Can the Perclose suture-mediated closure system be used safely in patients undergoing diagnostic and therapeutic angiography to treat chronic lower extremity ischemia?

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Purpose: Mechanical closure devices for arterial hemostasis after angiography, such as the Perclose suture-mediated closure system, are designed to decrease time to ambulation and improve patient comfort. Although these devices are safe and efficacious, to date there has been little reported about use of the Perclose device in a cohort consisting exclusively of patients with lower extremity peripheral vascular disease. The purpose of this study was to determine the safety and efficacy of routine use of the Perclose system in patients with documented peripheral vascular disease undergoing angiography to treat chronic lower extremity ischemia.

Methods: The Perclose device was placed for arterial closure after femoral artery access in 500 consecutive patients with documented peripheral vascular disease (ankle-brachial index, <0.8) who underwent diagnostic angiography or percutaneous intervention because of chronic lower extremity ischemia. These 500 patients composed 91% of all patients who underwent angiography because of chronic lower extremity ischemia between January 1, 2001, and April 1, 2002. All complications associated with the Perclose device were identified and reviewed.

Results: Of the 500 arteries, 54% were accessed for diagnostic angiography and 46% for intervention. Perclose device placement was successful in 475 attempts (95%). Overall major complication rate was 1.4% (7 of 500 arteries). Complications included one death from retroperitoneal hemorrhage; three episodes of limb ischemia, two requiring operation and one requiring lytic therapy; two pseudoaneurysms; and one hematoma, which prolonged hospitalization. The hematoma was the only complication in the 25 patients with failed Perclose device placement. There were no infections requiring admission or operation.

Conclusion: The Perclose suture-mediated closure device is efficacious and can be used safely in selected patients with documented peripheral vascular disease. Complications associated with this device tend to be more severe than those historically reported for manual compression. Substantial experience with use of this device is required to achieve excellent results in patients with difficult anatomy. (J Vasc Surg 2003;38:1305-8.)
pain, foot ulcer or gangrene, with associated ankle-brachial index less than 0.5.

Successful device deployment was defined as complete arterial hemostasis without need for extended additional manual compression. Successful device deployment was still reported if manual compression was necessary for only a short time (<2 minutes) to stop the minimal venous bleeding that may occur just after the procedure is completed.

A major complication was defined as an event that required either repeat intervention, operation, admission for 24 hours or longer compared with that initially planned, blood transfusion, or intravenous antibiotic therapy. Small hematomas and skin ecchymoses not requiring transfusion or prolonged admission were not listed as major complications.

**Exclusion criteria.** To develop a patient population as homogenous as possible, all patients with acute exacerbation of chronic lower extremity ischemia and all patients who underwent thrombolysis as part of the intervention were excluded from the study. We routinely use the Perclose suture-mediated closure device in such patients. It was concluded that several factors inherent in these patients, such as extended sheath insertion time in patients undergoing lysis and the higher percentage of such patients who require emergent surgery, might bias the results of the study and shift focus away from those patients that the study was primarily designed to include. Additional exclusion criteria included aneurysmal disease and brachial artery access rather than common femoral artery access for arteriography.

**Procedure.** The 6F (Closer) device and the 8F and 10F (Prostar) devices were used in the study. These devices function through placement of two or four suture-bearing needles through the arterial wall around the puncture site. After removal of the arterial sheath the device is tracked over the diagnostic guide wire into the artery. Accurate depth of the device is confirmed with pulsatile blood return from the device marker lumen. The needles are then deployed through the artery. The sutures are tied by hand or with a knot-tying device. Once the knot is preliminarily tied above the skin level, the device is removed and the knot is cinched down onto the artery. This closes the arteriotomy and achieves hemostasis. The remaining free suture is then cut just above the knot, and a dressing is placed on the wound. All patients who received a Perclose device in this study were required to remain supine in bed for 2 hours. All patients in whom Perclose placement failed were kept in bed for a minimum of 6 hours after 20 minutes of manual compression.

All physicians involved in the study had substantial experience with use of the Perclose device before the study. All patients who underwent diagnostic angiography or percutaneous intervention with a femoral artery approach were considered for placement of a Perclose device. In general, approximately 91% of patients (500 of 550) who underwent angiography received a Perclose device at the end of the procedure. Reasons for not placing a Perclose device included imminent open bypass procedure with the punctured femoral artery as an inflow or outflow vessel, puncture that was believed to be too close to the femoral bifurcation for safe placement of a closure device, presence of a bypass graft sewed to the punctured femoral artery, and physician judgment that there was too much scarring in the groin accessed or calcification in the artery punctured to safely allow placement of a closure device. These factors are relative contraindications to use of a Perclose device. All patients received pre-procedure antibiotic therapy, and all patients who underwent intervention received peri-procedure heparin and post-procedure antiplatelet therapy.

**RESULTS**

Of 500 arterial procedures, 270 arteries (54%) were accessed for diagnostic angiography and 230 arteries (46%) were accessed for an interventional procedure. The right common femoral artery was more commonly accessed (60%) than the left common femoral artery (40%). Of the 230 arteries accessed for an interventional procedure, 52% involved aortoiliac occlusive disease and 48% involved infrainguinal atherosclerotic vascular disease. Sheath size ranged from 5F to 10F, with 5F the most common size (64%). The most commonly placed Perclose device was the 6F Closer device (73%).

Placement of the Perclose device was successful in 475 of 500 (95%) attempts. In the 25 arteries in which the attempt failed, manual compression was used to attain arterial hemostasis in 21 patients and an alternative arterial closure device was used in 4 patients. Of the 25 patients with failed Perclose device placement, 15 attempts failed as a result of inability to deliver the device into the artery secondary to presence of scar tissue (n = 12) or heavy calcification (n = 3). In four patients the device did not deploy as expected, with difficulty in needle deployment or a question of device fracture. In the remaining six patients the device was deployed, but successful hemostasis was not achieved, and additional manual compression was necessary.

Seven major complications occurred, for an overall rate of 1.4% (7 of 500). Complications included one death secondary to retroperitoneal hemorrhage. Three patients had ipsilateral lower extremity ischemic events; surgical intervention was required in two of these patients, and lysis was necessary in one patient. The two patients who required surgical intervention to treat ischemia had bypass grafts originating from the common femoral artery in the groin in which the Perclose device was placed. Deployment of the device caused occlusion of the femoral artery, which required surgical intervention in both patients. Two pseudoaneurysms were identified; one warranted a surgical procedure, and one was managed with thrombin injection. Post-procedure hematoma in a single patient was the only complication that occurred in the 25 patients with failed Perclose placement. In five of seven patients with complications, arteries had been previously accessed or surgically exposed. No patients in the study group required readmi-
sion to the hospital or surgery because of groin infection after placement of a Perclose device.

**DISCUSSION**

Arterial closure devices for arterial hemostasis have been developed in response to the quickly growing field of percutaneous therapy for both coronary and peripheral arterial occlusive disease. Most of these procedures are performed with common femoral artery access. Hemostasis at the access site with manual compression is uncomfortable for the patient and requires prolonged bed rest. Closure devices are designed to increase patient comfort and decrease time to ambulation. Suture-mediated devices are designed to mechanically close the arteriotomy site with placement of a stitch through the arterial wall. Manufacturing guidelines recommend that these devices not be used in the setting of significant femoral arterial occlusive or calcific disease. Most studies of the safety and efficacy of these devices have been in patients with coronary artery disease who have undergone cardiac catheterization. The present study examined a patient population with chronic lower extremity ischemia who underwent diagnostic or therapeutic angiography. The goal of this review was to determine whether routine use of a suture-mediated closure device in this patient population could be accomplished efficaciously, with acceptable morbidity and mortality.

Successful deployment of the Perclose device was achieved in 95% of patients. This rate is consistent with rates reported in patients without documented peripheral vascular disease. In patients in whom placement attempts failed, inability to guide the delivery system into the artery was the most common reported problem. This difficulty is often encountered in vessels that have been previously accessed or surgically exposed. In our opinion, an aggressive approach toward Perclose device deployment in this group of patients requires substantial experience in use of these devices to avert a high complication rate. Of interest is that in the 25 patients with failed Perclose device placement there was only one complication. On the basis of these results, it appears that hemostasis can still be achieved safely after a failed attempt to place a Perclose device.

The overall 1.4% major complication rate is similar to that in previous reports involving patients in whom arteries were accessed for reasons other than chronic lower extremity ischemia. Two of seven patients in whom a complication occurred had a graft anastomosis to the femoral artery that was punctured. Difficulty with identification of the exact location of the hood of a graft in relation to the site of arterial puncture should make one hesitant to place a suture-mediated closure device.

None of the patients in this study had a major groin infection after Perclose placement. That all patients were given a single dose of intravenous antibiotic before the procedure may be a contributing factor. Although the incidence of infection after placement of a Perclose device has been low, the reported major consequences of such infection may be sufficient indication for pre-procedure antibiotic therapy.

Although this study included 500 consecutive patients who received a Perclose device after arteriography because of lower extremity ischemia, not every patient who underwent arteriography because of lower extremity ischemia during the study period underwent an attempt at placement of a Perclose device. Placement of a Perclose device was at the discretion of the physician. Approximately 9% of patients (50 of 550 consecutive patients) who underwent angiography or percutaneous intervention with a femoral artery approach did not receive a Perclose device. Reported reasons included presence of a bypass graft in the groin accessed for the procedure, severe groin scarring, puncture site thought too close to the femoral bifurcation for safe closure device placement, severe calcification, or reluctance to place a Perclose into an artery in a patient who was scheduled to undergo imminent bypass grafting with use of the femoral artery as the inflow or outflow vessel. Selection of the patient population reviewed may have improved our results, because the Perclose device was not placed in those patients whom the clinicians believed had little chance for successful device deployment or who were most at risk for complications.

The results of this study show that the Perclose suture-mediated closure device is effective and can be used safely in selected patients with documented peripheral vascular disease. We also found that use of the Perclose device in our patients improved patient comfort and shortened time to ambulation and discharge. Aggressive use in patients with scarred groins or heavily calcified arteries is best reserved for clinicians with extensive experience in deployment of these devices. We define extensive experience as 10 or more device deployments in normal arteries or 30 deployments in anatomically difficult arteries or scarred groins. It must also be emphasized that complications associated with this device often are more severe than those associated with manual compression. In this study, three of seven patients with complications required repeat interventions, and one patient died. Caution is particularly required when considering use of a suture-mediated closure device when the accessed femoral artery has a bypass graft anastomosis, unless imaging studies clearly demonstrate that the arterial puncture site is remote to the bypass graft hood. Pre-procedure antibiotic therapy and careful attention to sterile technique may help minimize potentially devastating infectious complications.

**REFERENCES**


