STUDY OF CLINICAL OUTCOMES OF SUBFASCIAL PERFORATOR LIGATION SURGERY IN PERFORATOR INCOMPETENCE

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ABSTRACT

BACKGROUND

Chronic venous insufficiency presents with a spectrum of clinical features ranging from pain or heaviness of affected limbs to non-healing ulcers over the lower limbs and usually require some form of surgical intervention, performing direct perforator vein division preferably by subfascial endoscopic perforator ligation surgery for perforator incompetence, as despite aggressive conservative therapy including compression, lifestyle modification and venotonic medications which are of high cost treatment with increased risk of increasing symptoms.

MATERIALS AND METHODS

A prospective longitudinal clinical study of 30 patients selected by systematic sampling method from November 2014 to September 2015 at our institution was conducted to determine the results of subfascial endoscopic perforator vein surgery (SEPS) in perforator incompetence.

RESULTS

For venous clinical severity scoring pre operatively and after 3 weeks post-surgery, the mean for VCSS pre-operatively was 6.66 and a standard deviation of 2.399. The T value was calculated and was found to be 4.9321 and p value of 0.00001(p value less than 0.05 is significant). Similarly for the cases with active ulcer, the size assessment pre-operatively and post-SEPS was again analysed using student t test and the mean ulcer size prior to surgery was found to be 3.3 and standard deviation of 1.984. The T value was calculated and was found to be 1.789009 and a p value of 0.04 (p value less than 0.05 is significant).

CONCLUSION

Our study concluded that favourable and significant ulcer healing rate with improvement and reduction in clinical severity suggests that SEPS plays an important role in surgical management of advanced stages of venous insufficiency.

KEYWORDS

Perforator Surgery, Varicose Vein, Subfascial Endoscopic Perforator Vein Surgery (SEPS), Venous Insufficiency, Non-healing ulcer.

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BACKGROUND

Chronic venous insufficiency presents with a spectrum of clinical features ranging from pain or heaviness of affected limbs to non-healing ulcers over the lower limbs. The development of this chronic venous insufficiency pathology is being well attributed to venous hypertension either caused by obstruction, valvular reflux or both involving superficial, deep or perforator veins. The patients with chronic venous insufficiency usually require some form of surgical intervention as despite aggressive conservative therapy including compression, lifestyle modification and venotonic medications which are of high cost treatment with increased risk of increasing symptoms. Primary valvular incompetence leading to cutaneous venous hypertension in 60% of the patients results in a series of cutaneous manifestation which in its severe form presents as ulcers over the medial malleolus. Perforating veins communicating the deep venous system to superficial system with inward flow if becomes incompetent is one of the leading cause for chronic venous insufficiency in lower limbs. Many studies have demonstrated that most patients with venous or varicose ulcers or long standing venous insufficiency have a large number of incompetent perforators compared to patients with uncomplicated varicose veins. In the standard saphenous surgery, it fails to correct the outward flow in perforators in most cases. This is because, the removal of superficial varicosities do not affect the transmission of high venous pressure from the calf pump to the microcirculation

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of the skin of the "gaiter area" called as the "blow out syndrome". The only way to tackle this pathway is by performing direct perforator vein division preferably by subfascial endoscopic perforator ligation surgery for perforator incompetence. This above theory has led the Edinburgh.[1] group to have formulated a classification for the incompetent perforator veins and the type of venous surgery suggested in order to correct the outward flow in the perforating veins.

AIM OF THE STUDY

To determine the results of subfascial endoscopic perforator vein surgery (SEPS) in perforator incompetence.

Parameters to be Evaluated-

1. Symptom reduction assessed by venous clinical severity scoring pre-operatively and post-operatively at 1, 2 and 3 week.
2. Rate of ulcer size healing-venous ulcer size assessment pre-operatively and post-operatively at 1, 2 and 3 weeks.

MATERIALS AND METHODS

Type of Study- This is a prospective longitudinal clinical study.

Size of The Study- 30 patients selected by systematic sampling method.

Duration of the study- November 2014 to September 2015

Place of Study- Department of general surgery. Government Kilpauk medical college and hospital.

Inclusion Criteria

- Patient presenting with various degrees of chronic venous insufficiency CEAP class 4 to class 6.
- Patients with duplex study suggestive of perforator incompetence.
- Patient of both sexes.
- Age from 18 years to 60 years.
- Patients who are willing to give consent for study will be included.

Exclusion Criteria

- Patients with Recurrent varicose veins.
- Deep venous reflux.
- Deep venous thrombosis.
- Saphenopopliteal reflux.
- Arterial occlusive disease.
- A previous lower limb surgery.
- Pregnancy.

Data Collection

- 30 eligible patients are chosen with the clinical diagnosis of varicose veins.
- One limb with perforator incompetence was considered as one case.
- History and signs are recorded.
- Basic routine investigations were done for all patients.
- CEAP classification category will be determined.
- Duplex study.
- Venous disability score preoperatively and reassessed post-operatively.
- Venous clinical severity scoring preoperatively and reassessed post-operatively.
- Ulcers and their size will be noted pre-operatively and reassessed post-operatively.
- Consent will be obtained for inclusion under study for surgery.

Surgical Technique

Preoperative Preparation- Pre operative evaluation included duplex scanning of the affected limb and the incompetence in superficial, deep and perforator levels were document. The incompetent perforator vein on the skin was marked accurately using a skin marker on the day of surgery which helps in as its the surgeon during surgery. All patients received a single dose prophylactic antibiotic just before induction of anaesthesia.

Operative Technique

The procedure of SEPS was performed under spinal anaesthesia. Patient in supine position and in Trendelenburg position with flexion and abduction and at hip and flexion at knee. In our study this technique was performed using two port technique. We did not use the tourniquet during the surgery. Limb was painted and draped. A skin incision was made measuring 13 mm one hand breadth or 5 cm below and medial to tibial tuberosity and was deepened in layers. Skin retractors applied for better visualization. The fascia muscularis was identified and incised.

A 10 mm trocar inserted through which a 0 degree rigid telescope and light source connected was introduced. No balloon dissector was used. Carbon di oxide insufflation done and using the scope a subfascial space was created with the instrument directing towards the medial malleolus. The insufflator pressure was maintained at 15 mm Hg. the subfascial space visualized. Under direct telescopic guidance another 5mm working port incision made 5 cm below and medial to the previous incision.

A Maryland forceps with bipolar cautery inserted through the working port. The large perforating veins bridging from the underlying gastrocnemius muscle to the fascia above were coagulated using bipolar cautery and with the help of endoscissors divided. This subfascial space was opened by blunt dissection from the shin of tibia to upto midline of posterior aspect of limb and distally upto about 2-3 cms above medial malleolus. After completing the procedure, the instruments and ports were removed and carbon dioxide was manually expressed out. The skin incision were closed and the limb was elevated and wrapped in an elastic bandage.

Post-operative Assessment

Once the spinal anaesthesia wears off, the patients were encouraged to ambulate on the same day as surgery and all patients received antibiotics for 48 hours post-surgery. Patients were discharged on 3rd day with post-operative

instructions on ambulation limb elevation and maintaining the elastic bandage regularly. Ulcer dressings were done regularly and skin sutures removed on follow up with assessment of clinical symptom reduction and ulcer size reduction at 1 ,2 and 3rd week post-surgery.

Venous Clinical Severity Scoring System

	None: 0	Mild: 1	Moderate: 2	Severe: 3
Pain or other discomfort (i.e., aching, heaviness, fatigue, soreness, burning) Presumes venous origin		Occasional pain or other discomfort (ie, not restricting regular daily activities)	Daily pain or other discomfort (ie, interfering with but not preventing regular daily activities)	Daily pain or discomfort (ie, limits most regular daily activities)
Varicose veins "Varicose" veins must be 3 mm in diameter to qualify in the standing position.		Few: scattered (ie, isolated branch varicosities or clusters) Also includes corona phlebectatica (ankle flare)	Confined to calf or thigh	Involves calf and thigh
Venous oedema Presumes venous origin		Limited to foot and ankle area	Extends above ankle but below knee	Extends to knee and above
Skin pigmentation Presumes venous origin Does not include focal pigmentation over varicose veins or pigmentation due to other chronic diseases	None or focal	Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of Calf
Inflammation More than just recent pigmentation (ie, erythema, cellulitis, venous eczema, dermatitis)		Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of Calf
Induration Presumes venous origin of secondary skin and subcutaneous changes (i.e., chronic oedema with fibrosis, hypodermitis). Includes white atrophy and lipodermatosclerosis		Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of Calf
Active ulcer number	0	1	2	3
Active ulcer duration (longest active)	N/A	3 mo	3 mo but 1 y	Not healed for 1 y
Active ulcer size (largest active)	N/A	Diameter 2 cm	Diameter 2-6 cm	Diameter 6 cm
Use of compression therapy	0 Not used	1 Intermittent use of stockings	2 Wears stockings most days	3 Full compliance:

Table 1. Venous Clinical Severity Scoring System

RESULTS

In our study which included a sample size- 30 Patients with perforator incompetence two third of the patients were male-20 patients (66%) and one-third were female -10 patients (33%).

The mean Venous clinical severity score for a sample size of 30 in our study population was 6.66 (data chart 1)

About 56.66% (17 of the patients) under study had a VCSS score between 6-10 and 36.66% (11 of the patients had a VCSS score between 1-5 and only 6.66% (2 patients) had a VCSS of 11-15 and none above 15.

7 patients amongst the 30 patients had an active ulcer at the time of presentation. 5 patient had a single ulcer. 1 patient had 2 and another had 3 ulcers.

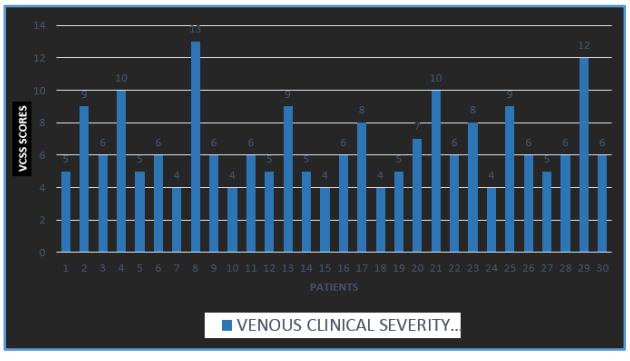

Chart 1. Venous Clinical Severity Scores of Patients Prior to Surgery for Perforator Incompetence

The mean VCSS for the patients under study was 6.66 pre-operatively.

The mean VCSS for the patients under study after 1week post SEPS was 6 (10% reduction compared to initial value).

The mean VCSS for the patients under study after 2 weeks post SEPS was 5.33 (19% reduction to pre operative score).

The mean VCSS for the patients under study after 3 weeks post SEPS was 4.2 (36.9% reduction in clinical severity).

So total mean VCSS reduction at the end of 3 weeks post surgery was 36.9% of the actual mean prior to surgery.

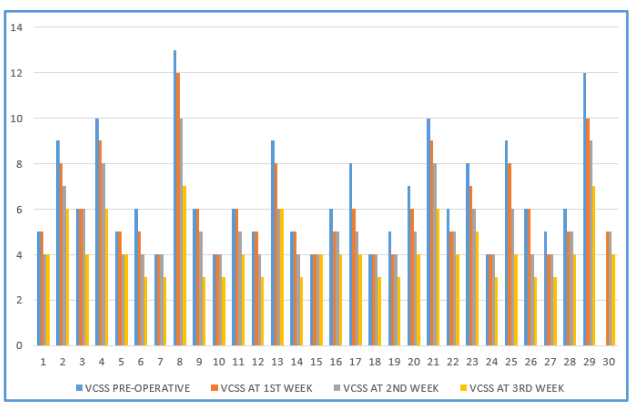

Chart 2. Representation of Clinical Reduction of Symptoms Post-Operatively at 1st Week, 2nd Week and 3rd Week

The majority of patients had a VCSS prior to surgery between 6-10 (56.66%) and post-surgery after 3 weeks about 80% of the patients under study had a reduction in clinical symptoms with VCSS less than 5.

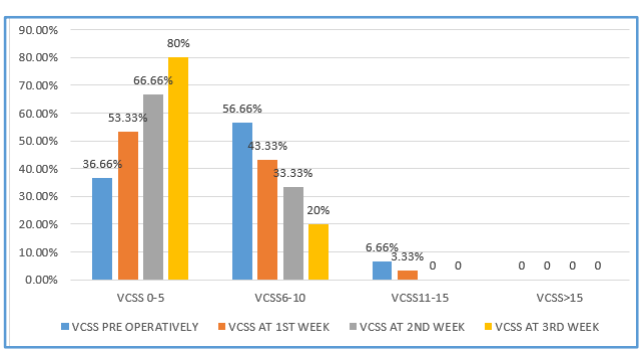

Chart 3. Representation of Symptom Reduction by Venous Clinical Severity Score at 1st Week, 2nd Week and 3rd Week Post-Operatively

The mean ulcer size in cm2 prior to surgery was 3.3 cm2

The mean ulcer size after 1 week post-surgery was 2.544 cm2 which is a size reduction of 22.9% of original mean ulcer size value.

The mean ulcer size after 2 weeks post SEPS was 1.95 cm^2 which is a size reduction of 40.54%of original mean ulcer size.

Finally after 3 weeks post SEPS the mean ulcer size was 1.54% which is a size reduction of 53.33%.

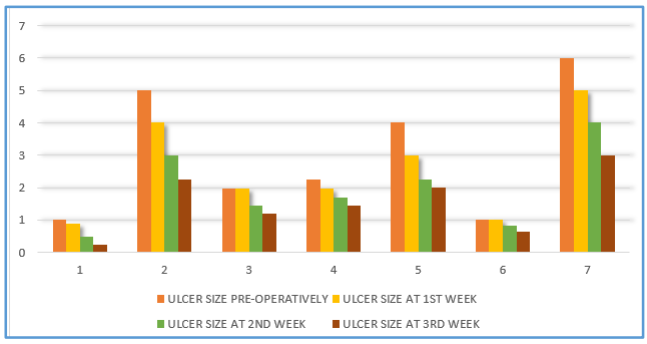

Chart 4. Representation of Ulcer Size Reduction at 1st Week, 2nd Week and 3rd Week

The above data that was obtained from the study, analysis of the data was done using student paired t test.

For venous clinical severity scoring pre operatively and after 3 weeks post-surgery, the mean for VCSS pre-operatively was 6.66 and a standard deviation of 2.399. The T value was calculated and was found to be 4.9321 and p value of 0.00001 (p value less than 0.05 is significant).

Similarly for the cases with active ulcer, the size assessment pre-operatively and post-SEPS was again analysed using student t test and the mean ulcer size prior to surgery was found to be 3.3 and standard deviation of 1.984. The T value was calculated and was found to be 1.789009 and a p value of 0.04 (p value less than 0.05 is significant).

Hence from the above data it is clear that the p value of the parameters that were evaluated in our study favour a positive and significant clinical outcomes in patients who underwent subfascial endoscopic perforator incompetence for perforator incompetence.

DISCUSSION

Our study was a prospective longitudinal study of clinical outcomes of subfascial endoscopic perforator incompetence in a study population of 30 patients with duplex scan confirmed perforator vein incompetence in the CEAP classification of 4,5 and 6. These patients after obtaining consent from the patients to be included in the study were assessed for two main parameters

1. Venous clinical severity scoring pre-operatively and at 1st, 2nd and 3rd week post-operatively for symptom reduction.
2. Ulcer size reduction in size at 1st, 2nd and 3rd week post SEPS.

In our study we observed that the majority of the patients about 66% were male and 33% were female.

Tenbrook et al[2] have compared data from 20 studies and a overall average sex distribution was 51% females and 49% males. The reason for male predominance is our study could be because more number of males turned up for treatment and that it is a male dominant society

In our study we observed that most of our patients (56.66%) were in the age group of 30-50 years with the mean age of 48.6 years. In the study published in Indian

journal of surgery 2014 observed that 58 out of 100 patients were in the age group of 16-35 with a mean of 33.6 years.

Most patients in our study had a perforator incompetence in the right lower limb (60%) and left side in (25%) and bilateral disease (15%). in case of bilateral disease in the limbs with advanced CEAP and VCSS score were operated. Gloviczki et al[3,4] reported right sided involvement in 49% patients and left in 46% of patients and bilateral in 5% of patients under study. Hauer et al[5] reported 19% right sided chronic venous insufficiency and 35% on the left side.

In our study the most common group of perforators ligated were the cockett group which were clinically tested to be incompetent were the most accessible group with this procedure.

In our study the patients were assessed based on clinical severity, the mean of which pre-operatively was 6.66 and reduced to 4.2 after 3 weeks post- SEPS (p value .00001). Gloviczki et al[3,4] USA reported "the results of north American subfascial endoscopic perforator ligation surgery registry which included 146 cases from 17 centres across USA and Canada reported a clinical score improvement of 3.98 from 8.93 for a complete follow up period of 2 yrs". In another study in 2014 by M.G. Vashisht and Nitin singhal reported that "patients with complaints of pain during walking could walk without feeling discomfort at 14 days after SEPS". Uncu et al[6] in his series of 28 patients observed "improvement in symptom by clinical improvement index after 3 months of SEPS from 8.14v/s 2.54 which was statistically significant". Baron et al[7] noted "decrease in oedema and regression of symptoms with subjective improvement in physical performance in all patients"

In our study we observed that the rate of ulcer size reduction after 21 days of post SEPS was 53.33% (p value of 0.04). Synbrandy et al reported "a ulcer healing rate of 95%after SEPS". Tenbrook et al reported "a median time as 30-60 days for complete healing after SEPS". Baron et al[7] reported "primary healing following SEPS in 41 out of 53 patients in 12 weeks and in the remaining 12 it took longer time but none exceeded 6 months". In a study done Anjay kumar included 21 patients of varicose veins with the perforating vein incompetence underwent SEPS using harmonic scalpel showed "ulcer healing in 8 weeks with no recurrences in 11.9 month of follow up". Negus and freugood[8] reported "84% ulcer healing rate".

In our study 10 % of the patients developed post-operative complications like wound site infection which subsided in 10 days with conservative management, haematoma formation which resolved in 2 weeks with medical management and dysaesthesia in one patient.

CONCLUSION

Venous ulcers are common cause of non-fatal disability. Though these venous ulcers can be managed by bed rest and limb elevation leading to its healing. The complications of these delayed wound healing ulcers are skin necrosis, wound infection which are sequelae of open exploration of the subfascial plane for ligation of incompetent perforating veins.

Hence a less invasive approach like the new endoscopic technique have been developed recently. These endoscopic techniques have an advantage of very minimal post-operative pain with early active mobilization within a few hours after surgery and allegedly reduce the morbidity caused due to prolonged immobilization post open surgeries.

Endoscopic exploration of subfascial area in patients with venous ulcers results in an uncomplicated primary healing of wound with very low wound complications.

These endoscopic procedures not only reduces the post-operative sequelae but also requires small skin incisions for port incision.

This procedure of subfascial endoscopic perforator ligation surgery can also be performed with available laparoscopic instruments and apparatus in a tertiary care centre provided there is also an availability of surgical expertise of performing SEPS for identification of the incompetent perforators with division of same.

The use of endoscopic technique allows clear identification of nearly all perforators in patients and in patients with advanced chronic venous disease.

This technique can also be utilized to perform ligation of the incompetent perforating veins in patients with lipodermatosclerosis (skin thickening and induration) and active ulcers to identify and ligate the perforators beneath the ulcer site which thus helps in ulcer healing and prevent ulcer recurrences.

Endoscopic subfascial division of incompetent perforating veins is a new promising technique and had gained popularity amongst surgeons as surgical treatment of venous ulcers as the trend is now towards minimally invasive surgery.

The accessibility of submalleolar perforators is feasible with subfascial plane exploration and further enhances the ulcer healing process.

SEPS should be an added procedure along with conventional varicose veins surgery in order to reduce long term recurrences of the venous ulcer and promote wound healing.

With better understanding of chronic venous disease, the ability to follow the clinically relevant outcomes should increase. The VCSS is considered the progeny of the CEAP clinical class.

This scoring system has been shown to be practical and easy one to use to assess the outcomes of treatment. VCSS is an instrument that can be accepted as valid, reliable, and useful by the international venous community. The revised VCSS along with clinical CEAP provides a standard tool and clinical language to document and compare differing approaches to chronic venous disease management.

SEPS not only helps in accurate removal of the incompetent perforators which are the main cause for venous ulcerations but also improves the haemodynamic changes in the deep venous system with reduction in clinical severity of chronic venous disease. The role of SEPS should be considered whenever patients has incompetent

perforators along with reflux in superficial system and also in patients in advanced stages of chronic venous disease like CEAP 4,5 and 6.

Hence with the favourable and significant ulcer healing rate with improvement and reduction in clinical severity suggests that SEPS plays an important role in surgical management of advanced stages of venous insufficiency.

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