Noninvasive Hemostasis Pad

This device is associated with significantly fewer complications after both diagnostic and interventional procedures.

BY BARRY R. ALTER, MD

Control of the arterial access site following percutaneous vascular procedures remains a crucial aspect of both invasive diagnostic and interventional cardiology. Most interventional procedures are performed with 6 to 8F or larger sheaths and frequently involve anticoagulants, fibrinolytic agents, and antiplatelet agents such as ASA (Aspirin, Bayer AG, Leverhausen, Germany), clopidogrel bisulfate (Plavix, Bristol-Myers Squibb, New York, NY), and GP IIb/IIIa platelet inhibitors. This has resulted in an increase in access site complications, a serious problem that can add significant morbidity and even potential mortality to the procedure. Complications have been reported in as much as 14% of patients undergoing interventional procedures.[1-3] These complications may also result in longer hospital stays and increased costs.

INVASIVE ARTERIOTOMY CLOSURE DEVICES

A variety of vascular closure devices can produce hemostasis in a shorter period of time and may allow for earlier ambulation and discharge when compared to manual compression.[3,4] This can be advantageous for the patient, the hospital, and third-party payers. Use of these devices, however, has resulted in a variety of vascular complications, and most patients require a femoral angiogram before placement of the device.[3-6] Hematomas, retroperitoneal bleeding, arterial occlusions, significant drops in hematocrit, and pseudoaneurysms have been reported. *The Gray Sheet* quoted an FDA finding of 1,879 serious injuries and 36 deaths related to arteriotomy closure devices.[6]

One study examined the incidence of vascular complications with manual compression compared to that of four leading arteriotomy closure devices: Angio-Seal (St. Jude Medical, St. Paul, MN), Vasoseal (Datascope, Montvale, NJ), Duett (Vascular Solutions, Minneapolis, MN), and Perclose (Abbott Laboratories, Abbott Park, IL).[7] Hematomas occurred in 9.3% of cases involving a closure device compared to 5.1% of cases with manual compression ($P<0.001$).

TABLE 1. DIAGNOSTIC PROCEDURES

Total Number of Cases:	1,170
Sheath Size:	5F: 519 6F: 614 7F: 6
Medications:	Chronic Aspirin: 418 Chronic Aspirin and Plavix: 62 Heparin: 19
Time to Hemostasis:	10 minutes or Less: 1,062 12-20 minutes: 108
Time to Ambulation:	90 minutes: 336 120 minutes: 272 180 minutes: 223 240 minutes: 339

TABLE 2. COMPLICATIONS

Pseudoaneurysms:	2
Rate of Complications:	0.17%

Five and two-tenths percent of patients treated with a closure device experienced more than a 15% decrease in hemocrit, compared to 2.5% with manual compression (P<0.001). The necessity for vascular surgical repair was 2.5% using a closure device and 1.5% using manual compression (P = 0.03). These data confirm other findings demonstrating that the above devices have increased complication rates compared to manual compression.[3-8]

NONWOVEN, HYDROPHILIC WOUND DRESSING

To address these problems, a soft, nonwoven, hydrophilic wound dressing has been developed. The Clo-Sur PAD (Scion Cardio-Vascular, Miami, FL) consists of naturally occurring biopolymer polyprolate acetate. This linear biopolymer is cationically charged, and this chain of positive charges gives it potent coagulating properties. The device has received FDA clearance for use in local management of bleeding wounds such as vascular-access sites. It provides an inexpensive, simple, and safe alternative to other closure devices and could potentially reduce vascular complications, shorten time in the recovery area, and decrease throughput time. In addition, it can potentially decrease time to ambulation and discharge for patients undergoing percutaneous vascular procedures.

The technique for using the Clo-Sur PAD is as follows. Hold proximal pressure above the puncture site, and then remove the sheath. Place the device over the puncture site and continue to hold proximal pressure. Allow a small

TABLE 3. INTERVENTIONAL PROCEDURES

Total Number of Cases:	316
Sheath Size:	6F: 312 7F: 4
Medications:	Chronic Aspirin: 208 Chronic Aspirin and Plavix: 58 Plavix loading dose postintervention: 258 Aspirin postintervention: 106 2B3A Inhibitor: 298 Heparin: 312 (4,000-7,000 units, ACT: 153-226 seconds) Thrombolytics prior to intervention: 26
Time to Hemostasis:	10 minutes: 266 15-20 minutes: 50
Time to Ambulation:	4 hours: 228 6 hours: 64 After 6 hours, due to medical instability: 21 After 6 hours, due to hematomas: 3

TABLE 4. COMPLICATIONS

Hematomas:	3* (One required transfusion and surgery for femoral artery laceration; the other two required transfusions)
Pseudoaneurysms:	3
Total Complications:	6
Rate of Complications:	1.9%

** All three hematomas were in very obese, elderly females. Hemostasis was difficult to obtain during sheath removal.*

TABLE 5. INTRA-AORTIC BALLOON SHEATH REMOVAL	
Total Number of Cases:	3
Sheath Size:	8F: 3
Medications:	Aspirin: 3 Plavix: 3 ReoPro (Eli Lilly, Indianapolis, IN) bolus followed by infusion: 3 Heparin stopped prior to removal: 3 (ACT: 110-130 seconds)
Duration of Sheath:	48 hours: 2 72 hours: 1
Time to Hemostasis:	10 minutes: 3
Complications:	0

TABLE 6. TOTAL OF ALL CASES	
Total Number of Cases:	1,488
Total Number of Complications:	8
Rate of Complications:	0.50%

amount of blood to contact the pad, then hold constant pressure for a minimum of 10 minutes. More time may be required depending on sheath size and ACT. Next, release the pressure and confirm hemostasis. Cover the site with a sterile dressing and leave it in place for 24 hours. After removal, the Clo-Sur PAD will dissolve in water.

Investigators have gained experience with the Clo-Sur PAD in both an outpatient setting (Heart and Vascular Center of Hollywood, FL) and with inpatients undergoing diagnostic cardiac catheterizations (Tables 1 and 2) or who had just undergone interventional procedures (Tables 3 and 4) at the Memorial Regional Hospital in Hollywood, Florida. The PAD was also used in 3 patients undergoing the removal of intra-aortic balloon sheaths (Table 5). Complications were defined as hematomas that required intervention, transfusion, or delayed discharge, hematocrit drop greater than 15%, retroperitoneal bleeding, pseudoaneurysm, arteriovenous fistula, or the necessity for any surgical intervention.

REDUCED COMPLICATIONS

Published data report vascular complication rates of as much as 6% for diagnostic procedures and from 2.5% to 14% for interventional procedures.[2-8] Most reports suggest higher rates of complications with the use of currently available closure devices.[7] Overall, the incidence of significant complications in these 1,488 cases using the Clo-Sur PAD was 0.17% for diagnostic procedures and 1.9% for interventional procedures. The complication rate for all patients combined was 0.50% (Table 6). These rates are well below the lower range of vascular complications in any reported study for both diagnostic and interventional procedures.

These data confirm the efficacy, usefulness, and low complication rate of the Clo-Sur PAD in patients who have undergone procedures involving femoral arteriotomy. Unlike other closure devices, the Clo-Sur PAD is totally noninvasive and in comparison, it is very effective, considerably less expensive, and apparently associated with a significantly lower incidence of serious complications. ■

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