Multicenter early experience with extended aortic repair in acute aortic dissection: Is simultaneous descending stent grafting justified?

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Objective: In acute type A aortic dissection, the extension of repair to downstream aorta has been controversially discussed. We present the early results of a multicenter study using a hybrid stent graft prosthesis.

Methods: Between January 2005 and January 2010, the data from 191 patients after combined proximal aortic replacement and antegrade stent grafting were collected in the database of the International E-vita open Registry. Of the 191 patients, 68 underwent surgery for acute aortic dissection and were included in the present study. Hypothermic circulatory arrest and selective cerebral perfusion were routinely used. Computed aortic imaging was performed for false lumen evaluation during follow-up.

Results: The in-hospital mortality rate was 13% (9/68). Along the stent graft, the rate of immediate complete false lumen thrombosis was 86% (51/59) and increased during follow-up (23 ± 17 months) to 94% (46/49). Distally, complete or partial false lumen thrombosis was initially observed in 61% (36/59) and in 82% (40/49) after follow-up. The 1- and 3-year actuarial survival rate was 82% and 74%, respectively.

Conclusions: Extended thoracic aortic repair of acute aortic dissection with a hybrid stent graft is feasible at acceptable early mortality and promotes false lumen thrombosis around the stent graft and below. (*J Thorac Cardiovasc Surg* 2010;140:S116-20)

In thoracic aortic surgery, a combination of a vascular prosthesis with a stent graft enables extension of the repair into the descending aorta using a median sternotomy.¹⁻⁴ Although the feasibility of this approach has been proved during the past 2 decades, in acute type A dissection extension of repair downstream from the arch is a matter of controversy.⁵ The use of a stent graft has been regarded as an additional surgical step in an already acute and critical situation increasing the risk of the procedure. Therefore, a multicenter study was initiated to evaluate extended aortic repair into the downstream aorta using a hybrid stent graft in acute aortic dissection. The present study reports the early results of this approach, including the behavior of the false lumen during the follow-up.

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MATERIALS AND METHODS

For patient collection and data analysis, the database of the International E-vita Open Registry was used.⁶ The data selection was approved by the Institutional Review Board of University of Essen, Essen, Germany. Between January 2005 and January 2010, the data from 191 patients with thoracic aortic disease were delivered to the Registry. In all cases, the E-vita open stent graft (Jotec GmbH, Hechingen, Germany) hybrid prosthesis⁷ was used, and the patients underwent surgery in 5 European centers (Barcelona, Spain; Bologna, Italy; Essen, Germany; Hietzing, Vienna, Austria; and Prague, Czech Republic). Of these patients, 68 underwent surgery for acute aortic dissection and were included in the present study. The decision to perform more aggressive therapy by a stent graft was made at the surgeon's discretion, and no criteria were established among the centers for patient selection. The mean age of the patients was 58 ± 12 years (range, 32-77 years), and the false lumen involved the proximal aorta and extended into the descending aorta in all cases. Acute was defined as dissection that underwent surgical repair within 14 days after the onset of symptoms. The patients requiring inotropics, with cardiac tamponade, cardiac malperfusion, and acute renal failure were classified as severely, hemodynamically compromised.

In 50 patients (74%), the primary diagnosis was made at an external clinic and in 18 (26%) at the treating institution. The extension of dissection was evaluated by computed tomography (64/68, 94%) and/or angiography (27/68, 40%). The choice of stent graft size was made according to the preoperative computed tomography measurements of the true lumen at the descending aorta level and/or according to intraoperative sizing of the true lumen distal to the left subclavian artery using flexible seizers. No guidelines regarding oversizing were agreed on among the surgeons. In addition, no standardized protocol was used for stent graft insertion (over-the-wire technique or not), for the level of the distal anastomosis, for reimplantation of the supra-aortic vessels (as an island or separate), or for the use of the integrated polyester prosthesis for arch replacement. For cerebral protection, selective bilateral antegrade cerebral perfusion was favored and performed in all patients.

During follow-up, the patients were examined by physicians, and the behavior of the false lumen was evaluated by computed tomography or

magnetic resonance imaging. In these cases, a follow-up was defined as complete. The follow-up examinations were performed postoperatively, after 6 and 12 months, and annually thereafter.

E-Vita Open Stent Graft

The E-vita open stent graft consists of a 15-cm-long, self-expandable, nitinol-covered stent graft with an integrated nonstented vascular prosthesis (7 cm unstretched) on the top. The stent graft was implanted antegradely into the descending aorta through the opened aortic arch using a flexible delivery system in an over-the-wire technique. After deployment, the stent graft was fixed continuously with the aortic stump by polypropylene suture, and the vascular prosthesis was pulled back to the arch position for continuous arch replacement and re-insertion of the supra-aortic vessels.

Statistical Analysis

The Statistical Package for Social Sciences, version 16.0, software package (SPSS Inc, Chicago, Ill) was used for statistical analysis. Categorical and continuous variables are expressed as frequencies and mean $\pm$ standard deviation, respectively. The 2-sided Fisher exact test in categorical and the 2-tailed unpaired *t* test in continuous variables were used for *P* value evaluation. The Kaplan-Meier actuarial method was performed for the evaluation of survival and the freedom of secondary interventions within the total patient cohort.

RESULTS

Status at Admission

Thirteen patients (19%) were intubated before admission to the surgical institution, and 58 patients (85%) underwent surgery within 24 hours after the onset of symptoms. A severe hemodynamic compromised status was documented in 33 cases (49%), including 21 patients (31%) requiring inotropic support, 13 (19%) with tamponade, 10 (15%) with cardiac malperfusion, and 18 (27%) with acute renal failure and anuria. Malperfusion syndromes occurred in 38 patients (56%) (Table 1). The primary entry was identified in the ascending aorta or in the arch in 61 patients (90%) and in the descending aorta 7 (10%). The presence of a re-entry along the descending aorta was verified in 36 patients (53%). A collapse of the true lumen was documented in 35 patients (52%), and the false lumen extended along the descending into the abdominal aorta in 63 (93%).

Intraoperative Data

Arch replacement was performed under selective cerebral perfusion (mean, 68 ± 20 minutes) in all cases. The mean interval of hypothermic circulatory arrest was 8 ± 6 minutes and the mean interval of visceral ischemia was 71 ± 22 minutes. In most cases, a 24-mm (32%) or 28-mm (34%) stent graft (mean, 28 ± 4 mm) was used, and an oversizing greater than 10% was performed in 12 cases (18%) (Table 2). Stent graft placement was achieved using the over-the-wire technique in 37 patients (54%) and without the technique in 31 (46%). One complicated stent graft insertion was reported by placement of the stent graft into a previously implanted uncovered stent at the distal descending level, but stent graft deployment was successful in all cases. For arch replacement, the integrated vascular prosthesis was

TABLE 1. Patient characteristics (n = 68)

Characteristic	Value
Age (y)	58 $\pm$ 12
Age $\geq$ 70 y	12 (18)
Male	52 (77)
Marfan syndrome	5 (7)
Emergency	58 (85)
Intubated before admission	13 (19)
Inotropic support	21 (31)
Cardiac tamponade	13 (19)
Aortic valve regurgitation $\geq$ 2	40 (59)
Malperfusion	
Cardiac	10 (15)
Cerebral	15 (22)
Visceral	8 (12)
Peripheral	10 (15)
Coronary artery disease	9 (13)
After stroke	4 (6)
After cardiovascular surgery	4 (6)

Data in parentheses are percentages.

used in 36 (53%), a branched prosthesis in 9 (13%), and another tubular prosthesis in 23 (34%). The supra-aortic vessels were re-implanted separately in 19 (28%) or as island in 49 patients (72%). Aortic valve repair was performed in 41 (60%) and coronary artery bypass grafting in 13 (19%). The period of cardioplegic cardiac arrest and cardiopulmonary bypass was 138 ± 47 minutes and 242 ± 64 minutes, respectively.

Outcome

The in-hospital mortality rate was 13% (9/68). Five patients died of cardiac failure. Of these patients, cardiac malperfusion was documented in 3 and coronary artery stenosis in 2. In addition, the cause of death was visceral ischemia in 2, pulmonary failure in 1, and stroke in 1. The re-exploration rate for bleeding was 16% (11/68), and 37% (25/68) underwent prolonged ventilation time longer than 72 hours. The incidence of new stroke was 10% (3 permanent and 4 regressive), and the incidence of paraparesis was 1% (1/68).

The follow-up was 100% (mean, 23 ± 17 months) and 6 deaths (9%) occurred, 4 non- and 2 aortic related. Of the 2

TABLE 2. Size of E-vita open stent graft in acute aortic dissection (n = 68)

Graft size (mm)	Patients
24	22 (32)
28	23 (34)
30	10 (15)
33	5 (7)
36	7 (10)
40	1 (1)

Data in parentheses are percentages.

aortic-related deaths, 1 occurred after 2 months of secondary visceral ischemia, verified by laparotomy, and 1 after secondary endovascular intervention and aorto-esophageal fistula 2 years postoperatively. The actuarial survival rate, including in-hospital mortality, was 82% after 1 and 74% after 3 years (Figure 1). Seven (10%) endovascular and one (1%) surgical secondary intervention was performed in the downstream aorta, five at the first hospital stay and three during follow-up. The endovascular re-interventions took place in the distal aorta in 5 and in the distal aortic branches in 2 cases. One patient underwent replacement of the thoracoabdominal aorta because of aneurysm progression. The rate of freedom from secondary intervention in the downstream aorta after 1 and 4 years was 92% and 82%, respectively (Figure 2). Of the 5 Marfan patients, to date, 1 required aortic endovascular re-intervention without complications. In the others, the aorta remained stable over time.

The status of the whole aorta and the false lumen perfusion was evaluated by computed tomography in 59 patients postoperatively. Along the covered part of the descending aorta thrombus formation in the false lumen was observed in all patients postoperatively and was complete in 51 (86%). Distal to the stent graft at the thoracoabdominal level, the rate of complete thrombosis was significantly less ($P < .01$) (Table 3). A complete aortic and clinical status evaluation was available at a minimum follow-up of 6 months for 49 patients (3 ± 2 follow-up examinations/patient). The rate of complete false lumen thrombosis at the stent graft level increased up to 94% (46/49, $P = .84$). At the thoracoabdominal level, the rate of complete and partial thrombosis increased and the incidence of false lumen patency decreased to 18% (9/49, $P = .11$). The clinical status was evaluated as normal in 36 patients (73%) and 4 patients (8%) required help for the daily activities. A total of 24 patients (49%) returned to

FIGURE 1. Actuarial survival by Kaplan-Meier method, including in-hospital and follow-up mortality.

FIGURE 2. Freedom of secondary intervention in downstream aorta and aortic branches.

work, but they were younger than those staying home (mean age, 50 ± 11 versus 64 ± 9 years, $P < .01$).

DISCUSSION

In acute type A aortic dissection, emergency surgery of the proximal aorta represents the standard treatment to achieve improved patient survival.⁸ Resection of the primary intimal tear and repair of the aortic sinuses and valve represent well-established surgical principles, but the extension of aortic repair distally remains a matter of controversy. Arch replacement is sometimes required for resection of primary or additional tears, for securing the distal anastomosis by resection of fragile aortic tissue, and for reconstruction of the head vessels. The procedure can be performed safely using hypothermic circulatory arrest and selective cerebral perfusion; thus, aggressive arch replacement seems to be acceptable for select cases.⁹⁻¹² The fate of the false lumen, which usually stays patent over time, correlates well to aortic enlargement, reoperation, and adverse outcome.¹³⁻¹⁷ The presumed rate of distal reoperation is 15% to 30% within 10 years; however, this

TABLE 3. Behavior of false lumen after antegrade stent grafting of descending aorta

Variable	False lumen postoperatively (n = 59)	False lumen in follow-up (n = 49)
Stent graft level		
Complete thrombosis	51 (86)	46 (94)
Partial thrombosis	8 (14)	3 (6)
Patent	—	—
Distal to stent graft		
Complete thrombosis	19 (32)	20 (41)
Partial thrombosis	17 (29)	20 (41)
Patent	23 (39)	9 (18)

Data in parentheses are percentages.

has probably been underestimated because most publications have used the Stanford classification and have not differentiated between extension of false lumen beyond the arch and extension solely in the proximal aorta, a distinction made under the DeBakey classification (type I and II), such that in the DeBakey type II, the process of dissection is interrupted after ascending aortic and/or hemiarch resection. Thus, simultaneous splinting of the true lumen to induce false lumen thrombosis is an attractive goal of this approach in DeBakey type I dissections. Of concern is the extension of a difficult and dangerous operation. However, the reported in-hospital mortality rate of 13%, although not fully satisfactory, is similar to the results of sole proximal repair. The International Registry of Acute Aortic Dissection has reported a mortality rate of 15% to 30%, depending on the clinical status of the patients at presentation, and similar results have been reported by others.^{24,25} Although not randomized, the International E-vita Open Registry data have demonstrated a cohort of 49% unstable patients before surgery, with 85% undergoing emergency surgery within 24 hours after onset of symptoms, explaining the mortality rate. The common cause of death was cardiac failure, which correlated to preoperative cardiac malperfusion or coronary artery disease.

Although the descending aorta cannot be inspected by the surgeon operating by way of a median sternotomy, stent graft placement in an antegrade fashion into the downstream aorta can be safely performed. Thus, additional entries can be excluded and stabilization of the true lumen can be achieved, splinting simultaneously the distal anastomosis between the descending aortic stump and the E-vita graft, because back-flow by way of the false lumen is eliminated, while protamine is administered. The hybrid stent graft in place represents a safe landing zone for potential late aortic complications, which can easily be treated by thoracic endovascular aortic repair. This approach is well established in Japan using home-made grafts^{3,19}; however, the excellent results could not reproduced in Europe using commercial stent grafts for the downstream aorta.²⁰ Complications such as proximal endoleak, bare spring penetration of the arch, pseudoaneurysm formation, and migration of the grafts led to the development of the E-vita open hybrid prosthesis. The immediate thrombosis rate of the false lumen along the covered descending aorta was satisfactory (86%), which increased to 94% during follow-up. However, the thrombosis rate distally increased to 41% over time with full-false lumen patency of only 18% during follow-up, although statistically not significant. Five endovascular and one surgical aortic reintervention demonstrated the importance of a close aortic imaging control. A secondary intervention can be performed safely using the stentgraft as an anchor.²¹ Previous studies demonstrated a tendency to progressive thrombus formation distal to stent graft and shrinkage of the false lumen^{22,23}; thus, the probability of

a need for a secondary endovascular intervention might be limited to cases of aneurysmal progression.

Of concern was the 10% rate of new temporary or permanent cerebral events. All participating centers favored moderate hypothermia combined with bilateral selective cerebral perfusion for brain protection. However, we demonstrated that the required time for stent graft placement and deployment does not increase the time of selective cerebral perfusion compared with total arch replacement, suggesting that the prevalence of stroke should be related to the results of sole arch replacement.⁴

The presented multicenter cooperation for the evaluation of antegrade stent grafting is unique but included considerable limitations, such as the lack of randomization and different operative protocols among the surgeons. However, the study results have confirmed the feasibility of a simultaneous proximal and distal aortic repair in acute dissection with results comparable with total arch replacement. Although long-term follow-up data are still to come, we propose the use of a hybrid stent graft in selected cases depending on the characteristics of the dissection. A spontaneous thrombosis of the false lumen after isolated proximal repair has been reported, with an incidence of about 20%; thus, the indication for additional stent grafting should be adjusted to the extent of the dissection, the characteristics of the distal perfusion and the identification of re-entries. A thrombosis rate of the false lumen of more than 90% can be achieved at the stent graft level and probably 40% distally. However, the prerequisite for this should be an interdisciplinary approach of cardiac surgeons, cardiologists, and anesthesiologists, with a fast, hemodynamically controlled, accurate diagnosis of an acute aortic dissection, ideally located within a hybrid room, and offering the option of immediate treatment, either surgery and/or intervention.

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