Tidsskriftet Tidsskrift for Den norske legeforening

Steam ablation versus stripping of great saphenous varicose veins

ORIGINAL ARTICLE

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BACKGROUND
Use of new technology can lead to changes in the treatment course for patients and in treatment costs for the health service. The aim of this study was to compare sickness absence and time to resumption of daily activities, as well as treatment costs, for two surgical treatments for varicose veins: endovenous steam ablation and vein stripping.

MATERIAL AND METHOD
This prospective observational study included 46 patients treated with steam ablation and 37 treated with vein stripping in the period 2015–2016. The two groups were matched with respect to age, sex, occupational status and classification. After treatment, patients were interviewed every other week until daily activities had been resumed. Detailed information on expenditure related to personnel, equipment, premises and materials was used to calculate the cost of treatment.

RESULTS
Patients treated with steam ablation resumed daily activities after a median of 0 (interquartile range 0–2) days versus 4 (2–7) days for vein stripping ($p < 0.001$), and sporting activities after 4 (2–9) days versus 11 (3–19) days ($p < 0.004$). For patients in employment, sickness absence after steam ablation was 2 (2–5) days versus 14 (6–21) for patients treated with vein stripping ($p < 0.001$). The estimated treatment cost for steam ablation was NOK 5 973, compared with NOK 10 109 for vein stripping.

INTERPRETATION
Steam ablation led to shorter convalescence and sickness absence for the patient, and lower costs for the hospital. Reduced sickness absence also implies lower costs for society.

Main message

Steam ablation of varicose veins was less costly for the hospital than vein stripping

Steam ablation results in more rapid resumption of daily activities

Steam ablation results in significantly shorter sickness absence

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Varicose veins in the legs are a common health problem with a prevalence of over 20 % in the adult population. They are caused by failure of valves in the superficial, or possibly the deep, venous system (1). The valve failure leads to reflux and increased pressure in the superficial venous system, with subsequent dilatation and lengthening of the vein, resulting in varicosity. Patients describe symptoms such as pain, heaviness, itching, leg cramps, and tired legs. Chronic venous failure can lead to partially irreversible changes such as eczema, pigmentation and ulceration. Incidence varies with sex, overweight, gravidity, age, genetics and ethnicity (1, 2). In Norway, 95 534 recorded interventions for varicose veins were financed by the public health service during the period 2003–2016 (3).

The aim of treatment is to abolish superficial venous reflux and remove the varicose veins. Common treatment methods are vein stripping via a groin incision, or endovenous ablation in which the vein is destroyed by thermal or chemical means. Thermal energy sources include steam, lasers or radio frequencies; chemical ablation involves the use of foam or medical glue. Vein stripping is usually performed under regional or general anaesthesia (1, 4). Endovenous ablation is most often performed under local anaesthesia and produces clinical outcomes comparable to those of vein stripping (5, 6).

Vein stripping has been the standard treatment at St. Olavs hospital, but outpatient steam ablation was introduced in addition in 2013. Although new treatment methods may require clinics to make greater investments in equipment, such investments may reduce the cost of treatment. The National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway states that both efficacy and costs should be considered before new techniques are adopted (7). Hospital costs are important, but the consequences for sickness absence may also be of interest.

The aim of this study was to compare the treatment costs of outpatient endovenous steam ablation versus day-surgery vein stripping in cases of great saphenous vein insufficiency, and to examine whether the two treatments differ in terms of time to resumption of normal activities and time to return to work.

Material and method

The study was a prospective observational study in an outpatient and day-surgery setting at two hospitals in the same healthcare region, and included patients treated during the period October 2015–October 2016. Endpoints were time to resumption of daily activities, and sickness absence. The project was exempt from the requirement for approval by the Regional Committees for Medical and Health Research Ethics (REC). Exemption from the duty of confidentiality was also granted to enable suitable patients to be identified via a surgery planner and patient administration programme (REC Central 2015/1458). All patients over the age of 18 who were scheduled for vein stripping or outpatient steam ablation were invited to participate, with invitations issued on a continuous basis. The project did not lead to changes in allocated treatment, as the patients had been assigned to treatment prior to the start of the study, with treatment method determined by the surgeon's level of experience and the capacity of the clinic at the time of allocation. Treatment data were recorded, and two questionnaires see appendix) were developed based on a previous study ((8). Part 1 of the questionnaire was completed at the time of enrolment. Patients received Part 2, about daily activities, sport and sickness absence, upon discharge and were interviewed by telephone every fourteen days until they had resumed their preoperative activity level.

Sample size calculations indicated that 28 patients were required in each group to be able to detect differences in sickness absence with a power of 80 % and significance level of 0.05 (two-tailed) (9). A difference of three days was considered clinically significant, and the standard deviation was set to four days based on a similar study (10).

If the patient resumed activity on the day of treatment or the following day, the number of days was set to zero. For patients who did not resume work and activities for reasons other than their varicose vein treatment, the number of days was estimated on the basis of information about when they believe they would have returned to work.

Data were analysed in Microsoft Excel and IBM SPSS Statistics version 24 (Armonk, NY, USA). Group differences in outcome measures were corrected for treatment location, sex, age, and dichotomous CEAP score (clinical-aetiology-anatomy-pathophysiology, 3 or above) using multiple linear regression, and bootstrap confidence intervals were calculated. Between-group comparisons of continuous data were performed using a Mann-Whitney U-test or Kruskal-Wallis test due to the data not being normally distributed. Categorical data were analysed using a Chi-Squared test or Fisher's exact test.

Costs were calculated from the hospital perspective. Standardised treatment costs for vein stripping and steam ablation were calculated using a microcosting approach (11). Prior to the start of the study, we conducted observation days at the outpatient clinic, observation unit and operating theatre in St. Olavs hospital to record the use of time and personnel, standard units and intervention costs, as well as other units or resources involved in the standard procedure. The standard surgical team for vein stripping comprised two surgical nurses, a surgeon, an anaesthesiologist and an anaesthetic nurse; the equivalent for steam ablation was two nurses and a surgeon. We calculated the average time use for each occupational group (prior to the start of the

study) based on information from 30 patients previously treated with vein stripping and 53 patients who had undergone steam ablation. Wages plus social costs were included in labour cost calculations. Unit costs were retrieved from the financial systems of St. Olavs hospital.

Results

Of the 86 patients invited, 83 agreed to participate. Steam ablation was performed on 46 patients, all at St. Olavs hospital. Vein stripping was performed on 37 patients, of whom 21 were treated at Molde hospital and 16 at St. Olavs hospital. Patient characteristics are shown in Table 1. There was no difference between treatment groups or treatment locations with respect to age, sex, occupational status, education or CEAP score.

Table 1

Characteristics of patients treated with steam ablation or vein stripping, subdivided by hospital. Percentages unless otherwise specified.

Characteristic	Steam	Stripping		p-value
	St. Olavs hospital (n = 46)	St. Olavs hospital (n = 16)	Molde hospital (n = 21)	
Age, median (interquartile range)	53.7 (43–64)	51.6 (47–63)	48.3 (42–64)	0.599[1]
Female	71.7	68.8	66.7	0.910[2]
In employment	65.2	75.0	81.0	0.390[2]
CEAP classification[3]				
C2	56.5	43.8	57.1	0.511[2]
C3–C6	43.5	56.2	42.9	0.645[2]
Higher education	56.5	50.0	42.9	0.576[2]

[1]Kruskal-Wallis test

[2]Chi-Squared test

[3]Clinical-aetiology-anatomy-pathophysiology, clinical classification of varicose veins

Patients treated with steam ablation reported 2 (0–3) days with limitations in daily activities, whereas those who underwent vein stripping reported 10 (4–16) days ($p < 0.001$). Patients treated with steam ablation resumed daily and sporting activities after 0 (0–2) and 4 (2–9) days respectively, versus 4 (2–7) and 11 (3–19) after vein stripping ($p < 0.001$) (Table 2).

Table 2

Self-reported time to resumption of daily and sporting activities for patients treated with steam ablation or vein stripping. Values are median (interquartile range) unless otherwise specified.

Variable	Steam (n = 46)	Stripping (n = 37)	Difference[1] (95 % CI)	p-value
Number of days until patient resumes daily activities	0 (0–2)	4 (2–7)	−4.1 (−6.9 to −1.3)	< 0.001
Number of days with limitations in daily activities	2 (0–3)	10 (4–16)	−8.5 (−13.2 to −4.6)	< 0.001
Number of days until patient resumes sporting activities	4 (2–9)	11 (3–19)	−5.1 (−10.6 to −0.6)	0.073

[1]Difference based on multiple linear regression, controlled for treatment location and age, and with bootstrap confidence interval and p-value.

Thirty of 46 patients treated with steam ablation and 29 of 37 treated with vein stripping were employed at the time of enrolment. Patients treated with steam ablation were back at work after a median of 2 (2–5) days, compared with 14 (6–21) days for patients who underwent vein stripping ($p < 0.001$) (Table 3). Twenty-two of the patients treated with steam ablation reported that they could have returned to work before the end of their allocated sickness absence, versus 12 of the patients treated with vein stripping. Patients treated with steam ablation reported needing 1 (0–4) day(s) of sickness absence, whereas patients treated with stripping reported needing 14 (7–20) days. Two patients in the group treated with vein stripping did not resume work, for reasons unrelated to the treatment.

Table 3

Self-reported sickness absence and need for sickness absence measured in days, in patients employed at the time of enrolment and treated with steam ablation or vein stripping. Values are median (interquartile range). Difference corrected for hospital, age, sex and classification.

Variable	Steam (n = 30)	Stripping (n = 29)	Difference[1] (95 % CI)	p-value
Sickness absence	2 (2–5)	14 (6–21)	−10.6 (−15.3 to −5.9)	< 0.001
Could have been back at work	0 (0–4)	12 (4–20)	−10.8 (−15.8 to −5.9)	< 0.001
Need for sickness absence	1 (0–4)	14 (7–20)	−11.2 (−14.9 to −7.9)	< 0.001

[1]Difference based on multiple linear regression, controlled for hospital, sex, age and CEAP (clinical-aetiology-anatomy-pathophysiology, clinical classification of varicose veins), and with bootstrap confidence intervals and p-values.

Treatment costs are shown in Table 4. Our calculations revealed that the standard cost for the hospital was NOK 5 973 per intervention for steam ablation and NOK 10 109 per intervention for vein stripping, i.e. a cost difference of NOK 4 136. Total personnel costs were NOK 1 638 for steam ablation and NOK 5 635 for vein stripping. This difference was due to the use of personnel in association with regional or general anaesthesia during vein stripping. In addition, surgical nurses spent 4.08 hours on each case of vein stripping, while the nursing time for steam ablation was 2.48 hours. The cost of disposable equipment was NOK 3 399 for steam ablation, compared with NOK 1 578 for vein stripping. This difference was due to the cost of the steam catheter. Costs related to cleaning and premises were NOK 1 312 for vein stripping and NOK 550 for steam ablation. Cost differences for reusable equipment, medicines and food are shown in Table 4.

Table 4

Cost per patient treated with steam ablation or vein stripping at St. Olavs hospital, calculated on the basis of cost units involved, volume and unit cost per unit volume. Costs are given in Norwegian kroner (NOK) and reflect 2015 prices.

Units included (unit of measurement)	**Volume/number**		**Unit cost**		**Calculated cost**	
	Steam	**Stripping**	**Steam**	**Stripping**	**Steam**	**Stripping**
Personnel						
Nurse (hours)	2.48		367		910	
Surgical nurse (hours)		4.08		403		1 644
Anaesthetic nurse (hours)		2.04		403		822
Intensive care nurse (hours)		2.54		403		1 024
Surgeon (hours)	1.13	1.29	644	644	728	831
Anaesthesiologist (hours)		2.04		644		1 314
Total personnel					*1 638*	*5 635*
Disposable equipment						
Vein stripper (number)		1		118		118
Steam catheter (number)	1		2 500		2 500	

Units included (unit of measurement)	Volume/number		Unit cost		Calculated cost	
	Steam	**Stripping**	**Steam**	**Stripping**	**Steam**	**Stripping**
Vein stripping pack (number)		1		1 460		1460
Steam ablation pack (number)	1		899		899	
Total disposable equipment					*3 399*	*1 578*
Cleaning						
Small operating theatre (number)	1		90		90	
Midsize operating theatre (number)		1		450		450
Observation unit (number)		1		100		100
Sterilisation of equipment, vein stripping (number)		1		666		666
Sterilisation of equipment, steam ablation (number)	1		420		420	
Personnel- and patient clothing, vein stripping (number)		1		96		96
Personnel- and patient clothing, steam ablation (number)	1		40		40	
Total cleaning					*550*	*1 312*
Premises						
Small operating theatre (hours)	1.20		182		218	
Midsize operating theatre (hours)		2.04		322		657
Observation unit (hours)		1.22		546		667
Total premises (including electricity)					*218*	*1 323*

Units included (unit of measurement)	Volume/number		Unit cost		Calculated cost	
	Steam	**Stripping**	**Steam**	**Stripping**	**Steam**	**Stripping**
Medicines						
Medicines, vein stripping (number)		1		218		218
Medicines, steam ablation (number)	1		61		61	
Total medicines					*61*	*218*
Reusable equipment						
Steam generator and pump (number)	1		56		56	
Ultrasound scanner (hours)	1.13	0.17	45	45	51	8
Total reusable equipment					*107*	*8*
Food and drink (procedure)		1		34	0	34
Overall total per treatment					**5 973**	**10 109**

Three of 46 patients treated with steam ablation and 11 of 37 treated with vein stripping reported procedure-related complications.

Discussion

Our calculations showed that the standard treatment costs for steam ablation were lower than those for vein stripping. In addition, we found that patients treated with steam ablation had shorter sickness absence, resumed daily and sporting activities sooner, and experienced fewer days with limitations in daily activities.

We calculated costs related to personnel and premises based on estimated time use in our own clinic. The need for training of healthcare personnel affects time use, and it is not always possible to streamline a clinic in the manner achieved by some institutions reporting short procedure times for vein stripping (6). Training requirements for surgeons affect the operating time and will have the greatest impact on vein stripping, which involves the most personnel. We have tried to compensate for this by assuming that only a single surgeon is used. Since endovenous steam ablation is a new procedure at our clinic, it is possible

that our personnel have not yet reached the top of the learning curve and may therefore require more time to perform the procedure. Lower staffing requirements and shorter treatment times may lead to reductions in the cost of steam ablation in the long term, which will further increase the differential cost in favour of steam ablation. Time use in our department is considered comparable to that of other institutions, both for vein stripping and for steam ablation (6).

We found that costs related to disposable materials were higher for steam ablation than for vein stripping, due to the price of the steam catheter. Some studies have found this cost to be the deciding factor with respect to which treatment method is cheaper (12, 13).

Costs were calculated for a standardised intervention, a method that has been used previously (14). Recording the use of resources for each operation would have provided information on variation in time use and costs, but was beyond the scope of this study. We found the cost of steam ablation to be lower than that of vein stripping, but there is reason to believe that the cost may vary as a result of local conditions related to anaesthesia and operating techniques, labour costs, organisation, and personnel allocation. This may be one explanation for why another Norwegian study found the cost of vein stripping to be somewhat lower than we did (15).

Expenditure on post-treatment health care should usually be taken into account too, but was omitted from our study as there has been little reported need for healthcare provision after varicose vein treatment (11, 12). In our study, however, several procedure-related symptoms and complications were reported in patients who underwent vein stripping. Future studies examining the cost of varicose vein treatment should include these costs in addition.

We defined daily activities as simple, personal activities such as dressing and undressing, whereas others have also included more complex activities such as childcare and driving a car (16). We found that patients who underwent vein stripping resumed daily activities after a median of four days and reported limitations in daily activities for ten days. Patients treated with steam ablation resumed daily activities on the first postoperative day and reported limitations for two days, in line with other studies (10), (17–19).

Median sickness absence was 14 days in our patients who underwent vein stripping. Others have reported sickness absence ranging from 4 to 26 days following vein stripping; this variation may reflect differences in sickness benefit schemes, in people's expectations, and in surgical techniques (10, 12, 13, 19)(19–26). Our patients who were treated with steam ablation resumed work after a median of 2 days; a substantial difference versus vein stripping of 12 days (uncorrected). As an illustration, 12 days may mean a cost saving for society in the order of NOK 27 000 if we assume an annual salary of NOK 518 000 (27). This gain would come in addition to the lower hospital costs associated with the use of steam ablation.

As our study design did not include randomisation and blinding, we cannot fully exclude the possibility that the observed differences in sickness absence and resumption of activities reflect other, unknown factors. Sampling bias may also have occurred as we recruited patients continuously. The results must

therefore be interpreted in light of these factors. Strengths of the study include the structured way in which questions relating to daily activities, exercise and sickness absence were delivered, as well as the fact that the patients were familiar with the questions in advance. This applied equally to both groups.

The short follow-up time and absence of a measure of clinical efficacy mean that we cannot draw conclusions about clinical outcomes *per se* or about the potential need for further treatment in the future, and thus we cannot draw conclusions about economic differences over time either. The results of another study, however, suggest that vein stripping and steam ablation are likely to have similar clinical outcomes, and no statistically significant differences in recurrence have been reported (28).

Another strength of our study is that all patients who were treated over a particular period were given the opportunity to participate, and only three declined. The patients were followed up closely, and we achieved a response rate of 100 %. We therefore assume that the risks of recall bias, follow-up bias and attrition bias are low (29).

There is little research in general on the short and long-term efficacy of steam ablation, and there is a need for good randomised clinical trials. There is also a need for better economic data, as shown by the results of a modelling study (15).

We wish to thank the staff at the surgical outpatient clinic and day-surgery unit at St. Olavs hospital and Molde hospital, as well as Snorre Gilde for calculation of personnel costs and other expenses.

The study is financed with limited funds from 'Samarbeidsorganet', a collaboration between Central Norway Regional Health Authority and universities and university colleges in the region.

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Publisert: 6 March 2019. Tidsskr Nor Legeforen. DOI: 10.4045/tidsskr.18.0525
Received 18.6.2018, first revision submitted 28.11.2018, accepted 3.1.2019.