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The efficacy of external valvuloplasty with silicone stents (Venocuff™) in the management of focal valvular incompetence as assessed by Doppler ultrasound

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ABSTRACT

Objectives: This study aims to assess the efficacy of external valvuloplasty with silicone stents in the management of isolated terminal or preterminal valve dysfunction at the saphenofemoral junction based on comparisons between pre- and postoperative findings on Doppler ultrasound of the lower limbs.

Patients and methods: This study included a total of 16 female patients (mean age 44.1±7.6 years; range, 32 to 58 years) who underwent valvuloplasty with the Dacron®-reinforced silicone cuff (Venocuff II™ Venous Valve Exostent) for the treatment of focal superficial venous insufficiency between April 2014 and September 2018. Postoperative color Doppler ultrasonography (CDUS) findings at three to six months were retrospectively compared to preoperative CDUS findings to analyze the efficacy of the surgical technique. Preoperative measurements of the diameter (in mm) of the great saphenous vein and reflux time at the saphenofemoral junction were compared to postoperative measurements. Valvular incompetence was graded 0 to 4 based on the reflux time. All assessments were performed with a 7.5 MHz superficial vascular probe on an CDUS scanner. Clinical improvement was assessed based on the revised Venous Clinical Severity Score (VCSS).

Results: The grade of great saphenous vein reflux was significantly lower after surgery compared to the reflux grade measured before surgery. A statistically significant decrease was detected in the mean diameter of the great saphenous vein ($p<0.05$), and the VCSS decreased statistically significantly after surgery.

Conclusion: The Venocuff™ procedure is an effective surgical option which can reduce future complications by alleviating venous insufficiency. Moreover, patients may feel more comfortable with the procedure compared to other surgical modalities. Venous CDUS is of paramount importance for the diagnosis of isolated venous valvular insufficiency, as well as for the follow-up of patients after surgery.

Keywords: Doppler ultrasound, focal valvular incompetence, great saphenous vein, Venocuff™.

Chronic venous insufficiency (CVI) is a common disease globally, and it affects one-third of the European population.[1] Venous diseases are responsible for 70% of chronic vascular ulcers in the lower extremities.[2] Recurrent venous stasis ulcers are the primary reasons for hospitalization in patients with CVI. Chronic venous insufficiency has been also associated with the socioeconomic decline due to productivity loss and high treatment costs.[3]

Currently, the most widely used modalities for the management of progressive, moderate-to-severe venous insufficiency include obliteration of the great saphenous vein (GSV) using endovenous laser, radiofrequency, sclerotherapy, or sealants. These therapeutic techniques are cost-effective and, consequently, they have replaced saphenous vein stripping, ligation, and division. Early diagnosis of venous insufficiency is of primary importance in the prevention of disease progression using conservative therapeutic approaches to reduce the degree of valvular dysfunction. Conservative management of venous insufficiency may include valvuloplasty, which is used to reduce the severity of venous insufficiency and, consequently, to prevent

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or minimize future complications. The venous cuff method is a valvuloplasty method.

In this study, we aimed to assess the efficacy of valvuloplasty with exovascular silicone stents in the management of isolated valve incompetence at the saphenofemoral junction (SFJ) and distal segment of the GSV based on comparisons between pre- and postoperative findings on color Doppler ultrasound (CDUS) of the lower limbs.

PATIENTS AND METHODS

This retrospective study was conducted at Fatih Sultan Mehmet Training and Research Hospital, Cardiovascular Surgery outpatient clinic between April 2014 and September 2018. Eligible patients were those who were diagnosed with focal valvular incompetence, gave their consent to the treatment, and in whom we were able to perform regular ultrasound monitoring and clinical follow-up. A total of 16 female patients (mean age 44.1±7.6 years; range, 32 to 58 years) who were diagnosed with isolated valvular (terminal or pre-terminal) incompetence at the SFJ based on CDUS of the lower limbs and underwent surgery with the venous cuff (the placement of an exovascular silicone stent) were included. Pre- and postoperative CDUS imaging studies at three to six months were performed at the Department of Radiology. A written informed consent was obtained from each patient. The study protocol was approved by the Institutional Review Board of Fatih Sultan Mehmet Training and Research Hospital of the University of Health Sciences (No.050.06, Approval Date: December 25, 2018). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Common presenting symptoms included swelling, pain or discomfort, and heaviness in the leg which could worsen with prolonged standing, followed by easy tiring; however, none of the patients presented with severe venous enlargement, skin discoloration, or ulcers secondary to valvular incompetence. Symptoms were gradually increasing, and the mean duration of symptoms before the admission was about one year. Clinical signs and symptoms were assessed with the 10-item revised Venous Clinical Severity Score (VCSS) for clinical and comparative study purposes. Pre- and postoperative (at 3 and 6 months) total VCSS values were compared.

Radiology procedures

The CDUS findings before and after the venous cuff surgery were compared retrospectively to analyze the efficacy of the surgical technique. The CDUS parameters used to evaluate the efficacy of venous cuff surgery were the GSV diameter (in mm) at the proximal thigh level before and after surgery and the presence, duration, and grade of venous insufficiency before and after surgery.

All assessments were performed with a 7.5 MHz superficial vascular probe on an Aplio 300 ultrasound scanner (Toshiba Medical Systems Corp., Otawara, Japan). All venous examinations were performed by a radiologist with more than 10 years of experience

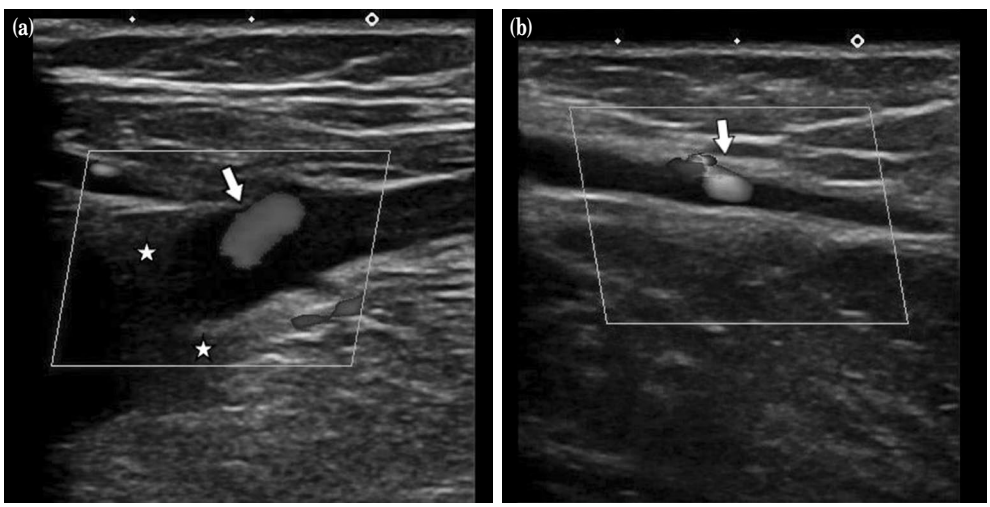

Figure 1. Color Doppler ultrasonography images showing focal valve incompetence in GSV: Foci of reflux flow localized to terminal **(a)** and preterminal **(b)** valve level (arrows). SFJ level is marked (with asterisks).

GSV: Great saphenous vein; SFJ: Saphenofemoral junction.

in the field. The CDUS examination was performed with the patient in the supine and upright positions. The femoral vein and GSV were first examined in the B-mode, and vein diameters were measured. The luminal filling was checked in the color mode. Any potential backflow, either spontaneous or elicited by the Valsalva maneuver, and venous structures of the lower limbs were checked. Every patient was able to perform the Valsalva maneuver effectively. Focal reflux findings were determined at the SFJ; specifically, the distal GSV (the last 5 cm before its junction with the femoral vein) at the terminal and preterminal valve level. No backflow was detected in the other parts of the GSV. Focal incompetence of the terminal and preterminal valves is shown in Figure 1a, b. The severity of insufficiency was divided into eight categories based on the reflux time, as shown in Table 1. Diameters were measured at 4 to 5 cm from the SFJ. The distance from junction was measured on a longitudinal plane, while vein diameters were measured holding the probe head in the transverse plane with no pressure. Reflux grades and diameters were evaluated before and after surgery, and pre- and postoperative measurements were compared. Figure 2 shows the B-mode sonographic view of the venous cuff.

During the process of patient selection, the two opposing valves were visible and mobile, and the GSV was not tortuous or severely dilated (>1 cm in women and >1.2 cm in men) in the B-mode ultrasound imaging. In the preoperative evaluation of patients with isolated valve incompetence, those who had acute or chronic thrombophlebitis,[4] or had previously underwent other interventional procedures or had accompanying perforating vein or femoral vein insufficiency (deep venous insufficiency) were deemed ineligible for the venous cuff procedure. Besides, patients with diffuse or long segment valvular incompetence in the GSV were also deemed ineligible for surgery.

Table 1. Rating system for degree of great saphenous vein valve reflux

Reflux grade	Time period (sec) of reflux
Grade 0	<1
Grade 1	1-2
Grade 1-2	2 sec
Grade 2	2-3
Grade 2-3	3
Grade 3	3-4
Grade 3-4	4-5
Grade 4	Over 5 sec/continuous

Surgical technique

The venous cuff is an implantable product developed to restore venous valve sufficiency by reducing the vein diameter. The Dacron-reinforced silicone cuff, Venocuff II™ (AllVascular, Sidney, Australia), were used fort he surgical procedure. The cuff is 1.5 cm wide with an adjustable length. The device is placed around the vessel where the valve is located to reduce the circumference of the vessel and to position the valve parts at opposite locations. There are separate versions for the right and left legs.

The procedure was carried out as follows: Under sedoanalgesia (wherein anesthesia was induced using a local anesthetic); an incision was made in the right or left femoral region to expose the SFJ. The GSV was found, and the SFJ and deep femoral vein were explored. The posterior surface of the VSM was dissected to turn around it at 1 to 5 cm proximal to SJF before dividing and suspending posterior branch of the GSV. The venous cuff silicone exovascular stent was rotated all around the GSV. The patient was, then, placed in a reverse Trendelenburg position. The evaluation of reflux was performed with intraoperative CDUS at the GSV-SFJ level to adjust the amount of compression exerted by the venous cuff. According to the preoperative grade of reflux, The venous cuff diameter was adjusted to provide venous compression leading to at least a 50% reduction. The suspended posterior branch of the GSV branch was released and, then, the Venocuff was secured with 7-0 prolene sutures to the wall of the vessel (Figure 3). The patient was re-placed in the supine position after the ligation

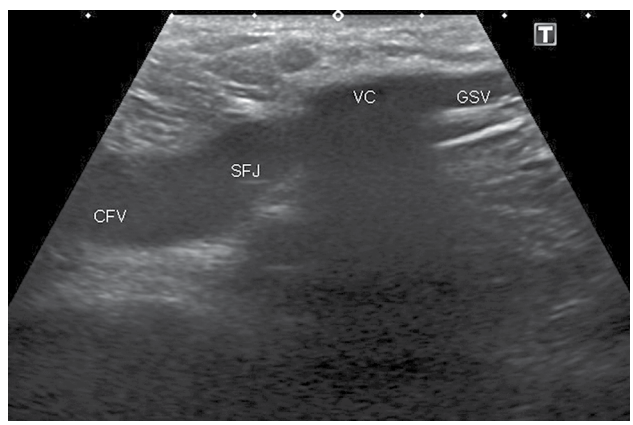

Figure 2. Postoperative ultrasound. Linear echogenic margin of Venocuff™ located approximately 1-cm distal to SFJ, accompanied by a marked posterior acoustic shadow.

CFV: Common femoral vein; SFJ: Saphenofemoral junction; VC: Venocuff™; GSV: Great saphenous vein.

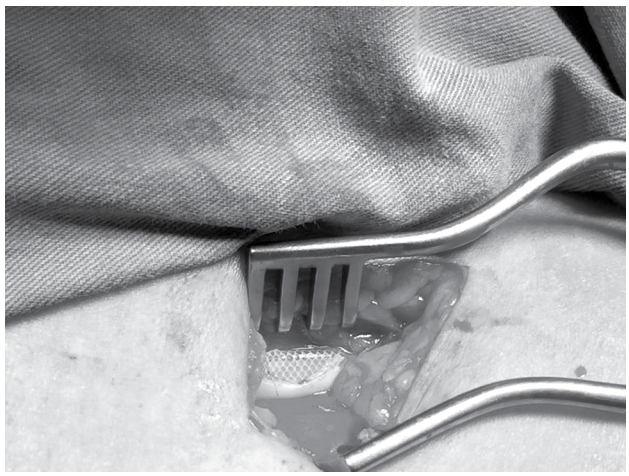

Figure 3. An intraoperative image. Exploration of saphenofemoral junction and placement of Venocuff™ into inguinal region.

of the posterior branch of the GSV. The incision was closed after bleeding control, and the patient was transferred to the ward. All patients were discharged from the hospital on the same or the next day after a minimum of eight hours of follow-up.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean ± standard deviation (SD), median (min-max) or number and frequency. The Shapiro-Wilk test was used to control whether the variables were normally distributed. The Wilcoxon signed-rank test was used to compare quantitative data. A p value of <0.05 was considered statistically significant.

RESULTS

Of the patients, the right lower limb was examined in eight patients and the left lower limb was examined in eight patients.

In our study group, the diameter of the GSV was found to be increased in 14 of 16 patients with focal valvular incompetence, and the mean preoperative diameter was 5.2±0.9 (range, 3.3 to 6.5) mm. In the postoperative period, the mean diameter was 3.2±1.2 (range, 2 to 4.6) mm. After surgery, the diameter of the GSV was found to decrease in all patients, except for one case. The comparisons between pre- and postoperative CDUS findings revealed a statistically significant decline in the reflux grades as well as in the diameter of the GSV (Table 2 and Table 3, respectively) (p<0.05).

The mean pre- and postoperative VCSS values were 6.3±1.5 (range, 4 to 9) and 2.5±1.2 (range, 1 to 4), respectively, indicating a statistically significant decrease (p=0.000 and p<0.05, respectively) (Table 4).

DISCUSSION

Vascular disorders in lower limbs are commonly encountered on a global scale. About 10 to 15% of males and 20 to 25% of females may have visible varicose veins.[5] There is a consensus that SFJ valve repair can decrease venous insufficiency symptoms distal to the SFJ and, at the same time, prevent the formation of varicose veins.[6] Incompetent GSV can be best spared by the reconstitution of junction competence, if the valves still efficiently function, and valvular dysfunction is associated with venous dilatation. Therefore, various devices and methods have been developed including banding of the junction area with the fascia lata, the use of prosthetic materials (Dacron® or polytetrafluoroethylene), venous cuff stapler (Dacron®/silicon banding with automatic caliber fixation), or Gore® External Valve Support (EVS), a nitinol-reinforced Dacron® device. Besides, perivenous injection of viscous fluids has been also used.[7,8]

To date, many researchers have provided positive data for external valvuloplasty (EVP). It has been commonly proposed that the external banding of the

Table 2. Evaluation of great saphenous vein reflux degree

	Median	Min-Max	*p*
Preoperative	Grade 3-4	Grade 1-2 - Grade 4	0.002*
Postoperative	Grade 0	Grade 0 - Grade 4	

Min: Minimum; Max: Maximum; Wilcoxon signed-rank test; * p<0.05.

Table 3. Evaluation of great saphenous vein diameter

	Mean±SD	Median	Min-Max	*p*
Preoperative	5.2±0.9	5.2	3.3-6.5	0.001*
Postoperative	3.2±1.2	3.6	0-4.6	

SD: Standard deviation; Min: Minimum; Max: Maximum; Wilcoxon signed-rank test; * p<0.05.

Table 4. Evaluation of clinical recovery after treatment

	Venous Clinical Severity Score			
	Mean±SD	Median	Min-Max	*p*
Preoperative	6.3±1.5	6	4-9	0.000*
Postoperative	2.5±1.2	3	1-4	

SD: Standard deviation; Min: Minimum; Max: Maximum; Wilcoxon signed-rank test; * p<0.05.

superficial femoral vein or SFJ can eliminate reflux and cure recurrent venous hypertension.[9-11] Karapolat and Özdemir[12] reported successfully implemented external banding in three patients with CVI and concluded that this treatment was less invasive compared to other methods, and it could provide an effective restructuring in the presence of isolated valvular incompetence in the SFJ.

In addition to studies showing that venous cuff treatment is a favorable option for early treatment of venous insufficiency in which vascular morphology is not yet disturbed, there are studies showing that it would contribute to the treatment of ulcers associated with CVI. In a study conducted by Yavuz et al.,[13] the venous cuff application was shown to be a favorable option for the prevention of the recurrence of stasis ulcers, as it reduced venous leakage.

Currently, CDUS is the gold standard for the evaluation of venous insufficiency, although it is highly user-dependent.[14] It can evaluate both anatomical details (i.e., vein diameter, valvular status, accessory venous structures, the relationship between reticular venous structures and main venous structures) and hemodynamic changes in the blood flow. In a study investigating inter-observer differences in the interpretation of CDUS findings, it was reported that there were highly compatible results in the detection of reflux (sensitivity 97.9%, specificity 99.7%, and accuracy 99.5%).[15]

In general, the venous flow is spontaneous and shows phasic variations with respiration. With the Valsalva maneuver, however, the flow stops. The diagnosis of reflux is usually made, when the retrograde flow exceeds 0.5 sec[16,17] in duration, although some clinics use a cut-off of >1 sec for the reflux time,[18,19] as in this study. In the evaluation of the grade of reflux during the Valsalva maneuver, both measurements were repeated twice, and variations between two trials were limited to a few msec. Therefore, a comprehensive grading was used in this study. Typically, the diameter of the vessel should be ≤4 mm. In veins larger than 7 mm, the incidence of reflux is high. Venous reflux may also occur in small vessels; however, it is often clinically insignificant.[20] In our study, the range diameter of the vein reduced from 5.8 mm to 2.4 mm and symptomatic improvement occurred in a patient, although no reduction was observed in the reflux grade.

The diameter measurements can help decide between different therapeutic modalities including radiofrequency, sclerotherapy, endovenous laser, and surgery. The recommended sites of measurements are 3 cm below the SFJ, the mid-thigh level and the knee.[16] In their study, Mendoza et al.[21] recommended performing GSV diameter measurements at the mid-thigh level, which is 15 cm distal from SFJ. However, our study investigated focal insufficiencies at the level of terminal/preterminal valve level, whereas the patients had venous insufficiencies at different extents and levels in the study sample of Mendoza et al.[21] In another study, the distance between the terminal and preterminal valves and the SFJ point was measured, and the mean distances were 0.4 cm and 3.1 cm, respectively.[22] Considering the location of the valve in each patient, diameter measurements for the comparisons were at a point 4 to 5-cm away from the junction to ensure that measurements were taken from below the preterminal valves.

In the literature, the most extended follow-up after a venous cuff procedure was reported by Joh et al.[11] where 31 patients were followed. After a mean follow-up of 92.6 months, the persistent/recurrent reflux rates were as high as 61.3% in some of the GSV trunk segments. Clinical relevance of this high rate was low: only six patients (19.4%) required re-treatment and no significant reductions occurred in the GSV diameter during the long-term follow-up. Consequently, the authors suggested that the venous cuff surgery was as an effective method for the treatment of this condition. The authors also emphasized the importance of interventions performed at the SFJ level, indicating that local reflux in GSV might cause less clinical problems than reflux at the SFJ.

The study conducted by Joh et al.[11] provided long-term results of vein diameter comparisons based on CDUS measurements. In a comprehensive study conducted by Lane et al.,[23] the short-term (month 3) recurrence rates were assessed using CDUS. A diameter larger than 3 cm and the presence of valvular incompetence were defined as recurrence. However, comparisons did not involve the grade or duration of reflux. Review of literature reveals no study evaluating the efficacy of venous cuff based on the duration of reflux, as assessed by CDUS.

In the present study, we used VCSS to score clinical findings. The VCSS includes 10 hallmarks of venous disease, each scored on a 0 to 3 severity scale. The revised VCSS parameters are pain, varicose vein, venous edema, inflammation and induration, skin pigmentation, ulcers (including number, size, and duration), and compression. The ease of use

makes it attractive as a stand-alone scoring instrument for longitudinal surveillance of venous disease.[24-27] All patients achieved clinical cure or symptomatic improvement, except for one. The difference between pre- and postoperative scores varied from 2 to 5, except for this particular patient. In this patient, the VCSS score decreased from 4 to 3, and this reduction reflected unsatisfactory clinical improvement, as confirmed by CDUS.

In our study, the reflux completely disappeared postoperatively in nine patients. Complete recovery did not occur and venous reflux persisted in the remaining seven patients. However, it is well-known that venous reflux may not be clinically relevant in all cases, and the persistence of venous reflux may not indicate surgical failure.[11] Clinical and radiological improvement was unsatisfactory in only one patient who underwent repair surgery with the venous cuff and required re-treatment. Follow-up CDUS revealed that the venous cuff was inserted away from the appropriate distance between the SFJ and GSV (or might have slipped, after it was fixed). This patient developed perforating vein incompetence in the postoperative period, and a sclerosing agent was used to obliterate the GSV segment and perforating vein.

The diagnosis of focal valvular incompetence with CDUS requires a meticulous examination. During the Valsalva maneuver, blood reflux may be seen as a round or oval-shaped focus at the valve level. The reflux can be overlooked, as it may not extend along the lumen. Therefore, it is recommended to examine valves in focal expansion areas.

The placement of the venous cuff at zero distance to the SFJ level is a widely used surgical technique. In our cases, the venous cuff was placed at a distance of 1 cm to the junction to decrease the possibility of femoral vein compression. Although general anesthesia is the technique of choice to perform the procedure in some institutions, we preferred to place the venous cuff under local anesthesia to avoid potential complications of general anesthesia. Furthermore, local anesthesia has some advantages over general anesthesia, such as early ambulation and shorter hospital stay. The procedure lasts for about 30 min. In the study group, any postoperative complications such as hematoma, infection, or venous thrombosis were not observed.

The limitation of this study is the relatively small sample size preventing us from forming two separate groups for preterminal valve incompetence and terminal valve incompetence. In addition, we were only able to evaluate early and mid-term outcomes. Follow-up activities are carried on to evaluate the long-term results of all cases of valvular incompetence.

In conclusion, early diagnosis of venous insufficiency should be the primary objective to reduce the severity of valvular incompetence and to avoid further disease progression using conservative therapeutic approaches. The venous cuff procedure is an effective surgical option which can reduce future complications by alleviating venous insufficiency. The CDUS is of paramount importance for the diagnosis of isolated venous valvular insufficiency, as well as for the follow-up of patients after surgery. Based on the findings of the present study, we suggest that surgical treatment with the venous cuff may provide a less invasive solution for early isolated venous insufficiency that does not involve the whole superficial venous system. The procedure is relatively simple surgery with shorter recovery time and allow the preservation of the junction and saphenous trunk.

Declaration of conflicting interests

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