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A Newsletter on

CLINICAL PHARMA PRACTICE

An Update on Clinical Research and Drug Information



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PHYSICIAN DESK



Dr. R. JAGANMOHAN, M.S.,
General Surgeon,
Vivekanandha Medical Care Hospital.

ACID PEPTIC DISEASE

Excessive secretion of acid and pepsin or a weakened stomach mucosal defense is responsible for damage to the delicate mucosa and the lining of the stomach, oesophagus and duodenum resulting in ulceration which is known as "Acid Peptic Disease".

Pathophysiology

Gastro esophagus reflux disease (GERD) occurs when the normal antireflux barrier between the stomach and oesophagus is impaired, either transiently or permanently. Therefore, defects in the oesophagogastric barrier, such as lower oesophageal sphincter incompetence, transient lower oesophageal sphincter relaxation, and hiatal hernia, are the primary factors involved in the development of GERD. Symptoms develop when the offensive factors in the gastroduodenal contents, such as acid, pepsin, bile acids, and trypsin, overcome several lines of oesophageal defense, including oesophageal acid clearance and mucosal resistance.

Signs and Symptoms : Heartburn, acid regurgitation, dysphagia, odynophagia, belching, chest pain, asthma, cough, hoarseness, sore throat, globus, and repetitive throat clearing.



Diagnosis

Endoscopy is the technique of choice to evaluate the mucosa in patients with symptoms of GERD. Erosions or ulcerations at the squamocolumnar junction, as well as the findings of Barretts oesophagus, are diagnostic of GERD. However, Barretts epithelium must be confirmed by a biopsy revealing intestinal metaplasia.

Management

The first step management is to identify Helicobacter Pylori (H. pylori) infection and users of nonsteroidal antiinflammatory drugs (NSAIDs). Antibiotic therapy is clearly indicated if H. pylorus is present in the setting of any history of ulcer disease. NSAID use is unavoidable; they should be used at the lowest possible dose and duration.

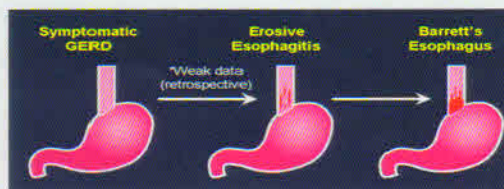
Antacids: Systemic-Sodium Bicarbonate, Aluminium Hydroxide, Magnesium Hydroxide, Magnesium Trisilicate, Calcium Carbonate. To be taken on 30 min before meal or 2 hrs after meal.

Simethicone: Forms a layer of foam on top of gastric contents & reduce reflux.

Oxethazaine: Surface anaesthetic.

Sucralfate: Ulcer protective salt of sucrose complexed to sulfated aluminium hydroxide (basic aluminium salt) Sucralfate taken on empty stomach 1 hr before meals. Concurrent use of antacids and H₂ antagonist should be avoided (as sucralfate needs acid for activation). It is mainly used in the treatment of NSAID induced ulcers and patients with continued smoking.

H₂ Antagonists: Cimetidine, Ranitidine, Famotidine, Roxatidine, Nizatidine and Lafutidine



PROGRESSION OF SYMPTOMATIC GERD

CLINICAL RESEARCH

AYER ANNOUNCES ENROLLMENT OF PHASE III TRIALS OF VILAPRISAN IN UTERINE FIBROIDS

Uterine fibroids, also known as leiomyomas, are the most common benign uterine tumors in women of reproductive age. The two most common symptoms of uterine fibroids for which women seek treatment are abnormal uterine bleeding (including heavy or prolonged menstrual bleeding) and pelvic pressure.

Treatment options depend on the size, number and location of the tumors as well as the patient's age and desire to maintain fertility. To date, there are no FDA-approved drug therapies for heavy menstrual bleeding associated with uterine fibroids. Surgical management, such as hysterectomy (removal of the uterus) and myomectomy (removal of the fibroids), remains the main course of action for the treatment of patients with symptomatic uterine fibroids. According to a survey in the American Journal of Obstetrics & Gynaecology, 79% of women indicated it was important to have a uterine fibroids treatment option that did not involve invasive surgery.

Phase III clinical study program will include several studies to investigate the efficacy and safety of vilaprisan 2 mg in patients with symptomatic uterine fibroids. The program aims to screen more than 1,400 women and randomize 750 patients at up to 140 centers in the U.S. Efficacy measures of the trial program will include the effect on heavy menstrual bleeding (amenorrhoea or controlled bleeding) and reduction in fibroid size.

Vilaprisan is a selective progesterone receptor modulator (SPRM), which is currently in clinical development for the oral treatment of symptomatic uterine fibroids. Progesterone, a naturally occurring hormone in the body, is critical to the development of the fibroid. Vilaprisan is thought to work by binding to the progesterone receptor and modulating its activity.

Anandkumar,
Assistant Professor
Ref: www.drugs.com

TYPE 1 DIABETES IS BELIEVED TO BE AN AUTOIMMUNE DISORDER. IMMUNOTHERAPY FOUND SAFE FOR TYPE 1 DIABETES IN LANDMARK TRIAL

The condition is thought to be an autoimmune disorder in which the body's immune system - its T cells, specifically - does not recognize the pancreas' insulin-producing beta cells and mistakenly attacks them. At present, there are no treatments for preventing T cells from killing off the body's beta cells. For type 1 diabetes, immunotherapies consist of molecules that imitate a natural insulin peptide. In this context, researchers based in the United Kingdom set out to examine the benefits of immunotherapy in a landmark trial that included a placebo control group.

The trial found no evidence of toxicity or negative side effects, and beta cells were not impaired or reduced as a consequence of the therapy. The authors write, "Treatment was well tolerated with no systemic or local hypersensitivity," which led researchers to conclude that "proinsulin peptide immunotherapy is safe."

Anu Philip,
Author
Ref: www.medicalnewstoday.com

SVCP Pharma Quiz

Emetine is used in the treatment of

- a) Malaria b) Tuberculosis c) Amebiasis d) None of the above

Incomplete antigens are called

- a) Immunogens b) Paratope c) Haptens d) Epitomes

The inhalation anesthetic with the fastest onset of action is

- a) Nitrous oxide b) Enflurane c) Isoflurane d) Nitric oxide

The drug bill was introduced in the year

- a) 1931 b) 1948 c) 1940 d) 1930

An addicting drug which produces little or no physical dependence is

- a) Amphetamine b) Diazepam c) Methadone d) Phenobarbitone



Answer : Page 4

r. T. Tamilselvan,
Pharm.D.,
Ref: www.pharmatutor.org

RECENTLY APPROVED DRUGS BY CDSCO

S. No.	DRUG NAME	DOSE	DOSAGE	INDICATIONS	APPROVED ON
1.	Brivaracetam	50/75/100mg	Tablet	Epilepsy	07.09.2017
2.	Efonidipine	10/20/40mg	Tablet	Hypertension	28.08.2017
3.	Mirabegron	25/50mg	Tablet	Urgency, Incontinence	18.08.2017
4.	Delamanid	50mg	Tablet	Tuberculosis	02.08.2017
5.	Fluticasone Furoate and Vilanterol Trifenatate	100mg+25mg	Powder for Inhalation	Chronic bronchitis	29.06.2017
6.	Argatroban Hydrate	250mg/2.5ml	Injection	Thrombocytopenia	30.05.2017
7.	Osimertinib	40/80mg	Tablet	Lung Cancer	29.05.2017
8.	Sofosbuvir + Velpatasvir	400mg+100mg	Tablet	Chronic Hepatitis C virus	04.05.2017
9.	Pomalidomide	1/2/3/4mg	Capsules	Multiple Myeloma	01.05.2017
10.	Teriflunomide	14mg	Tablet	Multiple Sclerosis	13.04.2017

Mrs. T. Kumutha,
Lecturer

Ref: www.cdsc0.nic.in

NEW DRUG PROFILE

DELAFLOXACIN

CATEGORY: Antibacterial

MOA: Inhibition of both bacterial topoisomerase IV and DNA gyrase enzymes which are required for DNA replication, transcription, repair and recombination.

INDICATION : Acute bacterial skin and skin structure infection (ABSSSI)

DOSE & DOSAGE : Injection- 300mg Delafloxacin IV and Oral- 450mg.

DRUG INTERACTION: Antacid, sucralfate, metal cation, multi vitamins.

PRECAUTION: Hypersensitivity reaction, Clostridium difficile associated diarrhoea.

ADVERSE DRUG REACTION : Nausea, diarrhoea, headache, transaminase elevations, vomiting.

BRAND NAME: Baxdela

DURVALUMAB

CATEGORY: Antineoplastic agent

MOA: Human immunoglobulin G1 kappa monoclonal antibody which blocks programmed cell death ligand 1 binding to PD-1 and CD80; PD-L1 blockade leads to increased T-cell activation, allowing T-cells to kill tumor cells.

INDICATION : Urothelial carcinoma, locally advanced or metastatic.

DOSE & DOSAGE : IV 10mg/kg once every 2 weeks until disease progression or unacceptable toxicity.

DRUG INTERACTION : Belimumab may enhance the adverse effects or toxic effect (avoid combination).

PRECAUTION : Adrenal insufficiency, Dermatological toxicity, Type-1DM, Gastrointestinal toxicity, Hepatotoxicity, nephrotoxicity, Thyroid disorders.

ADVERSE DRUG REACTION : Peripheral edema, fatigue, skin, rashes, hyponatraemia, infection, constipation.

PREGNANCY CATEGORY : X

BRAND NAME : Imfinzi

ABSELA KABEER, SILPA SUNNY, RINKLE PRIYA C, SANDRA WILSON (PHARM D INTERNS)

Ref : www.uptodate.com

DEPARTMENT ACTIVITIES

Achievements:

Pharm.D students won third prize in national level dance competition at IPA sponsored seminar & dance competition conducted by Vikas Institute of Pharmaceutical Sciences, Rajahmundry, Andhrapradesh on 02.09.17.



Department of Pharmacy Practice received seminar grant from The Tamilnadu Dr. M.G.R Medical University, Chennai for the seminar "Clinical Pharma Practice- Indian and Global Scenario" (CPP-IGS 2017).

Seminar Organized:

Department of Pharmacy Practice Organized TN. M.G.R Medical University co-sponsored seminar "Clinical Pharma Practice- Indian and Global Scenario" (CPP-IGS 2017) on 11.08.17. Eminent personalities from industries were invited as Speakers. They are Dr. R. Niroop, MD (Pharmacology), Senior Executive, Lotus Labs Private Limited, Bengaluru, Mr. Remiz Muhammed, M.Pharm., CEO, Hexa Business Transformation Services, Kozhikode. Mrs. A. Nagalakshmi, M.Sc (Life Sciences), CEO, Consortium Clinical Research(P) Ltd., Coimbatore.



Seminar/ Workshop Attended:

- ★ Pharm. D students and faculty of Department of Pharmacy Practice participated in AHS organized CME programme "Clinical Implication for Paramedics" on 24.06.2017.
- ★ Faculty of Department of Pharmacy Practice attended a Symposium on "Emerging Disease and Novel Drug Development" at VICAS on 07.07.17.
- ★ M.Pharm students and faculty of Department of Pharmacy Practice attended one day seminar "Clinical Pharmacy Practice Services – Current Scenario" at JKKN College of Pharmacy, Komarapalayam on 31.08.17.
- ★ Dr. T.Tamilselvan and Mr. S. Anandkumar attended "Role of Evidence Based Medicine in clinical decision making" workshop at Coimbatore on 06.09.17
- ★ Pharm.D and M. Pharm Students attended Bentham Sciences Workshop on 08.09.2017



Published Article:

Tamilselvan T, Parkavi Rani P, Anandkumar S, Kumutha T, Joseph Stalin D, A Study on Prevalence of Diabetic Foot Ulcer and Quality of Life of Type 2 Diabetes Mellitus Patients in A Multi Specialty Hospital, World Journal of Pharmacy and Pharmaceutical Sciences. 2017; 6(7): 1811-1816.



DIC ACTIVITIES	NUMBER
No. of Patients Counselling	924
Drug Information Queries Answered	12

SVCP PHARMA QUIZ

Answers

1. c) 2. c) 3. a) 4. a) 5. a)



Book Post

To

Please send your suggestions to
The Chief Editor

CLINICAL PHARMA PRACTICE NEWSLETTER

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