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Comparative Study between Ultrasound-Guided Foam Sclerotherapy, Radiofrequency Ablation & Endo-Venous Laser Ablation in Treatment of Great Saphenous Vein Reflux

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Abstract

Background: The main goal in the treatment of varicose veins is to reduce the symptoms and complications of chronic venous insufficiency and to improve health related quality of life (QoL) of patients. Surgery has been the standard of care in the treatment of saphenous varicose veins for more than a century.

Aim of Study: The aim of this work is to compare between the outcome after UGFS, RFA & EVLA concerning the treatment of great saphenous vein reflux, regarding success rate, recurrence rate and complications rate.

Subjects and Methods: This study was carried out at the Vascular Surgery Department, Zagazig University Hospitals during the period from August 2016 to August 2018, included a total of 51 treated lower limbs in 39 patients were divided into three different groups: Endovenous Laser Ablation (EVLA group) (n=18 legs in 13 patients; 1470nm, continuous mode, radial fiber), Radiofrequency Ablation (RFA group) (n=16 legs in 13 patients) and Ultrasound Guided Foam Sclerotherapy (UGFS group) (n=17 legs in 13 patients). All patients were subjected to complete clinical examination and laboratory investigations. Post procedure follow-up was done after one week, three month, six months & one year following treatment and all limbs were assessed clinically and by using DUS.

Results: All the three treatment modalities significantly improved VCSS and QoL as reflected by significant improvements in VCSS and CIVIQ; with no significant differences in the outcome between the groups. The improvements persisted throughout the 2 years and showed that EVLA, RFA and UGFS are efficient treatments with longerterm beneficial effects in patients with GSV varicose veins. This is true even though some patients in the UGFS group developed recanalization of the GSV. UGFS group was significantly longer regarding duration to return to work (p<0.01) than EVLA and RFA group which both had non-significant difference between them.

Conclusion: Our study demonstrated that EVLA & RFA are efficient modalities for the treatment of GSV varicose veins in the medium term. Notinga moderate rate of recanalization after UGFS, it appears that EVLA & RFA are superior to UGFS regarding clinical recurrence, VCSS and QoL. Postoperative patient comfort and the outcome of EVLA & RFA in short & medium-terms are superior to those after UGFS in terms of recanalization & effective ablation.

Key Words: *Endovenous laser ablation – Radiofrequency ablation – Ultrasound guided foam ablation – Varicose veins – Reflux.*

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Introduction

VARICOSE veins of the lower limbs were defined as dilated subcutaneous veins that are more than 3mm in diameter measured in standing. Varicosity can involve the main axial superficial veins; the Great Saphenous Vein (GSV); the Short Saphenous Vein (SSV) or any other superficial vein tributary ofthe lower limbs [1]. The CEAP-classification (0-6) is used for the description of Clinical signs of Chronic Venous Insufficiency (CVI), Etiology (Congenital, primary or secondary), Anatomy (Superficial, deep and perforating vein) and Pathophysiology (Reflux, obstruction or both). The CEAP-classification gives a systematicguide in the clinical investigation of patients. It is an orderly documentation system and gives a synthesis of the phlebological status. It also helps in selecting the appropriate treatment sequence. This classification made diagnosing CVI offered basis for more scientific analysis of management strategies [2]. UGFS is indicated in primary (linear and tortuous) varicose veins, previously treated varicosities and recurrence after surgery (i.e. Neovascularization). Varicosities with small and large diameters could be treated with UGFS but saphenous veins with di-

ameters of 10 millimeters or more may need frequent treatments and large volumes of foam (up to three sessions and 15cc of foam). UGFS could be used in patients with severe Chronic Venous Insufficiency (CVI) and may improve healing of ulcers. This technique is used also to treat perforator venous incompetence andcongenital venous malformations [3]. The indications for Radiofrequency ablation (RFA) are the same as EVLA, except that with RFA it is more difficult to treat veins with diameters more than 12mm. Even though, with ample use of tumescent anesthesia, such veins can be treated successfully. A 5F. (1.7mm) and a 8F. (2.7mm) catheter can be used for varicose veins between 4 and 8mm and as large as 12mm, respectively. The manufacturer introduced a new catheter of unique size that can be used independent of the diameter of the vein. Because of the catheter size & rigidity, to avoid perforation, extreme care is indicated in treating tortuous and relatively small veins [4]. EVLA can be used in the treatment of insufficient GSV. Because of the rigidity and size of the disposable catheters, linear primary truncal varicosities with diameter of five mm or more are ideal for EVLA. If thinner fibers are used, EVLA can be used for more tortuous veins suchas the accessory saphenous vein and also perforator veins. In the treatment of recurrent varicosities, care is indicated because introducing the laser may be more difficult with possible risk of inducing embolic events [5]. Both Endovenous Laser Ablation (EVLA) and Radiofrequency Ablation (RFA) are efficient in Great Saphenous Vein (GSV) occlusion on the long term. Lacking long-conducted large trials, the efficacy and reliability of ultrasound guided foam sclerotherapy to treat great saphenous vein-reflux is not affirmed [6].

Subjects and Methods

I- *Patients:*

This study is a prospective Randomized Controlled Clinical Trial (RCT). It was carried out in Vascular Surgery Department, Zagazig University Hospitals after obtaining approval by the Research Ethics Committee, during the period from August 2016 to August 2018. A total of 51 treated limbs in 39 patients were divided into three different groups: Endovenous Laser Ablation (EVLA group) (n=18 legs in 13 patients; 1470nm, continuous mode, radial fiber), Radiofrequency Ablation (RFA group) (n=16 legs in 13 patients) and Ultrasound Guided Foam Sclerotherapy (UGFS group) (n=17 legs in 13 patients).

II- *Inclusion criteria:*

1- Primary varicose veins.
2- Age between 18-60 years of age.
3- Sex, no predilection between males & females.
4- Primary varicose veins.
5- Age between 18-60 years of age.
6- Sex, no predilection between males & females.

III- *Exclusion criteria:*

1- Patients with previous Deep Venous Thrombosis (DVT).
2- Patients with congenital venous anomalies.
3- Patients with chronic ischemia (Ankle Brachial Index “ABI” <0.9).
4- Patients with abnormal coagulation profile.
5- Patients with active pulmonary or pleural disease.

IV- *Ethical consideration:*

1- Approval from Vascular Surgery Department in Zagazig University Hospitals.
2- Approval from institutional review board in Zagazig University Hospitals.
3- Informed consent from the patients or their relatives about the study according to policy of the Zagazig University Hospitals.
4- No harmful procedure will be performed or used for any patients.

V- *All patients were subjected to the following:*

1- A full history especially history of varicose veins disease.
2- Patient's demographics: Age, sex, smoking, body mass index.
3- *Occupation:* Job necessitates long standing.
4- *Medications history:* Allergy to anesthesia, contraceptive pills or usage of anti-coagulants (Warfarin) or antiplatelet drugs (Aspirin, Clopidigrel).
5- *Family history:* Similar condition, established thrombophilia.
6- *Past medical history:* History of hypertension, diabetes, cardiac diseases, superficial thrombophlebitis or Deep Vein Thrombosis (DVT).
7- *General examination:* Including cardiovascular, respiratory & abdominal examination.
8- *Laboratory investigations:* Including Complete Blood Count (CBC); Fasting Blood Sugar (FBS)

and (HbA1C) in diabetic patients; bleeding profile; serum urea and creatinine.

9- *Local examination:* Examination in the standing patient in a warm room and good light; the size, location, in addition to the distribution of varicose veins; complete pulse examination is accomplished to exclude peripheral arterial disease.

10- *Severity assessment:* The clinical severity of venous disease was established using CEAP [clinical, etiological, anatomical & pathological] and VCSS. Further the effect of disease specific quality of life was determined using the CIVIQ:

• In VCSS, each patient was given a score between 0 and 30 according to 10 parameters (pain, varicose veins, edema, pigmentation, inflammation, induration, number of ulcers, duration of ulcers, size of ulcers & compressive therapy) which are graded 0 to 3 (absent, mild, moderate & severe).

• In CIVIQ, each patient completed the 20 question Chronic Venous Insufficiency Questionnaire (CIVIQ) quality of life questionnaire after being translated to Arabic. The CIVIQ comprises 20 questions in four quality of life domains (physical, psychological, social & pain). All questions have a 5 point response category, with higher scores reflecting more severe impairment, and the global scores, were transformed into a scale of 0-100.

11- *Duplex ultrasonography:*

• The deep system was evaluated for patency& presence of abnormal reflux.

• The superficial system was evaluated as regarding the SFJ, GSV, SPJ & perforators; measuring reflux time & vein diameter is of great value.

• The presence of retrograde flow lasting >0.5s was considered significant.

• Before surgery, precise mapping (Cartography) was done using duplex-scanning method from the groin to the ankle to highlight tortuous veins, areas of ectasia and incompetent perforators.

VI- *Intraoperative performance:*

• The surgical procedure was performed with the patient under spinal anesthesia.

• The venous anatomy was mapped with duplex ultrasound, so the operator review it before beginning the procedure with measuring the size of the vein and noting areas of tortuosity and location of tributaries and perforators.

• Positioning: For GSV ablation; the patient was laid supine, for SSV; patient was laid prone with leg down.

• Anesthesia.

• Tumescent solution [(5mL epinephrine + 5mL bicarbonate) and 35mL lidocaine 2% diluted in 500mL saline solution or Ringer's lactate)] was administered into the perivenous space under US guidance using a syringe or mechanical infusion pump.

• The preferred site access site for the GSV was just below the knee.

1- *Ultrasound-Guided Foam Sclerotherapy protocol (UGFS):*

• The Tessari technique was used to produce the sclerosing foam: [(2mL of purified 2% Aethoxysklerol and 8mL of air (ratio 1:4)] were mixed with 2 syringes connected by a 3-way stopcock. The foam solution was created by a rapid mixing of the air with chemical back and forth between the two syringes. This rapid movement of solution from one syringe to the other was performed 20 times to produce 10mL of sclerosing foam.

• The procedure was performed under ultrasound guidance. Patients were positioned in reversed Trendelenburg position to permit better GSV and/or SSV visualization. We accessed the GSV and/or SSV via percutaneous technique using the Seldinger method using a 6F., 1 1cm long sheath to introduce catheter.

• Positioning of the catheter tip was then reconfirmed before starting the procedure. Continuous pull back was used while we deliver the foam under US guidance.

• Closure of the vein was visualized with duplex ultrasound to identify the foam inside the vein ensure sufficient sclerosis.

• The maximum safest amount used was 20mL of foam per session. Patients' legs were elevated for fear of complications of foam embolization such as dyspnea or retinal artery thrombosis.

2- *Radiofrequency Ablation protocol (RFA):*

• Access to the varicose vein was obtained with a 6F. needle under US guidance typically below knee level or distal to the point of reflux.

• The procedures were performed under ultrasound guidance. While patients were positioned in reversed Trendelenburg position; using the Seldinger method; using 8F., 13cm long sheath to introduce the catheter.

- The catheter was positioned 2cm distalto the sapheno-femoral junction under longitudinal US visualization (level of pre-terminal valve).
- A cuff or bandage was used to compress the blood out of the vein.
- Positioning of the catheter tip was then reconfirmed before startingthe procedure. Every pull back was confirmed by a peep from the device that ensured ablation of that 7cm of the venous segment, then serial pull backs was used at about 7cm/30 seconds.
- The first 7cm segment was subjected to 2 sessions of ablations.
- Device details: ClosureFastTM (VNUS) manufactured by© Covidien, Dublin, Ireland.
- To prevent skin burns or trauma to the entry site, we stopped when the tip of the catheter fiber was approximately 1-3cm above the entry site, which was followed by removal of the fiber and sheath.
- Closure of the vein was visualized with duplex ultrasound to identify an increase in echogenicity of the vein wall to ensure complete ablation.
- Complementary percutaneous ultrasound guided foam injection sclerotherapy using polidocanol (Aethoxysklerol 1 or 2%) was done for incompetent perforators and superficial varicosities using the Tessari technique.

3- *Endovenous Laser Ablation (EVLA):*

- Venous access was obtained by a puncture with a 6F. needle under US guidance using the Seldinger method as mentioned before.
- The insufficient GSV was entered at knee level because of ease of access (i.e. large diameter and linear course) with the least risk for nerve injury.
- After entrance to the vein was established, a guidewire was passed through the hollow needle into the vein. Then; the needle was removed & an introducer sheath was passed over the guidewire.
- The most pivotal step was positioning the echodense tip of the catheter 1-2cm distal to the sapheno-femoral junction under longitudinal US visualization (Level of pre-terminal valve) Fig. (1). The wave lengths used in EVLA target deoxygenated hemoglobin and/or water and range of 1470nm.
- Tumescent anesthesia was warranted. After activation, the laser was pulled back continuously with a pull-back speed of 1-3mm/s according to vein diameter.
- Device details: VenacureTM 1470, Diode Laser, CW, class IV; manufactured by Angiodynamics, US.
- Laser fiber: The procedure with radial firing fiber ensured a more homogenous, precise and controlled energy delivery. Radial emission leads to a homogeneous destruction of the vein wall exclusively, without any risk of damage to surrounding tissues.
- Positioning of the fiber tip was then reconfirmed before starting the procedure. Then, the laser was switched from standby to ready mode and the foot pedal was depressed to deliver energy.
- Power was set at 1 0W; the mean energy delivered was ranged from 70-90J/cm for treatment of incompetent GSV.
- Continuous pullback was used while we watched the real-time energy readout on the generator and gauged speed with the 1 cm marks on the sheath delivering 70-90J/cm according to the vein diameter Fig. (2).
- To prevent skin burns or trauma to the entry site, we stopped treatment by removing the foot from the pedal when the tip of the laser fiber was approximately 1-3cm above the entry site, followed by removal of the fiber and sheath.
- Closure of the vein was visualized with duplex ultrasound to identify an increase in echogenicity of the venous wall to ensure complete ablation.
- Complementary percutaneous ultrasound guided foam injection sclerotherapy using polidocanol (Aethoxysklerol 1 or 2%) was done as mentioned in RF procedure.

VII- *Post -procedural assessment:*

1- Patients were discharged at the same day of the procedure.

2- Compressive bandage or long compressive stocking class II was indicated for 2 weeks.

VIII- *Follow-up:*

1- *Clinical assessment:*

- During each patient's visit a standard set of information were collected.

- Venous Clinical Severity Score (VCSS) classification was determined and compared with the patient's score before the procedure.

- Patients were asked to complete another 20 question Chronic Venous Insufficiency Questionnaire CIVIQ quality of life questionnaire and compared with the patient's score before the procedure.

• Return to normal activity was asked & symptoms relief was assessed.

• Patients were asked to complete post-operative assessment data sheets for 30 days assessing for pain by 10cm Visual Analogue Scale (VAS).

2- *Duplex assessment:*

• Each patient had a follow-up by duplex ultrasound after one week, one month, three month, six months & one year following treatment for the presence of recurrent varicose veins (short and midterm).

Statistical analysis:

• Data collected were coded, entered and analyzed using Microsoft Excel software.

• Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) software for analysis.

• According to the type of data.

• Qualitative data were represented as numbers and relative percentages.

• Quantitative continuous data were represented by mean ± SD (standard deviation).

• The following tests were used to test differences for significance.

• Difference and association of qualitative variable by Chi square test (χ^2).

• Differences between quantitative independent groups by ANOVA test.

Results

The mean age was 30.23±8.22 in EVLA group, 32.92±6.08 in RFA group and 29.23±8.12 in UGFS group; with no significant difference among them. Females were the majority among groups as it were distributed as 53.8% in EVLA group, 69.2% in RFA group & 53.8% in UGFS group, while males were distributed as 46.2% in EVLA group, 30.8% in RFA group & 46.2% in UGFS group; with no significant difference among the groups regarding sex. As for BMI, the mean BMI (Kg/m^2) was 21.38 ±1.55 in EVLA group, 22.07±0.64 in RFA group and 22.0± 1.0 in UGFS group with no significant difference among the three studied groups (Table 1) and Fig. (3).

There was non-significant difference whether the lesion was unilateral or bilateral between the three studied groups. Most of RFA group patients were unilateral (Table 2).

There was non-significant difference in distribution of CEAP classification between the three studied groups. Majority of cases were in C4 category (Table 3).

Valve closure time was non-significant among the three studied groups; although p-value was <0.05, which was a coincidence (Table 4) & Fig. (4).

UGFS group was significantly longer regarding duration to return to work than EVLA and RFA group which both had non-significant difference between them (Table 5) & Fig. (5).

All patients had improvement in VAS after the three procedures with Significant Improvement in EVLA & RFA groups than UGFS group within the 1st week and after one month post-operative than pre-operative periods Fig. (6).

All patients had improvement in VCSS after the three procedures with a High Significant Improvement in both EVLA & RFA groups than UGFS group after six months postoperative than pre-operative periods Fig. (7).

Post-operative complications are reported graphically in Fig. (8); we specifically focused on:

1- *Hematoma:* No hematomas noted among the three studied groups during follow-up.

2- *Bruising and phlebitis:* Was significantly associated with EVLA and UGFS groups with non-significant association regarding bruising; we reported only a single case in RFA group & we didn't report any case of post-operative pain or hemorrhage (Table 6). All cases improved with conservative management within three weeks.

3- *Thermal related injury:* One case was reported in EVLA group & another in RFA group; in the form of mild erythema at a segment along the course of the vein (mainly at the knee) that might be due to insufficient tumescent anesthesia. All cases improved with conservative management within one month.

4- *Pigmentation:* Occurred in EVLA group & RFA group in 2 limbs each; along the course of GSV which might be due to vein ablation and persisted for 6 month and occurred in UGFS group in one patient (2 limbs) as a residue to the sclerosing material (Table 7).

5- *Paraesthesia:* Occurred in EVLA group & RFA group in 2 limbs each; along the supply of the saphenous nerve, improved within one month and no cases were reported in UGFS group.

Table (1): Demographic data of the three studied groups (age, BMI and sex distribution).

Variant	EVLA	RFA	UGFS	F/χ^2	*p*
Age	30.23±8.22	32.92±6.08	29.23±8.12	0.833	0.443
BMI	21.38±1.55	22.07±0.64	22.0±1.0	1.465	0.245
Sex:					
• *Female:*					
N	7	9	7	0.84	0.65
%	53.8%	69.2%	53.8%		
• *Male:*					
N	6	4	6		
%	46.2%	30.8%	46.2%		
Total:					
N	13	13	13	–	–
%	100.0%	100.0%	100.0%	–	–

Table (2): Lesion laterality among the three studied groups.

Variant	EVLA	RFA	UGFS	Total	χ^2	*p*
Bilateral:						
N	5	3	4	12	1.22	0.87
%	38.5%	23.1%	30.8%	30.8%		
Left:						
N	4	4	5	13		
%	30.8%	30.8%	38.5%	33.3%		
Right:						
N	4	6	4	14		
%	30.8%	46.2%	30.8%	35.9%		
Total:						
N	13	13	13	39	–	–
%	100.0%	100.0%	100.0%	100.0%		

Table (3): Clinical (CEAP) classification between the three studied groups.

Variant	EVLA	RFA	UGFS	Total	χ^2	*p*
CEAP:						
• *C2:*						
N	0	0	1	1	3.3	0.509
%	0.0%	0.0%	7.7%	2.6%		
• *C3:*						
N	2	4	4	10		
%	15.4%	30.8%	30.8%	25.6%		
• *C4:*						
N	11	9	8	28		
%	84.6%	69.2%	61.5%	71.8%		
Total:						
N	13	13	13	39	–	–
%	100.0%	100.0%	100.0%	100.0%	–	–

Table (4): Pre-operative valve closure time distribution among the three groups.

Variant	EVLA	RFA	UGFS	F	*p*
• Valve closure time	0.73±0.14	0.62±0.13	0.58±0.09	4.420	0.019*

Table (5): Return to work between the three studied groups.

Variant	EVLA	RFA	UGFS	F	*p*
Return to work	9.07±2.87	8.92±2.13	15.69±5.21	13.962	0.00**

Table (6): Post-operative phlebitis & bruising among the three studied groups.

Variant	EVLA	RFA	UGFS	Total	χ^2	*p*
Post-operative phlebitis:						
• *–ve:*						
N	9	13	7	29	7.53	0.023 *
%	69.2%	100.0%	53.8%	74.4%		
• *+ ve:*						
N	4	0	6	10		
%	30.8%	0.0%	46.2%	25.6%		
Post-operative bruising:						
• *–ve:*						
N	13	12	13	38	2.05	0.35
%	100.0%	92.3 %	100.0%	97.4%		
• *+ ve:*						
N	0	1	0	1		
%	0.0%	7.7%	0.0%	2.6%		
Total:						
N	13	13	13	39	–	–
%	100.0%	100.0%	100.0%	100.0%	–	–

Table (7): Post-operative pigmentation among the three studied groups.

Variant	EVLA	RFA	UGFS	Total	χ^2	*p*
Pigmentation:						
N	12	12	1	5	1.22	0.87
%	15.4%	15.4%	7.25%	38.05%		

6- *DVT:* No cases were reported during the 2 years follow-up of the study among the three studied groups.

7- Spinal headache: Occurred in EVLA group in one cases, found in 2 cases of RFA group and increased in UGFS group to 3 cases, which might be due to frequent changing the position of patient during the procedure.

8- Patient satisfaction & health related quality of life (QOL) [Chronic Venous Insufficiency Questionnaire] (CIVIQ): There was non-significant difference in the CIVIQ between the three studied groups pre-operatively, but 6 months later it was found that there was high significant difference in CIVIQ between EVLA, RFA groups in one hand & UGFS on the other hand; this is probably due to that 4 cases of UGFS group showed partial occlusion of GSV during follow-up DUS Fig. (9).

Clinical recurrence:

Follow-up was done after one week, one month, three month, six months & one year following treatment; clinically and by using DUS. Partial significant difference was found associated with UGFS group (Table 8); Figs. (10,11).

The need for complementary procedures (reoperation):

There was non-significant difference that required reoperations or complementary procedures; except in 4 cases in UGFS group, in whom required an additional session of UGFS for complete obliteration of GSV (Table 9); Fig. (12). Mean survival from failure in EVLA & RFA was 24 ±0 months, while in UGFS was 19.5±2.9 months Fig. (13).

Table (8): Post-operative duplex results among the three studied groups.

Variant	EVLA	RFA	UGFS	Total	χ^2	*p*
Complete occlusion:						
N	13	13	9	35	7.99	0.021*
%	100.0%	100.0%	69.3%	89.8%		
Partial occlusion:						
N	0	0	4	4		
%	0.0 %	0.0%	30.7%	10.2%		
Total:						
N	13	13	13	39	–	–
%	100.0%	100.0%	100.0%	100.0%	–	–

Table (9): Follow-up & recurrence among the three studied groups.

Variant	EVLA	RFA	UGFS	Total	χ^2	*p*
Recurrence (short-mid):						
• *–ve:*						
N	13	13	9	35	7.99	0.021*
%	100.0%	100.0%	69.3%	89.8%		
• *+ve:*						
N	0	0	4	4		
%	0.0%	0.0%	30.7%	10.2%		
Recurrence in 2 years:						
• *–ve:*						
N	13	13	9	35	7.99	0.021*
%	100.0%	100.0%	69.3%	89.8%		
• *+ve:*						
N	0	0	4	4		
%	0.0%	0.0%	30.7%	10.2%		
Total:						
N	13	13	13	39		
%	100.0%	100.0%	100.0%	100.0%	–	–

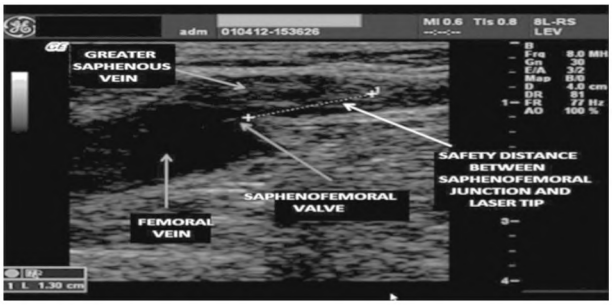


Fig. (1): Placement of the laser tip catheter near SFJ.

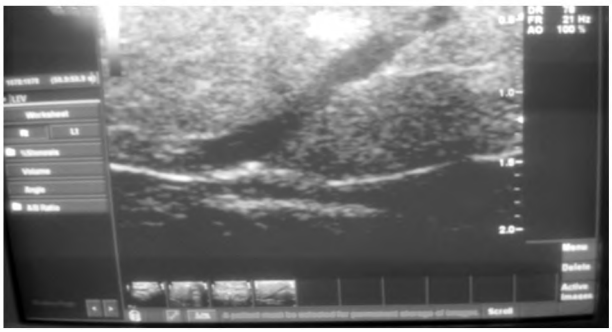


Fig. (2): US of laser catheter after tumescent anesthesia during pull-back.

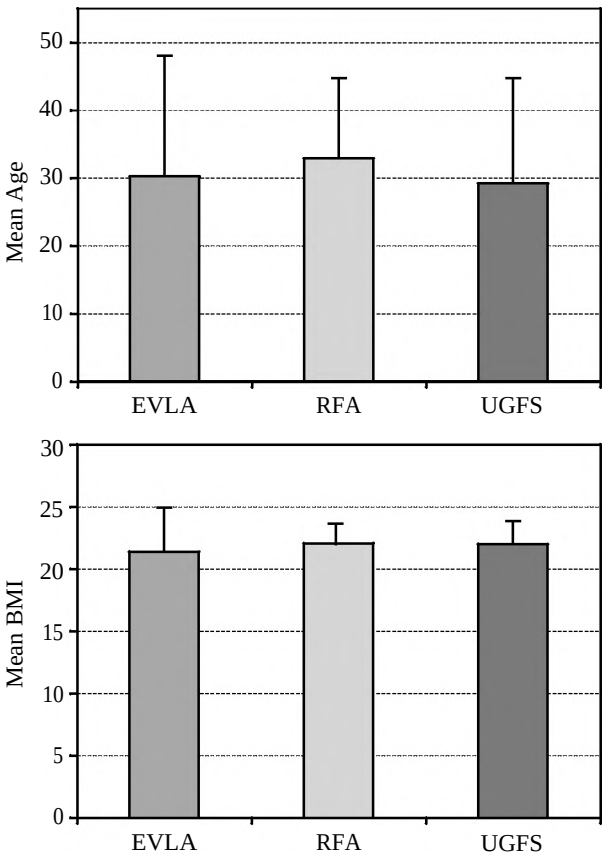


Fig. (3): Demographic data of the three studied groups (age & BMI distribution).

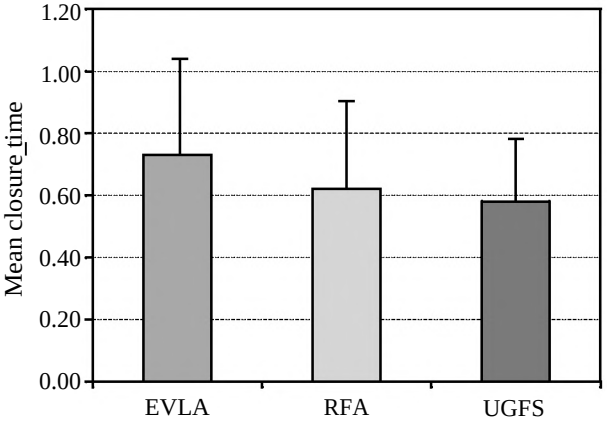


Fig. (4): Mean distribution of valve closure time between the three studied groups.

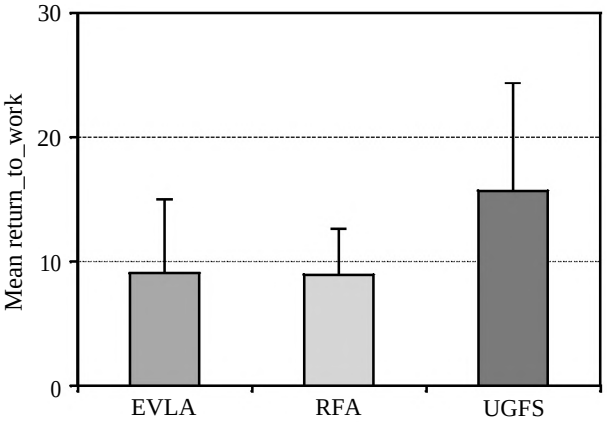
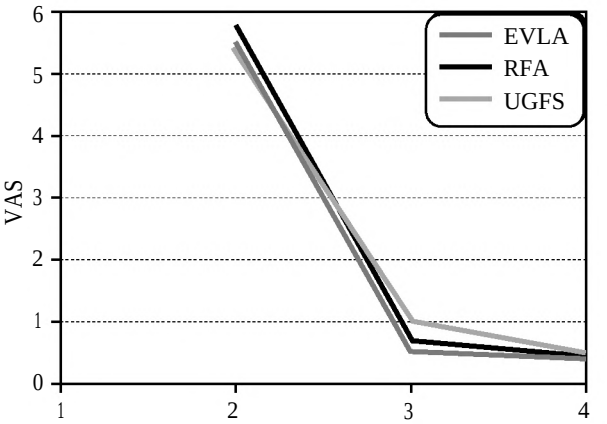
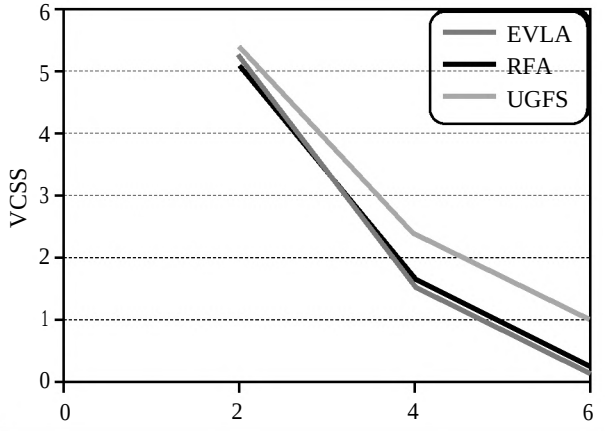


Fig. (5): Return to work between the three studied groups.



VAS preoperative	VAS within 1st week	VAS within 1st month
5.5	0.53	0.4
5.8	0.68	0.38
5.4	1	0.48

Fig. (6): Visual Analogue Scale (VAS) mean value from pre-operative to one month post-operative in the three studied groups.



VCSS preoperative	VCSS within 6 months
5.23	0.13
5.7	0.25
5.3	0.97

Fig. (7): Venous Clinical Severity Score (VCSS) mean value from pre-operative to 6 months post-operative in the three studied groups.

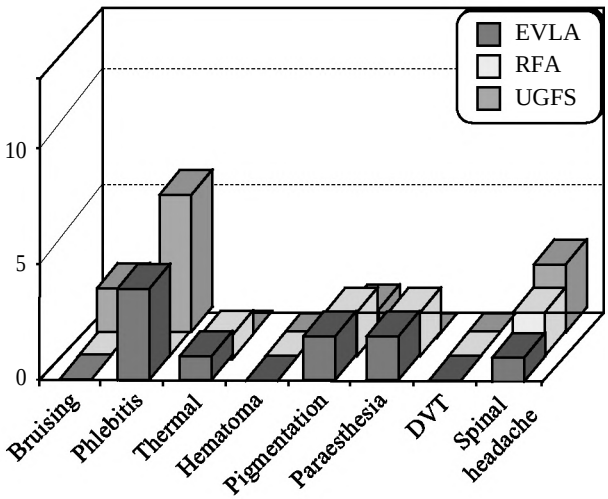
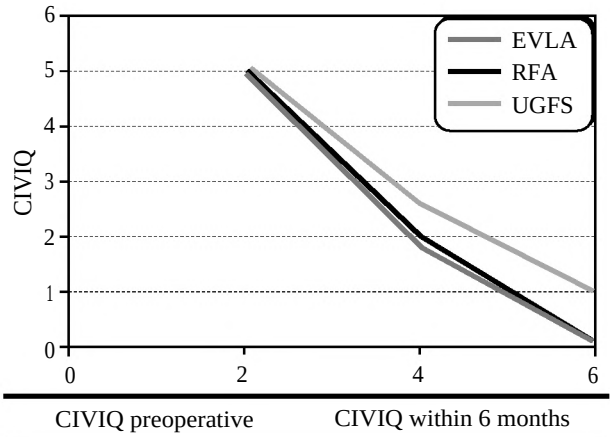


Fig. (8): Post-operative complications.



CIVIQ preoperative	CIVIQ within 6 months
4.93	0.05
5.08	0.07
5.1	0.98

Fig. (9): CIVIQ mean value pre-operative and 6 months post-operative in the 3 studied groups.

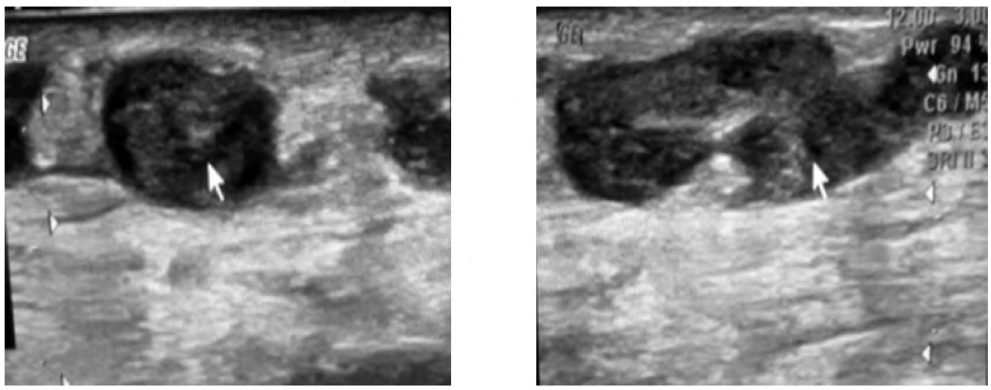


Fig. (10): Intra-operative partial occlusion of GSV following UGFS.

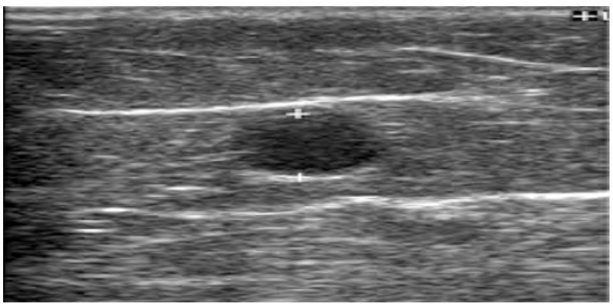


Fig. (11): 2 years follow-up after UGFS shows partial occlusion of GSV (recurrence).

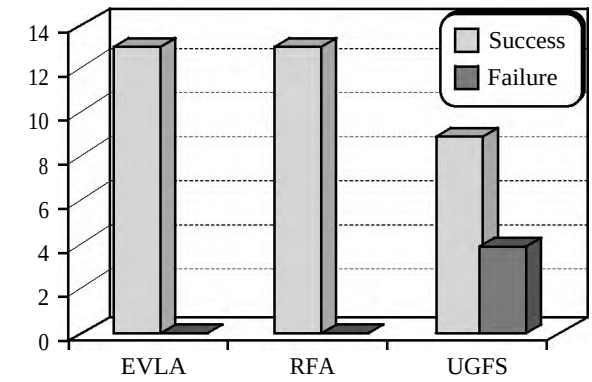


Fig. (12): Success & failure among the three studied groups.

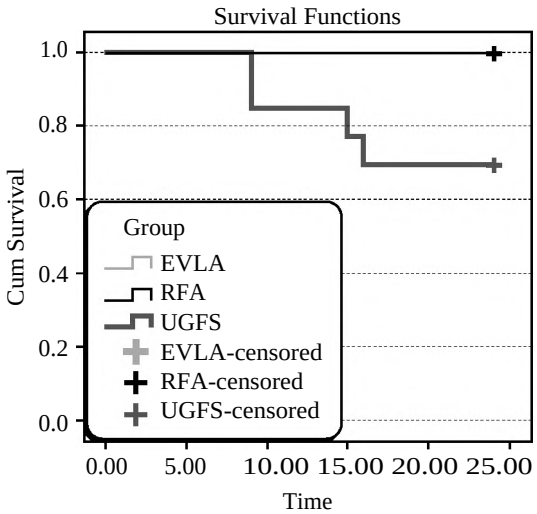


Fig. (13): Kaplan-Meier for failure among the three studied groups (August 2016-August 2018).

Discussion

Treatment for varicoseve in scan of fersubstantial health related quality of life (QoL) improvements to patients. The market ischaracterized bymany competing modalities and in novation continues toberapid. Established treatments of varicose veins include conservative care (CONS) (Suchas compression stockings), High Ligation surgery (HLS) (usually stripping and ligation of the great and small saphenous veins), Ultrasound Guided-Foam Sclerotherapy (UGFS), Endo Venous Laser Ablation (EVLA) and Radio Frequency Ablation (RFA) [7]. Recent international guidelines for themanagement of varicose veins havebeen issued in U.S and Europe. These guidelines recommend that endovenous thermal ablation (Laser or radiofrequency) should be offered before surgery forthe treatment of great saphenous vein reflux [8]. He et al., 2017 [9]; published a comparison of variousmodalities of treatment of varicose veins oflower limbs. Another study done by Mishra and his colleagues, 2016 [10]; compared UGFS and RFA in the management of GSV varicosities. In addition, a meta-analysis of studies performed in Japan in the period between 1998 and 2013 was made by the Japanese Society of Phlebology [11]. In our current study, we compared our results with all the above mentioned publications. Regarding to the clinical class; in our study 0% of patients were in C2, 15.4% as C3 and 84.6% as C4 in EVLA group; while 0% of patients were in C2, 30.8% as C3 and 69.2% as C4 in RFA group and 7.7% of patients were classified as C2, 30.8% as C3 and 61.5% as C4 in UGFS group. This indicates that patients seek medical advice in late stages of the disease. In the study of Rasmussen et al., 2013 [12]; 95% of patients were in C2-3 and 5% were C4-6 in EVLA group, 92% of patients were in C2-3 and 8% as C4-6 in RFA group and 96% of patients were classified as C2- 3 and 4% as C4-6 in UGFS group; this indicates that patients seek medical

advice in early stages in other countries before major complications happen. As regard to vein diameter; in our study the mean vein diameters were distributed as (10.15 ± 2.15), (9.61 ±3.12) and (9.46±2.51) in EVLA, RFA & UGFS groups respectively; which were ranged from (7-18mm) in EVLA group, (6-17mm) in RFA group and (7-16mm) in UGFS group. Those diameters did not affect the procedures as regard to tortuosity & vein lengths. Venermo et al., 2016 [13]; reported lower mean vein diameters of (6.3 ± 1.1mm), (6.2 ± 1.0mm) and (5.4± 1.3mm) in EVLA, RFA & UGFS groups respectively; which were ranged from (4-8mm) in EVLA group, (4-9mm) in RFA group and (3-7mm) in UGFS group. This lower mean vein diameter is probably because those patients in these studies early seek medical advice. Navarro et al., 2002 [14] suggested with evidence that clinical signs of disease correlate with GSV vein diameter, with increasing diameter being associated with greater disease severity. On the other hand; Gibson et al., 2012 [15], stated that GSV diameter is a poor surrogate marker for assessing the effect of varicose veins on a patient's QoL; thus, it is inappropriate to use GSV diameter as a sole criterion for determining medical necessity for the treatment of GSVreflux. Further correlations between QoL measures and duplex derived objective findings are warranted. Regarding to the valve closure time; in our study the mean valve closure times were distributed as (0.73 ±0.14), (0.62 ± 0.13) and (0.58±0.09) in EVLA, RFA & UGFS groups respectively; which were ranged from (0.5-1.0s) in EVLA group, (0.5-0.9s) in RFA group and (0.5 - 0.8s) in UGFS group. The valve closure times were significantly higher in EVLA group as compared to UGFS & RFA groups with no significant difference between UGFS & RFA groups. Darvall et al., 2010 [16]; studied valve closure times in 385 patients' undergone EVA procedures, and the study fulfilled a range of (0.6-1.0s) in EVLA group, (0.6-1.3s) in RFA group and (0.7-1.4s) in UGFS group. Another study carried out by Blomgren et al., 2011 [17], conducted for valve closure times in 214 patients revealed a range of (0.6-0.9s) in EVLA group, (0.4-1.0s) in RFA group and (0.5-1.2s) in UGFS group. As regard to anesthesia; in our study, all cases in the three studied groups were done by spinal anesthesia with addition of tumescent solution. Spinal headache is a drawback of spinal anesthesia which occurred in 5 cases and can be explained by frequent changing in the position during the procedure. Erzinger et al., 2016 [18]; used spinal or epidural anesthesia in all cases and concluded that tumescent solution proved prevention of minor neurological injuries, but didn't have any influence on the rates of bruising or occlusion of the GSV up to 30 days after EVA procedures.

As regard to UGFS, in our study we operated 17 legs in 13 patients with UGFS, with successful obliteration of GSV at follow-up US; 2 patients (3 legs) showed recanalization (30.7% recurrence) at 2 years follow-up and required additional set of intervention. This high rate of recurrence is probably due to small sample size compared to other studies. O'Hare et al., 2008 [19]; reviewed 32 legs 6 months after UGFS (3% STS foam) for recurrent VV. They found occlusion of treated veins on DUS at 6 months in 23/32 (72%) and 28/32 (88%) were satisfied with the results of treatment. Unfortunately, this represented less than 50% of their treated-cohort and they gave no further information regarding the type of recurrence treated. They also included some patients treated for SSV rather than GSV recurrence. Darvall et al., 2011 [16]; added further evidence that UGFS is a safe and clinically effective treatment for recurrent GSV. In their study; a primary course of UGFS, comprising oneand infrequently two treatment sessions, leaded to complete eradication of GSV reflux in virtually 100% of cases. Recanalization at 12 months was superior to that reported after surgery and similar to that observed following other minimally-invasive techniques. Recanalization was easily and successfully treated with a further single UGFS treatment. As regard to RFA, in our study we operated 16 legs in 13 patients, with successful obliteration of GSV at follow-up US over 2 years. No cases required re-intervention during the follow-up period. Abd Al-Rahman and colleagues, 2013 [20]; reported that segmental radiofrequency ablation actually provides high ablation rates in conjunction with a very moderate side effect profile. The advantages of RFA are far greater than its associated risks. The technique was extremely easy to apply, very reliable both in terms of patient's satisfaction and the clinical results. On the other hand, Whiteley et al., 2017 [21]; reported neovascularization, the most common cause of recurrence, in three patients (2%) in his study on fifty-eight patients (91 legs), the origin couldn't be confirmed, but all three patients under went previous traditional surgical procedures before presenting to their study for RFA. Therefore, it is highly unlikely it was theconsequence of RFA, especially considering the low neovascular occurrence within the remaining cohort and the previously published data of the lack of neovascularization after RFA in primary varicose veins as shown by Kianifard et al., 2006 [22]. As regard to EVLA, in our study we operated 18 legs in 13 patients, with successful obliteration of GSV at follow-up US over 2 years. No cases requiredre-

intervention during the follow-up period. The laser used in our study was Diode laser 1470nm in combination with a radial fiber; Rasmussen et al., 2013 **[12]**, Rustempasic et al., 2014 **[23]**, Velicka et al., 2015 **[24]** and Venermo et al., 2016 **[13]**; all used the same wavelength and comparing the results with UGFS & RFA groups. Recently published report by Hirokawa et al., 2015 **[25]**; compared a 1470nm radial 2 ring fiber with a 980nm bare tip fiber for ablation of saphenous veins. Their study indicates a significant difference between bruising and postoperative pain incidents. 14 patients who under went ablation with the 980nm bare tip laser experienced post-operative pain, compared to zero from the 1470nm radial 2 ring group; 32 events of bruising compared to 4 were recorded among the two groups respectively. Vourliotakis and colleagues, 2018 **[26]**; reported that the energy required for the ablation of an incompetent vessel segment, depends on its caliber. High wavelength diode laser such as the 1470nm require the application of approximately 65-100J/cm to cause complete-occlusion and fibrosis of the vein lumen, with technical success rates reaching approximately 90-100% observed during 1 year follow-up. In our study, power was set at 10W; the mean energy delivered was ranged from 70-90J/cm for treatment of incompetent GSV. Technical success was 100%, as demonstrated during 2 years follow-up. Cowpland et al., 2016 **[27]** reviewed the clinical evidence affecting optimal LEED and determined the different factors that affect the optimal LEED including the vein diameter, the design of the fiber, wavelength of the laser, rate of pullback and mode of laser delivery. On the other hand; Golbasi and his colleagues, 2015 **[28]** reported treatment failures using an average LEED of 70J/cm, with successful treatments employing a mean LEED of no less than 80 J/cm. A significant relationship between increasing the LEED and the rate of procedure related complications was noted. Increasing the LEED alone in hugely dilated veins is not sufficient to expose all of the vein wall layers to the thermal injury; that is why Elboushi and his colleauges, 2019 **[29]** applied multiple passes of the fiber guided by US. Studies of Massaki et al., 2013 **[30]**; and Kansaku et al., 2015 **[31]**; confirmed that pulsed wave mode delivers sufficient energy without causing excessive carbonization or vein wall perforation in comparison with continuous mode.

As regard to the time to return to normal activities; in our study the mean time (days) was 9.07 ± 2.87 in EVLA group, 8.92±2.13 in RFA group and 15.69±5.21 in UGFS group with a significant difference between UGFS group and the other two studied groups (p-value <0.001); with an average of 7-14 days in RFA & EVLA groups, compared to 10-21 days in UGFS group; we found that the decrease in the time to return to normal activities in of RFA & EVLA groups was due to the early ambulation of the patients, minimal post-operative complications, less post-operative pain, the minimal need for analgesics, the satisfaction of patients due to absence of surgical wounds. This goes in the same direction with the Brittenden et al., 2015 (class study) **[32]**; and Nandhra et al., 2015 (HELP-2 study) **[33]**; who both reported median time to return to work to be 7 days in EVLA & RFA-groups compared to 15 days in UGFS group. Roopram et al., 2013 (VESPA study) **[34]**; by contrast, asked participants at the two week clinic whether they had returned to work: 3/118 (2.4%) people in the EVLA & RFA groups and 6/57 (11%) people in the UGFS group had not returned to work within two weeks of the procedure as a result of the intervention they had received. The study authorsreported that "these percentages were significantly different (p<0.05)". As regard to post-operative pain; it was assessed in our study through the Visual Analogue Scale (VAS). All patients had improvement in VAS after the three procedures with a significant improvement in EVLA & RFA groups than UGFS group within the 1 st week and after one month post-operative than pre-operative periods. As regard to VCSS, in our study; all patients had improvement in VCSS after the three procedures with a significant improvement in both EVLA & RFA groups than UGFS group after six months post-operative than pre-operative. There was non-significant difference in the VCSS between the three groups pre-operatively, but 6 months post-operatively there was a high significant difference in VCSS in each group. There are some studies which disagree with ours; for example, Asser et al., 2013 **[35]**; showed significant improvementof VCSS 2 weeks following the UGFS in comparison to pre-intervention VCSS, where p-value was <0.0001. Also, there wassignificant improvement of VCSS 6 months following the UGFS in comparison to pre intervention VCSS, where p-value was <0.0001 11. Additionally, the disagreement continues with Varghese and his colleagues, 2017 **[36]**; where they reported significant improvement in VCSS in their patients who had no ulcer and who had low VCSS prior to UGFS. Our argue with them in that; they selected patients with low VCSS in the beginning of their study, also their follow-up was only for 2 months after treatment. Our 2 years follow-up detected a significant improvement in both EVLA group & RFA group compared to UGFS group after six months post-operative with a high significant

difference after 6 months between the three studied groups. Our results goes together with the study of De Oliveira and his colleagues, 2018 [37]; who studied 30 cases with UGFS and its impact on the GSV diameter, concluded reflux elimination in 90 days of (87%); which is comparable to rates described in our study. As regard to CIVIQ score, in our study all patients had improvement in CIVIQ after the procedures with a significant improvement in EVLA group & RFA group than UGFS group after 6 months post-operative. There was non-significant difference in the CIVIQ between the three studied groups pre-operatively, but 6 months post-operatively it was found that there is a high significant difference in CIVIQ between EVLA, RFA groups in one hand & UGFS on the other hand; this is probably due to that 4 cases of UGFS group showed partial occlusion of GSV during follow-up DUS. Kalteis et al., 2015 [38]; also evaluated CIVIQ scores and found significant improvement after treatment for both EVLA (12 points) and RFA (18 points) with no significant difference between the two treatments compared to UGFS. Epstein and his colleagues, 2018 [7]; concluded that endothermal procedures would be cost-effective therapeutic options in adult patients requiring treatment in the upper leg for incompetence of the GSV. As regard to clinical recurrence, in our study follow-up was done after one week, one month, and 3 months of the procedures then every 6 months up to 2 years clinically and by using DUS. Partial significant difference was found associated with UGFS group, where p-value was <0.05. Van der Velden and his colleagues, 2016 [39] implied several predictors for recanalization after EVA. For the change of QoL 1 year after treatment with EVA, GSV diameter, the type of device used and amount of energy delivered appeared to be the only predictors. However, the performance of each model was unsatisfactory and therefore cannot yet be used in clinical practice. On the other hand; studies of Lattimer and his colleagues, 2013 [40]; on UGFS have reportedaround 75% success rate at 1 year and 65% at 5 years in maintaining truncal occlusion when assessedsonologically, while on clinical assessment, the result was comparableto that of endothermal modalities. As regard to the need for complementary procedures, in our study there was non-significant difference or association that required reoperations or complementary procedures; except in 2 cases in UGFS group, whom required additional session of UGFS for complete obliteration of GSV. Mean survival from failure in EVLA & RFA was 24±0 months, while in UGFS was 19.5±2.9 months.This agrees with Elboushi and his colleauges, 2019 [29]; who showed good short-term results of EVLA inthe ablation of large-diameter GSV. Using appropriate LEED and multi-pass technique are good tips in improving the occlusion of the vein and inducing fibrosis of the vein wall. They also added that the use of EVLA has to be adynamic process where the surgeoncan change a variety of parameters like energy, pullback speed, multiple passes and the amount of tumescentfluid injected to optimize the final results of the procedure. This should encourage us to change the concept that EVLA is not suitable for varicose veinslarger than 12mm.

Limitations of the study:

This study had some limitations. It only included early clinical experiences from a limited number of patients and only had a short-term data. Some interesting conclusions, however, require longterm recurrence rate follow-up. A shortcoming of the study is that it was not blinded. Whereas a study comparing different thermo-ablation modalities may be blinded, it is not possible to blind the treatment for the patient in a study such as ours. Blinding of the observer may be possible, but it is difficult. It should be noted however, that QoL data are based on the patient's own completions of questionnaires. Furthermore, during follow-up visits, the observer would have no access to information of the primary procedure and little recollection of it.

Conclusion:

Our study demonstrated that EVLA & RFA are efficient modalities for the treatment of GSV varicose veins in the medium term. Notinga moderate rate of recanalization after UGFS, it appears that EVLA & RFA are superior to UGFS regarding clinical recurrence, VCSS and QoL. Post-operative patient comfort and the outcome of EVLA & RFA in short & medium-terms are superior to those after UGFS in terms of recanalization & effective ablation. Using of high wavelength laser (1470nm) with modified fiber tip (radial emission) with tumescent solution has a crucial role in achieving best results and minimizing the adverse effects. This allows a homogeneous destruction of the vein wall exclusively, without any risk of damage to surrounding tissues, and also successful ablation of large sized vein diameter.

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Nothing to declare.

Conflicts of interest:

There were no conflicts of interest.

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دراسة مقارنة بين العلاج بالرغوة المُصلبة بالقسطرة المُوجَهة بالموجات فوق الصوتية، الكى بواسطة التردد الحرارَى والكى بالليزر داخل الوريد فى علاج إرتجاع الوريد الصافن الآكبر

المقدمة: دوالى الآوردة السطحية للآطراف السفلية تم وصفها بآنها آوردة تحت الجلد قطرها ≤3مم وتقاس فى الوضع قائماً، وقد تُؤثر الدوالى على الآوردة السطحية الرئيسية، الوريد الصافن الآكبر، الوريد الصافن الآصغر آو آى روافد وريدية سطحية فى الآطراف السفلية.

وغالباً ما تتضمن الحالة إرتجاع فى الوريد الصافن الآكبر، وحتى وقت قريب كان العلاج الآمثل هو الربط العالى للوريد مع نزعه وإستئصاله، وقد آدى ذلك لتحسين الآعراض وكذلك جودة الحياة.

ويُشار إلى آن العلاج بالرغوة المُصلبة بالقسطرة المُوجهة بالموجات فوق الصوتية تُستخدم فى دوالى الوريد الصافن الآكبر الآولية، سواء كانت خطية آو متعرجة، الدوالى السابق علاجها والدوالى المرتجعة بعد الجراحة بسبب التروية الدموية الجديدة، كذلك الآوردة بقطر صغير آو كبير، ولكن الآوردة الصافنة بقطر ١٠مم آو آكثر قد تتطلب آكثر من جلسة علاج وكميات كبيرة من الرغوة (قد تصل إلى ٣ جلسات و١٥سم مكعب من الرغوة)، كما يمكن إستخدام الرغوة المُصلبة بالقسطرة المُوجَهة بالموجات فوق الصوتية فى المرضى الذين يعانون من القصور الوريدى المزمن، وقد تعزز شفاء القرح الوريدية المزمنة، وتستخدم هذه التقنية آيضاً لعلاج الآوردة الثاقبة والعيوب الوريدية الخلقية.

آما دواعى إستخدام التذبيل بواسطة التردد الحرارى فتُقارب دواعى التذبيل بالليزر داخل الوريد الصافن، فيما عدا آن الكى بواسطة التردد الحرارى آكثر صعوبة لعلاج الآوردة بآقطار آكبر من ١٢مم، ومع ذلك، فمع إنتشار إستخدام التخدير الموضعى التوَرُمى ، فيمكن علاج هذه الآوردة بنجاح، بإستخدام قسطرة بقطر (١.٧مم) آو بقطر ٨ (١.٧٥مم)، للآوردة بقطر ما بين ٤–٨مم وحتى ١٢ملم على التوالى، وقد آدخلت الشركات المصنعة قسطرة جديدة ذات حجم موحد، يمكن إستخدامها بصرف النظر عن قطر الوريد، ولكن يجب إستخدامها بحذر بسبب صلابتها وحجمها، لتجنب ثقب الدوالى المتعرجة والصغيرة نسبياً.

كما يمكن إستخدام التذبيل بالليزر داخل الوريد لعلاج إرتجاع الوريد الصافن الآكبر، ولكن بسبب صلابة وحجم المستهلكات، فالدوالى الجذعية الآولية المستقيمة، والتى يبلغ قطرها ٥ملم آو آكثر تعتبر مثالية للتذبيل بالليزر داخل الوريد، آما إذا تم إستخدام آلياف آرق، فيمكن إستخدام التذبيل بالليزر داخل الوريد للآوردة الآكثر تعرجاً مثل الآوردة الصافنة الإضافية والآوردة الثاقبة، ويجب الحذر عند إستخدام التذبيل بالليزر داخل الوريد لعلاج الدوالى المرتجعة، لآن إدخال الليزر قد يكون صعباً، وقد يسبب حدوث جلطة بالآوردة إن كلاً من طريقتى التذبيل بواسطة التردد الحرارى والتذبيل بالليزر داخل الوريد فعّال فى علاج إرتجاع الوريد الصافن الآكبر على المدى البعيد، ولكن قلة التجارب فى طريقة العلاج بالرغوة المُصلبة بالقسطرة المُوجَهة بالموجات فوق الصوتية لم تؤكد فعالية آو موثوقية هذه الطريقة.

الهدف من البحث: يهدف هذا البحث إلى المقارنة بين نتائج العلاج بالرغوة المُصلبة بالقسطرة المُوجَهة بالموجات فوق الصوتية، إستخدام التذبيل بواسطة التردد الحَرارى وإستخدام التذبيل بالليزر داخل الوريد لعلاج إرتجاع الوريد الصافن الآكبر، من حيث معدل إرتداد المرض ومعدل حدوث المضاعفات.

المواد وطرق البحث: آجريت هذه الدراسة بقسم جراحة الآوعية الدموية بمستشفيات جامعة الزقازيق للمرضى الذين يعانون من دوالى بالآودرة السطحية للآطراف السفلية.

النتيجة: توصلت الدراسة إلى آن إستخدام الطول الموجى لليزر (١٤٧٠ نانومتر) مع مقدمة القسطرة المُعَدَلة (إنبعاث نصف قُطرى) ومع التخدير التوَرُمى لهم دور فعال لتحقيق آفضل النتائج وتقليل الآعراض الجانبية، وذلك لآنه يسمح حصرياً بتدمير جدار الوريد دون التآثير على الآنسجة الجانبية، وكذلك تذبيل الآودرة ذوات القطر الكبير.

ونخلص بآن رفاهية المريض ما بعد العملية ونتائج التذبيل بواسطة التردد الحرارى آو التذبيل بالليزر داخل الوريد آعلى من نتائج العلاج بالرغوة المُصلبة بالقسطرة المُوجَهة بالموجات فوق الصوتية، فيما يتعلق بشروط التذبيل الفَعال ومعدلات الإرتداد.