MEDICAL PHARMACIES TABLET

Drug information and news for health care providers

May 2012

DO SLEEP MEDICATIONS INCREASE MORTALITY RISK?

News reports of late have given insomniacs more sleepless nights. A recent study of about 10,000 adults with prescriptions for sleeping pills reported a 4.6-fold increase in the risk of death over a period of 2.5 years compared with the 10,000 patients in the control group not taking hypnotics. It was found that larger quantities of prescribed doses resulted in a higher risk of death. Even "patients who were prescribed between 1 and 18 doses per year had more than a three-fold increase in the risk of death". The weakness of this observational study was that it did not document the doses of the sleeping medications taken or the diagnoses- factors that may confound the results.

More than 20 published studies have examined the association between sleeping pills and mortality. Most have found a significant association. Possible reasons include:

- reduced respiratory drive
- worsening sleep apnea and the associated cardiovascular complications (e.g. hypertension, heart disease, etc)
- impaired motor and cognitive skills resulting in falls, accidents, etc.
- depression and increased rate of suicide
- increased risk of gastroesophageal regurgitation and potential co-morbidities (e.g. infection, cancer)

In fact "sleeping problems themselves (e.g. sleep latency, poor sleep efficiency, short sleep duration) have been associated with an increased risk of mortality".

Drug treatment of insomnia is not particularly effective, particularly as a long-term option. Hypnotics tend to increase sleep time on average by only 30 minutes. Additionally, there are no data about the efficacy and safety of long-term use.

What are the options? … If drug therapy is used, the lowest effective dose of the hypnotic should be taken for a short duration, tapering the drug when possible. Hypnotics may be used alone or combined with cognitive therapy, sleep hygiene education, reducing stress and the use of relaxation techniques. It is important to rule out and treat underlying causes of insomnia (e.g. sleep apnea, restless leg syndrome, anxiety, depression, etc.). A review of concomitant medications is important to insure other drugs are not interfering with sleep (e.g. caffeine, SSRIs, stimulants, decongestants, diuretics, etc.). MPT

NEW SINUSITIS GUIDELINES

Acute sinusitis (or rhinosinusitis) caused by viruses accounts for about 90 % of cases and doesn't respond to antibiotic treatment. Only about 10 % of sinusitis is caused by bacteria. Inappropriate prescribing of antibiotics for a viral illness may result in unnecessary emergency room visits due to adverse events and the evolution of antimicrobial resistance.

It may be difficult to differentiate between a viral and bacterial illness. According to Canadian guidelines, "antibiotics should be considered in patients with symptoms of prurulent nasal secretions and at least one other symptom (e.g. maxillary pain or tenderness of the face or teeth) for at least 7 days". U.S. recommendations extend this interval to 10 or more days. Other considerations include:

- severe symptoms
- high fever (102° F or 39°C or higher)
- facial pain for at least 3 to 4 consecutive days (at the beginning of an illness)
- worsening of symptoms (e.g. new onset of fever, headache or increase in nasal discharge) after a typical upper respiratory tract infection lasting 5 to 6 days

Canadian 2011 practice guidelines suggest 5 to 10 days of amoxicillin as first-line treatment. In penicillin-allergic patients, trimethoprim-sulfamethoxazole or a macrolide antibiotic is an alternative. Second-line antibiotics include amoxicillin/clavulanate, levofloxacin or moxifloxacin. These agents may be appropriate where bacterial resistance is likely or in unresponsive patients. Other measures include acetaminophen or non-steroidal anti-inflammatory drugs for mild to moderate pain, saline irrigation and/or intranasal corticosteroids. Topical/oral decongestants or antihistamines may ease symptoms but their benefits have not been proven. MPT

DRUG NEWS

Rapaflo® (silodosin) 4 mg & 8 mg capsules Watson Pharma (not currently a benefit of ODB)

Rapaflo is a highly selective alpha-blocker indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). It relaxes the smooth muscles of the prostate, improving urine flow and reduces BPH symptoms. Rapaflo is similar in efficacy to tamsulosin (Flomax CR®) and alfuzosin (Xatral®).

Precautions & Contraindications

Rapaflo is contraindicated in patients:

- with severe hepatic impairment
- with severe renal impairment (CrCl < 30 ml/min)
- taking concomitant potent CYP3A4 inhibitors or alpha blockers (refer to Drug Interactions)

Precautions:

- Rapaflo may cause orthostatic hypotension that may (rarely) lead to syncope.
- Patients planning cataract surgery should inform their ophthalmologist that they are taking Rapaflo due to the risk of Intraoperative Floppy Iris Syndrome during cataract surgery.

Drug Interactions:

- Concomitant administration with potent CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, clarithromycin or ritonavir) may increase Rapaflo blood levels and should be avoided.
- Patients taking strong P-gp inhibitors (e.g. cyclosporine) should not take Rapaflo.
- Concomitant use with other alpha blockers, antihistamines and/or PDE5 inhibitors (e.g. sildenafil-Viagra®, etc.) may increase hypotension risk.

Adverse Effects: retrograde ejaculation (reversible upon discontinuation), dizziness, orthostatic hypotension, headaches, nasopharyngitis, nasal congestion.

Dose & Administration:

Adult dose: 8 mg once daily with a meal

Moderate Renal Impairment (CrCl 30-50 ml/min): 4 mg once daily with a meal. Rapaflo may also be administered by opening the capsule and sprinkling the powder in a spoonful of cool applesauce. The applesauce should be swallowed immediately (without chewing) with a glass of cool water. DN

Zenhale® (mometasone/formoterol) 50/5mcg, 100/5mcg & 200/5mcg Merck (a Limited Use benefit of ODB)

Zenhale is a combination of a long-acting beta agonist and corticosteroid indicated in patients 12 years of age and older for the treatment of reversible obstructive airway disease not controlled with inhaled corticosteroids and acute use of a short-acting beta-2 agonist (e.g. salbutamol-Ventolin®). Zenhale, similar in efficacy to Advair® and Symbicort® when used in equivalent doses, shares their precautions, contraindications, drug interactions and adverse effects.

Dose & Administration: 2 inhalations twice daily, shaking the inhaler before each inhalation. For best results Zenhale should be taken regularly, even when asymptomatic. After use, patients should rinse their mouth and gargle with water to prevent oral candidiasis; the water should not be swallowed. Rescue medications should be taken only to relieve acute asthma symptoms. Before using Zenhale for the first time, it should be primed by shaking well before each actuation and sprayed 4 times into the air (away from the face). Repriming is needed if not used for over 5 days.

Zenhale is supplied as 120 doses/canister and should be at room temperature before use. DN

(Refer to the product monographs for complete information)

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References on Request
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