU's College of Pharmacy, Belgaum, Karnataka

Drugs are used for the well being of an individual but apart from its effectiveness many adverse effects are observed. Antipsychotics are the mainstay of treatment for psychotic disorders. Most of the first generation and to a lesser degree second generation antipsychotic agents are associated with ADRs like extra pyramidal symptoms (EPS), sedation and anti-cholinergic side effects. The main objective of the study was to estimate the incidence of ADEs and evaluate ADEs based on various parameters like demographics, drug class implicated, individual drug implicated, organ system affected, and analysis of ADEs (causality, severity and preventability). This study was conducted at a tertiary care hospital after informed consent obtained from subjects. Subjects aged ≥18 years of either gender admitted to psychiatry department were included in the study. Subjects on OPD basis, emergency, ICUs and special population were excluded. A total of 58 subjects were enrolled into the study. Out of them, 46 subjects experienced 115 ADEs. The incidence rate was found to be 79.31%. Male (65.51%) preponderance was observed over females (34.48%). Benzodiazepine was reported to be one of the major drug class implicated in which Lorazepam accounted for 36.51% ADEs. CNS was one of the most prominent systems affected due to ADEs.
Our results showed incidence rate of 79.31%. Psychiatric patients were reported to have extrapyramidal adverse effects which require vigilant monitoring. To enhance spontaneous reporting through healthcare professionals, it is vital to have scientific tool for efficient monitoring, detection, analysis and reporting of ADEs.

YS-23
Prescription Audit in Dermatology for Rational Prescribing

RATHOD RM, RATHOD AM, SANTRA D, THAIM S, GAIKWAD NR.
Department of Pharmacology, DMIMS, Jawaharlal Nehru Medical College, Sawangi (M), Wardha

The present study was undertaken to evaluate the format, prescribing pattern and rationality of prescriptions of the patients attending Dermatology Out Patient Department of a tertiary care hospital for a period of 3 months. A total of 578 prescriptions were analysed in which 1884 drugs were prescribed with an average of 3.26 drugs per prescription. The patient's name and age was mentioned in all the prescriptions while superscription, dosage form, duration of therapy and prescriber's identity was written in 86.5%, 100%, 80.7% and 75.9% prescriptions respectively. Out of all drugs, 15.4% were from National Essential Drug List of India. Antihistamines (21.1%) were the most common group of drugs used, followed by corticosteroids (15.1%). Most of the drugs were given by topical route (49.8%). Dosage and dose schedule of drugs was written for 91.2% and 94.7% drugs respectively. The study showed aendency towards polypharmacy and prescribing by proprietary names.

YS-24
Impact of Inappropriate Surgical Chemoprophylaxis on Surgical Site Infection Rate, Direct Cost, Days of Hospitalization, and Number of Extra Drugs

DEVANG A RANA, SD MALHOTRA, VJ PATEL
Department of Pharmacology, Smt. NHL Municipal Medical College, Ahmedabad

Background: Surgical antibiotic prophylaxis is adjunct to good surgical technique. Antibiotic prophylaxis should be regarded as an effective measure to control surgical site infection.
Objectives: This study was aimed to analyze the pattern of surgical chemoprophylaxis, to check its rationality based

on Kunin's criteria and its impact on direct cost, hospital stay and number of extra drugs.
Materials and Methods: A prospective, observational study was performed on patients undergoingsurgery, in a tertiary care teaching hospital. Data was collected in a pro-forma which included thepatient's details, prescriptions from date of admission to discharge or any other outcome andoperative notes. Surgical site infection (SSI) as defined by Centre for Disease Control (CDC) criteria was recorded. Rationality was assessed based on Kunin's criteria.
Results: Total 220 patients were enrolled over a period of one year. Mean hospital stay was 8.67±5.17days. A total of 2294 drugs were prescribed out of which 840 (36.61%) were antimicrobials.Third generation cephalosporins were prescribed mostfrequently 64.74% and 64.40 % pre-operatively and post-operatively respectively. Antimicrobialprescribing was inappropriate in 52.28%. Total of 19 patients developed SSI. Average direct cost per patient was 5976.64±4732 INR.SSI rate was significantlyhigher (13.04 %) in patients receiving inappropriate chemoprophylaxis ($p<0.01$). SSI adds extra 11785.48 INR ($p<0.0001$), 9.98 days ofhospital stay ($p<0.0001$) and 3.57extra drugs ($p<0.0001$) as compared to group without SSI.
Conclusion: Inappropriate use of antimicrobials is highly prevalent in surgical chemoprophylaxisleading to increase in direct cost, hospital stay and number of drugs. Adoption of international standard and formulation of locally feasibleguidelines can help overcome this situation.

YS-25

Pharmacovigilance Profile of Antiretroviral Therapy in a Tertiary Care Rural Hospital

SOHIN A. THAIM, SACHIN B. KHOND, VAIBHAV K. GUPTA, MUZZAMIL KHAN A. PATHAN
Department of Pharmacology, JNMC, Sawangi (Meghe), Wardha, Maharashtra

Objective: To study the pattern of adverse drug reactions (ADRs) to anti-retroviral drugs.
Materials and Methods: This study was conducted by the Department of Pharmacolgy, JNMC, Sawangi (Meghe), Wardha, Maharashtra. The study duration was 6 months. All the suspected drug reactions were collected. The data was then analysed for age, gender, type of reaction, drugs implicated and outcome.
Results: There were 96 adverse drug reactions of which 33 were due to antiretroviral therapy. Male to female ratio was 18:15 with a mean age of 36±11.7 and 33.7±8.19 years respectively. Among 33 patients, 17 received Zidovudine (300mg) with Lamivudine (150mg) and Nevirapine (200mg) (Z+L+N), 14 received Stavudine (30mg) with Lamivudine (150mg) and Nevirapine (200mg) (S+L+N) and 2 were on combination of Efavirenz (200mg) with Stavudine (30mg) and Lamivudine (150mg) (E+L+S). 12 had gastritis and diarrhea within 2 weeks of treatment with Z+L+N and S+L+N. 5 developed anemia after 4 months of therapy with Z+L+N and S+L+N regimen. Hepatic enzymes elevation and rashes were common in females, anaemia and polyneuritis in males. 8 out of 33 had immune reconstitution syndrome, 5 had rashes and 1 had polyneuritis.
Conclusion: We observed that HIV infection is more in third decade of life. The most common adverse effect with currently used ART regimen is gastritis and diarrhea. Careful monitoring of ADRs, early detection and intervention wherever possible, will improve quality of life of patients.

YS-26

To Evaluate Role of Dexamethasone in Acute Bacterial Meningitis through Randomized Control Trials

SUSHANT KUMAR, SWARUPVERMA, ANKESH KUMAR
Department of Medicine, NIMS Medical College & Hospital, Jaipur

Introduction: Despite the availability of effective antibiotics, vaccination programs and skilled acute-care facilities, there is still a significant mortality and morbidity from bacterial meningitis. Diagnosis and treatment of acute community-acquired bacterial meningitis in adults, focusing particularly on the management of patients with neurological complications, and stressing the importance of adjunctive dexamethasone is an important measure to save lives.
Aim: To evaluate the role of dexamethasone as adjunctive therapy in adult acute bacterial meningitis (ABM) in two groups of patients treated with antibiotics alone or a combination of antibiotics and dexamethasone.
Method: Eightypatients aged above 15 years admitted in medicine department of NIMS Medical College & Hospital and diagnosed to have ABM. Patients were randomly divided into two groups (n=40 each group). Group-A received anti-microbial therapy for 14 days and Group-B received the same antimicrobial therapy with dexamethasone 0.6 mg/kg/day in 3 divided doses for 4 days.Outcomein term of clinical features and CSF parameters were measured and compared.
Results:There was early resolution of fever, headache and altered consciousness in group B as compared to group A. CSF inflammatory parameters (glucose, protein and WBC count) were significantly better in group B by day 5. No complications attributable to dexamethasone were seen in Group-B.
Conclusion: Thus it is concluded that with adjunctive dexamethasone therapy outcome of bacterial meningitis is improved.

YS-27

Prescribing Patterns of Cough and Cold Medicines in Central Gujarat

SUMIT PATEL, PARTH DESAI, RIMA SHAH, SAGUN DESAI
Pharmacology, SBKS Medical Institute & Research Center, Sumandeep Vidyapeeth, Piparia, Vadodara, Gujarat-391760

Aim: To analyze the prescribing pattern of 'cough and cold' medicines in Central Gujarat.
Material and Methods: An observational, cross-sectional, questionnaire- based study was carried out to assess the prescribing pattern of doctors with regard to cough and cold. A total of 100 prescribers with a graduate degree (n=50) or a post-graduate degree (n=50) from Central Gujarat were selected randomly. After interviewing all doctors, data were analyzed to find the percentage of patients prescribed 'cough & cold medicines', their types of dosage form, use of FDCs, indications, any adverse events encountered and non-pharmacological measures advocated.
Results: Prescribing FDCs for cough and cold was significantly higher (92% vs 72%, $P<0.05$) in post graduate prescribers attached to private hospitals than in graduate prescribers attached to government/teaching hospitals. Usage of solid dosage forms was significantly higher ($p<0.05$) in prescribers attached to government or teaching hospitals as compared to prescribers attached to private hospitals (84% vs 60%). About 18% of graduate and 25% of post graduate prescribers gave cough and cold medicines at patients' behest. Only 15% prescribers prescribed cough and cold medicines for dry cough while antihistamines were advocated by 96% of prescribers. About 50% of the physicians prescribed these medicines for conditions like upper and lower respiratory tract infections. Non pharmacological measures were recommended by 75% prescribers.
Conclusion: Efforts are needed to create awareness amongst prescribers about the rational use of cough & cold medicines and also pay attention to ADR caused by them. Reforms in medical education and CME are recommended.

YS-28

Knowledge, Attitude and Practice Regarding Oral Emergency Contraceptives Amongst Undergraduate Students

DIPTENDU SANTRA, SOHIN THAIM, MUZAMMILKHAN PATHAN, ROHEET RATHOD, AMEET RATHOD
Department of Pharmacology, JNMC, Sawangi, Wardha, Maharashtra

Objectives: To assess knowledge, attitude and practice regarding oral emergency contraceptives with more focus on its safety aspect, amongst undergraduate students.
Materials and Methods: A prevalidated questionnaire was circulated to assess KAP regarding usage of oral emergency contraceptives. 200 students were included out of which 100 were from medical college (Medicos) and 100 from engineering college (Non-medicos). The responses to the questionnaire were obtained and consequent statistical analysis done.
Results: 51% of medical students as compared to only 27% of non-medicos had significant knowledge about usage and safety aspect of oral emergency contraceptives. 73% of medicos had a positive attitude towards usage of oral emergency contraceptives, quite similar to non-medicos (69%). 18% of medical students and 24% of non-medicos had used oral emergency contraceptives (themselves or their partners) atleast once before the study. Out of these students, 54.76% had no significant knowledge about oral emergency contraceptives.
Conclusion: More students from both groups had awareness about oral emergency contraceptives, but less knowledge about its safety and actual usage. Provision of requisite information about oral emergency contraceptives focusing more on its safety aspects should be made available to undergraduate students.

YS-29

A Study to Assess the Usefulness of Pharmacological Agent in Treating Comorbid Anxiety Symptoms Associated with Dhat Syndrome

AKHIL DHANDA, TUSHAR JAGAWAT, VIKAS GAUR
Department of Psychiatry, Nims University Jaipur

Background: There are either none or very few studies comparing the efficacy of short-term psychotherapy and pharmacotherapy in treating comorbid anxiety symptoms associated with Dhat Syndrome.
Aim: The primary aim of this study was to assess the usefulness of pharmacological agent in treating comorbid anxiety symptoms associated with Dhat syndrome.
Setting and Design: Cross-sectional study carried out in outdoor Dhat syndrome patients attending Psychiatry department of NIMS Medical College, Jaipur, India.
Method: 100 patients suffering from Dhat syndrome attending the psychiatric OPD were recruited for the study and were randomized to receive either psychotherapy (1 session/week) or fluoxetine treatment (20-40 mg/day) in combination with psychotherapy for 8 weeks. Outcome was measured by administering HAM-A scale before and after the treatment.
Results: No statistically significant difference was noted between the treatments outcome of the two groups receiving either psychotherapy or a combination of pharmacotherapy and psychotherapy.
Conclusion: The results of this study suggest that comorbid anxiety symptoms associated with Dhat syndrome can be treated effectively with a non-

pharmacological management and there is no added benefit of using pharmacological agent (anti-depressants/anti-anxiety).

YS-30
Comparative Study of Ropivacaine with Ropivaccine and Clonidine in Peribulbar Anesthesia for Phacoemulsification Cataract Surgery

ANANT SHARMA[1], SWATI TOMAR[1], SUSHMA BHATNAGAR[1], ROHIT TANWAR[1]
Departments of Opthalmology and [1]Anesthesia, Nims Medical College, Nims University Jaipur

OBJECTIVE: This study was to determine whether administration of clonidine as a component of peribulbar block analgesia, increased sedation, improved akinesia, decreased intraocular pressure.
METHOD- A randomized double blind study was undertaken at NIMS Medical College and Hospital at Jaipur. Fifty outpatient undergoing unilateral phacoemulsification cataract surgery by a single surgeon under peribulbar block were evaluated. Patient were assigned into two groups of twenty five each: Ropivacaine group(R) & Ropivacaine clonidine group (RC). Group R received 10 ml of LA solution containing 5 ml of 2% lignocaine, 5 ml of 0.75% ropivacaine and 100 units of hyaluronidase while Group RC received 8 ml of a similar mixture with the addition of clonidine 1microgram per kg and saline to make a total volume of 10 ml. Heart rate(HR),mean arterial pressure(MAP),pulse oximetry (SPO2),respiratory rate(RR), intraocular pressure (IOP), eye muscle movement scores were observed and recorded throughout the study period at regular intervals. Observation was done for: Sedation, Intraocular pressure, Analgesia
CONCLUSION- Addition of clonidine to ropivacaine for peribulbar anesthesia causes decrease in the intraocular pressure, a sedative effect and an increased duration of analgesia and akinesia with relatively stable haemodyanamic parameters.

YS-31
Antiarthritic Domain Concomitant Administration of Curcumin and Methotrexate: An Experimental Intervention in Animal Model

GUPTA CD, JHA RK, NEMA P, GUPTA VK, PATEL JR, KALE AB
Department of Pharmacology, J. N. Medical College, Sawangi (Meghe), Wardha

Background: Methotrexate can result in adverse effects like gastrointestinal, hepatic, hematological and rarely respiratory disturbances. Curcumin is known to have many pharmacological activities such as anti-inflammatory, antioxidant, antimicrobial, etc. Hence, it was hypothesized that a combination of curcumin and MTX would be beneficial to toxicity produced by methotrexate.
Objective: To evaluate the antiarthritic efficacy of simultaneous administration of curcumin and methotrexate in Wistar Albino Rats.
Materials and Methods: Arthritis was induced in wistar albino rats by a single sub plantar injection (0.1 ml) of Complete Freund's Adjuvant (C.F.A.) containing heat killed Mycobacterium tuberculosis into the left footpad. Rats were divided into six groups of six animals each. Group I and II were control injected with saline and Freund's complete adjuvant (0.1 ml), respectively. Group III arthritic rats were treated with curcumin (100 mg/kg, i.p.) on alternate days. Group IV received methotrexate (MTX) (1 mg/kg, i.p.) twice a week. Group-V and VI were treated with MTX (0.5 mg/kg, i.p.) twice a week and after 30 min received curcumin (30 mg/kg and 100 mg/kg, thrice a week, i.p.) from 10 th to 45 th days, respectively. Body weight and paw volume were measured on 1st, 9 th, 16 th, 23 rd, 30 th, 37 th, and 45 th days.
Results: A significant ($p<0.05$) improvement in body weight and reduction in arthritis was observed with combination treatment as compared to the positive control group.
Conclusion: The combined treatment containing both curcuminand methotrexate exhibited a significant synergistic activity.

YS-32
Ocular Surface Changes with Long Term Topical Anti-Glaucoma Medications

PARTH GANDHI, SWATI TOMAR
Department of Opthalmology, Nims Medical College, Nims University Jaipur

The ocular toxicity of topically applied ophthalmic medication has been a major subject of interest to ophthalmologists. The increased use of a variety of new eye drop preparations has led to a dramatic rise in the number of cases of ocular toxicity from eye drops.
Topical ophthalmic medications with BAK preservatives are widely prescribed for by growing numbers of professionals. As the number and variety of topical agents increase and the number of professionals involved in their prescription grows, the risk of adverse reactions also increases. It is therefore important to raise awareness of the potential dangers of topical eye medications.
The preservatives used in topical preparation are responsible for a considerable compromise of ocular surface. In diseases like glaucoma, long term topical ophthalmic medications are required, which mostly contains BAK preservatives. Hence for patient requiring long term treatment, medications with low BAK content or with other preservatives like oxychlorocomplex or

preservatives free preparation should be used to minimize the side effects & increase tolerability of therapy.
For medical treatment to be effective, the adverse reaction need to be minimal. Also the chronic inflammation of conjuctival & corneal surface, has an adverse effect on surgical outcome. Therefore ocular hypotensive drug formulation with low level of preservatives should be chosen to minimize the adverse reaction & maximize the outcome.

YS-33
Toxicogenic potential of PHAF-1: An experimental evaluation in swiss albino mice model

JHA R K, PATHAK S S, PATEL J R, RATHOD A M, GUPTA C D, KALE A B
Department of Pharmacology, Jawaharlal Nehru Medical College, Sawangi (Meghe), Wardha, Maharashtra, India.

Background: PHAF-1 comprises aqueous extract of seven medicinal herbs found in Vidarbha region of Maharashtra.
Objectives: To study Toxicogenic Potential of PHAF-1.
Materials and Methods: Swiss Albino Mice were randomly divided into 6 groups. Dose spectrum of the formulation under investigation was 0.5gm/kg, 1gm/kg, 2gm/kg, 4gm/kg and 5gm/kg body weight. Single dose was administered orally to each animal. The animals were closely observed at different intervals at 1, 2, 4, 6 and 12 hours and then for next 14 days for change in behaviour, signs of increased or decreased motor activity, changes in Salivation, Respiration and Skin colour and ultimately, mortality.
Results: Neither mortality nor any behavioral modulation was observed in any group of Mice over the observational period of 14 days.
Conclusion: Single Oral Dose administration of PHAF-1 is safe at the given concentration in Swiss Albino Mice.

YS-34
Antibiotic Prophylaxis in Infective Endocarditis Use or Abuse

SAPNA SHARMA, MAHESH C.P.
Department of Periodontics, NIMS Dental College, NIMS University, Jaipur, India

Introduction: The American Heart Association recommendations for antimicrobial prophylaxis for infective endocarditis (IE) are controversial. According to new guidelines released by the AHA now, the only patients to receive antibiotics will be those at higher risk, i.e., those with prosthetic heart valve, a history of endocarditis, certain form of congenital heart disease or valvulopathy after heart transplantation, and only before certain dental procedures. Unfortunately, these guidelines are still based largely on expert opinion, with very little hard evidence to show that antibiotic therapy actually prevents IE.
The hypothesis: The reported incidence of bacteremia during dental intervention ranges from 10%-100% and, with daily brushing and flossing from, 20%-68%. Because bacteremia also occurs during brushing and flossing of teeth, why give prophylaxis just for dental procedures? Moreover the risk of causing adverse or anaphylactic reactions from antibiotics as well as contributing to the nationwide antibiotic resistance problem are issues not to be taken lightly.
Evaluation of the hypothesis: The hypothesis discusses the AHA recommendations for antimicrobial prophylaxis for IE, indicating some inherent limitations associated with it, and stresses upon the fact that these recommendation should be updated, if not completely changed, to cope up with the advancements in the proper treatment plan.

YS-35
A Comparative Study of Efficacy and Tolerability of Methotrexate alone Versus Combination of Methotrexate and Hydroxychloroquine in Patients of Rheumatoid Arthritis

POOJA SHARMA, RANI WALIA, B.K AGRAWAL, SHAFIQA ASLAM, JASPREET SINGH
Departments of Pharmacology, Medicine and Orthopedics, MMIMSR, Mullana, Ambala

BACKGROUND: Rheumatoid arthritis (RA) is a chronic multisystem disease of unknown cause.Among various treatments that are listed above disease-modifying anti-rheumatic drugs (DMARDs) are often required to inhibit or halt the underlying immune process and prevent long-term damage.
Aims &Objective: To compare the efficacy and tolerability of Methotrexate alone and in combination with Hydroxychloroquine in treatment of patients of rheumatoid arthritis.
MATERIAL & METHODS: A prospective, randomized, open, parallel study was carried out in 50 patients attending OPD of Medicine department MMIMSR Mullana (Ambala). 25 patients of RA were assigned randomly to either of the two groups: Group A or Group B. Group A: was treated with MTX alone with a dose of 7.5 mg once a week and Group B: was given MTX 7.5mg once a week and HCQ 200 mg twice daily. Subjects were evaluated for a total of 24 weeks using various (1) Clinical parameters (Visual Analogue Scale for pain, Ritchie Articular Index and Health Assessment Questionnaires) and (2) Laboratory parameters (RA Factor, CRP). The results were calculated and statistically analyzed. $P < 0.05$ was considered statistically significant
RESULTS: Mean VAS, RAI and HAQ was similar at baseline for both groups. Difference in mean reduction in VAS, RAI, HAQ in Group-A (2.6, 20.32 and 4.36) and in

Group-B (4.12, 37.52 and 8.40) respectively. There was statistically significant ($p<0.05$) in group B as compared to group A from baseline to 24 weeks. Both treatments were generally well tolerated. No significant change had been observed in RA factor and CRP.No predominant adverse effect or event had been noted.
CONCLUSION: Combination therapy with MTX & HCQ is more effective in patients than MTX alone in treating RA in the beginning and can prevent serious joint deformity if we treat the RA with combination therapy.

YS-36
Study of the Antimicrobial Prescription Pattern of Dentists for the Management of Oral Diseases

PUSHP RAJ GOUR, UMA ADVANI, SHOBHA KULSHRESHTHA, ATUL JAIN, SAURABH KOHLI, PANKAJ MODI
Department of Pharmacology NIMS Medical College, NIMS University, Jaipur Rajasthan

Objective: The aim of this study was to know the pattern & rationality of antimicrobial prescription by dentists.
Material and *Methods:* It was questionnaire based cross sectional study.A total of 170 questionnaire was distributed to dental practitioners working in the NIMS Dental college Jaipur and private practitioners of Jaipur.The questionnaire content question about age group of patient with oral diseases, diagnosis for which antimicrobial were prescribed, prescribed antimicrobial drugs for prophylaxis, chronic and acute condition and patient compliance.Data was expressed as counts and percentages.
Results: Out of 170 questionnaires distributed among the dentist, 150 were eligible in the study. Most (76%) dentist had practices less than 5 years duration. Most common indication for which antimicrobial prescribed were abscess, cellulitis, irreversible pulpitis, and acute gingivitis. Most common antimicrobial used for prophylaxis are Amoxicillin and metronidazole.For the treatment of chronic condition and Acute condition Amoxicillin, Metronidazole, ofloxocin and ornidazole along or in combination are used. Only 20% dentist advised culture & sensitivity tests. Patient compliance was good. 74% patients completes the course of antimicrobials.56% patients report adverse reaction (ADRs) of an antimicrobial drug. Most common were nausea and vomiting. Only 13% dentists report adverse reaction to proper authorities.
Conclusions: In this study, Amoxicillin and Metronidazole were the most common drugs used for the management of oral diseases, but were prescribed without culture & sensitivity in most cases. ADRs were complained of by 56% patients but only 13% dentists reported these ADRs to the proper authorities. Rational prescribing & ADR reporting needs to be promoted by appropriate measures.

YS-37
Effect of aspirin on lithium chloride induced head twitches in rats

NEMA PALLAVI, TOTADE SV, JHA RK, GUPTA CHETNA
Pharmacology Department, Jawaharlal Nehru Medical College, Sawangi (Meghe), Wardha, Maharashtra, 442004

Objective: To evaluate the effect of aspirin on lithium chloride induced head twitches in rats.
Method: Rats were divided into seven groups: control (pretreated with distilled water), Lithium Chloride (150mg/kg i.p.), ECS (150 V, 50 Hz sinusoidal with intensity of 210 mA for 0.5 s) + Lithium Chloride (150mg/kg i.p.), aspirin (6.75 mg/kg orally) + Lithium Chloride (150mg/kg i.p.), ondansetron (0.36 mg/kg orally)+ Lithium Chloride (150mg/kg i.p.), combined ECS,ondansetron and Lithium Chloride (150mg/kg i.p), and combined ECS, aspirin and Lithium Chloride (150mg/kg i.p) pretreated groups.Data was analyzed by one- way ANOVA followed by Dunnet's 't' test
Result: Findings show that administration of single ECS daily for consecutive 8 days results in enhancement of 5-HT-mediated behavior (lithium-induced head twitches). Ondansetron and aspirin significantly retarded the ECS-induced enhancement of 5-HT-mediated behavior.
Conclusion: Inhibition of the serotonergic transmission by aspirin is responsible for its neuroprotective actions.

YS-38
Quality of Life in Schizophrenic Patients: Correlation with Type of Anti-Psychotic, Number of Medication and Treatment Compliance

ARCHNA PATEL, VIKAS GAUR, TUSHAR JAGAWAT
Department of Psychiatry, NIMS Medical College and Hospital, Jaipur

AIM: The aim of this study was to assess the Quality of life in schizophrenic outpatients attending NIMS hospital Psychiatric OPD and to find it correlation with type of anti-psychotics taken, total number of medicines and treatment compliance.
SETTING AND DESIGN: Cross-sectional study carried out in outdoor Schizophrenic patient attending Psychiatry department of NIMS hospital, Jaipur, India.
METHOD: The study group consisted of 50 schizophrenic patients with minimum duration of illness being 2 year, who were living in community and taking regular maintenance treatment. Schizophrenic Patients fulfilling the inclusion criteria were registered and evaluated using appropriate scales. The data collected was analyzed using appropriate statistics.

RESULTS: Quality of life of patients did not showed any correlation with number of medication taken by patients. Patients who were on atypical antipsychotics had significantly higher scores on the quality of life facets such as, overall quality of life, general health and in social relationship domain. Patients having positive or neutral attitude towards treatment also reported better overall quality of life as compared to non-compliant group.
CONCLUSION: Regular treatment with atypical anti-psychotics and positive treatment compliance may play an important role in improving QoL of Schizophrenic patients.

YS-39

The Role of BCG in the Management of Superficial Bladder Cancer, Transitional Cell Carcinoma (TCC)

SHIVENDRA KUMAR SINGH, JAGDISH SHARMA, NASIR AHMED, LOKESH SHARMA
General Surgery, NIMS medical college, Nims University, Jaipur (Rajasthan) India

Context: Bacillus Calmette-Gue´ rin (BCG) remains the most effective intravesical treatment for TCC, but the clinical development of BCG has been accompanied by controversy. Recent publications have called into question a number of aspects related to its use.
Objective: To review by a systematic literature search about the current clinical role of Bacillus Calmette-Gue´ rin (BCG) in TCC, focusing on efficacy and tolerability as primary objectives and on strategies to predict response and decrease toxicity as secondary objectives.
Evidence synthesis: BCG is the most effective intravesical agent for preventing TCC recurrence, but its role in disease progression remains controversial. In intermediaterisk TCC, the superiority of BCG over chemotherapy is well established for disease recurrence but not for progression and needs to be balanced against higher toxicity. With regard to high-risk TCC, there is sufficient evidence to show that BCG is the most effective treatment of carcinoma in situ for ablation, disease-free interval, and progression, but the impact of BCG on the natural history of T1G3 tumors relies on a low level of evidence. Maintenance remains crucial for efficacy. The dose can be safely and effectively reduced to decrease its toxicity, which is slightly greater than chemotherapy.
Conclusions: BCG should still be viewed as the most effective intravesical agent, but its role in the progression of papillary tumors needs to be clarified. BCG remains an alternative to intravesical chemotherapy in intermedia.

YS-40

Drug Utilization Pattern in Burn I.P.D.: A Retrospective Observational Study in a Rural Set up

JHA RK, PATEL JR, KALE AB, GUPTA CD, PATHAN MA, NEMA P
Department of Pharmacology, Jawaharlal Nehru Medical College, Sawangi (Meghe), Wardha, Maharashtra, India.

Background: Burn injuries continue to be a major source of mortality and morbidity from trauma in many parts of the world, particularly in the low and middle income countries.
Objectives: (i) To analyze Drug Utilization Pattern in Burn Patients admitted in I.P.D of A.V.B.R.H Sawangi (Meghe), Wardha.
(ii) To study Cost effectiveness of drug utilized for the treatment of Burn Patients.
Materials and Methods: A retrospective study of 2 years duration was undertaken during 1st Oct 2010 to 30th Sept 2012 at Acharya Vinoba Bhave Rural Hospital., Sawangi (Meghe), Wardha. A total number of 54 patients were taken for the study.The collected data will be statistically analyzed by using the standard tests to ascertain the clinical relevance of the present study.
Results: Most commonly prescribed Antibiotics are Augmentin (Amoxycillin + Clavulenic Acid) (47%), followed by Metronidazole (19%), Amikacin (21%) and other groups of Antibiotics like Ceftazimide, Ceftriaxone, Linazolid, Vancomycin and Amphotericin B. Analgesics are cornerstone for treatment of Burns. Most commonly prescribed Analgesics are Tramadol (48%) followed by Diclofenac Sodium (35%) and Paracetamol (18%). Other drugs used are Antacid, Vitamins and Protein Supplementary Formulations.
Conclusion: By considering the low socioeconomic status of rural patients cost-effectiveness is one of the major factor, hence prescription of generic drugs should be promoted. So the result indicates that there is a need for improvement in prescription practice.

YS-41

Comparative study of pharmacological and non pharmacological therapy in treatment of comorbid anxiety and depression in patients of somato form disorders

SASHA RAIKHY, TUSHAR JAGAWAT, SAVITA JAGAWAT
Department of Psychiatry, Nims Medical College, Nims University, Jaipur

Background: There are very few studies comparing the efficacy of short term psychotherapy and pharmacotherapy in treating comorbid anxiety and depressive symptoms associated with somatoform disorders
Aim: The primary aim of this study was to assess the usefulness of non pharmacological and pharmacological agent in treating comorbid anxiety and depressive symptoms associated with somatoform disorders.

Settings and Design: Cross sectional study carried out in somatoform disorders patients attending psychiatry department of NIMS Medical College, Jaipur India.
Method: 100 patients suffering from somatoform disorders attending the psychiatric OPD were recruited for the study and were randomized receive either psychotherapy (1 session / week) or fluoxetine treatment (20-40 mg/day) in combination with psychotherapy for 8 weeks. Outcome was measured by administering HAM-A scale and before and after the treatment.
Results: Results and implication of study will be discussed during presentation.

YS-42
Corneal toxicity: The epithelium and stroma in factitious disease

CHHAVI JINDAL, SWATI TOMAR
Department of Opthalmology, Nims Medical College, Nims University Jaipur

Introduction: Factitious disease is either the result of mechanical trauma or the abuse of toxic eye drops. Classification systems for corneal toxicity are by disease, route of exposure and time course, or by agent. The cornea may be involved alone or with the conjunctiva. The clinical signs of both iatrogenic and factitious disease are usually nonspecific and identical to those resulting from other causes of corneal epithelial disease such as punctate keratopathy, coarse focal keratopathy, pseudodendrites, filamentary keratopathy, and persistent epithelial defect. Topical abuse initially results in nonspecific clinical features of toxicity but, when fully developed, has the characteristic findings of coalescent corneal infiltrates, iritis, a Wessely ring, and hypoyon.
Study location: nims medical college & hospital
Study design: consecutive case series
Case definition: cases were classified as drug reactions if they were (i) unanticipated, unrecognised, or misunderstood by the referring ophthalmologist, (ii) clinically unacceptable in terms of the underlying diagnosis, and (iii) clinically important.
Results: 13/100 eyes (13%) of a consecutive series fulfilled the case definition
All patients had conjunctival reactions, of which the commonest were papillary, follicular, or delayed hypersensitivity corneal involvement occurred in 11/13 of which 3 were confluent or persistent epithelial defects.
Days to improve: 2–30days.
Days to resolve: 7–60 days
Symptoms of OSD, lid and periorbital disease were greater.
Drugs: idoxuridine, aminoglycosides, pilocarpine, chloramphenicol, multiple treatments.
Preservatives: benzalkonium chloride, phenylmercuric nitrate.Underlying diagnoses (over 50% inactive at the time of diagnosis)
Inclusion criteria: KCS, HSV, postherpetic ulcer, no other diagnosis and glaucoma in patients.
Conclusions: Drug reaction was the second most common diagnosis in this centre. Patients with dry eyes are particularly at risk Idoxuridine and benzalkonium in artificial tears were the two most common precipitating drugs.The time taken for improvement and resolution of drug reactions may be prolonged.

YS-43
Assessment of post-chemotherapy nausea and vomiting in patients taking multiple cycle cancer chemotherapy along with newer anti-emetics

RITIKA H. JAGTIANI, C. HARITHA[1], BARNA GANGULY
Department of Pharmacology, Pramukhswami Medical College; [1]M. S. Patel Cancer Centre, Shri Krishna Hospital, Karamsad, Gujarat.

Objective: Aim of this study was to assess the occurrence of post-chemotherapy nausea and vomiting with two newer anti-emetic agents, Palonosetron and Ramosetron, given to cancer patients along with moderate to highly emetogenic chemotherapeutic agents in multiple cycles.
Materials and Methods: A total of 26 patients receiving moderate to highly emetogenic chemotherapeutic agents were enrolled in this study. Out of them, eleven were enrolled for two cycles, ten for three and five patients for four chemotherapy cycles. During each cycle patient was randomized to receive either Palonosetron or Ramosetron as anti-emetic drug ½ hour prior to receiving the prescribed chemotherapeutic agent/s. The patient was monitored in the day-care unit for the first 24 hours following chemotherapy, for signs of immediate nausea and vomiting. For the assessment of delayed (upto 72 hours) nausea and vomiting each patient was given a weekly home card which s/he filled and returned on subsequent visit.
Results: After decoding, it was found that there were two groups; one received the same anti-emetic agents in the subsequent cycles (n=12) and the other received different anti-emetic agents i.e. both Palonosetron and Ramosetron (n=14). A statistically significant difference was found between them in terms of increased occurrence of post-chemotherapy nausea and vomiting [z=2.58>1.96 for 95% confidence interval], thus proving that post-chemotherapy nausea and vomiting is more likely to occur in those patients receiving the same anti-emetic agent in the subsequent cycles than those receiving both Palonosetron and Ramosetron. No significant difference in terms of increased occurrence of post-chemotherapy nausea and vomiting was observed between the group which received Palonosetron in the various cycles (n=6) and the group which received Ramosetron (n=6). Also, such significant difference was not found between the group which

received Ramosetron (n=6) and the group which received different anti-emetic agents (n=14). But, a significant difference was observed when comparing the group which received Palonosetron (n=6) with the group which received both anti-emetic agents (n=14) [z=2.50>1.96 for 95% confidence interval].
Conclusion: It can be concluded that the occurrence of nausea and vomiting can be reduced using different anti-emetic agents prior to multiple cycle chemotherapy of same patient

YS-44
RP-HPLC Method for Simultaneous Estimation of Atorvastatin Calcium and Fenofibrate in Pharmaceutical Tablet Dosage Form.

GUPTA N.K
Department of Pharmaceutical Sciences, NIMS University, Jaipur.

Atorvastatin calcium is calcium salt of (βR,8R)-2-(4-fluorophenyl)-α,-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid trihydrate. Atorvastatin, HMGCoA reductase inhibitor indicated for lowering cholesterol. It is a selective competitive inhibitor of HMG-CoA reductase, the rate limiting enzyme that convert 3 hydroxy-3 methyl glutaryl coenzyme A to mevalonate, a precursor of steroids, including cholesterol. Fenofibrate is isopropyl [4-(4-chlorophenyl)-2-phenoxy-2-methyl] propionate. The fibrates (isobutyric acid derivative) primarily activate lipoprotein lipase which is a key enzyme in the degradation of VLDL resulting in lowering of circulating TGs. A Shimadzu HPLC system consisting of a LC-2010 CHT binary gradient pump, an inbuilt auto sampler, a column oven and dual wavelength absorbance detector (DAD) was employed throughout the analysis. The chromatographic analysis was performed by Hypersil BDS C18, 250 × 4.6 mm, 5 µ particle size with mobile phase consisting of methanol and acetate buffer (pH 3.7) in the ratio of 82:18 v/v, at a flow rate of 1.5 mL/min and eluents monitored at 248 nm. The method was validated for linearity, accuracy, precision, robustness and application for assay as per International Conference on Harmonization (ICH) guidelines. The retention times of atorvastatin and fenofibrate were 2.906 and 9.552 min, respectively. The calibration curves of peak area versus concentration, which was linear from 1-6 µg/mL for atorvastatin and 16-96 µg/mL for fenofibrate, had regression coefficient (r^2) greater than 0.999. The LOD and LOQ were found to be 0.0194µg/mL and 0.0587µg/mL, and 0.0038µg/mL and 0.0113µg/mL for ATR and FEN respectively. The recovery values were found to be in the range of 99.83-100.00% and 99.69-100.09% for ATR and FEN respectively. The values of % recovery and %COV were indicates that the method is accurate. The ATR and FEN content was found to be 100.21% and 99.77% respectively. The method had the requisite accuracy, precision, and robustness for simultaneous determination of atorvastatin and fenofibrate in tablets. The proposed method is simple, economical, accurate and precise, and could be successfully employed in routine quality control for the simultaneous analysis of atorvastatin and fenofibrate in tablets.

YS-45
Chronic Suppurative Otitis Media; Empiric Quinolones in Adult

GURLEEN KUMAR, S.P. SRIVASTAVA
Nims Medical College, Nims University, Jaipur

Objective: The aim of the study was to determine the most prevalent organism in chronic otitis media in adult and their susceptibility to various antimicrobial so that an appropriate empiric antibiotic can be started promptly while awaiting the results of the culture and sensitivity.
Design: Prospective observational study
Place and duration of study: NIMS Hospital from July 2011 to July 2012.
Subject and Method: A total of 156 patients more than 15 years of age were having discharge from one or both ears for at least 1 week with tympanic membrane perforation were included in the study. A sample of the ear discharge was collected on the swab and cultured on appropriate media. Out of 156 patients, 96 (61.5%) were males and 60 (38.9%) were females. The organism isolated were *Staphylococcus aureus* 79 (50.6%), *Pseudomonas aeruginosa in 45 (28.8%) patients and Proteus mirabilis 17 (10.9%), Escherichia coli, Acinetobactor sp and streptococci 14 (9.03%) patients. Staphylococcus aureus* was the commonest organism isolated followed by*Pseudomonas aeruginosa and Proteus mirabilis. 54 (33.3%) to* ciprofloxacin *and 42 (26.9%) to both* ciprofloxacin and gentarnicin. Among the *Pseudomonas aeruginosa* isolates 40 (25.6%) were sensitive to gentamicin, 27 (17.3%) to ciprofloxacin and 22 (14.1%) to both ciprofloxacin and gentarnicin. Out of 155 patients 93 (60%) and 62 (40%) were resistant to it, 114 patients (73.1%) had isolates which were sensitive to ciprofloxacin and gentamicin whereas 33 (27%) were resistant. Similarly 35 isolates (22.4%) were sensitive to sulphamethoxazole / trimethoprim whereas 66 (42.3%) were resistant. Among Proteus mirabilis isolates 12 were sensitive to gentamicin, 11 were sensitive to ciprofloxacin and 11 were sensitive to both ciprofloxacin and gentamicin.
Conclusion: Ciprofloxacin can be recommended to be given empirically in aduls with chronic discharging ears. The initial therapy can be modified and appropriate therapy started if the result of the culture and sensitivity report shows the isolate to be resistant to the antibiotic started.

POSTER PRESENTATIONS

P-01
Interaction of Anti-Cancer and Anti-Hepatitis Drugs with Liver Cystatin

Aaliya Shah, Medha Priyadarshini[1], Mohd Shahnawaz Khan[1], Mohd Aatif[1], Fakhra Amin[1]and Bilqees Bano[1]
SKIMS Medical College, Srinagar.
[1]Department of Biochemistry, AMU, Aligarh

The drug-protein interaction has been the subject of increasing interest over the past several years. In this study the interaction of liver cystatin with adriamycin (an anticancer drug) and adevofir dipivoxal (anti hepatitis drug) was studied by various spectroscopic methods. Binding of adriamycin with liver cystatin was found to be static with a binding constant of $1.08x10^6M^{-1}$ and the number of binding sites obtained was two. With increasing concentration of adriamycin liver cystatin was found to loose its inhibitory activity. On the other hand, intrinsic fluorescence studies in the presence of adevofir dipivoxal showed enhancement in fluorescence intensity suggesting that binding of adevofir to liver cystatin caused unfolding of the protein. The unfolding was also accompanied by significant loss of inhibitory activity. This further confirms the differential mode of interaction liver cystatin with various drugs. The possible implications of these results will help in combating drug induced off target effects.

P-02
Drug Induced Thrombocytopenia

ABHA SHARMA, PRAKASH ASWANI, KALPANA SANKALA, MANISH SINGHAL, SHILPA TOMAR
Department of Pathology, NIMS Medical College, Nims University, Jaipur

Drug induced Thrombocytopenia is a common condition especially in hospitalized patients. Although drugs are a common cause of acute immune-mediated thrombocytopenia in adults, the drug etiology is often initially unrecognized. Most cases of drug-induced thrombocytopenia (DITP) are caused by drug-dependent antibodies that are specific for the drug structure and bind tightly to platelets by their Fab regions but only in the presence of the drug.

Typically, DITP occurs 1 to 2 weeks after beginning a new drug or suddenly after a single dose when a drug has previously been taken intermittently. However, severe thrombocytopenia can occur immediately after the first administration of antithrombotic agents that block fibrinogen binding to platelet GP IIb-IIIa, such as Abciximab, Tirofiban, and Eptifibatide. We have done study on 10 patients of UFH and LMWH induced thrombocytopenia. Heparin induced thrombocytopenia is caused by antibodies directed against complex of heparin and platelet factor 4. Binding of antibodies to these complex activates platelets and promote thrombin, even in setting of thrombocytopenia.

Recovery from DITP usually begins within 1 to 2 days of stopping the drug and is typically complete within a week. Drug-dependent antibodies can persist for many years; therefore, it is important that the drug etiology be confirmed and the drug be avoided thereafter.. Drug induced thrombocytopenia can also be caused by non immune mechanism by selective impairment of platelet production such as alcohol, thiazides, cytotoxic drugs.

P-03
Nanomedicine- a Therapy for Neurodegenerative Disorder

ADITI GOYAL, AMRITA RANI BAL, NEELAM MAHALA, JAIN SURANSH, NEETU MISHRA
Amity Institute of Biotechnology, Amity University Rajasthan India

Neurodegenerative disorders (including Alzheimer's and Parkinson's diseases, amyotrophic lateral sclerosis, and stroke) are rapidly increasing as in geriatric persons. Alzheimer's disease alone currently affects 4.5 million Americans. Such numbers will be double in the ensuing decades. Tremendous efforts in the last several decades have been resulted in numerous inventions to improve Central Nervous (CNS) System drug delivery. Many of the systems have significant potential for clinical applications. Achieving early diagnosis would enable improved disease outcomes. Organic and inorganic nanoparticles (liposomes, nanoparticles, polymeric micelles, nanogels, and others) that interface with biological systems have recently attracted widespread interest in the fields of biology and medicine. Effective combination of several approaches, such as encapsulation of drugs into nanoparticles conjugated with vector moieties or using micelles of Pluronic block copolymers along with Pluronic "unimers" for drug efflux transporter inhibition in brain capillaries may yield promising outcomes. Recently, the abilities to package a variety of drugs in cells to affect neuroregeneration, anti-inflammatory activities, or prevent microbial infections within the CNS have received significant attention. Such approaches may improve diagnostic and therapeutic outcomes. New developments in Nanomedicine coupled with cell-based delivery strategies support the notion that diseases, that now have limited therapeutic options can show improved outcomes by advances in Nanomedicine.

P-04
Prediction of Some Novel Transpeptidase Inhibitors – Qsar and Docking Approach

AJEET, LAXMI TRIPATHI, PRAVEEN KUMAR
S. D. College of Pharmacy and Vocational Studies, Muzaffarnagar, India

Here Cephalosporin analogues have been used to correlate the inhibiting activity with the Eccentric Connectivity index (ECI), Fragment Complexity (FC) and Topological Polar Surface Area (TPSA) for studying the Quantitative Structure Activity Relationship (QSAR). Correlation may be an adequate predictive model which can help to provide guidance in designing and subsequently yielding greatly specific compounds that may have reduced side effects and improved pharmacological activities. We have used Multiple Linear Regression (MLR), one of the best methods for developing the QSAR model. Results from this QSAR study have suggested that ECI, FC and TPSA are the important descriptors for the antibacterial activities by transpeptidase inhibition. For the validation of the developed QSAR model, statistical analysis such as data point-descriptor ratio (n/p=4), fraction of variance (r^2=0.9014), cross validation test (q^2=0.9013), standard deviation, quality factor (positive), fischers test (24.37); internal validation such as Y-randomization test; and external validation such as prediction of bioactivity of positive control have been performed and all the tests validated this QSAR model. Now, novel cephalosporin analogues have been designed and inhibiting constant of all novel analogues have been calculated with the developed QSAR model. It was found that the calculated inhibiting constant of all novel analogues are within the same range as of the training set. Thereafter, all the novel analogues have been docked with the penicillin binding protein which shows docking in the same catalytic domain as of pre-existing cephalosporin do.

P-05
Neurochemical and Behavioral Changes in Sleep Deprived Rats

AKSHAY PAREEK, SADDAM KHAN, MEENA KANTA, MANISHA CHOUDHARY, DUSHYANT SINGH CHAUHAN, SANDEEP TRIPATHI
Department of Biotechnology, NIET, NIMS University, Jaipur (Rajasthan) 303121

Sleep deprivation (SD) is the public health problem and it may increase the risk of neurological disorders. There are several evidences that SD increases the risk of hypertension, diabetes, obesity, depression, heart attack and several neurological defects. Almost 20 percent of all serious car crash injuries in the general population are associated with driver sleepiness. Hundreds of billions of dollars a year are spent on direct medical costs related to sleep disorders such as doctor visits, hospital services, prescriptions, and over-the-counter medications. In the present study, a specific instrument was designed for sleep deprivation. Twenty four male albino rats were taken. After 14 days of sleep deprivation rats were allow to behavioral performance (SMA, Catalepsy, Gait, ataxia and posture), thereafter rats were sacrificed and brain was removed for neurochemical studies. Lipid peroxidation and antioxidant (superoxide dismutase, catalase and glutathione) were estimated in different brain tissues. We observed gait and ataxia in experimental rats along with the alterations in spontaneous motor activity. Increased lipid peroxide levels and decreased antioxidant levels were also observed in sleep deprived rats. On the basis of results it may be concluded that sleep deprivation or insufficient sleep induced neurochemical changes and neurobehavioral changes in rat. Therefore, it is suggestive that some antioxidant supplement may be useful in sleep deprivation.

P-06
Stem Cell Therapy: A Naive Treatment Strategy for Neurodegenerative Disorders

AMAN DONGRE, SWATI GUPTA, NEETU MISHRA
Amity Institute of Biotechnology, Amity University, Rajasthan

Neurodegeneration is the acronym for the progressive loss of structure or function of neurons, including death of neurons. Therefore, stem cell treatments, a type of intervention strategy that introduces new adult stem cells into damaged tissue in order to treat disease or injury and can serve as a suitable strategy. According to a recent study, via sugar side chains, the extracellular matrix determines which cell type a stem cell can generate. These chains in turn send out signals that direct transformation of stem cells into nerve cells. It also forms astrocytes or oligodendrocytes, responsible for the mineral balance of the nerve cells or which form their insulation layer. Hence, stem cell therapy can be used in neurodegeneration, but neural stem cells cannot be harvested from the brain or spinal cord without harming the donor, therefore muscle tissues, which makes up 50 percent of the body, are easily accessible and biopsies of muscle are relatively harmless to the donor, hence muscle stem cells also known as satellite cells can be used for generation of nerve cells which could be used potentially to treat brain or spinal cord injury, neurodegenerative disorders, brain tumors and many other diseases.

P-07
A Comparative Study of the Uptake of Open Access among the Indian Research Fraternity Against the Current Global Trends

AMAN VEER SINGH, S.P. MISHRA
Department of Pharmacology, Institute of Medical Sciences, Banaras Hindu University, Varanasi

Objective: To provide an overview of the mechanisms of Open Access to scholarly articles and impediments to Open Access in India along with an insight into the institutional and policy frameworks being put in place to popularize the uptake of Open Access among the Indian researchers and institutions.
Methods: Directory of Open Access Journals (DOAJ), Directory of Open Access Repositories (DOAR), Public Library of Science (PLoS), SPARC Europe and INDMED were used as resource materials to obtain latest trends in Open Access initiative. Related articles published in various journals online and offline were considered for analysis.
Results: Globally over the past decade, Open Access journal publishing has increased by about 1% annually. Approximately 17% of the 1.66 million articles published during 2011indexed in Scopus with 12% immediate publications and 5% delayed publications. As of now globally, there are 8300 plus open access journals (DOAJ) and 2800 plus open access repositories (DOAR). While the number of Indian open access journals is 390 and repositories 90 comprising 4.7% and 3.22% of the global figures.
Conclusion: Indian Academic output has suffered from low circulation-low visibility-low impact factor syndrome. A well worked out strategy needs to be put in place in accordance with the Budapest Open Access Initiative 2002 to develop Open Access systems in India. The best way forward can be setting up of Institutional Repositories to facilitate easy access to all the accepted final research publications in all universities and research institutes. Metadata from all the interoperable Open Access Repositories in the country will serve as a window to domestic research.

P-08
Drugs Utilization in Antenatal Care at a Tertiary Health Care Teaching Hospital

RATHOD AM, RATHOD RM, JHA RK, GUPTA VK, AHMED TABISH, SANTRA DIPTENDU
JNMC, DMIMS, Wardha Maharashtra

Background: Most of the drugs are contraindicated during pregnancy to prevent teratogenic effects. Some drugs are used with precaution followed by antenatal visits at regular interval. Prescription trend studies can help in minimizing the risk of drug use in pregnancy, by establishing the safety profile and outcome domain of drug consumption.
Objectives: To study the patterns of drug prescription during pregnancy and provide feedback and recommendations for health care provider in the tertiary care hospitals of Vidarbha Region.
Study Design: A Retrospective, Cross-Sectional study carried out at Acharya Vinoba Bhave Rural teaching Hospital. Wardha, Maharashtra.
Observation and Results: A total of 891 pregnant women were analysed, 300 (31.54%), 376 (39.53%) and 215 (28.91%) women were in the first, second and third trimester of pregnancy, respectively.A total of 2472 drugs were prescribed with an average of 2.77 drugs per prescription. Monotherapy was seen only in 5% of the patients whereas 95% of the patients received Polytherapy.
Conclusion: There is need of training of doctors to prescribe drugs by generic names to reduce the cost incurred by the patients. Awareness of low cost prescribing practices should be initiated among prescribers because a large percentage of patients visiting this hospital are from poor socio-economic background.

P-09
Human Genome Project: A Milestone in the Field of Biotechnology

ANIL KUMAR, PAYAL PANDAY, SONU SHARMA

In the modern era the pharmaceutical biology play this very important role in the field of microbiology.A Wide range of microbes are used in the field of medical though pharmaceutical biotechnology for the diagnosis,
Prevention and treatment of diseases: In the molecular biotechnology gene level research required. On this level a new research known as "human genome project" play very important role."Human genome project" was started in 1990 as international effort that has two purposes. First was to map the location of genes in the genome. The second was to find the sequence of nucleotides that make the DNA of human genome.Human genome project is to understanding the genetics make up of human species, the human genomic project also has focused on several other non human organism such as E.coli, the fruit fly and the laboratory mouse. It remains one of the largest single investigational Projects in modern science.Human genome Project was international scientific research with a primary goal to determine the sequence of chemical bases pairs which make up DNA & identify the approximately 25,000 genes of human genome sequencing multiple variation of each gene. Human genome project in biotechnology is just first step in understanding human at molecular level. In biotechnology it is make a major impact on biology based industries including Health care and Animal Health, Crop and Live Stock breeding and it is use in micro-organism and plant to produce high value raw materials and pharmaceutics.
Scope of human genome project in Gene therapy: Gene testing, pharmacogenomics, molecular medicine, Energy and Environment application, DNA forensics, Agriculture, Livestock breeding and bio processing in biotechnology

P-10
A Lexicon to Tumor Markers and Method of Estimation: A Biochemical and Immunohistochemical Approach in Lung Cancer

ANUMESH PATHAK, JITENDRA KUSHWAHA[1], RAHAT HADI, M.C PANT, NUZHAT HUSAIN
Dr. Ram Manohar Lohia Institute of Medical Sciences, Gomti Nagar, and [1]Department of Radiation Oncology, King George Medical University, Lucknow, 226003

Background: Lung cancer is the leading cause of cancer deaths among both men and women in the World.Creating a strategy for identification of unique biomarkers for early diagnosis as well as a targeted therapy, with maximum efficacy and less adverse event will give a tremendous breakthrough in translational cancer research. Tumors markers may be used to help identify the source of the cancer and differentiate in from other condition and also evalavuation can be used to help determine how blood markers have utility as a prognostic indicator of lungs cancer.

Objectives: The aim of this study is to investigate whether there is a correlation between lungs tumor markers (CEA CA-125, CA15.3) and biochemical investigations in patients with lung cancer for predicting ability of these markers with respect to the histological types and is a prognostic factor and raise/drop in its levels suggests advanced disease.

Methods:We carried out a retrospective analysis of 32 subject subjects (age range to 32 to 78 years) who undergone a lungs biopsy after a sputum cytology screening and chest x-ray examination, full routine biochemical investigations and the concentrations of serum CEA, CA-125 CA 15.3 had been measured with a ELISA (Enzyme Linked Immunosorbent Assay) kit method.

Results: Serum albumin and alkaline phosphates, was significantly higher in lungs cancer patients. Complete blood count and HB decrease serum electrolytes Na decrease while K increases and the value of CEA and CA125, CA 15.3 significantly higher. Insignificant changes in, and AST, ALT while, total bilirubin, urea and creatinine were found markedly differ from the control.

Conclusions:

The marker provided useful clinical information and whenever there is even the remotest possibility of altering the clinical course they should be included in the treatment plans.

P-11
Role of Pharmacovigilance in Bioequivalence & Bioavailability Study

ANUPAM ANAND, SHAILESH SHARMA, PRAFULL KUMAR SINGH
Nims Institute of Pharmacy, Nims University, Shobha Nagar, Jaipur, 303121

Pharmacovigilance is the science of collecting, monitoring, researching and evaluating data on the effects of medicinal drugs, biological products, herbals and traditional medicines with a view to identify new information about adverse reactions and preventing harm to patients. The term "Bioequivalence" refers to pharmaceutically equivalent drug products where the rate/extents of bioavailability of the actives are not significantly different under suitable test condition. In other words, this is a comparison of two or more products with respect to bioavailability. It is a relative term which denotes that the drug substance in two or more identical dosage forms, reaches the systemic circulation at the same relative rate and to the same relative extent i.e their plasma concentration-time profile will be identical without significant statistical differences. Bioequivalence studies are conducted by many companies (generics) in which pilot (small) & pivot (large) studies are included so, there is huge number of human volunteers are exposed to many or different types of adverse event & ADR are produces which need to be recorded and reported to the regulatory authorities. Such studies are also give chances to produces such adverse events and ADR which are not common and are of serious type and were not reported and produced during the clinical trial of those drugs, are also need to be recorded and reported to the regulatory. These studies also help directly and indirectly in pharmacoepidemiological studies to determine and detect any possible causal relationship between drug exposure and adverse event. Such type of studies also helps to provide the support to the existing hypothesis and provide chances to generate the new hypothesis about those drugs which are already marketed, so pharmacovigilance plays a very vital role during the conduct of bioequivalence study.

P-12
Formulations of Plant Extracts For Biological Control of Aflatoxins Producing Fungi

ANUPAM KUMAR, MADHVI BHARDWAJ[1], POONAM YADAV[1], AJOY KR. CHOUDHARY[2], ANAND MOHAN, ANNAPURNA S. AGASTHYA, SANDEEP TRIPATHI[1], SANDEEP KUMAR[1]
Department of Biotechnology, Lovely Professional University, Phagwara, Punjab, [1]Department of Biotechnology, N.I.E.T. NIMS University, Jaipur, Rajasthan, [2] Department of Botany, T.N.B. College, T.M.B.U. Bhagalpur, Bihar, India

Aflatoxins are one of the major classes of mycotoxin produced by *Aspergillus* species of fungi: *Aspergillus flavus* and *Aspergillus parasiticus*. Aflatoxins are potent carcinogen specially related to liver cancer and also correlated with several adverse health effects in many animal species like acute liver damage, liver cirrhosis,

induction of tumours and teratogenic effects. Aflatoxins often occur in crops in the field prior to harvest and postharvest contamination is also common during storage of the crop favoring mold growth. Insects or rodents infestation also facilitate mold invasion of some stored commodities. Aflatoxins are detected occasionally in milk, corn, peanuts, cottonseed, almonds and a variety of other foods and feeds.

Current study revealed that some plant formulations having anti fungal activities. Different infected crops like maize, wheat and groundnuts from private storage and FCI storage nearby Phagwara were collected; further favorable growth conditions were maintained on GAN, CDA, and CYE media. Proper identification was done by study of conidial wall to differentiate between *Aspergillus flavus* (Smooth) and *Aspergillus parasiticus* (Rough), when observed under 100 X objectives. Further separation of aflatoxin carried out by TLC and spectrophotometeric analysis was performed at 363 nm. Plant extracts from *Zingiber officinale*, *Allium sativum*, *Allium cepa*, and *Capsicum annum*, were used for antifungal activities, further zone of inhibition were identified and calculated as per standard methods. Therefore these plant extracts may play influential role to minimize the crop loss and health risks and can boost the Nation economy also.

P-13
Anti-Tuberculosis Drugs Related Hepatotoxicity; Incidence, Risk Factors, Pattern of Changes in Liver Enzymes and Outcome in Rural Population of Jaipur

ANUPAM, SHILPA TOMAR
Department of Respiratory Medicine, Nims Hospital, Jaipur

BACKGROUND: Tuberculosis is a curable disease if diagnosed and treated properly with anti-tuberculosis drugs.These drugs can cause severe adverse reactions including hepatotoxicity. Compliance is crucial for curing tuberculosis. Adverse effects often negatively affect the compliance, because they frequently require a change of treatment, which may have negative consequences for treatment outcome.

AIM: The primary aim of this study was to evaluate the rate and the time of incidence, pattern of alterations in liver enzyme, risk factors and outcome of anti-tuberculosis drugs induced hepatotoxicity.

Setting and Design: Prospective cohort study carried out in IPD/OPD patients attending Respiratory Medicine department of NIMS Hospital, Jaipur, India.

METHOD: 100 patients with tuberculosis diagnosis were followed during anti-tuberculosis drug treatment course. Drug related hepatotoxicity was defined as increase in serum alanine aminotransfrase or aspartate aminotransferase greater than three times of the upper limit of normal, with or without symptoms of hepatitis.

RESULTS: Anti-tuberculosis induced hepatotoxicity was detected in 28%. Risk factors are advanced age, female sex, malnutrition, pre-existent liver disease and concomitant use of hepatotoxic drug

CONCLUSION: Anti-tuberculosis drugs induced hepatotoxicity is a major problem in Indian tuberculosis patients and cause treatment interruption in 28%of patients.The exact mechanism of antituberculosis drug-induced hepatotoxicity is unknown, but toxic metabolites are suggested to play a crucial role in the development, at least in the case of isoniazid.

P-14
Probiotic as Oral Vaccine for Multiple Infections

ANUPAMA SINGH, RUBY SHARMA, CHANDAN KUMAR, MANTOSH K. SATAPATHY
Department of Biotechnology, NIET, NIMS University, Jaipur India

Microbes have been used since long in food and alcoholic fermentations and in the last few years have undergone scientific scrutiny for their ability for preventive and therapeutic aspect. This has led to the discovery of the new term probiotics. Lactic acid bacteria are normal micro flora of intestine of most animals. They play an important role in the humans and other animals, and as immune modulators. They are helpful in disease treatment and prevention as well as improvement of nutrients digestion and absorption. Probiotic micro-organisms include Lactic Acid bacteria (LAB) including Lactobacillus acidophilus, L.balgaricus, L.casei, L. plantarum and L. rhamnosus. The use of these live bacteria to elicit an immune response to itself or to a carried vaccine component is a new invention in vaccine development. Advantages of live bacteria vaccines are that they mimic with natural infections, intrinsic adjuvant properties and they can be given as oral. Components of pathogenic and non-pathogenic food related microbes are currently being evacuated as a candidate for oral vaccine. Present review has been aimed to accept the current trends in infectious diseases.

P-15
Evaluation of Hypertensive Factors Relevant to Modern Life Style in the Selected Group of Subjects

BHAVNA NOHWAR, RAHUL CHAUDHARY[1], ARUN KUMAR
Anand College of Pharmacy, Keetham, Agra, [1]Hind Institute of Medical Sciences, Lucknow[2]

Hypertension is a chronic medical condition in which the blood pressure in the arteries is elevated. It is a major risk factor for stroke, myocardial infarction, heart failure, aneurysm of arteries and is a cause of chronic kidney diseases. The present study was taken into consideration to

evaluate the most prevalent causes of hypertension in the selected groups of subjects in Agra city. The patients of age group of 40-65 of both sexes were included in the study and only 200 patients were found to fulfill the inclusion criteria. The patients were thoroughly asked about their life style and current health status. The study revealed that many of the hypertensive subjects were having some or other type of concurrent disease. But maximum patients were found to follow a lifestyle, which does not include exercise and prefer unhealthy and junk food at irregular timings, which leads to stressful conditions due to modern life style. Though, further study is required to confirm the findings but from the present study it can be concluded that the life style changes of the modern era have increased the occurrence of hypertension remarkably.

P-16
Analgesic Activity of Roots of Monochoria Vaginalis Presl

BIRESH KUMAR SARKAR, MANISH KUMAR GUPTA, SHIV KUMAR GARG, K. MRUTHUNJAYA[1], SIVA SHONKAR NAYAK[2], PRABHU PANDA[2]
Sri Balaji College of Pharmacy- Benad Road,Jaipur Rajasthan, [1]J.S.S. College of Pharmacy, JSS University, Mysore, Karnataka, [2]College of Pharmaceutical Sciences, Berhampur, Odisha

The present study was aimed at evaluation of the analgesic activity of total alcoholic and aqueous extract of root of *Monochoria vaginalis* P in mice. The alcoholic extract of *Monochoria vaginalis* P rootata dose of 200 mg/kg body weight has shown significant analgesic activity as compared to aqueous extract. The result of hot plate indicated that the total alcoholic extract shows a significant increase ($P<0.01$) in reaction time at 2 and 3 hours comparable to the reference drug pentazocin but lesser ($P<0.05$) at 1 hr. The tail immersion and hot plate test reveal that this plant has high analgesic activity. This is because some form of error may be introduced with the animal handing while the test is being elicited. Both test show highest degree of analgesia in alcoholic extract compared to aqueous extract.

P-17
Ethno Medicine – Contribution in Discovering Therapeutic Agent

CHANDAN KUMAR, NIHARIKA SINGH, PRASHANT SHEKHAR, SONU SHARMA
NIMS Institute of pharmacy, Jaipur, Rajasthan, India

Disease Ethno medicine may be defined as the use of plants by humans in the treatment of various ailments & a highly diversified approach to drug discovery involving the observation, description & experimental investigation of indigenous drugs & their biologic activity. During the ethno medicinal survey; collection of information identification and preservation is carried out. The plant based indigenous knowledge was passed down from generation to generation in various parts of the world throughout its history & has significantly contributed to the development of different traditional systems of medicine. These ethno medical history may be a stepping tools to take up a plant, finding new chemical entities(lead molecule) of therapeutic significance for which formulating an appropriate strategy, preparation of extracts, biological and chemical screening,isolating active compounds, conducting preclinical tests & chemical modification if necessary, submitting an investigational New Drug Application, Clinical trial, submitting a New Drug Application & beginning of commercial production of various dosage forms. It is evident from the above facts that Ethno medicinal history of plants will contribute to the ailing humanity, even though efforts to use it have been sporadic. Extensive mass screening will provide novel drugs at a greater rate than the ethno medicinal information already at hand. Ethan medicine date is mainly prepared by dividing it into main categories wise collection of plantandAgro climatic zone wise.However, it is interesting to note that the ethnomedicinal uses of plants is one of the most successful criteria used by the pharmaceutical industry in finding new therapeutic agents for the various fields of biomedicine.

P-18
Ricin: Nature's Poison Our Benefit

DEBASHREE KAR, SHRUTHI.V, PRIYA, SANDEEP TRIPATHI
Department of Biotechnology, NIET, NIMS University, Jaipur, India

Ricin, from the castor oil plant *Ricinus communis* is a highly toxic, naturally occurring protein. A small pinch it can kill an adult. The Lethal Dose of ricin is around 22 micrograms per kilogram (1.76 mg for an average adult, around 1⁄228 of a standard aspirin tablet/0.4 g gross) in humans if exposure is from injection or inhalation. Oral exposure to ricin is far less toxic. The US investigated ricin for its military potential during World War I. At that time it was being coated for bullets and shrapnel. Immunotoxins are made by linking a tumor-seeking antibody to a portion of the ricin toxin. Once bound to the cancer cell, it is internalized and killed. Because ricin is a protein, it can be genetically linked to a monoclonal antibody to target malignant cells recognized by the antibody. If any of the native internalization sequences are present in therapeutics, then the drug will be internalized and kill the untargeted epithelial cells as well as targeted cancer cells. It could be suggestive that the damaging side effects of current cancer therapies and therapies for viral disease, such as HIV, immunotoxins offer a promising alternative, where therapeutic agent could be delivered directly to abnormal

cells. Health care workers and public health officials should consider ricin poisoning in patients with gastrointestinal or respiratory tract illness in the setting a credible threat. Poison control centers and public health authorities should be notified of any known illness associated with ricin exposure.

P-19

Baccopa Monniera Modulates Neurochemical Changes during Sleep Deprivation

DEBASHREE MAITY, MANOJ KUMAR MAURYA, MAHMOOD ALAM, ABDAR RAHMAN, SUDHANSHU MISHRA, DEVESH K. JOSHI, SANDEEP TRIPATHI
Department of Biotechnology, NIET, NIMS University, Jaipur (Rajasthan) 303121

The cumulative effects of sleep loss and sleep disorders represent an under-recognized public health problem and have been associated with a wide range of health consequences including an increased risk of hypertension, diabetes, obesity, depression, heart attack and several neurological defects. Almost 20 percent of all serious car crash injuries in the general population are associated with driver sleepiness. Hundreds of billions of dollars a year are spent on direct medical costs related to sleep disorders such as doctor visits, hospital services, prescriptions, and over-the-counter medications. In the present study, a specific instrument was designed for sleep deprivation. Twenty four male albino rats were taken. After 14 days of sleep deprivation and co administration of *B. monnieri* thereafter rats were sacrificed and brain was removed for neurochemical changes. Lipid peroxidation and antioxidant (superoxide dismutase, catalase and glutathione) were estimated in different brain tissues. We observed significant increased lipid peroxide levels and decreased antioxidant levels in sleep deprived rats. While, the co administration of *B. monnieri reverses these changes near to the control rats.* On the basis of results it may be concluded that sleep deprivation or insufficient sleep induced neurochemical changes in rat brain. *Baccopa monnieri* ameliorates these changes. Therefore, it is suggestive that *Baccopa monnieri* may be useful in treatment of Insomnia, sleep apnea, periorbital puffiness and sleep related disorders.

P-20

Combined Administration of Peracetamole and Ibuprofen Influences Urinary Metabonomic Changes in Aluminium Treated Rats; a Proton Nuclear Magnetic Resonance Study

DEVESH KUMAR JOSHI, MANISHA CHOUDHARY, SUDHANSHU MISHRA, ANSHU RANI, PRIYANKA, SANDEEP TRIPATHI
Department of Biotechnology, NIET, NIMS University, Jaipur

Background: Aluminum (Al) is responsible for dialysis dementia and Alzheimer's disease. Patients with chronic kidney disease on regular haemodialysis treatment are exposed to Al. In the present study we evaluate the effect of paracetamole and ibuprofen on Al exposed rat urine metabolites using High resolution ^{1}H NMR Spectroscopy.The development of ^{1}H NMR spectroscopy for high throughput metabolic screening of rat urine. Here we are concerned with the detection of xenobiotic substance in urine spectra that can be used to combined administration of peracetamole and ibuprofen in Al treated rats.

Methodology: In this study, 100mg/kg b.w of $AlCl_3$ was given to rats for 14 days along with co administration of ibuprofen (600 mg) and peracetamole (400mg) combined as well as separately in a group (N=6). After 14 days rat urine was collected for NMR Spectroscopy. Moreover histopathological and biochemical investigation were carried out in isolated kidney.

Result: Metabolic profile of the combined administration of peracetamole and ibuprofen treated rat urine showed significantly decreased levels of citrate, creatinine, allantoin, trans-aconitate, succinate and increased acetate concentration. These results demonstrated the impairment urea cycle in kidney, which was further reinstated by clinical biochemistry and histopathological observations.

Conclusion: On the basis of results it may conclude that the combined administration of peracetamole& ibuprofen may deteriorate the level of urine metabolites and it also potentiate the kidney damage in rats.

P-21

Stem Cell: The Future of Bio Medicine

DIPESH KUMAR, SHAHNEELA ANSARI, SONU SHARMA, AYAZ AHMED
Nims Institute of Pharmacy, Nims University, Shobha Nagar, Jaipur

Stem cell is backbone of biomedical research. The application of cells in a therapeutic fashion may become a natural extension of the presumed potential of the unic cell population with wide ranging capability. Restoration of lost organ function cannot be achieved through traditional drug therapy is not effective in restoration of lost organ like damage to heart tissue, brain tissues and other organ by haemorrhage. Blood clot is usually extensive as to beyond the reach of drugs. In the case of catastrophic diseases cellular substrate of the organ irreversible damaged and replaced with dysfunctional scar tissue leaving the compromised.recent advancement in stem cell biology including embryonic and postnatal somatic stem cell, have made the prospects of tissue regeneration a potential clinical reality. Embryonic stem cell represents a potential source of cell with unlimited self. Renewal and

diffeciation capacity, its key features are these it is derived from a pluripotent cell population, able to give rise to all the somatic and germ line cells of the fully developed organism. These cells are "uncommitted" progenitors of the subsequent 3 embryonic germ layers: ectoderm, endoderm, and mesoderm. Patient –specific nuclear transfer stem cell lines are portable and should be available to the best brightest of the biomedical community to study and treat these human disease, which in aggregated are quite common. As with many new and exciting technologies must remain to be tested, proved, and delivered to separate the hope from the hype.

P-22

Adverse Effect of Lithium on Semen Quality in Patients with Mood Disorder

DUSHYANT SINGH CHAUHAN, SHOBHA TOMAR[1], ANURAG TOMAR[2], SANDEEP TRIPATHI, ABBAS ALI MAHDI[3]
Department of Biotechnology, NIET, [1]Department of Obstetrics and Gynaecology, [2]Department of Paediatrics, Nims Medical College, NIMS University, Jaipur, and [3]Department of Biochemistry, King George's Medical University, Lucknow, India

Lithium, in the form of lithium carbonate, is one of the most effective and frequently used drugs for treatment of bipolar disorder. There are several reports on its adverse effects during treatment like dysthymia, insomnia, etc. On the basis of animal studies we hypothesized that Li could affect on semen quality of human resulting in oxidative burden.

In the present study we recruited 27 patients (Male, 38±5years) from the particular disease and positive control (without Lithium treatment). After getting consent and history 5.0 ml of blood samples were taken and analyzed prolactin, Inhibin-B, LH and FSH in serum along with the oxidative stress parameters in RBCs lysate. Additionally sperm charecteristics i.e. sperm count, viability, motility and liquifraction time, was also carried out in both control and subjects. Results were compared with age matched control individuals. Analysis of semen samples revealed that sperm count and viability was significantly ($p>0.01$) decreased while the prolactin level was increased markedly ($p>0.05$) in subjects. On the other hand, LH and FSH levels were found to be reduced in subjects as compared with the positive control. Moreover, insignificant changes observed in the concentration of inhibin. On the basis of results it may conclude that the Li deteriorate the semen quality and increase rate of oxidative stress. It is suggestive that neurohomonal modulator and antioxidant therapy can be useful for patients those treating with Li. It is needed further study in depth for explanation of the above problem.

P-23

Acute Endosulfan Poisoning with Generalized Tonic-Clonic Seizure

FAKHAR ALAM, ANIL YADAV, N.S. KOTHARI, R.K. GEHLOT
NIMS Medical College, Nims University, Jaipur

Endosulfan is a widely used insecticide that is associated with a high fatality rate in humans when ingested accidentally or with the aim of suicide. We report a case of acute intentional endosulfan intoxication admitted in a state of altered consciousness, vomiting and genralised tonic-clonic seizure and in Nims Medical College & Hospital, Jaipur. The case is a 25 years old married female, case of suicidal attempt by endosulfan, which had genralised tonic-clonic seizure and finally developed cardiac failure. Toxicological analysis of Blood and urine samples revealed endosulfan as causative agent. Endosulfan is an organochlorine insecticide that causes overstimulation of central nervous system by inhibiting Ca2+ and Mg ATPase and antagosing chloride ion transport in gamma- aminobutyaric acid receptors. It is absorbed from gastrointestinal, skin or respiratory tract.Symptoms of poisoning include hyper activity, excitement, dyspnea,apnea, salivation, loss of unconsciousness, diarrhea, nausea, vomiting, insomnia, blurred vision, cyanosis, foaming at the mouth, tremor, dry mouth, lack of appetite, irritability, headache, decreased respiration, loss of memory, haematuria, albuminuria, confusion and dizzines. Hepatic, renal and myocardial toxicity, agranulocytosis, aplastic anemia and skin reaction have also been reported. Mortality and morbidity rates are high and there is no specific antidote. Supportive cares for these patients include decontamination of skin, gastric lavage, activated charcoal, lidocaine for arrhythmia and treatment of status epilepticus. Especially in the rural areas cases with acute generalized seizures should suggest endosulfan intoxication when etiology is uncertain even in the absence of any signs of intoxication.

P-24

Pharmacology of Anti - Amoebic Drugs

GAURAV KUMAR NIRWAL, HARENDRA SINGH, RAVI KUMAR MATHUR
Department of General Surgery, NIMS Medical College, Nims University, Jaipur

The drugs used to treat amebiasis can be classified according to their primary site of action. Luminal amebicides are poorly absorbed and reach high concentrations in the bowel, but their activity is limited to cysts and trophozoites close to the mucosa. Only two luminal drugs are available: iodoquinol and paromomycin. Indications for the use of luminal agents include eradication of cysts in patients with colitis or a liver abscess and treatment of asymptomatic carriers. The

majority of asymptomatic individuals who pass cysts are colonized with *E. dispar*, which does not warrant specific therapy. However, it is prudent to treat asymptomatic individuals who pass cysts unless *E. dispar* colonization can be definitively demonstrated by specific antigen-detection tests.

Tissue amebicides reach high concentrations in the blood and tissue after oral or parenteral administration. The development of nitroimidazole compounds, especially metronidazole, was a major advance in the treatment of invasive amebiasis. Patients with amebic colitis should be treated with intravenous or oral metronidazole. Side effects include nausea, vomiting, abdominal discomfort, and a disulfiram-like reaction. Another longer-acting imidazole compound, tinidazole, is also effective. All patients should also receive a full course of therapy with a luminal agent, since metronidazole does not eradicate cysts.

P-25
Evaluation of Factors Influencing the Clinical Response on Giving Intra-Articular Triamcinolone Hexacetonide in Knee Osteoarthritis

GOVIND SHARMA, NIRMAL JAIN, NAVEEN SHARMA
Department of Orthopedics, Nims Medical College, Nims University, Jaipur

Aims & Objectives: 1) To assess the efficacy and safety of a single intra-articular injection of triamcinolone hexacetonide (THA) in knee osteoarthritis (OA) 2) to examine factors that may relate to treatment efficacy.

Methods: Fourty two patients with clinical and radiographic evidence of knee OA were studied. It was a randomized control trial. Two groups were made each having 21 cases which were randomly selected the study was conducted in department of orthopedics NIMS Medical college and hospital for the duration of one year between june 2011 to july 2012 the groups were allocated to receive either THA (20 mg in 1 ml)or placebo (0.9% normal saline, 1 ml). Follow up assessments evaluated the following outcome variables: patient opinion of overall change in the treated knee, visual analogue pain score (VAS), distance walked in one minute (WD), and Health Assessment Questionnaire modified for lower limb function (HAQ).

Results: Seventy eight percent of THA and 49% of placebo treated patients reported overall improvement at week 1($p<0.05$). At week 6, improvement was reported in 57% and 55% of patient groups, respectively. VAS improved in both groups at week I (THA, $p<0-001$; placebo, $p<0.05$) and week 6 (both $p<0.01$). Improvement in VAS was significantly greater among THA treated patients at week 1 only ($p<0.01$). Subgroup analysis of THA treated patients revealed greater improvment in VAS among patients with clinical evidence of an effusion ($p<0.05$), and those who had synovial fluid successfully aspirated at the time of injection ($p<0.01$). WD improved in THA treated patients at 'week 1($p<0.001$), and in both groups at week 6 (THA, $p<0-001$; placebo, $p<0001$). Improvements in HAQ were seen in THA patients only at weeks 1 and 6 ($p < 0.05$).

Conclusion: THA provided short term pain relief in knee OA. Increased benefit was associated with both clinical evidence of joint effusion and successful aspiration of synovial fluid at the time of injection. Osteoarthritis (OA) of the knee is one of the most common rheumatic disorders and a frequent cause of pain and disability, particularly among the elderly. It is estimated that between 18 and 33% of individuals over 65 years of age have radiographic evidence of knee OA, this being more common in women and increasing to over 50% by age 80.3 between 20 and 60% of patients with radiographic disease have associated symptoms, and up to 50% report disability. Despite the enormous public health problem presented by this condition, there is no singularly effective medical treatment. Two double blind placebo controlled studies have reported a transient benefit from intra-articular triamcinolone hexacetonide (THA). In view of concern regarding efficacy and possible deleterious effects, judicious use of intraarticular steroids in OA has been advised. We conducted this placebo controlled study in an attempt to re-evaluate the efficacy of a single intra-articular injection of THA in knee OA and examine factors which may relate to treatment efficacy.

P-26
Type of Damage, Mechanism of Action of Various Ototoxic Drugs

GURLEEN KAUR, S.P. SRIVASTAVA.
NIMS Medical College, Nims University, Jaipur

Ototoxicity is broadly defined as damage of inner ear by a toxin, it can occur in cochlea, vestibular apparatus, auditory nerve. Cochlear side effecs are tinnitus, hearing loss (high frequency SNHL) and it is not reversible, distorted hearing hyperacusis. Vestibular side effects are dizziness, vertigo, ataxia, nystagmus, labrynthitis, oscillopsia, fatigue, memory loss, nausea & vomiting. CNS side effects include central auditory processing disorder. Outer and middle ear side effects are ceruminosis, ear pain, otitis externa. Major systemic ototoxic drugs are Aminoglycosides, Salicylates and nonsteroidal anti-inflammatory drugs, Loop Diuretics, Platinum Compounds, Iron chelating agents, Macrolides. Major topical ototoxic substances includes: Topical Aminoglycosides, Topical Chloramphenicol, Topical Polymyxin, Topical Antifungals, Surgical Disinfectants and Antiseptics. There are two elements in monitoring ototoxicity, cochlear and vestibular. Cochlear monitoring include: audiometry, high frequency audiometry. Vestibular monitoring includes Electronystagmography

(ENG), Rotational chair test, Computerized dynamic posturography. Clinical bed side tests include Oscillopsia test, the head shake test, The Halmagyi horizontal head test. Otoprotective therapies many compounds have been studied for their otoprotective properties especially in relation to the aminoglycoside antibiotics. These include Alpha- phenyl-tert-butyl-nitrone (PBN), antioxidants, methionine, salicylates, deferoxamine, tanshinone, superoxide dismutase, platinum compound otoprotection. Prevention of ototoxicity includes Audiogram before and weekly after starting, ENG prior if possible, History and physical examination daily (Romberg's), Adjust doses or switch drugs if toxic.

P-27

Drug Interaction in Poly Prescriptions; Evaluation and Management

HANIF AHMED, SURENDRA PRAJAPAT, SONU SHARMA, AYAZ AHMED
Nims institute of Pharmacy, Nims University, Shobha Nagar, Jaipur, 303121

Drug Interaction is increasing day by day leading to the major manifestations of Health care issues. According to "WHO" Drug Interaction was estimated to be from 6.2 % to 6.7 % per year. According to the "Journal of the American Medical Association" (JAMA 1996) reported that 108,000 American died in hospital and 2.2 million American had reaction to "FDA" permitted medication. To overcome for this scenario there are numerous sources of in sequence which accessible to Prescriber, Pharmacist and User about the Drug Interaction. In 2009, in the UK, drugs are gradually more obtainable over the counter and on-line devoid of prescription. Additionally, close at hand is widespread use of numerous herbal medicines from relatively under-regulated suppliers and the constituents of such products are often not known. This clinical reality of the widespread use of potent medicines – be they allopathic or traditional showed us the need for a practical hands-on guide that aims to be a compact, succinct and accessible source of Information for practitioners, prescribers and the public about adverse drug-Interactions. In this Cross Sectional Study total 300 Prescriptions were collected after analysis 250 informed consent have filled. Rest in 50 prescriptions the prescribing pattern errors have found including consent displeasure. In 250 prescriptions 70 is interacted and 180 is non-interacted or safe, without any significance level. The statically data have given below and graph demonstrates the interaction in all clinic, Government and private sectors hospitals. In this study poly prescription evaluation in primary, secondary and tertiary care hospitals. The percentage of interacted and non-interacted prescription is 28% in the city of Karachi, Pakistan. Female genders were more susceptible for interaction due to various causes about 17.6% and Male about 10.4% out of 28%.The major significance level is about 4% in Major Interaction, Moderate is about 13.6% and Minor is about 14.8%. Most Interaction Found in Cardiovascular is about 11.6% along with it 2.0 % interaction in Angina and 1.2% in Arrthymias.

P-28

Adverse Effect Profile of Cleborpride – A Prokinetic Agent Recently Approved in India

JAGJIT SINGH, RAJIV KUMAR
Department of Pharmacology, Government Medical College & Hospital, Chandigarh India

BACKGROUND: A number of prokinetic agents have been approved for the treatment of various disorders associated with gastrointestinal motility disorders. However, in the past the association of adverse effects have led to withdrawal of agents like cisapride from the market. Clebopride is a new anti-dopaminergic gastrointestinal prokinetic agent with non-selective 5HT4 receptor agonist action.
OBJECTIVE: To systematically access the adverse effect profile of Clebopride approved in India in Nov.2010
METHODS: We carried out a PubMed search using the words, "clebopride, ADRs" to identify studies on clebopride. References of selected articles on clebopride published in peer-reviewed journals were also searched.
RESULTS: A total of 52 studies were identified out of which 19 studies reported adverse effects of clebopride. High incidence of Extra Pyramidal Side effects (EPS) have been seen to be associated with clebopride. A 7-year Spanish Drug Watch study showed a 72.4% incidence of EPS with clebopride as compared to 48% with metoclopramide. Another 4 year study showed clebopride was associated with high incidence of drug induced Parkinsonism. Clebopride- induced Parkinsonism and tardive dyskinesia was seen in 3 and 5 studies respectively. Acute ADRs reported with clebopride were rabbit syndrome, belly dancers's syndrome, laryngeal dystonia, oculogyric crisis, hemifacial dystonia and restless leg syndrome.
CONCLUSION: Clebopride is not approved by US FDA but used in Europe for many years and associated with high incidence of both acute and chronic ADRs. It should be used cautiously since there are many safer agents approved for the treatment of gastrointestinal motility disorders. Well designed studies to analyze ADRs related to clebopride are required as per the Pharmacovigilance Programme of India (P v PI).

P-29
Advancement and Tribulations in Transdermal Drug Delivery System by Ethosomes

KAVERI SHARMA, VIVEK DAVE, SACHDEV YADAV, HIMANSHU AGARWAL, SARVESH PALIWAL
Department of Pharmacy, Banasthali University, Rajasthan

Optimization of drug delivery through human skin is important in modern therapy. Recently, the transdermal route vied with oral treatment as the most successful innovative research area in drug delivery. Transdermal delivery is an important delivery route that delivers precise amount of drug through the skin for systemic action. Ethosomal carriers are systems containing soft vesicles and are composed mainly of phospholipid, ethanol at relatively high concentration and water. It was found that ethosomes penetrate the skin and allow enhanced delivery of various compounds to the deep strata of the skin or to the systemic circulation. The vesicles have been well known for their important in cellular communication and particle transportation for many years. Vesicles would also allow to control the release rate of drug over an extended time, keeping the drug shielded from immune response or other removal systems and would be able to release just the right amount of drug and keep that concentration constant for longer periods of time. One of the major advances in vesicle research was the finding a vesicle derivative, known as an ethosomes. The potential advantages of avoidance of first-pass metabolism, avoidance of exposure to the chemical and biological conditions of the gastrointestinal tract, reduction or avoidance of adverse events, improved patient compliance, ethosome delivery system was established to develop a patented, passive, non-invasive, transdermal drug delivery technology they are interesting and pioneering vesicular systems that have appeared in the field of pharmaceutical technology and drug delivery in recent years.

P-30
Rationale of Quinazoline Alkaloid Safety: Pharmacovigilance and Pharmacoeconomics

R. H. KHISTE[1] H. K. JAIN
NIMS University, shobha Nagar, Jaipur,303 121, Rajasthan, India and M.M.M. College of Pharmacy, Kalewadi, Pune, 411033, [1]Sinhgad College of Pharmacy, Vadgaon (Bk) Pune, India

Herbs have been widely employed as important remedies all over the world. Progress in science and technology in recent decades has made possible not only to isolate and characterize the biologically active constituents of herbs, but also to evaluate their biological activities. Alkaloid-containing plants constitute an extremely varied group both taxonomically and chemically, a basic nitrogen being the only unifying factor for the various classes. For this reason, questions of the physiological role of alkaloids in the plant, their importance in taxonomy, and biogenesis are often most satisfactorily discussed at the level of a particular class of alkaloid. A similar situation pertains with the therapeutic and pharmacological activities of alkaloids. As most alkaloids are extremely toxic, plants containing them do not feature strongly in herbal medicine but they have always been important in the allopathic system where dosage is strictly controlled and in homoeopathy where the dose-rate is so low as to be harmless. The discipline of PV has developed considerably since 1972 WHO technical report, it remains a dynamic clinical and scientific discipline. It has been essential to meet the challenges of the increasing range and potency of medicines (including vaccines), which carry with them an inevitable and sometimes unpredictable potential for harm. Measures for unsafe use, negative outcomes of medication are usually used before measures of safe and effective use. To evaluate the outcomes of PV, PE study is one of the best tools. The rationale of drug safety can be assessed using the combination of PVPE studies.

P-31
Apheresis: Harvesting Hematopoietic Stem Cells from Peripheral Blood

SHARMA KHUSHBU, SINGH NITU, SENGUPTA SANDIPAN, GOVIND MOHAN
NIMS Institute of Pharmacy, Nims University, Jaipur

Apheresis is a medical technology in which the blood of a donor or patient is passed through an apparatus that separates out one particular constituent and returns the remainder to the circulation. Depending on the substance that is being removed, different processes are employed in apheresis. There are large categories of component collections: Plasmapheresis, Erythrocytapheresis and hematopoietic stem cells (HSC) harvesting from Peripheral blood. HSC are the progenitor cells that give rise to all the components of the bone marrow and immune system. HSC harvest apheresis is now the primary method for obtaining the cells that are used in bone marrow transplantation. This is used in the treatment of various types of leukemia, lymphoma and certain genetic diseases that lead to anemia or immune deficiency. Before the HSC collection, the patient receives injections of growth factor to increase the no. of peripheral stem cells in blood. When blood cell count has reached a sufficient level, blood is removed through catheter and circulated in a blood cell separator machine. The blood is separated and peripheral blood stem cells are transferred to a collection bag. Other blood components are circulated back to patients. After the sufficient collection of HSC, the patient undergoes chemotherapy in high doses to kill cancer cells. After this HSC are given back by transfusion, the cells migrate to the bone marrow and begin the process of creating new blood

cells, thereby rebuilding the bone marrow and immune system.

P-32
Comparative Study of Anti-Inflammatory Activity of piperine with aspirinin albino Rats

GIRI K R, GIRI R R, PALANDURKAR KM, TATKARE SN, TOTADE SV, JHA RK
Dept of Pharmacology, J.N. Medical College, Sawangi (M), Wardha.

Introduction: Since antiquity *Piperine* has been widely used in Indian traditional medicine. Piperine is an alkaloid isolated from the fruit of Black pepper.
Objective: To compare the anti-inflammatory property of piperine with standard as Aspirin against Carrageenan induced paw edema model in albino rats & Freund's Adjuvant induced arthritis.
Method: After approval from Institutional Animal Ethics Committee, albino rats of either sex (Wt. 150-250 gms) were divided into 7 groups with 6 animals in each. Acute inflammation was produced by sub-plantar injection of 0.1 ml of 1% freshly prepared Carrageenan in normal saline in right hind paw of rats & 0.1ml Freund's adjuvant arthritis. Control groups were treated with normal saline, Test groups with Ethanolic extract of Piperine (10 mg/kg p.o.), Standard groups with Aspirin (100mg/kg p.o.) one hour before Carrageenan injection & 2 hr before Freund's injection The paw volume was measured plethysmometrically at an interval of 1, 2, 3, 6 hrs after Carrageenan injection.On 1stday, 5thday, 15th day, 18th day, 21st day, 25th day, 28th day after Freund's Adjuvant injection. Body weight changes and Arthritic index were evaluated. Mean paw volume increase in ml (Mean + SE) and % inhibition of paw swelling was evaluated and analyzed statistically.
Result: Mean + SE and % inhibition of paw swelling are as follows: Piperine 0.325+0.012, 57.23%; Aspirin 0.3+0.006, 62.5% after 3 hrs respectively. $p<0.05$ is significant for Piperine as compare to control group. In test drug % inhibition of edema was 25.93% on day 5th, 35.30 % on day 15th, reduction in % inhibition on day 18th i.e. 31.45%, 32.93% on day 21st, 48.70% on day 28th. Peak percentage inhibition seen on day 28th.
Conclusion: Piperine exhibit potent dose dependent Acute & Chronic anti-inflammatory activity comparable to aspirin.

P-33
Design, Synthesis & Evaluation of Quercetin-Diclofenac Conjugate: a Mutual Prodrug for Safer NSAIDs

KIRAN GUPTA
NIMS Institute of Pharmacy, NIMS University Jaipur India

Gastrointestinal (GI) adverse events, ranging from mild to life-threatening are well recognized sequelae to NSAID use. In the present study Diclofenac has been conjugated with Quercetin a naturally occurring polyphenolic flavanoids well known for anti ulcerogenic activity due to its anti oxidant properties. The physicochemical properties, including aqueous solubility, partition coefficient, chemical stability of synthesized derivative have been studied to assess its prodrug potential. Its anti-inflammatory, antiulcer and analgesic activities were also evaluated. The mutual prodrugs shows improved anti-inflammatory activity with reduced ulcerogenic sideeffects. Based on the observations, it is suggested that co administration of antioxidants & NSAIDs in formulated dosage form may possibly decrease the risk of NSAIDs induced gastrointestinal side effects. Furthermore, Diclofenac with anti-oxidants physical mixture did not effectively reduce the risk of GI- side effect in comparison to their corresponding conjugates. These results suggest that there potential advantage in giving such drugs having complementary pharmacological activities in the form of single chemical entity i.e. Mutual Prodrugs.

P-34
Progeria Syndrome

KOMAL SHARMA, KAVERI SHARMA, VIVEK DAVE, SWAPNIL SHARMA AND ASHUTOSH PAREEK
Department of Pharmacy, Banasthali University Rajasthan

Progeria is a rare disease, fatal genetic condition that produces rapid aging, beginning in childhood also known as "Hutchinson–Gilford progeria syndrome" and "Hutchinson–Gilford syndrome" wherein symptoms resembling aspects of aging are manifested at an early age. It is a genetic condition that occurs as a new mutation and is not usually inherited, although there is a uniquely inheritable form. This is in contrast to another rare but similar premature aging syndrome, dyskeratosis congenita (DKC), which is inheritable and will often be expressed multiple times in a family line. Progeria signs include growth failure, loss of body fat and hair, aged-looking skin, stiffness of joints, hip dislocation, generalized atherosclerosis, cardiovascular (heart) disease and stroke. Progeria shows characteristic facial appearance including prominent eyes, thin nose with a beaked tip, thin lips, a small chin, and protruding ears, severe hardening of the arteries beginning in childhood. Transmission is most likely from a sporadic autosomal dominant mutation. Clinical manifestations are evident by the first or second year of life and include the physical characteristics usually associated with the elderly. These diseases almost never passed on from parent to child. Progeria is almost always caused by de novo point mutation in the lamina gene that

activates a cryptic splice donor site, producing a truncated mutant protein termed "progerin." Current research suggests an underlying defect of hyaluronic acid that may possibly account for the entire process. The protein believed to blame for Progeria is called progerin. In order to block normal cell function and cause Progeria, a molecule called a "farnesyl group" must be attached to the progerin protein. Farnesyl Transferase Inhibitor (FTIs) acts by blocking (inhibiting) the attachment of the farnesyl group onto progerin.

P-35
Detection of Adverse Drug Reactions in Wards of a Public Teaching Hospital

KUMAR A, TIWARI P[1], D'CRUZ S[1], SACHDEV A[1]
Dev Bhoomi Institute of Pharmacy and Research, Dehradun, Uttrakhand, India
[2]Department of Pharmacy Practice, National Institute of Pharmaceutical Education & Research, S.A.S. Nagar-160062, Punjab, India
[1]Dept. of General Medicine, Government Medical College & Hospital, Sector-32, Chandigarh

Monitoring of Adverse Drug Reactions is needed to improve patient safety as these are a common, often preventable, cause of illness and disability. A recent study on 4000 elderly ambulatory patients had shown that 10% of the patients suffered from an ADR. This prospective observational study was conducted at a public teaching hospital to profile the adverse drug reactions in the inpatients. The data was collected in standard format from case files & analyzed. The results were based on data from 1010 patients. Of this, 682 were male and 328 were female patients. The median age of the patients was found to be 43.5 years. The average number of diagnosis was 2±0.03, average number of medications prescribed 8.84±0.15 and average length of hospital stay was 6.5±0.13 days. In these patients, as much as 8.8% of patients had experienced one or more ADRs. The three most commonly occurring ADRs were constipation, hypokalemia and skin rash (18%>12%>11%, respectively). The cardiovascular drugs were responsible for majority of the ADRs (35%) which was followed by anti-infective drugs. Furosemide was the leading drug causing maximum number of ADRs (18%). These results indicate that there is a need for continuous monitoring of ADRs to promote patient safety & health.

P-36
Stem Cell: New Emerging Pharmacological Tools for Diagnosis and Treatment of Disease

KUNDAN KUMAR, RAHUL NAIR, NITESH TRIPURA, SULAV GURUNG, MANTOSH K. SATAPATHY, SANDEEP TRIPATHI
Department of Biotechnology, NIET, NIMS University, Jaipur India

A number of novel approaches for repair and regeneration of injured different tissue organs have developed over the past several years. The potential application of stem cells is making cells and tissues for medical therapies. Today, donated organs and tissues are often used to replace those that are diseased or destroyed. Unfortunately, the number of people needing a transplant far exceeds the number of organs available for transplantation. Pluripotent stem cells offer the possibility of a renewable source of replacement cells and tissues to treat a myriad of diseases, conditions, and disabilities including Parkinson's disease, amyotrophic lateral sclerosis, spinal cord injury, burns, heart disease, diabetes, and arthritis. The better understanding of endogenous stem and progenitor cells in the target organs that can function in reparative capacity as well as extensive exploration of the potential efficacy of administering exogenous stem or progenitor cells to function in repair. While the regeneration of a lost tissue is known to mankind for several years, it is only in the recent past that research on regenerative medicine/dentistry has gained momentum and eluded the dramatic yet scientific advancements in the field of molecular biology. Stem cells have been successfully isolated from variety of human tissues including orofacial tissues. Initial evidence from pioneering studies has documented the likely breakthrough that stem cells offer for various life-threatening diseases that have so far defeated modern medical care. Stem cells may also be used to treat brain degeneration, such as in Parkinson's and Alzheimer's diseases. The present study has support to explore the therapeutic potential of stem cell therapy in diagnosis and treatment of different diseases.

P-37
Pharmacovigilance: A Drug Safety Monitoring Master Key

KUNDAN SINGH BORA, ANUPAM SHARMA[1], VEERMA RAM
Sardar Bhagwan Singh Post Graduate Institute of Biomedical Science & Research Balawala, Dehradun, Uttarakhand, [1]University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh

According to WHO Pharmacovigilance is defined as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem'; it plays a vital role in ensuring that doctors, together with the patient, have enough information to make a decision when it comes to choosing a drug for treatment'. However, despite all their benefits, evidence continues to get those bigger adverse reactions to medicines which are common, yet often reventable, cause of illness, disability and even death. In some countries, adverse drug reactions (ADR) rank among the top 10 leading causes of mortality. There are many factors associated with under reporting of ADR; categorized as personnel and professional characteristics of

healthcare professional and their knowledge and attitude to ADR reporting. In order to prevent or to reduce harm to patients and thus improve public health, mechanisms for evaluating and monitoring the safety of medicines in clinical use are vital. Pharmacovigilance is an important and integral part of clinical research and these days it is growing in many countries. Today many pharmacovigilance centers are working for drug safety monitoring in this global pitch, however, at the turn of the millennium pharmacovigilance faces major challenges in aspect of better safety and monitoring of drugs. The present review emphasizes the drug safety, worldwide pharmacovigilance centers and their role, benefits and challenges of pharmacovigilance and its future prospective.

P-38
Stress-Induced Hypothalamic–Pituitary–Adrenal (Hpa) Axis Activation, Anxiety Like Behaviour, Oxidative Damage in Mice and Promising Neuroprotection through Rutin

LALIT MACHAWAL, ANIL KUMAR
Pharmacology Division, University Institute of Pharmaceutical Sciences, UGC Centre of Advanced Study, Panjab University, Chandigarh, India

Introduction- Stress has been well known to cause several neuropsychiatric problems. Neurobiology of stress and related cascades is also very complex. Besides, has been known to cause anxiety and related complications in human being. However, the exact pathological mechanism as well as suitable adequate treatment is not available so far.

Materials and Methods- Male Laca mice were used in the present study. Rutin (20, 40, 80 mg/kg p.o.) and vitamin E (50 mg/kg p.o.) were administered for 5 days before subjecting for immobilisation stress. Animals were immobilised for 6 hour and several behavioural (mirror chamber as well as locomotion performance tasks) and following by biochemical parameters (lipid peroxidation, nitrite concentration, reduced glutathione and catalase) were assessed in the brain and corticosterone level in serum.

Results- 6-hour Immobilisation stress significantly caused anxiety like behavioural both in mirror chamber as well as actophotometer tasks, raised corticosterone level and oxidative damage (as evidenced by raised lipid peroxidation, nitrite concentration, depletion of reduced glutathione and catalase activity) as compared to naïve group. 5-days pre-treatment with rutin (20, 40, 80 mg/kg) significantly attenuated anxiety like behaviuor in the test paradigms, corticosterone level as well as antioxidant like effect and also restored oxidant and antioxidant whole brain.

Conclusion- Results of the present study suggest the neuroprotective potential of rutin against immobilisation stress induced anxiety like behaviour and oxidative damage in mice. Study further provides a hope rutin could be used for effective management of stress induced anxiety like problems.

P-39
Sick Sinus Syndrome

LATIKA JOSHI
Department of Pharmacy, Banasthali University, Rajasthan

Sick sinus syndrome is a collection of heart rhythm disorders that includes Sinus bradycardia and Sinus pauses or arrest. Atrial tachycardia and Bradycardia-tachycardia are the other abnormal heart rhythms occurring with these disorders. It is known as Bradycardia-tachycardia syndrome or Sinus node dysfunction, usually occurring in people older than 50 years. Coronary artery disease, high blood pressure, and aortic and mitral valve diseases occur with it. It is caused often due to scar-like damage to the heart's conduction system. In children the common cause of sick sinus syndrome is heart surgery, especially on the upper chambers. Symptoms may include chest pain and angina, confusion or other changes in mental status, fainting, fatigue, dizziness or light headedness, sensation of palpations and shortness of breath, possibly only with activity. The heart rate may be very slow at any time. Blood pressure may be normal or low. It may cause heart failure to occur or get worse. It is diagnosed when the symptoms occur only during episodes of arrhythmia. An ECG may show abnormal heart rhythms. Holter monitoring is an effective tool to diagnose it. An intracardiac electrophysiology study (EPS) is a very specific test for this disorder. Abnormal heart rhythms are often made worse by medications such as digitalis, calcium channel blockers, beta-blockers, and anti-arrhythmics. A pacemaker can be implanted permanently if symptoms are related to bradycardia. Tachycardia may be treated with medications or radiofrequency ablation. Eating, exercising, maintaining a healthy weight, and avoiding tobacco can prevent many heart problems.

P-40
Pharmacotherapeutic Role of *Commiphora Wightii* on the Downregulation of Cholesterol Biosynthesis Pathway in Hyperlipidemic Rats

MADHVI BHARDWAJ, POONAM YADAV, ANUPAM KUMAR[1], SANDEEP TRIPATHI, SANDEEP KUMAR
Department of Biotechnology, NIET, NIMS University, Jaipur, Rajasthan,[1] Department of Biotechnology, Lovely Professional University, Phagwara, Punjab, India

Hyperlipidemia sounds to be a dominant cause of death in diverse cardiovascular afflicted patients in developed and developing nations. It is lipoprotein metabolism and genetic syndrome that results dyslipidemia, diabetes, obesity, atherosclerosis and hypertension. Herbal remedies

are increasingly being employed in an attempt to counteract the development of hypercholesterolemia associated disorders. The ayurvedic medica reported that oleogum resin gugulipid extracted from *Commiphora wightii* (family- Burseraceae), has remarkable hypercholesterolemic activity. In the present study, the effect of guggulsterone at the rate limiting step of cholesterol biosynthesis at HMG (3-hydroxy-3-methyl glutaryl)-Co-A reductase and eNOS have been investigated in order to assess the endothelial and hepatocyte dysfunction in rats who were fed with hyperlipidemia induced diet for 90 days. The study design incorporated five groups (n=6) rats including Control and hyperlipidemia induced diet (HPC) while three other group were fed with HPC and 200mg, 400mg, 800mg, guggul/kg b.w and one (HPC) + 4mg standard drug (Simvastatin)/kg b.w. Results of the present study showed that significant ($p<0.01$) reduction in HMG CoA reductase and eNOS in 400mg guggul treated rats. It is markedly associated with the reduced body weight and reverses lipoproteins concentration near to control rats. Moreover, the lipid peroxidation levels were also reduced compared with the positive control rats. The outcome of the study supports the salubrious effect over hyperlipidemia. Therefore, guggulesterone can be claim for the clinical trial to patients suffering from lipid disorders.

P-41
Adverse Effect of Iron Overload Produces Oxidative Burden in Cord Blood

MANISHA CHOUDHARY, ARCHANA AGGARWAL[1], DUSHYANT SINGH CHAUHAN, SUDHANSHU MISHRA, SURABHI TOMAR, VIJAYSHREE MAHASANI[1], SANDEEP TRIPATHI
Department of Biotechnology, NIET, [1]Department of Gynecology, NIMS Medical College, NIMS University, Jaipur

It has been reported that mitochondrial rich placenta may be responsible for oxidative burden in pregnant women. Iron, transitional metals, is particularly abundant in the placenta and it is important in the production of reacting oxygen species (ROS). The aim of the present study was to evaluate the effect of Fe dependent oxidative stress in pregnant women. In this study we recruited 23 pregnant women subject those having high concentration of Iron. The control was selected only sufficient Iron. The cord blood were collected for metal estimations (Fe, Cu, Zn and Se) using atomic absorption spectrophotometer and oxidative stress markers ie. lipid peroxide level, superoxide dismutase, catalase and reduced glutathione. We observed significantly reduced concentration of Cu, Se and increased level of Fe and Zn. The lipid peroxide level were found to be markedly ($p<0.001$) increased in Fe overload blood. On the other hand the antioxidant enzymes ie., superoxide dismutase, catalase and GSH content were reduced in subjects as compared with the controls. On the basis of results it may conclude that excessive iron potentiate oxidative stress and delineate the concentration of micronutrients levels. These may be harmful for the child. It is suggestive that Fe supplementation should be important during pregnancy. Further study also required to reveal this hypothesis.

P-42
Adverse Drug Reactions in Pediatric Patients: an Observational Study

MAULIK KORVADIYA, RUPESH MASAND, ALOK PUROHIT
Department of Pediatrics, NIMS Medical College, Nims University, Jaipur India

Introduction: Adverse drug reactions (ADRs) in pediatric population are an important major health care problem. Despite efforts being made to reduce the incidence of medication related adverse events, the morbidity and mortality in pediatric patients due to drug-induced reactions continue to be unacceptably high.
Aims & Objectives: To study the ADR pattern, demographic profile, causality and severity of the drug reactions in pediatric patients of a tertiary care hospital.
Methods: An observational study, involving active monitoring for ADRs, was performedin the Pediatric Wards, NICU,PICU& OPD of the Department of Pediatrics in a tertiary care hospitalfrom March to August 2012. All patients of the pediatric age group less than 12 years of age and of either gender were included in the study. Occurrence of adverse effects was based on questioning of the parents / caretaker in the OPD and by clinical monitoring of the admitted patientsin the Pediatric Wards, NICU, PICU followed by confirmation with appropriate laboratory investigations.
Results: A total of 56 ADRs were documented among pediatric patients in admitted in pediatric wards, NICU, PICU & in the OPD. Most of the ADRs (40%) occurred below the age of 1 year. Antibiotics comprised the major group of drugs causing ADRs (43%). Diarrhea was the most common type of ADR (37%) followed by rashes, vomiting, sedation. There were more occurrences of ADRs with multiple drugs compared to single drug therapy. About 82% of the ADRs were of probable causality. There were 55% mild reactions, with 40% of reactions being moderate and 5% of reactions being severe in the severity scale.
Conclusion: ADRs occur more among infants and antibiotics were more commonly implicated. Most of the reactions were of mild to moderate severity. This indicates the need for a rigid ADR monitoring among pediatric patients to ensure safety of drug therapy.

P-43

Anticonvulsant Hypersensitivity Syndrome associated with Carbamazepine Administration: Case Series

MAULIN MEHTA, JAY SHAH, TEJAS KHAKHKHAR, RIMA SHAH[1], K.G. HEMAVATHI[2]
Department of Pharmacology, S.B.K.S. Medical Institute & Research Center, Piparia, Vadodara, Gujarat

Background: Hypersensitivity reactions are common Adverse Drug Reactions (ADRs) associated with antiepileptics. Carbamazepine is one of the routinely prescribed drugs for the treatment of epilepsy and neuropathic pain. ADRs due to carbamazepine range from mild ADRs to severe Anticonvulsant Hypersensitivity Syndrome (AHS). AHS is the triad of fever, rash and internal organ involvement occurring 1 to 8 weeks after exposure to an anticonvulsant (1 in 1,000 to 10,000 exposures).
Case discussion: Spontaneously reported three cases of AHS-drug hypersensitivity reactions induced by carbamazepine are discussed here. Patient started reaction in 7 to 10 days after starting therapy and developed maculopapular skin rashes, fever and internal organ like liver or kidney involvement. The causal relationship between drug and ADR was found to be 'certain' in one case and 'probable' in other two cases with both WHO-UMC and Naranjo causality assessment scale. All three cases show category 4a according to Hartwig's severity scale as ADR was the cause for hospital admission. On assessing preventability of ADRs by modified Schumock and Thorntons' scale, one case was falling into category of 'definitely preventable' and other two were 'not preventable'.
Conclusion: AHS is rare but serious reaction with carbamazepine which requires vigilant monitoring by physicians to avoid major consequences.

P-44

Pharmacovigilance and Adverse Drug Reactions Publications from India: a Rising Trend in the New Millennium

MAYUR KHOSLA, RUCHI SINGH, PREM PARKASH KHOSLA
Department of Pharmacology Subharti Medical College, Meerut

Introduction: There has been a marked awareness about adverse drug reaction reporting in India due to concerted efforts by World Health Organization and Uppsala monitoring centre. The effect of these efforts is reflected in number and type of publications related with adverse drug reactions in Indian Journals.
Aim: The present study has been done to compare the Adverse Drug Reactions (ADRs) and Pharmacovigilance (PVG) related topics from 2000 to 2012 in Indian Journal of Pharmacology
Method: The journal was screened for all articles related to Pharmacovigilance and adverse drug reaction monitoring. All such articles published in 2000 to 2012 were reviewed.
Observation: There were 5 articles in 2000, 17 in 2005 (240% increase), 44(780% increase) in 2010 and 48(860% increase) in 2012. There is a shift in focus of articles. The articles in early years stressed need for conducting ADR studies, but the current focus is on actual reporting of adverse drug reactions. But so far large series of case reports has not been done. The World Health Organization (WHO) definitions of causality, severity, seriousness, preventability, ICD classification for the type of adverse reaction have been sparsely used. In recent years separate sections have been allocated for reporting of adverse reactions.
Conclusion: There is increase in number of publications on Pharmacovigilance and adverse drug reaction monitoring. There is a need for improvement of quality of reporting.

P-45

Comparative Study of Various Formulations of *"puga khanda"* using Hptlc

MITHILESH SINGH, VIKAS KUMAR PANDEY, SONU SHARMA, RAJU SHARMA[1]
Nims University, Shobha Nagar, Jaipur, Rajasthan, India, [1]Institute of pharmaceutical science and research centre, Bhagwant University, Ajmer, Rajasthan, India

Standardization of herbal formulation is essential in order to assess the quality of the drugs, based on the concentration of their active principles. This article reports on the standardization of *Puga Khanda* a Ayurvedic Polyherbal formulation used for emesis, pain, hyperacidity, syncope, Infertility, Excessive vaginal discharge, anaemia, Bleeding piles, foetal anomaly, senility, Oligospermia, loss of appetite, thirst, weakness, Dyspepsia, constipation, obstruction in urinary tract, Tuberculosis, improves strength and immunity, Improves complexion and vision. *Puga khanda* was prepared as per Ayurvedic Formulary of India. Standardization of the poly herbal formulation is possible by following modern scientific quality control procedure both for raw material and the finished product. The phytochemical constituents found to be present in the raw material used for the preparation of *Puga khanda* possibly facilitate the desirable therapeutic efficacy of standardized medicinal formulation as a whole, and also could help in knowing the underlying mechanisms of the pharmacological action.
In-lab preparation and marketed preparation have been standardized on the basis of organoleptic characters, physical characteristics, and physico-chemical properties. The set parameters were found to be sufficient to evaluate the *Puga khanda*. The obtained values of physical and chemical parameters for the finished products can be

adopted to lay down new pharmacopoeial standards to be followed for traditional preparation of *Puga khanda* (synonyms- Supari Pak) with batch-to-batch consistency.

P-46

Software Used In Pharmacovigilance: A Mini Review

MOHINI MISHRA, VIVEK JAIN, AUSHTOSH PAREEK, YASUMATI RATAN
Department of Pharmacy, Banasthali University, Banasthali, Rajasthan, India

Background: Increases in drug safety concerns in past decade with a number of drug withdrawals have led the foundation of pharmacovigilance programme worldwide by the regulatory bodies.
Introduction: Pharmacovigilance is branch of science dealing with collection, monitoring, researching, and evaluating information from healthcare providers and patients on the Adverse Drug Reactions (ADRs) of drugs, biologicals and traditional medicines with a vision to identify the newer ADR's linked with medicines along with invention of novel methods to prevent them. Due to increasing the availability of drugs to patients, number of ADRs reported, have also resulted in an increase in the quantity of data to be handled led to development of software system to assess multiple ADR's from huge drugs data pool.
Material Methods: All the available information of software used in pharmacovigilance was collected via scientific search engine like google scholar, science direct, pubmed, biomedsearch, Scirus, Scopus, Springer along with web of Uppsala monitoring centre, CDSCO, IT companies magazines etc.
Result: Various softwares identified like vigiflow, paniflow, EudraVigilance, Total safety, Oracle Argus Safety, TARA, Praxis Encota, PV-WORKS, PV WORKS (Vet.) etc. These tools can fulfill the data entry, storage and analysis requirements in the course of pharmacovigilance work. Most tools provide live access to up-to-date terminologies: the WHO Drug dictionary (DD), MedDRA and the WHO Adverse reactions terminology (WHOART). Standardized outputs are available for summary tabulations and a range of standard statistical analyses.
Conclusion: Availability of software system decreases the human errors & provides ease of work to pharmacovigilance professional.

P-47

Cancer and Mitochondrial Metabolism

MONIKA RATHOUR, DEEPAK KUMAR, SANDEEP KUMAR, SANDEEP TRIPATHI
Department of Biotechnology, NIET, NIMS University, Jaipur India

Emerging evidence indicates that impaired cellular energy metabolism is the defining characteristic of nearly all cancers regardless of cellular or tissue origin. In contrast to normal cells, which derive most of their usable energy from oxidative phosphorylation, most cancer cells become heavily dependent substrate level phosphorylation to meet energy demands. Evidence is reviewed supporting a general hypothesis that genomic instability and essentially all hallmarks of cancer, including aerobic glycolysis (warburg effect), can be linked to impaired mitochondrial function and energy metabolism. A view of cancer as primarily a metabolic disease will impact approaches to cancer management and prevention. Cancer is complex disease involving numerous tempo-spatial changes in cell physiology, which ultimately lead to malignant tumors. Abnormal cell growth (neoplasia) is the biological endpoint of the disease. Tumor cell invasion of surrounding tissues and distant organs is the primary cause of morbidity for most cancer patients.The biological process bu which normal cells are transformed into malignant cancer cell has been the subject of a large research effort in the biomedical sciences for many decades.

P-48

Development and Characterization of Herbal Potent Drug Loaded Chitosan-Alginate Microparticulate Drug Delivery System against Degenerative Liver Diseases

MOUMITA HAZRA, DALIA DASGUPTA MONDAL[1], TAMAL MONDAL[1], DIVAKAR GOLI
Acharya & B M Reddy College of Pharmacy,Bangalore, [1]National Institute of Technology,Chemical Engineering Department, Durgapur

For over 20 years, researchers have treasured the potential benefits of nano and micro technology in providing vast improvements in drug delivery and drug targeting. Improving delivery techniques that minimize toxicity and improve efficacy offers great potential benefits to patients, and opens up new markets for pharmaceutical and drug delivery companies. The objective of the present study was to prepare an orally bioavailable hepatoprotective quercetin loaded sodium alginate-chitosan microsphere by ionic cross linking method.The method includes the preparation steps in which quercetin (0.2%w/v) was dispersed within sodium alginate solution 3% (w/v) and the dispersion was then dropped in a solution containing both calcium chloride (4%, w/v) and chitosan 0.5, 1, 1.5% w/v (F1, F2, F3). In vitro drug release, swelling index, FTIR, XRD, SEM and DSC studies were also done for physicochemical characterization of the formulations. The study was also designed to assess the hepatoprotective effect of the formulations against paracetamol induced hepatotoxicity in rats. Swelling index study and quercetin release at a pH of 1.2, 6.8 and 7.4 were done which entails

that the swelling and release of the microspheres at pH 1.2 were minimal confirming the prevention of drug release in the acidic environment of stomach. Comparative release was seen from the formulations at pH 6.8 and pH 7.4.Histopathological findings suggest that the formulations possess hepatoprotective effect against paracetamol induced hepatotoxicity. The findings suggest that the formulations were a promising carrier for quercetin delivery for its improved oral bioavailability and hepatoprotective activity.

P-49
Antimicrobial Activity of *Gloriosa Superba* Tubers

MUKESH MAURYA, SATISH SURYAVANSHI, RAJIV DAHIYA[1]
Department of Pharmacology, Globus College of Pharmacy, [2]Department of Pharmaceutical Chemistry, Globus College of Pharmacy, Bhopal (MP)

Traditional system of medicine is found to have utilities as many accounts. Due to population rise, adequate supply of drug and high cost of treatment in side effect along with drug resistance has been encountered in synthetic drugs, which has lead to an elevated emphasis for the use of plants to treat human diseases. The affordability of herbals has also drawn the attraction towards their use. India is one of the oldest civilizations which are known for rich repository of medicinals plants. *Gloriosa superba* is one of the oldest ingredients of species from ancient time. Being native form Indian specially Southern India, it is known as glory lily and climbing lily - in English; Karihari - in Hindi; Langli - in Sanskrit. The phytochemicals present in it, lead to have analgesic, anti-inflammatory, antithrombotic, anticoagulant, enzyme inhibitory, antivenom and chemotherapeutic potential. Present investigation focuses on evaluation of antimicrobial activity of alcoholic extracts of *Gloriosa superba* tubers. In this study, alcoholic hot continuous extraction method (HCEM) and cold maceration extraction method (CMEM) extracts of *G. superba* tubers were investigated for antibacterial and antifungal activity against pathogenic microbes like *E. coil*, *P. aeruginosa*, *S. aureus*, *K. oxytoca*, *B. subtilis*, *C. albicans*). Extracts showed promising antimicrobial activity against gram-negative bacteria in comparison to gram-positive bacteria, and also showed good antifungal activity.

P-50
Applied Clinical Pharmacokinetics in Pharmaceutical Sciences

MUZZAMIL HUSSAIN, ANOOP KUMAR, SONU SHARMA
NIMS institute of Pharmacy, Nims University, Shobha Nagar, Jaipur

Clinical pharmacokinetics is the discipline that applies pharmacokinetic concepts andprinciples in humans in order to design individualized dosage regimens which optimizethe therapeutic response of a medication while minimizing the chance of an adverse drugreaction. Pharmacokinetics is the study of the absorption, distribution, metabolism, andexcretion of drugs.1 When drugs are given extravascularly (e.g., orally, intramuscularly, applied to the skin via a transdermal patch, etc.), absorption must take place for the drug molecules to reach the systemic circulation. In order to be absorbed, the drug moleculesmust pass through several physiological barriers before reaching the vascular system. Forexample, when a medication is given orally, the drug dosage form must release drug moleculesvia dissolution, and the molecules must pass through the various layers ofthe gastrointestinaltract where they enter capillaries. Distribution occurs when drug moleculesthat have entered the vascular system pass from the bloodstream into various tissues andorgans such as the muscle or heart. Metabolism is the chemical conversion of the drugmolecule, usually by an enzymatically mediated reaction, into anotherchemical entityreferred to as a metabolite. The metabolitemay have the same, or different, pharmacologicaleffect as the parent drug, or even cause toxic side effects. Excretionis the irreversibleremoval of drug from the body and commonly occurs via the kidney or biliary tract.

P-51
Combined Effect of Lithium and Ibuprofen on the Liver and Kidney in Male Albino Rat

NAYNA, NITIN SRIVASTAVA, RAVI KUMAR, CHANDAN KUMAR, ANCHAL ARORA, RUBY SHARMA, BILAL AHMAD, SANDEEP TRIPATHI.
Department of Biotechnology, Nims University, Jaipur, Rajasthan, India

Effect of lithium on oxidative stress and its association with administration of antipyretic drug is still unknown. Liver is the main organ to detoxification of xenobiotics and the kidney is eliminating its metabolite.The present study was to investigate the effect of Li induced toxicity along with ibuprofen (400mg/kg) on rats organs (kidney and liver of male albino rats). 100mg per kg b.w. of lithium chloride (licl3) was orally administered to rats for 14 days. The lipid peroxide labels (LPO, protein carbonyl (PC), Superoxide Dismutase (SOD) the catalase (CAT), gluthathione along with liver and kidney function test were evaluated. In addition liver and kidney histopathological changes were also investigated using H&E staining. In the organs (Kidney and Liver) of th group,oral administration of lithium + Ibuprofen increases LPO, PC and decreases the SOD and CAT enzyme significantly ($p>0.01$) in comparison to control (single administration of Lithium and Ibuprofen). Congestion and dilated cellular changes were seen in the lithium treated rats as compared with

controls.this findings suggest that oral administration of lithium along with ibuprofen may produce pro-oxidant effect in rats and could be of interest for understanding the controversial role of lithium in assessing hepato and nephrotoxicity in Lithium exposed population of patients with mood disorders.

P-52
Impact of Nanometerials on Type-2 Diabetes

NEETU MISHRA, AMRITA BAL, ADITI GOYAL, SURANSH JAIN, NEELAM MAHALA DEEYA ROY, SONAL GUPTA
Amity institute of Biotechnology, Amity University Rajasthan, Jaipur

Recently many scientists focused their research on nanomedicine and nanodiagnostics for many diseases, like diabetes, cancer, spinal cord injury etc. For the scientists the top priority is to synthesize the nanomedicine (hypoglycemic drugs) for diabetics to reduce the cost and pain of the patients. People with diabetes mellitus have five times more risk of having heart disease as people without diabetes. More than 60% of people with end-stage renal disease are people with diabetes. Diabetes is the leading cause of blindness in the United States. The WHO estimates that by 2025 as many as 200–300 million people worldwide will have developed type-2 diabetes. Nanomedicine has potential impact on the prevention, early and reliable diagnosis and treatment of disease. The objective of drug delivery systems is to target selected cells or receptors within the body. This technique is driven by the need on one hand to more effectively target drugs to the site of disease, to increase patient acceptability and reduce healthcare costs; and on the other hand to deliver new class of pharmaceuticals that cannot be effectively delivered by conventional means. Zengshuan Ma et al. proposed to use chitosan nanoparticles as a carrier for the oral delivery of insulin. As chitosan is a mucoadhesive polycationic polymer that can facilitate drug absorption by localizing drug concentration around absorptive cells and prolonging drug residence in the GUT.

P-53
Adverse Reactions of Cardiovascular Drugs in a Medical Intensive Care Unit of Private Tertiary Care Hospital

NEHA D, MALHOTRA S[1], TIWARI P
Department of Pharmacy Practice, National Institute of Pharmaceutical Education and Research, SAS Nagar-160062, Punjab, [1]Clinical Pharmacologist, Fortis Heart and Multispecialty Hospital, S.A.S Nagar, Mohali-160062, Punjab, India

ADRs are an important cause of morbidity and mortality (Ramirez et. al., 2009). Current studies reveal that ADRs occur in 6.5% to more than 20% of hospitalized patients. The aim of the study was to identify the pattern of adverse drug reactions and study the preventability in medical ICU of a private tertiary care hospital.

This was a prospective observational study. The patients' data was collected and analyzed from patients' case records. All the identified ADRs were classified and analyzed.

A total of 170 patients were included in the study during the period of two months. 34 patients had experienced ADRs. The average age was 56.9 ± 20.8 years. The average number of diagnosis was 1.82 ± 0.79 (Average ± SD).

A total of 57 ADRs were observed and 80% were type-A reaction. Drugs acting on cardiovascular system caused 35% of the ADRs followed by anti infectives (15%). Furosemide was the drug which caused maximum number of ADRs (20%). Hypokalemia (28%), diarrhoea (17.5%) and constipation (9%) were the most frequently observed ADRs. Majority of the ADRs were not preventable (73%).

As the patients in the ICUs are more prone for ADRs, because of complex clinical status, so careful and frequent monitoring of ADRs will promote patient safety and will reduce the occurrence of preventable ADRs.

The study is in progress and it is expected that by November, data on 350 patients will be available.

P-54
Concept of Essential Medicine

NEHA SHARMA, RIMJHIM JAIN, SHOBHA KULSHRESHTHA, UMA ADVANI, ATUL JAIN, SAURABH KOHLI, PANKAJ MODI
Department of Pharmacology, NIMS Medical College, Nims University, Jaipur

Essential medicines are those that satisfy the primary healthcare needs of majority of the population. These should be available at all times, in adequate amounts and in appropriate dosage forms (WHO 1975). The essential medicine list needs to be country specific adressing the disease burden of the nation. The medicines used in health care programmes, in emerging and reemerging infections should be adressed in the list.The primary purpose of National List of Essential Medicine (NLEM) is to promote rational use of medicines considering three important aspects i.e. cost, safety, and efficacy. It promotes prescription by generic names. NLEM is a dynamic document and is revised to address the changing disease prevalence, treatment modalities, introduction of newer medicines. The first National List of Essential Medicines of India was released in 1996. Revision of NLEM was based on two important ntional refrence documents i.e., Indian Pharmacopea and National Formulary of India. The revised 17th NLEM 2011 has been prepared by Expert

Core Committee. A total of 348 medicines are present in NLEM 2011 and has been categorized according to therapeutic area.181 medicines fall under the category of Primary, Secondary, Tertiary while 106 fall under the category of Secondary, Tertiary and 61 medicines are categorized as Tertiary only.

P-55
Adverse Drug Reactions: A Psychological Measurement

DR. NISHI FATMA, FAROOQUE
Department of Psychology, School of Humanities and Social Sciences
Nims University, Jaipur India

Adverse drug reaction (ADR) is unintended and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy. Panic attacks, activated by psychologically conditioned non-noxious stimuli, can explain many of the symptoms reported by patients, though the clinical picture is modified by other factors such as somatizaton, cognitive processes (i.e. learning, suggestion, over-valued belief systems) and concurrent psychiatric and medical conditions. Patients with anxiety and related disorders may present with psychogenic reactions, which involve physiologic responses originating from psychological, rather than organic factors. The aim of the present study was to examine the contribution of anxiety and related disorders to adverse drug events. Twenty participants from an adverse drug reaction were recruited as per their clinical history. A well defined questionnaire consisting of six subscales: anxiety, depression, dissociation, confusion, disorientation and learning & memories, sexual problems and sleep disturbance. The data were compared with the patients (without ADR) as positive control. The Anxiety, disorientation, depression, learning and confusion were found to be significantly ($p<0.01$) changes as compare with the control. On the basis of results it may suggest that mechanisms of symptom generation may be analogous to those operative in idiopathic environmental intolerance.

P-56
PCR to Detect Female Genital Tuberculosis

SINGH NITU, KUMAR PRAGATI
Department of Pharmacognosy, NIMS Institute of Pharmacy, Nims University, Jaipur

Female genital organs are one of the common tuberculosis occurring sites in women. It is a chronic disease, slowly destroying the organs. The disease may remain totally symptomless or may lead to pelvic pain, fever, menstrual disturbances or vaginal discharge. Sometimes fluid may accumulate in the abdomen. In very advance disease large pus filled masses may form in the tubes or ovaries. Infertility may be caused even by early or minimal disease. Fallopian tubes which transport eggs from the ovaries to the uterus are the most common organs involved and thus block the passages and lead to permanent infertility.[1] Early confirmation of the diagnosis of tuberculosis is a challenging problem. Conventional methods available for diagnosis have their own limitations. Due to advent of molecular biological techniques like polymerase chain reaction (PCR), it is now possible to detect viable MTB with increased specificity, sensitivity and rapidity rather than time consuming culture methods.[2,3]. In recent years, PCR has evolved as a useful and rapid technique for the diagnosis of pulmonary and extra-pulmonary tuberculosis.[4]A variety of PCR methods have been developed for detection of specific sequences of M. tuberculosis and other mycobacteria. These PCR assays may target either DNA or rRNA/and these could be based on conventional DNA based PCR, nested PCR and RT-PCR. Targets include insertion and repetitive elements, various protein encoding genes, ribosomal rRNA etc. A combination of PCR with other available techniques is the best method of achieving sufficient sensitivity and specifity for the diagnosis of female genital tuberculosis.

P-57
Pharmacovigilance of Cutaneous Drug Reactions: A Prospective Observational Study

PARAG AGRAWAL, D.C. DHASMANA, DR. JUHI KALRA, DR. SAMARJEET ROY[1], PULKIT SWAROOP
Departments of Pharmacology and [1]Dermatology, HIHT University, Jollygrant, Dehradun, Uttarakhand

Ninety patients with Adverse cutaneous drug reactions (ACDRs) attended the dermatology OPD over a period of 12 months were studied. Aim was to determine the frequency, severity and morphological pattern of ACDRs and their correlation with various risk factors. Total of 90 cases were reported over a period of one year duration of the study.ACDRs were observed with 0.5% incidence of patients attending OPD. ACDRs were commonly seen in adult age group (mean age 36.93 yrs) and have 3 or more drugs prescribed with equal gender distribution. As per Naranjo Algorithm, maximum number of ACDRs were of Possible type (74%), while 23 cases were of 'Probable' category with female and male preponderance respectively. 71 of ACDRs were Moderate in severity (79%) followed by 11% of mild and 10% of severe category. Most common clinical pattern was Urticaria with 32 cases followed by 24 cases of Maculopapular Eruptions, 9 cases of Acneiform eruptions and 8 of fixed drug reactions and SJ Syndrome. Commonest Drug groups causing ACDRs were Antibiotics (38%) and Antiepileptics (30%). This was followed by NSAIDs induced ACDRs (9%). Phenytoin was the most common drug causing 12 ACDRs followed by 6 with Cabamazipine and Ceftrixone

each and 5 cases with ATT. Out of 90 cases only 2 cases were 'definitely avoidable'. In Outcome, 71 cases required intervention and 11 were life threatening. In conclusion incidence was low as compared to global incidence, better steps must be needed to strengthen the activity of pharmacovigilance in this state of the country.

P-58
Immobilization of Amylase Enzyme on Magnetic Nanoparticles

DARSHANKUMAR A. PARECHA, PRANAV H. NAKHATE, PRITESH K. RELEKAR, V.P. GHODAKE, A.N. PATHAK
Amity Institute of Biotechnology (AIB), Amity University Rajasthan

Magnetic nanoparticles (MNPs) have demonstrated great promise for diagnostic and therapeutic applications. Due to their high specific surface area and easy separation from the reaction medium by the use of a magnet, they have been employed in enzymatic catalysis applications. In our experiment, Magnetic nanoparticles were synthesized by thermal co-precipitation of ferric and ferrous chlorides. The size and structure of the particles were characterized using scanning electron microscopy (SEM). The size of the particles was in the range between 100 and 150 nm. Amylase was successfully bound to the particles APTES and glutaraldehyde. FTIR spectroscopy was used to confirm the binding of amylase to the particles. Furthermore, the bound enzyme exhibited a better tolerance to pH, temperature and NaCl concentration. The conjugation of enzyme with magnetic nanoparticles seems to protect the enzymatic configuration from distortion or damage by heat exchange and as a result enzyme conjugated with magnetic nanoparticles could work in hostile environment with minimal activity loss. The improvements observed in activity, stability, and functionality of amylase resulted from structural and conformational changes of the bound enzyme. There was no leaching of enzyme found after 96 hours. The study indicates that the stability and activity of amylase could be enhanced via attachment to magnetic nanoparticles and subsequently will contribute to better uses of this enzyme in various industrial applications.

P-59
Postsurgical Hypomagnesaemia and Hypocalcaemia Induced Psychosis: Significance of Patient Compliance - A Case Report

PARUL SINGH, BHAGYA SATTIGERI, HEENA SHAH, P.S.KARELIA, SMIT DOSHI
Department of Pharmacology, SBKS Medical Institute& Research Center, Piparia, Vadodara, Gujarat

A 30 year old female was hospitalized with complaints of multiple bony swellings all over the body since 3 months with no other associated complaints and significant family history. On examination, patient had bony swellings on right side of mandible, left frontal region and left knee joint which were prominent. Radiological investigations revealed osteolytic lesions. Increase in Serum alkaline phosphatase = 1080U/ml, Serum Parathyroid Hormone > 1900mg/dl, Serum Calcium = 10.2mg/dl & Serum Phosphorus = 2.1mg/dl suggested increase in osteoclastic activity and hyperparathyroidism. CT scan of whole body and USG parathyroid revealed hypo echoic lesion on posteroinferior aspect of left lobe of thyroid gland along with left inferior thyroid artery. Patient was subjected to parathyroidectomy. Postoperatively, patient recovered uneventfully. Histopathological examination revealed it to be parathyroid chief cell adenoma. She was supplemented with tab. Shelcal and tab. Calcitriol. On follow up after 3months, Patient was readmitted with sleep disturbances, irritability, confusion, trembling, apprehension, nervousness with an episode of tetanic convulsions and urinary incontinence. The history revealed patient non compliance. On reinvestigation, hypomagnesaemia and hypocalcaemia were detected. Serum Calcium level was 7.5mg/dl and Serum Magnesium was 0.5mg/dl. Patient was treated with inj. Magnesium Sulfate 0.4mg/dl I.M. x 4 days, Tab. Shelcal TDS, Tab Calcitriol 1 O.D. Patient condition improved on 4th day. On 9th day, patient was reinvestigated. Serum Magnesium was 1.2mg/dl and Serum Calcium was 10mg/dl. So, patient was discharged on 10th day. Hence, the case is reported for postsurgical Magnesium and Calcium deficiencies that led to CNS manifestations which were reverted on correcting the deficiencies.

P-60
Herbal Drug and Protein Therapy for Treatment of Liver Disorders

PAYAL PANDEY, ANIL SINGH, PINKY KUMARI
NIMS Institute of Pharmacy, Nims University, Shobha Nagar, Jaipur

Liver is considered to be one of the most vital organs that functions as a centre of metabolism of nutrients such as carbohydrates, proteins lipids and excretion of waste metabolites Additionally, it is also handling the metabolism and excretion of drugs and other xenobiotics from the body thereby providing protection from the body thereby providing protection against foreign substances by detoxifying and eliminating them. The bile secreted by the liver has, among other
Things play an important role in digestion. Hepatic disease is a term that affects the cells, tissues, structures, or functions of the liver. Liver has a wide range of functions, including detoxification, protein synthesis, and production of biochemical necessary for digestion and synthesis as

well as breakdown of small and complex molecules, many of which are necessary for normal vital functions. Herbal drugs are more widely used than allopathic drugs as hepatoprotective because of them are inexpensive, better cultural acceptability, better compatibility, with the human body and minimal side effects. These herbal drugs have shown the ability to maintain the normal functional statues of the liver with or without fewer side effects. The liver plays an astonishing array of vital functions in the maintenance, performance and regulating homeostasis of the body. It is involved with almost all the biochemical pathways to growth, fight against disease, nutrient supply, energy provision and reproduction. Therefore, maintenance of a healthy liver is essential for the overall well being of an individual. Liver cell injury caused by various toxicants such as certain chemotherapeutic agents, carbon tetrachloride, thioacetamide etc., chronic alcohol consumption and microbes is well-studied. Since the Indian traditional Medicine like Ayurveda, Siddha and Unani are predominantly based on the use of plant materials. Herbal drugs have gained importance and popularity in recent years, because of their safety, efficacy and cost effectiveness. Several Indian medicinal plants have been extensively used in the Indian traditional system of medicine for the management of liver disorder. The use of natural remedies for the treatment of liver diseases has a long history and medicinal plants and their derivatives are still used all over the world in one form or the other for this purpose. Scientific evaluation of plants has often shown that active principles in these are responsible for therapeutic success. A large number of medicinal plants (Eclipta alba, Foeniculum vulgare, Trigonella foenum graecum) have been tested and found to contain active principles with curative properties against a variety of diseases.

P-61
Medication Errors in a Neonatal Intensive Care Unit

POOJA YADAV, DEEKSHA PARASHARI, SUSHIL SUTHAR
Department of Pharmacology, Mahatma Gandhi College of Pharmaceutical Science, Jaipur, India

Medication errors are defined as any preventable event that may cause an inappropriate medication. Medication errors account for 34% of all medical errors and identified as one of the important reasons for patient morbidity and mortality. The Categories of mediction errors are illegibly written orders, dispensing errors calculation errors, monitoring errors, administration errors.

Although error could be present in almost every medical practice, they are more frequent and potentially more dangerous in neonatal intensive care units (NICU) is more complex in newborns. The process for ordering drugs in the NICU is uniquely complex; more than three quarters of medication errors occurred during this stage. As doses are calculated according to the infant's weight, virtually all prescriptions require patient specific calculations and may need to be updated as the infant gains or loses weight. Neonates are vulnerable group for dosing and dispensing errors because neonates have a rapidly changing body surface area and weight; a rapidly developing system of drug absorption, metabolism and excretion; an inability to communicate with the provider; and off-label or unlicensed drug usage For premature infants, doses must also be modified on the basis of the developmental maturity of specific metabolic and excretory pathways.

Errors in the route of administration of drugs and enteral nutrition are also common, patient misidentification occurs commonly in the NICU communication. The involvement of clinical pharmacists in intensive care unit rounds significantly reduces dosing and other types of error.

The factors normally affects medication errors are personal neglect, heavy workload unfamiliarity with medication, new staff, complicated order, complicated doctor-initiated order, unfamiliarity with patient's condition, insufficient training, insufficient hospital training.

P-62
Wound Healing Potential of Ethanolic and Methanolic Extract of *Stevia Rebaudianabert*: Instreptozotocin Induced Diabetic Male Albino Rats

POONAM YADAV, MADHVI BHARDWAJ, PURNIMAKUMARI, SANDEEPTRIPATHI, SANDEEP KUMAR
Department of Biotechnology, NIET, NIMS University, Jaipur, Rajasthan, India

Background *Stevia rebaudiana* Bertoni (Asteraceae) is natural sweetner with zero calorie and contributing to various therapeutic properties like antidiabetic, antihypertensive, antimicrobial, antioxidative etc.The present study was carried out to evaluate the comparative wound healing potential of ethanolic and methanolic crude extract of *S.rebaudiana* leaf extract and standard wound healing drugs in experimental diabetic male albino rats.

MethodsThe crude ethanolic and methanolic extract in the form of oral dose (250 mg/kg/b.w) and in topical application (5% w/w) was used for evaluating the wound healing potential in excision wound model for 14 days. Ciprofloxacin (10mg/kg/b.w) andpovidone iodine ointment (5% w/w) was used as standard in oral and topical application respectively. Measurements of wound size, inflammatory markers i.e. IL-1, IL-3, IL-7, lipid peroxidationand antioxidative levels were investigated on 3rd, 7th, 9th and 14th day of treatment.

Results We observed significant wound contraction and decreased skin breaking strength in methanolic extract treated rats as compared with positive controls. IL-1, IL-3,

IL-7 and lipid peroxidation content were reverses in *S. rebaudiana* (methanolic extract) treated rats compared with ethanolic extract. Both the extracts reflect antioxidant potential in diabetic rats.
ConclusionsMethanolic extract of *S.rebaudiana*showed potential for use as alternative to ciprofloxacin, povidone iodine ointment for treatment of wounds in diabetic patients.

P-63
Stem Cell Therapy: "A Boon or a Bane?"

PRADKHSHANA VIJAY
Nims Dental College, NIMS University, Jaipur

Cells with unique capacity for self-renewal and potency are called stem cells. With appropriate biochemical signals stem cells can be transformed into desirable cells. Stem cell populations can be considered to be utilized for cell-based clinical therapies. Defect or dysfunction of the craniofacial tissues after post-cancer ablative surgery, trauma, congenital malformations and progressive deforming skeletal diseases can be treated by stem cells. However, there are certain risks which are associated with stem cell therapy such as teratoma formation and immune rejection etc. Here, we have emphasized on the possibilities of stem cell therapy in the oral and maxillofacial region including regeneration of tooth and craniofacial defects.

P-64
Pharmacovigilance Study of Combination of Vaccines

PRAFULL KUMAR SINGH, ANUPAM ANAND, AYAZ AHMED, SONU SHARMA, RAM GARG
NIMS institute of Pharmacy, Nims University, Jaipur

Background: In developing countries diphtheria, tetanus and whooping cough (pertussis) are the most common infectious diseases. In India Easy four (DTwP-Hib) and Easy five vaccines (DTwP-Hib-HepB) have been introduced by Panacea Biotech Ltd (PBL). The associated risks with immunization are revealed by the collection and assessment of adverse events during the post-licensing surveillance of vaccines (vaccine-vigilance). Pharmacovigilance of vaccines (vaccine-vigilance) post licensing period is therefore essential to detect rare or unanticipated adverse events and to ensure confidence in combination vaccine due to large number of antigens delivered in a single injection.
Aim & Objectives: To evaluate the safety reactogenicity profile of diphtheria, tetanus and pertussis based combination vaccines in Indian Infants
Material & Methods: The study was carried out using active surveillance & passive surveillance methods of pharmacovigilance. In active surveillance method a comparative study was conducted to assess the safety & reactogenicity profile of DTwP vaccines manufacture by Panacea Biotech Ltd & Triple antigen vaccine. The tetravalent (easy four) & pentavalent vaccine (easy five) used during the passive surveillance. The vaccines were administered by intramuscular injection in the anterolateral aspect of the thigh. For the purpose of recording drug reaction Suspected Vaccine Adverse Reaction Form (SVARF) was used. The SVARF forms as received from the participating investigators were reviewed & documented (Med DRA) version 13 was used for coding adverse events.
Result:-The solicited or unsolicited adverse event reported during the study was similar in the DTwP (PBL) vaccine 119 (66.11) & in the Triple antigen group 128 (71.11).A total of 39 suspected Adverse Events (AEs) were reported on which 29 AEs were reported from Easy five vaccine and 10 from Easy four vaccines.

P-65
Cervical Cancer Screening and Human Papilloma Virus Vaccination: Comprehensive Approach to Cervical Cancer Control

PRAGYA GUPTA, KALPANA SANKHALA, PRAKASH ASWANI
Department of Pathology, NIMS Medical College, Jaipur

India with its highest share of global burden of cervical cancer has to implement a population based cervical cancer control program to reduce the number of deaths.
Conventional PAP smear screening is the most effective way of screening in the developing countries. In spite of the success of cervical cancer screening, Pap cytology screening is yet to be effectively implemented or has failed to reduce cervical cancer rates to an appreciable extent. Screening appears to benefit only a small fraction of women although a much larger percentage endures the inconvenience of the Pap test in order to avoid cervical cancer. The establishment of Human Papilloma virus (HPV) infection as the necessary cause of cervical pre-cancers and cancers provides a tremendous opportunity for cervical cancer prevention through vaccination. WHO has recommended vaccination of young women to prevent cancer. Two vaccines, Gardasil and Cervarix are now available for primary prevention. They generate neutralizing antibodies to HPV capsid protein. The vaccines have been shown to confer more than 90 percent protection against cervical pre-cancers and genital warts caused by HPV types 16/18 in population with few or no side effects. Though there is some cross-protection, around 30 percent of cervical cancers will not be prevented by the vaccine. Combining screening techniques and universal prophylactic HPV vaccination is likely to produce the most advanced and cost-effective preventive strategy to fight cervical cancer worldwide.

P-66
Quorum Sensing - a Promising Application for Bio-Luminometer

PRANAV H. NAKHATE, DARSHANKUMAR A. PARECHA, PRITESH K. RELEKAR, SOUMI GAYEN, A.N. PATHAK
Amity Institute of Biotechnology (AIB), Amity University Rajasthan

Quorum Sensing (QS) is new topic in the microbiological world. Many Bacteria use such phenomena to interact within the same species or other species like *Pseudomonas aeruginosa*, *Haemophilus influenza*, *Candida albicans* etc. to form biofilm. Also, some of them are luminescences within the host using QS signaling like *Vibrio harveyi*, *Vibrio fischeri*. The importance of this field of study is to develop a solution to man's most troublesome problems such as biofilm formation can be useful in Gene therapy to check protein production in cancer cells, tissue damage detection, also in sewage sludge treatment etc. Hence, by precise study of toxicity- bioluminescence's relationship, sophisticated instruments like Bio-Luminometer can be designed which are capable of measuring exact light intensities emitted by bacteria. Such kits involve only microbes, hence easy to use, create no pollution and most importantly these are cost effective. Hence these may be considered as new diagnostic kits.

P-67
Bioimformatics to Play Important Role in Biotechnology

PRATEEMA KUMARI, SONU SHARMA
Nims institute of Pharmacy, Nims University, Shobha Nagar, Jaipur

The term bio-imfomatics is the short form of biological informatics, just as biotechnology is the short form of biological technology. Bio imfomatics is the the field of sciences in which biology, computer sciences, and imformation technology merge to form a single discipline.the ultimste goal of the field is to enable the discovery of new biological insight as well as to create a global perspective from which unifying principles in biology can be discerned.in permits research scientists to integrate their diverse data and tools under common graphical user interfares. It also permits Scientists to share information and provide powerful solution to archive data. The whole area of biology can immensely benefit from the bioimfomatics approach.bioimfomatics tools for efficient research will have significant implication in life sciences and betterment of human lives. 1. Application of bioimfomatics a) genomics: useful genes can be selected from a gene library thus constructed and inserted in to other organism for improvement or harmful genes can be silenced. b) proteomics: protemics involves the sequencing of amino acids in a protein,determining its three dimensional structure and relating it to the function of the protein. 2. Cheminformatics and drug design: cheminformatics involves organization of chemical data in a logical form to facilitate the process of understanding chemical properties, their relationship to structure and making inferances.

P-68
An Advanced Approach: Stem Cell Therapy

PRATILKSITA MISHRA, MANISH PAL SINGH
Department of Pharmacology, Rajiv Academy for Pharmacy, Mathura, Uttar Pradesh, India

Stem cell therapy is emerging as a potentially revolutionary new way to treat disease and injury, with wide-ranging medical benefits. It aims to repair damaged and diseased body-parts with healthy new cells provided by stem cell transplants. Disease and disorders with no therapies or at best, partially effective ones are the lure of the pursuit of stem cell research. Recently a plethora of work has been done in this field in world around including India. However, Stem cell research presents many ethical and scientific questions as well as future challenges. Nevertheless, stem cell therapy, a prologue to an era of medical discovery of cell-based therapies that will one day restore function to those whose lives are now challenged every day, is still at the beginning of the road.

P-69
Comparative Evaluation of Topical Calcipotriol vs. Coal Tar and Salicylic Acid Ointment in Chronic Plaque Psoriasis

PREETI SINGH
Subharti Medical College, Meerut

Aim:

- To compare the efficacy of conventional coal tar and salicylic acid ointment with topical Calcipotriol in Chronic plaque psoriasis.
- To evaluate the safety profile of both the drugs on patients with chronic plaque psoriasis.

Method: The present study was a prospective, right/ left randomised, open label comparative study with 8 week treatment phase and 6 week follow-up phase phase. Subjects were asked to apply Calcipotriol 0.005% (50 mcg / gm) twice a day on the right side and on left side, bland oil/cream in the morning and 6% coal tar and 3% salicylic ointment at night time. Approval from the Institutional ethical committee was taken before initiating the study.

Results: The mean PASI score on the right side, treated with calcipotriol was 3.98±2.81 and was 5.32±2.84 on the left side treated with coal tar and salicylic acid (p-value=0.001). The mean percentage reduction of PASI score on calcipotriol treated side was 62.73±24.04 and was 51.53±23.27 on coal tar and salicylic acid treated side (p-

value=0.011). The difference was found to be statistically significant.
Conclusion: The result of our study shows that calcipotriol is more efficacious as the percentage reduction was greater in this group when compared with coal tar for a period of eight weeks. Higher number of patients attained PASI 75 and PASI 50 at the end of treatment with calcipotriol again proving its efficacy over coal tar and salicylic acid. Calcipotriol does have advantages over coal tar in terms of its cosmetic acceptability and prompt relief. The only restrictive factor with calcipotriol is its high price when compared to the existing alternative of coal tar, which is much cheaper.

P-70
Alzheimer's disease

PREETI SINGH, SACHDEV YADAV
Department of Pharmacy, Banasthali University, Rajasthan

Alzheimer's disease is the most common form of dementia among older people. It involves parts of the brain that control thought, memory and language. Persons having mild cognitive impairment (MCI), face more memory problems. In Alzheimer's disease, brain cells degenerate and die, causing a steady decline in memory and mental function. The first symptoms of Alzheimer's disease noticed are increasing forgetfulness and mild confusion. Brain changes associated with Alzheimer's disease lead to growing trouble with memory, disorientation and misinterpreting spatial relationships, speaking and writing, thinking and reasoning, making judgements and decisions, planning and performing familiar tasks, changes in personality and behaviour.People with Alzheimer's may experience depression, anxiety, social withdrawal, mood swings, distrust in others, increased stubbornness, irritability and aggressiveness, changes in sleeping habits and wandering.It is caused due to age related changes in the brain, and genetic and environmental factors. One of the most recognizable symptoms of Alzheimer's is speech problem. It is diagnosed by physical and neurological examination, mental status testing, neuropsychological testing, brain imaging including Computerized tomography (CT), Magnetic resonance imaging (MRI), Positron emission tomography (PET). Two types of drugs are used to treat cognitive symptoms which are Cholinesterase inhibitors including donepezil (Aricept), galantamine (Razadyne) and rivastigmine (Exelon) but have side effects like diarrhea, nausea and vomiting. Memantine (Namenda) is sometimes used in combination with a cholinesterase inhibitor and have common side effect, dizziness. A safe and supportive environment, exercise and nutrition can also treat this disease. It can be prevented by reducing risk of heart disease.

P-71
Nutraceuticals: the New Era in Pharmaceutics

PRANAV H. NAKHATE, DARSHANKUMAR A. PARECHA, PRITESH K. RELEKAR, SOUMI GAYEN, A.N. PATHAK
Amity Institute of Biotechnology (AIB), Amity University Rajasthan

The quality of life in terms of income, outgoing and lifestyle has improved with development of economy. However, it has also thrown up a major challenge in the form of `lifestyle diseases'. Consumption of junk food has increased, which led to number of diseases like obesity, diabetes, hypertension, cardiovascular diseases. Nutraceuticals can play an important role in controlling them. Nutraceuticals are medicinal foods that enhance health, modulate immunity and thereby prevent and cure specific diseases.They may range from natural diets, herbal products to genetically engineered foods and processed products such as cereals, grains, and beverages. Biofortified crops have been considered as a complementary strategy for delivering nutrition to malnourished populations. Dairy products containing probiotic organisms such as Lactobacillus and Bifidobacterium species are also strategically one of the nutraceuticals. Many nutraceuticals, functional foods and genetically modified food that have been investigated and reported in various studies reveal that these products are extremely active, have profound effect on cell metabolism and often have little adverse effect. It is novel pharmacological activity helping in prevention and therapeutic in several diseases. Since prevention of diseases is better than their cure, a place for nutraceuticals in clinical practice is emerging, but important pharmaceutical and clinical issues need to be addressed by further research. Most of the pharmaceutical companies often lack motivation to pursue these difficulties in obtaining the patents. It is expected that government agencies and research centers will give support for further research in nutraceuticals in the interest of human health.

P-72
Particle Size and Shape: a New Pharmacological Parameter for Nanoscale Drug Delivery Carriers

PRIYA, DEBASHREE KAR, SHRUTHI.V, SANDEEP KUMAR, SANDEEP TRIPATHI
Department of Biotechnology, NIET, Nims University, Jaipur India

Encapsulation of pharmaco-therapeutic agents in polymer particles has been effectively used in the development of new drug carriers. A number of design parameters that administrate the functional behavior of carriers, including the choice of polymer, particle size and surface chemistry,

have been tuned to optimize their performance in vivo. Polymeric particles are versatile and can be used to deliver drugs via intravascular, subcutaneous, pulmonary and oral routes, each with different design requirements. However, particle shape, which may also have a strong impact on carrier performance, has not been thoroughly investigated. This is perhaps due to the limited availability of techniques to produce non-spherical polymer particles. In recent years, a number of reports have emerged to directly address this bottleneck and initial studies have indeed confirmed that particle shape can significantly impact the performance of polymer drug carriers. The study suggested another tool to further expand the possibilities for drug delivery particle design. There is obviously a great deal of work to be done in this field and contributions from materials, engineering, biology, immunology, anatomy, pharmaceutics and medicine will all be required.

P-73
Drug Induced Cholelithiasis and Management

PRIYAVART MEHARWAL, VEENA SAXENA, PRAKASH ASHWANI
Department of Pathology, NIMS Medical College and Hospital, Jaipur

A variety of drugs is reported to induce Gallbladder disease by various pathogenetic mechanisms. Epidemiological studies indicated a doubled risk of gallbladder disease in women taking oral contraceptives. The lithogenic index of bile is increased during intake of oral contraceptives. Estrogens cause hypersecretion of cholesterol in bile, due to increase in lipoprotein uptake by the hepatocyte. Progesterone inhibits Acyl coenzyme A-cholesterol acyl transferase activity, causing delayed conversion of cholesterol to cholesterol esters. Of the lipid lowering drugs, only Clofibrate increases the risk for gallstone formation. Ceftriaxone, a third generation Cephalosporin, induces biliary sludge in 25 to 45% of patients, which is reversible after discontinuing the drug. Long term use of Octreotide leads to gallstone formation in approximately 50% of patients after 1 year of therapy, due to gall bladder stasis. Hepatic artery infusion chemotherapy by implanted pump is associated with a very high risk of chemically induced cholecystitis. Prophylactic cholecystectomy at the time of pump implantation is therefore advocated therapy, due to gallbladder stasis. Total parenteral nutrition, is a pharmacologic mixture of glucose, fatty acids, amino acids, vitamins and minerals given intravenously to people who cannot take perorally. The high caloric content of TPN leads to decreased gallbladder motility and gallbladder sludge, increasing the risk of gallstone formation. Stopping the glucose infusion a few hours every day or the addition of certain medications helps decrease gallstone formation in TPN patients. This study shows that various drugs can cause Cholelilathiasis, they can be managed both by conservative and surgical treatment.

P-74
In Silico Studies of the Binding Efficacy of Inhibitors against Shikimate Pathway Enzymes of *Francisella*

PUSHPENDRA TRIPATHI, SURENDRA SINGH, MUKESH KUMAR, MANALI DATTA
Department of Biotechnology, Amity University, Jaipur (Rajasthan) India

Francisella belongs to a genus of pathogenic gram negative coccus. F. tularensis is the causative organism of tularemia, also known as rabbit fever. Other fransicella species have been have been found to cause septicemia and invasive systemic infections in humans. The bacterium is generally transmitted by an arthropod bite, ingestion, inhalation, or direct contact with infected tissues. Although tularemia has been removed from the list of epidemics, sporadic cases tend to aggravate the mortality due to this disease. Thus, it becomes a necessity to curb this highly neglected disease causing organism.

The shikimate pathway is involved in production of aromatic amino acids in micro organisms and plants. As the enzymes of this biosynthetic pathway are absent in humans, it becomes a potential target for the design of antimicrobial compounds. DAHP synthase, the first enzyme of the shikimate pathway convert phosphoenol pyruvate, D-erythrose 4-phosphate, H_2O in to 3-deoxy-D-arabino-hept-2-ulosorate 7-phosphate and phosphate EPSP synthase and chorismate synthase, act in tandem to each other to convert phospho enol pyruvate and 3-phospho shikimate into 5-enolpyruvylshikimate 3-phosphate (EPSP) followed by conversion to chorismate, which is the last common precursor in the biosynthesis of numerous aromatic compounds in bacteria, fungi, and plants.

In our present study we have compared the efficiency of binding of the available and designed inhibitors of the enzymes of shikimate pathway with three dimentional models designed for the enzymes. Outcome of structure function studies will assist in structure based drug designing and development of highly specific inhibitors against this class of organisms.

P-75
Protective Effect of *Baccopa monnieri* on Sleep Deprivation in Rats

PUSHPITA NAYAK, BAPPA BISWAS, KANHAIYA LAL JAT, HASSAN MOHAMED ALI, VIVEK P. SINGH, POONAM YADAV SANDEEP TRIPATHI
Department of Biotechnology, NIET, NIMS University, Jaipur (Rajasthan)

Baccopa monnieri has been found to be very beneficial in the treatment of anxiety neurosis and mental fatigue. It has been found to significant improve IQ levels, general ability, behavioral patterns and mental concentration in children. *Baccopa monnieri* is useful for improving mental clarity, confidence and memory recall. Sleep deprivation (SD) is the public health problem and it may increase the risk of neurological disorders. There several evidence that SD increases the risk of hypertension, diabetes, obesity, depression, heart attack and several neurological defects. In the present study, a specific instrument was designed for sleep deprivation. Twenty four male albino rats were taken.

In the present study, a specific instrument was designed for sleep deprivation. Twenty four male albino rats were taken. After 14 days of sleep deprivation rats were allow to behavioral performance i.e. spontaneous motor activity, Catalepsy, Gait, ataxia and posture. We observed gait and ataxia in experimental rats along with the alterations in spontaneous motor activity. *B. monnieri* (100mg / kg) modulate the behavioral alterations in rats. On the basis of results it may be concluded that sleep deprivation or insufficient sleep induced neurobehavioral changes in rat and co administration of *B. monnieri* ameliorate these changes. Therefore, it is suggestive that *Baccopa monnieri* may be useful in treatment of Insomnia, sleep apnea, periorbital puffiness and sleep related disorders.

P-76
Oral Manifestation of Adverse Drug Reactions

RAAHAT FATIMA, BUSHRA HUSSAIN[1]
NIMS Dental College, NIMS University, [1]Jaipur Dental College, Jaipur

The aim of this study is to present Oral Manifestation of the Drug Reactions. Some of the drugs that may cause adverse effects in the mouth and related structures are presented here.

Every drug can produce untoward consequences even when used according to standard or recommended methods and doses of administration. Adverse drug reactions can involve every organ and system of the body and are frequently mistaken for signs of underlying disease. The mouth and the associated structures can also be affected by many drugs and chemicals. Drug reactions can be categorized as to the parts of the oral complex such as the oral mucosa and tongue, periodontal tissues, dental structures, salivary glands, cleft lip and palate, muscles, and nerves.

P-77
Protective Effect of Root Extracts of *Bauhinia Variegata* Linn against Cisplatin-Induced Nephrotoxicity in Rats

RAJESH KUMAR SHARMA, GOVIND MOHAN, NITU SINGH
Department of Pharmacology NIMS Institute of Pharmacy, Shobha Nagar, Jaipur, Rajasthan, India

In this study, we aimed to investigate to possible protective effect of *Bauhinia variegata* Linn. on Cisplatin induced nephrotoxicity. Experimental were carried out in male Wistar rats weighing 200-250 g. Cisplatin (5 mg/kg body weigh i.p.) and Cisplatin together with ethanolic and aqueous root extracts of *Bauhinia variegata* (BVE)at 400 mg/kg b.w. respectively were administrated for 7 days. The animals were scarified 24 h after the last injection. Urine, blood, and tissue samples were collected form on the seventh day of the treatment before they were sacrificed. Kidneys were collected for histopathological studies and fixed in 10% buffered formalin solution. Significantly decrease in serum creatinine, serum urea, urine creatinin levels in extract treated groups which was elevated by Cisplatin..which was further confirmed by histopathological study. Histopathological examination showed that extracts of *Bauhinia variegata* prevented partly Cisplatin induced tubular damage. The result histopathologycally demonstrated that root extract of *Bauhinia variegata* has a protective effect against Cisplatin induced nephrotoxicity, lipid peroxidation and cellular damage in rats.

P-78
The Emerging Therapy with Probiotics in the Management of Inflammatory Bowel Disease-Current Status

RAJIV KUMAR, JAGJIT SINGH
Department of Pharmacology, Government Medical College & Hospital, Chandigarh, India

CONTEXT: Inflammatory Bowel Disease (IBD) comprises Ulcerative Colitis (UC) and Crohn's Disease (CD) with unknown aetiology. Most of the drugs used to treat IBD as standard treatment produce adverse effects during long term therapy. Evidence has suggested a role of intestinal microbiota in IBD. The use of probiotics and prebiotics is the natural approach to treat IBD.

OBJECTIVE: To systematically review the studies on Probiotics which cover the therapeutic status in Inflammatory Bowel disease?

METHOD / SEARCH STRATEGIES: Appraisal of published articles from peer reviewed journals, search from PubMed and Wiley Blackwell website for English language publications using defined keywords according to disease type.

RESULTS: Studies have shown that probiotic agents play an important role in IBD and these are VSL#3, Bifido-ferminted milk, *Escherichia coli* Nissle 1917, *Saccharomyces boulardii* and "BIO-THREE for inducing remission in patients with active UC, for preventing relapses in inactive UC patients and also in UC patients with ileo-anal pouch anastomosis. *Lactobacillllusrhamnosus* GG and *Lactobacillllus johnsonii*LA1 can prevent endoscopic recurrences in patients with inactive CD. Probiotic intervention study designs in IBD patients searched were RCT vs Placebo / RCT vs standard treatment. Studies – with uncontrolled design, with prebiotics intervention and with helminthes were also searched.
CONCLUSION: There is a promising role of probiotics and prebiotics in chronic mucosal inflammation that occurs in Inflammatory Bowel Disease. Sufficent evidence to support the role of probiotics in CD are not available. Well designed RCT studies based on intention -to- treat analyses are required.

P-79
To Analyse the Drug Utilization Pattern in Geriatric Patients Intertiary Care Teaching Hospital

R.R. SINHA, UMA ADVANI, SHOBHA KULSHERESHTHA, PANKAJ MODI, SAURABH KOHLI, ATUL JAIN, RAHUL PARAKH
Department of Pharmacology, NIMS Medical College, Nims University, Jaipur, Rajasthan

OBJECTIVE: 1. Data analyzed can help in assessing the quality of care given to the elderly. 2. To promote rational use of medicines
METHOD: - Study was cross-sectional prospective type, from Aug.to Oct. 2012, in 200 geriatric patients (above 60 years) in NIMS Medical College & Hospital. A proforma having patients detail, prescription details & ADR were recorded.
RESULTS: Out of 200 geriatric patient 120 was male & 80 were female. Most of these patients were in the age group of 60 to 70 years (80%). Most common disease in this study was Hypertension (51%), followed by Diabetic mellitus (22%), Ischemic heart disease (11%), arthritis & psychiatric disorder (11%), Hypothyroidism (5%). In 18% Patients both Hypertension & Diabetic mellitus is present. In cardiovascular patient most commonly drug prescribed was Calcium channel blocker (23%), followed by Angiotensin Receptor Blocker (21%), Beta blocker (20%), Diuretic (17%), Aspirin (13%), ACE inhibitors (10%), Statins (10%). In Diabetic patient most commonly prescribed drugs were sulfonylureas and Biguanides (17%). Multivitamins were also prescribed in higher number of geriatric patient (20%).Majority of patients were on Polypharmacy > or = 3 concurrent medications. The common ADRs were GIT disturbances, postural hypotension, ataxia, weakness & ankle edema.
CONCLUSION: In geriatric patients, most common disease observed was hypertension followed by diabetic mellitus. Most common drugs used overall were calcium channel blockers followed by angiotensin receptor blockers. In diabetic patients the most common drugs used were sulfonylureas & biguanides. There are numerous oppourtunities to improve prescribing practices.

P-80
Nanoparticles as Efficient Carrier for the Delivery of Doxorubicin for Treating Cancer

RAJNANDINI KASHYAP, SHWETA KULSHRESHTHA
Amity Institute of Biotechnology, Amity University of Rajasthan, Jaipur

Cancer is the leading cause of death worldwide and deaths cases are continue to rise, with an estimated 13.1 million deaths in 2030 (WHO). Doxorubicin is used to treat cancer by slowing downor stopping the growth of cancer cells. This drug prevents cell replication by inhibiting protein synthesis which then affects DNA synthesis. This drug also forms oxygen free radicals, which can result in heart and circulatory damage.The efficiency of this drug can be increased by the use of nanoparticles which will form nanomedicine.The effective nanomedicine development depends on two major goals: first, to understand how the biological system operates at the nanoscale and second, to use this information for engineering new structures that can be applied to treat cancer. Scientists have developed various types of doxorubicin loaded nanoparticles which are given to the patient suffering from cancer. Most of these drug loaded particles are delivered safely to the cancer affected site with increased efficiency. These drug loaded particles showed more cytotoxicity against cancer in *in vivo* and *in vitro* conditions with minimal systemic toxicity. Therefore, doxorubicin loaded nanoparticles (nanomedicine) provide tremendous opportunities for multimodal, site-specific drug delivery with enhanced intracellular uptake and reduced side effects.

P-81
Advances in Local Drug Delivery Systems in Periodontitis

RAKESH DORWAL, RASHMI KHANNA
Department of Periodontics, NIMS Dental College Hospital, Jaipur.

Periodontitis, a disease involving supportive structures of the teeth prevails in all groups, ethnicities, races and both genders. Antibacterial agents have been used effectively in the management of periodontal infection. Systemic administration of drugs leads to therapeutic concentrations at the site of infection, but for short periods of time,

forcing repeated dosing for longer periods. In the last decades, local delivery of antimicrobials has been investigated for the possibility of overcoming the limitations of conventional therapy. The treatment has been optimized for the use of drug delivery systems to the periodontal pocket, with the advantage of delivering the drug in the specific site, sustaining and/or controlling the drug concentration. The use of sustained release formulations to deliver anti-bacterials to the site of infection (periodontal pocket) has recently gained interest. These products provide a long-term, effective treatment at the site of infection at much smaller doses. Biodegradable polymers are extensively employed in periodontal drug delivery devices because of their abundant source, lack of toxicity, and high tissue compatibility. Recently, the use of new drug delivery systems has been receiving great interest. This poster depicts the main local drug delivery systems for the administration of drugs to the periodontal pocket and their effectiveness in the periodontal therapy.

P-82
Left Ventricular Dysfunction in Deteriorating Patients with Chronic Obstructive Pulmonary Disease

RANJIT SINGH BAJWA, SWARUPVERMA
Nims Medical College, Nims University Jaipur

OBJECTIVE: Co-relating the severity of chronic obstructive pulmonary disease (COPD) with percentage of Left Ventricular dysfunction (LVD) and its prevalence in elderly population.
DESIGN: Prospective cross sectional study of 50 patients with exacerbation of breathlessness or within one month of visiting the outpatient department with complaints of new or worsening dyspnea.
SETTING: Indoor and outdoor Medicine department of NIMS hospital.
PATIENTS: More than 50 years of age with exacerbation of chronic obstructive pulmonary disease (COPD) according to GOLD criteria.
MEASUREMENTS: History and physical findings, pulmonary function tests, transthoracic echocardiography, electrocardiogram, blood sugar levels, and chest radiograph.
RESULTS: The mean FEV1% is found lowest in the age group > 70 years (36.5 ± 6.93) as compared to age group 51 – 60 years (43.70 ± 6.24) and 61 – 70 years (41.21 ± 7.00). In total we found 15 patients of LVD which shows prevalence of 30% in our 50 patients of COPD. Seven patients who had COPD (GOLD stage II) no one had LVD i.e. prevalence of 0% and from 38 patients who were in GOLD stage III, 11 had LVD i.e. prevalence of 29% while from 5 patients with GOLD stage IV, 4 patients had LVD i.e. prevalence of 80%.
CONCLUSIONS: This study concludes that the prevalence of LVD was 30% in patients of COPD andits incidence is more in sixth to seventh decade of lifeand that the prevalence of LVD increases with the severity of COPD.

P-83
Co-Administeration of Lithium and Ibuprofen Polutiate Biochemical and Behavioral Changes in Rat Brain

RAVI KUMAR, CHANDAN KUMAR, NAYNA, NITIN SRIVASTAVA, ANCHAL ARORA, RUBY SHARMA, BILAL AHMAD, SANDEEP TRIPATHI.
Department of Biotechnology, Nims University, Jaipur, Rajasthan, India

To date, information on the interaction of lithium (Li) with oxidative markers in the rat organs was limited and unclear. Brain is the more susceptible organ for the oxidative stress. The present study was to investigate the effect of Li induced toxicity along with Ibuprofen (400mg/Kg) on rats brain regions (hippocampus and cerebellum) 100 mg per kg b.w. of Lithium chloride ($LiCl_3$) was orally administered to rats for 14 days along with Ibuprofen. The lipid peroxide levels (LPO, protein carbonyl (PC), superoxide dismutase (SOD), the catalase (CAT), glutathione along with behavioral profile were evaluated. In addition, histopathological changes were also investigated using H & E staining. The oral administration of Lithium and Ibuprofen increases LPO, PC, and decreases the SOD, CAT and GSH significantly ($p>0.01$) in comparison to positive control (single administration of Lithium). Congestion and dilated cellular changes were seen in the Lithium treated rats as compared with positive control. This finding suggest that oral administration of lithium along with Ibuprofen may produce pro-oxidants effect in rats and could be of interest for understanding the controversial roel of Lithium in assessing neurotoxicity in Lithium exposed population and patients with mood disorders.

P-84
Adult Stem Cell Preservation and Applications in Various diseases

RICHA BAJPAI, DEEYA ROY, SONAL GUPTA
Amity University, Jaipur Rajasthan

Adult stem cells can be found in children, as well as adults. They have the ability to divide or self-renew indefinitely and generate all the cell types of the organ from which theyoriginate.Unlike embryonic stem cells, the use of adult stem cells in research and therapy is not controversial. Adult stem cells can be isolated from a tissue sample obtained from an adult mainly studied in humans and model organisms such as mice and rats.

Lots of companies provide the facility of adult stem cell collection and preservation medical services worldwide. The company specializes in collecting, testing, and banking an individual's own healthy adult stem cells from the peripheral blood of adults. Adult stem cell treatments have been used to treat successfully leukaemia and related bone/blood cancers through bone marrow transplants. Adult stem cells are used to treat spinal cord injuries, heart tissue regeneration,Corneal Reconstruction, Autoimmune Disease, Diabetes, Lupus, Multiple Sclerosis, Parkinson's disease, Anemia's, Cancers, and Immune Deficiencies.
Autologous transplant process avoids immune rejection by the recipient and also protects the patients from viral, bacterial or other contamination from another individual in case of allogenic transplant. Autologous and allogenic transplants of hematopoietic stem cells are isolated from mobilized peripheral blood or from bone marrow.
Recently, scientists have discovered that human adipose tissue has a higher concentration of adult stem cells than any other tissue in the body.

P-85
Intellectual Property Rights: A System in Transition

RICHA PRIYA, SHIVANI PRIYAA, VIVEK DAVE, HIMANSHU AGRAWAL
Department of Pharmacy, Banasthali Vidyapeeth, Banasthali, Rajasthan

Topics of creation, security and utilization of intellectual property (IP) are gaining increasing importance. The new IP regimes cover wide ranging socio-economic, technological and political impact. As per the obligations under the Trade-Related Aspects of Intellectual Property Rights (TRIPS), all the members of World Trade Organization (WTO) are supposed to implement national systems of intellectual property rights (IPR) following an agreed set of minimum standards. However, there is an increasing feeling that harmonization is demanded from those that are not equal, either economically or institutionally. In this matter, the major suggestions about the way ahead are made. This includes the need for a fair play in technology transfer, creation of 'favourable economics' of essential medicines from the point of view of the Third World, protection of traditional knowledge, creation of digital database of traditional knowledge are an important conceptual step forward. The possible models for material transfer and benefit sharing when products are created based on community knowledge are also discussed. Other discussion includes the challenge of bridging the divide between the Third World and other developed nations, with special emphasis on intellectual property information sharing, capacity building with creation of appropriate physical and intellectual infrastructure and awareness building.

P-86
Mercury Toxicity in Dental Practice

JAIN RIMJHIM, SHARMA NEHA, KULSHRESHTHA S, JAIN A, ADVANI U, KOHLI S, MODI P
Department of Pharmacology, NIMS Medical College, Nims University, Jaipur, Rajasthan

Mercury is one of the toxic compound which most commonly affecting the neurologic, gastrointestinal (GI) and renal organ systems. Poisoning can result from mercury vapor inhalation, ingestion, injection, and absorption through the skin. For centuries, mercury was an essential part of many different medicines.
The history of use of mercury in dental amalgam a long one. Significant toxicity can occur when vapours of mercury are inhaled. 80% of mercury vapour inhaled or inspired is absorbed in the lungs and the toxic exposure is generally cumulative. Large dose of mercury vapour can cause acute pneumonitis, renal failure, neurological dysfunction. Patients with contacting amalgam fittings show high rate of mercury hypersensitivity in form of lichenoid lesions. Fine particulate mercury deposits were found in lysosomes of fibroblast and macrophages within the contacting lichenoid lesions.
Inspite of above said toxicities, use of mercury containing amalgam is still common, dentist must observe strict mercury and amalgam hygiene procedures as per "American Dental Association specification No.6 for dental mercury" so that the health of dental workers and patients is not put at risk. The safe method for disposal of mercury is through recycling.
An important part of program for handling toxic materials is periodic monitoring of actual exposure levels. Biological determination can be performed on office staff to measure mercury levels in blood and urine. The risk of mercury exposure to dental personnel cannot be ignored, but close adherence to simple hygiene procedures helps ensure a safe working environment.

P-87
Nonviral Gene Delivery: Current Concept and Advancements

RITU RANI, ASHUTOSH PAREEK, VASTVIKTA SAHAI, DIMPLE TOMAR, VIVEK JAIN, YASHUMATI RATAN
Department of Pharmacy, Banasthali University, Rajasthan

In last few decades gene therapy is fetching a promising therapeutic modality for the treatment of genetic and acquired disorders. Non viral approaches as alternative gene transfer vehicles to the popular viral vectors have received significant attention because of their favorable properties, including lack of immunogenicity, low toxicity and potential for tissue specificity. In the past, the primary focus has been on application of physical, chemical, and biological principles to development of a safe and efficient

method that delivers a transgene into target cells for appropriate expression. Nowadays cationic lipid/nucleic acid complexes or lipoplexes has been the subject of intensive investigations to understand the parameters governing the efficiency of transfection. Hence, present poster demonstrates various existing and emerging concepts of non viral gene delivery with a special concern on lipoplex and polyplexs. The presentation also critically reviews various structural aspects and provides a balanced view to fellow scientists to carry out their efforts in filling in the technological gaps.

P-88
Excessive Dose of Lithium Potentiate Cardiovascular Dysfunctioning in Rats

RITU RATHI, VICHITRA CHAUDHARY, SUDHANSHU MISHRA[1], MANISHA CHOUDHARY[1], DUSHYANT SINGH CHAUHAN[1], SANDEEP TRIPATHI[1]
Department of Biotechnology, Amity University, Jaipur
[1]Department of Biotechnology, NIET, NIMS University, Shobha Nagar, Jaipur

Excessive ingestion of lithium in the body can cause several damaging effect on the body organs like brain, heart and kidney. In this study, evaluation of the myocardiotoxic effect of Li and the role of oxidative stress was conducted. Doses (100 mg/kg Lithium chloride) were administered to the rats for 14 days. Lithium treatment for 14 days is known to be long enough to produce molecular changes and produce its efficacy. Our results indicate that body weight was significantly reduced.
The effect of Li on body weight gain, food intake and feed efficiency was progressively increased during the experimental period of both the groups. The final body weight of intoxicated rats with Li was significantly lower than that of the health normal group. These results clearly indicate that Li cause a significant decrease in body weight. This adverse effect of Li on the body weight gain was increased paralleled with increasing time of exposure. Moreover, the amount of food intake of both groups was unchanged. Electrocardiogram was recorded after treatment. There were insignificant changes in heart rate, QTC and QRS after treatment as compared to the pre treatment. Thereafter, heart was removed for biochemical and morphological studies.The most common hypothesis for the mechanism by which Li cause cardiotoxicity includes the formation of free radicals and superoxides. The oxidative stress (OxS) markers namely Lipid peroxide levels, super oxide dismutase and catalase were estimated. Alteration in SOD and catalase activities and increased LPO in the heart was observed. The histological changes were exhibited in altered myofibrils and congestion was seen in the Li treated rats. Overall, the present findings indicate that overdose of Li may increase lipid peroxidation and may lead cardiac toxicity.

P-89
Plant Product as Antibiotic Potentiators

RUBY SHARMA, DUSHYANT SINGH CHAUHAN, SANDEEP TRIPATHI, SANDEEP KUMAR
Department of Biotechnology, NIET, Nims University, Jaipur

To protect themselves, plants accumulate an armory of antimicrobial secondary metabolites. Some metabolites represent constitutive chemical barriers to microbial attack (phytoanticipins) and others inducible antimicrobials (phytoalexins). They are extensively studied as promising plant and human disease-controlling agents. Phytoalexins are antimicrobial substances synthesized de novo by plants that accumulate rapidly at areas of pathogen infection. They are broad spectrum inhibitors and are chemically diverse with different types of characteristic of particular plant species. Phytoalexins tend to fall into several classes including terpenoids, glycosteroids and alkaloids. The bioactivity of several phytoalexins and phytoanticipins defending plants against fungal and bacterial aggressors and those with antibacterial activities against pathogens affecting humans such as Pseudomonas aeruginosa and Staphylococcus aureus involved in respiratory infections of cystic fibrosis patients. Allixin (3-hydroxy-5-methoxy-6-methyl-2-pentyl-4H-pyran-4-one), a non-sulfur-containing compound having a γ-pyrone skeleton structure, was the first compound isolated from garlic as a phytoalexin, a product induced in plants by continuous stress. The progressing threat of MDR for public health and the incessant need for crop protection strengthen the importance of the research activities aiming at the isolation and characterization of plant secondary metabolites and the understanding of the mechanisms involved in the natural defenses of plants against microbial aggressors.

P-90
Evolution of Drug Regulations and Pharmacovigilance

RUCHI CHOUDHARY, MAYUR KHOSLA, PREM PARKASH KHOSLA
Department Of Pharmacology, Subharti Medical College, Meerut

Introduction- In last 164 years, therapeutic disasters have lead to enactment of new regulations for drug safety.
Aim: Identify therapeutic disasters and subsequent regulations
Methods: Major therapeutic disasters in the different countries of world will be traced & legislative actions followed by these will be identified.
Observations: In 1848 deaths due to ventricular fibrillation with chloroform, foundation of commission, collection & notification of side effects in 1893; 1901- deaths of children with diphtheria antitoxin in U.S.-Biological control act & law July 1902; 1906- Labeling of drugs- pure

food & drug act 1906; 1919- Poison act (India); 1920- Dangerous drugs act; 1936- death due to sulfanilamide elixir- Food, Drug & cosmetic act June 1938; Drugs & cosmetics Act (1940) & Rules (1945); 1951- Durham-Humphrey Amendment(or Prescription drug act) 1951; 1954- Drugs & magic remedies act (India); 1961- thalidomide disaster- Kefauver-Harri's amendment or Drug efficacy amendment 1962; 1963 (UK)- Sir Derric Dunlop committee & committee on safety of Drugs after thalidomide disaster; 1965- Directive 65/65/EEC1- First European pharmaceutical directive 1965 in EEC after thalidomide disaster; 1970- committee on safety of medicines; 1990- ICH guidelines for International regulations; 2003- MHRA(Medicine & health care product regulatory agency); 2005- commission on human medicines; 2005- Revision of Schedule Y.

Conclusion: Drug safety regulations have evolved globally and there is convergence of law at the international level. There is global trend towards uniform safety regulations for drugs and pharmaceuticals cutting across National boundaries.

P-91

Impact of TRIPS and Product Patent Regime on Indian Pharmaceutical Industry: Boon or Bane?

S.P. MISHRA, AMANVEER SINGH
Department of Pharmacology, Institute of Medical Sciences, Banaras Hindu University, Varanasi

Objective: Product patent regime that replaced process patent in 2005 was expected to bring about myriad of tremendous positive changes in Indian pharmaceutical industrial growth by stimulating inventive activity and investments, promoting technology transfer, providing healthy atmosphere for competition and facilitating international trade. Whether it has really been successful in meeting its objectives of domestic growth or not, requires detailed evaluation and analyses.

Methods: 'World patent report' and 'world intellectual property indicators', published by WIPO, Geneva and official websites of USPTO and CGPDTM were used to obtain latest patenting data and trends. Related articles published in various journals online and offline were considered for analysis.

Results: Only 0.1 to 0.6 % of total patents granted by USA have been to Indian inventors while 30 % of total applications filed in India are from USA alone. Filing of patents by foreign investors has risen from 55 % in 2000 to 83.27 % in 2009, leaving meager 16.63 % for Indians. Only 1406 out of 7520 mailbox applications (15.75 percent) were from Indian entities. Out of 300, only 9 universities in India are on list of patent applicants.

Conclusion: Despite tremendous rise in number of patent filings and grants in India, domestic inventive activity is still biting the dust. Most patents in India are owned by foreign inventors. India needs to gear up for the highly competitive TRIPS environment by eradicating non-productive research in universities and addressing the lack of research culture in educational institutes, allocating R&D funds and establishing industry-academia collaboration.

P-92

Leptospirosis

SARASWATI PATEL, SACHDEV YADAV
Department of Pharmacy, Banasthali University, Rajasthan

Leptospirosis is a rare and severe bacterial infection that occurs when people are exposed to certain environments. The other names for this disease are: Weil disease; Icterohemorrhagic fever; Swineherd's disease; Rice-field fever; Cane-cutter fever; Swamp fever; Mud fever; Hemorrhagic jaundice; Stuttgart disease; Canicola fever. Leptospirosis is caused by exposure to several types of the *Leptospira* bacteria, which can be found in fresh water that has been contaminated by animal urine. It occurs in warmer climates. It is not spread from person to person, except in very rare cases when it is transmitted through breast milk or from a mother to her unborn child. Risk factors include: Occupational exposure: farmers, ranchers, slaughterhouse workers, trappers, veterinarians, loggers, sewer workers, rice field workers, and military personnel. Recreational activities: fresh water swimming, canoeing, kayaking, and trail biking in warm areas. Household exposure: pet dogs, domesticated livestock, rainwater catchment systems, and infected rodents. Symptoms can take 2 - 26 days to develop, and may include: Dry cough, Fever, Headache, Muscle pain, Nausea, vomiting, and diarrhea, Shaking chills. The blood is tested for antibodies to the bacteria. Other tests that may be done: Complete blood count, Creatine kinase, Liver enzymes and Urinalysis. Medications to treat leptospirosis include: Ampicillin, Ceftriaxone, Doxycycline and Penicillin. Intravenous antibiotics may be required for persons with more severe symptoms. Complicated or serious cases may need supportive care or treatment in a hospital intensive care unit. The risk of acquiring leptospirosis can be greatly reduced by not swimming or wading in water that might be contaminated with animal urine, or eliminating contact with potentially infected animals. Protective clothing or footwear should be worn by those exposed to contaminated water or soil because of their job or recreational activities.

P-93

Efficacy of Intracameral Lignocaine 1% as a Mydriatric

SAUMYA SAXENA, SWATI TOMAR
Department of Opthalmology, NIMS Medical College, Nims University, Jaipur

PURPOSE: To evaluate pupil dilation by an intracameral injection of preservative free lidocaine 1% during cataract extraction and compare the results with those using conventional topical mydriatics.
SETTING: Department of Ophthalmology, NIMS Medical College & Hospital, JAIPUR
METHODS: A prospective comparative case series study which included 5O patients who were given topical mydriatics (30 eyes) or intracameral lidocaine (20 eyes) to dilate the pupil for cataract extraction and intraocular lens implantation. The topical group received 3 drops of tropicamide1% and phenylephrine 5% given 5 minutes apart starting 60 minutes before surgery. The intracameral group received preservative-free lidocaine 1% (0.2 to 0.3 mL) injected just before the procedure began. No epinephrine was added to the irrigating solution. In both groups, the horizontal pupil diameter was measured before and after pupil dilation using the same calliper. Total surgical time, need for a mydriatic agent during the procedure, and subjective surgical performance were recorded.
RESULTS: The mean age, sex, cataract density, baseline horizontal pupil diameter, and mean duration of the surgery were the same between the topical group and intracameral group. The mean pupil dilation was 4.50 mm +/- 0.08 (SD) in the intracameral group and 4.00 +/- 0.09 mm in the topical group; the difference between groups was statistically significant (P =.001). There was no significant difference between groups in the overall subjective surgical performance (P =.74). No patient in the intracameral group and 2 patients in the topical group required an intracameral mydriatic injection.
CONCLUSION: During cataract extraction, intracameral preservative-free lidocaine 1% provided rapid, effective mydriasis comparable that of topical mydriatics.

P-94
Nano Technology and Cancer Treatment

SHAURABH KUMAR, SONU SHARMA
NIMS Institute of Pharmacy, Nims University, Jaipur

Nano devices are some are some where from one hundred to ten thousand times smaller then human cells.they are similer in sizesto large biological molecules (biomolecules) such as enzymes and receptors as an example, hemoglobin, the molecule that carries oxygen in red blood cells is approximately 5 nanometers in diameters nanoscale devices smaller than 50 mnanometers can easily enter most cells, while those smaller than nanometers can move out of blood vessels as they circulate through the body because of their small size, nanoscale devices can readily interact with biomolecules on both the surface of cells and inside of cells. by gaining aceess to so many areas of the body, they have the potential to detect disease and deliver treatment in way unimagined before now.and since biological precess including events that leads to cancer, occur at the nanoscale at and inside cells, nanotechnology offers a wealth of tools that are providing cancer research with new and innovative ways to diagnose and treat cancer.

P-95
The Link between Thyroid Function and Depression

SHALU PRADHAN, SACHDEV YADAV
Department of Pharmacy, Banasthali University, Banasthali, Tonk (Rajasthan)

The relation between thyroid function and depression has long been recognized. Patients with thyroid disorders are more prone to develop depressive symptoms and conversely depression may be accompanied by various subtle thyroid abnormalities. Traditionally, the most commonly documented abnormalities are elevated T4 levels, low T3, elevated rT3, a blunted TSH response to TRH, positive antithyroid antibodies, and elevated CSF TRH concentrations. In addition, thyroid hormone supplements appear to accelerate and enhance the clinical response to antidepressant drugs. However, the mechanisms underlying the interaction between thyroid function and depression remain to be further clarified. Recently, advances in biochemical, genetic, and neuroimaging fields have provided new insights into the thyroid-depression relationship. Focus on Overview of thyroid hormone metabolism in the brain, neuropsychiatric manifestations of thyroid disorders, thyroid status in patients with depression, peripheral thyroid hormone concentrations, antithyroid antibodies, blunted TSH response and abnormal diurnal rhythm, thyroid hormone supplementation in depression, effect of depression treatment on thyroid status.

P-96
Phytosomes: A Herbal Revolution in Pharmaceutical Sciences

SHASHANK PANDEY, SONU SHARMA, SHAURABH KUMAR
NIMS Institute of Pharmacy, Nims University, Shobha Nagar, Jaipur

During the last few decades, much work has been directed towards the development of delivery systems. In recent time this phenomenon is also applied to Phytopharmaceuticals.Phytosomes are novel complexes which are prepared by reacting 2-3 moles but preferably with one mole of a natural or synthetic phospholipids such as phosphatidylcholine with one mole of component for

example flavolignanans either alone or in the natural mixture in aprotic solvent such as dioxane or acetone from which complex can be isolated by precipitation with non solvent such as aliphatic hydrocarbons or lyophilazation or by spray drying.Phytosomes are recently introduced herbal formulations that are better absorbed, and as a result produce better bioavailability and actions than the conventional phytomolecules or botanical extracts. Phytosomes are produced by a process whereby the standardized plant extract or its constituents are bound to phospholipids, mainly phosphatidylcholine producing a lipid compatible molecular complex. This phyto-phospholipid complex, phytosome resembles a little cell. The term "phyto" means plant while "some" means cell-like.Phytosomes exhibit better pharmacokinetic and pharmacodynamic profile than conventional herbal extracts. The phytosome technology has been effectively enhanced the bioavailability of many popular herbal extracts including milk thistle, Ginkgo biloba, grape seed, green tea, hawthorn, ginseng etc and can be developed for various therapeutic uses or as dietary supplements.. Most of the phytoconstituents are water soluble and possess multiple ring structure which leads to poor absorption in human body. These phytoconstituents can be associated with lipid-moieties to absorb better in lipophilic environment known as 'Phytosomes'.Clinical trials of Phytosomes have shown increase in bio-availability of herbal extracts to maximize the amount of the herb's active ingredients utilized by the human body. A standardized extract from Silybum marianum (milk thistle) is an excellent liver protectant but very poorly absorbed. Pharmacokinetic and clinical studies prove that the PHYTOSOME complex of milk thistle (called SILIPHOS) is far better absorbed, as well as safe and effective in subjects with impairment of liver function that ranges from mild to severe.

P-97
Magnetic Microsphers

SHELLY SINGH, SHIFALEE MAGAZINE[1]
Department of Pharmaceutics, Mahatma Gandhi College of Pharmaceutical Sciences
[1]Department of Quality Assurance, Mahatma Gandhi College of Pharmaceutical Sciences

Spherical microparticles having diameters in the micrometer range (typically 1μm to 1000 μm (1mm), which are capable of responding to magnetic fieldsare called as magnetic microspheres. The magnets applied outside the body attract the microspheres to the immediate area of diseased site, which enhances the efficiency of drug delivery, increases bioavailability and offers avoidance of toxic manifestations. They avail many other advantages as they can be filled with radioactive materials or chemotherapeutic agents to treat tumors and various illnesses, site specific drug delivery also lowers the whole body dose of drug, spheres made up of biodegradable polymers reduces toxicity inside the body even if they resides for a longer time duration inside the body.
The magnetic component of the magnetic microspheres in general is magnetite, Fe_3O_4, a proven biocompatible iron oxide. They can be prepared by various techniques such as preparation of biodegradable magnetic microspheres with poly(lactic acid)-coated magnetite, from water-in-oil emulsion stabilized by block copolymer dispersant, synthesis of amphiphilic magnetic microspheres by dispersion copolymerization of styrene and poly (ethylene oxide) macromonomer, microwave-assisted preparation of magnetic albumin microspheres, and by ultrasonic atomization. The amount of magnetic content of the carrier and the magnitude of the applied magnet should be properly balanced for drug targeting.
They have a broad range of applications including targeted drug delivery, tissue repair, in treating hyperthermia, magnetic cell separation, DNA analysis proteomics and understanding the pathways of cell cycle regulation. Microspheres are characterized by different analytical techniques such as SEM, TEM, FT-IR spectroscopy, X-ray diffractometeryand by light scattering methods.

P-98
Drug Induced Hemolytic Anemia

SHILPA TOMAR, KALPANA SANKALA, PRIYAVART MEHRWAL, VIDHI SHARMA, ABHA SHARMA
Department of pathology, NIMS Medical College, Jaipur

Drug induced Hemolytic Anemia (DIHA) are not uncommon. The drugs most frequently associated with DIHA are Methyldopa, Penicillin, Cephalosporins, Sulphonamides and Antimalarials. The extent of hemolysis produced depends upon dose, duration of drug intake along with history of previous sensitization to drug like Primaquine in G-6 PDdeficient patients. Site of hemolysis may be intravascular or extravascular depending upon mechanism of action of drugs on RBC's.
DIHA is attributed most commonly to drug dependent antibodies that can only be detected in the presence of drug (e.g. cephalosporin antibodies). DIHA can also be associated with drug independent antibodies, such antibodies do not need drug to be present to obtain in vitro reactions (e.g. Mefenamic acid, Diclofenac, Ibuprofen,Methysergide, Carbimazole).In these latter cases the drug affects the immune system, causing production of red cell auto antibodies. Their clinical and laboratory findings are identical to autoimmune Hemolytic Anemia (AIHA).
The most acceptable mechanisms involves the drugs like penicillin, that covalently bind to RBC membrane proteins, the RBCs become coated with drug in vivo and the drug antibody (usually IgG) attaches to the drug coated RBCs that are subsequently sequestred by spleen. Immune

complex mechanism in which IgG or IgM antibodies are formed, often activate complement leading to acute intravascular hemolysis and sometimes renal failure. Fatalities are more common in this group. Diagnosis of DIHA is done by peripheral smear, Bone marrow and urine examination along with biochemical, serological tests.

P-99
A Adrenergic Blockers in Lower Urinary Tract Symptoms (LUTS) and Benign Prostatic Enlargement

SHIVENDRA KUMAR SINGH, JAGDISH SHARMA, NISAR AHMED, LOKESH SHARMA.
Department of General Surgery, Nims Medical College & Hospital, Jaipur

Introduction: Lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH) commonly affect older men. These bothersome symptoms can lead to a decreased quality of life. Every male is potential risk of developing of BPH. Approximately 30% of American males older than 50 years have moderate to severe LUTS. Alpha blockers are the most effective, least costly, and best tolerated of the drugs for relieving LUTS.

Objective: Advantages of medical therapy shows that clinically significant outcomes are obtained with fewer, less serious and reversible side effects without any morbidity of the surgical procedure. High" symptom score alone is not a sufficient indication for medical therapy. Symptoms that are bothersome and negatively affect quality of life.Patient should be willing to make a long-term commitment to medical therapy. Medical therapy should not be offered to patients with absolute indications for surgery.

Results: α-adrenergic blockers are safe and efficacious for the treatment of BPH.The long-acting α_1 blockers are well tolerated. Tamsulosin (0.4 mg) achieves clinically significant effect without the requirement for dose titration represents unique advantage over the other approved alpha blockers, but this convenience came at the expense of ejaculatory dysfunction. Alfuzosin has comparable clinical efficacy to tamsulosin and the other approved alpha blockers but does not cause ejaculatory dysfunction

Conclusion: Drug is effective and adverse experiences are either nonexistent or minimal.

P-100
Medication Errors

SHRUTHI V, DEBASHREE KAR, PRIYA, MANTOSH KUMAR SATHAPATY, SANDEEP TRIPATHI,
Department of Biotechnology, NIET, NIMS University, Jaipur India

Medication errors are among the biggest issues devoted in health care. A new study has revealed startling statistics about the number of people killed each year worldwide. That number is now estimated to be 195,000 people. This is a health care crisis - people are being killed by preventable hospital errors and neglect. Unfortunately, it's also the norm in our modern medical system.Deaths in India due to Adverse Drug Reactions estimated to be 400,000 annually. Medication giving includes five basic rights: Right patient, Right medication, Right route, Right dose, and Right time. Contrary to the above are medication errors. Most common errors are occurred by –poor transcriptions, drug interactions, name confuse, poor documentation, wrong dose prescribed-Too Low leads to drug resistance-Too High. In addition, doctors and nurses make the medication errors by misreading and miswriting prescriptions such as misplacing points and misreading zero. To avoid such conditions with Introduction of Computerized Physician Ordered Entry system (COPE), Clinical Decision Support System (CDSS), computerized Pharmacovigilance system (CPS). If we had a national health care system that was based on prevention, nutrition, physical exercise, and consultation with patients rather than surgical procedures and prescription drugs, we would have far fewer deaths, and in fact, great improvements in the longevity and happiness of patients.

P-101
Umbilical Cord Blood Stem Cell Preservation and Applications in Various Diseases

SONAL GUPTA, DEEYA ROY, NEETU MISHRA, RICHA BAJPAI
Amity Institute of Biotechnology, Amity University Rajasthan, Jaipur

Umbilical cord blood is the blood that remains in the vein of the umbilical cord and placenta at the time of birth. Umbilical cord blood stem cells can be collected and stored for future use if the child needs a transplant for use by another child or adult. It is the newest form of stem cell transplant and has only begun being used in the past couple of decades.Cord blood collection is simple with no harm to the donor and has lower risk of graft-versus-host disease. Problems associated with it are limited number of cells available per sample and no opportunity to collect additional cells for transplant if needed, longer engraftment times. Possible additional costs associated with cell storage and transmission of undiagnosed genetic conditions from the donor. It is Easy, painless and risk-free collection process.Cord blood stem cells are currently used to treat a range of blood disorders e.g. anaemia and other diseases e.g. leukaemia, autoimmune diseases, diabetes, Alzheimer's, cerebral palsy, brain injuries and metabolic disorders. Today cord blood stems cells are used in the treatment of nearly 80 life-threatening diseases, including a wide range of cancers, genetic diseases. Cord Life India is the largest and most advanced cord blood facility in the

country, with a storage capacity of up to 150,000 cord blood units.

P-102
Phytochemical and Anti-Inflammatory Screening leaves Extract of *Holoptelea Integrifolia* (roxb.)

SONU SHARMA, GOVIND MOHAN, MITHILESH SINGH
Department of Pharmacognosy, NIMS Institute of Pharmacy, Nims University, Shobha Nagar, Jaipur

Natural product is a source for bioactive compounds and has potential for developing some novel therapeutic agent. Over the last decade there has been a growing interest in drugs of plant origin and such drugs formed an important class for disease control. Herbs are staging a comeback and herbal 'renaissance' is happening all over the globe. *Holoptelea integrifolia* is widely distributed and easily available in the nature, therapeutic use of this plant is detailed in charaka samhitha, Sushrutha samhita and other traditional systemsof medicine.*Holoptelea integrifolia* belongs to family *Ulmacea* commonly known as Indian Elm. The vernacular names of *Holoptelea integrifolia* are in Hindi- chirmil, chilbil, Gujrati- charel, Marathi- Papara, Sanskrit- chirbilva, *Holoptelea integrifolia* utilize in the treatment of inflammation, acid gastritis, dyspepsia, intestinal worms, vomiting, wounds, leprosy, diabetes, leucoderma, intestinal tumor, ringworm haemorrhoids, dysmenorrhoea and rheumatism.The dried leaves was subjected to mecaration extraction using solvent such as petroleum ether, and methanol. These solvent extracts were subjected to a phytochemical evaluation to detect the different chemical constituents i.e. petroleum ether extract contains steroids, antraquinone glycocides, reducing sugar, flavanoids, amino acid and tannins. Methanol extract contains carbohydrates, proteins, amino acid, steroids, tannins, phenolic compound, flavonoids, Carbohydrates, Amino acids, Steroids. Column Chromatography investigates the presence of β-amyrin, stigmasterol, β-sitosterol, histamine and histidine. Pharmacological evaluation of *Holoptelea integrifolia* leaves. Methanol, Petroleum ether extract of leaves of *Holoptelea integrifolia* (Roxb.) was screened for anti-inflammatory activity. It can be concluded that the *Holoptelea integrifolia* shows extremely significant positive Anti-inflammatory activity of both dose 100 mg/kg and 200 mg/kg metabolic extract and non significant of both dose 100 and 200 mg/kg with petroleum ether extract when compared with diclofenac sodium as standard anti-inflammatory drug. The activity may be due to presence of steroids and glycosides in methanolic extract. In this study methanolic extract showed better results statistical significance.

P-103
DNA Fingerprinting: The Code of Life

SOUMI GAYEN
Amity Institute of Biotechnology (AIB), Amity University Rajasthan (AUR)

An individual's entire DNA sequence is composed of over 3 billion nucleotides, although the sequence is about 99.9% the same as other humans, the remaining 0.1% about 3 million nucleotides is unique to that individual. DNA fingerprinting that allows identity establishment for precise individualization is also considered an essential component towards adding specificity to conventional drug assessment protocols for ensuring uniformity in efficacy of herbal medicine produced in different batches. The DNA fingerprinting process involves the analysis of these non-coding portions of the DNA strand, generally taken from a sample of hair, saliva or semen. This process is often confused with DNA sampling, which is the analysis of the entire DNA genome. A specific radioactive genetic probe is then allowed to hybridize to complementary fragments, therefore marking their location. Multiple sequences would then create bands on the Southern Blot, much like the bar code on a shopping product. These bands can then be compared, as each individual is specific and unique in terms of the position and length of sequences. DNA fingerprinting is mostly used in solving crimes and identifying criminals, biological parents and missing persons. Within DNA technology, DNA fingerprinting is one of the techniques that most of the general public has heard of simply because of the potential for it to impinge upon our own lives. Just as race and skin color can be discriminated against, as people cannot change these characteristics, so a genome could be used as a source of discrimination.

P-104
Duplex Real-Time PCR: A New Technology for Twin Viral Load Estimation

SOUMIK BANERJEE
Amity Institute of Biotechnology, Amity University Rajasthan

Influenza-A (H1N1) has been designated as pandemic by the World Health Organization in July 2009. Influenza-A (H5N1) has also been an epidemic in India. An experiment designed to detect the aforementioned influenza-A strains in real-time is as follows: The saliva from an infected mouse was collected. That saliva was used to detect the viral RNA. Saliva collected was brought to laboratory and duplex real-time PCR probes were used for detection. Once it has been detected reverse transcriptase PCR (RT-PCR) is performed to quantify the viral load. Collection of saliva is an easier venture and is better accepted for not being invasive.

Real time RT-PCR is a powerful tool for the specific and sensitive detection of virus-derived nucleic acids. The viral RNA was extracted from the saliva collected from mice. Different concentrations of H1N1 as well as H5N1 primers and probes were used in different sets of experiments. The reaction was incubated at around 50-60°C for a certain time and then at around 94-98°C for a lesser time. Then the normal denaturation, annealing and elongation are carried out. Fluorescence is observed at a certain temperature.

The final reaction should contain reaction buffer, reverse transcriptase enzyme, H5N1 and H1N1 primers and probes, and the RNA template. This is the part where reverse transcriptase PCR is performed. Duplex Reverse transcriptase PCR is more effective than single reverse transcriptase PCR assay as it reduces the chances of false positives. Duplex RT-PCR is more sensitive than single RT-PCR.

P-105

Association of Increased Oxidative Burden and Catarctogenesis: In-Vitro Study

SUDHANSHU MISHRA, ANANT SHARMA[1], MANISHA CHOUDHARY, SWATI TOMAR[1], SANDEEP TRIPSTHI

Department of Biotechnology, NIMS Institute of Engineering & Technology; [1]Department of Opthalmology, NIMS Medical College, Nims University, Jaipur

The leading cause of global blindness, cataract is present in more than half of all cases. Cataract is an age-related condition in which the lens of the eye becomes clouded, blurring vision. The aim of the present study was to established association with oxidative burden and cataractogenesis. The lipid peroxide level (LPO), protein carbonyl content (PC) and antioxidant enzymes i.e. superoside dismutase (SOD), catalse (CAT) glutathione peroxidase (GPx) and reduced glutathione (GSH) levels were measured in 55 operated eye lens. Moreover, the 18 patients each were selected in different grade of cataract patients for investigation of oxidative stress markers in blood. Results showed that gradually increased LPO and PC from grade 1to 4 cataract. Lens SOD, GPx and GSH levels were gradually declining, while MDA and PC were increasing with the increasing grade of cataract. These results suggest that poor glycemic control may upregulate systemic and ocular antiocidant activities contributing to lens oxidative stress and possibly to earlier onset of cataract.

P-106

Natural and Synthetic Antibiotics: A Comparative Analysis in the Light of Pharmacovigilance

SUMBUL REHMAN, ABDUL LATIF

Department of Ilmul Advia (Unani Pharmacology & Pharmaceutical Sciences), Faculty of Unani Medicine; Aligarh Muslim University, Aligarh

It is a general perception that with existence of human beings, diseases also came in light & pandemic diseases that occurred, also favoured sincere experimentation to check these diseases. An era of antibiotics controlled the epidemics but the antibiotics haphazard actions leads to newer dangerous diseases like cancer producing drugs due to 'antibiotics'. Different ways of thinking, experimentation and different ways of treating diseases gave way to different system of medicine and one of the oldest systems is Greco-Arab Medicine, generally known as Unani system of medicine.

The use of Unani drugs has increased in various health ailments including infectious diseases, mainly due to the failure of modern medicine to provide effective treatment for chronic diseases and emergence of multi-drug resistant bacteria and parasites. The adverse effects of chemical drugs, questioning of the approaches and assumptions of allopathic medicine, their increasing costs and greater public access to information on traditional medicine has also led to an increase in interest in alternative treatments. Right from the time that the world's first antibiotic, penicillin, became available in the 1940's, resistance has been a problem. Hitherto, as bacteria evolved ways to evade one drug, a newer one became available.

In view of the importance of alternative anti-microbial drugs it becomes imperative to bring these indigenous drugs to the front foot and evaluate their antimicrobial activities.

Therefore present study was aimed with an objective to scientifically validate the use of some Unani drugs in infectious disease, to evaluate their anti-microbial potential. These drugs were selected on the basis of their use mentioned in medico-ethno-botanical literature as antiseptic, anti-microbial, anti-fungal anti-infective or as blood purifier and are in use in clinics by Unani physicians for treating the infectious diseases. The selected drugs are rich in wide variety of secondary metabolites, such as glycosides, alkaloids, tannins, terpenoids, and flavonoids, which have been found in vitro to have antimicrobialproperties.

P-107
Indian Patent Law and Pharmaceutical Industry: Issues and Concerns

SURAJ PRAKASH SAKET, MANAS TRIPATHI, BHUPENDRA KUMAR TIWARI, SUNITA DAHIYA
Department of Pharmaceutics, Globus College of Pharmacy, Bhojpur Road, Bhopal (MP)

Congressional interest in the availability of prescription drugs has focused attention on the role of patents in the pharmaceutical industry. The industry has been described as patent-intensive. Enterprises within this sector frequently obtain patent protection and enforce patent rights, and reportedly place a higher comparative value on patents than do competitors in many other markets. The Indian patent system has suffered continuous modifications over the past decade, partly as a reflection of the diverging standpoints and changing priorities of government, national industry, public health NGOs and other stakeholders. India made three amendments in its original Patent Act 1970. First amendment was made in 1999, second amendment in 2002 and third amendment in 2005. India amended its patent legislations to make them TRIPS compliance as TRIPS agreement has flexibilities and developing countries should make use of such flexibilities. The process of patent reform in India has been characterized by strong involvement of the national pharmaceutical industry and NGOs. Indian patent system also plays the key role in lowering the price of essential drugs for poor. This paper covers background, salient features and current status of Indian Patent Act from its history to existence as well as their impact on growth and structure of pharmaceutical industry.

P-108
Pros and Cons of Nanoparticles in Cosmetics

SURANSH JAIN, NEELAM MAHALA, NEETU MISHRA, ADITI GOYAL, AMRITA BAL,
Amity Institute of Biotechnology (AIB), Amity University Rajasthan (AUR)

In recent years, many new nonmaterial-related applications have been developed. They are now finding their way into everyday cosmetic products such as UV-filters in sun creams and anti-odour textiles. Many sunscreens lotions are having active ultra violet (UV) filters which utilize minerals like zinc oxide and titanium dioxide, foundation and other liquid types of lotions, are harmless. They simply sit on the skin rather than absorbing in to the skin since they are too large to penetrate its protective barrier in soluble nanoparticles of titanium dioxide. When used at the nanoscale level, this mineral can change its properties and become invisible but still effectively absorb UV radiation. However, animal studies have shown that when they are applied to the skin, they penetrate tissues and cells causing damage when they begin to build up. The tiny size nanoparticles of zinc oxide and other ingredients like aluminum give the ability to travel the body extensively and can enhance their toxicity.The increasing use of nanoparticulate engineered materials possesses the question on the safety of those materials. Non acute toxic effects have been observed so far however, the observed effects of interaction between nanoparticles and biological structures calls for a better understanding of that interaction and a prudent development of consumer products based on nanoparticles.

P-109
Effects of Atorvastatin as an Add on Therapy to the Standard Regimen in Active Rheumatoid Arthritis

SUSHANT KUMAR, ANKESH KUMAR, SWARUP VERMA
Department of Medicine, NIMS Medical College Jaipur

INTRODUCTION: Rheumatoid arthritis (RA) is the most common inflammatory arthritis affecting 0.5 - 1 (India 0.9%) of the general population worldwide. Rheumatoid arthritis typically presents as symmetric arthritis principally affecting the small joints. RA can cause a variety of extra articular manifestation. Patients with RA are prone to develop macro vascular injury leading to coronary artery disease. There is an association between the levels of acute phase reactant, C reactive protein (CRP) and disease activity score in RA. Statins have been suggested to reduce inflammatory cytokine production, like tumor necrosis factor alpha and IL-1 β chemo tactic cytokine like IL-delta and IL-6.

OBJECTIVE: To assess the effects of atorvastatin as an Add on Therapy to the standard regimen in active rheumatoid arthritis.

MATERIAL AND METHOD: The study was conducted for6 months for every patient.Patients attending Medicine out Patient Department of NIMS Medical College & Hospital with active rheumatoid arthritis was included. Study sample of 80 Patients (each group n= 40) was included.

INCLUSION CRITERIA: Age 18 – 60 years both genders. Active rheumatoid arthritis inspite of taking standard regimen for more than 6 months. Rheumatoid factor positive C- reactive protein positive (> 6 mg/ lit.) Disease activity score > 6.

EXCLUSION CRITERIA: refusal for consent.

ASSESSMENT OF EFFICACY: The improvement in the disease condition is assessed by:

- Disease activity score 28
- C-reactive protein (CRP)

Treatment schedule:

Group A (standard treatment) (n = 40) Tablet Methotrexate10 mg weekly once on the same day of every week. Tablet Folic acid 5 mg weekly once.

Tablet Prednisolone 5mg daily in the morning after food. Tablet Diclofenac sodium 50 mg twice daily after food. Tablet calcium 1gm once daily.
Group B (n = 40) Standard treatment + Atorvastatin 20 mg daily at night. Follow up visit 1 (at the end of 3rd month) Follow up visit 2 (at the end of 6th month)
CONCLUSION
Atorvastatin produces beneficial effects in rheumatoid arthritis. So atorvastatin 20mg is more effective in reducing the disease activity in rheumatoid arthritis.

P-110
Parkinson's disease Scenario: Understanding the Clinical Need

TARU, YADAV SACHDEV
Department of Pharmacy, Banasthali University, Banasthali, Tonk (Rajasthan)

Parkinson disease is a disorder of the basal ganglia and is recognized as one of the most common neurologic disorders, affecting approximately 1% of individuals older than 60 years. In 1817 British physician, James Parkinson described and published a paper on what he called "the shaking palsy". In 1960 researchers identified disease the loss of brain cells that produces dopamine. It involves neurodegeneration of neurons in Substantia Nigra Pars Compacta and also the presence of lewy bodies.The four primary symptoms are tremor or trembling, rigidity or stiffness of the limbs, postural instability and bradykinesia. For diagnosis physician need to observe the patient until it is apparent that the tremor is consistently present. Its etiology includes environmental causes, MPTP, oxidation hypothesis, genetic factors, α-synnuclein. The goal of medical management of Parkinson disease is to provide control of signs and symptoms for as long as possible while minimizing adverse effects.The treatment includes putative neuroprotective therapy,symptomatic therapy, preoperative evaluation, transplantation,gene therapy,speech therapy etc.The medications include dopamine prodrug,dopamine agonist,anticholinergic agent, MAO-B inhibitors,N-methyl-D-aspartic acid inhibitor,acetylcholinesterase inhibitors, COMT inhibitors.

P-111
Adverse Effect of Lithium (Anti-Psychotic Drugs) in Rats: Protective Effect of Omega-3-Fatty Acid

MEHTA TATHAGAT, AHMAD NADEEM, MANISHA CHOUDHARY, SUDHANSHU MISHRA, DUSHYANT SINGH CHAUHAN, SANDEEP TRIPATHI, UMA ADVANI[1]
Department of Biotechnology, NIMS Institute of Engineering & Technology;
[1]Department of Pharmacology, NIMS Medical College, NIMS University, Jaipur (Rajasthan) India

Lithium has been extensively used during chronic therapy for mood disorders. Deposition of lithium in brain particularly cerebellum may cause disorientation, incoherence, paralysis, stupor, seizure, and coma. Permanent brain damage occurred in several patients on prolonged lithium therapy. The present study attempts to assess the protective efficacy of omega 3 fatty acid (100 mg/kg body weight) on lithium chloride (100 mg / kg b. wt.) mediated oxidative damage in the cerebellum of male albino rats (N=10) along with the associated dysfunctioning of neuromuscular coordination and motor activity. A significant decrease in the activities of antioxidant enzymes and increased total reacting oxygen species, lipid and protein peroxidation products observed in lithium exposed rats. We observed that treatment with DHA restored the altered antioxidant enzyme activities, when compared with lithium treated rats. Moreover, lithium treated groups of rats exhibited significant changes in behavioral profiles but these changes were reversed to near control following the treatment of DHA. The light microscopic studies revealed damaged Purkinje's neurons and altered granular cell layer in lithium treated rats. These changes were quite less pronounced in omega 3 fatty acid treated group than that of lithium and this may be due to the reduction of oxidative burden by DHA. On the basis of our results it may be concluded that excessive lithium may be linked with cerebellar degeneration and neuromuscular disorders. DHA ameliorate the lithium induced neurotoxicity in rats.

P-112
Subchronic Dose of Lithium Increases Lipid Peroxidation in Different Regions of the Rat Brain; a Behavioral and Biochemical study

UDITA KULSHRESTHA, PRIYANKA SINGH, MANISHA CHOUDHARY[1], SUDHANSHU MISHRA[1], DUSHYANT SINGH CHAUHAN[1], SANDEEP TRIPATHI[1]
Department of Biotechnology, Amity University, Jaipur
[1]Department of Biotechnology, NIET and Department of Pharmacology, NIMS Medical College, Nims University, Jaipur (Rajasthan) India

Excessive ingestion of lithium in the body can cause several damaging effect on the body organs like brain, heart and kidney. The nervous system is the primary target organ of lithium toxicity and neurologic effects occurring during prolonged therapy of Li in mood disorders. The aim of the present study was to evaluate the Li induced neuronal changes in the different regions of rat brain (Hippocampus and Cerebral cortex) in terms of behavioral, biochemical and morphological changes. In the present study, 100mg /kg body weight of lithium chloride was administered to male albino rats for 14 days. Learning and memory test using Morris water maze was tested after the experimental period. Hippocampus and cerebral cortex

were removed from the cranium for biochemical and morphological studies. The oxidative stress markers namely Lipid peroxide levels, super oxide dismutase, catalase and Glutathione were estimated. Treatment with lithium in rats selectively altered behavioural responses. Increased path length and escape latency were found. Moreover, alteration in SOD and catalase activities and increased LPO and PC in the brain region were observed. The histological changes indicated the damaged pyramidal neuron as well as dilatation occurred in the Li treated rats. Overall, the present findings indicate that excess lithium may delineate cellular changes in the hippocampus and cortex in rats supporting its neurotoxicity profile in bipolar disorder (BD) and, possibly, in neurodegenerative processes.

P-113

Selective Insulin Receptor Modulators: a Novel Therapeutic Approach for Diabetes

UPINDER KAUR, S.P. MISHRA, AMANVEER SINGH
Department of Pharmacology, Institute of Medical Sciences, Banaras Hindu University

Diabetes, a disorder of glucose metabolism is chronic disease with serious complications not only because of the disease but also due to various therapeutic modalities.Type 2 Diabetes is currently managed by oral hypoglycaemics including insulin secretagogues, glitazones and biguanides with GLP analogues,amylin analogues & DPP inhibitors being recently introduced. Insulin therapy is however the only option left in Type I diabetes & uncontrolled type 2DM cases. Insulin therapy controls hyperglycaemiasignificantly but is also associated with unwanted side effects such as hypoglycaemia, weight gain & increased tendency towards malignancies over long term.An important approach is therefore to develop a novel drug that could limit hyperglycaemia and at the same time is devoid of these adverse effects. One such compound recently discovered is XMetA, a monoclonal antibody which is structurally unrelated to insulin and binds to Insulin receptors with high affinity but as a partial agonist.XMetA has been found to show a high glucoregulatory activity in animal studies with limited potential to produce weight gainand hypoglycaemia. This review summarizes and evaluates the pharmacological profile of SIRMS and determines the promise it holds in the future in the pharmacotherapy of diabetes.

P-114

Antioxidant, Anti-Microbial and Anti-Inflammatory Activity of *Pleurotus Florida*

VIDUSHI SHARMA, DUSHYANT SINGH CHAUHAN[1], SAANDEEP TRIPATHI[1], REKHA DIXIT
Department of Biotechnology, Shobhit University, Modipuram, Meerut
[1]Department of Biotechnology, NIET, NIMS University, Jaipur, India

Pleurotus Florida finds to have antioxidant, immunomodulator, antitumor and anti-inflammatory activities. P. Florida is also a rich source of phenolics and flavonoids that are responsible for antioxidant potential. This work was undertaken to evaluate the antimicrobial activities of *Pleurotus Florida*. Mushroom basidocarp were extracted in water: ethanol and extract was used to determine antimicrobial activity against four species of bacteria.Bacterial and fungal cultures used in the present studies were obtained from Microbiology division, NIMS University, Jaipur. The bacterial strains were Staphylococcus aureus, Escherichia coli, Pseudomonas auruginosssa and Bacillus subtilis. Extract was dissolved in dimethylsulphoxide (DMSO) at a concentration of 1 mg/ml and used as working stocks. Ampicillin (25 µg) for bacteria was used as reference agents. Susceptibility test was determined by disc diffusion method. The nutrient agar plates were prepared by pouring 15 ml of molten media into sterile petriplates. The plates were allowed to solidify for 5 min, 0.1% inoculums suspension was swabbed uniformly. Extract was loaded on 6 mm discs. The loaded discs were placed on the surface of medium and the extracts were allowed to diffuse for 5 min and the plates were kept for incubation at 37°C for 24 hours. At the end of incubation, inhibition zones formed around the discs were measured with transparent ruler. The minimum inhibitory concentration was recorded as the lowest concentration at which no microbial growth was observed. In conclusion, our in vitro results on the antimicrobial activity of total extract from P.Florida shows the therapeutic importance of mushroom as food. These primary results are encouraging, but a more systemic approach for isolation, characterization and further in vivo studies are required to explore the therapeutic potential of mushroom.

P-115

Excessive Fluoride Exposure Delineating Cognitive Impairment: A Behavioral and Biochemical Case Control Study

VIVEK PRATAP SINGH[1,2], DUSHYANT SINGH CHAUHAN[1,2], VIKAS GAUR[1,3], MUKESH TIWARI[1,4], SANDEEP KUMAR[1,2], SANDEEP TRIPATHI[1,2], ANURAG TOMAR[1,5]
[1]National Referral Centre for Fluoride Poisoning in India, NIMS University, Jaipur
[2]Department of Biotechnology, NIET, NIMS University, Jaipur
Departments of [3]Psychiatry [4]Orthopedics and [5]Pediatrics, NIMS Medical College; Nims University, Jaipur

Background: It has been reported that the prolonged exposure of fluoride (F) can accumulate in the body and it

may cause significant damage to health like dental and skeletal fluorosis. Several clinical and experimental studies have reported that the F induces changes in cerebral morphology and biochemistry that affect the neurological development of individuals as well as cognitive processes, such as learning and memory.
Methodology: In the present study, 37 adults (age, 20 to 40 years) fluorotic patients were selected from the high fluoride region of the eastern regions of the Jaipur, where fluoride content in water is 5.5 ± 1.2 ppm. Moreover, age matched controls were selected from the Jaipur district where fluoride content in water was less than 1.5 ppm. 5.0 ml of blood sample were taken for estimation of fluoride and lipid peroxide levels. The GHQ60 questionnaire was used to assess behavioral changes in subject and control.
Results: Significantly increased rate of lipid peroxidation and depleted in antioxidant enzyme levels i.e. superoxide dismuatase, catalyse, glutathione peroxidase and glutathione (SOD, CAT, GPX and GSH) was observed. The concentration of fluoride was significantly ($p<0.0001$) elevated and it's correlated with the altered behavioural score (GSHQ60).
Conclusion: On the basis of the results it may conclude that fluoride exposure promote oxidative stress through increased production of malenodyaldehyde (MDA) in blood. These alterations may induce pathophysiological activities due to lack of antioxidants. Moreover, perturbed behavioral activity score directly proportion to the concentration of fluoride and rate of lipid peroxidation. However, further in depth studies is required for the understanding of pathophysiology of fluorosis.

P-116
Self Medication of OTC Drugs in Pregnancy: an Integrative Review

PALIWAL YOSHITA, MADHURI MIRIRYALAX
Department of Clinical & Translational Research, MUSC, USA

Background: Pregnancy, although a bliss, often comes with many physical and psychological changes and may create discomforts for women. Some common problems during pregnancy are nausea, heartburn, congestion, migraine, backache, and constipation. In an effort to alleviate these discomforts, pregnant women very frequently use OTC drugs for self-care. A few OTC drugs have a proven safety profile for use during pregnancy while others have not been well established and may adversely affect the fetus. There is a misconception that OTC medications are generally safe because they are available without a prescription. This perceived safety of OTC drugs is the main reason that pregnant women choose the OTC therapy.
Aim: To collate what is known about the self-medication of OTC drugs during pregnancy.
Methods: The following databases were surveyed: PubMed, Medline, Bio-Med Central and Science Direct. Inclusion criteria specified research assessing self-medicating of OTC drugs among pregnant women.
Results: About sixty studies were identified that fit into the inclusion criteria. Self- medication of OTC drugs was found to be a significant issue during pregnancy. Deeper analysis of studies revealed that pregnant women believed it was appropriate to self-treat with OTC medication in both acute and chronic conditions and those informal care paths were common during Pregnancy.
Conclusion: Self-treatment is highly embedded within the culture of pregnant women as an accepted way for the day to day conditions. These complex self-care behaviors are a public health hazards for both pregnant women and their babies. It is recommended that there should be continuous communication between a pregnant woman and her health care provider. Alsocareful preconception planning, effective management of conditions prior to pregnancy, and close medical supervision during pregnancy can help assure the best possible outcome for every woman and baby.

JOURNAL OF PHARMACOVIGILANCE & DRUG SAFETY

Annual Subscription Form

JOURNAL OFFICE :

Dr. Anurag Tomar,
Editor in Chief,
Journal of Pharmacovigilance & Drug Safety
NIMS City Center, 4, Govind Marg,
Jaipur-302004, India
Email : sopijaipur@gmail.com
dranuragt@gmail.com

For Office Use

Ref: No. .....

Cash/Cheque/ DD for Rs. .....

Cheque/DD No. .....

Receipt No. & Date .....

Name .....

Address .....

.....

City ..... State .....

Pin .....Phone (R) ..... (O) .....

Mobile ..... Email .....

Designation .....Qualification.....

I am enclosing a DD No/ At par Cheque No.....dated.....drawn on .....

Favoring **"Editor, SOPI" Payable at Jaipur-302004"** for Rs.....

Subscribe Today

Original research articles, reviews, update articles; brief communications & rare case documentation pertaining to Pharmacovigilance & Therapeutics are invited for publication. Any News/ Conference calendar etc., useful for the members of the society will be published free:

Annual Subscription Fee

Individual	- - - - - -	Rs. 500/-
Institutions	- - - - - -	Rs. 2,000/-

Payment through Demand Draft/ at par cheque in favour of **"Editor, SOPI" Payable at Jaipur-302004.** SUBSCRIPTION RATE includes postal charges under certificate of posting by surface mail within India Airmail charges would be extra, at rates applicable from time to time.

SOCIETY OF PHARMACOVIGILANCE (INDIA)
MEMBERSHIP FORM

I wish to become a member of the Society of Pharmacovigilance (INDIA). I have read the constitution of the society and agree to abide by it.

1. Name :
2. Educational Qualifications :
3. **Address**
   a. Office :
   b. Residence :
4. **Contacts**

   Phone with STD code :

   Office :

   Residence :

   Mobile :

   E-mail ID :
5. Are you actively engaged in work concerning Pharmacovigilance :
6. Field of Specialisation :

Date Signature

NOTE:

(1) The admission fee of Rupees Fifty only shall be chargeable at the initial admittance to the Society. The subscription for Life membership is Rs. 3500.00/- only. Please add Rs. 80.00 for outstation cheques payable at State Bank of India, S.N. Medical College, Agra.

(2) All payments be made either in cash or demand draft in favour of "INDIAN SOCETY OF PHARMACOVIGILANCE and should be sent alongwith this form completely filled in.

Address for sending the membership form:-

Prof. Govind Mohan
NIMS Institute of Pharmacy
NIMS University
NIMS City Center,
4-Govind Marg, Rajapark,
JAIPUR (RAJASTHAN) 302004
Mob. : +91 98972 22823
E-mail : govindmohanagra@yahoo.com

FOR OFFICE USE ONLY

Membership No.....

Cheque/DD No..... Date of Presenting.....

Bank.....

Bank Instrument in Bank..... Date of Issue.....,

Treasurer

INSTRUCTIONS TO AUTHORS

Aims and Scope: The Journal of Pharmacovigilance & Drug Safety (JPDS) is an official, and peer reviewed journal of Society of Pharmacovigilance, India (SOPI), that aims to encourage the practice and research in rational drug usage, drug safety and Pharmacovigilance. The journal invites submission of original research articles, reviews, commentaries and case reports on rational drug usage, therapeutic drug monitoring, drug safety, Pharmacovigilance, pharmacoepidemiology, drug surveillance, community medicine, community pharmacy, National or International drug policies and related issues. Journal will not consider basic drug research in animals unless they have direct relevance to the above-mentioned topics.

Submission of Manuscript: Manuscripts are reviewed for possible publication with the understanding that they have not been published, submitted, or accepted for publication elsewhere. They will be reviewed for scientific content, technical importance and significance by two independent reviewers of repute. The authors may suggest reviewers, but it is not mandatory and editor has a not to accept it.

The Journal will entertain research papers for publication under the following categories:

Original research article
Short Communication
Reviews (including Mini reviews)
Commentary
Case reports on drug safety

Original research article should be a comprehensive description of significant findings, whereas, short communication shall be limited to 1500 words. Review articles updating current topics will be entertained normally by invitation. A commentary on any specific field covered shall be limited to 500 words without any figure or table.

Three copies of manuscripts are required to be submitted along with CD containing the electronic version using Microsoft word or any other word-processing software. The manuscript should be sent at following address:

Dr. Anurag Tomar
Editor-in-Chief, JPVDS
NIMS City Centre,
4, Govind Marg, Jaipur - 302 004
sopijaipur@gmail.com, dranuragt@gmail.com

Preparation of the Manuscript

The manuscript should contain following sections:

Abstract: The abstract should state the purpose of the study or investigation, basic procedures (selection of study subjects or laboratory animals; observational and analytic methods), main findings (giving specific data and their statistical significance, if possible), and the principal conclusions.

The abstract should be self explanatory (limited to 200 words in one paragraph) suitable for reproduction without change. Abstract should have three sections (a) Objective (not more than 3 lines (b) Methods and Results, (c) Conclusions (not more than 3-4 lines).

Introduction: It should provide background information providing rationale of the study giving pertinent reference. Introduction should always end with objective of the study/article.

Methods: One should describe selection of the observational or experimental subjects (Patients including controls) clearly. The age, sex and other important characteristics of the subjects should be identified. The definition and relevance of race and ethnicity should be ambiguous. Authors should be particularly careful about using these categories. One should given the methods, apparatus (The manufacturer's name and address in parentheses), and procedures in sufficient detail to allow other workers reduce the results. Give references to established methods including statistical methods. All drugs and chemicals used, including generic name(s) dose(s) and route(s) of administration.

Results: Present your results concisely and in logical sequence in the text, tables and illustrations. Tables and figures should be devised in such a manner that the findings are accurately conveyed. The same data should not be used for more than one figure or table. Interpretation of the data should be given in the discussion only.

Discussion: The discussion must interpret the results and relate them to existing knowledge on the topic in as lucid a manner as possible, avoiding repetition or duplication of information. It should not be unnecessarily lengthy.

Include the implications of the findings and their limitations, including implications for future research. Relate the observations to other relevant studies. It should always end with concluding remarks.Link the conclusions with the goals of the study but avoid unqualified statements and conclusions not completely supported by the data. In particular, authors should avoid making statements on economic benefits and costs unless their manuscript includes economic data and analyses. Avoid claming priority and alluding to work that has not been completed. State new hypotheses when warranted, but clearly table them as such. Recommendations, when appropriate, may be included.

References: References should be numbered consecutively in the order in which they are first mentioned in the text. Identify references in text, tables and legends by Arabic numerals in parentheses. References cited only in tables or in legends to figures should be numbered in accordance with the sequence established by the first identification in the text of the particular table or figure

Standard journal article: List the first six authors followed by et al.

Vega KJ, Pina I, Krevsky B. Heart transplantation is associated with an increased risk for Pancreatobiliary disease. Ann Intern Med 1996 124(11):980-3.

More than six authors: Parkin DM, Clayton D, Black RJ,

Masuyer E, Friedl HP Ivanow E, et al. Childhood leukaemia in Europe after Chernobyl:5 year follow-up. Br J Cancer 1996; 73:1006-12.

Organization as author: The Cardiac Society of Australia and New Zealand. Clinical exercise stress testing. Safety and performance guidelines. Med J Aust 1996;164:284-4.

Books and other Monographs: Personal author(s): Ringsven MK, Bond D. Gerontology and leadership skills for nurses. 2nd ed. Albany (NY): Delmar Publishers; 1996

Chapter in a book: Philips SJ, Whisnant JP. Hypertension and stroke. In: Laragh JH, renner BM, editors. Hypertension: Pathophysiology, diagnosis and management. 2nd ed. New York: Raven Press; 1995.p.

Tables and Figure: These should be given in the end after references section consecutively, and provided with caption. Footnotes should be identified by lower case lettrs and cited in the tables as italicized
superscripts. All tables should be cited in the text. Figure should be kept to the inimum, colored figure, halftone figure will be charged @ Rs 200 per figure.

Acknowledgements: The author shouldacknowledgement advice from colleagues,financial/technical assistance, gifts etc. after obtaining consent from the people whose assistance is acknowledged. Any other footnotes may be given here.

Proofs and Reprints : Accepted paper's proofs will be sent to the corresponding author for verification against the original and appropriate corrections made. It will be mandatory to purchase at least 50 reprints. An order form for reprints will be sent with proofs. Please return the reprint order form with a cheque of Rs. 1000/- (India) in favour of "Editor-in-Chief, Journal of Pharmacovigilance and Drug Safety." Reprints will be posted within 15 days after printing the journal.

Issue to Consider before submitting a Manuscript
Redundant or Duplicate Publication
Redundant or duplicate publication is publication of a paper that overlaps substantially with one already published.
Readers of primary source periodicals deserve to be able to trust that what they are reading is original unless there is a clear statement that the article is being republished by the choice of the author and editor. The bases of this position are international copyright laws, ethical conduct, and cost-effective use of resources.
Most journals do not wish to receive papers on work that has already been reported in large part in a published article or is contained in another paper that has been submitted or accepted for publication elsewhere, in print or in electronic media. This policy does not preclude the journal from considering a paper that has been rejected by another journal, or a complete report that follows publication of a preliminary report such as an abstract or poster displayed for colleagues at a professional meeting. Nor does it prevent journals from considering a paper that has been presented at a scientific meeting but not published in full or that is being considered for publication in a proceedings or similar format. Press reports of scheduled meetings will not usually be regarded as breaches of this rule, but such reports should not be amplified by additional data or copies of tables and illustrations.

When submitting a paper, an author should always make a full statement to the editor about all submissions and previous reports that might be regarded as redundant or duplicate publication of the same or very similar work. The author should alert the editor if the work includes subjects about whom a previous report has been published. Any such work should be referred to and referenced in the new paper. Copies of such material should be included with the submitted paper to help the editor decide how to deal with the matter.

If redundant or duplicate publication is attempted or occurs without such notification, authors should expect editorial action to be taken. At the least, prompt rejection of the submitted manuscript should be expected. If the editor was not aware of the violations and the article has already been published, then a notice of redundant or duplicate publication will probably be published with or without the author's explanation or approval.
Preliminary release, usually to public media, of scientific information described in a paper that has been accepted but not yet published violates the policies of many journals. In a few cases, and only by arrangement with the editor, preliminary release of data may be acceptable- for example, if there is a public health emergency.

Requirements for the submission of manuscript
Double-space all parts of manuscripts.
Begin each section or component on a new page.
Review the sequence: title page, abstract and key words, text, acknowledgements, references, tables (each on separate page), and legends.
Illustration (uncounted prints) should be no large than 203x254 mm (8x10 in.).
Include permission to reproduce previously published material or to use illustrations that may identify human subjects.
Enclose transfer-of-copyright and other forms.
Submit the required number of paper copies.
Keep copies of everything submitted.

Undertaking by Authors

We, the undersigned, give an undertaking to the following effect with regard to our article entitled "

_____

_____

_____

submitted for publication in the **Journal of Pharmacovigilance and Drug Safety:-**

1. The article mentioned above has not been published or submitted to or accepted for publication in any form, in any other journal.

2. We also vouchsafe that the authorship of this article will *not* be contested by anyone whose name(s) is/are not listed by us here.

3. I/We declare that I/We contributed significantly towards the research study *i.e.,* (a) conception, design and/or analysis and interpretation of data and to (b) drafting the article or revising it critically for important intellectual content and on (c) final approval of the version to be published.

4. I/We hereby acknowledge JPVDSs **conflict of interest** policy requirement to scrupulously avoid direct and indirect conflicts of interest and, accordingly, hereby agree to promptly inform the editor or editor's designee of any business, commercial, or other proprietary support, relationships, or interests that I/We may have which relate directly or indirectly to the subject of the work.

5. I/We also agree to the authorship of the article in the following sequence:-

Authors' Names (in sequence)	Signature of Authors
1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____

Manuscript Submission Check List

1. Covering letter
2. Undertaking by Authors signed by all authors
3. Copyright Transfer Agreement Form signed by all authors
4. Three copies of manuscript with three sets of illustrations (one original & two copies)
5. Title page
   - Title of manuscript
   - Full name(s) and affiliations of author(s); institution(s) and city(ies) from which work originated
   - Name, address, telephone, fax numbers and e-mail address of the corresponding author.
   - Running title
6. Abstract in structured format along with key words (on a separate sheet)
7. Article
8. Acknowledgment
9. References
10. Tables (on separate sheets)

P-117

Utility of heparin flush for enhancing duration of peripheral intravenous catheter in neonates

JATIN GARG , RUPESH MASAND , BS TOMAR
Department of Pediatrics, NIMS Medical College, Nims University, Jaipur

Introduction:
Intermittently used intravenous catheter frequently block, due to blood clot at the distal end of the catheter, thus resulting in compulsive removal and reinsertion. Preventing repeated obstruction, can be beneficial in decreasing pain, risk of infection and stress.

Aims and Objectives:
Primary outcome:

- To evaluate the effect of heparin in maintaining the patency and improving the duration of use of peripheral intravenous catheter (PIVC) and its comparison with normal saline.

Secondary outcome:

- To record the adverse effect of heparin during the study period.

Methods:
A randomized control trial, involving term neonates in each group after screening platelet count, coagulation profile and USG brain. Group A received normal saline and Group B was administered 10U heparin flush. Insertion and fixation of PIVC was done according to the standard protocols with documentation of time of insertion, removal and site of insertion, in a medical college hospital with level III NICU; study assessed the first cannulae functional duration, and complication due to heparin.

Result:
Two comparable groups; comparable in terms of gestational age, sex, weight, site of cannulae and antibiotics used ; were studied with n=36 in each group after randomization. Average first cannulae functional duration in group A (NS group) was 60.86hrs. and in group B(heparin group) was 79.66 hours, difference between two groups favors heparinization of PIVC.

Conclusion:
No complications were noticed related to heparin group. No adverse effects in terms of platelet count, coagulation profile, intra ventricular or intra cranial hemorrhage or allergic reactions were noticed in heparinized group; on other hand there was increase in functional duration of PIVC with heparin.

P-118

MEDICAL MANAGEMENT OF BPH

HARENDRA SINGH, GAURAV KUMAR NIRWAL, RAVI KUMAR MATHUR
Department of General Surgery, National Institue of Medical Sciences, Jaipur, Rajasthan

Benign prostatic hyperplasia (BPH) is a histologic diagnosis that refers to the proliferation of smooth muscle and epithelial cells within the prostatic transition zone.
The exact etiology is unknown; however, the similarity between BPH and the embryonic morphogenesis of the prostate has led to the hypothesis that BPH may result from a "reawakening" in adulthood of embryonic induction processes.
The enlarged gland has been proposed to contribute to the overall lower urinary tract symptoms (LUTS) complex via at least two routes: (1) direct bladder outlet obstruction (BOO) from enlarged tissue (static component) and (2) from increased smooth muscle tone and resistance within the enlarged gland (dynamic component). Voiding symptoms have often been attributed to the physical presence of BOO. Detrusor over activity is thought to be a contributor to the storage symptoms seen in LUTS.3 This Presentation attempts to encompass the concept of LUTS in a broad spectrum of etiologies, and focuses on the Medical management BPH
Traditionally, the primary goal of treatment has been to alleviate bothersome LUTS that result from prostatic enlargement. More recently, treatment has additionally been focused on the alteration of disease progression and prevention of complications that can be associated with BPH/LUTS. A variety of pharmacologic classes are employed including alpha-adrenergic antagonists (alpha-blockers), 5-alphareductase inhibitors (5-ARIs), anticholinergics . Choosing the correct medical treatment for BPH is truly complex and ever-changing.

Tariffs For Advertisers

		Quarterly	Annually
Cover	Last Page(color)	Rs. 35,000	Rs. 1,08,000
	Inside back cover(color)	Rs. 25,000	Rs. 90,000
	Inner Front (color)	Rs. 25,000	Rs. 90,000
Inner	Inner Full Page (color)	Rs. 20,000	Rs. 72,000
	Full Page (B&W)	Rs. 15,000	Rs. 55,000
	Half Page (color)	Rs. 12,000	Rs. 40,000
	Half Page (B&W)	Rs. 10,000	Rs. 36,000

Payment through Cheque/Demand Draft in favour of
"Editor SOPI" Payable at Jaipur -302004
Advertising material be sent through Registered Post to:

Dr. Anurag Tomar,
Editor in Chief,
Journal of Pharmacovigilance & Drug Safety
NIMS City Center, 4 Govind Marg,
Jaipur - 302 004, India
Email: sopijaipur@gmail.com
anurag@nimsr.com

The Journal is circulated to all the Life members of Society of Pharmacovigiliance (India) (SOPI), Institutions of Pharmacoviglance, Medical and Pharmacy Colleges in the country & Pharmaceutical industries etc.

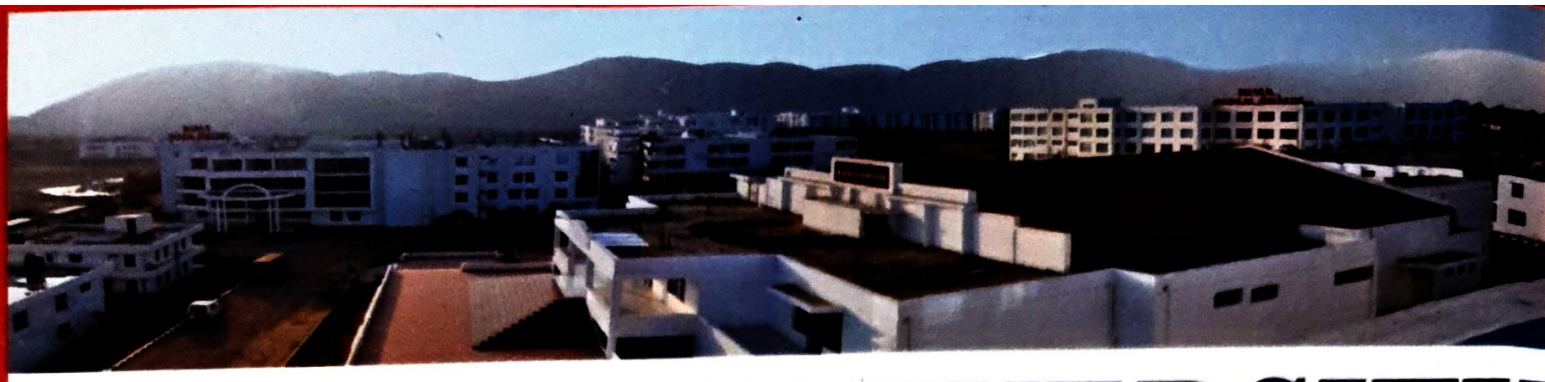
Original research articles, reviews, update articles; brief communications & rare case documentation pertaining to Pharmacovigilance & Therapeutics are invited for publication. Any News/ Conference calendar etc., useful for the members of the society will be published free.:

Subscribe Today

Annual Subscription Fee

Individual	.....	Rs. 500/-
Institutions	.....	Rs. 2,000/-

Payment through Demand Draft/ at par cheque in favour of **"Editor, SOPI" Payable at Jaipur-302004.** SUBSCRIPTION RATE includes postal charges under certificate of posting by surface mail within India. Airmail charges would be extra, at rates applicable from time to time.



NIMS UNIVERSITY

JAIPUR (RAJASTHAN)

Established by Government of Rajasthan vide N.U.R. Act, 2008 and recognized by U.G.C. & respective Councils

NIMS UNIVERSITY COURSES OFFERED

Medicine
- MBBS*
- MD / MS*

Anatomy, Physiology, Biochemistry, Pathology, Pharmacology, Microbiology, Forensic Medicine, Community Medicine, Gen. Medicine, TB & Chest, Pediatrics, Skin & VD, Surgery, Orthopaedics, ENT, Ophthalmology, Obst. & Gynae., Anaesthesia and Radio-Diagnosis

- M Sc (Medical)

Anatomy, Physiology, Biochem., Pharmacology & Microbiology

Dentistry
- BDS*
- MDS*

Oral & Maxillofacial Surgery, Periodontology, Oral Pathology & Microbiology, Prosthodontics and Crown & Bridge and Orthodontics & Dentofacial Orthopedics

- DORA (Dental Operating Room Assistant)

Pharmaceutical Science
- B Pharma
- M Pharm

Pharmaceutics, Pharmacology, Pharm. Chemistry, Pharm. Marketing, Pharmacovigilance, Quality Assurance, Pharmacognosy & Pharmacy Practice

- B Pharm + MBA (Inte.)
- D Pharm

Nursing
- M Sc Nursing

Medical Surgical, Obst. & Gynae. and Commu. Health Nursing

- B Sc Nursing
- GNM
- Post Basic B Sc Nursing

Paramedical
- M Sc
- B Sc

Medical Lab. Technology, Radiation Technology, Blood Transfusion Medicine and Operation Theatre Technology

- M Optom
- B Optom
- Diploma

Medical Lab. Technician, X-Ray Technician, ECG Technician, Operation Theatre Technician, Blood Transfusion Technician and Ophthalmic Technician

Advance/Basic Sciences
- M Sc
- B Sc (Hons)
- B Sc

Microbiology, Biochemistry, Biotech., Bioinfo & ES & Genetics

Physiotherapy
- MPT
- MOT
- BPT
- BOT

Aviation Technology
- B Sc Aviation
- Diploma

Law
- BBA + LLB (Integrated)

Ph.D. & M.Phil in all streams**

Advanced Engineering
- B Tech
- M Tech
- M Tech (Int)
- M Tech + Ph D

Nuclear Engg., Aerospace Engg., Oil & Gas Engg. and Energy & Power Engg.

Engineering & Technology
- B Tech
- M Tech
- M Tech+Ph D
- M Tech (Int)
- B Tech+MBA (Int)

Computer Science & Engg., Information Technology, Electronics & Communication Engg., Electronics & Instrumentation, Civil Engg., Mechanical Engg., Electrical Engg., Biotechnology, Agriculture Engg., Automobile Engg. and Chemical Engg.

- Diploma

Computer Science, Electronics Engg., Electrical Engg., Information Tech., Civil Engg. & Mech. Engg.

Management
- BBA
- MBA (Int)
- MBA

Health & Hospital Management / Administration, HR, Marketing, International Mktg., Retailing, Finance, Investment & Mutual Fund, Banking, IT & Systems, Event Mgmt., Pharmaceutical, Insurance

- BMS
- MMS
- BFMM
- MFMM

Computer Science
- BCA
- MCA
- MCA (Int)
- BSc
- M Sc

Architecture & Planning
- Bachelor of Architecture (B Arch)

Humanities, Social Sciences, Arts, Science, Fine Arts and Commerce
- BA/B Sc (Hons/Pass)
- BSW
- BPA
- BRS
- BVA
- Bachelor & Master of Fine Art
- BLISc
- B Sc/BA (Phy. Edu.)
- B Sc (Home Sc.)
- B Com
- B Com (Hons)
- MA
- MSW
- MRS
- MVA
- MPA
- M Com
- M Sc
- MLISc
- M Sc (Home Sc.)

Hotel Management and Tourism
- MHMCT
- PGDHM
- BHMCT
- BHM
- MHM
- MTTM
- BTTM
- M Sc /B Sc (Food Tech.)
- PG Diploma & Diploma

Journalism and Mass Comm.
- MJMC
- BJMC

Textile and Fashion Design
- M Sc
- B Tech.(T.T.)
- M Tech.(T.T.)
- PG Dip
- Diploma

Theatre, Film & Television Tech.
- M Sc/MA
- B Sc/BA
- PG Dip
- Diploma

DIPLOMA AND CERTIFICATE COURSES

Post-Graduate Diploma, Diploma, & Certificate Courses in (1- 3 Years) - (Paramedical, Hospital Management, Nursing, Pharmacy, Management, Computer Application and Health & Nutrition)










Nims University campus is a township having residential facilities for students (boys & girls separately), faculty & staff with facilities of Post Office, Bank, Shopping Complex, Modern Cafeteria, Auditorium, Stadium, Petrol Pump, Roadways Bus Stop, etc.

Campus Address:

Shobha Nagar, Jaipur-Delhi Highway,
Jaipur - 303 121 (Raj.)

Contact

8302704400

TOLL FREE : 18001201020

mail : anurag@nimsr.com

www.nimsuniversity.org

DISTANCE EDUCATION PROGRAMME

43 COURSES IN DISTANCE EDUCATION MODE