This is an author produced version of a paper published in European Journal of Vascular and Endovascular Surgery. This paper has been peer-reviewed but does not include the final publisher proof-corrections or journal pagination.

Citation for the published paper: Dias, N V and Sonesson, B and Koul, B and Malina, M and Ivancev, K. "Complicated Acute Type B Dissections-An 8-years Experience of Endovascular Stent-graft Repair in a Single Centre" European Journal of Vascular and Endovascular Surgery, 2005, Issue: Dec 20 <u>http://dx.doi.org/10.1016/j.ejvs.2005.11.005</u>

Access to the published version may require journal subscription. Published with permission from: Elsevier Complicated acute type B dissections – an 8-years experience of endovascular stent-graft repair in a single centre

Nuno V. Dias, Björn Sonesson, Bansi Koul, Martin Malina, Krassi Ivancev

From the Department of Vascular Diseases Malmö-Lund and Endovascular Centre, Malmö University Hospital, Lund University, Sweden (ND, BS, MM, KI) and Thoracic Surgery Department, Lund University Hospital, Lund University, Sweden (BK).

Corresponding Author:

Nuno V. Dias

Department of Vascular Diseases Malmö-Lund Malmö University Hospital – Entrance 59, 2nd floor 20502 Malmö Sweden

Tel: Work: +46 40 331000 / Mobile: +46 73 8024139 Fax: +46 40 338097 Email: nunovdias@hotmail.com

Manuscript Category: Original article

Short title: Endovascular Stent-graft Repair of Acute Type B Dissections

<u>Abstract</u>

Objectives – To analyze the experience of a single centre using stent-grafts for treatment of complicated acute aortic type B-dissections (EVR-ABD).

Design – Retrospective analysis of prospectively collected data from patients undergoing EVR-ABD between January 1997 and December 2004.

Methods – EVR-ABD was performed in 31 patients (20 males, 74 (IQR: 64-79) yearsold). Indications for treatment were aortic rupture (22 patients), intractable pain and hypertension (6 patients), acute bowel ischemia (2 patients) and one patient with transient paraplegia, lower limb and renal ischemia. Home-made devices in the initial phase (5 patients) and subsequently commercially available thoracic stent-grafts were used.

Results – Five patients (16%) died within 30 days of EVR-ABD. Postoperative complications occurred in 15 patients (48%, including 1 paraplegia reversed into paraparesis after cerebrospinal fluid drainage, 5 strokes, 3 lower limb ischemias, 3 myocardial infarctions, 2 pneumonias and 1 colitis). Reinterventions were required in 9 patients (29%). Six more deaths occurred during a median follow-up of 22 (IQR: 16-34) months, 2 related to the stent-graft and 4 due to cardiac disease.

Conclusions – Stent-graft repair of complicated acute type B dissections seems to provide acceptable results and, therefore, it may be considered a valuable alternative to open surgery.

Key words: Acute type B Dissection; stent-graft; Aorta

Introduction

Medical treatment controlling hypertension and pain is usually selected as the initial approach for uncomplicated aortic type B dissections. Surgery has been reserved only for complications, including aortic rupture, mal-perfusion of end-organs and/or persistent pain in spite of medical treatment.(1, 2)

Endovascular techniques have been proposed as a less invasive alternative to open surgery. Fenestration of the intimal membrane and stenting of dissected arteries have been applied as a means to correct the hemodynamic changes causing the compression of the true lumen.(3) However with these techniques the false lumen continues to be pressurized, which, together with the weakening of the false lumen wall caused by the absence of the inner layer, can prompt to further degenerative changes resulting in complications.(4) The rationale for the use of stent-grafts for endovascular repair of complicated acute aortic type B dissections (EVR-ABD) is based on the exclusion of the false lumen by coverage of intimal tears. This is expected to depressurize the false lumen and redirect the flow into the true lumen. The perfusion of the end-organs, may thereby, be improved and the hemorrhage stopped.(3)

Although the initial reports of EVR-ABD have been encouraging with decreased mortality and morbidity comparing to open surgery,(5, 6) there is a need for further reassessment of this new treatment technology as it is continuously evolving.

The aim of the present study is to analyze a single-centre experience with endovascular stent-graft repair of complicated acute type B-dissections (EVR-ABD).

Methods

Patients

Thirty-one patients (20 males and 11 females) with a median age of 74 (64-79) years-old underwent EVR-ABD at our tertiary university referral centre between January 1997 and December 2004. Patients' characteristics are listed in table 1. Indications for treatment were rupture (22 patients, 71%, figure 1), intractable pain and poorly controlled hypertension in spite of medical treatment (6 patients, 19%), acute bowel ischemia (2 patients, 6%) and one patient with transient paraplegia, lower limb and renal ischemia (3%). Dissections were considered as acute if less than 14 days had passed since the onset of symptoms.(7) Medical therapy consisted in intensive care control of hypertension and pain.

Preoperative imaging

Preoperative imaging included contrast-enhanced spiral-CT scan with slices of 3 mm or thinner. Angiogram was performed intraoperatively. Angiographic studies below the diaphragm in patients with high serum creatinine were performed using carbon dioxide as contrast-medium.

Stent-graft procedure

The procedures were performed initially in the operating theatre using a C-arm with digital subtraction abilities (Siremobil 2000, Siemens, Erlangen, Germany). After the last trimester of 2000 all operations were performed in an operating room fully equipped as

an angiographic suite (Angiostar Plus OR, Siemens, Erlangen, Germany). When Gore stent-grafts (Excluder and GoreTAG, Gore W. L. Gore & Associates, Inc, Flagstaff, Ariz, USA) were used, hypotension was induced at the time of stent-graft deployment using 100 µg intravenous bolus of natriumprusside. Percutaneous access has been routinely used since 2002 whenever the dissection did not extend into the femoral arteries.(8)

Home-made stent-grafts, based on stainless steel Z-stents sutured to Dacron grafts, were used until 2001.(9) Thereafter commercially available stent-grafts were employed on offthe-shelf basis. Stent-grafts were oversized by 10% to 15% compared to the diameter of the proximally non-dissected aorta. The stent-grafts used are listed in table 2. The uncovered Z-stent at the distal end of the Zenith TX-1 stent-graft was removed before deployment in order to avoid unwarranted rupture of the dissection membrane by the bare struts. Balloon dilatation of the stent-graft was avoided for the same reason. Right brachial approach was used occasionally in order to ascertain true lumen catheterization or when there was a need for through-and-through technique to overcome difficulties in inserting the stent-graft system due to tortuosity of the vessels. If the main intimal tear was identified in the pre- or intraoperative imaging, the stent-graft was placed at that level. When the main tear was not identified and the there was no aortic rupture, the stent-graft was placed from the aortic arch and extended distally depending on the effect upon the true lumen perfusion. However, if an aortic rupture was present, there was an effort to extend the stent-graft down to the level of the diaphragm (figure 2). The left subclavian artery was covered liberally whenever the left internal mammary artery was not used as a coronary bypass and the contralateral vertebral artery

was patent in the angiography preceding the deployment of the stent-graft. As opposed to elective procedures, no study of the intracranial circulation was routinely performed.

Follow-up protocol

Follow-up included chest X-ray and contrast-enhanced CT-scan at one and six months postoperatively and yearly thereafter. Digital subtraction angiography was used selectively when a reintervention was indicated. All unclear deaths were verified by autopsy.

Statistical analysis

Data was prospectively compiled in a computer-based database and a retrospective analysis was performed. Normal distribution was not assumed. Non-parametric tests were performed, using a significance value of p<0.05. Values are given as median with interquartile range in-between parenthesis when not stated otherwise. Statistical analysis was done using SPSS 12.0.1 (SPSS Inc, Chicago, USA).

This study was approved by the Lund University Ethical Committee.

Results

Intra-operative results

More than one stent-graft was implanted in 10 patients. One patient received an extra stent-graft to reinforce, and thereby fully expand, the initially placed endoprosthesis that had collapsed in the aortic arch. In the remaining patients the second stent-graft was used to cover a longer portion of the thoracic aorta and facilitate the accurate deployment of the distal end. Median operative time was 140 (108 - 197) minutes.

The left subclavian artery was intentionally covered by the stent-graft in 17 patients (55%). No symptoms of ischemia of the left arm or subclavian steal syndrome requiring secondary revascularization were identified during the study period. A patient presenting with transient paraplegia underwent a transposition of the left subclavian artery to the left carotid the day before EVR-ABD. Another patient with a concomitant aortic arch aneurysm underwent a combined open and endovascular procedure with replacement of the aortic arch with an elephant trunk. Seven patients (23%) required 12 intraoperative adjunctive procedures (table 3).

Early Results

Early postoperative complications occurred in 15 patients (48%, table 4). One patient (3%) experienced a transient paraplegia that was reversed to paraparesis by cerebrospinal fluid drainage. Ischemic strokes occurred in 5 patients (16%). Left subclavian artery coverage by the stent-graft was not associated with a higher incidence of stroke (4 of 17 patients versus 1 of 14, p=0.344). The posterior circulation was affected in only one of the patients where the left subclavian artery had been covered (bilateral cerebellar

infarct). Of the 5 patients with stroke, three died within the perioperative period (described below). The other 2 patients had non-disabling strokes with partial recovery of their neurological function after rehabilitation. Operative time was longer in patients with postoperative stroke (241 (166 – 355) minutes) than in the remaining ones (128 (106-165) minutes, p = 0.025). Furthermore, 4 of the 5 patients suffering stroke had periods of hypotension (3 due to aortic rupture and due to an access- related iliac rupture). The indications for treatment in patient suffering strokes had been aortic rupture (n=3, 2 fatal), bowel ischemia (n=1) and uncontrollable pain and hypertension (n=1, fatal). One patient (3%) with a complicated post-operative course developed a *Clostridium* pancolitis requiring total colectomy.

Five patients (16%) died within 30 days of EVR-ABD. Indications for treatment in these patients were aortic rupture (n=3), bowel ischemia (n=1) and persistent pain and hypertension (n=1). One patient presenting in hemodynamic shock due to aortic rupture died few hours after the operation due to multiorgan failure. The other two patients treated for an aortic rupture suffered strokes and multiorgan failure. One patient admitted with bowel ischemia requiring an intraoperative subtotal colectomy, had the visceral flow successfully restored by the aortic stent-graft and stents in the superior mesenteric artery and celiac trunk. However bowel gangrene progressed after further multi-segmental bowel resections and the patient died on the 12th postoperative day. One additional patient died due to renal insufficiency followed by multiorgan failure, stroke and sepsis.

Late Results

Six additional deaths occurred during a median follow-up of 22 (IQR: 16-34) months. Overall mortality during the study period was therefore 35% (11 patients). Two of the late deaths were stent-graft related. One patient died 2 months after the operation. At the autopsy the proximal end of the stent-graft (Zenith) was seen to erode through the aortic wall immediately distal to the left subclavian artery. The other death was caused by an aortic rupture 2.5 years postoperatively after an otherwise uneventful CT follow-up up to 4 moths before. The most likely explanation found at the autopsy was a failure of the stent-graft to provide proximal seal due to poor apposition of a stiff stent-graft to the aortic arch curvature (homemade device). The remaining four deaths were caused by cardiac disease and took place between 5 months and 4 years after the operation. No stent-graft migration was seen during the follow-up period.

Reinterventions

Reinterventions were required in 9 patients (29%). Eight of these were performed within the first 2 weeks after EVR-ABD (table 5). One patient already described above underwent a simultaneous resection of the remaining colon and the proximal jejunum at the time of the second look due to bowel gangrene. A proximal extension of the stentgraft was done after the initial prosthesis tilted in the distal arch, resulting in misalignment of the stent-graft and failure to exclude the false lumen. A re-explorative laparotomy was performed in a patient who had suffered an intraoperative access problem requiring a right external iliac interposition graft. Another patient with recurrent deep vein thrombosis received an inferior vena cava filter at 5 months postoperatively

and a right renal artery stent 2 weeks later.

Discussion

Endovascular stent-graft repair has been proposed as a less invasive method for the treatment of complicated acute aortic type B dissection.(5) Given the absence of randomized trials and the constant developments of the technique, there is a need for the continuous reevaluation of the results.

The majority of a ortic type B dissections have the main entry located immediately distal to the left subclavian artery origin. The left subclavian artery was intentionally covered in more than half of the patients in order to improve the alignment of the stent-graft in a relatively straight portion of the arch proximal to the main intimal tear. This aimed at avoiding the tendency of the proximal end of the stent-grafts to tilt, which can lead to aortic rupture by either erosion of the arterial wall or failure of the proximal seal provided by the stent-graft. Furthermore, the misalignment of the stent-grafts in angulated aortic arches, together with the high hemodynamic forces in this region, can cause structural instability of the stent-graft and its subsequent collapse.(10, 11) We have dealt with this problem in one patient by reinforcing the initial stent-graft with a new one. The policy of liberally covering the left subclavian artery seemed to be well tolerated in our group of patients, which is in accordance with previous reports in the literature.(12, 13) This seems therefore to be a reasonable solution for improvement of the implantation site until other technical possibilities like fenestrated or branched stent-graft become more widely available or the adaptability of the stent-grafts is improved.

The frequent use of more than one stent-graft in a single patient was a reflection of the advantage conferred by the overlapping of multiple endoprostheses. This allowed the precise deployment of both the proximal and distal ends of the stent-grafts and coverage of a longer portion of the aorta, which sealed a higher number of intimal tears. The length of the stent-graft used has been identified as a risk factor for the development of paraplegia.(14) We could not confirm such a relation, since we only had one patient suffering a paraplegia which was reversed into paraparesis by cerebrospinal fluid drainage and blood pressure control.(15, 16) The low incidence of paraplegia after EVR-ABD, both in our series and in other reports,(4, 17) may be another potential advantage of this technique when compared to open surgical repair.(18)

Open surgical treatment of complicated acute aortic type B dissections is associated with an operative mortality of 36-60%.(2, 19-21) The perioperative mortality rate of 16% in our group of patients can, therefore, be considered acceptable. On the contrary, the high incidence of complications, particularly, ischemic strokes in the postoperative period might be seen as a drawback of the technique. The coverage of the left subclavian artery does not appear to be the determining factor for stroke. Although it was associated with a higher frequency of stroke, it did not reach statistical significance and only one stroke was in the posterior circulation. The longer operative time required by the procedures in patients suffering strokes suggests endovascular manipulation of the aortic arch as a likely cause. Furthermore, the high number of patients with hypotension periods suggests that hypoperfusion can also play a role in the development of postoperative strokes, particularly when dealing with aortic ruptures. In these cases two potentially aggravating

factors are the avoidance of a complete intraoperative anticoagulation to prevent further hemorrhage and the emergency nature of the procedure. Care should, therefore, be taken to avoid unnecessary maneuvers and to have patients adequately anticoagulated during the procedure.

Transesophageal ehocardiography has been reported to be a useful tool during stent-graft repair of dissections, especially for the repositioning of the guidewire and identification of endoleaks and new intimal tears.(22, 23) We did not use this technique. However we do not expect these procedures to have changed greatly if transesophageal echocardiography had been used. One possible advantage might have been the assessment of the atherosclerotic burden of the aortic arch. This could allow us to retrospectively analyze the importance of that factor on the rate of cerebrovascular events.

The relatively high need to perform intraoperative adjunctive procedures and to reintervene, especially in the immediate postoperative period, might be a reflection of the complexity of the disease affecting multiple segments.

The two stent-graft-related deaths occurring later in the follow-up demonstrated the difficulties of the stent-grafts to conform to the curvature of the aortic arch, as previously discussed. Although some improvements have been seen with the more recent generations of endoprosthesis, this is still an incompletely solved problem. Further technological developments are needed to obtain a stent-graft that aligns well in the arch, and provides good fixation without traumatizing the friable aortic wall.

In conclusion, this study shows that endovascular repair of complicated acute aortic type B dissections provides acceptable results and can, therefore, be a valuable alternative to open surgery. Although the results of EVR-ABD are promising, the operative mortality and morbidity are not negligible. This technique should, thus, continue restricted to complicated cases until the long-term results and the results from randomized trials become available.

Acknowledgments

Mrs Christel Ekberg-Jönson and Ms Kristina Lindholm PhD for their assistance.

References

Elefteriades JA, Lovoulos CJ, Coady MA, Tellides G, Kopf GS, Rizzo JA.
Management of descending aortic dissection. Ann Thorac Surg 1999;67(6):2002-5;
discussion 2014-9.

2. Glower DD, Fann JI, Speier RH, Morrison L, White WD, Smith LR, et al. Comparison of medical and surgical therapy for uncomplicated descending aortic dissection. Circulation 1990;82(5 Suppl):IV39-46.

3. Chung JW, Elkins C, Sakai T, Kato N, Vestring T, Semba CP, et al. True-lumen collapse in aortic dissection: part II. Evaluation of treatment methods in phantoms with pulsatile flow. Radiology 2000;214(1):99-106.

4. Beregi JP, Haulon S, Otal P, Thony F, Bartoli JM, Crochet D, et al. Endovascular treatment of acute complications associated with aortic dissection: midterm results from a multicenter study. J Endovasc Ther 2003;10(3):486-93.

 Dake MD, Kato N, Mitchell RS, Semba CP, Razavi MK, Shimono T, et al.
Endovascular stent-graft placement for the treatment of acute aortic dissection. N Engl J Med 1999;340(20):1546-52.

Nienaber CA, Ince H, Weber F, Rehders T, Petzsch M, Meinertz T, et al.
Emergency stent-graft placement in thoracic aortic dissection and evolving rupture. J
Card Surg 2003;18(5):464-70.

7. Erbel R, Alfonso F, Boileau C, Dirsch O, Eber B, Haverich A, et al. Diagnosis and management of aortic dissection. Eur Heart J 2001;22(18):1642-81.

8. Börner G, Ivancev K, Sonesson B, Lindblad B, Griffin D, Malina M. Percutaneous AAA repair: is it safe? J Endovasc Ther 2004;11(6):621-6.

9. Resch T, Koul B, Dias NV, Lindblad B, Ivancev K. Changes in aneurysm morphology and stent-graft configuration after endovascular repair of aneurysms of the descending thoracic aorta. J Thorac Cardiovasc Surg 2001;122(1):47-52.

10. Melissano G, Tshomba Y, Civilini E, Chiesa R. Disappointing results with a new commercially available thoracic endograft. J Vasc Surg 2004;39(1):124-30.

 Sunder-Plassmann L. Masterclass V - Modern Management of Thoracic Aortic Dissection. In. London; 2005.

12. Rehders TC, Petzsch M, Ince H, Kische S, Korber T, Koschyk DH, et al. Intentional occlusion of the left subclavian artery during stent-graft implantation in the thoracic aorta: risk and relevance. J Endovasc Ther 2004;11(6):659-66.

13. Tiesenhausen K, Hausegger KA, Oberwalder P, Mahla E, Tomka M, Allmayer T, et al. Left subclavian artery management in endovascular repair of thoracic aortic aneurysms and aortic dissections. J Card Surg 2003;18(5):429-35.

Gravereaux EC, Faries PL, Burks JA, Latessa V, Spielvogel D, Hollier LH, et al.
Risk of spinal cord ischemia after endograft repair of thoracic aortic aneurysms. J Vasc
Surg 2001;34(6):997-1003.

15. Coselli JS, Lemaire SA, Koksoy C, Schmittling ZC, Curling PE. Cerebrospinal fluid drainage reduces paraplegia after thoracoabdominal aortic aneurysm repair: results of a randomized clinical trial. J Vasc Surg 2002;35(4):631-9.

16. Chiesa R, Melissano G, Marrocco-Trischitta MM, Civilini E, Setacci F. Spinal cord ischemia after elective stent-graft repair of the thoracic aorta. J Vasc Surg 2005;42(1):11-7.

Lonn L, Delle M, Falkenberg M, Lepore V, Klingenstierna H, Radberg G, et al.
Endovascular treatment of type B thoracic aortic dissections. J Card Surg
2003;18(6):539-44.

18. Safi HJ, Miller CC, 3rd, Reardon MJ, Iliopoulos DC, Letsou GV, Espada R, et al. Operation for acute and chronic aortic dissection: recent outcome with regard to neurologic deficit and early death. Ann Thorac Surg 1998;66(2):402-11.

 Cambria RP, Brewster DC, Gertler J, Moncure AC, Gusberg R, Tilson MD, et al.
Vascular complications associated with spontaneous aortic dissection. J Vasc Surg 1988;7(2):199-209.

20. Jex RK, Schaff HV, Piehler JM, King RM, Orszulak TA, Danielson GK, et al. Early and late results following repair of dissections of the descending thoracic aorta. J Vasc Surg 1986;3(2):226-37.

Fann JI, Smith JA, Miller DC, Mitchell RS, Moore KA, Grunkemeier G, et al.
Surgical management of aortic dissection during a 30-year period. Circulation 1995;92(9
Suppl):II113-21.

22. Rocchi G, Lofiego C, Biagini E, Piva T, Bracchetti G, Lovato L, et al. Transesophageal echocardiography-guided algorithm for stent-graft implantation in aortic dissection. J Vasc Surg 2004;40(5):880-5.

23. Koschyk DH, Nienaber CA, Knap M, Hofmann T, Kodolitsch YV, Skriabina V, et al. How to guide stent-graft implantation in type B aortic dissection? Comparison of angiography, transesophageal echocardiography, and intravascular ultrasound. Circulation 2005;112(9 Suppl):I260-4. Table 1 – Preoperative characteristics of the patients

	n (%)
Age	74 (IQR: 64-79)
Sex (M/F)	20 (65%) /11 (35%)
Cardiac Disease	10 (32%)
Hypertension	23 (74%)
Diabetes	2 (6%)
COPD	5 (16%)
Cerebrovascular Disease	2 (6%)
ASA	
Ι	1 (3%)
II	4 (13%)
III	17 (55%)
IV	8 (26%)
V	1 (3%)

COPD – Chronic obstructive pulmonary disease; ASA – American Society of Anesthesiology Classification

Type of stent-graft	n
Homemade	7
Zenith	27
Gore Excluder	1
Gore TAG	4
Endofit	3
Total	42

Zenith, William Cook, Europe A/S, Bjaeverskov, Denmark; Excluder and GoreTAG, Gore W. L. Gore & Associates, Inc, Flagstaff, Ariz, USA; Endofit, Endomed Inc,Phoenix, AZ, USA. Table 3 – Intraoperative adjunctive procedures (7 patients)

Procedure	Total
Stent	
SMA and Celiac trunk	1
Renal	1
Iliac (with fenestration)	1
Access complications	
Femoral Artery Repair	5
External iliac interposition graft	1
Lower limb thrombectomy	1
Carotid stent-graft (1)	1
Sub-total colectomy	1

(1) – Stent-graft of the left carotid artery due to partial coverage of the ostium by the proximal end of the aortic stent-graft

Table 4 – Early postoperative complications

Complication type	Number patients
Transient paraplegia	1
Stroke	5
Lower limb ischemia	3
Myocardial infarction	3
Pneumonia	2
Clostridium colitis	1

Table 5 – Reinterventions

Patient	FU duration	Reintervention
#1	2 days	Multisegmental bowel resection
#2	13 days	Thrombectomy and femoral patch angioplasty
	14 days	Femoro-popliteal bypass
#3	1 day	Thrombectomy and femoral patch angioplasty
#4	1 day	Thrombectomy and femoral angioplasty
#5	14 days	Total colectomy
#6	2 days	Proximal extension of the stent-graft
#7	5 days	Explorative laparotomy
#8	7 days	Renal stent
#9	5 months	Inferior vena cava filter
	5.5 months	Renal stent-graft

Figure Legends

- *Figure 1* Axial CT-scan from patient with ruptured acute aortic type B dissection.
- *Figure 2* Completion angiography after deployment of two stent-grafts for the treatment of a ruptured acute aortic type B dissection.



