OUTCOME OF RADIO FREQUENCY ABLATION OF VARIOUS STAGES OF VARICOSE VEINS

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Abstract:

Aim:

To study the outcome of Radiofrequency Ablation of varicose veins and its complications.

Methods and Materials:

We have done prospective study of 202 patients and 224 limbs of various stages of varicose vein, admitted in Government Kilpauk Medical College Hospital, Chennai, over a period of 15 months from the year 2013 to 2014. All patients were evaluated with Duplex- Doppler examination, in addition to routine investigations and underwent endovenous continuous RF ablation. Patients were followed up for 6 months period and findings were recorded.

Results:

The post-operative pain score, ulcer healing rate and complication rates were evaluated. The visual analogue score for pain dropped from an average of 7 to 2 at the end of 8 weeks and faster ulcer healing rate. The paresthesia, superficial thrombophlebitis and recanalizations rates were 2.6, 8.2 and 1.9 respectively. There were no cases of deep vein thrombosis observed in our study.

Conclusion:

Endovenous continuous radiofrequency ablation is safer and faster method of treating all stages of varicose vein and more patients are opting for endovenous ablation rather than conventional methods.
Introduction:

Lower limb superficial venous reflux or commonly called as varicose veins are benign disorders of the limbs. However they significantly affect the quality of life and also impacts socio-economic status. They are seen more in women than men aided by age, gender, gravitational forces, hormones, pregnancy, weight, race, occupation, previous DVT etc. (1). Recently large population studies such as Edinburgh vein study demonstrated age adjusted prevalence of 40% in men & 32% in women.

Incompetence of Great Saphenous Venous (GSV) system is the commonest underlying cause in varicose veins and it may or may not involve deep or perforator veins. So the principle behind earlier conventional surgeries is disconnecting GSV at Sapheno- Femoral junction followed by stripping with phlebectomies of minor varicosities. However such techniques caused significant postoperative morbidities such as pain, hematoma, longer hospitalization and Improper stripping caused recurrences. Sclerotherapy's success depends on sclerosing agent and vein size, which has been found to be short lived and recommended only as an adjuvant treatment (2). The desire to improve success rate and to reduce postoperative morbidities played a key role in popularizing the endovascular treatment options such as Radio Frequency Ablation (RFA) and Laser ablation.

This article summarizes the clinical outcomes of RFA we did combining our experiences with the available evidence in literature. RFA involves delivery of high frequency alternating current via bipolar endovenous catheter, which generates temperature, between 85 to 100 degree Celsius locally. This causes intimal and medial thermal ablation. The success of RFA depends on contact of catheter with venous wall which is facilitated by reverse Trendelenburg position, proper tumescent technique and subsequent compression of vein.

Materials and methods:

This is a prospective, non- randomized study done in a specialized vascular unit in our university hospital after clearance from ethical committee. Total of 202 Patients underwent the procedures in our hospital over a period of 15 months. The patients were selected according to the inclusion and exclusion criteria. Those who satisfied the selection criteria, underwent the Radio frequency ablation with or without foam sclerotherapy, depending on the associated perforator incompetence, after obtaining informed written consent explaining about all the possible complications and risk of recurrence.
Exclusion criteria:

- Absence of LSV reflux
- Presence of DVT
- LSV diameter >20mm
- Pregnancy
- Patients with co-existing arterial disease (ABPI<0.9)

Inclusion Criteria:

- Age between 18-70, both gender
- Duplex scan confirmed LSV & SSV reflux & suitability of RFA
- Patient ambulant
- Patient who can give informed consent

We used CEAP (Clinic, Etiology, Anatomy, and Pathophysiology) classification to categorize the patient for statistical analysis and better understanding of the disease burden. All patients underwent the procedure under regional anesthesia after getting proper anesthetic fitness. Pre-operatively incompetent venous segment and its junction with deep veins was marked using duplex imaging. Patient placed in supine position in case of great saphenous vein incompetence and lateral position in case of short saphenous vein incompetence. Under duplex guidance, the saphenous vein is punctured using modified seldinger technique with 18G needle, and 0.035 wire was used to place the 5F sheath of 11cm length.

### Table 1 showing baseline patient characteristics

<table>
<thead>
<tr>
<th>Sex ratio (F:M)</th>
<th>71:131</th>
</tr>
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<tbody>
<tr>
<td>Age</td>
<td>Mean=42</td>
</tr>
<tr>
<td>CEAP</td>
<td></td>
</tr>
<tr>
<td>C2</td>
<td>25</td>
</tr>
<tr>
<td>C2,C3</td>
<td>10</td>
</tr>
<tr>
<td>C2,C3,C4</td>
<td>40</td>
</tr>
<tr>
<td>,C5</td>
<td>37</td>
</tr>
<tr>
<td>C2,C3,C4,C5</td>
<td>39</td>
</tr>
<tr>
<td>Disease pattern</td>
<td></td>
</tr>
<tr>
<td>GSV</td>
<td>158</td>
</tr>
<tr>
<td>SSV</td>
<td>30</td>
</tr>
<tr>
<td>GSV+SSV</td>
<td>14</td>
</tr>
<tr>
<td>Unilateral:Bilateral</td>
<td>180:22</td>
</tr>
<tr>
<td>No of limbs</td>
<td>224</td>
</tr>
</tbody>
</table>

The radiofrequency probe, which measures 120 cm in length, with 10 cm segment marking, was inserted through 5F sheath and placed 2 cm away from the sapahenofemoral / popliteal junction. Normal saline was infiltrated along the course of the vein, within the saphenous canal under duplex guidance, to effectively compress the vein and to make thermo-protective layer around the vein, which prevents thermal injury to the surrounding structures. We used continuous ablation technique, wherein the radiofrequency probe was pulled at a rate of 0.5 to 1 cm/sec depends upon the size and spasm of the reflexing vein.
Duplex was used to evaluate the occlusion of veins on table and if needed foam sclerotherapy for incompetent perforators injected. The patency and competence of femoral vein and saphenofemoral/ popliteal junction was checked intraoperatively.

Postoperatively patients were placed on compression bandage and advised to use class II compression stockings from 1st postoperative day and encouraged to attend daily routine as early as possible. Four layered compression bandage continued in case of venous ulcers till the ulcer healed completely and later on placed with class II compression stocking. Patients were followed up at the end of 1st week, 6th week and then 6 months after the procedure. Successful treatment outcomes was confirmed by duplex imaging with complete absence of flow 3cm below SFJ at end of 1st week, and disappearance of vein at the end of 6 weeks.

Outcome of the study was measured by post-procedural pain score, ulcer healing rate and other complications like superficial thrombophlebitis, paresthesia and varicose vein recurrence. Pain was evaluated by obtaining 10 point visual analogue score. This was assessed pre-operatively, then on post- operative day 1, at discharge (mostly second or third post- operative day) and again at First week and 8th week of follow up in all the patients. The other complications were evaluated at the end 6 months and the percentages were shown here.

<table>
<thead>
<tr>
<th>Follow up</th>
<th>Average Pain score</th>
</tr>
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<tbody>
<tr>
<td>POD 1</td>
<td>5</td>
</tr>
<tr>
<td>At discharge</td>
<td>4</td>
</tr>
<tr>
<td>At 1st week</td>
<td>2</td>
</tr>
<tr>
<td>At 8th week</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 2

<table>
<thead>
<tr>
<th>Complications</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial thrombophlebitis</td>
<td>8.2</td>
</tr>
<tr>
<td>Paresthesia</td>
<td>2.6</td>
</tr>
<tr>
<td>Recanalization (6 months)</td>
<td>1.9</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>NIL</td>
</tr>
</tbody>
</table>

Table 3

Significant symptom relief was observed as early as 2 days after the procedure. The ulcer healed fast while accompanying edema decreased from 52.8% preoperatively to 3.2% at the end of 1st week. More than 80% of patients attended their routine work within the first post-operative week and the rest did so during the subsequent weeks.
Discussion:

Endovascular techniques are less invasive options and better alternative for high ligation and stripping of GSV. Many studies have proved their efficiency and faster post-operative recovery and patient comfort. Rautio and colleagues (3) reported significantly less postoperative pain, quantitated with a visual analog scale in the RFA group than in the stripping group at rest, on standing, and on walking, with the most distinct differences between the 5th to the 14th postoperative days.

The analgesics needed in the RFA patients were less than for the stripping group and physical function was restored faster in the RFA patients. Stotter et al(4) and Hinchcliffe RJ et al (5) concluded RFA was faster (25 minutes versus 40 minutes), associated with significantly less postoperative pain and bruising, and had higher patient preference. A multicenter prospective randomized trial called EndoVenous Obliteration versus Ligation and Vein Stripping - EVOLVES (6) found in their study that the mean time to return to normal activity was 1.15 days for the RFA patients compared with 3.89 days for vein stripping.

Success of RFA is complete occlusion of ablated vein which is initially hypo echogenic in duplex, later on turning hyper echogenic as described by pichot et al (7). They also had very low level of neovascularization in RFA compared to open surgery. Efficiency of RFA have been proved beyond doubt by many studies (7-14) and Merchant et al reported vein occlusion rate was 97% within 1 week and 92.6% at 6 months and 1 year.

Synbrady et al (15) reported a reflux free rate of 90% at 2 years. However recent studies show very high success rates. Proebstle et al (16) reported success rate of 99% at 6 months, similar to us. This increase in success rate is attributed to slow catheter pullback velocity which allows resistive heating of the vein wall to a target temperature of 85° to 90°C.

Also recent techniques allow the catheter to be stationary for a segment allowing much better ablation. Tumescent infiltration was initiated to reduce the risk of skin burns, which are rarely observed now. Incidence of DVT which was mainly due to improper positioning of catheter tip from SFJ and delayed ambulation has reduced less than 1%. Paresthesia was reported to occur in 9% to 19% of limbs within 1 week after the procedure (10), and gradually resolved over time (12). Limiting treatment to the above-knee segment decreases the risk of paresthesia. Open surgeries have higher rates of tenderness, ecchymosis and hematoma formation. Varicose vein recurrence after vein stripping have been reported between 20% and 50% at 2 to 5 years (19) and up to 70% by 10 years (21). The incidence is much higher if only SFJ Ligation is done (22).

The alternative endovascular method available is Endovascular laser treatment (EVLT). Earlier it was faster option than RFA due to rapid pullback of catheter. But newer RFA Catheters have nullified this advantage. EVLT have higher incidence of ecchymosis, thrombophlebitis and paresthesia (10).
Newer jacketed laser fibres have been developed which can reduce such complications. Vein closure after RFA was 87.2% in a multicenter study, and varicose vein recurrence was 27.4% at 5 year follow-up; vein obliteration after EVLT was reported by various groups to be 76% to 96.8% at 1- to 2-year follow-up (24).

Conclusion:
Radiofrequency powered continuous thermal ablation proves to be a faster and safer procedure in all aspects, with close to 100% early occlusion rate of treated saphenous vein. Despite delivering thermal energy the method was well tolerated by the patients, who showed an insignificant side effect profile, and when compared to open surgeries, the reduced morbidity and early mobilization makes patients to opt for more endovenous procedures than conventional procedures with better success rates.

References:


4. Sto¨tter L, Schaaf I, Bockelbrink A, et al. [Radiofrequency obliteration, invagination, or cryostripping: which is the best tolerated by the patients?]. Phlebologie 2005;34:19–24 [in German]


