ORIGINAL ARTICLE

CONTENTS

Comparison of high-frequency techniques in ablation of great saphenous vein for varicose vein treatment

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ABSTRACT

Aim: To evaluate the outcomes of patients who underwent two different high-frequency techniques of varicose vein endovenous ablation in the great saphenous vein (GSV) region (radiofrequency ablation [RFA] or high-frequency endovenous welding [HFEW]), and to find out the options to improve long-term results.

Materials and Methods: The retrospective study enrolled 120 patients with primary varicose veins in the GSV region with CEAP stages C2–C6, treated in two private centers and operated on by a single operator from 2019 to 2021. The enrolled sample was subdivided into RFA (VNUS ClosureFast [n=58]) and HFEW ("SVARMED", Ukraine [n=62]) groups. Primary (such as occlusion rates) and secondary outcomes (such as postoperative pain [by VAS scale], complications, and recurrence rates) were assessed at 7 days, and at 3, 6, and 12 months postprocedurally.

Results: Both RFA and HFEW techniques showed high occlusion rates at 12 months postoperatively (96% and 97%, respectively [p=1,000]). The adverse events and perioperative complication rates were low and comparable between the two studied groups. Recurrence of varicose veins at the 12-month follow-up was numerically, but non-significantly, higher in the RFA group compared to HFEW (total: 14% vs. 6%, respectively [p=0,230]; junction source: 10% vs. 3%, respectively [p=0,154]).

Conclusions: Ablation of the GSV in patients with varicose vein disease by RFA and HFEW showed comparable early and midterm results with high occlusion rates at 12 months postoperatively. Recurrences in the RFA group, being numerically higher compared to the HFEW group, were primarily caused by new reflux coming from the femoral junction. HFEW requires further research for technical improvement and widespread implementation in practice.

KEY WORDS: varicose vein, endovenous welding, radiofrequency ablation

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INTRODUCTION

Chronic venous disease and varicose veins are a major problem in healthcare systems all over the world. According to various data, the disease is widespread and affects up to 40–90% of the population, with a higher predominance among women [1]. Chronic venous insufficiency has a major impact on social life, quality of life, and healthcare systems. Various symptoms, ranging from small cosmetic defects and discomfort to pain, swelling, and trophic changes, including venous ulcers, affect quality of life and could lead to potential complications such as thrombosis, bleeding, and temporary disability. In the last two decades, many different techniques, including endovenous laser coagulation, radiofrequency ablation (RFA), high-frequency endovenous welding (HFEW), foam sclero-obliteration, endovenous mechanochemical obliteration, and adhesive methods of vein closure (glue), were developed to treat varicose veins [2]. All of them are reliable, with high technical success and occlusion rates, as well as symptomatic regression and healing of venous ulcers. Although primary occlusion rates are high for all techniques, the chronic character of varicose vein disease and often complicated anatomy lead to mid- and long-term recurrences, which are a major problem [3].

AIM

The study aim was to evaluate the outcomes of the patients who underwent RFA and HFEW for the treatment of primary varicose veins in the great saphenous vein (GSV) region, and to find out the options to improve long-term results.

MATERIALS AND METHODS

The retrospective analysis was performed by assessing the data from 120 patients (mean age [mean ± stan-

dard deviation] 40±17 years; 39 [32,5 %] males and 81 [67,5 %] females), who underwent RFA or HFEW for treatment of varicose vein disease in GSV region, being enrolled in two private centers from 2019 to 2021. Inclusion criteria were as follows: patients with incompetent GSV with reflux more than 500 ms, GSV diameter less than 2 cm, CEAP (Clinical-Etiology-Anatomy-Pathophysiology) classes C2-C6; patient age more than 18 years.

Exclusion criteria were applied to patients who underwent previous venous surgery, patients with recurrent varicose veins, with history of deep vein thrombosis (DVT) or superficial thrombophlebitis, with known intake of anticoagulation medication, with lower extremity infections and known thrombophilia, pregnancy, chronic peripheral arterial disease, lymphedema of lower limbs, history of narcotic addiction, and intravenous narcotic use, patients with chronic venous disease on both legs who underwent simultaneous procedure on GSVs bilaterally.

Among 120 patients, the distribution of CEAP stages was as follows: C2 – 40 (33,3 %); C3 – 54 (45,0 %); C4 – 15 (12,5 %); C5 – 8 (6,7 %); and C6 – 3 (2,5 %) cases. The enrolled sample was subdivided into two study groups: group 1 consisted of 58 (48,3 %) patients treated with RFA (VNUS ClosureFast); group 2 included 62 (51,7 %) patients treated with HFEW («SVARMED», Ukraine).

Preoperative diagnostics included analysis of typical symptoms of varicose vein disease, physical examination to assess the presence and spread of varicosities on the legs, as well as ultrasound (US) duplex scan to assess retrograde blood flow in the GSV. Those GSVs with retrograde blood flow of more than 500 ms in the standing position after manual compression of the calf were regarded as insufficient. Preoperative mapping of varicosities and reflux in- and outflow points, as well as puncture sites, was performed before the operation in the standing position. All the patients signed informed consent forms and were given chronic venous insufficiency questionnaires (CIVIQ-20) to fill out before the operation. The study included patients operated on by a single operator, a vascular surgeon experienced in endovenous procedures. Postoperative therapy included micronized flavonoid fraction medication for a month and nonsteroidal anti-inflammatory drugs for three days. Per protocol, an elastic compression bandage was applied directly after the procedure, as well as compression stockings for one day. Class II graduated elastic compression stockings were applied for three weeks. Procedures were performed in the reverse Trendelenburg position. Patients were operated on under local anesthesia with mild sedation in the supine or prone position. In most cases, the GSV was punctured 5–10 cm below the knee under US control, followed by introducer (5F or 9F, depending on the technique) insertion. The catheter was inserted and positioned according to the instruction for use recommendations (2.0 cm from the femoral junction for RFA, and just below the junction for HFEW [zero zone]). Catheter insertion was followed by US-guided application of tumescent anesthesia (cooled modified Klein's solution) along the vein.

Calf and thigh tributes were removed in the Varady technique through microincisions under local anesthesia as well. Perforators were not treated in the primary setting. Fourteen patients in both groups underwent additional sclerotherapy intraoperatively using 0.5% polidocanol for the treatment of telangiectasias. All patients were discharged home directly after the procedure with a recommendation of 30 to 60 minutes of intensive walking.

Postoperative controls were performed on the next day, in seven days, and at 3, 6, and 12 months postoperatively. During the check-ups, physical examination and duplex US were performed to assess occlusion rates of the GSV, rates of recanalization, and reflux.

Patients completed the CIVIQ-20 questionnaire and Visual Analogue Scale (VAS) to measure pain intensity at 3, 6, and 12 months postoperatively. The VAS consisted of a 10 cm line, with two endpoints representing 0 ("no pain") and 10 ("pain as bad as it could possibly be").

The data were analyzed using MedCalc v. 23.2.1 (MedCalc Software Ltd., Belgium). The continuous variables were presented as mean ± standard deviation. The qualitative variables were presented as absolute and relative (%) frequency. Two independent samples were compared using Student's t-test (for continuous variables), and $\chi 2$ or Fisher's exact tests (for qualitative variables). A p-value <0.05 was considered statistically significant.

ETHICS

The research was carried out in adherence to the core principles outlined in the Council of Europe Convention on Human Rights and Biomedicine, the Declaration of Helsinki by the World Medical Association on ethical guidelines for medical research involving human participants, and the relevant regulations of Ukraine. The study protocol received an approval from the local ethics committee. Considering the retrospective design of current study, the informed patient`s consent was not required.

RESULTS

The study groups were comparable in the majority of baseline characteristics, as presented in Table 1.

Table 1. Baseline characteristics of patients in the studied groups

Parameters			Group 1 N=58	Group 2 N=62	p
Age, years			38±17	41±18	0,368
Sex, n (%)	Men		17 (29)	22 (34)	0,560
	Women		41 (71)	40 (65)	
Treated veins diameter, mm			8±3	10±3	<0,001
CEAP stage, n (%)		C2	22 (38)	18 (29)	0,577
C3		23 (40)	31 (50)		
C4		6 (10)	9 (14)		
C5		5 (9)	3 (5)		
C6		2 (3)	1 (2)		

Table 2. The endpoints, adverse events and complications in the studied groups

Parameters	Group 1 N=58	Group 2 N=62	p
Adverse events and perioperative complications			
EHIT type 2, n (%)	0	3 (5)	0,245
Temporary paresthesia and hypoesthesia, n (%)	5 (9)	7 (11)	0,764
Induration and temporary pigmentation, n (%)	7 (12)	7 (11)	1,000
Postoperative pain (VAS score ≥3), n (%)	6 (10)	6 (10)	1,000
Bruising, n (%)	21 (36)	24 (39)	0,851
Primary endpoints (at 12-month follow-up)			
Partial recanalization, n (%)	2 (4)	2 (3)	1,000
Varicose vein recurrence in total, n (%)	8 (14)	4 (6)	0,230
Varicose vein recurrence, femoral perforator source, n (%)	2 (4)	2 (3)	1,000
Varicose vein recurrence, junction source, n (%)	6 (10)	2 (3)	0,154

Note: EHIT – endothermal heat-induced thrombosis

Although the treated vein diameter was larger in group 2, this was not significant with regard to clinical presentation but could potentially interfere with occlusion rates.

The mean procedure time was comparable in both groups: 46±13 vs. 48±15 in groups 1 and 2, respectively (p=0.453). All operations showed a 100% technical success rate with no operative complications. No postoperative surgical complications, such as skin burns, bleeding, pulmonary embolism, etc., were observed.

The data on patients` outcomes are presented in Table 2.

Forty-five patients presented with mild local bruising due to performed mini-phlebectomies: 21 (36%) and 24 (39%) in groups 1 and 2, respectively (p=0.851). Twelve patients reported postoperative pain with a VAS score ≥3, with no difference between groups (6 [10%] patients in both groups [p=1.000]). Twelve patients developed temporary paresthesia and hypoesthesia on the calf (5 [9%] and 7 [11%] in groups 1 and 2, respectively [p=0.764]), which disappeared during the first month of follow-up. Induration and temporary pigmentation along the epifascial thigh tributaries of GSV were noted in 7 patients in both groups (12% and 11%, respectively [p=1.000]).

No major thrombotic postoperative complications, including DVT or pulmonary embolism, were noticed in the study groups. Endothermal heat-induced thrombosis (EHIT) type 2 was observed in 3 patients (5%) in group 2 with no need for further treatment. No cases of study equipment failure were noticed. Occlusion rates of the GSV trunk as a primary endpoint were 100% in both groups up to 6 months of follow-up. The 12-month assessment showed partial recanalization in 2 (4%) and 2 (3%) in groups 1 and 2, respectively (p=1.000). We observed varicose vein recurrence in both groups at 12-month follow-up, including 4 cases of thigh perforator recurrence (2 [4%] and 2 [3%] patients in groups 1 and 2, respectively [p=1.000]), and 8 cases of junction recurrences (6 [10%] and 2 [3%] patients, respectively [p=0.154]). Overall, the RFA group demonstrated a numerically, but non-significantly, higher frequency of varicose vein recurrence events compared to the

HFEW group (8 [14%] vs. 4 [6%] patients, respectively [p=0.230]).

DISCUSSION

Minimally invasive percutaneous methods of treatment for varicose vein disease over the last 20 years have shown excellent results due to high trunk occlusion rates, low complication rates, a well-established safety profile, and low early recurrence rates. Therefore, they are considered the gold standard for varicose vein treatment, replacing open surgery, including high ligation and stripping [4]. In fact, many different thermal minimally invasive techniques have been developed in recent years, including endovenous laser ablation, RFA, HFEW, as well as non-thermal techniques, such as mechanochemical or cyanoacrylate ablation and sclerotherapy. According to available data and studies described in many publications comparing thermal and non-thermal techniques, in most cases, non-thermal techniques had slightly worse technical results in closing veins due to existing recanalization [5, 6]. Nevertheless, clinical results, patient satisfaction rates, and quality of life were at the same level as in patients treated with thermal methods [7]. Although GSV occlusion rates are taken as the primary endpoint of most studies, the most important issue is varicose vein recurrence and symptoms of chronic venous insufficiency in long-term follow-up [8].

Thermal ablation aims to achieve permanent vein lumen occlusion through thermal energy application on the wall, which can be effective depending on the amount of energy absorbed [9].

Endovenous RFA to treat the incompetent GSV (VNUS ClosureFast) is a catheter-based device that delivers optimal thermal energy via an electrode with a temperature feedback loop using a thermocouple, which allows it to be applied in a controlled manner. This ensures transmural heating of the vein wall, minimizing thermal spread to adjacent tissues. According to many studies, the satisfaction rate of RFA for GSV reaches 95%, and the frequency of DVT rarely exceeds 1% [10].

The HFEW technique («SVARMED», Ukraine) works through a bipolar configuration electrode with a diameter of up to 3 mm and a length of up to 5 cm. The operating cycle of the welding is performed at a voltage from 10 to 100 V and an AC frequency from 50 to 500 kHz, with modulation from 0.1 to 250 kHz and tissue resistance of 0.1 to 1000 Ohms. The cycle duration ranges from 5 to 12 seconds [11]. Resistance, instead of a temperature-based self-regulating principle, governs the exposure of the working electrode surface in the vein lumen, allowing dose- and time-independent heating of the vein wall. This could lead to better efficacy, convenience, and a better safety profile [12].

Our experience allows us to obtain comparative results with available series of studies. The sample size and the retrospective nature of the analysis could be potential limitations of our results. The same applies to the relatively low recurrence rate, which is insufficient for further analysis. Nevertheless, our results are acceptable and comparable with the presented series. A one-year follow-up, from our point of view, is not sufficient and may not reveal possible long-term results. Our data enable us to plan prospective studies to improve treatment outcomes.

CONCLUSIONS

High-frequency-based techniques, such as RFA and HFEW, are effective and reliable methods of varicose vein treatment in the GSV region. Although they show high occlusion rates and excellent early and midterm results, the late results (particularly recurrences) still remain an unresolved issue. The recurrences in the RFA group, being numerically but non-significantly higher compared to the HFEW group, were primarily caused by new reflux coming from the femoral junction. The modified HFEW technique, including the zero zone catheter positioning for endovenous crossectomy and adjunctive anterior accessory vein ablation in selected cases, could lead to better long-term results with fewer recurrences and needs further research.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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