Outcome of thoracic endovascular aortic repair in patients with thoracic and thoracoabdominal aortic aneurysms

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Objective: **This study reports the long-term results after thoracic endovascular aortic repair (TEVAR) in thoracic aortic aneurysms (TAAs) and thoracoabdominal aortic aneurysms (TAAAs).**
Methods: **Between 1997 and 2010, 269 patients were treated with TEVAR, 100 of them (72 male; mean age, 68.3 years) for aneurysmal disease. An intact TAA (iTAA) was present in 49 patients and an intact TAAA (iTAAA) in 18. In 25 patients, there was a ruptured TAA or ruptured TAAA (rTAA). Eight patients were admitted with a post-traumatic TAA (pTAA). Retrospective analysis was performed from a prospectively maintained database. Primary end points were 5-year all-cause and TEVAR-related mortality. Secondary end points were causes of death, complications, and reinterventions (RIs). A 5-year follow-up was complete in all cases.**
Results: **The overall 5-year mortality rate was 50% (40.8% in iTAA, 80% in rTAA, 12.5% in pTAA, and 50% in iTAAA, respectively; log-rank test, $P = .00012$). The overall procedure-related mortality was 21% (10.2% [n = 5] in iTAA, 40% [n = 10] in rTAA, 33% [n = 6] in iTAAA, and 0 in pTAA, respectively; log-rank test, $P = .00013$). Freedom from complication was 52%, 47.2%, and 47.2% at 1, 3, and 5 years, respectively. There were a total of 30 RIs in 25 patients. Freedom from RI was 82%, 77.8%, and 71.2% at 1, 3, and 5 years. Stepwise forward logistic regression analysis revealed rTAA and occurrence of complications were risk factors for survival (odds ratios, 7.7 and 4.2, respectively).**
Conclusions: **Long-term results after TEVAR for aneurysmatic aortic disease demonstrate considerable overall and procedure-related mortality in both elective and urgent indications. Complications and RIs occur still as late events and emphasize the necessity for long-term follow-up. (J Vasc Surg 2016;■:1-12.)**

In 1994, Dake et al[1] introduced thoracic endovascular aortic repair (TEVAR) for the treatment of thoracic aortic aneurysm (TAA) disease. Since then, TEVAR has become the treatment option of choice for a wide variety of thoracic aortic pathologies.[2] Endograft systems and the procedure itself have been continuously improved. The 30-day outcomes of the technique, such as death, spinal cord injury, or stroke, have been well documented. Despite the proven short- and midterm safety and efficacy, the durability of this minimally invasive modality is still a concern. Available data from single-center studies show considerable reintervention (RI) rates after TEVAR, notably due to progression of the aortic disease and endoleak (EL) formation.[3] So far, the literature on mid- to long-term outcomes after TEVAR for TAA is still limited. Few studies have addressed all-cause or TEVAR-related mortality or RI rates >1 year of follow-up (FU).[4] All-cause survival rates at 5 years are 47% to 78%, and RIs are reported in up to 32% of patients after TEVAR for TAA.[5] The most valid long-term data are derived from registry studies; however, these numbers may not represent real-world outcomes because high-risk patients are often excluded.[6,7] More outcome data are needed to improve clinical decision making and FU regimens after TEVAR. Therefore, the aim of this study was to report long-term results after TEVAR for aneurysmal disease.

METHODS

Patient population. The study design is a retrospective single-center analysis. Patients who undergo TEVAR at the Ruprecht-Karls University Department of Vascular Surgery are entered into a prospectively maintained database. Only adults who are able to give their consent are entered. The research was approved by an institutional Medical Ethics Committee (Protocol No.: S158/2015).

Between March 1997 and May 2010, 269 patients underwent TEVAR for various aortic pathologies (data are specified in the Supplementary Fig, online only). The study population consists of 100 aneurysm patients with TAA (n = 80) or thoracoabdominal aortic aneurysms (TAAAs, n = 20) and is divided into four different groups: (1) intact TAA (iTAA, n = 49), (2) ruptured TAA (rTAA, n = 25;

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Table I. Patient demographics and aortic disease characteristics

Indication	*Total (N = 100)*	*iTAA (n = 49)*	*rTAA (n = 25)*	*pTAA (n = 8)*	*iTAAA (n = 18)*	P
Age, mean ± SD (range) years	68.3 ± 11.2 (31-89)	68.2 ± 10.8	74.2 ± 8.3	50.6 ± 10.5	68.1 ± 7.4	.00001
Male sex, %	72	65.3	68	100	83	.140
Aneurysm diameter, mean ± SD (range) mm	66.1 ± 17.3 (34-135)	64.9 ± 14.8	66.7 ± 19.0	54.3 ± 12.9	73.1 ± 19.9	.094
Previous operation/intervention						
Abdominal aortic, % (n/N)	26.3 (26/99)	33.7 (16/49)	16.7 (4/24)	12.5 (1/8)	27.8 (5/18)	.399
Thoracic aortic, % (n/N)	3 (3/99)	2 (1/49)	4.2 (1/24)	—	5.6 (1/18)	.820

iTAA, Intact thoracic aortic aneurysm; *iTAAA,* intact thoracoabdominal aortic aneurysm; *pTAA,* post-traumatic thoracic aortic aneurysm; *rTAA,* ruptured thoracic aortic aneurysm; *SD,* standard deviation.

TAA in 23 cases and TAAA in two cases), (3) post-traumatic TAA (pTAA, n = 8), and (4) intact TAAA (iTAAA, n = 18).

Of 18 iTAAA patients, 12 had a Crawford type I aneurysm with a pathology extending beyond the diaphragmatic border.[8,9] All but two of these patients had a sufficient distal landing zone above the celiac axis. In two patients, the celiac axis was overstented. The remaining eight iTAAA patients had hourglass-shaped TAAAs with a thoracic portion suitable for TEVAR. Owing to the technical and clinical differentness of the approaches, the present analysis excluded 33 patients with hybrid TAAA procedures (visceral debranching and subsequent TEVAR) and two patients with branched or fenestrated endovascular TAAA repair.

Patient characteristics are reported in Table I. Mean age was 68.3 ± 11.2 years (range, 31-89 years), and 72 patients (72%) were male. Patients with pTAA were significantly younger than those in the remaining groups ($P = .0001$). By trend, patients with rTAA were older than patients with iTAA ($P = .064$). Aneurysm diameters were similar between the groups. Patient comorbidities are reported in Table II. The pTAA patients had fewer comorbidities and lower American Society of Anesthesiologists (ASA) Physical Status Classification scores. In rTAA patients, the most common ASA score was 4 (72.4%), whereas 75% of iTAA and 66.7% of iTAAA patients were classified as ASA 3.

Procedural data. All TEVAR procedures undertaken before October 2010 were performed in an operating theater equipped with an Axiom U imaging system (Siemens Healthcare, Erlangen, Germany). Since October 2010, TEVAR has been performed in a hybrid operating room featuring an Artis Zeego multiaxis imaging system (Siemens Healthcare). The implantation protocol has been previously published.[3]

FU protocol. FU included medical history, physical examination, and computed tomography angiography (CTA) scans before discharge and at 6 months, 1 year, and annually thereafter. A standardized TEVAR protocol for CTA scans has been followed that involves a 1-mm slice acquisition of the entire aorta, arterial, venous, and delayed venous imaging phases as well as three-dimensional image reconstructions. The interpretation of the CTA scans has been interdisciplinary. In a few patients, FU data were supplemented by examinations in other clinics. Data on causes of death were retrieved from autopsy, medical reports, or from correspondence with the patient's general practitioner. In case of missing information or indistinct assumptions, death is reported as indeterminate. Mean FU time was 56.7 months (range, intraoperative death-214 months). No patient was lost to FU ≤60 months.

Study end points and definitions. Primary research end points of the study were 5-year all-cause and TEVAR-related mortality. Secondary end points were causes of death, complications, and RIs. TEVAR-related mortality was defined as any death associated to TEVAR or associated to primary or secondary procedures, including open surgical conversion. RI was defined as endovascular, open, or hybrid procedure related to TEVAR or progression of the aortic disease, including early and late conversion. Serious adverse events (SAEs) were defined as any or all of the following: complications requiring medical or surgical intervention to prevent life-threatening illness, injury, or permanent impairment to a body structure or a body function, events associated with prolonged recovery, prolonged or permanent disability, or those associated with death. EL occurrence was reported according to the classification of White et al.[10] Proximal landing zones were defined according to Ishimaru et al.[11] The definitions used in this study meet the reporting standards for TEVAR published in 2010 by the Society for Vascular Surgery.[12]

Statistics. Plain information is provided by descriptive statistics. Data are expressed as mean ± standard deviation. Survival curves were estimated using Kaplan-Meier analysis with 95% confidence intervals (CIs). Log-rank tests were used for survival comparison. Stepwise forward logistic regression analysis was used to identify risk factors for death ≤60 months. The best model obtained was able to predict 82.9% of deaths correctly. Differences between groups of indications were investigated using one-way analysis of variance and the Fisher exact test. P values ≤.05 were considered significant. All statistical tests were conducted in SPSS 22.0 software (IBM Corp, Armonk, NY).