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ORIGINAL ARTICLE

Comparative study between Surgical Stripping and Foam Sclerotherapy in management of lower limb varicose Veins

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ABSTRACT

Keywords: Varicose Veins, Sclerotherapy

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Background: Lower limb Varicose Veins disease among the most prevalent of diseases, it affects all the strata of society, affecting around 20–30% of adults. **Objective:** Comparing Surgery versus Foam Sclerotherapy in 1ry Lower Limb Varicose Veins treatment. **Patients and Methods:** This prospective study was conducted on forty patients attended to outpatient clinic of Vascular surgery department Aswan University Hospital with 1ry Lower Limbs varicose veins in one year duration, from January 2018 to January 2019, and admitted to the department. Twenty of them had been Subjected to Surgical Treatment, and the other Twenty patients Subjected to Foam Sclerotherapy Injection. **Results:** A total of forty patients presented, twenty of them subjected to surgery and the other twenty patients subjected to Foam Sclerotherapy, with net result after one year follow up showed efficacy 85%, and 75% for surgery and Foam Sclerotherapy respectively, and non-significant statistical difference (P value = 0.695) to incidence of recurrence of varicosity. **Conclusion:** Sclerotherapy is promising less invasive, shorter duration intervention, with good short term efficacy, with promising results in comparison to surgery, with need for more data regarding long term efficacy.

INTRODUCTION:

Chronic venous disease (CVD) of the lower limb is among the most prevalent of disease today, and it is actually a spectrum of medical conditions that ranges from telangiectasia or spider veins to varicose veins, venous swelling, skin changes and venous ulcerations.[1]

It is affecting all strata of society. Gender, sex, occupation, obesity and pregnancy are among the common predisposing factors.[2]

Varicose veins are dilated, tortuous and prominent veins affecting around 20–30% of adults. They occur when the valves in the veins fail, allowing blood to flow in the wrong direction. This is known as venous incompetence.**3**

The aim of our study is to compare surgery with ultrasound guided foam sclerotherapy (UGFS), in treatment of patients with primary chronic venous insufficiency.

PATIENTS AND METHODS

This prospective study was conducted in one year duration form January 2018 to January 2019, on patients attended to outpatient clinic of Vascular surgery department Aswan University Hospital. We studied 40 patients who were presented with varicose veins in lower limbs Who had admitted

to vascular surgery department in Aswan university hospital. Twenty patients Subjected to Surgery, and the other Twenty patients Subjected to Foam Sclerotherapy injection.

Ethical committee approval:

This study had followed all regulations of the ethical committee of Faculty of Medicine at Aswan University. There was an informed consent that had all the required information about this study for patients. Only those who was signed the consent was enrolled in the study. Participants had the entire right to withdraw from this study at any time without giving any reason.

Inclusion criteria:

Patients aged 18–65 years old, with Sapheno-Femoral Junction, or Sapheno-Popliteal Junction refluxes associated with incompetence of the Great Saphenous Vein (GSV), or Small Saphenous Vein (SSV) respectively. Dilated GSV more than 6 mm in diameter. Dilated tributaries of GSV.

Exclusion criteria:

Patients Not fit for anaesthesia and elective Surgery, or Pregnant and nursing women, or Patients who had a pulseless pedal artery, or Patients who had Deep Vein Thrombosis (DVT), or Patients with Hypercoagulable state, or Patients with bleeding tendency, or Patients with Arterio-Venous fistula.

Data Collection:

All patients were interviewed and examined , and data were collected in the form of structured database, which includes the following data:

1) **Full history taking:** Personal data, Risk factors (smoking, DM, hypertension, hypercholesterolemia), Co-morbidity (heart failure, previous stroke, angina, MI...), Past history (DVT, superficial thrombophlebitis, or Past history of chronic lower limb ischemia ….etc).
2) **Full physical examination.** General and local examinations**.**
3) **Investigations include:**
   - **A. Laboratory:** Hematology (hemoglobin, white cell count, platelet count), Biochemistry (Creatinine, ESR, CRP, RBS, HbA1c), PT, PTT, INR, and Lipid profile.
   - **B) Noninvasive Imaging:** Duplex Ultrasound (DUS) study.
4) All Patients preoperatively admitted to Vascular Surgery Department one day before operation for preoperative preparation.
5) In our study, intervention was considered to be successful when total occlusion or partial recanalization without reflux was achieved. a criterion already adopted in other studies.

The Technique of intervention:

1) The Surgical Ablation of Saphenous Veins:

A) <u>High Ligation and Stripping of the Great Saphenous Vein:</u>

- Preoperative DUS-guided marking of the saphenofemoral junction (SFJ), improves the precision of incision placement and allows minimal incision size and subcutaneous dissection[4]
- Legs abducted 10”-15”.
- SFJ found 2cm below and lateral to pubic tubercle.
- SFJ identified before performing flush ligation of the GSV.
- All tributaries of the GSV, individually divided and ligated.
- GSV stripped retrogradely (from above-downward) up to just below knee joint level. [1]
- If indicated, concomitant stab avulsion of varicosities is performed before stripping of the vein.[5]

- Post-operative care: elevation of foot on bed for 12 hours, and Patient instructed to wear Class II stockings for at least 2 weeks[1]

B) High Ligation and Stripping of the Small Saphenous Vein:

- Patient prone with 20" - 30" head down
- SPJ and short saphenous vein identified between the two heads of gastrocnemius.
- SPJ ligated and divided
- The stripper is inserted in a retrograde fashion, and damage to the sural nerve is avoided **by carefully dissecting the distal end of the vein with the stripper within it, separating it** from the vein
- Stripping of SSV or/and multiple avulsions

C) Multiple avulsions:

- 1.5mm-3mm stab incisions made with No.11 blade.
- Fine hooks are utilized to bring veins to the surface.
- Veins held with mosquito forceps, avulsed and ligated.

2) Incision closed with 6mm steri-strips covered by small dressings.

3) Foam sclerotherapy

- The following supplies are needed: 25 to 30 gauge needles, two 5 mL Luer-Lock syringes, a three-way stopcock, adhesive tape, roller gauze, and compression bandage [6]
- After the treatment area is mapped, access to the first vein to be treated is achieved with a needle or butterfly under ultrasound guidance. Access is confirmed by return of blood, and the needle/butterfly is taped to the patient's leg. [7]
- The foam was made from Polidocanol. Tessari's method was used to produce the foam. The sclerosing agent is prepared by placement of one part Polidocanol in one syringe to 4 parts air in the other syringe [6]
- The foam solution is created by rapid mixing of air and chemical back and forth between the two syringes. This rapid movement of solution from one syringe to the other is performed 20 times. [6]
- After most of the solution has been moved to one syringe, the filled syringe is connected to the needle, and intravascular positioning is reconfirmed with ultrasound. A small amount of foam should be injected initially, under ultrasound, to confirm needle placement within the vein. The amount of foam delivered is determined during injection with the use of ultrasound to visualize when the targeted vein is filled with foam . Upon completion, full-length graduated compression stockings (30 to 40 mm Hg) are applied.[4]

STATISTICAL ANALYSIS:

The collected data were coded, processed and analyzed using the SPSS (Statistical Package for Social Sciences) version 25 for Windows® (IBM SPSS Inc., Chicago, IL, USA). Data was presented and suitable analysis was done according to the type of data obtained for each parameter. Parametric numerical data described by mean and standard deviation (Mean, SD), and Median (IQR) for non-parametric data. Where non-numerical data were described by frequency and percentage (N, %),. Student T Test , ANOVA test , Chi-square test and fisher exact test used to compare between categorical variables. P-value considered Significant if P-value < 0.05, Non-significant if P-value > 0.05, and highly significant if P-value < 0.01.

RESULTS:

- **Patients characteristics**

This study was conducted on 40 patients who were presented with varicose veins in lower limbs to outpatient clinic of vascular surgery department of Aswan university hospital during period from January 2018 to January 2019. After regarding inclusion criteria, patients divided into two equal groups, A twenty patients had been surgically managed, and the other twenty patients had been managed by foam Sclerotherapy injection.

After studying patient′s data the following facts noted statistically, The mean age of patients subjected to study is 32.83 years old, with +/- SD 8.8, all of them presented with 1ry varicosity in lower limb, with percentage of males to females 67.5% to 32.5% respectively (exact numbers 23 to 17 respectively), with 55% of them (22 patients) presented with left lower limb varicosity while 45% (18 patients) presented with right lower limb varicosity, 20 patients (50%) subjected to Surgery forming group (A), while the other 20 patients (50 %) subjected to Foam sclerotherapy forming group (B). [table: (1)]

Regarding Group (A) patients the following statistical facts noted, 12 patients were males (60%), while 8 were females (40%), 8 of them presented with right lower limb varicosity, and 12 with left lower limb varicosity, with mean age of group (A) was 32.05 years old.

While group (B) patients were 11 male patents (55%), and 9 female patients (45%), with 10 cases of right lower limb varicosity (50%), and 10 cases of left lower limb varicosity (50%), with the mean age of this group was 33.6 years old. [table: (2)][figure: (1)]

- In our study it took significantly less time to do UGFS than the conventional surgery. This is similar to many studies which have quoted a significantly less time in doing UGFS compared to surgery. **(8; 9;10)**

- **Edema** is a common annoying symptom in most patients of varicose veins. In our study both groups showed good results regarding edema as there is 90%, and 85% improvement in patients of surgery and sclerotherapy groups respectively.

- **Regarding the risk of thrombo-embolism**, previous studies have shown that the foam reaches the right ventricle easily, with no significant complication,**[11]**. In our study, foam was always found in the deep venous system; however, due to the small amount injected and to the high flow of the deep venous system, no complication occurred.

- **Post-operative follow up:**

Both groups were subjected for follow up clinically and by duplex study (duplex study was done at following intervals 1 month, 3 months, 6 months, and 12 months), with the following results noticed: [figure: (2)]

➢ **Duplex study follow up:**

✓ Duplex follow up done at **1 month**, showed that for group (A), 18 patients showed no varicosities (90%), and 2 Patients showed Varicosities (10%), and for Group (B) that 17 patients showed Total Occlusion (85%), and 3 Patients showed Varicosities (15%).

✓ Duplex follow up done at **3 months**, showed that for group (A) 17 patients showed no varicosities (85%), and 3 Patients showed Varicosities (15%), and for Group (B) that 16 patients showed Total Occlusion (80%), and 4 Patients showed Varicosities (20%).

✓ Duplex follow up done at **6 months**, showed that for group (A) 17 patients showed no varicosities (85%), and 3 Patients showed Varicosities (15%), and for Group (B) that 16 patients showed Total Occlusion (80%), and 4 Patients showed Varicosities (20%).

✓ Duplex follow up done at **12 months**, showed that for group (A) 17 patients showed no varicosities (85%), and 3 Patients showed Varicosities (15%), and for Group (B) that 15 patients showed Total Occlusion (75%), and 5 Patients showed Varicosities (25%).[table:(3)]

DISCUSSION:

Our study aimed at comparing outcomes of saphenous stripping versus a more recent method, namely UGFS, in a small group of patients with varicose vein disorders. we stress on aspect of efficiency of intervention in treating varicosities, which was assessed using US duplex study.

Any treatment for primary varicose veins should aim at being minimally invasive and capable of being used on primary and recurrent varicose veins so that it can be repeated as required. (***Van den Bos R*, et al., *2008***).**[12]** This applies in particular to foam sclerotherapy, as has been demonstrated by

case-control studies and prospective randomized controlled studies conducted in recent years. ***(Rasmussen LH, et al., 2011)*** [13]

In the treatment of incompetent saphenous veins, thermal ablation or surgery are well established methods. Nevertheless, treatment of saphenous veins by sclerotherapy is also a good and cost–effective treatment option. ***(Gohel MS, et al., 2010)*** [14]

Foam enables accurate injection of sclerosant under ultrasound guidance and has proved effective even in large varices. The increased volume of foam displaces more blood, at a lower dose, thus making it potentially more efficacious. ***(Vähäaho, K. et al., 2017)*** [15],and this was so obvious during our study as US use enabled a lot of accuracy, allowing more better assessment for the volume of injected amount and if it is enough to obliterate the vein or not, and helps in avoiding escape of foam to deep system via SFJ or SPJ, which allows better results in comparison to another randomized studies using Liquid sclerotherapy.

Duplex ultrasound has been frequently used in the assessment of foam sclerotherapy. Establishment of duplex ultrasound criteria to determine treatment efficacy is therefore extremely important. ***(Figueiredo M, et al., 2006).*** [10] In our study, intervention was considered to be successful when total occlusion or partial recanalization without reflux was achieved, a criterion already adopted in other studies. ***(Bountouroglou DG, et al., 2006)*** [16]

A number of reports have been published concerning the use of clinical scores for comparing the efficacy of different treatment methods. In 2003, an article validated clinical scores as the best way to assess results of the surgical treatment of primary varicose veins; the authors observed a linear relationship between treatment efficacy and the CEAP classification. Later, in 2006, the same scoring system was used in the comparison of post-treatment results in patients submitted to ultrasound-guided foam sclerotherapy with those submitted to surgery. ***(Bountouroglou DG, et al., 2006)*** [16]

Efficacy:

Some studies have assessed the efficacy of foam sclerotherapy for the treatment of primary varicose veins. In 2006, an article comparing surgical treatment and foam sclerotherapy demonstrated that the conventional surgery method was superior to foam sclerotherapy in terms of occlusion and elimination of reflux (86% vs. 63%). ***(Wright D, et al., 2006)***[17]

One of these trials compared surgery and foam sclerotherapy and showed an 89% saphenous obliteration rate in the surgery group compared with 78% in the foam sclerotherapy patients; in another trial, saphenous reflux was abolished in 85% of surgery patients and 84% of foam sclerotherapy patients 12 months after treatment. ***(M. Figueiredo, S. , et al., 2009)***[10]

In a meta-analysis including 12,320 patients from 64 studies who had undergone treatment of truncal veins with Radio frequency Ablation (RFA), Endovenous Laser Ablation (EVLA), foam sclerotherapy, or surgery, the results over 32 months demonstrated nearly equal outcomes. "Success rates were 78% for surgery, and 77% for foam sclerotherapy. ***(Anton N. Sidawy, et al., 2019)*** [4]

Our study outcomes regarding ablation of varicosities and disappearance of reflux showed highly encouraging results regarding efficacy, which was 90% for surgery and 85% for UGFS after 1st month, reaching 85% for Surgery, and 75% for UGFS after one year follow up**,** with less invasive technique and shorter duration, which is an encouraging results.

Intervention Duration:

In our study it took significantly less time to do UGFS than the conventional surgery. This is similar to many studies which have quoted a significantly less time in doing UGFS compared to surgery. **(8; 9;10)**

Edema is a common annoying symptom in most patients of varicose veins. In our study both groups showed good results regarding edema as there is 90%, and 85% improvement in patients of surgery and UGFS groups respectively.

Regarding the risk of thrombo-embolism, previous studies have shown that the foam reaches the right ventricle easily, with no significant complication, ***(Morrison N, et al., 2008)***[11]. In our study, foam was always found in the deep venous system; however, due to the small amount injected and to the high flow of the deep venous system, no complication occurred.

The results obtained with our patients suggest that both surgery, and UGFS have nearly similar efficacy in patients with 1ry Lower limbs varicose veins, and UGFS presents a good alternative which can be carried out in shorter time, with possibility to be done under local anaesthesia, with less postoperative hospital stay, also the fact that no major complication was found in UGFS group which is also established in many other published literature. So foam sclerotherapy is quite a safe efficient procedure if done with proper US guidance.

In the Brazilian public health-care system, patients have to wait a long time to receive surgical treatment, whereas ultrasound-guided foam sclerotherapy represents a treatment option that can be carried out safely in outpatient clinics and at significantly lower costs. ***(M. Figueiredo, S. , et al., 2009)***[10]

Although the encouraging results of comparing UGFS to more invasive traditional surgery, but still The main limitations of the present study refer to the small number of patients assessed and the short period of follow-up. On the other hand, the fact that we were working with a homogeneous sample allowed discussing the management of this specific type of patient. Further studies involving homogeneous samples should be carried out with the aim of defining a more accurate classification profile.

CONCLUSION:

According to The encouraging results of our study comparing foam sclerotherapy versus surgery, we can consider Sclerotherapy is promising less invasive, shorter duration intervention, need more less postoperative duration to return to normal life, with good short term efficacy, and may be available later as outpatient procedure if well trained surgeons available, , and that agree with a lot of published studies, but still there is a lack of data regarding long term efficacy.

Also never neglect the fact that Surgery still has the advantage of no risk for anaphylaxes, nor thromboembolic side effects due to sclerosing agents used.

So studies including larger number of population with longer follow up duration are needed to complete the knowledge about this comparison.

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Table (1): Demographic data for whole study group.

		Mean / N	SD / %
Age		**32.83**	**8.87**
Diagnosis	**Rt. LL. 1ry V. V.**	**18**	**45.0%**
	Lt. LL. 1ry V. V.	**22**	**55.0%**
Management	**Stripping of G.S.V.+ Trendelenburg Operation**	**15**	**37.5%**
	Stripping of G.S.V. & S.S.V. + Trendelenburg Operation	**3**	**7.5%**
	Stripping of S.S.V.	**2**	**5.0%**
	Foam Injection Sclerotherapy	**20**	**50.0%**

Table (2): Age and diagnosis between 2 studied groups (surgical and sclerotherapy injection).

		Group		Test of significance	
		Surgery	Foam Injection Sclerotherapy		
		Mean ± SD N (%)	Mean ± SD N (%)	P-Value	Sig.
Age		**32.05 ± 9.17**	**33.6 ± 8.72**	**0.587(T)**	**NS**
Diagnosis	**Rt.LL.1ryV.V.**	**8 (40%)**	**10 (50%)**	**0.525(C)**	**NS**
	Lt. LL. 1ry V. V.	**12 (60%)**	**10 (50%)**		

Table (3): Postoperative DU Follow up of both Studied Groups

		Group		Fisher's Exact test	
		Surgery	Foam Injection Sclerotherapy		
		N (%)	N (%)	P-Value	Sig.
Duplex Study Follow up at 1 month	**No Varicosities**	18 (90%)	17 (85%)	1.00	NS
	Varicosities	2 (10%)	3 (15%)		
Duplex Study Follow up at 3 months	**No Varicosities**	17 (85%)	16 (80%)	1.00	NS
	varicosities	3 (15%)	4 (20%)		
Duplex Study Follow up at 6 months	**No Varicosities**	17 (85%)	16 (80%)	1.00	NS
	Varicosities	3 (15%)	4 (20%)		

Duplex Study Follow up at 12 months	**No Varicosities**	17 (85%)	15 (75%)	0.695	NS
	Varicosities	3 (15%)	5 (25%)		

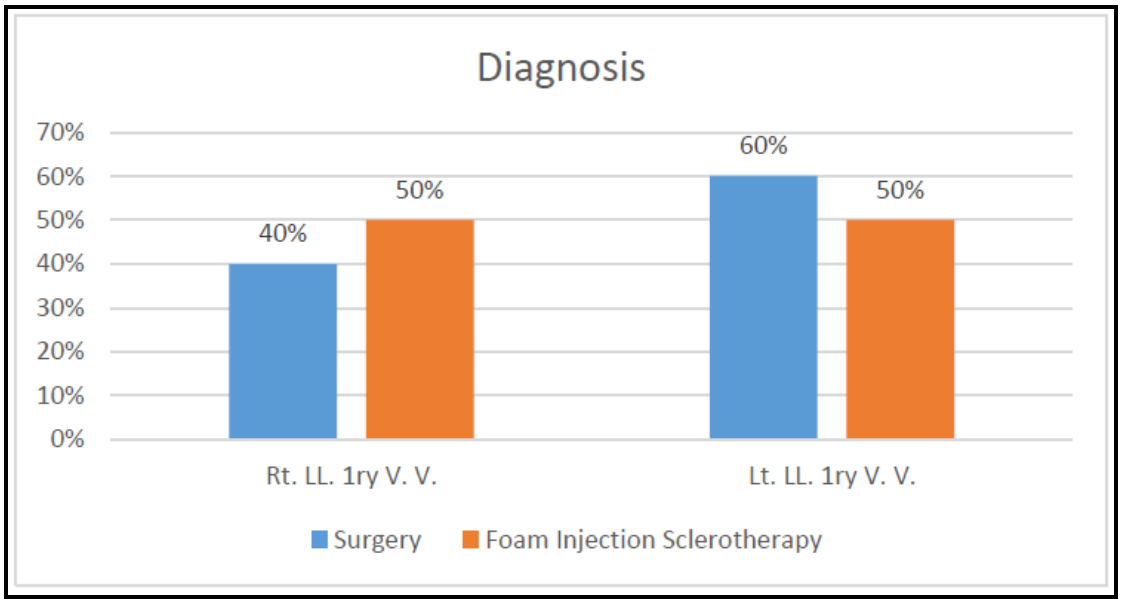

Figure (1): Diagnosis

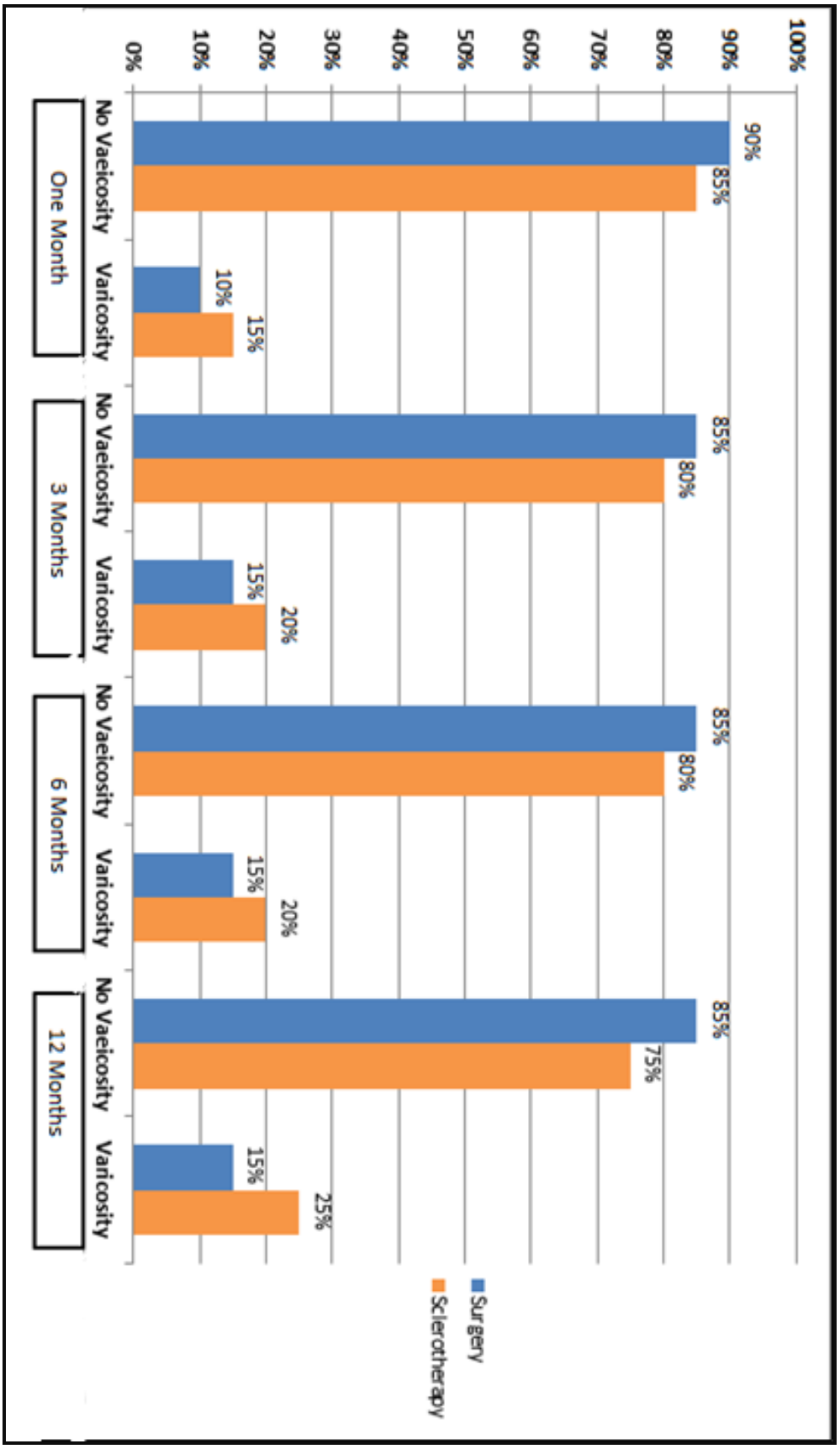

Figure (2): one year efficacy follow up for both groups