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ORIGINAL PAPER

Outcome of Endovenous Laser Ablation of Varicose Veins

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ABSTRACT

Introduction: In Bosnia and Herzegovina according to available data, treatment of incompetent superficial lower extremity varicose veins by endovenous laser ablation (EVLA) has been introduced two years ago and so far no paper has been published regarding results of EVLA treatment of patients from our country. We wanted to present our results with EVLA treatment. **Aim of study:** to evaluate and compare primary posttreatment outcomes of endovenous laser ablation (EVLA) with classical surgical method of varicose vein treatment. **Patients and methods**: The study was clinical and prospective. It was carried out at Clinic for vascular surgery in Sarajevo where fifty-eight (58) patients received surgical treatment for varicose veins and in Aesthetic Surgery Center " Nasa mala klinika" in Sarajevo were sixty-one (61) patients with varicose veins were treated by endovenous laser ablation. Total 119 patients (limbs) with pathologic reflux only in great saphenous vein were evaluated between 1st of January 2013 and 31st of April 2014. Following primary outcome endpoints were evaluated: mean day of return to normal everyday activities, patient subjective quantification of pain during first seven days after intervention, incidence of deep venous thrombosis (DVT), incidence of wound bleeding requiring surgical intervention, incidence of peri-saphenous vein hematoma and infection rate. **Results**: Mean of return to normal activities (expressed in days after intervention); EVLA vs. stripping (surgery) =1.21vs12.24, T test 13,619; p=0, 000, p<0,05. T test was used for comparing Mean value of visual pain analog scale for the first 7 days between groups, for all seven days pain was significantly higher in surgical group of patients as compared to EVLA group; p<0,05. Incidence of hematoma greater than 1% of total body surface area was significantly higher in patients receiving surgical treatment; Pearson Chi Square=23,830, p<0,05; odds ratio:10,453.Incidences of infection, deep venous thrombosis and posttreatment bleeding were not statistically different between analyzed groups; EVLA vs Surgery: (Pearson Chi Square =3,237; p>0,05; Pearson Chi Square=2,139, p>0,05, Pearson Chi Square=2,139,p>0,05 , respectively.) **Conclusion**: EVLA offers better patient recovery in terms of significantly lower post treatment pain, faster return to everyday activities and lower incidence of bruising (hematomas).

Key words: varicose veins, EVLA, surgical treatment, comparison.

1. INTRODUCTION

In the recent past the gold standard in the treatment of lower extremity varicose veins with incompetent great saphenous vein (GSV) or small saphenous vein (SSV) was classical surgicall method of ligation and stripping of incompetent saphenous vein along with varicectomies. However, during the last decade other minimal invasive techniques have been invented and introduced to treat the incompetent saphenous vein and varicosities. Endovenous laser ablation (EVLA) is one of them and it has been used as minimally invasive replacement to classical surgical way of treating varicose veins for many years (Figure 1, Figure 2). Avoiding surgical incisions, mechanical disruption of the sapheno-femoral junction (SFJ) as well as aggressiveness of avulsion of saphenous vein, EVLA may offer reduced postoperative pain, post intervention bleeding and peri-saphenous vein hematoma along with decreased rate of wound infection and potentially shorter periods of absenteeism from work. In addition neo-vascularisation is significantly reduced which in turn might cause decreased incidence of varicose vein recurrence (1, 2, 3, 4).

In Bosnia and Herzegovina according to available data, endovascular laser ablation of incompetent superficial lower extremity veins has been introduced two years ago and so far no paper has been published regarding EVLA treatment of patients from our country. Since many papers on this topic have certain contradictory results we wanted to present our experience with these two methods of varicose vein tretament.

2. AIM OF STUDY

To evaluate and compare primary posttreatment outcomes of endovenous laser ablation (EVLA) with classical surgical method of varicose vein treatment

3. PATIENTS AND METHODS

The study was clinical and prospective. It was carried out at Clinic for vascular surgery in Sarajevo where patients received surgical treatment for varicose veins and in Aesthetic Surgery Center " Nasa mala klinika" were endovenous laser treatment of varicose vein was performed. Total 119 patients with pathologic reflux only in great saphenous vein were evaluated between 1st of January 2013 and 31st of April 2014. Sixty-one (61) patients who received endovenous laser treatment for varicose veins in Aesthetic Surgery Center " Naša mala klinika" were assigned to group A, while fifty-eight (58) patients that received surgical treatment of varicose veins at the Clinic for Vascular surgery were assigned to Group B.

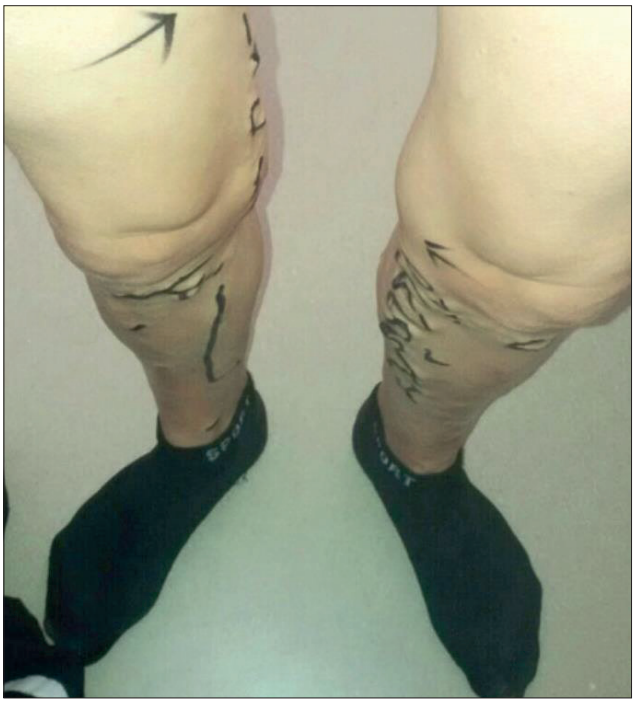

Figure 1. *Varicose veins before treatment*

Primary outcome endpoints were evaluated: mean day of return to normal everyday activities, patient subjective quantification of pain during first seven days after intervention, incidence of deep venous thrombosis (DVT), incidence of wound bleeding requiring surgical intervention, incidence of peri-saphenous vein hematoma and infection rate. Every day activities were defined as ability for self-care and all other professional, recreational, household or outdoor physical activities that used to be carried out before varicose vein treatment. Return to those activities was advised to all patients to be as soon as possible and the information about the day of return to those activities were recorded when patient resumed them without any difficulty ie pain. Infection was defined as redness of skin around wound (phlebectomy site) along with presence of pus in the wound (site of intervention) with or without patient being febrile. Hematoma along the direction of treated saphenous vein was examined on 7th day and its surface area estimated by comparing its total surface to the surface area of the palm of individual patient (1% of total body surface area)–procedure similar to the method used in assessment of burned skin surface area. Patients were then categorized either as having hematoma less than 1% or having hematoma ≥ 1% of total body surface area. Pain score was measured using a visual analogue scale ranging from 0 (no pain) to 5 (most severe pain) (Figure 3).

In case of presence of clinical signs of lower extremity deep venous thrombosis (DVT) Color Doppler examination was performed. Any bleeding after intervention that required surgical intervention either in the form of surgical revision of bleeding or need for additional surgical suture were noted and defined as postintervention bleeding. Return to normal activities were recorded taking 30 days after intervention as maximum period. This period was sufficient for full mobilization of patient even in the case of unwanted outcome endpoints like DVT. Each patient had a pre-operative duplex ultrasound examination that was performed in order to identify the site of pathologic reflux and evaluate suitability for intervention on superficial venous system. Ultrasonography was performed by vascular surgeon using Mindray 6 apparatus for group of patients treated surgically or GE ultrasound for patients treated by endovascular laser ablation. Ultrasonographic mapping of the venous systems was performed in all patients in standing position. Incompetence of the GSV was defined as reflux > 0.5 s in duration following calf compression. Exclusion criteria were: previous surgical treatment of the GSV, GSV diameter ≥ 2 cm, pregnancy, allergy to lidocaine, active superficial phlebitis, presence of any dermatologic phlebostatic changes in leg like hyperpigmentation or skin ulcer, positive history of previous deep venous thrombosis, diabetes mellitus and arterial disease. Mechanical stripping of great saphenous vein was performed in general anesthesia. After a groin incision, high ligation of the GSV and ligation of all tributaries were performed. Access to distal part of GSV was achieved through a small incision at the level of knee joint. GSV stripping was performed by metalic stripper. Varicosities were removed by minimal stab avulsion technique (Klapp/Smetana method). In the EVLA group of patients, endovascular access for laser fiber introduction into GSV was ultrasonically guided and performed at the knee level. The laser fiber tip was positioned 1 cm distal to the SFJ. Before laser ablation was started tumescent anesthetic (25 ml

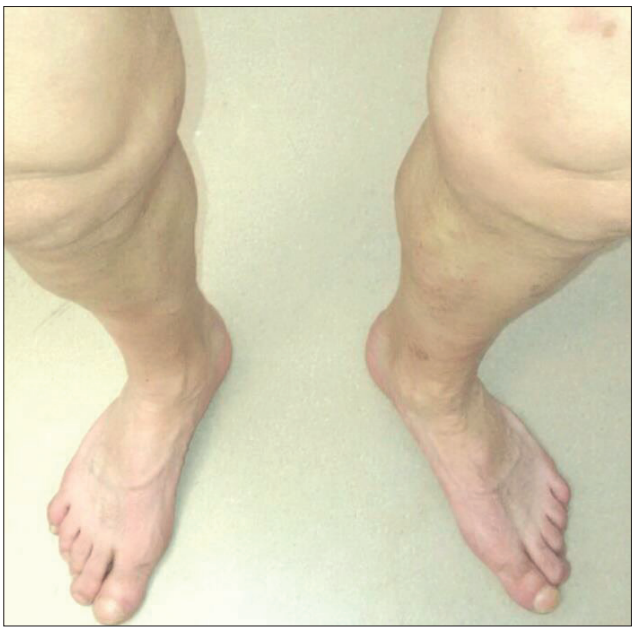

Figure 2. *Same patient after EVLA treatment*

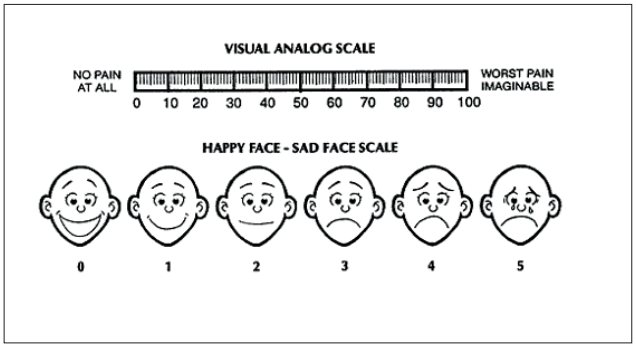

Figure 3. *Visual analog scale pain estimation*

Lidocaine 2% in 500 ml of normal saline 0,9%) was injected all around GSV under ultrasound guidance. Thermal ablation of great saphenous vein was performed by Biolitec 1470 nm radial fiber with energy 70J/cm at 10 watts. Varicosities were removed by microphlebectomy technique. Post procedurally elastic venous compression was applied to both group of patients for 30 days in surgically treated group and for only 7 days in group of patients that received laser ablation treatment. Wound dressings were changed every three days and wounds were disinfected with povidone- iodine solution and sutures removed on 10th postoperative day in surgical group of patients. Wound dressing in EVLA group of patients was left intact for total 7 days and then removed along with compressive stocking.

4. RESULTS

Statistical data analysis was performed using the IBM SPSS version 22.0. In this study we analyzed continuous and categorical (dichotomous) variables. Statistical data analysis was performed using mainly methods of inferential statistics. For continuous variables, parametric independent-samples t-test was performed. Non-parametric chi-square test was performed for testing hypothesis for categorical variables. Both tests were calculated on the basis of 95% confidence level. Odds ratio was calculated only for the incidence of hematoma. For other variables odds ratio calculation was not possible because of zero frequencies in the cross tabulation cells. Mean of return to normal activities was expressed in days after intervention ei EVLA vs surgery (stripping) =1.21vs12.24, T test 13,619; p=0, 000, p<0,05 (Table 1). T test was used for comparing Mean value of visual pain analog scale (figure 3) for first 7 days between groups, for all seven days pain was significantly higher in surgical group of patients as compared to EVLA group; EVLA vs Surgery: 1st day T test= -17.900, p<0.05; 2nd day T test=-19,817, p<0.05; 3rd day T test=-21.986, p<0.05; 4th day T test=-4.898, p<0.05; 5th day T test=-4.355, p<0.05; 6th day T test -3,643,p<0.05; 7th day T test=2.386,p<0.05.

Group	Number of patients	Mean of return to normal activities (days after intervention)	Std. Deviation	Std. Error Mean	T test
EVLA	61	1,21	,413	,053	13,619 P=0.000<0.05
Surgery	58	12,24	6,154	,808	

Table 1. *Mean of return to normal activities in days after intervention*

Group	Number of patients	Mean value of visual pain scale – day 1	Std. Deviation	Std. Error Mean	T test
EVLA	61	,93	,704	,090	-17.900; p=0.000<0.05
Surgery	58	3,12	,623	,082	
Group	Number of patients	Mean value of visual pain scale – day 2	Std. Deviation	Std. Error Mean	T test
EVLA	61	,34	,602	,077	-19.817; p=0.000<0.05
Surgery	58	2,22	,421	,055	
Group	Number of patients	Mean value of visual pain scale – day 3	Std. Deviation	Std. Error Mean	T test
EVLA	61	0,00	0,000	0,000	-21.986; p=0.000<0.05
Surgery	58	1,45	,502	,066	
Group	Number of patients	Mean value of visual pain scale – day 4	Std. Deviation	Std. Error Mean	T test
EVLA	61	0,08	,277	,035	-4.898; p=0.000<0.05
Surgery	58	,45	,502	,066	
Group	Number of patients	Mean value of visual pain scale – day 5	Std. Deviation	Std. Error Mean	T test
EVLA	61	,03	,180	,023	-4.355; p=0.000<0.05
Surgery	58	,45	,705	,093	
Group	Number of patients	Mean value of visual pain scale – day 6	Std. Deviation	Std. Error Mean	T test
EVLA	61	,05	,218	,028	-3.643; p=0.000<0.05
Surgery	58	,31	,503	,066	
Group	Number of patients	Mean value of visual pain scale – day 7	Std. Deviation	Std. Error Mean	T test
EVLA	61	,05	,218	,028	2.383; p=0.019<0.05
Surgery	58	,19	,395	,052	

Table 2. *Mean value of visual pain scale for first seven days after intervention*

Group	Number of patients	Postintervention hematoma	Pearson Chi-Square =23.830; p=0.000<0.05 Odds ratio:10.453
EVLA	61	5	
Surgery	58	28	

Table 3: *Incidence of hematoma greater than 1% of total body surface area*

Group	Number of patients	Postintervention infection	Pearson Chi-Square =3.237; p=0.072>0.05
EVLA	61	0	
Surgery	58	3	

Table 4: *Incidence of infection*

Group	Number of patients	Postintervention bleeding	Pearson Chi-Square=2.139; p=0.144>0.05 Fisher exact test: p=0.235>0.05
EVLA	61	0	
Surgery	58	2	

Table 5: *Incidence of wound bleeding after intervention*

Group	Number of patients	Postintervention deep venous thrombosis	Pearson Chi-Square =2.139; p=0.144>0.05
EVLA	61	0	
Surgery	58	2	

Table 6: *Incidence of deep venous thrombosis after intervention*

Incidence of hematoma greater than 1% of total body surface area was significantly higher in patients receiving surgical treatment; Pearson Chi Square=23,830, p<0,05; odds ratio:10,453 (Table 3).Incidences of infection, deep venous thrombosis and posttreatment bleeding were not statistically different between analyzed groups; EVLA vs Surgery: (Pearson Chi Square =3,237; p>0,05; Pearson Chi Square=2,139, p>0,05, Pearson Chi Square=2,139,p>0,05 , respectively (Table 4, Table 5 and Table 6).

5. DISCUSSION

Return to normal everyday activities in EVLA group was on first day after intervention (mean) while in surgical group it was on 12th day (Mean: 1.23 vs. 12. 24); (Table 1). The difference was statistically significant p<0.05. All patients immediately after EVLA procedure was finished, left Clinic walking without any difficulties and regular every day walking was advised as only measure for prevention of DVT in this group.

Pain was quantified every day (for all seven days after intervention/operation) by each patient on scale from 0-5 (Figure 1) based on mean value of visual pain scale. In EVLA group for all seven days after intervention mean value of pain intensity was significantly less than in surgical group (Table 2). Less pain is probably related to avoiding trauma to skin (groin incisions) and trauma to subcutaneous tissue caused by avulsion (mechanical stripping of great saphenous vein). These results are opposite to results published by Pronk et al. where EVLA patient had more pain in second week as compared to surgical group of patients (5). Underlying reason for greater

pain in their EVLA group is probably the type of laser apparatus they used (older type) because new Laser systems with higher wavelengths like 1470 nm have a better absorption in water and cause less pain and bruising after the procedure because they cause less vein wall perforation (6, 7). This is in accordance with recommendation that low-energy EVLA with the use of a 1,470-nm laser fiber with linear endovenous energy density (LEED) of 80 J/cm or less is advisable option for the treatment of incompetent saphenous veins (8). Regarding post intervention hematoma, in our study there were 5 cases of hematoma in EVLA group and 28 cases being ≥ 1% of total body surface area in surgical group. This difference was statistically significant, $p<0.05$ (Table 3). Similar results were obtained by study of Siribumrungwong et al in which they had statistically significant advantage of EVLA method over surgery in hematoma appearance (9). Postoperative hematomas were also significantly smaller after EVLA than those after stripping in the study of Kalteis et al. (10).

Incidence of infection in this study was smaller in EVLA group (0 patients) as compared to surgical group of patients (3 patients) but this difference was not statistically significant, $p>0.05$ (Table 4). These findings have similar correlation with results of meta-analysis on 2245 limbs by Pan et al. which reported also fewer complications with EVLA as compared to high ligation and stripping in case of bleeding and hematoma (1.28% versus 4.83%) as well as wound infection (0.33% versus 1.91%) (11). Striping itself is mechanically tissue destructive procedure which after removal of saphenous vein leaves avulsed tributaries that are left to bleed into subcutaneous tissue and amount of bleeding can be controlled only by subsequent compression. In that regard we had to additionally control bleeding after operations in 2 patients while there was no need to control any unwanted bleeding in patients after EVLA, (Table 5). However, this difference was not statistically relevant, $p>0.05$. We had no cases of DVT in EVLA group while 2 cases of crural DVT were recorded in surgical group of patients that were confirmed by color Doppler. Both of them received low molecular weight heparin therapy with switch to oral anticoagulation according to standard protocol for DVT treatment. Recovery was uneventful.This difference in incidence of DVT between groups was not statistically significant, (Table 6), $p>0.05$. Incidence of deep vein thrombosis (DVT) after varicose vein surgery vary between 0.4% historically and 5.7% while after EVLA from 0 to 7.7% (12). We administered LMWH prevention for surgical group of patients during their hospital stay although according to some authors there is no superiority of a short-term regimen of LMWH, early ambulation and compression therapy as compared with early ambulation and compression therapy alone (13, 14). This decision was guided by idea that mobilization of patient after surgery due to general anesthesia was delayed as compared to EVLA group. EVLA treatment is rarely related to possible endovenous heat-induced thrombosis (EHIT) that leads to clinically significant DVT. EHIT may be caused by heat that is delivered by laser catheter placed in the saphenous vein. This brings about closure of the vein by denaturing the vessel wall with consequent thrombus formation. There are no relevant guidelines regarding advice for routine anticoagulation for EVLA patients.

6. CONCLUSION

According to obtained results this endovenous laser ablation (EVLA) enables patients after treatment of varicose veins with better recovery in terms of significantly lower post treatment pain, faster return to everyday activities and lower incidence of bruising (hematomas).

It has also shown that EVLA had offered no advantages in terms of significantly lower incidence of post intervention bleeding, infection rate or DVT.

LIMITATIONS: Study was carried out on patients with varicose veins without dermatologic complications so further evaluation is required especially regarding need for inclusion of patients with C3 level of disease or higher according to CEAP classification. In addition patient expectations might have had influence on subjective pain score scale since they have received information about so far published advantages of EVLA before intervention was performed.

CONFLICT OF INTEREST: NONE DECLARED

REFERENCES

1. McBride, KD. Changing to endovenous treatments for varicose veins: how much more evidence is needed?.Surgeon. 2011; 9: 150-159.
2. Min RJ, Zimmet, SE, Isaacs, M, Forrestal M. Endovenous laser treatment of the incompetent greater saphenous vein. J Vasc Interv Radiol. 2001;2:167-1171.
3. Vuylsteke M, Vanden Bussche D, Audenaert EA, Lissens P. Endovenous laser obliteration for the treatment of primary varicose veins. Phlebology.2006; 21: 80-87.
4. Darwood RJ, Theivacumar N, Dellagrammaticas D, Mavor AID, Gough MJ. Randomized clinical trial comparing endovenous laser ablation with surgery for the treatment of primary great saphenous veins. Br J Surg. 2008; 95: 294-301.
5. Pronk P, Gauw SA, Mooij MC, Gaastra MTW, Lawson JA, et al. Randomised Controlled Trial Comparing Sapheno-Femoral Ligation and Stripping of the Great Saphenous Vein with Endovenous Laser Ablation (980 nm) Using Local Tumescent Anaesthesia: One Year Results. European Journal of Vascular and Endovascular Surgery. 2010; 40(5): 649-656.
6. Doganci S, Demirkilic U. Comparison of 980 nm Laser and Bare-tip Fibre with 1470 nm Laser and Radial Fibre in the Treatment of Great Saphenous Vein Varicosities: A Prospective Randomised Clinical Trial. European Journal of Vascular and Endovascular Surgery. 2010; 40(2): 254-259.
7. Almeida J, Mackay E, Javier J, Mauriello J, Raines J. Saphenous laser ablation at 1470 nm targets the vein wall, not blood. Vasc Endovascular Surg. 2009; 43 (5): 467-472.
8. Park JA, Park SW, Chang IS, Hwang JJ, Lee SA, Kim JS, Chee HK, Yun IJ. The 1470-nm Bare-Fiber Diode Laser Ablation of the Great Saphenous Vein and Small Saphenous Vein at 1-Year Follow-up Using 8-12 W and a Mean Linear Endovenous Energy Density of 72 J/cm. J Vasc Interv Radiol. 2014 Aug 22 [Epub ahead of print].
9. Siribumrungwong B, Noorit P, Wilasrusmee C, Attia J, Thakkinstian A. A systematic review and meta-analysis of randomised controlled trials comparing endovenous ablation and surgical intervention in patients with varicose vein. Eur J Vasc Endovasc Surg. 2012 Aug; 44(2): 214-223.
10. Kalteis M, Berger I, Messie-Werndl S, Pistrich R, Schimetta W, Pölz W, Hieller F. High ligation combined with stripping and endovenous laser ablation of the great saphenous vein: early results of a randomized controlled study. J Vasc Surg. 2008 Apr; 47(4): 822-829.
11. Pan Y, Zhao J, Mei J, Shao M, Zhang J. Comparison of endovenous laser ablation and high ligation and stripping for varicose vein treatment: a meta-analysis. Phlebology. 2014 Mar; 29(2): 109-119.
12. Marsh P, Price BA, Holdstock J, Harrison C, Whiteley MS. Deep Vein Thrombosis (DVT) after Venous Thermoablation Techniques: Rates of Endovenous Heat-induced Thrombosis (EHIT) and Classical DVT after Radiofrequency and Endovenous Laser Ablation in a Single Centre. European Journal of Vascular and Endovascular Surgery. 2010 Oct; 40(4): 521-527.
13. San Norberto García EM, Merino B, Taylor JH, Vizcaíno I, Vaquero C. Low-molecular-weight heparin for prevention of venous thromboembolism after varicose veinsurgery in moderate-risk patients: a randomized, controlled trial. Ann Vasc Surg. 2013 Oct; 27(7): 940-946.
14. Van Rij AM, Chai J, Hill GB, Christie RA.Incidence of deep vein thrombosis after varicose vein surgery. Br J Surg. 2004 Dec; 91(12): 1582-1585.