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Office Based Endovenous Radiofrequency Ablation of Truncal Veins: A Case for Moving Varicose Vein Treatment out of Operating Theatres

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WHAT THIS PAPER ADDS

The study showed that endovenous radiofrequency ablation (EVRFA) of truncal veins as a standalone procedure without concomitant phlebectomies or sclerotherapy in an office based setting under tumescent anaesthesia for the treatment of symptomatic varicose veins resulted in resolution of symptoms in >75% of patients without the need for further interventions within a minimum of one year follow up in the study group. As a day case procedure with concomitant phlebectomies or sclerotherapy, this is less costly than EVRFA under general anaesthesia in an operation theatre. This would also free up theatre capacity and therefore it is suggested that it should be adopted for all suitable patients.

Objectives: This study aims to assess the efficacy and outcomes at one year after office based endovenous radiofrequency ablation (OBEVRFA) as a standalone procedure for varicose veins under local anaesthesia.

Methods: A retrospective study of prospectively collected data of all OBEVRFAs done in the vascular unit from April 2014 to June 2016 was performed. The demographics, clinical findings, initial venous duplex ultrasound (DUS) findings, the vein ablated, and immediate complications were recorded. Patients were reviewed at six weeks and again if necessary with or without a repeat DUS. The follow up period ranged from 12 to 38 months. Patients undergoing further procedures for symptomatic residual veins within the follow up period were recorded. Average cost and income were obtained from the hospital Patient Level Information and Costing Systems data.

Results: A total of 523 limbs were listed for OBEVRFA during the study period. Ninety-four (18%) were cancelled on the day of surgery for various reasons. A total of 429 procedures in 394 patients were performed. There were 35 bilateral cases; each limb performed on separate occasions. The female to male ratio was 1.2:1. The median age was 54 years (range 17—88 years). The CEAP (Clinical, Etiologic, Anatomic and Pathophysiologic) classification was C2 to C3, 291 (68%); C4 to C5, 11 (26%), and C6, 26 (6%). Forty-seven (11%) recurrent varicose veins were treated. There were three recorded cases of endovenous heat induced thrombosis (EHIT). Sixty (14%) patients were lost to follow up. One hundred and five (29%) patients underwent repeat DUS for persistent symptoms. In the follow up period, only 86 patients (23%) needed further multiple avulsions.

Conclusions: OBEVRFAs of the truncal veins for the treatment of varicose veins is safe and effective and could be performed in all suitable patients to free up theatre capacity.

Keywords: Endovenous thermal ablation, Office based, Radiofrequency ablation, Tumescent anaesthesia, Varicose veins
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INTRODUCTION

Varicose veins are a major healthcare problem affecting nearly one third of the UK population.[1] They affect patients in their most productive years, usually in the fourth or fifth decade of life, and have a significant psychosocial and economic impact.[2,3] Traditionally, the surgical treatment for symptomatic varicose veins has been open surgery in the form of high/flush ligation of the saphenofemoral junction (SFJ) and stripping of the great saphenous vein (GSV), often combined with multiple phlebectomies under general anaesthesia (GA) or spinal anaesthesia.

The introduction of endovenous thermal ablations (EVTAs) in the late 1990s and early part of this century revolutionised the treatment of symptomatic varicose veins.[4,5] It is a minimally invasive percutaneous endovenous technique that works by causing direct thermal injury to the vein wall, resulting in destruction of the endothelium,

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collagen denaturation of the media, and thrombotic and fibrotic occlusion of the vein. Trials have shown that EVTA is better than or on par with open surgery with significant advantages of early mobility, faster return to work, and improved quality of life.[6–8]

EVTA was recommended as the primary intervention in symptomatic patients with truncal reflex by the National Institute for Health and Care Excellence (NICE) in 2013, the European Society for Vascular Surgery (ESVS) in 2015, and the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) in 2011.[9–11] The two main techniques are endovenous laser ablation (EVLA) and endovenous radiofrequency ablation (EVRFA). Both these techniques have high success rates and have similar patient satisfaction outcomes. However, EVRFA has distinct advantage of reduced post-procedure pain, bruising and lower incidence of phlebitis.[12–17]

The majority of the centres offering these treatments usually combine EVTA with phlebectomies or injection sclerotherapy. This is performed either as a staged procedure or concomitantly under GA in a day case theatre.[9] The incidence of patients requiring subsequent treatment of residual varicosities after initial ablation is quoted at 30%—60%.[18]

The study aimed to determine the outcomes, complications, and costing of endovenous radiofrequency ablation done as an office based procedure under tumescent anaesthesia, especially assessing its efficacy as a single procedure, without the need for any additional procedure within one year of the index ablation.

METHODS

A retrospective study was conducted of all EVRFA for varicose veins listed to be done as an office based procedure in a vascular surgery firm. This information was obtained from the vascular surgical admissions officer and electronic patient information management system

The listed patients were initially assessed by either the consultant or the registrar in the vascular surgery clinic using the results of the venous duplex scan, which was usually performed on the same day. The standard approach was to offer suitable patients EVRFA to be done as an office based procedure under tumescent anaesthesia.

Exclusion criteria agreed were (i) veins diameter < 3 mm, (ii) too superficial, (iii) patient apprehension due to needle phobia, and (iv) patient choice. Three consultant vascular surgeons (H.R., D.V., and R.G.) worked on a rota to perform this procedure on a Saturday morning in the outpatient clinic treatment room.

Patient demographics, clinical findings, laterality, and initial venous duplex ultrasound (DUS) findings that had been documented prospectively on electronic patient records (EPRs) were recorded. The number of patients cancelled on the day of the procedure was recorded along with the reasons for cancellation.

Closure FAST™ (Medtronic, Fridley, MN, USA) endovenous radiofrequency ablation (RFA) catheters were employed for segmental ablation of the vein/s. A post-procedure completion DUS was performed to confirm obliteration of the ablated vein to exclude any immediate complication of heat induced thrombus extending in to the deep vein. All these patients were venous thromboembolism risk assessed and received a single prophylactic dose of low molecular weight heparin as a unit protocol and further doses prescribed based on risk assessment. They were advised to ambulate early and wear class II compression hosiery for a minimum of four weeks.

The patients were reviewed on their first post-procedure follow up at six weeks. At follow up their collateral veins were checked to see if they had become less bulging, and a decision was made with the patients if they were symptomatic enough to need further intervention, which could be phlebectomies or sclerotherapy. Further follow ups were arranged with or without a repeat DUS based on the clinical findings. In patients undergoing repeat DUS, rates of complete and partial recanalisation were recorded. The primary outcome measure was the need for the patient to undergo further procedures for symptomatic residual veins within the one year follow up period.

Average cost and average income were obtained from the hospital Patient Level Information and Costing Systems (PLICS) data and validated independently with itemised costing.

Data collected from the EPR system was entered into a Microsoft Excel spreadsheet. Each limb was assigned a CEAP (Clinical, Etiologic, Anatomic and Pathophysiologic) classification based on the recorded symptoms present at the pre-surgical outpatient appointment (OPA). Recurrence of varicose veins and further interventions were recorded by reviewing the patient's history, OPA note, and the DUS finding.

RESULTS

In the 26 month study period from April 2014 to June 2016, 523 office based EVRFA ablations were scheduled. Ninety-four (18%) procedures were cancelled on the day of the surgery for a variety of reasons which predominantly included perceived vein unsuitability by the operating surgeon ($n = 39$), failure to cannulate ($n = 37$), needle phobia ($n = 13$), and others ($n = 5$) (Table 1).

A total of 429 limbs were treated in 394 patients. Thirty-five (9%) were bilateral procedures. However, each limb was treated at a different sitting. There was slight female preponderance with the female to male ratio of 1.2:1. The age ranged from 17 to 88 years with the median age being 54 years and the interquartile range 23 years. A total of 226 (53%) right lower limbs were treated compared with 203 (47%) left lower limbs. Forty-seven (11%) recurrent varicose veins were treated. The CEAP classification was used to clinically categorise the severity of the varicose veins treated. The CEAP classification was C2 to C3, 291 (68%), and C4 to C5, 112 (26%). Of note, 26 (6%) of the patients had active venous ulcers (C6 category).

Table 1. Reasons for 94 'on the day' cancellations in 523 scheduled office based endovenous radiofrequency ablations

	n (%)
Unsuitability of vein	39 (7.5)
Cannulation failure	37 (7.1)
Needle phobia	13 (2.5)
Others (patient travelling soon, unwell patient pending medical investigations, etc.)	5 (1.0)
Total	**94 (18)**

The predominant finding on the initial venous DUS was SFJ and GSV incompetence in 367, saphenopopliteal junction (SPJ) with small saphenous vein (SSV) incompetence in 64 and SFJ and anterior thigh vein (ATV) incompetence in 10 patients resulting in 441 vein ablations. There were three (0.7%) recorded cases of endovenous heat induced thrombosis (EHIT), which were immediately recognised and treated by therapeutic anticoagulation. There were no thermal burns, pulmonary embolism, or vessel perforations in the study group.

Sixty (14%) patients were lost to follow up. The majority of the patients who attended follow up were discharged after the initial visit. One hundred and five (29%) patients underwent repeat DUS for persistent symptoms; complete recanalisation was noted in five patients and segmental recanalisation in 14 patients.

In the follow up period, which ranged from 12 months to 38 months, 86 patients (23%) needed further phlebectomies. Five underwent SFJ ligation plus stripping after initial failed EVRFA.

Hospital PLICS data were used to interrogate the average cost of RFA procedures done in an office suite. The cost for office based procedures was calculated to be £691 compared with £1301 when done in day surgery as unilateral varicose vein RFA combined with multiple avulsions under GA. The average income for varicose vein procedures was £1124.

During the study period another 95 patients underwent EVRFA and phlebectomies under GA in day surgery theatres and 85 patients had flush ligation of SFJ with GSV stripping and phlebectomies under GA in day surgery.

DISCUSSION

The concept of EVTA is based on the descending theory of the varicose vein pathophysiology where reflux starts in the saphenous trunk, from where it extends into primary and then secondary tributaries. Hence, treating the truncal reflux should in turn treat the secondary varicosities which reduce the venous hypertension resulting in symptomatic relief for the patients.[10]

Following the 2013 NICE recommendations, EVTA with its distinct advantages has been offered increasingly to treat varicose veins compared with open surgery. At the centre, EVRFA has been offered as this can be performed in the ambulant, office based setting under tumescent anaesthesia. It has the advantage that it can be safely offered to elderly patients with comorbidities and to patients on anticoagulants without the need to cease this treatment.[19,20]

Operations were, and are still, performed on Saturday mornings as this is convenient for the patients, who do not need to take time off from their work to have this procedure done.

There are only a few reasons to offer this procedure under GA, which include (i) vein unsuitability, either too superficial, tortuous, too narrow (<2 mm), or (ii) patient apprehension due to needle phobia, and (iii) inability to cannulate the vein/vein spasm, etc. Hence, to avoid same day cancellations, patients should be screened for these prior to listing them for EVRFA. A high rate of on the day cancellations was noted in the initial period of the study. This number reduced as uniform guidelines for listing patients were discussed with all junior doctors who were listing them for these procedures. There were only five failures to cannulate after October 2015.

Other relative contraindications included history of superficial thrombophlebitis resulting in a partially obstructed GSV, uncorrectable coagulopathy, liver dysfunction limiting the use of local anaesthetic, pregnancy, and breast feeding, and those with previous deep vein thrombosis (DVT) as superficial veins in these patients may be an important venous outflow.[11]

In the treatment of recurrent varicose veins, EVRFA may be offered after careful evaluation of the patient and detailed DUS to assess the aetiology, source, type, and extent of recurrent varicose veins. Forty-seven (11%) of the limbs treated had a history of recurrent varicose veins. The recurrence was usually following previous open surgery in the form of SFJ ligation plus stripping, and was due to neovascularisation, the remnant GSV becoming incompetent, or to the presence of an accessory GSV. These patients were listed for EVRFA only after confirmation by DUS that there was a suitable length of incompetent vein that could be ablated.

As expected, the majority of the patients who were treated belonged to the C2 — C3 category of the CEAP classification. Notably, however, patients with advanced disease were treated, which included 26 (6%) active venous ulcers. Eight (31%) of these patients with active venous ulcers needed phlebectomies due to persistent ulcers following EVRFA.

In 10 patients, more than one vein was ablated at the same sitting, which was indicated by the DUS finding. Vein diameter was not recorded in this study as it was not noted to be useful due to the variable diameter in different thigh segments.

No major complications were encountered in more than 400 EVRFA procedures that were performed in the study period. However, three endovenous heat induced thromboses (EHIT) were recognised immediately following the procedure and appropriate therapeutic anticoagulation was initiated with low molecular weight heparin injections after liaising with the haematology team. The patients were not scanned at week 1 or week 2; therefore, the true incidence of EHIT cannot be calculated. EHIT is a well recognised

complication that can result in pulmonary embolism. In order to identify this possibility, a completion DUS should always be performed. The reported occurrence after EVTA varies between 0.3% and 7.8%,[10] to which the figure of 0.7% compares favourably. It has been reported that the incidence of EHIT is higher after concomitant phlebectomy.[19] Treating patients in an outpatient setting under local tumescent anaesthesia permits early ambulation and reduces the risk of possible thromboembolic complications.[10]

The majority of the patients were reviewed and discharged at their first six week follow up and only those patients who had persistent symptoms were offered a repeat DUS. Of the 105 (29%) patients who underwent repeat DUS, failure of treatment was noted in five, who then underwent traditional open surgery. The cause of failure could not be ascertained in these patients and is assumed to be technical. Fourteen patients were found to have segmental recanalisation and did not require any further treatment.

Although there were residual varicosities noted during follow up, patients did not need further intervention during the study period as they had complete symptom relief. Eighty-six (23%) patients who attended follow up underwent further phlebectomies for persistent symptoms and residual varicosities. This percentage of patients requiring subsequent intervention for residual varicosities is less than reported in other studies.[10,18]

Hospital PLICS data were used to obtain the average costs and income. The average cost of each procedure done in the outpatient setting was £691 against a tariff of £1124 paid by the commissioners. The average cost of unilateral day case EVRFA combined with phlebectomies done under GA was £1301. This simple calculation indicates that it makes economic sense to move EVRFA from a day surgery setting to be done as an office based procedure under tumescent anaesthesia. Similar cost savings can probably be achieved in other healthcare settings across the globe using RFA or other forms of endovenous treatment of varicose veins.

There is no consensus regarding offering EVTA as a staged or synchronous procedure with phlebectomies or injection sclerotherapy. In this age of office based procedure under tumescent anaesthesia, concomitant treatment with phlebectomies or injection sclerotherapy may take longer and may be associated with increased morbidity.[9] There is likely to be a population of post-procedure patients who prefer not to have varicosities treated if it is not absolutely needed. Patient preference should be considered, which may obviate an unnecessary intervention.[18,20] The first treatment was restricted to truncal vein EVRFA alone and offered sclerotherapy or phlebectomies as second stage procedures only if needed. It was found that in a majority of patients (>75%), it was not needed.

CONCLUSION

This study has shown that office based endovenous radiofrequency ablation of truncal veins for the treatment of varicose veins as a single procedure is safe, effective, and offers symptomatic relief for great majority of patients. EVRFA could be moved out of theatre to an office suite to free up theatre capacity. This could be considered the standard practice for suitable patients across all healthcare settings.

CONFLICT OF INTEREST

None.

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COUP D'OEIL

Neck Swelling in a Type 1 Neurofibromatosis Patient

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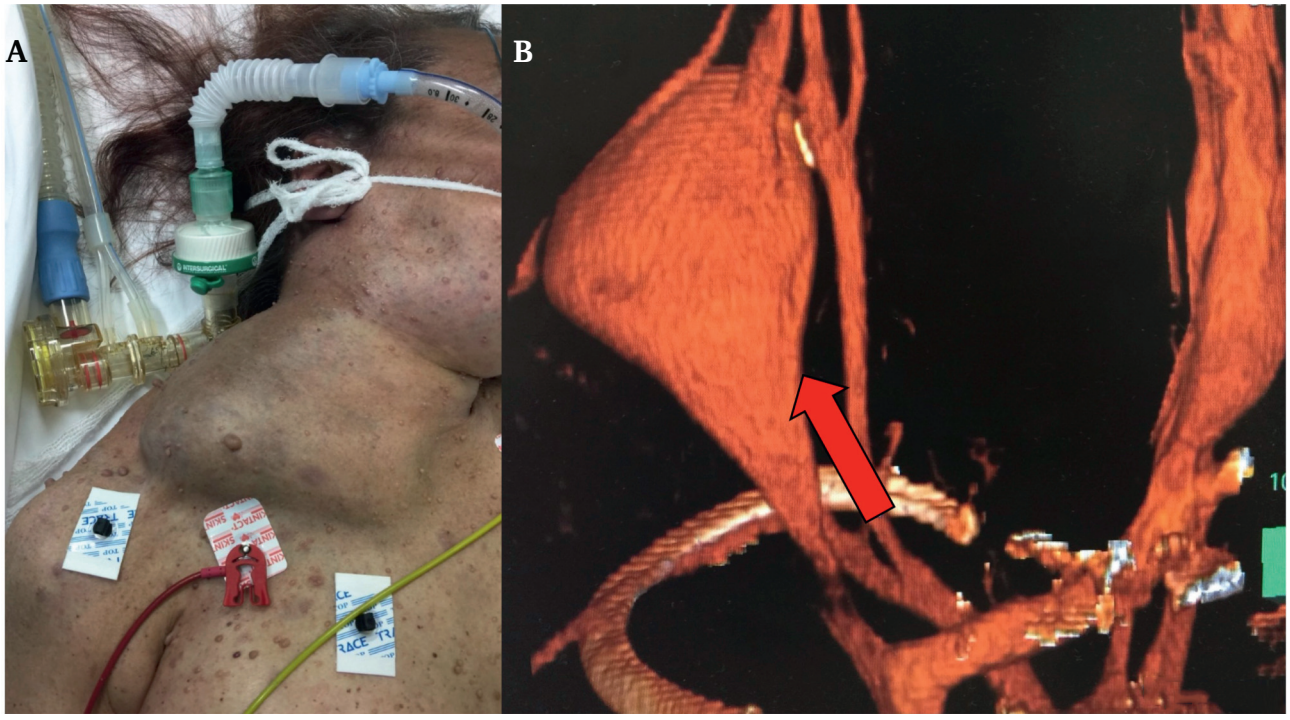

A 50 year old female with type 1 neurofibromatosis presented to the emergency department with neck swelling (A) and pain; because of the risk of airway obstruction, she was protected by endotracheal intubation. An urgent computed tomography scan showed an intact 10 cm internal jugular vein aneurysm (arrow, B), an extremely rare condition. Owing to continued neck enlargement and considering the chance of rupture, she was taken to the operating room for successful internal jugular venous ligation (proximal and distal to the aneurysm) with aneurysm excision. The patient was discharged five days after the procedure and nine months later complains of local neuropathic pain only.

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