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Mid-term Survival and Costs of Treatment of Patients with Descending Thoracic Aortic Aneurysms; Endovascular vs. Open Repair: a Case-control Study

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Objectives. *To evaluate the results of open surgery or endovascular stent graft repair of descending thoracic aortic aneurysm (TAA).*
Design, materials and methods. *This is a retrospective multicenter study of 95 patients undergoing TAA repair (42 stent grafts, 53 open repair). The median age was 67 years. Post-operative complications, mid-term survival and costs were assessed. The results were pooled with data in the literature.*
Results. *After a mean follow up of 26 months (open group) and 15 months (endovascular group) survival was similar for patients treated by either repair method. Post-operative pneumonia was more in the open group (p < 0.02). The hospital costs of open treatment were 40% more than that of the endovascular procedure. Combining the present results with pooled data from the literature the peri-operative mortality and paraplegia rate was less in the endovascular group (p < 0.05).*
Conclusions. *These retrospective data suggest that endografting of descending thoracic aneurysms can be performed with less peri-operative morbidity, at lower hospital costs, but with equal mid-term life expectancy, compared with open grafting.*

Keywords: Thoracic; Descending; Aneurysm; Endovascular; Grafting; Mortality; Survival; Paraplegia; Costs.

Introduction

Open 'conventional' surgical repair of descending thoracic aortic aneurysms is still considered to be the standard reference treatment. However, this operation is associated with significant peri-operative morbidity and mortality. In large series mortality rates of 5.5–8.8% and paraplegia rates of 2.7–14.3% have been reported.[1–6].

Endovascular thoracic stent graft repair offers the theoretical advantage of a minimal invasive operation combined with a short aortic occlusion time. In 1997 the first large series of 44 patients were reported in which aneurysms were repaired using home made stent grafts. Outcome was favourable with a mortality rate of 6.8% and a paraplegia rate of 4.3%.[7] To date there are no randomised trials available comparing open and endovascular repair of descending thoracic aneurysms.

The present study was performed to evaluate the survival and treatment costs of all patients treated for a descending thoracic aortic aneurysm by either open surgery (OPEN) or endovascular stent graft repair (ENDO) in three vascular centres in Amsterdam.

Materials and Methods

Medical records of all consecutive patients operated between January 1997 and April 2003 for a descending thoracic aneurysm in three hospitals. (Academic Medical Center (AMC), Vrije Universiteit Medical Center (VUMC) and Onze Lieve Vrouwe Gasthuis (OLVG)) were reviewed. All consecutive patients with elective presentations with a chronic fusiform or saccular aneurysm of the descending aorta were included. Patients with trauma, aortoenteric fistulas, type B dissection or an acute ruptured aneurysm were excluded.

In 1997 all patients were treated by open repair. Endovascular treatment was introduced in January 1999 and from the year 2001 on this technique has been first choice treatment in the three vascular centres.

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Operative technique

Transthoracic aneurysm repair

Open surgery was performed by a left lateral thoracotomy and graft replacement of the descending aorta. Atriofemoral shunting was used by surgeon preference and availability. CSF drainage was used routinely.[8]

Endovascular repair

Vascular access for the endovascular treatment was obtained through surgical exposure of the common femoral artery or common iliac artery in case of an external iliac artery diameter of less than 8 mm. A five French pigtail catheter was positioned in the ascending aorta, to be changed by a 0.035 in. diameter back-up Meier guide wire (Boston Scientific-Schneider, Bülach, Switzerland). In selected patients an additional angiography catheter was inserted in the ascending aorta through the right brachial artery. Angiography was performed before and after stent graft deployment. If necessary, balloon dilatation of the proximal and distal anchoring zones further expanded the stent grafts. Three types of stent graft have been used: the AneuRx™ thoracic stent graft (Medtronic AVE, CA, USA) in 1 patient, the Gore™ thoracic aortic graft in (WL Gore and Associates, AZ, USA) in 17 patients and the talent™ thoracic endoprosthesis (Medtronic AVE, CA, USA) in 24 patients.

These two groups were compared in a case-control study with regard to post-operative complications and mid-term survival. Post-operatively patients were followed by 6 (endovascular group) or 12 monthly (open group) CT-scans. Survival was assessed by review of patients' notes since when a patient died during follow up a note, extracted from the registrar's office, is made in the file. Pooled data for post-operative paraplegia and mortality from the literature were then compared to our results.

The mean costs of the diagnostic process, the operative procedure, the costs of implants and adjunctive procedures were calculated for each patient from the mean outcome values of the study-cohort.

Statistical analysis was performed using univariate analysis (χ^2-test and Fisher's exact test when necessary) for pre- and post-operative variables. Multivariate Cox regression analysis was used to identify the independent predictors of survival. Several possible factors were analysed which might influence the survival in a step-wise model. Factors that were associated with a change of more than 10% in the regression coefficient were left in the model for identification of independent predictive factors of survival. Odds ratios (OR) and 95% confidence intervals were calculated in univariate analysis for pre- and post-operative parameters. The hazard ratio (HR) was calculated for predictive factors of survival in the multivariate model. A p-value of less than 0.05 was considered statistically significant. Analysis was done in SPSS version 11.0.

Results

Between January 1997 and April 2003, 95 consecutive (59 males, 36 females) patients with a mean age of 67 years (range 39–81 years; no statistically significant differences between the open and endovascular group) were operated on for a descending thoracic aneurysm. Sixteen patients were operated non-electively (recent onset of pain or contained rupture): 9 in the open group and 7 in the endovascular group. The mean diameter of the aneurysm was 65 mm (range 45–90 mm) in the open group and 61 mm (range 40–80 mm) in the endovascular group. All aneurysms commenced at least 1 cm distal to the subclavian artery and there was at least 3 cm of non-dilated aorta proximal to the celiac trunk.

Patient characteristics and pre-operative risk factors are listed in Table 1. Fifty-three patients underwent open surgical repair (AMC $n=20$, VUMC $n=21$, OLVG $n=12$), 42 patients were treated with stent grafts (AMC $n=18$, VUMC $n=9$, OLVG $n=15$). A mean of 2.1 endografts (range 1–4) per patient were implanted. The pre-operative risk factors were not statistically different between groups.

The mean anaesthesia time (300 vs. 160 min; $p<0.0001$), in hospital time (30 vs. 10 days; $p<0.0001$) and mean length of stay on the intensive care (11 vs. 14 days; $p<0.0001$) was statistically significant different, in favour of the endovascular group. Blood loss was also less in the endovascular group, but too many missing values prohibited calculation of significance. There was no difference in post-operative morbidity between the two groups, except that pneumonia appeared significantly more in the open group (29 vs. 9%, odds ratio 0.3, 95% confidence interval 0.08–0.8; $p<0.02$) (Table 2).

Reoperations during the same admission were performed in 13 patients in the open group. The reasons for reinterventions were: post-operative bleeding ($n=11$), duodenal perforation ($n=1$) and persistent thoracic duct leakage ($n=1$). There were 5 early reinterventions in the endovascular group due to post-operative bleeding at access site in one patient, type I endoleak in 2 patients requiring additional stent graft implantation and paraplegia in 1 patient in whom an emergency open procedure was performed.[9]

Table 1. Pre-operative risk factors of patients (percentage of patients in each group) with a descending thoracic aneurysm; open: treatment by thoracotomy and graft replacement of the aorta, endo: groin incision and endografting

	Open *N*	Open percentage (%)	Endo *N*	Endo percentage (%)	*p*-value
Hypertension	40	75	36	86	0.21
Smoking/COPD	43	81	25	60	0.38
Diabetes	3	6	5	12	0.31
Angina pectoris	6	11	9	21	0.20
Previous myocardial infarction	8	15	10	25	0.30
CABG in history	4	8	7	17	0.23
Renal failure	7	13	6	14	0.70
TIA/CVA/carotid surgery in history	5	9	8	19	0.23

During follow up one reoperation in the open group was performed after 1.5 years because of a false aneurysm. In the endovascular group 2 late reoperations were performed: 1 patient with a type I endoleak after 6 months, which was converted to an open procedure and 1 patient had a contained perforation caused by a bare stent after 4.5 months which was treated by an additional endovascular graft.

Paraplegia was less in the endovascular group, but this was not statistically significant (8 vs. 2%, odds ratio 0.3; 95% confidence interval 0.03–2.7; $p=0.24$). Of 14 patients in the open group that were operated on without distal perfusion three developed paraplegia rate vs. only one case of paraplegia in 39 patients operated with distal perfusion ($p<0.01$, univariate analysis).

There was no statistical significant difference in hospital mortality between both treatment groups: 6 patients (12%) in the open group vs. 2 patients (5%) in the endovascular group ($p=0.23$, odds ratio 1.4; 95% confidence interval 0.7–2.6).

Survival after a mean follow up of 26 months (range 3–82 months) in the open group and a mean follow up of 15 months (range 1–48 months) in the endovascular group did not show a significant difference (Fig. 1). The proportion of survivors was 92% after 1 year and 73% after 3 years. Five years survival was 58%, however, there were only patients with open repair left for this analysis.

Several factors, which might influence the mid-term survival, were investigated in a prediction model by means of Cox regression analysis, including pre-operative factors (cardiac failure, renal failure, acute aneurysm, diameter of the aneurysm and smoking) and post-operative factors (reoperation rate, occurrence of pneumonia, paraplegia, cardiac or intestinal ischaemia, time of anaesthesia, intensive care stay and hospital admission).

None of these factors proved to be significantly associated with the mid-term survival in either treatment group. In Table 3 a multivariate model is shown of the factors which gave a more than 10% change of the regression coefficient in the multivariate model, which might indicate possible bias.

When the incidences of paraplegia of recent studies mainly consisting of patients treated for a thoracic descending aneurysm are pooled, the incidence of paraplegia is 6.1% in 604 patients with an open procedure and 2.4% in 544 patients with an endovascular procedure: $p<0.01$.[1,3–7,10–16] The absolute difference is 3.7% (95% confidence interval 1.3–6.0%) resulting in a number needed to treat (NNT) with an endograft of 27 patients (95% confidence interval 17–76) to prevent 1 case of paraplegia.

The post-operative hospital mortality rate in these studies is 10.9% in open procedures compared to 7.0% in patients with a stent graft: $p<0.05$. The absolute difference is 3.9% (95% confidence interval 0.6–6.0%): NNT = 26 (95% confidence interval 17–166) (Table 4).

Table 2. Post-operative morbidity (percentage of the patients in each group) in patients operated for a descending thoracic aneurysm (univariate analysis)

	Open *N*	Open percentage (%)	Endo *N*	Endo percentage (%)	*p*-value	Odds ratio (95% confidence interval)
Mortality	6	11	2	5	0.33	1.4 (0.7–2.6)
Reoperation	15	28	8	19	0.25	0.6 (0.2–1.5)
Post-op. bleeding	9	17	2	5	0.10	0.2 (0.05–1.1)
Pneumonia	15	28	4	9	0.02	0.3 (0.08–0.8)
Myocardial infarction	2	4	1	2	0.66	0.6 (0.05–6.7)
TIA/CVA	2	4	0	0	0.50	0.5 (0.4–1.7)
Paraplegia	4	8	1	2	0.24	0.3 (0.03–2.7)
Intestinal ischaemia	0	0	2	5	0.12	0.5 (0.4–1.6)
Renal failure	6	11	1	2	0.12	0.2 (0.02–1.6)

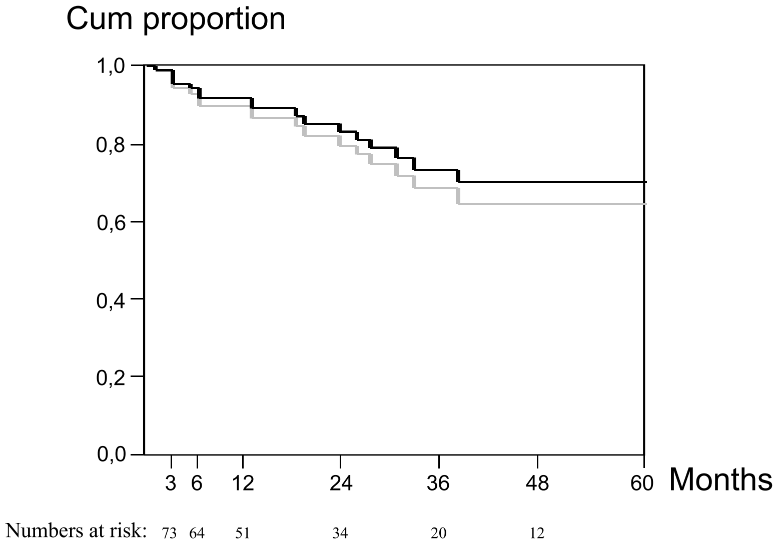

Fig. 1. Proportion of survival of patients with a open procedure (grey line), compared to patients with an endovascular procedure (black line).

In Table 5 the hospital costs of both treatments are calculated. The mean hospital costs per patient operated by endografting is 20,663 vs. 33,770 euros, for a patient operated by an open procedure.

Discussion

The main outcome of the present study is that the mid-term survival for patients operated for a descending thoracic aneurysm, after 3 years, is equal for both the open and endovascular technique. There were no pre- or post-operative factors, which could independently predict survival. Only four peri- and post-operative parameters could be identified in univariate analysis to be statistically significant in favour of the endovascularly treated group: operation time, duration of hospital admission, duration of intensive care stay, incidence of pneumonia.

In multivariate analysis these factors, as well as other potential confounders, were not independently predictive of a more favourable mid-term probability of survival. These figures must be interpreted with cautious, because the endovascular group had a shorter mean follow up.

To our knowledge only one other case-control series is published where these two treatment groups were compared. Ehrlich reported a series of 68 patients, with a mean age of 51 years and a mean aneurysm diameter of 7 cm. Ten patients were treated with an endovascular graft and 58 patients served as controls. The 30 day mortality was 10% in the endovascular group vs. 31% in the open group, the paraplegia rate was 0 vs. 12%, the mean intensive care stay was 4 vs. 13 days, the mean hospital stay was 6 vs. 10 days and length of intervention was 150 vs. 320 min.[3] Due to the small numbers the differences in mortality and paraplegia were not significant. These findings are in concordance with the results from the present study, however, no mid-term follow up was reported.

Our mid-term survival is in concordance with patient series reported in the literature. The following actuarial survival rates are reported in the literature: 81% ($n=103$) after 1 year (10), 73–90% after 2 years ($n=103$)[10] ($n=38$)[13] and 63–82% ($n=44$)[7] ($n=54$)[16] after 3 years.

Table 3. Multivariate analysis model of potential confounders and significant factors from univariate analysis which might independently predict survival

Variable	Standard error	Wald	*p*-value	Hazard ratio	95% confidence interval
Age	0.08	2.25	0.13	0.89	0.77–1.04
Angina	1.57	0.18	0.67	1.95	0.09–42.00
CABG	1.55	0.02	0.89	1.24	0.06–25.89
COPD/smoking	1.42	0.03	0.86	1.28	0.08–20.77
Pneumonia	1.59	0.04	0.84	1.37	0.06–30.8

Table 4. Pooled incidence of post-operative paraplegia and mortality of studies presenting cohort series of patients dominantly treated for a descending thoracic aneurysm

Author	Patients open *N*	Patients endo *N*	Paraplegia open *N* (%)	Paraplegia endo *N* (%)	Mortality open *N* (%)	Mortality endo *N* (%)
Galloway 1996	78		6 (8)		8 (10)	
Semba 1997		44		2 (5)		3 (7)
Ehrlich 1998	58	10	6 (10)	0 (0)	20 (34)	1 (10)
Mitchell 1999		104		3 (3)		9 (9)
Biglioli 1999	143	54	7 (5)	0 (0)	8 (15)	2 (4)
Cooley 2000	132		11 (8)		17 (13)	
Greenberg 2000		25		3 (12)		5 (20)
Estrera 2001	193		7 (4)		13 (7)	
Criado 2002		74		0 (0)		1 (1)
Bell 2003		67		3 (4)		5 (7)
Bergeron 2003		38		0 (0)		3 (8)
Orend 2003		74		2 (3)		7 (10)
Czerny 2004		54		0 (0)		2 (1)
Total	604	544	37 (6.1)	13 (2.4)	66 (10.9)	38 (7.0)

Paraplegia open vs. endo: $\chi^2=7.5$. $p<0.01$. Mortality open vs. endo: $\chi^2=4.7$. $p<0.05$.

It can be concluded that we are dealing with a patient group with a life expectancy less than that of the general population of that age. We know from large series that many patients die of non-aneurysmal related reasons. Long term follow up seems to be mandatory for endografts, because of late rupture due to material fatigue.[17] We did not calculate the costs of follow up for patients with an endograft, however, the costs of serial CT-scans is just a small percentage of the hospital costs.

The incidence of reoperations for endoleaks is reported to be 47% at a mean duration of 3.7 years in the first generation stents,[10] and 4.1–13.5% in second generation stents, the type of stents used in our study.[14,16] Our incidence of 2/42 is in concordance with the literature and not different from the incidence of late reoperations in the open group.

The incidence of paraplegia in patients with a descending thoracic aneurysm is reported to be rather low, compared to thoracoabdominal surgery, although it is still significant. The incidence is strongly related to clamping time. In a multivariate analysis model it has been concluded that aortic cross clamping is a risk factor ($p<0.008$) for the development of paraplegia with an odds ratio of 1.03/min and for hospital mortality with an odds ratio of 2.5/min clamping time. During follow up the survival was reported to be negatively associated with the occurrence paraplegia ($p<0.05$).[4]

Our paraplegia rate was 2% in the endovascular group and 8% in the open group. Due to the small numbers this was not statistically significant, so a type II error can occur. For this reasons we performed a small meta-analysis of a cumulative cohort of patients reported in recent literature, who are treated for a descending aneurysm by endovascular or open repair. From this meta-analysis of pooled data of more than 1000 patients it can be concluded that the paraplegia

Table 5. Costs per patient operated by endovascular or open repair

		Endo (€)	Open (€)	Costs calculation remarks
Peri-operative				
	Operation costs. Including anaes-thesia time	1333	4000	Endo: €500/h, Open: €800/h. including distal perfusion and personnel
	Prosthesis	10,000	500	Two Talent stents/patient Dacron graft for open
	Specialists	600	1000	Endo: surgeon and radiologist; open surgeon and cardiothoracic surgeon
	Radiological investigations	2000	400	
	Laboratory	200	200	
Nursing costs				
	Intensive care	2310	18,150	Mean stay see text
	Ward	1620	3420	Mean stay see text
Post-operative				
	Paraplegia reha-bilitation	2600	6100	Costs of life long care (rehospitalisation etc.) not included. Calculation according to percentages in text
Total		20,663	33,770	

and mortality rate is less for patients treated by endografting, however, the number needed to treat is rather high.

Even in studies report on patients who received stent grafts on a compassionate use base because they were unfit to undergo open repair the pooled mortality and paraplegia rate is significantly lower in patients treated with an endograft. This lower figure will influence the mean hospital costs of these patients, as we showed, as well as their life expectancy.

We studied this period of time (1997–2003), because during this period we changed gradually our policy from open treatment to endovascular treatment. Operations were performed by the same surgeons. Also in this strict period of time other potentially time dependent biases, like experience of the team, patient case mix and anaesthetic technique will not be a strong confounder in statistical analysis. On the contrary we have the impression that since the introduction of the endograft our inclusion of compassionate cases has increased, however, this is not reflected by the patient characteristics in Table 1.

Mortality and paraplegia rates for open procedures have been used to create mathematical models to perform risk analyses for patients with TAA.[18–20] Risk of rupture within 1 year can be estimated by an equation, where independent risk factors for rupture (age, pain, COPD, aortic diameter) are included.[18]

It can be calculated that the operative mortality for the open procedure is less than rupture risk at aneurysms with a diameter of more than 6–7 cm. Patients operated with an endograft, who have a lower peri-operative mortality, will have a benefit in survival when operated with an aortic diameter from 5 to 6 cm. It therefore seems justified to operate on patients with a descending aortic aneurysm, by endografting, with a diameter of 5 cm or more at any age. For open procedures we consider the age of 80 years as maximum, because of the higher complication rate, as reported in literature even in selected cases with a mortality of 25%.[21]

Successful operations for thoracic aneurysms result in good quality of life in the mid and long term.[22,23] However, similar to endovascular treatment of infrarenal aneurysms, the quality of life could be impaired in patients with a stent graft caused by the new technology and the strict follow up.[24] For thoracic stenting no quality of life studies are available yet.

In this study we have shown that the total peri-operative costs of a patient treated with an endoprothesis is 61% less than for a patient operated by open repair, despite the higher costs of prosthetic material.

In conclusion, it seems, from this retrospective analysis, that in our hospital system in Amsterdam endografting of descending thoracic aneurysm can be performed with less peri-operative morbidity, at lower hospital costs, but with equal mid-term life expectancy, compared with open grafting. Therefore, when technically feasible, we consider endografting to be the preferred procedure for the treatment of patients with a descending thoracic aneurysm.

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