

CONVENTIONAL STRIPPING VERSUS PIN STRIPPING OF GREAT SAPHENOUS VEIN: A PROSPECTIVE RANDOMISED STUDY



General Surgery

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ABSTRACT

Surgery is still one of the common treatment modalities for treatment of varicose veins. But there has been some debate whether Perforate Invaginate (PIN) Stripping or Conventional stripping is better. The present study has been done to evaluate the efficacy of Perforate Invaginate (PIN) Stripping in comparison to the Conventional Stripping of Great Saphenous Vein (GSV) in varicose vein patients. Study was done on 50 patients divided in two groups of 25 each. In group A, Perforate Invaginate (PIN) Stripping of long saphenous vein was done while In group B, Conventional Stripping was done as described by Babcock. Mean age of total patients in our study was 36.8 years There were 36 males (72%) and 14 females (28%) in our study. Right lower limb was involved in 21 (42%) patients and left lower limb was involved in 29 (58%) patients. PIN Stripping group had less average blood loss, less time consuming, less size of exit wound, less post operative pain and less area of significant bruising as compared to conventional stripping. There was no major complication. Hence Perforate Invaginate stripping of the GSV in uncomplicated primary varicosis may be associated with less surgical trauma compared to a conventional stripping technique.

INTRODUCTION

Varicose veins are defined as dilated, usually tortuous, subcutaneous veins > 3mm in diameter measured in the upright position with demonstrable reflux.¹ A varicose vein permits reverse flow through its faulty valves. Chronic venous disease affects 27% of adults with a substantial effect on physical health aspects of quality of life.² Varices of the major tributaries of saphenous veins or the saphenous veins themselves are large (5-15 mm) in diameter and usually start in the calf. Later, varices of the long saphenous system may also appear in the thigh.

The pathophysiology of varicose vein is probably related to defective connective tissue and smooth muscle in the vein wall leading to secondary incompetence of the valves rather than to a primary defect in the valves, which occurs in a small subgroup of patients.⁴ Majority of varicose veins can be assessed from history and clinical examination. The CEAP (Clinical-etiology-anatomy-pathophysiology) classification for chronic venous disorder is a recent scoring system that stratifies the venous disease.¹

Varicose veins can be managed conservatively via elastic compression stockings and injection sclerotherapy but surgery has been the standard treatment for varicose veins. The main principles of surgical treatment are to ligate the source of the venous reflux (usually the SFJ or the SPJ) and to remove the incompetent saphenous trunks and the associated varices. The problem of recurrent varicose vein may be eliminated by stripping the great saphenous vein and short saphenous vein.⁵⁻⁷ The stripping does not increase the incidence of wound complications or paraesthesia along the distribution of the saphenous nerve.⁸

The optimal method of vein removal is still under debate. Many advocate a conventional approach using a classic acorn tip mounted on the stripper, whereas others favour an invaginated procedure. The aim of the present study is to evaluate the efficacy of Perforate Invaginate (PIN) Stripping in comparison to the Conventional Stripping of Great Saphenous Vein (GSV) in varicose veins and to study the post operative complications in both the study groups.

MATERIAL AND METHODS

A prospective, randomized study was conducted on 50 patients with clinical features suggestive of primary varicose veins attending the Out-patient Department of Surgery and Venous Disease Clinic of Pt. B.D. Sharma Post Graduate Institute of Medical Sciences (PGIMS), Rohtak having SFJ incompetence clinically and on colour doppler examination.

In all the patients, a detailed history was taken including the history of duration of symptoms like pain, swelling, any skin changes and ulceration in lower limbs with special focus on the risk factors. The severity of the illness was recorded as per clinical grading of CEAP classification. A thorough physical examination was carried out by clinical tests for varicose veins. All the patients were subjected to routine laboratory investigations and Colour doppler examination was done to check the patency of the deep veins and to study the great saphenous vein, short saphenous vein and perforator incompetence. Before surgery, pain was measured using a visual analog scale (VAS). A written consent was signed by the patients and they were randomized to one of two surgical methods for GSV stripping, groups 'A' and 'B' by draw of ballots.

In both groups high ligation of saphenofemoral junction with ligation of all the tributaries at groin, subfascial ligation of incompetent perforators and multiple superficial phlebectomies were done. In group A, Perforate Invaginate (PIN) Stripping of long saphenous vein was done where the vein was stripped inside out after tying the vein at tip of stripper with a on needle 2-0 suture. In group B, Conventional Stripping was done as described by Babcock⁹

Both the groups were studied in terms of time taken to strip the vein, the completeness of the vein stripped, amount of bleeding from the stripped track measured by weighing the dry gauze and wet gauze after the procedure, size of the exit wound and length of stripped out vein. The patients were followed up at 1st, 3rd and 6th weeks and were examined for pain, significant bruising, paraesthesia, wound condition and symptomatic relief. A score of more than 5 on VAS was taken as significant post operative pain. Patients were given compressive lower and upper leg dressings with crepe bandages. The patients were advised compression stockings for 6 weeks on the

second postoperative day and were encouraged to do daily routine activities. The data collected was tabulated and analyzed statistically. Statistical analysis was performed using the Chi square (χ^2) test when comparing discrete variables and the t-test when appropriate. The p-value less than 0.05 ($p < 0.05$) was considered as significant.

OBSERVATIONS

Demography

Mean age = 36.8 yrs
 Males = 36
 Females = 14
 CEAP Grading = C1--0, C2--38, C3--2, C4--7, C5--1, C6--2
 Occupations = Housewives, Labourers, Farmers, Policeman, Barbers
 Side involvement= Right side - 21, Left side - 29
 Presenting symptoms = Dilated veins -50, Pain and Discomfort- 26,
 Swelling of limb- 2, Skin changes - 10, Ulcer healed/active- 3
 Family history of varicose veins = Positive in 5 males and 2 females,

Mean age of total patients in our study was 36.8 years. The youngest patient being 18 years old and oldest was 65 year old. There were 36 males (72%) and 14 females (28%) in our study. Fifteen female patients were house wives (93.7%) while 1 female was peon (6.25%). Maximum number of affected males were labourer (23.5%) and students (23.5%) followed by farmers (20.5%) who were involved in heavy work or strenuous activity. Other occupations of male patients were 3 barbers (8.8%), 2 policemen/army-men (5.8%), 2 shopkeepers (5.8%), one cook (2.9%), one driver (2.9%), one watchmen (2.9%) and one teacher (2.9%). Most of the patients in the present study have prolonged standing occupation. Most of the females were housewives who used to do standing work for a long time for household requirements.

Right lower limb was involved in 21 (42%) patients and left lower limb was involved in 29(58%) patients. Thus, left lower limb was more commonly involved as compared to right side. Dilated vein was the presenting symptom in 50 patients (100%). Out of 50 patients, pain and discomfort was present in 26 patients (52%), 2 patients had swelling over limbs (4%), 10 patients had skin changes over ankle region (20%), while 3 patients presented with associated venous ulcer over leg (6%)

Thirty eight patients (76%) presented with C2 severity, 2 patients presented with C3 severity (4%) and 7 patients (20%) had C4 severity. One patient (2%) presented with C5 severity while 2 patients (4%) presented with C6 severity. On color doppler, deep veins were normal in all the 50 patients. Spheno-femoral junctions were incompetent in all the patients whereas sapheno-popliteal junction was competent in all the patients. A total of 13 patients demonstrated no perforator incompetence despite presence of varicose veins (26%). Eleven patients had single perforator incompetence (22%), 15 had two incompetent perforators (30%), 10 had three incompetent perforators (20%), while only a single patient demonstrated more than 3 incompetent perforators (2%).

A total of 5 male patients had a positive family history of varicose veins in first degree relatives (14.7%). However, only 2 female patients had positive family history of varicose veins in first degree relatives (12.5%). Overall, positive family history was found in 14% of patients. Only 2 out of 16 female patients had a positive history of taking hormonal therapy presenting with varicose veins (12.5%). No male patient was taking any type of hormonal therapy who presented with varicose veins in the present study.

PIN versus Conventional stripping of GSV

Table 1

Serial no.	Parameter	Conventional stripping	Pin stripping	P value
1	Nerve Injury	1	0	0.147
2	Post operative pain	6	1	0.0755

3	Average blood loss	34 gm	17 gm	0.000045
4	Exit wound length	2.63	1.21	0.00001
5	Mean operation time	6'23"	6'05"	0.0002703
6	Significant bruising	3	0	0.0919
7	Incomplete stripping	0	1	0.322
8	Wound infection	0	0	

After 'PIN' stripping the average blood loss was 17 g as compared to 'Conventional' stripping in which average blood loss during stripping was 34 g. There was significant difference (The p value = 0.000045 i.e. less than 0.05) in blood loss in two methods of GSV Stripping. During 'PIN' stripping, the average size of exit wound was 1.21 cm as compared to 'Conventional' stripping in which average size of exit wound was 2.63 cm. Hence, there was significant difference (p value=0.00001 i.e. less than 0.05) in size of exit wound in two methods of GSV stripping.

Cases with incomplete 'PIN' stripping of GSV were 1 out of 25. The incomplete stripping was due to excessive tortuosity of vein and the vein got broken from middle part. The residual vein had to be removed by conventional stripping. All the cases of 'Conventional' GSV stripping were 'complete'. Hence, there was no significant difference (p value = 0.322 i.e. not less than 0.05) in terms of efficiency between the two methods of GSV stripping. Average time taken during 'PIN' stripping was 6'05" minutes while it was 6'23" minutes during 'Conventional' stripping. Hence, significant difference (p value = 0.0002703 i.e. less than 0.05) of average 18 seconds was noted in GSV stripping by PIN method when compared to Conventional method in terms of time taken for GSV stripping between the two methods of GSV stripping.

Pain evaluation was performed at 1st, 3rd and 6th post operative week. Pain was measured (minimal 0, maximum 10) with a visual analog scale (VAS). A score of more than 5 on VAS was taken as significant post operative pain. Only 1 patient was having post operative pain on follow-up at first week after 'PIN' stripping (4%). In contrast, post operative pain was present in 6 patients at 1st week during 'Conventional' stripping (24%). At 3rd post operative week, all patients of 'PIN' stripping were relieved of post operative pain while only 2 patients complained of pain that underwent 'Conventional' stripping. Only 1 patient was having paraesthesia on follow-up at 1st week after 'Conventional' stripping (4%) which persisted up to 6th week. In contrast, paraesthesia was absent in all patients of 'PIN' stripping (0%). The p-value was 0.417 and found to be not significant ($p > 0.05$).

Significant bruising was present in 3 cases of 'Conventional' stripping at 1st week of follow up (12%), out of which 2 persisted up to 3rd week. Bruising disappeared on follow up at 6th week. No case of significant bruising was present during 'PIN' stripping of GSV. The p value was found as 0.0919. The result was not statistically significant ($p > 0.05$). Symptomatic relief was present in all cases of 'Conventional' and 'PIN' stripping at 1st week of follow up. All wounds were healthy after PIN and Conventional stripping of GSV. No any case of wound infection was seen in any group.

DISCUSSION

Earlier studies by Oesch, Goren and Conrad had incorporated GSV and SSV stripping with the PIN method.10-13 As the stripping of SSV is frequently associated with saphenous and sural nerve damage, it has been discontinued. A frequently used vascular reference book has introduced invagination as the gold standard surgical technique for GSV varicosis, although studies on long term results are absent.14

PIN versus Conventional stripping studies in literature

Table 2

Sr. No.	Author	Study type	GSV	Stripping Technique	Results
1	Lacroix 15 (1999)	Randomized	60	Conventional (n= 30) vs PIN (n= 30)	No significant difference between PIN and Conventional stripping of GSV.
2	Durkin 16 (1999)	Randomized	80	Conventional (n= 37) vs PIN (n= 43)	PIN stripping is better method of GSV stripping than Conventional stripping.
3	Scheltinga 17 (2007)	Randomized	92	Conventional (n= 46) vs PIN (n = 46)	PIN stripping is better method of GSV stripping than Conventional stripping.
4	Present study (2017)	Randomized	50	Conventional (n= 25) vs PIN (n = 25)	PIN stripping is better method of GSV stripping than Conventional stripping.

In the present study, fifty patients were randomized to conventional and PIN stripping and were followed up for 6 weeks postoperatively. PIN stripping group had less average blood loss, less time consuming, less size of exit wound, less postoperative pain, less area of significant bruising and without any major complication when compared to conventional stripping.

Lacroix did a prospective, randomized study to test the hypothesis that PIN stripping of the GSV is associated with less pain, smaller hematomas and less frequent injury to the saphenous nerve. The results showed that the benefit of PIN stripping is not as obvious as is generally suggested.¹⁵ A prospective, randomized trial carried out by Durkin showed that the choice of stripping device remained the surgeon's, bearing in mind that the PIN stripper achieved slightly better cosmesis.¹⁶ Scheltinga demonstrated that invagination of the GSV in uncomplicated primary varicosis is associated with less surgical trauma compared to a conventional stripping technique.¹⁷

In the present study, only a single case of incomplete invagination was seen (4%) while Scheltinga (n=46) also demonstrated a single such case (2.17%).¹⁷ Goren had demonstrated no case of incomplete invagination in his study.¹¹ Oesch had demonstrated 13.25%, while Conrad, Durkin and Lacroix studies had demonstrated 15%, 18.6% and 26.66% cases of incomplete invagination respectively.^{10,13,15,16} A possible disadvantage associated with invagination stripping is saphenous vein rupture, usually at the level of the mid-thigh perforator. This unforeseen event occurred only once in the present study (2%). A rupture happens if any portion of the GSV is weaker compared to its strength at the level of the perforator. The removal of remaining parts of the GSV was done by conventional stripping in the present study. Patients who have previously suffered from an ascending thrombophlebitis of the GSV are thought to be at risk for such ruptures.

Incidence of nerve injury after GSV stripping

In the present study, a single case of nerve damage was associated with the GSV stripping (4%) by conventional method. No case of nerve damage was associated with GSV stripping by PIN method. Oesch, Goren and Conrad reported no case of nerve damage by PIN method of GSV stripping in their respective studies.^{10,11,13} Lacroix has reported 13% incidence of nerve injury with PIN stripping and 17% incidence with Conventional stripping while Durkin has reported 3.03% incidence of nerve damage in their studies by Conventional method of stripping but there was no nerve injury in PIN method.^{15,16} Scheltinga had reported 8.7% cases with nerve damage following conventional stripping while no such case was seen by PIN method.¹⁷

The clinical relevance of saphenous nerve damage is subject to debate. Most studies show that symptoms usually disappear in the first post-operative year. One study demonstrated that saphenous nerve damage did not result in any significant morbidity or loss of quality of life after 4.5 years.¹⁸ Nevertheless, saphenous nerve damage following stripping is probably a parameter of surgical damage associated with the operation and should be avoided.

Incidence of post operative pain

In the present study, post operative pain was less during PIN stripping (4%) when compared to conventional method of GSV stripping (24%). Earlier studies by Lacroix, Durkin and Scheltinga have also reported slightly higher incidence of postoperative pain with conventional method of stripping.¹⁵⁻¹⁷

Average blood loss during GSV stripping

In the present study, patients who underwent conventional stripping lost almost twice as much blood (17g in PIN while 34 gm in Conventional stripping of GSV) compared to the invagination patients. Most studies on PIN stripping suggest that there is attenuated blood loss following inverted stripping. However, volume of blood loss was measured in one study, and this report demonstrated a 50% reduction in blood loss (conventional 50 ml vs. inverted 25 ml).¹⁹ Postoperative hematoma surface as a possible reflector of total blood loss was similar in three randomized studies.^{15,17,19} One study measuring clot formation using a red blood cell labeling technique demonstrated that venous inversion resulted in diminished thigh blood pooling compared to conventional stripping.²⁰

Exit wound size

In the present study, the infragenual incision in invagination method was only half as long as that in the conventional group (12.1mm versus 26.3 mm). Due to smaller exit wound, there was better cosmesis following PIN method of GSV stripping when compared with conventional method. Most authors have reported improved cosmesis following invagination (PIN) method of GSV stripping in comparison to conventional GSV stripping. Durkin and Scheltinga also demonstrated statistically significant shorter length of the exit wound.^{16,17} The smaller exit wound contributed to better cosmesis and rapid healing of the wound.

Mean operation time

The present study demonstrated that the mean operation time was significantly reduced (p value= 0.0002703 i.e. less than 0.05). Hence, there is significant difference in terms of time taken for GSV stripping between the two methods of GSV stripping.) in PIN stripping of GSV by an average of 18 seconds in comparison to conventional stripping. Durkin reported similar results for the both groups.¹⁶ Scheltinga also demonstrated reduced operation time by PIN method when compared to conventional method in their study.¹⁷

CONCLUSION

In the present study, we concluded that PIN stripping is a better method of GSV stripping. It has less average blood loss, less time consuming, less size of exit wound, with less post operative pain and less area of significant bruising, without any major complication. Invagination of the GSV in uncomplicated primary varicosis may be associated with less surgical trauma compared to a conventional stripping technique.

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