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Has external banding become a historical technique during venous valve repair?

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SUMMARY

OBJECTIVE: In deep venous valve repair, transcommissural external valvuloplasty (TEV) is the commonly used technique. In some cases, external banding (EB) is combined with this procedure to improve the patency and durability of the surgical procedure.

METHODS: We retrospectively analyzed patients who underwent deep venous valve repair from 1998 through 2018. Patients were divided according to the surgical procedure: Group A: TEV alone and Group B: TEV+EB. Early postoperative outcomes of the procedure were compared between the groups.

RESULTS: There were 265 patients in Group A and 165 patients in Group B. The mean follow-up period was 4.2±3.7. The rate of recurrence of venous reflux, ulcer, and reoperation were 31.9 versus 30.9, 21.2 versus 21.8, and 16.7 versus 13.9 in Group A and Group B, respectively. There were 67 reoperations in the follow-up period. At reoperation, external valvuloplasty was performed in 64% of the reoperations in Group A, while this rate was 13% for Group B.

CONCLUSIONS: There is no more need for EB during the venous valve repair with the increased experience of valvuloplasty techniques. TEV might be enough with acceptable long-term outcomes during deep venous reconstruction.

KEYWORDS: Venous insufficiency. Venous valves. Venous thrombosis.

INTRODUCTION

In recent times, the importance of deep venous insufficiency, which threatens patient comfort, has been better understood. Even in the earlier stages of the disease, it affects a patient's daily life with disturbing symptoms. In patients with deep venous insufficiency, superficial venous surgery with/without perforator surgery may not be enough to relieve symptoms. Deep venous valve repair is indicated in symptomatic patients as a consequence of conservative treatment failure and superficial/perforator surgical procedures¹⁻³. In symptomatic patients with severe deep venous insufficiency combined with superficial venous insufficiency, both systems may undergo surgery in the same session.

Deep venous valve reconstruction techniques improve patients' quality of life and decrease the Venous Clinical Severity Score (VCSS). However, valvuloplasty procedures should be performed by highly skilled physicians at specialized centers². Different surgical techniques including internal valvuloplasty, external valvuloplasty, external banding (EB), neovalve, valve transposition, and valve transfer have been reported for deep venous valve reconstruction^{1,4-8}. External valvuloplasty has the advantage of not needing venotomy with acceptable mid- and long-term results^{1,2}. This technique closes the wide angle between the valve attachment lines⁸. However, its results are related to the surgeon's experience because it is performed without direct vision. To improve the outcomes of external valvuloplasty, angioscopic guidance has been reported, but its use has not widened since external valvuloplasty has similar outcomes in experienced centers. In the early terms, external valvuloplasty was combined

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with EB to improve valve competence and to avoid further dilatation^{1,2}. Currently, as a result of increased surgical experience, external valvuloplasty alone has recently been reported to have similar results with internal valvuloplasty or EB combined with external valvuloplasty with a 5-year success rate of 70%².

In symptomatic patients with recurrent deep venous insufficiency, reoperation might be needed in the long term, especially in the presence of venous ulcers. During reoperation, the dissection of the vein wall might be difficult due to the inflammatory response to the synthetic material in the patients with the external band. Choices of venous reconstruction techniques might be restricted related to the condition of the vein and valves. In this study, we present our outcomes with external valvuloplasty alone and with EB and our experience of their reoperations.

METHODS

We retrospectively analyzed patients who underwent transcommissural external valvuloplasty (TEV) alone or TEV combined with EB (TEV+EB) due to deep venous insufficiency from 1998 through 2018. This study was initiated after the approval of the institutional review board. Demographic and clinical information including long-term results, reoperations, and ultrasonographic reports were collected from a review of the medical records, which included the surgical database.

Patients with primary venous insufficiency and who underwent TEV at a single vein site (common femoral vein (CFV)) were included in this study. Patients who underwent other venous reconstruction techniques (i.e., internal valvuloplasty, neovalve, and valve transposition) or had surgery at a different venous site, patients with secondary venous insufficiency, and patients with the peripheric arterial disease were excluded from this study. The history of venous thrombosis and major trauma was the other exclusion criteria.

Patients were evaluated using the Clinical, Etiologic, Anatomic, and Pathophysiologic (CEAP) classification, VCSS, and Doppler ultrasonography. The Doppler ultrasonographic examinations were performed both preoperatively and postoperatively while patients were standing. A reflux time >0.5 s was considered as venous insufficiency. Venous valve reconstruction was planned in patients with venous ulcers or severe symptoms. External valvuloplasty, which is a less invasive procedure, does not require venotomy, does not directly interfere with the vascular endothelium, and was preferred as the first option for the venous valve reconstruction.

We divided patients into two groups according to their surgical procedures. Patients who underwent TEV alone were assigned to Group A, and patients with TEV+EB were in Group B. All patients underwent surgery by the same surgical team under spinal or epidural anesthesia. In patients with superficial venous insufficiency, ankle-to-groin stripping of the greater saphenous vein was performed. The CFV and superficial femoral vein (SFV) were then dissected free around their circumference, and the side branches were divided. Topical papaverine solution was applied to induce vasodilatation, and the patient was then asked to perform the Valsalva maneuver in a reverse-Trendelenburg position to detect venous deformity or dilatation. Diameters of the CFV and SFV adjacent to the dilated venous segment were measured using calipers⁵. Intravenous heparin (5,000 IU) was introduced prior to the valve reconstruction. External valvuloplasty was performed using the technique we previously described⁵. We performed valvuloplasty with a continuous suture using 7.0 polypropylene to strengthen the lines of the valves on the wall⁹. In Group B, additional external wrapping using a Dacron patch was performed. The same approach was performed during reoperations, but the surgical procedure was decided according to the condition of the venous wall and the durability of the valvuloplasty techniques.

All patients were ambulated on postoperative day 1 and wore 30–40 mmHg compression stockings. The patients were administered oral warfarin treatment, which began on the day of the operation and continued for 6 months to maintain international normalized ratio (INR) levels between 2.0 and 2.5.

The early postoperative outcomes of the procedure including ulcer healing, ecchymosis, lymphatic leakage, wound infection, hematoma, and paresthesia were compared. The patients' symptoms were evaluated using the VCSS. Patients were followed up through the Doppler ultrasonographic examinations before discharge, and 2 months, 6 months, and 1 year postoperatively, and annually thereafter by the same investigator. Failure of the valve repair was accepted as >2-s reflux at a repaired site⁴. Reoperation was performed in patients with recurrent venous ulcers or severe symptomatic patients with recurrent venous insufficiency.

Categorical variables are presented as the number of patients and percentage; continuous variables are presented as mean (SD). Groups were compared with a two-sample *t*-test and chi-square test.

RESULTS

A total of 428 patients underwent deep venous valve reconstruction with external valvuloplasty. Of these, 165 patients had additional EB. All patients underwent superficial venous valve surgery during the same period or prior to the venous valve reconstruction. The mean age was 45.4 years, and 146 were men. The patients' primary symptoms at admission are shown in Table 1.

All patients in both groups had superficial and deep venous insufficiency. The patients' characteristics were classified in accordance with the CEAP classification and VCSS (Table 2).

	Group A (n=263)	Group B (n=165)	р		
Age	46.1±8.5	44.4±9.4	0.023		
Male (%)	91 (34.6)	55 (33.3)	0.788		
Primary complaint					
Ulcer	160 (60.8)	105 (63.6)	0.562		
Pain	199 (75.7)	124 (75.6)	0.904		
Presence of dermatitis	63 (24.0)	39 (23.6)	0.940		
Leg swelling	231 (87.8)	146 (88.5)	0.84		

Table 1. Patient's characteristics at admission.

Table 3. Rates of recurrence and reoperation techniques.

	Group A (n=263)	Group B (n=165)
Venous reflux recurrence (%)	84 (31.9)	51 (30.9)
Venous ulcer recurrence (%)	56 (21.2)	36 (21.8)
Reoperation	44 (16.7)	23 (13.9)
External valvuloplasty	28	3
Internal valvuloplasty	6	2
Valve transposition	3	11
Neovalve	5	3
External banding	2	4

Table 2. Clinical findings of patients.

	Group A (n=263)	Group B (n=165)	р		
Clinical					
C3	49 (18.6)	24 (14.5)	0.029		
C4	55 (20.9)	38 (23.0)			
C5	71 (27.0)	45 (27.3)			
C6	88 (33.5)	58 (35.2)			
Etiology					
Primary	263 (100)	165 (100)	NA		
Secondary	-	-			
Anatomic	S and D reflux	S and D reflux	NA		
Pathophysiology	S and D reflux	S and D reflux	NA		
VCSS	6.6±2.6	6.2±2.7	0.0627		

VCSS: venous clinical severity score.

The mean follow-up period was 4.2 ± 3.7 . In the follow-up period, the rate of recurrence of venous reflux and ulcers was 30% and 20%, respectively. In the comparison of the groups, recurrence rates were similar (Table 3).

There were 67 reoperations in the follow-up period. Surgical procedures in the reoperation were related to the prior reoperation. In Group A, external valvuloplasty was performed in almost two-third of the patients. However, in Group B, the rates of valvuloplasty procedures were lower (Table 3).

DISCUSSION

To our knowledge, this is the first study to examine the outcomes of external valvuloplasty alone and the combination of external valvuloplasty with EB. In the comparison of the groups, preoperative characteristics were similar. Although there were similar rates of recurrence of postoperative venous insufficiency, venous ulcers, and reoperation, the reoperative procedures were more complex in patients with EB. Dissection of the venous wall was difficult due to the inflammatory response to the EB tissue. In most cases, the effort to relieve the femoral vein around its circumference and external band was not enough to perform second valvuloplasty procedures. In these situations, we performed alternative venous reconstruction procedures, which were more complex and have lower long-term results than valvuloplasty procedures.

Primary deep valve incompetence is the second cause of deep venous insufficiency². It occurs due to prolapsed valves, dilatation of the valve ring, and asymmetric insertion of the cusps; these anomalies can easily be repaired with valvuloplasty procedures². Many reconstruction techniques have been reported in the treatment of deep venous insufficiency. Valvuloplasty techniques have more durable results than the other venous reconstruction techniques⁴. Lehtola et al.⁴ reported that external valvuloplasty was a more durable technique with a 71% durability rate; however, there was a selection bias in their study because internal valvuloplasty procedure was mostly performed in post-thrombotic patients.

Direct angioscopy might be used during external valvuloplasty; but, it is unnecessary because widened valve attachment lines will easily get closer in a certain way in experienced centers¹⁰. We did not use angioscopy in any of our patients. EB in addition to external valvuloplasty might be preferred to restore valve competence by reducing the caliber of the vein. Dacron, Venocuff, polytetrafluoroethylene (PTFE), and bovine pericardium might be used for EB¹¹. If external sleeves increase the rigidity of the vein wall, this can limit the motion of the valve cusps⁷. Fibrotic/thrombotic occlusion of the vein station might develop in cases with external cuffs³. Also, the inflammatory response to these foreign materials might cause a more complex second procedure. In that situation, the alternatives of re-valvuloplasty techniques are restricted. Autologous valve transfer or cryovalve insertion might be performed in this clinical condition. In our reoperated patients, the rates of valvuloplasty procedures were 77% and 21% in Groups A and B, respectively. In Group B, almost half of the patients had undergone valve transposition.

Cryovalves have poor mid-term outcomes with high occlusion rates and are recommended only as a secondary choice¹². Neovalve reconstruction is an alternative technique for deep valve surgery with high competence and ulcer healing rate⁶. This technique might be used in secondary valve insufficiency and reoperation as an alternative to external valve repair. Recently, neovalve procedures have become our first option in cases where we cannot perform valvuloplasty techniques. In our cases, we performed neovalve reconstruction in eight patients with acceptable results.

Less than 10% of chronic venous insufficiency is caused by deep venous insufficiency alone9. In the patients with combined superficial and deep venous insufficiency, saphenous vein ablation solves the deep venous problem in one-third of patients¹³. In addition to superficial venous surgery, subfascial endoscopic perforator ligation might be effective to reduce deep venous insufficiency and to improve patients' outcomes¹⁴. After superficial venous surgery, segmental deep venous valve insufficiency is more likely to become competent¹³. It is impossible to identify whether surgery of the superficial venous system will be enough to improve the symptoms of patients with superficial insufficiency combined with moderate-severe deep venous insufficiency¹⁵. Deep venous valve repair is needed, especially if they have venous ulcers and severe symptoms. A surgery of at least one valve of the femoral vein in addition to superficial venous surgery relieves patients' symptoms and improves long-term outcomes9. In our patients, we performed deep venous reconstruction in addition to the superficial venous surgery due to pain, swelling, and venous ulcer in patients with severe deep venous insufficiency. In the follow-up period, patients' symptoms were relieved without any complications.

The main treatment methods for leg ulcers are compression therapy and surgical correction of superficial venous incompetence¹⁶. These procedures relieve symptoms and heal leg ulcers in 80% of patients¹⁷. Remaining 20% of patients were refractory to conservative treatment and superficial venous surgery; deep venous valve repair should be considered in this group of patients¹⁷. Treatment of the deep venous insufficiency in experienced centers increases the success of treatment strategies and decreases recurrence rates. In patients with mild-moderate deep venous insufficiency, a combination of ligation of the incompetent superficial vein and valvuloplasty has moderate and sustained improvement for 7–10 years¹⁸. The recurrence of venous ulcers may develop due to patients' poor compliance with compression therapy or an underlying deep venous defect¹⁶. In our study, the rate of freedom from venous ulcers was 80% in the long term.

Valvular reconstruction was reported to be more effective in primary valvular reflux than in secondary reflux³. The reoperation rate was 4% after valve reconstruction⁸. Joh et al.¹⁹ reported 19.4% recurrence after EB valvuloplasty of the greater saphenous vein. In our long-term results, the reoperation rate was 15%, and we could not find any potential advantage of EB in deep venous reconstruction.

The coronavirus disease 2019 (COVID-19) pandemic, which the world has been struggling with recently, might cause thromboembolic complications such as deep venous thrombosis and pulmonary embolism. Thromboembolic complications have been reported in 15–25% of COVID-19 patients^{20,21}. Venous thrombosis caused by COVID-19 might damage the valve structure and will lead to the emergence of more deep venous insufficiency patients in the future. Therefore, the follow-up and treatment of patients with deep venous insufficiency will gain more importance over time.

In this retrospective study, the data were gained from the medical records; thus, it has inherent limitations of retrospective studies. As a nature of retrospective studies, we could not give the exact rate of the reoperations or recurrence. We could only comment on our medical records. Before 2009, we usually prefer EB. However, due to the difficulty of reoperation of EB and increased experience with deep venous valve repair, we started to prefer first the external valvuloplasty alone. It could be advocated to compare these groups, but we aimed to share the long-term results of our perspective after the progress about venous valve repair.

CONCLUSIONS

In experienced centers, the combination of superficial venous surgery with deep venous surgery improves the long-term outcomes⁹. External valvuloplasty might be preferred with acceptable long-term results. In the earlier period of the procedure, external valvuloplasty was combined with external bands to improve outcomes. However, with surgeons' increased experience of external valvuloplasty, the need for the external band has been decreased. In addition, synthetic tissue may increase the complexity of second procedures, if necessitated. The venous valve repair operations should be performed in experienced centers, and external valvuloplasty should be kept in mind as a first option with the advantages of easy to perform, durability, and decreased risk of reoperation.

AUTHORS CONTRIBUTIONS

MHU: Conceptualization, Data curation, Formal analysis, Methodology, Resources, Supervision, Validation, Writing – reivew & editing. **MU:** Conceptualization, Formal analysis, Visualization, Writing – original draft.

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