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

Fetal fibronectin does not affect outcomes of preterm labor

Lowe MP, Zimmerman B, Hansen W. Prospective randomized controlled trial of fetal fibronectin on preterm labor management in a tertiary care center. Am J Obstet Gynecol 2004; 190:358–362.

CLINICAL QUESTION

Does use of fetal fibronectin in management of preterm labor affect age at delivery or rates of interventions?

BOTTOM LINE

Use of fetal fibronectin in the assessment of women presenting to labor and delivery units with symptoms of preterm labor does not affect the gestational age at delivery, frequency of use of medical interventions, length of stay in labor and delivery, or rate of inpatient admissions. (Level of evidence [LOE]=**1b**)

STUDY DESIGN

Randomized controlled trial (nonblinded)

SETTING

Inpatient (ward only)

SYNOPSIS

Fetal fibronectin evaluation has been introduced to try to discriminate between women who are more or less likely to deliver preterm on presentation to labor and delivery for symptoms of preterm labor. It has not been shown to influence outcomes.

Women at 23 to 34 weeks' gestation were randomized (allocation concealed) to testing of fetal fibronectin (n=46) or not (n=51). Fetal fibronectin results were available within approximately 1 hour to the physicians of the women in the tested group. There were no differences between groups for median gestational age at delivery, hours spent in labor and delivery, rate of inpatient admissions, or use of corticosteroids, antibiotics, or magnesium sulfate.

Within the fetal fibronectin–tested group there were significant differences between those with positive and negative test results for more hours spent in labor and delivery and higher rate of inpatient admission among those who tested positive. The observed sensitivity and specificity of fetal fibronectin for birth within 7 days was 67% and 79%, respectively. The positive predictive value for delivery within 7 days was 18% and negative predictive value was 97%.

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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, InfoRetriever and POEMS for Primary Care are registered trademarks of InfoPOEM, Inc. POEMS and Patient-Oriented Evidence that Matters are trademarks of InfoPOEM, Inc. These POEMs are copyrighted by, and published with the express permission of InfoPOEM, Inc. and may not be copied or otherwise reproduced without the prior written consent of InfoPOEM, Inc.

Prochlorperazine more effective than ketorolac for pediatric migraine

Brousseau DC, Duggy SJ, Anderson AC, Linakis JG. Treatment of pediatric migraine headaches. A randomized, double-blind trial of prochlorperazine versus ketorolac. Ann Emerg Med 2004; 43:256–262.

CLINICAL QUESTION

Is ketorolac more effective than prochlorperazine in the treatment of pediatric migraine in the emergency setting?

BOTTOM LINE

Prochlorperazine (Compazine) is more effective than ketorolac (Toradol) in the treatment of children presenting to the emergency department with migraine. One additional child will experience headache relief for every 4 children receiving prochlorperazine instead of ketorolac. (LOE=**1b**)

STUDY DESIGN

Randomized controlled trial (double-blinded)

SETTING

Emergency department

SYNOPSIS

This study is a start in the right direction toward clearing up the lack of information regarding treatment of pediatric migraine in the emergency department. The investigators recruited 62 children aged 5 to 18 years presenting with migraine in either of 2 pediatric emergency departments. Migraine was defined as recurrent headache with at least 3 of the following symptoms: an aura; unilateral location; throbbing pulsatile pain; nausea, vomiting, or abdominal pain; relief after sleep; and a family history of migraine.

Using concealed allocation, researchers randomized patients deemed to require intravenous medication to receive either prochlorperazine 0.15 mg/kg, up to 10 mg, or ketorolac 0.5 mg/kg, up to 30 mg, over 10 minutes. Children not experiencing at least a 50% reduction in pain within 60 minutes were given the alternative study drug and evaluated again.

Using the Nine Faces Pain Scale, 85% of prochlorperazine-treated children and 55% of ketorolac-treated patients experienced at least a 50% relief in pain (number needed to treat [NNT]=4; 95% confidence interval [CI], 2–13). One third of children treated with prochlorperazine achieved complete relief, compared with 7% of children receiving ketorolac (NNT=4; 95% CI, 2–13). Headache recurrence within the following 2 days occurred at a similar rate in both groups (27% and 31%, respectively).

No long-term benefit shown for bones after HRT

Yates J, Barrett-Connor E, Barlas S, Chen YT, Miller PD, Siris ES. Rapid loss of hip fracture protection after estrogen cessation: evidence from the National Osteoporosis Risk Assessment. Obstet Gynecol 2004; 103:440–446.

CLINICAL QUESTION

Does hormone therapy continue to provide protection from hip fractures after the treatment is stopped?

BOTTOM LINE

Women taking short-term hormone replacement therapy (HRT) for symptom relief cannot expect long-term bone protection. Hip fracture risk is at least as great for women who stop postmenopausal hormone therapy as that for women who have never used it. The loss of protection occurs within 5 years of cessation of treatment. (LOE=**1b**)

STUDY DESIGN

Cohort (prospective)

SETTING

Population-based

CONTINUED

SYNOPSIS

The National Osteoporosis Risk Assessment (NORA) study began in 1997 as a longitudinal observational study of postmenopausal women aged >50 years at study entry. It includes 140,584 women, of whom 48% were taking HRT at study entry and an additional 14% had used postmenopausal estrogen in the past. Ninety-two percent of the women were white. A total of 53,737 women never used HRT, 8723 quit taking it within the last 5 years, and 10,151 quit more than 5 years ago. The rest of the women were currently using HRT.

Unadjusted hip fracture rates per 1000 women per year were 2.24, 2.17, 2.51, and 0.81, respectively. After adjustments for factors including age and race, only the current users had a significantly different hip fracture rate (odds ratio=0.60; 95% confidence interval, 0.44–0.82; $P<.001$).

3 days ciprofloxacin adequate for UTI in older women

Vogel T, Verreault R, Gourdeau M, et al. Optimal duration of antibiotic therapy for uncomplicated urinary tract infection in older women: a double-blind randomized controlled trial. CMAJ 2004; 170:469–473.

CLINICAL QUESTION

Is 3 days of ciprofloxacin as effective as 7 to 10 days of the same drug for older women with urinary tract infection?

BOTTOM LINE

This reasonably large study found that 3 days of ciprofloxacin (Cipro) twice daily is as effective and better tolerated than 7 days of treatment for healthy older women with urinary tract infection (UTI). Although a much larger study might find a small difference in outcomes, it is unlikely to be clinically meaningful; this study was powered to detect a modest 10% difference in outcomes. (LOE=**1b**)

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■ **STUDY DESIGN**
Randomized controlled trial (double-blinded)

■ **SETTING**
Outpatient (any)

■ SYNOPSIS

We know that 3 days of antibiotics is effective for uncomplicated lower UTI in young healthy women. However, most physicians still use a longer course of 7 to 10 days for older women.

In this study, women aged >65 years with a positive urine culture and at least 1 symptom of UTI were randomized to receive either oral ciprofloxacin 250 mg twice daily for 3 days plus placebo for 4 days (n=93) or ciprofloxacin 250 mg twice daily for 7 days (n=89). Women with diabetes, an indwelling catheter, abnormal renal function, sepsis, recent use of antibiotics, or signs of pyelonephritis (not specified what they are) were excluded. Groups were similar at baseline, allocation was appropriately concealed, and analysis was by intention to treat. Patients were followed up for a total of 6 weeks.

Four patients withdrew from the 7-day group because of adverse events, compared with 1 in the 3-day group. There were 2 deaths in each group (the study included some hospitalized patients, since it was organized via a central laboratory). Most had *Escherichia coli* (71%), and 15.8% had *Klebsiella pneumoniae.* There was no difference between groups at 2 days after completion of antibiotic therapy regarding bacterial eradication (98% for the 3-day group vs 93% for the 7-day group) or symptom improvement (98% for the 3-day group vs 92% for the 7-day group). The same was true at 6 weeks, with similar rates of reinfection (14% vs 18%) and relapse (15% vs 13%). Adverse effects—drowsiness, loss of appetite, and nausea or vomiting, in particular—were more common in the 7-day group.

Useful signs and symptoms to evaluate vaginal complaints

Anderson MR, Klink K, Cohrssen A. Evaluation of vaginal complaints. JAMA 2004; 291:1368–1379.

■ CLINICAL QUESTION

How useful are the history, physical examination, and routine office-based laboratory studies in the diagnosis of vaginitis?

■ BOTTOM LINE

In the diagnosis of vaginitis, useful symptoms include information about itching. Useful signs include odor and the presence of inflammatory changes. Office microscopy is the most accurate laboratory test. (LOE=**3a**)

■ **STUDY DESIGN**
Systematic review

■ **SETTING**
Outpatient (any)

■ SYNOPSIS

The 3 major causes of vaginitis include vaginal candidiasis, bacterial vaginosis, and trichomoniasis. The authors thoroughly searched Medline and the bibliographies of recent reviews, and contacted primary authors of identified studies, for articles evaluating the usefulness of the history and physical examination in conjunction with routine office-based laboratory testing in the diagnosis of vaginitis.

Articles were included if they involved original research on symptomatic premenopausal women in a primary care setting, compared a diagnostic sign/symptom/test with a recognized reference standard, and allowed the calculation of sensitivity and specificity. A total of 18 studies met the established criteria. All 18 studies were evaluated for quality: of these, 15 received

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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

a score of 2 (1= best, 3=worst), and 3 studies received a score of 3.

Symptoms useful in diagnosis included a lack of itching (making candidiasis less likely; negative likelihood ratio [LR–] = 0.18–0.79) and a lack of perceived odor (making bacterial vaginosis unlikely; LR– = 0.07). Useful physical examination signs were limited. Findings predictive of candidiasis included the presence of inflammation (eg, erythema, edema, excoriations; positive likelihood ratio [LR+] range = 2.1–8.4) and a lack of odor (LR+ = 2.9).

The presence of a high "cheese" odor was predictive of bacterial vaginosis (LR+ = 3.2). The whiff test (fishy odor from the slide after the application of potassium hydroxide) is part of the reference standard for bacterial vaginosis and was therefore not evaluated independently.

Of the various office laboratory tests available, microscopy of vaginal discharge was the most useful. The presence of many leukocytes was uncommon in candidiasis and bacterial vaginosis. In the absence of trichomonads, it is important in this instance to consider other causes, such as gonorrhea or chlamydia.

DRUG BRAND NAMES

Ciprofloxacin • Cipro
Ketorolac • Toradol
Prochlorperazine • Compazine