JSS University

Clinical Pharmacy

A Newsletter of Drug and Prescribing Information

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ADVERSE DRUG REACTION REPORTS: JAN- APR 2016

A total of 777 Adverse Drug Reactions (ADRs) were reported or detected by the Department of Clinical Pharmacy during January to April 2016. 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.

5-Fluorouracil	.....	Mucositis
Amlodipine *Plus* Atenolol	.....	Lichen planus
Aspirin *Plus* Clopidogrel	.....	Ecchymosis
Atorvastatin	.....	Gynaecomastia
Betamethasone	.....	Acniform eruption
Carbimazole	.....	Photocontact dermatitis
Ciprofloxacin	.....	Lymphadenopathy
Co-trimoxazole	.....	Steven Johnson Syndrome
Lidocaine	.....	Dysrhythmia
Metoclopramide	.....	Muscle rigidity
Rasagiline	.....	Postural hypotension
Rosuvastatin	.....	Hyperkalemia
Telmisartan	.....	Urticarial vasculitis
Tigecycline	.....	Abdominal pain
Trihexyphenydyl	.....	Hyperuricemia

5-Fluorouracil induced Mucositis

5-Fluorouracil (5-FU) is a commonly used drug for the treatment of malignant cancers. However, approximately 80% of patients undergoing 5-FU treatment suffer from gastrointestinal mucositis. 5-FU induced inflammation in the small intestine, characterized by the increased intestinal wall thickness and crypt length, the decreased villus height, and the increased myeloperoxidase activity in tissues and proinflammatory cytokine production in sera. Nuclear factor-KB (NF-KB) was the critical molecule associated with the pathogenesis of 5-FU-induced mucositis, and inhibition of NF-KB activity ameliorates the mucosal damage caused by 5-FU. 5-aminosalicylic acid inhibits 5-FU-induced NF-KB activation and proinflammatory cytokine production.

Metoclopramide induced Muscle Rigidity

Like anti-dopaminergic drugs, the antiemetic metoclopramide can also result in extrapyramidal side effects. The mechanism of action of metoclopramide on the lower esophageal sphincter (LES) muscle is a dose-related and increase LES muscle active tension. The maximal and submaximal LES muscle response to metoclopramide could not be antagonized by atropine/hyoscine. Metoclopramide do not augment the submaximal muscle responses to gastrin I, acetylcholine, or norepinephrine. Anticholinergic drugs are used to control neuroleptic-induced extra-pyramidal symptoms, although akathisia may require beta blockers or even benzodiazepines.

Telmisartan induced Urticarial Vasculitis

Angiotensin-converting-enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARB) along with thiazide diuretics (ex. telmisartan *Plus* hydrochlorothiazide) combination is a frequently prescribed antihypertensive in patients who do not achieve the desired effect after monotherapy. Henoch-Schönlein purpura, atypical lymphoid cutaneous infiltration, purpuric rash, urticaria with vasculitis or acute nephritis, and polycyclic rash with systemic illness, and urticaria with or without angioedema are infrequently reported cutaneous adverse effects with ARBs. The treatment includes drug which kill or decrease the function of immune system cells causing the inflammation. They include azathioprine, methotrexate and cyclophosphamide.

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)

DRUGS APPROVED BY US FDA: JAN - APR 2016

DRUG	BRAND	USE
Dermatology		
Ixekizumab	Taltz	For the treatment of plaque psoriasis
Hematology		
Coagulation Factor IX (Recombinant), Albumin Fusion Protein	Idelvion	For the treatment of hemophilia B
Antihemophilic Factor (Recombinant)	Kovaltry	For the treatment of hemophillia A
Venetoclax	Venclexta	For the treatment of chronic lymphocytic leukemia with 17p deletion
Hepatology		
Defibrotide sodium	Defitelio	For the treatment of hepatic veno-occlusive disease with renal or pulmonary dysfunction following Hematopoietic stem cell transplantation (HSCT)
Elbasvir and grazoprevir	Zepatier	For the treatment of chronic HCV genotypes 1 or 4
Infections and infectious Diseases		
Obiltoxaximab	Anthim	For the treatment of inhalational anthrax
Emtricitabine and tenofovir alafenamide	Descovy	For the treatment of HIV-1 infection
Emtricitabine, rilpivirine, and tenofovir alafenamide	Odefsey	For the treatment of HIV-1 as initial therapy
Elbasvir and grazoprevir	Zepatier	For the treatment of chronic HCV genotypes 1 or 4
Neurology		
Brivaracetam	Briviact	For the treatment of partial onset seizures related to epilepsy
Pimavanserin	Nuplazid	For the treatment of hallucinations and delusions associated with Parkinson's disease
Sumatriptan nasal powder	Onzetra Xsail	For the treatment of migraine
Oncology		
Cabozantinib	Cabometyx	For the treatment of advanced renal cell carcinoma
Venetoclax	Venclexta	For the treatment of chronic lymphocytic leukemia with 17p deletion
Pulmonary/Respiratory Diseases		
Glycopyrrolate and formoterol fumarate	Bevespi Aerosphere	For the treatment of chronic obstructive pulmonary disease
Reslizumab	Cinqair	For the treatment of severe asthma

Reference: https://www.centerwatch.com/drug-information/fda-approved-drugs/

DRUGS APPROVED BY CDSCO, INDIA: JAN - APR 2016

DRUG	STRENGTH	INDICATION
Nintedanib	100/150mg soft Gelatin Capsule	For the treatment of Idiopathic Pulmonary Fibrosis (IPF)
Cisatracurium Besylate	Bulk & 2mg/ml injection	As an adjunct to general anaesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery
Fomepizole	Bulk &1.5gm/Ampoule	As an antidote for Ethylene glycol or Methanol used poisoning or for use in suspected Ethylene glycol or Methanol ingestion, either alone or in combination with hemodialysis
Tofacitinib	5mg Tablets	For the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to Methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs)

Reference: http://www.cdsco.nic.in/forms/list.aspx?lid=2034&Id=11

Is it Safe to Use Metformin in Patients with Reduced Kidney Function?

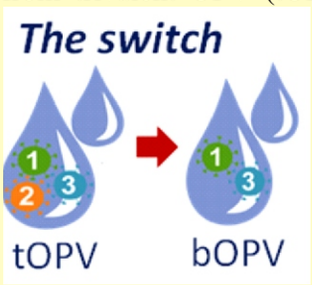
Since FDA approved metformin in 1995, its labeling has included a contraindication against use in some patients with renal disease or dysfunction. The recent literature review shows that metformin may be safely used in patients with mild to moderate renal impairment. In addition, published clinical trials, population-based studies, and retrospective case series in the United States and abroad indicate that metformin is often used in clinical practice outside of the current labeling indications and is prescribed to patients with mild to moderate chronic kidney disease.

FDA recommends that the measure of kidney function used to determine whether a patient can receive metformin be changed from one based on a single laboratory parameter (blood creatinine concentration) to one that provides a better estimate of kidney function in patients with kidney disease (i.e., glomerular filtration rate estimating equation (eGFR)).

Reference: FDA Drug Safety Communication: FDA revises warnings regarding use of the diabetes medicine metformin in certain patients with reduced kidney function. Available from http://www.fda.gov/Drugs/DrugSafety/ucm493244.htm

A Critical Step in Polio Eradication

Polio Eradication and Endgame Strategic Plan 2013-2018 calls for an important transition in the vaccines used to eradicate polio and requires the removal of all oral polio vaccines (OPVs) in the long term. This will eliminate the rare risks of vaccine-associated paralytic polio (VAPP) and circulating vaccine-derived poliovirus (cVDPV). The withdrawal of OPVs must occur in a globally synchronized manner, starting in April 2016 with a switch from trivalent OPV (tOPV) to bivalent OPV (bOPV), removing the type 2 component (OPV2) from immunization programmes.



Advantages: bOPV offers the same advantages as OPV. In addition: 1) For both types 1 & 3 polio, bOPV is more effective than OPV and almost as good as the monovalent vaccines, yet in a package that delivers both at once; 2) bOPV allows countries to simplify vaccine logistics and optimize protection; 3) In areas where access to children is limited, using bOPV helps maximise the impact of each contact with a child.

Efficacy: bOPV is at least 30% more effective than tOPV and almost as good as the respective monovalent OPVs.

Preparation for the removal of OPVs also includes the introduction of at least one dose of inactivated polio vaccine (IPV) into routine immunization programmes in all countries and was started during the end of 2015.

References: 1) Replacing trivalent OPV with Bivalent OPV. Available from http://www. who.int/ immunization/ diseases/ poliomyelitis/ endgameobjective 2/oral poliovaccine/en/ 2) Global polio eradication initia-tive. Available from http:// www.polioeradication.org/ Polioandprevention /Thevaccine/ BivalentOPV.aspx

First Biosimilar Agent in the United States

US Food and Drug Administration (US FDA) approved first biosimilar agent Filgrastim-sndz (ZARXIO Injection, Sandoz Inc.) in the United States for use in treating neutropenia in a number of situations including for patients receiving chemotherapy; patients having hematologic cell mobilization; and patients with absolute neutropenia.

The formulation of ZARXIO differs from that of US-licensed Neupogen in one inactive component. The structural and functional studies demonstrated that ZARXIO has the same amino acid sequence as US-licensed Neupogen. These studies also demonstrated that functional properties such as biological activity and receptor binding as well as physicochemical properties such as higher order structure, and product-related substances and impurities of ZARXIO are highly similar to US-licensed Neupogen. In addition, ZARXIO was found to have a similar stability profile as US-licensed Neupogen.The results from studies demonstrated that ZARXIO is highly similar to US-licensed Neupogen, notwithstanding minor differences in clinically inactive components. The analytical similarity studies did not raise residual uncertainties about the demonstration of highly similar between ZARXIO and US-licensed Neupogen.

Safety data were evaluated in 204 healthy subjects and in 214 patients with breast cancer. The safety profile of ZARXIO was similar to that of US-licensed or EU-approved Neupogen.

Reference: Filgrastimsndz. Available from http://www.fda.gov/Drugs/InformationOnDrugs/ Approved Drugs/ucm436953 .htm

DEPARTMENT ACTIVITIES

Second Asia Pacific Pharmacovigilance Training Course

The Second Asia Pacific Pharmacovigilance Training Course took place from 18th-29th January 2016 at JSS College of Pharmacy, Mysuru in collaboration with Uppsala Monitoring Centre (UMC), the WHO Collaborating Centre for Interna-tional Drug Monitoring in Sweden. The course aimed at building pharmacovigilance capacities amongst healthcare professionals in the Asia Pacific region and beyond.

Inauguration of Training Course

The two-week course was taught by field experts from JSS College of Pharmacy and UMC, as well as by external speakers from India and abroad. In total, Twenty two internationally known experts from Sweden, Switzerland, Australia, The Netherlands, United Kingdom, United States, Republic of Vanuatu and India were attended; the covered topics ranged from health impacts of low quality medicines to effects of inappropriate use of medicines and adverse drug and vaccine reactions. The course drew 14 attendees from national regulatory authorities, pharmaceutical companies, academia, contract research organizations, and the health care sector in eight Asian and two African countries.

The training built around lectures, workshops and hands-on exercises, took place in an open and interactive environment. Plenty of opportunities to interact with JSS University staff, UMC staff, faculty experts and fellow

Speakers with Participants

course participants were provided. Social activities and events like official course dinner and sightseeing tours were also included in this training course.

Participants at Mysuru Palace

All the participants unanimously expressed that this training course helped them to gain more knowledge on spontaneous adverse reaction reporting, data management and analysis tools, signal detection, causality assessment, communications in Pharmacovigilance, Pharmaco--vigilance methods, Pharmacoepidemiology and regulatory aspects of Pharmacovigilance and vaccine Pharmacovigilance. Also, participants expressed that, the knowledge and skills gained during the course of training would help them to initiate or further strengthen the Pharmacovigilance activities in their respective country or organization.

Clinical Case Discussion

Mr. Frank W. May, MappSci (Pharm), FISPE, who worked as a Service Director, Drugs And Therapeutic Information Service (DATIS), Repatriation General Hospital, Adelaide, Australia visited Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru between 28th & 31st January 2016. During his visit, Mr. Frank May delivered a lecture on 'Role of Pharmacoepidemiological studies in drug safety' at 'Second Asia Pacific Pharmacovigilance Training Course' held at JSS College of Pharmacy, Mysuru from 18th to 29th January 2016. Mr. Frank May along with his colleagues from Australia **Ms. Tasma Wagner and Ms. Amanda Sanburg** facilitated the clinical case on 'Chronic Kidney Disease' presented by Ms. Krupa Desai, Pharm.D intern.

Mr. Frank May, Ms. Amanda Sanburg and Ms.Tasma Wagner facilitating the case presentation

During the case presentation, Mr. Frank May and his colleagues shared their experiences with Pharm.D interns in dealing with similar cases in Australia.

Research Work Progress Presentation

M. Pharm and Ph.D Research Scholars presented their theses work progress before **Mr. Frank May, Ms. Tasma Wagner and Ms. Amanda Sanburg** along with staff of the Department. During their presentations, Mr. Frank May and his colleagues gave valuable suggestions to students that would improvise the standards of their research work.

Journal Club Discussion

Mr. Frank May facilitated the 'Journal Club' discussion on the topic 'Cumulative use of strong anticholinergics and incident of dementia: A prospective cohort study' published in 'JAMA Internal Medicine'. Pharm.D interns attended the 'Journal Club' discussion and analysed the selected published paper for its merits and demerits. This gave a good understanding to Pharm.D interns about how to evaluate the published paper for its worthiness, and decide whether or not to consider for decision-making process in the pracitce of evidence based medicines.

Mr. Frank May facilitating Journal Club

Guest Lectures

Dr. David Warner, Director, Residency Program Development, Accreditation Services Division, American Society of Health-System Pharmacists delivered a guest lecture on 'Residency Program in Clinical Pharmacy-ASHP Perspective' for Staff of Department of Pharmacy Practice at JSS College of Pharmacy on 16th March 2016. Following which he delivered a guest lecture on 'Contribution of ASHP to Advanced and Speciality Pharmacy Practice' for Pharm D. students.

Also, Dr. David Warner visited Department of Clinical Pharmacy at JSS Hospital on 16th March 2016. During his visit, he was briefed about the Clinical Pharmacy services provided by the Department. Later he had a meeting with hospital staff, and discussion with Clinical Pharmacy Staff.

Dr. David Warner delivering the lecture

Dr. David Steeb, Clinical Assistant Professor & Director of Global Engagement, Eshelman School of Pharmacy, University of North Carolina (UNC) delivered a guest lecture on the topic 'Community Pharmacy in the United States' on 22nd January 2016. During his talk, Dr. David has provided a broad overview of the profession of Pharmacy in the United States. He discussed about various roles and activities of Community Pharmacists, and how Community Pharmacy Practice is integrated within the UNC Pharm.D curriculum. Also, he highlighted on future of Community Pharmacy Practice in USA. Fifth year Pharm.D students and staff of Pharmacy Practice Department attended the lecture.

Dr. David Steeb delivering the lecture .

Dr. Miranda Law, Global Engagement Fellow, Eshelman School of Pharmacy, University of North Carolina (UNC) delivered a guest lecture on the topic 'Residencies and Fellowships in the United States' on 22nd January 2016. During her talk, Dr. Miranda has discussed in detail of preparation for applying residencies and fellowships in industry and academia. Also, she highlighted licensure requirements for Pharmacist in US. Also, she touches upon residencies at UNC hospitals. Fifth Pharm.D students and staff of Pharmacy Practice Department attended the lecture.

Dr. Miranda Law delivering the lecture .

Faculty Attended International Conference

Mr. Himanshu Patel, Lecturer, Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru attended 'XV International Symposium on Oncology Pharmacy Practice' organized by International Society of Oncology Pharmacy Practitioners held from 17th-20th April 2016 at Santiago, Chile. He was awarded travel grant of CAD$ 2000 by the organizer to attend this event and to present his research work in the area of oncology. He presented two papers, one on 'Pharmacovigilance of anti-cancer medicines' and other on 'Pharmacoeconomic assessment of treatment provided for head & neck cancer patients under different reibursement schemes.

Mr. Himanshu Patel at the conference

Awards / Prizes

Ms. Reshma Merin Reji received ***Second Prize*** for the research paper titled 'Drug and its demerits- cardiovascular iatrogenic adverse drug reaction - Role of pharamcist' co-authored by ***Vineetha Bharathan Menon, Krishna Undela, M. Ramesh*** during 'National Seminar on Strategic Initiative on Strengthening Pharmacy Practice Services' held at Ezhuthachan College of Pharmaceutical Science, Neyyatinkara, Trivandrum on 23rd April 2016

Ms. Rinu Philipose received ***First Prize*** for the review paper titled 'Stempeutics- A novel trend in therapeutics' co-authored by ***Chanchal AM, Krishna Undela*** during 'National Seminar on Strategic Initiative on Strengthening Pharmacy Practice Services' held at Ezhuthachan College of Pharmaceutical Science, Neyyatinkara, Trivandrum on 23rd April 2016

Ms. Chanchal AM received ***Second Prize*** for the review paper titled 'Online drug dispensing system for community patients' co-authored by ***Rinu Philipose, Marlyn Mary Mathew, Justin Kurian, Adepu Ramesh*** during 'National Seminar on Strategic Initiative on Strengthening Pharmacy Practice Services' held at Ezhuthachan College of Pharmaceutical Science, Neyyatinkara, Trivandrum on 23rd April 2016

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 free of cost. We request you to avail the drug and poison information services.

Toll free - 1800-425-0207; 0821-2335577; Extn. 5577; E-mail: dic.jsscp@jssuni.edu.in; pic.jsscp@jssuni.edu.in;
Website: picjsscp.jssuni.edu.in

Your suggestions are welcome. Please send your comments/suggestions to the editors at: dic.jsscp@jssuni.edu.in

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