Midterm results of endovascular stent graft treatment for descending aortic aneurysms including high-risk patients

Abstract

Methods: 21 patients (17 men, 4 women; mean age 66.1 years, range 29-90 years) with 15 true aneurysms, and 6 type B-dissections were treated by implantation of a Talent™ Endoluminal Stentgraft System from February 2000 to July 2003. In 3 cases it was necessary to over-stent the left subclavian artery, in 1 case to over-stent the left common carotid.

Results: 2 patients (9.5%) died during the first 30 days (1 myocardial infarction, 1 pneumonia). Two patients (9.5%) suffered from cerebral ischemia and needed revascularisation. No paraplegia, no stroke occurred. One endoleak required additional stenting. No patient needed conversion. Follow-up, average 25.4 months (range 0-39), was 100% complete. During this another two patients died of myocardial infarction i.e. 9.5% (the above mentioned endoleak, but no late migration were detected in the remaining patients). In all cases the graft lumen stayed patent.

Conclusions: Treatment of descending thoracic aortic aneurysm with an endovascular approach has acceptable mortality and morbidity-rates even in high risk patients. Procedural overstenting of the subclavian artery requires subclavian revascularisation in a minority of cases.

Keywords: descending aortic aneurysm, endovascular stent graft treatment, midterm results

Zusammenfassung

Methoden: 21 Patienten (17 Männer, 4 Frauen, Altersdurchschnitt 66,1 Jahre, Bereich 29-90 Jahren) mit 15 echten Aortenaneurysmen und 6 B-Typ Dissektionen wurde eine Talent™ Endoluminal Prothese eingesetzt im Zeitraum Februar 2000 - Juli 2003. In 3 Fällen war ein Überstenten der linken A. subclavia, in einem weiteren Fall der linken A. carotis communis notwendig.

Resultate: 2 Patienten (9,5%) verstarben innerhalb der ersten 30 Tage (ein Myokardinfarkt, eine Pneumonie). 2 Patienten erlitten eine Hirnischämie, welche eine Revascularisierung erforderlich machte. Weder Paraplegien noch Schlaganfälle traten auf. Eine Endoleckage erforderte zusätzliches Stenten. Keiner der Patienten benötigte Konversion. Die Nachsorgephase, im Durchschnitt 25,4 Monate, -spanne: 0-39 Monate, wurde zu 100% durchgeführt. Währenddessen verstarben zwei weitere Patienten an einem Myokardinfarkt (9,5%). Die oben erwähnte Endoleckage, aber keine Spätstadienmigration wurde in den verbleibenden Patienten festgestellt. In allen Fällen blieb der Durchmesser der Gefäßendoprothese offen.

Schlussfolgerung: Die Aneurysmabehandlung im Bereich der absteigenden Aorta thoracica mit endovaskulären Prothesen weist akzeptable Mortalitäts- und Morbiditätsraten auf, auch bei Hochrisikopatienten.
Das Überstenten der A. subclavia während der Prothesenimplantation erfordert bei einer Minderheit der Fälle eine Revaskularisierung.

**Schlüsselwörter:** Aneurysma Aorta thoracalis descendens, Stentgraft, mittelfristige Behandlungsergebnisse

### Introduction

Descending aortic aneurysm has an incidence of approximately 3 in 100,000 people per year. The mortality within five years is about 50% for untreated aneurysms [1]. Acute aortic dissection affects 10 to 20 individuals per million in western populations [2], [3]. Treatment of patients with aneurysms of the descending aorta still remains a challenge. Open surgical repair with graft implantation has been the standard therapy for patients with asymptomatic descending aortic aneurysms larger than 5-6.5 cm, while aortic dissections without complications generally have been treated conservatively [4], [5]. Within the last years, new and much less invasive treatment modalities have been developed. In 1991 the first stent graft implantation was reported for a thoracic aortic lesion [6]. Since then there has been a major development in graft configuration and some clinical experiences have been published since the first clinical series were published by the Stanford group in 1994 [7]. We report our midterm results after stent graft repair of descending aortic aneurysms focusing on cerebral and spinal cord ischemia in high risk patients.

### Patients, material and methods

Between February 2000 and July 2003 a total of 21 patients with lesions of the descending thoracic aorta were treated with endovascular stent grafting in general anaesthesia. Informed consent was obtained from all patients. General inclusion criteria were: adequate vascular access through the iliac arteries and the abdominal aorta, adequate landing zone free of thrombus with minimal calcification, aortic neck diameter <44 mm, and a length of at least 15 cm. Indication for endovascular surgery in true aneurysms were a diameter >50 mm and significant risk factors (Table 1) with a high risk for open surgery. In dissections endovascular stenting was indicated for acute dissection in patients with hypertension which were refractory to medical treatment of pain with clinical signs of malperfusion of the lower limbs. Patients in the study underwent preprocedural imaging with spiral computed tomography (CT) using 3-mm slices. In cases of dissection preoperative assessment included visualisation of the false lumen and re-entry sites.

### Table 1: Risk factors in 21 patients undergoing endovascular repair of the descending thoracic aorta

| Risk Factor                        | Count |
|------------------------------------|-------|
| Hypertension                       | 17    |
| Nicotine abuse                     | 14    |
| Cerebro-vascular disease           | 9     |
| COPD                               | 7     |
| Diabetes mellitus                  | 4     |
| Myocardial infarction              | 4     |
| Abdominal aneurysm                 | 3     |
| Reconstruction of peripheral vessels | 3    |
| Renal insufficiency                | 3     |
| Chronic atrial fibrillation        | 2     |
| ASA – classification II            | 6     |
| ASA – classification III           | 15    |

Within the 40 months period, 21 (17 men, 4 women; mean age 66.1 years, range 29-90 years) patients with aortic pathologies were evaluated at our institution with 15 true aneurysms and 6 type B-dissections (Stanford classification). The aneurysms had a mean diameter of 6.1 cm (min.-max. range: 3.2-7.1 cm). All of the patients with pathologies of the descending aorta were not suitable for open surgery because of their comorbidities and their clinical classification (ASA mean: 2.7). Patients with ASA score = 3 were defined as high risk patients. All 21 patients were evaluated electively. A team of two vascular surgeons performed the procedures using a Talent™ Stent Graft System (World Medical, a division of Medtronic Vascular, Sunrise, FL, USA) in all cases with an oversize of 4-6 mm. 19 procedures were performed in the operating room (OR) under general anaesthesia and endotracheal intubation, 2 in local anaesthesia. Patients were placed supine and slightly (20-30 degrees) rotated to the right on a fluoroscopic image compatible operating table. Perioperative imaging was performed using a mobile C-arm machine. Intravenous heparin (10,000 IU) was administered as a bolus dose. In all cases we performed a single shot antibiotic prophylaxis by application of a 2nd generation cephalosporine. If it was necessary to cover the left subclavian artery, neither a transposition nor a carotid-subclavian bypass was performed before overstenting the subclavian artery. The decision whether to reconstruct the left subclavian artery was made after overstenting according to the major clinical aspects. In one case a carotid bypass was per-
formed before procedural occlusion of the left common carotid artery. Usually the right femoral artery was exposed by cutdown and controlled proximally and distally. Nearly in all cases a 0.035 inch Terumo guidewire (Terumo®, Frankfurt am Main, Germany) was inserted over a sheath and positioned in the ascending aorta. This was followed by the introduction of a 6-F pigtail catheter and an angiography (Figure 1) of the aortic arch and the descending aorta using a high pressure injection-pump with a non-ionic contrast medium (Imeron® , Altana Pharma, Germany). After marking the aortic arch with its branches as well as the descending aorta and the landing zone on the screen, a stiff guide wire was inserted and the angiography catheter removed. A delivery sheath (22, 24 or 25 F) was introduced with the puncture of the common femoral artery. After pharmacologically controlled hypotension was induced (RR <80 mmHg), the stent graft was deployed under X-ray guidance (Figure 2). The proximal and distal end of the device were dilated using a catheter to achieve optimal graft contact to the aortic wall. A final arteriogram verified sealing of the aortic lesion. The introducer sheath was removed and the artery sutured. Wound closure completed the procedure.

Patients with cardiovascular risk factors (Table 1) were treated with 300 mg aspirin per day. Follow up with clinical examination and CT scans was performed at discharge, 3, 6, and 12 months after and then annually. Aortic size, perfusion of the false lumen, endogenous leakages and graft migration were evaluated.

Results

For the aneurysms, the procedures took 97.8 minutes (average; range was 55-145 minutes). Mean blood loss was 163.3 ml (50-350 ml), mean contrast agent dosage 56.7 ml (45-70 ml). In one of the cases we found an early distal endoleak after the procedure. This patient with peripheral leakage remained without surgical intervention,
and the leak was occluded after three months. The patients were discharged from the ward after 10.1 days in average. Within 30 days 2 patients died: one of myocardial infarction, and one of severe pneumonia. In one case the left common carotid artery had to be bypassed using a carotid-carotid graft before stenting the aorta. In 3 patients we had to overstent the left subclavian artery, thereof in two cases a subclavian steal syndrome with significant neurological deficit (markedly reduced vigilance, no peripheral neurological deficits) developed. After excluding cerebral haemorrhage using CT we had to perform a carotid-subclavian bypass in the two, and a subclavian transposition in the third case on the first postoperative day. After revascularisation both patients became asymptomatic immediately.

For the B-dissections, the procedures took 75 minutes (average; range was 55-95 minutes). Mean blood loss was 141.7 ml (50-300 ml), mean contrast agent dosage 55 ml (45-70 ml). The patients were discharged from the ward after 10.7 days in average. 21 of 21 procedures were primarily technically completely successful without conversion to open surgery. Within the follow-up period (mean 25.4 months) another two patients (one with an aneurysm, the other with a B-dissection) died of myocardial infarction. There was no rupture of aneurysm or dislocation of stent graft during the observation period. The postprocedural data are summarized in Table 2.

Table 2: Postprocedural data in 21 patients undergoing endovascular repair of the descending thoracic aorta

| Death        | ≤30 days | >30 days |
|--------------|----------|----------|
|              | 4        | 2        | 2        |
| Cerebrovascular accident | 0         |          |          |
| Paraplegia   | 0        |          |          |
| Subclavian steal (overstenting left subclavian artery) | 3        |          |          |
| Revascularisation of subclavian artery | 2        |          |          |
| Dissections proximal to the endografts | 0        |          |          |
| Respiratory insufficiency, temporary | 0        |          |          |
| Renal failure, temporary | 0        |          |          |
| Endoleak, type 1 | 1        |          |          |
| Repeat stent graft | 1        |          |          |
| Conversion to open surgery | 0        |          |          |

Discussion

Catheter-associated techniques have changed the face of modern vascular surgery. The treatment of aneurysms of the descending aorta using endovascular stents is one of the more recent advances in treatment, still receiving increasing attention as alternative to open surgery. Several reports have shown the feasibility of stent graft treatment of aneurysms of the descending thoracic aorta [8], [9], [10]. 30 day mortality ranges from 0%-20% in different reports [8], [9], [11], [12], [13] which is encouraging although long term results are unknown [14], [15]. For patients with high risk from concomitant diseases, for patients with previous thoracic operations, and for those with multiple traumas the endoluminal technique offers an alternative to open surgery although endoluminal surgery is accompanied by complications as well as open surgery [8], [9], [16], [17]. The often discussed 6 cm diameter threshold reflects the surgeon's reluctance to open repair because of serious risks of morbidity and mortality. In our opinion a diameter >5 cm, or twice the size of an adjacent nonaneurysmal aortic segment seems to be more reasonable [18].

Our average procedure time for aneurysms and B-dissections together was 91.3 minutes (range 55-145 minutes), and correlates well with data of other groups [18], [19], [20], whereas much longer operating times are described in literature [21]. In our investigation the cumulative 30-day-mortality-rate was 9.5% and correlates well with comparable patient groups [21], [19], [20]. However, all deaths of 4 out of 21 patients were not associated with endovascular treatment: Two patients died of myocardial infarction and pneumonia within 30 days after stenting. Total mortality during follow-up (mean 25.4 months) was 19% (4/21). The 4.8% (1/21) incidence of endoleaks in our study is in the lower range of comparable studies [11], [22], [21], [19]. In the case with a small distal endoleak we waited 3 months for spontaneous sealing, and then performed a second procedure, overstenting the leak successfully. The deployment of endovascular stent grafts in the thoracic aorta may cause devastating neurological complications. In our patients we saw no stroke as described from other groups who explain those complications by severe hypovolaemia in those patients treated emergently or by alterations of the aorta by the guidewire during its passage through the arch and consecutive cerebral embolism [21]. We overstented the left common carotid artery after bypassing the vessel by a carotid-carotid bridge in one case, and occluded the left subclavian artery in 3 out of 21 cases (14.3%) and found a postoperative neurological deficit in 2 patients i.e. 9.5%. In those two patients whose blood pressure had been extremely stable during the operative procedure we found a psychological alteration which we thought had its origin in the occluded left subclavian artery. A consecutive subclavian steal syndrome could be documented using duplex sonography. The brain scintigrams were recorded to verify the supposed steal phenomenon in the patients suffering from a temporary organic brain syndrome. So we decided to perform a transposition in one and a carotid-subclavian bypass in the other patient on the first postoperative day, and both patients were asymptomatic indeed immediately after revascularisation. This experi-
ence correlates well with the data of other investigators [18]. Another dreaded complication, paraplegia, results from spinal cord ischemia secondary to intercostal artery occlusion, and is described in about 7% of the cases [9], [11], [12], [21]. In our patients no paraplegia occurred. As described by others [21] we routinely increase the mean blood pressure to about 90 mm Hg for 24 hours immediately after exclusion of the aneurysm. A drainage of the cerebrospinal fluid as described in literature [21] was performed in none of our patients because the benefit in respect to paraplegia is not yet definitively proven [23], [24], [25], [26].

Patients with acute or chronic type-B dissection represent a cohort in whom the indication for stent graft treatment is still debated. In our study we treated 6 patients with acute dissection using endografts. Indications for endovascular treatment of B-dissections were: a progressive dissection, malperfusion of organs, therapy-refractory pain and/or hypertension. In all cases the entry site was patent but the patients did not have any symptoms. The aorta of both patients did not show progressive dilatation. Because of a long dissection in both cases with perfusion of the celiac trunk, the superior mesenteric artery and the left renal artery through the false lumen, we decided not to cover the re-entry site but to treat it conservatively in order to avoid paraplegia after occlusion of some pairs of intercostal arteries [27], [28] as well as mesenteric ischemia. In the remaining cases the false lumen was obliterated within the first follow up examination period, and the patients did well. Dissections proximal to the endografts have not been observed during the follow-up.

Conclusions

In summary our results demonstrate that endovascular treatment of the descending aorta is feasible with acceptable early complication rates and acceptable mean term results even in high risk patients. Procedural overstenting of the subclavian artery requires subclavian revascularisation in the minority of cases. In selected patients endovascular treatment may be the most suitable therapeutic option.

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