Trendelenberg's procedure with and without venous stripping of varicose veins - A prospective randomized comparative study.

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Abstract

Introduction: Varicose veins of the lower extremities are one of the most common peripheral vascular diseases. A variety of treatments methods have emerged as an alternative to traditional surgery but are limited by their need for equipment and expertise which increases the cost of treatment making it unviable especially in rural India. Thus traditional surgery still forms the mainstay of treatment.

Aims: To evaluate and compare the outcomes in patients undergoing Trendelenberg's procedure with stripping and without stripping of varicose veins.

Materials and methods: The study comprised of 50 patients who were admitted with varicose veins. They were allocated into two groups of 25 each where they either underwent Trendelenberg's procedure with stripping or without stripping of varicose veins. The patients were followed up for six months to assess the efficacy of the procedure as per the parameters of the study. Results were analyzed using SPSS software. Percentages and proportions were used for qualitative data; mean and standard deviation were used for quantitative data. Chi-square test and student t test were applied where appropriate.

Results: In the group undergoing stripping, 28% (7 of 25) patients developed hematoma, post operative pain scores on day 0,3,7 and 10 were 3.8±0.9, 2.6±0.7, 1.1±0.6 and 0.2±0.4 respectively. Mean post operative ambulation was achieved on 3.88 days and recurrence at 6 months was seen in 12% (3 of 25) patients. In the group undergoing ligation alone, 4% (1 of 25) patients developed hematoma, post operative pain scores on day 0,3,7 and 10 were 3.0±0.8, 1.6±0.8, 0.8±0.5 and 0.1±0.3 respectively. Mean post op ambulation was achieved on 2.16 days and recurrence at 6 months was seen in 20% (5 of 25) patients.

Conclusions: With lesser rates of hematoma formation, better post operative pain scores and quicker ambulation in patients undergong ligation of veins alone, we conclude that Trendelenberg's procedure without stripping is a better procedure than Trendelenberg's procedure with stripping of veins in the treatment of varicose veins.

Keywords: Varicose veins, Trendelenberg's procedure, Veins, Stripping of veins

Introduction

Varicose veins of the lower limbs appears to be the price mankind has to pay for his erect posture. It is one of the most common peripheral vascular disorders with a prevalence of 20-60% and upto 25% adults with at least one limb affected[1].

The reasons for low rates in India could be due to difference in stature as Indians are short statured and have less hydrostatic pressure in their lower limb veins. This can also be due to the fact that most patients do not seek medical attention till complications like pain and ulceration develop[2].

A variety of treatment methods are available for those who develop symptoms or complications. Endovenous treatment methods have emerged as a viable alternative to traditional surgery but are plagued by limitations like cost of infrastructure, expertise and a greater learning curve, which makes these methods scarcely available in rural India. Thus traditional surgical methods still form the mainstay of treatment in such parts of the country.

This randomized study was undertaken to evaluate and compare outcomes in patients who undergo Trendelenberg`s procedure with and without venous

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stripping for varicose veins.

Aims and Objectives of the study

To compare outcomes of Trendelenberg's procedure with and without stripping of veins as a surgical treatment for varicose veins with respect to -

1. Hematoma formation
2. Post operative pain
3. Post operative ambulation
4. Recurrence at 3 and 6 months

Methodology

This study was undertaken at a tertiary health care centre in Bagalkot, Karnataka, India. Patients admitted under all surgical units with complaints of varicose veins were considered for the study during the study period January 2019 to June 2020.

Inclusion criteria:

1. Age between 20 and 70 years
2. Patients willing to give informed consent
3. Patients with tortuous dilated veins >3mm of lower limbs with saphenofemoral valve incompetence and perforator incompetence

Exclusion criteria

1. Patients with DVT
2. Patients with secondary varicose veins

Sample size calculation

According to the study conducted by Anim et al in 2017 62% of patients had no recurrent varicosities following saphenofemoral junction ligation with stripping as compared to 16% without stripping[3]. So at 95% confidence level and 80% power of study, and considering a Drop out rate of 4-8, Sample size is 25 in each group. Calculated using the formula

$n = 2(z_\alpha + z_\beta)^2 pq / (p_1-p_2)^2$

Ethical clearance was obtained from the Institute Ethics Committee (Human Studies). Fifty patients admitted for varicose vein treatment were selected, based on the inclusion/exclusion criteria already specified. Investigations like routine hematology and venous doppler study were undertaken to confirm the diagnosis and aid the surgery. The patients were then be allocated into two groups of 25 each randomly with the help of a computer generated randomizer. Group A consisted of patients with varicose veins undergoing Trendelenberg`s procedure with venous stripping and Group B consisted of patients with varicose veins undergoing Trendelenberg`s procedure without venous stripping. Blinding of the operating surgeons/ patients was not done. The patients then underwent the proposed procedure in the respective units they were admitted in.

Procedure

Group A

Patients underwent Trendelenburg procedure where a transverse incision of length 5cm just below the groin crease extending from femoral artery was made medially. The tributaries of long saphenous vein were identified, ligated and divided. The incompetent perforators in the thigh and leg were ligated and divided. Then the long saphenous vein was stripped from groin to just below the knee by passing stripper into the vein.

Group B

Patients underwent Trendelenburg procedure where a transverse incision of length 5cm just below the groin crease extending from the site femoral artery was made medially. The tributaries of long saphenous vein were identified, ligated and divided. The incompetent perforators in the leg are ligated and divided subfascially.

In both groups the wounds were closed with good hemostasis, limb elevated and elastocrepe bandage was applied.

Post operative period

The patients were put in Trendelenberg's position with foot end elevation under the cover of broad spectrum antibiotics and adequate analgesics. IV antibiotics (Injection Cefotaxime 1g) were given for a total of three days. IV analgesics were tapered as per pain of the patient. Elastocrepe bandage was removed on the third day, clinically examined for hematoma and reapplied. Patients were motivated to ambulate from post-operative day 1. The procedures were assessed on the basis of outcomes such as hematoma formation, post operative pain and time required to achieve comfortable ambulation post operatively. For the purpose of this study, post operative pain was assessed using Visual Analogue Scale and post operative ambulation was defined as time needed to be able to walk without debilitating pain. Sutures were removed on 10th post op day. Patients were discharged and followed up in surgical OPD at 3 months and 6 months after surgery.

Results

In this study, the age group 41-50 years formed the majority of sample size at 32% followed by 31-40 years with 28% and 51-60 years with 18% representation in the sample size.

Male patients formed the bulk of the study population with 41 out of 50 patients being male, constituting 82% of the sample size.

The left leg was more commonly involved 62% when compared to the right=38%. In Group A right and left limbs were involved in 8 and 17 patients respectively. In Group B right and left limbs were involved in 11 and 14 patients respectively.

Table 1: Hematoma formation in Group A and Group B

Hematoma	Group A	Group B	Total
Present	7	1	8
Absent	18	24	42
Total	25	25	50

Patients were examined clinically for hematoma formation in the thigh post operatively. Out of all patients in the study,7 Patients in Group A and 1 patient in Group B were observed to have hematoma formation, with Fischers exact test p<0.02 which was statistically significant (Table 1)

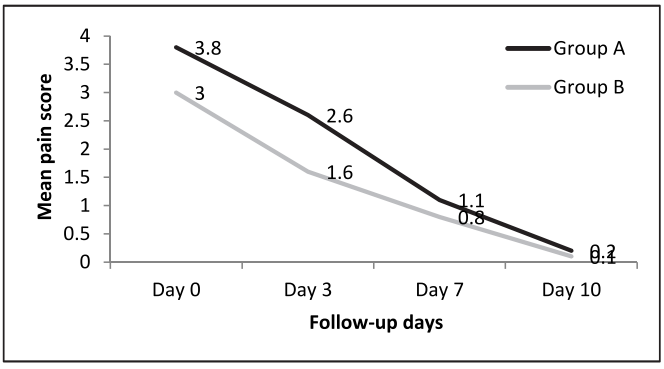

Figure 1: Mean Pain scores in Group A and Group B on Post operative Day 0,3,7 and 10.

Pain scores were taken on evening of the day of the surgery i.e. post-operative day (POD) 0 and on post-operative day 3, 7 and 10 using Wong Baker pain Visual Analogue Scale(VAS). The mean pain score on POD 0 was 3.8 ± 0.9 for Group A and 3.0 ± 0.8 for Group B with p=0.002 and on POD 3 was 2.6 ± 0.7 for Group A and 1.6 ± 0.8 for Group B with p=0.001 which were statistically significant. Mean pain scores on POD 7 were 1.1 ± 0.6 and 0.8 ± 0.5, p=0.112 and on POD 10 were 0.2 ± 0.4 and 0.1 ± 0.3,p=0.276 for Group A and Group B which were statistically insignificant (Figure 1)

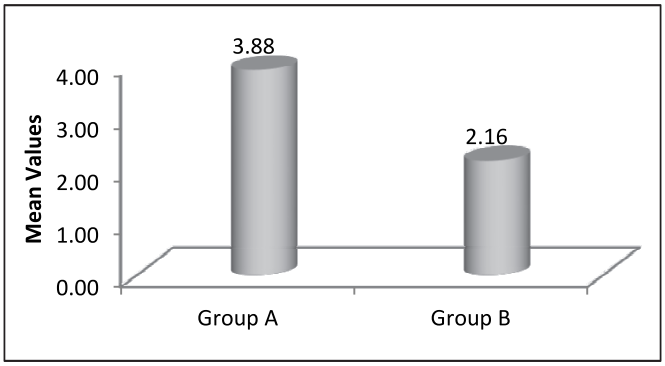

Figure 2: Post operative ambulation

Mean post op ambulation was achieved on 3.88 and 2.16 days in Group A and Group B respectively with p=0.001 which was statistically significant (Figure 2).

Table 2: Recurrence of varicose veins on follow up at 3 months and 6 months

Recurrence		Group A	Group B	Chi Square Value	P Value
At 3 months	Absent	25	25		
	Present	0	0		
At 6 months	Absent	22	20	0.595	0.44
	Present	3	5		

For the purpose of this study, reappearance of visible varicose veins on clinical examination was considered as recurrence. Recurrence was seen in 3 patients in Group A and 5 patients in Group B at 6 months follow up which was not significant at chi square value = 0.59 and p=0.44. (Table 2)

Discussion

Of all vascular disorders, varicose veins of the lower limbs is the most common problem causing impairment in quality of life. The incidence increases with the age. In this study, most patients were in the age group 41-50 years. This is comparable to the observations made by Prasad and Balraj[4] in a similar study where maximum patients were in the age group 40-50 years.

A pilot survey by Weddell JM [5] reported greater prevalence in women when compared to men. These observations where again established in the Framingham [6] study. The current study shows a male preponderance with males constituting 82% of the study population compared to 18% females which is in contrast to the previous studies. But it would be false to assume that males are more susceptible than females, since females are more likely to be hesitant to seek medical assistance or as a result of being neglected by their families in rural areas reported less to the hospital.

In the present study, the left leg was more commonly involved 62% compared to the right - 38%. This is similar to the findings reported by Prasad and Balraj[4] and can be attributed to the fact that the left iliac vein joins the right at right angles and is compressed by loaded colon and also by right and left common iliac arteries.

Hematoma formation in this study was seen in 28% of patients who underwent venous stripping compared to 4% in patients who did not undergo venous stripping. With p value at 0.02, this was found to be statistically significant. This is in contrast to the study by Anim et al[3] where the incidence of hematoma was comparable in the two groups.

Post operative pain scores were higher in the group undergoing venous stripping on day 0 and day 3 and was found to be statistically significant compared to the group that didn't undergo venous stripping. Post operative pain scores for both the groups on day 7 and day 10 were statistically insignificant. This can be attributed to the fact that with venous stripping, incidence of tissue trauma is higher leading to increased pain in the immediate post operative period.

Patients in Group B were observed to achieve comfortable post operative ambulation quicker than patients in Group A. Mean post operative ambulation was achieved on 3.88 and 2.16 days in Group A and Group B respectively with p=0.001 which was statistically significant. This was similar to the findings of Natraj et al[7] This can be attributed to higher pain and paraesthesia in the group undergoing venous stripping owing to greater tissue damage compared to the group undergoing ligation alone.

On follow up at 6 months after procedure, recurrence was seen in 3 patients from the group that underwent venous stripping and in 5 patients from the group that underwent ligation alone which was not statistically significant. Various studies conducted over the years in the past have reported varied incidences of recurrence on follow up. Jakobsen in a clinical study reported a 10.2% recurrence rate in the group where high ligation with stripping was done as compared to a 34% recurrence rate in cases where only high ligation of the saphenofemoral junction was done[8]. Munn et al. reported recurrence in 36% of cases when LSV stripping was done while in the high-ligation group recurrence was observed in 60% cases[9]. Hammarsten et al. demonstrated a recurrence rate of 12% after stripping and an 11% recurrence rate after high ligation only. This study was based on clinical basis and findings on strain gauge plethysmography[10]. Sarin et al. showed recurrence in 45% of cases after high ligation without LSV stripping and in 18% cases after high ligation with long saphenous vein stripping. This study was based on clinical basis and colour Doppler examination[11].

Saphenous nerve injury is one of the most common long term complications following venous stripping of varicose veins. This is attributed to its anatomical relation to the long saphenous vein. Various methods of vein stripping include - proximal stripping with a probe (Babcock method), proximal stripping with invagination/inversion of the vein and distal stripping[12]. Long stripping without invagination is associated with higher rates of nerve injury when compared with proximal stripping with invagination and distal stripping without invagination. Distal stripping with invagination of the vein is associated with the least rates of complication [13]. An alternative method is short stripping till knee joint which greatly limits the chances of injury to the saphenous nerve[14].

More recently, Prasad and Balraj[4] in their study concluded that residual reflux at 3 months follow up was less with ligation and stripping compared to ligation alone, with the incidence of nerve palsy, bleeding and hematoma comparable in both groups. Anim et al[3] concluded that SFJ ligation with LSV stripping is the treatment of choice even though is associated with greater morbidity, prolonged hospital stay and greater risk of nerve injury, since the outcomes are better in the long run. These observations were in contrast to the results of the stud by Natraj et al[7] who concluded that there was no significant difference in healing of leg wounds, hospital stay and pain relief in the group that underwent ligation and stripping compared to the group that underwent ligation alone and hence Trendelenburg procedure with incompetent perforators ligation without venous stripping was the treatment of choice.

Conclusion

In low resource / rural centres, Trendelenberg's procedure remains the mainstay of treatment for varicose veins. In the current study, it is observed that Trendelenberg's procedure with venous stripping is associated with greater incidence of hematoma formation and higher levels of pain, with a longer duration to achieve ambulation in the post operative period but comparable rates of recurrence at 6 months follow up when compared to Trendelenberg's procedure without venous stripping.

Hence we conclude that Trendelenberg's procedure without venous stripping appears to be a better procedure than Trendelenberg's procedure with venous stripping in the treatment of varicose veins.

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