Successful "Pre-Closure" of 7Fr and 8Fr Femoral Arteriotomies With a 6Fr Suture-Based Device (The Multicenter Interventional Closer Registry)

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The arterial sheath remains a cause of vascular complications, restricted mobility, and discomfort in patients who have undergone percutaneous interventional procedures.[1] The rate of vascular complications and bleeding increases with longer sheath dwell times.[2,3] Larger sheath sizes further elevate this risk, as might the administration of antithrombotic agents and intravenous glycoprotein IIb/IIIa inhibitors. Arterial closure devices have been advocated as a means of increasing patient comfort and facilitating rapid ambulation after interventional procedures, while possibly decreasing complication rates.[4] Arterial closure with the 8Fr or 10Fr suture-based Prostar-Plus (Perclose Inc., Redwood City, California) has previously been shown to provide effective hemostasis.[5] Use of the 6Fr suture-based Techstar has been shown to be effective for closure of 6Fr sheaths, but use of the smaller 6Fr device for 7Fr and 8Fr holes has not been systematically examined.[5] Although the 8Fr device can provide hemostasis for 8Fr sheaths effectively, the current version requires subcutaneous dissection with formation of a soft tissue tract from the skin to the level of the artery. Such a tract can lead to continuous oozing, particularly in the presence of glycoprotein IIb/IIIa blockade. Potentially, such a tract may also increase the risk of infection. Therefore, use of a smaller device to close the hole formed by a larger sheath, without the need for tract formation, could represent an advance in suture-based arterial closure. The goal of this study was to determine if such an approach is safe and effective.

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The Closer trial is a prospective registry of 380 patients conducted at 10 centers in the United States from March 2000 to December 2000. Of these, 160 patients undergoing coronary or peripheral intervention through 7Fr to 8 Fr sheaths had percutaneous sutures deployed before sheath placement ("preclose" arm), with tying of sutures after sheath removal. The preclose arm of the Closer trial was prespecified and independently powered for analysis. Informed consent was obtained from all patients. The technique of preclosure involves initial placement of a smaller size sheath than the size intended for the procedure (Figure 1). Specifically, a 6Fr sheath was placed initially. An angiogram of the femoral artery was performed to ensure placement of the sheath above the bifurcation of the superficial femoral artery and the profunda femoris branch. A femoral artery diameter of at least 5 mm and absence of any significant atheroma at the puncture site were required. If these conditions were met, then the sheath was exchanged over a guidewire for the 6Fr Closer device. The device was positioned in the artery, the sutures deployed, and the device removed over the wire, with placement of the 7Fr or 8Fr sheath. The interventional procedure was performed and once completed, the sheath was removed and the sutures tied, obtaining hemostasis. If the operator elected to maintain arterial access during this last step, the wire was reintroduced as the knot was tightened, with the wire removed just before the knot was cinched.

The prespecified historical control consisted of interventional patients randomized to manual compression from the Suture To Ambulate aNd Discharge (STAND II) trial.[5] The primary safety end point was the incidence of 30-day major groin complications, whereas the primary efficacy end point was time to discharge, measured from the time of sheath removal to the time the patient left the hospital. Secondary end points included time to hemostasis and ambulation, as well as device and procedural success. Differences in means were calculated with 95% confidence intervals. Tests of significance were performed using the nonparametric Wilcoxon method. Statistical calculations were performed with Intercooled Stata 6.0 (Stata Corp., College Station, Texas) and Microsoft Excel 5.0 (Microsoft Corp., Redmond, Washington).

The mean activated clotting time was 232 seconds in the Closer patients. There were no significant differences in baseline characteristics, other than more

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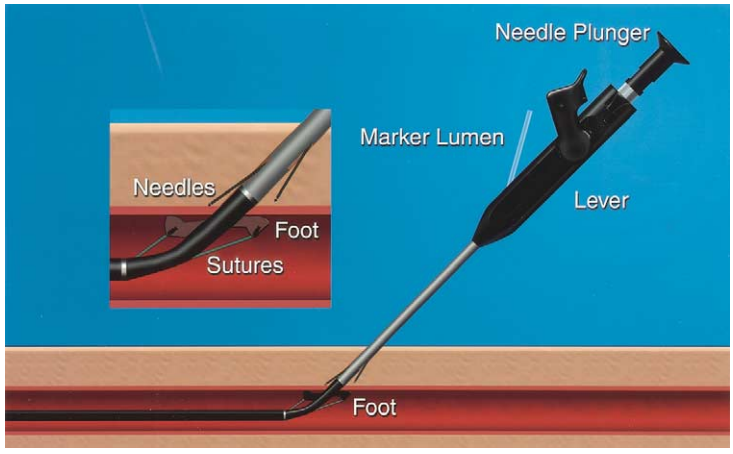

FIGURE 1. Schematic drawing of the 6Fr Closer used for "preclosure" of 7Fr or 8Fr sheaths.

TABLE 1 Baseline Characteristics

Demographics	"Pre-Close" With the Closer (n = 160)	Manual Compression (n = 170)
Age (yrs)	64.2	66.4
Men	70.0%	69.4%
Weight (lb)	182.7	177.0
Systemic hypertension	69.6%	50.6%
Systolic pressure (mm Hg)	144.0	126.6
Diabetes mellitus	22.5%	27.1%
Claudication	4.1%	4.7%
Glycoprotein IIb/IIIa inhibitors	70.4%	20.0%

TABLE 2 Percentage of Patients Experiencing an Adverse Event

	No.(%)
Complication (per event basis)	
Device malfunction	14 (8.8%)
Device complication	1 (0.6%)
Surgical repair*	1 (0.6%)
Transfusion*	1 (0.6%)
Infection—IV antibiotics	1 (0.6%)
Hematoma >6 cm	1 (0.6%)
Pseudoaneurysm	0 (0%)
Infection—IM or PO antibiotics	1 (0.6%)
Retroperitoneal bleed	0 (0%)
Complications (per patient basis)	
Any complication	3 (1.9%)
Major complication	2 (1.2%)
No major complication	158 (98.8%)

*Major complication.
IM = intramuscular; IV = intravenous; PO = oral.

TABLE 3 Efficacy End Points Expressed as Median Times

End Point	"Pre-Close" With the Closer (n = 160)	Manual Compression (n = 170)
Time to hemostasis (min)	1.5	376.0*
Time to ambulation (h)	2.2	18.3*
Time to discharge (h)	22.5	25.2*

*p <0.0001.

use of glycoprotein IIb/IIIa inhibitors in the Closer patients than in the control group (70.4% vs 20%) (Table 1). The rate of device success with the Closer was 89.4%, with successful hemostasis achieved in 98.8% (Table 2). The rate of 30-day major vascular/bleeding complications was 1.2%, which was no different from the control group rate of 1.8% (RR 0.7; 95% confidence interval 0.1 to 6.2) despite the greater use of glycoprotein IIb/IIIa inhibitors in the Closer patients. The efficacy end points, time to discharge, time to hemostasis, and time to ambulation were all significantly better in the Closer patients (Table 3).

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Groin complications remain a major challenge to interventional cardiologists. Although the trend has been to use smaller 6Fr sheaths for femoral procedures, there are still situations that mandate the use of larger size sheaths. Debulking with large rotational atherectomy burrs, thrombectomy devices such as Angiojet and X-Sizer, and some brachytherapy systems all use 8Fr delivery catheters.

Preclosure allows use of a larger sheath than the size of the suture-based closure device. The diameter of suture capture with the 6Fr Closer is larger than an 8Fr hole, thus accommodating stretching of the arteriotomy from 6Fr to 8Fr (Figure 2).[6] Situations in which the technique of preclosure may be particularly useful include before placement of intra-aortic balloon pumps or large sheaths for aortic valvuloplasty or abdominal aortic stent grafts.[7–12] Indeed, with continuing miniaturization of stent-graft technology, the technique of preclosure may allow performance of abdominal aortic stent grafting via an entirely percutaneous approach. Furthermore, the technique of preclosure may move select interventional cardiology procedures 1 step closer to being performed on an outpatient basis.[13]

Other collagen plug or thrombin-collagen closure devices are also available.[14,15] Whereas these devices can also provide effective hemostasis for 8Fr sheaths, a period of bedrest is still required.[16] Furthermore, it is not uniformly possible to reaccess the same groin for a period of 3 months to allow collagen plugs to dissolve. Thus, the 6Fr Closer, when used for 7Fr or 8Fr holes, provides a number of advantages compared with other modalities of arterial closure.

The technique of "preclosing" with the 6Fr Closer safely and significantly improves times to hemostasis, ambulation, and discharge in patients undergoing interventions through 7Fr or 8Fr sheaths, even in the presence of potent concomitant

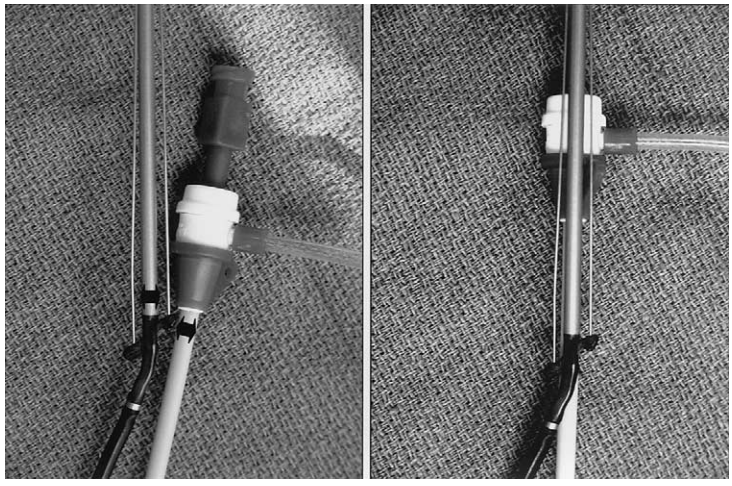

FIGURE 2. Illustration showing that the diameter of suture capture with the 6Fr Closer is larger than an 8Fr sheath.

antithrombotic therapy. "Preclosure" is an effective means of obtaining hemostasis while improving patient comfort after interventional procedures using large femoral sheaths.

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Serum Cardiac Troponin I in Acute Rheumatic Fever

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Acute rheumatic fever (ARF) is a microbially induced autoimmune disease of the connective tissue that mainly affects the joints and heart. Involvement of the heart is the most serious complication and occurs in about 1/2 of cases during the initial attack. The aim of our study was to determine the amount of cardiomyocyte injury in ARF by measuring serial cardiac troponin I (cTnI). We measured serial cTnI in the serum of patients with ARF who had and did not have carditis. We compared their levels to those of age-matched patients with scarlet fever.

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The ARF and scarlet fever sera used in this study were from the Rockefeller University rheumatic fever serum bank. The bank stored sera from the personnel at the Great Lakes Naval Station, where there was an ARF outbreak in 1944. All personnel diagnosed with scarlet fever were enrolled and followed for several

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