

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 cm², 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