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A News letter on

CLINICAL PHARMA PRACTICE

An Update of Clinical Research and Drug Information



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PHYSICIAN DESK



Dr. P. DHANASELVI, M.D(MICRO)..

Physician

Vivekanandha Medical Care Hospital

CASE STUDY ON HAEMORRHAGIC DENGUE FEVER

29 years old male patient was admitted with high grade fever for 1 week associated with body pain, severe low back pain, headache, vomiting & loose stools. Eyes - congested. On evaluation: Total Cell Count: 12,100/cmm, Polymorphs - 86%, Platelet count: 79,000/cmm, Dengue IgM - Positive, Total Bilirubin - 4.1mg%, SGPT - 234U/dl, SGOT - 192U/dl, urine albumin - 2+. Patient developed melena & right hypochondriac pain.

He was treated with Ceftriaxone 2 gm intravenously twice daily and oral Synriam (Arterolane Maleate and Piperaquine Phosphate - 180/750 mg) once daily for 3 days.

On day 4, patient developed tachypnoea with hypoxia and SpO2 dropped to 86% in room air. Chest X ray showed bilateral lower zone haziness (+). Patient continued to have fever. Mean while reassessment was done which revealed scrub typhus antibody positivity.

USG abdomen revealed mild splenomegaly, hypochoic peripherally placed lesion in spleen. Surgeon's opinion obtained for splenic lesion and it was planned to continue conservative management.

CT abdomen revealed Hematoma/ Abscess rupture into the sub-capsular space, small laceration in the medial spleen, minimal pericardial effusion and minimal left pleural effusion. Patient's temperature settled with Doxycycline, Ceftriaxone and other supportive measures. No abdominal pain. Patient was stable at the time of discharge.

Diagnosis : Primary haemorrhagic dengue fever/ Early ARDS (acute respiratory distress syndrome)/ Scrub typhus/ splenic abscess with rupture - spontaneous healing

Transmission of Dengue Fever and Scrub Typhus : In dengue bite of Aedes aegypti mosquitoes. In scrub typhus by chigger bite (Larva of trombiculid mite)

Incubation Period : In dengue fever 3 to 14 days, but most often it is 4 to 7 days. Typhus, 6-20 days (average-10days).

Clinical features of dengue fever and scrub typhus: Sudden-onset fever, headache (typically located behind the eyes), severe muscle and joint pains ("break bone fever"), and a characteristic skin rash are common.

Complications : Dengue hemorrhagic fever, resulting in bleeding, low levels of blood platelets and blood plasma leakage or into dengue shock syndrome, where dangerously low blood pressure occurs.

Treatment : Intravenous fluids and Acetaminophen for mild or moderate disease. For more severe cases platelet and blood transfusion may also be required.

Scrub typhus or bush typhus : Typhus caused by the intracellular parasite Orientia tsutsugamushi, a gram negative bacterium of family Rickettsiaceae.

Diagnosis : Weil-Felix test and the gold standard is indirect immunofluorescence test. Other methods are culture and polymerase chain reaction.

Treatment : The drug of choice is Doxycycline but Chloramphenicol is an alternative. In resistant cases Rifampin and Azithromycin are alternatives. Azithromycin is an alternative in children and pregnant women with scrub typhus and when doxycycline-resistance is suspected

Prevention : No licensed vaccines are available for both. Prevention is by reducing mosquito habitat and limiting exposure to bites.

Ref: www.ncbi.nlm.nih.gov/pmc/articles/pmc3028954

**FIRST NEW ANTIBIOTIC IN 30 YEARS
DISCOVERED IN MAJOR BREAKTHROUGH**

Teixobactin is a recently described antibiotic of a new class produced by a hitherto undescribed soil microorganism (provisionally named *Eleftheria terrae*). It was isolated with a new tool, the iChip, that allowed the environmental bacterium to grow and for the antibiotic it produced to be isolated and subsequently identified. Teixobactin has activity against Gram-positive (but not Gram-negative) organisms and mycobacteria and a novel mode of action inhibiting peptidoglycan biosynthesis. In vitro no teixobactin-resistant *Staphylococcus aureus* or *Mycobacterium tuberculosis* were selected. In experimental infections of MRSA and *Streptococcus pneumoniae* in mice, teixobactin was effective at reducing the bacterial load. Although teixobactin is at an early stage of development and there are no guarantees it will make it to market, the use of the iChip will hopefully result in the discovery of further potential new antibiotics. The World Health Organisation has also classified antimicrobial resistance as a 'serious threat' to every region of the world which 'has the potential to affect anyone, of any age, in any country.' Crucially, the scientists believe that bacteria will not become resistant to Teixobactin for at least 30 years because of its multiple methods of attack.

Dr. T. TAMILSELVAN, Head, Department of Pharmacy Practice

Ref : <http://www.telegraph.co.uk/science/2016/03/14/first-new-antibiotic-in-30-years-discovered-in-major-breakthrough/>

**FDA GRANTS ACCELERATED APPROVAL TO
FIRST DRUG FOR DUCHENNE MUSCULAR
DYSTROPHY**

DMD is a rare genetic disorder characterized by progressive muscle deterioration and weakness. It is the most common type of muscular dystrophy. DMD is caused by an absence of dystrophin, a protein that helps keep muscle cells intact. The first symptoms are usually seen between three and five years of age, and worsen over time. The disease often occurs in people without a known family history of the condition and primarily affects boys, but in rare cases it can affect girls. DMD occurs in about one out of every 3,600 male infants worldwide. The U.S. Food and Drug Administration today approved Exondys 51 (eteplirsen) injection, the first drug approved to treat patients with Duchenne muscular dystrophy (DMD). Exondys 51 is specifically indicated for patients who have a confirmed mutation of the dystrophin gene amenable to exon 51 skipping, which affects about 13 percent of the population with DMD.

Mrs. T. KUMUTHA, Lecturer.

Ref : <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm521263.htm>

**H1N1 SWINE FLU VACCINE UNLIKELY TO
RAISE BIRTH DEFECT RISK**

Swedish researchers report that the vaccine against the H1N1 "swine flu" strain of influenza doesn't seem to have a link to birth defects. New Swedish study indicates that first trimester administration of H1N1 vaccine does not seem to increase congenital birth defects. U.S. Centers for Disease Control and Prevention advise all pregnant women to receive a seasonal flu vaccine since they are especially vulnerable to complications from influenza. The new study was led by Dr. Jonas Ludvigsson of the Karolinska Institute in Stockholm. His team looked at the risk of birth defects -- overall and in terms of congenital heart disease, cleft palate and limb abnormalities - in more than 40,000 children of mothers who were exposed to the H1N1 vaccine, Pandemrix.

Dr. D. JOSEPH STALIN, Assistant Professor

Ref : <http://www.webmd.com/cold-and-flu/news/20160919/h1n1-swine-flu-vaccine-unlikely-to-raise-birth-defect-risk>

**LINK BETWEEN DEPRESSION AND
GESTATIONAL DIABETES WORKS TWO WAYS**

A recent study, carried out by the National Institutes of Health, finds a link between depression in early pregnancy and development of gestational diabetes at a later stage. The researchers also found that gestational diabetes was associated with an increased risk of developing postpartum depression. Women with the highest depression scores during the first and second trimesters had almost triple the risk for gestational diabetes compared with women who had lower scores for depression. Additionally, the investigators found that not only did early depression predict later gestational diabetes, gestational diabetes also predicted the development of depression at a later stage. Also, increased glucose levels can lead to inflammation and hormonal changes, which might themselves lead to (or worsen) symptoms of depression.

Mr. S. ANANDKUMAR, Assistant Professor

Ref : <http://www.medicalnewstoday.com/articles/312965.php>

NEW DRUGS APPROVED BY CDSCO-INDIA

No.	Name of Drug	Indication	Date of issue
1.	Ceftaroline Fosamil Injection 600 mg/Vial	Community-acquired Pneumonia Patients With \geq 18 Years	09.05.2016
2.	Panobinostat Hard Gelatin Capsules 10 mg / 15 mg / 20 mg (Panobinostat lactate)	Multiple Myeloma	27.05.2016
3.	Bepotastine Besilate Bulk & Bepotastine Besilate 1.5 % w/v Ophthalmic solution	Allergic Conjunctivitis	08.06.2016
4.	Ibutilide Bulk & amp ; Ibutilide Fumarate Injection 0.1mg/ml	Atrial Fibrillation or Atrial Flutter of recent onset Arrhythmias	10.06.2016
5.	Sacubutril + Valsartan film coated tablets 50 mg / 100 mg / 200 mg	Heart Failure and reduced Ejection Fraction	14.07.2016
6.	Lurasidone Hydrochloride Bulk & Lurasidone Hydrochloride Tablets 40 mg / 80 mg	Schizophrenia	18.07.2016
7.	Fenticonazole Nitrate Vaginal Capsule 600 mg	Vulvovaginal Candidiasis	10.08.2016
8.	Palbociclib Capsules 75 mg / 100 mg / 125 mg	Breast Cancer	11.08.2016
9.	Midodrine Hydrochloride 2.5 mg Tablet	Symptomatic Orthostatic Hypotension	02.09.2016
10.	Phospholipids Fraction from Bovine Lung (surfactant) 50 mg/vial	Respiratory Distress Syndrome	12.09.2016

C. AROKIA RANI, M. LEENA PRIYA

Ref: <http://www.cdscsco.nic.in/forms/list.aspx?lid=2034&ld=11>

NEW DRUG PROFILE

TOFACITINIB

CATEGORY : Rheumatoid arthritis.

MOA : It is an inhibitor of the enzyme janus kinase 1 (JAK1) and janus kinase 3 (JAK3) there by inhibiting the production of inflammatory mediator.

INDICATION :

For the treatment of adult patients with moderately to severely active rheumatoid arthritis who have inadequate response or intolerance to Methotrexate.

DOSE AND DOSAGE :

Monotherapy or in combination with methotrexate or other non biologic disease-modifying antirheumatic drugs (DMARDs). The recommended dose is 5 mg twice daily Oral tablet and extended release tablets : 5 mg twice daily.

DRUG INTERACTION :

Azathioprine, Tacrolimus, Cyclosporine.

PRECAUTIONS :

Skin test for tuberculosis before start using this medicine avoid people with infections because this drug temporarily lower the WBC count in blood.

ADVERSE REACTIONS :

Upper respiratory tract infections, headache, diarrhea & nasopharyngitis.

PREGNANCY CATEGORY : D

BRAND NAME : Xeljanz, Xeljanz XR.

LURASIDONE HYDROCHLORIDE

CATEGORY : Antipsychotic

MOA : Latuda is mainly blocking the D2 receptor (high affinity for D2 receptors).

INDICATION :

For the treatment of Patients with Schizophrenia.

DOSE AND DOSAGE :

Starting dose is 40 mg once daily. Initial dose titration is not required. Shown to be effective in a dose range of 40 mg per day to 160 mg per day. The maximum recommended dose is 160 mg per day. Tablet : 20 mg, 40 mg, 80mg, 160 mg

CONTRAINDICATION :

In patients with dementia-related psychosis

PRECAUTIONS :

Kidney problems, liver problems, stroke, breast cancer, diabetes (including family history), obesity, low blood pressure, seizures, low white blood cell count, dementia (such as Alzheimer's Disease), trouble swallowing. Do not drive, use machinery.

ADVERSE REACTIONS :

Sleepiness or drowsiness, Akathisia (restlessness or feeling a need to move around), Difficulty moving, Slow movements.

PREGNANCY CATEGORY : B

BRAND NAME : Latuda

S.SWETHA, R.NITHYA, H.KALAIVANI

Ref : http://www.druglib.com/druginfo/xeljanz/interactions_overdosage_contraindications/

DEPARTMENT ACTIVITIES

GUEST LECTURE

Dr. S.G. VIJAYAKUMAR, M.Pharm. Ph.D., Project Manager, Aurobindo Pharma.U.S.A delivered a guest lecture entitled "Drug Development and FDA Regulation" for Pharm.D , B. Phram and M. Pharm Students on 10.06.2016.

Dr. RADHAKRISHNAN RAJESH, M.Pharm., Ph.D., Asst. Professor, Dept of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal University, Karnataka delivered guest lecture on the topic entitled "Credentials and Career of Pharm.D Graduates: The Voyage Never Ends" on 01.10.2016.

CONFERENCE ATTENDED / PRESENTATION

Dr. T. TAMILSELVAN, Mr. S. ANANDKUMAR & M.Pharm (Pharmacy Practice) students participated in State Level Seminar on "Recent Advances in Pharmaceutical Sciences" at Erode College of Pharmacy, Erode on July 22, 2016.

Dr. T. TAMILSELVAN, Mr. S. ANANDKUMAR & M.Pharm (Pharmacy Practice) students H. KALAIVANI, S SWETHA, R. NITHYA, E. JENIFFER participated in "Best practices in Pharmacovigilance for Healthcare Professionals in Contemporary Indian Scenario" at Coimbatore Medical College, Coimbatore on August 12, 2016.

Dr. T. TAMILSELVAN, Mr. S. ANANDKUMAR & M.Pharm (Pharmacy Practice) students H. KALAIVANI, S. SWETHA, R. NITHYA, E. JENIFFER actively involved in motivation program Conducted by Dr. REDDY'S Lab facilitator Mr. S. SRIRAM, at Vivekanandha Medical Care Hospital, Elaympalayam, Tiruchengode on August 13, 2016.



PHARMA SCIENCE EXPO - 2016

Pharm-D students actively participated in Vivekanandha Educational Institutions organized Internal Science Expo-2016 and demonstrated the respiratory functions and various Food & Drug Incomaptibilities with scientific models at Swamy Vivekanandha College of Pharmacy on September 20, 2016.



PUBLICATION

Mr. S. ANANDKUMAR et al, Clinical Efficacy study of Atorvastatin, Simvastatin, Pravastatin in Hyperlipidemia Patient. International Journal of Pharmacy & Pharmaceutical Research 2016; 4(6) : 524-27.

DRUG INFORMATION CENTER ACTIVITIES (MAY - AUG)

ACTIVITIES	NUMBER
No. of Drug Queries Answered	105
No. of Patients Counseled	1442
No. of ADR reported	12



Book Post



Please send your suggestions to

The Chief Editor

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