Reintervention after thoracic endovascular aortic repair of complicated aortic dissection

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Objective: **This study assessed predictive factors for reintervention after thoracic endovascular aortic repair (TEVAR) for complicated aortic dissection (C-AD).**
Methods: **An institutional review of consecutive TEVAR for C-AD was performed.**
Results: **Between 2000 and 2011, 41 patients underwent TEVAR for a C-AD involving the descending thoracic aorta. Primary indications included aneurysm >55 mm in 24, rapid aneurysmal enlargement or impending rupture in 6, saccular aneurysm >20 mm in 1, malperfusion in 1, intractable chest pain in 3, and rupture in 6. Technical success was achieved in 100%. The 30-day mortality rate was 5% (n = 2). Fourteen secondary procedures were performed in 13 patients (32%) for indications of device migration in 2, proximal type I endoleak in 5, distal type I endoleak in 2, type II endoleak in 1, aneurysmal evolution of the descending thoracic aorta in 2, aneurysmal expansion of the dissected abdominal aorta in 1, and retrograde dissection in 1. Multivariate analysis demonstrated that oversizing ≥20% (odds ratio [OR], 16; $P = .011$), bare-spring stent in the proximal landing zone of the stent graft (OR, 12; $P = .032$), and anticoagulant therapy (OR, 78; $P = .03$) were significant factors for reintervention. On univariate analysis, large aneurysm was a risk factor for reintervention ($P = .002$), whereas complete false lumen thrombosis at the stent graft level was protective ($P < .05$).**
Conclusions: **This study confirms the feasibility of TEVAR for C-AD, although the rate of reintervention is high. Excessive oversizing, a bare-spring stent graft in the proximal landing zone, large aortic dilatation, and anticoagulant therapy were factors associated with reintervention. Complete false lumen thrombosis at the stent graft level was protective. (J Vasc Surg 2014;59:327-33.)**

Initially designed to treat degenerative aneurysms, thoracic endovascular aortic repair (TEVAR) was introduced as an alternative minimally invasive procedure for the treatment of complicated aortic dissection (C-AD) in 1999.[1] Endovascular repair works by covering the proximal tear, thus reducing or preventing flow in the false lumen and thereby allowing true lumen expansion. As a consequence of lower perioperative morbidity and mortality compared with open surgery, consensus has now shifted such that many now consider TEVAR as the first-line therapy for C-AD.[2,3]

However, the long-term durability of this endovascular approach is still being debated. Some reports suggest a high rate of reintervention[4-6] of up to 46% in the acute setting.[7] This has raised concerns regarding the long-term outcomes and costs of TEVAR for C-AD. Recent cost-effectiveness analyses have demonstrated that the postintervention costs of TEVAR are increased eightfold in those with ($31,696) compared with those without ($3668) secondary procedures.[8] It is important that significant clinical and technical factors associated with secondary intervention are identified and mechanisms of failure elucidated so that we may prevent and manage them in future. Published data in this area have been lacking.

The aim of our study was to identify the risk factors for reintervention after TEVAR for the treatment of C-AD involving the descending thoracic aorta.

METHODS

The Institutional Review Board approved this study, and informed consent was obtained from each participant.

Patients selection and follow-up. The study included all consecutive patients undergoing TEVAR for C-AD, defined as aortic aneurysm >55 mm, rapid aneurysmal enlargement or impending rupture (>5 mm over 6 months), rupture, saccular aneurysm >20 mm, malperfusion syndrome, or intractable chest pain under medical therapy involving the descending thoracic aorta between October 2000 and December 2011 at our unit.

Aortic dissection was defined as chronic 14 days after onset of acute symptoms. According to the Reporting Standards For Thoracic Endovascular Aortic Repair,[9] technical success was defined as complete coverage of the primary entry tear without a type I leak at the end of the procedure.

Patients were preoperatively evaluated with respect to age, sex, smoking, obesity, hypertension, diabetes, long-term anticoagulant therapy, renal insufficiency, history of ascending or abdominal aortic repair, and according to

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the American Society of Anesthesiologists Physical Status Classification. They were prospectively monitored by scheduled clinical observation and with contrast-enhanced computed tomography (CT) preoperatively, before hospital discharge, at 1, 3, 6, and 12 months, and annually thereafter. All aortic CT measurements were taken in a perpendicular plane using centerline reconstructions. Preoperative and postoperative measures included neck diameter and length for device sizing, maximal aortic diameter, and aortic diameters at the levels of the proximal thoracic aorta (2 cm below the left subclavian artery ostium), the midthoracic aorta (at the level of the left inferior pulmonary vein), the celiac artery, and both renal arteries. Extension of the dissection above or below the celiac axis and false lumen status at the level of the stent and more distally were also analyzed. The number of visceral and renal vessels perfused by the false lumen was also reported, but we did not analyze that variable in terms of reintervention.

With regards to outcomes, patients were grouped by those with and without reintervention. Reintervention was defined as any intervention after the original procedure that was related to the dissection or a complication of the original procedure.

Endovascular device and procedural details. All endovascular procedures were performed in an operating theater under general anesthesia. Open femoral cutdowns were used to facilitate catheter-based access to the true lumen and the aortic arch. Transesophageal echocardiography was frequently used to verify the position of the guidewire in the true lumen. Angiograms were performed before stent graft deployment to clearly delineate the proximal tear site and after deployment to confirm entry tear sealing and absence of endoleak. For patients with a short proximal landing zone (<20 mm), hybrid operations, combining extra-anatomic debranching of the supra-aortic vessels with immediate endovascular stent graft deployment, were performed to enable coverage of the proximal entry tear.

During the period of study inclusion, five different stent grafts were implanted, comprising the Thoracic Excluder and C-TAG (W.L. Gore and Associates, Flagstaff, Ariz), Talent and Valiant (Medtronic, Santa Rosa, Calif), and Zenith TX2 (Cook, Bloomington, Ind). Stent graft selection was at the discretion of the surgeon. For the analysis, the stent grafts were grouped depending on the presence of a proximal bare spring: The Excluder, the C-TAG, and the TX2 were classified as "membrane-covered proximal-spring," and the Valiant and the Talent as "proximal bare-spring" stent grafts.

Statistical analysis. All primary procedural, reintervention, and outcomes data were prospectively collected in a vascular registry. Patients who did and did not undergo reinterventions were compared. Univariate and multivariate logistic regressions were performed to assess the influence of initial variables on the occurrence of reintervention. Variables of initial characteristics significantly associated with reintervention by univariate logistic regression ($P < .05$) were entered into the model. Postoperative false lumen thrombosis was considered as a variable of follow-up and was not analyzed in the multivariate logistic regression. This variable was analyzed separately. The multivariate model was built by a step-down procedure. The adjusted odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. Univariate and multivariate logistic regressions were performed with the Firth penalized likelihood method because some models had quasi-complete separation of data and the results of logistic regression with maximum likelihood estimates are unreliable for small samples. A P value of <.05 was considered statistically significant. All statistical analyses were performed at the Clinical Research and Epidemiology Department of the Centre Hospitalier Universitaire Montpellier with SAS 9 software (SAS Institute Inc, Cary, NC).

Table I. Clinical and demographic characteristics of the 41 patients at the initial procedure

Characteristics[a]	*All patients (N = 41)*
Age, years	66 ± 11
Male sex	34 (83)
Hypertension	31 (76)
Diabetes	2 (5)
Smoker	18 (44)
Coronary artery disease	6 (15)
Dyslipidemia	5 (12)
COPD	9 (22)
Renal insufficiency	2 (5)
Obesity	6 (15)
Prior aortic surgery	16 (39)
Corticosteroid therapy	5 (12)
Anticoagulant therapy	5 (12)
Marfan syndrome	1 (2)
ASA classification	
2	16 (39)
3	22 (54)
4	3 (7)

ASA, American Society of Anesthesiologists; *COPD,* Chronic obstructive pulmonary disease.
[a]Continuous data are shown as mean ± standard deviation and categoric data as number (%).

RESULTS

Patient demographics. Between October 2000 and December 2011, 41 patients underwent stent graft placement for a C-AD involving the descending thoracic aorta. Patients characteristics are reported in Table I. The patients were a median age of 66 years (range, 42-94 years), with a male-to-female ratio of 4.9:1. Dissection characteristics are reported in Table II. The median interval from the initial dissection to stent graft repair was 1.5 months (interquartile range, 0.3-36 months). The dissection was treated at the acute phase in 15 patients and at the chronic phase in 26. The indication for repair included aneurysm >55 mm in 24, rapid aneurysmal enlargement or impending rupture (>5 mm over 6 months) in 6, saccular aneurysm >20 mm in 1, malperfusion syndrome in 1, intractable chest pain under medical therapy in 3, and rupture in 6.