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TRANSLUMINAL PLACEMENT OF ENDOVASCULAR STENT-GRAFTS FOR THE TREATMENT OF DESCENDING THORACIC AORTIC ANEURYSMS

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Abstract *Background.* The usual treatment for thoracic aortic aneurysms is surgical replacement with a prosthetic graft, but the associated morbidity and mortality are considerable. We studied the use of transluminally placed endovascular stent-graft devices as an alternative to surgical repair.

Methods. We evaluated the feasibility, safety, and effectiveness of transluminally placed stent-grafts to treat descending thoracic aortic aneurysms in 13 patients over a 24-month period. Atherosclerotic, anastomotic, and post-traumatic true or false aneurysms and aortic dissections were treated. The mean diameter of the aneurysms was 6.1 cm (range, 5 to 8). The endovascular stent-grafts were custom-designed for each patient and were constructed of self-expanding stainless-steel stents covered with woven Dacron grafts.

Results. Endovascular placement of the stent-graft prosthesis was successful in all patients. There was complete thrombosis of the thoracic aortic aneurysm surrounding the stent-graft in 12 patients, and partial thrombosis in 1. Two patients initially had small, residual patent proximal tracts into the aneurysm sac, but both tracts thrombosed within two months after the procedure. In four patients, two prostheses were required to bridge the aneurysm adequately. There have been no deaths or instances of paraplegia, stroke, distal embolization, or infection during an average follow-up of 11.6 months. One patient with an extensive chronic aortic dissection required open surgical graft replacement four months later because of progressive dilatation of the arch.

Conclusions. These preliminary results demonstrate that endovascular stent-graft repair is safe in highly selected patients with descending thoracic aortic aneurysms. This new method of treatment will, however, require careful long-term evaluation. (N Engl J Med 1994; 331:1729-34.)

THORACIC aortic aneurysms are potentially life-threatening. The majority are caused by atherosclerosis,[1] most commonly of the descending aorta; clinical manifestations are due to the compression of adjacent structures, dissection, or rupture.[2] Rupture of a thoracic aneurysm is almost always rapidly fatal. Several reports have estimated the risk of rupture in patients with untreated thoracic aortic aneurysms to range from 46 to 74 percent, with actuarial five-year survival rates estimated to range from 9 to 13 percent.[3,4] This prognosis is worse than the five-year survival rate for patients with untreated abdominal aortic aneurysms.[4,5]

The traditional treatment of thoracic aortic aneurysms is the surgical placement of a graft. Although substantial advances in the operative care of patients with thoracic aortic aneurysms have been achieved over the past 30 years, the variety of underlying diseases, the frequency of coexistent cardiovascular diseases, and the unpredictable need for emergency surgical intervention continue to pose vexing challenges. The difficulty presented by this problem is underscored by studies documenting a mortality rate of more than 50 percent in patients requiring emergency operative treatment and in those with particular characteristics or coexisting conditions, such as advanced age or the presence of congestive heart failure.[6,7] The risk associated with elective surgical repair is lower, with a mortality rate of 12 percent reported in one large contemporary series.[6]

Transluminally placed endovascular stent-graft prostheses offer an alternative approach to treatment that is potentially less invasive and less expensive, with a lower risk than standard operative repair. The clinical feasibility of transluminal endovascular grafting has been recently described for the treatment of abdominal aortic aneurysm,[8] subclavian-artery aneurysm,[9] arteriovenous fistula,[10] and femoral occlusive disease.[11] We report our experience with transluminally placed endovascular stent-grafts for the repair of descending thoracic aortic aneurysms in 13 patients.

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METHODS

From July 1992 through January 1994, 13 patients underwent transluminal endovascular grafting of thoracic aortic aneurysms after approval was obtained from the institutional review board of

Stanford University Medical Center. Informed consent was obtained in each case.

Patients

Endovascular grafting was attempted in 11 men and 2 women with Dacron-covered, self-expanding stainless-steel stent–grafts. The average age of the patients was 61 years (range, 39 to 77). The patients were selected for treatment if they met one or more of the following criteria: the proximal and distal aneurysm "neck" did not involve the origin of the left subclavian artery or celiac axis; the aneurysm neck was of reasonably small caliber (i.e., <4.0 cm); the aneurysm was relatively localized or false; the aneurysm had morphologic and anatomical pathological characteristics that were considered amenable to the placement of a stent–graft (e.g., patients with chronic dissections were excluded if they had very small or distorted true lumens and large, eccentric false lumens); there was adequate peripheral arterial (or infrarenal abdominal aortic) access for the large (24 French) delivery device; and there were major contraindications to a second surgical approach, such as multiple previous thoracotomies.

The aneurysms had diverse causes, but the majority were due to atherosclerosis. Eight of the 13 patients had previously undergone at least one operation for the treatment of cardiovascular disease, including coronary-artery bypass grafting in five cases.

During the same 19-month period, 155 patients underwent conventional surgical repair of ascending, transverse-arch, descending, thoracic, or thoracoabdominal aneurysms in the same hospital; thus, only 8 percent of the patients were deemed suitable for endovascular stent–grafting and agreed to undergo the procedure. When only descending thoracic aortic or thoracoabdominal aneurysms in the overall group of patients were considered, the fraction suitable for a stent–graft was 26 percent (13 of 50); when only those with descending thoracic aneurysms were considered, 37 percent (13 of 35) underwent the procedure.

The main reasons for not pursuing the endovascular stent–graft approach were inadequate peripheral arterial access, the absence of an aneurysm neck or an excessively large neck, and inappropriate morphologic features (e.g., extensive chronic aortic dissections).

Imaging Protocol

All the patients underwent chest radiography, spiral computed tomographic (CT) scanning with three-dimensional vascular reconstruction, and arteriography before the procedure and at intervals after the procedure, as defined by our protocol.

Endovascular Prosthesis

The endovascular stent–graft was custom-designed for each patient and composed of a stainless-steel endoskeleton consisting of Z-shaped stent elements and woven Dacron graft material (Fig. 1). The cylindrical metallic framework was covered with a Cooley Veri-Soft woven Dacron graft (Meadox Medicals, Oakland, N.J.), with the crimp ironed out. The graft was attached to the stent by a series of interrupted 5-0 polypropylene sutures.

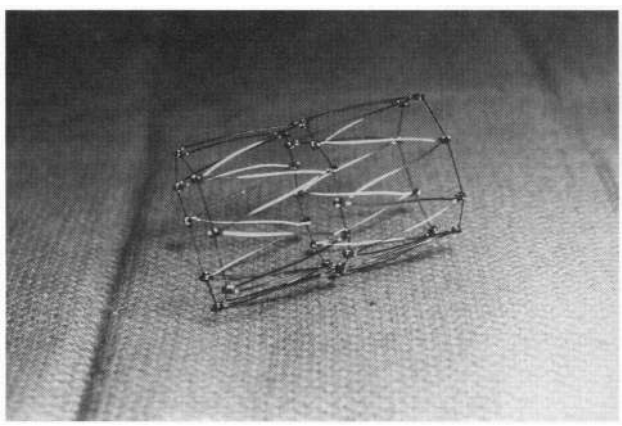


Figure 1. Stainless-Steel Endoskeleton Composed of Z-Shaped Stent Bodies.

The diameter, length, taper, and curvature of the prosthesis and the decision about whether to cover all stent bodies were based on measurements obtained from each patient's spiral CT scan.

Endovascular Procedure

All procedures were performed with the patients under general anesthesia, with endobronchial intubation and mechanical ventilation. Pulmonary-artery catheters and probes to monitor transesophageal echocardiography were inserted; there was standby capability for cardiopulmonary bypass. Prophylactic antibiotic therapy was initiated with 1 g of cefazolin given intravenously and was continued every four hours for a total of eight doses. The patient was placed in a shallow lateral decubitus position on a radiolucent table. The operative field was prepared and draped for thoracotomy in the event the endovascular device could not be deployed or a major complication occurred. A portable radiographic image intensifier capable of video playback and hard-copy image processing, along with a mechanical injector of rapid contrast medium, was used for intraoperative aortography.

As a preliminary procedure, a 5-French angiographic pigtail catheter (Mallinckrodt, St. Louis) was placed in the aortic arch to permit arteriography immediately before the stent–graft was deployed. In nine patients, a femoral artery was surgically isolated and a transverse arteriotomy was performed after the intravenous administration of 300 U of heparin sodium per kilogram of body weight. The angiographic catheter was then introduced over a 0.89-mm (0.035-in.) guide wire previously placed in the aortic arch under fluoroscopic guidance. After an initial aortogram was obtained, the angiographic catheter was removed and a 24-French (8.0-mm) Teflon sheath and dilator were introduced over the guide wire. Under fluoroscopic control, this delivery system was advanced until the sheath was positioned proximal to the aneurysm. A valve apparatus (Cook Urological, Bloomington, Ind.) was attached to the end of the sheath to provide hemostasis. With the sheath placed across the aneurysm, the radiologist removed the dilator and introduced the stent–graft from its loading cartridge by advancing a solid Teflon pusher. The pusher and the prosthetic device were then advanced within the sheath under fluoroscopic monitoring to the appropriate location proximal to the aneurysm.

Just before the device was released, vasodilator and beta-blocker drugs were administered intravenously to decrease the mean arterial pressure to the range of 50 to 60 mm Hg in order to reduce the risk that arterial flow would cause the stent–graft to migrate downstream when it was initially deployed. The radiologist deployed the stent–graft by holding the pusher firmly in position and quickly withdrawing the sheath, thereby allowing rapid expansion of the prosthesis. After the device was deployed, arteriograms were obtained to confirm that it was properly positioned and that flow had been excluded from the aneurysm. Subsequently, the sheath was removed, the arteriotomy repaired, and the effect of heparin reversed with protamine sulfate. No further anticoagulation was administered.

In two patients (Patients 5 and 6), the 24-French delivery system was inserted by direct puncture into the infrarenal abdominal aorta to avoid damage to iliac arteries that were unlikely to accommodate the large sheath safely because they were small, diseased, or both. In these patients, the infrarenal aorta was exposed with a left retroperitoneal approach. In two other patients (Patients 12 and 13), endovascular grafting of a thoracic aortic aneurysm was performed in conjunction with surgical resection of an abdominal aortic aneurysm. In both procedures, the device was introduced through the abdominal aortic graft with use of either one limb of a bifurcated graft or a 10-mm side-arm graft.

The clinical characteristics of the 13 patients are shown in Table 1. Four true aneurysms and nine false aneurysms of the thoracic aorta were treated. An atherosclerotic degenerative process was responsible in nine cases (Fig. 2). Endovascular stent–grafts were used to manage a ductus diverticulum aneurysm[12] in one patient (Fig. 3) and giant, penetrating aortic ulcers associated with large false aneurysms in five patients.

The average transverse diameter of the aneurysms was 6.1 cm (range, 5.0 to 8.0). In these 13 cases, the mean diameter of the stent–

Table 1. Characteristics of 13 Patients Who Received Transluminal Endovascular Stent–Grafts to Treat a Descending Thoracic Aortic Aneurysm.

Patient No.	Age	Sex	Cause of Aneurysm	Diameter of Aneurysm	Diameter of Proximal Neck	Diameter of Distal Neck	Length of Aneurysm or Breach in Aortic Wall*
	yr				centimeters		
1	47	M	Patch repair of aortic coarctation	6.5	2.8	3.2	7.5
2	71	M	Atherosclerosis	5.0	2.8	2.8	6.5
3	53	M	Atherosclerosis	5.0	3.0	3.0	6.5
4	39	M	Chronic trauma	8.0	2.8	2.6	12.0
5	71	F	Atherosclerosis	7.0	3.4	3.2	1.0
6	45	M	Aortic rupture	5.5	4.5	4.0	2.0
7	68	F	Aortic dissection	6.5	3.0	3.0	1.5
8	66	M	Aortic dissection	7.0	3.8	3.4	6.0
9	77	M	Atherosclerosis	5.5	3.4	3.0	4.5
10	64	M	Atherosclerosis	5.0	3.6	3.4	6.0
11	61	M	Atherosclerosis	6.0	4.0	3.8	11.0
12	67	M	Atherosclerosis	5.5	3.2	3.2	6.5
13	62	M	Atherosclerosis	6.0	3.2	3.2	4.5

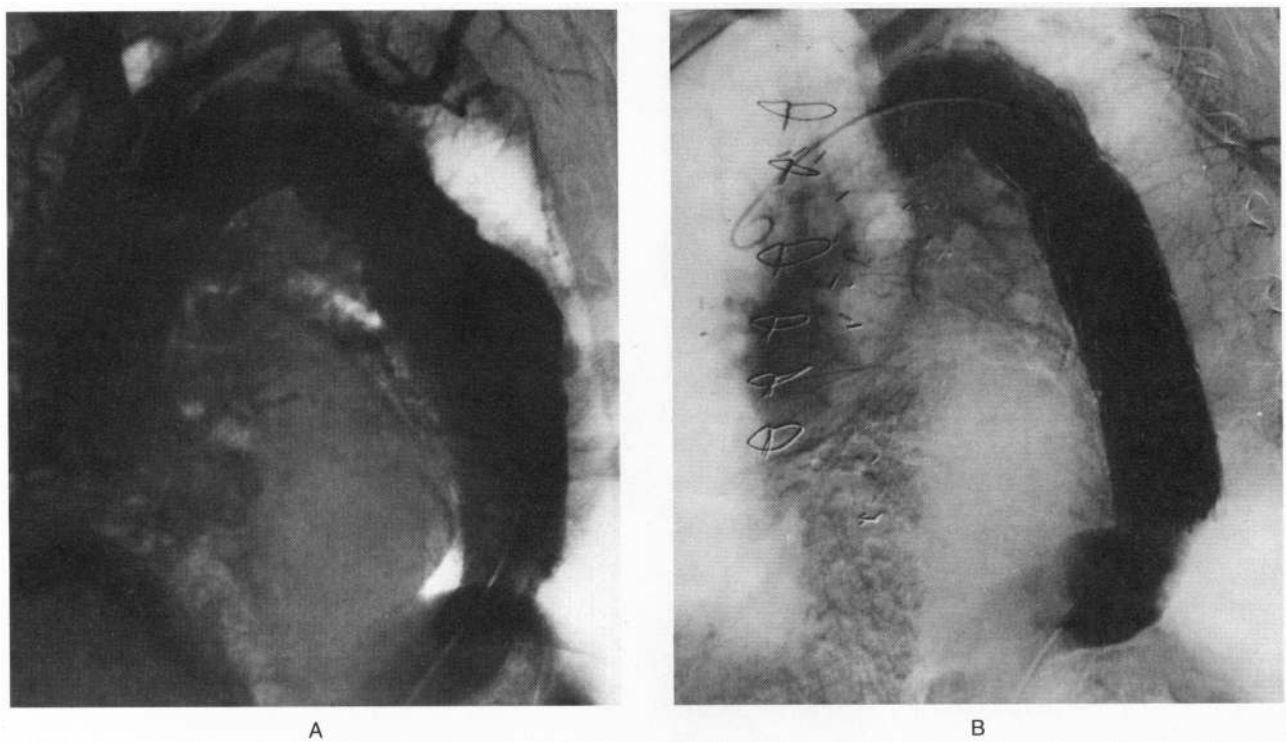
*For Patients 4, 6, and 7, the measurement shown is for a breach in the aortic wall.

graft implanted was 3.6 cm (range, 3.0 to 4.5), and the average length of the device was 10.2 cm (range, 5.0 to 16.0).

Results

The deployment of the stent–graft was technically successful in all cases. Thrombosis of the aneurysm surrounding the endovascular stent–graft was complete in 12 patients, but 2 of them initially had small patent proximal tracts communicating with the aneurysm; these tracts thrombosed within two months. In four patients two separate stent–graft prostheses were needed to attain complete coverage of the aneurysm after residual filling from either a proximal communication (Patients 3 and 7) or a distal communication (Patients 6 and 13) was identified. In two of these patients (Patients 6 and 7), a second procedure requiring general anesthesia was necessary within five days; in the other two, an additional stent–graft was deployed at the time the initial prosthesis was inserted.

All patients were treated electively except Patient 7. This patient had had an acute type A aortic dissection four years earlier that was managed by emergency replacement of the ascending aorta. Postoperatively, the false lumen of the distal ascending aorta, transverse arch, and descending aorta had continued to dilate, reaching 6.5 cm in diameter. After presenting at another hospital with acute back pain, the patient was



A B

Figure 2. Left Anterior Oblique Views of the Aorta in a 71-Year-Old Woman (Patient 5) with Back Pain and an Abnormal Chest Radiograph Who Had Previously Undergone Coronary-Artery Bypass Grafting.

Before the placement of the stent–graft, an aortogram (Panel A) shows a long, atherosclerotic aneurysm of the descending thoracic aorta associated with an irregular lumen. After the procedure, an arteriogram (Panel B) shows good flow of contrast medium through the device, with no leakage into the surrounding aneurysm.

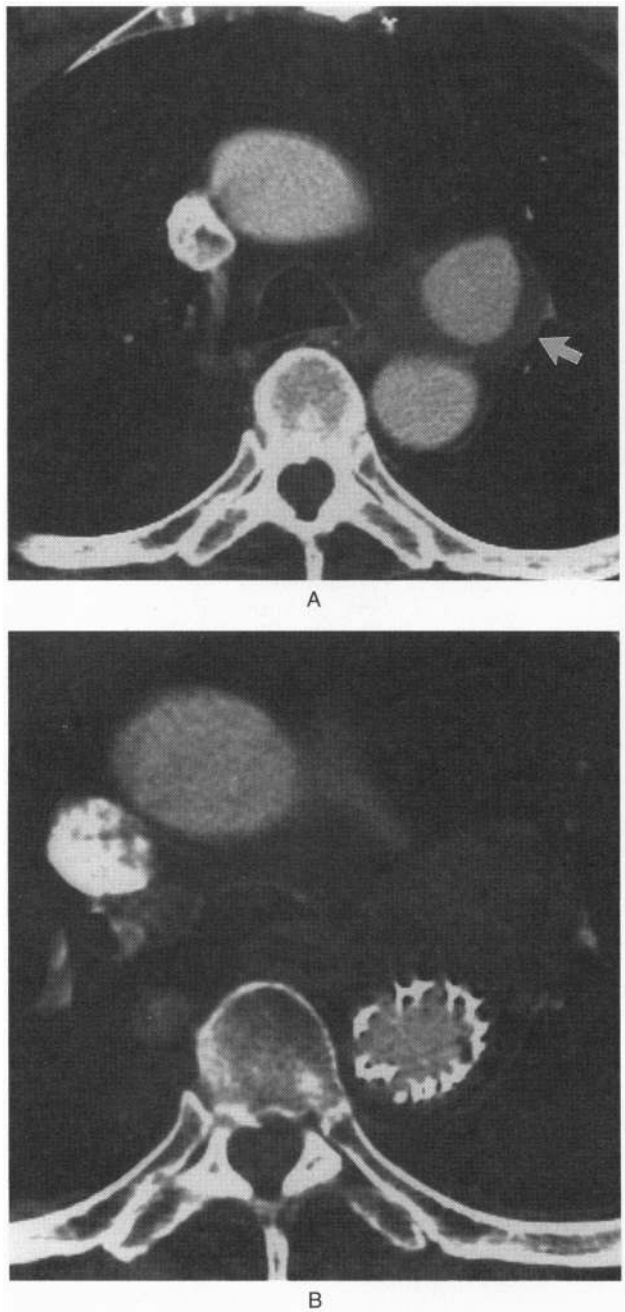


Figure 3. Axial CT Images Inferior to the Transverse Aortic Arch in a 77-Year-Old Man (Patient 9) with Previous Coronary-Artery Bypass Grafting and Recent Hoarseness Associated with an Aneurysm of an Aortic Ductus Diverticulum.

Panel A shows a round aneurysm about the same size as the descending thoracic aorta and containing mural thrombus (arrow). Panel B shows thrombosis of the aortic diverticulum aneurysm after endovascular grafting. The patient was discharged from the hospital in good condition on the third postoperative day.

transferred to our institution. Her extensive chronic type A dissection was now complicated by a large, expanding, localized false aneurysm filling the left hemithorax and originating from the false lumen of the descending thoracic aorta. Two endovascular stent–grafts obliterated this perforation site, but only partial thrombosis of the dissection-related false lumen was obtained. Four months after the procedure, a follow-up CT scan showed that the residual false lumen in the descending thoracic aorta outside the stent–graft had enlarged; there was also marked expansion of the ascending and arch components. Operative intervention was required to replace the aortic valve, ascending aorta, and arch; the entire descending thoracic aorta and the stent–graft were isolated from the circulation, and an extra-anatomical bypass graft was constructed from the ascending aortic graft to the distal abdominal aorta.

No other patients required a second operation to address any morbid conditions involving the thoracic aorta or any complications of the endovascular stent–graft. The early results of endovascular grafting are shown in Table 2. The average hospital stay after the procedure was 4.8 days (range, 2 to 11).

As of this writing, none of the 13 patients treated has died or has had paraplegia, stroke, distal embolization, or infection. The only clinically important early morbid event was pleuritic chest discomfort and left pleural effusion in four patients. This pain resolved in an average of four or five days. A left thoracentesis in one patient yielded straw-colored transudative fluid.

The average follow-up is currently 11.6 months (range, 6 to 24). Arteriography and spiral CT scanning after the procedure have shown widely patent stent–grafts, no recurrence of aneurysm, no migration of the stent–graft, no false aneurysms, and no change in the configuration of the stent–graft in the 12 patients treated electively.

Discussion

The transluminal placement of endovascular stent–grafts has recently been used to treat a variety of lesions, including abdominal aortic aneurysms. The feasibility of treating experimental aneurysms in animal models has been reported by a number of investigators[13-18] since Dotter initially proposed the concept of a transluminally placed endovascular graft in 1969.[19] In 1991, Parodi and his colleagues reported studies in animals and the first five clinical cases of management of abdominal aortic aneurysms with balloon-expandable prostheses composed of Dacron grafts sutured to modified Palmaz stents.[8]

When an endovascular stent–graft is considered for a patient with a thoracic aortic aneurysm, a number of anatomical and technical matters must be addressed. Anatomical suitability, a prerequisite for the safe transfemoral, endoluminal deployment of such a device, depends on the patient's anatomy as defined by imaging studies; it pertains both to the configuration of the aneurysm and to vascular accessibility (e.g., through the iliac arteries).

In addition, imaging studies provide the exact transverse and longitudinal measurements needed to design a prosthesis to fit each individual patient's anatomy. Given the experimental nature of stent–grafts at present, we believe that aortography before the procedure is essential in order to determine which intercostal arteries are still patent and to define the anatomical rela-

Table 2. Results of the Placement of an Endovascular Stent–Graft in 13 Patients with Thoracic Aortic Aneurysms.

Patient No.	Characteristics of Stent–Grafts				Extent of Aneurysm Thrombosis	Complications	Length of Follow-up
	Artery used for access	No. of devices	Diameter	Length			
			cm				*mo*
1	Femoral	1	3.2	10.0	Complete	Transient chest pain	24
2	Femoral	1	3.2	10.0	Complete	None	15
3	Femoral	2	3.2, 3.8	8.0, 8.0	Complete	Transient chest pain	13
4	Femoral	1	3.0	16.0	Complete	Transient chest pain	13
5	Aorta	1	3.4	12.5	Complete	None	11
6	Aorta	2	4.5, 4.5	7.5, 7.5	Complete	2nd procedure needed	10
7	Femoral	2	3.0, 3.8	5.0, 10.0	Complete	2nd procedure needed	10
8	Femoral	1	3.8	15.0	Partial	None	9
9	Femoral	1	3.4	15.0	Complete	None	9
10	Femoral	1	3.6	9.0	Complete	None	8
11	Femoral	1	4.0	12.5	Complete	Pleural effusion	8
12	Aorta	1	3.2	9.0	Complete	None	6
13	Aorta	2	3.2, 3.4	9.0	Complete	None	6

tions of the aneurysm neck with the nearby major aortic arterial branches — i.e., the left subclavian artery and the celiac axis. Whether a preprocedural aortogram will be needed in all patients after more clinical experience is gained remains unknown.

Although no patients were excluded from consideration for treatment because of the anatomy of their intercostal arteries, it is well recognized that there is a considerable risk of paraplegia as a result of interruption of the intercostal blood supply to the spinal cord during the operative treatment of descending thoracic aortic aneurysms. What effect endoluminal repair will have on the risk of paraplegia is not known; disruption of intercostal arteries may be minimized with an endoluminal approach, and this may translate into a lower risk of paraplegia. Conversely, there is no opportunity to reimplant patent intercostal arteries; for long-segment repairs and aneurysms with minimal thrombus and numerous patent intercostal arteries, the inability to implant these vessels again may expose the patient to a higher risk of paraplegia. Unfortunately, there is no easily obtainable test that can readily predict the possibility of paraplegia after the interruption of intercostal arteries.

In contrast to the balloon-expandable style of prosthesis described by Parodi to treat abdominal aortic aneurysms, the device used in our patients is self-expanding. The self-expanding rather than balloon-expandable stent was chosen because of the relatively large diameter of the thoracic aorta. The average diameter of the devices placed in this series was 3.6 cm, whereas the largest balloon catheter commercially available for intravascular use is 2.5 cm in diameter. The metallic stent support was used throughout the length of the device to buttress the Dacron material and avert kinking, buckling, or collapse of the graft, which might result in an unfavorable hemodynamic situation, including acute total aortic occlusion.

The potential for the opposite phenomenon — further expansion of the aneurysm wall despite intraluminal thrombus within the aneurysm sac outside the prosthetic graft — certainly exists and could represent the Achilles' heel of this endovascular approach. To date, such expansion has not been reported after the treatment of infrarenal abdominal aortic aneurysms, but the maximal follow-up is only 45 months.[8]

In our limited preliminary experience, the use of transluminally placed endovascular stent–grafts appears to be a feasible alternative to standard surgical procedures in the treatment of highly selected patients with aneurysms of the descending thoracic aorta or large penetrating ulcers associated with intramural hematomas. The effectiveness of such devices in the case of a thoracic aortic aneurysm associated with aortic dissection is more problematic, however, owing to the anatomical and hemodynamic complexity and to idiosyncratic variation among patients. The applicability of this procedure to the repair of traumatic tears involving the descending thoracic aorta is also unknown, but it may be possible to use the procedure for that purpose.

Note added in proof: Since this article was written, endovascular stent–grafts have been placed in an additional 20 patients with 23 descending thoracic aortic aneurysms. Complete thrombosis of the aneurysm occurred in 22 cases, and partial thrombosis in 1. Multiorgan failure developed in two patients, who died 27 and 31 days after the procedure. Death in the latter patient was preceded by paraplegia. There was one other case of paraparesis with partial recovery, but no instances of stroke, distal embolization, renal failure, or surgical conversion.

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