

Abs.PH.01

Factors influencing Prescribing Behaviour of general practitioners in Rural Health Care Centres of Eastern Maharashtra: A questionnaire based survey

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Objective : To evaluate the attitudes and the factors which influence physician prescribing decisions and practice.

Method : A questionnaire was developed and administered to a sample of 100 physicians and residents working in rural health care centres of rural Eastern Maharashtra. The questionnaire-part one had questions regarding demographic details and part two contained questions regarding prescribing behaviour and practice.

Results : Physicians and residents take many criteria under consideration, such as the drug form, recommended daily dose and individual patient preferences before prescribing drugs. The list of main sources of information for physicians includes: medical journals, medical textbooks, conferences and pharmaceutical sales representatives. Only half of prescribers considered the cost carried by their patients. The majority of doctors agreed that the effectiveness, safety and efficacy of generic drugs may not be excellent but it is acceptable. Physicians and residents believe that new drugs are not always better and their higher

prices are not necessarily justified. Majority of doctors do not inform the authorities on adverse drug reactions.

Conclusion: The present study highlights the attitudes and the factors influencing physician and residents behaviour and may be used for developing policies to improve their choices and hence to increase clinical and economic effectiveness and efficiency in rural areas.

Abs.PH.02

Comparative Efficacy of Bisoprolol and Metoprolol for the Treatment of Mild to Moderate Hypertension in Young Adults

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Objective : Hypertensive patients younger than 50 years old may benefit more from beta blockers than older patients, as they have different hemodynamic form of hypertension. Beta blocker (BB) remain drugs of crucial importance in situations like HTN with angina pectoris, post MI & heart failure. Evidence to date suggests that BB other than atenolol should be chosen when beta blockade is required. So, the aim was to compare the antihypertensive efficacy and tolerability of bisoprolol with those of metoprolol.

Method : 50 patients (27 men, 23 women, age range 41-60 years) with mild to moderate hypertension were randomly allocated to treatment with either 10-20 mg/d bisoprolol

or 50-100 mg/d metoprolol ER after a 2 week placebo period, in an open label, single blind study for 8 weeks. Blood pressures were recorded 24 hr after drug intake.

Results : After 8 weeks active treatment with individually titrated doses both treatment showed a significant antihypertensive effect ($P < 0.01$) with supine blood pressures of 128.3/82.5 and 139.5/87.9 mm Hg for bisoprolol and metoprolol group respectively. Bisoprolol significantly reduced supine blood pressures by 14.6 mm Hg (diastolic) and 22.2 mm Hg (systolic) compared with 7.44 and 12.3 mm Hg respectively for metoprolol. Target pressures of $\leq 140/90$ were reached in 92% (23/25) with bisoprolol and 48% (12/25) with metoprolol ($P < 0.05$). Non significant changes in lipoprotein pattern and tolerable side effects were observed.

Conclusion : Results suggest that bisoprolol may be more effective antihypertensive agent than metoprolol but larger studies are necessary to confirm these findings.

Abs.PH.03

New Drug Development and Indian Pharmaceutical Industry

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Objective : One of the major expectation after the introduction of product patent regime in 2005 was that the new patent regime would prompt Indian pharma companies to conduct

greater R&D for the development of new drugs. This study tries to analyze the performance of Indian pharma companies in this regard.

Method : For our study, we have included top 15 Indian pharmaceutical and biopharmaceutical companies which were owned and promoted by an Indian till 2005. Data was collected from the annual reports of these companies from 2005 to 2011 (wherever available). To avoid missing any relevant data, information was also sought on google using keywords like "New drug AND company name".

Results : Out of the 15 companies we analysed, only 10 were involved in new molecular entity research and development. Companies like Glenmark, Piramal life Sciences and Lupin are at the forefront of new drug discovery and development while others like Ranbaxy and Dr. Reddy's who were the major R&D spenders in the past, have taken a backseat after several setbacks. Some big names like Cipla and Aurobindo Pharma have refrained themselves from getting involved in this high risk- high return business of new drug discovery and development.

Conclusion : It may be concluded that even after 6 years of product patent regime, Indian pharma industry is still in its nascent stage in new drug discovery and development. As failure in drug development is a global phenomenon, so the setbacks in new drug development can't be considered as the death of Indian innovation. With increasing experience, better collaborations and government willpower these generic-giants can transform into innovative research based industry.

Abs.PH.04

Impact of Chronic Drug Therapy With Sodium Valproate On Bone Health In Pediatric Epilepsy

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Objective : To evaluate the impact of chronic anti epileptic drug therapy with Sodium Valproate on bone health in pediatric population in a tertiary care teaching hospital.

Methods : All the patients (4-18 yrs) visiting pediatric department who are diagnosed with epilepsy and are on Anti Epileptic drug therapy with Sodium Valproate for minimum 6 months were recruited into study with parent's consent. A specially designed proforma was used to collect patient demographics, anthropometric measurements, past medical, medication history and medications prescribed by direct patient interview *method*. Pediatric populations who were on oral Calcium/VitD supplements and non ambulatory were excluded from the study. Patients were made to undergo following investigations like Blood Count, Serum Calcium, Serum Phosphorus, and Alkaline Phosphatase. And as a result patients with normal levels of the above mentioned parameters were given a maintenance dose of Vit D and Calcium. Patients who were found to have decreased Calcium and increased

alkaline phosphatase levels were treated with therapeutic dose of Vit D & Calcium and followed up by respective unit.

Results : The *results* showed increased level of alkaline phosphatase and decreased calcium levels in more than 40% of pediatric population.

Conclusions : Therapeutic dose of Vit D and Calcium were found to be useful as a preventive measure for the maintenance of the bone health.

Abs.PH.05

To Find the Incidence and Study Various Aspects of Adverse Drug Reactions in the Outpatients and Inpatients Attending Medicine Department of HIMS, A Tertiary Care Teaching Hospital

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Objective : To find the incidence & study various aspects of Adverse drug reactions in the outpatients and inpatients attending medicine department of, a tertiary care teaching hospital in Uttarakhand.

Method : A prospective study including approx. 17000 patients attending medicine department over a period of six months was carried out to find the incidence rate of ADR and various aspects of ADR were studied like drugs frequently causing ADRs, causality assessment etc.

Results : 169 of the 17000 patients developed ADR. As the number of administered drugs in the patient increased incidence of ADRs also increased. Maximum ADRs (76%) were caused by anticancer drugs followed by Antibiotics group of drugs (7.02%). ADRs related to skin were most frequent. When causality assessment was done majority of them belonged to possible category.

Conclusion : Incidence of ADRs was found to be much lower approx. 1% than has been reported worldwide. The present study has provided baseline data for further larger studies and has ascertained the importance of prospective ADR monitoring in pharmacovigilance studies.

Abs.PH.06

To Evaluate the Prescribing Pattern of Analgesics in a Tertiary Health Care Setup of Rural India

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Objective : To evaluate the prescribing pattern of analgesics in a tertiary care hospital.

Method: A prospective observational study was carried over six months.300 prescriptions were analysed.

Results : The result shows that Paracetamol and Diclofenac were the most commonly prescribed analgesics. The use of analgesics depends upon the severity of pain. In mild

pain,single analgesics are commonly used where as two or more analgesics are used in moderate and severe pain.

Conclusion : The study summarizes that, the cost of therapy can be reduced by changing of prescription of drugs from brand name to Generic name. This also an important role in Rational use of Drug.

Abs.PH.07

Effect of Atorvastatin with and Without Estradiol on Neurological Functions in Insulin Hypoglycemia

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Objective : Long term administration of statins is desired for the management of dyslipidemia in chronic diabetic patients. Incidence of hypoglycaemia is high in stringently controlled diabetes which can have detrimental effects on neurological functions. The present study was planned to see the effect of atorvastatin on neurological functions in insulin hypoglycaemia with and without estrogen in female rats.

Method : Female rats divided into six groups (n=8) received atorvastatin (20 mg/kg, orally), vehicle of atorvastatin, estradiol benzoate (100 µg/kg, ip), vehicle of estradiol benzoate, estradiol benzoate + atorvastatin, vehicle of atorvastatin + estradiol benzoate daily for 15 days. Rats of all the groups were exposed to insulin hypoglycaemia and neurological

outcome scores were recorded using 18-point scale at 0, 15, 45 and 60 minutes before and after 7 and 15 days of initiation of treatment.

Results : Insulin hypoglycaemia caused significant ($p < 0.001$) impairment of neurological functions by way of increasing the neurological outcome scores. Atorvastatin and estradiol benzoate deteriorated the neurological functions which were further aggravated when they were given in combination in hypoglycaemia.

Conclusion : Atorvastatin aggravated the deterioration of neurological functions in presence of estradiol benzoate during insulin hypoglycaemia.

Abs.PH.09

Safety and Tolerability of Botulinum Toxin Type A: A Meta-Analysis

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Objective : To assess the safety and tolerability profile of botulinum toxin type A (BTX-A), one of the most commonly used preparation of this toxin across the common therapeutic indications for its use.

Method : All those studies which were double-blind, randomized, crossover, or of parallel group design using BTX-A or placebo and having at least 12 weeks of duration were included. The evaluation was limited to the safety profile of BTX-A. The adverse effects reported in various studies were collated and assessed qualitatively to know the

spectrum of the adverse drug reactions and quantitatively to assess the overall incidence.

Results : The pooled data of 1490 subjects, who met the inclusion criteria, was analyzed. 1023 subjects received BTX-A treatment and 551 subjects received placebo. The *results* of meta-analysis show that 551/1023 patients (53.8%) in the BTX-A-treated group compared with 199/467 patients (42.6%) of control group showed mild to moderate adverse events ($P < 0.001$). Myalgia (30.3%), Injection site pain (7.9%), skin rashes (3.6%) and flulike symptoms (2.7%) were most common adverse events with BTX-A. No severe or serious adverse events related to BTX-A was reported in these studies.

Conclusion : Most of adverse drug reactions caused by BTX-A were mild or moderate and resolved at their own without any active intervention. BTX-A was thus found to be safe and well tolerated.

Abs.PH.10

Efficacy and Safety of Various Antimicrobials in Surgical Site Infections – An Observational Study

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Objective : To evaluate the incidence, risk factors, common organisms involved and rationality of the antimicrobial therapy in surgical site infections (SSIs).

Method : A prospective observational study was carried out in the Department of General Surgery and Department of Pharmacology at the Himalayan Institute of Medical Sciences, Dehradun, India from March 2010 to February 2011. Identification of the drug sensitivity of common pathogens and pattern of antimicrobial usage in postoperative wound infection was the primary end point. Secondary end point was to identify the risk factors and to determine the cost effectiveness of the treatment regimen.

Results : The overall incidence of established culture positive SSI was 10.4%. Majority of the cases were seen in emergency laparotomy surgeries of two hours or more duration. Usage of surgical drain was a major risk factor for SSI development followed by diabetes and smoking. Cefuroxime and Metronidazole combination was the most commonly used preoperative prophylaxis. Escherichia coli was the most common organism isolated but was resistant to all Penicillins and Cephalosporins. Meropenem for gram negative and Vancomycin for gram positive isolates were the major sensitive antibiotics in the study but these therapies were less cost effective.

Conclusion : SSIs were common in the study and led to increased cost of treatment and prolonged hospitalization. An effective surveillance programme for SSI should be a critical component of any hospital infection control programme to reduce the rate of SSI.

Abs.PH.11

Background Noise in Pre Menstrual Phase: A Confounding Factor in Clinical Trials and Pharmacovigilance Studies

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Objective : To record Background noise in pre menstrual phase in normal females who are neither suffering from a disease nor taking any medication for comparisons in Clinical Trials.

Method : The study was conducted in 150 normal females in the 18-45 age group, who accompanied the patients in Obstetrics & Gynaecology outpatient department of, Gian Sagar Medical College, Banur. Institutional Ethical clearance were taken. They were neither suffering from any disease nor taking any treatment. The exclusion criteria were : pregnancy, lactation, any concurrent disease or treatment. A 22-symptoms' questionnaire was administered during last 7 days of menstrual cycle. Subjects were asked if they experienced any of these symptoms during the last 24 hours and rate it as: absent (0), mild (1), moderate (2) or severe (3).

Results : The background noise observed was: backache(67%); fatigue ,abdominal cramps (55%); generalised aches (54%); irritability (50%); mood swings (42%); abdominal bloating (23%); breast tenderness, headache, nervous tension, anxiety (19%); weight gain (11%); crying, insomnia & swelling of extremities (10%); craving for food & dizziness (9%), forgetfulness (8%); heart pounding (7%); confusion (6%); increased appetite and depression (5%). Only 5% females were without any symptom. More than 50% had 5 or more symptoms and 74% had

3 or more symptoms despite the fact that they were not taking any medication or suffering from any disease.

Conclusion : There is need to record background noise in adverse drug reaction monitoring as well as efficacy studies. Appropriate steps need to be taken to minimize these confounding factors in clinical trials and pharmacovigilance studies of drug used in premenstrual syndrome.

Abs.PH.12

Pattern of Antimicrobial Prophylaxis in Patients Undergoing Elective Surgeries in a Tertiary Care Teaching Hospital in North India

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Objective : To study the antibiotic prophylaxis pattern in patients admitted in Surgery wards of a tertiary care teaching hospital in North India.

Method : A prospective, observational, non interventional and analytical study to evaluate the presurgical antimicrobial prescription pattern in patients who underwent surgeries through a period of one and a half years from December 2009 to June 2011 at Era's Lucknow Medical College Hospital. 150 patients were enrolled in our study and data concerning demographic profile, type of surgery, and parameters of antibiotic therapy

(selection of antibiotic, dose, route and duration of therapy) were collected and analyzed.

Results : It was found that third generation cephalosporins were the most commonly prescribed class of antibiotics. No consistency was noted in the timing of administration of prophylactic antimicrobials agents. The antibiotics were prescribed 30 minutes to 6 hours before surgery. The dose was not repeated during surgery. Although majority of antibiotics were prescribed from National List of Medicine (2003), India, prescription by generic names was rare. Surgical site infection was low.

Conclusion : Surgical prophylaxis was inappropriate in terms of choice of antimicrobial agent, timing of administration as well as the total duration of prescription in majority of the cases. Interventions are warranted to promote the development, dissemination and adoption of evidence based guidelines for antimicrobial prophylaxis.

Abs.PH.13

Assessment of Achievement of Low Density Lipoprotein Cholesterol Goals in Patients of Diabetes with Administration of Statins – A Comparative Prospective Randomised Study

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Objective : To assess the percentage of patients with diabetes who reach low density lipoprotein cholesterol goals with administration of statins. To compare the incidence of adverse events in diabetic patients when on statins.

Method : The study was carried out in Acharya Vinoba Bhave rural hospital, Wardha, Maharashtra from November 2010 to May 2011. It was a prospective, randomized, double blind, parallel groups, unicentre study. Group I received Atorvastatin 10 mg once daily and Group II received Atorvastatin 20 mg once daily for 3 months. Safety reporting was done by monitoring the incidence of adverse events.

Results : There was a statistically significant ($P < 0.001$) difference between the two groups in the number of patients achieving goal LDL-C (32% patients in 10 mg group vs. 77.27% patients in the 20 mg group). Not a single patient receiving the 10 mg dose attained the optional LDL-C goal of < 70 mg/dL while 36.36% of patients receiving 20 mg dose attained this goal. The difference in achieving the optional goal was statistically highly significant ($P < 0.0001$). There was no statistical significance in the incidence of adverse events at both the doses.

Conclusion : Physicians will have greater success in treating diabetic dyslipidemia if they administer statins to patients.

Abs.PH.14

Comparison of Minocycline vs Hydroxychloroquine as an Add-on Therapy to Methotrexate for the Treatment of Rheumatoid Arthritis

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Objective : To compare the efficacy and safety profile of minocycline versus hydroxychloroquine as an add-on therapy to methotrexate in treatment of Rheumatoid arthritis.

Method : A prospective, open, randomized, comparative, clinical study was conducted on 50 patients. The patients were randomly divided in two groups of 25 each to receive either of the following two treatments: oral methotrexate (7.5–25 mg orally in divided doses weekly), hydroxychloroquine (200mg bid) & etoricoxib (400 mg hs); or oral methotrexate (7.5–25 mg orally in divided doses weekly), minocycline (100 mg bid) & etoricoxib (400 mg hs). The efficacy assessment parameters recorded at 2, 6 & 12 weeks were: Pain assessment on VAS scale, Grip strength, Disease activity score -28 (DAS-28), Clinical disease activity index (CDAI) score, Health assessment questionnaire (HAQ) score, Erythrocyte sedimentation rate (ESR). The safety assessment was done by recording side effects of the drugs.

Results : There was a statistically significant difference in improvement in the parameters i.e : Pain assessment on VAS scale (2.2 vs 4.3), Grip strength (right hand 98.4 vs 92.0; left hand 109.2 vs 94.2), DAS-28 (3.3 vs 4.1), CDAI score (5.6 vs 16.2) with minocycline group over the hydroxychloroquine group at 12 weeks. No statistically significant

difference was observed for HAQ score & ESR when two groups were compared. The observed adverse effects were mainly gastrointestinal symptoms in both the groups. Dizziness was more observed in minocycline group whereas headache was more in hydroxychloroquine group.

Conclusion : Minocycline as compared to hydroxychloroquine as an add on therapy to methotrexate in treatment of Rheumatoid arthritis was found to be more efficacious but having almost similar side effect profile.

Abs.PH.15

Drug Utilization Study in a Secondary Care Hospital in Meghalaya – A Pilot Study

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Objective : To analyze the prescription pattern in a secondary care hospital in Meghalaya for promoting rational use of medicines and to guide policy and decision making in the state of Meghalaya.

Method : A total of 444 Prescriptions were collected from Ganesh Das hospital, Shillong, Meghalaya (OPD) at random for a period of 1 (one) month from 11.00 am to 12.00 noon daily. Prescriptions from the government hospital were analyzed based on the following variables: (a) total number of drugs prescribed, (b) generic Vs brand, (c) total Parenteral drugs prescribed, (d) fixed dose combinations (e) drugs prescribed from

Essential Drug List (EDL) (f) Antibiotics.

Results : On analyzing the *results* the prescription have been found to consist of drugs prescribed by Generic name which was 220 (49.5%), fixed dose combination was 4 (0.9%), Parenteral drugs prescribed was 12 (2.7%), drugs prescribed from EDL was found to be 124 (27.9%) and Antibiotics at 84 (18.9%). It was also noticed that most of the prescriptions contain of not more than 3 drugs in each.

Conclusion : The above study indicates that the trend of drug prescription in Shillong, Meghalaya follows a good prescribing pattern consisting of generic drugs and drugs conforming to the essential drug list in the majority of cases. It is hopeful that the pilot study will be used as a guideline for a broad based future study to generate more data that will inculcate the practice of rational drug use among the physicians in the state of Meghalaya.

Abs.PH.16

To Study Calcium Channel Blocking Activity of a Newly Synthesized Dihydropyridine Deratives (BK V) in Isolated Smooth Muscle Preparation

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Objective : Dihydropyrimidines are potent mimics of dihydropyridine calcium channel

blockers in their in vitro activity. One such compound 6-methyl-4(3, 4 dimethoxy) phenyl-2-S ethyl-1, 4-dihydropyrimidine 5-carboxylic acid ethyl ester (BKV), has been studied to find out its biological activity on aortic smooth muscles.

Method : Descending thoracic aorta of rabbit was excised and aortic strips were prepared by spiral section. Aortic strips were suspended in organ bath containing oxygenated modified Krebs's solution. The tissue was relaxed for 90 min. with tension load of 3 g. Then it was suspended in Ca²⁺ free Krebs's solution containing EDTA for 10 min. and then in Ca²⁺ Free-K⁺ rich Krebs solution. Responses were taken by putting 10 mM Calcium chloride and recorded for 10 min. The whole procedure was repeated in presence of the test compound after washing with modified Krebs's solution. Six experiments were conducted with each of four doses and mean values calculated.

Results : BK V produced inhibition of Ca²⁺ induced contractions with bath concentration of 10 µg/ml which is statistically significant (P<0.01) while *results* at other doses were statistically not significant.

Conclusion : It can be concluded that BK V which is structural analogue of 1, 4,-dihydropyrimidine had shown significant relaxant effect on aortic smooth muscles but dose dependent increase in relaxant effect was not observed.

Abs.PH.17

Evaluation of Analgesic Efficacy of Topical DIP-1in Pain Management and Therapy in Frostbite and Buerger's Disease

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Objective : DIP-1 an innovative product from alcoholic extract of Aloe vera leaves, containing prostanoids/modulatory chemicals. It reverts pathophysiological morbidities in frostbite at high altitude, and pathogenesis of arterial changes in Buerger's disease in multifarious effective manners. Objective of present study is to evaluate analgesic efficacy of DIP-1 for pain relief/healing wounds through reversal of microcirculation and maintaining physiological functions.

Method : Our tri-phasic studies were conducted for: i) Determination of analgesic efficacy of DIP-1 in frostbite (animal model): Pain response was induced by Hot Plate Analgesia Meter before and after cold insult, followed by medication till recovery. Frostbite was induced in hind limbs of adult albino rats(n=10), by exposing to -15°C for 1hr. Frozen limbs were dipped in DIP-1 for 1hr with 10 min gap after thawing, and continued till recovery. Controls(n=10) were similarly treated with alcohol (90%). Nociception in treated/control rats was monitored through indication of hind paw lick latency (HPLL) in second at base line, after thawing, and with medication till recovery. The mean time of HPLL (in sec) was determined. ii) Determination of improved microcirculation:

Early blood pool scintigraphy done in frostbite patients (n=20) with gangrene/inflammation/pain/numbness, and paresthesia. A dose of 10 mCi technetium 99 m pertechnetate administered intravenously, microcirculatory changes monitored before and after 2 hr, then at 14 days of follow up treatment. Afflicted feet/hand digits of frostbite/Buerger's disease were treated by dipping in DIP-1 solution for 6-9 h daily, and continued till recovery. In consequence of pain threshold, subjective perception of pain sensitivity in patients, assessed using 10 points visual analogue scale (VAS) at base line/in medication/at recovery and follow up stages. iii) Determination of in vitro effects of DIP-1 in migration pattern of endothelial cells, by studying endothelial monolayer wound healing model.

Results : Changes in HPLL in treated/control rats showed initial delay till 50hr of treatment, possibly due to surface-anaesthetic effects of phospholipids/magnesium in DIP-1, frost induced numbness, and paraesthesia. Return of HPLL within 60 hr to base line, indicates significant changes in rapid recovery from paraesthesia with negligible tissue damage. While in controls, absence of nociception till 60 sec stay on hot plate, indicated deeper tissue damage. Patients also demonstrated remarkable relief in pain, early wound healing avoiding amputation/sequelae/adverse effects. Observation of microcirculatory reversal in ischemic parts after 2 hr topical doses indicates sustained treatment response till 14 days. Maximum migration of endothelial cells was seen after 4 hrs of treatment with 2% of DIP-1.

Conclusion : Analgesic efficacy of topical DIP-1 an evidence based rational remedy is

highly beneficial for pain amelioration/wound healing.

Abs.PH.18

Combining Herbal Supplements With Multivitamin and Mineral Preparations: Present Scenario

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Objective : The use of herbs to treat diseases has been almost universal among the non-industrialized societies. Nowadays, even the industries are banking on this concept and merging the plant supplements with medicines. This study analyzes the use of multivitamin and mineral preparations with herbal constituents.

Method : A market survey was done in which about 750 multivitamin and mineral preparations were assessed for their constituents.

Results : Among the assessed preparations, about 125 had herbal constituents along with the vitamins and minerals. It was found that 53 preparations had lycopene, 24 had ginseng, 12 had spirulina, 12 had lutein and zeaxanthin, 6 had soy isoflavones, 4 had grapeseed extract, 2 had green tea extract, 1 had neem while 11 had more than one herbal constituents. When a cost analysis for these combinations was conducted, these were found to be more expensive than the preparations without the herbal constituents.

All the more, no substantial studies were found to show the superiority of these combinations.

Conclusion : It is a commonly known fact that multivitamin and mineral preparations are among the most commonly prescribed pharmaceutical products. Despite the lack of convincing data and trial *results* regarding the superior effectiveness of the combinations over those without the herbal constituents, these continue to be prescribed by the physicians, posing a heavy load on the pocket of the common man. Considering this fact, cost effectiveness of the preparations needs to be kept in mind while prescribing.

Abs.PH.19

Exploring the Risk of Metabolic Syndrome in Olanzapine Versus Risperidone Treated Schizophrenic Patients

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Objective : Metabolic syndrome is seen as a complication of treatment with some atypical antipsychotics. In this study we compared the incidence of metabolic syndrome occurring after olanzapine and risperidone administration for treatment period of 8 weeks.

Method : A randomized, comparative, open clinical study was conducted on 60 schizophrenic patients. The patients were divided into two groups, one receiving olanzapine and the other receiving risperidone for 8 weeks. BPRS score was used for assessing the changes in

disease severity and modified NCEP ATP III criteria was applied for detection of metabolic syndrome in the patients at the end of study. The number of patients fulfilling the criteria of metabolic syndrome was compared between the two treatment groups.

Results : A significant change in the values was seen at the end of the study in all of observed parameters in both the groups except diastolic blood pressure in risperidone treated patients. Intergroup comparison was significant only for TG levels which were higher in olanzapine treated patients. Incidence of metabolic syndrome was numerically more in olanzapine treated patients (36.66% vs. 16.66%) but this difference was not statistically significant. Statistically higher number of olanzapine treated patients fulfilled the central obesity criteria of metabolic syndrome. More males as compared to females fulfilled the individual criteria of metabolic syndrome in both the groups, except waist circumference.

Conclusion : Both drugs are efficacious for the treatment of schizophrenia. Metabolic syndrome is seen to occur as a complication of the treatment with both drugs, more so with olanzapine.

Abs.PH.20

Sertraline Worsen the Cognitive Impairment During Antidepressant Therapy : A Pharmacovigilance Case Study

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Objective : This study designed to investigate any new possible side (adverse) effect during SRT antidepressant therapy. The purpose of this study was to examine whether Sertraline (SRT) therapy improve or impair cognitive functioning in depression with preparation of individual case safety report (ICSR) and periodic safety update reports (PSUR).

Method : Pharmacovigilance case study *method* with spontaneous questioning was used for this study. 150 outpatients having age 20 to 50 years old with major depressant disorder (MDD) and dysthymic disorder were enrolled from the outpatient department and assessed before the initiation of treatment and reassessed during treatment (SRT therapy for 6 months; 50 mg; oral) and also follow-up after recovery. Patients were interviewed using spontaneous reporting system with 40 specific questions. Neuropsychological assessment for cognitive impairment has been identified across a number of specific cognitive domains including IR memory, Recent memory, Psychomotor Speed, disorientation, processing speed, intelligence, abstract thinking, executive function, complex attention, insight and judgement was done by various *methods* like Glasgow coma test and digit span test.

Results : Data obtained from this case study suggest that 76% patients with MCI(Mild cognitive impairment) receiving SRT therapy progressed to moderate cognitive impairment and rest of them did not shown any further impairment of cognitive function. Also the MDD patients with MCI shown moderate (65% patients) impairment of cognitive function. After termination of therapy 27% patient still shown the sign of cognitive impairment after follow-up 6 week.

Conclusion : Based on preliminary research this study indicate that cognitive performance in these MDD patients with mild cognitive impairment is worsened on SRT therapy and marginally improved when they recover from depression. However, recovery from cognitive impairments due to depression may have a longer time course. Study is needed more research to confirm and widen these findings.

Abs.PH.21

Antiemetic Prophylaxis with Granisetron, Ondansetron and Metoclopramide in Laparoscopic Cholecystectomy: A Comparison

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Objective : Postoperative nausea and vomiting (PONV) is the most unpleasant and distressing consequence during laproscopic cholecystectomy. This study aims to evaluate and compare the efficacy patient acceptance and side effects of granisetron, ondansetron and metoclopramide as prophylactic antiemetic for laproscopic cholecystectomy.

Method : 75 patients of ASA grade I and II in the age group 20-60 yrs undergoing laproscopic cholecystectomy under GA were randomly assigned in a double blind manner into 3 equal groups. Group A received 10 mg Metoclopramide; Group B received 4 mg ondansetron; Group C received 3 mg granisetron. All the drugs were given through slow intravenous injection diluted in saline

over 5-10 min. before induction of anaesthesia. Episode of nausea and vomiting were recorded in the first 24 hours post operatively at the intervals of 0-2, 2-6, 6-12,12-24 hrs. Pain was assessed by visual analog scale (VAS) 0-10. Patient satisfaction with the study medication was assessed using a five point scale, 24 hours after the end of drug administration. The safety of study drugs were assessed by monitoring adverse effects throughout the 24 hour period. All the observation were compiled and statistically analyzed by one way- ANOVA, chi square test using (SPSS 6.0).

Results : Among 75 patients, 65 were female and 10 were male (Table: 2). Patients in all three groups were statistically comparable. As prophylactic antiemetic granisetron was more significantly efficacious than ondansetron and metoclopramide in between 2-12 hours. Similar result was seen in the satisfaction score. There was no statistically difference in VAS pain score. There were no major adverse effect observed in 24 hrs post-operative period. Common minor adverse effect was dizziness and mild constipation.

Conclusion : The *results* of our study revealed that in the management of PONV, Granisetron was more effective than Ondansetron and Metoclopramide. Therefore.

Abs.PH.22

To Study the Compliance to Medication of Patients Visiting the COPD Clinic in a Tertiary Care Hospital

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Objective : Non Compliance in patients with COPD (Chronic Obstructive Pulmonary Disease) to the medication can result in worsening of the disease and increases the hospital admissions. The study aimed at examining the dimensions of compliance to the medication, life style and smoking cessation in COPD patients.

Method : It was a tertiary care hospital based open labeled questionnaire based 6 months study. The data of total of 60 patients was collected who met the inclusion criteria, gave the written consent to participate and completed the study. A pre validated questionnaire comprising of 15 questions was administered at 0 week, 2 weeks and at 6 weeks to assess the compliance of patients to the medication, life style modification and to quit smoking in smokers.

Results : Clinical and demographic data was assessed. Eighty percent of the patients were of rural origin. Overall compliance of the patients was 74%. Ninety % of the patients took the prescribed oral drugs in correct dose, correct timings and 77% visited the hospital as being told. Only 36% of the patients were compliant to the use of inhaler at the first visit which improved to 59% with time. Most of the pts were satisfied with the treatment, life style changes related to diet and exercise were followed by 32% patients. 65% of the patients were aware to quit the smoking and only 19% of them quitted.

Conclusion : Although the compliance levels

with the oral medication were acceptable but with the use of inhaler were low. In order to improve compliance levels education regarding the use of inhalers and counseling to quit smoking are recommended.

Abs.PH.23

Role of Edaravone as a Free Radical Scavenger in Conservative Management of Severe Head Injury Patients

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Objective : To study the effects of edaravone, a free radical scavenger, in patients with severe head injury, managed conservatively, in neurosurgery unit of a tertiary care center in Uttarakhand.

Method : Patients with Glasgow coma scale (GCS) <8 requiring conservative therapy were divided into two groups of 25 patients each, one group administered edaravone 30 mg i.v over half an hour; twice a day for 14 days with standard therapy while the other group received standard therapy alone. The primary efficacy points, GCS & Rankin scores, & the secondary efficacy parameters, Glasgow coma outcome score (GOS), were evaluated at 0 week, 2nd week & 12th week of initiation of therapy. Safety & tolerability was evaluated by actively recording the adverse events in both the groups for the duration of the study.

Results : Significant improvement was seen in GCS (P<0.05) & Rankin scores (P<0.01) at the end of 3 months period with edaravone than standard therapy alone. The secondary efficacy point (GOS) also showed better improvement 3 months after the initiation of therapy (P<0.01). Adverse events were evenly distributed in both the groups & showed no statistical difference.

Conclusion : Edaravone, a free radical scavenger, was associated with a better neurological outcome & improved disability in patients with severe head injury thus proved to be an effective add on therapy to standard therapy for such patients in this trial.

Abs. PH.25

Prulifloxacin : Better Option for the Treatment of Uncomplicated Enteric Fever

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Objective : To compare the effectiveness of Prulifloxacin with that of Azithromycin/ Cefixime in treatment of uncomplicated enteric fever.

Method : The present study was conducted on total no. of 174 patients of proved enteric fever attending the out patient department of medicine at Subharti Medical College and associated Hospital, Meerut. Total no. of patients were divided in to three groups- 59 in Group A received Tab. Prulifloxacin 600

mg OD, 58 in Group B received Tab. Azithromycin 500 mg BD and 57 patients in Group C received Tab. Cefixime 200 mg for total of 5 days.

Results : The primary outcome response fever clearance time (FCT) was 3.90 ± 0.86 days in group C (Cefixime), 3.77 ± 0.73 days in Group B (Azithromycin) and 2.86 ± 0.92 days in Group A (Prulifloxacin) ($P < 0.001$). In secondary outcome response, overall treatment failure (acute treatment failure and relapse) rate was 35.0% in Group C (Cefixime), 22.4% in Group B (Azithromycin) while in Group A (Prulifloxacin) it was only 11.8%. ($P < 0.001$) None of patients developed any complication during study period. No serious side effects were noticed in any of the studied groups.

Conclusion : It is been concluded Prulifloxacin is a better drug of choice for the treatment of uncomplicated enteric fever.

Abs.PH.26

Assessment of Incidence and Severity of Adverse Drug Reactions to Antiretroviral Treatment in a Tertiary Care Hospital

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Objective : With the increase in the incidence of HIV in India, use of antiretroviral therapy (ART) is also steadily rising. This study was conducted to detect the incidence and severity of adverse drug reactions (ADRs)

with ART in a tertiary care setup in North India.

Method : All HIV patients presenting to ART center, Safdarjung Hospital, New Delhi and receiving ART were followed up for a period of 6 months for assessment of ADRs, as part of an intensive monitoring pharmacovigilance study.

Results : Intensive monitoring detected 140 (27.34%) ADRs in 512 patients. Average age of the patients was 36.2 ± 9.93 years and 101 (72.1%) were males. Median CD₄ count was 160 cells/ μ l. The most common systems involved were gastrointestinal 50.7% (n=71), cutaneous 26.4% (n=37), systemic 12.1% (n=17) and nervous system 9.3% (n=13). Suspected drugs were zidovudine 74.3% (n=104), nevirapine 15.7% (n=22) and stavudine 7.1% (n=10). Median time to onset of ADRs was 41 days and median duration of ADRs was 1 day. Some form of intervention was required in 97.1% (n=136) and 71.4% (n=100) of cases had severe reactions. Multivariate logistic regression revealed that independent risk factors for development of severe reactions were CD4 levels less than 200 ($P = 0.042$) and involvement of GI system ($P < 0.001$). Causality assessment showed that 17.1% (n=24) were definitely related and 35.7% (n=50) were probably related to the suspected drug. The ADRs were preventable in only 6.4% (n=9) of patients.

Conclusion : Adverse reactions associated with ART commonly involved the gastrointestinal and cutaneous system and some form of intervention was required in most cases. CD4 levels less than 200 cells/ μ l and involvement of GI tract were associated with severe reactions.

Abs.PH.27

Perception of Treatment Providers to Adverse Drug Reporting in a Medical College of North India

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Objective : WHO advocated the use of pharmacovigilance for improving the patient safety and public health in relation to use of medicines. The aim of this study is to investigate the knowledge and attitude of Doctors in a teaching hospital about pharmacovigilance and to suggest possible ways of improving ADR reporting.

Methods : A questionnaire was designed and sent to the interns, postgraduate students and faculty doctors of various departments. The questionnaire sought the demographics of doctors, their level of education, training in pharmacovigilance, knowledge, attitude in pharmacovigilance. Provision was also made for suggestion to improve the drug safety.

Results : The response rate was 99%. Most of the respondents (77.85%) have knowledge about the pharmacovigilance. But only 39.55% of the respondents were aware about National Pharmacovigilance Program. None of the respondents had ever reported any ADR's under National Pharmacovigilance Program; only two of the respondents had reported ADR's as case reports in journals. Education and training was suggested by 99% of the respondents to improve ADR's reporting.

Conclusion : The knowledge of ADR's reporting and National Pharmacovigilance Program is inadequate among doctors working in a teaching hospital. The integration of the policy makers and health care professionals with dissemination of the knowledge among them would certainly help to improve practice of pharmacovigilance.

Abs.PH.28

Renoprotection by Lacidipine in Experimental Diabetic Nephropathy

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Objective : To Study the preventive effects of lacidipine (a DHP type, Ca²⁺ channel blocker) in STZ induced diabetic nephropathy in rats.

Method : Albino rats (250-300 g) of either sex were used. Diabetic nephropathy (DN) was induced by injecting STZ (50 µg/kg, iv). Animals were divided in to 4 groups of 10 each. Group I - Control, Group II - Diabetic control (STZ), Group III - Lacidipine (0.5 mg/kg, po, 5 days prior to STZ & continued for further 12 weeks. Group IV - Insulin + STZ. *Results* were confirmed biochemically (Blood/urine sugar, blood urea, serum creatinine & urinary protein) as well as histologically. After 12 weeks histological study was performed by standard technique.

Results : Biochemical parameters in lacidipine pretreated rats showed beneficial effects. Severe and gross histological changes in the

kidney section of STZ diabetic rats (diffuse sclerosis with nodules, swelling & vacuolization of epithelial cells. Fibrin caps present in basement membrane. BM thickening, segmental sclerosis. In lacidipine pretreated rats kidney section showed mild, focal glomerular sclerosis & mild inflammatory changes.

Conclusion : Biochemical and histological *results* demonstrate preventive effect of lacidipine in STZ induced diabetic nephropathy.

Abs.PH.29

Hepatocytes Isolated from Steatotic Rat Liver are more Susceptible to the Toxic Effect of Acetaminophen *In Vitro*

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Objective : Acetaminophen (APAP) overdose is the most common cause of acute liver failure in humans, and non-alcoholic fatty liver disease (NAFLD) is one of the most frequent chronic liver diseases in the world. The aim of our work was to compare the effect of APAP on intact rat hepatocytes and hepatocytes isolated from steatotic liver in primary cultures.

Method : Male Wistar rats were fed by standard diet (ST-1, 10% energy from fats) or high-fat gelled diet (HFGD, 70% energy from fats) for 6 weeks. Hepatocytes were isolated by

two-step collagenase perfusion and then cultured in William's E medium in a gassed atmosphere (5% CO₂) on collagen-coated plastic dishes. After cell attachment, APAP at concentrations of 1; 2.5; 3.75 and 5 mmol/l was added to culture media for up to 24 hours. The statistical significance was analysed using one-way ANOVA followed by Tukey-Kramer's post-hoc test.

Results : APAP causes more severe dose-dependent damage of steatotic hepatocytes in primary culture as documented by increased release of lactate dehydrogenase (LDH) to culture medium and LDH leakage, decreased activity of cellular dehydrogenases (WST-1 test) and reduced albumin production (ELISA). MDA production (TBARS) and ROS formation (DCFDA) were also significantly increased in steatotic hepatocytes treated with APAP. Intact steatotic hepatocytes contained lower amount of GSH (P<0.05, vs. controls). APAP (1; 2.5 and 3.75 mmol/l) caused more pronounced decrease in GSH in steatotic hepatocytes compared to non-steatotic hepatocytes.

Conclusion : Our *results* indicate that steatotic hepatocytes exert higher sensitivity to the toxic action of APAP. This sensitivity may be caused by lower content of GSH in intact steatotic hepatocytes and by more pronounced APAP-induced decrease in intracellular concentration of GSH, higher lipoperoxidation and higher production of ROS in steatotic hepatocytes.

Abs.PH.30

Anti-inflammatory Effect of Artesunate in Carrageenan Induced Paw Edema Model

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Objective : The present study was carried out to evaluate the anti-inflammatory property of artesunate.

Method : Edema was induced in the hind paw of rat by sub-planter injection of 0.1 ml of 0.5% of carrageenan. The paw volume was measured with the help of plethysmometer before and 3 hour after inducing edema and the edema volume was calculated. Artesunate was administered orally 1 hour before injecting carrageenan at the doses of 50 and 150 mg/kg and the % inhibition was calculated with respect to control. The effect was compared with diclofenac (5 mg/kg).

Results : Artesunate, an anti-malarial drug produced a dose – dependent inhibition of paw edema induced by carrageenan and its effect was comparable to standard anti-inflammatory drug diclofenac.

Conclusion : The present study shows that artesunate has the potential to be used in the treatment of various inflammatory disorders.

Abs.PH.31

Effect of Vincristine on Gastric Emptying in Albino Rats

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Objective : The present study aimed to see if the presence of the alkaloids in the gut lumen by itself influences the gastric emptying or it influences the gastric emptying only through its presence in the circulation.

Method : The experiments were performed on adult wistar albino rats. Wistar albino rats bred and raised under standard lab condition. The animals were given vincristine by intragastric Administration in varying doses. And gastric emptying was assessed by barium meal technique at various time intervals following the administration of dose of vincristine.

Results : The observation suggests that vincristine by its presence in gastric lumen or small intestine might influence gastric emptying. Gastric emptying is delayed due to the administration of vincristine.

Conclusion : Thus, after this experiment we conclude that vincristine might influence the gastric emptying while in circulation and also its presence in gut lumen.

Abs.PH.32

Role of Saccharomyces Boulardii in Prevention of Beta-Lactam Induced Diarrhoea

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Objective : The study was carried out to assess the role of Saccharomyces boulardii in

preventing diarrhoea occurring as a side effect of commonly prescribed beta lactam antibiotics.

Method : Prospective, randomized, open parallel clinical trial was done to evaluate the role of administering *Saccharomyces boulardii* prophylactically to prevent β lactam antibiotic induced diarrhoea. [>3 mushy loose stools in a day]. 300 children in the age group 6 month – 2 yrs were included in the study and divided into two groups – Control [receiving only antibiotic] and Test [receiving antibiotic +S *boulardii*], each having 150 patients. The patients were given beta lactam antibiotics for various ailments like URTI, Otitis media, Tonsillitis, UTI, etc. The drugs were given for seven days and a follow up was done for one week. Patients already having diarrhoea were excluded from the study.

Result : 36 [24%] out of 150 patient in control group developed diarrhoea whereas only 8 [5.3%] out of 150 in test group developed diarrhoea. The *results* were statistically significant. ($P < 0.001$) as calculated by Chisquare test.

Conclusion : *Saccharomyces boulardii* was effective in preventing β lactam induced diarrhoea in children. Hence it can be used prophylactically to prevent AAD in children.

Abs.PH.33

Estimation of Lethal Doses of Acyclovir, Insulin And Ondansetron on Developing Chick Embryo

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Objective : The insulin & ondansetron are widely used by pregnant women. Similarly intake of acyclovir is also not so uncommon among gravid ladies. There is dearth of published data as far as lethal doses of acyclovir and ondansetron related to developing chick embryo is concerned. So it is thought pertinent to conduct such study to estimate lethal doses for these drugs. Special stress was laid on estimation of median lethal doses for these drugs. Study also aims in estimating other measures of toxicity for chick embryo as Lowest published toxic concentration (TCLo), Lowest published lethal dose (LDLo), No Observable Adverse Effect Level (NOAEL), Lowest Observable Adverse Effect Level (LOAEL).

Method : Total of 96 eggs were used with prior permission from institutional ethics committee. These were divided into 4 major groups (one each for Insulin, Ondansetron, Acyclovir & control). These major groups were further sub divided into minor groups on the basis of doses of drugs are concerned. The different doses of drugs were injected on 3rd day of incubation. The hatched eggs were dissected out on 19th day to check mortality and other gross malformations if any.

Results : Cent percent mortality was seen in group injected with 2 mg of ondansetron. The dose 5IU of insulin was estimated as lethal dose for developing chick embryo and the dose was estimated as estimated as lethal dose for developing chick embryo. Similar observations for acyclovir were also done

which matches with data already published.

Conclusion : The data thus obtained will be of utmost utility because of paucity of references for further researchers. Detailed histological & histochemical study will add more knowledge in discovering intricacies & relevant use of these drugs.

Abs.PH.34

Study of Visual Reaction Time among Basketball Players

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Objective : To find out the visual reaction time in healthy controls and in basketball players. To compare visual reaction time of healthy controls and basketball players. To find out any difference and if present, its statistical significance and to analyze for observed facts.

Method : Sample included 100 participants aged 15-25 years, which were divided into two group. Group-1 has 50 basketball players and group 2 has 50 healthy controls. This study was done under three modules. 1st module contains detail medical history of participants. The medical history was taken to rule out any medical or surgical diseases which would affect reaction time of individual. 2nd included recording of visual reaction time in healthy controls and basketball players with the reaction time instrument which has resolution of 0.001 second. The visual reaction times were measured under two categories. (1) Simple reaction time task (2) Choice reaction time task. 3rd module

consisted of the statistical analysis of the reaction time measurements. The reaction time were taken as mean & standard deviation. The level of significance between basketball players and controls were tested by the student's t-test (unpaired). The observation was taken as significant if P-value <0.05.

Results : Simple visual reaction time found be less than choice visual reaction time in healthy controls as well as in basketball players. Basketball players were found to have faster reaction time than controls. The quicker reaction time in basketball players as compared to controls is due to improved concentration, alertness, better muscular co-ordination and improved performance in the speed and accuracy task.

Conclusion : The study shows that basketball players show faster reaction time than healthy controls. As reaction times gives the information how fast a person gives a response to stimuli, it is a good indicator of performance in reactive sports like basketball.

Abs.PT.01

Effect of Herbal Preparation on Radiation Induced Skin Injury

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Objective : To study the effect of herbal preparation on radiation induced skin injury in patients with head and neck carcinoma.