POEMs

Patient-Oriented Evidence that Matters

In my experience, patients who are alcohol-dependent not only create psycho-social dysfunction for themselves and those that care for them but they are also difficult to treat. Topiramate is effective in helping these patients, at least in the short-term. A major drawback in New Zealand is the cost (300mg daily is likely to cost more than the alcohol they consume). I was also intrigued to read that included in the manufacturer's prescribing information is the instruction to 'avoid alcohol' while taking this medicine! I have included the POEM on migraine not because it adds much to resolve the difficulty we often have of correctly classifying headaches but to stimulate reflection on the comment 'a diagnosis, whether correct or not, is unimportant unless it leads to appropriate management decisions, a reality sometimes forgotten by health care providers'. Finally, dyspepsia responds as well to 20mg of omeprazole as it does to 40mg and my guess is that this is considerably less expensive! Editor.

Clinical question

Can topiramate help improve the quality of life of alcoholics?

Bottom line

In addition to reducing alcohol consumption, in actively drinking adults with alcoholism, topiramate (Topamax) is more effective than placebo in improving overall well-being and life satisfaction for up to three months. This study lasted only 12 weeks, so the long-term health consequences and safety of topiramate treatment for alcoholism remain uncertain. (LOE=1b-)

Reference

Johnson BA, Ait-Daoud N, Akhtar FZ, Ma JZ. Oral topiramate reduces the consequences of drinking and improves the quality of life of alcohol-dependent individuals. Arch Gen Psychiatry 2004; 61:905–12.

Study design

Randomised controlled trial (double-blinded)

Allocation

Uncertain

Setting

Outpatient (any)

Synopsis

In actively drinking adult alcoholics, topiramate is more effective than placebo in reducing alcohol consumption. To determine whether topiramate also improves psychosocial functioning, the investigators randomly assigned (uncertain allocation concealment) alcoholics to receive topiramate or matching placebo. Topiramate dosing started at 25mg daily and progressively increased over two months to 300mg daily. Eligible patients were aged 21 years to 65 years and met DSM-IV-TR criteria for alcohol dependence. All patients concurrently participated in brief behavioural treatment to enhance medication compliance. Outcomes were obtained by self-report using various psychosocial evaluation questionnaires. Using intention-to-treat analysis, topiramate statistically improved the odds of overall well-being and life satisfaction compared with placebo. No serious adverse events occurred in either treatment group. Since this study only lasted 12 weeks, however, no long-term data on persistent abstinence or improved health outcomes are reported. The authors report that 16% of randomised patients were lost to follow-up at 12 weeks.

Clinical question

Is a diagnosis of migraine more appropriate for patients who have headaches attributed to sinus symptoms?

Bottom line

Patients with frequent sinus headaches may actually have migraine. A more useful study would determine what proportion of patients with sinus headaches actually respond to migraine-specific treatment. A diagnosis, whether correct or not, is unimportant unless it leads to appropriate management decisions, a reality sometimes forgotten by health care providers. (LOE=2b)

** Patient-Oriented Evidence that Matters. See editorial (NZFP 2003; 30:150)*

Reference

Schreiber CP, Hutchinson S, Webster CJ, Ames M, Richardson MS, Powers C. Prevalence of migraine in patients with a history of self-reported or physician-diagnosed 'sinus' headache. Arch Intern Med 2004; 164:1769-72.

Study design

Cohort (prospective)

Setting

Outpatient (primary care)

Synopsis

A diagnosis is a label placed on a collection of signs, symptoms, and findings used to guide management decisions. This study explored the labelling of patients with frequent headaches. The investigators screened patients at 452 North American primary care sites and identified 2991 with at least six self-described or physician-diagnosed 'sinus headaches' during the six months before screening. They excluded patients with a diagnosis of migraine or who had 'radiologic evidence of sinus infection' (whatever that is) or fever or purulent nasal discharge associated with their headaches. These patients were then evaluated to determine whether they met International Headache Society criteria for migraine. A big limitation to this study is revealed at this point: Clinicians making the migraine diagnosis were aware of the patients' previous diagnoses and their response to medication. There is a real risk that the clinicians saw what they wanted to see, and thus found many more migraines than there actually were, especially since this study was sponsored by a manufacturer of a migraine drug. And so: 88% of these patients met criteria for migraine. Yet 84% also reported sinus pressure and 82% reported sinus pain. This study probably overestimates the rate of misdiagnosis.

Clinical question

Is 40mg omeprazole more effective than 20mg for primary care patients with dyspepsia?

Bottom line

Omeprazole (Prilosec) 20mg is highly effective for the treatment of acid-related dyspepsia. There was no advantage to higher doses, and relapse following the initial two-week treatment period was common. (LOE=1b)

Reference

Meineche-Schmidt V. Empiric treatment with high and standard dose of omeprazole in general practice: two-week randomized placebo-controlled trial and 12-month follow-up of healthcare consumption. Am J Gastroenterol 2004; 99:1050–58.

Study design

Randomised controlled trial (double-blinded)

Allocation

Concealed

Setting

Outpatient (primary care)

Synopsis

A common primary care strategy for patients with dyspepsia and no alarm symptoms is to prescribe a proton-pump inhibitor. This pragmatic study took place in a Danish primary care research network with 103 participating physicians and 829 patients. Adults presenting with dyspepsia (that their physician thought was acid-related) and no alarm symptoms were randomised to omeprazole 40mg per day, omeprazole 20mg per day, or placebo. Alarm symptoms were defined as rectal bleeding or hematemesis, unintended weight loss, vomiting, dysphagia, jaundice, or other signs of serious disease. Groups were similar at baseline, with a mean age of 50 years; 58% were women. Allocation was concealed and outcomes were blindly assessed, with analysis by intention to treat. Patients were treated for two weeks, and then medications were discontinued. During the remaining year of observation, in which 92% of the patients participated, the author tracked the time until symptom relapse and the consumption of health care resources. The most common symptoms in both groups were epigastric pain, regurgitation, heartburn, bloating, and pain at night. Symptoms were rated as moderate by 63% of patients and severe by 15%. At two weeks, sufficient relief was reported more often in the 40mg and 20mg groups than in the placebo group (71%, 69.6%, and 43%, respectively), as was complete relief (66.4%, 63%, and 34.9%). The number needed to treat was between three and four for both outcomes. Results were similar for Helicobacter pylori-positive and H pylori-negative patients. Most patients in all three groups had a relapse of symptoms during the year following their initial treatment.