

# Endovascular treatment of thoracic aortic diseases: Combined experience from the EUROSTAR and United Kingdom Thoracic Endograft registries

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**Purpose:** The objective of this study was to assess the initial and 1-year outcome of endovascular treatment of thoracic aortic aneurysms and dissections collated in the European Collaborators on Stent Graft Techniques for Thoracic Aortic Aneurysm and Dissection Repair (EUROSTAR) and the United Kingdom Thoracic Endograft registries.

**Methods:** Four hundred forty-three patients underwent endovascular repair of thoracic aortic disease between September 1997 and August 2003 (EUROSTAR, 340 patients; UK, 103 patients). Patients represented 4 major disease groups: degenerative aneurysm (n = 249), aortic dissection (n = 131), false anastomotic aneurysm (n = 13), and traumatic aortic injury (n = 50).

**Results:** Mean age in the entire study group was 63 years. Fifty-two percent of patients were deemed at high risk for open surgery because of major comorbidity. Sixty percent of patients underwent an elective procedure, and 35% required emergency treatment. Conventional indications for treatment of aortic dissection, including aortic expansion, continuous pain, rupture, or symptoms of branch occlusion constituted the basis for endograft placement in 57% of patients, whereas in 43% of patients aortic dissections were asymptomatic. Primary technical success was obtained in 87% of patients with degenerative aneurysm and in 89% with aortic dissection. Paraplegia was a postoperative complication in 4.0% of patients with degenerative aneurysm and 0.8% of patients with aortic dissection (not significant). Thirty-day mortality in the entire study group was 9.3%, with mortality rates after elective procedures of 5.3% for degenerative aneurysms and 6.5% for aortic dissection. Mortality for degenerative aneurysm after emergency repair was higher (28%;  $P < .0001$ ) than after elective procedures. For aortic dissection the emergency repair rate was 12% (not significant compared with elective repair of aortic dissection, and  $P = .025$  compared with emergency repair of degenerative aneurysm). One-year follow-up was complete in 195 patients. The outcome at 1 year was more favorable for aortic dissection than for degenerative aneurysm with regard to aortic expansion (0% vs 15%;  $P = .001$ ) and late survival (90% vs 80%;  $P = .048$ ). In the groups with false anastomotic aneurysm and traumatic aortic injury, 30-day mortality rates were 8% and 6%, respectively.

**Conclusion:** This multicenter experience demonstrates acceptable rates for operative mortality and paraplegia after endovascular repair of thoracic aortic disease. Outcome after 30 days and 1 year was more favorable for aortic dissection than for degenerative aneurysm. However, the durability of this technique is currently unknown, and continued use of registries should provide data from long-term follow-up. (J Vasc Surg 2004;40:670-80.)

Elective endovascular treatment of thoracic aortic disease has been used to treat degenerative aneurysms, false aneurysms, infected aneurysms, and chronic dissections. Emergency indications for stent-graft treatment include ruptured aneurysms, traumatic aortic injuries, acute type B aortic dissections, and intramural hematomas. The mortality rate associated with open surgery is considerable, and

ranges from 5% to 20% in thoracic aortic aneurysm (TAA) disease and from 6% to 67% in type B aortic dissection.<sup>1-9</sup> The advent of endovascular technology offers a minimally invasive alternative treatment for thoracic aortic disease. Several small series have reported encouraging early results with this technique.<sup>1,10-16</sup> We report the combined experience from 2 voluntary multicenter registries involved with data recording and evaluation of endovascular repair of thoracic aneurysms and dissection. The first was organized by the European Collaborators on Stent Graft Techniques for Thoracic Aortic Aneurysm and Dissection Repair (EUROSTAR), and the second by the United Kingdom Thoracic Endograft Registry. The objective was to assess early and 1-year results in a large patient series to obtain insight about endovascular repair of thoracic aortic disease in Europe.

## METHODS

A total of 443 patients with aneurysm or dissection in the thoracic aorta who underwent endovascular repair during the

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Competition of interest: none.

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5 years from August 1997 to August 2003 constituted the basis of this analysis. Ten patients with thoracic aortic abnormalities classified as penetrating ulcers were excluded from the assessment, because this number was considered too small for meaningful conclusions. Thirty-seven patients who received treatment between August 1997 and January 2000 were entered retrospectively into the EUROSTAR database. From January 2000 data were entered prospectively on an intent-to-treat basis into EUROSTAR (340 patients) and the UK Thoracic Endograft Registry (103 patients). All patients who survived the operation period underwent minimal follow-up of 1 month (range, 1-60 months).

Patients were recruited from 62 European institutions (see Appendix). Centers participated in only 1 of the 2 registries. Patients received the following commercially available, Communauté Européenne (CE)-approved devices: Talent (Medtronic/AVE), Excluder (W. L. Gore & Associates), Zenith (William Cook Europe), or Endofit (Endomed).<sup>17</sup> Patients were categorized into 4 groups: degenerative TAA, aortic dissection, false anastomotic aneurysm, and traumatic rupture of the thoracic aorta. Emergency procedures were defined arbitrarily as those that required treatment within 7 days of first presentation. Collected baseline data included information about comorbidity, fitness for open surgery (classification according to the American Society of Anesthesiologists [ASA]), aneurysm anatomy, and operative details. The information was recorded by the participating institutions on case record forms, and was submitted for inclusion to either the United Kingdom or continental European data registry center.<sup>18</sup> Findings at follow-up visits, which involved clinical examination, computed tomography (CT), angiography, magnetic resonance imaging, or thoracic or transesophageal echocardiography were recorded on data forms and returned at regular intervals to the data registry centers for processing and analysis. There was no outside monitoring of the centers, nor involvement of a core laboratory for evaluation of CT scans or other imaging studies. Early complications included intraoperative device-related problems, including inability to advance the delivery system, inability to deploy the device, stent-graft migration, occlusion, and stenosis; arterial injuries; postoperative systemic complications, including cardiac, pulmonary, and renal function impairment; and neurological complications. Primary technical success was defined as complete exclusion of the aneurysm or coverage of the proximal entry tear in aortic dissection, survival of the patient, and absence of a primary endoleak. Patients were followed up at 1, 6, and 12 months, and annually thereafter. Satisfactory findings at CT were defined by absence of endoleak, stent-graft migration, kinking, stenosis, thrombosis, and aneurysm expansion. In case of dissection additional criteria included complete thrombosis of the false lumen and, in extensive dissection, thrombosis of the proximal segment of the dissection (partial thrombosis). Reminders for overdue follow-up data were regularly sent to the institutions participating in the project.

Outcome reporting adhered to the guidelines from the ad hoc Committee for Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery/American Association for Vascular Surgery.<sup>18</sup> Data were presented as means and ranges. Missing data were indicated as such in this overview. Death occurring within 30 days of the initial procedure was categorized as operative death, and deaths occurring after 30 days as late deaths. Other outcome events observed during follow-up included endoleak, graft migration, device disintegration, and continued aneurysm expansion. Statistical significance of differences in proportions was determined with  $\chi^2$  tests. The Kaplan-Meier method was used to determine cumulative survival. The data were analyzed with SAS statistical software, version 8.0 (SAS Institute).

## RESULTS

The entire study cohort consisted of 443 patients, of whom 331 (75%) were male and 112 (25%) were female. Mean patient age at operation was 63 years (range, 13-89 years). Degenerative aneurysm was present in 249 patients, aortic dissection in 131 patients, false anastomotic aneurysm in 13 patients, and traumatic aortic injury in 50 patients. Comorbid factors were frequently present in all groups. In the entire cohort previous cardiothoracic surgery had been performed in 7.2% of patients, a previous myocardial infarction had occurred in 17% of patients, and chronic obstructive pulmonary disease was observed in 21% of patients. Moreover, 52% of patients had preoperative ASA class 3 or 4 disease (Table I). The main differences between the 4 patient categories were a higher prevalence of female patients in the false anastomotic aneurysm group (61%;  $P = .002$ ), older age in the degenerative aneurysm group (mean, 71 years;  $P < .0001$ ), higher prevalence of smokers in the degenerative aneurysm group (44%;  $P < .0001$ ), and lower prevalence of previous cardiac events (myocardial infarction, angina, congestive heart failure) in the false anastomotic aneurysm group (7.7%;  $P = .036$ ) and the traumatic aortic injury group (6.0%;  $P < .0001$ ). In addition, a higher prevalence of previous cardiac thoracic surgery in the false anastomotic aneurysm group was observed (69%;  $P < .0001$ ).

Ten percent to 14% of patients in most subgroups had involvement of the aortic arch or the ascending thoracic aorta. In contrast, in the false anastomotic aneurysm group the arch was involved in 38% of patients (Table II). One or more segments of the descending thoracic aorta were affected in 77% to 93% of patients with aneurysmal lesions and in 100% of patients with aortic dissection. The maximum diameter was largest (66 mm) in patients with degenerative aneurysm compared with the other groups. Degenerative aneurysm and false anastomotic aneurysm were most frequently treated electively (69% and 62%, respectively), whereas, and understandable, most patients with traumatic aortic injury required emergency treatment 54% (Fig). In patients with aortic dissection equal proportions

**Table I.** Patient demographic data

	<i>Degenerative aneurysm</i>		<i>Aortic dissection</i>		<i>False anastomotic aneurysm</i>		<i>Traumatic rupture</i>	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
<i>Patients (N = 443)</i>	249	56.2	131	29.6	13	2.9	50	11.3
Sex								
Male	185	74.3	101	77.1	5	38.5	40	80
Female	64	25.7	30	22.9	8	61.5	10	20
Age (y) (range)	71.25	(34–89)	61.5	(18–86)	46.1	(30–78)	46	(13–76)
ASA $\geq 3$	145	58.2	55	42.0	6	46.1	24	48
Smoker	110	44.2	26	19.8	4	30.8	12	24
Pregips cardiac intervention	22	8.8	10	7.6	1	7.7	1	2
Previous cardiothoracic surgery	11	4.4	12	9.2	9	69.2		
History of MI	55	22.1	18	13.7	1	7.7	1	2
History of angina	40	16.1	11	8.4			1	2
History of CHF	15	6	12	9.2			1	2
History of COPD	70	28.1	17	13.0	1	7.7	5	10

MI, Myocardial infarction; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease.

**Table II.** Anatomic and procedural details

	<i>Atherosclerotic aneurysm (n = 249)</i>		<i>Aortic dissection (n = 131)</i>		<i>False anastomotic aneurysm (n = 13)</i>		<i>Traumatic rupture (n = 50)</i>	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
<i>Patients (N = 443)</i>								
Localization of thoracic aortic disease*								
Ascending	—		3	2.3	1	7.7	—	
Aortic arch	26	13.9 <sup>†</sup>	13	9.9	5	38.5	6	12.0
Descending TAA	173	92.5 <sup>†</sup>	131	100.0	10	76.9	43	86.0
Proximal third	97	51.9 <sup>†</sup>	63	63.0 <sup>‡</sup>	7	53.5	41	82.0
Middle third	94	50.3 <sup>†</sup>	28	28.0 <sup>‡</sup>	—		1	2.0
Distal third	70	37.4 <sup>†</sup>	14	14.0 <sup>‡</sup>	3	23.5	1	2.0
Maximum diameter, TAA (range)	66.3	(30–116)	45.8	(42–100)	57	(40–85)	54.5	(30–80)
Minimum diameter, true lumen (range)	NA		14.9	(10–40)	NA		NA	
Regional or local anesthesia	38	15.2	14	10.7	1	7.7	2	4.0
Access to disease								
Femoral artery	195	78.3	109	83.2	11	84.6	42	84.0
Iliac artery	28	11.2	5	3.8	1	7.7	8	16.0
Abdominal artery	13	5.2	3	2.3	1	7.7	—	
Number of stents used <sup>  </sup>								
1	85	34.1	83	63.4	11	84.6	40	80.0
2	91	36.5	35	26.7	2	14	8	16.0
$\geq 3$	64	25.7	13	9.9	—		—	
Additional procedures								
Endovascular <sup>¶</sup>	58	23.3	8	6.1	—		1	2.0
Surgical <sup>#</sup>	66	26.4	39	29.7	4	30.8	15	30.0

TAA, Thoracic aortic aneurysm.

\*Multiple sites per patients possible.

<sup>†</sup>Data for 62 patients missing. Percentages calculated on the basis of 187 patients.

<sup>‡</sup>Data for 31 patients missing. Percentages calculated on the basis of 100 patients.

<sup>||</sup>Data for 11 patients missing.

<sup>¶</sup>Included stents in iliac or abdominal aorta, balloon fenestration of dissection flap, and coiling of endoleak.

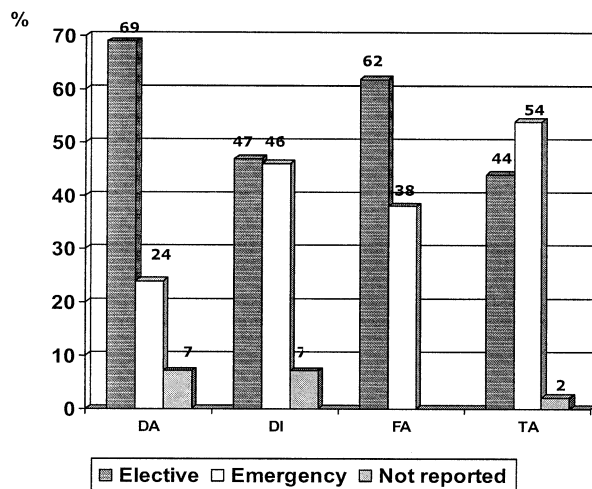
<sup>#</sup>Included open surgery of thoracic or abdominal aorta and subclavian carotid or innominate artery transposition or bypass.

of elective and emergency repairs were performed (47% and 46%, respectively).

A more favorable outcome after endovascular repair of aortic dissection compared with degenerative aneurysm included lower 30-day mortality for emergency repair ( $P = .025$ ), no late aortic expansion ( $P = .001$ ),

and higher 1-year survival ( $P = .048$ ). In addition, trends were observed for lower rates of postoperative paraplegia and 1-year aneurysm-related death (Tables III and IV).

**Degenerative aneurysms.** Of the 249 patients with degenerative aneurysm, three fourths were male (Table I).



Distribution of various thoracic aortic diseases treated with elective and emergency procedures. DA, Degenerative aneurysm; DI, aortic dissection; FA, false anastomotic aneurysm; TA, traumatic aortic injury.

Approximately one fourth of these patients required emergency repair (Fig). More than half (58%) of the patients in this group were classified as at high risk (ASA class 3 or 4) and would not have been considered candidates for open surgical TAA repair. The degenerative aneurysm was located in the aortic arch in 14% of patients, with an approximately even distribution in the proximal, middle, and distal descending thoracic aorta (Table II). The configuration of the aneurysm was fusiform in 64%, saccular in 32%, and not recorded in 4.4%. To obtain an adequate proximal landing zone it was necessary to place a stent graft over the origin of the left subclavian artery in 42 patients (17%). Of these, 22 patients had preemptive revascularization with subclavian artery transposition or bypass. Of the total of 66 adjunctive surgical procedures, 14 were performed in the abdominal aorta and 2 in the thoracic aorta.

Primary technical success was achieved in 87% (Table V). Device-related complications occurred intraoperatively in 16% of patients, and arterial injuries in 2.4% of patients. Neurologic events in most cases (59%) consisted of paraplegia or paraparesis. Postoperative systemic problems included cardiac, pulmonary, and renal function impairment, and occurred in approximately one fourth of patients. Thirty-day mortality rate in the entire group with degenerative aneurysm was 10%. However, in patients who underwent an emergency procedure the mortality rate was 28%, and in those who underwent elective repair was 5.3% ( $P < .0001$ ; Table III). One year after operation 80% of patients with available follow-up data had satisfactory findings at CT examination (Table IV). Expansion of the aneurysm was the most frequent adverse event, occurring in 14.5% of patients. The mortality rate between 1 and 12 months was 10%. In 2.1%, death was aneurysm-related. Late aneurysm rupture occurred in 1 patient. The overall cumulative survival rate in this subgroup was 80% after 12 months.

**Aortic dissection.** Patients with aortic dissection were on average 10 years younger than those with degenerative aneurysm. Forty-two percent of these patients had an ASA classification of 3 or greater (Table I). Dissections were type A in 7 patients (5.3%), and type B in 106 patients (81%). In 18 patients (14%), classification was not available. The dissection was located in the descending aorta in all patients. In addition, dissection was present in the ascending aorta in 2.3% of patients, and in the aortic arch in 10% of patients (Table II). At the time of the procedure 43% of patients had no symptoms, and 57% had symptoms of rupture, aortic expansion, or side branch occlusion. Elective and emergency repair in this group was performed in similar proportions of patients (Fig). Emergency procedures were associated with acute symptoms in almost all patients (Table VI). In elective procedures symptoms were present in 74% of patients. The severity of the dissection was characterized by the following findings: the dissection extended down to the descending aorta in 27% of patients, to the celiac trunk in 20% of patients, to the abdominal aortic bifurcation in 17% of patients, and into the iliac arteries in 22% of patients. The proximal extension of the aortic dissection reached to the left subclavian artery in 39% of patients, into the aortic arch in 9.2% of patients, to the ascending aorta in 7.6% of patients, and to the aortic valve in 0.8% of patients. The minimum diameter of the true lumen was 15 mm, and the maximum diameter of the overall aorta was 46 mm. The endograft procedure with aortic dissection did not involve any stent-graft placement in the ascending aorta. Additional supra-aortic vessel revascularization was performed in 15 patients (12%), and abdominal aortic procedures in 2 patients (1.5%). Subclavian artery overstepping was performed in 37 patients, of whom subclavian artery revascularization was performed in 15 patients. Of these operations, 1 was performed as a secondary procedure, because of symptoms.

In 89% of patients primary technical success was achieved; the remaining 11% had either incomplete covering of the entry tear, persistent flow without thrombosis of the largest portion of the false lumen, no expansion of the true lumen, or endoleaks (Table V). This success rate was 86% in the elective group versus 95% in the emergency group. The true lumen expanded from 15 mm to 26 mm. Neurologic complications consisted of paraplegia in 1 patient who initially underwent emergency repair, and stroke in 2 patients who underwent elective procedures. Systemic postoperative problems occurred in one third of patients. The overall 30-day mortality rate was 8.4%. Patients who underwent an emergency procedure had an early mortality rate of 12%, versus 6.5% in elective cases ( $P = .55$ ; Table III). One year after operation 94% of patients followed up during this interval had satisfactory findings at CT examination (Table IV). New endoleaks were observed in 2.8% of patients. Late death occurred in 1.5% of patients, and the cumulative survival rate after 1 year was 90% in patients with aortic dissection.

**False anastomotic aneurysm.** In contrast with the other subgroups, the proportion of female patients (61%) was significantly greater than male patients (39%) ( $P = .006$ ). This

**Table III.** Thirty-day mortality in elective vs emergency procedures

	<i>Degenerative aneurysm</i> ( <i>n</i> = 249)		<i>Aortic dissection</i> ( <i>n</i> = 131)		<i>False anastomotic aneurysm</i> ( <i>n</i> = 13)		<i>Traumatic rupture</i> ( <i>n</i> = 50)	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Type of procedure								
Elective	171		62		8		22	
Emergency	61		60		5		27	
Not reported	17		9		—		1	
30-Day mortality								
Elective	9	5.3*	4	6.5*	—		—	
Emergency	17	27.9*	7	11.7*	1	20.0*	3	11.1
Not reported	—		—		—		—	

\*Percentages calculated by dividing numbers of deaths by total number of patients per type of procedure.

**Table IV.** One-year outcome

	<i>Degenerative aneurysm</i> ( <i>n</i> = 96)		<i>Aortic dissection</i> ( <i>n</i> = 67)		<i>False anastomotic aneurysm</i> ( <i>n</i> = 8)		<i>Traumatic rupture</i> ( <i>n</i> = 24)	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Satisfactory findings at CT	77	80.2	63	94.0	7	87.5	20	83.3
Endoleak	4	4.2	1	1.5	—		—	
Migration	—		—		—		—	
Expansion aneurysm	14	14.6	—		1	12.5	2	8.3
Late intervention	5	5.2	1	1.5	—		—	
Late rupture	1	1	—		—		—	
TAA related death	2	2.1	—		—		—	
Unrelated death	8	8.3	1	1.5	—		3	12.5
Cumulative survival rate		80.3		90.2		92.3		82.3

TAA, Thoracic aortic aneurysm.

group consisted of relatively younger patients (mean, 46 years). Forty-six percent of this group was considered unfit for open operation because of the aneurysms, and 69% had undergone previous cardiothoracic surgery (Table I). Two thirds of these patients were operated on electively, and one third required emergency repair (Fig). The false anastomotic aneurysm was located in the ascending aorta in 1 patient (7.7%), in the aortic arch in 39% of patients, and in the descending aorta in 77% of patients (Table II). In the patient with involvement of the ascending aorta a stent graft was placed in that segment.

During the operation, device-related complications occurred in 46% of patients (Table V). However, most complications were overcome, and technical success was 92%. After treatment, neurologic complications occurred in 1 of 13 patients (7.7%). Systemic complications were observed in 15% of patients. Early death in patients with false anastomotic aneurysm occurred in 1 patient (7.7%). This patient was 1 of 5 who underwent an emergency procedure (Table III). One year after operation 88% of patients had satisfactory CT findings (Table IV). Enlargement of the aneurysm developed in 13% of patients. No late deaths,

conversions, or ruptures were reported. The cumulative survival rate at 12 months in this group was 92%.

**Traumatic rupture of thoracic aorta.** The average patient age in this group was 46 years, which was lower than in the other subgroups ( $P < .0001$ ; Table I). Of no surprise, most patients (55%) in this group required emergency treatment (Fig). traumatic aortic injury was located in most patients (82%) in the proximal descending aorta (Table II).

The primary technical success rate in this category was 96%. Intraoperatively, device-related complications and arterial injuries both were observed in 12% of patients (Table V). After treatment, neurologic complications occurred in 6.0% of patients. In 32% of this category systemic problems were reported. Three patients (6.0%) died within 30 days after operation. All 3 were among the 27 patients who required an emergency procedure. No patient with delayed or elective endograft treatment of traumatic aneurysm died early (Table III). One year after operation 83% of patients had satisfactory findings at CT examination (Table IV). Late death occurred in 13% of patients. However, no late ruptures or conversions were documented. The cumulative survival rate at 1 year in this group was 82%.



**Table V.** Early (30-day) outcome

	<i>Atherosclerotic aneurysm (n = 249)</i>		<i>Aortic dissection (n = 131)</i>		<i>False anastomotic aneurysm (n = 13)</i>		<i>Traumatic rupture (n = 50)</i>	
	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>
Technical success	217	87.1	116	88.6	12	92.3	48	96.0
Intraoperative complications								
Device-related	39	15.7	3	2.3	6	45.1	6	12.0
Arterial	6	2.4	1	0.8	—	—	6	12.0
Complications from operation to discharge								
Neurologic	17	6.8	3	2.3	1	7.7*	3	6.0†
Paraplegia or paresis	10	4.0	1	0.8	—	—	—	—
Stroke	7	2.8	2	1.5	—	—	1	2.0
Systemic	72	28.8	46	35.1	2	15.4	16	32.0
Endoleak								
Proximal	12	4.8	2	1.5	1	7.7	—	—
Midgraft	4	1.6	2	1.5	—	—	—	—
Distal	3	1.2	2	1.5	—	—	—	—
Perfusion from side branches	4	1.6	2	1.5	—	—	—	—
30-Day mortality	26	10.4	11	8.4	1	7.7	3	6.0

\*Vocal cord dysfunction.

†In 2 patients the kind of neurologic complication could not be retrieved.

**Table VI.** Presence and type of preoperative symptoms in patients undergoing elective or emergency procedures to treat dissection of thoracic aorta

	<i>Elective procedure (n = 62)</i>		<i>Emergency procedure (n = 60)</i>	
	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>
No symptoms	20	32.3	1	1.7
Persisting back pain/expansion aneurysm/ rupture of thoracic aorta	41	66.1	57	95.0
Symptoms of sidebranch occlusion*	5	8.1	17	28.3

\*Includes paraparesis, paraplegia, intestinal ischemia, renal insufficiency, limb ischemia.

## DISCUSSION

A lower incidence of TAA in comparison with abdominal aortic aneurysm has resulted in slower development and less widespread experience with endovascular procedures to treat TAA. Stent-graft repair of thoracic aortic disease is an appealing alternative to open surgery, because it avoids thoracotomy, aortic cross-clamping, and left-sided heart bypass. The descending thoracic aorta is suitable for this minimally invasive approach because, although it may be elongated and tortuous in patients with aneurysm, it usually enables good adaptation of endografts. Operation time and hospital stay are significantly shorter compared with those with open surgery.<sup>19</sup> The application rate of stent-graft repair in 1 series on various pathologic conditions of the descending thoracic aorta was as high as 57%.<sup>15</sup> In the present analysis patients were categorized into 4 categories accordingly to type of aortic disease, that is, degenerative aneurysm, aortic dissection, false anastomotic aneurysm, and traumatic aortic injury. A high prevalence of comorbid factors was noted, and a large proportion of patients

(52%) were classified at ASA greater than 3 and would thus not be suitable candidates for open thoracic aortic repair. The population with degenerative aneurysm were relatively older (mean, 71 years) in comparison with series on open descending TAA repair (range, 47-65 years).<sup>20,21</sup> The possibility to use this technique in frailer and older patients may increase the applicability of TAA treatment significantly. Given the higher prevalence of patients at poor risk, the perioperative mortality rate in the present overview of 8% in the aortic dissection group and 10% in the degenerative aneurysm group is acceptable and in agreement with the previously reported mortality rate with endografts, which ranged from 3.5% to 12.5%.<sup>6,7,10,15,22</sup> Because of incomparability of patients, these early mortality rates cannot simply be compared with the results of open surgery. Surgical mortality rates ranging from 8% to 26% have been reported.<sup>6,20,21</sup>

When stent-graft attachment is required in the proximity of the left subclavian artery it is acceptable to overstent the origin of this vessel to extend the length of neck available for fixation and seal. Opinions diverge about the

need for extra-anatomic revascularization of the subclavian artery under these circumstances. Overstenting has the potential for complications, including possible retrograde endoleak via the subclavian artery, left arm ischemia, and posterior cerebral stroke, and may increase the risk for paraplegia. Although these events are infrequent, several investigators favor routine left subclavian artery revascularization from the common carotid artery.<sup>11,16,22,23</sup> In the degenerative aneurysm and aortic dissection groups in the present series, subclavian artery overstenting was required in 17% and 28%, respectively, and additional revascularization procedures were performed in almost half of these patients.

The technical success rate in endovascular procedures performed to treat degenerative aneurysm was 87%. In elective degenerative aneurysm the 30-day mortality was 5%, which is lower than the previously reported rate of 12.5% with endografting.<sup>10</sup> Successful endovascular management of acute thoracic rupture was first reported by Semba et al,<sup>24</sup> who observed perioperative death in 2 of 11 patients. In emergency repair in the present atherosclerotic aneurysm group the 30-day mortality rate was 29%, comparable with the results of Semba et al<sup>24</sup> and with the 33% reported by Greenberg et al.<sup>10</sup> The incidence of spinal cord ischemia and paraplegia has been consistently low after endovascular repair of thoracic aneurysms, even in patients in whom long aortic segments and the "danger zone" (T9-L1) that usually gives origin to the anterior spinal artery had been covered by the endograft. It was noted that the risk for paraplegia in the degenerative aneurysm group was highest (4%), whereas in 66% of patients 2 or more stent grafts were used, indicating long covered aortic segments. In the aortic dissection group the rate of paraplegia was significantly lower (0.8%), and multiple endografts were used in only 37%. However, more factors than the covered aortic length may determine the risk for spinal cord ischemia. In comparison, the risk for spinal complications reported in the endograft literature ranges from 0% to 12%.<sup>10,22,25</sup> Avoidance of clamping of the proximal aorta and prolonged episodes of hypotension may account for the low incidence of spinal problems. The overall incidence of stroke was 3%, with manipulation with the introducer device and guide wire across the aortic arch in proximity of the orifices of the carotid arteries as known risk factors. Endoleak after stent-graft treatment of descending TAAs was relatively infrequent, and was usually graft fixation-related type I. Type II endoleaks were relatively uncommon in the present overview, which is in concordance with the literature.<sup>7</sup> Late migration of the endoprosthesis occurs, according to the literature, with an incidence of 0% to 30%. The higher rates are typically associated with use of early designs of thoracic endografts and multiple overlapping of "thrombosed" endografts.<sup>7,22,26</sup> Because device migration was not reported during the relatively short follow-up of 1 year in the present study, proper correlation with the use of single or multiple endografts was not possible. A 1-year survival rate of 80% in the degenerative aneurysm

group was observed, which was comparable with the rate of 82% recently reported by Demers et al.<sup>27</sup>

Reports of successful closure of the entry tear of a dissection by a stent graft were first published in the late 1990s, and raised optimism for improvement of both early and late patient survival. The principle of stent-graft repair in dissection is based on redirection of flow from the false lumen and reconstruction of the true lumen when it is collapsed. The goal is to cause thrombosis of the false lumen, which is assumed to lead to a healing process of the aortic wall and decreased risk for late aortic enlargement.<sup>28</sup> The indications for stent-graft treatment of type B dissection include, in the first place, symptoms from progression of the dissection, such as enlargement of the aortic diameter, ongoing pain despite adequate hypotension, branch involvement resulting in end-organ ischemia (visceral, renal, lower extremity, spinal cord), or rupture.<sup>29-31</sup> A second indication category consists of patients with few or no symptoms after the initial phase. In these patients stent grafting may be used in an attempt to prevent late aneurysm formation, which occurs in 30% to 40% of patients who receive conservative management.<sup>32</sup> At this time there is no firm evidence that endografting will reduce late sequelae of dissection. A clinical trial is in progress to assess whether this category indeed will benefit from remodeling of the aorta and reduced risk for late complications.<sup>32,33</sup> The indications followed by the participants in this registry included both asymptomatic (43%) and symptomatic (57%) disease.

Use of endografts in aortic dissection differs from that in degenerative aneurysm in that the expanding stent may perforate the dissecting flap, causing reentry of flow, enabling the false lumen distal from the stent graft to remain patent. No or incomplete thrombosis of the false lumen was observed in 14% of patients with aortic dissection in this study, which is in concordance with previous institutional observations.<sup>34</sup> As a consequence, stent-graft technique in dissection must include use of flexible devices, with no bare stents at the extremities, to avert damage to the vulnerable aortic wall or dissecting septum, and minimal oversizing or ballooning of the stent graft.<sup>35,36</sup>

In 89% of patients with aortic dissection treated with an endovascular technique the procedure was performed successfully. The 30-day mortality rate of 6.5% in elective dissections is comparable with the rate of 7% reported by Shim et al.<sup>37</sup> This rate is lower than with open surgery to treat type B dissection, which may be associated with a mortality rate as high as 67%.<sup>20,29,37-44</sup> Again, direct comparison may not be justified, because of differences in patient selection. The 30-day mortality rate in the emergently treated dissection group was 12%, comparable with the previously reported mortality rate of 16% with endovascular treatment.<sup>45</sup> Paraplegia from spinal artery occlusion occurred in only 1 patient, which compares favorably with the reported 7% to 36% in patients who underwent surgery, and was in accord with previous experience of 1.7% with percutaneous stent-graft placement covering the entry tear in the descending aorta.<sup>17,18,26,32,39,41</sup> The 1-year cumulative survival rate in this group was 90.2%, which compares favorably with a surgically treated group, in whom the

12-month mortality rate was 33%.<sup>46</sup> That in the current aortic dissection group no aortic expansion was observed may be due to the short follow-up time of only 1 year.

Endograft repair of false anastomotic aneurysm is usually a straightforward procedure, with placement of a single stent graft and with a high technical success rate. Our findings confirm the conclusion of a recent study that stent-graft repair of false anastomotic aneurysm may be preferable to surgical treatment.<sup>38</sup> Rupture of thoracic aorta from trauma is associated with a mortality rate as high as 90%, because most patients die at the site of the accident. Of patients who reach the hospital alive, 15% die before the operation.<sup>47</sup> Surgical treatment of a traumatic thoracic rupture has a 30-day mortality rate of 15% to 30%, and a risk for paraplegia of 2% to 20%.<sup>48-52</sup> In the present series, comparable with other reports,<sup>52</sup> endovascular treatment was associated with an early mortality rate of 6%, which is considerably lower than the above indicated rates with surgery. Because of the complexity of the clinical situation in these patients, who often have multiple injuries, the timing of open surgical repair has long been controversial.<sup>9,45</sup> Unless a life-threatening hemothorax exists, deliberately delayed surgical repair has been mostly reported. The use of stent-graft treatment has proved effective, and this approach is considered by some as the first choice in management in these often severely ill patients.<sup>25,53</sup> Greater feasibility of endovascular repair in the acute phase of thoracic aneurysm may be an additional advantage over open surgery.<sup>54</sup> In the present series, comparable with other reports, endovascular treatment demonstrated a considerably lower early mortality rate (6%) compared with the above indicated rates with surgery.

There are several weaknesses of this review. First, registries in general consist of unaudited data, which may result in underreporting of complications. However, data collections in which the center is anonymous, such as national or regional reviews, as a rule report higher rates of postoperative deaths and complications than institutional reports do.<sup>55</sup> This makes it difficult to make any assumption if, and to what extent, underreporting of complications was the case. Second, the present report was a compilation of the data of 2 separate and independent registries. Although the main items corresponded well, the case record forms used for data collection were not completely congruent, and for assessment of some of the questions only the data from 1 of the registries were used. Finally, voluntary registries must be concise, because lengthy questionnaires may result in poor compliance of data reporting. This has caused some lack of information. For example, no differentiation was made between different types of side branch occlusions at presentation or different additional procedures (surgery for access or side branch revascularization).

In conclusion, patients selected for endovascular repair of diseases of the thoracic aorta had a considerable prevalence of preexisting comorbidity.

Considering the number of patients unfit for open surgery and the incidence of emergency procedures, the overall 30-day and 1-year related outcomes in different diseases were encouraging. Patients with dissections had better outcomes than did those with degenerative aneurysms. However, long-term efficacy of endovascular treatment of TAAs and dissections remains to be demonstrated, and lifelong surveillance remains necessary.

## APPENDIX

### Participating institutional coordinators of the EUROSTAR Registry

Prof A. Nevelsteen, Louvain, Belgium  
Dr J. Buth, Eindhoven, The Netherlands  
Prof H. Myhre, Trondheim, Norway  
Dr P. Harris, Liverpool, England  
Dr E. Verhoeven, Groningen, The Netherlands  
Prof W. Stelter, Frankfurt, Germany  
Dr M. Wyatt, Newcastle, England  
Dr V. Rimbau, Barcelona, Spain  
Dr P. Peeters, Bonheiden, Belgium  
Dr R. Balm, Amsterdam, The Netherlands  
Dr R. H. Geelkerken, Enschede, The Netherlands  
Dr R. Verhelst, Brussels, Belgium  
Prof P. C. Maurer, Munich, Germany  
Prof H. Kortmann, Hamburg, Germany  
Dr A. de Smet, Rotterdam, The Netherlands  
Mr S. Darke, Bournemouth, England  
Dr M. van Betsbrugge, Antwerp, Belgium  
Dr H. Massin, Gilly, Belgium  
Dr F. van Elst, St Truiden, Belgium  
Dr Schroë, Genk, Belgium  
Dr van Sambeek, Rotterdam, The Netherlands  
Dr M. Scoccianti, Rome, Italy  
Dr Th. Nordh Larzon, Orebro, Sweden  
Dr Sanchez-Corral, Madrid, Spain  
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Dr E. Sebrechts, Vilvoorde, Belgium  
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Prof M. Storck, Leipzig, Germany  
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Dr J. Bleyne, Deurne, Belgium  
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Dr P. van den Brande, Brussels, Belgium  
Dr Vahl, Amsterdam, The Netherlands  
Dr Fishwick, Leicester, England  
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### Participating institutional coordinators of the United Kingdom Thoracic Endograft Registry

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Mr N. Cheshire, London, England  
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 Dr M. Matson, London, England  
 Dr R. Morgan, London, England  
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 Dr J. Moss, Glasgow, Scotland  
 Mr S. Parvin, Bournemouth, England  
 Dr P. Kennedy, Belfast, Northern Ireland  
 Mr M. Wyatt, Newcastle, England  
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 Dr T. Cleveland, Sheffield, England  
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## INVITED COMMENTARY

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Stent-graft repair of thoracic aortic pathology has proceeded at a frustrating pace on the North American side of the Atlantic. The engineering, regulatory, and commercial interest issues responsible for this slow (compared with abdominal aortic aneurysm) development have been the subject of considerable discussion among the involved parties. At the present time, except for a very few centers holding physician-sponsored Investigational Device Exemptions, this technology is only available in the United States in the form of 3 Phase II clinical trials, which are currently restricted to treatment of degenerative thoracic aneurysms (DTA) in candidates for open surgery. Furthermore, given the "morbidity quotient" of conventional surgery for thoracic aortic (TA) pathology, the clinical need for stent-graft repair in this area is both obvious and pressing. The good news is that the latter is now recognized by all parties involved and, with the imminent publication of the first US pivotal trial,<sup>1</sup> there likely will be a commercially available graft in the United States within a year.

The present Eurostar/United Kingdom registry report is certainly the largest compendium of patients treated with thoracic aortic stent grafts. Readers of the *Journal of Vascular Surgery* are accustomed to valuable clinical reports from the Eurostar registry, and the present study will certainly serve (at least temporarily) as a benchmark for periprocedural results achievable with TA stent grafts. Procedural mortality was in line with the available literature, particularly since many patients treated with TA stent grafts are in genuinely desperate clinical circumstances. Emergency treatment was required in half the dissection patients and in 25% of those with DTA. The authors' results with respect to central nervous system complications are admirable. Stroke has been a vexing problem in this arena, and I concur with their sanguine discussion concerning the low—but not zero—risk of spinal cord ischemia.

Limitations of this study are many and a function of the registry format. This report is a cataloging of procedures performed and, accordingly, cannot address the important issues of patient clinical and anatomic selection criteria. We know little or nothing of the indications for treatment, relative experience and expertise with open surgery at the 62 contributing institutions, nor even the vigor of these data. Fewer than 50% of patients had 1-year follow-up data available. According to the data that were available, a disturbing 15% of DTA patients experienced aneurysm expansion (although not defined) despite low rates of endoleak and a zero graft-migration rate! Although aneurysm-related death was rare, these data are in need of clarification as more follow-up data become available.

As for the different pathologies treated, in the TA the spectrum is wide, from focal lesions (eg, traumatic tear, anastomotic false aneurysm, penetrating ulcer) for which TA stent-graft repair seems ideal, to complex clinical/anatomic circumstances (eg, Type III B dissections) wherein definitive data can be generated only by well-designed clinical trials. The authors record treatment of 50 cases of traumatic aortic tear with excellent overall results. Given the incidence of this injury, this is a large number of cases, and readers of JVS will soon be availed of other reports detailing similar results with stent-graft repair of traumatic aortic tear. Despite the general need of US endovascular surgeons to apply abdominal aortic "cuffs" in an off-label application to repair traumatic tears, it seems evident that the TA stent graft will soon be the treatment of choice for this lesion. Such can hardly be considered the case in the complexities of type B aortic dissection. Although the authors treated some 130 cases, the indications for treatment and the clinical circumstances thereof are vague and debatable, and the desired detail in this regard is likely not retrievable from the registry format. In type B dissection, stent-graft repair at the aortic entry