REVIEW ARTICLE

Mechanochemical Ablation for Treatment of Truncal Venous Insufficiency: A Review of the Current Literature

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ABSTRACT

Mechanochemical ablation (MOCA) is a nonthermal nontumescent technique used in the treatment of superficial venous disease. This review analyzed the available data on the efficacy and safety of MOCA. A systematic literature search was performed. Of 101 studies identified, 14 were suitable for inclusion. The studies were found to be heterogeneous in design, and the quality of evidence was found to be low or very low. MOCA was demonstrated to be effective in the short-term with minimal complications. Consensus guidelines and definitions of reporting outcome measures must be standardized to allow comparison with other techniques.

ABBREVIATIONS

EVLA = endovenous laser ablation, GSV = great saphenous vein, IQR = interquartile range, MOCA = mechanochemical ablation, SSV = short saphenous vein, VCSS = Venous Clinical Severity Score

Chronic venous insufficiency is a common clinical problem affecting 30%–40% of people in their lifetime (1,2). It is now appreciated that varicose veins are responsible for a marked reduction in quality of life (3). Traditional surgery is associated with postoperative pain, risk of complications (4), and slow return to normal activities (5). Endothermal procedures such as radiofrequency (RF) ablation and endovenous laser ablation (EVLA) are now recommended as first-line treatment of varicose veins (6,7). Although highly successful with fewer complications, faster return to work, and comparable success rates, these procedures rely on the delivery of thermal energy to the vein and therefore require tumescent anesthesia (8–10). These procedures present the problem of specific complications relating to the use of heat, such as prolonged pain and, less commonly, neuralgia and skin burn.

The desire to obviate the need for tumescent anesthesia has led to the introduction of nonthermal nontumescent technologies (11). These newer technologies obviate the need for uncomfortable thermal ablation and tumescent infiltration, while retaining the potential for a similar level of efficacy as RF ablation and EVLA, at least in the short-term. Ultrasound (US)-guided foam sclerotherapy does not require tumescence; however, there is lower efficacy, and multiple treatments are often required (12,13).

The development of mechanochemical ablation (MOCA) using the ClariVein device (Vascular Insights, LLC, Madison, Connecticut) addresses the disadvantages of US-guided foam sclerotherapy and endothermal ablation. MOCA combines mechanical damage to the endothelium by a rotating wire with simultaneous catheter-guided infusion of a liquid sclerosant (14). The liquid sclerosant causes irreversible damage to the cellular membranes of the endothelium, resulting in fibrosis of the vein (15). Treatment with MOCA does not involve thermal energy or the use of tumescence. It is important to evaluate the data on the use of MOCA as medium-term to long-term data are becoming available. Current trials investigating the efficacy and safety of MOCA lack standardized procedural protocols and outcome measures (16). Therefore, this review aims to synthesize the current literature on MOCA using ClariVein and assess its efficacy and safety in the treatment of superficial venous disease.

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MATERIALS AND METHODS

Study Selection

A comprehensive search of the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (January 1966 to March 2017), and EMBASE (January 1980 to March 2017) databases was performed. The search terms used were "ClariVein" and "mechanochemical ablation." Identified studies were assessed independently by 2 authors (J.J.S., M.M.C.) to determine eligibility for inclusion in the analysis. The most recent search was performed on March 21, 2017. The search method followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement for reporting systematic reviews (**Fig 1**) (17). Pilot, cohort, and observational studies and randomized controlled trials including at least 10 patients undergoing MOCA for treatment of great saphenous vein (GSV) and/or small saphenous vein (SSV) insufficiency were deemed to be eligible for inclusion. Case reports describing only 1 patient, review articles, studies involving < 10 patients, and duplicate data (the most recent series was included) were excluded. These reasons are detailed numerically in **Figure 1**.

Data were extracted independently by 2 authors (J.J.S., M.M.C.) using a specifically designed form. Studies omitting follow-up data or studies in which there was any ambiguity surrounding procedure data were excluded. Eligibility criteria for patients in all studies included age $>$ 18 years; not pregnant; no previous surgical treatment of varicose veins; and no contraindications to MOCA, such as allergy to the sclerosant. The primary outcomes were anatomic success, defined by US as occlusion of the incompetent vein and the absence of reflux; clinical success, measured by improvements in the standardized Venous Clinical Severity Score (VCSS); and technical success, defined as an absence of technical failure. Secondary outcomes were pain during and after the procedure measured by patient-reported scores, complications after the procedure, quality of life using disease-specific questionnaires, and time to return to normal work or normal activity.

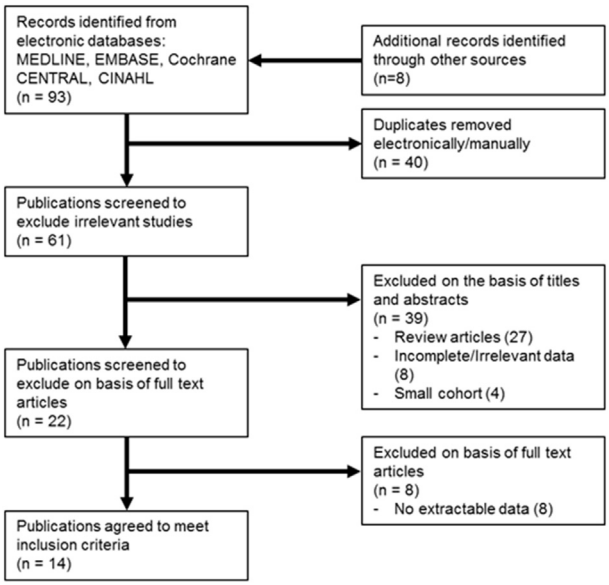

Figure 1. Study selection. Preferred Reporting Items for Systematic Reviews and Meta-Analyses workflow.

Search criteria identified 93 articles from electronic databases. A further 8 articles were identified by hand searching, yielding 101 articles (**Fig 1**). Of these, 14 studies were deemed to be suitable for inclusion (18–31). Three groups published further data with more patients in an additional article (20,21,31). The original publications (19,22,29) are referenced as well, as these included data not reported in the subsequent publication. Duplicate data were included only once and from the most complete series. If longer follow-up of the original cohort was published in the subsequent article, this was extracted, and this is stated in the results. Treatment selection was not randomized in most studies; further information about the quality of studies is presented in **Table 1** (16,20–22,24–34).

Risk of Bias and Quality Assessment

Two authors (J.J.S., M.M.C.) independently assessed the included studies for the risk of several biases (32), including selection, performance, detection, attrition, and selective reporting bias. We deemed there to be a high risk of attrition bias if the follow-up rate was $< 80\%$. Performance bias was determined to be low risk in publications where no subjective patient-reported outcomes were used even in the absence of participant blinding. GRADE assessment was used to evaluate the quality of evidence for each outcome measure (**Table 2**) (33).

Statistical Analysis

Estimation for the global effect for each variable was assessed through an inverse variance weighted estimate of the pooled data (where applicable), and given the nonparametric nature of the data, Mann-Whitney *U* test was used for direct comparisons over multiple time points. Application of a generic inverse-variance random-effects analysis with standardized mean differences and 95% confidence intervals was used for dichotomous data. For continuous data, the Mantel-Haenszel method was used. Descriptive statistics were used for pooled data analysis. Analysis was performed using either RevMan Analysis (RevMan 5.3; The Cochrane Collaboration, Copenhagen, Denmark) software or IBM SPSS Statistics for Windows version 22 (IBM Corp, Armonk, New York).

RESULTS

Risk of Bias and GRADE Assessment

A summary of the risks of bias is illustrated in **Figure 2**, and a description of the decision making is presented in **Table 1**. The quality of evidence was deemed to be "very low" for 4 of the outcomes and "low" for 3 outcomes (**Table 2**).