

Study of The Comparative Efficacy of Surgical Versus Conservative Intervention in The Management of Recurrent Venous Ulcers - (Post Operative) Venous Ulcers

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Abstract

Background: Recurrent venous leg ulcers after previous saphenofemoral junction ligation and great saphenous vein stripping remain difficult to manage, particularly when perforator incompetence persists. **Objective:** To compare six-month wound-area outcomes after conservative and surgical management of recurrent venous leg ulcers. **Methods:** This prospective, non-randomized comparative study included 64 patients treated at two Kasturba Medical College hospitals in Mangalore from August 2013 to August 2015. Patients selected conservative or surgical management (32 per group). All received wound care, compression, and limb elevation. The surgical group underwent treatment of incompetent perforators, with repeat saphenofemoral junction ligation when indicated. Foam sclerotherapy was recorded in 8 conservative-group patients and all 32 surgical-group patients. Wound area was assessed at baseline and at 1, 3, and 6 months. Unadjusted between-group comparisons were performed at each time point. **Results:** The duration of the current ulcer was longer in the conservative group than in the surgical group (15.31 ± 10.36 vs 10.16 ± 6.09 months; $p = 0.009$). Baseline wound area was similar (91.22 ± 80.58 vs 80.38 ± 49.78 ; $p = 0.898$). Between-group differences were not statistically significant at 1 month (81.59 ± 79.95 vs 65.81 ± 54.80 ; $p = 0.386$) or 3 months (69.84 ± 49.15 vs 59.59 ± 55.88 ; $p = 0.209$). At 6 months, mean wound area was 88.03 ± 85.48 in the conservative group and 55.72 ± 57.51 in the surgical group ($p = 0.024$). The conservative-group mean decreased through month 3 but increased again by month 6. **Conclusion:** The surgical-management group had a smaller wound area at 6 months, but the non-randomized design, baseline difference in ulcer duration, unequal use of foam sclerotherapy, and absence of a repeated-measures analysis prevent attribution of this finding to perforator ligation alone. The results should be interpreted as an association and require confirmation in a study with standardized co-interventions and longitudinal analysis.

Keywords: venous leg ulcer; recurrent ulcer; perforator incompetence; compression therapy; surgery.

INTRODUCTION

Venous ulceration is the most common type of leg ulceration. 60 to 80% of leg ulcers have a venous component¹⁻⁷. The Lothian and Forth Valley Study examined 600 patients with leg ulceration and found that 76% of ulcerated legs had venous disease and 22% had arterial disease. 10 to 20% of cases had both arterial and venous insufficiency. 9% of ulcerated legs were in patients with rheumatoid arthritis. 5% of the patient group had diabetes⁸.

Chronic venous leg ulceration has an estimated prevalence of between 0.1% and 0.3% in the United Kingdom and the prevalence increases with age^{1-6,9}.

1% of the population, approximately will suffer from leg ulceration at some point in their lives¹⁰.

Venous ulcers arise due to venous valve incompetence and calf muscle pump insufficiency which leads to venous stasis and hypertension resulting in microcirculatory changes and localised tissue ischaemia^{11,12}.

Natural history of the venous ulcer disease is of a continuous cycle of healing and breakdown over decades and chronic venous leg ulcers are associated with considerable morbidity and impaired quality of life¹³. Leg ulcers in patients from the most deprived communities take longer to heal and are more likely to be recurrent¹⁴.

Treatment of this major health problem results in a considerable cost to the NHS. The cost of treating one ulcer was estimated to be between £1,298 and £1,526 per year based on 2001 prices and in the context of a trial conducted within a specialist leg ulcer clinic¹⁵.

In the Scottish Leg Ulcer Trial, the six months healing rate for community based treatment was 45%. In specialist clinics healing rates of around 70% at six months have been achieved. Twelve month recurrence rates vary between 26% and 69%¹⁶⁻¹⁸.

In this guideline, chronic venous leg ulcer is defined as an open lesion between the knee and the ankle joint that remains unhealed for at least four weeks and occurs in the presence of venous disease. Studies reviewed

in this guideline included patients with venous leg ulcers, irrespective of the method of diagnosis of venous insufficiency.

Post-Operative Venous Ulcers are those which occur in the patients after initial superficial venous surgery ie. sapheno-femoral ligation with great saphenous vein stripping. (SFJ ligation with GSV stripping). The main reason for the development of these ulcers is due to incompetent perforators.

The perforator veins were not described until the drawings of Justus Christian Loder in 1794, but the actual role of perforators in venous disease was described by Veneuil and John Gay²⁹.

Beecher and Warren formulated the concept of ambulatory venous hypertension and laid foundation for perforator incompetence. Linton advocated perforator ligation as the standard procedure for perforator incompetence.

In this study we would know about the management options for venous ulcers which occur post SFJ ligation and GSV stripping and their outcome.

Aim of the present study is to compare the efficacy of surgical versus conservative intervention in the management of recurrent venous ulcers - (post operative) venous ulcers.

MATERIALS AND METHODS

Study will be conducted in two hospitals belonging to Kasturba Medical College, Mangalore.

1. Government Wenlock Hospital
2. Kasturba Medical College Hospital, Attavara

From August 2013 to till August 2015 and the study population included all patients who had undergone surgical intervention for varicose veins or ulcers and now present with new ulcer again.

Inclusion Criteria

All patients who had undergone surgical intervention for varicose veins or ulcers and now present with new ulcer again [sapheno femoral ligation with gratersaphenous vein stripping]

Exclusion Criteria

- a. All patients with venous ulcer due to acute deep vein thrombosis.
- b. Patients with venous ulcers and peripheral vascular disease with critical limb ischemia
- c. All patients who had not operated for venous veins or venous ulcers.
- d. Patients with immunocompromised state like underlying malignancy or on steroid treatment and diseases like HIV, diabetes, tuberculosis or leprosy.

Method of Study

A prospective comparative longitudinal study was conducted at Kasturba Medical College Hospitals. All patients satisfying the criteria of recurrent venous ulcer is studied by comparing conservative versus surgical intervention in the management of these ulcer

Sample Size;

$$N = \frac{Z_{\alpha} \sqrt{PQ} + Z_{\beta} \sqrt{p_1 q_1 + p_2 q_2}}{[p_1 - p_2]^2}$$

p1=60% p2=90%

q1=40% q2=10%

64 is the sample size with 95% confidence limit and 80% power

Methodology:

Patients with above inclusion criteria are taken up for study. Initial blood investigations are done followed by venous doppler to rule out any signs of deep vein thrombosis and sapheno femoral, perforator incompetence. A total of 64 patients divided into two groups that is either surgical or conservative group 32 each depending on the patients choice.

Based on the blood investigations, venous doppler reports and depending on the patient choice either conservative or surgical management will be considered.

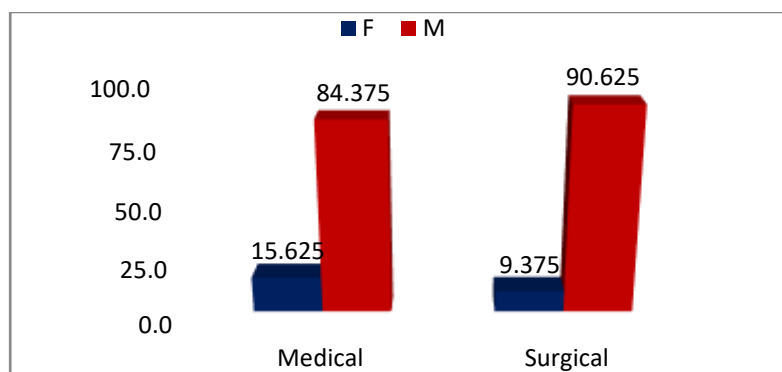
Conservative or surgical management has been done as previously mentioned and then patients are followed up after every 1,3 and 6 months.

On follow up clinical examination is done regarding Size of the ulcer. Surface area was measured with standard manual method of transparent sheet and graph paper.

Analysis was done based upon the response of the ulcer to the above mentioned treatment modalities.

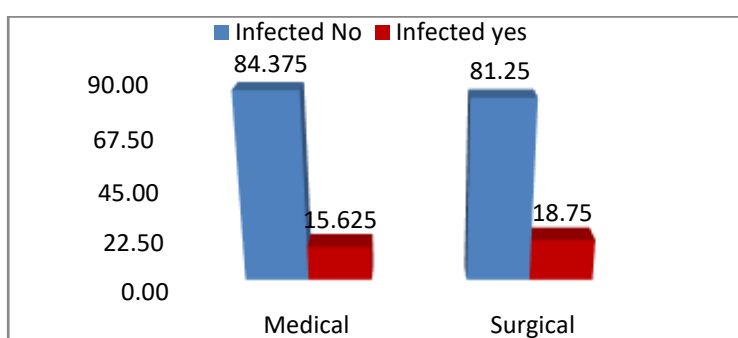
RESULTS:

		Group		Total
		Medical	Surgical	
Sex	F	5 15.6%	3 9.4%	8 12.5%
	M	27 84.4%	29 90.6%	56 87.5%
Total		32 100.0%	32 100.0%	64 100.0%



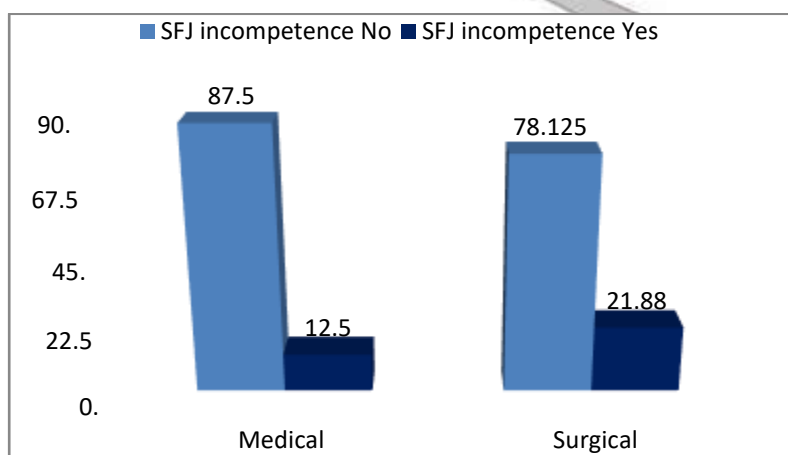
Total no. of patients included in this study was 64 of which 32 in each of conservative and surgical group. Of these 32 in conservative group 5(15.6%) were in females and 27(84.4%) were males. Of 32 in surgical group 3(9.4%) were females and 29(90.6%) were males.

		Group		Total
		Medical	Surgical	
Infected	No	27 84.4%	26 81.3%	53 82.8%
	yes	5 15.6%	6 18.8%	11 17.2%
Total		32 100.0%	32 100.0%	64 100.0%



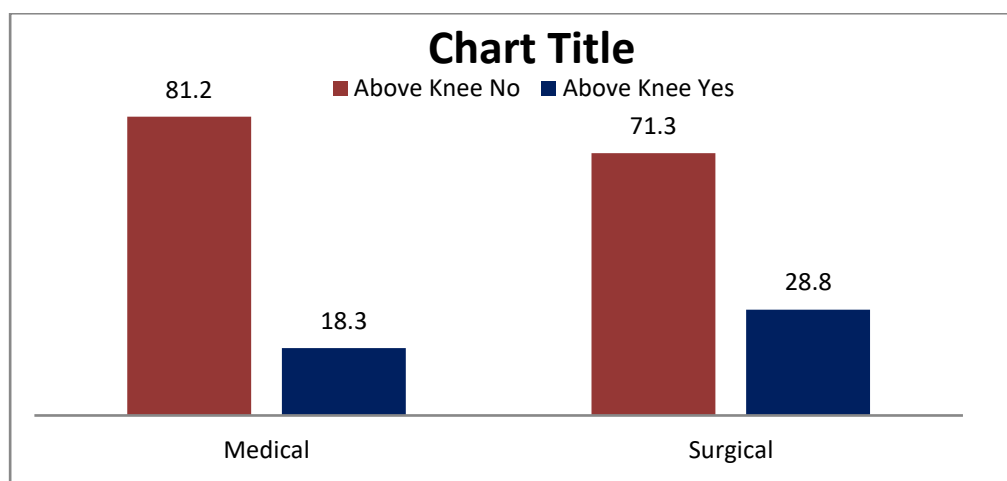
Of the total 32 in conservative group 5(15.6%) wounds got infected and 6(18.8) got infected in surgical group.

		Group		Total
		Medical	Surgical	
SFJ incompetence	No	28 87.5%	25 78.1%	53 82.8%
	Yes	4 12.5%	7 21.9%	11 17.2%
Total		32 100.0%	32 100.0%	64 100.0%



Of the total 64 cases 11(17.2%) cases showed SFJ incompetence along with perforator incompetence.

		Gr		T
		Me	Sur	
Ab	N	2	2	4
		81.2%	71	76
v		6	9	1
		18	28	24
T		3	3	6
		100	100	100



Of the total 64 cases above knee perforator incompetence is observed in 15(24.5%) cases and of which 6(18.3%) were in conservative group and 9(28.8) were in surgical group.

		Group		Total
		Medical	Surgical	
Below knee	Yes	32	32	64
		100.0%	100.0%	100.0%
Total		32	32	64
		100.0%	100.0%	100.0%

Below knee perforator incompetence is noted in all cases of the study group.

	Group		Total
	Medical	Surgical	
Dressing of wound Yes	32 100.0%	32 100.0%	64 100.0%
Total	32 100.0%	32 100.0%	64 100.0%

	Gro		T
	Medi	Surai	
Crepe n	0	0	0
applicati	0	.	0
v	3	3	6
	10	100.	10
T	3	3	6
	100.	100.	100.

Dressing of wound was done for all patients included in the study

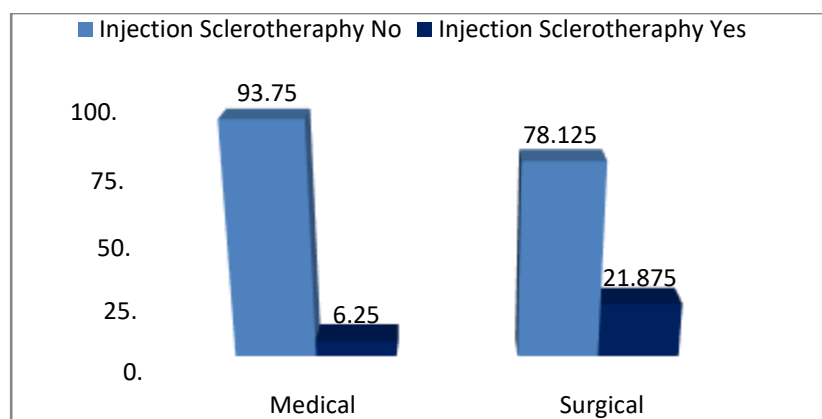
Dressing of wound is done in all cases included in the study

Crape bandage application was done to all patients included in the study.

	Group		Total
	Medical	Surgical	
limb elevation yes	32 100.0%	32 100.0%	64 100.0%
Total	32 100.0%	32 100.0%	64 100.0%

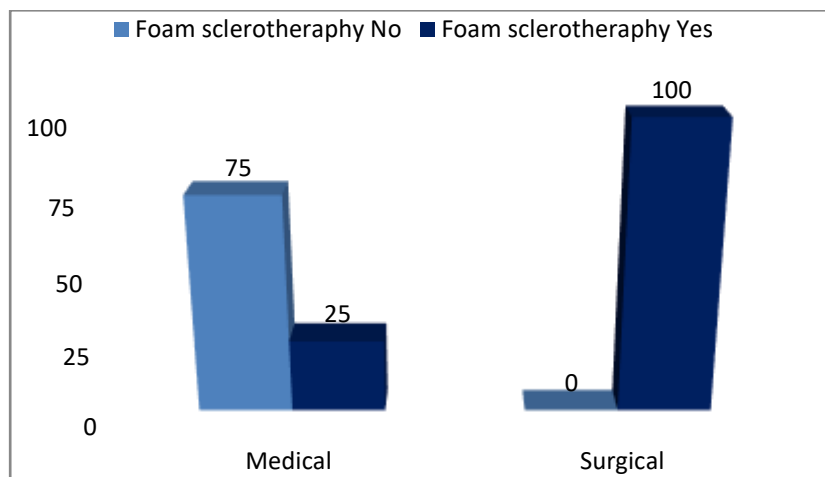
Limb elevation is given to all patients included in the study.

	Group		Total
	Medical	Surgical	
Injection Sclerotherapy No	30 93.8%	32 100%	62 96.9%
Yes	2 6.3%	0 0%	2 4.1%
Total	32 100.0%	32 100.0%	64 100.0%



Of 32 patients in the conservative group 2 cases (6.3%) were given injection sclerotherapy.

		Group		Total
		Medical	Surgical	
Foam sclerotherapy	No	24 75.0%	0 .0%	24 37.5%
	Yes	8 25.0%	32 100.0%	40 62.5%
Total		32 100.0%	32 100.0%	64 100.0%

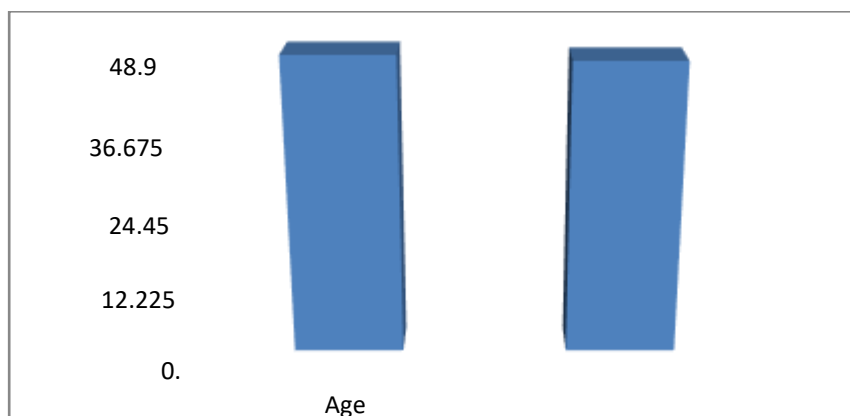


Of 32 patients in conservative group 8 cases (25%) were given foam sclerotherapy.

	chi square test/Fishers exact test p value	
Sex * Group	.450	NS
Infected * Group	.740	NS
SFJ incompetence * Group	.255	NS
Above knee * Group	.219	NS
Below knee * Group		
Dressing of wound * Group		
Crepe bandage application * Group	.313	NS
limb elevation * Group		
Injection Sclerotherapy * Group	.074	
Foam sclerotherapy * Group	p<0.001	HS

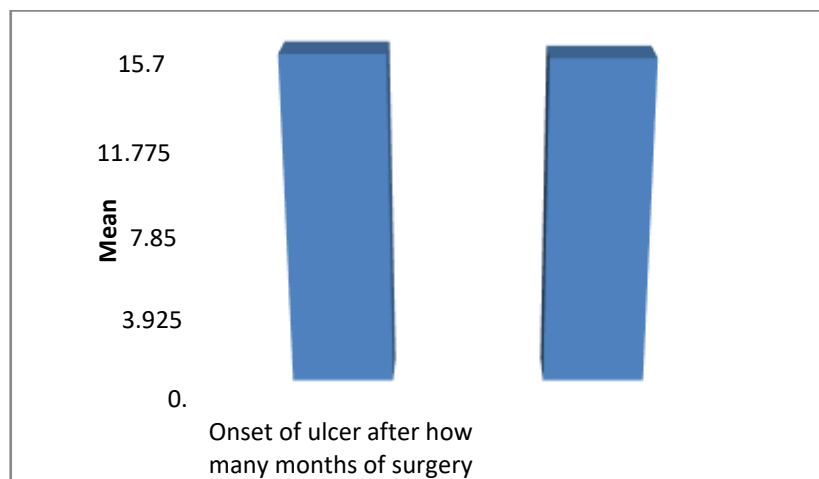
Of all the above mentioned parameters foam sclerotherapy has been highly significant with p valve <0.00.

Age					
Group	N	Mean	Std. Deviation	t test	
				Value	p value
Medical	32	48.81	14.304	.242	.809
Surgical	32	47.91	11.462		NS



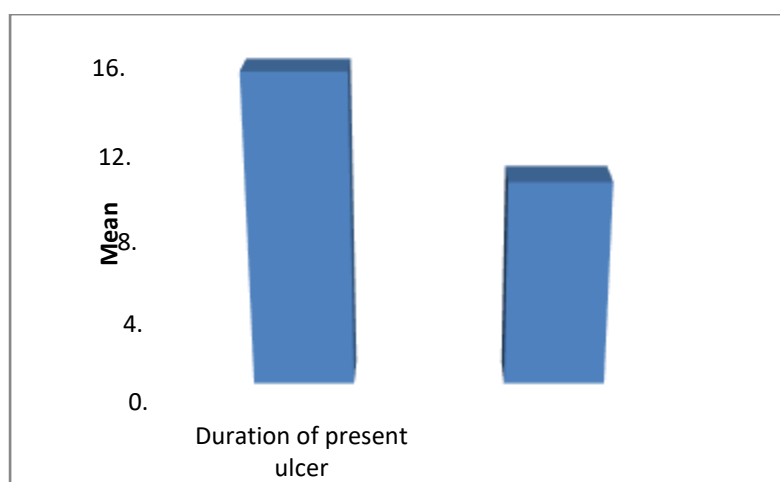
Mean age of the patients in the conservative group is 48.81 and that of surgical group is 47.91

Onset of ulcer after how many months of surgery					Mannwhitney test	
Group	N	Mean	Std. Deviation	Median(IQR)	Value	p value
Medical	32	15.63	6.568	15.5(9.25-21.75)	.061	.952
Surgical	32	15.44	5.483	14.5(12-21)		NS



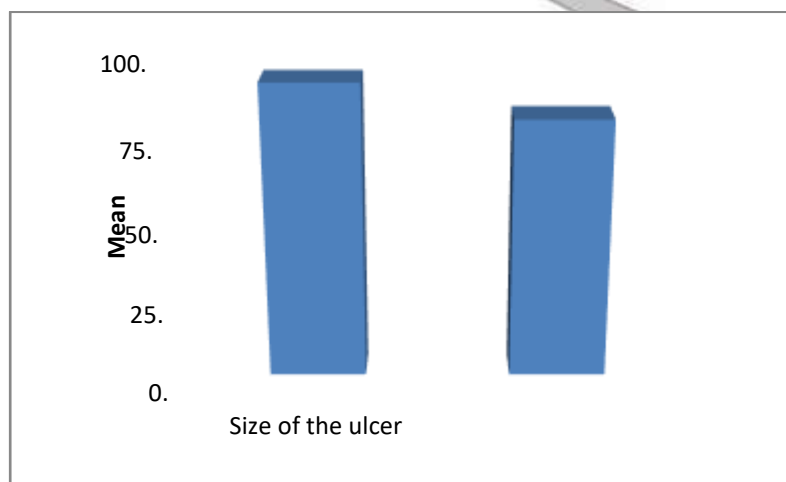
the mean duration of onset of ulcer following surgery in conservatives' group is 15.63 and surgical group is 15.44

Duration of present ulcer					Mannwhitney test	
Group	N	Mean	Std. Deviation	Median(IQR)	Value	p value
Medical	32	15.31	10.356	15.5(8.25-19.75)	2.610	.009
Surgical	32	10.16	6.086	9.5(5.25-12)		HS



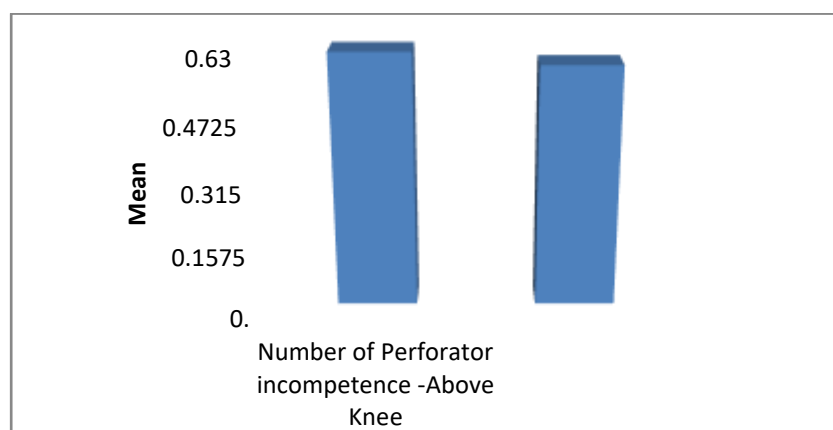
Mean duration of onset of ulcer in conservative group is 15.31 and in surgical group is 10.16 with a significant p value (0.009).

Size of the ulcer					Mannwhitney test	
Group	N	Mean	Std. Deviation	Median(IQR)	Value	p value
Medical	32	91.22	80.576	71.5(44.25-108.25)	.128	.898
Surgical	32	80.38	49.781	71.5(44.25-94.75)		NS



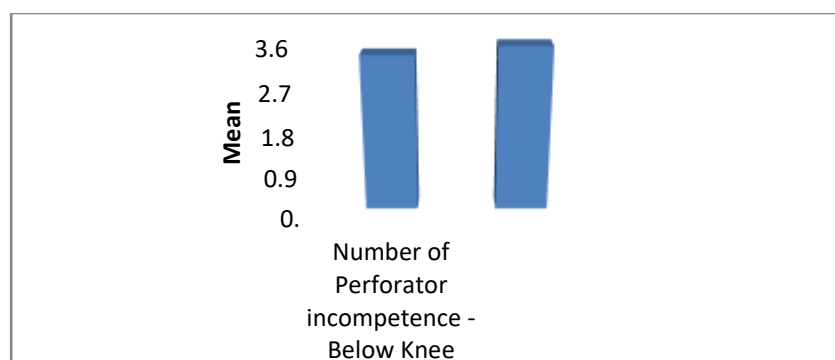
Mean size of the ulcer in conservative group is 91.22 and in surgical group is 80.38 and here p value is 0.898.

Number of Perforator incompetence -Above Knee						
Group	N	Mean	Std. Deviation	Median(IQR)	Mannwhitney test	
					Value	p value
Medical	32	.63	.907	0(0-1)	.054	.957
Surgical	32	.59	.837	0(0-1)		NS



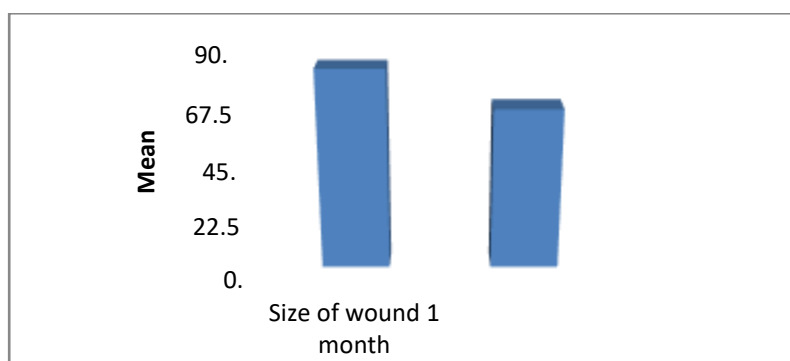
Mean no. of perforators (above knee) in conservative group is 0.63 and in surgical group is 0.59 with p value of 0.957

Number of Perforator incompetence - Below Knee						
Group	N	Mean	Std. Deviation	Median(IQR)	Mannwhitney test	
					Value	p value
Medical	32	3.34	.865	3(3-4)	.779	.436
Surgical	32	3.53	.950	4(3-4)		NS

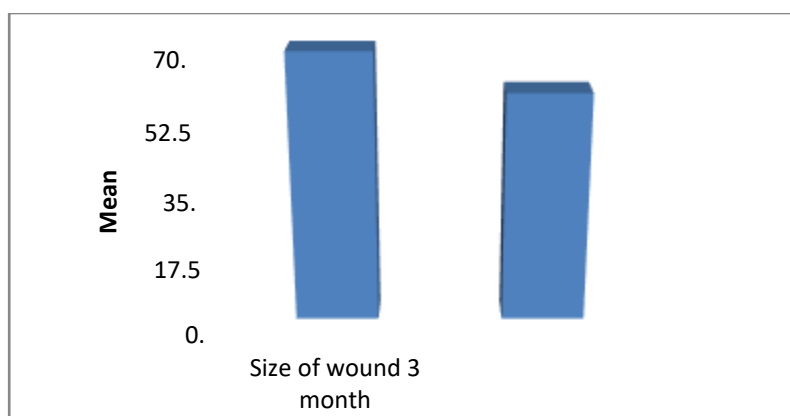


Mean no. of perforators (below knee) in conservative group is 3.34 and in surgical group is 3.53 with a p value of 0.436

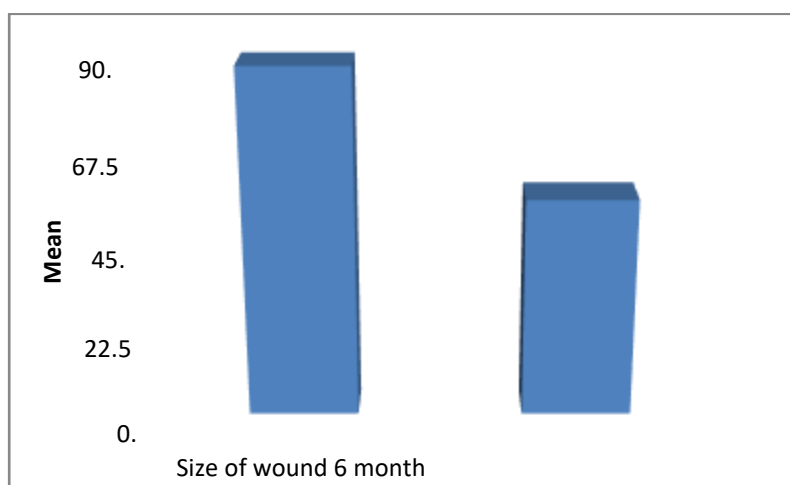
	Group	N	Mean	Std. Deviation	Median(IQR)	Mannwhitney test	
						Value	p value
Size of wound 1 month	Medical	32	81.59	79.950	65(37.25-107.25)	.866	.386
	Surgical	32	65.81	54.803	41(27-88)		
Size of wound 3 month	Medical	32	69.84	49.152	65.5(30.5-87)	1.256	.209
	Surgical	32	59.59	55.884	37(22.5-88.25)		
Size of wound 6 month	Medical	32	88.03	85.478	72(34.25-101.75)	2.263	.024
	Surgical	32	55.72	57.514	35(16.5-90.5)		



Mean size of the wound in conservative and surgical group after 1 month of follow-up are 81.59 and 65.81 respectively with a p value of 0.386.



Mean size of the wound in conservative and surgical group after 3 months of followup are 69.84 and 59.59 respectively with a p value of 0,209.



Mean size of the wound in conservative and surgical group after 6 months of followup are 85.478 and 57.514 respectively with a significant p valve of 0.024.

DISCUSSION

Venous ulceration is a common cause of severe disability and it has been commonly observed that after bed rest and limb elevation the ulcers tends to heal and re-appear again requiring repeated hospitalization.

Here in this study, we have done comparison between conservative versus surgical intervention in the management of venous ulcers which develop following the SFJ ligation and GSV stripping. The main reason for the development of these ulcers is due to incompetent perforators.

Wijnand B. van Gent *et al.* 2001 have done studies on 170 patients comparing SFJ ligation with GSV stripping and perforator ligation with standard compression therapy and found that surgery combined with compression therapy showed better results³⁰.

O. Nelze'n and I. Fransson, 2007 studied results of Superficial venous surgery alone with combined perforator ligation showed that recurrence rate was decreased following perforator ligation³¹

But in this study we have observed in some cases SFJ incompetence again after previous ligation, the reason for this is A) failure to find and ligate the main saphenous trunk, a large tributary is treated instead. B) a non terminal or non flush saphenous vein ligation³². These patients were again treated with SFJ and incompetent perforator ligation.

The patients in our study are divided into surgical and conservative group based on the similar baseline characteristics that is post SFJ ligation and GSV stripping and patients with comorbid conditions like diabetes mellitus, acute DVT and immunocompromised states were excluded from the study and patients were compared in the terms of wound healing (size of the wound and its response) after a specified period.

Arterial disease was ruled out by establishing that pedal pulses are present on physical examination and/or that the ankle : brachial index (ABI) is > 0.8. (Any ABI less than 1.0 suggests a degree of vascular disease and compression therapy is usually considered to be contraindicated with an ABI < 0.7.)

Many definitions have been used to diagnose venous leg ulcers including clinical history and examination, invasive, and noninvasive testing. It is important to understand how the diagnosis was made and to understand the limitations of the method. Color duplex ultrasound scanning performed with proximal compression or a Valsalva maneuver is useful in providing anatomic and physiologic data helping to confirm a venous etiology for the leg ulcer.

In this study all patients were treated with standard compression therapy, regular dressing of wound and in some cases sclerotherapy was done after identifying the perforators through venous Doppler and depending on the patients choice.

Dressings are often used under compression bandages to promote faster healing and prevent adherence of the bandage to the ulcer. A wide range of dressings are available, including hydrocolloids, foams, hydrogels, pastes, and simple non-adherent dressings. A cohcrane 1998 meta-analysis of 42 randomized controlled trials with a total of more than 1,000 patients showed no significant difference among different types of dressings. So all the patients in our study group were done simple non-adhesive dressing.

Pentoxifylline was given as a adjuvant for all patients in the conservative group.

Pentoxifylline increases microcirculatory blood flow, oxygenation of ischemic tissues, increase red and white cell filterability and decrease whole blood viscosity, platelet aggregation and fibrinogen levels.

Falanga *et al.* demonstrated statistically significant improvement in the pentoxifylline group when compared with the placebo group, both groups receiving compression³³.

A Cochrane collaboration study done in 2002 reported that pentoxifylline is effective as an adjuvant to compression therapy for treating VLU³⁴. A well-conducted review identified 11 randomized controlled trials (RCTs) comparing pentoxifylline with placebo or no treatment. Treatment with pentoxifylline 400 mg 3 times daily improved VLU healing rates by 21% when used as adjuvant to compression or by 23% when used as solo therapy³⁵.

In 1992, Thibault and Lewis reported their early experience with injection of incompetent perforating veins by using ultrasound guidance which showed that perforator veins remained successfully obliterated in 83.7% at 6 months after treatment³⁶. In 2000 at the Pacific Vascular Symposium in Hawaii, Jerome Guex from France reported his experience with direct perforator treatment with ultrasound guidance. The sclerosing agent used was Sotradecol (3%) or polidocanol (3%) for veins >4 mm, and a more dilute solution used for veins <4 mm. He estimated that 90% of perforators could be eliminated after one to three sessions of injections³⁷. In the current study most of our patients primarily had isolated perforator disease (82.5%) without concomitant axial reflux from the thigh to the calf in the saphenous or deep systems.

The effectiveness of treating perforators with isolated reflux was suggested in the randomized trial reported in 1974 by Hobbs comparing compression sclerotherapy with surgery and included saphenous vein stripping and subfascial ligation of perforators. He found that in the face of great or short saphenous vein reflux, surgery

proved to have better than sclerotherapy alone³⁸. On the other hand, when incompetent perforator veins were present without concomitant saphenous vein disease, sclerotherapy of calf perforators proved better than surgery. Like the data presented by Hobbs⁵³, our study suggests that patients with perforator disease without axial reflux appear to benefit from foam sclerotherapy when compared with compression alone.

In both groups age, sex, duration of onset of ulcer following the initial surgery, size of the ulcer, no of perforators had shown no significant influence on ulcer healing but duration of present had a positive effect on ulcer healing.

However when we compare surgical and conservative groups the primary end point i.e.... decrease in the size of the ulcer or response of the ulcer at 1 and 3 months had no significant differences but on 6 months follow up significant response was noticed in the surgical group indicating the influence of perforator ligation on long term healing rates and preventing recurrences.

CONCLUSION:

Our study indicates that venous ulcers are common among males in the age group of 45 to 50 years. It shows that foam sclerotherapy combined with compression gives better response than compression therapy alone. Surgical therapy in the form of incompetent perforator ligation combined with compression therapy have shown significant positive results on long term follow up indicating the importance of perforator ligation.

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