POEMs®
PATIENT ORIENTED EVIDENCE THAT MATTERS®
Practice Recommendations from Key Studies

Effective and ineffective interventions for infant colic

Garrison MM, Christakis DA. Early childhood: colic, child development, and poisoning prevention. A systematic review of treatments for infant colic. Pediatrics 2000; 106:184–190.

CLINICAL QUESTION

What interventions are effective in the treatment of infantile colic?

BOTTOM LINE

Interventions with some evidence of effectiveness for infantile colic include hypoallergenic diets and formula, soy formula, decreased infant stimulation, herbal tea, and dicyclomine (Bentyl). Reports of severe adverse effects of dicyclomine in infants younger than 7 weeks caused a black-box warning for use in those aged less than 6 months. The following interventions are essentially equal to or worse than placebo treatment: simethicone (Mylicon, Gas-X), scopolamine, lactase enzyme (Lactulose), fiber-enriched formula, increased carrying, car-ride simulators, and sucrose. (Level of evidence [LOE]=**1a–**)

STUDY DESIGN

Systematic review

SETTING

Various (meta-analysis)

SYNOPSIS

Numerous interventions are recommended for the treatment of colic, although few have been rigorously evaluated for their effectiveness. The authors of this meta-analysis performed a careful search of multiple databases, including Medline, the Cochrane Clinical Trials Registry, bibliographies of relevant reviews, and the Medical Editors Trial Amnesty for randomized controlled trials (RCTs) published in the English language. Only trials using the official definition of colic—unexplained paroxysmal bouts of fussing and crying lasting longer than 3 hours a day, for more than 3 days a week, for more than 3 weeks of duration—were included. Trials were individually assessed for adequacy of allocation concealment and blinding of individuals assessing outcomes.

From an original yield of 53 articles, 9 were considered to have adequate case definitions, 12 to have adequate double-blinding, and only 5 to have both. All were considered to have adequate randomization.

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What is a POEM?

Each month, the POEMs (Patient-Oriented Evidence that Matters) editorial team reviews 105 research journals in many specialties, and selects and evaluates studies that investigate important primary care problems, measure meaningful outcomes, and have the potential to change the way medicine is practiced. Each POEM offers a Bottom Line observation and summarizes the study's objective, patient population, study design and validity, and results. InfoPOEMs, Info-Retriever and POEMS for Primary Care are registered trademarks of InfoPOEM, Inc. POEMS and Patient-Oriented Evidence that Matters are trademarks of InfoPOEM, Inc.

Neither carrying the infant more nor the use of a car-ride simulator reduced colic symptoms significantly

Of the RCTs evaluating pharmaceutical interventions, 3 studied simethicone, 3 dicyclomine, and 1 scopolamine. None of the simethicone trials found any significant benefit over placebo. Dicyclomine performed significantly better than placebo in all 3 trials (number needed to treat [NNT]=3). However, severe adverse effects have been attributed to dicyclomine use (apnea, seizures, and coma), especially in infants aged <7 weeks. Thus, the manufacturer has contraindicated its use in infants aged <6 months. The only trial of scopolamine found no benefit compared with placebo, but a higher incidence of adverse effects.

Nine different trials evaluated various dietary interventions. In breastfeeding women, a maternal hypoallergenic diet free of milk, egg, wheat, and nut products reduced colic symptoms by 25% or more (NNT=6) compared with a usual diet. In bottle-fed infants, both soy (NNT=2) and hypoallergenic formula (NNT=6) were more effective than regular formula. Treatment with lactase enzymes and fiber-enriched formula was no more effective than placebo.

With regard to behavioral intervention, neither carrying the infant more often (ie, with a Snugli) nor the use of a car-ride simulator (SleepTight) reduced symptoms significantly. Interestingly, advising parents to "reduce stimulation" reduced symptoms (NNT=2).

Two naturopathic interventions were evaluated. One RCT comparing herbal tea (containing chamomile, vervain, licorice, fennel, and balm-mint) with placebo tea given at the onset of colic episodes, with a maximum dose of 150 mL up to 3 times per day, found a significant reduction in the number of infants meeting the criteria for colic (NNT=3). One RCT evaluating sucrose found a significant benefit compared with placebo that lasted less than 30 minutes.

Steroid injections effective for knee osteoarthritis

Arroll B, Goodyear-Smith F. Corticosteroid injections for osteoarthritis of the knee: meta-analysis. BMJ 2004; 328:869–870.

CLINICAL QUESTION

Are intra-articular corticosteroids effective for symptoms of osteoarthritis of the knee?

BOTTOM LINE

Intra-articular steroids produced some measure of improvement greater than placebo, with approximately 2 to 4 patients requiring treatment for an additional 1 patient to benefit. This meta-analysis, however, included relatively few patients, and the magnitude of the benefit was not quantified in this study. (LOE=**1a**)

STUDY DESIGN

Meta-analysis (randomized controlled trials)

SETTING

Various (meta-analysis)

SYNOPSIS

The authors of this meta-analysis identified 10 studies of randomized placebo-controlled trials of intra-articular corticosteroids for osteoarthritis of the knee by searching 3 databases, contacting authors, and checking references of identified articles. In the 6 small studies (n=317) that measured symptom improvement, overall improvement was seen following the injection (number needed to treat [NNT]=1.3–3.5). The actual response (not response rate), however, could be small—any improvement was taken to be clinically relevant. An evaluation of the only 2 high-quality studies showed more improvement after 4 to 6 months with steroid injection than with placebo (NNT=4.4; 95% confidence interval, 1.8–23.8). Doses were equivalent to 6.25 mg to 80 mg of prednisone. The authors did not look at long-term effects.

Peak expiratory flow rate does not predict asthma exacerbations

Tierney WM, Roesner JF, Seshadri R. Assessing symptoms and peak expiratory flow rate as predictors of asthma exacerbations. J Gen Intern Med 2004; 19:237–242.

CLINICAL QUESTION

Does measuring peak expiratory flow rate predict asthma exacerbations?

BOTTOM LINE

Routine measurement of peak expiratory flow rate does not predict subsequent asthma exacerbations. Therefore, routine measuring of lung function in this way is not useful. A peak flow meter does have a role in asthma management, but spot-checking in the office, other than to evaluate technique, is not helpful. (LOE=**1b**)

STUDY DESIGN

Nonrandomized controlled trial

SETTING

Outpatient (any)

SYNOPSIS

This study was conducted in an interesting setting: 36 pharmacies spread over a wide geographic area were enrolled to study the effect of care provided by pharmacists to patients with asthma. Randomized by pharmacy, patients received either a peak flow meter with instructions from the pharmacist on how to use it, a peak flow meter with written instructions, or usual care (no peak flow monitor given). The 660 patients were evaluated at enrollment and at 6 and 12 months using the McMaster Asthma-Specific Quality of Life Questionnaire and measured peak expiratory flow rate (PEFR). Patients also were telephoned monthly to obtain their PEFR measurement and information about any recent emergency department visits and hospitalizations.

During the follow-up, 13% of the patients experienced at least 1 asthma exacerbation. A PEFR of less than 50% at baseline predicted an exacerbation over the following 12 months, but PEFR change was not a better independent predictor than quality-of-life scores. By contrast, the quality-of-life scores were independently predictive of an exacerbation at both 4 months (hazard ratio=0.63; 95% confidence interval [CI], 0.46–0.87) and 12 months (hazard ratio=0.66; 95% CI, 0.54–0.82).

Open hernia repair better than laparoscopic

Neumayer L, Giobbie-Hurder A, Jonasson O, et al. Open mesh versus laparoscopic mesh repair of inguinal hernia. N Engl J Med 2004; 350:1819–1827.

CLINICAL QUESTION

Is an open or laparoscopic approach better for inguinal hernia repair?

BOTTOM LINE

Although laparoscopic repair is associated with a small reduction in pain and it gets your patient back to work a day sooner, it carries a greater risk of serious complications and recurrence. (LOE=**1b**)

STUDY DESIGN

Randomized controlled trial (nonblinded)

SETTING

Inpatient (any location) with outpatient follow-up

SYNOPSIS

Open surgical repair of inguinal hernias involves use of a prosthetic mesh, the possibility of local anesthesia, and discharge often within a few hours of the procedure. A laparoscopic procedure has been introduced that requires general anesthesia, but claims to reduce postoperative

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pain and allow earlier return to usual activities. Which is better?

The researchers randomized (allocation concealed) 2164 patients at 14 Veteran's Affairs medical centers to receive either the open or laparoscopic procedure. Of the 2164 initially randomized, 1983 actually underwent surgery. The surgical protocol was standardized for each type of procedure, and surgeons must have performed at least 25 of their chosen procedures to qualify for the study. Patients were followed up for 2 years, and 1696 (86%) completed the follow-up. Crossover from laparoscopic to open repair occurred in 9.8% of patients, compared with only 1.6% crossing over in the other direction. Patients were analyzed by the group to which they were originally assigned, though, which is appropriate.

Patients undergoing laparoscopic repair experienced less pain after surgery and returned to work sooner (4 vs 5 days; 95% confidence interval [CI] for the difference, 1.1–1.3). However, the difference in pain was generally minor: between 6 and 10 on a 100-point visual scale. In general, differences less than 15 points are unlikely to be clinically important.

There were more complications with laparoscopic repair, including more life-threatening complications (0.1% vs 1.1%; odds ratio=11.2; 95% CI, 1.3–95.3). The recurrence rate at 2 years was also lower in the open repair group (4.9% vs 10.1%; absolute risk reduction=5.2%; number needed to treat=20).

Watch for these articles coming soon

Resting injured limbs delays recovery: a systematic review

Changes in recommended treatments for mild and moderate asthma

Results of colonoscopy in young patients with hematochezia

Petroleum jelly does not reduce recurrent pediatric epistaxis

Loughran S, Spinou E, Clement WA, et al. A prospective, single-blind, randomized controlled trial of petroleum jelly/Vaseline for recurrent paediatric epistaxis. Clin Otolaryngol 2004; 29:266–269.

CLINICAL QUESTION

Does petroleum jelly reduce the likelihood that epistaxis will recur in children?

BOTTOM LINE

In this highly selective group of patients with recurrent epistaxis, petroleum jelly (Vaseline) applied twice daily for 4 weeks did not reduce the number of bleeds in the subsequent 4 weeks. This should make you question this commonly recommended treatment. But don't abandon it just yet, since it may work in children with less severe disease in the primary care setting, and because there was potential for recall bias by parents in this study. (LOE=**2b**)

STUDY DESIGN

Randomized controlled trial (single-blinded)

SETTING

Outpatient (specialty)

SYNOPSIS

Recurrent nosebleeds are a common problem in children. Many doctors advise the application of petroleum jelly (Vaseline) to the anterior nares,

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since bleeding is thought to result from drying, picking, rubbing, and all the other things children do to their noses.

In this small but well-designed study, 105 children aged 1 to 14 years referred to otolaryngologists for recurrent epistaxis were identified. The median duration of symptoms was 12 months and the median duration of bleeds was 5 minutes. The children were randomized (allocation concealed) to receive 1 of 2 letters: instructions to apply Vaseline twice daily for 4 weeks and keep a nosebleed diary, or simply instructions to keep a nosebleed diary.

Patients were assessed after 8 weeks, and the primary outcome was the percentage with recurrent bleeds in the previous 4 weeks. Analysis was by intention to treat, and the physician assessing outcomes was blinded to treatment assignment and was careful not to ask about treatment adherence until the end of the visit. Groups were similar at baseline. They were also similar after the intervention: 27.5% in the treatment group and 33.9% in the control group (P=.47) had no bleeds during the 4 weeks prior to the visit and after the intervention.

The study had limitations, though. Approximately 14% of patients never came in for evaluation (evenly split between groups), and most parents were noncompliant with the diaries. The researchers therefore used parental recall instead of the diaries to assess the primary outcome.

DRUG BRAND NAMES

Dicyclomine • Bentyl
Scopolamine • Transderm-Scop; Transderm-V
Simethecone • Myclion, Gas-X

THE JOURNAL OF FAMILY PRACTICE

Evidence-based medicine ratings

THE JOURNAL OF FAMILY PRACTICE uses a simplified rating system system called the Strength of Recommendation Taxonomy (SORT). More detailed information can be found in the February 2003 issue, "Simplifying the language of patient care," pages 111–120.

Strength of Recommendation (SOR) ratings are given for key recommendations for readers. SORs should be based on the highest-quality evidence available.

- **A** Recommendation based on consistent and good-quality patient–oriented evidence.
- **B** Recommendation based on inconsistent or limited-quality patient-oriented evidence.
- **C** Recommendation based on consensus, usual practice, opinion, disease-oriented evidence, or case series for studies of diagnosis, treatment, prevention, or screening

Levels of evidence determine whether a study measuring patient-oriented outcomes is of good or limited quality, and whether the results are consistent or inconsistent between studies.

STUDY QUALITY

1—Good-quality, patient-oriented evidence (eg, validated clinical decision rules, systematic reviews and meta-analyses of randomized controlled trials [RCTs] with consistent results, high-quality RCTs, or diagnostic cohort studies)

2—Lower-quality patient-oriented evidence (eg, unvalidated clinical decision rules, lower-quality clinical trials, retrospective cohort studies, case control studies, case series)

3—Other evidence (eg, consensus guidelines, usual practice, opinion, case series for studies of diagnosis, treatment, prevention, or screening)

Consistency across studies

Consistent—Most studies found similar or at least coherent conclusions (coherence means that differences are explainable); *or* If high-quality and up-to-date systematic reviews or meta-analyses exist, they support the recommendation

Inconsistent—Considerable variation among study findings and lack of coherence; *or* If high-quality and up-to-date systematic reviews or meta-analyses exist, they do not find consistent evidence in favor of the recommendation