Five-Year Outcomes From the United States Pivotal Trial of Valiant Captivia Stent Graft for Blunt Aortic Injury

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Background. **The Clinical PeRformancE of the Valiant Thoracic Stent Graft with Capitvia Delivery System for the EndovaSCUlar treatment of Blunt Thoracic Aortic Injuries (RESCUE) study evaluating thoracic endovascular repair using the Valiant Captivia endograft for blunt thoracic aortic injury reported promising 30-day outcomes. We now describe 5 years of follow-up of this cohort.**

Methods. **Fifty patients (mean age 40.7 ± 17.4 years, 76% male, mean injury severity score 38 ± 14.4) were treated for blunt thoracic aortic injury (2010 to 2012) with this endograft. Seventy percent (n = 35) of blunt thoracic aortic injury extent was grade III or higher. Extent of arch repair required full (40%) or partial (18%) left subclavian artery coverage. At 5 years, clinical and imaging compliance was 90.3% (28 of 31) and 67.7% (21 of 31), respectively.**

Results. **Thirty-day mortality was 8%. Three additional patients died of non–device-related causes (respiratory failure, infection, metastatic cancer) through 5-year follow-up, yielding a Kaplan-Meier survival of 85.2% through 5 years. Neither stroke nor spinal cord ischemia was observed at 5 years. Two type II endoleaks seen at 30 days resolved spontaneously, and no additional endoleaks were described in the study cohort through 5 years. No secondary endovascular procedures or conversion to open surgery were reported through 5 years. Four subjects underwent left subclavian revascularization for symptomatic indications. Finally, complete exclusion of the traumatic injury was maintained with no incidences of stent graft kinking, fracture, loss of patency, or migration through 5 years in all patients.**

Conclusions. **This multicenter clinical trial describes excellent 5-year outcomes and durable exclusion of blunt thoracic aortic injury using a novel stent graft system. Thoracic endovascular repair with this endograft appears to be a safe and effective treatment option for patients with blunt thoracic aortic injury.**

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Blunt thoracic aortic injury (BTAI) is the second leading cause of mortality from nonpenetrating trauma in the United States.[1] Although it is estimated that more than 85% of patients sustaining this injury die before hospital admission, nonoperative management has traditionally been associated with high inhospital mortality.[2] Since the commercial introduction of thoracic endovascular aortic repair (TEVAR) in 2005, it has emerged as the dominant method of treatment for BTAI. Potential advantages of this paradigm over conventional open repair include reduction of early morbidity as well as avoidance of thoracotomy.[3-6]

We previously reported early results of TEVAR for BTAI with the Medtronic Valiant Captivia thoracic stent graft system.[7,8] This study describes the 5-year results of the Food and Drug Administration-sponsored multicenter RESCUE clinical trial.

Patients and Methods

The Clinical PeRformancE of the Valiant Thoracic Stent Graft with Capitvia Delivery System for the EndovaSCUlar treatment of Blunt Thoracic Aortic Injuries (RESCUE) trial (NCT#01092767) is a prospective, nonrandomized study evaluating the Valiant thoracic stent

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graft system with the Captivia delivery system (Medtronic, Santa Rosa, CA) for the treatment of blunt thoracic aortic injury. Briefly, subjects were required to be more than 18 years old, meet specific anatomic criteria, and treated within 30 days of their BTAI (complete inclusion and exclusion criteria are listed in Table 1). A total of 50 subjects at 20 sites across North America underwent TEVAR with the Valiant stent graft system for BTAI. Before patient enrollment, the trial protocol and informed consent form were approved by local Institutional Review Boards in the United States or Research Ethics Board in Canada. Informed consent was obtained from all patients, and the trial conformed to the Declaration of Helsinki and applicable local regulations. Trial enrollment occurred between April 2010 and January 2012, and the 5-year results are complete as of the final data lock in May 2017.

Full data monitoring protocols and follow-up schedules can be found in the previous reports of the 30-day and 1-year results.[7,8] The primary endpoint of the trial was 30-day all-cause mortality. Secondary endpoints, including delivery and deployment success, adverse events, and aortic related mortality through 30 days, have been previously reported.[7] The yearly follow-up visits starting at 12 months and continuing through 5 years included a physical examination, contrast-enhanced computed tomography angiogram or contrast-enhanced magnetic resonance angiogram, and an adverse event assessment. In addition, chest radiographs were required at the 1-, 3-, and 5-year visits. Whereas Core Laboratory data were available at timepoints up to the 12-month visit, only site-reported data were available for the yearly follow-ups at 2, 3, 4, and 5 years.

Statistical Analysis

Summary statistics are presented as a mean ± SD for continuous variables and as a percentage of patients for categoric variables. Kaplan-Meier survival analyses were used to assess all-cause mortality, procedure- or aortic-related adverse events, and secondary procedures through 5 years. Device oversizing was calculated using the proximal stent diameter (P) and aorta diameter 2 cm proximal to the injury (A) following the formula: percent oversizing = 100*(P-A)/A. Analyses were performed using SAS 9.4 (SAS Institute, Cary, NC).

Table 1. Inclusion and Exclusion Criteria

Inclusion criteria
Subject has blunt thoracic aortic injury:
Confirmed, at a minimum, by diagnostic contrast-enhanced CTA or contrast-enhanced MRA
Which occurred no more than 30 days before the stent implant procedure.
Subject is 18 years of age or more.
Subject or subject's legally authorized representative has signed IRB-approved informed consent.
Subject is hemodynamically stable.
Subject's anatomy must meet all of the following anatomic criteria:
Aortic diameter (adventitia to adventitia) of proximal and distal landing zones must be 18 to 44 mm.
Patent iliac or femoral arteries or can tolerate iliac conduit allowing endovascular access to injury site with delivery system of appropriate sized device.
Centerline distance from distal margin of LCCA to injury must be ≥20 mm.
Exclusion criteria
Planned placement of covered portion of stent graft over celiac axis or CCA, or in case of bovine anatomy, innominate artery.
Subject has systemic infection.
Subject is pregnant.
Subject has received previous stent or stent graft or previous surgical repair in DTA.
Subject has history of bleeding diathesis, coagulopathy, or refuses blood transfusion.
Subject is participating in an investigational drug or device clinical trial that would interfere with endpoints or follow-up of this study.
Subject has known allergy or intolerance to device components.
Subject has known hypersensitivity or contraindication to anticoagulants or contrast media, not amenable to pretreatment.
Subject is in extremis, defined as having nonsurvivable injury or condition.
Subject has had cerebrovascular accident within 2 months before implant procedure.

CCA, common carotid artery; CTA, computed tomography angiogram; DTA, descending thoracic artery; IRB, Institutional Review Board; LCCA, left common carotid artery; MRA, magnetic resonance angiogram.

Results

Demographics and comorbidities of the 50 enrolled subjects are provided in Table 2. Subjects had a mean age of 40.7 ± 17.4 years and were predominantly male (76%) and Caucasian (68%). Hypertension was the most prevalent comorbid condition (24.5%). As previously reported,[1,2] the main cause of BTAI was motor vehicle accidents (60%). The location of the aortic injury was primarily in the isthmus (84%) with a grade III or IV severity (70%, n = 35). Investigators reported successful device access, delivery, and deployment in all 50 subjects with a mean device oversizing of 11.5%, and 90% of subjects (45 of 50) with oversizing between 0% and 20% (Figure 1). Compliance with clinical follow-up through 5 years was 90.3% (28 of 31), with 7 deaths, 3 subjects voluntarily withdrawing from the study, and 9 subjects lost to follow-up after several contact attempts by research staff. Compliance with imaging follow-up through 5 years was 67.7% (21 of 31).

Late Mortality

There was an 85.2% freedom from all-cause mortality through 5 years in the Kaplan-Meier survival analysis (Figure 2). Four subjects died within the first 30 days, as discussed in detail previously.[7] Through the remainder of the trial, 3 subjects died on postimplant days 59, 169, and 1086 as a result of respiratory failure, infection, and seizure from stage IV cancer. All of the deaths were adjudicated by the Clinical Events Committee to be

Table 2. Subject Baseline Demographics and Medical History

Baseline Demographics[a]	Values
Age, y	40.7 ± 17.4 (50)
Male	76 (38/50)
Ethnicity	
Hispanic or Latino	20 (10/50)
Not Hispanic or Latino	72 (36/50)
Not available	8 (4/50)
Race	
White	68 (34/50)
Black or African American	20 (10/50)
Asian	4 (2/50)
Other	4 (2/50)
Not available	4 (2/50)
Subject medical history[b]	
Diabetes mellitus	2 (1/49)
Congestive heart failure	2 (1/49)
Myocardial infarction	0 (0/49)
Hypertension	24.5 (12/49)
Chronic obstructive pulmonary disease	4.1 (2/49)
Paraplegia	2 (1/49)
Gastrointestinal conditions[c]	2.1 (1/48)
Stroke	0 (0/49)
Renal insufficiency	0 (0/49)
Extent of injuries	
Injury Severity Score	35 (13-75)
Extent of aortic injury	
Grade 1, intimal tear	18 (9/50)
Grade II, intramural hematoma	12 (6/50)
Grade III, aortic pseudoaneurysm	68 (34/50)
Grade IV, free rupture	2 (1/50)

[a]Based on intent to treat subjects with available data; [b]Based on number of enrolled subjects with available data; subject 00182-001 died of injuries before answering medical history questionnaire; [c]Gastrointestinal condition was listed as unknown for subject 00325-003.

Values are mean ± SD, percent (n/N), or median (range).

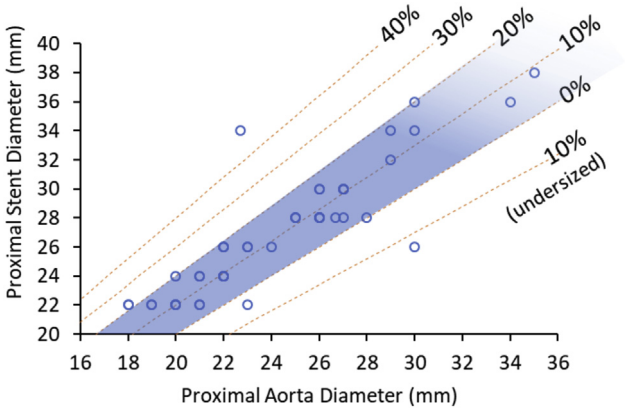

Figure 1. Extent of device oversizing. All but 3 patients were treated with devices oversized by 0% to 20% as reported by the sites. There were no consequences related to sizing outside traditional windows, and in particular, no instances of endoleak, rupture, migration, or secondary aortic procedures.

unrelated to the device, procedure, or the aorta. Additional details on these events are as follows.

SUBJECT 00339-003. A 76-year-old man presented with a BTAI with an Injury Severity Score of 38 and medical history including chronic obstructive pulmonary disease and lung cancer, for which he was receiving chemoradiation. The TEVAR was successful but the patient was unable to wean from ventilatory support secondary to his underlying lung disease. Care was eventually withdrawn, and the site identified the cause of death as respiratory failure secondary to pneumonia, underlying chronic obstructive pulmonary disease, and lung cancer.

SUBJECT 00340-004. A 74-year-old woman presented with a BTAI, an Injury Severity Score of 38. The TEVAR was successful and the subject completed the 1-month follow-up visit with no complications. On day 169 after the procedure, the subject was admitted as unresponsive, and computed tomography angiogram imaging was consistent with bowel ischemia. The site identified the cause of death as infection not related to the device.

SUBJECT 00325-001. A 43-year-old man presented with BTAI, an Injury Severity Score of 41, and medical history including metastatic stage IV prostate cancer. The TEVAR was successful and the subject completed follow-up visits through 24 months with no complications. Three years later, the subject had a seizure, which was presumed to be secondary to brain metastasis from his stage IV cancer. The subject was admitted to a hospice care unit, where he died. The site identified the cause of death as recurrent metastatic prostate cancer.

Adverse Events

Serious adverse events are presented in Table 3, and none were device related as determined by site investigators. Notably, the two neurologic adverse events were anoxic encephalopathy and convulsion; there were no occurrences of stroke or paraparesis through 5 years. There were four vascular-related adverse events in the first year, including one femoral artery dissection secondary to access, one case of intermittent claudication, and two cases of peripheral ischemia. Cardiac adverse events included 1 patient with an arrhythmia and 1 with myocardial infarction. Kaplan-Meier analysis shows the majority of events occurred within the first 30 days after the procedure (Figure 3).

Late Aortic-Related Events

In this population of BTAI patients, there were no reported cases of retrograde type A dissections, conversions to open repair, or aortic perforations through 5 years. The traumatic injury was successfully covered and stent graft integrity was maintained through 5 years in 100% of the patients. There were no site-reported incidents of stent graft migration, fracture, loss of patency, kinking, or twisting. Although there were two site reported type II endoleaks at the end of the procedure, these were no

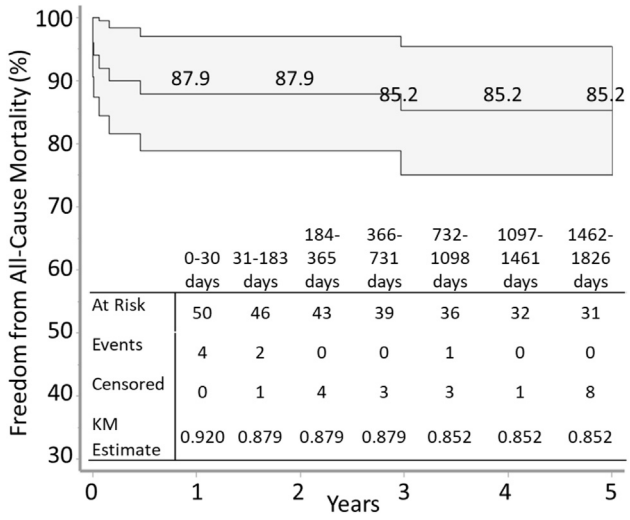

Figure 2. Freedom from all-cause mortality. Kaplan-Meier (KM) analysis shows 5-year freedom from all-cause mortality was 85.2%.

longer visible at the 1-month visits.[7,8] Through 5-year follow-up, there were no type I or III endoleaks. Kaplan-Meier freedom from secondary procedures is shown in Figure 4. Four reinterventions, all left subclavian artery bypasses, were required for symptomatic left subclavian artery (LSA) coverage. Details on these events are as follows.

SUBJECT 00112-004. This subject had intentional complete coverage of the LSA during TEVAR and had left arm claudication on day 30 after the procedure. The patient underwent a left carotid artery to subclavian artery bypass on postprocedure day 103, leading to resolution of symptoms 21 days after surgery.

SUBJECT 00344-002. This patient had intentional complete coverage of the LSA during TEVAR and had upper left upper extremity ischemia on postprocedure day 36. The patient underwent LSA bypass on postprocedure day 36 and it led to immediate relief of symptoms.

SUBJECT 00325-002. This patient had partial coverage of the LSA during TEVAR and had peripheral arm ischemia on day 7 after the procedure. The patient underwent LSA bypass on postprocedure day 9, leading to resolution of symptoms.

SUBJECT 05010-002. This subject had partial coverage of the LSA and left arm pain developed on day 176 after the procedure. The subject underwent LSA bypass on postprocedure day 784 and it led to resolution of the event.

Comment

The paradigm of treatment for blunt thoracic aortic injury in the United States has shifted.[4,5] Observation of low-grade injury, defined as intimal injury without dissection, pseudoaneurysm formation, or rupture, is emerging as a potential therapeutic option, particularly as improved imaging techniques have redefined pathoanatomic extent and progression of traumatic aortic wall injuries.[7,9] Multicenter prospective studies from the American Association for the Surgery of Trauma have been helpful in defining the changing roles of open and endovascular approaches. In the decade between the first (1997) and second (2007) American Association for the Surgery of Trauma trials, TEVAR assumed a dominant role, albeit with a high risk (20%) for device-related complications. A recent report using data from the National Trauma Data Bank suggested a reduced operative mortality from 16.6% for open repair to 9.3% after TEVAR.[5]

Although national data have suggested that early outcomes are better with TEVAR, late results— particularly in aortic pathologies frequently occurring in the younger patient population—are less understood.[6] In addition, the original stent grafts approved by the Food and Drug Administration were better suited for straighter portions of the aorta, and less well designed to address the narrow curvature and the often hostile "gothic" anatomy of the aortic arch in a young patient.[6] Additional considerations unique to arch TEVAR include the hemodynamic and stress/strain physical force differences between the aortic arch and infrarenal abdominal aorta. The anatomic tortuosity that can occur in the aortic arch and descending thoracic aorta and the added risk for developing retrograde type A dissection are also considerations when placing an endograft in this location.

With these known anatomic challenges in the region of the aortic arch and the limitations of first-generation stent graft design in mind, the Valiant thoracic stent graft with Captivia delivery system was designed. The RESCUE study was a prospectively designed multicenter Food and Drug Administration-sponsored descriptive study to evaluate this device system in 50 patients with BTAI. The primary endpoint of acceptable 30-day all-cause mortality (8%, n = 4), 1-year survival of 87.9%, and 1-year freedom from aortic-related mortality of 95.9% have been previously reported.[7,8]

The current study focuses on 5-year outcomes of the original cohort. In this report, the 5-year Kaplan-Meier survival was 85.2%, with 3 deaths reported after 30 days. None of these was adjudicated as related to the device by the Clinical Events Committee. No device-, procedure-, or aorta-related deaths occurred after 6 months. Importantly, through the 5-year study period, there were no reports of stroke, retrograde type A dissection, or endoleak. All secondary procedures were related to left subclavian artery coverage for patients who did not undergo LSA bypass at the time of TEVAR.

In considering these results, several questions arise. First, for BTAI, where the risk of developing a new endoleak after TEVAR is likely lower than when TEVAR is performed for other aortic pathologies, can the frequency of imaging follow-up be reduced, given the younger patient population demographics and the radiation risks associated with frequent computed tomography angiograms? Second, in this typically younger patient population, if the only late secondary procedure is likely to be LSA revascularization, does this suggest that the next step in advancing trauma care with endovascular methods should revolve around development of

Table 3. Serious Adverse Events

Category	Number of Days					
	0 to 30	31 to 365	366 to 731	732 to 1096	1097 to 1461	1462 to 1826
Total	18 (9/50)	6.5 (3/46)	0 (0/39)	5.6 (2/36)	0 (0/32)	3.2 (1/31)
Cardiac disorders	2 (1/50)	0 (0/46)	0 (0/39)	0 (0/36)	0 (0/32)	3.2 (1/31)
Gastrointestinal disorders	0 (0/50)	0 (0/46)	0 (0/39)	2.8 (1/36)	0 (0/32)	0 (0/31)
Infections and infestations	0 (0/50)	2.2 (1/46)	0 (0/39)	0 (0/36)	0 (0/32)	0 (0/31)
Injury, poisoning, and procedural complications	6 (3/50)	0 (0/46)	0 (0/39)	0 (0/36)	0 (0/32)	0 (0/31)
Musculoskeletal and connective tissue disorders	0 (0/50)	2.2 (1/46)	0 (0/39)	0 (0/36)	0 (0/32)	0 (0/31)
Nervous system disorders	2 (1/50)	0 (0/46)	0 (0/39)	2.8 (1/36)	0 (0/32)	0 (0/31)
Respiratory, thoracic, and mediastinal disorders	4 (2/50)	0 (0/46)	0 (0/39)	0 (0/36)	0 (0/32)	0 (0/31)
Vascular disorders	6 (3/50)	2.2 (1/46)	0 (0/39)	0 (0/36)	0 (0/32)	0 (0/31)

Values are percent (number of subjects in category/number of subjects who had serious adverse event or who died during the interval or who were followed at least until the lower endpoint of the interval).

branched devices for the distal aortic arch? This study revealed that 58% of the cohort had either partial or complete LSA coverage, suggesting that patients with BTAI would benefit from branched arch TEVAR. Third, should further engineering refinements in stent graft compliance occur to address the needs of this typically younger patient population? As a recent computational and clinical study by van Bakel and colleagues[10] suggests, by virtue of placement of a graft stiffer than native aorta in the chest, thoracic aortic repair may increase the impedance on cardiac ejection and lead to adverse cardiac remodeling over decades of life.

Limitations of this study include the lack of randomization, the relatively small study population, and the number of patients (9) lost to follow-up in this cohort of patients. This phenomenon has been reported as prevalent particularly among patients with BTAI. An additional limitation is the lack of Core Laboratory follow-up and data for years 2 to 5. Although no instances of stent graft kinking, twisting, fracture, or loss of patency were required to be specified (none observed), proximal and distal neck diameter evolution was not captured. Prior work suggests these data are important to secure in future BTAI studies as the aorta is expected to grow with increasing age.[11] This type of data is most important in the younger patient population. Device sizing is often difficult, particularly if TEVAR is performed emergently when the patient is dehydrated and the observed aortic diameter is not a reflection of its actual diameter when a young patient is fully hydrated and hemodynamically stable.[12] In our study, 10% of patients were outside the typical 0% to 20% oversizing guidelines, and particularly in this group, anatomic detail may have been instructive. Another limitation includes the lack of intracranial vascular anatomy, which could potentially inform the reader of the risk of left subclavian territory ischemia in patients who required delayed revascularization. Finally, a definition and incidence with extent of "bird beaking" of the leading proximal

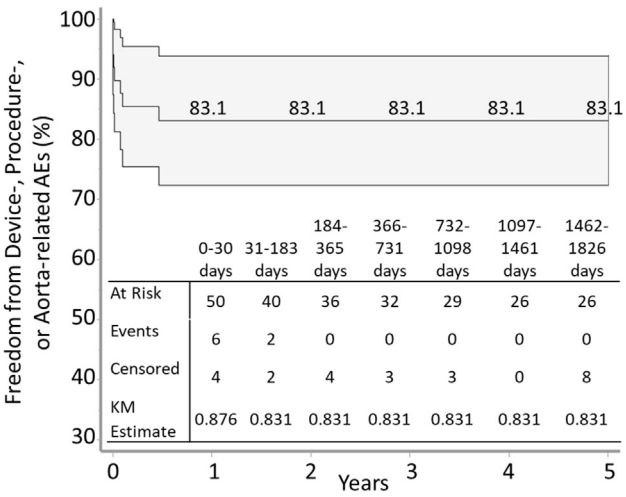

Figure 3. Freedom from adverse events. Kaplan-Meier (KM) analysis shows freedom from device-, procedure-, or aortic-related adverse events (AEs) of 83.1% at 5 years, with the majority occurring within the first 30 days after the procedure.

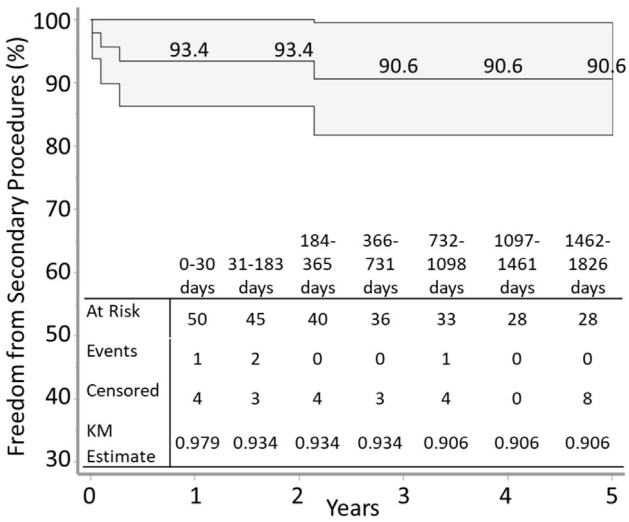

Figure 4. Freedom from secondary procedures. Five-year freedom from secondary procedures was 90.6%. All secondary aortic procedures were related to arm ischemia in patients who underwent thoracic endovascular aortic repair with left subclavian artery coverage. There were no instances of conversion to open repair, late endoleaks, or loss of stent graft patency. (KM, Kaplan-Meier.)

edge of the stent graft could also have been instructive in determining the rate of future complications. However, no cases of endograft collapse were identified in this study.

We conclude that the multicenter RESCUE study reveals excellent midterm results with the Valiant Captivia thoracic stent graft system in the treatment of BTAI. The late risk for aortic-related complication, treatment, or device failure and mortality is relatively low. Further studies will elucidate the long-term durability of this treatment paradigm for BTAI.

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