Stent-graft repair for thoracic aortic disease: Results of an independent nationwide study in France from 1999 to 2001

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Background: The purpose of this study was to assess the overall short-term outcome of stent-graft repair for thoracic aortic disease in France between June 1999 and May 2001.

Methods: This retrospective study was designed by the French National Health Insurance Fund for Salaried Workers. To ensure objectivity, data were retrieved at each center and checked by a team of medical advisors.

Results: Between June 1999 and May 2001, a total of 166 stent-graft repairs for thoracic aortic disease were performed in 166 patients, mainly by surgeons in the operating room (88%). Patients were classified according to the American Society of Anesthesiologists as status I or II in 24% of cases, status III in 56%, and status IV or V in 20%. The diameter of the thoracic aneurysm was less than 50 mm in 17% of cases. Seventeen patients (10%) died during the first 3 months, including 8 within the first 30 days after the procedure. A total of 49 complications were noted in 34 patients (20.5%). Endoleaks occurred in 27 patients (16.3%), including 8 that necessitated further treatment. Other stent-related complications included rupture (n = 3), aortoesophageal or tracheal fistula (n = 3), paraplegia (n = 6), stent migration (n = 2), visceral embolism (n = 5), and cerebral embolism (n = 2). There were 14 delivery-related complications (8%) at the catheterization site. Non-stent-related complications occurred in 14 (8%).

Conclusions: This nationwide study demonstrates that stent-graft repair for thoracic aortic disease can be performed with acceptable postoperative morbidity. However, it is not a risk-free procedure and should continue to be used in an investigative setting.

Endovascular repair is a potentially beneficial alternative to conventional open surgery for the entire spectrum of thoracic aortic disease (TAD). Even when performed at specialized centers, conventional open repair is associated with significant morbidity, including paraplegia, and 30-day mortality rates from 5% to 20% in degenerative aneurysm and 6% to 67% in type B aortic dissection.¹⁻⁸

Use of endovascular techniques has progressed more slowly for TAD than for infrarenal aortic aneurysm. However, the use of endovascular stent-graft procedures for TAD has increased since the first procedures were reported first by Volodos and colleagues⁹ in 1991 and then by Dake and colleagues¹⁰ in 1994.

Abbreviations and Acronyms

ASA = American Society of Anesthesiologists

CI = 95% confidence interval

TAD = thoracic aortic disease

In June 2000, the French Agency for Sanitary Safety of Healthcare Products, in compliance with European Directive 93/42 EEC of June 1993, conducted a thorough study to evaluate the safety of aortic stent grafts.¹¹ In 2002, the French National Health Insurance Fund for Salaried Workers undertook an exhaustive nationwide survey to evaluate postoperative complications after placement of stent grafts for abdominal aortic aneurysm and TAD. The results of the survey concerning abdominal aortic aneurysm were published in 2003.¹² The purpose of this article is to describe the findings concerning the overall short-term outcome of stent-graft repair for TAD in France between June 1999 and May 2001.

Patients and Methods

Study Design

This study was designed to allow analysis independent of administrative or commercial interests. It was conducted by a team of medical advisors from the French National Health Insurance Fund for Salaried Workers. Medical advisors are physicians responsible for overseeing reimbursements. No medical advisor investigated an institution where he or she had formerly practiced.

Data Collection

Data were collected from the medical charts of all patients who underwent stent-graft repair for TAD in France from June 1, 1999, to May 31, 2001. Patients were identified by using the list of all centers performing vascular surgery, interventional radiology, or cardiology in France. In addition, the computerized PMSI (Le Programme de Médicalisation du Système d'Information) coding system (diagnosis-related groups) was searched to identify institutions caring for patients with TAD. The key words for the search included aortic aneurysm as the principal diagnosis in association with 10 International Classification of Diseases codes (171.0 to 171.9) and the so-called surgical homogenous patient groups in the diagnosis category 05 (homogenous patient groups 158, 159, 160, 168, and 172). To further ensure that no procedure was over-

TABLE 1. Etiology of thoracic aortic disease treated with stent grafts in France from June 1, 1999, to May 31, 2001

Etiology	No. of patients	%
Degenerative aortic aneurysm	90	53
Type B chronic dissecting aneurysm	33	20
Traumatic pseudoaneurysm	17	11
Aortic ulcer with intramural hematoma	23	14
Septic aortic aneurysm	3	2

TABLE 2. Maximum diameter of 126 thoracic aortic aneurysms* treated with stent grafts in France from June 1, 1999, to May 31, 2001

Aneurysm diameter	No. of patients	%
<50 mm	21	17
50-59 mm	27	21
≥60 mm	78	62
Total	126	100

*Forty patients (24%) with trauma or aortic ulcer were excluded.

looked, medical advisors met with representatives of medical device vigilance departments to obtain a list of all reported devices and accidents and consulted compulsory registers for procedures performed in operating rooms and radiology suites.

Scope of Data

All data concerning procedures involving insertion or ablation of a stent graft for TAD were recorded, including clinical setting, patient characteristics, TAD features, clinical findings, and postoperative outcome. For adverse outcomes, a distinction was made between stent- or procedure-related events and non-stent-related complications.

Statistical Analysis

Statistical analysis was performed with GraphPad software (GraphPad, San Diego, Calif). Variables were cross-checked, and queries concerning missing or aberrant data were sent to regional project directors. Percentages were calculated with 95% confidence interval (CI). Life-table analysis was performed by using the Kaplan-Meier method with 95% confidence interval.

Results

During the 2-year study period, 166 endovascular stent-graft repairs for TAD were performed in 29 centers. The number of stent grafts inserted per center was 1 at 8 centers, 2 to 5 at 17 centers, and 6 to 15 at 4 centers.

TABLE 3. Type of aortic stent grafts used in patients undergoing endovascular repair for thoracic aortic disease in France from June 1, 1999, to May 31, 2001

Stent-graft model	No. of patients	%
Excluder tag (Gore*)	88	53
Talent (Medtronic†)	52	31
Stenford (Stenford‡)	6	4
AneuRx (Medtronic)	3	1.5
Vanguard II (Boston Scientific§)	1	0.5
Custom-made by surgeon	16	10
Total	166	100

*W. L. Gore & Associates, Inc (Flagstaff, Ariz). †Medtronic, Inc (Minneapolis, Minn). ‡SARL (Paris, France). §Boston Scientific (Natick, Mass).

TABLE 4. Concomitant procedures (n = 39) in patients undergoing stent-graft repair for thoracic aortic disease in France from June 1, 1999, to May 31, 2001

Procedure	No. of Patients	%
Transposition of the left subclavian artery*	15	9
Repair of infrarenal abdominal aortic aneurysm	8	5
Aortic or iliofemoral bypass	9	5.5
Iliac angioplasty (stenting)	3	1.7
Miscellaneous (trauma patients)	4	2.3
Total	39	23.5

*In addition, 4 patients had the left subclavian artery covered but not transposed.

TABLE 5. Postoperative mortality as a function of etiology in patients undergoing stent-graft repair for thoracic aortic disease in France from June 1, 1999, to May 31, 2001

Etiology	No. of patients	No. of deaths	%
Degenerative aortic aneurysm	90	6	6.6
Type B chronic dissecting aneurysm	33	5	15.2
Traumatic pseudoaneurysm	17	1	5.8
Aortic ulcer with intramural hematoma	23	3	13.1
Septic aortic aneurysm	3	2	66.6
Total	166	17	100

Mortality corresponds to deaths occurring during the postoperative period.

Patient Characteristics

Most patients, ie, 86% (n = 142), were men. The mean age was 69 ± 15 years (range, 20-91 years). American Society of Anesthesiologists (ASA) scores were determined on the basis of associated risk factors in 129 patients (78%). There were 31 patients (24%) with ASA status I or II, 72 (56%) with ASA status III, and 26 (20%) with ASA status IV. The overall median duration of hospitalization was 10 days

(range, 5-64 days). As shown in Table 1, the most common type of TAD was asymptomatic degenerative aneurysm, in 53% of cases (n = 90). Patients with chronic dissecting aneurysm (n = 33) presented no complications before stent-graft insertion, but 4 had thoracic pain without hemothorax.

Preoperative Workup

All 166 patients underwent preoperative imaging with spiral computed tomographic scan. In addition, digitized angiography with placement of a graduated catheter in the thoracic aorta was performed in 127 cases (77%). All lesions were located in the descending thoracic aorta. As shown in Table 2, the maximum aneurysm diameter, excluding patients with trauma (n = 17) and aortic ulceration (n = 23), was less than 50 mm in 21 patients (17%).

Stent Grafts and Implantation Procedures

As shown in Table 3, 6 different stent-graft models were used. All commercially available devices used in this study had received the CE mark. Implantation was performed in an operating room equipped with a C-arm in 147 cases (88%) and in a radiology suite in 19 cases (12%). The procedure involved first-time stenting in 160 cases (96%) and repeat stenting in 6 cases (3.6%). As shown in Table 4, stent-graft repair was associated with other procedures in 39 patients (23.5%). Concomitant transposition of the left subclavian artery was required in 15 patients (9%) who had aneurysms with short necks arising near the origin of the subclavian artery. Concomitant aortic or iliac bypass was needed to allow implantation of the stent graft in 9 patients (5.5%). Concomitant infrarenal abdominal aortic aneurysm repair was performed in 8 patients (5%).

Immediate Complications

Thirty-day follow-up data were available for 163 patients (98%; CI, 95%-99%), including angiography, computed tomography with helical 3-dimensional reconstructions, and plain chest radiography. In the first 30 days, there were 8

TABLE 6. Mortality and morbidity, excluding endoleaks, as a function of the ASA score in patients undergoing stent-graft repair for thoracic aortic disease

Status	No of patients	Deaths, n (%)	Procedure- or stent-related complications, n (%)	Non-stent-related complications, n (%)
ASA I and II	31	0 (0)	5 (6.1)	1 (3.2)
ASA III	72	11 (15.3)	17 (23.6)	6 (8.3)
ASA IV and V	26	4 (15.4)	6 (23.1)	5 (19.2)
ASA unknown	37	2 (5.4)	7 (18.9)	2 (5.4)
Total	166	17 (10.2)	35 (21.1)	14 (8.4)

ASA, American Society of Anesthesiologists. In this series, 17 patients died, and 34 patients had 49 complications (see Table 9 for details). Mortality was significantly lower in patients with ASA status I and II as compared with ASA status III to V ($P = .02$). Procedure-related or stent graft-related complications and non-stent-related complications were not significantly different in patients with ASA status I or II compared with ASA status III to V.

TABLE 7. Mortality and procedure- or stent-related morbidity, including type I and III endoleaks, as a function of the extent of aorta covered by the stent graft in patients undergoing endovascular repair for thoracic aortic disease

Extent of aorta covered*	No. of patients	Deaths, n (%)	Procedure- or stent-related complications, n (%)	Type I endoleaks, n (%)
A	23	3 (13.1)	6 (26.1)	4 (17.4)
B	61	4 (6.5)	9 (14.7)	1 (1.6)
C	35	2 (5.7)	6 (17.1)	0 (0)
B + C	40	6 (15.0)	13 (32.5)	3 (7.5)
D	7	2 (28.5)	1 (14.2)	1 (14.3)
Total	166	17 (10.2)	35 (21.1)	9 (5.4)

*A, distal arch and proximal descending aorta; B, middle third of the descending thoracic aorta; C, distal third of the descending thoracic aorta; D, any category above with concomitant open repair of abdominal aortic aneurysm.

deaths. Nine additional deaths related to immediate postoperative complications occurred during hospitalization beyond the first 30 days. In all, 17 patients (10%; CI, 6%-16%) died in the hospital. Tables 5 and 6 show analysis of mortality as a function of etiology and ASA score, respectively. Table 7 shows analysis of mortality and procedure- or stent-related morbidity, including type I endoleaks, as a function of the extent of aorta covered by the stent graft. Table 8 shows mortality and morbidity as a function of the diameter of the thoracic aneurysm. The percentage of complications with each of the stent-graft models was comparable ($P = .04$). Survival based on life-table analysis was $86\% \pm 6\%$ at 6 months (Figure 1).

Table 9 summarizes the failures and complications observed. Endoleak occurred in 27 cases (16.3%; 95 CI, 11%-22%), including 6 type I endoleaks that necessitated further treatment: conversion to open repair in 1 case and repeat stent grafting in 5 cases. These type I endoleaks were related to suboptimal proximal landing zones of 10 to 15 mm in length with an angulation of 60° or more from the transverse arch. In addition, 3 type III endoleaks occurred between 2 stent grafts with an angulation of 60° to 80° in the descending thoracic aorta. Finally, 18 type II endoleaks were diagnosed on postoperative computed tomographic scans performed within the first postoperative month and were left untreated. In addition to endoleaks, there were 49 complications (29%; CI, 23%-37%) in 34 patients (20%; CI, 15%-

27%). Thirty-five complications were related to the stent graft or procedure, and 14 were not stent related. The stent- or procedure-related complications were rupture in 3 cases, aorto-esophageal or tracheal fistula resulting from stent-graft insertion in 3, paraplegia in 6, visceral embolism in 5, stent migration with visceral ischemia in 2, cerebral embolism in 2, and catheterization-site complications in 14, including iliac artery perforation in 5 cases and iliac thrombosis or peripheral embolism in 9 cases. All 6 cases of paraplegia (3.6%; CI, 1.5%-7.9%), including 5 that were fatal, occurred within 48 hours after the procedure. Three cases occurred in patients with extensive degenerative aneurysm of the descending aorta with concomitant open repair of an infrarenal aortic aneurysm. Three other cases occurred in patients with type B dissecting aneurysms with a stent graft covering proximal entry tears in the descending thoracic aorta. Paraplegia was also associated with other major complications in 5 patients (Table 9). Spinal drainage was not used in these patients because in 1999 to 2001, there was no evidence that cerebrospinal fluid drainage was necessary in these patients.^{10,13} Although no definitive statement about the comparative risks of spinal cord ischemia with open repair is possible, this study suggests that even if the risk of spinal cord ischemia with thoracic stent graft is low, these patients should have cerebrospinal fluid drainage and prevention of hypotension, as used in open repair. In this series,

TABLE 8. Mortality and morbidity as a function of the diameter of 126 thoracic aortic aneurysms treated with stent grafts in France from June 1, 1999, to May 31, 2001

Aneurysm diameter	Patients, n (%)	Deaths, n (%)	Procedure- or stent-related complications, n (%)	Non-stent-related complications, n (%)
<50 mm	21 (17)	1 (4.7%)	2 (9.5)	2 (9.5)
50-59 mm	27 (21)	2 (7.4)	3 (11.1)	3 (11.1)
≥ 60 mm	78 (62)	10 (12.8)	19 (24.3)	7 (8.9)
Total	126	13 (10.3)	24 (19.0)	12 (9.5)

Forty patients (24%) with aortic trauma or aortic ulcer were excluded. Mortality associated with stent-grafting in patients with thoracic aortic aneurysms (TAA) less than 50 mm in diameter (4.7%) was not significantly lower than that in patients with TAAs 50 mm or larger (11.4%; $P = .69$).

Figure 1. Kaplan-Meier curve depicting the cumulative survival of the patient cohort with 95% confidence intervals (*dotted lines*) and patients at risk for each interval. Survival at 6 months was $86\% \pm 6\%$.

Figure 2. Kaplan-Meier curve depicting freedom from failure and complications, ie, rupture, endoleak, migration, embolism, conversion, and non-stent-related complications, with 95% confidence intervals (*dotted lines*) and patients at risk for each interval. The cumulative freedom from failure and complications at 6 months was $63\% \pm 7\%$.

actuarial freedom from endoleak and other complications at 6 months was $63\% \pm 7\%$ (Figure 2).

Discussion

This exhaustive study of 166 patients undergoing stent-graft repair of TAD provides useful insights into the short-term postoperative outcome. Like previous studies,¹³⁻¹⁷ our find-

TABLE 9. Complications and treatment failures during the postoperative period

Complications and treatment failures	No.	Deaths
Treatment failures		
Endoleak	27	0
Stent- or procedure-related complications		
Complication related to stent-graft delivery*	14	0
Paraplegia†	6	5
Renal or visceral embolism	5	2
Tracheal or esophageal fistula	3	1
Rupture of thoracic aortic aneurysm	3	3
Migration of stent graft and visceral ischemia	2	1
Cerebral embolism, stroke	2	1
Non-stent-related complications		
Acute respiratory failure	4	0
Nosocomial infection	4	0
Myocardial infarction	6	4
Total complications and treatment failures	76	17

There were 27 (16.3%) treatment failures (endoleaks) and 49 complications in 34 patients (20.5%). Seventeen deaths (10%) occurred, including 13 (7.8%) that were stent or procedure related and 4 (2.2%) that were not stent related. *Complications related to stent-graft delivery included iliac artery perforation ($n = 5$) and arterial thrombosis or peripheral embolism ($n = 9$). †Paraplegia was associated with other major complications in 5 patients, who died.

ings demonstrated that stent-graft repair could provide a less invasive alternative to conventional open repair. However, it must be emphasized that follow-up was limited to the postoperative period.

Only 4 (2.4%) of the 17 deaths in this series were in direct relation to preoperative patient status. This relatively low general mortality is especially remarkable insofar as 76% of patients were classified as ASA status III to IV. Indeed, all 17 deaths (10%) occurred in patients classified as ASA status III to IV. Only 8 deaths (4.8%) occurred within the first 30 days, but 9 other patients died as a consequence of postoperative complications beyond 30 days.

Thirty-five complications were related to the stent graft or procedure, including 3 ruptures in relation to endoleak, 3 aortoesophageal or tracheal fistulas, and 7 cases of postoperative visceral ischemia. Intraoperative stent-graft migration was observed during deployment in 2 patients with suboptimal proximal landing zones, and this necessitated transposition of the left subclavian artery. These 2 complications provide further evidence of the importance of careful assessment of anatomic features for patient selection.

In addition to the 3 patients who had fatal endoleak-related rupture, endoleaks were observed in 24 patients. Type I endoleaks occurred at the proximal landing zone in patients with a large proximal neck diameter or sharp angulation of the thoracic aorta. A predisposing factor for type I endoleak was separation and dislocation of modular devices with sharp angulation of the descending thoracic aorta. The incidence of endoleaks in this series (16.3%) is in agreement with previous reports¹⁷ and emphasizes the importance of patient selection and the need for improving

stent-graft design, especially with regard to column strength and attachment.^{18,19}

This high rate of stent-related complications is currently a major limitation for using endovascular repair in low-operative-risk patients, in whom conventional open repair usually achieves durable results with a negligible risk of graft complications or aortic rupture.^{20,21} However, this disadvantage may be offset by the lower postoperative mortality and morbidity of stent-graft repair in comparison with open surgery.

Paraplegia was observed in only 6 patients (3.6%) in this study. This rate is similar to that reported by Mitchell and associates¹⁶ in a comparable series. All 6 patients in whom paraplegia developed in our series had a large aneurysm of the descending aorta. In 3 cases, stent-graft repair was associated with concomitant abdominal aortic aneurysm repair, which was cited as a risk factor for paraplegia in the Stanford experience.²²

Our data indicate that stent-graft repair for type B aortic dissection has yet to overcome limitations associated with multiple re-entry tears and flow to aortic branches provided by the false lumen.²³ Mortality after stent-graft repair for type B aortic dissection was 15.2% in our series, similar to the results described by Dake and associates.²² These findings contradict previous suggestions that stent-graft repair for type B dissection has the potential advantages of containing rupture, obliterating the false lumen, and protecting against the long-term risk of aneurysm.²²

Our study suggests that stent-graft repair is a valuable alternative to emergency surgical replacement for traumatic pseudoaneurysm. In this subgroup, only 1 patient (5.8%) died, and none had paraplegia. These rates contrast with those reported in contemporary series²⁴ using emergency surgical repair for aortic trauma.

This study shows that stent-graft repair for septic aneurysm is particularly challenging. Two of the 3 patients treated for septic aneurysm died during the postoperative period. Despite the publication by Semba and colleagues²⁵ of 2 cases of septic thoracic aneurysm successfully treated by stent graft, this concept is not substantiated by evidence even as a bridge to open repair with a homograft.

A disappointing finding of our study was the failure of some surgeons to apply the basic consensus guidelines, which recommend surveillance rather than treatment for thoracic aneurysms smaller than 50 mm.⁵ Seventeen percent of the stent-graft procedures, excluding patients with aortic ulcer and trauma, involved patients with aneurysms smaller than 50 mm in diameter. Several explanations can be proposed, including overenthusiasm for the short-term benefits of a new "less-invasive" technology. However, it should be noted that, as shown in Table 8, mortality from thoracic aortic aneurysms smaller than 50 mm in diameter (4.7%)

was not significantly different ($P = .69$) from that of thoracic aortic aneurysms 50 mm or larger (11.4%).

Several factors may restrict the value of this study, including its retrospective nature, the absence of a matched surgical group, short-term follow-up, and use of first- or second-generation stent grafts. These weaknesses are balanced by the fact that data including complications were thoroughly collected and cross-checked. Despite these limitations, it should be said that our data mirror the experience of other investigators^{10,13,22} and are comparable to those of other investigators who used last-generation stent grafts.^{14,15,24} This nationwide study demonstrates that stent-graft repair for TAD can be performed with acceptable postoperative morbidity.

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