Drug Monitor

Relief for *All* Symptoms of Seasonal Allergy?

Mometasone furoate (MF) nasal spray, an intranasal corticosteroid, has proved effective in relieving nasal allergic rhinitis symptoms. According to researchers from the University of North Texas, Fort Worth; the University of Cincinnati, Ohio; and Merck Research Laboratories, Kenilworth, New Jersey, it also can help relieve tearing, burning, and itching eyes. In the 15-day study—the first one performed to prospectively evaluate ocular effects—429 patients with seasonal allergic rhinitis were randomly assigned to receive once-daily MF nasal spray 200 µg or placebo. Patients' ocular symptoms and quality-of-life scores were assessed.

MF nasal spray treatment produced greater improvement in all seasonal allergic rhinitis symptoms from baseline: –31.3%, vs –21.7% for placebo. The treatment significantly reduced morning "instantaneous" symptom scores and reflective scores for all symptoms except eye redness, which improved but not to statistical significance. Quality-of-life scores also showed "clinically meaningful" improvement, with total scores decreased by 41.5% vs 23.4% with placebo. The improvements lasted for 24 hours.

The treatment was well tolerated by the patients. The incidence of treatment-emergent adverse events was comparable in the treatment and placebo groups (14.5% vs 12%). The researchers say their findings suggest MF nasal spray may be used as a first-line, single-effective treatment for the symptoms of seasonal allergic rhinitis.

Source: *J Allergy Clin Immunol.* 2010;125(6):1247–1253. doi:10.1016/j.jaci.2010.03.004.

Epoetin Alfa Aids Hip Fracture Recuperation

Intertrochanteric hip fracture is a threat to an older person for a number of reasons, not least of which is the danger of blood loss, especially if the patient is anemic. And if autologous blood isn't available, allogeneic blood transfusion comes with its own risks for an older anemic patient, including fever, hemorrhagic syndromes, hyperkalemia, thrombocytopenia, and diseases passed on from viruses, bacteria, ricettsiae, and parasites, among others. Researchers from General Hospital of Levadia and the University of Athens, both in Greece, propose an alternative to transfusion: epoetin alfa. Although shown to increase hematocrit (Ht) and hemoglobin (Hb) levels in patients undergoing elective orthopedic surgery, epoetin alfa has not been tested in patients undergoing surgery for traumatic fracture.

They divided 79 patients with intertrochanteric hip fracture into 2 groups, 1 to receive 10 daily doses of 20,000 IU epoetin alfa beginning from the day of admission and 1 to receive placebo. All patients received parenteral iron 100 mg daily and underwent surgery for their fractures at a mean of 3 days following admission.

Although there were no differences between the groups' mean Ht and Hb levels at admission, the researchers found that the epoetin alfa group had significantly higher Ht and Hb values at 7 days postoperation (P = .019 and P = .015, respectively) than the control group and required significantly less units of allogeneic blood (P = .034).

Mean follow-up time was 34 months. Three patients were lost to follow-up despite doing well at their last examination. Eight patients died of causes not directly related to the hip fracture or to epoetin alfa administration. Complications were minor—5 patients had a skin inflammatory response or bruising and 1 patient had chills and fever after the fifth injection. No patient had to stop receiving medication because of adverse effects. Six patients reacted to the parenteral iron administration but all responded favorably to a reduced infusion.

Epoetin alfa is cost-effective, the researchers say. The therapy costs roughly 85% of the cost of preparing and conserving 1 unit of allogeneic blood. While the research suggests a reduction in the need for allogeneic blood transfusions, a treatment protocol with epoetin alfa for patients with major trauma needs to be established.

Source: *J Crit Care.* 2010;25(3):348–353. doi:10.1016/j.jcrc.2009.04.008.

Does Attitude Affect Adverse Event Reporting?

Of 874 respondents asked to rate statements (such as "Having to take medicines worries me" and "I sometimes worry about the long-term effects of my medicines") and questions about medicine in an Internet-based survey of Medicare beneficiaries, 20% self-reported an adverse drug effect (ADE), according to researchers at South Dakota State University, Brookings, and the University of Iowa, Iowa City.

The survey, conducted by a marketing research firm, also asked whether respondents had visited a health care provider about any adverse effects, unwanted reactions, or problems from taking their medicines in the past year. Patients with stronger concerns and beliefs about medicines were

more likely to report ADEs, as were patients who had more symptoms. The researchers note that patients "assign meaning to their symptoms and have specific interpretations of the cause, consequences, and means of controlling the symptoms," which could include reporting the ADE to a provider. Moreover, patients with stronger concerns about their medicines may be more likely to attribute their symptoms to an ADE. However, the researchers add that this sample was highly educated, with more access to information about medicine risks, which may have increased concerns compared with the general population. Respondents also may have been better able to identify when symptoms were due to medicines and readily report them.

Although nearly half of the respondents had been inappropriately prescribed a medication, the study revealed no association between inappropriate medications and self-reported ADEs—patients didn't know when they were receiving an inappropriate medicine, therefore had no reason to link the 2. Paying more attention to medicines' effects can help, the researchers suggest. For instance, patients who self-report potential ADEs prevent them from worsening.

The researchers suggest using cognitive-behavioral interventions to make self-monitoring a healthy, rather than a worry-based, motivation for patients with strong anxieties and concerns about their medicines.

Source: *Am J Geriatr Pharmacother.* 2010;8(3):245–257. doi:10.1016/j.amjopharm.2010.06.002.

Ranolazine and HbA_{1c} and FPG

For a patient who has cardiovascular disease and poorly controlled diabetes, adding ranolazine (a first-in-class anti-angina drug) to standard treatment may help lower fasting plasma glucose (FPG) and hemoglobin A_{1c} (HbA_{1c}) levels without the risk of serious hypoglycemic events. Researchers examined data from the MERLIN-TIMI-36 study of 6,560 patients with non-ST elevation acute coronary syndrome (ACS). Patients were randomly assigned to receive either ranolazine 1,000 mg twice daily or placebo. The patients returned for study visits at 14 days, then every 4 months until the end of the study at 16 months. The analysis includes 5,244 patients assessed at month 4.

Ranolazine, in addition to anti-anginal and anti-ischemic action, had clinically meaningful effects on FPG and HbA_{1c} levels. The reduction was steepest in patients with HbA_{1c} levels between 8% and 10%—adding ranolazine reduced HbA_{1c} by 1.2%. In patients with FPG levels between 150 mg/dL and 400 mg/dL, ranolazine reduced FPG by 25.7 mg/dL. The researchers say it is important to recognize that effects, while appearing small, were assessed as add-on to established therapies with dose adjustments of concomitant medications permitted, which is not typical for studies examining glycemia as the primary endpoint.

Because ranolazine has established cardiovascular safety in patients with ACS, the finding that the drug was not associated with increased rates of severe hypoglycemia was noteworthy, say the researchers—especially since such patients are infrequently investigated during early development of diabetes-specific therapies.

Source: *Diabetes Care.* 2010;33(6):1163–1168. doi:10.2337/dc09-2334.

Adherence to Heparin: The Type Makes a Difference

Patients prescribed injection-based thromboprophylaxis are more likely to adhere to the regimen if it's low-molecular-weight heparin (LMWH) prescribed once per day rather than unfractionated heparin (UFH) prescribed 2 or 3 times per day, say researchers from Brigham and Women's Hospital and Harvard Medical School, both in Boston, Massachusetts. In their study of consecutive patients, 125 received LMWH and 125 received UFH (97 received it twice daily and 28 received it 3 times daily). They found that 95% of patients took their LMWH as prescribed, compared with 87% of those taking UFH. Only 47% of patients taking UFH received every scheduled dose, whereas 78% of those taking LMWH received every dose.

For both heparin types, patient refusal was the most common reason for omitting a dose. The researchers note that patients may refuse injection-based prophylaxis because of fear, anxiety, discomfort, or inconvenience. Novel anticoagulant agents with oral dosing could help. Patients also may refuse prophylactic injections if they don't understand their risk of venous thromboembolism and the purpose of prophylaxis.

Shorter hospital stays and the fact that patients are often in transit within the hospital for procedures and diagnostic testing also are obstacles to adherence. Enhanced patient monitoring using personal digital assistants, "smart" phones, or other new technologies may improve dose delivery but are more costly and time consuming. The researchers conclude that improved patient-provider communication and education may empower patients to improve adherence.

Source: *Am J Med.* 2010;123(6):536–541. doi:10.1016/j.amjmrd.2009.11.017.