Endovascular Treatment of Thoracic Aortic Disease
Four Years of Experience

Alessandro S. Bortone, MD, PhD, FESC; Emanuela De Cillis, MD; Donato D'Agostino, MD; Luigi de Luca Tupputi Schinosa, MD

Background—The aim of this retrospective study is to investigate efficacy and middle-term results of the stent graft treatment for diseases of descending thoracic aorta.

Methods and Results—From March 1999 to October 2003, 132 patients (113 male and 19 female, mean age 62±14 years) were enrolled. They were divided into 4 groups: aneurysms (43, group A), post-traumatic lesions (24, group B), and complicated type B dissections (43, group C). Twenty-two further patients, with chronic type B dissection and not suitable for endovascular or surgical or hybrid techniques because of multiple entry tears without difference between the true and false lumen and poor clinical conditions, were obliged to receive medical management only (group D). All patients underwent computed tomography (CT) scan and angiography as preoperative assessment. An optimal deployment with exclusion of the aneurysm and/or closure of the entry tear in dissection was achieved in 96.4% (106/110) of the patients that were discharged in good conditions within 6 days. No spinal cord injuries were observed. The follow-up (average 20.82±10.01 months, range 1 to 55 months), performed with serial chest CT scans, was 100% complete. No stent graft-related complications were detected, although only in 1 case, an asymptomatic rupture of the Excluder connecting bar was found with a perforation of the fabric and an intra-aortic exposition of the bar itself. In 2 patients with chronic dissection an asymptomatic type II endoleak was detected. A total of 4 hospital deaths resulted in an overall operative mortality of 3.9%. Seven patients (6.3%) died during the follow-up 5 of them for other diseases (4.5%). However, a 40.9% mortality was observed within the obliged medical treatment group.

Conclusions—Endovascular treatment of thoracic aortic diseases, even in the acute phase, may represent a valid option with a low mortality rate. Moreover, the efficacy is proved in the middle-term whereas the long-term follow-up is still pending. **(*Circulation*. 2004;110[suppl II]:II-262–II-267.)**

Key Words: thoracic aortic disease ■ endovascular ■ middle term

Diseases of the thoracic aorta represent often life-threatening conditions, and despite growing consciousness among the physicians about the role of early diagnosis in determining the appropriate treatment, they are still far from holding precise guidelines in management of acute and chronic aortic syndromes.

Aortic resection and replacement with graft interposition has been for many years the preferred method of treatment in the aneurysmatic lesions of thoracic aorta.[1] Although great strides have been achieved during the past years in the management of patients with thoracic aortic aneurysm by new surgical techniques, postoperative mortality and morbidity rates still remain high.[1–3] In contrast, the preferred treatment for most patients with Stanford uncomplicated type B dissection is medical therapy. Nonetheless, the current mortality rate among patients who received medical therapy for type B dissection remains ≈20%.[2,3]

The technique of endoluminal aortic stent graft placement has recently been introduced for repair of abdominal and thoracic aneurysms.[4–6] Stent grafting of descending thoracic aneurysms was the first endoluminal repair to be performed on the thoracic aorta.[4–6] The first case ever treated with a homemade stent graft was described by Voldos in the early 1990s. After initial "pioneer-like" attempts performed in a few institutions,[4–6] the endovascular stent graft treatment has emerged as a valid option in the management of all kinds of aortic disease.[7–18] Especially in the high-risk setting of patients affected by aortic dissection, endoluminal repair is a new therapeutic strategy that is yielding encouraging results.[7,8,14,15,17,18] Furthermore, some reports have appeared on stent graft repair of post-traumatic pseudoaneurysms.[10,11]

This study represents a retrospective analysis of the past 4 years, executed in our department, focusing on efficacy and middle-term results in terms of morbidity and mortality of the endovascular stent graft treatment of thoracic aortic disease. Moreover, we try to search for the real behavior of native aortic wall in response of modifications in the acute and chronic phase induced by aortic disease as well as by

From Division of Cardiovascular Surgery, Department of Emergency and Organ Transplantation, University of Bari School of Medicine, Bari, Italy.
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Correspondence to Alessandro S. Bortone, MD, PhD, FESC, Dipartimento Emergenza e Trapianti d'Organo, Sezione di Cardiochirurgia, Piazza Giulio Cesare 11 70124 Bari, Italy. E-mail abortone@cardiochir.uniba.it

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Clinical, Operative, and Postoperative Data

Patients	Group A n=43	Group B n=24	Group C n=43	Group D n=22 (medical treatment)
Average age	67.66±9.88 y	30.78±10.90 y	61.36±7.13 y	60.25±9.32 y
Aortic lesion	Aneurysm 37 (3 pt ETC)	Acute False Aneurysm 14	Acute dissection 24	Chronic dissection 21
	Acute aneurysm rupture 6	Chronic false aneurysm 10	Chronic dissection 19 (ETC 2 pt)	Aneurysm 1
ASA class	Class II 7	Class II 8	Class II 8	
	Class III 13	Class III 7	Class III 14	
	Class III–IV 6	Class IV 9	Class IV 21	
	Class IV 17			
Main procedure	Talent 30 (4 pt 2 grafts, 1 pt 3 grafts)	Talent 13	Talent 45 (7 pt 2 grafts, 1 pt 3 grafts)	None
	Excluder 14 (3 pt 2 grafts)	Excluder 14 (1 pt 3 grafts)	Excluder 9 (1 pt 2 grafts)	
	Zenith 9			
	Endofit 2			
Right subclavian approach 3		Iliac fenestrations only 2		
Concomitant procedure	PTCA+Stent 1		CSBG 3 iliac fenestrations 3	
	PTA+Stent in SMA 1	CSBG 2	Renal stent 1	
	Aortobifemoral bypass 1		Axillobifemoral bypass 1	None
	CSBG 2		Ascending aorta innominate left carotid artery bypass 1	
	EVAAR 5			
Outcome	Good 40	Good 23	Good 40	Good 13
	Hospital death 1			
	Minus stroke 1	Open surgery 1	Hospital death 3	Death 9
	Pleural effusion 1			

ETC indicates elephant trunk completion; ASA, American Society of Anesthesiology Classification of Physical Status (grades physical status on a scale from I to V); CSBG, left carotid subclavian bypass graft; EVAAR, endovascular abdominal aortic repair; SMA, superior mesenteric artery; pt, patient.

introducing a noncompliant system in a semi-compliant structure such as aorta.

Methods

From March 1999 to October 2003, 132 consecutive patients (113 male and 19 female) were admitted with clinical and instrumental diagnosis of either acute (44) or chronic (88) aortic disease. They were divided into 4 groups (Table): atherosclerotic aneurysms (43, 6 of which acutely ruptured, group A), post-traumatic lesions (24, 14 acute and 10 chronic, group B), all of them caused by "decelerating injuries," complicated type B dissection (43, 24 acute and 19 chronic, group C). Twenty-two further patients (21 with chronic type B dissection, 1 with aneurysm) not suitable for endovascular or surgical or hybrid treatment, because of multiple entry tears without difference between the true and false lumen and poor clinical conditions, were obliged to receive medical management only by using β-blockers or vasodilating agents (group D). Altogether 110 patients (91 male and 19 female) subdivided among different groups underwent endovascular treatment (Table). All patients underwent 5-mm contrast-enhanced computed tomography (CT) scan as preoperative assessment. The arteriography was reserved at the time of implantation or to study peripheral vascular access sites. All the anatomic inclusion criteria, ie, length of landing zone, angle of descending aorta off of the arch, and the study of possible dominant left vertebral artery, in case of short proximal neck, were satisfied in all treated patients. Mandatory is transesophageal echocardiography (TEE) monitoring for aortic dissection in each step of procedure to detect proximal then distal entry tears, to follow the sealing of proximal communication by stent graft positioning, and restoring of blood flow in the true lumen with thrombosis of the false one, as well as the absence of perigraft leakage. All procedure were performed in the angiography suite, with patient under general anesthesia, and controlled hypotension according to our well-established protocol.[15] The common femoral artery was the most frequent access site, but in some cases we have also used the common iliac or right subclavian artery approach. One hundred IU/kg of intravenous bolus heparin were administered in each case. According to vascular anatomy, a percutaneous left or right brachial artery approach was selected, allowing a 6-French pigtail catheter to be inserted over a hydrophilic guide wire to localize the left subclavian artery, the celiac trunk, and to be used for angiographic controls. The narrow proximity of the lesion to left subclavian artery in 7 cases calls for us to perform carotid subclavian bypass grafting. This occurred in the first 2 years of our experience. Actually, we do not perform this routinely because we did not see any case of symptomatic left arm ischemia and we never detected a dominant left vertebral artery. The only indication to this concomitant procedure is the involvement of left subclavian artery in dissection with retrograde alimentation of false lumen. In 5 patients affected by atherosclerotic aneurysm, in a single procedure, we have also treated the abdominal aortic aneurysm by endovascular techniques. In 5 cases the stent graft deployment has represented the endovascular completion of elephant-trunk technique. We have used different stent graft systems, such as Talent (Medtronic), Excluder (Gore), Zenith (Cook), and Endofit (Endomed).

Results

As summarized in the Table, a good clinical outcome was achieved in 106 patients out of a total 110 (96.4%) patients

treated by endovascular procedure, with an optimal deployment and exclusion of the aneurysm and/or closure of the entry tear in dissection. All these patients were discharged in good overall conditions within 6 days. Three patients affected by chronic complicated type B dissection underwent multiple percutaneous balloon fenestration to restore homogeneity of blood flow between the 2 aortic chambers and therefore increase the distal perfusion. Endovascular completion of the elephant-trunk technique was successfully performed in 5 patients. Despite some reported occurrences of paraplegia after deployment of multiple stents, we have never observed spinal cord injuries in our series. A total of 4 hospital deaths were observed, resulting in an overall operative mortality of 3.6%. In 1 case, the patient was affected by acute rupture of thoracic aneurysm associated with abdominal aneurysm, whereas in the others an abrupt retrograde dissection was observed after the deployment of stent graft for treatment of chronic type B dissection, possibly related to the free-flow of Talent stent graft. Only 1 case required conversion to elective surgery because of a large calcified aneurysm that was still causing compression on the trachea and left main bronchus, even if totally excluded by the stent graft.

The follow-up (range 1 to 55 months; mean, 20.82 ± 10.01), performed with serial 5-mm angio chest CT scans after 3, 6, and 12 months and once per year, was 100% complete. None of the patients treated in the acute phase died in the observation period and are still asymptomatic without any complications at the middle-term follow-up. One patient was retreated by a proximal implantation of a second stent graft after 3 months because a new entry tear was detected at CT scan and probably related to a late retrograde dissection because of in-wall penetration of the Talent free-flow. In 2 patients with chronic type B dissection, an asymptomatic type II endoleak was detected. In the aforementioned patients, the endoleak was associated with a complete thrombosis of the false lumen in the thoracic aorta and a nonsignificant retrograde flow distally to the stent graft and between the celiac trunk and superior mesenteric artery without any expansion of the abdominal aorta false lumen and actually under hypotensive medical treatment. During the follow-up, 7 patients (6.3%; 3 from group A and 4 from group C) died. Two patients affected by chronic type B dissection died because of progression of the disease itself despite treatment. Five patients died for other disease that was not stent-related. However, a 40.9% (9/22 patients) mortality rate was observed within the obliged medical treatment group.

Discussion

Our experience suggest that nonsurgical repair may be an effective therapeutic option for patients with descending thoracic aortic diseases such as aneurysms, pseudoaneurysms, or dissections.

Aneurysm of descending thoracic aorta was the first thoracic aortic disease to be repaired by a stent graft endovascular procedure. Effectively thoracic aneurysm stent graft treatment has the longest and most established long term results.[4–6] In the past, our management of descending thoracic aortic aneurysm was medical unless clinical and instrumental signs of rupture were evident and required immediate surgery. At the present time, indications for stent graft treatment are presence of an uncomplicated aneurysm and history of hypertension with chest discomfort, or signs of compression on surrounding organs, as well as a diameter >6 cm or expansion >5 mm per year. However, if a patient is considered to be a candidate for stent graft placement, several major factors have to be taken into account. The most important are location and morphology of the aneurysm; then, a distal vascular access of sufficient size and, last but not least, a limited tortuosity of the abdominal and thoracic aorta. During preoperative assessment, the determination of the proximal and distal "landing" zones of the stent graft is essential, because they serve as a friction anchor at each end. The grafts are generally oversized in diameter by 3 to 4 mm to allow sufficient radial force for fixation. In the case of a short proximal neck close to the left subclavian artery, we favor the coverage of the artery itself. With the Talent system, the proximal end of the graft has polyurethane uncovered nitinol spring bars that can be safely placed across the origin of the left subclavian artery. In case of persistent perigraft leakage, a second endoluminal stent graft can be inserted within the first graft in a "telescope" fashion with the aim to "patch" the leaking site during the same procedure or in the event of a new entry tear. This is a feasible and handy solution when some persistent leakage is observed and has already been described.[11] The postoperative death of our series occurred in group A despite optimal stent graft deployment, because of extremely poor preoperative overall conditions, whereas in the follow-up all patients died for other disease that was nonstent-related.

Not many series appear in literature that report results of endoluminal stent graft repair of acute and chronic post-traumatic aortic pseudoaneurysms (group B).[10,11,17] The outcome in this group of patients was satisfactory; therefore, this technique can be considered a valid option, especially when standard surgical procedure cannot be performed for other reasons. Despite one particular case characterized by a giant chronic pseudoaneurysm, our experience is overall satisfactory because each patient with a post-traumatic aortic pseudoaneurysm received endoluminal treatment avoiding replacement of the aorta, which has higher morbidity and mortality.[1–4,7,10,11] In the aforementioned case, the stent graft was the bridge between the endovascular procedure and the open surgery, because it was possible to displace and resect the aneurysm itself safely and without pulsatile flow in the aneurysm sac.

As in the previous 2 groups, patients with complicated type B aortic dissection endoluminal stent grafting have experienced encouraging results. In the past, our management of patients with type B aortic dissection was medical, unless clinical and instrumental signs of aortic rupture were found. This policy was suggested by the significant morbidity and mortality generally observed in patients after surgical standard procedure. In particular, the high surgical mortality lies in rupture of the aorta and splanchnic ischemia. These events are particularly serious if they occur in patients older than 70, with a mortality rate of 70%.[19] During the endovascular procedure for type B dissection repair, it is imperative to locate the primary entry tear, because aortic rupture is by far

the most frequent cause of death in this group of patients.[7,8] Our experience, as well as the experience of others,[7,8] suggests that stent graft placement over the primary entry tear in patients with complicated type B dissections may be an effective alternative to open surgery. The therapeutic result is similar to surgical obliteration of the entry tear because the stent graft can exclude the blood flow through the initial tear in the intima and redirect it exclusively into the true lumen. Furthermore, with stent graft implantation, aortic remodeling is induced by thrombosis of the false lumen and by the endoprosthesis itself. Even in the acute type B dissection using a relatively short stent graft to cover just the proximal entry, a complete thrombosis of the false lumen of the dissected thoracic aorta was observed within 3 to 6 months[7,8] in the absence of distally thoracic accessory entry tears. Even if only partial thrombosis of the false lumen is achieved, an endovascular stenting procedure can still be advantageous. It may protect the false lumen from enlarging over time, because systemic blood pressure is no longer directly transmitted from the aorta through a large primary tear in the intima.[7,8] With regard to visceral and peripheral vascular ischemia, there is a complication rate of ≈30% to 50% in type B aortic dissection. Stent graft placement alone across the primary entry tear may be an effective treatment that avoids this complication in dynamic obstruction. In a patient in our series, adjunctive deployment of a stent within the true lumen of a dissected aortic branch or intimal flap fenestration may still be necessary to effectively treat the static obstruction caused by direct extension of the flap into the branch vessel. The 2 techniques may be used in the case of static plus dynamic obstruction. The 3 deaths that occurred in the first 2 years of our experience were related to the fact that we stented too much proximally to left common carotid artery and the uncovered nitinol stent caused the suddenly propagation of the retrograde fatal dissection. Actually, in these cases, we propose the hybrid technique to override this problem, because we are treating the arch by using the first stage of elephant-trunk technique.[20] Then we complete, before discharging the patient from hospital, with endovascular technique.

It should be noted that no cases of paraplegia were encountered in our series. In the case of aneurysms, many intercostal branches are already occluded, and the spinal cord is perfused by collaterals. Furthermore, the sudden deployment of the stent followed by the occlusion of the intercostal branches does not produce steal syndrome in the perfusion of the spinal cord.[9] In patients with type B dissection, the use of short stent grafts and deployment far from vertebrae T8 to L2 further minimizes the risk of paraplegia, as compared with the risk of surgical aortic replacement and graft interposition.[7,8] Most important, endoluminal stenting is a much shorter procedure than surgery. Therefore, stenting circumvented the need for circulatory arrest and cross-clamping of the aorta, which may represent one of the causes of spinal cord injuries and the associated ischemia and reperfusion injury. It is also been reported that the paraplegia in patients treated by endovascular thoracic endoprosthesis occurred only in those previously treated by surgical abdominal aneurysm repair because of the absence of lumbars and hypogastric collateral circulation. Moreover, it averted postoperative respiratory failure and prolonged hypotension and the delayed risk of paraplegia. Even successful reimplantation of the intercostal arteries and cross-clamping for <30 minutes have not totally eliminated the risk of paraplegia after surgery.[1,8,19] The hospital stay after the procedure in most cases does not exceed 5 days, and at the end of the procedure the patient was extubated in the angiography suite and monitored in intensive care for only 24 hours.

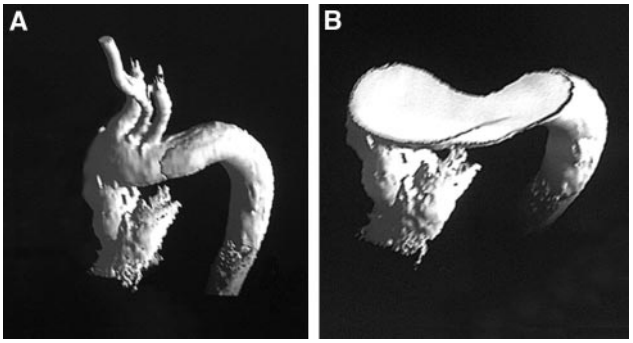

Figure 1. A and B, Three-dimensional reconstruction of angio-CT scan in patient affected by acute uncomplicated type B dissection.

In our series we observed an operative mortality rate of 3.6% (4/110). With regard to follow-up, only 7/110 patients (6.3%) died. Moreover, only 2 (1.8%) of them died from progression of chronic type B dissection despite the endovascular procedure, whereas the remaining died from other disease that was nonstent graft-related. With regard to the morbidity rate, we observed in the follow-up that only 2 (1.8%) patients affected by chronic type B dissection presented a type II endoleak without any symptom and therefore are undergoing observation with hypotensive medical therapy. Only in 1 patient, affected by chronic posttraumatic lesion, was a rupture of Excluder bar detected. The same patient is still asymptomatic and undergoing observation. However, in the obliged medical treatment group an overall mortality rate of 40.9% (9/22) was observed in the follow-up.

Our retrospective analysis of 4 years of endovascular treatment of all types of aortic lesions has led us to believe

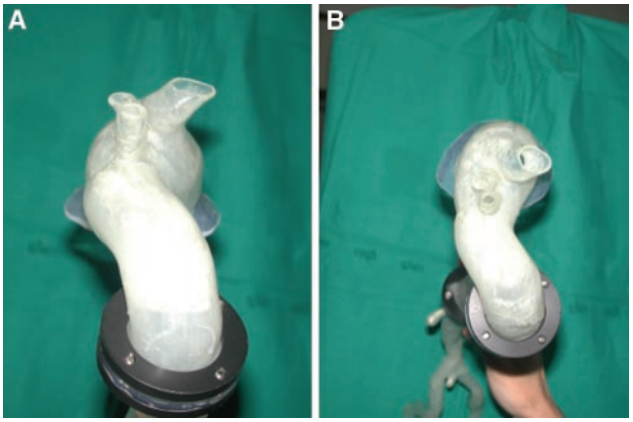

Figure 2. A and B, Cast model of the same patient that clearly shows the "double S" configuration of the isthmus area in the spatial 3 axis.

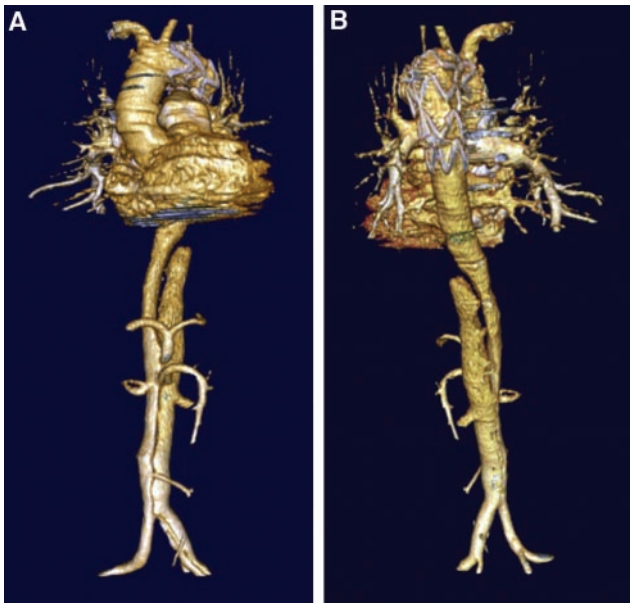

Figure 3. A and B, Three months follow-up. Positive remodeling after successfully endovascular treatment with complete thrombosis of false lumen in the thoracic aorta and patent abdominal branch vessels.

that descending aortic disease is essentially a pathology of isthmus and that the keystone of treatment of all types of aortic lesion lies on understanding the morphology of this region (see Figures 1 and 2).

It is likely that future indications to endovascular stent-grafting may be broadened when more flexible prostheses with arms for aortic branches stenting will be available for clinical use.

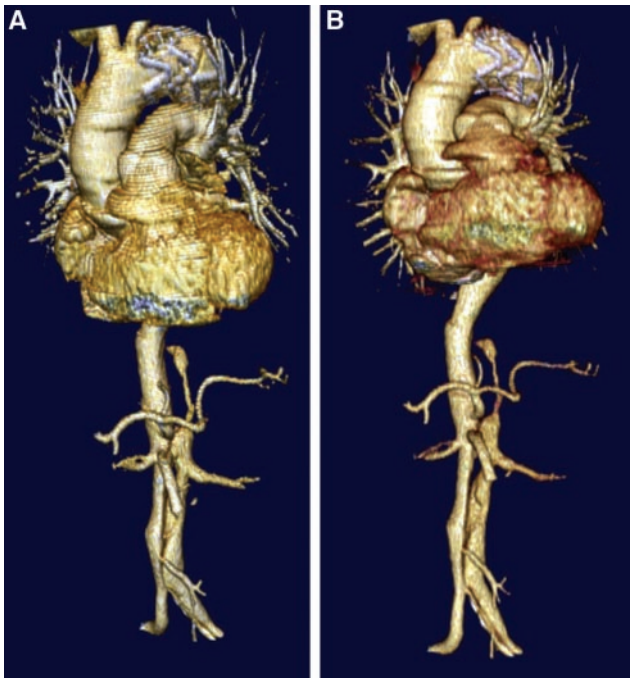

Figure 4. A and B, Six-month follow-up. Complete remodeling with a progression of thrombosis of false lumen in the abdominal aorta and patent abdominal branch vessels in the same patient.

Moreover, on the basis of our data previously reported,[15] it would be highly desirable for all patients with aortic lesions to be treated in the acute phase whenever possible. Significantly, in the patients affected by acute aortic type B dissection, we have reach 100% procedural success with covering of proximal entry tear, thrombosis of the false lumen, and remodeling of the entire aorta at 3 and 6 months. Restoring of side branch flow was also observed without any need for implementing additional techniques as well as the progression of false lumen thrombosis immediately and in the middle-term follow-up (Figures 3 and 4).

Despite these encouraging results, the problem of durability and resistance of actual compounds and their conformability to the altered anatomy and hemodynamics remains. In fact, whether this material is outstanding in terms of adaptability of a straight segment of diseased aorta, the behavior within the isthmus region that is gifted with a "double S" conformation needs the delivery system to be arch-compatible, flexible but stiff enough, and 3-dimensional–oriented. Moreover, the stent graft has to follow the "double S" configuration of the isthmus to increase the conformability of the device itself, molding the anatomy as well as the torsion forces of this critical region, taking into account that the aortic thoracic disease usually involves this area (Figures 1 and 2).

In conclusion, endovascular stent graft treatment of thoracic aorta diseases, even in the acute phase, may represent, at present, a valid option with a low risk. The major limitation is that the efficacy in the middle-term is proven, in our experience, by a retrospective analysis. Moreover, we were not able to compare the groups because they had different aortic diseases. The high mortality rate of the obliged medical treatment group was expected because of the poor medical condition of these patients. Nonetheless, prospective randomized trials with larger series of patients with longer follow-up are desirable to confirm these initial positive findings to establish indications of this kind of treatment and assess its real advantages over conventional surgical or medical treatment.

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