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# Radiofrequency Ablation vs Conventional Surgery for Varicose Veins — a Comparison of Treatment Costs in a Randomised Trial☆

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**KEYWORDS**
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**Abstract** *Objective:* To compare the costs involved (from procedure to recovery) following radiofrequency ablation and conventional surgery for lower limb varicose veins in a selected population.
*Design:* Prospective randomised controlled trial.
*Methods:* Patients with symptomatic great saphenous varicose veins suitable for radiofrequency ablation were randomised to either RF ablation or surgery (sapheno-femoral ligation and stripping). The hospital, general practice and patient costs incurred until full recovery and the indirect cost to society, due to sickness leave after surgery, were calculated to indicate mean cost per patient under each category.
*Results:* Ninety three patients were randomised. Eighty eight patients (47 — RF ablation, 41 — surgery) underwent the allocated intervention. Ablation took longer to perform than surgery (mean 76.8 vs 47.0 min, $p < .001$). Ablation was more expensive (mean hospital cost per patient £1275.90 vs £559.13) but enabled patients to return to work 1 week earlier than after surgery (mean 12.2 vs 19.8 days, $p = 0.006$). Based on the Annual Survey of Hours and Earnings (Office of National Statistics, UK) for full time employees, the cost per working hour gained after ablation was £6.94 (95% CI 6.26, 7.62).
*Conclusion:* The increased cost of radiofrequency ablation is partly offset by a quicker return to work in the employed group (ISRCTN29015169http://www.controlled-trials.com).


## Introduction

Varicose veins affecting the lower limb is a major health problem in the Western World and often impairs the quality of life (QOL).[1,2] Surgical treatment, based on clinical presentation and underlying pathophysiology, has been

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shown to improve QOL.[1,3] Over 30,000 operations are performed annually for varicose veins in England and Wales at a considerable cost to the UK National Health Service (NHS).[4,5] The vast majority of these operations involve sapheno-femoral ligation and stripping of the great saphenous vein (GSV), inevitably followed by a variable period of recovery that may last a few weeks. Surgery, even in the absence of complications, may cause considerable early morbidity and prolong recovery.[6,7] This may have an impact on productivity in a societal context. Varicose veins are thus of clinical and economic importance to the NHS and also have a significant socio-economic impact on society.

Recent years have seen the development of less invasive, minimal access endovenous techniques of ablating varicose veins with the potential to reduce postoperative morbidity, facilitate quicker recovery and improve patient satisfaction and treatment outcome. Radiofrequency ablation (RFA) is one such method that uses radiofrequency energy to achieve vein ablation in selected patients with varicose veins due to superficial venous incompetence. Its potential early benefits over conventional surgery (CS) have now been confirmed by randomised controlled trials.[8,9] Five year outcomes after RFA are comparable to CS.[10] Although it is becoming increasingly popular it involves the use of specialised equipment and is still perceived as a more expensive alternative option to conventional surgery. This is particularly so within a public healthcare system such as the UK NHS where a tight financial budget may limit the provision of a more expensive treatment option unless it is proven to be overwhelmingly beneficial in a clinical context. However the higher costs associated with RFA could be offset against the benefit of a shorter recovery period and this may have an impact on its future application. Few studies have estimated the cost differences between RFA and CS either in the short-term or in the long-term.[8] It is important that costs incurred with any new treatment be accurately determined and balanced against its potential benefits over established conventional methods. This is best achieved by a comparison of the outcomes between the treatments in a prospective randomised controlled trial.

This paper reports the short-term costs incurred from procedure to recovery between RFA and CS performed in a selected population within a prospective randomised controlled trial. The primary aim of the trial was to compare the clinical outcome between the two procedures with the primary outcome measure being the time taken to return to full level of normal household activities. An estimation of the involved treatment costs was performed simultaneously and is the subject of this paper.

## Methods

The trial was carried out in the Vascular Surgical Unit of a tertiary referral hospital. Approval was obtained from the Local Research Ethics Committee. The inclusion and exclusion criteria are summarised in Table 1. Over 12 months consecutive patients between 18 and 70 years with symptomatic varicose veins (clinical, etiologic, anatomic, pathophysiologic (CEAP) Clinical Class 2–6) underwent clinical assessment and duplex ultrasonography in a one-stop venous clinic. Patients with primary or recurrent varicose veins due to isolated GSV incompetence (i.e. no associated deep venous or short saphenous vein incompetence) on duplex ultrasonography and suitable for RFA were consented for participation in the trial and allocated to receive either RFA or CS by a web-based randomisation method. All operations were performed under general anaesthetic. Patients randomised to RFA received tumescent infiltration followed by ablation of the GSV from just below the sapheno-femoral junction to the level of the knee (VNUS® Closure® procedure, VNUS Medical Technologies, Inc., San Jose, CA). Patients randomised to CS underwent sapheno-femoral disconnection and stripping of the GSV to the level of the knee. Both groups underwent simultaneous phlebectomy of pre-operatively marked varicosities using phlebectomy hooks. All RFA procedures were performed by one Consultant Surgeon with over 3 years' experience of this procedure.[11] Either a Consultant Surgeon or a Senior Registrar in Vascular Surgery was actively involved in all the operations in the other arm (CS). Patients were followed up towards the end of the first and fifth weeks after their intervention. Costs related to medical and nursing care during the postoperative period were recorded at each hospital follow up along with other outcome measures (morbidity, duration of recovery, patient satisfaction, QOL, radiological) being evaluated in the trial by an independent observer not involved in the original operation. The details of any treatment or consultation that was performed at the general practice or patient's home for any postoperative problem was also recorded.

**Table 1** Inclusion and exclusion criteria.

*Inclusion criteria*
- Age between 18 and 70 years, both sexes
- Duplex scan confirmed GSV incompetence (primary or recurrent) requiring surgery
- Duplex scan confirmed suitability for RFA (see exclusion criteria)
- Patient fit for a general anaesthetic
- Physical condition allowing ambulation after the procedure
- Patient able to give informed consent
- Requirement for intervention agreed between patient and the surgeon
- Availability of patients for all follow up visits

*Exclusion criteria*
- Varicose veins without GSV incompetence on duplex scan
- Associated short saphenous or deep venous incompetence on duplex scan
- Tortuous GSV above the knee felt to be unsuitable for catheterisation
- GSV diameter $<3$ mm or $>12$ mm in the supine position
- Thrombus in the GSV
- Patients with a pacemaker or internal defibrillator
- Concomitant peripheral arterial disease (ankle-brachial pressure index of $<0.9$)
- Pregnancy
- Unable to complete QOL questionnaires due to poor English language skills

Costs were estimated mainly from the perspective of UK NHS but general practice-related costs, patient-related costs and indirect costs to society due to sickness leave during the post-intervention period were also considered. The emphasis was on estimating the difference in costs between the two treatments. Thus protocol-driven costs related to hospital visits, duplex ultrasound scans and routine postoperative District Nurse home visits were excluded from the final analysis as the number of events was evenly matched in both groups. The costs incurred by the hospital (Table 2), general practice (Table 3) and patients were calculated to indicate the mean cost per patient under each category. Estimation of theatre costs was based on the recorded mean total time spent in theatre (between entry into and exit from theatre suite) and the number of operating staff normally present for both types of operation being compared in this trial. Additional costs for RFA resulted from the use of intraoperative duplex ultrasound scan and the disposable ablation catheter (prevailing purchase price of £550.00 per catheter at the time of the trial for Closure® PLUS Intravascular catheter (REF CL6-100, 6F or REF CL8-100, 8F supplied by VNUS® Medical Technologies Inc., San Jose, CA). The unit cost for consultations with the general practitioner or practice nurse and activities such as patient visits and District Nurse home visits was obtained from standard sources.[12] Patient costs included the cost incurred by patients for undertaking visits to their general practice or non-protocol hospital follow up visits and the cost of purchase of antibiotics or analgesics for any postoperative problem.

The indirect costs to society or loss of productivity from being unable to work has been reported in previous studies.[8,13] The time taken to return to work following treatment, the nature of employment and wages relevant to the time of the trial were considered for this analysis. Patients were asked whether, despite an uneventful recovery, any operation-unrelated factor or factors had delayed their return to work and whether they had taken

**Table 2** Costs incurred by the hospital per patient.[a]

| Cost of the operation (theatre cost) | Scale (where relevant) | Salary point (where relevant) | Quantity | Unit cost (£) | RFA (£) | CS (£) |
|---|---|---|---|---|---|---|
| Mean total theatre time (min) | | | | | 83.6 | 55.7 |
| Surgeon (Consultant) | MC72 | 08 | 1 | 61.90 per hour | 86.25 | 57.46 |
| Surgeon assistant (SpR) | MN25 | 09 | 1 | 30.02 per hour | 41.83 | 27.87 |
| Anaesthetist (Consultant) | MC72 | 08 | 1 | 61.90 per hour | 86.25 | 57.46 |
| Anaesthetic assistant (ODA) | XR 61 Band 6 | 12 | 1 | 22.30 per hour | 31.07 | 20.70 |
| Scrub Nurse | XR 61 Band 6 | 12 | 1 | 22.30 per hour | 31.07 | 20.70 |
| Floor Nurse | XR 51 Band 5 | 12 | 1 | 17.78 per hour | 24.77 | 16.51 |
| Portering | Band 2 | | 1 | 5.36 per hour | 4.97 | 4.97 |
| Consumables | | | 1 | | 50.00 | 50.00 |
| Staffing overhead[b] | | | 1 | 3.3% | 11.75 | 8.44 |
| Other Trust overhead[c] | | | 1 | 30.0% | 106.86 | 76.70 |
| Ablation catheter | | | 1 | 550.00 | 550.00 | 0.00 |
| Duplex scan[d] | | | 1 | 37.00 | 37.00 | 0.00 |
| Theatre cost | | | | | 1061.83 | 340.82 |
| Cost of day case ward | | | 1 | 210.80 per day | 210.80 | 210.80 |
| Cost of non-protocol outpatient visits | RFA — 2 visits for 47 patients<br>CS — 4 visits for 41 patients | | | 77.00 per visit | 3.28 | 7.51 |
| Cost of non-protocol duplex ultrasound scans | RFA — none<br>CS — none | | | 60.00 per scan | 0.00 | 0.00 |
| Mean hospital cost per patient | | | | | 1275.90 | 559.13 |

[a] Calculations based on 1 Consultant surgeon, 1 Specialist Registrar (SpR) in Surgery, 1 Consultant anaesthetist, 1 Anaesthetic ODA (operating department assistant), 1 Scrub nurse, 1 Floor nurse being involved in each operation, with staff wage rates at maximum of salary scale using 2005—2006 pay rates.

[b] Standard overhead based on overall costs — 3.3% of direct theatre costs (includes sterile services, administration, domestic services, laundry).

[c] Standard Trust overhead based on overall costs — 30% of direct theatre costs (includes estates, energy, capital charges, administration, etc.).

[d] Cost excludes cost of a technician as the scan was performed by the Surgeon.

**Table 3** Costs incurred by general practice per patient.

| | Unit cost (£)[a] | RFA | | CS | |
|---|---|---|---|---|---|
| | | Total contacts | Cost per patient (£) | Total contacts | Cost per patient (£) |
| GPR consultation (10 min) | 24.00 (2.40 per minute)[b] | 17 contacts for 47 patients | 8.68 | 24 contacts for 41 patients | 14.05 |
| Practice nurse consultation | 10.00 per consultation[c] | 4 contacts for 47 patients | 0.85 | 18 contacts for 41 patients | 4.39 |
| Non-protocol District nurse home visits | 23.00 per home visit[d] | None | 0.00 | 3 contacts for 41 patients | 1.68 |
| Mean general practice cost per patient | | | 9.53 | | 20.12 |

GPR = General Practitioner.
[a] Unit costs of Health and Social Care 2005 (http://www.pssru.ac.uk/pdf/uc/uc2005/uc2005.pdf — last accessed 28 Apr 2009).
[b] Includes the cost of training and direct care support staff cost.
[c] Includes the cost of training.
[d] Includes the cost of training and travel costs.

extra leave of a different type on termination of their sickness leave to allow themselves an extended break from work. Information regarding gross weekly earnings for employees in the UK and the duration of weekly paid hours of work was obtained from standard sources.[14] A difference of 7 days to return to work between the two treatments was taken to indicate a difference of one working week (5 working days + weekend).

Power calculation for the trial, based on an expected clinically significant (75%) improvement in the primary outcome (authors' experience indicated that 40% of patients returned to normal activities within a week following CS), obtained a sample size of 84 patients, 42 in each arm (80% power and significance level of 5%), with an additional 10% to account for potential follow up loss. Analysis of costs was based on the type of treatment received. Continuous parametric data were analysed using Student's *t*-test and non-parametric data using Mann—Whitney *U*-test for significance. Categorical variables were compared using Chi-square or Fisher's Exact test as appropriate. (MINITAB™ Statistical Software, v 13.32, Minitab Inc., USA). $p < 0.05$ was taken to indicate statistical significance.

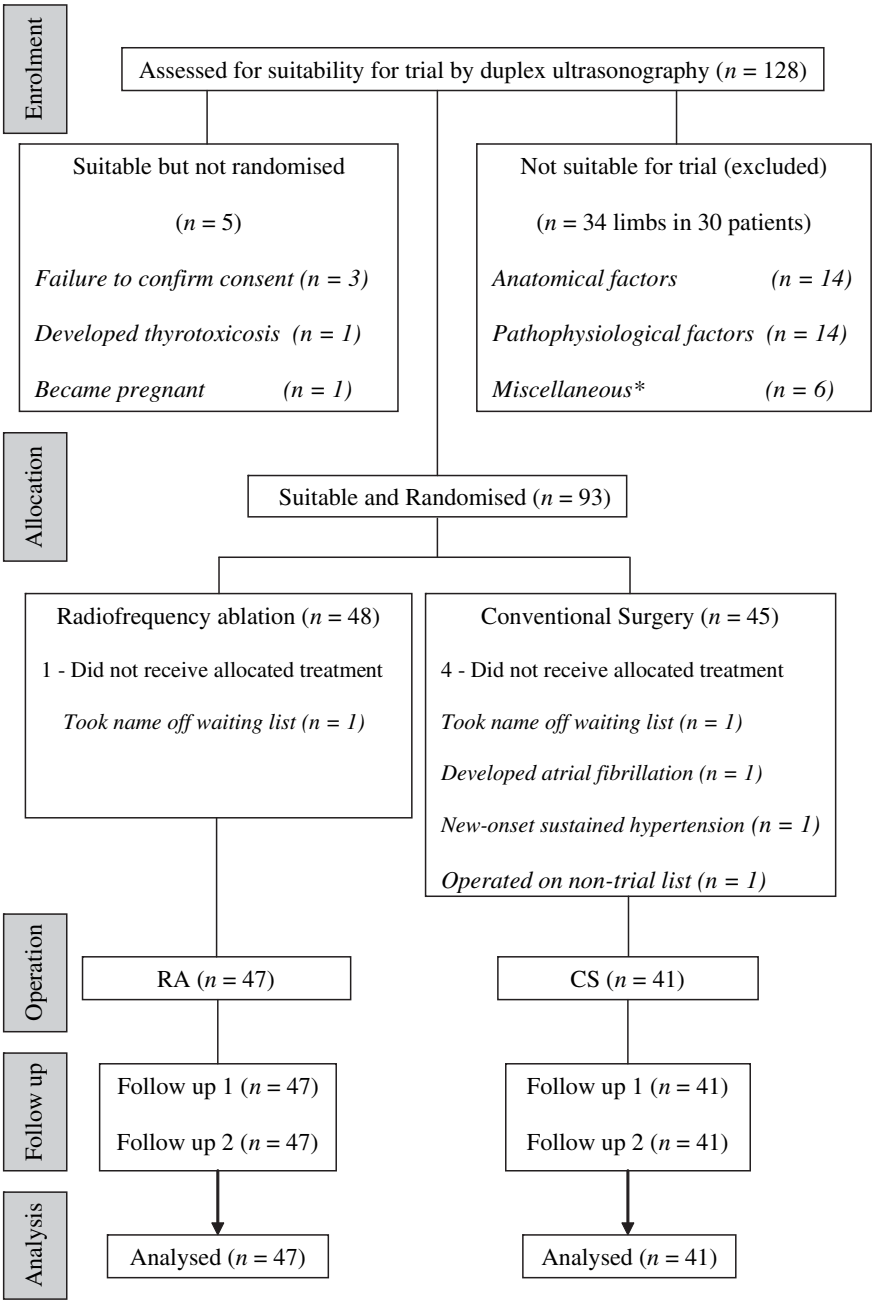
## Results

Of the 93 patients randomised, 88 patients (47 — RFA (13 men, 34 women), 41 — CS (14 men, 27 women)) underwent the allocated intervention with a median (interquartile range [i.q.r]) age of 47 (38—58) and 45 (37—53) respectively (Fig. 1). There was no follow up loss at a median (i.q.r) of 6 (5—7) and 37 (34—42) days respectively. CEAP Clinical Class was recorded (C2:C3 RFA 37:9 vs CS 33:7, C4 — one patient [RFA], C6 — one patient [CS]). The preoperative varicosity score (Aberdeen Varicose Vein Questionnaire (AVVQ)) was similar between the groups (median (i.q.r.) score RFA 1.55 (1.03—2.24) vs CS 1.72 (1.29—2.23), 95% confidence interval (CI) −0.43, 0.19, $p = 0.457$, *t*-test).

Patients who underwent RFA showed no demonstrable flow in the treated GSV on the duplex scan at first follow up. There were seven cases of incomplete stripping in the CS group showing varying degrees of segmental reflux. Patients returned to their normal activities (median (i.q.r) 3 (2—5) vs 12.5 (4—21) days, 95% CI −12.00, −2.00, $p < 0.001$, Mann—Whitney *U*-test) significantly quicker following RFA than after CS. Pain (visual analogue score) during the first week was significantly less following RFA (median (i.q.r) 1.7 (0.5—4.3) vs 4.00 (2.35—6.05), 95% CI −2.80, −1.00, $p < 0.001$, Mann—Whitney *U*-test). Ninety eight percent of those who underwent RFA were willing to recommend the procedure to others while only 78% would do so after CS ($p < 0.01$, Fisher's exact test). QOL (AVVQ) improved significantly for the whole group after intervention with a higher, though statistically not significant, improvement after RFA (mean improvement in QOL score −9.12 vs −8.24, 95% CI −3.64, 1.89, $p = 0.532$, *t*-test).

The total theatre time (between entry into and exit from theatre suite) was significantly longer for RFA than for CS (mean (standard deviation [SD]) 83.6 (SD 14.5) vs 55.7 (SD 10.9) min, 95% CI 22.40, 33.41, $p < .001$, *t*-test) and was used in the estimation of theatre costs (Table 2). The actual procedure time (from commencement, i.e. marking the course of the GSV with duplex scan in RFA or preparing the operative field with antiseptic in CS, to completion i.e. the application of a compression bandage in both cases) was also significantly longer with RFA (mean (SD) 76.8 (SD 14.5) vs 47.0 (SD 10.8) min, 95% CI 24.35, 35.32, $p < .001$, *t*-test). The number of phlebectomy incisions above and below the knee as well as the timing of the phlebectomy incisions in relation to main part of the operation were comparable between the two groups and did not impact on the time differences observed between the procedures.

The mean (SD) hospital cost per patient for RFA was £1276 (SD £69.6) and for CS was £559 (SD £52.4) (Table 2). Thus RFA resulted in an additional expenditure of £717.00 (95% CI 690.4, 743.2, *t*-test) per patient. The difference in the mean cost per patient incurred by the general practice (Table 3) and by the patient for undertaking visits to their general practice for any postoperative problem (£3.40 for RFA and £7.79 for CS) was small between the two groups as




** Patient preference for conventional surgery (3), patient decided against intervention (3)*

**Figure 1** CONSORT diagram (follow up 1 & 2 = median 6 and 37 days, respectively).

out-of-hospital services were only sought in a minority of cases. Costs incurred by the patient for undertaking non-protocol hospital visits during the postoperative period (RFA — two visits for 47 patients, CS — four visits for 41 patients) or from the purchase of antibiotics (RFA — $1 \times 1$ week course in 47 patients, CS — $3 \times 1$ week course in 41 patients) and analgesics were not considered in the final analysis as the number of such events was considered too small to make a significant difference to the overall costs.

Patients returned to work (median (i.q.r) 10 (4—13) vs 18.5 (11—28) days, 95% CI −13.00, −3.00, $p < 0.001$, Mann—Whitney *U*-test) significantly quicker following RFA than after CS. This was taken to be equivalent to a gain of 1 working week for patients undergoing RFA. Majority of patients (68/88) in the trial were in employment and worked for a median (i.q.r) of 39 (24—40) h per week at median (i.q.r) wages of £9.85 (5.52—12.88) per hour with no significant difference between the two groups. Thus the cost of employment was estimated to be £384.15 per week. This would indicate the indirect cost to society for being unable to return to work for an additional week following CS. Thus the increased cost of performing RFA was partly offset by patients returning to work 1 week earlier than following CS. The resultant difference in the overall cost

**Table 4** Comparison of overall costs in employed patients in the trial.

| Cost category | RFA (£) (mean cost per patient) | CS (£) (mean cost per patient) |
|---|---|---|
| Hospital cost | 1275.90 | 559.13 |
| General practice cost | 9.53 | 20.12 |
| Patient cost | 3.40 | 7.79 |
| Indirect cost | 0.00 | 384.15 |
| TOTAL | 1288.83 | 971.19 |
| DIFFERENCE | £317.64 | |
| Additional cost of RFA per working hour gained (see text) | 317.64/39 = £8.14 | |

RFA = radiofrequency ablation, CS = conventional surgery.

between the two procedures (£317.64) was the additional cost incurred in performing RFA for a gain of 1 week or 39 h of employment (Table 4). Thus the cost per every additional working hour gained following RFA was £8.14 (95% CI 7.47, 8.82, *t*-test). This may be interpreted as the extra cost (to the hospital, practice and patient combined) over and above the cost of conventional varicose vein surgery for each additional hour of paid employment gained following radiofrequency ablation treatment.

To obtain a national perspective the hours and earnings data from trial patients in the above calculation was substituted by similar data for full time employees in the UK obtained from employment data maintained by the Office of National Statistics.[14] The median gross weekly earnings for full time employees in the UK was £431.00 and the mean weekly paid hours of work for full time employees in the UK was 39 h. Based on these data, the difference in the overall costs between the two procedures would be £270.79 and the extra cost incurred in performing RFA for each additional hour of full time employment gained would be £6.94 (95% CI 6.26, 7.62).

Estimation of indirect costs to society in the unemployed group was difficult as the number of patients was too small in this category and accurate national estimates of the cost of unpaid household work for the period of the trial was not readily available.

## Discussion

RFA has been shown to be superior to CS in terms of short-term and medium-term outcomes such as postoperative pain, return to activities, QOL and patient satisfaction.[9,10] One of the key factors that determines the widespread acceptance of a new intervention is its affordability. Although long-term outcomes are needed in order to estimate parameters such as cost-effectiveness of a particular intervention it is useful to have knowledge of the actual costs involved in carrying out the procedure as a starting point in a cost comparison exercise. This is particularly so if the intervention in question is likely to bring about a quicker recovery that enables an earlier return to work, thus potentially off-setting some of the increased costs of treatment against societal gains. Recent studies involving RFA have not fully addressed this issue. This has led many to view RFA as an expensive modality despite its clinical advantages. One previously reported randomised trial that involved 28 patients, performed partly during the learning experience of the authors, indicated that RFA appeared to be cost-saving for society, particularly among the employed group, when productivity loss was included in the cost analysis.[8] Our study involved 88 patients with procedures in both arms being performed by experienced personnel.[11] In estimating hospital costs, we calculated the actual costs involved in carrying out the procedure rather than using reference costs which are used by many hospital trusts in the UK for estimation of theatre and procedural expenses. Reference costs may not yield an accurate picture as this method results in costs being averaged out over low and high cost procedures and is likely to allocate too much to a fairly simple procedure like varicose vein surgery. Indirect costs to society were estimated both within the context of the trial and also based on national employment data from reliable sources.[14]

Several factors need to be borne in mind when interpreting the results. The method of allocation of overheads may vary between hospitals. The cost analysis did not consider the issue of re-treatment of early failures in either group by the same or different method, as these events did not occur. Bilateral surgery in the same setting or treatment of incompetent duplicated GSV would not increase the costs of RFA treatment significantly as the same catheter may be reused for the additional treatment required. The trial did not involve any bilateral operations and only one case of duplicated GSV, both trunks of which required RFA treatment. Costs related to treatment of major complications like deep vein thrombosis and pulmonary embolism were also not considered as no such event occurred during the trial. As these are rare events with either treatment, the exclusion of these is unlikely to have significant cost implications. Hours and earnings data provided by a specialist government department, however reliable and accurate they may be, may not always be applicable to a particular local population. For the same reason they may not be directly applicable to other countries. In our study, however, the final cost outcome was not significantly dissimilar in this context between trial participants and outcome based on national data.

Several factors influence the cost differential between the treatments. The difference in the hospital costs between the procedures was mainly due to cost of the RFA catheter, which contributed to approximately 80% of the cost difference. The remaining 20% of the difference

resulted from the longer theatre time expended during RFA treatment. Due to the infrequent incidence of post-operative problems in either group, the costs incurred by general practice and patient did not impact heavily on the cost difference between the treatments. When indirect costs are considered, the cost differential between the treatments is also influenced by the nature of employment of the target population and the time taken to return to that employment after treatment. For example, the higher the wages of the target population, the lower the overall cost of RFA for every gained hour of employment that was brought about by its use. However the cost differential between the two treatments is likely to get smaller in future for several reasons. Firstly as the procedure becomes more widely accepted the cost of the catheter is likely to come down. Secondly the innovative design of the newer VNUS® ClosureFAST™ catheter allows for a 'segmental ablation' approach and a significantly faster ablation time. Typically a 45-cm vein length may be ablated in 3–5 min. The median (i.q.r) length of GSV that was ablated in the trial was 31 cm (29–34.5) and took a median (i.q.r) of 14 (12.6–15.7) min. Treatment with this newer RFA catheter could bring about a significant reduction in theatre time and hence a reduction in theatre and overall hospital costs for RFA treatment. Lastly RFA is routinely performed under tumescent infiltration alone in many centres. Within the trial all patients were operated under a general anaesthetic irrespective of the procedure. Avoiding an anaesthetic would potentially reduce theatre time by a further 10–15 min for patients undergoing RFA and contribute to a further reduction in theatre costs.

Employment wages may rise in future thus further narrowing the overall cost differential between the treatments, although, this factor is unpredictable and would depend on the target population being treated. The type of employment may also matter, as in the case of the self-employed, where there is likely to be an additional need and incentive for an earlier return to work than those who are in salaried employment. Only 22% (8/36) and 16% (5/32) of those employed in the RFA and CS groups respectively were self-employed. This did not permit a satisfactory sub-group analysis to be performed. Even if employment wages are not considered, a reduction in the cost of the catheter combined with a quicker procedure performed with newer catheters under tumescent infiltration may make the overall costs comparable between the two treatments.

Future studies on RFA are likely to report on the use of these instruments with better sophistication and design. It is however important to remember that CS also improves QOL and symptoms in the majority of patients with varicose veins and has been shown to be effective in reducing long-term recurrence and risk of reoperation.[15,16] An analysis based on long-term anatomical, physiological, patient-based and clinical outcomes alone would reveal the true cost-effectiveness of RFA treatment. Until then purchasers and providers within a healthcare system such as the NHS in the UK may continue to view radiofrequency ablation as a more expensive option, despite its significant early benefits when compared to conventional surgery, in suitable patients.

## Funding/Conflict of Interest

VNUS Medical Technologies, Inc., San Jose, CA provided some of the Closure® PLUS radiofrequency ablation catheters used in the trial. They were not involved in the running of trial, data collection, interpretation or analyses. The authors had full freedom in the preparation of this manuscript and take full responsibility for its content.

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