POEMs

Patient-Oriented Evidence that Matters

We have a mixed bunch of POEMs for December! The first of these reassures us that delaying the insertion of grommets is not associated with worse outcomes. With the long waiting lists for this procedure in NZ this is probably just as well! We then have a report of a meta-analysis that questions the usefulness of cholinesterase inhibitors in Alzheimer's. Our third POEM lends support to the recent decision to restrict the supply of test strips for home monitoring in non-insulin taking diabetic patients. The final POEM comments on a systematic review of the management of chronic constipation. Editor.

Clinical question

Does early insertion of tympanostomy tubes improve important clinical outcomes more than delayed insertion?

Bottom line

Early insertion of tympanostomy tubes does not improve long-term clinical outcomes of importance (speech acquisition and hearing) in children with persistent otitis media with effusion. Delaying six months for bilateral effusion and nine months for unilateral effusion before revisiting the decision to insert tubes is the preferred approach to management, since it results in fewer procedures with equivalent outcomes. (LOE = 1b)

Reference

Paradise JL, Campbell TF, Dollaghan CA, et al. Developmental outcomes after early or delayed insertion of tympanostomy tubes. N Engl J Med 2005; 353:576-86.

Study Design

Randomised controlled trial (single-blinded)

Allocation

Concealed

Setting

Outpatient (any)

Synopsis

The initial report of this study's results found that early insertion of tympanostomy tubes in children with persistent otitis media with effusion did not improve outcomes at three years of age over delaying up to nine months (see: Delaying tymp tubes doesn't worsen outcomes in effusion. N Engl J Med 2005; 344:1179-87). In brief, children were enrolled before two months of age and underwent pneumatic otoscopy monthly until three years of age. If they had a persistent otitis media with effusion – defined as 90 days of bilateral effusion, 135 of unilateral effusion, or at least 67% of 180- and 270-day periods for bilateral and unilateral effusion in children with intermittent effusion – they were randomised to either immediate insertion of tympanostomy tubes or delaying six months to nine months and only inserting tubes at that time if the effusion persisted. Outcome assessors were blinded to treatment assignment and allocation was concealed. At the end of the study, 85% in the early treatment group had received tubes, compared with only 41% in the delayed insertion group. Of course, the children who received immediate tubes could hear and speak better, right? Although that would make perfect sense, it is not what happened in this carefully done follow-up study that reports outcomes at six years of age. There was no difference between groups in tests of intelligence, speech complexity, hearing, auditory processing, behaviour, or parental stress. With approximately 200 children in each group, the study had adequate statistical power to detect clinically meaningful differences if they existed.

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

Clinical question

Are cholinesterase inhibitors effective in patients with Alzheimer's disease?

Bottom line

The evidence supporting the effectiveness of cholinesterase inhibitors is based on exceedingly small effects found in poorly analysed studies. Studies of Alzheimer's drugs need to be carefully scrutinised for methodologic errors that inflate the appearance of benefit. (LOE = 1a)

Reference

Kaduszkiewicz H, Zimmermann T, Beck-Bornholdt HP, van den Bussche H. Cholinesterase inhibitors for patients with Alzheimer's disease: systematic review of randomised trials. BMJ 2005; 331:321-27.

Study Design

Meta-analysis (randomised controlled trials)

Setting

Various (meta-analysis)

Synopsis

Three treatments for Alzheimer's disease work by inhibiting cholinesterase: donepezil (Aricept), rivastigmine (Exelon), and galantamine (Razadyne). The authors of this meta-analysis combined the results of 22 randomised controlled trials evaluating the drugs' effects on clinical outcomes. The research was identified by searching three databases for research in any language. Three researchers independently selected studies on the basis of predetermined criteria. The quality of the studies was poor for many of these studies; the most common problem was that the results were not analysed by intention to treat, the lack of which tends to inflate evidence of benefit. Most studies used the standard evaluation tool, the Alzheimer's Disease Assessment Scale—cognitive subscale, which uses scores ranging from 0 (no impairment) to 70 (very severe impairment). For all three drugs, the differences between the treatment groups and placebo groups was a minimal 1.5 points to 3.9 points. In 12 trials, effectiveness was also measured using the Clinician's Interview Base on Impression of Change; these scores were not significantly different between treatment and placebo groups. One study that used a measure of cognitive decline showed an average five months delay with donepezil compared with placebo before a clinically evident functional decline was seen.

Clinical question

In patients with type 2 diabetes who are not using insulin, does home monitoring of blood glucose improve care?

Bottom line

Intensive monitoring of blood glucose in patients with type 2 diabetes not using insulin results in a small decrease in hemoglobin A1c (HbA1c) levels but does not change fasting blood glucose levels. Urine glucose monitoring works just as well. More casual monitoring of blood glucose, such as once a day, has not been studied. There is a strong possibility that the weak study design was largely responsible for the difference seen in the study. Blood glucose monitoring is expensive: At the intense level of monitoring used in some of these studies (six times a day), the cost of the monitoring strips alone can be $2000 US per year. (LOE = 1a)

Reference

Welschen LM, Bloemendal E, Nijpels G, Dekker JM, Heine RJ, Stalman WA, Bouter LM. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin. Diabetes Care 2005; 28:1510-17.

Study Design

Meta-analysis (randomised controlled trials)

Setting

Outpatient (any)

Synopsis

The researchers conducting this meta-analysis started by searching three databases for randomised controlled studies evaluating blood glucose self-monitoring with typical care in patients with type 2 diabetes who were not using insulin. They also searched the reference lists of identified studies for other studies. They did not attempt to find unpublished studies, research that's usually rejected because it doesn't find a difference. Two authors independently reviewed the studies for inclusion and evaluated the methodologic quality, and two authors independently extracted the data. The study quality was moderate for four of the studies and high for two of the studies. However,

patients in the six studies included in this analysis were not blinded. Concealed allocation was either not done or not described in any of the studies, allowing the very real possibility that the patients in the blood glucose monitoring groups were different from those in the control groups. They were also highly motivated patients; patients doing the self-monitoring checked blood glucose levels from twice every other day to six times per day, six days per week. The comparison groups in the study either did no self-monitoring or monitored urine glucose. In the five studies that compared blood glucose monitoring with no monitoring, HbA1c levels were nominally but significantly lower in the blood glucose monitoring group (-.39%; 95% CI, -0.56 to -0.21) after approximately six months of follow-up. Blood glucose monitoring did not produce better HbA1c levels than urine glucose monitoring. Fasting blood glucose levels were not different in the two studies that evaluated it, and quality of life was not different with blood glucose monitoring in the two studies that evaluated it. In one study of more than 700 patients in which it was monitored, no serious hypoglycemic episodes occurred in any patient.

Clinical question

What is the best approach to evaluating and treating chronic constipation?

Bottom line

Diagnostic testing is not needed for most patients with chronic constipation. The evidence is strongest for the efficacy of psyllium, polyethylene glycol, lactulose, and tegaserod. Research is not available to support the routine use of stimulant laxatives, lubricants, stool softeners, calcium polycarbophil, bran, or any herbal products. (LOE = 1a)

Reference

American College of Gastroenterology Chronic Constipation Task Force. An evidence-based approach to the management of chronic constipation in North America. Am J Gastroenterol 2005; 100:S1-S4.

Study Design

Systematic review

Setting

Outpatient (any)

Synopsis

This evidence-based guideline is based on a careful accompanying systematic review. Chronic constipation is defined as infrequent stool passage and/or difficult stool passage, incomplete evacuation, prolonged time to stool, or the need for manual manoeuvres to pass stool, for at least three months. It is estimated that the prevalence of chronic constipation is approximately 15%; it is more common in women. Patients with alarm symptoms for cancer or bleeding should undergo a thorough diagnostic work-up. Otherwise, routine diagnostic testing is not recommended for patients with chronic constipation who have no alarm symptoms and no signs of organic disorder such as hypothyroidism after a careful history and physical examination. Regarding treatment: Of the bulking agents, psyllium increases stool frequency but data are insufficient regarding calcium polycarbophil, methylcellulose, or bran. There is insufficient evidence regarding the efficacy of stool softeners or milk of magnesia. There is good evidence that polyethylene glycol and lactulose both improve stool frequency and consistency. There are few data regarding stimulant laxatives, but the available data suggest that they are of little benefit. Tegaserod improves the frequency and consistency of stools and reduces straining, particular in younger patients. There are insufficient data regarding alternative treatments, herbal supplements, lubricants, or combination laxatives.

Early experience with pay-for-performance: from concept to practice

'Paying clinicians to reach a common, fixed performance target may produce little gain in quality for the money spent and will largely reward those with higher performance at baseline.'

Rosenthal MB, Frank RG, Li Z, Epstein AM. JAMA. 2005 Oct 12; 294(14):1788-93.