From the New England Society for Vascular Surgery

Results of the VALOR II trial of the Medtronic Valiant Thoracic Stent Graft

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ABSTRACT

Background: The 1-year results of endovascular exclusion of degenerative descending thoracic aortic aneurysms (DTA) with the Valiant Thoracic Stent Graft (Medtronic Vascular, Santa Rosa, Calif) have been previously reported. With long-term follow-up now complete, the 5-year results are reported.

Methods: The VALOR II trial (Evaluation of the Clinical Performance of the Valiant Thoracic Stent Graft System in the Treatment of Descending Thoracic Aneurysms of Degenerative Etiology in Subjects Who Are Candidates for Endovascular Repair) was a prospective, nonrandomized trial of the Valiant Thoracic Stent Graft system in patients with degenerative DTA. The trial involved 24 sites in the United States and enrolled patients between December 2006 and September 2009. Standard follow-up included physical examination, computed tomography, and chest radiography through 5 years.

Results: The study enrolled 160 patients. The average age was 72.2 years (range, 36-85 years), 95 (59%) were men, 150 (94%) had hypertension, and 26 (16%) had renal insufficiency. There were 50 patients (31%) who presented with symptoms; back pain was the most common (34 [68%]). The average aneurysm diameter was 57 mm (range, 32-96 mm). There were 103 patients (64%) with a fusiform aneurysm and 57 (36%) with a saccular aneurysm or penetrating ulcer. Two or more devices were implanted in 126 patients (79%), and the maximum number of grafts implanted was four. There were 54 deaths during the study. The 5-year actuarial survival was 64%. There were eight aneurysm-related deaths (5 deaths ≤30 days of implant), and the 5-year freedom from aneurysm-related death was 95%. There was one conversion to open repair at 36 months. Eleven patients underwent 13 secondary procedures (9 for endoleak, 3 for aneurysm expansion, and 1 rupture). Follow-up imaging was available at 5 years for 56 patients. The average aortic diameter decreased >5 mm in 27 patients (48%), increased >5 mm in 6 patients (11%), and remained unchanged in 23 (41%).

Conclusions: The VALOR II 5-year results demonstrate that the reintervention and aneurysm-related death rates are low. The Valiant Thoracic Stent Graft is an effective treatment of degenerative DTA. (J Vasc Surg 2017;66:335-42.)

Thoracic endovascular aortic repair (TEVAR) of descending thoracic aortic aneurysms (DTA) has replaced open repair as first-line therapy for anatomically suitable patients because of superior perioperative morbidity and mortality even in high-risk patients.[1-4] However, owing to the relative rarity of DTA compared with abdominal aortic aneurysms, thoracic endograft technology has evolved slowly. Early-generation stent grafts were plagued by large, cumbersome delivery systems, which did not easily traverse calcified or tortuous vessels, and by a lack of graft conformity to the aortic arch that led to graft collapse and other iatrogenic injuries.[5-7]

The Valiant Thoracic Stent Graft System (Medtronic Vascular, Santa Rosa, Calif) is a next-generation stent graft that contains a nitinol scaffolding attached to the outside of the graft material with proximal bare springs that aid in apposition of the graft along the curve of the aortic arch, and the stacked tubular construct of the graft facilitates accurate deployment and conformity to the aortic wall. In addition, the delivery system allows for better trackability, which facilitates advancement of the graft into the thoracic aorta, especially in tortuous and diseased vessels.

The VALOR II trial (Evaluation of the Clinical Performance of the Valiant Thoracic Stent Graft System in the Treatment of Descending Thoracic Aneurysms of Degenerative Etiology in Subjects Who Are Candidates for Endovascular Repair) was designed to test the

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safety and efficacy of this stent graft system. The 30-day and 1-year pivotal results have been reported and demonstrated that the Valiant Thoracic Stent Graft System is a safe and effective treatment for patients with DTA.[5] The trial has now completed long-term follow-up, and the 5-year results are reported here.

METHODS

Enrollment. The VALOR II trial is a multicenter, prospective, nonrandomized trial designed to evaluate the safety and efficacy of the Valiant Thoracic Stent Graft System for the treatment of descending thoracic aortic aneurysms (DTA). The trial enrolled patients at 24 institutions in the United States between December 2006 and September 2009. All patients enrolled in the study were considered to be reasonable risk for open surgical repair of DTA.

The complete list of anatomic and medical inclusion and exclusion criteria has been previously published.[5] In brief, the anatomic limits for the study included: (1) a ≥20 mm seal zone distal to the left common carotid artery and proximal to the origin of the celiac artery, (2) proximal and distal nonaneurysmal neck diameter between 20 and 42 mm, and (3) adequate access vessels or the ability to tolerate a vascular conduit. Anatomic enrollment criteria were evaluated by the implanting surgeon and verified by an independent physician reviewer. Patients with DTA rupture, connective tissue disease, or mycotic aneurysms were excluded from the study as were those who had undergone previous DTA repair and those with significant mural thrombus in either of the seal zones.

The trial was approved by the individual Institutional Review Boards of each participating institution, and all patients gave informed consent to participate.

Device description. The Valiant Thoracic Stent Graft has been previously described.[5] It is a tubular, self-expanding stent graft supported by a nitinol scaffolding that is attached to the outside of the graft material. Devices were available in up to 200 mm lengths. The proximal stent graft has an eight peak bare-metal fixation that is designed to improve contact along the proximal seal zone by distributing the radial force across the points of contact. The distal piece does not have a bare spring component on either end.

Definitions. Aneurysm-related death was defined as any death that occurred ≤30 days of the indexed procedure, within the same hospitalization, or any death secondary to thoracic aneurysm rupture, conversion to open repair, or after any additional procedure that was performed for a graft or aneurysm-related indication. Endoleaks were defined according to the standard nomenclature as types I to IV, with type V reserved for those of unknown origin. Graft migration was defined as movement of at least 10 mm in either direction compared with initial postoperative imaging. Aneurysm expansion was defined as an increase in maximum aortic diameter of >5 mm compared with the 1-month scan, and a sac regression was defined as a decrease in maximum diameter of >5 mm.

Follow-up. The standard follow-up protocol for the study included a physical examination, computed tomography angiography, and chest radiography at 1, 6, and 12 months and then yearly thereafter for 5 years. All imaging studies were performed at the participating sites and were then reviewed by a core laboratory, which made the final determination with regard to aortic-related events and changes in aortic diameter over

ARTICLE HIGHLIGHTS

- **Type of Research:** Prospective non-randomized multicenter trial
- **Take Home Message:** This prospective 5-year follow-up study of the Valiant graft (Medtronic Vascular, Santa Rosa, Calif) demonstrated a low rate of graft-related complications, infrequent need for reintervention, and a sustained protection from aneurysm-related events.
- **Recommendation:** The trial results support the recommendation that the Valiant Stent Graft is an excellent option for treatment of descending thoracic aortic aneurysms

Table I. Patient demographics

Variable	Mean ± SD or No. (%) (N = 160)
Age, years	72.2 ± 9.1
Male gender	95 (59)
Caucasian race	138 (86)
Tobacco use in last 10 years	71 (44)
Hypertension	150 (94)
Chronic obstructive pulmonary disease	57 (36)
Hyperlipidemia	118 (74)
Diabetes	34 (21)
Coronary artery disease	71 (44)
Congestive heart failure	20 (13)
History of	
Myocardial infarction	34 (21)
CABG	22 (14)
Stroke	17 (11)
Paraplegia/paraparesis	1 (1)
Abdominal aortic aneurysm	62 (39)
Ascending aneurysm	13 (8)
Renal insufficiency	26 (16)
Peripheral vascular disease	40 (25)
SVS 2-3	142 (89)

CABG, Coronary artery bypass grafting; *SD*, standard deviation; *SVS*, Society for Vascular Surgery.

Table II. Preimplant anatomic dimensions as reported by individual sites

Aneurysm dimension	Mean ± SD, mm	Median, mm	Minimum, mm	Maximum, mm
Proximal neck diameter	32.1 ± 4.5	32	20	42
Distal neck diameter	31.4 ± 5.2	31	21	42
Proximal neck length[a]	60.0 ± 39.2	40	20	198
Aneurysm length	117.0 ± 66.4	106	18	385
Distal neck length[b]	88.9 ± 59.0	70	20	286

SD, Standard deviation.
[a]Distance from the top of the arch to the proximal aneurysm.
[b]Distance of the nonaneurysmal neck to the celiac axis.

Table III. Patients with endoleaks and other device related safety measures reported during follow-up

Event	1 month, % (n/N)	1-12 months, % (n/N)	1-2 years, % (n/N)	2-3 years, % (n/N)	3-4 years, % (n/N)	4-5 years, % (n/N)
Endoleak	17.9 (25/140)	6.7 (9/134)	6.1 (6/98)	5.2 (4/77)	4.1 (3/73)	1.7 (1/60)
Type I	3.6 (5/140)	2.2 (3/134)	3.1 (3/98)	2.6 (2/77)	2.7 (2/73)	0.0 (0/60)
Type Ia (proximal)	0.7 (1/140)	0.7 (1/134)	0.0 (0/98)	0.0 (0/77)	0.0 (0/73)	0.0 (0/60)
Type Ib (distal)	2.9 (4/140)	1.5 (2/134)	3.1 (3/98)	2.6 (2/77)	2 (2.7)	0.0 (0/60)
Type II	10.7 (15/140)	4.5 (6/134)	1.0 (1/98)	0.0 (0/77)	0.0 (0/73)	1.7 (1/60)
Type III	0.7 (1/140)	0.0 (0/134)	0.0 (0/98)	0.0 (0/77)	0.0 (0/73)	0.0 (0/60)
Type IV	1.4 (2/140)	0.0 (0/134)	0.0 (0/98)	0.0 (0/77)	0.0 (0/73)	0.0 (0/60)
Type V (unknown)	1.4 (2/140)	0.7 (1/134)	2.0 (2/98)	2.6 (2/77)	1.4 (1/73)	0.0 (0/60)
Loss of patency	0.0 (0/140)	0.0 (0/134)	0.0 (0/98)	0.0 (0/77)	0.0 (0/73)	0.0 (0/60)
Migration	NA	0.0 (0/144)	0.0 (0/111)	0.0 (0/98)	0.0 (0/83)	0.0 (0/70)
Loss of stent graft integrity	0.0 (0/147)	0.0 (0/138)	0.0 (0/99)	0.0 (0/92)	0.0 (0/69)	0.0 (0/61)

time. All deaths and major adverse events were reported by the participating site and adjudicated by the clinical events committee to determine whether they were secondary to a failure of the device or related to the procedure, or both. Three patients were included on an intent-to-treat basis but did not receive a TEVAR, and an additional nine patients withdrew or were lost to follow-up during the 5-year study. The average follow-up for the entire study population was 46 months.

Statistics. Summary statistics of dichotomous variables are presented as the number in each category with the percentage of known values for each category. Continuous variables are expressed as a mean and standard deviation. Long-term outcomes were determined using Kaplan-Meier life-table analysis. A P value of $<.05$ was considered significant.

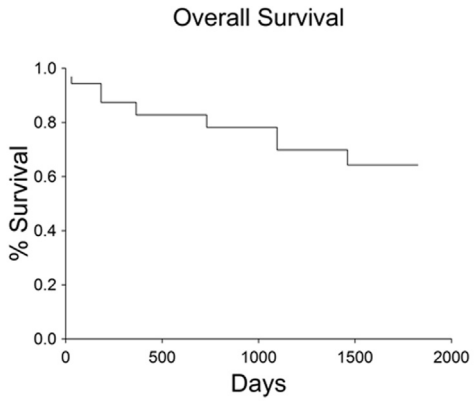
RESULTS

Study cohort. The study enrolled 160 patients. The average age was 72.2 ± 9.1 years (range, 36-85 years), 95 patients (59%) were men, and 138 (86%) were Caucasian. Most patients (94%) had a history of hypertension, and 26 (16%) had renal insufficiency. Demographics and clinical risk factors are summarized in Table I. At presentation, 50 patients (31%) were considered symptomatic, with the most common symptoms being back pain in 34 (21%) and chest pain in 25 (16%). Patients also presented with abdominal pain (2 [1%]), hoarseness (3 [2%]), and nausea (3 [2%]).

A fusiform aneurysm was present in 103 patients (64%) and a saccular aneurysm or penetrating ulcer in 57 (36%). The average aneurysm diameter was 57 ± 10.2 mm (range, 32-96 mm), and 134 (84%) had an aneurysm that was >50 mm at the time of device implantation. A review of the preimplant imaging showed that 139 patients (87%) had no thrombus in their proximal neck, and only eight (5%) were considered to have significant thrombus. The thrombus burden was similar in the distal neck, with 138 patients (86%) having none and 22 (14%) having some degree of thrombus in the seal zone. The site-reported preimplant anatomic measurements are summarized in Table II.

Two or more devices were implanted in 126 patients (79%), and the maximum number of grafts used was four in five patients (3%). The left subclavian artery was covered in 51 patients (33%) but was only revascularized in 22 (14%). A spinal drain was used in 86 patients (54%).

Open conversion and rupture. One conversion to open repair occurred during the 5-year follow-up period. The patient initially had two grafts placed covering zones 3 and 4. This patient then presented at 36 months with complaints of chest pain. A computed tomography



Days	30	183	365	731	1096	1461	1826
At Risk	160	155	151	135	125	116	100
% Survival	0.969	0.944	0.874	0.828	0.782	0.699	0.643
SE	0.014	0.018	0.026	0.03	0.033	0.037	0.039

Fig 1. Kaplan-Meier estimate for freedom from all-cause mortality over 5 years of the VALOR II (Evaluation of the Clinical Performance of the Valiant Thoracic Stent Graft System in the Treatment of Descending Thoracic Aneurysms of Degenerative Etiology in Subjects Who Are Candidates for Endovascular Repair) trial.

angiography showed an increase in sac size from 66 to 74 mm, without an obvious endoleak, and the patient underwent open conversion.

There were two patients with late aneurysm ruptures as well. In the first patient, three devices were placed covering zones 2 to 4, and a type Ib endoleak was identified at 1 year that resulted in a reintervention with placement of a distal extension. The patient then presented at day 605 with chest pain and was found to have aneurysm growth with a contained rupture secondary to a known persistent type Ib endoleak. The patient was treated endovascularly with a distal extension and did well, with resolution of the endoleak and seal of the rupture. The final patient had three devices placed covering zones 3 and 4, and a type Ib endoleak was identified at 1 year that was treated with a distal extension. The patient then presented at day 1062 with a free rupture and could not be saved.

Serious adverse advents. The distribution of serious adverse events during the 5-year follow-up period included pulmonary complications in 31.9% (51 of 160) of patients and renal events in 7.5% (12 of 160), with four patients experiencing renal failure during the study period. Cardiac events occurred in 24.4% (39 of 160) of the patients, and 20.6% (33 of 160) had a bleeding event. Neurologic events occurred in 17 of 160 patients (10.6%), with 2 patients (1.3%) experiencing paraplegia, 11 (6.9%) having a stroke or transient ischemic attack, and 4 having other events. Arterial vascular events occurred in 26.3% (42 of 160) of patients, and cancer developed in 11.9% (19 of 160). Overall, at least one major adverse event occurred in 84.4% (135 of 160) of patients during the 5-year follow-up period, and 15% (24 of 160) had a device-related event.

Device-related safety measures. No general graft complications were reported during the study period. There were no graft infections, no episodes of limb kinking or thrombosis, and no loss of graft patency. No graft perforations or wire form fractures were noted, and there was no graft migration over time. Endoleaks were observed in 24.2% (38 of 157) of patients with imaging follow-up during the study period, and most of these were type II. The details of endoleaks are presented in Table III.

Secondary interventions. During the study 13 secondary interventions performed in 11 patients. Interventions were performed for a new persistent type I endoleak in 9 patients, aneurysm expansion in 3, and rupture in 1. The average time to intervention was 900 days (range, 9-1586 days), and all interventions but one were performed after at least 1 year of follow-up.

Change in sac diameter. Follow-up imaging was evaluated for 79 patients at 3 years and 56 patients at 5 years. At the 3-year mark, 37 patients (47%) had a decrease in aortic diameter by >5 mm, 39 (49%) showed no change, and only 3 patients (4%) had an increase in size of >5 mm. At the 5-year mark, six of 56 patients (11%) showed an increase in sac size of >5 mm, and the rest showed a decrease in sac size (27 of 56 [48%]) or no change (23 of 56 [41%]).

Mortality. There were 54 deaths during the 5-year follow-up period, and the 5-year actuarial all-cause survival was 64.3% (Fig 1). The most common causes of death were cardiac related (19 of 54 [35%]) and secondary to cancer (8 of 54 [15%]). Two patients died of ruptured abdominal aortic aneurysms, and one patient died in a motor vehicle crash. The causes of death after TEVAR are summarized in Table IV. Five patients (3.8%) died ≤30 days of the indexed procedure, and one death occurred at 80 days but within the same hospitalization as the indexed procedure. In addition, there were two late aneurysm-related deaths for a total of eight aneurysm-related deaths. The 5-year freedom from aneurysm-related death was 94.8% (Fig 2). The details of the aneurysm-related deaths are summarized in Table V.

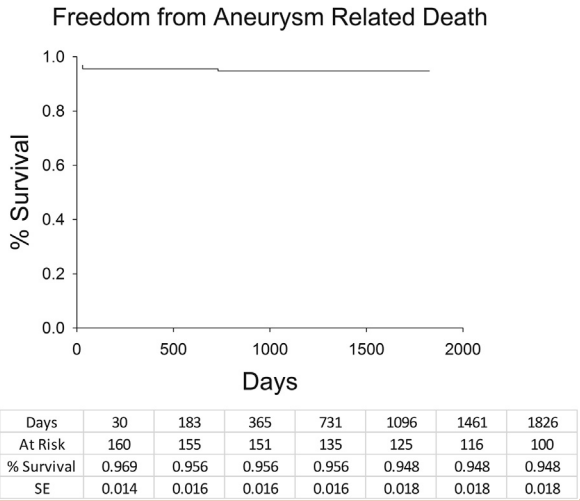
DISCUSSION

Most reports with long-term follow-up after TEVAR have included early-generation devices. The changes in the Valiant stent graft design were made to improve contact with the aorta along the proximal and distal seal zones through better graft conformity and proximal bare-metal fixation. This led to a decrease in early secondary procedures compared with the VALOR test group.[5] This report details the 5-year follow-up of these patients and adds to the limited literature from prospective, multicenter TEVAR trials of the next generation of

Table IV. Summary of all-cause mortality during the 5-year follow-up period after thoracic endovascular aortic repair (TEVAR)

Cause of death[a]	Patients, No.	Time to death, average (range), days	Comment
Cardiac related	19	943 (88-1668)	16 MI/arrest, 3 CHF
Aneurysm related	8	169 (0-1067)	Table V[b]
Cancer	8	995 (398-1643)	No leukemia or lymphoma
Pulmonary related	6	638 (259-1460)	2 COPD, 4 respiratory failure
Neurologic	4	518 (163-1326)	1 stroke, 3 ICB
GI bleed	3	992 (308-1519)	
AAA rupture	2	1481 (1288-1675)	Thoracic repair intact in both patients
ESRD	2	559 (340-689)	1 patient refused dialysis
Other	1	1249	Multisystem organ failure
Trauma	1	679	MVA, patient dead at scene

AAA, Abdominal aortic aneurysm; *CHF,* congestive heart failure; *COPD,* chronic obstructive pulmonary disease; *ESRD,* end-stage renal disease; *GI,* gastrointestinal; *ICB,* intracranial bleed; *MI,* myocardial infarction; *MVA,* motor vehicle accident.
[a]As adjudicated by the clinical events committee.
[b]Details of aneurysm-related deaths are presented in Table V.



Days	30	183	365	731	1096	1461	1826
At Risk	160	155	151	135	125	116	100
% Survival	0.969	0.956	0.956	0.956	0.948	0.948	0.948
SE	0.014	0.016	0.016	0.016	0.018	0.018	0.018

Fig 2. Kaplan-Meier estimate for freedom from aneurysm-related mortality over 5 years of the VALOR II (Evaluation of the Clinical Performance of the Valiant Thoracic Stent Graft System in the Treatment of Descending Thoracic Aneurysms of Degenerative Etiology in Subjects Who Are Candidates for Endovascular Repair) trial.

stent grafts. The graft performed very well over time, with a relatively small number of type I endoleaks, no loss of graft integrity, and no evidence of graft migration. These data support the improved durability of TEVAR for DTA with next-generation grafts in appropriate patients.

The need for secondary interventions after TEVAR can limit the long-term durability of the procedure. The rate of secondary intervention after elective TEVAR has been reported to range from 5% to 12%, depending on the duration of follow-up.[8-11] In a review of the European Collaborators on Stent-Graft Techniques for Abdominal Aortic Aneurysm Repair (EUROSTAR) registry, Leurs et al[11] noted a 12% reintervention rate with an average occurrence at 8 months, and most were performed because of endoleak or device-related complications. Dumfarth et al[9] evaluated 421 patients during a 13-year period and reported a 5% reintervention rate with a mean interval to occurrence of 24 months. Perioperative events were excluded, however, and this underscores the importance of patient selection in the promotion of long-term durability. In addition, Lee et al[10] reported a 10% reintervention rate in 83 patients, with seven procedures performed for persistent endoleak and one for aneurysm expansion without an identifiable endoleak. The reintervention rate of 7% in the current study compares favorably with these data because only one reintervention was performed in the early follow-up period and the average time to intervention was just under 3 years. This may be the result of improvement in device design but also is likely a reflection of the importance of adherence to a graft's instructions for use when planning TEVAR procedures.

Most of the late interventions in the study were performed because of persistent type I endoleaks or for aneurysm expansion where the source of the endoleak could not be identified. This is common to other studies. In a literature review in 2010, Ricotta[12] noted that the most commonly reported type of endoleak requiring intervention after TEVAR was type I, thought to be related to the challenge of obtaining an adequate seal in the tortuous aortic arch with stiff and often unforgiving grafts. Wiedmann et al[13] recently reported a 14-year experience (1996-2010) with 300 TEVARs and noted type I endoleaks in 16% of patients. Early industry-sponsored trials reported similar results with a greater number of type I endoleaks than type II.[14,15]

Improvements in graft design and operative technique have led to a decrease in the incidence of type I endoleaks. Desai et al[16] compared a cohort of 502 TEVAR patients treated from 1999 to 2009 and divided them into early and late groups. They found that the

Table V. Details of aneurysm-related deaths in the VALOR II trial

Patient	Time to death, days	Cause of death	Why aneurysm related	Procedure/device related[a]
1	0	Aortic rupture	Aortic rupture	Both
2	3	Aortic dissection	Aortic dissection	Both
3	3	Sepsis, multisystem organ failure, mesenteric infarction	30-day death	Procedure
4	12	Aspiration pneumonia	30-day death	Procedure
5	21	Respiratory failure	30-day death	Procedure
6	80	Cardiac standstill, patient never left hospital after index procedure	Death related to procedure	Both
7	163	Acute type A dissection	Aortic dissection	Device
8	1067	Aortic rupture	Aortic rupture	Device

VALOR II, Evaluation of the Clinical Performance of the Valiant Thoracic Stent Graft System in the Treatment of Descending Thoracic Aneurysms of Degenerative Etiology in Subjects Who Are Candidates for Endovascular Repair.
[a]As adjudicated by the clinical events committee.

perioperative endoleak rate in the late group was almost half that of the early group.[16] In addition, a report of the 5-year results of a next-generation thoracic graft yielded few type I endoleaks.[17] Indeed, the overall type I endoleak rate in the current study was 8.3%, which is an improvement over results with earlier generation grafts.

The best management of type II endoleaks after TEVAR remains unknown. In the current study, the first follow-up computed tomography scan showed 10.7% of patients had a type II endoleak, but only one persisted after 1 year of follow-up. One patient underwent an intervention on postoperative day 5, and the remaining endoleaks appear to have resolved spontaneously. This yields a reintervention rate of 0.7% for type II endoleaks and supports the notion that this is a benign entity.

Bischoff et al[18] monitored 30 type II endoleaks after TEVAR (8.7% of their total population) and reported a 30% rate of intervention but that most of their endoleaks (7 of 9) originated from the left subclavian artery or celiac trunk where proximity to seal zones and large vessel size can cause these to behave like a type I endoleak. Alsac et al[19] reported a 19.4% endoleak rate with an average follow-up of 27 months, but only 29% of these were type II. They managed all of these conservatively, and 25% spontaneously thrombosed during follow-up. Finally, Morales et al[20] identified 13 type II endoleaks in 200 TEVAR patients during a mean follow-up of 30 months. Three were from the left subclavian artery and were successfully treated. The remaining 10, which were from intercostal and bronchial arteries, were managed conservatively, and all spontaneously resolved with no associated enlargement in sac size.[20] It is clear that type II endoleaks that arise from the left subclavian artery should be treated, whereas those that originate from intercostal or bronchial arteries can be observed with the expectation of spontaneous resolution over time.

One surrogate measure for successful aneurysm exclusion is decrease in sac size over time. Factors that influence this include the presence of intramural thrombus, endoleaks, and the transmission of endotension through the graft. This is often hard to quantify over time because of patient attrition resulting from death, reintervention, or lack of follow-up. However, change in sac diameter is a major predictor of late rupture and, therefore, is often the indication for reintervention. In the current study, changes in sac diameters were calculated at each time point in relation to the sac diameter on the initial 1-month scan. At 5 years, 89% of the patients had a decrease or no change in sac diameter. This is slightly better than the 84.5% result seen at 5 years in the VALOR trial and confirms that most patients will have a durable result after TEVAR.[14]

The ultimate goal of any repair of thoracic aortic aneurysms is to prevent aneurysm-related death. This was defined in the current study as any death ≤30 days of the procedure, any death within the same hospitalization as the procedure, or late death from a thoracic aneurysm-related cause. The overall aneurysm-related mortality for this cohort was 5%, with five of eight deaths occurring ≤30 days of the initial procedure and one cardiac event occurring at 80 days; however, the patient was not discharged after the initial procedure. These results are in agreement with other industry-sponsored trials that reported similar 5-year aneurysm-related mortality rates.[15,17] The late thoracic aortic-related deaths in this trial included one type A dissection (163 days) and one aortic rupture (1062 days). This yields an aortic-related death rate of 1.2% in patients that survived the initial TEVAR procedure.

Fattori et al[21] detailed long-term follow-up from a retrospective registry of 422 patients who survived the initial TEVAR procedure and identified 11 late aortic-related deaths (2.4%), thus confirming the long-term efficacy of TEVAR. However, these excellent results may be driven by patient selection within the confines of a multicenter trial. A recent report by von Allmen et al[22] used linked hospital data from the National Health Service database in England to identify 354 patients who underwent

TEVAR for intact thoracic aneurysms and reported a 5-year aneurysm-related mortality of 17.6%.

No randomized study has compared open vs endovascular repair of DTA, and it is unlikely that one will ever be performed. To wit, the comparative effectiveness of open repair and TEVAR on long-term survival has been evaluated through historic controls and administrative databases. Conrad et al[4] compared open repair vs TEVAR in the Medicare population from 2004 to 2007 and found that although TEVAR offered an early survival advantage, the curves crossed at 5 years and yielded no difference between the two groups (55.8% TEVAR vs 59.7% open). In addition, Goodney et al[23] showed similar results in patients from 1998 to 2007, where the 5-year survival was 72% after open repair vs 62% after TEVAR. Both studies were performed during the infancy of TEVAR, and it is possible that many patients undergoing TEVAR during that era would not have been considered open surgical candidates because of prohibitive risk. More recent studies have yielded a 5-year survival after TEVAR that ranges from 55% to 65%.[13,17,24] The 5-year survival of 64% in the current study falls at that high end of that range and reflects a healthier population and low aortic-related mortality.

CONCLUSIONS

This multicenter trial of the Valiant Thoracic Stent Graft System has completed 5 years of prospective follow-up and confirmed that this graft can be used to safely treat DTA. These data have demonstrated a low rate of graft-related complications, infrequent need for reintervention, and a sustained protection from aneurysm-related events such as rupture and death. The changes in graft design have improved conformability to the proximal seal zone and decreased the incidence of type I endoleaks. Late events do occur, and long-term follow-up is necessary to maintain these results.

AUTHOR CONTRIBUTIONS

Conception and design: MC, JT, RF, JB, RF, RW
Analysis and interpretation: MC
Data collection: JT, RF, JB, RF, RW
Writing the article: MC, JT, RF, JB, RF, RW
Critical revision of the article: MC, JT, RF, JB, RF, RW
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INVITED COMMENTARY

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Thoracic endovascular aortic repair (TEVAR) is now the treatment of choice for most, if not all, thoracic aortic pathology. The study, "Five-year results of the VALOR II trial of the Medtronic Valiant Thoracic Stent Graft," provides additional contemporary information on the durability and effectiveness of TEVAR. The authors, on behalf of VALOR II investigators, detail the 5-year outcomes of 160 patients with descending thoracic aortic aneurysms treated by the Valiant stent graft (Medtronic, Minneapolis, Minn).

The ultimate goal of TEVAR is durable prevention of aortic rupture. This was achieved in the current study, as indicated by a 95% freedom from thoracic aneurysm-related death at 5 years. Endoleaks were documented in 24% of patients, but most were type II, and less than one-third required reintervention. Conversion to open repair was necessary in only one patient. Aneurysm sac expansion, currently the best surrogate marker for potential risk of rupture, was seen in only 4% of patients at 5 years, whereas sac shrinkage, a marker for complete aneurysm exclusion, occurred in almost 50%.

Other device-related outcomes were infrequent, with no documented wire fracture, fabric tear, infection, migration, or loss of graft patency. These device-related outcomes represent an improvement from the previous-generation Medtronic device, which was based on the Talent stent graft construct.[1,2] These outcomes are also superior to other first-generation thoracic stent grafts, where wire fractures were documented in TX2 (4%; Cook Medical, Bloomington, Ind) and TAG (14%; W. L. Gore & Associates, Flagstaff, Ariz), and device migration was observed in TX2 (7.5%).[3,4] Medtronic's improvements in design were aimed at increasing graft apposition to the aortic wall and facilitating conformability and trackability. The results documented by the authors show this was achieved and associated with long-term durability, absence of device failure, and prevention of aneurysm rupture.

However, these excellent results should be interpreted in the context of the patients included in the study. As is the case with all pivotal stent graft trials, strict adherence to the instructions for use is a given. In VALOR II, this resulted in a highly selected group of patients in which focal aortic pathologies, namely penetrating ulcers and saccular aneurysms, comprised one-third of the entire cohort. This was attended by an overall stent graft sealing configuration that consisted of a mean proximal neck length of 60 mm and distal neck length of 89 mm for aneurysms that were an average length of 117 mm. These seal lengths are far in excess of the 20 mm recommended by the instructions for use and clearly different from those in most patients treated by TEVAR in contemporary surgical practice.

Nevertheless, the VALOR II experience documents that continued refinements in stent design do result in improvements in the durability and effectiveness of TEVAR. Patient outcomes are incrementally improved, and endovascular insights into the necessary structural requirements for graft apposition and conformability in the thoracic aorta are advanced. These advances are necessary foundational steps toward the goal of achieving the next frontier; namely, total endovascular management of pathology involving the ascending aorta and aortic arch.

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