SHORT REPORT

Retrospective analysis of routine use of a double heat cycle (DHC) during radiofrequency segmental ablation (ClosureFAST™) of saphenous veins

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Abstract

Background  Recent experimental evidence suggests that increasing energy delivered during radiofrequency segmental ablation (RFSA) of varicose veins might further improve outcomes.

Objectives  To evaluate occlusion rates and safety of the routine use of double heat cycle (DHC) during RFSA of incompetent saphenous veins up to 3 years after the initial treatment.

Methods  Retrospective review of prospectively collected duplex ultrasound (DUS) and complication rate data of successive patients from the Viennese, Lower Austrian and Slovenian regions treated for incompetent saphenous veins, followed up on a yearly basis for up to 3 years after the procedure.

Results  Between 2007 and 2011, 258 patients (389 veins; 322 great saphenous veins (GSV)] had been treated with DHC ClosureFast. Patients’ return was 46% (122 subjects) 3 years after RFSA [140 GSV and 31 small saphenous veins (SSV)] with a mean follow-up time of 24.93 ± 11.77 months. At 36 months Kaplan–Meier survival analysis showed the occlusion probability of 98.6% (95% CI: 1.005–0.966). All SSV were closed. Except for three cases of dyseaesthesia which disappeared within a year, there have not been major side-effects.

Conclusions  Results of the retrospective analysis indicate that the routine use of DHC during RFSA for incompetent saphenous veins is equally safe but potentially more efficacious considering mid-term venous closure rates.

Conflict of interest

None

Funding source

None.

Introduction

Endovascular radiofrequency segmental ablation (RFSA) is now widely accepted as an efficacious minimally invasive treatment of saphenous veins’ insufficiency which compares favourably in short-term to endovenous laser ablation.1–3 A previous version of the radiofrequency catheter was shown in two 2-year randomized comparative studies to be at least equal to high ligation and stripping of the great saphenous vein (GSV).4,5 Outcomes of RFSA in the treatment of GSV insufficiency in terms of venous closure and clinical improvement after 1, 2, 3 and 5 years have been recently published.6–8 A standard procedure of RFSA recommended by the manufacturer and employed in all studies reported so far involved the application of two cycles of RF energy at the first segment which includes the junctional area, and single cycles in all other segments. At the very beginning of the use of the new RFSA catheter in 2007, after a few ex vivo experiments on stripped saphenous veins, we decided to routinely use double heat cycles (DHC) all along the treated veins. Very recently, initial clinical and histological studies suggested that increasing delivered energy (by stacking heat cycles) might increase efficacy of the treatment.9,11

Here, we retrospectively analysed closure rates and side-effects in a cohort of our patients up to 3 years following completion of the RFSA with a consistent use of DHC of radiofrequency energy all along the vein.

†Both authors have equally contributed to the manuscript.
Materials and methods
Presented are results of a retrospective analysis of 498 patients (706 veins) patients who underwent RFSA of GSV and/or small saphenous veins (SSV) from March 2007 to March 2011. All C classes (CEAP) were represented with the following distribution: C0 = 0 (0%), C1 = 10 (2%), C2 = 305 (61.2%), C3 = 101 (20.2%), C4 = 63 (12.6%), C5 = 13 (2.6%), C6 = 6 (1.2%). All patients had reflux duration in saphenous veins >0.5 s. The procedure was essentially performed as described and recommended previously.10 The point of venous access was chosen at the most distal part of the incompetent saphenous vein: for GSV it was anywhere from the mid-thigh to the distal lower leg; for SSV it was in the mid-calf or the distal calf. Tumescent anaesthetic solution containing in normal saline 0.05% lidocaine and 1:1000000 adrenaline, and buffered with sodium bicarbonate, was abundantly infiltrated under the US guidance around the vein in the saphenous fascial compartment (100–125 ml per 10 cm of the vein length). The RF ablation was started with DHC of RF energy (tip temperature of 120 °C at 40 W), delivered in incremental steps of 6.5 cm till the total length of vein was closed. In special circumstances [if power at the end of the second cycle was above 12 W or a very dilated (<1.5 cm) segment of the vein was treated] we applied a third heat cycle. After the procedure patients were instructed to wear graduated compression stockings for 10 days and eighty-nine veins were treated: one vein per patient was treated with RFSA in 132 subjects (51%), two veins in 112 patients (43%) and three veins in 13 patients (5%). Only seven patients (1.4%) required analgesics post-operatively. Over the period of 3 years only four recanalized veins (all GSV) were detected – three within the first, and one within the second year of follow-up. The recanalized segments were from 10 to 26 cm in length, in two GSV extending from the saphenofemoral junction downward (10 and 26 cm), in another two (13 and 16 cm) affecting an intervening segment in the thigh or lower leg. Noteworthy, there has not been a single saphenous vein with the axial reflux. According to Kaplan–Meier analysis, probabilities of occlusion with 95% confidence intervals for yearly follow-up intervals were as follows: at 1 year 0.9898 (1.001–0.978), at 2 years 0.9857 (1.000–0.970), and at 3 years 0.9857 (1.005–0.966) (Fig. 1).

Neither patient with US-detected failure had any subjective or objective signs of recurrent varicose disease except for the ultrasound findings of patent segments of the veins. Also we did not see any neovascularization in the groin in our patients. In 85.3% (146) of patients examined at least 3 years after the procedure, a residual stump was seen, generally with a patent superficial epigastric vein. Venous trunk was not visible at the last DUS in 238 out of 303 scanned GSV (78.54%), and in 34 out of 59 scanned SSV (58%). Side-effects following the procedure were rare and minor (Table 2). In three patients with dysaesthesias, the sensory disturbances regressed within a year. Six patients were diagnosed with PASTE class I or II at the saphenofemoral junction, and the thrombus retracted after 7–14 days of low molecular weight heparin treatment. A common long-term side-effect of RFSA (4–6%) we observed in our patients was secondary telangiectasias within the area of treated veins. They usually appeared 3–6 weeks after the procedure if patients were aware of them. More than a half regressed spontaneously within several months, others were treated successfully with sclerotherapy.14

Discussion
The results support our hypothesis that DHC treatment all along the vein improves the occlusion rate, maintaining it above 98% at least 3 years after the procedure, without compromising its safety (Fig. 1 and Table 2). The largest patient pool of RFSA of
GVF reported so far by Proebstle and the European Closure Study Group7,8 had the closure rates after 2 and 3 years, 94.5 and 92.6%, respectively. In a prospective randomized comparative study Rasmussen et al.15 obtained similar Kaplan–Meier estimates for occlusion probability of GSV of 93% by RFSA after 3 years. Another report on RFSA based on a retrospective analysis of data in 118 saphenous veins (47% of treated patients were available for analysis) after an average follow-up of 12.2 months (range 1–29), showed a technical success rate of 94.1%.16 In a similar retrospective review of prospectively collected data on RFSA from Korea, the authors reported occlusion rates of 94.6% (53/56) in GSV and 94.5% (17/18) in SSV 2 years after the intervention (mean follow-up was 13.9 months) – patients’ return for analysis was 35%.17 Almost the same primary occlusion rate of GSV (94.5%) was reported by Helmy ElKaffas et al.18 in 90 patients up to 24 months following RFSA. In our patients there was not a single recanalized vein with the axial reflux, whereas Proebstle et al.8 reported five patients with axial reflux in treated GSV (2%). The very low number of patent veins (4 of 281 examined veins after 2 years) among vessels with widely varying diameters (up to 21 mm) is supported by the preliminary data recently published by a Russian group in the abstract form.10 It is now shown that two heat cycles consistently lead to the tunica intima and media homogenization, and in some places, may affect the tunica adventitia as well.11 The third RFSA treatment cycle leaves all vein wall layers completely homogenized.11 A short-term analysis showed that there is a faster shrinkage of GSV treated with DHC compared to a single cycle.7 We believe that a useful guide may be final power delivered to raise and maintain temperature at 120 °C at a given vein segment – it should be below 12 W. It has been previously shown that for a constant temperature, there is a positive correlation between the power consumption and tissue (lesion) volume in radiofrequency catheter ablation of myocardium.19 In other words, if the power is maintained higher it may mean that the volume of the tissue (e.g. vein with blood) is larger and, consequently, the destruction of the vein may not be complete, and vice versa.

Among the treated SSV there was not a single recanalized vein at any time point. It is similar to published short-term, and better than mid-term and long-term data on occlusion rates of RFSA in SSV.17,20,21

The venous stump persistence has no relevance to the technical outcome of the procedure: the vast majority of successfully ablated saphenous veins are accompanied by a patent stump even 3 years and more after the procedure. The results are similar to our previous DUS findings 2 years after radiofrequency ablation (ClosurePLUS) of 60 GSV.22 Complete abolition of saphenofemoral junction (SFJ) was seen in 8.3% patients and open SFJ with short (≤5 cm) patent GSV segment in 88.3% of patients.22 Others8 also found that after the first 3 months the stump length has not changed significantly over the ensuing 3 years. The patent stump without or with various configurations of epigastric and anterior accessory veins is the most common occlusion pattern after RFSA.17

The routine use of DHC does not lead to an increase in side-effects (Table 2). The frequency of side-effects after the RFSA in our patients was actually lower than usually reported.23 In similarly conducted retrospective reviews, the incidence of dysaesthesias was higher varying from 8% to 16%, whereas other side-effects were comparable, like phlebitis (1.4–3.4%), ecchymoses (1.4–3%) and PASTE (0–1.3%).16,17

Table 2 Incidence of side-effects during follow-up after radiofrequency segmental ablation (n = 258). Local side-effects at sites of mini-phlebectomies and/or foam sclerotherapy are not included herein

<table>
<thead>
<tr>
<th>Side-effect</th>
<th>Frequency (%)</th>
</tr>
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<tbody>
<tr>
<td>Hyperpigmentation</td>
<td>0</td>
</tr>
<tr>
<td>Burns</td>
<td>0</td>
</tr>
<tr>
<td>Hypesthesia†</td>
<td>1 (0.38)</td>
</tr>
<tr>
<td>Hyperaesthesia (alldynia)‡</td>
<td>2 (0.77)</td>
</tr>
<tr>
<td>Ecchymoses</td>
<td>4 (1.55)†</td>
</tr>
<tr>
<td>Hematomas</td>
<td>0</td>
</tr>
<tr>
<td>Thromboembolic events</td>
<td>0</td>
</tr>
<tr>
<td>Phlebitis</td>
<td>4 (1.55)</td>
</tr>
<tr>
<td>Deep vein thrombosis (PASTE)</td>
<td>6 (2.3)‡</td>
</tr>
</tbody>
</table>

*Minimal ecchymoses at sites of venous puncture.
†PASTE, post-ablation superficial thrombus extension: in three patients class I and in three patients class II.
‡Tactile hypesthesia was diagnosed by applying a light touch; tactile hyperaesthesia (alldynia) was defined as abnormal increase in sensitivity to a light touch.

Figure 1 Kaplan–Meier life-table analysis of occlusion probability (with 95% CI) on duplex imaging after radiofrequency segmental ablation (RFSA). Numbers in the lower-most line indicate legs at risk given follow-up time intervals (in months). Mean follow-up time was 25 months.
Years after procedure the only side-effect that could be ascribed to the intervention itself was secondary telangiectasia. They are probably caused by a sudden block in outflow in previously healthy subcutaneous veins draining directly into treated saphenous vein. Some may disappear spontaneously over the following months, others can be successfully closed by sclerotherapy. The absence of hyperpigmentation and very low incidence of sensory abnormalities in our patients may be explained by meticulous and abundant infiltration of tumescent solution within the saphenous compartment and, if required, also subcutaneously.

Despite the obvious weakness of the retrospective nature of the review, the results do suggest that the routine use of DHC during the RFSA of saphenous veins along with meticulous and abundant use of tumescent solution may increase the mid-term closure rates of treated vessels with the unaltered safety profile. It is seen when compared to similarly performed retrospective analyses of unselected patients treated by RFSA having an advantage of a ‘real-life’ setting. If a realistic goal is to detect at least a 5% difference in the occlusion rates of GSV, then a randomized trial comparing single- vs. double heat cycle RFSA may have to recruit 200 patients in each arm. We believe that such a trial would be worth conducting.

References