

Safety and Efficacy of Radiofrequency Ablation for Varicose Veins: An Initial Experience from Pakistan

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ABSTRACT

Objective: To evaluate the safety and efficacy of radiofrequency ablation (RFA) for varicose veins.

Study Design: Observational case series.

Place and Duration of Study: Section of Vascular Surgery, Aga Khan University Hospital, Karachi, from September 2016 to August 2018.

Methodology: Data of RFA procedures performed on 40 patients were collected on a questionnaire from the medical records. It included patients' demographics, pre- and postoperative clinical, etiological, anatomical and pathological (CEAP) system score, venous clinical severity score (VCSS), procedural details and intra- or postoperative complications. Outcome measures were 'safety of the procedure, which was measured by presence of any complications; and 'efficacy of the procedure' which was measured by improvements in the CEAP and VCSS score.

Results: The mean age of the patients was 44.7 ± 11.5 years. Twenty-one (52.5%) patients were women. Preoperative median VCSS [range] was 7 [2-15], which improved to 1 [0-3] ($p < 0.001$). Preoperative median CEAP [range] was 3 [2-6] and improved to 1 [0-4] ($p < 0.001$). One patient had recurrence and five patients (12.5%) had minor complications, which were treated conservatively.

Conclusion: RFA in patients with symptomatic varicose veins can be performed with minimal complications. This modality is also effective in reducing the disease severity.

Key Words: Radiofrequency ablation, Thermal ablation, Endovenous ablation, Great saphenous vein, Varicose veins.

INTRODUCTION

Varicose veins (VVs) develop due to incompetent superficial venous valves leading to reflux of blood.¹ These may present from cosmetically disfiguring veins to non-healing leg ulcers,² and are commonly associated with poor disease-related quality of life.³ VVs affect about 20-30% normal healthy individuals.³ Traditional treatment is surgery, which usually involves dissection and disconnection of saphenofemoral junction (SFJ) in the groin.⁴ In most of cases, the great saphenous vein (GSV) is stripped out. In patients with saphenopopliteal junction reflux, it also needs disconnection. Open surgery is effective and is performed under general or regional anesthesia requiring hospital stay. It can be associated with wound-related complications and phenomenon of neovascularisation and recurrence.⁵

Endovenous ablation methods, such as radiofrequency ablation (RFA) or endovenous laser ablation (EVLA) are alternative to surgery.⁶ The mechanism of action of these minimally invasive techniques is to damage the venous wall by thermal energy.⁶ Several randomised

controlled trials showed short-term safety and efficiency of these procedures compared to open surgery.⁵ Most of these results are from matured centres, which have bypassed the 'learning curve'. In low and middle income countries, this modality is new and there are few studies which share real-world experience.

The objective of the study was to evaluate the efficacy and safety of this procedure in a university hospital in Pakistan.

METHODOLOGY

After obtaining approval from the Institutional Ethical Review Committee (2018-0521-537), an observational study was conducted at the Section of Vascular Surgery, Aga Khan University Hospital, Karachi, Pakistan. The study included patients who underwent RFA procedures for VVs from September 2016 to August 2018. Patient who had saphenofemoral disconnection and stripping of GSV or lost to follow-up were excluded from the study.

Patients were assessed for severity of disease by two criteria preoperatively. One was based on the clinical manifestations, etiological factors, anatomical distribution of disease and underlying pathophysiological basis of the disease: CEAP system score, according to which clinical severity of VVs was graded from 1 to 6. The second criterion was venous clinical severity score (VCSS), which comprised total of ten parameters and each parameter was graded as 0 to 3. Parameters in VCSS included patient-reported description of pain; severity of VVs and severity of lower extremity edema;

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degree of skin pigmentation; extent of inflammation and distribution of induration; number, duration and size of active ulcers and whether the patient has used compression therapy within last 3 months or not. Patients had preoperative venous duplex scan to document superficial venous reflux, and to rule out deep venous thrombosis. GSV measuring more than 3 mm with relatively straight course was considered suitable for RFA.

The procedures were performed in operating room with patient in supine position. Standard preparation and draping was performed with antiseptic solution. The table was placed in reverse Trendelenburg position and the room was kept warm to maximize venous dilatation. GSV was cannulated under ultrasound guidance around the knee. After placing appropriate size sheath, RFA catheter was passed through the sheath and directed towards the SFJ. Catheter tip was placed 2 cm below the junction distal to the inferior epigastric vein. Table position changed to the Trendelenburg position. Perivenous tumescent anesthesia was infiltrated under ultrasound guidance. It was made by mixing 500 ml of normal saline with 20 ml of lidocaine with adrenaline (1:200,000), and 25 ml of sodium bicarbonate. Each 7-cm GSV segment was ablated for 20 seconds and the catheter pulled back in a retrograde fashion. Upper segment ablated twice while rest of vein ablated with one cycle of radiofrequency. Compression bandage placed from ankle to groin placed for next 48 hours. Patients were encouraged to ambulate immediately after the procedure.

Patients were reevaluated at the time of discharge, 48 hours, two weeks and 6 months after the procedure. After 48 hours, compression bandage was removed. Early complications like paresthesia, skin pigmentation, skin burns and hematoma, if any, were recorded. Patients were advised to wear venous compression stocking class II (22-32 mmHg), reaching upto the midhigh level for next two weeks. In each follow-up visit, patients were evaluated for any improvement in disease severity.

The data was collected on a questionnaire from patients' medical records. It included patient's demographics, comorbidities, preoperative CEAP and VCSS, ultrasound findings, type of anesthesia, duration of procedure, hospital stay, any intra- or postoperative complications, residual varicosities and improvement, if any, in the post-procedure CEAP and VCSS.

The data was analysed on SPSS version 22. Continuous variables were expressed as mean \pm SD or median with range, wherever appropriate. Median CEAP and VCSS were calculated by Wilcoxon signed-rank test. A p-value of <0.05 was considered as significant.

RESULTS

During the study duration, 40 patients had been operated. The mean age of the patients was 44.7 ± 11.5 years.

Table I: Outcomes of the limbs treated with radiofrequency ablation (n=56).

Variables	n = (%)
Operated side	
Right	24 (42.9)
Left	32 (57.1)
Clinical stage on CEAP classification	
C2 - Varicose veins	9 (16.1)
C3 - Edema	23 (41.1)
C4 - Lipodermatosclerosis	6 (10.7)
C5 - Healed venous ulcer	5 (8.9)
C6 - Active venous ulcer	13 (23.2)
Ultrasound findings	
GSV reflux	56 (100)
Incompetent perforators	32 (57.1)
Incompetent SPJ	13 (23.2)
Concomitant procedure	
Injection sclerotherapy	19 (33.9)
SPJ disconnection	14 (25)*
Stab avulsions	15 (26.8)

GSV: Great saphenous vein; SPJ: Sephanopopliteal junction.

* One patient had SPJ disconnection on the peroperative ultrasound findings of SPJ reflux.

Twenty-one (52.5%) patients were females. A total of 56 legs had RFA procedures. Most of the patients presented with C3 or C6 on CEAP classification (Table I). Out of the treated legs, 32 (57.1%) legs had incompetent perforator, while 13 (23.2%) legs has saphenopopliteal junction incompetence (Table I).

Twenty-eight (70%) patients were treated under general anaesthesia. Twenty-seven (67.5%) patients had hospital stay of one day, 12 (30%) patients had procedures as day care, and one (2.5%) patient had hospital stay more than one day.

Preoperative median VCSS [range] was 7 [2-15], which improved to 1 [0-3] ($p < 0.001$). Preoperative median CEAP [range] was 3 [2-6] and improved to 1 [0-4] ($p < 0.001$).

One patient had recurrence. She had persistent VVs and leg swelling. On ultrasound, there was incomplete GSV cannulation. She later underwent SFJ disconnection and stripping of GSV. Five patients (12.5%) had minor complications. Three patients had bruising, which resolved in couple of weeks. One patient developed leg swelling which resolved with time. She did not have deep venous thrombosis. One patient had dressing allergy. All were treated conservatively.

DISCUSSION

RFA is the minimally invasive technique, which utilises radio-frequency waves to produce thermal energy. This leads to endothelial damage, collagen contraction, wall thickening and vein fibrosis,⁷ and abolishes the superficial venous reflux. The catheter is placed away from groin; hence, patients do not need groin dissection. Therefore, prevented from wound related complications and neovascularisation.⁸ Many society guidelines recommend RFA as the 'alternative' to surgery for the management of VVs.⁹

To the best of the authors' knowledge, this is first reported series from Pakistan. The authors used objective criteria for measuring efficacy of procedure using VCSS and CEAP scores.⁹ Both scores support each other and provide comprehensive evaluation of disease severity.¹⁰ Patients had statistical improvement in the median VCSS and CEAP scores postoperatively. Median VCSS improved from 7 to 1 ($p < 0.001$). The present results are comparable with other studies reported in literature.¹¹⁻¹⁵ Most of the patients presented with advance stage of disease (C3-C6). There were few complications noted and all were treated conservatively. We found a positive impact of this procedure on patients' health.

For the last one decade, endovenous ablation methods, with its minimal complications, have emerged as standard of care for varicose veins patients. But few of the complications are more than the traditional open surgery. These includes DVT, which was reported 1.3% compared to 0.2% with open surgery;¹⁶ pulmonary embolism, which was reported 0.07% compared with 0% in open surgery;¹⁷ and skin burns of 1.8%.¹⁸ These complications have been reduced with the development of newer generation catheters and the standardised technique of tumescent anesthesia.

This is the experience of a unit that had been treating VVs by traditional approach till recently. The challenge was developing team and equipment for this procedure. The operating team took some time to be familiarised to ultrasound. In difficult cases, open access for cannulating the GSV was also used. As for any new technique developing at a new place, there is lack of auxiliary equipments. Same was the issue with the non-availability of tumescent infiltration pump system. We used hand-held pump system instead of the above stated pump and found it quite useful.

The presently described approach was a one-stop solution. Majority of procedures were performed under general anesthesia and most of them were having either bilateral RFAs or concomitant procedures. Ligation of SPJ and incompetent perforators was performed in the same setting, if needed. About 25 patients in this study had simultaneous stab avulsions.

The limitations of this study are being a retrospective study, and from a single centre with a short follow-up. The long-term results of this procedure are awaited. Despite these constraints, this study showed that RFA is an effective treatment modality. This can help in adopting this technology in local setting.

CONCLUSION

Radiofrequency ablation in patients with symptomatic varicose veins can be performed with minimal complications. This modality is also effective in reducing the disease severity.

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