POEMs

Patient-Oriented Evidence That Matters

Antibiotic and Corticosteroid Treatment Effective for Acute Exacerbations of COPD

Clinical Question

What treatments are effective for patients with an exacerbation of chronic obstructive pulmonary disease (COPD)?

Bottom Line

Short-term antibiotic treatment and short-term systemic corticosteroids are both associated with a faster resolution of COPD symptoms and fewer treatment failures. (Level of Evidence = 1a)

Synopsis

The researchers searched several databases, including Cochrane CENTRAL, for English-language randomized controlled trials that evaluated treatments for exacerbations of COPD. Pairs of reviewers selected studies for inclusion, extracted the data, and evaluated the research quality. Based on 68 randomized trials, they found that antibiotic treatment of an acute exacerbation, regardless of severity, doubled the likelihood of resolution by the end of treatment (odds ratio = 2.03; 95% CI, 1.47 to 2.80) and halved the likelihood of treatment failure (odds ratio = 0.54; 95% CI, 0.34 to 0.86), with a moderate strength of evidence. Systemic corticosteroid treatment for one day to 56 days was associated with less frequent treatment failure but higher adverse effects, with a low strength of evidence. Current research does not provide good guidance on which antibiotic is best, or the optimum dose or duration of corticosteroid treatment. Other approaches (i.e., inhaled corticosteroids, inhaled bronchodilators, various inhaled combinations, aminophylline, magnesium sulfate, and anti-inflammatory treatments) had little or no effect on outcomes. Given the small number of studies for each comparison, the researchers were unable to determine publication bias. They did not find heterogeneity among study results due to the small number of studies.

Study design: Meta-analysis (randomized controlled trials)

Funding source: Foundation

Setting: Various (meta-analysis)

Reference: *Dobler CC, Morrow AS, Beuschel B, et al. Pharmacologic therapies in patients with exacerbation of chronic obstructive pulmonary disease: a systematic review with meta-analysis.* Ann Intern Med. *2020;172(6):413-422.*

Allen F. Shaughnessy, PharmD, MMedEd
Professor of Family Medicine
Tufts University
Boston, Mass.

Watch-and-Wait Strategy Is an Option for Primary Spontaneous Pneumothorax

Clinical Question

Is conservative management effective for the treatment of uncomplicated primary spontaneous pneumothorax?

Bottom Line

Conservative observation of patients presenting with a first primary spontaneous pneumothorax is as effective as immediate chest tube insertion in achieving full lung re-expansion at eight weeks. Conservative therapy leads to fewer complications and fewer days in the hospital. (Level of Evidence = 1b–)

Synopsis

Patients who presented to the emergency departments of 39 hospitals in Australia and New Zealand with a unilateral, moderate to large, primary spontaneous pneumothorax were randomized to receive immediate intervention (n = 154) or conservative observation (n = 162).

POEMs (patient-oriented evidence that matters) are provided by Essential Evidence Plus, a point-of-care clinical decision support system published by Wiley-Blackwell. For more information, see http://www.essentialevidenceplus.com. Copyright Wiley-Blackwell. Used with permission.

For definitions of levels of evidence used in POEMs, see http://www.essentialevidenceplus.com/product/ebm_loe.cfm?show=oxford.

To subscribe to a free podcast of these and other POEMs that appear in *AFP*, search in iTunes for "POEM of the Week" or go to http://goo.gl/3niWXb.

This series is coordinated by Sumi Sexton, MD, editor-in-chief.

A collection of POEMs published in *AFP* is available at https://www.aafp.org/afp/poems.

In the intervention group, patients had a chest tube inserted (water seal for one hour, then clamped for four hours) and were monitored for re-expansion of the lung using chest radiography. If the lung re-expanded and the pneumothorax did not recur, then the chest tube was removed, and the patient was discharged. If the lung did not re-expand or the pneumothorax recurred, the patient was admitted to the hospital. In the conservative group, patients were observed for four hours. Patients whose symptoms were controlled, were walking comfortably, were hemodynamically stable without the need for supplemental oxygen, and had a stable pneumothorax on repeat chest radiography were discharged. Those who required further intervention were managed at the discretion of the treating physician. The mean age in the two groups was 26 years, and 86.1% of the patients were men. There were fewer current smokers in the conservative group (42.5% vs. 49.3%). At eight weeks, 98.5% of the intervention group and 94.4% of the conservative group had complete radiographic resolution of the pneumothorax, satisfying the prespecified noninferiority criteria of −9 percentage points (risk difference = −4.1 percentage points; 95% CI, −8.6 to 0.5; P = .02). Radiologists were less likely than treating physicians to assess that a pneumothorax had completely resolved (radiologists: 91.9% intervention vs. 94.8% conservative; treating physicians: 99.2% intervention vs. 99.1% conservative). Median time to radiographic resolution was shorter in the intervention group (16 days vs. 30 days). Ultimately, 85% of patients in the conservative group did not require any invasive drainage procedures. The conservative group had shorter hospital stays, required fewer days off work, experienced fewer adverse events, and were less likely to have recurrences during the next 12 months.

Study design: Randomized controlled trial (nonblinded)

Funding source: Government

Allocation: Concealed

Setting: Emergency department

Reference: *Brown SGA, Ball EL, Perrin K, et al.; PSP Investigators. Conservative versus interventional treatment for spontaneous pneumothorax.* N Engl J Med. *2020;382(5):405-415.*

Nita Shrikant Kulkarni, MD
Assistant Professor in Hospital Medicine
Northwestern University
Chicago, Ill.

Low-Dose Aspirin Beneficial for the Prevention of Preterm Birth in Nulliparous Patients with Singleton Pregnancy

Clinical Question

Does initiating low-dose aspirin use in early pregnancy reduce the incidence of preterm birth among nulliparous patients with singleton gestation?

Bottom Line

The routine use of low-dose aspirin, 81 mg daily, starting as early as six weeks' gestational age provided a statistically significant absolute risk reduction (nearly 2 percentage points) in the incidence of preterm birth among nulliparous patients with singleton gestation in resource-poor countries. No significant treatment harms were observed, but the study was not powered to assess rare events. It is not clear whether the results can be generalized to patients in advanced economies. (Level of Evidence = 1b)

Synopsis

The study was carried out at seven community sites in six resource-poor countries (India, Pakistan, Zambia, Democratic Republic of Congo, Guatemala, and Kenya). The authors enrolled 11,976 nulliparous patients at least 14 years of age with singleton pregnancies and randomized them to receive 81 mg of aspirin or placebo starting between 6 0/7 and 13 6/7 weeks' gestational age and continued until 37 0/7 weeks' or delivery. Patients were excluded for allergy to aspirin, previous aspirin use for at least seven days during the pregnancy, more than two first-trimester pregnancy losses, or medical conditions that might be considered a contraindication to study participation (e.g., diabetes mellitus or hypertension). Further screening required a blood pressure of less than 140/90 mm Hg, a hemoglobin level of at least 7 g per dL (70 g per L), and a viable fetus without anomaly. For the primary outcome of preterm birth, the authors planned a modified intention-to-treat analysis to include only patients who delivered at 20 0/7 weeks' gestation or later (n = 11,558). At least 90% adherence to treatment based on pill counts was high: approximately 85%. Preterm birth before 37 0/7 weeks' occurred in 11.6% (668 out of 5,780) of patients in the aspirin group vs. 13.1% (754 out of 5,754) in the placebo group (relative risk = 0.89; 95% CI, 0.81 to 0.98; P = .012; number needed to treat = 66;

95% CI, 37 to 308). The authors estimated the absolute risk difference at 2%. More than 20 secondary outcomes were considered and treated as exploratory. Among those outcomes that were statistically significant and better in the aspirin group were early preterm delivery (less than 34 weeks) and fetal loss after 16 weeks' gestation and up to seven days postpartum. There were no differences in the overall incidence of hypertensive disorders, maternal bleeding problems, and fetal growth abnormalities. There were no statistically significant harms of aspirin treatment, although the study was not powered to assess rare catastrophic outcomes.

Study design: Randomized controlled trial (double-blinded)

Funding source: Government

Allocation: Concealed

Setting: Outpatient (primary care)

Reference: *Hoffman MK, Goudar SS, Kodkany BS, et al.; ASPIRIN Study Group. Low-dose aspirin for the prevention of preterm delivery in nulliparous women with a singleton pregnancy (ASPIRIN): a randomised, double-blind, placebo-controlled trial [published correction appears in* Lancet. *2020;395(10228):e53].* Lancet. *2020;395(10220):285-293.*

Linda Speer, MD
Professor of Family Medicine
University of Toledo
Toledo, Ohio

A Specific Probiotic Decreases Crying in Infants Younger than Two Months with Colic

Clinical Question

Is probiotic supplementation effective in decreasing crying in infants with colic?

Bottom Line

The treatment of breastfed infants with colic using a specific probiotic—*Bifidobacterium animalis* subsp. *lactis*—significantly decreased crying duration and episodes. The probiotic decreased the daily crying duration by at least one-half in 80% of infants (number needed to treat = 2). Other studies have not consistently shown benefit. This study is small, but it may be that the particular probiotic matters. If you recommend a probiotic to parents, suggest they check labels to find this specific one. (Level of Evidence = 1b–)

Synopsis

The researchers worked with community pediatricians to identify breastfed infants younger than eight weeks with reported colic for at least one week, consisting of crying or irritability without obvious cause for at least three hours a day and at least three days per week. Identified infants were followed up for one week before the intervention started to confirm the diagnosis. Then, 80 infants were randomized using concealed allocation to receive placebo or supplementation with the probiotic *Bifidobacterium animalis* subsp. *lactis* (Bifidolactis Infant) each morning by mouth for 28 days. Parents kept a diary and patients were evaluated weekly by a pediatrician. Follow-up was 100% in both groups and analysis was by intention to treat. The primary outcome, a reduction of 50% or more of average daily crying duration after 28 days of intervention, occurred in 80% of the treated infants compared with 33% of the untreated children ($P < .0001$) and began with the first week of treatment. The average minutes of crying per day, the number of crying episodes, and the number of daily stools were lower with treatment.

Study design: Randomized controlled trial (double-blinded)

Funding source: Industry

Allocation: Concealed

Setting: Outpatient (primary care)

Reference: *Nocerino R, De Filippis F, Cecere G, et al. The therapeutic efficacy of* Bifidobacterium animalis *subsp.* lactis *BB-12® in infant colic: a randomised, double blind, placebo-controlled trial.* Aliment Pharmacol Ther. *2020;51(1):110-120.*

Allen F. Shaughnessy, PharmD, MMedEd
Professor of Family Medicine
Tufts University
Boston, Mass.

Editor's Note: Dr. Shaughnessy is an assistant medical editor for *AFP*. ■