Percutaneous Repair of Abdominal Aortic Aneurysms Using the AneuRx Stent Graft and the Percutaneous Vascular Surgery Device

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Endovascular exclusion of abdominal aortic aneurysms (AAAs) was developed in an effort to treat patients who were at high risk for complications following standard surgical repair. Stent grafts used for endovascular repair of AAAs require the use of large-bore sheaths and surgical exposure of the common femoral arteries (CFAs). To decrease the invasiveness of AAA repair, we attempted to perform the procedure percutaneously utilizing the Prostar XL Percutaneous Vascular Surgery Device and the preclose technique. Thirty patients underwent an attempted percutaneous AAA repair. These patients were followed prospectively to assess the success of the procedure. Twenty-eight patients (93%) had successful percutaneous repair of both CFA access sites. One patient had inadequate hemostasis of the 22 Fr CFA entry site and one patient had inadequate hemostasis of the 16 Fr CFA entry site. Both of these CFA sites underwent open surgical repair. The rate of successful repair of the 22 Fr CFA access site was 29 of 30 (96%); for the 16 Fr CFA access site, 29 of 30 (96%). No in-hospital groin complications were seen. The procedure time was 105 ± 21 min. The estimated blood loss was 90.6 ± 50 cc. The hemoglobin loss was 1.54 ± 0.89 mg/dL and the hematocrit loss was 5.04% ± 2.8%. Complete percutaneous endoluminal AAA repair is feasible using the preclose technique. CFAs with sheaths up to 22 Fr can be safely and successfully accessed and repaired percutaneously using this technique. This method provides secure hemostasis and reduces the invasiveness of procedures requiring large-bore sheaths. Cathet Cardiovasc Intervent 2002;55:281–287.

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INTRODUCTION

Endovascular exclusion of abdominal aortic aneurysms (AAAs) was developed in an effort to treat patients who were at high risk for complications following standard surgical repair [1]. This technique has significantly reduced the invasiveness of the repair of AAAs [2,3]. Deployment of stent grafts used for endovascular repair of AAAs, however, requires the use of large-bore sheaths and surgical exposure of one or both common femoral arteries (CFAs). The exposure of the CFA with surgical techniques increases the invasiveness of the procedure and the risk for complications.

The AneuRx stent graft (Medtronic AVE, Santa Rosa, CA) is one of the two FDA-approved stent graft devices available for use in the United States. This device requires placement of a 22 Fr sheath in the CFA and a 16 Fr sheath in the contralateral CFA. Previous studies have shown that the 16 Fr CFA access site can be safely and successfully accessed and repaired percutaneously using the Prostar XL Percutaneous Vascular Surgery Device (PVS; Perclose, Menlo Park, CA) and the preclose technique [4,5]. More recently, a modification of the preclose technique has been described to repair the 22 Fr CFA access site percutaneously [6,7].

In an effort to further decrease the invasiveness of the repair of AAAs, an attempt to perform the procedure completely percutaneously was made utilizing the above-mentioned CFA closure techniques. This report describes our early experience in a small series of patients using the bilateral preclose technique after endoluminal exclusion of AAAs with the AneuRx stent graft.

MATERIALS AND METHODS

Patient Selection

Between January 2001 and April 2001, complete percutaneous AAA repair was attempted in 30 consecutive patients...
patients undergoing AAA repair with the AneuRx stent graft. All patients were informed and signed a written consent to the procedure. The patients’ baseline characteristics are listed in Table I.

The surgical access group referenced in Table II (n = 96) consisted of consecutive patients who had open common femoral artery exposure through a groin incision to introduce the AneuRx delivery device. They had their 16 Fr entry site closed using the perclose technique and had their 22 Fr arterial entry site repaired surgically through a groin incision.

**Technique**

The procedures were performed in the cardiac catheterization laboratory endovascular suite under general endotrachial anesthesia. Intravenous heparin was administered to all patients after arterial access to achieve and maintain the activated clotting time at > 250 sec. Protamine was not used to reverse the effects of heparin. All patients received a single intravenous dose of antibiotics at the time of the procedure, which was followed by 3 days of oral antibiotics. The patients were given aspirin 325 mg/day and clopidogrel 75 mg/day for 1 month following the procedure.

Both CFAs were accessed percutaneously using the modified, front wall puncture, Seldinger technique, and a 6 Fr sheath was inserted in the CFA designated for the 22 Fr sheath and a 9 Fr sheath was inserted into the CFA designated for the 16 Fr sheath. The skin above the CFA access sites was widened with a scalpel to 1 cm, and the subcutaneous tissues were bluntly dissected with a hemostat.

The 9 Fr sheath was then removed over a wire and a 10 Fr PVS device was advanced into the CFA. When pulsatile blood flow was seen through the marker lumen, indicating that the sutures and needles were within the vessel lumen, all four needles and sutures were deployed. The sutures were then removed from the PVS device hub, and care was taken to identify the upper and lower sets. The sutures were left untied and secured on the table. The PVS device was removed from the femoral artery over a wire, and after progressive dilation, a 16 Fr, 35 cm long, valved sheath (Cook, Bloomington, IN) was placed in the CFA.

The 6 Fr sheath was then removed over a wire and an 8 Fr PVS device was then advanced into the CFA designated for the 22 Fr sheath over a wire. Once good blood flow was achieved through the marker lumen of the 8 Fr PVS device, the needles and sutures were deployed. The sutures were then removed from the PVS device hub, and care was taken to identify the upper and lower sets. The sutures were left untied and secured on the table. The wire was inserted through the wire lumen of the 8 Fr PVS device into the CFA. The 8 Fr PVS device was removed and a 10 Fr PVS device was then advanced into the CFA over the wire. Once good blood flow was achieved through the marker lumen, the 10 Fr PVS device was rotated 90° in reference to the previously deployed 8 Fr PVS device. After this rotation, the four needles were deployed from the 10 Fr PVS device.

The delivery of the second set of needles is perpendicular to the delivery of the first set, which is facilitated by the marker arrow on the PVS device. This rotation prevents the sutures of each PVS device from being placed in the same location in the arterial wall. The sutures were removed from the 10 Fr hub, and care was taken to identify the right and the left set of sutures. These sutures were left untied, secured to the table, and marked with colored tape to keep them separate from the 8 Fr PVS device sutures. The device was removed over a wire, which was reinserted through the guidewire port on the 10 Fr PVS device, and a 12 Fr sheath was placed into the CFA. A 260 cm long, extra-stiff Lunderquist guidewire (Cook) was placed through the arterial sheath in the CFA and advanced to the descending thoracic aorta. The CFA and iliac arteries designated for the 22 Fr sheath were progressively dilated with 12, 14, 16, 18, and 20 Fr, 20 cm long, percutaneous vessel dilators (Cook). After successful dilation, a 22 Fr, 20 cm long sheath with a Keller Timmerman valve (Cook) was advanced percutaneously over the guidewire to the abdominal aorta.
Hemostasis of the Keller Timmerman valve was obtained with a clamp or by coaxial insertion of smaller sheaths through the valve. Saline solution was also flushed briefly through the side port of both the 16 and 22 Fr arterial sheaths during introduction and removal of the stent graft to prevent blood loss through the valve. These techniques were not necessary when the 22 Fr Cook check-flow sheath was used because the hemostasis was adequate with this valve (Fig. 1). The sheath with a Keller Timmerman valve was used in the first 16 patients and the 22 Fr Cook check-flow sheath in 14 patients.

Once the AAA was excluded from the circulation, the PVS sutures were cleaned thoroughly with saline and 10 cc of 1% lidocaine with epinephrine (1:100,000) was injected into the subcutaneous tissues surrounding both sheath entry sites. The 16 Fr sheath was removed, and the two PVS sutures were tied with the sliding knot technique. The 22 Fr sheath was then removed and the four PVS sutures were tied with the sliding knot technique (Fig. 2). Special care was taken to identify and separate the 8 Fr from the 10 Fr PVS sutures so they could be knotted and tied separately. The 8 Fr sutures were advanced to the CFA entry site first followed by the 10 Fr sutures. A knot pusher (Perclose) was used to advance and secure the knots to the CFA entry site. After the first five patients, the guidewire was removed prior to tying the sutures. A vascular surgeon was on standby for possible surgical femoral artery repair in case of failure of the Perclose technique and persistent bleeding.

After achieving hemostasis, the sutures were cut, and the incision edges were approximated with adhesive steri strips. Both entry sites were cleaned with betadine and dressed with sterile telfa pads and clear tegaderm. Five-pound sandbags were placed on each entry site for 4 hr following the procedure. Following the procedure, the patient was kept at bedrest for 4-6 hr with their legs straight for 4 hr. After bedrest, the patients ambulated under observation. Ankle brachial indexes (ABI), abdominal and lower extremity duplex ultrasound scans, and complete physical examinations were performed pre-procedurally, at 1-month, 6-month, and 1-year follow-up.

Study Definitions and Statistical Analysis

The results are expressed as the mean ± standard deviation. Differences between groups were evaluated with the two-tailed student’s t-test. Differences were reported as significant if the P value was less than 0.05.

Procedure time was measured from the initial arterial access puncture to surgical closure of the femoral artery access site. The anesthesia staff using visual assessment and measurement of blood accumulation in the aspiration container calculated estimated blood loss. Hemoglobin and hematocrit were measured the day of the procedure and the day following the procedure in all patients. Hemoglobin loss is the preprocedure hemoglobin minus the postprocedure hemoglobin. Hematocrit loss is the preprocedure hematocrit minus the postprocedure hematocrit.

Fig. 1. Percutaneous placement of the 22 Fr Cook sheath (black arrow) in the right common femoral artery and the 16 Fr sheath (white arrow) in the left femoral artery. The AneuRx delivery device can be seen exiting the 22 Fr sheath (black arrowhead).
RESULTS

Thirty patients underwent an attempted percutaneous AAA repair. All CFAs were successfully accessed with 22 and 16 Fr sheaths. Twenty-eight patients (93%) had successful percutaneous repair of both CFA access sites (Table III). One patient had inadequate hemostasis of the 22 Fr CFA entry site and one patient had inadequate hemostasis of the 16 Fr CFA entry site. Both of these CFA entry sites underwent successful open surgical repair. Thus, the rate of successful repair of the 22 Fr CFA access site was 29 of 30 (96%) and the rate of successful repair of the 16 Fr CFA access site was 29 of 30 (96%). Three patients required a PVS device tamper (Perclose) for 1 hr (Fig. 3). All of the AneuRx stent graft devices were successfully deployed. The mean iliac artery diameter was 13.3 ± 5.6 mm with a range of 6–35 mm.

No in-hospital local groin complications, such as hematoma, infection, bleeding, and femoral neuropathy, were seen in any of the 30 patients. No patient required a blood transfusion. The mean procedure time was 105 ± 21 min. The mean estimated blood loss was 90.6 ± 50 cc. The mean hemoglobin loss was 1.54 ± 0.89 mg/dL. The mean hematocrit loss was 5.04% ± 2.8%. The mean hospital stay was 1.3 ± 0.6 days.

Table II provides a comparison of blood loss and procedure time between patients who had surgical access and repair of their femoral arteries and those treated percutaneously with the AneuRx stent graft. Percutaneous repair was associated with significantly shorter procedure times and significantly less blood loss.

One-month follow-up is available in all patients. At 1-month follow-up, no groin or lower extremity distal embolization complications have been seen. There has been no decrease in ankle brachial indexes noted (Fig. 4).

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<th>Table III. Procedure Results</th>
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<tbody>
<tr>
<td>Percutaneous repair (n = 30)</td>
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<tr>
<td>Successful bilateral closure</td>
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<tr>
<td>Successful 22 Fr closure</td>
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<td>Successful 16 Fr closure</td>
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<td>Tamper use (number of limbs)</td>
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<tr>
<td>Hematoma</td>
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<tr>
<td>Transfusion</td>
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<td>Groin infection</td>
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<tr>
<td>Length of stay (days)</td>
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Fig. 2. Four tied PVS sutures can be seen exiting the skin at the 22 Fr common femoral access site with excellent hemostasis.
DISCUSSION

Two stent graft devices, AneuRx and Ancure (Guidant, Menlo Park, CA), are now approved for endovascular AAA exclusion in the United States. Several other stent grafts are currently undergoing evaluation in this country [2,3,8–12]. These devices have significantly decreased the invasiveness and complications associated with standard surgical AAA repair. The current technique of accessing the CFA consists of surgical exposure of the CFA, which increases the invasiveness of the endovascular procedure, and the associated complications [2,3,13–15].

There have been a few reports of complete percutaneous access and closure of the femoral artery entry sites for the delivery of endovascular AAA stent grafts, but these reports are limited by a small number of patients, smaller delivery devices, or have shown poor success [6,7,16]. We have shown in previous studies that femoral arteries can be safely repaired after removal of 16 Fr sheaths using the Prostar XL Percutaneous Vascular Sur-
gery Device [4,5] and have performed this technique in over 200 patients. Although it has been shown that the 22 Fr CFA sheath entry site can be repaired with two Prostar XL devices, the risk of suboptimal arterial repair might be too high to warrant the routine use of this procedure [6,7,16]. Traul et al. [7] recently reported their early experience with percutaneous access and repair of large-bore CFA entry sites. They were only able to access and repair percutaneously both the 22 Fr CFA entry site and the 16 Fr CFA entry site in 6 of 13 attempts (42%). The difference in our success may be due to a significant learning curve with this technique or possible differences in the technique. We rotate the second PVS device in the 22 Fr CFA 90° as opposed to 45° as described in their study. After placement of the PVS devices, we gradually dilate the common femoral and iliac arteries using vessel dilators prior to placing the sheaths, which may result in less vessel injury. We use an 8 Fr PVS device followed by a 10 Fr PVS device as opposed to two 10 Fr PVS devices. We feel that by using an 8 Fr PVS device first the second 10 Fr device will bite more tissue since the artery was not previously dilated to 10 Fr by the first device. We also feel that by using different diameter devices the sutures are placed in slightly different planes around the arterial access site. This should decrease the chance that two sutures will exit the exact same location in the artery. This also decreases the chance that the second set of needles will transect the first set of sutures. We used 22 Fr sheaths, as opposed to 24 Fr, to deliver the bifurcated segment of the AneuRx stent graft. We also remove the guidewire prior to tying and advancing the sutures.

Two patients failed to have adequate hemostasis following attempted percutaneous closure. One patient had unsuccessful percutaneous closure of the 22 Fr CFA access site and the other had unsuccessful percutaneous closure of the 16 Fr CFA site. Both of these patients had successful percutaneous closure of their contralateral CFA access site. Hemostasis was obtained with local hand pressure followed by surgical access and closure. Neither patient had excessive blood loss or required blood transfusion. In both patients, surgical exposure of the CFA revealed that the PVS sutures had tied on the wire, above the artery, that was left in the CFA during sheath removal and suture advancement. Since then, we have removed the wire prior the sheath removal and have had no further failures.

Three patients have required use of the PVS tamper device (Fig. 3) due to oozing from the access site. Hemostasis was obtained in all three patients and the device was removed in the catheterization laboratory holding area when the ACT returned to normal. The tamper device is a 10 cm long plastic tube. The tied PVS sutures are threaded through the tamper lumen and the tamper is advanced to the anterior surface of the CFA. The proximal edge of the tamper provides gentle pressure to the external surface of the CFA entry site, thus providing hemostasis.

Despite the risk of major bleeding with this technique, we have not observed this complication even in the two patients who failed percutaneous closure and required open surgical repair of their CFA. This technique has actually resulted in a significant decrease in blood loss and procedure time (Table II). Because of this success, we have made percutaneous AAA repair routine in our patients being treated with the AneuRx stent graft (Fig. 5). In this study, if the femoral and iliac arteries were adequate for the AAA exclusion procedure, we attempt to close them percutaneously, regardless of tortuosity or calcification.

In conclusion, our early experience in this larger patient population has shown that sheaths up to 22 Fr can be
successfully introduced and the sites closed using a percutaneous technique with the PVS device. This method provides secure hemostasis and further reduces the invasiveness of procedures requiring large-bore sheaths. Complete percutaneous endoluminal AAA repair is certainly feasible and on the horizon, but before it becomes routine more experience in larger number of patients will be needed.

REFERENCES