Endovascular stent grafting in the presence of aortic neck filling defects: Early clinical experience

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Objective: **Although endovascular grafts have been increasingly applied to the treatment of abdominal aortic aneurysms, their use in clinical trials is limited by well-defined anatomical exclusion criteria. One such criterion is the presence of thrombus within the infrarenal neck of an aneurysm, which is thought to (1) prevent the creation of a permanent watertight seal between the graft and the vessel wall, resulting in an endoleak; (2) contribute to stent migration; and (3) increase the risk of thromboembolism. This article summarizes our experience with endovascular abdominal aortic aneurysm exclusion in 19 patients with large aortic aneurysms, significant medical comorbidities, and apparent thrombus extending into the pararenal aortic neck.**

Methods: **Of 268 patients undergoing abdominal aortic aneurysm repair, 19 (7%; 17 men; mean age, 71 years) demonstrated computed tomographic and angiographic evidence of intramural filling defects at the level of the aortic neck. In no instance did these filling defects extend above the renal arteries. Endovascular grafting was performed through use of a balloon-expandable Palmaz stent and an expanded polytetrafluoroethylene graft, delivered and deployed under fluoroscopic guidance. Follow-up at 3, 6, and 12 months and annually thereafter was performed with computed tomography and duplex ultrasound scan.**

Results: **Spiral computed tomography and aortography revealed an irregular flow-limiting defect, occupying up to 75% of the aortic circumference, in every case. The mean aneurysm size, aortic neck diameter, and neck length before the procedure were 6.1, 2.43, and 1.4 cm, respectively; the mean aortic neck diameter after the procedure was 2.61 cm. No primary endoleaks were observed after graft insertion, and no delayed endoleaks have been detected during follow-up, which ranged from 7 to 48 months (mean, 23 months). In one patient, an asymptomatic renal artery embolus was detected on immediate follow-up computed tomography, and in another patient, an asymptomatic posterior tibial embolus occurred.**

Conclusion: **No primary endoleaks, endograft migration, or significant distal embolization were observed after endografting in patients with aortic neck thrombus. The deployment of the fenestrated portion of the stent, above the thrombus and across the renal arteries, allows for effective renal perfusion, graft fixation, and exclusion of potential mural thrombus from the circulation. The presence of aortic neck thrombus may not necessarily be a contraindication to endovascular repair in select patients. (J Vasc Surg 2001;33:340-4.)**

Endovascular grafts are being tested for the treatment of abdominal aortic aneurysms (AAAs). The advantages of endovascular grafting techniques in comparison with conventional aortic repair include a minimum amount of discomfort to the patient, the potential for fewer postoperative cardiopulmonary complications, and reduced hospital stay.[1,2] However, not all AAAs may be amenable to repair with currently available endovascular devices. The use of commercial endografts in current US-based clinical trials is limited by well-defined anatomical criteria.

One important aortic pathology that excludes patients from clinical trials is the presumed presence of thrombus within the aortic neck, identified as intraluminal filling defects on computed tomography (CT) images. It has been suggested that the presence of thrombus within the aortic neck may predispose to incomplete AAA exclusion, resulting in aneurysm expansion or proximal stent migration or being associated with the risks of thromboembolism.[3-9] Other exclusion criteria include the presence of a short aortic neck (< 1.5 cm) and an aortic neck diameter greater than 28 mm[2].

In this article, we analyze our experience with endovascular grafting in 19 patients with AAAs having defined mural filling defects within the aortic neck. All patients underwent endovascular repair through use of a custom-designed device that has been described in detail elsewhere.[10] The results of our experience using this device were analyzed with regard to the following outcomes: primary proximal endoleak, delayed endoleak, graft migration, and thromboembolization.

MATERIAL AND METHODS

Of a total of 268 patients undergoing endovascular repair of AAAs, 19 (7%; 17 men; mean age, 71 years) were found to have intraluminal filling defects within the proximal aortic neck. There was no significant difference in neck angulation between patients in this study group and those without neck thrombus. Patients with significant cardiac and pulmonary comorbidities, which would have placed

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them at high risk for conventional open repair (American Society of Anesthesiologists class III or class IV), were offered endovascular graft procedures. Each patient underwent spiral CT and angiography in order to properly plan the subsequent endovascular procedure and define the pathology. An irregular flow-limiting defect in the aortic neck occupying greater than 75% of the aortic circumference was seen on CT scanning in each case. The maximum thickness of the thrombus (impingement on aortic lumen) was 3 mm. Aortic aneurysms ranged in diameter from 5.2 to 7.8 cm (mean, 6.1 cm); the mean aortic neck diameter and neck length were 2.43 and 1.4 cm, respectively.

Patients were considered for endografting in accordance with an investigator-sponsored Investigational Device Exemption from the US Food and Drug Administration after informed consent was obtained. Under spinal/epidural anesthesia, aortounifemoral stent grafts, each composed of a P5014 Palmaz balloon-expandable stent (Cordis Endovascular/Johnson & Johnson, Warren, NJ) and a polytetrafluoroethylene graft (Impra, Tempe, AZ) (Fig 1), were mounted onto an angioplasty balloon within a 23Fr delivery sheath. A gold marker affixed to the margin of the graft at the site of attachment to the Palmaz stent facilitated radiographic localization and graft placement with respect to the lowest renal artery. Endovascular grafts contained within the delivery catheter were advanced over a 0.038-in Amplatz superstiff guidewire to the pararenal segment of the aorta. A diagnostic catheter was inserted through the contralateral femoral artery and positioned within the aorta to permit dynamic angiography for precise device positioning before deployment.

The delivery catheter containing the endograft was retracted caudally, and the graft was finally positioned within the aorta before deployment in such a way that the gold marker on the graft margin was aligned with the inferior border of the lowest renal artery. In every patient, this position allowed the open portion of the stent to extend across the orifices of both renal arteries while permitting blood flow through the stent interstices.[11] Twenty-four milligrams of adenosine was administered to each patient to induce a short (7- to 10-second) period of asystole before balloon inflation to ensure that the graft would not migrate caudally during balloon expansion and stent deployment.[12] The contralateral common iliac artery was occluded with a Parodi-type occluding stent; this permitted pelvic visceral perfusion through the internal iliac artery ipsilateral to the common iliac occlusion. Cross-pelvic and contralateral femoral perfusion was accomplished through placement of a femorofemoral bypass graft constructed with a Vantage Dacron graft (Meadox Medical, Natick, Mass) having a diameter of 8 mm. In each patient, intraoperative completion angiography of the pararenal aorta, endograft, and outflow femoral vessels was performed in two views. Follow-up examination was performed through use of dynamic, intravenous contrast-enhanced CT angiography.

All patients underwent examination at 3, 6, and 12 months and annually thereafter. The scanner used for the examination was a GE Cti (General Electric, Milwaukee, Wis). A C-minus examination result was followed by the administration of 130 mL of intravenous contrast (Omnipaque, 240); CT angiography was then performed through use of 3-mm cuts, the pitch ranging from 1.5 to 3. In addition, each patient underwent color-flow duplex scan imaging at these time points. Aneurysm size was measured as cross-sectional diameter on multiple CT scans (performed identically preoperatively and postoperatively) and compared slice by slice. No significant increases in sac diameter were noted, and volume calculations were not performed.

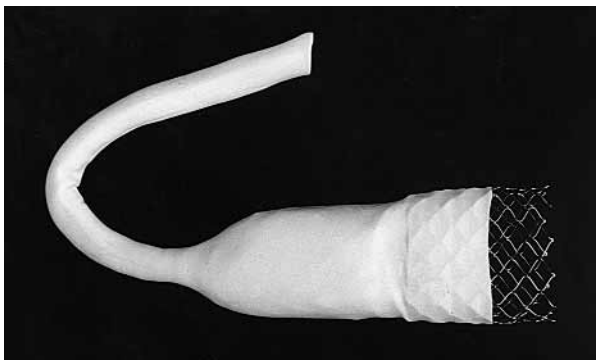

Fig 1. All patients recruited into the study underwent endovascular repair through the use of a handmade device composed of a balloon expandable Palmaz stent sutured to tapered PTFE graft.

RESULTS

Nineteen patients with intraluminal filling defects diagnosed on CT scan and occupying greater than 75% of the circumference of the aortic neck were treated with endoluminal stent grafting for exclusion of their AAAs (Fig 2). The mean aortic neck diameter increased slightly after insertion of the device, from 2.43 to 2.61 cm (7.4%). No early endoleaks were detected by means of angiography at the completion of the procedure or within 1 week on dynamic, contrast-enhanced CT.

No delayed endoleak or graft migration was seen in any of the patients during follow-up, which ranged from 7 to 48 months (mean, 23 months). Furthermore, no increase in aneurysm sac size was noted. After the procedure, the immediate, 30-day, and late survival rates were each 100% in this study group.

Two cases (10%; 2/19) of asymptomatic thromboembolism were seen. Renal artery embolization secondary to proximal graft deployment was diagnosed on the basis of a wedge-shaped infarct on postoperative CT scanning in one patient; there were no associated changes in creatinine, back pain, hematuria, or development of new-onset hypertension in this patient. Another patient was noted to have a decrease in the left posterior tibial pulse, which was asymptomatic.

DISCUSSION

Several factors account for the strong interest in the use of endovascular grafts for the treatment of AAAs. The potential for a less invasive treatment allows a patient with

severe medical comorbidities to have aneurysm exclusion, possibly eliminating the risks of rupture. More important, it makes possible the treatment of patients with cardiac and pulmonary disease that would have otherwise precluded conventional repair. In addition, recent reports have documented the average length of stay for endovascular aneurysm repair at 4.1 ± 2.6 days; this compared with 8.8 ± 4.1 days for a control group of patients who underwent open aneurysm repair ($P < .05$).[1] Similar findings have been reported in another large prospective study, with a mean length of stay of 3.4 ± 2.7 days for endovascular repair versus 9.4 ± 2.7 days for conventional open aneurysm repair ($P < .01$).[2]

The use of endovascular grafts in these US-based clinical trials is limited by well-defined anatomical exclusion criteria. The presence of thrombus within the infrarenal aortic neck of an aneurysm is considered a contraindication for endovascular repair for three principal reasons.

First, it is widely believed that thrombus at the aortic neck will prevent a watertight seal of the stent graft against the aortic luminal surface, thus allowing endoleakage of blood and not effectively excluding the aneurysm. Persistent endoleaks contribute to aneurysm expansion and potentially to their ultimate rupture.[3-5] Moreover, late lysis of the thrombus may allow channel formation around a previously intact seal of the device against the aortic wall, resulting in a delayed endoleak, aneurysm expansion, device migration, and risk of rupture.

Second, there may be ineffective purchase of the stent in the thrombus,[6-8] leading to immediate device migration. In a series published by Chuter et al,[7] every case of device migration was associated with one of the following factors: the neck was less than 10 mm in length; the neck was lined with thrombus; or the device was implanted more than 15 mm from the renal neck. Other investigators have reiterated this finding, reporting that nearly 20% of stent graft migrations occur in association with thrombus-lined proximal aortic necks.[6]

Third, there is concern that in the presence of proximal aortic neck thrombus, there is a greater risk of distal embolization than may be engendered by the obligatory intraluminal manipulation of the sac contents by the guidewires and devices during the positioning and deployment phases of the endovascular procedure. A recent study has shown that endovascular repair is accompanied by a nearly threefold increase in embolic events in comparison with open repair.[9]

CT scans are routinely used by most centers, including our own, both for screening and for planning of the appropriate therapeutic intervention in patients presenting with an AAA. It is well recognized that CT scanning is a useful diagnostic modality for monitoring the progression and regression of atherosclerosis in the descending thoracic aorta.[13,14] More recent literature has emphasized the usefulness of CT scanning in the detection of aortic atheromas as a source of emboli leading to stroke[15]; the investigators found it comparable to transesophageal echocardiography for the diagnosis of patients with this pathology in the thoracic aorta. CT scanning is also useful for the diagnosis of patients with acute injury to the thoracic aorta.[16] However, CT scanning cannot reliably differentiate between different components of the plaque (thrombus, fibrous tissue, lipid, etc). This distinction is important, inasmuch as the diagnosis of thrombus within the aortic neck is frequently made in CT scanning on the basis of the presence of a filling defect. Patients with these CT-diagnosed lesions are therefore excluded from endovascular repair.

Magnetic resonance imaging has recently emerged as a useful technique for differentiation of the various components of the atherosclerotic plaque. Recent in vivo studies[17] have shown its usefulness, but it is not yet widely available in most centers. Intravascular ultrasound scan is another imaging modality that may be useful for the perioperative assessment and characterization of lesions within the aortic neck. The use of high-resolution catheters may effectively distinguish between thrombus (echolucent on ultrasound scan) and fibrous tissue (echogenic).[18]

Because CT imaging cannot give a pathologic or tissue diagnosis but is instead limited to measuring relative radiopacity, there is a strong likelihood that what is read as "thrombus" is in fact a heterogeneous collection of material ranging from organized thrombus to fibrous or atherosclerotic plaque. Although the former has a high potential for embolization and negligible adherence to the underlying aortic wall—thus providing an inadequate purchase for the stent to anchor the graft proximally—the latter is an integral part of the vessel wall and, although deformable, is unlikely to jeopardize stent graft fixation.

Both a short proximal neck and a neck diameter greater than 30 mm have been implicated in complications of endovascular aortic aneurysm exclusion, especially with difficulty in achieving a seal.[7] Interestingly, the placement of stents across the renal arteries has been shown to be well tolerated in animal experiments.[19-21] Clinical studies have also shown that transrenal placement of stents for graft fixation is not associated with deleterious side effects in patients undergoing transfemoral endovascular aneurysm repair.[11,22]

The presence of thrombus within the aortic neck has previously been considered a contraindication to endovascular repair because of its association with such complications as immediate and delayed endoleaks, graft migration, and distal embolization. The successful treatment of patients with diagnosed thrombus in the aortic neck by transrenal placement of stents that effectively anchor the endograft in the infrarenal proximal aortic segment has not been previously described.

Our experience has shown that the presence of "thrombus" within the aortic neck, diagnosed on the basis of CT scanning, does not necessarily constitute a contraindication to endovascular repair. Transrenal fixation of the stent anchoring the endovascular device, which is overdilated in the infrarenal segment to achieve effective fixation against the aortic wall, leads to successful exclusion of the aneurysm in patients with these lesions. We also believe that it is the transrenal fixation to normal suprarenal aortic tissue that has

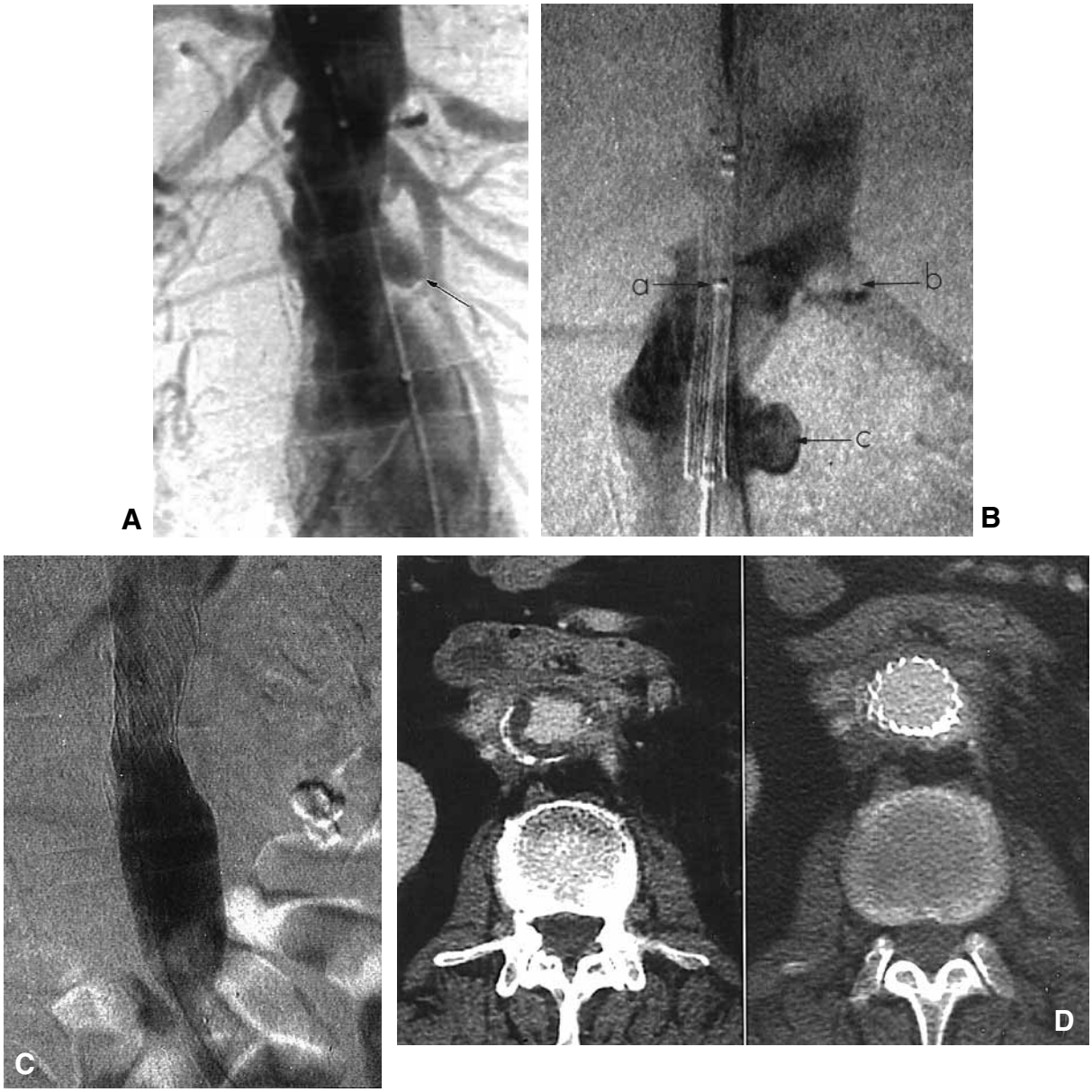

Fig 2. A, Angiogram shows infrarenal aneurysm measuring 6.2 cm. Aortic neck diameter is 2.2 cm (irregular); aortic neck length is 1.5 cm. *Arrow* points to site of penetrating aortic ulcer. **B,** Intraoperative angiogram in same patient shows optimal positioning and deployment of balloon-expandable endovascular graft. Endovascular stent graft is positioned in such a way that marker on cephalad end of graft (*a*) is at level of left (lowest) renal artery (*b*). This positioning was chosen specifically to exclude previously identified penetrating aortic ulcer (*c*). **C,** Completion angiogram shows deployment of balloon-expandable endograft. Renal artery perfusion through open portion of stent interstices is apparent. Penetrating aortic ulcer and surrounding aortic neck irregularities have also been successfully excluded. **D,** CT scans taken before (*left*) and after (*right*) aortic endografting demonstrate mild compression of underlying aortic wall material with rounding of aortic contour.

prevented the occurrence of early and late endoleaks in this study population.

Although long-term results are awaited, no statistically significant increase in aortic diameter was noted during the follow-up period. Two patients (10%) were diagnosed as having asymptomatic thromboembolism. One of these patients acutely developed CT evidence of renal embolization, although this was not associated with biochemical evidence of deterioration in renal function or the development of hypertension. The etiology of this embolus, which is unclear, is presumed to be a result of cephalad displacement of aortic neck material. The second patient experienced an asymptomatic diminution in a pedal pulse. No other evidence of procedure-related thromboembolism was detected.

Previous investigators have reported a higher incidence of proximal endoleaks and device migration secondary to endovascular device deployment in patients with thrombus-lined aortic necks; this has been explained on the basis of poor purchase of the device after deployment within the thrombus. In the current series of 19 patients, no early or delayed endoleaks were detected. This may be due to effective stent deployment and seating in the thrombus-free transrenal and suprarenal segments of aorta.

We therefore think that the presence of an intraluminal filling defect on a preoperative CT scan may unnecessarily preclude patients from selection for endovascular repair because of the technical limitations of this otherwise indispensable diagnostic imaging tool. Such exclusion has the principal disadvantage of preventing access to endovascular repair for a large population of patients who may otherwise benefit from this minimally invasive approach. The early follow-up results of this experience have shown that the fears articulated by several current commercial protocols about endovascular repair in the setting of proximal aortic neck thrombus may not be as well justified as was once thought. However, such patients should be approached with the understanding that they are at increased risk of thromboembolization during device deployment, and this risk may be similar to or greater than that seen in comparable patients undergoing open repair. As with any novel technique, favorable long-term follow-up will establish the role of endovascular aortic repair in patients with significant contraindications to open repair, aortic neck thrombi, and "short" (< 15 mm) necks.

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