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Original Article

"Comparative hospital based observational study on endovenous laser ablation versus conventional surgery in patients with lower limb varicose veins at our tertiary care hospital"

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ABSTRACT

Introduction: Even though EVLA is increasingly popular and together with other minimally-invasive techniques is rapidly replacing surgical stripping, surgical treatment is still widely used. Our study aimed to compare the clinical outcomes and the quality of life following either endovenous laser ablation (EVLA) or conventional surgery for varicose veins of the lower limbs.

Aim and Objective of the study: the present study is aimed to compare the clinical outcomes and the quality of life in varicose veins patients who had undergone endovenous laser ablation or open surgery.

Materials and Methods: It is a prospective randomised study. A total of 268 patients were treated for symptomatic varicose veins since the previous year, among them 130 patients underwent open surgery and 138 patients received endovenous laser ablation.

Results: Disease-specific quality of life at six weeks was significantly better in the EVLA group. Similarly, VCSS and AVVQ scores at six weeks were also better in the EVLA group. Patients in the EVLA group experienced less postoperative pain and therefore needed fewer supplementary analgesic drugs. In addition, patients in the EVLA group managed to return to work and normal activities sooner than those in the surgery group. However no statistically significant differences were found between groups for clinical recurrence, overall satisfaction, rate of complications and secondary procedures at the end of one year.

Discussion and Conclusion: Both techniques — EVLA and surgery — yielded similar results in terms of efficacy, clinical recurrence rates and overall patient satisfaction. Although in the present study we did not find EVLA to be superior to surgical stripping in the long term, a significant difference was seen in the immediate post operative period in terms of post operative pain and the duration of time required to return to work.

Therefore, we assume that EVLA should be recommended over surgical stripping, especially for patients who need to resume to work in post-operative period.

Key-words: endovenous ablation laser surgery, conventional surgery, varicose veins, surgical stripping and VCSS score

INTRODUCTION

Varicose veins in the lower extremities is affecting nearly 10−20% of the adult population. The prevalence is increasing with the increase in age, affecting 12% adults in the age group 18-24 years and 56% in the age group 55-64 years [1,2]. Having regard to the ageing of the human population, in several decades this disease is predicted to affect roughly half of the adult population [3]. Due to serious complications like the development of gaiter area ulcers

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in particular, this pathology adversely affects the patients' quality of life and places a heavy burden on the healthcare system [4]. The main objectives of the treatment for varicose veins include prevention of complications, alleviation of symptoms, and improvement of the patients' quality of life. The most common method of treatment for this condition is an open surgery proposed by W. Keller 110 years ago [5]. During a surgical procedure, the saphenofemoral junction is disconnected from the venous system via ligation in the case of the great saphenous vein disease or the saphenopopliteal junction is ligated in the case of the small saphenous vein damage. The ligation is usually followed by the great or the small saphenous vein removal (stripping). The surgical intervention usually alleviates the symptoms and yields the desired results, yet sometimes the postoperative period is aggravated by the development of complications such as pain, bleeding, infection (inguinal or popliteal), thrombophlebitis, saphenous nerve damage, or impaired lymph drainage. Furthermore, the procedure leaves postoperative scars and there is a risk of hyperpigmentation [6]. Moreover, recurrent varicose veins are known to be a common problem after surgery: the literature demonstrates a recurrence rate of 60% after 5 years of follow-up observation [7, 8]. The recurrence is mostly caused by neovascularisation, anatomic peculiarities (e.g. a double great saphenous vein), surgical technique errors, or an incomplete procedure [9].

The last decade has seen the emergence of minimally invasive methods of treatment for varicose veins, like the endovenous laser ablation (EVLA) . EVLA is a percutaneous minimally invasive technique where a laser fibre is inserted under ultrasound guidance into the trunk of the affected vein. Within the lumen of the vein the energy generated by the laser produces temperature of up to 1000°C [10]. During EVLA, the walls of the vein are directly affected by the laser energy [11], heat [12], and steam bubbles [13], which results in venous wall microperforation due to the high temperature [14], eventually followed by shrinkage of the venous wall, complete subsequent scarification, and vein occlusion.

EVLA is a simpler and less complicated procedure [15]. The treatment requires only local rather than general or spinal anaesthesia. In addition, it can be done in a day surgery setting, which means that patients do not need to be hospitalised and they can sooner return to their normal life [16]. Moreover, laser ablation is associated with less postoperative pain, leaves no scars and may be applied in patients under anticoagulant therapy without the need to discontinue the treatment.

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Some authors claim that EVLA is superior to the conventional open surgical treatment because it is not as radical as an open surgery and it is also characterised by minimised tissue damage and thus a lower number of postoperative complications, a better index of the postoperative quality of life, a better cosmetic effect, and an earlier return to normal activity [17–19]. Although the procedure-related costs were found to be higher for EVLA than for conventional surgery [19, 20], EVLA has been identified as having the highest chance of being the most cost-effective method of treatment for varicose veins in the long term [21, 22]. Even though EVLA is increasingly popular and together with other minimally-invasive techniques is rapidly replacing surgical stripping, surgical treatment is still widely used. Our study aimed to compare the clinical outcomes and the quality of life in patients with varicose veins of the lower limbs, who received endovenous laser ablation or open surgery.

AIM AND OBJECTIVES OF THE STUDY: the present study is aimed to compare the clinical outcomes and the quality of life in varicose veins patients who had undergone endovenous laser ablation or open surgery.

MATERIALS AND METHODS

Source of data: This study was conducted at Dept. of Vascular Surgery at Nizams institute of medical sciences.

Study population: We included the subjects in the age group of 40-60 years of both the genders presenting with varicose veins and had either undergone endovenous laser ablation or open surgery.

Study Design: It is a prospective randomised study. A total of 268 patients were treated for symptomatic varicose veins since the previous year, among them 130 patients underwent open surgery and 138 patients received endovenous laser ablation.

Inclusion criteria: We included the subjects in the age group of 40-60 years of both the genders presenting primary, symptomatic varicose veins with isolated saphenofemoral or saphenopopliteal junction incompetence and the great saphenous vein (GSV) or the small saphenous vein (SSV) reflux on duplex ultrasound imaging who has undergone endovenous laser ablation or open surgery

Exclusion Criteria: We excluded the patients age under 18, CEAP clinical grades C1, C5 or C6, pregnancy or breastfeeding, III° obesity (BMI> 40 kg/m2), arterial insufficiency or incompetence of the deep venous system

Data Collection: Patients who were found eligible for the study were asked to sign a written consent to participate in the study. Prior to the surgery, patients' demographic data (sex, age

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at the time of the treatment, and BMI) were collected, the clinical grade according to the CEAP classification was determined, and the vein (the great saphenous vein [GSV] or the small saphenous vein [SSV]) to be surgically treated was recorded.

The severity of the symptoms was evaluated using the Venous Clinical Severity Score (VCSS). This is an instrument based on the evaluation of nine main symptoms of the disease: pain, varicose veins, venous oedema, skin pigmentation, inflammation, induration, and ulcers (duration, number, and size of active ulcers) [23]. The VCSS-based evaluation was conducted by a consulting vascular surgeon. The total score ranges from 0 (represents no significant venous disease) to 30 (maximum). Before the study, the patients were also asked to fill out the Aberdeen Varicose Veins Questionnaire (AVVQ). This questionnaire consists of 13 items allowing for a detailed evaluation of the symptoms of chronic venous insufficiency. The AVVQ evaluation includes both symptoms (pain and itching) and clinical signs (oedema, hyperpigmentation, and ulceration). The questionnaire also includes questions related to the effect of the disease on the patient's quality of life, which is highly important in the contemporary studies in the field of phlebology [24]. The total score of the questionnaire ranges from 0 (no effect on the quality of life) to 100 (a maximum effect). The postoperative complications were grouped into: 1) minor, which do not require hospitalisation; and 2) major, which cause long-term adverse effects or death, and require hospitalisation and treatment. Postprocedural pain scores and the intake of analgesics were evaluated during the first seven days after the procedure at the end of the day. Pain scores were taken by the patient with the help of a 10-cm visual analogue scale (0 — no pain, 10 — the greatest pain). In addition, the time needed to return to normal activity and work was also registered.

Interventions: All patients were marked before the surgery or EVLA using guidance by duplex ultrasonography. An open surgery was performed under general or spinal anaesthesia. Depending on whether the trunk of the GSV or the SSV was affected, usually either the saphenofemoral or saphenopopliteal junction was ligated and the respective trunk was stripped.

EVLA was performed under perivenous tumescent anaesthesia.

The procedure started with a percutaneous insertion of a 19-G needle into the affected venous trunk under ultrasound guidance. Subsequently, a guidewire was passed through the needle to the site of the saphenofemoral or saphenopopliteal junction. Then the needle was removed, and a 5-Fr catheter was inserted over the guidewire. Finally, the guidewire was removed and an optical fibre was inserted approximately 1−2 cm distal from the saphenofemoral or

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saphenopopliteal junction. The laser energy was obtained by applying a 1470-nm diode laser generator probe with a radial-tip fibre (Ceralas E, Biolitec, Jema, Germany). In both patient groups, the varicosities and incompetent perforators in the thigh and/or the calf were removed by performing mini-phlebectomies via stab incisions over varicose tributaries, which were avulsed using a vein hook or a Kocherised mosquito clamp. The mean duration of surgery was 62.5 (SD 14.1; range 25−90) minutes, while EVLA lasted for 55.6 (SD 12.8; range 20−75) minutes ($p = 0.148$).

Postoperative care: The postoperative management was the same for both groups. After the procedure, a non-stretch compression bandage was applied on patient's leg. After 48 hours, the patient removed the bandage and continued using an elastic class II compression stocking during the day only for at least one week after the operation.

All patients were advised to mobilise immediately after the treatment. In addition,the patients were administered analgesics for pain management postoperatively.

Follow-up: The patients were invited to follow-up evaluations by a vascular surgeon at six weeks, one year, and two years after the surgery. The evaluation included patient examination, clinical examination, assessment of the VCSS, the overall satisfaction with the operation, and disease recurrence. Patient's satisfaction was assessed by asking whether the patient would agree to undergo same intervention again if necessary, or recommend it to a friend. Clinical recurrence was defined as new varicose tributaries at least 3 mm in diameter arising after treatment.

During the follow-up evaluations, the patients filled out the AVVQ questionnaire again. Some of the patients either could not or refused to arrive for follow-up evaluation and thus they were interviewed in great detail via telephone. A complete follow-up was available for all the patients at six weeks.

Statistical analysis

Statistical analysis was performed using SPSS 22.0 software package. Normally distributed data are presented as mean together with standard deviation (SD) and compared with paired and unpaired Student's t-tests. Non-parametric data are presented as median together with interquartile range (IQR) and compared using the Mann-Whitney U test for unrelated samples and the Wilcoxon signed ranks test for paired data. Categorical variables were compared using chi-square (c2) and Fisher's exact test. We considered p values of less than 0.05 statistically significant.

RESULTS:

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We included the subjects in the age group of 40-60 years of both the genders presenting with varicose veins who had undergone endovenous laser ablation or open surgery. It is a prospective randomised study. A total of 268 patients who were age ,gender ,BMI matched were treated for symptomatic varicose veins and baseline characteristics were tabulated. Baseline median vcss and avvq scores were documented in both the groups (Table 1)

Among them 130 patients underwent open surgery and 138 patients received endovenous laser ablation.

Table 1: Baseline Characteristics of Subjects

	Conventional Surgery (n=130)	**EVLA (n = 138)**
Age (years)	45.5±12.32	46.12±11.68
Male	84 (64.61%)	86 (62.31)
Female	46 (35.38%)	52 (37.68%)
BMI	29.4±6.23	28.66±7.32
CEAP clinical grade		
C2	18 (13.84%)	79 (57.24%)
C3	74 (56.92%)	36 (26.08%)
C4	38 (29.23%)	23 (16.66%)
Baseline VCSS (median)	6 (4-8)	6 (4-8)
Baseline AVVQ (median)	14.6	14.2

The median AVVQ and VCSS scores had a significant improvement in each of the CEAP grade studied in patients who underwent EVLA as compared with the patients who underwent open surgery during the early postoperative period with p value <0.05. However during the long term follow up there was no significant difference between the two groups. (table 2,3)

The number of minor complications seen were also marginally more in patients who underwent open surgery as compared with patients who underwent EVLA. (Table 4)

Table 2: AVVQ results in patients with different clinical grades of CEAP classification at different time intervals after the treatment. Also AVVQ results in patients with GSV or SSV procedure. (GSV-Great Saphenous Vein, SSV-Small Saphenous Vein)

	6 weeks	**p value**	**1 year**	**p value**
C2				
Surgery	9.4		1.4	

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EVLA	3.2	<0.001	1.4	NA
C3				
Surgery	8.6	<0.001	0	<0.001
EVLA	2.8		6.2	
C4				
Surgery	12	<0.008	0.8	0.016
EVLA	2.8		1.8	
GSV				
Surgery	9.8	<0.001	0	0.024
EVLA	6		2.8	
SSV				
Surgery	9.6	0.013	0	0.046
EVLA	3.4		2.2	

Table 3: VCSS results in patients with different clinical grades of CEAP classification at different time intervals after the treatment. Also AVVQ results in patients with GSV or SSV procedure. (GSV-Great Saphenous Vein, SSV-Small Saphenous Vein)

	6 weeks	p value	1 year	p value
C2				
Surgery	4.6	<0.001	0	NS
EVLA	0		0	
C3				
Surgery	4	<0.001	0	NS
EVLA	0		0	
C4				
Surgery	5.4	<0.001	0.8	0.002
EVLA	2.2		4.6	
GSV				
Surgery	5	<0.001	0.6	NS
EVLA	2		0.6	
SSV				
Surgery	4	<0.001	1	NS
EVLA	1		1	

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Table 4: The rates of minor complications which occurred in the first six weeks after EVLA and conventional surgery

Complications	Conventional Surgery n=130 (%)	EVLA n=138 (%)
Symptomatic phlebitis	8 (6.15%)	3 (2.17%)
Bruising	4 (3.07%)	3 (2.17%)
Hematoma	10 (7.69%)	3 (2.17)
Discoloration	1 (0.77%)	7 (5.07%)
Infection	5 (3.84%)	1 (0.724%)
Sensory disturbance	4 (3.07%)	11 (7.97%)

DISCUSSION

Results obtained in our study confirm that EVLA is not only as effective as surgical stripping but also provides significantly better quality of life during the early post-treatment period and earlier return to work and normal activities. In our study, 6 weeks after the treatment, statistically significantly lower AVVQ scores in all CEAP clinical grades were observed in the EVLA group. This shows that during the short postoperative period disease- specific quality of life was better after EVLA. At one and two years after the treatment better AVVQ scores were found in the surgery group. In a randomised controlled study [21] conducted in 2015, which included 294 patients in the surgery group and 212 patients in the EVLA group, no statistically significant differences in the AVVQ scores between the EVLA and the surgery groups were found six weeks or six months after the treatment. A study by Mekako et al. [18] yielded similar results to those obtained in our study, i.e. a better disease-specific QoL in the EVLA group 6 and 12 weeks after treatment. So far there have been few studies analysing the AVVQ in different CEAP clinical grades. The results of our study showed that in clinical class C2, at one and two years after the initial treatment the AVVQ scores did not differ statistically significantly between the surgery and the EVLA groups. Meanwhile, at one and two years after the intervention in classes C3 and C4 statistically significantly better results were observed in the surgery group.

Most of the studies described in the literature indicate that after the treatment the clinical symptoms decrease equally statistically significantly and no difference in the VCSS between the surgery and the EVLA groups is found [20, 21]. In this study, six weeks after the treatment statistically significantly lower VCSS scores in all CEAP clinical grades were observed in the EVLA group. At one year after the intervention the treatment results in the groups converged and the difference was no longer statistically significant. The only

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exception was the C4 clinical group, where at one year after the treatment the VCSS scores were better in the surgery group.

Most of the studies found no statistically significant difference between the groups at one or two years after the treatment [23]. The results of a randomised controlled trial [24] conducted in 2013 showed no difference in recurrence rates at five years after the initial treatment.

CONCLUSION

Both techniques — EVLA and surgery — yielded similar results in terms of efficacy, clinical recurrence rates and overall patient satisfaction. Although in the present study we did not find EVLA to be superior to surgical stripping in the long term, during the short postoperative period, results in the EVLA group were significantly better than those of the surgery group. Therefore, we assume that EVLA should be recommended over surgical stripping, especially for patients who find good quality of life during the early post-treatment period and early return to work and normal activity important.

REFERENCES

1. Staffa R (2002) Chronic venous insufficiency-epidemiology. Bratisl Lek Listy; 103: 166–168.
2. Evans CJ, Fowkes FG, Ruckley CV, Lee AJ (1999) Prevalence of varicose veins and chronic venous insufficiency in men and women in the general population: Edinburgh Vein Study. J Epidemiol Community Health; 53: 149–153.
3. Margolis DJ, Bilker W, Santanna J, Baumgarten M (2002) Venous leg ulcer: incidence and prevalence in the elderly. J Am Acad Dermatol; 46: 381–386.
4. Kurz X, Kahn SR, Abenhaim L et al (1999) Chronic venous disorders of the leg: epidemiology, outcomes, diagnosis and management. Summary of an evidence-based report of the VEINES task force. Venous Insufficiency Epidemiologic and Economic Studies. Int Angiol; 18: 83–102.
5. Keller W (1905) A new method of extirpating the internal saphenous and similar veins in varicose conditions: a preliminary report. New York Med J; 82: 385–386.
6. Critchley G, Handa A, Maw A, Harvey A, Harvey MR, Corbett CR (1997) Complications of varicose vein surgery. Ann R Coll Surg Engl; 79: 105–110.
7. Beebe-Dimmer JL, Pfeifer JR, Engle JS, Schottenfeld D (2005) The epidemiology of chronic venous insufficiency and varicose veins. Ann Epidemiol; 15: 175–184.
8. Robertson L, Evans C, Fowkes FGR (2008) Epidemiology of chronic venous disease. Phlebology; 23: 103–111.
9. Van Rij AM, Jiang P, Solomon C, Christie RA, Hill GB (2003) Recurrence after varicose vein surgery: a prospective long-term clinical study with duplex ultrasound scanning and air plethysmography. J Vasc Surg; 38: 935–943.
10. Disselhoff BCVM, Rem AI, Verdaasdonk RM, Kinderen DJ Der, Moll FL (2008) Endovenous laser ablation: an experimental study on the mechanism of action. Phlebology; 23: 69–76.
11. Mordon SR, Wassmer B, Zemmouri J (2007) Mathematical modelling of 980-nm and 1320-nm endovenous laser treatment. Lasers Surg Med; 39: 256–265.

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12. Van den Bos RR, Kockaert MA, Neumann HAM, Bremmer RH, Nijsten T, van Gemert MJC (2009) Heat conduction from the exceedingly hot fiber tip contributes to the endovenous laser ablation of varicose veins. Lasers Med Sci; 24: 247–251.
13. Proebstle TM, Lehr HA, Kargl A et al (2002) Endogenous treatment of the greater saphenous vein with a 940-nm diode laser: Thrombotic occlusion after endoluminal thermal damage by laser-generated steam bubbles. J Vasc Surg; 35: 729–736.
14. Weiss RA (2002) Comparison of endovenous radiofrequency versus 810 nm diode laser occlusion of large veins in an animal model. Dermatologic Surg; 28: 56–61.
15. Navarro L, Min RJ, Bone C (2001) Endovenous laser: a new minimally invasive method of treatment for varicose veins-preliminary observations using an 810 nm diode laser. Dermatol Surg; 27: 117–122.
16. Rautio T, Ohinmaa A, Perala J et al (2002) Endovenous obliteration versus conventional stripping operation in the treatment of primary varicose veins: a randomized controlled trial with comparison of the costs. J Vasc Surg; 35: 958–965.
17. De Medeiros CAF, Luccas GC (2005) Comparison of endovenous treatment with an 810 nm laser versus conventional stripping of the great saphenous vein in patients with primary varicose veins. Dermatol Surg; 31: 1685–1694.
18. Mekako AI, Hatfield J, Bryce J, Lee D, McCollum PT, Chetter I (2006) A nonrandomised controlled trial of endovenous laser therapy and surgery in the treatment of varicose veins. Ann Vasc Surg; 20: 451–457.
19. Rasmussen LH, Bjoern L, Lawaetz M, Blemings A, Lawaetz B, Eklof B (2007) Randomized trial comparing endovenous laser ablation of the great saphenous vein with high ligation and stripping in patients with varicose veins: short-term results. J Vasc *Surg; 46: 308–315.*
20. Rasmussen LH, Lawaetz M, Bjoern L, Vennits B, Blemings A, Eklof B (2011) Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins. Br J Surg; 98: 1079–1087.
21. Brittenden J, Cotton SC, Elders A et al (2015) Clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation and surgery for varicose veins: results from the Comparison of LAser, Surgery and foam Sclerotherapy (CLASS) randomised controlled trial. Health Technol Assess (Rockv); 19: 1–342.
22. Gohel MS, Epstein DM, Davies AH (2010) Cost-effectiveness of traditional and endovenous treatments for varicose veins. Br J Surg; 97: 1815–1823.
23. Rasmussen LH, Bjoern L, Lawaetz M, Lawaetz B, Blemings A, Eklof B (2010) Randomised clinical trial comparing endovenous laser ablation with stripping of the great saphenous vein: clinical outcome and recurrence after 2 years. Eur J Vasc Endovasc Surg; 39: 630–635.
24. Rasmussen L, Lawaetz M, Bjoern L, Blemings A, Eklof B (2013) Randomized clinical trial comparing endovenous laser ablation and stripping of the great saphenous vein with clinical and duplex outcome after 5 years. J Vasc Surg; 5