Valve Repair and Wrap Round: Role of Femoral Vein Valve Repair in Recurrent Chronic Venous Stasis Ulcers

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Abstract: <u>Objective</u>: This study is mainly intended to high light the results of venous valve repair (VVR) when all other modalities of treatment has failed to get the desired results (ulcer healing). <u>Method</u>: We have selected 28 patients who had non healing ulcers after the classical treatment, like compression therapy, Trendelenburg surgery, saphenous vein stripping and perforator ligations. The study extended for a period of 9 years from 2009 to 2018 and these patients were having painful non healing ulcer for more than 1 to $2\frac{1}{2}$ years. Patients with recurrence of symptoms were grouped under CEAP grade as 3 & 4 according to US doppler evaluation, and then taken for definite treatment.(primary deep vein valve repair and wrap round with fascia lata). Post operative evaluation was done with US Doppler study and the healing of wound assessed by sterile blotting paper assessment, and any reduction in size of the ulcer from the pre- operative assessment, was taken as improvement. This is mainly a retrospective analysis and no personal details of the patient were given in this study and hence ethical evaluation not needed. All patients were treated by the first author himself. <u>Results</u>: This study showed a reversion of the reflux from Grade 3 & 4 for a total of 25 out of 28 cases which is considered as good result and 3 patients in the main group out of 28 continued to be in the severely diseased group 3 and had no complete healing of the wound was seen even after 1 year. In other words 89.2% of the cases had good recovery and 10.8% of the cases had no complete remission even after 1 year even though they are symptomatically better. All the cases were followed for a further period of 3 to 5 years with no further deterioration of the Doppler findings.

1. Introduction

Varicose vein and chronic venous insufficiency were previously thought to be the direct effect of superficial venous stasis. But now we know, the deep venous system and its valve integrity play a role in the development of chronic venous insufficiency (CVI) along with superficial venous system. Kistner is the first person to introduce the concept of valve incompetence in the development of CVI¹. Various reconstruction procedures were developed after this concept and many modalities of repair procedures were implemented like Valvuloplasty, venous valve transposition/transplantation, external valve wrapping and primary reconstruction of the deep venous valves.

Valves in the deeper leg veins normally allow flow of the blood towards the heart. Back flow of the blood occurs when there is valvular dysfunction like incompetent valves damaged valves or congenital absence of them. So the veins remain engorged with blood when the person is standing. Prolonged standing in stationary position can result in gradual dialatation of the venous wall which in turn produce further valve incompetence.

BMJ of surgery in 1994 ^{3, 4} has mentioned that 50% of the general population can have varicose veins in their period of life and stasis and ulcer can result in 1% of these groups. Out of this 1%, 50% can go for chronicity for more than 12 months and 72% is recurrent in nature. This shows the gravity of the disease and this can affect the quality of life.

Diagnosis of the deep vein pathology especially valvular incompetence was detected in previous years by descending venogram which is an invasive procedure⁵ and now it is

replaced with duplex ultrasound, and has helped in a grate way in detection and follow up of the cases with accuracy.

Deep vein valve repair surgery is done only for those cases where external compression therapy and superficial venous surgeries have failed to relieve the symptoms. Such patients have skin changes leg pain and ulceration which is chronic and repeated breakdown of the healed ulcers can occur. When it occurs in the productive age group of the patient can result in job loss.

In this study only selected group of patients who had femoral vein incompetence detected by duplex ultrasound and these patients have undergone Trendelenburg, vein stripping, perforator ligation, in-spite of all these procedures they have chronic venous ulcers.

2. Materials and Methods

We have conducted the study on a selected group of 28 patients during a period of 9 years from 2009 to 2018. All these patients were surgically treated for varicose vein in different centres with recurrence of ulcer. They were counselled and consent obtained for surgical intervention. Many cases with recurrence were reluctant to do a second surgery because of the previous surgical failure. So we have taken only the cases who voluntarily consented for this surgery. Other causes of chronic ulcer formation like, diabetic mellitus, peripheral arterial diseases (PAD), anaemia, hypoproteinaemia were detected prior to surgery. Peripheral arterial disease was excluded from this study. All other treatable causes were corrected/ controlled prior to including in this study. Chronic ulcer with specific infection and active ulceration were given antibiotic treatment before

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taking up for surgery. Cases with venous incompetence of grade 3 and 4 were only included in the study.

Г	able	1 ⁵ :	CEAP	grading
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0	Normal valve competence; no reflux demonstrated beyond			
0	upper limit of femoral vein			
	Minimal incompetence; reflux exits beyond the uppermost			
1	valve in the femoral vein but beyond the proximal aspect of			
	the thigh			
2	Mild incompetence; reflux occurs in the femoral vein to the			
2	level of knee			
3	Moderate incompetence; reflux below the knee			
4	Severe incompetence; reflux occurs into pair calf veins to			
4	the level of ankle.			

Inclusion criteria

- 1) Cases with previous surgery done for varicose veins with recurrence of venous ulcers and oedema of lower limb were taken in the study
- 2) Patients with CEAP grade 3 and 4 were alone subjected to surgery for this study
- 3) Patients with bilateral varicose veins, the limb with maximum disease was selected

Exclusion criteria

- 1) Patients with PAD, uncontrolled diabetes, deep vein thrombosis (DVT)
- 2) During surgery valve pathology other than valve incompetence like absence of valve or complete destruction of the valve were not included in the study (such cases were subjected to other modalities of surgical correction)
- 3) Patients with bleeding diathesis, cerebrovascular accident and peptic ulcers who cannot undergo anticoagulation therapy were also excluded from this study.

2.1 Method

All the patients (28) were subjected the same procedure of valve repair and is done on the redundant valves.

Procedure: Under general / spinal anesthisia the patient is positioned in supine and the groin and external genitalia drapped and inguinal region with the upper part of thigh exposed. Steri-drape was used to cover the exposed skin. A lazy-S incision was put on the inguinal region and upper part of thigh. Through this incision a femoral vein was exposed for a length of 4 -5 cm on either side of the vein valve. The valve itself is identified by the external bulge out of the femoral vein which is incompetent. An umbilical tape is put around on the upper and lower part of the vein. At this time 5000 units of heparin was given IV to maintain an activated clotting time(ACT) of above 300 seconds. After securing the femoral vein with vascular clamps an incision is put horizontally 0.5 cm above the valve bulge out. Through this rent the valves are identified and checked for incompetence with saline instillation. The redundant valve cusp margins were plicated to achieve opposition of the two valves. Sutures were tied on either side outside the vein valve. 6-0/7-0 double armed prolene were used for repair and closure of femoral vein. Competency of the valve is checked by instilling saline and valve cusp should hold saline for few seconds. After closure of the horizontal incision of the femoral vein, facia- lata harvested from the same patient and made into a thin layer was wrapped round in the dilated portion of the femoral vein for a length of 1.5 cm on either side of the valve. This is done without any tension on the vein so that no further dilatation can occur at the regional valve. (Now prosthetic materials are available for wrap round at the venous valve side. But we haven't used this materials as they are very expensive and many of our patients were from low socio economic status so that they are not in a position to afford it. The facia lata prepared from the same patient gave an equally good result). The wound was closed in layers with 10F ready vac suction drain. Post operative heparinisation was instituted and later converted to oral anti coagulation.

Integrity of the repaired valve were checked in the immediate post operative period 1^{st} week, 3^{rd} week, 3^{rd} month, 6^{th} month and one year and yearly followed up.

Assessment of chronic venous ulcer in the post operative period was carried by sterile blotting paper method. In this technique an imprint of the ulcer is taken with the blotting paper and its wet area measured. This was compared with the preoperative value. Any reduction in imprint area is considered as an improvement. This was carried out along with duplex ultrasound at intervals of 1st week, 3rd week, 3rd month, 6th and one year.



3. Results

Between a period of 2009 and 2018 (9 years) we have done reconstruction procedures for femoral valve in 28 selected cases. Varicosities regressed in all cases post-operatively. We had no DVT in the post-operative period as all patients were put on anticoagulation treatment for 3 months.

Out of 28 cases 25 cases showed reduction of CEAP grade from 3 & 4 to grade 1 & 2 and 3 cases did not show the excepted reduction of venous reflux grade.

Majority of cases showed a good result 89.2% and the rest with not that flashy result. Even though they could not come to grade 1 or 2, these cases reverted to a better grade 3 from grade 4 with improvement in the clinical symptoms. The

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maximum number of cases were in the age group 41-50 years, out of which, 9 were male and 7 female and all 3 cases without good results were in this age group.

Age group and sex distribution chart.

Table 2: Pre-operative grade						
Ago	Male	Female	Male	Male	Female	Female
Age	numbers	numbers	grade 3	grade 4	grade 3	grade 4
28-40	5	1	3	2	1	0
41-50	9	7	2	7	2	5
51-62	2	4	0	2	0	4

Table 3:	Post-operative	grade
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Age	Male	Female	Male grade	Female grade	
	numbers	numbers	1.2.3.4	1.2.3.4	
28-40	5	1	4.1.0.0	0100	
41 -50	9	7	3420	1510	
51-62	2	4	2000	2. 2. 0. 0	

The patients with grade 1 & 2 postoperatively showed a good healing of ulcer when compared to the other 3 cases that showed a slow healing. (10.2%). They showed no complete healing of wound even after one year of follow up. Variables that are involved in healing process we're treated prior to surgery like diabetes, hypertension, hypoprotineamia and anaemia. Specific infections of the ulcer were also treated with specific antibiotic as per culture study.

4. Discussion

Studies showed evidence of vein wall defect with good valve cusp in varicose vein patients and vein wall is more distensible than normal vein in these patients¹⁶. Edward and Edward¹⁷ found in their study that separation of commissaries is the early change in varicose vein. Phlebographic study of patients with chronic deep venous insufficiency showed no evidence of phlebitis damage ¹⁸ but noted cusp stretching and argued as primary valve defect. Ferris and Kistner performed plication of venous valve and Hallburg and Raju¹⁹ in their study placed a cuff around the vein to maintain competence.

The above mentioned observations are the main stay in our study.

CEAP grade or severity was used to estimate the severity of incompetence of the valves. Duplex ultrasound was used to assess pre and post operative venous reflux. If the reflux time is more than 0.5 second and the reflux could be traced below knee the repair was considered unsuccessful. That is severity grade 3 and more. The flow volume can also be calculated by velocity profile.²⁰

There are now many surgical modalities that are available in the treatment of CVI, like valve transplantation, valve transposition including cryogenic preserved allografts and neo valves. These are done for completely destroyed valves. Surgery for venous wall includes valve wrapping, ringing, circum suturing and external Valvuloplasty. The main aim of all these are to correct the back reflux in superficial and deep veins. Our study is aimed at correction of the back reflux by reconstruction of the femoral valves and wrap round with fascia lata in our selected cases, as all of them have undergone a previous surgery for superficial veins.

For effective treatment reduction of the venous hypertension by superficial venous surgeries combined with femoral valve reconstruction will be a better option. But the problem with this combined approach, is that we were not in a position to pin point which one (repair of deep femoral valve or the superficial venous surgery) has resulted in good result.

Whereas in our study all cases have undergone superficial venous surgery and the results are only due to the femoral vein reconstruction, which has shown an 89.2% good result.

Data representing more than 5 years of follow up indicated that internal or external Valvuloplasty is effective for 70% of the cases, with clinical improvement with no recurrence of ulcers. Hardy et all ¹³ concluded that Valvuloplasty combined with superficial vein surgery can produce a sustained improvement for 7 to 10 years.

We have chosen the first femoral valve for repair as the position of the valve is constant and the valve is firm in structure and surgical access to this area is more superficial than the rest of the deep valves. The reconstruction of this valve will prevent the first back reflux and the venous hypertension can be reduced there by shrinking the rest of the venous system and reducing the vein valve size.

The technique we have done is simple and reproducible and can be done in any surgical centre. The learning curve for this technique is short and can be mastered with perfection. We have done the surgery in CEAP reflux grade 3 and 4 and our results are gratifying.

5. Conclusion

Study included only the cases where all modalities of superficial venous surgeries were offered and presented with residual lesions like non healing ulcer. Post operatively they are followed for a period of 3 to 5 year and no worsening of the CEAP grading nor scar break down seen in the these patients with good result. Factors that may play a role in the delayed healing were corrected before they are taken for surgery and findings of good healing could be attributed to the surgical repair of the valve and its grading like 1 & 2 and also by the fact that patients with grade 3 showed a delayed healing.

- 1) From this we can comfortably come to a conclusion, that repair of the incompetent valves to CEAP grade 1 & 2 gives good prognosis.
- 2) If this procedure is combined with classical saphenous vein surgery in patients with femoral vein incompetence a better cure rate can be obtained in the initial surgery itself, and a second surgery can be avoided.
- 3) Valve wrap round is done with the patient's own facia lata and there is no additional expenditure incurred.

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