Percutaneous repair of abdominal aortic aneurysm

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Objective: Percutaneous treatment of an abdominal aortic aneurysm (AAA) is feasible, but is associated with a unique set of risks. A comparison of Excluder endograft deployment with femoral artery cutdown (FAC) versus percutaneous femoral access (PFA) for treatment of infrarenal AAA was undertaken.

Methods: A single-institution, controlled, retrospective review was carried out in patients who underwent either bilateral FAC or bilateral PFA for endovascular repair of infrarenal AAA with the Gore bifurcated Excluder endograft between March 1999 and November 2003. To November 2000, 35 patients underwent bilateral FAC; since then, 47 patients have undergone bilateral PFA. All have been followed up for at least 30 days.

Results: Mean AAA size was 5.7 cm in the FAC group and 6.0 cm in the PFA group. During hospitalization there were six access-related complications in the FAC group; three required early surgical intervention. In the PFA group nine perioperative access-related complications occurred, all consisting of either hemorrhage or arterial occlusion; seven required additional intervention, and were recognized and ameliorated while the patient was still in the operating room.

At 30-day follow-up there were no additional access-related complications in the PFA group. There were eight other access-related complications in eight additional patients who underwent FAC. In patients undergoing bilateral PFA total operative time was shorter (PFA 139 minutes vs FAC 169 minutes; P = .002), total in-room anesthesia time was less (PFA 201 minutes vs FAC 225 minutes; P < .008), and use of general anesthesia was reduced (P < .001). No significant differences were observed between groups with respect to estimated blood loss (PFA 459 mL vs FAC 389 mL; P = .851).

Conclusion: Complete percutaneous treatment of AAA may have some advantages over open femoral artery access, but it is not free from risk. Percutaneous treatment of AAA can be completed successfully in most patients, but should be performed at an institution where conversion to an open procedure can be completed expeditiously if necessary. (J Vasc Surg 2004;40:12-6.)

With Food and Drug Administration approval, endograft repair of abdominal aortic aneurysm (AAA) is rapidly gaining widespread clinical acceptance. Four commercially available devices have been approved for general use. Thoracic endografts are undergoing refinement and are not yet available commercially, but some industry manufactured investigational devices are being used to treat thoracic aortic aneurysm, dissection, and traumatic transection, with institution-specific investigational device exemptions.

All of these devices are placed, at least in part, through relatively large (18F-24F) sheaths, and must be positioned appropriately within the aorta after the sheaths are passed through access sites in the common femoral or iliac vessels.

With few exceptions, this type of access has traditionally required open surgical exposure; the sheaths are passed through an open arteriotomy after vascular clamps are applied to control the vessels. In general, this process is safe, but it must be performed by practitioners experienced in open surgical technique. In many institutions open femoral artery exposure mandates operating room availability and general or spinal anesthesia. Furthermore, open arterial access is not without potential for complication.

With smaller access sheaths and with the development of certain arterial closure devices, the complete percutaneous treatment of AAA with local anesthesia has become feasible.1-4 In addition, percutaneous endoluminal treatment of thoracic aortic disease is a viable option. Potential advantages to percutaneous endograft deployment include shorter procedure time, better patient acceptance, earlier ambulation, and reduced risk for wound complications. However, percutaneous sheath placement has its own unique set of risks. For the past 3 years we have made an attempt to place all infrarenal aortic devices and a select few thoracic endovascular grafts with percutaneous techniques.

For the last 5 years we have maintained a prospective database that has enabled us to compare and contrast patients who have undergone placement of the bifurcated Gore-Tex Excluder infrarenal endograft (W. L. Gore & Associates) via percutaneous femoral access (PFA) with a historic control group of patients who received the same device via femoral artery cutdown (FAC) for treatment of infrarenal AAA.

METHODS

Eighty-two consecutive patients who underwent endovascular repair of an AAA at Northwestern Memorial Hospital with the Gore Bifurcated Excluder endograft between March 1999 and November 2003 were studied for evidence of access-related complications. One hundred fourteen other industry-manufactured devices (Guidant Ancure, n = 47; Medtronic AneuRx, n = 65; Cook Zenith, n
incisions with a pre-closure technique with a 10F Prostar device after a tract is cleared through the super access site. The sheath is then exchanged for the Prostar 18-gauge needle. A standard J-wire is positioned in the procedure percutaneously, arterial access is initiated with an arteriotomy is created, and the appropriate sheath (12F units) is administered, the vessels are clamped, an arteriotomy is created, and the appropriate sheath (12F × 30 cm [inner diameter, 0.162 ± 0.004 in/–0 in; outer diameter, 0.185 ± 0.002 in] or 18F × 30 cm [inner diameter, 0.212 ± 0.002 in; outer diameter, 0.242 ± 0.003 in/–0.001 in]) is passed through the opening under direct vision. When the procedure is complete, the sheaths are removed, noncrushing vascular clamps are reapplied, and the arteriotomy is repaired with interrupted, fine monofilament suture.

Percutaneous access was performed through small stab incisions with a pre-closure technique with a 10F Prostar XL device (Perclose; Abbott). When performing the procedure percutaneously, arterial access is initiated with an 18-gauge needle. A standard J-wire is positioned in the aorta, and a short 6F or 8F sheath is placed to pre-dilate the access site. The sheath is then exchanged for the Prostar device after a tract is cleared through the superficial soft-tissue, down to the artery, using a hemostat or a finger. The two Perclose 3-0 braided polyester sutures (one device) are deployed before placement of the endograft deployment sheaths (12F and 18F), and are left untied to rest on the patient in radial orientation until after the endograft deployment is complete. Patients undergoing percutaneous access are also administered intravenous heparin for device deployment, but in doses smaller than for FAC (1000-3000 units). When the procedure is complete, the sheaths are removed while an assistant maintains proximal pressure manually. The sutures are generously soaked with heparinized saline solution and tied with a slipknot or a standard surgeon’s knot while manual pressure is maintained. The incisions are closed with a single suture or a Steri-Strip.

All patients in the two groups underwent physical examination and determination of ankle-brachial index preoperatively, postoperatively in the recovery room, and daily during hospitalization. Outpatient follow-up consisted of evaluation at 1, 6, and 12 months, and yearly thereafter. All 82 patients attended 1-month follow-up, in which they underwent complete physical examination with determination of ankle-brachial index, plain abdominal radiography, and abdominal computed tomography. Eight patients died during follow-up, at 4, 5, 9, 14, 15, 19, 24, and 36 months, of cancer (n = 3), myocardial infarct (n = 2), respiratory failure (n = 2), and hip fracture (n = 1). Of 82 patients, 69 have attended 6-month follow-up.

Primary end points were any access-related complication, including infection, bleeding, arterial occlusion, arterial emboli, arterial dissection, femoral neuropathy, lymphocele, leg pain, and leg edema. Secondary end points included total operative time, total anesthesia time, type of anesthesia used, estimated blood loss, transfusion requirement, time to first oral intake, time to first ambulation, and hospital length of stay.

Data are expressed as mean ± SEM. Differences between the two groups were determined with the Student t test for normally distributed data, and the Mann-Whitney rank sum test for nonparametric data. The χ2 test or Fisher exact test was used to compare nominal variables between the two groups. Statistical significance was assumed at P < .05. Statistical analysis was performed with Sigma Stat (SPSS).

RESULTS

Mean aneurysm size was 5.7 cm in the FAC group and 6.0 cm in the PFA group. There were no significant differences with respect to demographic data or patient comorbid conditions between the two groups (Table 1). In the immediate postoperative period six patients (17%) in the FAC cohort had access-related complications (Table II). Complications included groin hematoma (n = 2) and femoral artery dissection, wound infection, femoral nerve injury, and occlusion of a femoropopliteal artery bypass graft (n = 1 each). Three complications (dissection, groin hematoma, graft occlusion) required returning the patient to the operating room for further treatment.

In the PFA group, access-related complications occurred more frequently (n = 9, 19%) during the immediate postoperative period compared with the FAC cohort (Table II). All PFA complications were the result of hemorrhage (n = 7) or arterial occlusion (n = 2). Seven of the nine complications (both arterial occlusions, five incidences of hemorrhage) required immediate additional surgical intervention. All seven complications were recognized and ameliorated after the index operation before the patient was
allowed to leave the operating room. We were unable to determine retrospectively whether the patients with perioperative events had particular risk factors that predisposed them to complications.

During the index hospitalization some patients in each group required blood transfusion (FAC group 4 [11%] vs PFA group 6 [13%]). No access-related complications were detected, and no apparent source of bleeding was identified in more than half of these patients (FAC group 3 vs PFA group 2). The remaining blood transfusions were required secondary to access-related complications (FAC group 1 vs PFA group 4). In the FAC cohort one patient required transfusion secondary to blood loss incurred during repair of a common femoral artery (CFA) dissection. In the PFA cohort two patients received transfusions secondary to blood loss incurred during thrombectomy of a CFA thrombosis. Two other patients in the PFA group received blood transfusions because of bleeding of the CFA secondary to failed pre-close technique. These numbers are too small to make any generalizations or reach any statistical conclusions.

An analysis of total operative time, anesthesia time, estimated blood loss, time to first oral intake, time to first ambulation, and hospital length of stay was conducted (Table III). Patients undergoing bilateral PFA had shorter total operative time (PFA 139 minutes vs FAC 169 minutes; \( P < .002 \)), reduction in total in-room anesthesia time (PFA 201 minutes vs FAC 225 minutes; \( P = .008 \)), and reduction in the use of general anesthesia (\( P = .001 \)). No significant differences were observed between the groups with respect to estimated blood loss (PFA 459 mL vs FAC 389 mL; \( P = .851 \)), time to first oral intake (PFA 0.17 days vs FAC 0.46 days; \( P = .065 \)), time to first ambulation (PFA 0.81 days vs FAC 0.80 days; \( P = .704 \)), or hospital length of stay (PFA 1.49 days vs FAC 1.89 days; \( P = .411 \)).

At 30-day follow-up, no additional access-related complications were detected in the PFA group (0%). However, there was a higher frequency of access-related complications in the FAC group; eight additional access-related complications were detected in eight additional patients (23%) in the FAC group (Table IV). Late complications included femoral neuropathy (n = 3), lymphocele (n = 3),

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### Table I. Patient demographic data

<table>
<thead>
<tr>
<th></th>
<th>Bilateral femoral artery cutdown</th>
<th>Bilateral percutaneous femoral access</th>
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<tbody>
<tr>
<td></td>
<td><strong>n</strong></td>
<td><strong>%</strong></td>
</tr>
<tr>
<td>No. of patients</td>
<td>35</td>
<td>47</td>
</tr>
<tr>
<td>Mean age (y)</td>
<td>74</td>
<td>75</td>
</tr>
<tr>
<td>Patient weight (kg)</td>
<td>85.1</td>
<td>84.8</td>
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<tr>
<td>Mean AAA size (cm)</td>
<td>5.7</td>
<td>6.0</td>
</tr>
<tr>
<td>Male gender</td>
<td>33</td>
<td>94</td>
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<tr>
<td>Hypertension</td>
<td>20</td>
<td>57</td>
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<tr>
<td>Coronary artery</td>
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<td>57</td>
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<tr>
<td>Cerebrovascular disease</td>
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<tr>
<td>Diabetes</td>
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<td>20</td>
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<td>Renal dialysis</td>
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<td>Hypercholesterolemia</td>
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<td>Current tobacco use</td>
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<td>23</td>
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<td>Bleeding disorder</td>
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<td>0</td>
</tr>
<tr>
<td>Current steroid use</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>History of claudication</td>
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AAA, Abdominal aortic aneurysm; COPD, chronic obstructive pulmonary disease.

### Table II. Access complications detected during immediate postoperative period

<table>
<thead>
<tr>
<th></th>
<th>Bilateral femoral artery cutdown ( (n = 35) )</th>
<th>Bilateral percutaneous femoral access ( (n = 47) )</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bilateral femoral artery cutdown</td>
<td>Bilateral percutaneous femoral access</td>
</tr>
<tr>
<td>CFA dissection*</td>
<td>CFA occlusion*</td>
<td>CFA occlusion*</td>
</tr>
<tr>
<td>Femoropoplitical graft</td>
<td>CFA occlusion*</td>
<td>CFA occlusion*</td>
</tr>
<tr>
<td>occlusion*</td>
<td>CFA occlusion*</td>
<td>CFA occlusion*</td>
</tr>
<tr>
<td>Groin hematoma*</td>
<td>CFA bleed*</td>
<td>CFA bleed*</td>
</tr>
<tr>
<td>Wound infection</td>
<td>CFA bleed*</td>
<td>CFA bleed*</td>
</tr>
<tr>
<td>Groin hematoma</td>
<td>CFA bleed*</td>
<td>CFA bleed*</td>
</tr>
<tr>
<td>Femoral nerve injury</td>
<td>CFA bleed*</td>
<td>CFA bleed*/scrotal hematoma</td>
</tr>
<tr>
<td></td>
<td>CFA bleed*</td>
<td>Groin hematoma</td>
</tr>
<tr>
<td></td>
<td>CFA bleed*</td>
<td>Groin hematoma</td>
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</tbody>
</table>

CFA, Common femoral artery.

*Required repeat operation.

Table III. Operative and postoperative outcomes

<table>
<thead>
<tr>
<th></th>
<th>Bilateral femoral artery cutdown ( (n = 35) )</th>
<th>Bilateral percutaneous femoral access ( (n = 47) )</th>
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<tr>
<td>Total operative time</td>
<td>169</td>
<td>139</td>
</tr>
<tr>
<td>Time to first oral intake (d)</td>
<td>0.46</td>
<td>0.17</td>
</tr>
<tr>
<td>Time to first ambulation (d)</td>
<td>0.80</td>
<td>0.81</td>
</tr>
<tr>
<td>Hospital length of stay (d)</td>
<td>1.89</td>
<td>1.49</td>
</tr>
</tbody>
</table>

Anesthesia

- Spinal or epidural: 3 vs 9 vs 13 vs 27 = .061
- Local: 0 vs 0 vs 6 vs 13 = .035
- General: 32 vs 91 vs 28 vs 60 = .003
scrotal edema (n = 1), and wound infection (n = 1). None of these delayed access-related complications required additional therapeutic intervention. At 6-month follow-up, no additional access-related complications were detected in either patient cohort; however, in the FAC group, at 6-month follow-up femoral neuropathy persisted in one patient, as did lymphedema in the patient with the lymphocele at 1-month follow-up.

DISCUSSION

Endovascular treatment of infrarenal AAA has become commonplace. As a viable alternative to open aneurysm repair, this represents a major advancement, particularly in the elderly and infirmed with AAAs that otherwise likely would remain untreated. The advantages of complete percutaneous endograft deployment are small but real when compared with device deployment through open femoral exposure. Percutaneous AAA repair requires special expertise, however, and practitioners must become familiar with particular arterial closure devices before they abandon open access.

Arterial closure devices were originally developed for use with smaller access sheaths. Bioabsorbable sponges (Angio-Seal, Kensey-Nash), bovine collagen plugs (VasoSeal VHD, Datascopc), fibrin and thrombin procoagulant glues (Duett, Vascular Solutions), and small suture-mediated closure devices (Closer, Perclose; X-PRESS, X-Site Medical) work relatively well after arterial puncture with 6F and 8F sheaths. These adjuncts to manual pressure save time, limit patient discomfort, and enable earlier patient ambulation, but they cannot be used safely after arterial access with 10F or larger sheaths.

Suture-mediated closure devices such as Prostar Plus and Prostar XL (Perclose) can be used off-label to repair the defect that remains after removal of the larger sheaths used during endovascular AAA and thoracic aortic aneurysm repair. Deployment of one or two of these devices per femoral artery provides safe and secure arterial closure through a simple stab incision in the groin.

Some real and some theoretic advantages to percutaneous aneurysm repair exist. In our experience, patients who underwent percutaneous endograft deployment experienced more rapid repair of the AAA, although it is quite possible that this was related to the design of the study and the learning curve associated with the Gore Excluder specifically as well as with endovascular AAA repair in general. More patients received local or regional anesthesia, rather than general anesthesia. We admit that this difference may well be institution-specific, given that many others choose regional anesthesia regardless of the access method. Also, in theory, patients should proceed to ambulation sooner than with open arterial access. Clearly, wound complications noted after hospital discharge were less frequent after percutaneous access compared with open arterial exposure.

Percutaneous access and arterial repair with suture-mediated FAC devices is not risk-free. Device entrapment, acute arterial thrombosis with limb ischemia, arterial injury, suture breaks resulting in hemorrhage, arterial dissection, suture infection, and pseudoaneurysm or arteriovenous fistula formation have all been described after use of this closure technique. In this review 15% (7 of 47) experienced immediate access site complications that required urgent attention. Bleeding complications and acute arterial occlusion were not uncommon, and often required treatment with surgical exposure of the accessed artery immediately, before taking the patient from the operating suite. When bleeding or ischemic complications occur, it is usually necessary to treat the problem immediately. Therefore we continue to recommend that complete percutaneous AAA repair be performed by surgeons and in an operating room. Alternatively, percutaneous AAA repair can be undertaken in a cardiac catheterization laboratory or an interventional radiology suite when both a surgeon and an operating room are on standby for immediate assistance and transfer if problems arise. The cost of maintaining an open operating room and a surgeon on standby is not insignificant. It also must be noted that this approach may risk patient outcomes during the time lost to transport, repeat preparation, and conversion to open exposure if hemostasis is lost in a setting outside the operating room. It is worth emphasizing that, while percutaneous access may be most appealing to those performing these procedures outside the operating suite, this is the precise setting in which the risk for failure is highest.

Although Perclose suture infection was not observed in any of our patients, this is a well-described complication. While the management of Perclose suture infection is beyond the scope of this article, suffice it to say this is a vexing problem that requires specific vascular surgical expertise. In this series there were no late Perclose complications despite close long-term patient observation.

We now generally consider all endograft patients to be candidates for percutaneous repair. In our institution, all patients who undergo AAA repair with the Gore Excluder are taken to the operating room with the intent to repair the aneurysm percutaneously. We have also treated a substantial number of AAAs with other endograft types (Ancure, Guidant; AneuRx, Medtronic; Zenith, Cook Inc) that require larger (24F) sheaths with percutaneous techniques. In addition, we have successfully managed a handful of patients who have undergone endograft repair of thoracic
aortic disease, including aneurysms and acute aortic tran-
ssections, with percutaneous access. Patients with very small,
severely calcified, or aneurysmal femoral arteries are not
ideal candidates for percutaneous repair, and must be
treated with caution. In patients who are morbidly obese
percutaneous treatment can also be more difficult, but
these patients may also reap the greatest benefit when the
approach is successful and an incision can be avoided.

CONCLUSION

Complete percutaneous treatment of AAA may have
some advantages over open femoral artery access, but it is
not free of risk. Certainly complete percutaneous treatment
of AAA can be performed with safety and efficacy equiva-
ient to open femoral artery access. Percutaneous treatment
of AAA can be attempted in most patients, but should be
performed in a sterile environment or where open arterial
access can be obtained rapidly if required.

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