The Use of Percutaneous Suture-Mediated Closure for the Management of 14 French Femoral Venous Access

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ABSTRACT: Background. Little has been reported regarding the utility or outcomes of femoral venous vascular closure using arterial suture closure devices. We describe results using a pre-closure approach with a 6 French (Fr) Perclose Closer S device in patients who underwent antegrade aortic valvuloplasty using 14 Fr percutaneous femoral venous access catheters. **Methods.** Forty-five patients underwent antegrade aortic valvuloplasty and suture-mediated closure with a 6 Fr Perclose™ device. A 6 Fr Closer S suture device was preloaded into the femoral vein after 6 Fr sheath access, prior to insertion of a 14 Fr venous sheath. Upon completion of the procedure, the 14 Fr femoral venous sheath was removed through the existing sutures. **Results.** Of 45 patients (mean age 82.4 years; 17 males), immediate hemostasis was achieved with percutaneous suture closure in 43 (95.6%). Only 2 failures occurred which were subsequently successfully treated with manual compression. No late access site bleeding occurred from sutured sites. In all other patients, hemostasis using a 6 Fr Perclose suture-mediated device was successful and immediate. There was no need for transfusion, no clinical venous thrombosis, and no infections occurred at the access site. Two hospital deaths were documented from causes unrelated to suture-mediated closure. **Conclusions.** In conjunction with 14-Fr size percutaneous sheaths during antegrade aortic valvuloplasty, percutaneous suture-mediated closure is a highly effective method for achieving hemostasis. This has simplified postprocedural management in terms of early mobilization and diminished late access site bleeding.

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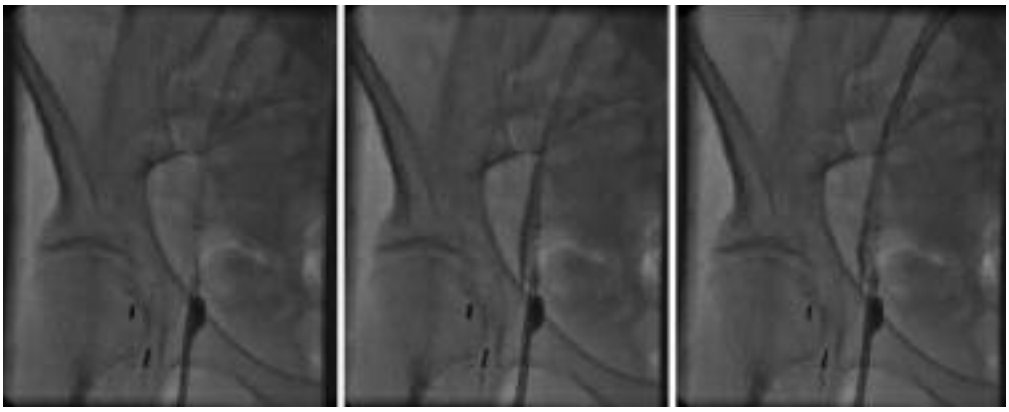

Figure 1. *Three panels from a cine angiogram showing contrast injection through the marker port of a Perclose™ device. The device is in position on the left, and no contrast has been injected. The next 2 frames show contrast streaming in the femoral and iliac veins. In the event that the marker port is outside the vessel, there is a contrast stain in the subcutaneous tissues, without streaming in the venous system. This technique can be helpful for device positioning prior to deployment, but does not show the sheath entry point into the venous system.*

Suture-mediated closure devices have had extensive use for closure of arterial access sites using 6–8 French (Fr) sheaths.[1] Some experience with suture closure for large vessel arterial access has been described as well.[2,3] The utility of these devices for closing venous puncture is less well characterized.[4] We have developed an experience using 6 Fr arterial closure devices for percutaneous closure of 14 Fr venous access procedures. The approach involves using "pre-closure", which has previously been shown to be effective for closure of oversized arterial access with smaller sheath sizes.

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Methods

We conducted a retrospective review of 45 patients who underwent antegrade balloon aortic valvuloplasty (BAV) via a 14 Fr venous sheath and suture-mediated closure with a 6 Fr Perclose™ device *(Abbott Laboratories, Abbott Park, Illinois)* between September 2002 and January 2005. In all cases, a 6 Fr Perclose Closer-S device was used for closure of the venotomy. The BAV procedure has been described previously.[5]

Procedure. The technique of "pre-closure" involved preloading a 6 Fr Perclose suture closure device into the femoral vein after access with a 6 Fr or 8 Fr dilator, prior to insertion of a 14 Fr venous introducer sheath used for antegrade aortic valvuloplasty. Venograms to assess the location of entry into the vein were not preformed. Intravenous placement of the Perclose device within the venous system was then verified by either back-bleeding from the marker port, or contrast injection through the marker port with fluoroscopic visualization of a contrast stream in the inferior vena cava prior to suture deployment (Figure 1). Back-bleeding through the marker port occurs in most cases, but there is a delay of a few seconds, and the amount of back-bleeding is small compared to

what is seen in the arterial system due to low pressure in the venous system. A breath in and out is sometimes needed to see back-bleeding. Next, the needles were pulled and the sutures clipped, and after the sutures were deployed, a guidewire was placed into the femoral vein through the Perclose device, and an exchange was made over the wire for a 14 Fr sheath while the sutures were laid alongside of the puncture and covered with betadine-soaked gauze. Upon completion of the procedure, a wire was passed through the 14 Fr sheath to secure the vessel in case the suture closure failed. Heparin was not reversed. The sheath was then removed through the existing sutures, and the sutures were tied around the guidewire. If hemostasis was successfully achieved with the suture, the wire was gently removed, and the knot pushed further to complete the closure. Antibiotics were not given prophylactically, and no patients received them postprocedure for suspected or known puncture site infections. Patients on chronic warfarin therapy were either maintained on heparin or enoxaparin until the INR achieved a therapeutic level, or in many cases, was restarted on warfarin on the first postprocedure day without intercurrent heparin therapy. The latter approach was used for lower-risk patients for thromboembolism, such as those with atrial fibrillation and no history of prior stroke.

Data collection. Success or failure of the vascular closure, as well as complications associated with suture-mediated closure using a 6 Fr Perclose device, were assessed during the hospitalization. Patient demographics, hemodynamic and technical data were reviewed. Hemodynamic data are presented as mean values ± standard deviations. Differences between baseline and postantegrade aortic valvuloplasty were analyzed using a paired two-tailed t-test. Probability values $p < 0.05$ were considered statistically significant.

Results

Forty-five patients underwent antegrade aortic valvuloplasty using preclosure with a 6 Fr Perclose Closer S suture device. The patients' demographic characteristics are summarized in Table 1. These patients were referred for valvuloplasty, as they were deemed high-risk surgical candidates due to advanced age and other comorbidities. Other reported comorbidities along with advanced age were poor left ventricular function, previous CABG, angina, prior PTCA, severe chronic obstructive pulmonary disease, diabetes, syncope and peripheral vascular disease in order of prevalence. The mean age was 82.4 years and 17 were males (38%). The mean New York Heart Association class was 3.2, with a mean ejection fraction of 41.5%. Coronary artery disease was present in 82% of the males and 75% of the females.

Table 2 shows the various pre- and postprocedural data with respect to aortic valve size and hemodynamics. Pre- versus post-BAV, there were statistically significant changes in all variables except aortic systolic pressure ($p = 0.43$), pulmonary artery systolic pressure ($p = 0.30$), and mean aortic pressure ($p = 0.96$). Aortic valve area was significantly increased from a mean of 0.6 to 1.1 cm^2 ($p < 0.001$). The mean gradient decreased from 44.7 to 20.3 mmHg ($p < 0.001$), as did the left ventricular systolic pressure from 192.0 to 166.2 mmHg ($p < 0.001$).

The results of the outcomes associated with venotomy closure using the 6 Fr Perclose device are shown in Table 3. The ACT was 216 ± 45 seconds when the 14 Fr sheath was removed. Of the 45 patients, there were 2 failures of percutaneous suture-mediated closure. A guidewire already in place

Table 1. Patient demographics.

Age *(years)*	82.4 ± 10.5
Gender *(male)*	17 (38%)
NYHA Class *(mean)*	3.2 ± 0.7
I	*n* = 0
II	*n* = 4
III	*n* = 17
IV	*n* = 9
Ejection Fraction *(%)*	41.5 ± 22
Coronary Artery Disease	
Males	14 (82%)
Females	21 (75%)
Comorbidities	
Previous CABG	*n* = 12
Diabetes	*n* = 2
PVD	*n* = 1
Angina	*n* = 9
Syncope	*n* = 2
PTCA	*n* = 6
Bridge to surgery	0
Poor LV function	*n* = 16
COPD	*n* = 4

NYHA = New York Heart Association; CABG = coronary artery bypass surgery; PVD = peripheral vascular disease; LV = left ventricle; COPD = chronic obstructive pulmonary disease.

Table 2. Pre- and postprocedural hemodynamic data.

	Pre-Vavuloplasty	Post-Vavuloplasty	*p*-value
	Average St. Dev.	Average St. Dev.	
AVA *(cm^2)*	0.6 ± 0.2	1.1 ± 0.5	< 0.01
Mean Gradient	44.7 ± 15.1	20.3 ± 9.3	< 0.01
Cardiac Output *(L/m)*	4 ± 1.9	4.4 ± 1.1	< 0.01
Systolic Blood Pressure			
Aortic	137 ± 29	141 ± 333	NS
Left Ventricle	192 ± 35	166 ± 34	< 0.01
Pulmonary artery	54 ± 14	60 ± 19	NS
Right atrium	15.3 ± 5.9		
End-Diastolic Pressure			
Left ventricle	24 ± 7	21.2 ± 6.7	< 0.01
Mean Aortic Pressure	93 ± 18.4	94 ± 22	< 0.01

AVA = aortic valve area; p-value < 0.05 is significant; NS = nonsignificant p-value; St. Dev = standard deviation.

Table 3. Procedure outcomes.

Venous sheath size	14 French
Maximum balloon-inflated diameter *(mm)*	24.8 ± 1.8
Activated clotting time	216 ± 45
Perclose™ failure	n = 2
Need for transfusions	0
Deaths	n = 2

+ indicates values for standard deviation from the mean

allowed replacement of the sheath and subsequent removal utilizing manual compression with no complications. Among all other patients, immediate hemostasis using a 6 Fr Perclose device was demonstrated, negating the need for compression for hemostasis or prolonged bed rest. There were no transfusions, no clinical evidence of venous thrombosis or occlusion, no cases of late bleeding, no subsequent site infections and no prolonged hospitalization requirements reported in any of the patients.

Two deaths were documented from causes unrelated to suture-mediated closure. During the antegrade procedure, both patients had hypotension and subsequent asystole after balloon inflation, which was unresponsive to CPR, ionotropes and pacing. Both patients had reduced left ventricular function, and 1 had severe multivessel coronary disease.

Discussion

Antegrade aortic balloon valvuloplasty requires a 14 Fr venous sheath.[5] Closure of the site has been customarily achieved by manual compression, with staff occupied for at least 30 minutes, followed by bed rest for 6 to 12 hours once hemostasis has been achieved. Patient discomfort associated with prolonged immobility is a frequent complaint, particularly in the elderly patients who undergo BAV. There is also a risk of venous thrombosis with prolonged femoral compression and bed rest. Little evidence exists to characterize outcomes of suture-mediated closure of the femoral venotomy.[4]

The most important limitation of this report is the lack of a control group. Our experience with manual compression in mitral and antegrade aortic vavuloplasty patients has included frequent oozing from the puncture site and episodic rebleeding in the first 2 postprocedure days. Oozing can be persistent in these patients who are often taking warfarin. These cases of rebleeding are infrequent, but have occurred outside of the hospital, and are disturbing to patients and troubling to us. The use of suture closure has eliminated both problems.

In this study, we report our experience using a Perclose suture closure device for hemostasis in patients who underwent antegrade aortic balloon valvuloplasty. In all patients, a 14 Fr sheath was used for procedural access and all venotomies were closed using a 6 Fr Perclose Closure-S device. The use of a 6 Fr closure device for a 14 Fr puncture was made possible by "pre-closing" the venotomy with the 6 Fr Closure device and subsequent dilatation of the access site until a 14 Fr sheath was inserted. This method of preloading may afford the advantage of securing adequate "bite" of the vessel walls. Previous experiences utilizing this pre-closure technique in femoral arteriotomies has yielded excellent results with minimal complications.[5–8] Prior reports on venous closure included smaller numbers of patients and predominantly smaller punctures.[2,4]

Generalizations from arteriotomy experiences to the venous system are not feasible.[8] The arterial system is a high-pressure system with thick walls, whereas venous circulation is a low-pressure, thin-walled, passive flow system. Arterial walls contain a greater comparative muscular layer and more elastic fibers than veins. Given these general fundamental differences in physiology and anatomy between the arterial and venous vessels, it is not reasonable to expect venous device closure to necessarily have similar results to arterial closure.[9–11]

There are some technical considerations for venous preclosure. Since veins are comparatively thin-walled, the amount of tension applied when pulling back the Perclose device is necessarily less than for arterial closure. It is possible to securely contact the vessel wall with the foot of the device while applying steady pressure, with less force than needed for arterial closure. Back-bleeding through the marker port occurs in the vast majority of cases. Due to the lower pressure in the venous system, this is of course less prominent than in arterial closure. Usually, a slow dribbling of blood from the marker port can be noted. There is a delay in the appearance of back-bleeding due also to the low venous pressure, and this may be accentuated by having the patient take in a deep breath or by employing the Valsalva maneuver.

Failure to achieve hemostasis occurred in 2 cases in this series. The potential mechanisms for failure of suture closure include completely missing the vein when the suture was initially deployed, suture breakage, or tearing out of the suture after initial adequate placement. There is no clear way to define the mechanism of failure in most cases. Since a guidewire can be placed through the sheath while the knots are being tied at the end of the procedure, the vessel is secure even when suture failure occurs, and it is possible to replace the sheath and then use conventional compression.

The most fundamental question regarding preclosure for large sheath venous access is whether this procedure is needed at all. Venous access is in a low-pressure system, and initial hemostasis can be achieved easily and rapidly with manual compression in most patients. Even anticoagulated patients may have relatively rapid hemostasis from large-caliber venous punctures. Despite this, prolonged bed rest is sometimes necessary, and in our experience with valvuloplasty patients, both continued oozing and late rebleeding are common enough to make the initial hours of ambulation uncertain from the standpoint of bleeding. Rebleeding from a large-bore venous access site can be substantial in its volume and rapidity. Thus, the immediate and secure hemostasis achieved with suture closure affords more rapid ambulation, shortened bed rest, and greater comfort for both patient and physician in terms of the likelihood of durable hemostasis.

Comparisons of complication rates with those known to occur for arterial closure procedures are not necessarily reasonable. At the same time, the potential for some complications cannot be expected to be different for venous closure.[9–11] For example, no infections occurred in this series, but there is no reason to believe that they should be less frequent than with arterial closure. Venograms to determine the site of entry into the femoral vein were not performed in any of these cases. Venography via the marker port was frequently needed and does not show the sheath entry site. The potential for closure of a branch of the femoral vein, rather than the femoral vein, certainly exists. Thromboembolic complications or venous occlusion are possible, but particularly in a branch vein, may have clinical consequences that are not apparent. None of these complications were encountered in this series.

In conclusion, it has been our experience that the use of a 6 Fr Perclose suture-mediated closure device for venous access sites in antegrade aortic balloon valvuloplasty represents a useful method for achieving immediate hemostasis. Suture-mediated closure may alleviate patient discomfort and allow for quicker time-to-ambulation and discharge.

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