



CLINICAL PHARMA PRACTICE

An Update of Clinical Research and Drug Information



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PHYSICIAN DESK



Dr. A. PANNEERSELVAM, M.D(Gen. Med)., DNB (Cardio), Interventional Cardiologist Vivekanandha Medical Care Hospital

CORONARY HEART DISEASE IN INDIAN'S

Case Study: India is undergoing a rapid health transition with rising burden of Coronary Heart Disease (CHD). Among adults over 20 yrs of age, the estimated prevalence of CHD is around 3–4 per cent in rural areas and 8–10 per cent in urban areas, representing a two-fold rise in rural areas and a six-fold rise in urban areas between the years 1960 at 2000.

In addition, a reversal of socio-economic gradients for CHD risk factors has emerged in the Indian population. This combined with lack of support mechanisms for evidence based treatment and follow up for Acute Myocardial Infarction (AMI), results in almost 49.1 per cent higher mortality among the poor as compared to richest.

This study concluded that abnormal lipids, smoking, hypertension, diabetes, abdominal obesity, psychosocial stress, decreased consumption of fruits and vegetables, moderate consumption of alcohol and physical activity accounted for most of the risk of myocardial infarction worldwide.

Entry deposits Adventitia; outermost layer, contains nerves for signaling. Fatty deposits Blood Clot / Thrombus Blood Clot / Thrombus Separates Internal elastic lamina External elastic lamina extracellular matrix for contraction. Fig: Progress of Atherosclerosis Adventitia; outermost layer, contains nerves for signaling.

Results of the South Asian component of the inter heart study

- South Asian men encountering AMI were 5.6 yrs younger than women.
- The higher risk for AMI in South Asians in their younger age is largely determined by the higher levels of risk factors and the nine conventional risk factors (abnormal lipids, smoking, hypertension, diabetes, abdominal obesity, psychosocial factors, consumption of fruits & vegetables, alcohol and regular physical activity) collectively explain 86 percent of the AMI risk in South Asians.
- ★ Abnormal Apo-B / Apo A-1 ratio and smoking are the most important risk factors.
- ★ Low education level is associated with increased risk of AMI worldwide.
- ★ Lack of protective measure such as lifestyle factors, leisure time, physical activity and regular intake of fruits and vegetables are markedly lower among South Asians than Western population, while harmful risk factors such as elevated ApoB/ApoA-1 ratio are higher in South Asians.
- South Asians have significantly higher population attributable risk associated with waist-hip ratio.
- ★ Higher level of risk factors in both cases and controls under the age of sixty.
- Regular alcohol consumption is not protective for AMI in South Asians.

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

CLINICAL RESEARCH

PIOGLITAZONE AFTER ISCHEMIC STROKE OR TRANSIENT ISCHEMIC ATTACK

In this trial involving patients without diabetes who had insulin resistance along with a recent history of ischemic stroke or TIA, the risk of stroke or myocardial infarction was lower among patients who received pioglitazone than among those who received placebo. Pioglitazone was also associated with a lower risk of diabetes but with higher risks of weight gain, edema, and fracture.

Ref: N Engl J Med 2016 April 7, 2016

ONDANSETRON SHOULD NOT BE FIRST CHOICE FOR NAUSEA IN PREGNANCY

Ondansetron given to relieve nausea and vomiting in pregnant women during the first trimester is associated with a low risk for birth defects, and possibly a small increase in the incidence of cardiac malformations in newborns, according to a systematic review.

Ref: Medscape April 08, 2016

REDUCTION IN LATE MORTALITY AMONG 5-YEAR SURVIVORS OF CHILDHOOD CANCER

The strategy of lowering therapeutic exposure has contributed to an observed decline in late mortality among 5-year survivors of childhood cancer.

Ref: N Engl J Med 2016 March 3, 2016.

METFORMIN SAFE FOR SOME PATIENTS WITH RENAL PROBLEMS

In a response to mounting evidence, the US Food and Drug Administration (FDA) announced today that the diabetes drug metformin can be used safely in patients with mild and, in some cases, moderate kidney impairment after decades of warning against it.

Ref: Medscape April 08, 2016

BLOOD-PRESSURE AND CHOLESTEROL LOWERING IN PERSONS WITHOUT CARDIOVASCULAR DISEASE

The combination of rosuvastatin (10 mg per day), candesartan (16 mg per day), and hydrochlorothiazide (12.5 mg per day) was associated with a significantly lower rate of cardiovascular events than dual placebo among persons at intermediate risk who did not have cardiovascular disease.

Ref: N Engl J Med 2016 April 2, 2016

ZIKA VIRUS INFECTION WITH PROLONGED MATERNAL VIREMIA AND FETAL BRAIN ABNORMALITIES

The current outbreak of Zika Virus (ZIKV) infection has been associated with an apparent increased risk of congenital microcephaly. We describe a case of a pregnant woman and her fetus infected with ZIKV during the 11th gestational week. The fetal head circumference decreased from the 47th percentile to the 24th percentile between 16 and 20 weeks of gestation. ZIKV RNA was identified in maternal serum at 16 and 21 weeks of gestation. At 19 and 20 weeks of gestation, substantial brain abnormalities were detected on ultrasonography and magnetic resonance imaging (MRI) without the presence of microcephaly or intracrar calcifications. On postmortem analysis of the fetal brain, diffuse cerebral cortical thinning, high ZIKV RNA loads, and viral particles were detected, and ZIKV was subsequently isolated.

Ref: N Engl J Med 2016 March 30, 2016

ANTENATAL BETAMETHASONE FOR WOMEN AT RISK FOR LATE PRETERM DELIVERY

Administration of betamethasone to women at risk for late preterm delivery significantly reduced the rate of neonatal respiratory complications.

Ref: N Engl J Med 2016 April 7, 2016

Some of Fixed Dose Combination Banned in India

- 1. Aceclofenac + Paracetamol + Rabeprazole
- 2. Diclofenac + Tramadol + Chlorzoxazone
- 3. Paracetamol + Cetirizine + Caffeine
- 4. Diclofenac + Tramadol + Paracetamol
- 5. Omeprazole + Paracetamol + Diclofenac
- 6. Azithromycin + Cefixime
- 7. Amoxicillin + Dicloxacillin
- 8. Amoxicillin 250 mg + Potassium Clavulanate Diluted 62.5 mg
- Azithromycin + Ofloxacin
- Metformin 1000/1000/500/500mg+Pioglitazone 7.5 / 7.5 / 7.5 / 7.5mg + Glimepiride 1/2/1/2mg

Ref: http://indianexpress.com/article/india-300-banned-drugs/

RECENTLY APPROVED DRUGS BY FDA

S. No.	BRAND NAME / COMPANY	MOLECULE NAME	INDICATIONS	APPROVED MONTH AND YEAR
1.	Ofev / Boehringer Ingelheim	Nintedanib	Idiopathic Pulmonary Fibrosis	March 2016
2.	Nimbex / Abb Vie	Cisatracurium Besylate	Skeletal Muscle Relaxation	March 2016
3.	Antizol / Sandoz	Fomepizole	Ethylene Glycol, Methanol Poisoning	March 2016
4.	Xtandi / Astellas	Enzalutamide	Prostate Cancer	December 2015
5.	Mydacla / Mylan	Daclatasvir Di-hydrochloride	Chronic Hepatitis C Virus	December 2015
6.	Myhep Lvir / Mylan	(Ledipasvir /Sofosbuvir)	Chronic Hepatitis C (Chc)	December 2015
7.	Imbruvica / Janssen Biotech	Ibrutinib	Chronic Lymphocytic Leukemia	October 2015
8	Tractocile / Ferring	Atosiban Acetate	Delay Imminent Pre-Term Birth in Pregnant Women	September 2015

Ref: cdsco.nic.in/forms/list.aspx?lid=20342ID=11

NEW DRUG PROFILE

BRIVAR	ACETAM	
PINIALM.		

INDICATION

Indicated as adjunctive therapy for Partial-Onset Seizures (POS) in patients age 16 years and older with epilepsy.

DOSAGE AND ADMINISTRATION

The recommended starting dosage is 50 mg twice daily (100 mg per day). The dosage may be adjusted down to 25 mg twice daily (50 mg per day) or up to 100 mg twice daily (200 mg per day).

DOSAGE FORMS AND STRENGTHS

Film Coated Tablet: 10 mg, 25 mg, 50 mg, 75 mg & 100 mg

Oral Solution: 10 mg /ml, Injection or infusion: 10 mg /ml

CONTRAINDICATIONS

Hypersensitivity reaction

PRECAUTIONS

Suicidal Ideation and Behaviour

Dose adjustments in hepatic patient

ADVERSE REACTIONS

Somnolence/Sedation, Dizziness, Fatigue Nausea/Vomiting

PREGNANCY CATEGORY : C

Ref: medscap.com/drug/briviact-brivaracetam-1000083

SOFOSBUVIR

INDICATION

Indicated for the treatment of genotype 1, 2, 3 or 4 Chronic Hepatitis C Virus (HCV) infection as a component of a combination antiviral treatment regimen.

DOSAGE AND ADMINISTRATION

One 400 mg tablet taken once daily with or without food. Should be used in combination with Ribavirin or in combination with Pegylated interferon and Ribavirin for the treatment of HCV.

DOSAGE FORMS AND STRENGTHS

Tablet: 400 mg

CONTRAINDICATIONS

Combination with Peginterferon Alfa / Ribavirin or Ribavirin contraindicated to pregnancy patient.

PRECAUTIONS

Serious symptomatic bradycardia may occur in patients taking amiodarone. Use with other drugs containing sofosbuvir is not recommended.

ADVERSE REACTIONS

Fatigue, Head ache, Nausea

Insomnia, Anemia

PREGNANCY CATEGORY : B

Ref: medscap.com/drug/sovaldi-sofosbuvir-999890

DEPARTMENT ACTIVITIES

CONFERENCE ATTENDED

Dr. S. Ananda Thangadurai, Dr. T. TamilSelvan, Mr. S. Anandkumar, Dr. Sojan P Paul, Mrs. T. Kumutha, Mr. Joseph Stalin D, M.Pharm (Pharmacy Practice), V-Pharm.D and III - Pharm.D students participated in Indian Congress of Pharmacy Practice 2016 and 2nd Convention of IACP on the topic "The Responsible Pharmacist: Transforming Patient Care" at Hotel Le Meridien, Coimbatore on 2nd and 3nd April 2016.

CONFERENCE PRESENTATIONS

★ H. Kalaivani, presented a research article on "A Prospective study of the Laxative Therapy and Quality of Life of Geriatric Patients Causing Constipation" in National Level Conference on Applications of Recent Methodologies in Exploring Revolutionary Biopharmaceuticals for Lifestyle Disease on 4th and 5th March 2016 at Kanchipuram.

- ★ S. Anand Kumar presented a research article on "Current Trends of Antibiotics Prescription in Preoperative and Post operative Patient at a Private Hospitals Constipation" in National level conference on Applications of Recent Methodologies in Exploring Revolutionary Biopharmaceuticals for Lifestyle Disease on 4th and 5th March 2016 at Kanchipuram.
- ★ S.Swetha presented a research article on "Assessment of Cost Effectiveness Ratio for Oral Hypoglycemic Agents in Type –II Diabetic Patients" in National Level Conference on Applications of Recent Methodologies" in Exploring Revolutionary Biopharmaceuticals for Lifestyle Disease on 4th and 5th March 2016 at Kanchipuram.
- ★ S Anandkumar, Dr. T. Tamilselvan presented a research article on "Prevalence and Incidence of Dispensing Ayurvedic Products along with Allopathic Medicines by Community Pharmacist as OTC" in IACP Conference-2016, Coimbatore.
- ★ T. Kumutha, Dr. T. Tamilselvan presented a research article on "Pharmacist attitude towards the patient services: Urban Vs Rural" in IACP Conference-2016, Coimbatore.
- ★ Sojan P Paul presented a research article on "Assessment and Prevention of Cardiovascular Risk among Hypertensive Patients in a Tertiary Care Hospital" in IACP Conference-2016, Coimbatore.
- ★ R. Nithya presented a research article on "The Prospective Study of Laxative Therapy and Quality of Life in Geriatric Patients Causing Constipation" in IACP Conference-2016, Coimbatore.







GUEST LECTURE

★ Dr. P.R. Anand Vijaya Kumar, Prof. Dept. of Pharmacy Practice, JSS College of Pharmacy, Ooty has delivered a guest lecture on Pharmacy Practice in India for Pharm.D & M.Pharm (Pharmacy Practice) students on 27.04.2016.

DRUG INFORMATION CENTER ACTIVITIES

ACTIVITIES	NUMBER
Drug Information Queries Answered	30
No. of Patients Counseled	1287
No. of ADR reported	6

Book Post



Please send your suggestions to The Chief Editor

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