Medical Briefs

An abridged look at current events in and around the health-care industry

This Month:

Can Sunscreen Irritate My Skin?

The Rosacea Awareness Program released key findings from a patient questionnaire that surveyed 8,500 Canadians with rosacea (33% responded). The survey discovered that close to 50% of rosacea patients suffer from skin irritations caused by sunscreen, especially in female and younger patients.

Implication: "It is believed that the heat of the sun or infrared, rather than UVA/UVB rays, may cause rosacea symptoms to flareup. But UVB is still a contributing factor. For outdoor activities I recommend a sunscreen with an SPF of 15 or higher. This can be used as needed following the application of the topical rosacea medication. Due to the sensitivity of their skin and eyes, many rosacea patients will need to try several sunscreens before finding the one which best suits their individual needs. Many patients will require several attempts to find a sunscreen that is well tolerated," says Dr. Neil Shear, professor and chief of dermatology at the Sunnybrook and Women's College Health Sciences Centre, University of Toronto.

Survey Finds Half of Rosacea Patients Suffer From Skin Irritations Caused By Sunscreen. Press Release, Montreal, Quebec, March 1, 2003.

Enalapril Helps Fight Diabetes as Well

In a study conducted by the Montreal Heart Institute (MHI), enalapril, a drug used to treat hypertension and heart failure, substantially reduced the incidence of new cases of diabetes in patients suffering from heart disease.

Implication: The results of the study are useful in the treatment of high-risk patients. Of the 291 patients that constituted the study population at the MHI, 153 received enalapril and 138 a placebo. Of the patients in the placebo group, 24.4% developed diabetes compared with 5.9% of patients in the enalapril group. The effect of enalapril was even more striking in the subgroup with abnormal fasting plasma glucose levels at baseline, where diabetes appeared in 3.9% of patients treated with enalapril compared to 48% in the placebo group.

Montreal Heart Institute Study Finds Drug Enalapril Reduces Incidence of Diabetes in Patients With Heart Failure. Press Release, Montreal, Quebec, March 11, 2003.

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Gleevec Helps Patients With Newly Diagnosed CML

According to a recent study, newly diagnosed patients in the chronic phase of chronic myeloid leukemia (CML), are substantially more likely to achieve a complete cytogenetic response when treated first with Gleevec® than with the traditional combination therapy, interferon and cytosine arabinoside (IFN/Ara-C). In addition, Gleevec significantly delayed the progression of the disease to advanced stages. The data is from an 18-month followup of the International Randomised Study of Interferon vs. STI571 (IRIS), the first head-to-head study comparing Gleevec and IFN/Ara-C.

Implication: Glivec should be considered as a first treatment option for patients with newly diagnosed CML. The study was conducted in 11,106 patients. After 18 months, 74% of newly diagnosed patients treated with Gleevec (taken orally at 400 mg daily), had achieved a complete cytogenetic response, compared with 8% of those treated with IFN/Ara-C. A major cytogenetic response was achieved by 85% of patients taking Gleevec compared with 22% of patients treated with IFN/Ara-C. Patients taking Gleevec (92%) had an improved overally progression-free survival compared with those taking IFN/Ara-C (74%). Two per cent of patients in the Gleevec arm crossed over to the IFN/Ara-C arm compared to 58% of patients in the IFN/Ara-C arm crossed over to the Gleevec arm because of tolerability reasons or lack or loss of response to treatment. Another 12% of patients in the Gleevec arm withdrew from the study, compared with 32% of patients in the IFN/Ara-C arm. Severe side effects were much more common in the IFN/Ara-C arm, consistent with the high turnover rate due to intolerance.

Data prove Glivec® is superior treatment for patients newly diagnosed with chronic myeloid leukemia. Press Release, Basel, Switzerland, March 13, 2003.

Stomping Out Community-Acquired Pneumonia

The U.S. Food and Drug Administration (FDA) has approved a supplemental new drug application for Avelox®, tablets or intravenous (IV), as a treatment for community-acquired pneumonia (CAP) due to penicillin-resistant *Streptococcus pneumoniae* (PRSP). Health Canada is reviewing the IV formulation of Avelox for the treatment of mild, moderate, and severe CAP due to susceptible micro-organisms.

Implication: Each year more than 6,000 Canadians die from pneumonia, and after lung cancer, pneumonia is the second leading cause of death due to lung disease. Avelox, a highly active agent in the fluoroquinolone class, is now an option in treating PRSP. Data provided to the FDA showed that Avelox was effective in each of the 21 cases investigated of pneumonia caused by PRSP. The clinical and bacteriologic efficacy of the drug in the treatment of *Streptococcus pneumoniae* was evaluated in nine clinical studies, which totaled 244 Avelox treated patients with CAP due to *S. pneumoniae*.

FDA Approves Avelox® (moxifloxacin HCl) For Community Acquired Pneumonia Due to Penicillin-Resistant Streptococcus Pneumoniae. Press Release, March 14, 2003.

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Things Are Looking up for Patients with ED

The European Commission of Urology approved Levitra™ (vardenafil HCI), as the newest treatment for male erectile dysfunction (ED).

Implication: There is a growing body of evidence that shows Levitra significantly improves erectile function in men with ED and works reliably over time. Results from the first placebo-controlled study of 309 men with ED due to a broad range of causes, showed that nearly three times as many men taking Levitra, 10 mg, reported improved erections than men taking a placebo pill over the course of three months, and patients experienced a significant improvement in erectile function continually from week four to week 12. In the second flexible-dose study, 92% of men reported improved erections based on the global assessment question, no matter which dose sequence was used throughout the course of the study.

Most Men With Erectile Dysfunction Reported Improved Erections in Flexible-Dose Studies of Levitra™ (vardenafil HCI). Press Release, Madrid Spain, March 13, 2003.

A New Agent in The Battle Against H. Pylori

The Therapeutic Products Directorate of Health Canada approved Helicide®, a patented single capsule triple therapy, for the eradication of *Helicobacter pylori* (*H. pylori*).

Implication: *H. pylori* is now recognised as being the main cause of gastric and duodenal ulcers. Studies have shown that Helicide is as effective as the most widely prescribed therapeutic regimen for the eradication of *H. pylori*, and it can be administered in patients who are resistant to existing therapies. Each Helicide capsule contains the equivalent of 40 mg of bismuth biskalcitrate (bismuth), 125 mg of metronidazole and 125 mg of tetracycline hydrochloride (tetracycline), and is administered with a proton pump inhibitor. Studies have shown that Helicide is effective in eradicating metronidazole-resistant strains of *H. pylori* whereas the omeprazole, amoxycillin and clarithromycin combination, the most widely prescribed therapeutic regimen for *H. pylori* eradication, is not as effective against clarithromycin-resistant strains of *H. pylori*. Helicide, unlike clarithromycin-based therapies, may be successfully administered not only to patients who are infected by metronidazole-resistant strains but also to those who are resistant to clarithromycin-resistant *H. pylori* strains.

Axcan Receives Canadian Approval for Helicide, A Single Capsule Triple Therapy for the Eradication of Helicobacter Pylori. Press Release, Mont Saint-Hilaire, Quebec, March 17, 2003.

Patients With COPD Can Breath Easier

An international study concluded that budesonide/formoterol in a single inhaler (Symbicort®) reduced the mean number of severe exacerbations (defined as those requiring medical intervention such as hospitalisations) of chronic obstructive pulmonary disease (COPD) per patient per year by 24% versus placebo, and 23% versus formoterol alone. The one year study was conducted with more than 800 patients being treated for moderate to severe COPD.

Implication: COPD is the fourth leading cause of death in the world and affects more than 750,000 Canadians. Exacerbations requiring medical intervention are important clinical events in COPD. The budesonide/formoterol combination also provided early and sustained improvements in lung function and symptoms, together with improvements in health-related quality of life compared with placebo. The study showed the beneficial effect of budesonide/formoterol in symptomatic moderate to severe COPD patients who have a history of exacerbations.

Press Release, Montreal, Quebec, March 17, 2003.

First New Treatment in Nine Years for Bipolar Disorder

The first treatment in nine years for bipolar disorder has been approved in Canada. Zyprexa® (olanzapine) has been approved for the treatment of manic and mixed episodes associated with bipolar disorder.

Implication: One to two per cent of the adult population will suffer from bipolar disorder, and 25% to 50% of patients will attempt suicide at least once. Clinical studies have shown Zyprexa has a higher rate of response (65% versus 43% placebo) and has been shown to produce a significantly greater improvement in symptoms of mania versus divalproex. The drug has been shown to manage depressive symptoms in patients with manic and mixed episodes. There was nearly a sevenfold improvement in depressive symptoms when Zyprexa was added to another mood stabiliser. A year long study showed that in the maintenance of bipolar disorder, patients taking Zyprexa relapsed into mania only half as often as patients taking lithium.

First Treatment in Nine Years Approved for Bipolar Mania in Canada. Press Release, Toronto, Ontario, March 18, 2003.