POEMs

Patient-Oriented Evidence that Matters

An interesting collection of POEMs that have encouraged me to reflect on some areas of my practice! Our first POEM reports that patients treated for rosacea do not think that oral tetracyclines are better than topical agents. The second POEM reassures me that giving opiates to patients who have severe abdominal pain before they depart on their journey to hospital does not increase the risk of management errors. The third POEM provides clinical guidelines to predict serious intracranial injury in children with head injuries and our final POEM advises care in the use of atypical antipsychotics in patients who have Alzheimer's disease. Editor.

Clinical question

What treatments are effective for rosacea?

Bottom line

Effective treatments for rosacea include topical metronidazole, benzoyl peroxide 5%/erythromycin 3% gel, benzoyl peroxide 5%/clindamycin 1% gel, benzoyl peroxide alone, azelaic acid, and sodium sulfacetamide10%/sulfur 5%. Oral tetracycline was significantly better than placebo by physician assessment, but not by patient assessment. (LOE = 1a)

Reference

van Zuuren EJ, Gupta AK, Gover MD, Graber M, Hollis S. Systematic review of rosacea treatments. J Am Acad Dermatol 2006;online:Nov 3.

Study Design

Meta-analysis (randomised controlled trials)

Funding

Unknown/not stated

Setting

Various (meta-analysis)

Synopsis

These investigators thoroughly searched multiple databases — including MEDLINE, EMBASE, The Cochrane Registry of Clinical Trials, Science Citation Index, and reference lists — and consulted with experts. They also searched unpublished literature through correspondence with authors and pharmaceutical companies. Two reviewers independently performed searches and assessed articles for eligibility. Disagreement was resolved by consensus discussion. From a total of 71 possible clinical trials, the authors included 29 randomised trials meeting appropriate criteria for high quality (eight) and intermediate quality (21). Fourteen trials used adequate blinding to treatment allocation and 17 used intention-to-treat analysis. Only data on outcome measures from trials on topical metronidazole, topical azelaic acid, and oral tetracycline could be pooled. The primary outcome measure, quality of life, was not assessed in any of the studies and only a few studies assessed the participant's own opinion regarding rosacea severity. The following medications were significantly superior to placebo: topical metronidazole, benzoyl peroxide 5%/erythromycin 3% gel, benzoyl peroxide 5%/clindamycin 1% gel, benzoyl peroxide alone, azelaic acid, and sodium sulfacetamide10%/sulfur 5%. Oral tetracycline was significantly better than placebo by physician assessment, but not by patient assessment. There was no significant difference in efficacy between topical metronidazole and azelaic acid or between topical metronidazole and oral tetracycline. Rilmenidine and permethrin were not significantly better than placebo.

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

Clinical question

Does opiate administration to patients with acute abdominal pain affect treatment management?

Bottom line

Opiate analgesia for adults and children presenting with acute abdominal pain may alter the physical examination, but does not increase the risk of management errors. Since most patients prefer pain control, it makes sense to abandon the outdated and incorrect practice of withholding opiate analgesia from patients with acute abdominal pain. (LOE = 1a)

Reference

Ranji SR, Goldman LE, Simel DL, Shojania KG. Do opiates affect the clinical evaluation of patients with acute abdominal pain? JAMA 2006;296:1764-1774.

Study Design

Systematic review

Funding

Government

Setting

Various (meta-analysis)

Synopsis

Surgical dogma traditionally discourages the administration of opiate analgesia to patients with acute abdominal pain, fearing that management errors will increase as a result of altered history and physical findings. These investigators thoroughly searched multiple sources including MEDLINE, EMBASE, and article bibliographies for placebo-controlled trials of opiate administration to patients presenting with acute abdominal pain providing information relating to changes in the history, physical examination, or clinical management. Two authors independently evaluated each study for inclusion criteria and methodologic quality. From an initial 492 citations, 12 independent studies met inclusion criteria, including nine and three enrolling adults and children, respectively. Overall, there were no significant differences in the clinical evaluation or treatment management between patients receiving and not receiving opiate analgesia. When the analysis was restricted to the eight trials reporting significantly adequate analgesia for patients receiving opiates compared with the placebo group, a statistically significant difference was found for changes in the physical examination. However, opiate administration was still not significantly associated with an increased risk of management errors in both the adult and pediatric trials. The findings from the various trials were not significantly heterogeneous, further supporting the conclusions of this review.

Clinical question

Can clinical factors be used to identify children with low risk of serious intracranial pathology after head injury?

Bottom line

Clinical factors can accurately predict which children don't have serious intracranial pathology after head injury. The clinical prediction rule developed in this study requires validation. (LOE = 3b)

Reference

Dunning J, Daly JP, Lomas JP, et al, for the Children's Head injury ALgorithm for the prediction of Important Clinical Events study group. Derivation of the children?s head injury algorithm for the prediction of important clinical events decision rule for head injury in children. Arch Dis Child 2006;91:885-891.

Study Design

Cohort (prospective)

Funding

Foundation

Setting

Emergency department

Synopsis

This team of researchers identified more than 22 000 children younger than 16 years with any head injury. Specially trained physicians assessed each child with a standardized history and physical, including mechanism of injury and Glasgow Coma Scale. The authors then developed a set of clinical criteria to identify children with "clinically significant intracranial injury," defined as death as a result of head injury, requirement for neurosurgical intervention, or marked abnormalities on the computed tomography (CT) scan. A total of 744 of the children provided CT scans, but all children completed a clinical follow-up with the authors. The clinical prediction rule (summarized below) was highly sensitive (98%; 95% CI, 96-100) and also had decent specificity (87%; 86-87). The positive likelihood ratio of 7.5 (6.9-7.7) and negative like-

lihood ratio of 0.02 (0-0.05) suggests this rule is best at ruling out serious intracranial injury. This prediction rule needs to be validated. The clinical decision rule: A CT scan is required if any of the following criteria are present: History: Witnessed loss of consciousness of greater than 5 minutes duration. History of amnesia (either antegrade or retrograde) of greater than five minutes duration. Abnormal drowsiness. More than three discrete episodes of vomiting after head injury. Suspicion of nonaccidental injury. Seizure after head injury in a patient who has no history of epilepsy. Examination: Glasgow Coma Score (GCS) <14, or GCS <15 if younger than one year. Suspicion of penetrating or depressed skull injury or tense fontanelle. Signs of a basal skull fracture (blood or cerebrospinal fluid from ear or nose, panda eyes, Battle's sign, hemotympanum, facial crepitus, or serious facial injury). Focal neurologic deficit. Presence of bruise, swelling or laceration >5 cm if younger than one year. Mechanism: High-speed road traffic accident either as pedestrian, cyclist, or occupant (defined as accident with speed above 40 miles per hour). Fall of more than 3m in height. High-speed injury from a projectile or an object. If none of the above variables are present, the patient is at low risk of intracranial pathology.

Clinical question

Are the newer atypical antipsychotics effective in patients with Alzheimer's disease?

Bottom line

Atypical antipsychotics are minimally, if at all, effective for patients with Alzheimer's disease (AD), and they have significant adverse effects. They should not be routinely used for the treatment of psychosis, agitation, or aggression in these patients. (LOE = 1b)

Reference

Schneider LS, Tariot PN, Dagerman KS, et al, with the CATIE-AD Study Group. Effectiveness of atypical antipsychotic drugs in patients with Alzheimer's disease. N Engl J Med 2006;355:1525-1538.

Study Design

Randomised controlled trial (double-blinded)

Funding

Government

Allocation

Uncertain

Setting

Outpatient (any)

Synopsis

Although atypical antipsychotics are widely used in the treatment of psychosis, agitation, and aggression in patients with AD, clinical trials to date have been of limited duration and have not adequately addressed the tolerability of the drugs. In addition, there are new concerns regarding the safety of these drugs, with recent studies* finding an increased risk of death (relative risk = 1.6 - 1.7). In this study, the authors identified 421 outpatients with probable AD, a Mini-Mental State score between five and 26, and delusions, hallucinations, aggression, or agitation. They were randomized in a 2:2:2:3 ratio to olanzapine (Zyprexa, 2.5 mg or 5.0 mg), quetiapine (Seroquel, 25 mg or 50 mg), risperidone (Risperdal, 0.5 mg or 1.0 mg), or placebo. Whether to use the smaller or larger dose of each drug was determined by the study physicians, who were blinded to treatment assignment. They chose an unidentified small or large pill from an envelope, then adjusted the dose on the basis of patient response. Patients were followed up for up to three years; the primary outcomes were the time to discontinuation of the study drug and the degree of improvement on the Clinical Global Impression of Change (CGIC) scale at week 12. Groups were balanced at the start of the study and analysis was by intention to treat. The patients' mean Mini-Mental State score was 15, their average age was 78 years, 56% were women, and 18% were African-American. The average final doses of each drug were olanzapine 5.5 mg, quetiapine 56 mg, and risperidone 1.0 mg. The mean time to discontinuation was between 5.3 weeks and 8.1 weeks for the four groups, with no significant difference between groups. The atypical antipsychotics were more likely to be discontinued because of adverse effects (16%–24% vs 5% for placebo), while placebo was more likely to be discontinued because of lack of efficacy (70% vs 39% – 53% vs 70% for active drugs). There was no significant difference between groups regarding the response as measured by the CGIC scale at 12 weeks (21% for placebo vs 26%–32% for active drugs). Adverse effects occurring more frequently in patients receiving an active drug included parkinsonism or extrapyramidal signs (olanzapine and risperidone), sedation and weight increase (all three active drugs), and confusion (olanzapine and risperidone).

*http://www.fda.gov/cder/drug/advisory/antipsychotics.htm