SHPHK joins "Care for your Heart" (「關心您的心」) to alert drug-food interaction of warfarin

SHPHK jointly conducted a survey on patient receiving warfarin from April to June 2001 with Care for your Heart, a cardiac patients mutual support association. 300 patients on warfarin for an average of 3 years or more were interviewed. The results showed that:

- 53% of patients did not know about drug- and/or food-interactions of warfarin

- 73% of patients had taken food that should not be taken during warfarin therapy;

- 26% of patients had taken food in amounts more than recommended during warfarin therapy;

- 9% of patients had been admitted to hospital due to side effects of warfarin.

So Yiu Wah, President of SHPHK and Dr. David Siu, cardiologist, both addressed that patient counseling is very important in the anticoagulation treatment with warfarin. Attention should be paid on patient education to avoid warfarin-interacting drugs and food substances, including health supplements, over-the-counter medicines and traditional Chinese medicine, without prior consultation with a doctors or a pharmacists.available.0mg film-coated tablets. Summary of Product Characteristics. Revised May 2009.

FDA alerts possible QT prologation with high dose citalopram and potential interaction between citalopram and CYP2C19 inhibitors

FDA has received post-marketing reports of QT interval prolongation and Torsade de Pointes associated with Celexa (Citalopram) and its generic equivalents. In addition, FDA has evaluated the results of a thorough QT study assessing the effects of 20-mg and 60-mg doses of citalopram on the QT interval in adults. In this randomized, multi-center, double-blind, placebo-controlled, crossover study, 119 subjects received citalopram 20 mg per day (Day 9), citalopram 60 mg per day (Day 22), and placebo. The overall summary of findings is as follows:

Citalopram Dose	Increase in QT Interval (ms) (90% Confidence Interval (ms))
20 mg/day	8.5 (6.2, 10.8)
60 mg/day	18.5 (16.0, 21.0)
40 mg/day	12.6* (10.9, 14.3)*

* Estimate based on the relationship between citalopram blood concentration and QT interval.

Compared to placebo, maximum mean prolongations in the individually corrected QT intervals were 8.5 and 18.5 milliseconds (ms) for 20 mg and 60 mg citalopram, respectively. For 40 mg citalopram, prolongation of the corrected QT interval was estimated to be 12.6 ms. As a result, FDA recommended that:

- Citalopram causes dose-dependent QT interval prolongation. Citalopram should no longer be prescribed at doses greater than 40 mg/day.

- Citalopram should not be used in patients with congenital long QT syndrome.

- Patients with congestive heart failure, bradyarrhythmias, or predisposition to hypokalemia or hypomagnesemia because of concomitant illness or drugs, are at higher risk of developing Torsade de Pointes.

- Hypokalemia and hypomagnesemia should be corrected before administering citalopram. Electrolytes should be monitored as clinically indicated.

- Consider more frequent electrocardiogram (ECG) monitoring in patients with congestive heart failure, bradyarrhythmias, or patients on concomitant medications that prolong the QT interval.

- The maximum recommended dose of citalopram is 20 mg/day for patients with hepatic impairment, who are greater than 60 years of age, who are CYP 2C19 poor metabolizers, or who are taking concomitant cimetidine, however, no dose adjustment is necessary for patients with mild or moderate renal impairment.

- Patients should be advised to contact a healthcare professional immediately if they experience signs and symptoms of an abnormal heart rate or rhythm while taking citalopram.

FDA approves Soliris for rare pediatric blood disorder

On Sept. 23, 2011, The U.S. Food and Drug Administration approved eculizumab (Soliris) to treat patients with atypical Hemolytic Uremic Syndrome (aHUS), a rare and chronic blood disease that can lead to renal failure and is also associated with increased risk of death and stroke.

Eculizumab is a monoclonal antibody that binds with high affinity to compliment protein C5, which inhibits its cleavage to C5a and C5b and prevents the geneeration of termination compliment complex C5b-9. In patients with paroxysmal nocturnal hemoglobinuria (PNH), eculizumab inhibits terminal complement mediated intravascular hemolysis.

The FDA first approved eculizumab in March 2007 to treat paroxysmal nocturnal hemoglobinuria (PNH), a rare type of blood disorder that can lead to disability and premature death. Eculizumab is classified as an orphan drug, i.e. those that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. It is indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis, and for the treatment of adult and pediatric patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy. It is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

The most frequently reported adverse reactions of eculizumab in the PNH randomized trial (≥10% overall and greater than placebo) are: headache, nasopharyngitis, back pain, and nausea. The most frequently reported adverse reactions in aHUS single arm prospective trials (≥15% combined per patient incidence) are: hypertension, upper respiratory tract infection, diarrhea, headache, anemia, vomiting, nausea, urinary tract infection, and leukopenia. Terminal complement inhibition with eculizumab increases the susceptibility to serious meningococcal infections. Eculizumab is thus contraindicated in patients with unresolved serious Neisseria meningitidis infection and patients who are not currently vaccinated against Neisseria meningitidis, unless the risks of delaying eculizumab treatment outweigh the risks of developing meningococcal infection.

There are no other FDA-approved treatments for aHUS, and the safety and effectiveness of current standard treatment, plasma therapy (plasma exchange or fresh frozen plasma infusion), have not been studied in well controlled trials. Eculizumab will continue to be available only through a restricted program, and prescribers must enroll in a registration program and provide a medication guide to patients who receive the drug.

Recent increase in ceftibuten-resistant gonococci

Table 1 - Percentage of Neisseria gonorrhoeae strains with reduced susceptibility to ceftibuten isolated from patients of the SHS in 2011.

Month in 2011	Isolates with reduced susceptibility to ceftibuten
January	2 / 77 (2.6%)
February	0 / 94 (0%)
March	1 / 100 (1.0%)
April	8 / 95 (8.4%)
May	9 / 112 (8.0%)
June	2 / 76 (2.6%)
July	13 / 94 (13.8%)
August	26 / 130 (20%)
September	10 / 83 (12.0%)

The Centre for Health Protection is switching the standard first line treatment of gonococcal infection in SHS from ceftibuten to ceftriaxone due to reduced susceptibility to ceftibuten.

Neisseria gonorrhoeae is a Gram-negative cocci that causes genital tract infection, gonorrhea, in human. Urethritis in men and cervicitis in women are the most common clinical disease manifestation of Neisseria gonorrhoeae infection. Untreated infection may result in ascending infection such as pelvic inflammatory disease or even disseminated infection.

Ceftibuten 400 mg in a single oral dose has been adopted by Social Hygiene Services (SHS) as the first line antibiotic of choice for uncomplicated gonococcal infections since 1997. It has remained effective against most strains of gonococci with non-susceptible rates largely less than 5% till mid 2011.

Starting from July 2011, the Public Health Laboratory Centre (PHLC) of CHP detected a rise in gonococcal strains with reduced susceptibility to ceftibuten from patients of the SHS at rates of above 5% for three months consecutively. This had also been observed in some other countries such as the UK and Japan. Such reduction susceptibility is mainly conferred by the presence of a mosaic penA gene in these strains. At present, ceftriaxone is still highly active against these strains. Based on these observations, CHP is switching the standard first line treatment of GC in SHS from ceftibuten to ceftriaxone. CHP also recommended ceftriaxone to be the antibiotic of choice for empirical treatment of gonococcal infection by community based doctors.

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