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Patients' Expectations before and Satisfaction after Ultrasound Guided Foam Sclerotherapy for Varicose Veins

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KEYWORDS

Varicose veins;
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Abstract *Objectives:* Ultrasound guided foam sclerotherapy (UGFS) is a minimally invasive treatment for varicose veins (VV) whose clinical and cost-effectiveness remains incompletely defined. The aim of the current study was to examine patients' expectations before and satisfaction after UGFS for VV in terms of relief of lower limb symptoms, improvement in appearance, and beneficial effect on life-style.

Methods: A consecutive series of 351 patients (464 limbs) undergoing UGFS for VV completed questionnaires one week prior to and six months after treatment.

Results: Pre and post-treatment response rates were 80%; 60% returned both questionnaires. Virtually all patients were expecting improvement in lower limb symptoms; these were exceeded in a third. Most patients expected cosmetic improvement and these were largely met. Two-thirds of patients expected significant life-style (clothes, work, social) benefits and outcomes were slightly less than expected. A quarter expected improvement in their interpersonal relationships. This benefit was greater than expected occurring in one-third of patients. Overall, a quarter of patients had their expectations exceeded and 10% (appearance and relationships) to 25% (clothing, work and social and leisure activities) were left with unmet expectations.

Discussion: When specifically asked most patients admit to having a wide range of expectations in relation to their VV treatment, many of them probably unanticipated by the clinician. However, present data indicate that UGFS is usually able to meet, and often exceeds, these physical and psychosocial needs and expectations. UGFS is, therefore, a highly effective treatment for VV from the patients' perspective.

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Introduction

Many studies have demonstrated that varicose veins (VV) have a deleterious effect on disease-specific and generic health-related quality of life (HRQL),^{1–4} and that significant improvement in HRQL can be obtained following intervention.^{2,4–10} Despite this, up to 20% of patients have reported dissatisfaction with VV surgery and such surgery remains the commonest cause of litigation against vascular surgeons in the UK.^{7,11–13} It has been suggested that this is due to unrealistic expectations of surgery.^{7,11–13} However, unless one knows what those expectations are and understands the limitations of the treatments one is offering, one cannot define what is unrealistic and what is not. When specifically asked, most patients admit to having a wide variety of expectations in relation to their VV treatment, many of them probably unanticipated by the clinician. It is perhaps not surprising, therefore, that the patient and the clinician can find themselves inadvertently talking at cross-purposes with resulting dissatisfaction and even recourse to medicolegal action.¹²

Ultrasound guided foam sclerotherapy (UGFS) is a minimally invasive treatment for varicose veins (VV) whose clinical and cost-effectiveness remains incompletely defined. The aim of the present study is to examine patients' expectations before and satisfaction after UGFS for VV in terms of relief of lower limb symptoms, improvement in appearance, and beneficial effect on life-style.

Methods

Patients and pre-treatment assessment

Following local ethical committee approval and the taking of written informed consent a consecutive series of 351 patients undergoing UGFS for symptomatic VV of 464 legs were sent questionnaires one week prior to (Appendix 1) and six months after (Appendix 2) treatment. All patients were referred by their general practitioners to National Health Service (NHS) vascular surgeons at a single hospital (Heart of England NHS Foundation Trust). All patients were seen and assessed in a consultant-led vascular outpatient clinic. Patients were examined and the severity of venous disease according to the CEAP clinical classification was determined.¹⁴ All underwent duplex scanning in the clinic to identify sites of superficial and deep venous reflux. Patients were examined standing with their weight on the contralateral limb and the leg to be examined slightly bent with the heel on the floor to relax the calf muscle while maintaining stability, with a Sonosite Micromaxx[®] (Sonosite Ltd, Hitchin, Herts, UK) fitted with a 10 MHz transducer. The following venous segments were insonated: proximal and distal superficial femoral vein; above and below knee popliteal vein; saphenofemoral and saphenopopliteal junctions, the whole length of the great saphenous vein (GSV) and the small saphenous vein (SSV), and the anterior accessory saphenous vein (AASV). All veins were assessed for patency and compressibility. Reflux was induced with

a manual calf squeeze and was defined as reverse flow of greater than 0.5 s.

UGFS treatment

UGFS was performed by one of the authors (AB, DA) on an outpatient basis in a treatment room. All treatments took less than 30 min. Immediately prior to treatment patients underwent repeat venous duplex scanning (GB) and the incompetent truncal and superficial varices were marked on the skin. The patient then reclined and the incompetent trunk vein was cannulated with a peripheral intravenous catheter (Optiva[™], Medex Medical Ltd, Rossendale, UK) under direct ultrasound guidance. 18–22 g cannulae (green, pink or blue) were used according to the size and depth of the target vein. 1 or 2 cannulae were sited in the SSV, 1 or 2 in the AASV, and 1–3 cannulae in the GSV. Once all cannulae were secured the limb was held in an elevated position for injection of the foam. Prior to injection all cannulae were flushed with normal saline to ensure no movement had occurred during the changes in limb position.

Sclerosant foam was prepared by a modified Tessari's method using two, 2 ml syringes connected by a 3-way tap and a 5-micron filter (B Braun Medical, Sheffield, UK) and comprised 0.5 ml 3% sodium tetradecyl sulphate (Fibro-vein[®], STD Pharmaceuticals Ltd, Hereford, UK) and 2 ml air. Foam was injected in 2 ml aliquots and its distribution and resultant venous spasm observed by duplex imaging. At least 30 s was allowed to pass between injecting each aliquot of foam. After each injection patients were asked to dorsi- and plantar-flex their ankle several times to clear any foam that might have entered the deep venous system. Volumes of foam used were 2–8 ml for the SSV and 4–12 ml for the GSV (with or without AASV). When all the trunk and tributary veins and the varices were in spasm and fully occluded with foam the cannulae were removed and compression was applied with the limb still held in the elevated position. A roll of Velband[®] (Johnson and Johnson Medical, Ascot, Berkshire, UK) was applied directly along the line of the previously marked saphenous trunk and superficial varices, and retained using Peha[®] cohesive bandage (Hartmann, Germany). This regime produces direct compression over the treated veins. A thigh-length class II compression stocking (Credelast[®], Credenhill, Ilkeston, Derbyshire, UK) was applied over the bandage. The bandaging was left intact for 5–10 days, depending on the size of the veins after which time the bandaging was removed and the class II stocking worn alone for a further three weeks.

Pre-intervention questionnaire

Section 1 asked how much improvement was expected in lower limb symptoms (pain or aching, itching, tingling, cramps, restless legs, swelling and heaviness). The answers were sought separately for each leg to be treated. Section 2 asked about expected improvements in appearance, life-style (choice of clothes, work performance, social and leisure activities) and relationships. Possible responses were 'an awful lot', 'a lot', 'quite a bit', 'a little', and 'not at all' or 'I do not have this symptom'.

Post-intervention questionnaire

Patients were asked to grade the improvement (if any) that they had experienced in terms of symptoms, cosmesis, life-style and relationship using the same menu of responses. Pre- and post-treatment questionnaires were compared to ascertain whether expectations had been met.

Analysis

The responses 'an awful lot' and 'a lot' were grouped together to represent 'a significant improvement', and the responses 'quite a bit' and 'a little' were combined to signify 'a moderate improvement'. Symptoms were analysed by the number of limbs treated; other outcomes by number of patients. Subgroup analysis was performed to determine the effects of age, gender, CEAP clinical grade, and previous superficial venous surgery on the expectations and whether they were met using Chi-squared (χ^2). The Statistical Package for the Social Sciences (SPSS), version 14.0 software (SPSS, Chicago, IL, USA) was used for data analysis.

Results

Response rates and patient characteristics

282 (80%) patients returned the pre-treatment questionnaire and 281 (80%) returned the post-treatment questionnaire; 209 patients (60%) completed both questionnaires. Patients who completed post-treatment questionnaires (median age 59 years, IQR 48–68 for responders; median age 49, IQR 39–61 for non-responders; $P < 0.0005$, Mann–Whitney U test) and those who returned both questionnaires (median age 60, IQR 50–69 for responders; median age 51, IQR 40–62 for non-responders; $P < 0.0005$, MWU test) were significantly older than the non-responders. Otherwise, there were no significant differences between responders and non-responders including gender, severity of venous disease, and the proportion being treated for recurrent disease (previous VV surgery in the same saphenous trunk distribution). Thirty-five percent of patients were male, 25% had recurrent disease, two-thirds had uncomplicated VV (CEAP clinical grades 2 and 3) and one-third had complications of chronic venous insufficiency (CEAP clinical grades 4, 5 and 6). All patients were symptomatic (C2–6_S); all had VV of primary aetiology (E_P); 97% had superficial venous reflux only (A_S) and 3% had both superficial and deep venous reflux (A_{SD}); and all cases were secondary to reflux (P_R) not obstruction. Seventy-six percent of legs were having treatment of the great saphenous vein alone (GSV), 10% small saphenous vein (SSV) alone and the remainder a combination of GSV, SSV and AASV (anterior accessory saphenous vein).

Lower limb symptoms

These data were analysed by leg. Pre-treatment questionnaires were returned for 373 legs (80%), post-treatment questionnaires for 365 legs (79%), and both questionnaires for 270 legs (58%). Pain or ache was the most common

symptom being present in 85% of legs. Itching, restlessness, swelling, heaviness and cramp were less common occurring in 70%, 65%, 64%, 61% and 55% of the legs respectively; and tingling was the least common symptom occurring in only 38% of legs. A significant improvement in symptoms was expected in around one-third of legs, and a moderate improvement in the remaining two-thirds (Fig. 1). Between 49% and 63% of legs had a significant improvement in symptoms after UGFS, around 10% showed no improvement at all (Fig. 2). Expectations in respect of lower limb symptoms were met or exceeded in 80% legs (Fig. 3).

Patients who had had previous surgery were less likely to have their expectations met than those with primary veins in terms of pain (71% vs. 83%, $P = 0.042$), tingling (58% vs. 91%, $P = 0.002$), and restless legs (66% vs. 83%, $P = 0.033$).

Cosmesis

These data are analysed by patient. Over 90% of patients expected an improvement in the appearance of their legs (Fig. 4), 96% of patients experienced a significant cosmetic improvement (Fig. 5), and 86% of patients had their pre-intervention cosmetic expectations met (Fig. 6).

Life-style benefits

Approximately two-thirds of patients expected to be able to wear different clothes as well as an improvement in their working performance and social and leisure activities clothes as a result of their treatment (Fig. 4). Over 50% of patients experienced such improvements (Fig. 5) and almost 75% of patients had their expectations met with regard to these outcomes (Fig. 6).

Relationships

One quarter of patients expected improvement in their personal relationships following treatment (Fig. 4) and about 30% experienced such an improvement (Fig. 5). However, over 80% who had hoped for such an improvement

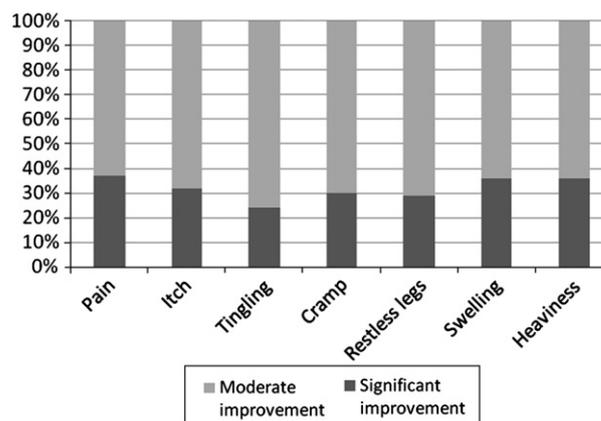


Figure 1 Percentage of limbs expecting a significant or moderate improvement in each lower limb symptom prior to treatment.

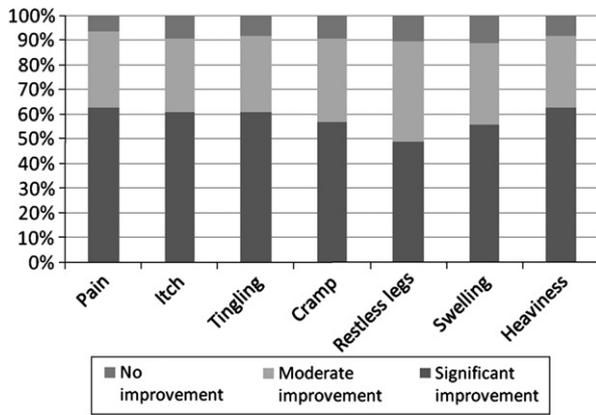


Figure 2 Percentage of limbs with improvement in lower limb symptoms six months following treatment.

had their expectations met or in a quarter of cases exceeded (Fig. 6).

Factors affecting outcomes

There was no difference in terms of cosmetic and social expectations according to whether the patient had had previous VV surgery or not. Younger patients (<55 vs. ≥55 years) were significantly more likely to be expecting an improvement in appearance of their legs (96% vs. 89%, $P = 0.034$), and the same was true for C2 disease compared with C5/6 (97% vs. 68%, $P < 0.0001$). Women (81% vs. 57%, $P < 0.0001$), patients <55 years (78% vs. 64%, $P = 0.016$) and C2 patients (vs. C5/6; 77% vs. 46%, $P = 0.0001$) were all more likely to expect improvements in their ability to wear different clothes after treatment. There were no observed differences in expectations of improvement in terms of work, relationships and social and leisure activities by gender, age, previous surgery or CEAP clinical grade.

Discussion

The main finding of this study is that UGFS for VV produces significant improvements in lower limb symptoms, cosmetic appearance, life-style and relationships in the majority of

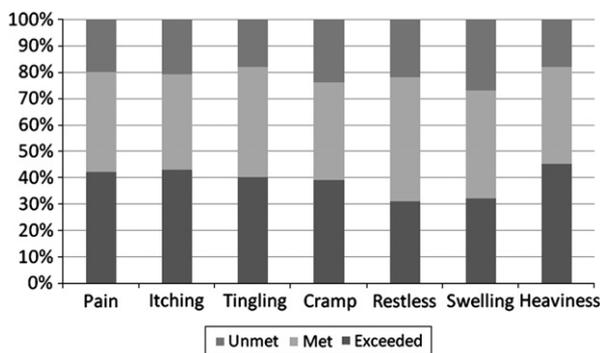


Figure 3 Percentage of limbs in which expectations of improvement in each lower limb symptom were exceeded, met or unmet.

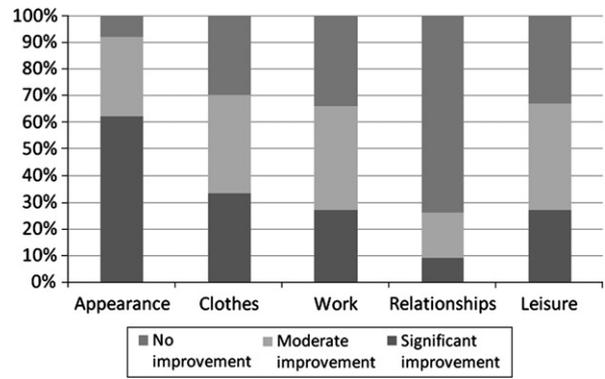


Figure 4 Percentage of patients expecting an improvement in cosmesis, and social and leisure activities prior to treatment.

patients. Furthermore, the great majority who expect such benefits have their expectations met or exceeded.

Virtually all patients were expecting treatment to improve their lower limb symptoms, and most did report such an improvement and had their expectations met or exceeded. In this regard, UGFS appears to be at least as effective as surgery,^{11,15-17} radiofrequency ablation (RFA) and LASER.¹⁸

The cosmetic aspects of VV treatment are well-recognised and in this series over 90% patients were expecting an improvement in the appearance of their legs.^{2,17} As has been reported by others after UGFS,¹⁵ 96% of patients experienced such an improvement, and more than 85% of patients had their cosmetic expectations met or exceeded. Again, these data suggest that UGFS is at least as effective as other treatments for VV.¹⁹

Perhaps not surprisingly, these favourable physical and cosmetic outcomes translated into a range of significant life-style benefits such as the ability to wear different clothes, improved work performance, and more satisfying social and leisure activities for those that wished them. This supports a number of studies showing that venous disease has a greater effect on physical (“what a person can do”) rather than mental (“how a person feels”) status.¹⁻⁴ However, these parameters are obviously



Figure 5 Percentage of patients who had an improvement in cosmesis, and social and leisure activities six months after treatment.

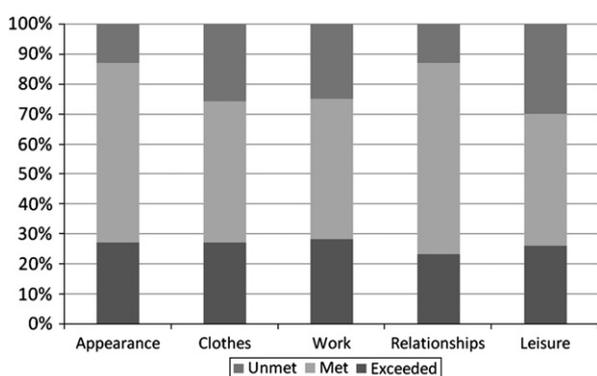


Figure 6 Percentages of patients in which the expected improvements in cosmetic, social and leisure outcomes were exceeded, met or unmet.

interconnected. Thus, UGFS also resulted in improvements in the quality of personal relationships in those patients who were seeking such benefits with the majority having their expectations met or exceeded.

Several studies have demonstrated that conventional surgery,^{2–10,16} LASER,¹⁰ RFA,²⁰ and UGFS^{8,15} for VV results in significant improvement in HRQL as determined by validated disease-specific and generic instruments. However, such studies and instruments do not allow patients to express their individual expectations of treatment and to what extent these expectations were met. The present type of study therefore adds value to traditional HRQL research in this patient group by personalising the treatment aims and by reducing the risks of the patient and the clinician talking at cross-purposes when discussing the risks and benefits of intervention.^{7,11}

Although the primary purpose of this study was not to compare UGFS with other treatments for VV, it is worth noting that when overall patient satisfaction has been assessed after VV surgery it has been found wanting,²¹ with only 23% reporting “complete satisfaction” and 26% reporting being “very dissatisfied” up to 10 years after surgery.¹¹ It seems likely that many medicolegal claims following VV surgery result from a lack of understanding, poor history taking and communication.^{7,11–13,17,22}

In this study the questionnaires were administered by post. The self-completion method was chosen, rather than a face-to-face or telephone interview to reduce the likelihood of introducing interviewer or social desirability bias. Self-administration could cause bias due to respondents’ lack of comprehension or motivation. Response rates were good at each time-point (around 80%), and although both questionnaires were available for only 60% of the cohort, this is comparable to other questionnaire studies in VV patients of 59–85%.^{2,6,7,9,22} Systematic bias in the loss of respondents is unlikely as those who were unhappy with treatment may be more likely to respond.

In conclusion, we have found that when specifically asked most patients admit to having a wide range of different expectations in relation to their VV treatment. Many of these expectations may be unanticipated by the clinician and thus remains unknown to them unless specifically sought during patient interview. Present data indicate that UGFS is usually able to meet, and often exceeds,

these physical and psychosocial needs and expectations 6 months after treatment. UGFS is, therefore, a highly effective treatment for VV from the patients’ perspective.

Conflict of Interest/Funding

None.

Appendix Supplementary material

Supplementary material can be found, in the online version, at [doi:10.1016/j.ejvs.2009.07.014](https://doi.org/10.1016/j.ejvs.2009.07.014)

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