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Comparative effectiveness of surgical interventions aimed at treating underlying venous pathology in patients with chronic venous ulcer

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Objective: **Chronic venous ulcers (CVUs) remain the leading causes for nonhealing wounds in the lower extremities. Although multilayer compression dressing remains the treatment gold standard, there are various surgical procedures aimed at healing CVUs with little or no evidence on the efficacy of these treatment methods. We conducted a systematic review of the effects of various surgical treatments for CVUs, in terms of ulcer healing rates, complete time to heal, recurrence rates, mortality, pain, and quality of life.**

Methods: **We searched MEDLINE, EMBASE, the Cochrane Central Register for Controlled Trials, and the Cumulative Index for Nursing and Allied Health Literature databases from January 1980 through July 2012. We included studies that compared a surgical procedure with multilayer compression therapy or another surgical procedure among patients with CVUs. We also included studies without a comparison group if they were of sufficient quality. Two independent reviewers screened titles, abstracts, and articles for eligibility. Two reviewers extracted data on study design, applicability, results, and quality.**

Results: **We identified 10,676 citations, of which 22 studies (23 publications) were included. Eight studies (six randomized controlled trials, two cohorts) compared a surgical procedure with compression. Fourteen studies evaluated different surgical interventions. Adding superficial vein ligation and stripping to compression did not improve wound-healing rate. However, the recurrence rate was 50% reduced when surgery corrected the underlying superficial venous pathology (moderate to high strength of evidence [SOE]). Adding subfascial endoscopic perforator surgery with superficial vein surgery to compression does not improve the healing rate of venous ulcers or reduce the recurrence rate except for medial and large ulcers (high SOE). The SOE was insufficient to support a conclusion about the effects of sclerotherapy when added to compression in healing CVUs. There was insufficient evidence on the surgical treatment of CVUs secondary to deep venous reflux and venous obstruction. We are unable to draw conclusions about the effects of surgical procedures on mortality, pain, and quality of life.**

Conclusions: **Our ability to draw conclusions on most surgical techniques is limited due to poorly designed and executed studies, with no uniformity of treatment methods, follow-up or reporting, and lack of randomization. We found some evidence to suggest superficial vein ligation and stripping may reduce the risk of wound recurrence, but these surgical techniques are infrequently performed. The newer minimally invasive techniques lack evidence. Randomized controlled trials for the endovenous procedures used today for treating CVUs are needed. (J Vasc Surg: Venous and Lym Dis 2014;2:212-25.)**

Chronic venous ulcers (CVUs) affect up to 2 million people in the United States annually,[1] and prevalence increases with age.[2] Besides the direct medical costs, CVUs cause major disability and economic impact, in both patients and caregivers. Overall wound care costs in developed countries are estimated to be as high as 3% of the total health budget.[3]

Most authorities define CVUs as being present for at least 6 weeks, most frequently located on the medial aspect of the lower calf and associated with other signs of venous insufficiency such as varicosities, edema, hyperpigmentation, hemosiderosis, lipodermatosis, and venous eczema. CVUs are long-standing, and in some studies have a mean duration of 9 months, with almost two-thirds lasting over 5 years.[4]

The underlying pathophysiology is venous hypertension, which is commonly due to venous reflux in the superficial, deep, or perforator venous systems or a combination. Although venous obstruction is a less common etiology, it can cause severe disease. Venous hypertension leads to local tissue inflammation and ulceration.[3] Reflux or obstruction may also occur in conjunction and can be diagnosed by duplex ultrasound, which also can rule out arterial insufficiency disease.

A variety of practitioners, including primary care providers, wound specialists, vascular surgeons, dermatologists,

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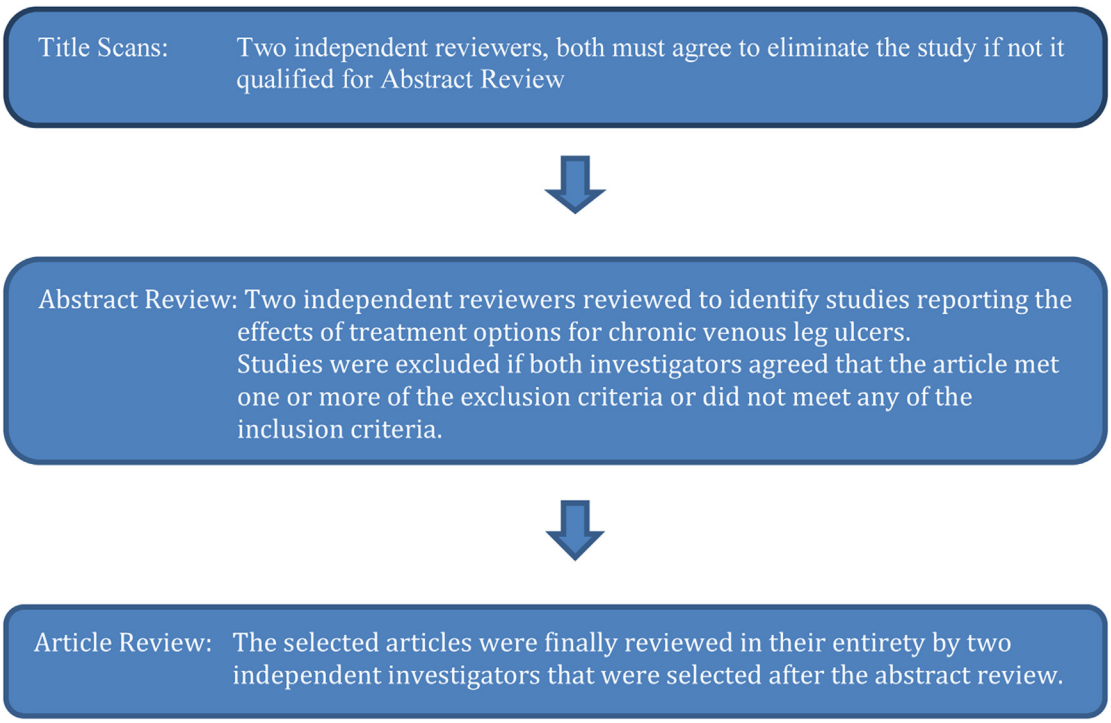

Fig 1. Summary of study selection strategy.

and trained nursing specialists, manage CVUs. Multilayer mechanical compression (at least two layers achieving 20 to 30 mm compression that effectively reduces venous hypertension) is effective in healing more than half of CVUs.[5] Several minimally invasive surgical approaches have been developed to eliminate the underlying venous pathology. However, little guidance exists about the settings and circumstances where surgical procedures should be used and whether they provide any benefit over noninvasive standard of care.

Our goal was to systematically review the efficacy and safety of surgical procedures for CVUs compared with compression therapy or other surgical procedures in terms of wound healing, recurrence rates, morbidity, and mortality.

METHODS

This review is part of a larger systematic review. The Agency for Healthcare Research and Quality contracted the Johns Hopkins Evidence-based Practice Center to perform a systematic review of the safety and effectiveness of different treatments for CVUs. The final report with the details of our methods is available on AHRQ's website.[6] A separate publication compared the benefits and harms of advanced wound dressings for patients with CVUs.[7] This article focuses on surgical treatments.

Development of Key Questions. We developed the Key Questions with input from AHRQ, wound care experts, stakeholders, and public comment. The final surgical Key Questions were:

1) For patients with a CVU, what are the benefits and harms of surgical procedures aimed at the underlying venous abnormalities when compared with using solely compression systems?
2) For patients with a CVU, what are the comparative benefits and harms of different surgical procedures for a given type of venous reflux and obstruction?

Benefits included wound healing, time to healing, reduction in wound recurrence rate, and improvement in quality of life (QOL), pain, or functional status. Harms included mortality, infection, bleeding, and skin irritation or burning.

Search strategy. We searched MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials, and the Cumulative Index to Nursing and Allied Health Literature for primary studies in any language from January 1980 through July 2012. Our search strategy included medical subject headings and text terms relevant to CVUs and surgical procedures. Our search strategy is provided in the protocol and in Appendix A of the full report.[6] We scanned the references of included articles and relevant reviews to identify any potential additional references.

Study selection. Two independent investigators reviewed title, abstract, and full article. For an article to be eliminated at any level of review, both reviewers had to agree on its exclusion. Disagreements were resolved by consensus or third-party adjudication (Fig 1).

Inclusion criteria. We included studies that evaluated the effect of surgical procedures aimed at correcting the