Percutaneous Endovascular Abdominal Aortic Aneurysm Repair

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In this prospective, nonrandomized study, we compared outcome with percutaneous femoral artery closure to that with open femoral arteriotomy in 95 patients who underwent endovascular AAA repair. Devices were introduced using 22 Fr and/or 16 Fr sheaths. The 8 Fr/10 Fr Perclose devices (Perclose Inc., Redwood City, CA) were used in an off-label “preclose technique.” Thirty-three patients had bilateral open femoral arteriotomies, 44 patients had bilateral attempted percutaneous closure, and 18 patients had open femoral arteriotomy on one side and attempted percutaneous closure on the other side. Percutaneous closure was successful in 85% (47/55) of 16 Fr sheaths and 64% (29/45) of 22 Fr sheaths (p < 0.027). Bilateral percutaneous closure was successful in 63% (28/44) of patients. Conversion to open femoral arteriotomy due to bleeding occurred in 24 of 106 percutaneous attempts. There were no dissections, arterial thromboses, or pseudoaneurysms associated with percutaneous arterial closure. Wound complications were seen in 3.6% (3/84) of open arteriotomies and 0.9% (1/106) of all percutaneous attempts and arterial closures (p > 0.05). Gender, previous femoral access, obesity, and iliac occlusive disease were not predictive of percutaneous failure. Procedural success for percutaneous AAA repair is affected by sheath size. Devices delivered through 16 Fr or smaller sheaths will have successful femoral artery closure rates of at least 85%.

INTRODUCTION

Percutaneous suture devices are routinely used for femoral artery closure following diagnostic and therapeutic cardiac and peripheral arteriography. Successful hemostasis at the femoral access sites after intervention decreases time to ambulation, decreases length of stay, and increases patient comfort. In randomized trials comparing manual compression to the Perclose Prostar device, equivalent hemostasis after catheterization and no significant difference in infection rates have been reported. Vascular complications using the Prostar device are uncommon and include failed hemostasis with hematoma, infection, pseudoaneurysm, device malfunction, and arterial thromboses. Arterial complications following 6 Fr and 8 Fr punctures requiring vascular surgical repair are uncommon. Interventional techniques to treat occlusive and aneurysmal disease of the aorta and iliac vessels require large-bore (≥16 Fr) vascular access. Suture-mediated percutaneous closure of large-bore access sites has been described using the “preclose technique.” The Perclose Prostar XL device (Perclose Inc., Redwood City, CA) is placed before passage of the large delivery sheath and vascular intervention to ensure adequate purchase of the artery wall. Percutaneous endovascular an-
eurysm repair is technically feasible\(^1\) using a modification of the currently available Federal Drug Administration (FDA) approved femoral closure device, Prostar XL (Perclose). In this study, we compared the outcome of endovascular aortic aneurysm repair using open femoral arteriotomy with that using percutaneous closure of large-bore femoral access.

**PATIENTS AND METHODS**

Between January 1999 and August 2000, 150 patients underwent aortic aneurysm repair in an operative endovascular suite. Patients undergoing open aneurysm repair (\(n = 38\)) and thoracic aneurysm repair (\(n = 2\)) were excluded. Patients with prohibitively small-access vessels with an overall lumenal diameter \(\leq 6\) mm, who were not candidates for open aneurysm repair were treated with a retroperitoneal conduit, aortouniliac endograft and femoral-femoral bypass (\(n = 15\)) and were also excluded. In this prospective, nonrandomized, independent study we examined the femoral artery closure method of the remaining 95 patients (75 men, 20 women, mean age 74 years) who underwent endovascular abdominal aortic aneurysm (AAA) repair. The approach for femoral artery closure, percutaneous versus open femoral arteriotomy, was the primary surgeon’s choice. All patients met current surgical indications for aneurysm repair with a mean aneurysm (AAA) size of 5.8 cm. Demographic data were collected from a database registry. Operative notes were reviewed retrospectively. Factors that may have affected successful percutaneous closure—patient gender, obesity, iliac occlusive disease, diabetes, recent femoral access, and sheath size—were noted. Operative time, blood loss, transfusion requirements, length of stay, wound complications, return to normal activity, and morbidity and mortality were recorded.

Clinical follow-up was obtained at 1 week, 1 month, and then every 6 months and ranged from 6 to 20 months, with a mean of 12 months. Computed tomography (CT) of the abdomen/pelvis, including the femoral vessels, and abdominal plain films were obtained at 30 days and biannually. Ankle-brachial indices (ABIs) were recorded prior to and after endovascular aneurysm repair. Intravascular ultrasound and preoperative arteriography were reviewed retrospectively for the patients in whom percutaneous closure failed. The Rand 36-Item Health Survey\(^4\) was distributed to patients with planned bilateral arteriotomy and successful bilateral percutaneous closure at discharge. Surveys were returned at the first postoperative visit.

All endografts were delivered via Cook (Bloomington, IN) 22 Fr and 16 Fr introducer sheaths. The sheaths were placed after deployment of the Perclose Prostar XL devices using a preclose technique in the patients treated percutaneously. The introducer sheaths remained in place until completion of the aneurysm repair, serving as the platform for multiple catheter and wire exchanges. Two Prostar XL devices were used for each attempted large-bore percutaneous closure. The endovascular grafts used included both FDA-approved manufactured devices Aneurx, in 88 patients (Medtronic, Sunnyvale, CA), and Ancure, in 2 patients (Guidant Corp., Menlo Park, CA). Five additional patients were repaired using a custom stent graft approved by the Investigational Review Board of Baptist Hospital East (Louisville, KY) and the FDA under an Investigational Device Exemption. The custom graft is constructed using balloon-expanded 10-mm polytetrafluoroethylene (PTFE) (Bard-Impra, Tempe, AZ) sutured over a Gianturco Z-stent (Cook) endoskeleton. Eighty-five bifurcated systems were delivered through 22 Fr and 16 Fr sheaths. Ten tube grafts were deployed from a single large-bore (22 Fr) sheath with an 8 Fr contralateral femoral sheath for diagnostic access.

Eighty-nine of the study patients underwent preoperative angiography and intravascular ultrasound through an 8 Fr femoral sheath that was closed percutaneously using a Prostar XL device within 2 months of aneurysm repair. Access vessel diameters and stenoses were measured. In six patients the iliofemoral vessels were evaluated only by CT scan. These patients were repaired emergently or their diagnostic studies were performed at an outside facility. Thirty-four patients with stenoses of the iliofemoral vessels (<7 mm) requiring angioplasty or sequential dilatation to allow passage of the delivery sheaths were identified and included in the study. There were no femoral artery aneurysms.

Data were organized according to sheath size and femoral artery approach—percutaneous versus standard open femoral arteriotomy. To identify characteristics predicting successful percutaneous closure, retrospective data were recorded including patient gender, comorbidities, height and weight, recent femoral access and iliofemoral occlusive disease, and whether dilation and/or stent placement was required to allow access for endovascular aneurysm repair. Primary percutaneous closure rates of 8 Fr punctures following preoperative diagnostic arteriography and intravascular ultrasound were used as a control. The chi-squared test, Fischer’s exact test, and analysis of variance