Endovascular repair of abdominal aortic aneurysms and other arterial lesions

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**Purpose:** This report describes our experience with endovascular stented graft repair of abdominal aortic aneurysms and other arterial lesions.

**Methods:** Between September 1990 and April 1994, 57 patients were treated with endovascular stented grafts (50 with abdominal aortic aneurysms or iliac aneurysms; five with traumatic arteriovenous fistulas; one with an infected femoral false aneurysm; and one with a false aneurysm of the proximal right common carotid artery). The devices consist of either a Dacron or an autogenous vein graft sutured to a balloon-expandable stent. The stented grafts are placed through remote arteriotomies, advanced under fluoroscopic guidance to their predetermined sites, and secured into position.

**Results:** Forty of the 50 endovascular stented graft procedures used to treat abdominal aortic aneurysms or iliac aneurysms were considered successful, even though some secondary treatment was required in six patients (two open operations; four secondary endovascular procedures). The 10 failures include four early procedural deaths, one late procedural death, and five leaks. All five arteriovenous fistulas and the two false aneurysms were successfully treated with endovascular stented grafts.

**Conclusions:** Although our experience with endovascular stented grafts has been promising, remaining problems require resolution, and further follow-up is needed. However, the potential advantages of these endovascular grafts warrant their continued evaluation.

(J VASC SURG 1995;21:549-57.)

The diagnosis of abdominal aortic aneurysm (AAA) has been established with increasing frequency during the past 2 decades. Although AAA may cause distal embolization, rupture remains the most common and deadly complication. For nearly 40 years, elective replacement with a synthetic graft has proven to be the most appropriate method to prevent AAA rupture, and it has been associated with a postoperative mortality rate of less than 5% at most medical centers. Nonfatal complications occur with some regularity, irrespective of the setting in which the operation is performed.

Increasingly, vascular surgeons are encountering older patients with severe comorbid medical conditions, which can increase operative morbidity rates and may significantly elevate mortality rates for aortic surgery. Alternative forms of treatment, such as axillofemoral bypass in conjunction with induced AAA thrombosis, have generally been abandoned despite preliminary reports of their success.

In 1976, we began to develop a plan for the endovascular graft treatment of AAAs and performed studies of experimental aneurysm treatment with such grafts in dogs. The first several clinical cases were described in 1991. This report describes the status of this procedure, which has now been performed on 50 patients with AAAs or aortoiliac aneurysms. In addition, it will describe seven additional patients who had endovascular graft treatment of other arterial lesions: five posttraumatic arteriovenous fistulas (AVFs), one infected femoral false aneurysm, and one false aneurysm of the right common carotid artery.
Fig. 1. These elements comprise endovascular stented graft device. These include (from top): valvuloplasty balloon catheter with tapered tip; guide wire; Teflon sheath with hemostatic valve at end closest to operator; Palmaz-type stent; and crimped Dacron graft.

Fig. 2. Illustration of assembled endovascular stented graft device (bottom). Also depicted are methods for affixing graft to stent and wrapping graft to give it low profile (top) so that it can be inserted within sheath (middle).

MATERIAL AND METHODS

Stented graft device

We use a 45 cm long, 18F (inner diameter), Teflon sheath that contains the balloon catheter and a hemostatic valve at the operator end (Fig. 1). The balloon catheter consists of a 9F polyethylene shaft and one nylon balloon that is 3.5 cm in length and either 30, 25, or 16 mm in inflated diameter. Mounted on the deflated balloon is a balloon-expandable stent. A thin-walled, crimped, knitted Dacron graft is sutured to the stent overlapping one half of its length (Fig. 2).

The stent we are currently using is a modification of the Palmaz stent, which was redesigned so that it could reach 30 mm in diameter when deployed. The length of the stent when it is not deployed is 3.5 cm, and the initial diameter is 4.6 mm. The balloon-expandable stent is constructed in one piece to prevent motion between the parts. The material used in these stents is the same as that used in the Palmaz stent (Johnson & Johnson, Warren, N.J.) namely stainless steel, 316L. These stents are not commercially available. They are manufactured for us by Barone Industries (Buenos Aires, Argentina).
The Dacron graft is a thin-walled (0.2 mm wall thickness), weft-knitted tube constructed from polyester fibers (E.I. du Pont de Nemours and Company). The compliant ends of the graft can be expanded up to 45% of their initial diameter. This compliance is obtained by knitting the graft with a wider net. Extra yarns are knitted into the graft to prevent unraveling. The diameters of the grafts are 18 and 20 mm when tubular grafts are used and 18 and 8 mm when tapered grafts are used for aortoiliac placement. These grafts are not commercially available and are manufactured for us by Barone Industries. We currently use balloons that are constructed of a nylon material that has some degree of compliance. This compliance has allowed us to use only two balloon sizes (25 and 30 mm in diameter). For aortoiliac grafting two independent balloons (25 and 12 mm in diameter) are used. In cases in which AVFs or false aneurysms were treated, an expandable Dacron graft was used to cover most of a single stent. However, in two cases the stent was covered with autogenous vein because of the possibility of infection.

Procedure

Details of the procedure for treatment of AAAs have been previously reported. After administration of local or epidural anesthetic, the patient is prepared and draped as for a standard AAA resection. A small incision is made over the common femoral artery that is distal to the straightest, widest iliac artery. A soft-tipped guide wire is advanced into the aorta up to the level of the diaphragm. A pigtail diagnostic catheter is advanced over the wire and placed inside the lumen of the aorta with the tip located proximal to the renal arteries. An injection of 30 cc of contrast media is made. The pigtail catheter has radiopaque marks on its surface every 2 cm to facilitate length and diameter measurements. By use of previously obtained arteriographic and computed tomography (CT) scan images, as well as the operative angiogram, target areas for stent deployment are defined. These include the proximal neck of the aneurysm and distal cuff (if it exists) or the common iliac artery (in the absence of a distal cuff). Under fluoroscopic guidance, the preloaded sheath, which contains the stented graft mounted on the balloon, is placed inside the lumen of the aneurysm. Once in place, the sheath is retracted and the cranial balloon is inflated with a dilute solution of ionic contrast media and saline solution. The balloon is kept inflated for 1 minute and then deflated. Before proceeding with balloon inflation, the mean blood pressure is lowered to 70 mm Hg with use of a nitroglycerin drip and maintained at that level during balloon inflation. The size of the balloon to be used is determined before the procedure and is based on the diameter of the neck of the aneurysm as measured on the previous angiogram and CT scan. After securing the proximal stent, the second or distal stent is placed separately to seal the distal end of the graft by friction. In four cases a “kissing balloon” technique was used to deploy the distal stent completely without injuring the proximal common iliac arteries. Completion arteriography is performed. In those cases in which an aortoiliac graft was placed, the final step involved the placement of a detachable balloon or closed, covered stent to occlude the contralateral common iliac artery and the performance of a femorofemoral bypass (Fig. 3).

Two common femoral artery aneurysms were corrected surgically at the time of the procedure, and four common iliac artery temporary conduits were constructed with 10 mm tubular Dacron grafts to permit access to the aorta in the presence of very tortuous, stenotic iliac arteries. When a complex procedure was anticipated, the blood lost from the field was collected by a cell saver and retransfused after filtration. Blood loss occurred when sheaths of different diameters had to be changed and when additional procedures (such as implanting a covered stent) were necessary.

When an aortoiliac procedure was performed in a small aneurysm with non tortuous, wide lumen iliac arteries, the procedure lasted 20 to 45 minutes. When an aortoiliac graft plus a femorofemoral bypass and occlusion of the contralateral iliac artery were needed, the time spent in the operating room exceeded 3 hours.

The procedures performed are summarized in Table 1.

Patients

Fifty patients (45 men; 5 women) with abdominal aortic aneurysms with or without iliac aneurysms or with an isolated iliac aneurysm (Table I) were treated between September 1990 and April 1994. The average age was 73 years (range 57 to 87). Five patients were admitted with pain probably related to their aneurysm, but none of the aneurysms had ruptured; one patient was admitted on an emergency basis for a rapidly growing aortic dilation caused by an infrarenal aortic dissection; and two were admitted with the diagnosis of “blue toe” syndrome, with the source of the thrombus being an AAA. In all but three patients, the size of the aneurysm at the time of treatment was more than 5 cm in diameter. Two
patients with small aneurysms causing microembolization were included in this therapeutic group. The third patient with an aneurysm of less than 5 cm had bilateral carotid endarterectomies and coronary artery bypass performed the same year and decided to have his 4.5 cm AAA treated by the endoluminal method. The aneurysms ranged in size from 3.8 cm to 12 cm. All patients had at least one associated morbid condition (Table II). Twenty-five patients were in the high-risk group. Of these, the conditions of 17 patients were considered inoperable by at least two other vascular surgeons, and eight were considered to be treatable with standard surgical procedures. These patients opted to have their AAA treated by an endovascular graft. The criteria for inclusion in the high-risk group included age, ejection fraction of less than 30%, forced expiratory volume in 1 second of less than 800 cc, renal insufficiency, and multiple previous abdominal operations. In addition, the patient must have been examined by two independent vascular surgeons who believed that the risk of standard surgery was prohibitive.

Five other patients had traumatic AVFs, one had an infected femoral false aneurysm, and one had a false aneurysm of the proximal right common carotid artery. These seven patients were treated with an endovascular stented graft repair.

Written informed consent for this new procedure was obtained from each of the 57 patients, as well as from a close relative of the patient.

RESULTS

Forty of the 50 procedures (80%) for AAA or aortoiliac exclusion were considered successful, although four of the patients required placement of a second covered stent to repair an initial leak. The definition of a successful procedure included the complete exclusion of the aneurysm with restoration
of normal blood flow. In these 40 patients, the stented graft was in contact with normal aortic wall proximally and distally or iliac wall distally, and all flow was observed to traverse the graft without leakage. When the stented graft was deployed in clot, leakage usually occurred and was considered a failure of the procedure. Patients with successful procedures recovered very rapidly, had breakfast the next morning, walked within 24 to 48 hours after the procedure, and were usually discharged from the hospital within 3 or 4 days.

Failures (deaths and complications)

Ten of the 50 AAA procedures (20%) were considered to be failures, defined as procedural death or imperfect placement of the stented graft or leakage of blood into the aneurysmal sac. This was usually determined by arteriography or contrast CT scanning. Of these 10 patients with AAA who had failure of their endovascular graft procedure, four in the high-risk group died, and the graft in one patient was salvaged after standard operative aneurysm repair. Details of the five failures are as follows: incomplete deployment of the proximal stent resulting in migration of the graft occurred in one patient with liver cirrhosis, ascites, and gastrointestinal bleeding. This patient was treated with a standard AAA resection. The patient survived the operation but died the next day as a consequence of abnormal bleeding. One patient died suddenly 2 days after the procedure. Postmortem examination disclosed intestinal ischemia and renal infarcts, probably related to embolization during the procedure. Two patients had massive microembolization after difficult endovascular procedures in large, tortuous aneurysms and died after development of multiple organ failure. In the fifth case there was misplacement of the proximal stent. This was eventually treated by a standard surgical procedure. The patient survived and did well.

There were three other cases of proximal leak. In one, the size of the aneurysm decreased in spite of a minimal leak. Contrast CT performed a few weeks later showed that the leak sealed. The patient died of an unrelated cause 6 months after the procedure. The second patient with a large proximal leak died of a rupture of his aneurysm 2 months after his endovascular procedure, and the third patient with a large proximal leak died of congestive heart failure 7 months after his endovascular procedure.

There were two other cases with distal leaks. One leak lasted for 3 weeks and then could not be identified. In the second patient a minimal distal leak persisted until he died of pulmonary and cardiac insufficiency 8 months after the endovascular procedure.

Other complications

In addition to the complications already described, there were several other untoward events (Table III). In six of the 50 aortic procedures, the proximal uncovered portion of the stent was placed across the renal ostia. However, the graft attached to the stent was placed distal to the renal arteries. None of these patients had development of renal insufficiency. Color-flow duplex scanning of renal artery flow has remained normal. Balloon dilation of the iliac arteries was performed in three cases before inserting the stented graft device. In one case, surgical repair of a ruptured iliac artery was required.

Late results

All patients have been monitored by clinical examination, color-flow duplex studies at least every 6 months, and CT scanning at least once a year. Angiograms were performed in selected patients, as well as in those in whom the color-flow duplex or CT scanning suggested a leak, dilation, or any change from the study performed immediately after the procedure. The mean follow-up period has been 17 months, with a range of 1 to 43 months. We are currently in the process of reviewing the CT scans obtained on all our patients, but it is difficult to obtain a measurement of the diameter of the aneurysm at precisely the same level as that obtained on the preprocedure study. However, it appears that in successful cases, if the lumen of the aneurysm is large, 10% to 20% reduction in the aneurysm diameter is evident.

In addition to the 10 AAA patients whose procedures were considered failures, one patient had development of a distal aortic dilation 18 months after the initial procedure. The distal stent was placed too far proximal to the aortic bifurcation and was in contact with mural thrombus instead of undilated aortic wall. This was corrected at open operation by

<table>
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<tr>
<th>Complications</th>
<th>No. of patients</th>
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<tr>
<td>Groin hematoma</td>
<td>2</td>
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<tr>
<td>Stent across renal ostia</td>
<td>6</td>
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<tr>
<td>Injury to the external iliac artery treated by suture repair</td>
<td>1</td>
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<tr>
<td>Minimal distal microembolization treated by intraarterial injection of prostaglandin</td>
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Table III. Other complications
adding a short segment of graft and performing a surgical anastomosis between the old graft and the aortic bifurcation. The patient had an uneventful recovery. Three patients who had been treated with a device having only a proximal stent had development of distal reflux with shortening of the graft at 8, 18, and 24 months after the procedure. At the time of this report, two of these patients have been successfully treated by additional endovascular procedures in which a covered stent was inserted at the distal end of the original graft. One patient died 13 months after the procedure of carcinoma of the colon and another died of heart failure and respiratory insufficiency 8 months after the initial procedure.

Thus of the 50 patients with AAAs or aortoiliac aneurysms treated by the endovascular procedure, there have been four early procedural deaths (8% mortality rate), one late procedural death, and four unrelated deaths. Although some secondary treatment has been required in six of the remaining 41 patients (two open operations; four secondary endovascular procedures), the ultimate outcome has been satisfactory for the 1 to 43 months (mean 17 months) of follow-up in these patients.

Arteriovenous fistulas and false aneurysms

Five patients with AVFs were treated with endovascular stented grafts. The first, with a right subclavian AVF that developed after a gunshot wound sustained 2 years previously, had development of congestive heart failure as a consequence of his fistula. A stented graft was inserted with the patient under local anesthesia via the brachial artery to close the abnormal communication. The fistula was eliminated, and the patient has done well for the subsequent 30 months. The second patient had a common iliac-inferior vena cava fistula after avascular injury sustained at laparoscopic surgery. A stented graft was inserted from the ipsilateral common femoral artery. The fistula was eliminated, and the patient remains symptom free after 17 months. A third patient with a left subclavian AVF was successfully treated by the same method and remains well after 8 months. The fourth patient with an AVF sustained a gunshot wound several months before admission and had undergone four surgical attempts to treat an aortocaval fistula. The last open operation had been unsuccessful and ended with cardiac arrest after exsanguination. The patient was transferred to our hospital and was treated by placement of an endovascular stented graft. This was placed via an open femoral arteriotomy performed with the patient under local anesthesia. The fistula was eliminated, and the patient was discharged the following day. He has remained well for 6 months. The fifth patient was a young woman who sustained a gunshot wound to her right thigh resulting in an AVF between the superficial femoral artery and vein. A covered stent was inserted percutaneously via the common femoral artery. The AVF was eliminated, and the patient has remained well for 4 months.

Another patient with renal insufficiency and unstable angina was admitted with an infected false aneurysm of the common femoral artery caused by a coronary stenting procedure performed 10 days previously. A Palmaz stent covered with autologous vein was deployed through the superficial femoral artery. The false aneurysm was eliminated, and the remaining abscess cavity was drained and debrided. The patient remains well 2 months later. A 20-year-old man with acquired immune deficiency syndrome had a gunshot wound of the chest. He was admitted to our hospital with a large false aneurysm of the right common carotid artery near its origin from the innominate artery. A Palmaz stent covered with an autologous saphenous vein graft was deployed via a right common femoral open arteriotomy to close the carotid artery defect. The false aneurysm was eliminated, and the patient remains well 3 months later.

DISCUSSION

Fifty-two endovascular stented graft procedures were used to treat aortic or aortoiliac aneurysms in 50 patients, and seven were used for other applications (AVFs and false aneurysms). Based on our preliminary data, we conclude that the procedure is feasible, and when successfully applied it has the added attractions of simplicity and less invasiveness.

In this generally favorable early experience, we have encountered several problems that limit the success and general applicability of these endovascular stented graft procedures. First, measurements of diameter and length of the involved arteries and the lesions are crucial. After great effort, we learned how to obtain reasonably reliable data by use of enhanced CT scanning, biplanar arteriography, and three-dimensional reconstruction with magnetic resonance or CT scanning. Intraluminal measurements and geometric calculations have also been helpful. Cognition of the fact that elongation occurs as dilation of the aorta develops and that elongation occurs in different planes facilitated the more accurate estima-
tion of graft length required to treat the aneurysm adequately.

Second, several difficulties involved access problems. Small-caliber, stenotic, and tortuous iliac arteries were responsible for these difficulties. The rigid stent and the large diameter of the sheath needed for the implantation were limitations. We were able to overcome some of these problems by modifying the device and reducing the diameter of the sheath. With an extra stiff guide wire, the “pull down” maneuver and occasional implantation of a temporary graft sutured to the common iliac artery via a retroperitoneal approach were also helpful in overcoming some of these problems. The “pull down” maneuver consists of dissecting the common femoral and external iliac arteries and pulling these inferiorly to straighten the tortuosity.

We studied the morphologic changes in aneurysms and have found that, in the initial stage, most AAAs have proximal necks and distal cuffs greater than 2 cm. In the later stages, the distal cuff becomes shorter and tends to disappear, the proximal neck also becomes shorter and elongation takes place, which creates tortuosity.

Thus a third problem is absence of a distal aortic cuff, which does not exist in most large aneurysms. This requires use of a bifurcated graft or an aortoiliac graft supplemented by placement of an occlusion device in the opposite common iliac artery and construction of a femorofemoral bypass (Fig. 3).

A fourth problem was stent migration, which occurred in one of our patients. This was probably due to incomplete stent deployment within the aneurysm neck. This problem may be obviated by use of intraluminal ultrasonography to control stent deployment.

Finally, microembolization appears to be the most important and as yet unresolved problem with endovascular graft treatment of aortic aneurysms. Microembolization occurred four times in our experience, and in three, death of the patient resulted. The two cases that had massive microembolization also had technically difficult procedures performed in patients with large aneurysms. In one case, visceral embolization and ischemia were present at postmortem examination. It appears that large, tortuous aneurysms with a substantial amount of intraluminal thrombus pose an increased potential for embolization.

The use of stented grafts to treat arterial trauma appears to be one of the most important uses for this method, because it transforms a complicated and potentially dangerous procedure into a simple, safe one. However, long-term follow-up will be required to determine the durable patency of these stented grafts, particularly in medium-sized arteries.

In conclusion, our experience to date with endovascular stented grafts has been encouraging but has been associated with a number of problems. It is obvious that much work remains to be done to solve these problems and to develop devices that will be suitable for all cases. Moreover, it is imperative that the functional adequacy of these stented graft devices be evaluated by appropriate mid-term and long-term follow-up studies. Nevertheless, the potential advantages of these endovascular grafts justify their continued use and careful evaluation.

At the time of the last revision, three more late failures were identified. These late failures consisted of two cases of distal neck dilation with incomplete sealing of the graft, which resulted in leakage of blood into the aneurysmal cavity, and one case of proximal neck dilation, but in this case with no leakage into the aneurysmal cavity.

REFERENCES

Submitted July 22, 1994; accepted Nov. 11, 1994.
DISCUSSION

Dr. Timothy A. M. Chuter (Rochester, N.Y.). Leaving aside the case of trauma, this is a most important study on endovascular aneurysm repair for four reasons. It is the largest series, personal or otherwise. The follow-up covers the longest period.

The patients were not selected to meet the narrow inclusion criteria of a formal clinical study, but they exhibited a wide variety of arterial anatomy and comorbid disease. The same insights that enabled Dr. Parodi to make endovascular repair a reality are reflected in his analysis of the results. An 80% success rate is remarkable, given the challenging circumstances present in many of these cases. Perhaps the most troubling of the reported complications and failures is microembolization, because it is not amenable to surgical correction and can be deadly. Large aneurysms and extensive manipulation were identified as contributing factors. How does this influence your patient selection? I ask this, not having seen embolism, but having excluded a patient from endovascular repair on the basis of the follow-up study on endovascular aneurysm repair for four reasons. It is the largest series, personal or otherwise. The follow-up covers the longest period.

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Regarding the importance of preoperative measurement, could you describe your current protocol and comment on any disparities seen when multiple techniques were used?

Three anatomic patterns were described: small aneurysms with a distal neck, larger aneurysms with relatively symmetric iliac arteries, and large aneurysms with marked twisting and angulation of the aorta and iliac arteries. I agree that the disappearance of the distal neck and increasing tortuosity of the aorta and iliac arteries that accompany aneurysm enlargement clearly have important implications on the technique of endovascular repair. Having treated 18 aneurysms with bifurcated grafts, I have yet to find any patients suitable for straight graft repair (group 1), and I do not regard iliac tortuosity as a contraindication to bifurcated graft repair. Do you have any data on the range of aneurysm size typical of each group?

I find little evidence to support the contention that the Palmaz stent represents the ideal proximal attachment device. The purpose of the proximal stent in an endovascular prosthesis is to prevent leakage and migration. In my experience, a graft secured with a self-expanding Z-stent in the neck of the aneurysm, does not leak and does not migrate.

The same cannot be said of the Palmaz stent.

I agree that intravascular ultrasonography may have an important role in assessing stent implantation and revealing irregularities in the graft surface. But, like you, I have very limited clinical experience with this imaging modality.

Two helpful techniques are described for dealing with access problems, which are worth repeating. One is the application of traction to a partially dissected external iliac artery to induce straightening. I have used this twice; it works. Another is the insertion of a guide wire from the axillary artery when the aneurysm is large. Volodos has reported using this method since the late 1980s.

One technical point that was less clear regarding possible modifications in the delivery system. Could you tell us whether the 18F sheath, containing the graft/stent/balloon assembly, was introduced directly into the artery or passed through another, larger sheath?

Dr. Juan C. Parodi. Regarding patient selection to prevent microembolization, we have seen three patients with spontaneous microembolization, and we did not have any troubles with them, but they had small aneurysms. I am not planning to exclude any patient at this point. What I am planning to do is just be more careful and come down from the brachial artery, perhaps with a small balloon catheter, which we are now developing. With that balloon catheter we can insert the wire upward. Regarding how we measured the aneurysm, the best way is to have spiral CT scanning with special software to rotate the image 360 degrees and have 10 segments of this image, because you have a two-dimensional screen and a three-dimensional aneurysm. So by rotating the reconstructed image and getting the longest segment of any kind of rotation, we can measure the length exactly.

Regarding the patterns we found in different stages of aneurysm evolution, we do not see this in all cases. Sometimes we have large aneurysms with no tortuosity and with good proximal and distal neck, but, at least in most of our patients after their aneurysm reaches 5.5 cm in diameter, it becomes tortuous. When you find small aneurysms of 3.5 or 4.0 cm, usually you have a good proximal and distal neck. Five-centimeter aneurysms start losing the distal neck. With aneurysms larger than 5.5 cm, you start having tortuosity.

Regarding attachment devices you can use several malleable plastic or metallic devices. Regarding the delivery system, I use a one-sheath system, 16F with a nose cone at the end. If you use a double sheath system, you should use a 20F sheath.

Dr. Michael Marin (New York, N.Y.). With regard to the use of different types of stents as Dr. Chuter has instructed, it is clear that anybody who has performed enough of these procedures and has seen the complexity of the disease will know that any stent, even in the best of designs, will produce some degree of leak in certain patients. Anybody who has seen no leaks around the stent and into the graft area in endoluminal grafts has not done enough cases. We also have had experience with this particular problem, which is of great concern and frequently can be fatal. Is there anything we can learn before operation that can predict this complication? For instance, are there features in CT scanning, such as the thrombus itself, that we can diagnose in a preoperative setting that would tell us which patients would be at risk for development of this horrible complication?
Dr. Parodi. We reviewed the medical literature about this, and we are now studying surgical cases by comparing the CT scan results and studying the inner surface of the thrombus. When you have a double lumen and an irregular surface inside, the patient is at high risk. Spontaneous embolization in a patient indicates the presence of friable material. I think we have to work and refine this technique.

Dr. Luis A. Queral (Baltimore, Md.). Of all the aneurysm cases that are referred to you, what percent do you submit for endovascular treatment and what percent do you submit for standard surgical treatment or traditional approach, and what criteria do you use to make this important decision?

Dr. Parodi. We started with very difficult cases, and we were successful in the beginning. We had a very strange learning curve. We did not have problems in the beginning, but when we had some experience, we started treating all cases, even ones with a 1 cm proximal neck. After case number 20, we started to have problems. I was close to quitting after case 22. I had two consecutive cases with microembolization, and I stopped the trial for 2 weeks. Then we monitored a case that was very simple, and we started again. Now we are more careful than we were before. I think it is wise to do what Dr. Moore is doing, which is to treat simple cases with small aneurysms. But very often we receive patients who have an aneurysm that has grown 2 or 3 cm in the last month, and the patients are having back pain, ejection fraction of 12%, and congestive heart failure. We decide to go ahead and treat it because that patient is going to have a ruptured aneurysm and die anyway. So the risk is high but it is not as high as the normal evolution.