Reinterventions during midterm follow-up after endovascular treatment of thoracic aortic disease

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Objectives: **To report incidence, indication, and timing of reinterventions after thoracic endovascular aortic repair (TEVAR) and identify subgroups most prone to reinterventions.**
Methods: **Between January 1997 and March 2010, a total of 264 patients received TEVAR in our institution. During follow-up, 58 patients (39 men, median age 63 years, range 28-87 years) required a total of 68 reinterventions, which represent the study population of this retrospective, single center analysis. The mean follow-up of all 264 patients was 31.2 months (range 0-141 months).**
Results: **The overall reintervention rate was 22%: 1-, 3-, and 5-year free reintervention rates were 82% ± 3%, 74% ± 3%, and 70% ± 4%, respectively. Indications for reintervention were predominately endoleaks (41%) and progression of the underlying aortic disease (29%). Reinterventions were performed by endovascular means in 44%, by open repair in 35% (including 11 conversions), and by hybrid procedures in 21%. Multiple logistic regression analysis revealed patients with chronic expanding aortic dissections (odds ratio [OR]: 2.35), hybrid aortic procedures (OR: 2.11), and connective tissue diseases (OR: 7.54) at an increased risk for reintervention. The necessity for reintervention did not influence survival in this cohort (log-rank test $P = .1706$).**
Conclusions: **TEVAR is associated with a relevant reintervention rate, predominately caused by endoleaks and progression of the aortic pathology. Patients with chronic expanding aortic dissections, hybrid aortic procedures, and connective tissue diseases are at an increased risk for reintervention and should therefore undergo close follow-up.**

Over the last decade, thoracic endovascular aortic repair (TEVAR) has evolved as the first-line treatment option for many thoracic aortic pathologies due to reduced perioperative morbidity and mortality rates in selected patients.[1-3] The main drawback of TEVAR consists of procedure-associated complications, especially endoleak formation, migration, material fatigue, or stent graft collapse that endanger early-, mid- and long-term treatment success and cause further open/endovascular reinterventions. Additionally, a significant proportion (12%-60%) of patients, especially with aortic dissections, experience disease progression during follow-up after TEVAR, and thus requires further surgical procedures.[4-6]

The aim of this study was, therefore, to analyze incidence, indication, and timing of required reinterventions after TEVAR and to identify potential predictors for patients most prone to reinterventions.

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METHODS

Patient population. The study design represents a retrospective single-center analysis. Between January 1997 and March 2010, a total of 264 patients received TEVAR in our institution. During a mean follow-up of 31.2 months (range, 0-141 months), a total of 58 (21.9%) patients (39 men, median age 63 years; range, 28-87 years) required 68 reinterventions. Indications for treatment are shown in Table I and show a significantly higher reintervention rate ($P = .013$) in patients treated for chronic expanding aortic dissections (CEAD). Baseline characteristics in these patients are shown in Table II and revealed a significantly higher proportion of patients with connective tissue disease (CTD) in the reintervention group ($P = .003$).

Procedure. All surgical procedures were performed in an operating room equipped with fluoroscopic and angiographic capabilities (Series 9800; OEC Medical Systems, Inc, Salt Lake City, Utah until April 2007, after that Axiom U; Siemens, Forchheim, Germany) and a carbon fiber operating table. The following stent grafts have been used: Talent/Valiant/Captivia (Medtronic Vascular, Santa Rosa, Calif), TAG/C-TAG (W. L. Gore and Associates, Flagstaff, Ariz), Zenith (Cook Inc, Bloomington, Ind), and Endofit (LeMaitre Vascular, Burlington, Mass). The procedure protocol has been published before.[7] Procedure-related data are presented in Table III and showed no influence of the type of stent graft used, or the time period of initial treatment regarding reintervention. There was a significant higher rate of reinterventions in elective cases ($P = .015$) and for patients needing aortic (arch and/or visceral) hybrid procedures ($P = .018$).

Table I. Indication of all thoracic endovascular aortic repair (TEVAR) patients (n = 264)

Indication	*Total (n = 264)*	*No reintervention (n = 209)*	*Reintervention (n = 58)*	P *value*
Aneurysm	129 (49%)	101 (78%)	28 (22%)	.881
PAU	49 (11%)	43 (88%)	6 (12%)	.120
CEAD	34 (13%)	21 (62%)	13 (38%)	.013
Acute aortic dissection	32 (12%)	27 (84%)	5 (16%)	.495
Traumatic transection	17 (6%)	15 (88%)	2 (12%)	.539
ABF	12 (5%)	9 (75%)	3 (25%)	.721
IMH	9 (3%)	5 (56%)	4 (44%)	.098
Patch rupture/aneurysm	6 (2%)	5 (83%)	1 (17)	.998

ABF, Aortobronchial fistula; *CEAD,* chronic expanding aortic dissection; *IMH,* intramural hematoma; *PAU,* penetrating aortic ulcer.

Table II. Baseline characteristics of all thoracic endovascular aortic repair (TEVAR) patients (n = 264)

Parameter	*Total (n = 264)*	*Free of reintervention (n = 209)*	*Reintervention (n = 58)*	P *value*
Gender (male)	188 (71%)	149 (71%)	39 (70%)	.995
Age	63 (21-89)	63 (21-89)	63 (28-87)	.984
Hypertension	230 (87%)	180 (86%)	50 (89%)	.377
History of smoking	126 (48%)	102 (49%)	24 (43%)	.453
Diabetes	32 (12%)	23 (11%)	9 (16%)	.357
Renal insufficiency	65 (25%)	52 (25%)	13 (23%)	.862
COPD	55 (17%)	40 (19%)	15 (27%)	.265
CHD	98 (37%)	77 (37%)	21 (36%)	.999
CTD	9 (3.4%)	3 (1.4%)	6 (11%)	.0035
Previous aortic surgery	60 (23%)	46 (22%)	14 (25%)	.719

CHD, Coronary heart disease; *COPD,* chronic obstructive pulmonary disease; *CTD,* connective tissue disease.
Values are presented as median (range) or n (%).

Table III. Procedure-related data of all thoracic endovascular aortic repair (TEVAR) patients (n = 264)

Parameter	*Total (n = 264)*	*Free of reintervention (n = 209)*	*Reintervention (n = 58)*	P *value*
Stent grafts				
- TAG	158 (60%)	121 (77%)	37 (23%)	.446
- Talent	44 (17%)	34 (77%)	10 (23%)	.840
- Valiant	34 (13%)	27 (79%)	7 (21%)	.998
- Zenith	18 (7%)	16 (88%)	2 (12%)	.378
- C-TAG	3 (1%)	3 (100%)	0 (0%)	NA
- Captivia	1 (0.3%)	1 (100%)	0 (0%)	NA
- Other	8 (3%)	6 (71%)	2 (29%)	NA
Treatment period				
- 1997-2001	51 (19%)	37 (73%)	15 (27%)	.134
- 2002-2006	115 (43%)	95 (82%)	20 (18%)	.334
- 2007-2010	98 (37%)	76 (77%)	22 (23%)	.999
Procedure				
- Elective	126 (48%)	90 (72%)	36 (28%)	.015
- Emergency	138 (52%)	117 (84%)	21 (16%)	.015
Hybrid procedures	75 (28%)	51 (68%)	24 (32%)	.018

Follow-up schedule included postoperative computerized tomographic angiography (CTA) before discharge, clinical examination, plain chest radiography and CTA/magnetic resonance angiography (MRA) 6 and 12 months postoperatively and annually thereafter.

Definitions and statistical analysis. Reintervention was defined as any TEVAR and/or aortic disease related additional open, endovascular or hybrid procedure during follow-up, including early and late conversion. Endoleaks were categorized as previously described by White et al.[8] Hybrid procedures were defined as aortic arch vessel and/or visceral vessel debranching combined with TEVAR to exclude the aortic pathology. Our experience with aortic hybrid repair has been reported before.[9,10] Disease progression was defined based on the underlying aortic pathology. This includes progression of and/or de novo develop-

Table IV. Indication and type of reintervention (n = 68) in all patients (n = 58)

Cause of reintervention	*Number of reinterventions (n = 68)*	*Type of reintervention*		
		OR	*EVR*	*HAR*
Endoleak	27 (41%)	3 (11%)	13 (48%)	11 (41%)
- Type I	21	1	10	11
- Type II	4	2	2	
- Type III	2	0	1	
Disease progression	20 (29%)	4 (20%)	13 (65%)	3 (15%)
Bypass occlusion/stenosis (hybrid cases)	6 (9%)	5 (83%)	1 (17%)	NA
Arm claudication/subclavian steal	4 (6%)		Subclavian transposition	
Retrograde type A dissection	2 (3%)		Conversion	
Stent graft collapse	2 (3%)		Conversion (n = 1) Palmaz XXL stent (n = 1)	
Stent graft compression	1 (1.5%)		PTA overlapping zone	
Paraplegia	1 (1.5%)		Subclavian transposition	
AEF	2 (3%)		Conversion	
Aortobronchial fistula	1 (1.5%)		Stent graft extension	
Material fatigue (wire fracture) with ABF	1 (1.5%)		Conversion	
Stent graft infection	1 (1.5%)		Conversion	

ABF, Aortobronchial fistula; *AEF*, aortoesophageal fistula; *EVR*, endovascular repair; *HAR*, hybrid aortic repair; *OR*, open surgical repair; *PTA*, percutaneous transluminal angioplasty.

ment of an aortic aneurysm/penetrating aortic ulcer (PAU) in the thoracic aorta. Progression of disease in acute type B dissections/intramural hematoma (IMH) was defined as new onset of pathology-related complications (eg, rapid expansion/rupture/end organ ischemia) after TEVAR. In chronic aortic type B dissections, continuous aortic expansion in the dissected aortic segment was defined as disease progression. In aortobronchial fistula (ABF), recurrence of typical clinical symptoms was defined as disease progression. Data are expressed as mean ± SD or median (range). Survival and reintervention-free survival estimates were generated using the Kaplan-Meier analysis. Log-rank test was used for survival comparisons. Fisher exact test and Mann-Whitney *U* test were used for categorical, respectively continuous variables. Multiple logistic regression analysis was used to identify risk factors affecting reintervention. All statistical analysis was performed using MedCalc (Version 9.5.2; MedCalc Software, Mariakerke, Belgium).

RESULTS

Overall reintervention rate was 22% (58/264), with a total of 68 reinterventions performed in 58 patients. Six patients required two reinterventions and one patient (Marfan syndrome) required five reinterventions. Indication for reinterventions (Table IV) consisted predominantly of endoleaks (41%) and progression of the aortic disease (29%). Additional causes included stent graft collapse (two patients with acute aortic transections) and stent graft compression at the overlapping zone of two endografts caused by a rigid dissection membrane in a patient with a CEAD.[11] One patient received a subclavian transposition after paraplegia in sequel of a thoracoabdominal hybrid procedure and primary overstenting of the left subclavian artery (LSA). One patient with a recurrent episode of hemoptysis 5 years after TEVAR for a thoracic aortic aneurysm received distal and proximal stent graft extension to cover successfully a suspected ABF.

Table V. Risk factor analysis regarding reintervention

Variable	*Odds ratio*	*95% CI*	P *value*
CEAD	2.35	1.05-5.28	.037
Hybrid procedures	2.11	1.11-4.01	.023
CTD	7.54	1.72-32.99	.007

CEAD, Chronic expanding aortic dissection; *CTD*, connective tissue disease.

Conversion was necessary in 11 patients (4.1%). This includes three patients with a disease progression at the ascending aorta/aortic arch, two patients with retrograde dissection after TEVAR (initially treated for a CEAD/IMH), and two patients with an aortoesophageal fistula which received planned conversion after bridging TEVAR. Additionally, one patient showed a longitudinal wire fracture with aortic wall perforation and consecutive ABF and received successful conversion. One patient experienced stent graft infection after repeated trauma surgery and underwent successful conversion. Emergency conversion was necessary in two further patients (one intraoperative stent graft collapse; one aortic rupture due to a type I endoleak two years after TEVAR).

Reinterventions were performed by endovascular means in 44% (30/68), by open repair in 35% (24/68, including 11 conversions), and by aortic hybrid procedures in 21% (14/68). Parameters showing a significant higher reintervention rate in univariate analysis (CTD, CEAD, and aortic arch hybrid procedures) were entered in a multiple logistic regression model (Table V), which proved those parameters as risk factors for reinterventions. The 1-, 3-, and 5-year reintervention free survival was 82% ± 3%, 74% ± 3%, and 70% ± 4%, respectively (Fig 1). The

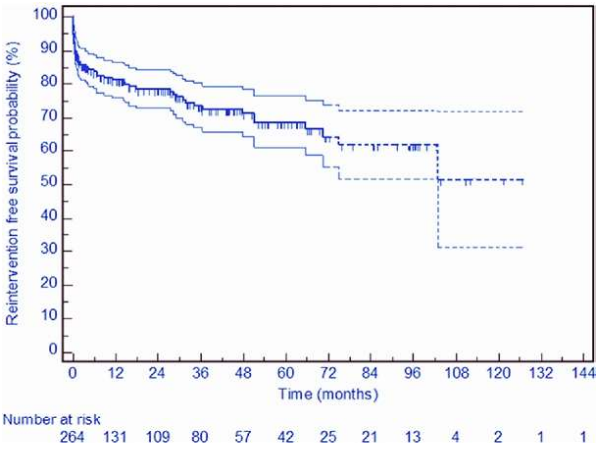

Fig 1. Kaplan-Meier analysis (including 95% CI interval) regarding reintervention-free survival of all patients (n = 264).

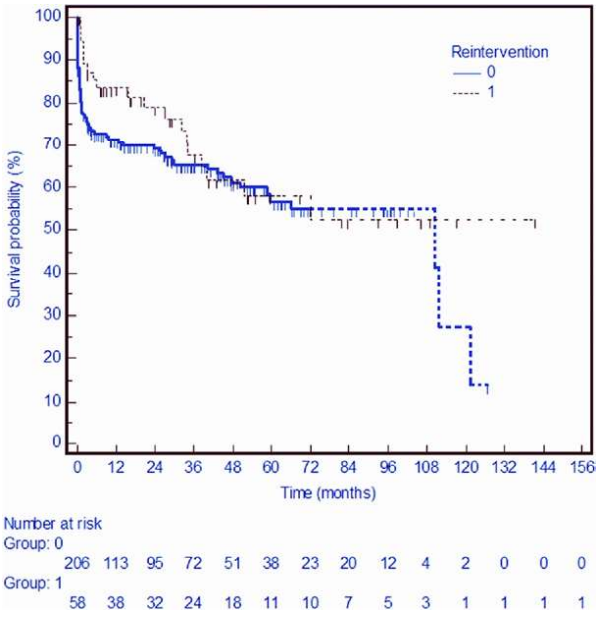

Fig 2. Kaplan-Meier analysis showing no influence (log-rank test $P = .1706$) on survival for 58 patients with reintervention (1) vs no reintervention (0) in 206 subjects.

necessity for reintervention did not influence survival (Fig 2) in this cohort (log-rank test $P = .1706$).

DISCUSSION

The present series shows that TEVAR is associated with a relevant reintervention rate (22%), predominately caused by endoleaks and progression of the aortic pathology. The analysis further revealed patients with chronic expanding aortic dissections (odds ratio [OR], 2.35), hybrid aortic procedures (OR, 2.11), and connective tissue diseases (OR, 7.54) at an increased risk for reintervention.

Reintervention rates after TEVAR vary between 3.6% and 8.2% in the large multicenter trials performed to evaluate the safety and efficiency of the three most commonly used endografts (TAG, Talent, Zenith TX2) and are thus below our reported rate.[1-3] These trials included only patients with thoracic aortic aneurysms (TAG, Talent, TX2) or PAU (TX2), with aortic dissections and CTD being an exclusion criteria. Additionally, hybrid procedures were only included in regard to LSA revascularization. In our series, CEAD (13%), CTD (3.4%), and hybrid procedures (28%) significantly influenced reintervention and might, therefore, explain a higher rate of reinterventions. Six out of nine patients with CTD required reinterventions in this series, which supports a questionable midterm treatment success of TEVAR in these patients. This findings correlate with Ehrlich et al that could show in the Talent thoracic registry Marfan syndrome to be the strongest independent predictor for late conversion (HR, 9.7).[12] Given excellent results for open surgery, the role of stent graft placement in this subgroup might, therefore, be limited to bridging or hostile operation fields (eg, after recurrent open surgery). We perform TEVAR in these patients only under the aforementioned selection criteria.[13-15]

The second subgroup of patients requiring a high rate of reinterventions (38%) in this series, were patients with CEAD. The reported reintervention rates for these patients vary between 6% and 60% with endoleak formation and continuing false lumen expansion, especially distal to the covered aortic segment, being the most common cause of second procedure. Distal re-entries often prevent false lumen thrombosis and lead to retrograde perfusion, expansion, and thus reintervention.[16] Furthermore, segmental arteries arising from the false lumen are usually not excluded from retrograde blood flow in the false lumen. Additional causes for reintervention in our series included stent graft compression by the rigid dissection membrane and retrograde aortic dissection. In regard to these early and midterm complications, patient selection criteria (eg, anatomic considerations/timing of the procedure/amount of re-entries) for a successful, durable TEVAR procedure and the ultimate role of TEVAR in patients with CEAD have yet to be defined.[5,6,17-20] In our perspective, the present issue in patients with CEAD is to identify patients most prone to reintervention and to compare long-term outcome in patients who underwent stent grafting. Despite the fact of missing data on controlled efficacy, stent grafting is an alternative option for high-risk surgical candidates with chronic aortic dissection. This is in line with the expert consensus document published in 2008.[17]

The most common cause of reintervention in this series was the occurrence of an endoleak, which is in line with the European Collaborators Registry (EUROSTAR) data, that showed an increased risk for reintervention (relative risk, 5.21) for patients with endoleaks.[21] This is explicable as most endoleaks in the thoracic aorta are type I endoleaks (21 out of 27 in this series), which commonly demand further reintervention. In this series, 11/27 patients (41%) required proximal or distal debranching before stent graft extension to seal the endoleak. Reasons include short landing zones (<2 cm,) which might have been accepted in a

first approach (especially emergency cases) to avoid complex extended hybrid procedures. Type II endoleaks in the thoracic aorta that required reintervention in this series were via a covered LSA and a covered celiac trunk. We generally only treat type II endoleaks with associated aneurysm sac enlargement. Treatment of type II endoleaks of the LSA included transbrachial placement of an Amplatzer (AVP; AGA Medical, Plymouth, Minn) vascular plug proximal to the origin of the left vertebral artery or open LSA ligation/transposition. Persistent endoleaks via a covered celiac trunk were sealed using coil embolization. A total of 7/68 reinterventions were associated with the LSA, which includes three patients with a persistent endoleak type II and four patients with persistent arm claudication/subclavian steal syndrome. This is a result of our concept of performing LSA revascularization prior to stent graft coverage only in selected cases (eg, long covered aortic segment). We routinely evaluate the cerebral circulation (including both vertebral arteries) prior to LSA coverage to decide if carotid-subclavian transposition is needed at the time of the TEVAR. Routinely, embolization of the origin of the LSA before coverage to prevent type II endoleaks is not performed.[22] Aortobronchial or esophageal fistulas (AEF) caused reintervention in four patients in this series. The few available literature on this topic indicates that TEVAR in patients with ABF can offer a definite treatment solution, which could be proven in this series, where only three out of nine patients required reintervention.[23,24] Contrary to that, TEVAR is considered to be a bridging method (as used in this series) for patients with AEF and staged conversion is mostly recommended.[25-27] Reported conversion rates after TEVAR vary between 3.8% and 4.6% with endoleaks, disease progression, retrograde aortic dissection, and aortoesophageal fistulas being the most common cause, which is in line with our series (conversion rate, 4.1%).[12,28,29] There was a lower reintervention rate for emergency cases in this series. This is possibly caused by the higher mortality rate of patients requiring emergency TEVAR, leaving fewer patients at risk for reinterventions.[30]

The 1-, 3-, and 5-year reintervention-free survival rate was 82%, 74%, and 70% in this series, which is in line with Leurs et al who reported a 86% and 83% reintervention-free survival rate after 1 and 2 years, respectively.[21] Additionally, their analysis of the EUROSTAR data showed a significantly ($P = .0001$) reduced 2-year cumulative survival rate (85% vs 58%) of patients requiring secondary interventions after TEVAR. In our series, reintervention did not influence survival ($P = .1706$).

Lessons learned in the last decade of performing TEVAR in our institution follows: (1) There is still no ideal stent graft fitting all aortic pathologies, specifically in (2) the aortic arch that is the "Achilles' heel" of TEVAR. Regarding these two issues, especially conformability and radial force are key issues of future stent graft design to reduce reintervention rates. (3) The indication to treat acute uncomplicated type B dissections and chronic expanding aortic dissections is still not solved. (4) Reinterventions, especially in patients with connective tissue disorders are frequently necessary.[13] (5) Accurate preoperative imaging with postprocessing using workstations added more useful information while planning, sizing, and selecting patients. Nevertheless, further dynamic imaging studies and research is needed to fully understand the geometry, physiology, and morphology of aortic pathologies and to provide future navigation tools. (6) Even knowing the risk factors of spinal cord ischemia such as length of stented/covered aorta, covering of LSA, and previous infrarenal aortic replacement, clinical appearance of paraplegia remains unpredictable and not fully understood. Surgical reintervention options in these patients are unfortunately limited or impossible.

Limitations. This patient cohort covers a large time period, including the learning curve of the early worldwide experience with TEVAR. Although our reintervention rate did not significantly change over the 13 years, this might presumably be biased by the increasing complexity of TEVAR cases over the time, which is difficult to present in an analysis like this. Due to the large spectrum of thoracic aortic pathologies, patient heterogenity is an inherent limitation of our approach. The present analysis represents midterm results. At the 3-year follow-up, only 80/264 patients (30%) were "at risk for reintervention" (Fig 1). Reasons include early and midterm mortality in this cohort, the referral pattern of our university center, and an increasing number of patients treated during the last years of the analysis. It is thus possible that the actual number of reinterventions is underestimated and likely to increase during further long-term follow-up.

CONCLUSIONS

TEVAR is associated with a relevant reintervention rate, predominately caused by endoleaks and progression of the aortic pathology. Patients with chronic expanding aortic dissections, hybrid aortic procedures, and connective tissue diseases are at an increased risk for reintervention and should therefore undergo close follow-up.

AUTHOR CONTRIBUTIONS

Conception and design: PG, DB
Analysis and interpretation: PG, DB, AD
Data collection: DK, SH, TA, AD
Writing the article: PG, DB
Critical revision of the article: DB, DK
Final approval of the article: PG, DB
Statistical analysis: PG
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