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) =1.21 vs 12.24, T test 13.619; p<0.000, p<0.05. 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 surgical 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 treatment.

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.
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 metallic 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...
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) $=1.21\pm12.24$, $T$ 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 $=2.386, p<0.05$.

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.

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

| Group | Number of patients | Mean of return to normal activities (days after intervention) | Std Deviation | Std Error Mean | T test | p value |
|-------|--------------------|---------------------------------------------------------------|---------------|----------------|--------|---------|
| EVLA  | 61                 | 1.2                                                           | .413          | .053           | 13.619 | <0.000  |
| Surgery | 58               | 12.24                                                         | 6.154         | .808           |        |         |

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

| Group       | Number of patients | Mean value of visual pain scale (days after intervention) | Std Deviation | Std Error Mean | T test | p value |
|-------------|--------------------|----------------------------------------------------------|---------------|----------------|--------|---------|
| EVLA        | 61                 | 1.03                                                      | .704          | .080           | -17.900 | <0.000  |
| Surgery     | 58                 | 4.12                                                      | .623          | .081           |        |         |

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

| Group | Number of patients | Postintervention hematoma | Pearson Chi-Square | Odds ratio |
|-------|--------------------|---------------------------|--------------------|------------|
| EVLA  | 61                 | 5                         | 23.830             | 10.453     |
| Surgery | 58               | 28                        |                    |            |

**Table 4:** Incidence of infection

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

**Table 5:** Incidence of wound bleeding after intervention

| Group       | Number of patients | Postintervention deep venous thrombosis | Pearson Chi-Square | p value |
|-------------|--------------------|----------------------------------------|--------------------|---------|
| EVLA        | 61                 | 0                                      | 3.139              | >0.05    |
| Surgery     | 58                 | 2                                      |                    |         |
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

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