Side effects and occlusion rate after tumescentless treatment of the great saphenous vein with EVLA

Retrospective analysis

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Keywords
Endovenous laser ablation (EVLA), tumescence, compression, ecchymosis, great saphenous vein

Summary
We have performed a retrospective analysis of side-effect profile of endovenous laser ablation (EVLA) of great saphenous veins in patients operated on in general sedation or general/regional anesthesia with or without tumescence solution injection. The results confirmed our initial assumptions that omitting tumescence (and in addition, avoiding any external compression and cooling) may actually significantly reduce the incidence of moderate/severe postoperative pain and brusing without compromising closure rates. As these are probably caused by vessel wall perforations they seem to be more common in the tumescence cohort. The results are in line with recent basic research which showed that fiber tip centering may reduce perforations (easier to perform in vessels filled with blood), that blood itself does not either reduce or enhance laser’s effect, and that various lasers over a wide range of wavelengths (from hemoglobin-absorbing to water-absorbing) have comparable clinical efficacy. Hence, omitting tumescence and external compression probably reduces the incidence of postoperative pain and brusing in patients treated with EVLA.

Schlüsselwörter
Endovenöse Laserablation, Tumeszenz, Kompression, Vena saphena magna

Zusammenfassung
tip and hot blood surrounding it) – retention of some blood volume within the vein may actually be desirable (5). Thus laser’s wavelength (e.g. so called “hemoglobin-absorbing” and “water-absorbing” lasers) is generally unimportant for final thermal and consequently clinical effect. Numerical simulation of EVLA treatment of great saphenous vein (GSV) suggested that as long as the vein is located more than 10 mm below the skin surface the temperature of the skin does not exceed 45°C (6).

Back in 2002 we noted that our patients who had undergone EVLA in intravenous sedation or regional anaesthesia due to either personal preferences or insurance requirements and treated without tumescent solution experienced actually less pain and bruising than those injected with the solution. Having treated some 50 patients with and 50 patients without tumescence we decided to switch completely to tumescenceless approach due to apparent advantages of the latter. We have retrieved the data and compared them in order to look for possible differences in outcomes.

**Patients and methods**

We analyzed retrospectively the database of our patients treated in years 2002 and 2003 for GSV insufficiency with EVLA. In brief, patients were marked preoperatively using duplex ultrasound. Cannulation of the GSV was performed at the lowest point of reflux. A 5F catheter was introduced into the vein using the Seldinger technique, and its tip was positioned 1–2 cm below the SFJ using ultrasound. A sterile baretipped 600 mm laser fiber connected to the laser was inserted into the sheath and advanced until the distal marker on the fiber reached the introducer. While the fiber was held, the introducer sheath was withdrawn 3 cm until the proximal marker on the fiber reached the introducer opening.

Under ultrasound control, tumescent local anesthetic (0.05 % lidocaine and adrenaline (1:1,000,000) neutralized with sodium bicarbonate (8.4 %) was administered within the fascial sheath of the GSV (roughly 10 ml per cm of the vein length). In cases involving spinal anaesthesia, only 0.9 % NaCl was administered. Manual compression was applied over the GSV while 12W continuous laser energy (Diomed, Andover, Massachusetts, USA) was delivered at a pull-back rate of 0.2 cm/s from 1 to 2 cm below the SFJ to the access site. After the procedure, a graduated class 2 compression stocking was worn for 2 weeks. Pain was relieved, if needed, with Diclofenac (100 mg bid). Patients were instructed to walk immediately after the procedure and to resume their normal daily activities.

In follow-up, patients were examined by clinical evaluation and duplex imaging, performed within 6 weeks of the operation. For the purpose of additional analysis we randomly selected files of 60 patients (via an Excel tool) and checked for ultrasound documentation of GSV closure documented by ultrasound scans performed 2–6 years after the EVLA procedure.

Data are presented as absolute numbers and percentages or as mean standard deviation. Groups were compared using the Student t test and the Fisher exact test. p<0.05 was considered to indicate a significant difference.

**Results**

The patients’ data after the initial follow-up examination are given in [Tab. 1](#). The incidence of bruising and especially postoperative pain graded moderate or severe

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**Tab. 1** Data on patient cohorts treated in 2002 and 2003 for great saphenous vein insufficiency by EVLA with or without tumescence.

<table>
<thead>
<tr>
<th></th>
<th>No tumescence</th>
<th>Tumescence</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>125</td>
<td>46</td>
<td>NA</td>
</tr>
<tr>
<td>Females (%)</td>
<td>92 (74 %)</td>
<td>36 (78 %)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Age</td>
<td>61.2010.85</td>
<td>63.2011.65</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Veins</td>
<td>167</td>
<td>57</td>
<td>NA</td>
</tr>
<tr>
<td>LEED (J/cm)*</td>
<td>53.3015.20</td>
<td>51.4112.92</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Ecchymosis</td>
<td>48 (38.4 %)</td>
<td>24 (52 %)</td>
<td>0.03</td>
</tr>
<tr>
<td>Pain**</td>
<td>16 (13 %)</td>
<td>19 (41.3 %)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1 (0.8 %)</td>
<td>1 (2.2 %)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Phlebitis</td>
<td>4 (3.2 %)</td>
<td>0</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Hyperpigmentation</td>
<td>5 (4 %)</td>
<td>0</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

Significant values are shown in bold (either Fisher exact test or Student-t test); *: LEED, linear endovenous energy density; **: moderate or severe postoperative pain requiring oral analgesics for at least 7 days.
and requiring oral analgesics for at least one week were significantly more common in patients injected tumescence: p=0.03 and p<0.0001, respectively (▶ Tab. 1). In randomly selected 60 patients (92 GSV), after a median follow-up of 3 years (range 6 months to 6 years), recanalization (5 cm in length) was documented in 11% and 7% of veins treated without and with tumescence, respectively (Fisher exact test: 0.7172, not significant) (▶ Fig. 1).

Discussion

The results do not support the view that tumescence anaesthesia by itself reduces side effects of EVLA like postoperative ecchymoses and pain available data provide some evidence to the contrary. It seems valid for both 810 nm and 980 nm lasers (4). In contrast to Hernandez Osma et al. (4) we have used neither external compression nor cooling, without adverse consequences. It may be argued that the bare-tipped fibres and 810 nm or 980 nm devices are now obsolete but, as stated in the introduction, it is the principle which may be valid in the setting of longer wavelengths and radial fibres as well (10). Though studies support the view that treatments with 1470 nm radial fibres result in fewer side effects compared to bare-tipped fibres of the same wavelength, it does not take into account the contribution of tumescence anaesthesia (11).

Moreover, there is still no firm evidence to favour one over another wavelength regarding efficacy of EVLA. Our long-term occlusion rates are comparable to outcomes published in studies using similar lasers (8, 9). Although tumescent local anaesthesia is generally preferable to other modes of anaesthesia, a significant proportion of patients still require general sedation or regional anaesthesia (psychological reasons or when more veins are treated simultaneously along with multiple phlebectomies).

The higher incidence of short-term side effects is probably in part a consequence of more frequent vessel wall perforations in veins surrounded by the tumescent solution. Indeed, a better fibre centring may reduce the incidence of perforations – it is obviously easier to achieve with bare-tipped fibres in veins filled with blood and not externally compressed (7). It seems reasonable, when bare-tipped fibres are used irrespective of laser wavelength in general or regional anaesthesia, to perform the procedure without addition of tumescent solution. Should it be the case for radial fibres as well needs a further study. Even with radial fibres (1470 nm) more than 60% of treated patients require postoperative analgesia (11). Finally, the omission of tumescent solution has not had an impact on long-term closure rates after EVLA both in our and hands of others (4).

Though the data do not permit to generalize conclusions it seems that in rare cases of EVLA performed in general or regional anaesthesia with bare-tipped fibres of lasers of all wavelengths, the omission of tumescent solution may reduce immediate side effects.

Conflict of Interest

The authors declare no conflict of interest.

Ethical Guidelines

The study was conducted according to the national laws and the Helsinki declaration. Patient’s consent was given.

References