Neurologic complications associated with endovascular repair of thoracic aortic pathology: Incidence and risk factors. A study from the European Collaborators on Stent/Graft Techniques for Aortic Aneurysm Repair (EUROSTAR) Registry

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Objective: **Endovascular treatment of thoracic aortic disease may be associated with severe neurologic complications. The current study used the data of a multicenter registry to assess of the incidence and the risk factors for paraplegia or paraparesis and intracranial stroke.**

Methods: **The European Collaborators on Stent/Graft Techniques for Aortic Aneurysm Repair (EUROSTAR) database prospectively enrolled 606 patients. Thoracic pathologies with urgent or elective presentation, which included degenerative aneurysm in 291, aortic dissection in 215, traumatic rupture in 67, anastomotic false aneurysm in 24, and infectious or nonspecified disorders in 9. Study end points included evidence of perioperative spinal cord ischemia (SCI) or stroke. Univariate analysis and multivariate regression models were used to assess the significance of clinical factors that potentially influenced the occurrence of neurological sequelae.**

Results: **Paraplegia or paraparesis developed in 15 patients (2.5%) and stroke in 19 (3.1%); two patients had both complications. At multivariate regression analysis, independent correlation with SCI was observed for four factors: (1) left subclavian artery covering without revascularization (odds ratio [OR], 3.9; $P = .027$), (2) renal failure (OR, 3.6; $P = .02$), (3) concomitant open abdominal aorta surgery (OR, 5.5; $P = .037$) and (4) three or more stent grafts used (OR, 3.5; $P = .043$). In patients with perioperative stroke, two correlating factors were identified: (1) duration of the intervention (OR, 6.4; $P = .0045$) and (2) female sex (OR, 3.3; $P = .023$). A neurologic complication (paraplegia or stroke) developed in 8.4% of the patients in whom left subclavian covering was required compared with 0% of patients with prophylactic revascularization ($P = .049$).**

Conclusion: **Perioperative paraplegia or paraparesis was significantly associated with blockage of the left subclavian artery without revascularization. The clinical significance of this source of collateral perfusion of the spinal cord had not been confirmed previously. Intracranial stroke was associated with lengthy manipulation of wires, catheters, and introducer sheaths within the aortic arch, reflected by a longer duration of the procedure. (J Vasc Surg 2007;46:1103-11.)**

Conventional thoracic aortic surgery is primarily used in patients in relatively good medical condition, and even in centers of excellence, the first-month mortality for the descending thoracic aorta is considerable, ranging from 6% to 13%.[1-4] In contrast, endovascular treatment of thoracic aortic aneurysms, dissections, traumatic lesions, and other disorders has been demonstrated to provide a relatively low-risk treatment for these conditions.[5,6] Although endovascular repair of thoracic aortic disease now has become a widespread treatment option, the risk of complications has not been eliminated. Neurologic adverse events do occur after endografting of the thoracic aorta, with a mean incidence of 2.2% for perioperative paraplegia and of 2.7% for intercranial stroke.[5,7-10]

The current study includes an analysis of a large database of endovascular repair of various thoracic aortic pathologies, the European Collaborators on Stent/Graft Techniques for Aortic Aneurysm Repair (EUROSTAR) Registry. The perioperative incidence of the two main neurologic complications of perioperative paraplegia and intercranial stroke and the relative influence of different risk factors at baseline and during the procedures were

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assessed. Strategies to modify these factors were discussed. Finally, the survival of patients after neurologic events was assessed.

METHODS

The data on which the present report is based come from the EUROSTAR Thoracic Registry. This voluntary observational study was established in 2000. It is linked in terms of administration and protocol with the EUROSTAR Registry of Endovascular Repair of Abdominal Aortic Aneurysms. Aggregated data from the EUROSTAR and UK Thoracic Registry, which are compatible registries, were published in 2004.[11]

This analysis was based on 606 patients with aneurysm or dissection in the thoracic aorta who underwent endovascular repair between July 2000 and July 2006. Only patients who had been prospectively entered in the registry were considered. Ten patients with thoracic aortic abnormalities classified as penetrating ulcers without coexisting dissection or aneurysm were excluded from the assessment because this number was considered too small for meaningful conclusions.

Patients were recruited from 58 European institutions (Appendix 1, online only). Patients received the following commercially available devices approved for use in countries of the European Community (CE approved): Talent (Medtronic/AVE, Minneapolis, Minn) in 386, TAG-Excluder (W. L. Gore & Assoc, Flagstaff, Ariz) in 119, Zenith TX2 (William Cook Europe, Bjaeverskov, Denmark) in 39, Valiant (Medtronic/AVE, Minneapolis, Minn) in 28, Endofit (Endomed, Phoenix, Ariz) in 12, AneuRx (Medtronic/AVE, Minneapolis, Minn) in 4, Relay (Bolton Medical, Sunrise, Fla) in 2, and 16 other or unknown devices.

Emergency procedures were defined arbitrarily as those that require treatment ≤7 days of first presentation, except for dissections, in which the conventional period of 2 weeks for discrimination between acute or chronic condition was followed.

Collected baseline data included comorbidities, fitness for open surgery as classified according to the American Society of Anesthesiology (ASA), aneurysm anatomy, and operative details. Aneurysmatic lesions were categorized according to their primary anatomic location and extend in lesions within (1) the ascending thoracic aorta or arch, (2) proximal, (3) middle, (4) distal one-third of the descending thoracic aorta, and (5) lesions in three or more of these segments. Dissections were categorized similarly according to the site of the primary intimal tear.

Conduct of the thoracic endograft procedures, adjunct operations, and perioperative monitoring was at the discretion of the managing physicians. Covering of different levels of intercostal arteries was judged on intraoperative fluoroscopy combined with assessment of the preoperative computed tomography (CT) study.

Data were collected on case record forms before October 2004 and thereafter entered by the participants onto the database by using the EUROSTAR Web site. 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.[12] Groups that were compared consisted of patients with postoperative symptoms of spinal cord ischemia (SCI), those with stroke or neurologic event, and patients without neurologic event. Definitions and incidence rates of technical success, follow-up methods, and data on the entire study cohort and subgroups are presented in Appendix 2 (online only).[13-24]

Data were presented as means and ranges or standard deviations. Odds risk ratios (OR) and 95% confidence intervals (95% CI) were calculated to correlate patient characteristics and operative technical factors with the main outcome events in this study. Multivariate logistic regression was performed to assess the independent correlations of potential risk factors and outcomes were presented as *P* values, OR, and 95% CI.

Variables entered in the multivariate model were selected because of significant differences between subgroups at univariate comparison or because of clinical considerations. Death occurring ≤30 days of the initial procedure or during the hospital admission period was categorized as operative death and death occurring >30 days as late death (results presented in Appendix 2, online only).

Statistical significance of differences in proportions was determined with χ^2 tests or Fisher tests and differences in continuous parameters with the Mann-Whitney test. The Kaplan-Meier method was used to determine cumulative survival. $P < .05$ was considered statistically significant. The data were analyzed with SAS 8.02 software (SAS Institute Inc, Cary, NC).

RESULTS

The study cohort consisted of 606 patients, of whom 471 (77.7%) were men. Mean patient age was 63.2 years (range, 13 to 91 years, Table I). Degenerative aneurysm was present in 291 patients, aortic dissection in 215, anastomotic false aneurysm in 24, and traumatic aortic injury in 67. Two patients with mycotic aneurysm were treated by thoracic stent grafts, and in seven, the diagnosis was not clearly recorded. Penetrating ulcer was diagnosed in 30 patients (5%), usually in association with aortic dissection, but was a degenerative aneurysmatic aorta in 14. The maximum diameter in patients with aneurysmatic lesions (excluding patients with dissection without aneurysmatic dilatation) was 62.7 ± 15.3 mm (range, 29 to 120 mm). Disorders were chronic in 379 patients and acute in 205; whether the disease was chronic or acute was not clear in 22 patients.

Stent grafts were a mean length of 12.4 ± 3.7 cm, and 1.8 ± 0.97 stent grafts were used per patient. Data on length of overlap zones between devices and overall covered aortic length were not available. In 78 patients (13%), there was involvement of the aortic arch or ascending thoracic aorta. The proximal one-third segment of the descending thoracic aorta was involved in 393 patients (65%), the middle one-third in 240 (40%), the distal one-

Table I. Patient characteristics and comorbidity

	With paraplegia (n = 15)	*With stroke (n = 19)*	*Other patients (n = 574)*	P*	*OR (95% CI)*
Patient factors†					
Age, mean (range)	66.0 (37-83)	71.7 (59-82)‡	62.9 (13-91)	.008‡	5.89 (1.35-25.75)‡
Male	14 (93.3)	11 (57.9)§	448 (78.1)	.0388	0.39 (0.15-0.98)
ASA IV	6 (40.0)§	5 (26.3)	96 (16.7)	.0187	3.32 (1.15-9.54)
ASA ≥III	10 (66.7)	9 (47.4)	268 (46.7)		
Previous MI/AP/HF	5 (33.3)	5 (26.3)	143 (24.9)		
Previous PTCA/CABG	1 (6.7)	0 (0.0)	55 (9.6)		
Diabetes ≥1#	2 (13.3)	1 (5.3)	57 (9.9)		
Hypertension ≥1#	12 (80.0)	8 (42.1)§	399 (69.5)	.0113	0.32 (0.13-0.81)
Renal function impairment (SVS/ISCVS score ≥1)#	7 (46.7)§	4 (21.1)	101 (17.6)	.0041	4.10 (1.45-11.56)
Cardiac disease ≥1#	6 (40.0)	7 (36.8)	201 (35.0)		
Previous thoracic aortic procedures	0 (0.0)	0 (0.0)	64 (11.2)		
Unfit for open thoracic repair	6 (40.0)	3 (15.8)	185 (32.2)		

OR, Odds ratio; *CI,* confidence interval; *ASA,* American Society of Anesthesiologists; *MI,* myocardial infarction; *AP,* angina pectoris; *HF,* heart failure; *PTCA,* percutaneous transluminal coronary angioplasty; *CABG,* coronary artery bypass graft; *SVS/ISCVS,* Society for Vascular Surgery/American Association for Vascular Surgery.

* *P* values for three groups. In text, *P* values are for a study group vs control group.

†Data are presented as number (%) unless indicated otherwise.

‡Age dichotomized at ≥65 years was significantly higher in stroke patients.

§Statistically significant from control group (other patients).

#Indicates Society for Vascular Surgery/International Society for Cardiovascular Surgery class ≥1.

third in 145 (24%), and the entire length of the descending thoracic aorta in 69 (11%).

During the first month after the thoracic stent graft procedure, neurologic complications were observed in 32 patients. Of these, 15 patients had evidence of paraplegia or paraparesis and constituted the group with postoperative SCI. Two patients, one with temporary sensory loss in the lower extremities and one with minimal symptoms described as "possibly caused by spinal cord infarction," were not included in the SCI group because of the diagnosis was uncertain. Symptoms of cerebrovascular accidents were present after the stent graft procedure in 19 patients, and they constituted the group with postoperative stroke. A combination of SCI and stroke symptoms was observed in two patients, and they were included in both study groups. Excluded from the group with stroke were six patients with temporary cerebral symptoms, including three with obvious transient ischemic attacks and three with atypical symptoms. During the first month, 574 patients had no symptoms of paraplegia/paraparesis or stroke. General outcome events in groups with and without neurologic events, including technical success rates of procedures, morbidity, early and late mortality (Appendix 2 Fig, online only), and a comparison with previous publications[13-24] is presented in Appendix 2 (online only).

Patient factors, procedural details, and correlation with neurologic complications. Patients with postoperative stroke were significantly older, more frequently women, and less frequently known with preoperative hypertension. Paraplegic or paraparetic patients had more frequently a high ASA classification (class IV) and renal function impairment (Table I). In patients with SCI, degenerative aneurysm as the primary thoracic aortic pathology was more frequently observed than in other patients. No other significant differences were observed in the distribution of aortic disorders or the prevalence of acute or chronic presentation in the two groups with neurologic events compared with the other patients (Table II). Localization of the aortic pathology demonstrated a higher incidence of aortic arch or ascending thoracic aorta involvement in patients with stroke compared with patients without neurologic events: six patients (32%) vs 83 (14%), respectively (OR, 2.61; 95% CI, 1.02 to 6.70; $P = .040$).

No difference was observed between groups with and without neurologic events in type of anesthesia (regional or local anesthesia was used in 7.1% of patients in the entire cohort), induced hypotension or use of adenosine for cardiac cessation (43%), or use of iliac artery, abdominal aorta, or surgical implanted prostheses for access to the thoracic aorta (13%). The duration of the procedure was significantly longer in patients with stroke at 195.6 ± 152.6 vs 124.4 ± 78.6 minutes for patients with ≥160 minutes vs a shorter procedural time (OR, 3.67; 95% CI, 1.46 to 9.25; $P = .003$). From one to seven stent grafts were used, and significantly more stent grafts were used in patients with paraplegia or paraparesis, with three or more device components in 53% vs 19% in controls (OR, 4.94; 95% CI, 1.76 to 13.92; $P = .0009$).

The frequency of covering of intercostal arteries at the T9, T10, T11, and T12 levels was similar in patients with stroke and without neurologic events. However, intercostal arteries at the T10 level were more frequently occluded in patients with SCI compared with those without neurologic events (6 patients [40%] vs 102 [18%], respectively; $P = .034$, OR, 2.98; 95% CI, 1.04 to 8.55).

Table II. Classification of thoracic aortic pathologies

Pathology	*With paraplegia (n = 15), No. (%)**	*With stroke (n = 19), No. (%)**	*Other patients (n = 574), No. (%)*
Degenerative aneurysm	11 (73.3)†	11 (57.9)	270 (47.0)
Chronic	8 (72.7)	7 (63.6)	209 (77.4)
Acute	3 (27.3)	3 (27.3)	48 (17.8)
Unknown	0 (0)	1 (9.1)	13 (4.8)
Dissection	3 (20.0)	7 (36.8)	206 (35.9)
Chronic	0 (0)	3 (42.9)	110 (53.4)
Acute	3 (100)	4 (57.1)	96 (46.6)
Traumatic rupture	1 (6.7)	1 (5.3)	65 (11.3)
Chronic	0 (0)	1 (100)	26 (40.0)
Acute	1 (100)	0 (0)	38 (58.5)
Unknown	0 (0)	0 (0)	1 (1.5)
False anastomotic aneurysm	0 (0)	0 (0)	24 (4.2)
Chronic	0 (0)	0 (0)	15 (62.5)
Acute	0 (0)	0 (0)	9 (37.5)
Infectious complications	0 (0)	0 (0)	2 (0.4)
Chronic	0 (0)	0 (0)	2 (100)
Acute	0 (0)	0 (0)	0 (0)
Unknown etiology	0 (0)	0 (0)	7 (1.2)
All etiologies‡			
Chronic	8 (53.3)	11 (57.9)	361 (62.9)
Acute	7 (46.7)	7 (36.8)	192 (33.5)
Unknown	0 (0)	1 (5.3)	21 (3.7)

*Percentage calculated in regard to the number of patients in each specific pathology group for each study group.
†Statistically significant from control group (other patients): Odds ratio, 3.10; 95% confidence interval, 1.00 to 9.84; $P = .0441$.
‡Total number of patients with chronic, acute or unknown etiology was 379, 205 and 22 respectively in the entire cohort (accounting for the two patients who had SCI and stroke combined).

Table III. Left subclavian artery covering and correlation with neurologic event

	Paraplegia (n = 15), No. (%)	*Other (n = 591), No. (%)*	P
With LSA artery covering	6 (40.0)	153 (25.9)	**.2199**
Without transposition/bypass	6 (40.0)*	113 (19.1)	**.0444**
With transposition/bypass	0	40 (6.8)	**.2971**
	Stroke (n=19), N (%)	*Other (n = 587) N (%)*	
With LSA artery covering	5 (26.3)	154 (26.2)	**.9937**
Without transposition/bypass	5 (26.3)*	114 (19.4)	**.4565**
With transposition/bypass	0 (0)	40 (6.8)	**.2954**

LSA, Left subclavian artery; *NS,* not significant.
*One patient with left subclavian artery covering without revascularization had combined paraplegia and stroke.

The correlation of additional procedures and the occurrence of postoperative neurologic deficits were assessed in detail. The left subclavian artery (LSA) was covered by the device in 159 patients (26%), of whom 40 were additionally treated with a LSA revascularization by transposition or bypass, and 119 of these patients did not undergo LSA revascularization (Table III). The incidence of LSA occlusion without revascularization was significantly higher in the study group with paraplegia/paraparesis than in other patients at 40% vs 19% (OR, 2.82; 95% CI, 1.00 to 8.08). The frequency of LSA covering was comparable in stroke patients and others. However, the rate of combined neurologic complications (paraplegia or stroke) in the group with LSA covering without revascularization was 8.4% (10 of 119), which compared unfavorably with the 0% rate in 40 patients with revascularized LSA covering ($P = .049$). Simultaneous open repair of the abdominal aorta was significantly more frequently performed in the SCI group (n = 3, 20%) compared with other patients (n = 18, 3.1%; OR, 7.96; 95% CI, 2.06 to 30.68; $P = .0003$).

Multivariate analysis of risk factors for spinal cord ischemia and stroke. Multivariate regression analysis demonstrated an independent correlation of SCI and the variables of the number of stent grafts used, covering of the LSA without revascularization, renal function impairment, and simultaneous abdominal aortic repair (Table IV). Of the four variables with significant correlation in this model,

Table IV. Multivariate regression analysis for paraplegia

Risk factor	P *value, paraplegia (n = 15)*	*OR (95% CI)*
Degenerative aneurysm	.1406	2.75 (.72-10.6)
Localization disease at proximal, middle, and descending thoracic aorta	.4866	.54 (.10-3.03)
Number of stent grafts ≥3	**.0428**	3.49 (1.04-11.7)
Left subclavian artery covering without transposition/bypass	**.0274**	3.94 (1.17-13.3)
Occlusion by device T10	.2474	2.07 (.60-7.11)
Renal failure (score ≥1)*	**.0215**	3.63 (1.21-10.9)
Concomitant open abdominal surgery	**.0371**	5.52 (1.11-27.5)

OR, Odds ratio; *CI,* confidence interval; *NS,* not significant.
*Society for Vascular Surgery/American Association for Vascular Surgery risk classification.

Table V. Multivariate regression analysis for stroke

Risk factor	P *value, stroke (n = 19)*	*OR (95% CI)*
Degenerative aneurysm	.4626	.65 (.20-2.04)
Proximal into arch or ascending aorta	.7760	1.20 (.34-4.26)
Duration of procedure ≥2 h 40 min	**.0134**	5.25 (1.41-19.6)
Left subclavian artery covering without transposition/bypass	.4782	1.58 (.44-5.65)
Female sex	**.0395**	2.95 (1.05-8.26)
Maximum diameter aneurysm	.7924	1.00 (.98-9.02)
Age	.0937	1.05 (.99-1.11)

OR, Odds ratio; *CI,* confidence interval; *NS,* not significant.

two or more were present in 11 of the patients with SCI and three or more in eight.

In patients with stroke, two factors had an independent significant correlation: the duration of the stent graft procedure and female sex (Table V). None of the other tested variables had an independent correlation with stroke.

DISCUSSION

The incidence of paraplegia after open surgical repair varies from 2% to 21%, depending on the extent of the descending thoracic aorta replacement.[25-29] In conventional surgery, much effort is directed to preserving intercostal arterial inflow by reattachment of these vessels, in particular those between the T8 and T12 level. A variety of diagnostic and therapeutic adjunctive methods have been used, including cerebrospinal fluid (CSF) drainage, to reduce the arterial-cerebrospinal fluid gradient.[27,30-33] Despite the large choice in available options to prevent SCI, neurologic deficit remains a considerable threat in open repairs.[29]

The introduction of endovascular techniques as an alternative option for the treatment of thoracic aortic disease gave rise to some optimism in that the risk of paraplegia seemed reduced somewhere in the range of 0% to 6%.[5,7,8,10,13,14,34] Avoidance of thoracic aortic clamping and prolonged episodes of hypotension most likely account for a lower incidence of spinal ischemic symptoms.

Only two studies have compared the incidence of SCI directly with a control group undergoing open surgery. The first study observed an insignificantly lower rate of perioperative paraplegia of 6.7% in the endovascular and 8.6% in the open surgical group.[18] The second study demonstrated a statistically lower SCI incidence in patients treated by endografts (3% vs 14%).[35]

A number of studies have analyzed which factors increase the risk of SCI after endograft treatment.[7,8,18,36,37] Simultaneous or previous open infrarenal aortic replacement has been recognized as a factor associated with a higher incidence of paraplegia.[5,8,9,36] Our multivariate analysis demonstrated this variable as an independent risk factor for SCI. The EUROSTAR registry only recorded data on concomitant infrarenal aortic replacement, and no conclusions could be drawn about whether previous abdominal aortic repair is associated with similar risks.

It has recently been documented that a compromised hypogastric artery inflow constituted a significant risk factor for SCI.[38] Some authors suggest that patients with combined aneurysmatic disease of the thoracic and abdominal aorta be treated with staged procedures to better allow a gradual development of collateral spinal cord blood flow from lumbar and hypogastric arteries.[8,37]

Extensive covering of the thoracic aorta by stent grafts also presents an increased risk for SCI, as was first documented by Greenberg et al[7] and confirmed by several other studies.[8,20,21] The present series demonstrated that the number of stent grafts used per patient correlated with development of paraplegia at univariate and multivariate analysis. The number of stent grafts per patient clearly corresponds with the covered aortic length; therefore, our observation seems in agreement with the previous observations on the importance of the covered aortic length.

Clinical studies of surgical thoracic and thoracoabdominal aneurysm repairs have documented a significant correlation of renal function and SCI injury.[26] The underlying metabolic mechanism is not exactly known; however, renal failure may reflect more advanced peripheral atherosclerosis, including intercostal arteries and collaterals to the spinal cord. The present analysis also indicates renal failure (Society for Vascular Surgery/International Society for Cardiovascular Surgery class ≥1) as an independent risk factor for SCI. Other previously observed risk factors for paraplegia after open thoracic aorta surgery included symptomatic disease or rupture of the aorta and perioperative hypotensive episodes. Perioperative blood pressure data were not available in the present series; however, Chiesa et al[37] reported in 2004 that a lowest mean arterial blood pressure of ≤70 mm Hg presented a significant predictor of SCI.[37]

Although many of the risk factors discussed here are difficult to modify, some precautions can be taken. Caution is warranted with the continuation of antihypertensive

medication, which is used by many patients with thoracic aortic disease. Postoperatively, these medications may lead to episodes of hypotension that sometimes is difficult to treat. In practice, many physicians involved in the management of thoracic aortic disease now frequently (particularly in patients presenting with risk factors for SCI) reduce or withhold any antihypertensive medication before endovascular treatment, with the exception of β-blockers.

The role of CSF drainage is less well documented in endovascular than in open repair of thoracic aorta disease. Many experts, however, advise the selective use of prophylactic CSF drainage in cases requiring coverage of long segments of thoracic aorta, in particular when the territory distally of T10 is involved.[8,18,37] These patients may be more vulnerable to postoperative hypotension and so-called delayed paraplegia. Our data set had no information on whether paraplegia presented immediately or delayed after the procedure and whether CSF drainage was used.

The role of unimpeded flow into the left subclavian and its first branch, the vertebral artery as supplier of the anterior spinal artery, appeared of considerable importance, because occlusion of the LSA was associated with an almost fourfold increased incidence of paraplegia. Another less well recognized collateral source of spinal cord blood supply is the internal mammary artery and its anterior intercostal branches. This pathway becomes also compromised by LSA overlapping. When thoracic aortic disease is localized near the LSA, the surgeon has to decide whether the origin of this vessel can be covered by the stent graft fabric or will need a revascularization by subclavian-carotid transposition or bypass.[39-43]

Most authors seem to agree that the LSA can be overstented in most cases, and suggest that preoperative computed tomography (CT), magnetic resonance imaging (MRI), or angiography may be helpful in selecting candidates for adjunct LSA revascularization.[40,41,43] These assessments should provide information about whether the left vertebral artery is a dominant source of collateral flow to the anterior spinal and basilar arteries and identify any acquired disease or congenital anomalies of the supra-aortic, vertebral, and internal mammary vessels that preclude safe occlusion of the LSA.

Few data, however, are available on the association of occlusion of the LSA and the rate of paraplegia. In a 2006 publication, Peterson et al[44] reported a review of the literature on the outcome of subclavian artery covering during thoracic stent grafting in 218 patients, of whom 114 were treated by a subclavian artery transposition. The mean incidence of paraplegia in patients with covered LSA in this review was 1%, which was lower than the 5% in our study. It must be noted that in patients with LSA overlap, this vessel was revascularized in 52% in the compilation of series from the literature by Peterson et al compared with only 25% in the current EUROSTAR series. This may reflect that many surgeons considered the covering of the LSA origin as an innocuous detail.

Most of the patients with SCI had several risk factors for a compromised spinal cord perfusion, and loss of collateral flow from the subclavian vertebral system contributed to the event. The best treatment in the patient with a short proximal landing zone to the LSA should be selected on the basis of high-quality imaging of the supra-aortic vessels to ascertain a functional collateral connection between the right-sided vertebral and mammary arteries and the spinal cord circulation. In our experience, many preoperative CT or MRI studies do not provide this kind of detailed information.

It should be recognized that LSA transposition is a low-risk procedure. Simply ignoring the LSA take off and occluding it by the stent graft seems no longer appropriate in most patients considering the data reported here. Options to maintain the perfusion of supra-aortic branches with fenestrated devices or retrograde stent deployment through the device are presently being developed.[45,46]

The incidence of stroke, similar to SCI, varies widely. In a review of the literature reported in 2006, an intracranial stroke developed in average of 2.2% of patients undergoing thoracic aortic endograft treatment,[10] which is in agreement with the 3% observed in the present study. The location of the cerebral infarctions after thoracic endografting suggests multiple emboli to the anterior or posterior circulation. These emboli are most likely caused by catheter, guidewire, or endoprosthesis manipulation in a diseased arch. Other potential etiologic factors for stroke include air embolism, cervical carotid, and vertebral-basilar atherosclerotic disease.

A significant risk factor for stroke in our study was a duration of the procedure ≥2.6 hours. A longer endovascular procedure will inevitably be associated with more manipulation of catheters, guidewires, and introducer systems. The second factor correlating with an increased stroke risk was female sex. Evidence is growing that female sex has an adverse influence on treatment outcomes of aortic aneurysms.[47] The higher complication rate in women has been attributed to more advanced atherosclerosis as well as to smaller diameter peripheral arteries.

Precautions to prevent cerebral embolism include careful preinterventional planning to reduce procedural time. A poor quality arch with mural thrombus can be identified best by transesophageal echography. Five of 19 stroke patients (26%) in this EUROSTAR series had LSA occlusion without revascularization, which did not present a significant correlation. In other studies,[19] however, this variable correlated statistically with the risk of stroke; therefore, similar vascular anatomic criteria to perform a LSA transposition to prevent SCI may also apply in perioperative stroke prevention.

CONCLUSIONS

Severe neurologic complications are not rare after endovascular thoracic aortic procedures. The combined incidence of stroke and paraplegia was 5% in the current series. Risk factors for both complications were identified, and strategies for modification of these variables were discussed. The perhaps the most important precaution that emerged from this study involved the revascularization of the LSA in

patients who need incorporation of the origin of this vessel in the proximal landing zone of the stent graft. In this series, neurologic complications were only observed in patients in whom prophylactic rerouting of the blood flow had not been performed, and 8.4% of this category had a severe neurologic event (stroke or paraplegia) compared with 0% in patients with revascularization of the LSA. To properly select patients for subclavian revascularization considerable expertise with imaging of this vascular territory is required. If after careful CT, MRI, or angiography, or a combination of these, there still is doubt about the collateral supply of the spinal cord, a left subclavian–carotid transposition may be the safest option.

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DISCUSSION

Dr Richard Cambria (Boston, MA): Dr Buth, thanks for bringing to our Society yet another chapter from the EUROSTAR database.

Your report seems to echo a recent review assembled by Mark Morasch and his colleagues from Northwestern and published in the *JVS* within the last year, calling attention to the fact that perhaps a cavalier attitude towards left subclavian artery coverage is inappropriate. And in the Tag 9901 study, Dr Mike Makaroun pointed out that left subclavian artery coverage seemed to be an increased risk factor for stroke, not paraplegia, perhaps being a surrogate for manipulation of stent grafts in the arch.

I have a few questions, and thank you for giving me a copy of the manuscript, it certainly is exhaustively detailed. Did you analyze the risk of paraplegia as a function of pathology, dissection versus degenerative aneurysm, and the clinical circumstances of the procedure, urgent procedure versus elective procedure? Also, the overall rates of both paraplegia and stroke in this registry are admirably low. Just about 25 minutes ago I showed a series of stent grafts, all in urgent cases, but with a stroke rate of 10%. And indeed, in our own 250 cases, that figure is 9%; so I think the overall results in this study are in fact excellent.

I presume, and it is in your conclusion, you are prepared to recommend that cavalier left subclavian artery coverage is no longer appropriate?

Dr Jacob Buth: Starting with your last comment. Yes, I certainly recommend to revascularize in most instances the left subclavian artery unless the preoperative imaging is impeccable and indicates clearly collateral communications with the spinal cord. The imaging in our experience is often not conclusive.

With regard to the previous articles that you mentioned, Dr Morasch had an increased incidence of complications because of left subclavian artery, because there are many other complications that may occur by covering this artery. I remember he more often observed endoleakage or arm complications, not so frequently paraplegia.

Dr Makaroun found that stroke significantly correlated with LSA covering. In the current study, this comparison just did not make the level of statistical significance. However, if we combined stroke and spinal cord ischemia, this rate was statistically significantly higher in the group with a non-revascularized left subclavian artery covering.

Regarding your first comments, degenerative aneurysms had 2.5 times as frequent paraplegia than other thoracic disease, i.e. 3.7% compared to a 1.5% rate of paraplegia. This difference was not statistically significant.

Dr Roy Greenberg (Cleveland, Ohio): Dr Buth, I also want to thank you for a copy of the manuscript ahead of time, and I enjoyed the presentation. I had a couple of questions regarding your analysis, and I was a little bit surprised (or confused) as to how the proximity of the aneurysm to the subclavian was not significant, while the need for subclavian artery coverage was significant. Is there another reason to cover the subclavian besides aneurysmal involvement? I had believed the two entities to be inexorably linked.

The other question falls back on Dr Cambria's question, which would be to clarify the message we should take from the paper. The EUROSTAR database involves a broad range of institutions, and nonconsecutive patient enrollment with a variety of diseases and other issues that come into play. Should we now universally recommend preoperative carotid subclavian bypass? Are there specific factors that you can tell us where we should be doing that and specific times when we don't need to?

Dr Buth: Regarding the fact that we did not find a correlation between SCI and the localization of the disease and the LSA, this distance it was not measured as such. It was represented rather as a thoracic aorta segment. Thus, we had no accurate information of the localization of the lesion in relation to the left subclavian artery. This clearly is the reason that that was not a significant factor, while the covering itself was a significant factor for the development of neurologic complications.

With regard to the management recommendation based on our observations, I would think that we still have to learn more about vertebral artery imaging. In particular, how are the collaterals to the anterior spinal artery, which is the dominant side of supply, and how is the anatomy of the basilar artery of the circle of Willis. Sometimes one encounters an unexpected case of paraplegia. For example in a recent report, a patient with a traumatic tear of the thoracic aorta was described. This patient had a covering of the left subclavian artery and paraplegia developed quite unexpectedly. I know of other similar cases. I think that imaging of the collateral communication between the vertebral artery and the spinal cord often is imperfect.

Dr Girma Tefera (Madison, Wis): Enjoyed your presentation. I have two questions: One, when the strokes occurred, which hemispheres did it involve? Two, what is your philosophy regarding spinal protection. We always use CSF drainage and pharmacological protection. Did you analyze data pertaining to adjuncts for CSF protection? Thank you.

Dr Buth: The localization and the type of intercranial stroke (ie, whether anterior and posterior strokes were observed) could not accurately be retrieved from our data; similarly for left and right strokes. From what we could find and from previous reports, we know that there is not a straightforward correlation. So strokes are not always in the left anterior territory.

With regard to spinal cord protection, I can only quote from the literature because there was very little information on used methods of protection or on the late spinal cord ischemia in the current series in the registry's case record form. Protection measures in TEVAR [thoracic endovascular aneurysm repair] usually are based on what is customary and what is known to be effective in open thoracic aorta repair. Frequently spinal fluid drainage is used. In reality, we don't know exactly whether it is really necessary.

INVITED COMMENTARY

Timothy A.M Chuter, *San Francisco, Calif*

The main strength of the accompanying study is its size. Even though the study group included two very different diseases, aneurysm and dissection, the numbers were still large enough to demonstrate significant variations in the rates of relatively rare neurologic complications. It appears that repeatedly instrumenting a diseased ascending aorta or arch in an elderly patient raises the risk of stroke, and occluding the left subclavian artery, isolating a long segment of aneurysmal thoracic aorta, and simultaneously repairing an abdominal aortic aneurysm (AAA) raises the risk of paraplegia. Admittedly, these conclusions rest on slightly tenuous assumptions. For example, the duration of the procedure was a surrogate for the extent of aortic instrumentation, and the number of stent grafts was a surrogate for the length of the covered segment. Nevertheless, the findings make sense and they agree with the findings of other studies.

In general, there are two ways to respond to this kind of information: change the procedure, or change the selection criteria. The current study indicates several risk factors for stroke that affect patient selection but not the conduct of the operation. All the possible procedural modifications relate to the risk of paraplegia. Although, the overall protective effect of carotid–subclavian bypass was quite modest, collateral flow through branches of the left subclavian artery may be more critical in patients who have other reasons for spinal arterial compromise. The same may be said of cerebrospinal fluid drainage, which has been shown in studies of open repair to have a spinal protective effect. The risks of simultaneous AAA repair have been noted before, but whether staging the operation would prevent paraplegia depends on the relative importance of hemodynamic instability, lumbar artery occlusion, and collateral development between stages.

Despite many publications on this subject, the occurrence of paraplegia remains a largely random event owing to the effects of currently unidentified risk factors. Some of this uncertainty may yield to new methods of imaging the spinal blood supply. Preliminary findings suggest that the source of spinal perfusion may be a strong predictor of paraplegia risk after open repair. The current study suggests that collateral pathways may be equally important. Imaging studies and other more direct measurements may also strengthen the analysis by providing a continuous variable, such as spinal perfusion, oxygenation, or metabolism, as an alternative to the current dichotomous outcome.

Appendix 1 (online only).

European Collaborators on Stent/Graft Techniques for Aortic Aneurysm Repair (EUROSTAR) collaborative centers that contributed their data for this study.

Belgium: Aalst, Onze Lieve Vrouwe Hospital; Antwerpen, Hospital Middelheim, University Hospital, Monica Hospital/OLV/Eeuwfeestkliniek; St Augustinus Hospital; Arlon, Clinique St Joseph; Assebroek, Hospital St Lucas/St Jozef; Bonheiden, Imelda Hospital; Brugge, Hospital St Jan; Brussels, Hospital Erasme, Free University Hospital, Clinique de l'Europe St Michel, University Hospital St Luc, and Clinique Saint Jean; Charleroi, University Hospital; Dendermonde, Hospital St Blasius; Genk, St Jan Hospital; Gent, University Hospital and Hospital Maria Middelares - St Jozef; Gilly, St Joseph Hospital; Haint Saint Paul, Hospital de Jolimont; Hasselt, Virga Jesse Hospital; La Louvière, Central Hospital de Tivoli; Leuven, University Hospital; Liège, University Hospital; Mont Godinne, Hospital de Mont Godinne; Mouscron, Central Hospital; Namur, Central Hospital Regional and Hospital St Elisabeth; Roeselare, Heilig Hart Hospital; St Truiden, St Trudo Hospital; Tongeren, Hospital Vesalius; Turnhout, St Josef Hospital; and Vilvoorde, St Josef Hospital.

Germany: Frankfurt, City Hospital; Hamburg, Altona General Hospital; Leipzig, Park-Hospital; München, City Hospital; Oldenburg, Pius Hospital.

Ireland: Dublin, St James Hospital.

Italy: Roma, Hospital San Giovanni.

The Netherlands: Amsterdam, Academic Medical Centre and Onze Lieve Vrouwe Hospital; Eindhoven, Catharina Hospital; Enschede, Medisch Spectrum Twente; Groningen; University Hospital; Rotterdam, Dijkzicht Hospital.

Norway: Trondheim, University Hospital.

Spain: Barcelona, University Hospital; Madrid, Hospital Ramon y Cajal; Malaga, HR Carlos Haya; Valladolid, Hospital Valladolid.

Sweden: Örebro, Medical Centre.

Switzerland: Lugano, Cardiocentra Ticino.

United Kingdom: Bournemouth, Royal Hospital; Leicester, Royal Infirmary; Liverpool, Royal University Hospital; New Castle-Upon-Tyne, Freeman Hospital.

Appendix 2 (online only). General outcome events

Methods

Primary technical success was defined as complete exclusion of the aneurysm or coverage of the proximal entry tear in aortic dissection and absence of primary endoleak or significant endoluminal graft stenosis. Findings at follow-up visits, which involved clinical examination, computed tomography (CT), occasionally angiography, magnetic resonance imaging, or transesophageal echocardiography, were recorded. Patients were followed up at 1, 6, and 12 months, and annually thereafter. The mean follow-up of the entire patient cohort was 14.1 months and of first-month survivors, 15.5 months (range, 1 to 72 months). Satisfactory findings at CT were defined by absence of endoleak, stent graft migration, and aneurysm expansion. In case of dissection, additional criteria included complete thrombosis of the false lumen and, in extensive dissection, thrombosis of the treated proximal segment of the dissection (partial false lumen thrombosis).

Results

The device label did not make a difference for the incidence of neurologic events. Technical success of the stent graft procedure was observed in all 15 patients (100%) with spinal cord ischemia (SCI), in 16 patients (84%) with stroke, and in 515 of the patients (90%) in the control group, which rates were comparable. Device-related complications occurred more frequently in patients with postoperative stroke: four patients (21%) vs in 39 of controls (6.8%; OR, 3.66; 95% CI, 1.16 to 11.55; $P = .018$).

Systemic complications occurred more frequently in patients with SCI and with stroke: 8 patients (53%) and 12 (63%), respectively, vs 112 patients (19.8%) in controls (stroke: OR, 6.96; 95% CI, 2.68 to 18.09; $P < .0001$; SCI: OR, 4.64; 95% CI, 1.65 to 13.07; $P = .0015$).

Duration of the stay at the intensive care unit (ICU) and hospital admission time lasted at least twice as long in the SCI and stroke groups compared with controls: 189 and 132 hours vs 99 hours, and 21 and 23 days vs 10.4 days, respectively (for ICU stay dichotomized at ≥120 hours, $P = .003$ and $P < 0.001$ for SCI and stroke patients vs controls respectively; and for hospital admission dichotomized ≥14 days, $P = .0006$ and $P = .002$ for SCI and stroke patients vs controls, respectively).

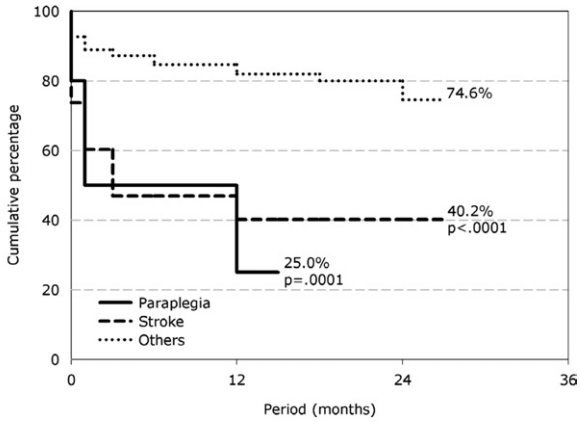
The incidence of endoleaks at completion angiography was 9.4%. and at 30 days, 6.8%. There were no differences between the subgroups.

The 30-day mortality in the entire cohort was 9.9%. There were no significant differences between the different etiologic categories: degenerative aneurysm, 10.7%; dissection, 9.3%; traumatic injury, 9.0%; false anastomotic aneurysm, 12%; and other causes, 0%. The 30-day mortality in patients receiving elective treatment was 5.3% compared with 19% in acute operations (OR, 4.35; 95% CI, 2.47 to 7.68; $P < .0001$). The 30-day mortality included six patients (40%) in the SCI group, seven (37%) in the stroke group, and 49 (8.5%) in the control group (SCI: OR, 7.14; 95% CI, 2.44 to 20.90; $P < .0001$; stroke: OR, 6.25; 95% CI, 2.35 to 16.60; $P < .0001$). Conversion to open repair occurred in 12 patients (2%) in the entire cohort. No conversions were required in the category with neurologic complications.

The 12-month rates for endoleak were 15.2%, device migration, 0.5%; need for secondary intervention, 10.9%; and aneurysmal expansion ≥7 mm, 7.7%. The cumulative survival after 1 year in patients with SCI and stroke was 25% and 40%, respectively; in comparison, respective the 1- and 2-year survival in controls was 88.9% and 87.2%, (Appendix 2 Fig, online only). The greatest mortality was in the first month, with the respective survival in the SCI and stroke groups of 50% and 60.3%.

Discussion

Most vascular specialists currently believe endovascular treatment of thoracic aortic disease to be superior to conventional surgery. In recently published series, including patients with different aortic pathologies, combining elective and emergency procedures, the perioperative mortality was 2% to 10%.[13-21] An observed 30-day mortality of 5.3% in elective patients and 9.9% in the entire current EUROSTAR series was in agreement with these previous series. Other outcome measures at follow-up included 1-year rates of secondary procedures in 11%, endoleaks in 15%, device migration in 0.5% and stable or shrinking aneurysms in 92%. These figures are also in concordance with other published experience.[15,22-24]



Overall survival (freedom from mortality), cumulative percentage and patients at risk

Period (month)	Paraplegia N=15 (%)	At risk	Stroke N=19 (%)	At risk	Other N=574 (%)	At risk	All N=606 (%)	At risk
0	80.0	15	73.7	19	92.7	574	91.9	606
1	50.0	8	60.3	11	88.9	420	87.5	438
3	50.0	5	46.7	9	87.2	362	85.4	376
6	50.0	4	46.7	9	84.6	338	83.0	349
12	25.0	2	40.2	7	82.0	287	79.9	296
18	25.0	1	40.2	7	80.0	202	78.0	208
24	25.0	1	40.2	5	74.6	178	72.9	184

Appendix 2 Fig (online only). Overall survival during follow-up in patients with paraplegia, stroke, and other patients.