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Editorial Team

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ORIGINAL ARTICLES

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Effectiveness of thermal radiofrequency minimally invasive methods for the treatment of varicose veins: surgical experience in the Ukrainian population

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ABSTRACT

Aim: Evaluate the results of study of the effectiveness of radiofrequency ablation in patients with chronic venous insufficiency in the Ukrainian population.

Materials and Methods: Observation included the evaluation of the great saphenous vein occlusion and reflux at the patients undergone radiofrequency ablation on great saphenous vein. The condition was assessed according to the clinical severity scale of chronic venous disease and CEAP classification. Data were interpreted according to an analysis of the Kaplan-Meyer survival model.

Results: After radiofrequency ablation all the patients under observation had complete occlusion of the great saphenous vein when being discharged. By the one-year of the observation, Kaplan Meyer's analysis determined that over the course of 12 months, the probability of an outcome without recurrence of varicose after radiofrequency ablatio was 98,77%. Reflux of blood was determined in reopened perforating vein of the leg in one patient in three months according to the results of duplex ultrasound. According to the CEAP scale at the time of admission, there were 56.72% of the patients with C2, and 34.33% with C3, 8.96% with C4. The average clinical severity scale scores improved from 4.69 in the preoperative period to 2.90 on the first day after surgery and 2.52, 1.27, 0.92, 0.71, 0.64, 0.60 on the 7th day, 1, 3, 6, 9 and 12 months respectively.

Conclusion: Radiofrequency ablation showed its efficiency for endovenous treatment of incompetent great saphenous vein with sustained clinical and anatomical success for most patients.

KEY WORDS: venous insufficiency [c14.907.952], radiofrequency ablation [e04.014.760], endovascular procedures [e04.502.382], ultrasonography, doppler [e01.370.350.850.850]

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INTRODUCTION

Chronic venous insufficiency (CVI) is a common problem that affects an average number of women from 1% to 40%, and men from 1% to 17%. At the same time, more people suffer from varicose veins (VV): correspondingly from 1% to 73% of female and from 2% to 56% of male [1]. Chronic venous insufficiency may be manifested as a cosmetic skin irritation at early stages and eventually develop to the state of decompensation. Signs and symptoms of this condition include visible varicose veins, pain or swelling of legs, cramps or fatigue in lower extremities and heavy legs. Depigmentation of the skin, formation of sealing tissues and trophic ulcers may occur without treatment [2]. Very frequently incompetent valves in the great or small saphenous veins cause pathological venous reflux and contribute to the development of severity of the condition. Surgical treatment of great or small saphenous veins incompetence by its removal or elimination out of lower limb venous system either removes or reduces signs and symptoms of the disease. Since open legation the surgical treatment of vascular diseases of the lower extremities has significantly improved. Such minimally invasive procedures are efficiently used as: foam sclerotherapy, endothermal ablation technology, endovenous laser therapy (ELT), endovenous radiofrequency ablation (RFA) and the methods of mechano-chemical ablation (MOCA) having been introduced into practice recently as well. ELT and radiofrequency ablation (RFA) were recommended as primary surgical procedures in the treatment of venous disease according to the recommendations of the NICE 2013 and they showed their preference to open surgery

and foam sclerotherapy [3]. The EVRF® system (Endo Venous Radio Frequency) (F Care Systems, Belgium) has proved to be safe and efficient. However, there is the limited number of clinical evaluations of using of EVRF system and medium-term results of treatment in the literature [4]. Thus, in our investigation we have tried to fill a gap in current knowledge and we have assessed one-year results after using RFA by EVRF system in patients with VV of lower limbs.

AIM

The aim of the study was to evaluate the results of a two-year study of the effectiveness of radiofrequency ablation in patients with chronic venous insufficiency in the Ukrainian population; to analyze the short-term and long-term results of the impact of this surgical method on the clinical picture of varicose veins and the chances of recurrence.

MATERIALS AND METHODS

This prospective investigation was made to evaluate the medium-term effects RFA of great saphenous vein (GSV) with using EVRF system which includes a monopolar radiofrequency catheter with integrated heating element of the production F Care Systems (Belgium). There were taken patients examined in advance with signs and symptoms of venous insufficiency of the lower limbs in the GSV system with confirmed reflux for this investigation. The reflux was determined as the retrograde flow of blood more than 500 ms in Duplex ultrasound (DUS). It was the indication for endovenous ablative therapy. The inclusion criteria were as follows: age from 18 to 80 years old at the time of the examination, physical condition allowing active lifestyle after the procedure and the opportunity to be present at the control examinations during the investigation. Patients with vein thrombosis, pregnant women and the ones who had allergy to medicines used in the investigation were excluded. There were 134 patients taken part in the investigation with 174 incompetent GSV who received RFA therapy. All the investigators had experience to work with RFA by EVRF® system (F Care Systems, Belgium) and underwent the appropriate training for using this system before the start of the investigation. The control visit of the patient included clinical examination and diagnosing according to CEAP, filling clinical severity scale of chronic venous disease (VCSS) profiles, DUS of the lower extremities' veins in the horizontal position and the reverse Trendelenburg position. The key point of the examination was the reflux absence and complete occlusion of the RFA treated vein, which was interpreted as absence of recurrence of VV at the time of examination. According to the DUS examination of the GSV, which was treated by the RFA was assessed in all the length of the vein as a closed, not closed / re-open or de novo. Commission of the Ethics approved the research protocol with compliance. The investigation was conducted in compliance with the Declaration of Helsinki and subsequent additions. All the subjects of research provided written informed agreement. Control visits took place before the operation, on the 1st and 7th day after the operation, on the 1st, 3rd, 6th, 9th and 12th month after the procedure.

Intraoperative manipulation included the vein puncture, RFA of GSV trunk and perforating or communicating veins. RFA was made under the DUS guidance with the help of ultrasound machine ULTIMA PA Expert of RADMIR company (Ukraine) using of a linear probe. Performing RFA procedure had a number of additions without coming into conflict with NICE's 2013 recommendations. To perform the first stage of the procedure the CR45i guide wire was used. It was put into the great saphenous vein in its distal part next to the medial condyle using the Seldinger technique with 6F introducer up to 1.5 cm distal inferior to the sapheno-femoral junction (SFJ). We should mention that obliteration of GSV is performed only with distal part of 0.5 cm which is withdrawn little by little to close the vein completely. Fast entry and withdrawal of the catheter is provided by special polytetrafluoroethylene (PTFE) coating of its flexible part.

After the satisfactory positioning of the guide wire had been confirmed with ultrasound, tumescent anesthetic solution was injected into the soft tissue surrounding the target vein along its entire length. Tumescent anesthesia with standard Klein's solution was used by mixing 20 mL of 2% lidocaine with 1L of normal saline and adding 0.5 mL of epinephrine 1:1000 and 12.5 mL of 8.4% $NaHCO_3$.

CR12i and CR30i wires with special introducers were used for the RFA of varicose tributaries of the GSV with diameter from 1.5 to 5 mm and for the perforating veins. As the generator of radio frequent impulses was used system EVFR. Thus, for coagulation of GSV trunk there was used the power of 25 W and consequently for the perforating and collateral veins from 8 to 20 W based on the vein diameter. The metal wire tip produced the radio frequent signal with 4 MHz frequency. Under the influence of this radio frequency the wall of the surrounding vein was heated and coagulated.

After the procedure, compression stockings and bandages were applied to reduce postoperative bruising and tenderness. Within 7 postoperative days Nadroparin was administered subcutaneously for the

venous thromboembolism prevention. The first dose was injected in the hospital after that in an outpatient setting. There was also recommended intake of outpatient-based combination therapies by Diosmin and Hesperidin.

Patient's data as well as case histories, clinical symptoms of VV were summarized and analyzed in accordance with the descriptive statistics, which included mean, median, standard deviation at 95% confidence interval. The primary endpoint of the investigation was to identify recurrence of VV after RFA within 12 months. The secondary endpoint was to assess the clinical course of the investigated patient groups according to the classification scales CEAP and VCSS. Endpoints were assessed before the surgery and on the 1st and 7th day after the surgery and also in 1, 3, 6, 9 and 12 months. The investigation included patients who were examined on the 1st day after the surgery. The patients with VV on the two lower limbs were analyzed as a whole during analyzing the subject characteristics of the investigation. In assessing the VV in patients who have vein disease on both lower limbs, each leg was analyzed separately. Kaplan-Meier analysis was used to describe the presence of reflux or recurrence in the veins treated by RFA. Analysis of variance (ANOVA) and multiple comparison procedure Tukey-Cramer performed on all of control visits to protection between logical conclusions and save of conventional threshold for declaring statistical significance and the error rate of type 1. There was made the comparison of control visits according to the Dunnett test. To confirm the null hypothesis there has been calculated value of the standard error in each control visit. All the analysis was made using software Microsoft Excel 2017 and XLSTAT 2017 by Addinsoft SARL, Paris, France.

RESULTS

During the period from November 2022 to November 2024 there were 134 patients with varices of the 174 GSV (VV of both lower limbs were in 40 patients) were treated at Poltava 2-nd City Hospital. Among 134 patients treated by RFA on the 12th month of the investigation 124 patients with varices of the 158 GSV (92.5%) were left. Thus, the contact with 10 of them (7.46%) was lost before the deadline of investigation.

The average age of the patients was 49.33 ± 13.03 (range 18-71) years. At the start of the investigation there were 98 (73.13%) females. At each control visit the number of women was not less than 67%. The average body mass index of 134 patients was 27.5 ± 6.2 (range 18.4-42.1) kg/m^2. Concomitant diseases were observed less than in 1/3 of the patients: 34 patients (25.37%) with hypertension history. Treatment of VV in both lower limbs by RFA was performed in 40 of 134 patients (30%). There were 84 right lower extremities and 90 left once of 174 lower limbs involved in the investigation. The average length of GSV from saphenofemoral junction (SFJ) to the venipuncture site in the most distal reflux point was 35.2 ± 10.3 cm. During the RFA procedure tumescent anesthesia with standard Klein's solution was used, its averaged volume was 400 ± 100 ml and it was injected into the soft tissue surrounding the GSV. Taking into consideration the length of the vein the volume of Klein's solution was average 11.4 ± 4.4 ml per cm. 12 patients (9%) were operated on for the veins without affecting GSV before the investigation. These surgeries included 10 sclerotherapies and 2 unspecified surgeries. If it was impossible to finish the surgical procedure only by means of RFA on the VV additional manipulations were used, such as: conventional stripping operation (phlebectomy) of 40 lower limbs (22.9%); foam sclerotherapy of 30 lower limbs (17.2%); the usage of CR30i wire for perforator veins in 20 lower limbs (11.49%).

The average preoperative GSV diameter was 10.87 ± 3.63 (range 2,0-22) mm at the distance of 3 cm from the SFJ. Most veins' diameter was measured in the supine position, in accordance with the guidance provided in the investigation design.

The occlusion of all length the GSV was achieved in the 134 patients (100%) and was confirmed according DUS. The average GSV diameter at the distance of 3 cm from the SFJ immediately after the RFA procedure was 3.16 ± 1.81 (range 1,0-9) mm. The difference between the average preoperative and postoperative diameter of GSV on the same segment was 7.86 mm. The occlusion of GSV on the next day after RFA procedure was observed in 172 lower limbs (98.85%), with an average distance from the SFJ 13,4 ± 2,8 (range 10-18) mm. In one case the occlusion of the GSV was delayed, it was confirmed on the 7th day during the control DUS.

Ultrasound observation was carried out during all control visits to measure the veins diameters treated by RFA. The frequency of DUS control on the first day after the RFA was 100% of all 87 lower limbs of the investigation group; on the 7th day they were 98.51%; in a month – 76.12%, in 3 months – 56.72%; in 6 months – 40.3%; in 9 months – 16.42% and in 12 months they were 7.46%. The average diameter of the fibrous strand of GSV after the RFA, measured at 3 cm from the SFJ, decreased from 3.16±1.81 mm on the first day to 2.88±1.56 mm in 7 days (86 lower limbs) and 2.8 ± 1.39 mm in a month (66 lower limbs); 2.61 ± 1.39 mm in 3 months (48 lower limbs); 2.39 ± 1.13 mm in 6 months (29 lower limbs); 2.08 ± 0.79 mm in 9 month (15 lower limbs); 1.8 ± 1.1 mm in 12 months of investigation (5 lower limbs), it is represented in Fig. 1. Tukey-Kramer's analysis stated

Table 1. Analysis Tukey, honestly significant difference test (HSD)

Contrast	Difference	Standardized difference	Critical value	Significant
0 vs 365	9.0657	9.2482	3.0507	Yes
0 vs 270	8.7823	13.2503	3.0507	Yes
0 vs 180	8.4728	17.8067	3.0507	Yes
0 vs 90	8.2604	19.2370	3.0507	Yes
0 vs 30	8.0618	20.5169	3.0507	Yes
0 vs 7	7.9869	21.7802	3.0507	Yes
0 vs 1	7.7015	21.0813	3.0507	Yes

Source: compiled by the authors of this study

statistically significant reduction in the diameter of the GSV fibrous strand between the examination before surgery and subsequent visits with 95% confidence interval. It is confirmed in (Table 1).

The table presents the data portion according to the ANOVA analysis, which shows a significant and stable distinction of GSV diameter at the distance of 3 cm from the SFJ within the visit before surgery - 0 and analogically for 12 months with 95% confidence intervals. It shows the comparison of difference, a standardized difference, the critical value, the significance of differences. When comparing the data of control visits after surgery there were not revealed significant differences.

The average stump length at the SFJ remained stable in time: 13.4 ± 2.76 mm on the first day; 13.35 ± 2.73 mm in 7 days; 13.33 ± 2.89 mm; 13.34 ± 2.74 mm; 13.11 ± 2.74 mm; 13.00 ± 2.73 mm; 12.2 ± 2.39 mm in 1, 3, 6, 9, 12 months after treatment accordingly (Fig 1).

On the third month of observation during the control DUS there was diagnosed perforator vein reflux in the distal third of the GSV and treated as re-opened in two patients. Reflux was accompanied by appropriate clinical picture, there were observed varicose veins below the knee. Besides, the patients mentioned the presence of heavy leg and diffuse brown pigmentation on it.

The burn of the skin appeared in the other two patients in the lower third of the leg after RFA using CR12i and CR30i wires for performant veins. Its size was 3×1.5 cm, which consequently healed by secondary intention. In a month of observation, the site of the burn was determined by minor skin pigmentation.

Kaplan-Meier analysis showed no recurrence probability VV outcome using the RFA 98.77% (Fig. 2). Confidence interval at 95% was the bottom bound - 0.936, the top bound -1.000. Standard errors for the evaluation were 0.0123. The average survival time (without recurrence of VV) was totally 238.15 days.

During the observation period, all the patients were diagnosed according to CEAP during the control visits at the time of the admission, on the first and on the seventh day and in 1, 3, 6, 9, 12 months after the RFA (Fig. 3).

In the test group before the surgery, the patients with C2 were 56.72%, with C3, C4, respectively 34.33% and 8.96%. By the third month of the observation, the patients with C3 were 21.05%. And by the sixth month, their part decreased to 3.70%. At the same time, the number of the patients with C2 increased from 15.79% in 3 months to 29.63% in 6 months. A part of the patients with C4 did not rise above 9% and tended to decrease clinical class according to the CEAP. As in 3 months the number of patients with C4 was 5.26%, then in 6 months there were no finds.

By the 9th month of the investigation and further in all the observed patients there was determined C0 (45.45%) and C1 (54.55%) clinical classes, according to the CEAP classification.

At the beginning of the investigation, the average meaning of VCSS for 174 lower limbs was 4.69 ± 2.04 (range 1-9) points. It was represented by VV without complications or venous edema not above the ankle in the evening. The showings according to VCSS improved significantly at the following visits. Thus, on the seventh day since the RFA procedure VCSS evaluation made on the average 2.52 ± 1.92 (range 0-7) points, in a month – 1.27 ± 1.22 (range 0-5) points and reached a value of 0.6 ± 0.55 (range 0-1) points for the 10 lower limbs till the 12-th month of the observation (Fig. 4).

Varicose veins were present in 100% of the lower limbs at the beginning of the investigation, 54% of them were coming out of GSV (score on the scale VCSS - 2). According to VCSS assessment, in all patients in 7 days varicose veins were not revealed in the lower limbs. A part of the lower limbs with varicose veins (score on the scale VCSS - 1) increased to 4.6% in 12 months. However, at the same time, VV appeared in 2.3% of the lower limbs in 3 months of investigation (determined by the reflux of blood through the re-opening of perforating vein in the leg) with the corresponding clinical symptoms (score on the scale VCSS - 4).

Swelling of the lower limbs with VV in the preoperative period was observed in 55.17% of the patients. In 1 month after the RFA procedure, it was observed in

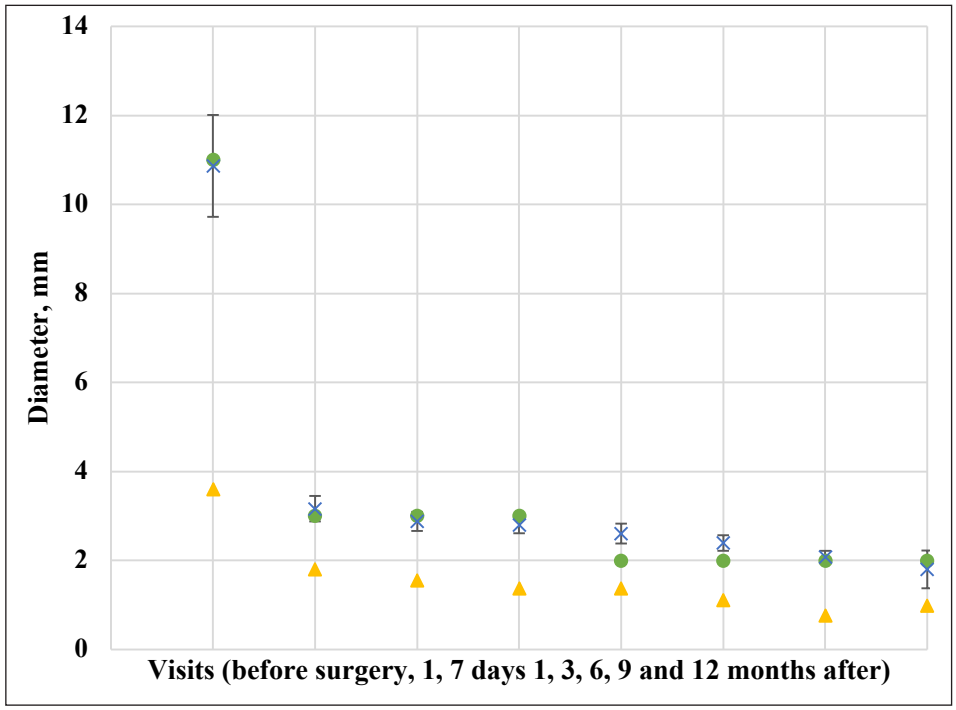

Fig. 1. The GSV diameter at the distance of 3 cm from the SFJ before and after RFA – in 1, 7 day's and 1, 3, 6, 9, 12 months of observation. Mean (blue cross), the median (green dot), standard error of variance at all study visits (black line with horizontal outside) and the standard deviation - n (yellow triangle)
Picture taken by the authors

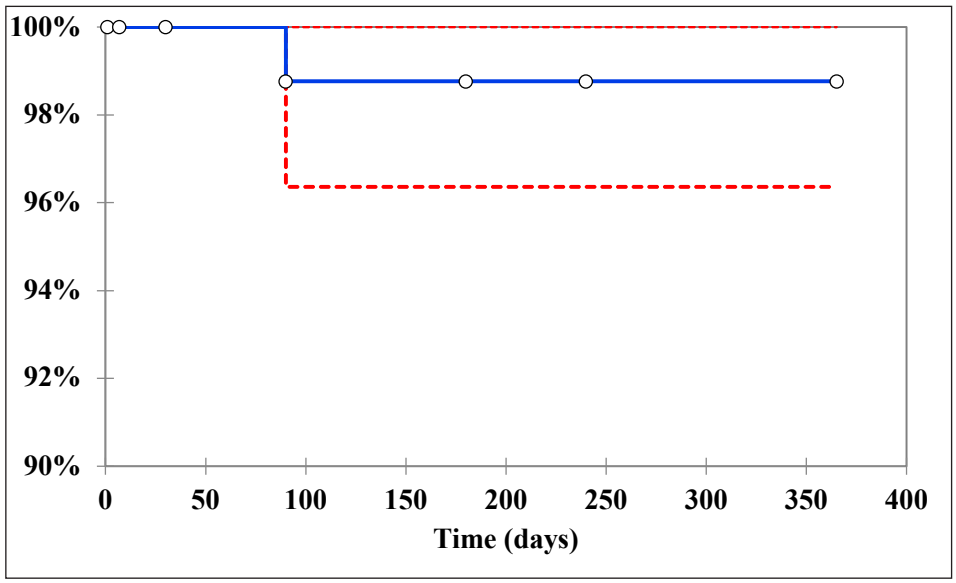

Fig. 2. The distribution function of Kaplan-Meier shows the probability of the outcome without recurrence of VV using RFA (blue line). The black circles indicate the control visits of the patients in the sample. The red dotted line marks the upper and lower limit of the confidence interval. Standard error throughout the investigation was less than 0.05
Picture taken by the authors

12.64% of the lower limbs. It appeared in the evening and did not extend above the leg (VCSS 2 points). In 12 months, swelling was observed during the control visit at 20.68% of the patients, but it did not extend above the ankle and appeared only in the evening (score on the scale VCSS - 1).

According to the survey, 62.06% of the respondents at the time of admission complained of pain according to VCSS. At 40.23% it was an episodic pain without affecting the activity and did not require analgesics. At 19.54% it was a daily pain, which moderately restricted the activity and required to take analgesics episodically. At 2.3 % of cases, it was a daily pain, which essentially restricted the activity and required to take analgesics regularly. In a month after the treatment, the pain reduced to 22.99%, and in 3 months it reduced to 19.54%. There was assessed episodic pain (17.24%) and daily pain, which moderately restricted the activity and required to take analgesics episodically (2.3%). In 9 months after the treatment that index decreased to 9.2% of the lower limbs: episodic (6.9%) or daily (2.3%) respectively. In 12 months, only 1.15% of patients complained of episodic pain.

DISCUSSION

The results of 12 months observation of used firstly the monopolar RFA EVFR system in patients with GSV

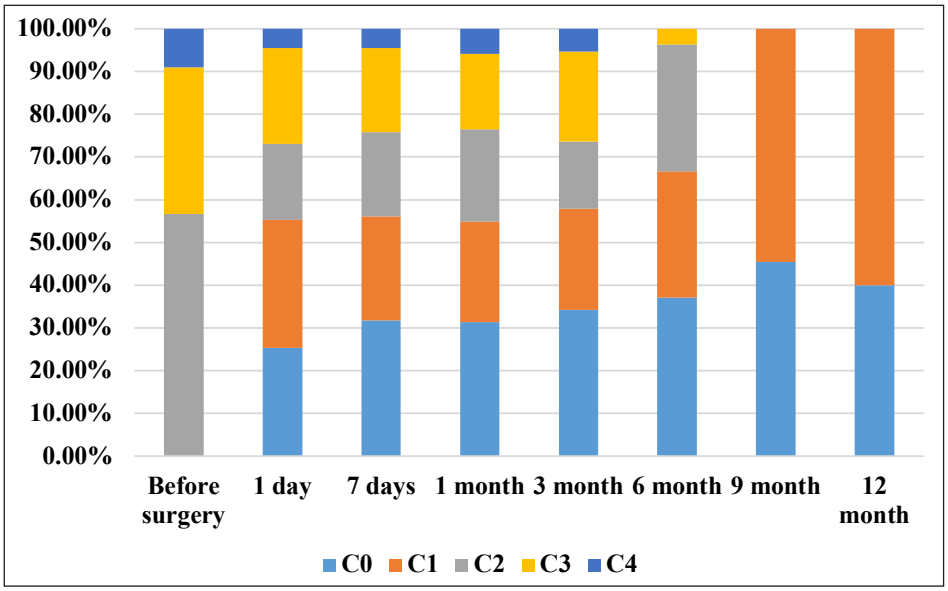

Fig. 3. The proportion of the patients according to the CEAP classification before the procedure, on the first and seventh days and in 1, 3, 6, 9, 12 months of observation. C0 (blue column), C1 (brown column), C2 (gray column), C3 (yellow column), C4 (blue column)
Picture taken by the authors

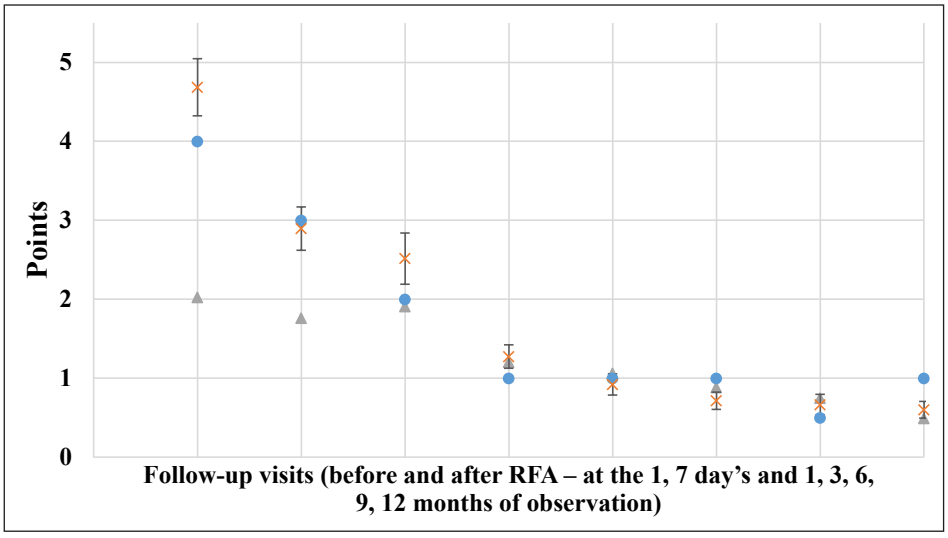

Fig. 4. The average meaning of VCSS before the procedure, on the first and seventh days and in 1, 3, 6, 9, 12 months after RFA (orange cross). The blue circles show the median of VCSS at the time of control visit. Standard error variance at all visits of the investigation was less than 0.8 (the black line with the horizontal limits) and the standard deviation - n (gray triangle)
Picture taken by the authors

incompetence are submitted in the mentioned above investigation. A limited set of the side effects of RFA combined with a high frequency of long-term occlusion of GSV is confirmed with prospectively multicenter comparisons with endovenous laser and classical surgery [5]. Different investigations have acknowledged the auspicious by-effect profile of RFA versus endovenous laser ablation (EVLA) [6-7]. The pain and swelling were observed more rarely for the first fortnight after the RFA procedure versus EVLA procedure. The patients who got the RFA came back to work 4 days sooner than those ones who got EVLA [8]. When we compare the RFA with modern technology of Mechanochemical ablation (MOCA), we can see that MOCA is not so painful and contributes to patients returning to work earlier [9]. Nevertheless, there is evidence that after a year observation at RFA group occlusion of the lumen of the GSV was achieved in 100% cases, while the successful occlusion of the GSV in MOCA group was 82%, and the quality of life of the patients was similar in the groups of comparison [10]. According to the recent investigation, the RFA provides a low frequency to reflux recurrence in 12 months [11]. This method is characterized as one having minimal side-effect profile.

At present, most modern methods of treatments of saphenous vein incompetence are concentrated on minimum by-effects and qualitative well-being after the procedure [12]. By the way, it is worth taking into consideration the original goal of reliable and long-term absence of vein reflux. For example, there is the foam sclerotherapy of the saphenous veins, which looks attractive at first sight due to its easy and quick use and minimal decline in the quality of life [13]. In reference to foam sclerotherapy, we mustn't choose it as the therapy of the first-line at saphenous veins incompetence, at their large diameter in particular, because the risk of unsuccessful grows if the vein diameter is larger than 6 mm [14]. Taking into consideration the mentioned

above data, the anatomic long-term outcomes of MOCA show that the degree of recanalization and detection of reflux in treated veins is higher than after RFA and EVLA [15]. Besides, the revision of protocols for using EVLA with lower doses of energy is necessary, as there are the data showing that the rate of postoperative pain and hematoma was higher than using the wavelength 1470 nm. With the reduction of the energy dose of laser radiation side effect profiles may be improved, but the anatomical success rates may fall below standard benchmarks.

The definition of occlusion was very specific and limited key criteria in this investigation: complete occlusion and the absence of reflux in the treated vein 3 cm below of the SFJ. There was determined blood flow in the perforator vein of GSV in the leg 5 cm length at 1 patient after the RFA in 3 months. In such cases, a real unsuccess of treatment is doubtful since the localization of venous tributaries can affect the final occlusion of GSV.

CONCLUSIONS

In 12 months, the RFA demonstrated its efficiency as a method of endovenous treatment of incompetent great saphenous vein from the point of view of sustainable clinical and anatomic success for the majority of treated patients.

In spite of the fact that in this investigation the quality patients' life was not evaluated, the VCSS and a few of its items distinctly showed the improvement of long-term clinical progress after the RFA. Within 12 months of the observation VCSS assessment improved significantly and tended to decrease the number of points. According to the evaluation VCSS, the presence of VV (sum score 1-3) fell to a minimum of less than 3% just on the first day after the procedure and then remained stable of about 2% in 12 months. It reflects the natural course of vein disease. According to VCSS pain index improved a lot in the medium term. On the baseline only 37.94% of the affected lower limbs didn't feel pain, while its part was more than 98.85% till the 12th month of investigation. The RFA is an efficient way to treat the GSV incompetence in the medium term. Complex investigation of other techniques within 12 months is necessary to select the optimal method of treatment for GSV incompetence.

No adverse events or serious side effects related to the procedure were recorded, and local manifestations were less pronounced compared to laser ablation, allowing patients to return to work faster. Based on our evaluation of clinical data, it can be concluded that RFA is an effective treatment for GSV insufficiency in the medium term. However, to select the optimal treatment method and prevent recurrence of varicose veins and GSV insufficiency after one year, a comprehensive study of other methods over 12 months and long-term follow-up of all patients is necessary.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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