A systematic review of the efficacy and limitations of venous intervention in stasis ulceration

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ABSTRACT

Background: Surgical techniques to address various components of chronic venous disease are rapidly evolving. Their efficacy and generally good results in treating superficial venous reflux (SVR) have been documented and compared in patients presenting with pain and swelling. A growing amount of literature is now available suggesting their efficacy in patients with venous leg ulcer (VLU). This review attempts to summarize the efficacy and limitations of commonly used venous interventions in the treatment of SVR and incompetent perforator veins (IPVs) in patients with VLU.

Methods: A systematic review of the published literature was performed. Two different searches were conducted in MEDLINE, Embase, and EBSCOhost to identify studies that examined the efficacy of SVR ablation and IPV ablation on healing rate and recurrence rate of VLU.

Results: In the whole review, 1940 articles were screened. Of those, 45 were included in the SVR ablation review and 4 in the IPV ablation review. Data were too heterogeneous to perform an adequate meta-analysis. The quality of evidence assessed by the Grading of Recommendations Assessment, Development, and Evaluation for the two outcomes varied from very low to moderate. Ulcer healing rate and recurrence rate were between 70% and 100% and 0% and 49% in the SVR ablation review and between 59% and 93% and 4% and 33% in the IPV ablation review, respectively. To explain those variable results, limitations such as inadequate diagnostic techniques, saphenous size, concomitant calf pump dysfunction, and associated deep venous reflux are discussed.

Conclusions: Currently available minimally invasive techniques correct most venous pathologic processes in chronic venous disease with a good sustainable healing rate. There are still specific diagnostic and efficacy limitations that mandate proper match of individual patients with the planned approach. (J Vasc Surg: Venous and Lym Dis 2017;■:1-23.)

Chronic venous disease (CVD) is a common medical condition. Venous leg ulcer (VLU) is the most severe clinical presentation of CVD. Active VLUs are present in up to 0.5% of the adult Western population, whereas healed VLUs are seen in 0.6% to 1.4%.[1] In the United States, >2 million adults have advanced CVD, and at least 20,556 patients receive a new diagnosis of VLU each year. Delay in ulcer healing and ulcer recurrence are often seen and most often require prolonged therapy.

The underlying pathologic process contributing to the occurrence of CVD includes varying degrees of superficial venous insufficiency, deep venous insufficiency, deep venous obstruction, and calf muscle pump dysfunction.[2-5] Both superficial reflux and deep reflux are common in patients with VLU. In 264 patients with venous ulceration, the anatomic distribution of reflux was noted as follows: deep venous reflux (DVR; 71%), superficial venous reflux (SVR; 57%), and incompetent perforator veins (IPVs; 17%).[5] Reflux in more than one venous compartment is extremely common, occurring in as many as two-thirds of patients with healed or active ulceration.[2,5] Isolated perforator insufficiency is extremely rare as a basis of VLU; most are instead associated with reflux in other territories (secondary perforator insufficiency).[3]

In the last two decades, technology has rapidly evolved from open to minimally invasive techniques to correct these pathologic processes. All open and minimally invasive techniques have shown good results in patients with leg pain and swelling. Less well documented are their efficacy and limitations in patients with VLU. A logical algorithm as to how the various techniques should be used, in what sequence and in what combinations, for optimal results also has yet to be established. The purpose of this article was first to summarize in a systematic review the efficacy of commonly used open and minimally invasive techniques and then to highlight their limitations. A stepwise approach combining those techniques in the management of VLU is suggested on the basis of our estimate of efficacy, limitations, and relative risk of the various techniques.

METHODS

A systematic review of the literature, adhering to the Preferred Reporting Items for Systematic Reviews and

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Author conflict of interest: S.R. holds a U.S. patent regarding intravascular ultrasound diagnostics in chronic venous disease and has stock in Veniti.

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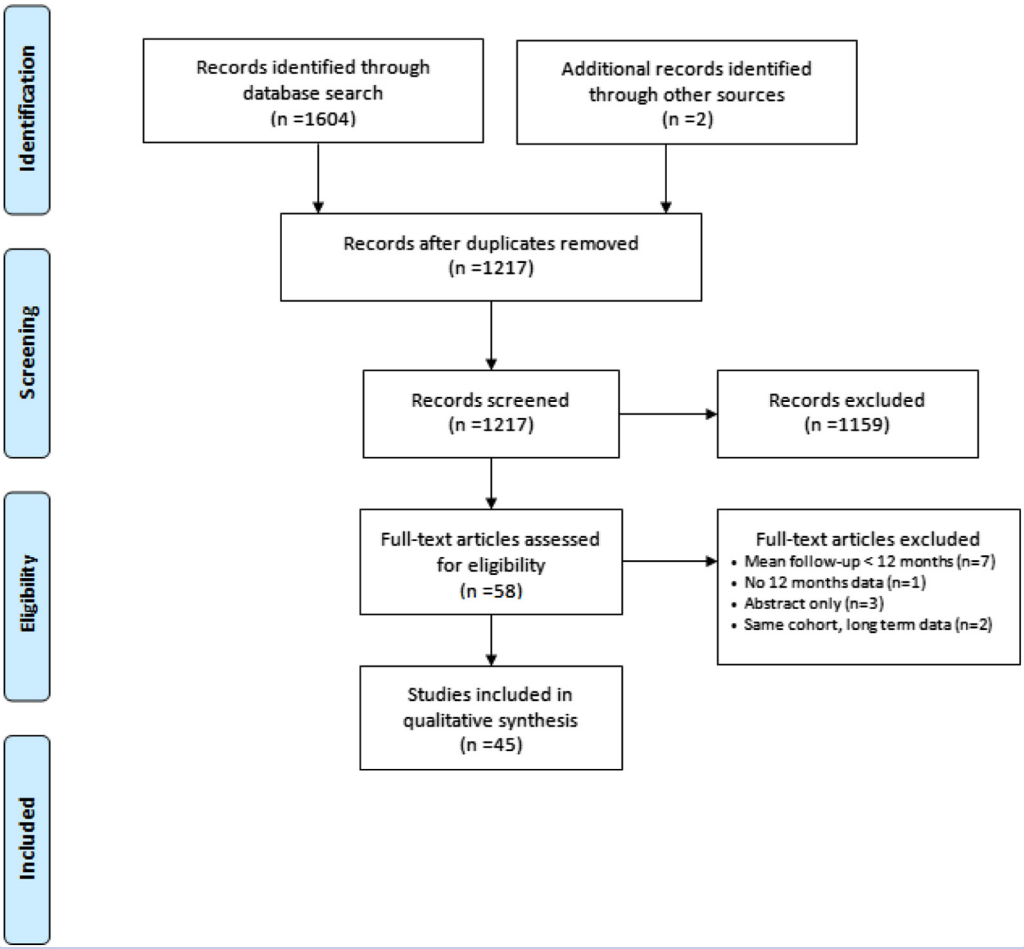

Fig 1. Superficial venous reflux (SVR) ablation.

Meta-Analysis recommendations, was performed.[6] The aim of the study, eligibility criteria, and outcomes were predefined. Two different searches were conducted to identify studies that examined the efficacy of SVR ablation and IPV ablation in patients with VLU.

Study eligibility

Type of studies. All observational studies and randomized controlled trials (RCTs) were eligible. Review articles were searched to identify additional relevant publications. Articles not yet published were excluded. No time limit was set for inclusion or exclusion. Despite changing technology over time, effects of correcting specific disease (eg, superficial reflux) appear to be the same as detailed herein regardless of specific technique used.

Type of patients. Participants of all ages with a healed or active medial VLU (C5-C6) were included. A minimum of 20 patients with Clinical, Etiology, Anatomy, and Pathophysiology clinical class C5 to C6 score were required. The SVR ablation search included all techniques of great saphenous vein (GSV), small saphenous vein (SSV), and varicose vein ablation. Studies with both SVR ablation and IPV ablation were included in that search. The IPV ablation search considered articles in which IPV ablation was the only intervention, either because no SVR was present or because SVR had been previously ablated.

Outcomes. The primary outcomes were ulcer healing and ulcer recurrence. Outcome measurement at 12 months or a mean follow-up of 12 months was determined to be the minimal requirement to assess the chosen outcomes.

Search strategy

An electronic search was conducted in January 2017. MEDLINE, Embase, and EBSCOhost databases were searched with English-language restraint and without publication date limitation. The references of included studies and of relevant review articles were manually searched for additional publications. Key words used for each search are shown in the Appendix (online only).