Tips from Other Journals

Tips from Other Journals are written by the medical editors of *American Family Physician.*

The trade names of drugs listed in Tips from Other Journals are based on what is currently available and not necessarily the brand of drug that was used in the study being discussed.

Lansoprazole Does Not Improve Asthma Symptoms in Children

Background: Gastrointestinal and respiratory symptoms of gastroesophageal reflux disease (GERD) are commonly reported in children with asthma, and it has been postulated that untreated GERD may worsen asthma control. Although some evidence suggests that proton pump inhibitor (PPI) use improves asthma control in adults with symptomatic GERD, more research is needed to determine the role of PPI use in children with asthma and asymptomatic GERD. Despite inconsistent evidence, children with poorly controlled asthma have been increasingly prescribed PPIs in the hopes of improving asthma symptoms. Writing for the American Lung Association Asthma Clinical Research Centers, Holbrook and colleagues conducted a double-blind placebo-controlled study to determine whether PPI use is effective for the treatment of poorly controlled asthma in children.

The Study: The Study of Acid Reflux in Children With Asthma was conducted at 19 centers in the United States. Children between six and 17 years of age were included in the study if their asthma was categorized as poorly controlled despite adequate use of inhaled corticosteroids. Poor asthma control was defined as any one of the following criteria: using short-acting beta agonists two or more times per week; having more than one nocturnal asthma episode per week; or having two or more emergency department visits, unscheduled physician visits, hospital admissions, or courses of prednisone therapy in the previous year. Children were excluded if they had symptomatic GERD, a history of PPI use, antireflux surgery or tracheoesophageal fistula repair, a history of neonatal respiratory distress or premature birth (before 33 weeks' gestation), or forced expiratory volume in one second of less than 60 percent of the predicted value. The primary outcome was improvement in the Asthma Control Questionnaire (ACQ) at 24 weeks. This scale ranges from 0 to 6, with higher values indicating worse asthma control; patients with ACQ scores of 0.75 or less have well-controlled asthma, whereas those with scores of 1.5 or greater are considered to have inadequately controlled asthma. A 0.5-point change in the scale reflects meaningful clinical improvement.

Participants were randomized to receive weight-based dosing of lansoprazole (Prevacid) or placebo for six months. Before randomization, 152 participants underwent esophageal pH testing. Of the 115 children who had adequate results for interpretation, 49 (43 percent) had abnormal esophageal acid exposure indicative of GERD. There were no differences in gastrointestinal symptoms between those in the normal and abnormal pH groups.

Results: Of the 2,453 children screened, 157 were randomized to placebo and 149 to lansoprazole. The mean ACQ score at baseline was 1.6 for both groups, indicating poor control. At 24 weeks, there was no significant change in ACQ scores in either group (–0.1 for the lansoprazole group and –0.2 for the placebo group). Subanalysis of the children with asymptomatic GERD revealed no effects from lansoprazole use. Compared with placebo, lansoprazole use was associated with a statistically significant increase in upper respiratory tract infections, sore throats, and bronchitis. ▶

Conclusion: Lansoprazole use does not improve asthma symptoms in children with asymptomatic GERD, even in those with pH-probe–documented acid reflux.

AMY CRAWFORD-FAUCHER, MD

Source: Writing Committee for the American Lung Association Asthma Clinical Research Centers; Holbrook JT, et al. Lansoprazole for children with poorly controlled asthma: a randomized controlled trial. *JAMA.* January 25, 2012;307(4):373-381.

Decreasing Fall Risk in Older Adults with Nutritional Intervention

Background: Falls are a common cause of morbidity and mortality in older persons. Among well-nourished older adults at risk of vitamin D deficiency, vitamin D_3 supplementation has been shown to reduce fall risk in epidemiologic studies. Malnutrition is also associated with a greater incidence of falls, but whether general nutritional intervention can affect fall risk in malnourished adults is unclear. Neelemaat and colleagues conducted a randomized controlled trial examining the effects of nutritional intervention on malnourished adults 60 years and older who had recently been hospitalized.

The Study: Eligible participants were identified on hospital screening as malnourished (i.e., body mass index of 20 kg per m^2 or less, at least 5 percent unintentional weight loss in the previous month, or at least 10 percent unintentional weight loss in the previous six months). Patients were excluded if they had been diagnosed with dementia. A total of 210 participants were randomized equally between the control and intervention groups. The intervention group received standardized nutritional support, including an energy-enriched diet during hospitalization (providing 750 kcal and 30 g of protein more per day than the regular hospital menu); two bottles of oral nutritional supplementation per day (providing a total of 600 kcal, 24 g of protein, 176 IU of vitamin D_3, and 364 mg of calcium per day); and an additional 500-mg calcium/400-IU vitamin D_3 supplement each day. All components of nutritional support were continued for three months following discharge. Telephone counseling by a dietitian was also provided every other week after discharge. In contrast, the control group received usual care, which included nutritional support only if the patient's treating physician prescribed it. Dietary intake, serum 25-hydroxyvitamin D levels, and fall incidents were monitored for three months after hospital discharge.

Results: No significant differences were observed between the groups at baseline, including functional limitations, body weight, grip strength, vitamin D levels, or physical activity level. At baseline, 30 of 105 persons (29 percent) in the control group and 23 of 105 persons (22 percent) in the intervention group were receiving nutritional support with a prescription from a physician or dietitian; by the end of the study, 31 percent of the control group and 84 percent of the intervention group were receiving nutritional support. Eighty percent of the intervention group adhered to the oral nutritional supplementation regimen, with a mean intake of 1.6 bottles per day (target of two per day), and 96 percent adhering to the calcium/vitamin D_3 supplementation and dietetic counseling. By the end of the study, caloric intake was significantly greater in the intervention group (mean kcal per day of 2,152 versus 1,766 in the control group; $P = .002$), but there was no difference in the percentages of patients with serum 25-hydroxyvitamin D levels of 20 ng per mL (50 nmol per L) or greater (37 versus 47 percent for the intervention and control groups, respectively; $P = .30$). In total, 57 falls occurred: 16 in the intervention group and 41 in the control group. Although there was no difference in the mean number of falls per person among patients who had fallen (1.6 versus 1.7 for the intervention and control groups, respectively; $P = .55$), significantly more persons in the control group experienced falls (23 percent of the control group versus 10 percent of the intervention group; hazard ratio = 0.41).

Conclusion: Compared with usual care, short-term intervention with oral nutritional supplementation, vitamin D_3 supplementation, and dietetic counseling significantly decreases falls in malnourished older adults.

KENNETH T. MOON, MD

Source: Neelemaat F, et al. Short-term oral nutritional intervention with protein and vitamin D decreases falls in malnourished older adults. *J Am Geriatr Soc.* April 2012;60(4):691-699. ▶

Do Intranasal Steroids Improve Symptoms of Acute Sinusitis?

Background: Acute sinusitis is a common problem in the ambulatory setting, affecting 31 million Americans annually. Many patients are prescribed antibiotics despite little evidence of benefit. Intranasal steroids may improve symptoms, but the benefits are unclear. A 2009 Cochrane review of four randomized controlled trials (RCTs) demonstrated a small improvement of acute sinusitis symptoms at 15 to 21 days with intranasal steroids; however, interpretation was limited by the heterogeneity of outcome measures. Hayward and colleagues provided an updated systematic review and meta-analysis of the effectiveness of intranasal steroids for acute sinusitis in the ambulatory care setting while accounting for heterogeneity among RCTs.

The Study: This systematic review included RCTs that compared intranasal steroids with placebo in children or adults who presented in the outpatient setting with signs and symptoms of acute sinusitis or rhinosinusitis. Studies examining patients with chronic or allergic sinusitis and studies examining specific populations with underlying chronic conditions were excluded from the meta-analysis. Primary outcomes included the percentage of participants with improvement or complete resolution of symptoms. Secondary outcomes included average change in symptom scores over 0 to 21 days, adverse events, recurrence rates, and days missed from school or work.

Results: In five RCTs that studied the resolution or improvement of symptoms at days 14 to 21, intranasal steroids had a significant but modest clinical benefit with a number needed to treat (NNT) of 13. Because of the heterogeneity among RCTs, a subgroup analysis on outcome timing and dosage was performed. Intranasal steroids had a significant effect on symptom improvement at 21 days (NNT = 9), but no significant effect at 14 to 15 days. Three trials assessing mometasone (Nasonex) nasal spray demonstrated a significant effect at days 15 to 21, with an NNT of 13. A significant dose-response relationship was found for mometasone; 800 mcg per day (NNT = 8) led to a greater reduction in symptoms than 400 mcg per day (NNT = 14). Compared with patients taking placebo, those who used intranasal steroids reported significantly greater improvement in facial pain, nasal congestion, rhinorrhea, headache, and postnasal drip. Meta-analysis did not demonstrate a significant difference in the rate of adverse events between patients using intranasal steroids and patients using placebo. Common adverse events included headache, epistaxis, nasal irritation, and pharyngitis. Recurrence of acute sinusitis occurred in 5 to 15 percent of patients taking intranasal steroids and in 4 to 37 percent of patients taking placebo.

Conclusion: Intranasal steroids for the treatment of acute sinusitis provide a small but significant improvement in symptoms, most notably for facial pain and nasal congestion. This benefit is most marked when treatment is provided for a longer period of time (21 days) and when medications are given at higher dosages (up to 800 mcg of mometasone per day). The authors surmised that 66 percent of patients with acute sinusitis would improve in 14 to 21 days with placebo, and an additional 7 percent would improve with intranasal steroids.

MALLORY BARNETT, MSIV

Source: Hayward G, et al. Intranasal corticosteroids in management of acute sinusitis: a systematic review and meta-analysis. *Ann Fam Med.* May-June 2012;10(3):241-249.

EDITORS' NOTE: The most common etiology of acute sinusitis is a viral infection, with only 0.5 to 2 percent of cases progressing to an acute bacterial infection requiring antibiotics.[1] Viral and bacterial acute sinusitis generally are self-limited illnesses. Nevertheless, antibiotics are commonly prescribed in the outpatient setting. For patients with 10 or more days of persistent symptoms, watchful waiting without antibiotic or steroid therapy is appropriate.[1] Hayward and colleagues provide modest evidence supporting the use of intranasal steroids for acute sinusitis. However, an accompanying editorial notes that the only two specific symptoms demonstrated to significantly improve with intranasal steroids were nasal congestion and facial pain, which had relatively small improvements for the potential cost of the medicine.[2] More studies examining antibiotic-naïve ▶

patients are needed before recommendations can be made on the use of intranasal steroids for acute sinusitis. Until then, intranasal steroid therapy remains an individual decision to be made between patient and physician.[3]—M.B. and SUMI SEXTON, MD, Associate Editor, *American Family Physician*

REFERENCES

1. Hwang PH. A 51-year-old woman with acute onset of facial pressure, rhinorrhea, and tooth pain: review of acute rhinosinusitis. *JAMA*. 2009;301(17):1798-1807.
2. Hickner J. Intranasal steroids for acute sinusitis? *Ann Fam Med.* 2012;10(3):196-197.
3. Rosenfeld RM, Andes D, Bhattacharyya N, et al. Clinical practice guideline: adult sinusitis. *Otolaryngol Head Neck Surg.* 2007;137(3 suppl):S1-S31.

Sublingual Buprenorphine vs. Morphine for Acute Pain

Background: The undertreatment of acute pain remains a problem in emergency departments. Although morphine is the analgesic of choice for the treatment of acute pain in an emergent setting, it is commonly administered intravenously, which often results in the delay of pain relief. Moreover, morphine use has serious potential adverse effects, such as respiratory depression, central nervous system depression, hypotension, and gastrointestinal problems. One possible alternative treatment is buprenorphine (Subutex), which is administered sublingually and has a high clinical safety profile and more prolonged duration of action. Jalili and colleagues investigated whether sublingual buprenorphine is as effective as intravenous morphine in managing pain in patients with acute bone fracture.

The Study: This double-blind randomized controlled trial enrolled patients 16 years or older who presented to the emergency department with acute extremity fracture. Patients were eligible for participation if they rated their pain as higher than 3 on a scale of 0 to 10, with 0 being no pain and 10 being the worst possible pain. A total of 89 patients were randomized, with 44 patients in the buprenorphine group and 45 patients in the control group. Patients in the buprenorphine group received 0.4 mg of sublingual buprenorphine and 5 mL of intravenous sterile water, whereas those in the control group received 5 mg of intravenous morphine plus a sublingual placebo. Pain was assessed using the same numeric rating scale used at baseline, and again at 30 and 60 minutes after the medications were administered. Adverse effects were recorded.

Results: Pain scores were similar between groups at 30 and 60 minutes after the medications were administered (median pain scores of 5 at 30 minutes and 2 at 60 minutes in both groups). Adverse effects were minimal in both groups and included nausea, dizziness, and hypotension.

Conclusion: In adults with acute bone fracture presenting to the emergency department, sublingual buprenorphine is as effective and safe as intravenous morphine, with quicker and easier administration.

KARI KUBALANZA, MSIV

Source: Jalili M, et al. Sublingual buprenorphine in acute pain management: a double-blind randomized clinical trial. *Ann Emerg Med.* April 2012;59(4):276-280. ■