

EFFECTIVENESS OF SUPERFICIAL VENOUS SURGERY IN TERMS OF QUALITY-ADJUSTED LIFE YEARS AND COSTS

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ABSTRACT

Aims: To assess the impact of superficial venous surgery (SVS) on health-related quality of life (HRQoL) and to explore the cost-utility of venous surgery.

Material and Methods: 143 patients (110 female and 33 male) enrolled for SVS between 2003 and 2005 in Helsinki University Central Hospital filled in the 15D survey before and six months after operation. Direct hospital costs were obtained from a patient administration database and were examined from the perspective of secondary care provider.

Results: After SVS, the HRQoL score improved in 71% of the patients, and the mean score increased from 0.919 (on a 0–1 scale) preoperatively to 0.933 postoperatively at 6 months ($p < 0.001$). Patients with a clinically important result from SVS (≥ 0.03 increase in the HRQoL score) had significantly worse HRQoL at baseline. At 6 months postoperatively, the mean (SD) hospital costs were 1637€ (693) and the mean quality-adjusted life year (QALY) gain 0.504 (1.674), respectively. Thus, the mean cost per QALY gained during a 6-month period was 3248€ for SVS.

Conclusions: Superficial venous surgery improves HRQoL, and is a cost-effective treatment of symptomatic superficial venous insufficiency.

Key words: Cost-utility; health-related quality of life; superficial venous surgery; venous insufficiency; varicose veins; treatment

INTRODUCTION

Surgery for superficial venous insufficiency constitutes a considerable part of the surgical workload. Studies of health-related quality of life (HRQoL) have

shown that even uncomplicated superficial venous insufficiency affects physical health aspects of quality of life (QoL) significantly (1) and that superficial venous surgery (SVS) improves patients' HRQoL when measured with either disease-specific or general questionnaires (2–5).

A major difficulty when evaluating the effects of different treatments for superficial vein insufficiency is the poor correlation between symptoms, signs, and results of examinations (6–7). Thus, introduction of a new method that improves surgical results is not necessarily followed by an increase in patient satisfaction. It is now widely recognized that the evaluation

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of treatments in chronic conditions, such as superficial vein insufficiency, must take into account the impact on HRQoL (8–10). As superficial vein insufficiency is such a common medical condition in the Western world, the cost of surgical treatment for the health system is a matter of concern for many regulatory authorities (10–12). Cost-utility analyses of SVS in an everyday setting are rare.

The aim of the present study was to explore the cost-utility of SVS in a real-world setting.

MATERIAL AND METHODS

Our hospital, a university referral clinic provides secondary and tertiary healthcare services for approximately 1.4 million inhabitants in Southern Finland. Since 2002 we have been running a large trial exploring the feasibility of evaluating the utility of routine services by collecting data on HRQoL before and after interventions (13). This approach enables the estimation of the number of quality-adjusted life years (QALYs) gained by treatment. Furthermore, data on utility of services can be combined with costs of providing treatment allowing comparison of the cost-utility of services offered for the patients.

A total of 308 consecutive patients entering scheduled hospital treatment in superficial vein surgery between 2003 and 2005 were invited to participate and fill in the 15D HRQoL questionnaire, and 175 (57%) of them agreed to do so. Six months after the operation, a follow-up questionnaire was mailed to all patients who had returned the first questionnaire. 82% of them returned also the follow-up questionnaire, and complete data for analysis were available from 143 patients (46% of the 308 patients invited).

All included patients were treated in an ordinary clinical setting. The indication for surgery was assessed clinically by combining the findings of the surgeon's clinical examination and the colour flow Duplex examination with the patient's symptoms and signs. Signs were classified according to CEAP clinical classification (C0, no visible or palpable signs of venous disease; C1, telangiectasias or reticular veins; C2, varicose veins; C3, edema; C4, pigmentation, eczema or lipodermatosclerosis; C5, healed venous ulcer; C6, active venous ulcer. According to this clinical classification the patient distribution was as follows: C0-C1: no patients, C2: 32 patients (22%), C3: 60 patients (42%), C4: 44 patients (31%), C5: 3 patients (2%) and C6: 3 patients (2%), one patient was not classified (1%). Dissection of the saphenofemoral or saphenopopliteal junction and short-stripping of the great saphenous vein (GSV) from the groin to just below the knee level or the small saphenous vein (SSV) from the popliteal fossa to the mid-calf perforator level is the standard operative technique in our clinic. Additional stab avulsions were performed for varicosities. No routine control at the outpatient clinic was scheduled.

UTILITY OF INTERVENTIONS

HRQoL was measured by the 15D HRQoL instrument (14–15). It is a generic, 15-dimensional, standardized self-administered HRQoL instrument that can be used both as a profile and a single-index score measure. The 15 dimensions are: moving, seeing, hearing, breathing, sleeping, eating, speech, eliminating, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity. For each dimensions, the respondent is asked to choose one of the 5 levels best describing his/her state of health at the moment (the best level being 1 and the worst level being 5). The valuation system of the 15D is

based on an application of the multi-attribute utility theory. A set of utility or preference weights, obtained from the general public through a 3-stage valuation procedure, is used in an additive aggregation formula to generate the utility score, i.e., the 15D score (single index number) over all the dimensions (for details, see <http://www.15d-instrument.net/15D>). The maximum score is 1 (no problems in any dimension) and the minimum score is 0 (being dead). The minimally important difference (MID) ≥ 0.03 is considered clinically significant or important (15). In most of the important properties, the 15D compares favourably with other similar HRQoL instruments (15–17).

COST-UTILITY

The standpoint for the analysis was that of the healthcare provider. Direct hospital costs were obtained from the Ecomed (Datawell Ltd., Espoo, Finland) clinical patient administration system, where all costs of hospital treatment of individual patients are stored on a routine basis. The summary costs used for analysis covered all relevant speciality-related costs (operation, ward, ambulatory visits, laboratory, radiology, pathology) including pre- and post-operative outpatient visits to the hospital from baseline to 6 months. Indirect costs, such as period of disability, were not included. In all patients the indication for operation was superficial trunk vein insufficiency, which does not significantly affect life expectancy. The HRQoL gain representing the utility of the intervention was thus assumed to last until the end of the remaining statistical life expectancy of each patient (18). Although this may not be strictly true, as HRQoL of SVS patients can deteriorate over the years as symptoms aggravate, this approach is often used for the calculation of QALYs gained by medical interventions.

ETHICS

All patients received previously scheduled routine treatment. Besides being asked to fill in the 15D questionnaire and to give a written informed consent, they were not approached in any other way. The study protocol was approved by the Ethical committee of the Helsinki and Uusimaa Hospital District (registration number HUS Dnro 537/E6/03).

STATISTICS

Data were analyzed using SPSS for Windows statistical software version 14.0 (SPSS Inc., Chicago, Illinois). The results are given as a mean and standard deviation (SD), or as percentages. The significance of the differences between baseline and 6-month follow-up HRQoL scores was analyzed with Student's paired t-test for dependent samples. When comparing percentage distributions between the groups, Chi-square test was used. P-values less than 0.05 were considered statistically significant.

RESULTS

The HRQoL score improved in 71% of the patients (Table 1). Of the 15 dimensions of health covered by the HRQoL instrument, "sleeping" and "discomfort and symptoms" improved in a statistically significant manner after SVS (Fig. 1).

The mean HRQoL score increased from 0.919 (on a 0–1 scale) preoperatively to 0.933 at 6 months postoperatively ($p < 0.001$). Mean (SD) hospital costs at 6

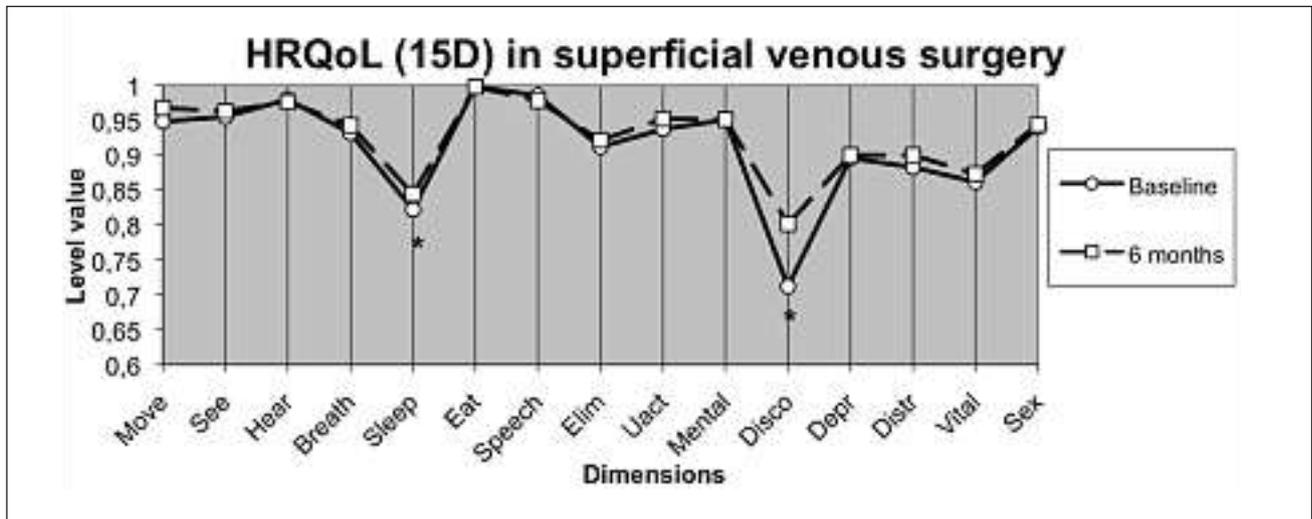


Fig. 1. 15D profile before and six months after superficial venous surgery (* denotes significant improvement at the $p < 0.05$ level).

months were 1637 € (693) after superficial venous surgery. Mean cost per QALY gained was 3248 € for superficial venous surgery.

Those with a clinically significant result from SVS (≥ 0.03 increase in the HRQoL score) had markedly worse HRQoL at baseline ($p < 0.001$) (Table 2). There were no other differences between the patients whose HRQoL improved in a clinically significant manner and those with little or negative change.

The mean HRQoL score increased from 0.927 preoperatively to 0.939 at 6 months postoperatively ($p = 0.012$) in the group of patients with uncomplicated venous disease (clinical classes C2–C3). Similarly, in the group of patients with complicated venous disease (C4–C6) the mean HRQoL score increased from 0.904 to 0.921 ($p = 0.017$). There was no statistically significant difference in the HRQoL score change between these two patient groups (uncomplicated vs. complicated venous disease).

In sensitivity analysis the cost per QALY gained in SVS ranged from 2,097 to 7,200 depending on the assumptions used in the analysis (Table 3).

A total of 156 patients (111 female) decided not to take part in the study. Those participating were

slightly, although not statistically significantly, more often female (77% vs 71%, $p = 0.36$), and somewhat older (48 years vs. 44 years, $p = 0.002$) than patients not participating.

TABLE 1

Health-related quality of life (HRQoL) and cost data. Values are percentages or means with standard deviations (SD) in parentheses.

	Varicose vein surgery
Mean HRQoL at baseline	0.919 (0.067)
Mean HRQoL at 6 months	0.933 (0.066)
HRQoL improved at 6 months, % of patients	71
Mean hospital costs at 6 months, €	1637 (693)
Mean OALYs gained at 6 months	0.504 (1.674)
Mean QALYs gained at 6 months (discounted by 5%)	0.228 (0.755)
Cost per QALY, €	3248

TABLE 2

Characteristics of the patients operated with superficial venous surgery whose health-related quality of life (HRQoL) improved in a clinically significant manner (improvement ≥ 0.03 at six months) compared to those with little or negative change (HRQoL change < 0.03). Values are percentages or means with standard deviations (SD) in parentheses.

Variable	Worse or clinically insignificant improvement (HRQoL change < 0.03)	Clinically significant improvement (HRQoL change ≥ 0.03)	p-value
Number of patients	100	43	–
Mean HRQoL at baseline	0.938 (0.055)	0.875 (0.074)	< 0.001
Mean age, years	47 (10.1)	49 (11.3)	0.43
Women, %	76	77	0.87
Mean hospital costs at 12 months, €	1640 (666)	1632 (761)	0.95
Mean waiting time, days	327 (180)	353 (255)	0.55

TABLE 3

Cost-utility analysis: base case and sensitivity analyses (SA) varying the discount rate between 1% and 5%, using median values, and using the upper and lower values of the 95% confidence interval (CI) for the mean differences in treatment effectiveness (improvement in health-related quality of life (HRQoL)) and costs.

	Costs €	QALY gain	Cost per QALY gained, €
Base case analysis using mean values	1637	0.504	3248
median values	1336	0.377	3541
SA varying the discount rate for QALYs			
discount rate 5%	–	0.228	7194
discount rate 3%	–	0.300	5456
discount rate 1%	–	0.417	3923
SA varying treatment effectiveness (QALY gain)			
upper 95% CI	–	0.781	2097
lower 95% CI	–	0.227	7200
SA varying treatment costs			
upper 95% CI	1752	–	3476
lower 95% CI	1522	–	3020

DISCUSSION

We found that SVS is an effective intervention in improving HRQoL of patients. This is in accordance with earlier reports on the effect of SVS on HRQoL (2–5). In our study, however, SVS was also found to be a cost-effective treatment with lower cost per QALY gained than found for some other surgical treatments, such as total knee or hip arthroplasty (19).

We acknowledge that there are some shortcomings in our study. First, we estimated the cost per QALY from the point of view of the healthcare provider, as only direct hospital costs were included in the analysis. Nowadays, conventional venous surgery has endovenous treatment options, from which patients often recover more rapidly (20). Indirect costs of those treatments, such as the period of disability, may be much lower than after surgery. However, the method of using cost data that are readily available from the hospital accounting system instead of tediously collecting data from individual patients can be seen a way of acquiring reasonably reliable cost data. Further, the new endovenous methods were not yet in everyday clinical use at our institution at the time of the data collection. Second, our follow-up was relative short. Using the generic HRQoL questionnaire Short Form (SF)-36, Blomgren et al (5) showed, that surgery for varicose veins improves HRQoL in the physical domain “bodily pain” of the SF-36 questionnaire after 2 years. Longer follow-up is needed to observe whether the HRQoL deteriorates over time. Indeed, the need for reoperations would decrease the gain. The major strength of our study is that it reports the cost-utility of SVS in the context of routine follow-up in a real-world setting in our hospital. The findings are based on unselected patient material and thus reflect results obtained in normal practise. The

approach taken follows the standpoint that economic evaluations are more valid, if effectiveness data reflects normal practise (21).

The 15D HRQoL instrument is not a disease-specific tool for QoL measurements. Disease-specific instruments such as the Aberdeen Varicose Veins Questionnaire, the Chronic Venous Insufficiency Questionnaire, and the Venous Insufficiency Epidemiological and Economic Study (VEINES)-QoL and VEINES symptom (VEINES-Sym) questionnaires are more sensitive for changes of QoL for venous disease (22–24). On the other hand, 15D is standardized for the calculation of QALYs gained by medical interventions. Thus, it also enables routine comparison of the cost-utility of services offered for the patients over a wide range of medical specialties. Such data are essential in order to be able to ensure that healthcare is effective and that available resources are allocated to treatments that have been shown to be cost-effective.

Compared to some other interventions studied in Southern Finland, the cost per QALY gained in SVS was quite low: it was similar to disc herniation surgery (25), half of the cost per QALY of hip replacement surgery, fourth of that of knee replacement surgery (19). Further, it was clearly below the commonly used threshold level for the cost per QALY (30,000–50,000). In fact, the cost per QALY gained by SVS is one of the best reported. This should help to inform decisions about how venous surgery should be prioritised appropriately within national health services. To our best knowledge, this is the first study to explore the cost per QALY among SVS.

In conclusion, SVS improves HRQoL in patients with symptomatic superficial venous insufficiency. It is also a cost-effective treatment when compared to many other surgical procedures studied so far. Those patients with severe preoperative symptoms seem to benefit most from SVS. Longer follow-up is needed to see, whether the results deteriorate over time. There is also a clear need for prospective series comparing effectiveness of SVS to that of modern endovenous treatments.

ACKNOWLEDGEMENTS

This study was financially supported by Karin and Einar Stroem Foundation.

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Received: February 16, 2009

Accepted: August 27, 2009