

## Mid-term Outcomes of Endovenous Laser Ablation in Patients with Active and Healed Venous Ulcers: A Follow-up Study

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### WHAT THIS PAPER ADDS

To the authors' knowledge this is the largest follow-up study with the longest follow-up time of a cohort of patients with an active and healed venous ulcer treated with endovenous laser for superficial venous incompetence. While waiting for randomised controlled studies comparing compression, conventional venous surgery and endovenous treatments in this patient group, the study confirms the findings of other studies that endovenous treatment can be safely offered to patients with active and healed venous ulcers, even the elderly with significant comorbidities, achieving low ulcer recurrence rates after more than three years.

**Objectives:** The aim of this study was to assess the mid-term ulcer recurrence rate in patients with healed or active venous ulcers treated with endovenous laser ablation (EVLA) for incompetent superficial axial veins and to search for possible risk factors for non-healing and recurrence.

**Methods:** Consecutive patients treated with EVLA because of a healed or active venous ulcer between 2006 and 2013 were identified in the medical records and quality registry and invited to follow-up, including clinical history, study examination, Duplex ultrasound scanning, ankle brachial pressure, photoplethysmography, venous clinical severity score (VCSS), and health related quality of life (HRQoL) measured with EQ5D. Of 228 patients, 170 (195 legs) fulfilled the inclusion criteria. Twenty patients were interviewed by phone, 27 were unreachable and 11 were excluded. Univariate and multivariate regression analyses were performed to identify possible risk factors for recurrence.

**Results:** The mean follow-up time was 41 months (range 14–89 months). The average age was 66.6 years (range 36–87 years). All 86 legs operated on for an active ulcer had this ulcer healed sometime between the operation and the study examination, but thereafter it recurred in 14 patients (16%). In 109 legs operated on for a healed ulcer, the ulcer recurred in 17 legs (16%). Complications such as permanent sensory loss were seen in 16 legs (8%) and deep venous thrombosis in two legs (1%). Thirty legs (15%) were re-treated for superficial venous incompetence (SVI). Reduced ankle mobility was a risk factor for recurrence in both univariate and multivariate analysis ( $p = .048$ ).

**Conclusions:** These midterm results demonstrate that endovenous laser ablation of SVI in patients with healed or active venous ulcers achieves good healing and low ulcer recurrence rates, with a low rate of complications and an acceptable re-intervention rate.

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### INTRODUCTION

Chronic venous disease (CVD) is one of the most common pathologies in the general population of adults in both industrialised and developing countries.<sup>1</sup> The most severe form of CVD is venous ulceration with a prevalence of about

1%.<sup>2</sup> Venous ulcers are often painful and affect quality of life negatively.<sup>3</sup> Overall annual costs of CVD represent 1–2% of total healthcare expenditure in Western European countries and in the United States.<sup>2</sup>

The standard treatment for a venous ulcer (VU) is compression, but the recurrence rate is high.<sup>4</sup> The ESCHAR study showed that when VU patients were treated by compression and superficial venous surgery, the recurrence rate of VU was reduced with an absolute risk reduction of 25% compared with compression only.<sup>5</sup> In the authors' clinical experience many patients with VU are not referred for surgical treatment as they are considered either too old,

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with too many comorbidities or the doctor waits for the ulcer to heal before referral. However, with the new endovenous methods that can be performed under local anesthetic it may be possible to treat more patients.

Currently, there are no published randomised trials comparing endovenous methods with superficial venous surgery or compression in VU patients, but the methods have been studied in patients without VU.<sup>6,7</sup> When endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) were compared with high ligation and stripping in treating varicose veins (VVs), treatments were found to be as effective and safe 5 years after treatment.<sup>8</sup> In clinical practice EVLA and RFA are increasingly used to treat patients with VU and there are several reports of low recurrence rates but with small groups and short follow-up.<sup>9,10</sup>

The aim of this study was to assess the ulcer recurrence rate after a longer follow-up in a larger cohort of patients with healed or active VU treated with EVLA for superficial venous incompetence (SVI) and to search for possible risk factors for non-healing or recurrence.<sup>11</sup>

## MATERIAL AND METHODS

### Setting

The study was a single centre follow-up study conducted at a private clinic in Stockholm, Sweden, between April 2013 and February 2015. The clinic is dedicated to treating VVs and Stockholm County Council pays for the treatment. The main methods at the original treatment were EVLA, ambulatory phlebectomies, and ultrasound guided foam sclerotherapy (UGFS). Pre-operative duplex ultrasound scanning (DUS) was done by the surgeon in the majority of cases; in some cases the patient was referred to a vascular laboratory. The policy at the clinic was to treat all SVI found on DUS, which meant that all patients with few exceptions underwent concomitant phlebectomies. Treated veins included the great saphenous vein (GSV), below and above the knee, small saphenous vein (SSV), the anterior accessory saphenous vein (AASV), and perforator vein incompetence (PVI). Low molecular weight heparin was given selectively. VU patients were not treated differently from others; follow-up was routinely scheduled after 1 year, but patients were told to come back earlier in the event of any complication, residual varices, or non-healing ulcer. The patient's district or community nurse administered compression therapy pre- and post-operatively, with varying quality depending on the level of training.

### Patients

Consecutive, eligible patients were identified from the quality registry, from procedure codes for EVLA, and from diagnosis codes for venous ulceration in the medical records. Patients treated with EVLA for SVI and who at the time of treatment had a healed or open VU of clinical class C5 and C6 according to the CEAP classification (Clinical—Etiology—Anatomy—Pathophysiology) were invited to participate in the study.<sup>12</sup> PVI was treated at the discretion

of the surgeon, in a few cases with EVLA and in some cases with UGFS or phlebectomies. Medical records for the identified patients were studied and patients who had received treatment other than EVLA or who had another aetiology of leg ulcer were excluded (Fig. 1). The excluded 11 patients included three deaths unrelated to the EVLA treatment and occurred more than a year post-operatively. The remaining patients were invited by means of a written letter, and a repeat invitation was sent to patients who did not answer the first invitation, then attempts were made to make contact by telephone. Those who answered by telephone and chose not to participate were asked for a short interview about their current ulcer status and recurrence. The final sample included in the analysis comprised only the patients who were examined clinically, 170 patients (195 legs).

### Medical history and clinical examination

Medical records and the quality registry were studied for pre-operative C class, DUS findings, anatomical locations treated with EVLA, post-operative complications, and repeat treatments.

At follow-up a medical history was taken including the presence of cardiovascular disease (coronary heart disease or congestive heart failure), diabetes mellitus (DM), smoking (currently or ceased within the last 5 years), VV treatment before and after EVLA, history of deep venous thrombosis (DVT), non-healing or recurrent VU, and post-operative complications such as DVT, infection, and nerve injury. Ulcer recurrence was defined as any ulcer recurrence on the same lower leg. Patients with a body mass index (BMI, kg/m<sup>2</sup>) of 30 or above were considered obese in accordance with the World Health Organization criteria.<sup>13</sup>

Generic health related quality of life (HRQoL) scoring was measured using the EuroQOL five dimensions questionnaire (EQ-5D)<sup>14</sup> as there is currently no disease specific HRQoL questionnaire for VV or VU in Swedish.

Clinical examination included the C class of CEAP, venous clinical severity score (VCSS), ankle brachial pressure index (ABPI), and ankle mobility.<sup>15</sup> An ABPI < .85 was considered pathological. Ankle mobility was evaluated in conjunction with photoplethysmography (PPG) that required the patient to perform a series of controlled dorsiflexions of the foot. As non-impaired ankle mobility was a prerequisite for the PPG; the examination was also used as a measure of ankle mobility. Stiffness of the ankle and failure to dorsiflex sufficiently for reproducible refilling times and pump volumes was considered impaired mobility.

### Duplex ultrasound scanning

DUS was performed by an experienced vascular sonographer using a colour flow duplex imager (Logic S8, GE Healthcare Global Headquarters, Chalfont St Giles, Buckinghamshire, UK). The femoral and popliteal veins were scanned for post-thrombotic changes by testing compressibility. Valvular function was evaluated in the femoral, popliteal, tibial, fibular, perforating, and superficial veins

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