Surgery or combined endolaser ablation and sclerotherapy for varicose veins, a new trend in a developing country (Iraq); a cohort study

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Received: September 2018; Accepted: October 2018; Published: November 1, 2018
Citation: Bashar Hanna Azar, Ashur Yohanna Izac Oraha, Emad Abdulrahman Hussen. Surgery or combined endolaser ablation and sclerotherapy for varicose veins, a new trend in a developing country (Iraq); a cohort study. World Family Medicine. 2018; 16(10): 4-8. DOI: 10.5742MEWFM.2018.93509

Abstract

Introduction: Management of varicose veins has changed in the last few decades in favor of minimal invasive interventions. The developing world lately became part of this revolution. The aim of this study is to report and compare early experience of surgery and endovascular ablation combined with sclerotherapy.

Patients and methods: A retrospective multicenter cohort study included patients diagnosed as cases of primary lower limb varicosities. The patients underwent either of two procedures: Surgical intervention and endolaser ablasion combined with sclerotherapy. Sociodemographic and clinical data as well as outcomes, were compared.

Results: The study included 71 patients, with mean age of 36.26. Thirty-nine patients (54.9%) were male. The most common finding was bilateral affection (27, 38%). Forty patients (56.3%) underwent surgical intervention and the other 31 (43.7%) had endolasar ablation and sclerotherapy. Although early complications occurred more with the surgical intervention, the difference did not reach statistical significance. Overall, the late complications were not significantly different in both arms of the interventions. Both (late and early complications) were highly significantly related to the severity of the CEAP classifications (both p-values were less than 0.001).

Conclusion: Endolaser ablation with sclerotherapy is starting in Iraq. Although it is in the early stage of its development, it has a better outcome compared to the classical surgical intervention.

Key words: endolaser, sclerotherapy, varicose vein, saphenofemoral junction

Introduction

Lower limb varicose veins are defined as dilated subcutaneous veins, more than three millimeters in diameter assessed in the standing position. They can affect the principal axial superficial veins being the small and great saphenous veins or other superficial tributaries. The majority of varicosities are related to primary venous diseases. The leading cause is probably an intrinsic biochemical or biologic anomaly in the venous wall, however other multifactorial causes can lead to it.

Secondary causes are also well-known contributors to the development of varicose veins and these include, deep venous obstruction, deep venous thrombosis, arteriovenous fistula or superficial thrombophlebitis. Congenital cases may present as venous malformations [1].

For a long time, varicose veins have been well known for their cosmetic issues only. However, nowadays, it is well-known that they are frequent causes of pain, disability, loss of working days and declining of the quality of life.

Precedently, the standard treatment for varicosity was operation. The latter involves high ligation and stripping near the knee level with multiple phlebectomies. In the last decade, newer treatments arose in the form of endovenous ablation of great saphenous vein with laser, radiofrequency ablation and ultrasound guided foam sclerotherapy [2].

Regardless of the type of management, all share common aims, which can be summarized as: ablation of the varicosities, boosting venous function, treatment and prevention of complications of chronic venous disorders, relief and/or improvement of venous symptoms, attaining better quality of life, and gaining better aesthetic appearance [3].

The aim of this study was to compare early and late outcomes of the patients undergoing endovascular ablation with sclerotherapy in a developing country (Iraq) compared with those undergoing surgical intervention.

Patients and Methods

Study design and protocol: This was a retrospective multicenter cohort study that included patients diagnosed as cases of lower limb varicosities. Doppler ultrasound was done for all patients before the intervention to confirm the diagnosis, determine the level of the incompetence and exclude deep venous thrombosis. Secondary varicosities were excluded. The patients underwent either of two procedures. Surgical intervention or endolaser and sclerotherapy.

Surgical intervention included saphenofemoral junction ligation (or sapheno-popliteal junction ligation according to the level of incompetence) with multiple stab venous avulsion under spinal anesthesia, followed by bandaging for 12 days. The second type of intervention included under spinal anesthesia, cannulation of the great or small saphenous vein at the most accessible part below the knee, followed by localization of the saphenofemoral junction under duplex ultrasound guide. While keeping the probe on, the endovenous laser catheter is advanced over a guide wire and the ablation of the junction was performed, through the same port. Foam sclerosing agent is injected using a 1%, 2% or 3% polidocanol, then the catheter is drawn slowly with continuous laser pulses till the whole main stem of the vein is completed.

In the area where the vein was very superficial, we used normal saline injection to separate and cool the tissues. The remaining varices and spider veins were managed by foam sclerotherapy in the same session.

The patients were discharged on the same day and compression stockings were advised to be applied for a week.

Clinical data: For each of the cases, information regarding sex, age, past medical and surgical history, clinical presentation, features of varicose vein, investigations, clinical stage of the diseases (CEAP), types of interventions and follow up were obtained from the medical record. For missed data, the patients were contacted whenever feasible.

Data analysis: Data entry and coding were performed using Microsoft Excel, version 2013; later, the data were transferred to and analyzed by Statistical Package for the Social Sciences (SPSS) software, version 24. Descriptive statistics (percentage, mean, and standard deviation) were calculated to present socio-demographic and clinical data. Chi square test was analyzed to compare categorical data.

Results

The study included 71 patients, with mean age and standard deviation of 36.26±11.28. Thirty-nine patients (54.9%) were male and 32 (45.1%) were female, 29 (40.8%) of the cases had positive family history for varicose vein. Regarding laterality, the most common finding was bilateral affection (27, 38%), followed by left leg (24, 33.8%) and the least one was the right leg lower limb (20, 28.2%). Pain was the most common clinical manifestation (53, 74.6%), followed by swelling (11, 15.5%), eczema and pigmentation found in 4 (5.6%) cases, ulcer in 1 (1, 1.4%) and in 2 (2.8%) cases there was more than one clinical sign and symptom. Forty patients (56.3%) underwent surgical intervention and the other 31 (43.7%) had endolasar ablation and sclerotherapy. The severity of the varicosity was not significantly related to the types of the procedure (Table 1). Pain was the most common early and late complication (Figures 1 and 2). Although early complications occurred more with the surgical intervention, the difference did not reached statistical significance (Table 2). The most common late complication which significantly differed across the groups was residual varicosity (1 (2.5%) case in surgical group and 7 (22.6%) cases in the group with laser ablation and sclerotherapy, P-value 0.008). Overall, the late

Table 1: Relationship of severity of the varicosity with the types of procedure

Occupation	N					P.Value
	1	2	3	4	5	
Housewife	0	22	6	2	0	0.148
Worker	0	16	1	1	1	
Employee	0	5	3	0	1	
Military	0	2	3	1	0	
Student	1	2	0	0	0	
Unemployed	1	4	0	0	0	

Table 2: Early complications and types of interventions.

Early complications	Surgical producer N		P.Value
	Surgical	Endolaser ablation	
No complication	36	30	0.622
Pain	2	1	
Hematoma	1	0	
Wound infection and hematoma	1	0	

Table 3: Late complications in the two different treatment modalities

Late complications	Surgical producer N		P. Value
	Surgical	endolaser ablation	
NO	28	13	0.057
Recurrence varicose veins	3	1	
Pain	6	4	
Residual varicosity	1	7	
Skin discoloration	0	2	
Oedema	0	1	
Parathesia and pain	0	1	
Parasthesia and itching	0	1	
Parathesia	1	1	
Pain and edema	1	0	

complications were not significantly different in both arms of interventions (Table 3). Neither early nor late complications were significantly related to the site of incompetence (p-value 0.125, p-value 0.894 respectively) while both (late and early complications) were highly significantly related to the severity of the CEAP classifications (both p-values were less than 0.001).

Discussion

In VEDICO (Venous Disease Control) trial, a statement was made in its first part, clarifying that, even in centers of excellence; there are no golden rules for the treatment of varicose veins. Different regional and national variations exist related to different aspects, being medical or financial [4]. In some developing countries (at least in Iraq) still the operation, in the form of saphenofemoral junction ligation and multiple stab venous avulsion, is the standard method of intervention for management of primary varicosity of the lower limbs whenever intervention is indicated.

During the past decade, the revolution in endovascular technology has changed the ways of treatment and evaluation of varicose veins worldwide. Endovenous ablations and foam sclerotherpy have been considered as a less invasive alternative to vein stripping, and has lready gained popularity among vein surgeons in developed countries [1][5].

In trying to keep up with the updates in this subject as a developing country, we tried to present our experience of both techniques. The present study confirmed that overall, minimal invasive therapy (endolasar ablation and sclerotherapy) is preferred over the surgical intervention although the difference has not reached a statistically significant level. This may be explained by the small sample size and short period of follow up.

In a prospective randomized trial performed by Rasmussen et al, comparing EVLA without high ligation and stripping with high ligation, a noticeable reduction in postoperative bruising and pain following laser ablation has been reported [5]. In the current study, hematoma and pain was observed as twice in the surgical group as compared to the endolaser and sclerotherapy arm.

Recurrent varicosity following treatment is considered a serious problem. In a randomized trial by Carradice et al, that discussed the clinical and technical outcomes of endovenous laser ablation, they confirmed the higher rates of recurrence post surgery in comparison with EVLA [6].

In the clinical practice guidelines of the society for vascular surgery and the American venous forum that were published in 2011, recurrent rate ranging from 6.6% to 37% has been reported. This picture decreased afterwards [1]. Two patients complained of residual varices after endovenous laser ablation in a randomized clinical trial comparing endovenous laser ablation to conventional surgery by D. Carradice et al [6]. In another prospective study that studied EVLA, with a patient sample of 280, only three patients were documented to have residual varicosity [7]. In this study, one patient (2.5%) had residual varicosity following surgical treatment while 7 patients (22.6%) complained of residual varicosity after combined endolaser and foam sclerotherapy treatment. This high rate of residual varices might be explained by the fact that the latter form of therapy in this region is in the early stage and extensive experience is lacking.

Considering post treatment hematoma, we had only one patient with hematoma following surgical intervention, treated by evacuation; comparing this to the literature, in a study published by Manfred Kalteis et al, comparing surgical management versus EVLA, rates of 10% and 12% were reported respectively [5].

Conclusion

Endolaser ablation with sclerotherapy is starting in Iraq. Although it is in the early stage of its development, it has better outcome compared to the classical surgical intervention. Sharing experience within the region is highly recommended.

Figure 1: Distribution of the early complications

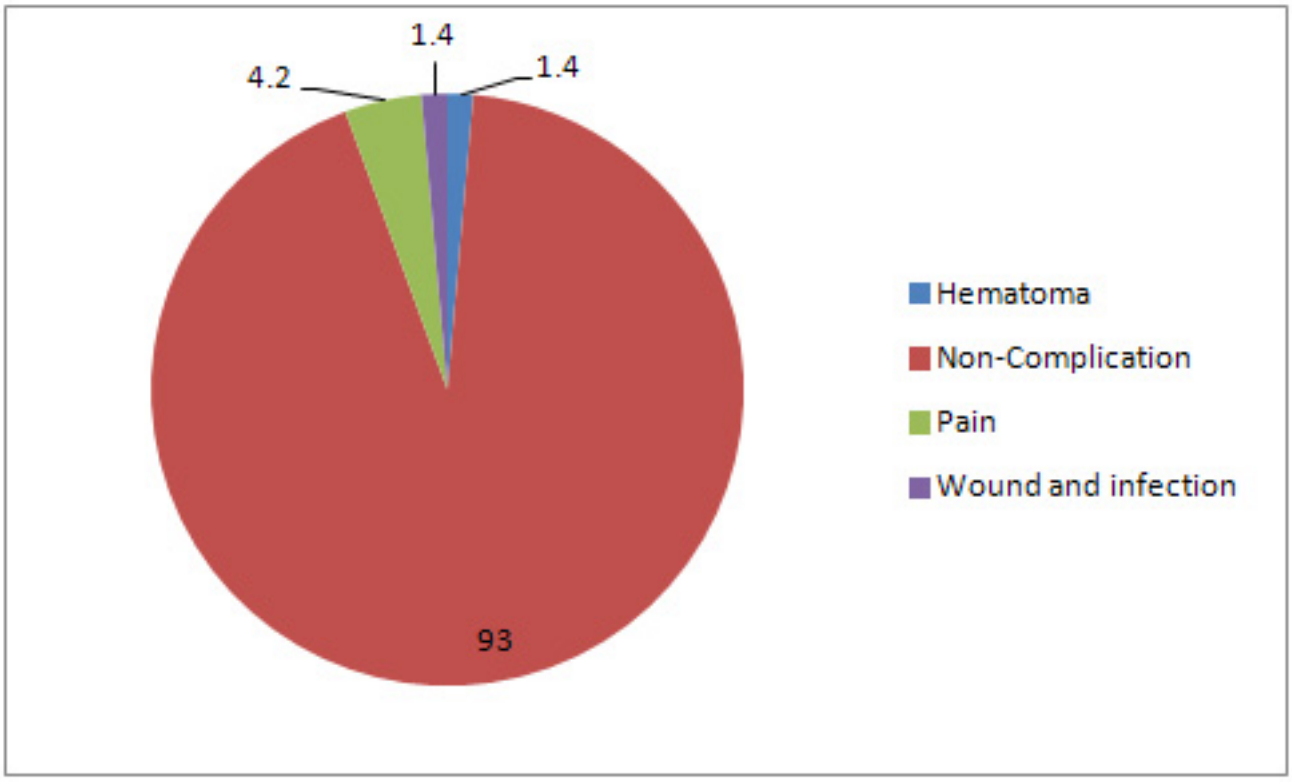
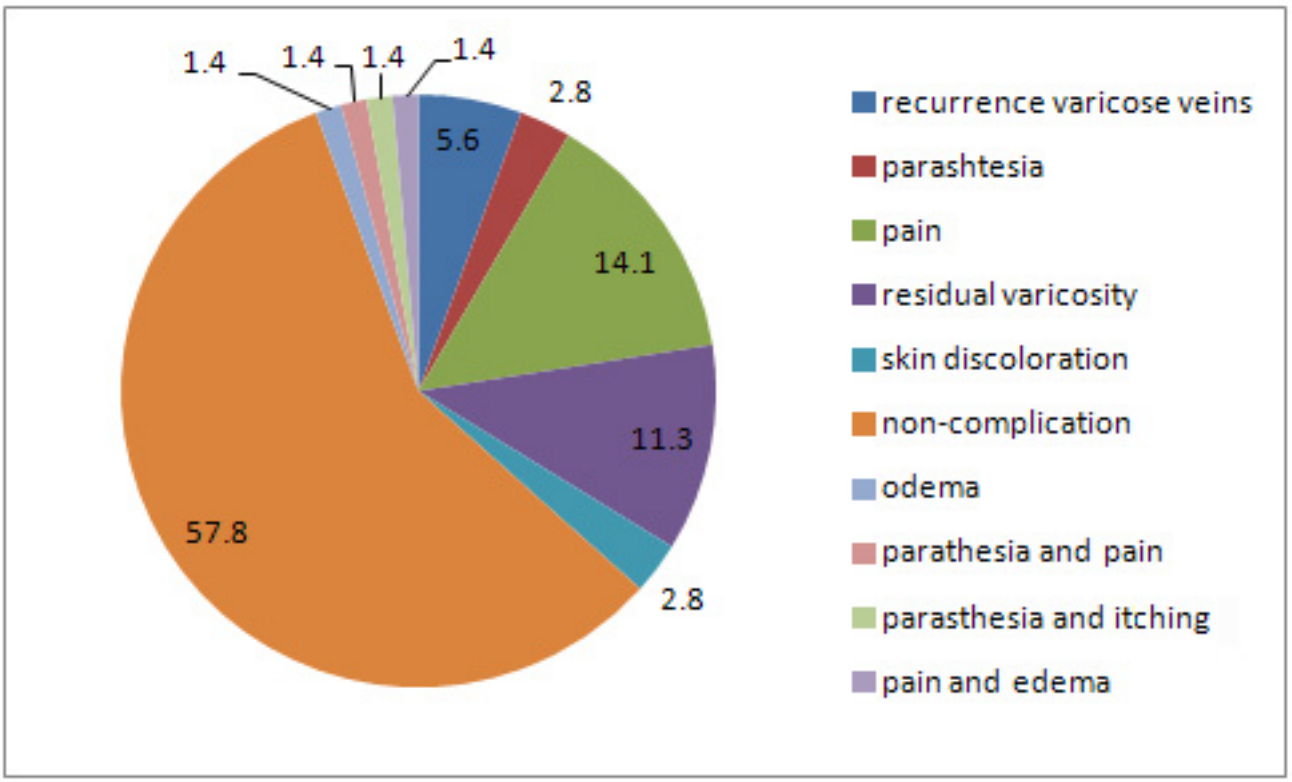


Figure 2: Distribution of the late complications



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