Cost-effectiveness Analysis of Current Varicose Veins Treatments

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ABSTRACT

Objective: To analyze the effectiveness and cost-effectiveness of technologies for treatment of varicose veins over 5 years - conservative care (CONS), surgery (HL/S), ultrasound guided foam sclerotherapy (UGFS), endovenous laser ablation (EVLA), and radiofrequency ablation (RFA), mechanochemical ablation (MOCA) and cyanoacrylate glue occlusion (CAE).

Methods: A systematic review was updated and used to construct a Markov decision model. Outcomes were re-intervention on the truncal vein, re-treatment of residual varicosities and quality-adjusted life years (QALY) and costs over five years.

Results: UGFS has a significantly greater re-intervention rate than other procedures, while there is no significant difference between the other procedures. The cost per QALY of EVLA versus UGFS in our base-case model is £16966 ($23700) per QALY, which is considered cost-effective in the UK. RFA, MOCA and CAE have greater procedure costs than EVLA with no evidence of greater benefit for patients.

Conclusions: EVLA is the most cost-effective therapeutic option, with RFA a close second, in adult patients requiring treatment in the upper leg for incompetence of the GSV. MOCA, UGFS, CAE, CONS and HL/S are not cost-effective at current prices in the UK National Health Service. MOCA and CAE appear promising but further evidence on effectiveness, re-interventions and
health-related quality of life is needed, as well as how cost-effectiveness may vary across settings and reimbursement systems.

**KEY WORDS**

Cost-effectiveness; Economic evaluation; Varicose veins; Endothermal; Nonthermal
Introduction

Varicose veins, affecting a significant proportion of the population [1], [2], impact patients adversely with symptoms as severe as leg ulceration. Treatment of this condition provides proven patient benefit and whilst also being cost-effective and supported by national and international guidelines, however despite this, varicose vein treatments are often given low priority in health system budgets leading to long waiting lists.[3]

The ongoing SARS-CoV-2 (Covid-19) pandemic has led to further significant priority changes with disease management as this global health emergency restricts the resources being made available to treat varicose veins [4]. Indeed, the Vascular Society of Great Britain and Ireland (VSGBI) and GIRFT (Getting it Right First Time) initiative have classified vein interventions as the lowest priority (Priority Level 4: procedures that can be delayed for more than 3 months) [5] meaning longer waiting times for treatment and potentially worsening the severity of the initial venous complaint. With the large sums currently being used to control this pandemic [6], only scarce amounts would inevitably be spent on management of benign but symptomatic conditions such as varicose veins. Thus, prioritising cost-effective interventions in healthcare systems has become more crucial than ever.

This paper updates a systematic review and economic analysis of treatments for varicose veins published in 2018 [7]. At that time, there was little evidence available from randomised studies of MOCA or CAE. Since then, several new RCTs have been published, considerably expanding the evidence base and hence this is an opportune moment to review the effectiveness and cost-effectiveness of these interventions. Additionally, CAE has moved in 2020 from special arrangements for use to standard arrangements for use according to NICE Intervventional Procedures Guidance [8], allowing its use throughout the National Health Service (NHS) in the United Kingdom as a standard procedure. Furthermore, the cost of CAE
has significantly reduced in the time since the last review was published, which may significantly affect the outcome of the cost-effectiveness analysis.

The analyses were carried out according to guidelines for economic evaluation [9]. Further data, model and code are available online [10].

**Methods**

**Systematic review**

For the purposes of this cost-effectiveness analysis, a systematic review was first undertaken to gather data regarding treatment modalities for varicose veins. The methods looked at include compression therapy (CONS), surgery (high ligation and stripping, HL/S), foam sclerotherapy (UGFS), endothermal ablation (radiofrequency ablation, RFA, and endovenous laser treatment, EVLA) and non-thermal ablation (mechanochemical ablation, MOCA and cyanoacrylate CAE). Details regarding operative time, re-interventions on the GSV, residual re-treatments and sick-days absent from work or unable to conduct normal activities after the procedure were deemed essential.

Medline and Embase databases were searched for English language articles describing RCTs published between 1974 and October 2020 that compared the treatment options studied in this paper. References of other reviews were also examined. The search terms are listed in the material online [10]. Risk of bias was assessed using the Cochrane tools [11]. The protocol was previously registered in the International Prospective Register Of Systematic Reviews (CRD42015029618).

**Odds ratios of re-interventions on the truncal vein**

The primary measure of effectiveness in this study was re-intervention on the GSV. The number of randomized patients and the number of re-interventions reported were extracted for each arm of each trial. Synthesis of evidence from the multiple treatment options was
conducted using random-effects direct meta-analysis (MA) and random-effects network meta-analysis (NMA) [13]. Both approaches assume proportional hazards, that is, the relative treatment effect is constant over the study follow-up time. NMA allows an indirect estimate to be obtained of relative effectiveness of two treatments that have not been compared in a direct RCT, and estimates confidence intervals that take account of all the data in the network.

**Model structure**

The model evaluates the cost-effectiveness of therapeutic options for symptomatic varicose veins in adult patients without active ulcer (CEAP 2 to 5) requiring treatment in the upper leg for incompetence of the great saphenous vein (GSV) (the “truncal” vein) over 5 years. Health outcomes are measured in quality-adjusted life years (QALYs), and the cost perspective is the United Kingdom National Health Service (NHS) and social care system at 2020 prices. The discount rate for costs and QALYs is 3.5% per year [12]. Outcomes evaluated in the literature review are re-interventions on the GSV, operative time, days off work and days to return to normal activities.

The decision model is a Markov model (material online [10]). It is assumed that re-intervention on the GSV is undertaken because the index treatment has failed to control symptoms or symptoms have recurred. The AVULS study found that the quality of life, measured by the EQ-5D index, of patients who required further re-intervention and those that did not was 0.719 *versus* 0.846, mean difference 0.127 (SE 0.054) [14]. This is varied ±25% in sensitivity analysis. It is assumed in the model that this decrement in QOL lasts for 6 months until a re-intervention can be arranged. The rate of re-intervention associated with each modality is estimated by the systematic review and meta-analyses. The CLASS study found that 12% of patients requiring re-intervention were treated by surgery, 42% of by UGFS, and 46% by EVLA [15]–[18]. Based on van Groenendael et al., it is assumed that re-
intervention will be successful in 90% of cases (varied in sensitivity analysis from 75% to 100%) [19]. It is assumed that patients will not be offered more than one re-intervention in the UK NHS.

The AVULS study found that 36% of patients required re-treatment of surface varicosities under a delayed strategy versus 2% under a concomitant strategy, and concluded that concomitant treatment was the preferred strategy, where feasible [14]. It is assumed in the model that any treatments of tributary veins or surface varicosities will be undertaken at the same time as the index treatment [14], except for UGFS because this treatment does not employ appropriate anaesthetic..

Carradice (2011) found a significant reduction in periprocedural EQ-5D index at one week compared with baseline (mean difference 0.05, p-value=0.024) for both EVLA and HL/S [20], but patients returned to work faster after EVLA. Based on these data, and the results of this review comparing endothermal procedures to HL/S for time to return to normal activities and work (Supplementary Figure 1), it was assumed that patients experience reduced QOL for two weeks after surgery and one week after other procedures.

**Correlation between outcomes**

The base-case model assumes the rate of re-intervention and the rate of re-treatment for varicosities are independent outcomes, but they might be correlated (for example, if patients who are more likely than average to require re-intervention are also more likely to require treatment for superficial varicosities). A possible correlation between outcomes was introduced in sensitivity analyses by assuming a correlation coefficient of ±0.4 [21].

**Estimated rate of re-interventions after HL/S**
The re-intervention rate for HL/S was estimated by Poisson regression of the arms of the included studies, with the number of re-interventions as the dependent variable, dummy indicators for each treatment and person-years of follow-up as the exposure variable, and individual studies modelled as random effects to account for between-study variation in baseline characteristics of patients.

The absolute re-intervention rate of any other treatment \( j \) can then be estimated, assuming proportional hazards, by multiplying the re-intervention rate after HL/S by the relative effect of treatment \( j \) versus HL/S obtained from the systematic review.

Cost-effectiveness analysis

Incremental cost-effectiveness ratios were calculated for treatment options that had greater mean cost and greater mean QALY than the next-best alternative. The threshold cost-effectiveness ratio in the UK is considered to be between £20,000 to £30,000 per QALY ($28,000-$42,000). Probabilistic sensitivity analysis was carried out to assess how the model results (mean costs and QALY) were affected by uncertainty in all the model parameters together. Uncertain parameters were assigned probability distributions: costs of procedures and utility decrements were characterised by gamma (\( \alpha, \beta \)) distributions, where \( \alpha=\text{mean}^2/\text{SE}^2 \) and \( \beta=\text{SE}^2/\text{mean}^2 \); the incidence rate of re-intervention after HL/S, and the relative risks of re-interventions were assigned log-normal distributions, and probability of re-treatment for varicosities under a delayed strategy was assigned a beta distribution. 1000 Monte-Carlo simulations of the model were carried out. Results are presented using cost-effectiveness acceptability curves (CEAC) [22], which show the probability of each treatment having greatest net benefit, and rank probabilities, which show the probability each treatment has the greatest, second-greatest, third-greatest net benefit, etc. Rank probabilities show a
fuller picture than the CEAC of the uncertainty in the decision for multiple treatment comparisons [23]. Prices are converted to US$ at 2020 purchasing power parity ($1=£0.716).

Results

Results of systematic review of the literature

Figure 1 shows the PRISMA chart for study selection. 70 publications met our inclusion criteria, of which 47 were unique, independent studies [18], [24]–[69] (Supplementary Table S1). One article reported two RCTs [68]. Patient characteristics were similar across the included trials [70]. All studies treated the GSV, 6 also treated the SSV and 3 treated other veins. Few studies included patients with recent previous treatment of varicose veins. Across studies, between 0 and 4% had unhealed ulcer (CEAP 6), between 0 and 10% of patients had healed ulcer (CEAP 5), the mean age was between 29 and 62 years, and between 16% and 93% were female. Length of follow-up ranged from 6 months to 10 years (online material [10]). Most studies were conducted without blinding of patients and practitioners, as is usual in pragmatic surgical studies (Supplementary Table S2). There was no evidence of publication bias (see online material, Funnel Plot [10]).

Operative time of procedures

Operative times are shown in the online material [10]. Compared to EVLA, operative time was shortest for UGFS, second-shortest for CAE, and similar for RFA, MOCA and HL/S.

Re-interventions on the truncal vein

The network of pair-wise comparisons available from the literature are shown in the online material [10]. Supplementary Figure S2 shows the direct odds ratios (random-effects MA). Mixed effects (estimated by random-effects NMA) are shown in online material [10], using HL/S as the reference treatment. There was substantial between-study variation in the
comparison of UGFS vs HL/S ($I^2>60\%$), but moderate to low between-study variation for other treatment comparisons (Supplementary Figure S2). In general, the direct and mixed estimates gave comparable results (material online [10]). Both methods show that UGFS has a significantly greater re-intervention rate than other procedures, while there is no significant difference between the other procedures. Confidence intervals are widest for MOCA and CAE (material online [10]).

Based on these data, MOCA, CAE, RFA, EVLA and HL/S are considered to have the same rate of re-intervention in the base-case model, though with wider confidence intervals for CAE and MOCA. Sensitivity analyses used the results of the NMA [10] as inputs to the economic model, or the results of the direct meta-analysis (Supplementary Figure S2).

The data for the number of re-interventions in each arm of each study are shown graphically in the online material [10]. The predicted incidence rate after HL/S from the Poisson regression using these data was 49 re-interventions per 1000 person-years of follow-up (SE ±10).

Estimated costs of procedures

The CLASS RCT found staff procedure costs (SD, N) to be: EVLA, mean £349 (SD £163, N=183), UGFS mean £157 (SD £118, N=182) and HL/S mean £637 (SD £340, N=195) at 2010-2011 UK prices [67]. HL/S was performed in a day-case operating theatre (that is, the patient was admitted but with no overnight stay), while other modalities were conducted in outpatient clinics. Costs were updated in the model for health service pay inflation [71]. CAE generally requires shorter procedure time than EVLA, while MOCA and RFA have similar operative time and cost to EVLA.

The procedure cost of UGFS includes the ultrasound machine, consumables and IV cannula. EVLA uses an ultrasound aachine, a leased laser generator and a non-reusable laser fibre [68].
RFA uses ultrasound, a generator, and a non-reusable catheter [67]. Generally in the UK the rental cost of the generator is included in the price of the laser fibre or catheter. Equipment costs for HL/S include an electrocardiograph (ECG), pulse oximeter and non-invasive blood pressure monitor [68]. Current list prices for EVLA (£256 or $357), RFA (£280 or $391), MOCA (£375 or $524) and CAE (£640 or $894) were obtained from manufacturers (data on file). The costs of the index procedures are given in Supplementary Table S3. Other procedure-related costs such as performing venous duplex ultrasound and testing during or before clinic time are similar for all modalities and have not been included in the model.

Estimated probability of re-treatment for residual varicosities

Considerably fewer patients given concomitant phlebectomy require re-treatment, compared with delayed phlebectomy, (odds ratio 0.04, 95% CI 0.00-0.28) and have better HRQOL [13]. It was assumed in the model that concomitant ablation of the varicosities was conducted where feasible.

Cost-effectiveness analysis

The material online [10] gives the base-case model estimates of the total costs per person over 5 years and Figure 2 shows total mean costs and QALYs per person in the cost-effectiveness plane. EVLA has the greatest mean net benefit if the threshold is greater than £16966 ($23700) per QALY (that is, the ICER). Conservative care has slightly greater costs than UGFS once interventions for recurrent symptoms are taken into account.

The CEAC shows that at a threshold of £20,000/QALY ($28,000), EVLA has 28% probability of having highest net benefit, RFA has 22% probability of having highest net benefit, and UGFS has 33% probability (Figure 3). Figure 4 shows the rank of each treatment in terms of mean net benefit and the variation in the rank obtained from the Monte-Carlo simulations. At a threshold of £20,000/QALY ($28,000), EVLA ranked first, RFA second,
UGFS third, MOCA fourth, HL/S fifth, with CAE sixth and CONS last. There is greatest uncertainty in the rank of MOCA: in >25% of simulations it ranks second or better, and in >25% of simulations it ranks sixth or worse (Figure 4). Univariate sensitivity analyses are shown in Figure 5 as a tornado chart. The ICER of EVLA versus UGFS might be greater than £20000 per QALY ($28,000) if the rate of re-intervention was 25% lower than the basecase, or the utility decrement for symptomatic treatment failure was 25% lower than the basecase, or if 100% of re-interventions are successful. A low rate of re-intervention, or a low utility decrement associated with symptomatic varicose veins, makes UGFS seem relatively more attractive (as there is less dis-benefit for patients associated with treatment failure).

Discussion

Summary of main findings

UGFS is the interventional procedure with lowest cost over five years, but is also the least effective as measured by QALYs. The cost per QALY of EVLA versus UGFS in our base-case model is around £16966 per QALY ($23700), which is considered cost-effective in the UK. RFA, MOCA and CAE have greater procedure costs than EVLA with no evidence of greater benefit for patients. These procedures would need to be provided at lower prices if they are to offer value for money to the NHS. HL/S requires longer operating theatre time and longer time off work for the patient, and is not a cost-effective option.

Another recent review and economic modelling paper finds EVLA to be most cost-effective in Norway from a societal (patient and NHS cost) perspective, and steam vein sclerosis to be most cost-effective from a NHS-only perspective over a one-year time horizon [72]. However, this paper includes uncontrolled observational and single-arm studies in the evidence base, and so results are unreliable. Only one RCT has published data about steam
vein sclerosis [73] but this study did not report re-interventions and so we could not include this modality in the model.

**Strengths and weaknesses**

As in our previous paper, [7] the primary effectiveness endpoint is re-interventions. Outcomes such as recurrence, occlusion, failure, patency etc. are defined inconsistently in the literature [55], [74], which makes them unsuitable outcomes for evidence synthesis, or unrelated with patient quality of life.[75] Re-intervention indicates the patient has continued to experience unacceptable symptoms after initial treatment that their clinician considered severe enough to merit further procedures. This would be consistent with the move internationally to assess interventions on a symptomatic rather than technical basis.

Unfortunately, the model is limited by the data provided – extensive and exemplary RCTs have been performed but reporting of procedural data and outcome data is sadly still limited despite over a decade of reporting standard [76]. Most importantly description of repeat procedure needs to clearly be defined – studies have interchangeably utilized re-intervention and re-treatment to variably describe repeat truncal vein treatment, delayed varicosity treatment and repeat varicosity treatment. We would suggest that standardization of reporting of this data would greatly help future analyses and aid choice of treatment.

We assume that concomitant phlebectomy is being used where feasible, because it has been shown to improve patient outcomes [14]. In practice, the treatment of non-truncal varicosities may depend on surgeon and patient preference.

The benefits of MOCA and CAE as shown by the published literature are limited, as they do not surpass the efficacy of EVLA or RFA, but with higher costs. The cost saving from not needing tumescent anaesthesia is minimal (local anaesthetic costs are approximately £4 per patient), and in this model it is assumed that concomitant varicosity treatment is performed to
give the optimal QOL outcomes, which necessitates local anaesthetic for phlebectomies or
sclerosant for foam sclerotherapy (which is the same monetary cost).

However, equally it is important to note that both options offer alternatives for those in which
thermal ablation is not suitable, and that over time costs should continue to reduce for these
modalities. All modalities still represent clinically effective treatments and so provide
alternative options, however routine care with thermal ablation (first line EVLA) and
phlebectomies is suggested by this study to be the most cost-effective option.

Our economic model estimated the average cost to the hospital of providing the service.
Hospitals in the United Kingdom are reimbursed according to a standard national tariff, and
so some providers may find that their local cost of provision exceeds the tariff received.
Reimbursement factors may influence their willingness to provide varicose vein procedures.
Our study does not monetize other societal impacts such as the lost production from work
absence. Most patients are of working age, and so these factors may also influence decision
makers as well as patients’ choices. Costs of kit are based on manufacturers’ list prices,
following UK methodological practice. The prices actually paid depend on discounts
negotiated between manufacturers and service providers.

**Conclusions**

In conclusion, EVLA would be the most cost-effective therapeutic option, with RFA a close
second, in adult patients requiring treatment in the upper leg for incompetence of the GSV.
MOCA and CAE appear promising but they are not cost-effective options at current prices.

This would mean that at this stage, there is very little indication to contemplate a change in
treatment guidelines towards using more non-thermal technologies. Since our previous paper
[7] there have been further studies of MOCA and CAE and with longer follow-up. However,
there still remains considerable uncertainty around the effectiveness of these modalities
compared with thermal technologies, and so further evidence as regards the clinical and cost-benefit of MOCA and CAE would be desirable, along with steam vein sclerosis. Hopefully, this would be achievable once the Covid-19 pandemic is under control [77].

Further research is needed to further delineate the different modalities with granular details on time and motion to truly provide costs and efficacy data, with standardized reporting. Whilst such trials would be limited due to the logistics of size required, it may be that a large cohort registry with fine granular details for monitoring is the appropriate next step. However, this would need extensive clinician buy-in to ensure accurate data is entered and may require integration with electronic health record systems.

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