Drug Safety Communication

Ponatinib: - Increased Reports of Serious Blood Clots In Arteries And Veins

ISSUE: FDA is investigating an increasing frequency of reports of serious and life-threatening blood clots and severe narrowing of blood vessels (arteries and veins) of patients taking the leukemia chemotherapy drug ponatinib. Data from clinical trials and post market adverse event reports show that serious adverse events have occurred in patients treated with ponatinib, including heart attacks resulting in death, worsening coronary artery disease, stroke, narrowing of large arteries of the brain, severe narrowing of blood vessels in the extremities, and the need for urgent surgical procedures to restore blood flow.

BACKGROUND: Ponatinib is a prescription medicine used to treat adults diagnosed with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) or Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL), who are no longer benefiting from previous treatment or who did not tolerate other treatment. At the time of ponatinib’s approval in December 2012, the drug label contained information about the risks of blood clots in the Boxed Warning and Warnings and Precautions sections. In clinical trials conducted before approval, serious arterial blood clots occurred in 8 percent of ponatinib-treated patients, and blood clots in the veins occurred in 3 percent of ponatinib-treated patients. In the most recent clinical trial data submitted by the manufacturer to FDA, at least 20 percent of all participants treated with ponatinib have developed blood clots or narrowing of blood vessels.

RECOMMENDATION: Health care professionals should consider for each patient whether the benefits of ponatinib treatment are likely to exceed the risks of treatment. Patients taking ponatinib should seek immediate medical attention if they experience symptoms suggesting a heart attack such as chest pain or pressure, pain in their arms, back, neck or jaw, or shortness of breath; or symptoms of a stroke such as numbness or weakness on one side of the body, trouble talking, severe headache, or dizziness. FDA is providing this information to patients and health care professionals while it continues its investigation.

- Report from FDA

Medication Non-Adherence In Ambulatory Diabetic Patients

Diabetes mellitus is a chronic disease and the prevalence for all age-groups worldwide was estimated to be 2.8% in 2000 and 4.4% in 2030. Medication non-adherence is a pervasive medical problem that is common among patients with chronic disease. This study was conducted for a period of 1 month. It includes 154 randomly selected patients who were interviewed by using a questionnaire regarding socio-economic characteristics, adherence rates, barriers that affect adherence to medication use (using Morisky self report scale) and counseled by pharmacist for 20-30 minutes.

Among the 154 patients, 42 (27.2%) male and 112 (72.7%) female were taking a mean of 5.3 medicines per patient to control diabetes and related co-morbidities. Of the total, 97 (62.9%) were adherent and 57 (37.01%) were non-adherent to medications. In our study the commonly cited intentional non-adherence was found to be self-decision (35.08%) and omission of drugs because of experiencing side effects (22.8%), confusion in dosage frequency (17.5%), forgetfulness (10.5%) and financial difficulty (8.7%) were the other contributing factors for non-adherence. Efforts were taken to increase the medication adherence and self care through patient education by pharmacists.

Hence patient’s medication compliance is a multifactor behavior in which the role of patient’s attitude is very important. Interventions are needed to increase medication adherence so that patients can realize the full benefit of prescribed therapies.

New Drug Information - Dapagliflozin

A new pill to treat adults with type 2 diabetes has been approved by the US Food and Drug Administration on Jan 9th, 2014. DAPAGLIFLOZIN tablets were approved to improve patient’s blood sugar control, in combination with diet and exercise. The approval is based on findings from 16 clinical trials that included more than 9,400 people with type 2 diabetes. The trials showed improvement in HbA1c (glycosylated hemoglobin or a measure of blood sugar control).

DAPAGLIFLOZIN is a sodium-glucose co-transporter (SGLT2) inhibitor that blocks the re-absorption of glucose by the kidney, increases glucose excretion and lowers blood sugar levels. This has been studied as a standalone therapy and in combination with other type 2 diabetes therapies including metformin, pioglitazone, sitagliptin and insulin.

MECHANISM OF ACTION:
Sodium-glucose co-transporter 2 (SGLT-2) expressed in the proximal renal tubules, is responsible for the majority of the re-absorption of filtered glucose from the tubular lumen. DAPAGLIFLOZIN is an inhibitor of SGLT2 and thus it reduces the re-absorption of filtered glucose and thereby increases urinary glucose excretion.

DOSAGE FORM: Supplied as film-coated tablets.

DOSE: 100 mg (Adult dose)

CONTRAINDICATIONS:
- Patients who have Type 1 diabetes and with increased ketones in their urine and blood.
- Patients with moderate or severe renal impairment or end stage renal disease or those on dialysis.
- Patients with active bladder cancer.

SIDE EFFECTS:
- It causes dehydration and low blood pressure, particularly among older patients, those with impaired renal function and those receiving diuretics.

ADR:
- Genital mycotic infection.
- Urinary tract infection.


Single Pill To Simplify Heart Disease

A single combination pill used to treat blood pressure, cholesterol and platelet control could prove more beneficial for patients with or at risk of heart disease, compared with standard preventive therapy - according to a study published in JAMA (The Journal of the American Medical Association). Researchers from the International Centre for Circulatory Health at Imperial College London conducted a randomized trial involving 2004 patients in India and Europe who either had heart disease or were at risk for it.

All participants were randomly assigned to either a fixed-dose combination of aspirin, statins and two blood pressure lowering agents or they continued with their usual care strategy. One group of patients took a fixed-dose combination of 75 mg aspirin, 40 mg simvastatin, 10 mg lisinopril and 50 mg atenolol. The second group of patients continued with usual care or 75 mg aspirin, 40 mg simvastatin, 10 mg lisinopril and 12.5 mg hydrochlorothiazide.

The researchers say that at the baseline of the study, average blood pressure (BP) was 137/78 mmHg, low-density lipoprotein cholesterol (LDL-C) was 91.5 mg/dL. Additionally, 1233 of the participants reported use of antiplatelet statin and two or more medications for lowering blood pressure. Both groups were followed-up for an average of 15 months.

Overall, results at the end of the study showed that systolic blood pressure and low-density lipoprotein cholesterol were significantly lower in the group with the fixed-dose combination (FDC) treatment, compared with the usual care group.

The study authors say that to the best of their knowledge, “this was the first randomized trial to assess the long-term use of an FDC containing antiplatelet, statin, and BP-lowering drugs compared with usual care in patients with CVD.”


Dr. Praveen participated in the CME Program

Dr. G. Praveen Kumar participated in the Continuing Medical Education Program (CME) for medical officers at Ordnance Factory Hospitals, Avadi, Chennai. This program was held from 10th to 12th January, 2014 and Dr. Praveen spoke on ‘Effective Communication between Physicians and Pharmacists’ which was well appreciated.
Dosing Profile - Sirolimus (Immuno Suppressant)

1) Adult
   2 mg oral tablet formulation is clinically equivalent to 2 mg oral solution.
   a) Renal transplant rejection: high immunologic risk
      Prophylaxis
      • Weight less than 40 kg:
        Initial loading dose: 3 mg/m² orally as soon as possible on day 1 post transplantation
      Maintenance: 1 mg/m²/day orally once daily starting on day 2 post transplantation in combination with cyclosporine starting at up to 7 mg/kg/day in divided doses and prednisone orally starting at a minimum of 5 mg/day
   • Weight 40 kg or more:
      Initial, loading dose up to 15 mg orally as soon as possible on day 1 post transplantation
      Maintenance, 5 mg orally once daily starting on day 2 post transplantation in combination with cyclosporine starting at up to 7 mg/kg/day in divided doses and prednisone orally starting at a minimum of 5 mg/day
   Dosage adjustment in clinical studies used the target of whole blood sirolimus trough concentrations ranging from 10 to 15 ng/ml (chromatographic assay) until week 52
   b) Renal transplant rejection: Low to moderate immunologic risk
      Prophylaxis
      • Weight less than 40 kg
        Loading: 3 mg/m² orally
        Maintenance: 1 mg/m²/day orally once daily
      • Weight 40 kg or more
        Loading: 6 mg orally
        Maintenance: 2 mg orally once daily

Reference: micromedexsolutions.com/micromedex2

A Step towards success...
Visit of Fulbright specialist Dr.Douglas Slain to our college

The college management are pioneers in providing quality and effective pharmacy education system for the past 33 years. As part of academic enhancement to upgrade the profession to the next level by providing knowledge to students to compete at global level, C.I.L. Baid Metha College of Pharmacy applied for the Fulbright fellowship program. The Fulbright Program is the flagship international educational exchange program sponsored by the U.S. government and is designed to increase mutual understanding between the people of the United States and the people of other countries. The college was the first Pharmacy college in India to be chosen for the Fulbright Specialist program in Public Health.

Dr. Douglas Slain Pharm.D., BCPS, FCCP, FASHP, Associate Professor of Pharmacy and Medicine and an Anti-infective Clinical Specialist at West Virginia University, USA, visited the college for two weeks in June, 2013. Dr. Slain was actively involved in enhancing the clinical skills of faculty and student by promoting effective clinical pharmacy services and thereby providing better health care to the society. Dr. Slain trained the staff and students in various clinical skills such as bedside patient care, case analysis, prescription audit, medication errors, adverse drug reaction monitoring and reporting, drug information services and patient counseling. Hands-on training by Dr. Slain at Apollo Hospitals to the Pharm.D students and clinical pharmacists of Apollo hospital was an eye-opener for their profession needs.

Faculty members with Dr. Douglas Slain (4th from left), Mr. Vinod Khanna-Chairman (5th from left), Mr. R. Srinivasan – Vice Chairman (6th from left).
Seminar on ‘Global Threat Of Antibiotic Resistance – An Indian Initiative’

A seminar on “GLOBAL THREATS OF ANTIBIOTIC RESISTANCE - AN INDIAN INITIATIVE” was held on 22nd June 2013 at Hotel Accord Metropolitan, Chennai. The main speaker Dr. Douglas Slain gave an effective presentation on ‘Antibiotic Resistance and its Overuse’. The highlight of the seminar was a presentation on ‘Chennai Declaration – An Indian initiative to a global problem’ by Dr. Abdul Chafur MBBS, MD(Med), MRCP(UK), FRCPath(UK), consultant in Infectious Diseases, Clinical Mycology and Infection Control in Apollo Hospital, Chennai. Dr. Lalit Kanodia MD, PDCR, MBA coordinator for Apollo Pharmacovigilance Centre and Adjunct Assistant Professor, Research and Development in Apollo Hospital Education and Research Foundation, New Delhi gave a talk on ‘Role of Pharmacists in antibiotic resistance-Indian scenario’.

The program ended by a presentation on Fulbright Fellowship Opportunities by Ms. Lalitha Nageswar, Administrative Co-ordinator, US-India Education. The seminar was sponsored by Sanofi India Ltd.

Pharmacists Day, 25th September, 2013

The college celebrated ‘Pharmacists Day’ on 25th September, 2013 to boost the morale of the pharmacists and student pharmacists in particular. The focus of the activities to mark this special day was to motivate the student pharmacists to take pride in their chosen profession. The college organized a rally and a human chain which was flagged off by the Vice Chairman of the college, Mr. R. Sriram. The students distributed pamphlets to the public titled ‘Be Alert on Drug Alert’ and had important information on drugs useful to the general public. The pamphlet discussed drug facts like expiry, use of SR preparations, dry syrups, few points on storage and antibiotic use. Alert for parents to protect children from drugs was also included. More than 1000 such pamphlets were distributed on the busy Rajiv Gandhi Salai.

International Education Week

The International Education Week was celebrated on 15th October, 2013. The chief guest was Dr. Christine Birnie, Associate Professor, St John Fisher College, Rochester, USA. She addressed the staff members on the topic ‘The Use of Active Learning to enhance Classroom Teaching’. It was an interactive session in which Dr. Bernie gave practical ideas to improve student participation and enhance classroom teaching. The second session was with the Pharm D students and the topic was ‘The US Pharmacy Education System: Pharm D and Beyond’. Dr. Bernie gave a brief talk on the Pharm D program in US and enlightened the students on opportunities abroad.

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