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ADVERSE DRUG REACTION REPORTS: SEPT - DEC 2014

A total of 1014 Adverse Drug Reactions (ADRs) were reported or detected by the Department of Clinical Pharmacy during September to December 2014. The following are some of the suspected ADRs that were either reported to or detected by the Department of Clinical Pharmacy. In most of the cases there was a change in drug therapy e.g. cessation of suspected drug or reduction in dose, and/or either specific or symptomatic treatment for the suspected ADR.

	Tachycardia
	Pityriasis rosea
	Syncope
	Moniliasis
······	Ichthyosis
	Wheals
·····	Leukocytoclastic vasculitis
	Neutropenia
	Tingling sensation
	Somnolence
	Sialorrhea
	Back pain
	Pancytopenia
	Dyspnoea
	Fatigue

Olanzapine Induced Sialorrhea: Though the physiological mechanism of olanzapine induced hypersalivation (Silorrhoea) is unclear, salivary flow depends upon balance of parasympathetic and sympathetic input on salivary glands. The parasympathetic nervous system acts via cholinergic input on M3 muscarinic receptors resulting in copius watery saliva, whereas sympathetic nervous system acts via nor-epinephrine input on alpha receptors resulting in proteinacious salivation. Treatment strategies for sialorrhea includes alpha-2 agonists such as clonidine or antimuscarinic agents such as benztropine.

Temozolomide Induced Pancytopenia: Temozolomide (TMZ) is an alkylating agent, giving rise to methylation at O6 position of guanine in DNA, thereby exerts anti-tumour effect on tumor cells. However, the tumour is effectively repaired by a DNA enzyme repair method O6 methyl guanine DNA methyl transferase (MGMT) it resulted in sensitivity to TMZ in glioblastomamultiforme. TMZ use results in lack of MGMT promoter methylation which leads to myelosupression and pancytopenia.

Topiramate Induced Fatigue: Topiramate, a sulfamate substituted monosaccaride, is a very effective antiepileptic agent. The efficacy and safety profile (such as renal stone formation and fatigue, anorexia) of topimirate is due to its inhibitory effect on carbonic anhydrase enzyme. Carbonic anhydrase inhibition causes a series of electrolyte changes at the renal level, a net loss of bicarbonate occurs, leading to rise in urinary PH. The renal loss of bicarbonate causes a decrese in serum bicarbonate levels, which can cause metablic acidosis, subsequently, as a compensatory mechanism the level of serum ion or potassium ions may increase or decrease the levels of serum chloride.

We encourage you to report all suspected adverse drug reactions to Department of Clinical Pharmacy. Adverse drug reaction reporting forms are available at all nursing stations. Alternatively you may call Department of Clinical Pharmacy on 2335555 Extn. 5577 or SMS to 07411137840 (Format: ADR/IP or OP Number/Name of the patient/Ward).

Effects of Inhaled Corticosteroids on Growth of Asthmatic Children

According to the findings of two Cochrane Systematic Reviews published recently, Inhaled Corticosteroids (ICS) may suppress the growth of the children with asthma in the first year of treatment, but lower doses may minimize the effects. ICS are the most effective drugs for asthma control, reducing asthma mortality, hospital visits, and exacerbations while improving quality of life. Although they are generally considered first-line treatment for persistent asthma, their potential effect on childhood growth was previously undefined, and the potential for growth retardation and other systemic adverse effects continues to be a matter of concern. Of the seven ICS currently available worldwide (beclomethasone, budesonide, ciclesonide, flunisolide, fluticasone, mometasone, and triamcinolone), ciclesonide, fluticasone and mometasone are newer and are thought to have a better safety profile.

A review published by Zhang L, et al. suggests that children treated daily with ICS may grow approximately half a centimetre less during the first year of treatment compared with placebo or nonsteroidal drugs. But this effect is less pronounced in subsequent years, is not cumulative, and seems minor compared to the known benefits of the drugs for controlling asthma and ensuring full lung growth. Authors included 25 trials in their review. The trials enrolled a total of 8471 participants aged 18 years or younger who had mild to moderate persistent asthma treated with any of the available

inhaled corticosteroids except for triamcinolone. Fourteen of these trials, enrolling a total of 5717 children, reported on growth over the course of a year.

A review by Pruteanu AI, et al. included 22 trials of low or medium doses of inhaled corticosteroids in children, with data on different doses of all drugs except triamcinolone and flunisolide. Of three trials reporting follow-up for at least 1 year in a total of 728 children, one tested 3 different dosing regimens. All the 3 trials showed that reducing the inhaled corticosteroid dose by about one puff per day was associated with improved growth by a quarter centimeter at one year. Authors recommend that the minimal effective dose be used in children with asthma until further data on doses becomes available.

References:

- 1. Zhang L, Prietsch SOM, Ducharme FM. Inhaled corticosteroids in children with persistent asthma: effects on growth. *Cochrane Database of Systematic Reviews* 2014, Issue 7.
- 2. Pruteanu AI, Chauhan BF, Zhang L, Prietsch SOM, Ducharme FM. Inhaled corticosteroids in children with persistent asthma: dose-response effects on growth. *Cochrane Database of Systematic Reviews* 2014, Issue 7.

Can Osteoporosis Medication Lower Fracture Risk?

Several osteoporosis medications like bisphosphonates, denosumab, teriparatide and raloxifene are able to reduce fracture risk in individuals with bone density in the osteoporotic range and/or preexisting hip or vertebral fracture, according to an updated systematic review published recently in the Annals of Internal Medicine. The authors screened 52,000 titles, 315 articles were included in this update and found very few head-to-head comparisons between different medications used to treat osteoporosis. On the basis of that trial and on the observational study data that are available, this study estimate that bisphosphonates, denosumab and teriparatide treatment result in a risk reduction for vertebral fractures of 0.40 to 0.60 relative to placebo. The relative risk reduction for nonvertebral fractures was 0.60 to 0.80. Raloxifene has only been demonstrated to reduce vertebral fractures. In other words, they estimate 60 to 89 patients need to be treated with a bisphosphonate, denosumab, teriparatide, or raloxifene to prevent one vertebral fracture over the course of one to three years of treatment. Fifty to 60 patients need to be treated with a bisphosphonate, denosumab, or teriparatide to prevent a single nonvertebral fracture.

Major limitation in this systematic review is that it does not reflect data for women who are older than 80 years.

Approximately 75% of osteoporotic fractures occur in patients who are 65 years of age or older, and many of these patients are older than 80 years. Although this information is helpful to guide clinicians and their patients, it is advised that the clinicians should recognize that these conclusions may not apply to patients aged 75 years or older and especially not to those aged 80 years or older with nonskeletal risk factors for falls. Such patients are insufficiently represented in the clinical trials of pharmacologic treatments for fracture prevention included in this careful evidence review.

However, a paucity of comparative studies makes it difficult to determine the relative effectiveness of the medications. The ongoing Vertebral Fracture Treatment Comparisons in Osteoporotic Women (VERO) study will be completed in 2016, however, and the resulting data should shed some light on the relative efficacy and safety of the different options.

Reference:

Crandall CJ, Newberry SJ, Diamant A. Comparative Effectiveness of Pharmacologic Treatments to Prevent Fractures: An Updated Systematic Review. *Ann Intern Med* 2014;161(10):711-23

DEPARTMENT ACTIVITIES

Pharmacy Practice Preceptor Development Program

Indian Association of Colleges of Pharmacy (IACP) and JSS University, Mysore jointly organized Pharmacy Council of India (PCI) sponsored Pharmacy Practice Preceptor Development Program from 15-17 September 2014 at Sri Rajendra Centenary Auditorium, JSS Hospital, Mysore. The theme of this program was "Preparing Effective Advanced Pharmacy Practice Educators". The Programme was inaugurated by Prof. K. Chinnaswami, President, Indian Association of Colleges of Pharmacy. Dr. B. Suresh, President, Pharmacy Council of India and Vice-Chancellor, JSS University was the chief guest of the function. The keynote address was delivered by Dr. K. Wayne Hindmarsh, Dean Emeritus, Ledlie Dan Faculty of Pharmacy, University of Toronto, Canada.

A total of 71 faculties from different pharmacy institutions located across India participated in the programme. During the three-days scientific session of the programme, various topics on preceptors' development were deliberated.

Dr. Krishna Kumar from Howard University, Washington DC, USA; Dr. Mark Decerbo from Roseman University of Health Sciences, Nevada, USA; and Dr. Elizabeth Sherman from Nova Southeastern University, Florida USA were the resource persons. During the three-days of training program, participants had opportunities to learn various aspects on preceptorship like roles and responsibilities of preceptors during internship, developing learning outcomes of clinical rotation(s) and its evaluation during internship, methods to support slow learners and hands on preceptor training in few clinical specialties like Acute care setting, Infectious diseases, Nutritional care and Neurology.



Inauguration of Preceptor Development Program

Faculty Participated in International Training Course in Pharmacovigilance

Dr. Justin Kurian, Lecturer, Department of Pharmacy Practice, JSS College of Pharmacy, Mysore had attended 16th International Training Course on Pharmacovigilance -The Study of Adverse Drug Reactions & Related Problems held at Uppsala Monitoring Centre (UMC) - WHO collaborating centre for international drug monitoring, Sweden during 7th to 21st May 2014. He received a special fellowship of Rs. 350000 from UMC for attending this training program. The Department of Clinical Pharmacy actively involved in the medication monitoring program at JSS Hospital, Mysore and the hospital is identified as the one of the adverse drug reaction monitoring centre (AMC)

and also southern regional resource centre for training and technical support under Pharmacovigilance Programme of India (PvPI), Ministry of Health & Family Welfare, Government of India which works in association with UMC.



Guest Lectures

The Department of Pharmacy Practice in association with Indian Pharmaceutical Association, Mysore Branch organised a guest lecture on the topic 'Collecting Pebbles from the Shores of Pharmacology' on 6th November 2014. **Dr. B. R. Sainath Iyer**, Retired Professor of Pharmacology from Kesar Sal Medical College, Ahmadabad, Gujarat deliverd the lecture. During his talk, Dr. Sainath Iyer has highlighted the importance of medication safety and value based education in the current day scenario. Also, he briefed about the extent of association of iatrogenic diseases with the modern medicine system and the role of Clinical Pharmacist in preventing iatrognic diseases. Also, he stressed on the importance of bridging the gaps between various health care systems to give the optimum and safe medication care to the patient. Sixth Pharm.D students, postgraduate students and research scholars of Pharmacy Practice and Pharmacology Department attended the lecture.

Dr. Deepti Vyas, Assistant Professor, Department of Pharmacy Practice, University of Pacific, USA visited the Department of Pharmacy Practice and interacted with students and staff of the department. Also, she delivered a guest lecture on 'Clinical Pharmacy Practice in USA' to Pharm.D studentson 9th December 2013. During her lecture, Dr. Deepti highlighted about the clinical pharmacy practice at University of Pacific and how it is useful in improving the patient care.





Participation in the Forensic Fare

The Department of Pharmacy Practice took an active part in the one-day long Forensic Fare organized by Department of Forensic Medicine, JSS Medical College, Mysore in association with Karnataka State Police Academy, Mysore held on 16th November 2014 at JSS Medical College, Mysore. The Drug & Poison Information Centre located at Department of Clinical Pharmacy, JSS Hospital, Mysore opened a stall on "Poison Information Center" and created awareness amongst the public about the Poison Information Centre's facility (including Toll Free Number), services and its accessibility. Also, public were educated regarding the safe handling of pesticides, prevention of accidental poisoning, and first aid measures during the fare.



Abstracts of Pharm.D. Project Work

Assessment of risk of diabetes mellitus associated with the use of statins

A cross sectional study was conducted to assess the risk of development of Diabetes Mellitus (DM) among statin users and also to investigate the impact of different statins and their doses on this association. A total of 1715 patients were included in the study. After adjustment for basic demographics and co-morbid conditions, statin use was associated with 11% increased risk for development of DM (RR 1.11, 95% CI 1.00-1.29). On subgroup analysis, increased risk of diabetes mellitus was specifically observed for statin user since 5 - 9.9 years (RR 1.09, 95% CI 1.01-1.24), rosuvastatin (RR 1.14, 95% CI 1.02-1.39) and high doses (40 & 80 mg) of atorvastatin (RR 1.15, 95% CI 1.04-1.47). The study concluded that statin use was associated with significant increased risk for development of new onset DM. Increased risk was observed in current statin users, statin users since five to ten years, rosuvastatin and high dose of atorvastatin users. Alina Mary Antony, Ashok R, Bodala Swathi

Utilization evaluation of anti-emetics in chemotherapy induced nausea and vomiting in oncology hospital

A study was conducted at Speciality Cancer Hospital to assess utilization pattern and appropriateness of anti-emetics in chemotherapy induced nausea and vomiting in patients with breast cancer. Of the 316 patients' record reviewed, majority (74%) of them were prescribed with drugs which are highly emetogenic followed by 17% of them with moderately emetogenic and 9% of them with low emetogenic potential. Overall, selection of anti-emetic regimen was inappropriate for 32% (n=112) of patients. Dosage, frequency and duration of antiemetic use were inappropriate in 18%, 38% and 8% respectively. It was observed that the anti-emetics used in chemotherapy induced nausea and vomiting were not compliant with national comprehensive cancer network (NCCN) guidelines. Many patients received same treatment for highly emetogenic drugs and moderately emetogenic drugs. Cost of drug was influencing factor in selection of an appropriate anti-emetics. Administration of anti-emetics can be improved by proper training of nursing staff. Bolla Naresh Babu, Davan Bevoor, Edara Amarendra Chowdary

Assessment of prescribing pattern of topical corticosteroids in dermatology practice

A prospective observational study was carried out to assess prescribing pattern of topical corticosteroids and also the cost associated with the use of topical corticosteroids in the dermatology practice. Forty-one percentage of prescriptions contained topical corticosteroids. The most commonly prescribed topical corticosteroids were intermediate potent steroids in both inpatients (54.54%) and outpatients (39.02%). In 27.71% of cases, combinations of topical corticosteroids were prescribed. The average cost per prescription of topical corticosteroids in outpatients and inpatients was found to be INR 96.56 and INR 79.66 respectively. It was observed that the prescribing information was adequate in majority of the cases. The prescription pattern may be affected due to the availability of preparation of topical corticosteroids in the hospital pharmacy and the individual choice of the dermatologist. Bhawana G, Mounika Tejaswi G, Sushma G, Jibin Jacob

Active surveillance of adverse drug reactions (ADRs) in hospitalized paediatric patients

A prospective, observational study was conducted with the aim of determining the incidence, pattern, predictability, preventability, severity, predictors and direct cost associated with the management of adverse drug reactions (ADRs) in paediatric population. A total of 64 ADRs were identified from 54 patients, and the incidence of ADRs in hospitalised paediatric patients was 4.99%. Majority (68.52%) of patients who experienced ADRs were male. Drugs most commonly implicated in ADRs were Amoxicillin + Clavulanate (21.87%) followed by Ceftriaxone (20.31%). Most (51.56%) of the reported ADRs belonged to the gastrointestinal system disorders. Majority (87.5%) of the reactions were of probable in their causality category. Among the ADRs reported, 82.85% of ADRs were of mild in their severity. Majority (89.1%) of the ADRs was found to be 'predictable' and 96.9% were not preventable. Serious adverse reactions accounted for 3.13%. There was a significant association between occurrence of ADRs and the use of ≥ 4 number of medications, age (infants) and gender (male). The total and average cost incurred in the management of ADRs was INR 6295 and INR 169.8 respectively. Jinu, Jintu, Chaithanya KRK, Sowjanya K

Assessment of usefulness of patient information leaflets among patients with chronic diseases - A randomized study

A prospective, randomized, interventional study was conducted over a period of six months to assess the usefulness of the patient information leaflets (PIL) in patients with selected chronic diseases. At baseline, knowledge, attitudes and practice (KAP) of patients towards their disease management was assessed using suitably designed KAP questionnaire. After one month follow up, post education KAP scores were assessed. Usefulness of the leaflets was assessed using Patient Information Leaflet Usefulness Assessment Questionnaire (PILUAQ). It was observed that patient education with information leaflets have a significant (p<0.05) impact on KAP of the diabetic and hypertensive patients. By applying PILUAQ it was found that the leaflets are useful to the general population. The study concluded that the use of PILs and counseling showed a significant improvement in KAP scores in the study populations. Lisa Sara Abraham, Mini Johnson Christudas, Niphy Annie Varghese, Noel. M. Isaac

Study of health related quality of life in rheumatoid arthritis patients

A prospective interventional study was conducted to study of Health Related Quality of Life (HRQoL) in Rheumatoid Arthritis (RA) patients. A total of 105 patients who met the study criteria were enrolled in to the study. Among the total number of patients, 47 (44.7%) patients were newly diagnosed RA during our study. The female gender [85 (80.95%)] was three folds predominant than the male gender [20 (19.05%)]. The overall HRQoL based on Health Assessment Questionnaire (HAQ) in early RA and old RA patients were found to be 4.13±1.53 and 3.61±1.83 respectively. The early RA patients had a mild to moderate disease activity with Disease Activity Score 28 (DAS28) mean score as 5.1±1.2. The old RA patients had a DAS28 mean score of 6.44±0.82 with moderate to severe (no response) disease activity. Also, a statistically significant (P<0.05) correlation between the HAQ, Morisky Medication Adherence (MMA) and DAS questionnaires was observed in the study. The study concluded that the early RA patients had a 'mild to moderate' disease activity with 'good to fine' mental health. The old RA patients had 'moderate to severe' disease activity with 'fine to bad' mental health. The HRQoL (by HAQ) was found to be directly proportional to disease activity (by DAS 28) and indirectly proportional to medication adherence (by MMA). Rovin, Rakshitha, Preethi, Tejaswini

Initiation & evaluation of patient reporting adverse drug reactions in outpatient department of JSS hospital

A prospective observational study was conducted in the out patient department of General Medicine in a tertiary care hospital which was intended to initiate & evaluate patient reporting of suspected adverse drug reactions (ADRs) in an ambulatory care setting. During the study period, 1125 patients were enrolled. Of which 128 patients reported 95 ADRs [response rate 8.44%]. The mean age of the study population was $50.14\% \pm 16.39$ years. The number of females [54 (57%)] reporting ADRs was found to be higher than males [41 (43%)] [P=0.001]. Maximum number of reports were obtained from

patients in the age group of 40-60 years [38 (40%)]. It was also observed that the number of reports were more as the education was higher [UG 38.8%]. Gastrointestinal Disorders [34 (35.78%)] and Skin & Appendages [22 (23.10%)] were the most commonly implicated system organ class. A comparison of the Modified Hartwig & Siegel plot of patient reported ADRs with that of physician reported ADRs reveals that health care professionals report mainly Moderate (57.57%) reactions in contrast to patient reports which included Mild reactions more often (66.15%). However, Paired T-test determined this difference is not significant (P=0.986). *Rohith P, Pranav Varma, Gokul Raj P, Rakshith UR*

Study of anti-hypertensives among patients visiting nephrology out-patient department

This study was conducted among patients visiting nephrology outpatient department of JSS Hospital, Mysore to assess the optimal lowering of blood pressure with anti-hypertensives and the factors associated with worsening of renal function. Of the 251 patients enrolled in the study 177 were males. The mean GFR of study population was 22.54 ± 15.68 ml/min and majority of patients received three drug combination (32.66%). Calcium channel blockers had a significant systolic blood pressure (SBP) reduction of 7.93 mmHg (p<0.01) and diastolic blood pressure (DBP) of 0.79 mmHg when used alone. Among dual therapy, calcium channel blockers plus beta blockers (BBs) had a significant SBP reduction of 15 mm Hg (p<0.01) and DBP reduction of 10.58 mmHg. Among drug class combination used, triple therapy, CCB plus diuretics plus central sympatholytics had a significant SBP reduction of 22.26 mmHg (p<0.01) and DBP reduction of 8.20 mmHg. Among those who received two anti-hypertensives, significant SBP reduction of 14.25 mm Hg (p<0.01) and significant DBP reduction of 6.40 mm Hg (p<0.01) was achieved. Patients in stage 5 chronic kidney disease (CKD) had a significant SBP reduction of 18.80 mmHg (p<0.01) and DBP reduction of 6.79 mmHg. Medication adherence among study population found to be 10.6 % of low adherers, 24.3 % medium adherers, and 66.93 % high adherers by the end of the study when compared to baseline adherence. Among 46 hemodialysis patients, significant reduction of systolic blood pressure was observed from first to fifth visit (P<0.01). It was found that, calcium channel blockers were the most commonly prescribed anti hypertensive. All patients had significant blood pressure reduction irrespective of age, gender, disease condition and number of anti-hypertensives. Three drug combinations had a significant BP reduction. Among monotherapy, calcium channel blockers were found to be more effective in reducing blood pressure. Among dual therapy, calcium channel blockers and beta blockers followed by calcium channel blockers and central sympatholytics were found to be more effective. There was significant blood pressure reduction among CKD patients with stage 4 and 5 in comparison with all other stages. In hemodialysis patients, blood pressure reduction was significant at fifth visit (P < 0.05). Patients who scored high on the adherence scale were more likely to have their blood pressure under control compared with patients who scored medium or low. Noyal Mathew, Madhavi Sharma, Madhuri Reddy

Study of impact of health education on knowledge, attitude and practice related to dengue fever

A prospective, educational interventional study was conducted to assess the impact of education on Knowledge, Attitude and Practice (KAP) about dengue fever in patients suffering from dengue fever and also to assess the association of dengue fever KAP with demographic, socio-economic and literacy pattern. A total of 177 patients were enrolled in the study [107 (60.4%)] males and 70 (39.6%) females]. All the study subjects answered the pre and post education questionnaire. Analysis of data showed significant improvement in the mean knowledge score from pre to post- education (from 2.5 to 12.5). Similar significant improvement was found in attitude and practice regarding dengue fever with a score of 38.4 to 52 and 2 to 7 respectively. Both pre (27.9%) and post (73.8%) education KAP score was high in females when compared to males (24.11% and 69.2%). Similar results were found among the age groups where patients less than 20 years of age had greater KAP scores (pre-education -34.8 and post-education -73.2) when compared to other age groups. People with graduation level of education have high KAP in pre-education score of 36.4 and post-education score of 75.11 respectively. Also, significant (p <0.05) improvement between the total KAP score of pre-education (mean=24) and post-education (mean=72.5) for all the respondents. This study concludes that

Pharmacist mediated education has improved the patient's KAP about dengue fever and this in turn can lead to better adoption of measurements for prevention of dengue fever. Lalremruata, Bhanu Vaishnavi, Frency Susan Baby, Esther Laldinpuii

A study on assessment of knowledge on nutritional and dietary requirements in pregnant women

A prospective interventional study was conducted to assess the knowledge of pregnant women regarding nutritional aspects and provide them with information on maternal nutrition. A total of 90 pregnant women were enrolled and divided into control and test group by 'simple randomization' technique. The level of significance was measured statistically by performing paired t-test. There was a significant increase in score of test group (P < 0.05) over control group (P > 0.05) during the follow up visit. Also, there was an increase in knowledge in test group from 58.51% during the initial visit to 91.11% during the follow up visit i.e. after the trainee clinical pharmacist intervention. The significant increase in the total score obtained by the test group over the control group after the trainee clinical pharmacist intervention reveals that there was a significant increase in knowledge regarding maternal nutrition in pregnant women. Further studies can focus on creating awareness regarding maternal nutrition to pregnant women for increased health related aspects and better outcomes. Raghava Kalyan M, Yashaswini Y, Jack Jose

The Drug & Poison Information Service

Our Department can help you with any questions you might have on the use of medicines or the management of poisoned patients. We can also assist you with any medication related problems you face in your daily practice. The services are made available on all working days and it is provided at free of cost. We request you to avail the drug and poison information services.

Toll free - 1800-425-0207; 0821-2335555; Extn.5577; E-mail: dic.jsscp@jssuni.edu.in; pic.jsscp@jssuni.edu.in; Website: picjsscp.jssuni.edu.in

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