

Clinical Pharmacy

A Newsletter of Drug and Prescribing Information

Prepared by
Department of Clinical Pharmacy
JSS College of Pharmacy at
JSS Hospital, Mahatma Gandhi Road,
Mysuru – 570004

Editors : Dr. M. Ramesh, Ms. Karin Nyfort-Hansen, Ms. Juny Sebastian and Mr. Krishna Undela

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ADVERSE DRUG REACTION REPORTS : May - Aug 2018

A total of 642 Adverse Drug Reactions (ADRs) were reported or detected by the Department of Clinical Pharmacy during May to August 2018. 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.

DRUG (S)	REACTION
Amlodipine	Lichenoid Dermatitis
Cefixime	Excessive Flatus
Domperidone + Ondansetron	Gyneacomastia
Fenofibrate	Photosensitivity Reaction
Isoniazide+Rifampicin+	
Pyrazinamide+ Ethambutol	Melanosis
Levetiracetam	Neutropenia
Metformin + Glimepiride	Altered Taste
Phenytoin	Dyskinesia
Piperacillin + Tazobactam	Bullous Pemphigoid
Piperacillin + Tazobactam	Otitis Media
Prochlorperazine	Neck rigidity
Salbutamol	Fever
Teneligliptin	Hyponatremia
Tinidazole	Fixed Drug Eruption
Zidovudine + Lamivudine+	
Nevirapine	Avascular Necrosis

Tinidazole induced Fixed Drug Eruption (FDE)

The exact mechanism of Tinidazole inducing FDE is not known. However, both immunological and toxic mechanisms are known to cause the reaction. The reaction usually occurs seven to ten days after the second or third or more exposures to the same drug. The treatment includes stopping of the offending drug and treating with oral and topical corticosteroids. The reaction will subside within two weeks of treatment.

Phenytoin induced Dyskinesia

Phenytoin induced dyskinesia is a rare reaction which is commonly seen in children and young adults. The exact mechanism of phenytoin induced dyskinesia is not known. However, possible mechanism explains that dopaminergic hypersensitivity after long term treatment might be responsible for drug induced dyskinesia. This reaction may last for hours, days or even more. Withdrawal of the suspected drug will alleviate the symptoms completely.

Amlodipine induced Lichenoid Dermatitis

Amlodipine induced Lichenoid Dermatitis or Lichenoid Tissue Reaction is a rare skin reaction. Although the exact mechanism is not clearly understood. Cell-mediated cytotoxicity is regarded as a major mechanism of pathogenesis. This reaction may develop weeks or months after initiation of the treatment. The management of amlodipine induced Lichenoid Dermatitis includes dechallenge of the suspected drug and symptomatic treatment with corticosteroids.

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 9035664802 (Format: ADR / IP or OP Number/ Name of the patient/ Ward)

DRUGS APPROVED BY US FDA

The following are the drugs that are approved by the US Food and Drug Administration (FDA) during the period May - August 2018.

DRUG	BRAND	INDICATION
Erenumab-aooe	Aimovig	For the preventive treatment of migraine in adults
Lefoxidine	Lucemyra	For the mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults
Coagulation factor Xa (recombinant)	Andexxa	For the reversal of factor Xa inhibitors
Avatrombopag	Doptelet	For the treatment of thrombocytopenia in adults with chronic liver disease scheduled to undergo a procedure
Sodium Zirconium Cyclosilicate	Lokelma	For the treatment of hyperkalemia
Pegvaliase -pqpz	Palynziq	For the treatment of phenylketonuria
Tildrakizumabasn	Ilumya	For the treatment of plaque psoriasis

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

DRUGS APPROVED BY CDSCO, INDIA

The following are the drugs that are approved by the Central Drugs Standard Control Organization (CDSCO) during the period May to August 2018.

DRUG	STRENGTH	INDICATION
Baricitinib film coated tablets	2mg/4mg	For the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modification antirheumatic drugs. Baricitinib may be used as monotherapy or in combination with methotrexate
Vortioxetine Hydrochloride film coated tablets	5mg/10mg/ 15mg/20mg	For the treatment of major depressive disorder in adult
Vardenafil Hydrochloride Trihydrate(BULK) & Vardenafil tablets	2.5mg/5mg/ 10mg/20mg	Treatment of erectile dysfunction in adult men
Trientine Hydrochloride capsule	250mg	For the treatment of Wilson's disease (hepatolenticular degeneration) in patients intolerant to Penicillamine. It should be used when continued treatment with Penicillamine is no longer possible because of intolerable or life endangering side effect
Apremilast bulk & Apremilast film coated tablets	10mg/ 20mg/ 30mg	Indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
Gadoteridol Injection	279.3mg/ml - 10ml, 15ml and 20ml.	Lesions with abnormal vascularity in the brain (intracranial lesions), spine and associated tissues in adults and paediatric patients over 2 years of age Lesions in the head and neck in adults
Emtricitabine and Tenofovir Alafenamide tablets	25mg / 200mg	In combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus type I

Reference: <http://www.cdsc0.nic.in/forms/list.aspx?lid=2034&Id=11>

New GamaStan Immune Globulin for Measles, Hep A Exposure

The US Food and Drug Administration (FDA) has approved a new formulation of Grifols' GamaSTAN immune globulin (human) for prophylaxis following exposure to hepatitis A virus (HAV) and for prevention or modification of measles in susceptible individuals exposed fewer than 6 days previously. The new formulation is manufactured using a caprylate chromatography process in accord with the highest quality and safety standards, according to the company. GamaSTAN is the only immune globulin product available in the United States to protect against HAV and measles following exposure. GamaSTAN for intramuscular injection comes in two vial sizes (10 mL and 2 mL).

In addition to HAV and measles, GamaSTAN is also approved for postexposure prophylaxis of varicella and rubella. It is not indicated for routine prophylaxis or treatment of viral hepatitis type B, rubella, poliomyelitis, mumps, or varicella. GamaSTAN is contraindicated in patients who have had anaphylactic or severe systemic hypersensitivity reactions to immune globulin (human) and in IgA-deficient patients with antibodies against IgA and a history of hypersensitivity. Thrombosis may occur with immune globulin products, including GamaSTAN.

Reference : FDA Clears New GamaStan Immune Globulin for Measles, Hep A Exposure - Medscape. <https://www.medscape.com/viewarticle/901764>

Antidepressants Lack Effectiveness for Depression in Dementia

A systematic review of 10 studies was conducted by a research team headed by Dr. Robert Dudas from the University of Cambridge in the U.K to evaluate the efficacy and safety of any type of antidepressant for patients who had been diagnosed as having dementia of any type and depression as defined by recognized criteria. Researchers report based on high-quality evidence from eight studies, that there was little or no difference in scores on depression symptom rating scales between antidepressant and placebo treated groups after six to 13 weeks. Moderate-quality evidence also suggested little or no difference between groups after six to nine months. Moderate-quality evidence from four studies, however, indicated that remission rates at

12 weeks were significantly higher in the antidepressant group (40%) than in the placebo group (21.7%).

High-quality evidence showed no effect of antidepressants on performance of activities of daily living at weeks six to 13, and moderate-quality evidence showed little or no effect of antidepressants on cognition. Participants on antidepressants seemed to be more likely to drop out of treatment, and adverse events emerged in significantly more patients on antidepressants (49.2%) than on placebo (38.4%).

Reference : Antidepressants Lack Effectiveness for Depression in Dementia - Medscape . Available from: <https://www.medscape.com/viewarticle/901687>

Are all the poisoning cases treated with antidotes? A case report of paediatric poisoning with unknown compound

Case Description: A 14 year old female patient was brought to JSS Hospital (JSSH) on August 31st 2018 at 7PM with alleged consumption of Alta/Parani poisoning. At admission, child was conscious and oriented. There was no vomiting after that. At Emergency Department gastric lavage was performed and the child shifted to Paediatric Intensive Care Unit.

On examination: The child was afebrile and the vitals were as follows: HR-84bpm, BP-120/70mmHg, RR-18bpm, SpO₂-100% at room air, Capillary fill time-<3sec. No abnormality found during the systemic examination. The child was kept nil by mouth for 12hrs, started on maintenance IV fluids. The health care professionals (HCPs) treating the child identified the content of Alta as Azo dye (Anthraquinone group) and Para Phenylenediamine (PPD) based on the available literature. The child was monitored for symptoms of Azo dye poisoning. The child was treated symptomatically and discharged after three days following psychiatry counselling.

Identification of poisoning: The Department of Clinical Pharmacy investigated the product to identify the content and the concentration present in it. Though the product was easily available in the local market, the details of the content or concentration was not available on the label. Surprisingly, the outer packet and the inner bottle of the product had two

different manufacturers details. On further investigation, it was found that one of the labelled manufacturers is a garment manufacturer and the other is a plastic manufacturer.



Product consumed by the child

Lesion learnt from the Exercise: In managing the poisoning cases, wherein the consumed product is unknown, HCPs can opt for immediate symptomatic treatment with continuous close monitoring. Although the child was well managed in this case fake drugs/compounds like this which have no labelled content and whose manufacturers are unknown not only makes the HCPs difficult to manage the poisoning cases and are potentially serious threat to the life of the victim.

DEPARTMENT ACTIVITIES (MAY-AUG 2018)

Basic Life Support and Advanced Cardiovascular Life Support Courses

Basic Life Support (BLS) course offered by American Heart Association was provided to fifth year Pharm.D students on 25th July 2018 at Sri Rajendra Auditorium, JSS College of Pharmacy, Mysuru. The BLS guidelines were provided to the students one month prior to the course. During the course, the students got training in essential skills individually, as part of a team, and as team leader in different learning stations based on simulated clinical scenarios.



Fifth Pharm.D students during BLS Training.

Advanced Cardiovascular Life Support (ACLS) Course offered by American Heart Association was provided to Pharm.D Interns on 26th & 27th July 2018 at Sri Rajendra Auditorium, JSS College of Pharmacy, Mysuru. The ACLS guidelines were provided to the students one month prior to the course. During the course, the students got training in essential skills individually, as part of a team, and as team leader in different learning stations based on simulated



Sixth Pharm.D students during ACLS training session

clinical scenarios. Realistic simulations were focused on the following key concepts: proficiency in basic life support care, recognizing and initiating early management of peri-arrest conditions, managing cardiac arrest, identifying and treating ischemic chest pain and acute coronary syndromes, recognizing other life-threatening clinical situations such as stroke and providing initial care, ACLS algorithms and effective resuscitation team dynamics. At the end of BLS and ACLS courses, students appeared for a written test to evaluate the knowledge on clinical interventions for the emergency management of life threatening conditions. The students who successfully completed the course were provided with American Heart Association Advanced Cardiac Life Support certification card. The BLS and ACLS training was provided by Tech2People, Healthcare & Education Pvt. Ltd., Manipal.

Series of Guest Lectures Organised at the Department

Brian E. Lawson, Director, Professional Affairs for the Board of Pharmacy Specialties (BPS), Washington, D.C. delivered two talks on the topics 'Credentials to Grow Your Career' and 'Navigating Communication Conflicts on the Healthcare Team with Confidence' to Pharm.D and M. Pharm Pharmacy Practice students and PhD scholars on 2nd and 3rd May 2018. During his talk on credentials to grow your career, licensure exam in United States of America and difference between certificate and certification were emphasised. Further, the residency programs and the curriculum in specialised clinical departments were discussed for the benefit of Indian pharmacy practice students. Thereafter, the importance of recertification of practicing pharmacists was discussed and later the session was made open for question and answers to the students. During the second talk, Lawson emphasised the importance of communications in the day to day conflicts in the work environment and the ways to confront. He made audience realised that conflicts in the work environment are common and are necessary for the productivity. Dr. M. Ramesh, Professor & Head, Department of Pharmacy Practice introduced the speaker to the audience, and Dr. T. M. Pramod Kumar, Principal, JSS College of Pharmacy, Mysuru felicitated Dr. Brian Lawson at the end of the session.

Department of Pharmacy Practice in association with Pharmacy Education Unit (PEU) of JSS College of Pharmacy, Mysuru organized a Guest Lecture on 'User Awareness Training for Web of Science and End Note' on 23rd



Dept Staff & Students with Dr. Brian Lawson

June 2018 at Regulatory Affairs Seminar Hall, JSS College of Pharmacy, Mysuru. **Dr. Subhasree A. Nag**, Solution Consultant, Scientific & Academic Research, Clarivate



Dr. Subhasree A. Nag during her session

Analytics (Formerly the IP & Science Business of Thomson Reuters) was the speaker for this lecture.

Department of Pharmacy Practice in association with Pharmacy Education Unit (PEU) of JSS College of Pharmacy, Mysuru organized a Guest Lectures on the topics 'Benefit-Risk Assessment' and 'Drug Safety Evaluation and Pharmacovigilance' on 23rd July 2018 at Seminar Hall,

Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru. **Dr. John Talbot**, Senior Lecturer, Pharmacovigilance, University of Hertfordshire, United Kingdom was the speaker for this lecture. Dr. John Talbot explained about the definition, reasons, and process of Risk Management, Risk Mitigation activities and Risk Management plans. During the second talk, he explained the importance of Pharmacovigilance in pre-marketing studies like Clinical Trials with few real-time examples. He also explained about the limitations of pre-marketing clinical studies in identifying safety issues and addressing these limitations through post-marketing studies like spontaneous reporting and other Pharmacovigilance studies.

Department of Pharmacy Practice in association with Pharmacy Education Unit (PEU) of JSS College of Pharmacy, Mysuru organized series of Guest Lectures on 'Clinical Pharmacy Practice' on 3rd August 2018 at Seminar Hall, Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru. **Dr. Dixon Thomas**, Asst. Professor & Chair, Department of Pharmacy Practice, Gulf Medical University, Ajman, UAE was the speaker for these lectures.

The topics of the guest lectures were 'Clinical Services of Pharmacists – Global Perspectives', 'Self-Directed Learning by Pharmacists' and 'Abilities of a Pharmacy Student while Graduation - International Expectations'. The objective of the first lecture was to make the participants understand the terms used to describe the roles of pharmacist and clinical



Dr. John Tolbot during his lectures
pharmacy roles in community settings. He also explained the differences between Theory Vs. Practical and Practice Vs. Research. The objective of the second lecture was to give an awareness to participants about the self-evaluation for the learning needs and find the information and critically appraise it. Participants appreciated Dr. Dixon Thomas for his informative lectures with real-time examples. At the end of the session, participants got an opportunity to interact with the speaker and clarify their doubts.



Dr. Dixon Thomas and Dr. M Ramesh during the interaction

Clinical Rotation of International Students from Howard University, USA

Two Pharm.D interns from Howard University USA, Ms. Adoma Appiahene Yeboah & Ms. Morgan Ashley Merritt completed their international advanced pharmacy practice experience rotation at the department of Clinical Pharmacy, JSS Hospital, Mysuru from 31st July 2018 to 30th August 2018. They were posted to the departments of Pediatrics, Medicine, Surgery, Ashakirana hospital and Bhart Cancer Hospital with a special emphasize on infectious diseases that are not commonly seen in their practice setting. This was the 4th consecutive year, the students from Howard University, USA completing their international clinical rotation at Department



Howard University students with the staff and students of the department of Clinical Pharmacy, JSS Hospital, Mysuru. The rotation was well appreciated by the students.

Health Screening Camp

Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru organized a Health Screening Camp for the benefit of public of Mysuru city on 21st August 2018 at three different locations Viz., Bal Bhavan, Chamundi Hills Footsteps and Lalith Mahal Gate between 6.00 AM and 9.00 AM. The aim of the health screening camp was to sensitize the people about the importance of regular monitoring of health and safe use of medications. During the camp, interested public were screened for blood pressure and blood glucose levels. In all three venues, a total of 189 people (Bal Bhavan: 51, Chamundi Hills Footsteps: 54 and Lalith Mahal



Dept staff & students during health screening camp

Gate: 84) were monitored for their blood pressure and blood glucose levels.

Participation in National Deworming Day

Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education & Research, Mysuru participated in the National Deworming Day (NDD) held on 10th August 2018 along with District Health & Family

Welfare Society, Mysuru. The program in the Mysuru region was coordinated by the District Health & Family Welfare Society, Mysuru. Inauguration was held at Good Sheppard Convent High School in the presence of District Health

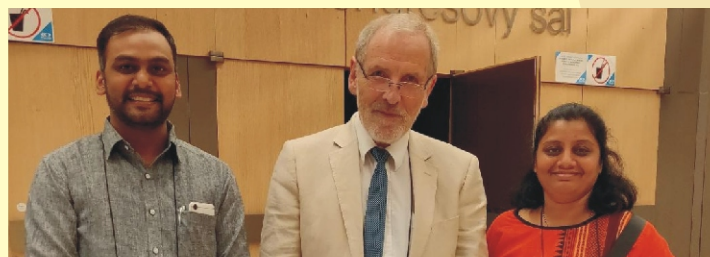
Officer (DHO), Mysuru. The aim of participation of the Clinical Pharmacy Department was to monitor the adverse events, if any, due to administration of Albendazole on National Deworming Day. During the event, Staff of the Department and the Patient Safety Pharmacovigilance Associate of AMC made personal visit to 15 different schools located in the Mysuru city. The school authority and the children were encouraged to report any kind of reactions that children may experience after receiving Albendazole. A follow-up visit was made a week after the administration of albendazole to monitor the safety.



*Dept staffs & students along with DHO officers
During the inaugural function of National Deworming Day*

Research Presentations

Mrs. Shilpa Palksha and **Mr. Sri Harsha Chalasani** received a travel grant of 900 US Dollars and complementary registration (700USD) from International Society for Pharmacoepidemiology (ISPE) to attend 34th International Conference on Pharmacoepidemiology at Prague, Czech Republic from 22 – 26 August 2018. Mrs. Shilpa presented a research paper entitled ‘Predisposing Factors, Incidence and Severity Assessment of Antibiotic-Induced Hypersensitivity Reactions in Inpatients of a Tertiary Care Hospital in India’ during the conference. Mr. Harsha presented his research papers entitled ‘Assessment of Medication Errors in the Surgery Department in a Developing Contry’s Tertiary Care Teaching Hospital’ and ‘Medication Errors, Impact of Work-shifts, and Associated Contributing Factors: A Cross-sectional Study in a Developing Country Scenario’ during the conference.



Mrs. Shilpa and Mr. Sri Harsha during ISPE Conference

M. Pharm students of the department **Mr. Abhishek S. & Ms. Sharvani P.** won first prize for the poster presentation on the research paper entitled ‘A Review Article on Safety, Efficacy, and Management of Proprotein Convertase Subtilisin/ Kexin Type 9 (Pcsk9) Inhibitors in The Treatment



*Students Receiving the Best Poster Presentation Award
of Familial Hyperlipidemia(FH)’ during National Forum For Pharmacy Students (NFPS) International Summit-2018 held at Hyderabad on 18th August 2018.*

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.

We extended our services 24x7 from 8th October 2018 for the benefit of HCPs and Patients.

24x7 Mobile Number: 6363539153, Toll free Number - 1800-425-0207 Landline Number: 2335555, Extn - 5577

E-mail: dic.jsscp@jssuni.edu.in; pic.jsscp@jssuni.edu.in;

Website: www.picjsscpm.jssuni.edu.in

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

To,

