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Review Article

Comparative study between Cyanoacrylate Embolization and Radiofrequency Ablation in varicose veins with Incompetent Sapheno-femoral junction

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ABSTRACT

Keywords: surgical stripping, radiofrequency ablation, cyanoacrylate embolization.

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Background: Varicose veins are common, and their management has undergone a number of changes over the years. Surgery has been the traditional treatment option, but towards the 21st century, new endovenous thermal ablation techniques, namely, radiofrequency ablation, was introduced which have changed the way varicose veins are treated. Cyanoacrylate ablation is the newest nonthermal vein ablation technique, **Aim and objectives**; to compare between the efficacy and clinical outcomes of CA and RFA for patient with lower limb varicose vein with incompetent SFJ, **Subjects and methods**; This is an open labeled RCT, conducted on patients presented to our department, with varicose veins with Incompetent Sapheno-femoral junction, aged > 18 years, and dilated GSV. Participants were randomly allocated into two groups, Group A: underwent RFA and Group B: underwent CA. **Result**; In this study we included 40 patients. The mean operative duration for group A was (15.25±0.55) and for group B (19.52 ± 0.95). There was very highly statistically significant improvement in VAS score over time in both group. **Conclusion**: CA offers comparable success rates with lower midterm complication rates as RFA.

INTRODUCTION

Chronic venous disorders (CVD) are a public health problem that have existed since the very earliest time and that represent socio-economic problem (1). It's known that about 50% of the population suffers from CVD with recent estimation that 60% of population has some degree of CVD according to the CEAP classification, (2) Saphenous reflux is contributing factor to symptoms and progression of venous disease. (3)

Varicose vein (VV) is one of the CVD. It's a common problem worldwide and commonly occurred in the lower extremities and in superficial veins. (4,5)

Treatment of VV aims to eliminate symptoms, improve appearance and to prevent deterioration. The options available includes compression stocking, sclerotherapy, ambulatory

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phlebectomy, surgical stripping, surgical ligation and radiofrequency ablation (RFA) (6) and endovenous cyanoacrylate, ether singly or in combination.

However (7) found that CA embolization is a promising intervention in comparison to RFA ablation in term of rates of successful occlusion and fewer complications than RFA, reporting that more studies are needed to establish the non-inferiority of CA embolization to RFA.

Our aim of this study is to compare between the efficacy and clinical outcomes of endovenous cyanoacrylate embolization and endovenous thermal ablation for patient with lower limb varicose vein with incompetent SFJ.

PATIENTS AND METHODS

This is a 1:1 randomized comparitive clinical trial, conducted on patients presented to vascular surgery department, Aswan University hospital, with varicose veins with Incompetent Sapheno-femoral junction. The protocol of the study was approved by institutional review board, Faculty of Medicine, Aswan University.

Participants

Patients with primary varicose veins with incompetent SFJ, aged > 18 years, and dilated GSV (exceeding 5.5mm in diameter 2 cm below SFJ) was included. While patients with DVT, acute superficial thrombophlebitis, hypercoagulability state, extremely tortuous GSVs or declined to participate in the study were excluded.

Included participants were randomly allocated into two groups, Group A: Included 20 patients who underwent thermal ablation (radiofrequency) of great saphenous vein and Group B: included 20 patients who underwent cyanoacrylate glue embolization of great saphenous vein.

Patient were evaluated outpatient clinic, the evaluation include detailed history and physical examination: personal data (Age and gender), Risk factors (prolonged standing occupation and hereditary) Symptoms (cosmetic, leg heaviness, cramp, ankle swelling and superficial thrombophlebitis).

Physical examination included: Inspection of the skin of the lower 3rd medial aspect of the leg to detect skin affection (swelling, redness, pigmentation, eczema & ulceration).

All patients had duplex ultrasound with color mapping pre-operatively to evaluate GSV depth and maximum diameter. Moreover, the laboratory investigations included: Hemoglobin, white cell count, platelet count, PT, PTT and INR.

Technique:

Group I: radiofrequency saphenous ablation with tumescent anesthesia was performed as reported in Ay et al., study. (8)

Patients were discharged at postoperative day 1, with an instruction to continue using elastic stockings for 1 week.

Group II: cyanoacrylate glue embolization of great saphenous vein was performed according to Yasim et al., study. (9)

Patients were discharged on the same day with prescription of elastic compression stockings for 3 days.

Post-operatively external compression was applied to all patients. Compression included graduated elastic compression stockings and short-stretch bandages.

Evaluation

Both groups were evaluated clinically immediately after the surgery, 3, 6 and 12 months for Pain, Tender along the course of the GSV, Ecchymosis and Venous duplex to evaluate GSV closure.

Statistical Analysis:

Data was collected, coded, and entered using Microsoft Excel software. Data analysis was done using Statistical Package for the Social Sciences (SPSS version 20.0). According to the type of data, qualitative data represent as number and percentage, quantitative data represent by mean ± SD. To assess the difference between categorical variables we used we used Chi ^2. For

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numerical variable we used two sample independent t-test. Repeated measure ANOVA was done to compare between each group in follow up measures. P- value was considered significant if it was < 0.05.

RESULTS

In this study we included 40 patients. Participants were divided into two groups according to the intervention: group A (thermal ablation (radiofrequency)) and group B (cyanoacrylate glue embolization). The demographics data of the included participants by group are reported in Table 1 and 2.

The mean operative duration for group A (15.25±0.55) was statistically significantly lower than group B (19.52 ± 0.95) p-value< 0.05. while there was not statistically difference between the two groups in term of intra-operative bleeding.

Regarding the post-operative evaluation of the studied cases, there was no statistically difference between group A and group B either immediately post-operative, after 3 months, 6 months or 12 months in terms of ecchymosis or having tender along the course of the GSV.

However, there was a good reduction in ecchymosis, as the number of patient was 8 in group A immediately after the operation, and become only 1 after 3 months and become 0 in the further follow-up visits, while 12 cases reported Ecchymosis in group B immediately after the operation, which reduced to become only two cases after 3 months, and one cases after 6 months which become 0 after 12 months.

Also, number of patients with tender along the course of the GSV was 5 in group A immediately after the operation, then become only 1 after 3 months and become 0 in the further follow-up visits, while 8 cases reported tender along the course of the GSV in group B immediately after the operation, which reduced to become only two cases after 3 months, and one cases after 6 months which become 0 after 12 months.

On the other hand there was very highly statistically significant difference in VAS Immediately post-operative between group A (2.09±0.3) and B (3.05±0.01) p-value < 0.001*, after 3 months group A (0.9±0.1) and B (1.4±0.5) p-value < 0.001*, after 6 months group A (0.5±0.09) and B (1.1±0.4) p-value < 0.001* and After 12 months group A (0.1±0.02) and B (0.6±0.2) p-value < 0.001*. Moreover, there was very highly statistically significant improvement in VAS score over time in both group p-value < 0.001.

DISCUSSION

Varicose vein (VV) is a common manifestation of chronic venous disease. The saphenous veins is considered to be the most frequently affected vessels. (10) In the last decade, the advancements of endovenous thermal ablation techniques including radiofrequency ablation (RFA) have significantly changed the management of VVs. (11)

However, the efficacy of RFA is one of the main line of treatment of VVs, tumescent anesthesia is still required in the technique, which contributes to significant procedural time as well as discomfort. (12)

Treatment with CA circumvents the need for tumescent anesthesia and postoperative compression stockings. Initial results of CA from industry sponsored studies have demonstrated promising clinical outcomes compared to EVLA and RFA. (10)

So, we conducted this study to compare between the efficacy and clinical outcomes of CA and RFA for patient with lower limb VV with incompetent SFJ.

Our study showed that CA has statistically significant shorter duration than RFA p-value< 0.05. this was in line with Balcı et al. as they reported that the duration of procedure (minute) was significantly shorter in the CA group. (13) On the other hand, Kalteis et al. found that there was no statistically significant difference between RFA to CA in term of operative time. (14)

The present study illustrated that there was insignificant difference between both groups as regard Venous duplex. This was in line with Eroglu and Yasim as regard Diameter or Depth. (15)

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Our study reported that there was high significant difference between both groups as regard post-operative pain. Similar to our results, Ahmed et al. showed that post-operative pain significantly decrease in group B when compared with group A from the 1st day till the 7th day. (16). However, Tawfik et al. reported non-significant difference between both groups, as pain improved significantly postoperatively in the two groups. (17). Also, Mohamed et al. reported nonsignificant difference between both groups regarding postoperative pain. (18)

This study showed that there was significant difference between both groups as regard pain in follow up visits after 3 months, 6 months, 12 months. In line with our results El Mahdi et al. study showed that there was significant decrease in pain score in each group. (19)

Out study has some limitation, sample size is one of the major limitation, also, our follow-up periods are relatively shorter than other published reports and we do not reported quality-of-life improvements.

Conclusion

CA offers comparable success rates with lower midterm complication rates, better post-operative pain and operative duration in comparison to RFA.

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Conflict of Interest: The Authors declare that there is no conflict of interest

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Table 1: The demographic characteristics of patients.

		Group A N= 20	**Group B N= 20**
Age (years)		48.9±4.54	49.1±4.51
Weight		76.2 ± 3.10	76.4 ± 3.15
BMI		26.2 ± 2.1	26.4 ± 2.4
Gender	Female	12	13
	Male	8	7
Prolonged standing occupation		11	12
Hereditary		9	8
Cosmetic		2	1
leg heaviness		10	11
Cramp		2	3
Ankle swelling		4	5
Swelling		1	1
Redness		8	9
Pigmentation		2	4
Eczema		5	5
Ulceration		4	1

Table 2: summary statistics of the lab investigation

	Group A	**Group B**
White blood cells (x10³ /ml³)	6.52 ± 1.23	6.22 ± 1.04
Red blood cells (x10³ /ml³)	4.02 ± 0.72	4.5 ± 0.50
Hemoglobin (g/dl)	10.4 ± 1.44	13.5 ± 1.35
Platelet (x10³ /ml³)	189.9±12.22	181.47±19.82
AST(U/L)	26 ± 8.54	27.0 ± 8.6
ALT(U/L)	25.5 ± 8.76	25 ± 7.12
Total-Bilirubin (mg/dl)	0.9 ± 0.20	0.95 ± 0.22
Direct Bilirubin (mg/dl)	0.19 ± 0.02	0.18 ± 0.01
Serum albumin(g/dl)	3.53 ± 0.42	3.1 ± 0.12
INR	1.2 ± 0.12	1.21 ± 0.13
PT(s)	12.6 ± 2.1	12.9 ± 2.2

Table 3: the studied groups as regard Venous duplex

	Group A	**Group B**	**Test**	**P- value**
Depth (mm)	16.1 ±6.7	15.8 ±6.4	t-test	0.84
Diameter (mm)	7.6 ±1.9	7.8 ±1.95	t-test	0.95

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Duration of the operation, minutes	15.25±0.55	19.52 ± 0.95	t-test	0.02*
Bleeding	5	6	Chi ^{2}	0.72

Table 4: follow-up evaluation of studied cases

		Group A	**Group B**	**Test**	**P-value**
Ecchymosis	Immediately post-operative	8	12	Chi ^{2}	0.2
	After 3 months	1	2	Chi ^{2}	0.54
	After 6 months	0	1	Chi ^{2}	0.54
	After 12 months	0	0	Chi ^{2}	-
Tender along the course of the GSV	Immediately post-operative	5	8	Chi ^{2}	0.31
	After 3 months	1	2	Chi ^{2}	0.54
	After 6 months	0	1	Chi ^{2}	0.54
	After 12 months	0	0	Chi ^{2}	-
Pain assessment using a visual analog score	Immediately post-operative	2.09±0.3	3.05±0.01	t-test	0.001*
	After 3 months	0.9±0.1	1.4±0.5	t-test	0.001*
	After 6 months	0.5±0.09	1.1±0.4	t-test	0.001*
	After 12 months	0.1±0.02	0.6±0.2	t-test	0.001*
	p-value	<0.001	<0.001		

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