

# POEMs

## *Patient-Oriented Evidence that Matters*

Each month, the POEMs editorial team reviews more than 80 journals of interest to primary care physicians, identifying articles you need to know about to stay up to date. We call these articles POEMs (Patient-Oriented Evidence that Matters) because they address common primary care problems, report outcomes that matter to patients, and, if valid, require us to change the way we practice. The 8 most important articles are critically appraised here each month. Occasionally, we include articles that confirm an important practice for which there had been only weak evidence previously (POEs – Patient-Oriented Evidence) or research that is focused on intermediate outcomes (DOEs – Disease-Oriented Evidence). We call attention to the latter so improper changes in currently valid practices are prevented. The collected reviews are available online. Additional POEMs and other important evidence-based material are published in a monthly newsletter called *Evidence-Based Practice* (available through subscription—phone: 1-201-782-5726; fax: 1-201-391-2778; Internet: www.infopoems.com).

### ■ MANAGEMENT OF FIRST-TRIMESTER SPONTANEOUS ABORTION

Geyman JP, Oliver LM, Sullivan SD. Expectant, medical, or surgical treatment of spontaneous abortion in first trimester of pregnancy? A pooled quantitative literature evaluation. *J Am Board Fam Pract* 1999; 12:55-64.

**Clinical question** What is the best management approach for first-trimester spontaneous abortion?

**Background** First-trimester spontaneous abortion is estimated to occur in 15% to 20% of recognized pregnancies. The traditional management of this problem has been surgical evacuation of retained products of conception (POC) by dilatation and curettage (D & C). Recent developments, including studies involving expectant management, a greater utility of transvaginal sonography, and studies using medical treatment for abortion, call into question the widespread use of surgical management.

**Population studied** This review included a total of 2151 patients with first-trimester ( $\geq 13$  weeks) spontaneous abortions. These patients were managed expectantly (545), medically (198), or surgically (1408). Patients with any other type of abortion or spontaneous abortion beyond 13 weeks were excluded from the study. Other exclusion criteria included fever ( $>100.4$  °F), hemodynamic instability, uncontrolled vaginal bleeding, evidence of endometritis or pelvic inflammatory disease, and findings suggestive of ectopic pregnancy.

**Study design and validity** This thorough systematic review of the English language literature included 18 studies meeting the following inclusion criteria: (1) more than 15 patients treated by expectant, medical, or surgical management; (2) medical treatment with antiprogesterone or prostaglandin agents; (3) surgical treatment including sharp and suction curettage and manual vacuum aspiration; (4) objective outcome data,

and (5) sufficient follow-up of at least 2 weeks. Of these 18 studies, only 3 were randomized controlled trials (RCTs). The authors point out the important fact that formal statistical techniques of meta-analysis were not possible given the small number of RCTs.

**Outcomes measured** The primary outcome was successful treatment of first-trimester spontaneous abortion. This was defined as vaginal bleeding for  $\leq 3$  weeks, fully expelled POC by 2 weeks, no complications (infection, transfusion, uterine perforation, hospitalization, or death), and, if measured, negative human chorionic gonadotropin levels by 30 days.

**Results** Pooled weighted success averages were calculated for each treatment group. On the basis of 9 studies, expectant management had a success rate of 93%, which dropped to 80% when only data from RCTs were reviewed. In each of these studies, initial transvaginal sonography demonstrated an empty uterus or POC  $< 50$  mm in AP diameter. If POC were  $> 50$  mm, patients were managed surgically. Three studies addressed medical management with an average success rate of 52%. Surgical treatment resulted in an average success rate of 94% according to 10 studies, and 92% according to the 3 RCTs.

**Recommendations for clinical practice** This review supports expectant management as a reasonable option for treatment of first-trimester spontaneous abortion in a select population of patients, though more RCTs are needed to compare surgical, medical, and expectant management. To be considered for expectant management, patients should be afebrile with stable vital signs and no excessive pain or bleeding. Although the use of transvaginal sonography shows promise in helping to determine patients for whom expectant management will be effective, further studies are needed to clarify its role. Serial human chorionic gonadotropin measurements should be considered for patients choosing expectant management. However, the appropriate interval for such

measurements is uncertain. Further studies are also needed to clarify the potential role of medical management and also to assess informed patient preferences.

Christy Cone, MD  
Mark H. Greenawald, MD  
Richard Schaffer, Jr, MD  
Carilion Family Practice Residency Program  
Roanoke, Virginia  
E-mail: mgreenawald@carilion.com

## ■ EMLA CREAM FOR THE DÉBRIDEMENT OF VENOUS LEG ULCERS

Lok C, Paul C, Amblard P, et al. EMLA cream as a topical anesthetic for the repeated mechanical débridement of venous leg ulcers: a double-blind, placebo-controlled study. *J Am Acad Dermatol* 1999; 40:208-13.

**Clinical question** How effective is eutectic mixture of local anesthetics (EMLA) cream in reducing the pain and decreasing the number of mechanical débridements necessary to treat venous leg ulcers?

**Background** Mechanical débridement of venous leg ulcers is an accepted means of obtaining a clean ulcer and increasing healing rates. Débridement removes dead tissue and fibrinous plaques to allow the growth of granulation tissue. The effectiveness of EMLA cream as a local anesthetic for débridement has been demonstrated in previous studies.

**Population studied** A total of 69 patients from 9 departments of dermatology or phlebology who were scheduled for mechanical débridement of a venous leg ulcer were enrolled. The average age was 71 years for the intervention group and 73 years for the placebo group. Forty-nine of the participants were women. Ulcer areas were 5 to 50 cm<sup>2</sup>, with debris and necrosis on 50% or more of the area, for which débridement was required 3 times a week for at least the first week. Patients had not used EMLA cream previously.

**Study design and validity** This was a randomized double-blind placebo-controlled trial. All patients were given a dose of 30 mg dextropropoxyphene and 400 mg acetaminophen an hour before débridement. A thick layer of either EMLA or placebo cream (maximum 10 g) together with an occlusive dressing (plastic wrap) was applied for 30 to 45 minutes. Débridement was started within 10 minutes of cream removal. After débridement, ulcers were dressed with sterile petrolatum dressing. After the first week, the frequency of continued débridement was determined by participating physicians. A maximum of 15 débridements was allowed during the study. An ulcer was defined as clean if 75% or more of

its area was free from necrotic or fibrinous tissue. The number of débridements, the size of an ulcer, patient perception of pain during débridement, physician's assessment of quality of débridement, and local reactions were recorded.

**Outcomes measured** The primary outcome measured was the number of débridements needed to obtain a clean ulcer. Secondary outcomes included pain, duration and quality of débridement, ulcer area at study termination, local reactions, and plasma levels of the drugs and metabolites.

**Results** The type of ulcer, size of ulcer at admission and study termination, dose of cream and mean time between débridements were not statistically different between placebo and treatment groups. The median number of débridements necessary to obtain a clean ulcer was significantly lower in the EMLA group (11.5 compared with more than 15 in the placebo group,  $P = .019$ ). The percentage of patients at the end of the study with a clean ulcer was significantly higher in the EMLA group (66.7% vs 33.3%,  $P = .008$ ; number needed to treat = 3). Pain scores were decreased by 50% in the EMLA group compared with placebo ( $P = .003$ ). There was no significant difference in the median duration of débridement (4 minutes with EMLA vs 3 minutes in the placebo group,  $P = .253$ ). EMLA cream significantly improved the physician assessment of the quality of débridement. Local reactions were not statistically different between the 2 groups.

**Recommendations for clinical practice** EMLA cream produces effective pain relief for the mechanical débridement of venous leg ulcers, reduces the number of débridements necessary, and results in a higher success rate of obtaining clean ulcers.

Betsy A. Johns, MD  
University of Pittsburgh Medical Center -  
St. Margaret  
Pennsylvania  
E-mail: bajohns@pitt.edu

## ■ OMEPRAZOLE OR RANITIDINE FOR INTERMITTENT TREATMENT OF GERD?

Bardhan KD, Möller-Lissner S, Bigard MA, et al. Symptomatic gastroesophageal reflux disease: double-blind controlled study of intermittent treatment with omeprazole or ranitidine. *BMJ* 1999; 318:502-7.

**Clinical question** Should omeprazole or ranitidine be used for intermittent treatment of gastroesophageal reflux disease?

**Background** Gastroesophageal reflux disease (GERD) is a common diagnosis in primary care, but