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ORIGINAL ARTICLE

Great saphenous vein sparing versus stripping in Trendelenburg operation for primary varicose veins: a prospective study

Porównanie podejścia oszczędzającego i strippingu wielkiej żyły odpiszczelowej w operacji Trendelenburga żylaków pierwotnych: badanie prospektywne

Authors' Contribution:
A – Study Design
B – Data Collection
C – Statistical Analysis
D – Manuscript Preparation
E – Literature Search
F – Funds Collection

Ashikesh Kundal[1ABCDEF], Navin Kumar[1ABCDEF], Deepak Rajput[1BDEF], Udit Chauhan[2BDEF]

[1]Department of General Surgery, All India Institute of Medical Sciences, Rishikesh, India
[2]Division of Interventional Radiology, All India Institute of Medical Sciences, Rishikesh, India

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ABSTRACT:

Objective: The purpose of this study was to compare the outcome of the great saphenous vein (GSV) sparing versus stripping during Trendelenburg operation for varicose veins.

Methods: This was a prospective randomized study of primary varicose vein patients who underwent Trendelenburg operation. Data of patients operated on over a period of 16 months was collected, including: below knee GSV diameter by Duplex Ultrasound and revised venous clinical severity score (rVCSS), calculated preoperatively and postoperatively at 2nd, 4th, and 8th week.

Results: A total of 36 patients undergoing Trendelenburg operation were included in the study. Nineteen patients underwent GSV sparing while 17 underwent stripping of GSV till just below the knee after juxtafemoral flush ligation of the great saphenous vein. There was a significant decrease in the below-knee GSV diameter (19% after 2 months) and rVCSS (60.8%) in the sparing group. The stripping group also showed an almost similar decrease in below-knee GSV diameter (19.6% after 2 months) and rVCSS (66.3%). However, no significant difference was found between the two groups in terms of change in GSV diameter (P = 0.467) and rVCSS (P = 0.781).

Conclusion: Trendelenburg procedure with sparing of GSV can be done routinely for operative management of varicose veins, where surgery is needed.

KEYWORDS: GSV sparing, GSV stripping, revised venous clinical severity score (rVCSS), trendelenburg operation, varicose veins

STRESZCZENIE:

Cel: Celem niniejszego badania było porównanie wyników podejścia oszczędzającego i strippingu wielkich żył odpiszczelowych (WŻO) w ramach operacji Trendelenburga w leczeniu żylaków.

Metody: Niniejsze badanie było prospektywnym, randomizowanym badaniem z udziałem pacjentów z pierwotnymi żylakami poddawanych leczeniu operacyjnemu metodą Trendelenburga. Na przestrzeni 16 miesięcy badania gromadzono dane pacjentów poddawanych leczeniu operacyjnemu, w tym pomiary średnicy WŻO poniżej kolana z wykorzystaniem ultrasonografii dupleksowej oraz ocenę w zmodyfikowanej skali ciężkości chorób układu żylnego (rVCSS) przed operacją oraz 2, 4 i 8 tygodni po operacji.

Wyniki: Do badania włączono łącznie 36 pacjentów poddanych operacji metodą Trendelenburga. U 19 pacjentów oszczędzono WŻO, natomiast u 17 wykonano stripping WŻO tuż poniżej kolana po podwiązaniu wielkiej żyły odpiszczelowej przy żyle udowej. W grupie leczenia oszczędzającego odnotowano znaczny spadek średnicy WŻO poniżej kolana (19% po 2 miesiącach) i wyniku w skali rVCSS (60,8%). W grupie pacjentów poddanych zabiegowi strippingu obserwowano niemal takie samo obniżenie średnicy WŻO poniżej kolana (19,6% po 2 miesiącach) i wyniku w skali rVCSS (66,3%). Nie stwierdzono jednak istotnych różnic między obiema grupami w zakresie zmian w średnicy WŻO (p = 0,467) i wyniku w skali rVCSS (p = 0,781).

Wnioski: Zabieg Trendelenburga z oszczędzeniem WŻO może być elementem rutynowego leczenia żylaków w przypadkach, gdy wymagana jest operacja chirurgiczna.

SŁOWA KLUCZOWE: operacja Trendelenburga, oszczędzenie WŻO, stripping WŻO, zmodyfikowana skala ciężkości klinicznej chorób układu żylnego (rVCSS), żylaki

ABBREVIATIONS

GSV – great saphenous vein
rVCSS – revised venous clinical severity score
SFJ – saphenofemoral junction

INTRODUCTION

Varicose veins with a disease burden of 10–15% in males and 20–25% in females is a significant cause of decreased quality of life [1]. Various risk factors have been attributed to the development of varicose veins including pregnancy, family history, high body mass index, and prolonged standing jobs [2]. Varicose veins are the result of increased pathological hydrostatic pressure in lower limb veins, further leading to complications like edema, pain, inflammation, skin pigmentation, skin thickening, itching, and ulcers [3]. CEAP classification is a clinical, etiological, anatomical, and pathological classification for varicose veins given by the International Consensus Conference on Chronic Venous Disease in 1994 which was revised in 2004 [4]. In 2008, a revised Venous Clinical Severity Score with 10 descriptors, each having a score of 0 to 3, was devised to supplement the CEAP classification to provide a better insight (Tab. I.) [5, 6, 7]. Venous duplex ultrasound is the most common and a reliable mode for testing varicose veins. It uses B-mode imaging and pulsed doppler assessment of flow and evaluates the visibility, compressibility, venous flow, and augmentation. Various treatment modalities for varicose veins have been available, including aescin, flavonoids, compression therapies, endovenous thermal ablation, sclerotherapy, and open surgery [8]. Open surgery in the form of saphenofemoral junction (SFJ) ligation with the stripping of great saphenous vein (GSV) has been the gold standard for varicose veins but stripping has been associated with complications like hematoma, edema, and pain. Hence flush ligation of SFJ with GSV sparing has come into the light which has shown promising results and decreased morbidity in patients undergoing treatment for primary varicose veins [9].

This study was done to compare the outcome of Trendelenburg operation in varicose veins with great saphenous vein sparing versus stripping in terms of changes in revised clinical severity score and below knee great saphenous vein diameter.

METHODS

This was a prospective randomized study of patients operated on for primary varicose veins between January 2019 and April 2020 in the Department of General Surgery at All India Institute of Medical Sciences, Rishikesh, Uttarakhand. The study protocol was approved by the Institutional Ethics Committee (reference no. 283/IEC/PGM/2018). Informed consent was taken from all the participants included in the study. Patients with primary varicose veins with saphenofemoral junction incompetence with CEAP grade 2–6 and age between 18–65 years were included. Those with sapheno-popliteal insufficiency, isolated perforator incompetence, deep vein thrombosis, recurrent disease, congenital disease, and pregnancy were excluded from the study. A total of 36 patients undergoing Trendelenburg operation during the study period were included in the study. Patients were assigned to either the Stripping or No Stripping (sparing) group using a randomization table from GraphPad QuickCalcs software (GraphPad software 2018, San Diego, California, USA). Seventeen patients were assigned to the group "Stripping" and underwent Trendelenburg surgery with stripping of the great saphenous vein from the groin down to the level just below the knee under spinal anesthesia. Nineteen patients were assigned to the group “No Stripping (sparing)" and

Tab. I. Revised Venous Clinical Severity Score [5–7].

DESCRIPTORS	SCORE			
	None (0)	Mild (1)	Moderate (2)	Severe (3)
1.Pain or other discomfort (aching, heaviness, fatigue, soreness, burning)	None	Occasional pain or discomfort that does not restrict regular daily activities	Daily pain or discomfort that interferes with, but does not prevent, regular daily activities	Daily pain or discomfort that limits most regular daily activities
2. Varicose Veins	None	Few, scattered, varicosities that are confined to branch veins or clusters. Includes “corona phlebectatica” (ankle flare), defined as 5 blue telangiectases at the inner or sometimes the outer edge of the foot	Multiple varicosities that are confined to the calf or the thigh	Multiple varicosities that involve both the calf and the thigh
3. Venous Edema	None	Edema that is limited to the foot and ankle	Edema that extends above the ankle but below the knee	Edema that extends to the knee or above
4.Skin Pigmentation	None	Pigmentation that is limited to the perimalleolar area	Diffuse pigmentation that involves the lower third of the calf	Diffuse pigmentation that involves more than the lower third of the calf
5. Inflammation	None	Inflammation that is limited to the perimalleolar area	Inflammation that involves the lower third of the calf	Inflammation that involves more than the lower third of the calf
6. Induration	None	Induration that is limited to the perimalleolar area	Induration that involves the lower third of the calf	Induration that involves more than the lower third of the calf
7. Active ulcer number	None	1 ulcer	2 ulcers	>3 ulcers
8. Active ulcer duration	No active ulcers	Ulceration present for <3 months	Ulceration present for 3–12 months	Ulceration present for >12 months
9. Active ulcer size	No active ulcer	Ulcer <2 cm in diameter	Ulcer 2–6 cm in diameter	Ulcer >6 cm in diameter
10. Use of compression therapy	Not used	Intermittent use	Wears stockings most days	Full compliance: stockings

Tab. II. Demographic distribution of cases.

PARAMETERS	GROUP		
	Sparing (n = 19)	Stripping (n = 17)	P value
Age (Years)	34.68 ± 12.55	38.29 ± 10.41	0.353
Gender Male Female	 17 (89.5%) 2 (10.5%)	 14 (82.4%) 3 (17.6%)	 0.650
Smoking history	10 (52.6%)	8 (47.1%)	0.738
BMI (kg/m²)	25.23 ± 4.99	25.25 ± 2.65	0.466
Duration of Symptoms (years)	4.92 ± 4.20	3.24 ± 1.30	0.486
Pain	16 (84.2%)	14 (82.4%)	1.000
Night Cramps	4 (21.1%)	2 (11.8%)	0.662
Itching	4 (21.1%)	5 (29.4%)	0.706
Pigmentation	10 (52.6%)	9 (52.9%)	0.985
Induration	2 (10.5%)	3 (17.6%)	0.650
Edema	7 (36.8%)	11 (64.7%)	0.095
Ulceration	3 (15.8%)	1 (5.9%)	0.605
Compression Therapy Used Not Used	 9 (47.4%) 10 (52.6%)	 10 (58.8%) 7 (41.2%)	 0.492

underwent Trendelenburg surgery with flush ligation of the great saphenous vein at the saphenofemoral junction and no stripping of the vein under spinal anesthesia. A total of revised venous clinical severity score (rVCSS) was recorded as per the descriptor in Tab. I. for each patient along with the below-knee great saphenous vein diameter preoperatively and at the 2nd, 4th, and 8th week in both groups (Sparing & Stripping). The statistical analysis was performed using SPSS software version 23.0 (IBM, Armonk, New York, USA). Wilcoxon rank sum test was used to compare the two groups in terms of below-knee GSV diameter and rVCSS at each timepoint. Friedman test was used to explore the change in below-knee GSV diameter and rVCSS over time within each group. The Generalized Estimating Equations method was used to explore the difference in change in the below-knee GSV diameter and rVCSS between the two groups over time.

RESULTS

A total of 36 patients had undergone the Trendelenburg procedure for varicose veins and met the inclusion criteria of the study. Out of those, 19 patients underwent GSV sparing and 17 had stripping of GSV. Both groups were similar for age distribution, sex ratio, BMI, and symptomatology (Tab. II.). In the Sparing group, the mean below-knee great saphenous vein diameter decreased from 7.87 mm to 6.26 mm (19% change) at the 8th week, which was statistically significant ($P \leq 0.001$). In the Stripping group, the mean diameter change of GSV below the knee was from 7.88 mm in the preoperative period to 5.98 mm (19.6% change) at the 8th week, which was statistically significant ($P \leq 0.001$) (Tab. III.). But there was no significant difference between the two groups in terms of change in below-knee GSV diameter from pre-operative values to postoperative time points ($P = 0.467$) (Tab. IV.). In the Sparing group, mean rVCSS decreased from 7.47 in the preoperative period to 2.47 (60.8% change) at the 8th week postoperatively, which was statistically significant ($P \leq 0.001$). In the Stripping group, mean rVCSS decreased from 7.47 in the preoperative period to 2.47 (66.3% change) at the 8th week postoperatively, which was statistically significant ($P \leq 0.001$) (Tab. V.). But there was no significant difference in the rVCSS trend in the groups ($P = 0.781$) (Tab. VI.). A decrease in rVCSS signifies clinical improvement. A decrease in rVCSS increases the efficacy of the procedure as well as patient satisfaction.

DISCUSSION

The lower limb venous system includes superficial and deep veins along with perforators which connect the deep system to the superficial system. Valves are present in the venous system including the perforators which allow unilateral flow from the superficial to deep system and caudal to cephalad direction. The great saphenous vein has between 10–20 valves with a mean diameter between 3 and 4 mm normally. Normal reflux of less than 0.5 seconds is seen before the valves close [10]. Valvular damage due to thrombosis in secondary varicose veins or pathologically raised hydrostatic pressure can lead to functional and anatomical dysfunction of valves causing marked reflux and in turn higher ambulatory venous pressures. This results in dilatation and stretching due to the destruction of the muscular layer and the proliferation of collagen fibers. Venous wall destruction can lead to a wide spectrum of manifestations of varicose veins like dilated

Tab. III. Change in below knee GSV Diameter (mm) from Pre-Operative to Follow-up.

Timepoint Comparison	Change in below knee GSV Diameter (mm) from Pre-Operative to Follow-up Timepoints						Comparison of the Two Groups in Terms of Difference of below knee GSV Diameter (mm) from Pre-Operative to Follow-up Timepoints	
	GSV Sparing			GSV Stripping				
	Mean (SD) of Absolute Change	Mean (SD) of % Change	P Value of Change Within Group	Mean (SD) of Absolute Change	Mean (SD) of % Change	P Value of Change Within Group	P Value of Absolute Change	P Value of % Change
2 Weeks Postoperative	-0.85 (1.13)	-9.4% (8.5)	0.079	-0.96 (1.70)	-9.1% (9.8)	0.108	0.388	0.410
4 Weeks Postoperative	-1.26 (1.36)	-14.4% (10.0)	<0.001	-1.44 (2.15)	-14.3% (11.8)	<0.001	0.362	0.536
8 Weeks Postoperative	-1.61 (1.43)	-19.0% (10.3)	<0.001	-1.90 (2.57)	-19.6% (13.7)	<0.001	0.643	0.419

Tab. IV. Difference between the two groups in terms of change in below-knee GSV diameter from pre-operative values to postoperative.diameter from pre-operative values to postoperative.

Below knee GSV Diameter (mm)	Surgery Performed				P value for comparison of the two groups at each of the timepoints (Wilcoxon Test)
	GSV Sparing		GSV Stripping		
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Pre-Operative	7.87 (2.72)	7.00 (0.95)	7.88 (3.00)	7.00 (1.10)	0.937
2 Weeks	7.02 (2.18)	6.40 (0.80)	6.92 (1.55)	6.60 (1.20)	0.787
4 Weeks	6.61 (2.14)	6.10 (0.75)	6.45 (1.09)	6.40 (1.10)	0.739
8 Weeks	6.26 (2.14)	5.70 (0.95)	5.98 (0.85)	6.00 (1.10)	0.837
P Value for change in GSV Diameter (mm) over time within each group (Friedman Test)	<0.001		<0.001		
Overall P Value for comparison of change in GSV Diameter (mm) over time between the two groups (Generalized Estimating Equations Method)	0.467				

Tab. V. Change in rVCSS from Pre-Operative to Follow-up.

Timepoint Comparison	Change in rVCSS from Pre-Operative to Follow-up Timepoints						Comparison of the Two Groups in Terms of Difference of rVCSS from Pre-Operative to Follow-up Timepoints	
	GSV Sparing			GSV Stripping				
	Mean (SD) of Absolute Change	Mean (SD) of % Change	P Value of Change Within Group	Mean (SD) of Absolute Change	Mean (SD) of % Change	P Value of Change Within Group	P Value of Absolute Change	P Value of % Change
2 Weeks Postoperative	-2.68 (1.95)	-35.1% (19.3)	0.058	-2.65 (1.06)	-35.5% (12.2)	0.067	0.408	0.924
4 Weeks Postoperative	-4.21 (1.90)	-55.2% (16.0)	<0.001	-4.35 (1.32)	-57.5% (12.8)	<0.001	0.374	0.534
8 Weeks Postoperative	-4.68 (1.77)	-60.8% (12.5)	<0.001	-5.00 (1.32)	-66.3% (7.2)	<0.001	0.429	0.118

Tab. VI. Difference in the rVCSS trend in both the groups from pre-operative to postoperative.

rVCSS	Surgery Performed				P value for comparison of the two groups at each of the timepoints (Wilcoxon Test)
	GSV Sparing		GSV Stripping		
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Pre-Operative	7.74 (2.51)	7.00 (4.00)	7.47 (1.62)	8.00 (2.00)	0.898
2 Weeks	5.05 (2.44)	4.00 (3.00)	4.82 (1.51)	5.00 (2.00)	0.923
4 Weeks	3.53 (2.06)	3.00 (2.00)	3.12 (0.93)	3.00 (2.00)	0.830
8 Weeks	3.05 (1.58)	3.00 (1.00)	2.47 (0.62)	2.00 (1.00)	0.406
P Value for change in rVCSS over time within each group (Friedman Test)	<0.001		<0.001		
Overall P Value for comparison of change in rVCSS over time between the two groups (Generalized Estimating Equations Method)	0.781				

veins, edema, hyperpigmentation due to hemosiderin deposition, lipodermatosclerosis, and ulceration [3]. CEAP classification revised in 2004 by the American Venous Forum classifies chronic venous insufficiency and defines varicose veins as subcutaneous dilated veins more than 3 mm in diameter [4]. The Revised Clinical Severity Score (rVCSS) came into existence in 2008 to supplement the CEAP classification and gave a detailed insight especially in class 4 to 6 of clinical classification. It has 10 descriptors each having scoring between 0–3 viz pain, varicose veins, venous edema, skin pigmentation, inflammation, induration, active ulcer number, active ulcer duration, active ulcer size, and use of compressive therapy [11]. Various testing modalities have been used to diagnose chronic venous insufficiency with ambulatory venous pressure measurement as the gold standard, but being an invasive modality, it is rarely used [12]. Venous duplex imaging being non-invasive, is the modality of choice now and highly

recommended in clinical practice guidelines. It combines B--mode imaging and pulsed Doppler to look for flow and morphology of the venous system. The cut-off value for reflux is recommended at 500 ms for the saphenous system. Various treatment options are available for the treatment of varicose veins. Synthetic drugs like calcium dobesilate, benzarone, and natural compounds like aescin and flavonoids are used in reducing edema, pain, and itching. Compression treatment in the form of elastic stockings, providing an ankle pressure of 20–30 mm Hg, has been seen to aid in ulcer healing and as an adjuvant to an ablative or operative procedure. Sclerotherapy has been used in the treatment of spider veins and telangiectasia. Endovenous thermal ablation has gained vast acceptance in the treatment of varicose veins, which is a minimally invasive day care procedure, with the use of local tumescent anesthesia [8]. Complications include bruising, skin burns, and heat-induced thrombosis. Hence thermal ablation is contraindicated in too superficial and tortuous veins, where open surgery is an option [13]. Open surgical management by stripping of the saphenous vein has been the standard of care for centuries. REACTIV trial has suggested that surgical management has a better symptomatic relief and quality of life compared to compression therapy [14]. Bernardo Cunha et al. studied 22 limbs that underwent varicose vein surgery without stripping of the great saphenous vein and found a significant decrease in great saphenous vein diameter and improved rVCSS after 3 months [9]. Dwerryhouse et al. in 1999 studied 110 limbs comparing the stripping and the non-stripping group, showing significantly lower reflux in a residual vein in the stripping group after 5 years owing to neovascularisation [15]. In our study, both groups showed a significant decrease in GSV diameter with a 19% change in the sparing group and a 19.6% change in the stripping group after 2 months. But when both groups were compared with each other, the results were not statistically significant. In terms of rVCSS also, there was a significant decrease in both groups with the sparing group showing a 60.8% decrease and the stripping group showing a 66.3% decrease after 2 months but statistically insignificant results in terms of comparison between the two groups.

CONCLUSION

SFJ ligation with GSV sparing can be considered where surgery is required as an alternative option keeping in view the increased chances of pain, hematoma, and bruising associated with GSV stripping and equal symptom relief in both procedures. The limitation of the study was a smaller sample size and a shorter period of follow-up.

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Corresponding author: Dr. Navin Kumar; Assistant Professor, Department of General Surgery, All India Institute of Medical Sciences, Rishikesh, India; Uttarakhand 249203, Indie; Phone: +91 9760755163; E-mail: surgeon_navin@yahoo.co.in

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