CLINICAL RESEARCH STUDIES

Results of a multicenter, prospective trial of thoracic endovascular aortic repair for blunt thoracic aortic injury (RESCUE trial)

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Objective: **To evaluate the early outcomes of patients undergoing thoracic endovascular aortic repair for blunt thoracic aortic injuries.**

Methods: **A prospective, nonrandomized, multicenter trial using the Medtronic Valiant Captivia stent graft was conducted at 20 sites in North America. Fifty patients with blunt thoracic aortic injuries were enrolled between April 2010 and January 2012 and will be followed for 5 years. The injuries were classified into categories (grades I-IV) based on severity: intimal tear, intramural hematoma, pseudoaneurysm, or rupture. The primary end point was 30-day all-cause mortality. Secondary end points were adverse events occurring within 30 days that were related to the procedure, device or aorta, and aortic-related mortality. Technical success was measured as successful device delivery and deployment.**

Results: **Seventy-six percent (38/50) of patients were male with mean age of 41 ± 17 years. Fifty-one Medtronic Valiant Captivia thoracic stent grafts and a single Talent thoracic stent graft were implanted within a median of 1.0 days following injury (mean, 1.8 ± 4.0 days). Seventy percent (35/50) of aortic injuries were grade III or higher, including one patient with free rupture. Mean injury severity score was 38 ± 14. Fifty-four percent of stent grafts were ≤26 mm (28/52). The left subclavian artery was completely covered in 40% of patients (20/50) and partially covered in 18% of patients (9/50). Four patients underwent subclavian artery revascularization: one at the time of the endograft procedure and three others after developing arm ischemia after the initial endograft procedure. Cerebral spinal fluid was drained in two patients. The median procedure time was 91 minutes, and median hospital stay was 12 days. There was 100% successful device delivery and deployment. Four (8%) patients died within 30 days. Nonfatal adverse events within 30 days that were related to the procedure, device, or aorta were experienced by 12% (6/50) of patients. No nonfatal adverse events related to the device were reported; a single death was conservatively adjudicated as device-, procedure-, and aorta-related because of insufficient information. No patient developed spinal cord injury, and there were no cerebrovascular accidents. However, one patient had an anoxic brain injury following aortic rupture. No patient underwent conversion to open repair or required an endovascular reintervention.**

Conclusions: **Based on the early outcomes, the Medtronic Valiant Captivia stent graft appears to be a promising treatment modality for blunt thoracic aortic injuries. Long-term follow-up is necessary to substantiate the effectiveness of thoracic endovascular aortic repair in treatment of blunt thoracic aortic injuries. (J Vasc Surg 2013;57:899-905.)**

Blunt thoracic aortic injury (BTAI) remains the second leading cause of death from blunt trauma after head injury,[1] with preadmission mortality as high as 85%,[2] despite modern advances.[3] Thoracic aortic injury is involved in a third of blunt injury cases, with the majority of deaths occurring at the scene.[4] Based on a report from the National Trauma Databank,[5] 0.3% of trauma admissions in the United States represent patients with blunt aortic injury. Thoracic endovascular aortic repair (TEVAR) is an emerging alternative to open repair in this challenging

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*The Clinical PeRformancE of the Valiant Thoracic Stent Graft with the Captivia Delivery System for the EndovaSCUlar trEatment of Blunt Thoracic Aortic Injuries. A complete list of the RESCUE investigators can be found in the Appendix (online only).

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patient population. The advantages of TEVAR include reducing the morbidity and adverse effects of cardiopulmonary bypass such as significant systemic heparinization, paraplegia, and performance of a thoracotomy. Multiple studies[3,6-15] and meta-analyses[16-19] have documented favorable early outcomes with TEVAR compared with the traditional open surgical approach for BTAI. TEVAR may be performed as a bridging or definitive therapy, allowing stabilization of the patient so that competing traumatic injuries can be treated.

The aim of the Clinical PeRformancE of the Valiant Thoracic Stent Graft with the Captivia Delivery System for the EndovaSCUlar trEatment of Blunt Thoracic Aortic Injuries (RESCUE) trial is to capture the 30-day and 5-year outcomes of TEVAR using the Medtronic Valiant Captivia stent graft (Medtronic Vascular, Santa Rosa, Calif), a Food and Drug Administration (FDA)-approved stent graft for aneurysmal indications, in patients with BTAI.

METHODS

A prospective, nonrandomized, multicenter trial using the Medtronic Valiant Captivia stent graft (Medtronic, Inc)[19] was conducted at 20 sites in North America (NCT# 01092767). Fifty patients underwent TEVAR for BTAI between April 2010 and January 2012; a total of 69 patients were screened using established inclusion and exclusion criteria (see below). The primary end point was all-cause mortality within 30 days. Secondary end points were nonfatal adverse events occurring within 30 days that were related to the procedure, device or aorta, and aortic-related mortality. Technical success, measured as successful device delivery and deployment, was also reported. Patients will be followed for 5 years.

All imaging was provided to an independent core laboratory for analysis of stent graft fracture, twisting, and kinking, loss of patency, and migration $>$ 10 mm (M2S, Inc; West Lebanon, NH). All deaths were adjudicated by a Clinical Events Committee (CEC) coordinated by Harvard Clinical Research Institute (Boston, Mass). Harvard Clinical Research Institute also coordinated an independent data monitoring committee, which reviewed all adverse events associated with a death during the conduct of the study. Relatedness for nonfatal adverse events was determined by the investigator. All source documents were monitored and queries issued regarding any additional potential related events.

Inclusion criteria. The patients were evaluated by preoperative computed tomographic angiography (CTA) for BTAI. The aortic injury was confirmed at the time of repair using angiography or intravascular ultrasound. Enrolled patients were at least 18 years old and underwent TEVAR within 30 days of injury. Informed consent was obtained for all procedures, offered through an Investigational Device Exemption (IDE) approved by the U.S. FDA (IDE# G090201) or an Investigational Testing Authorisation (IST) approved by Health Canada (IST# 171559). Anatomic enrollment criteria included aortic diameter (adventitia to adventitia) of the proximal and distal landing zones between 18 and 44 mm, adequate diameter and quality of the access vessels, and at least 20 mm distance from the distal margin of the left common carotid artery to the intimal disruption on center-of-flow imaging reconstructions

Exclusion criteria. Patients with the following conditions were excluded from the RESCUE trial: planned placement of the stent graft cloth over the left common carotid artery (or the innominate artery in a case of a bovine arch) or the celiac artery; evidence of systemic infection, pregnancy, previous history of descending thoracic aortic intervention or operation, history of bleeding diathesis, coagulopathy, allergy to the device components, participation in conflicting investigational drug or device clinical trials, known hypersensitivity or contraindication to anticoagulants or contrast media that was not amenable to pretreatment; nonsurvivable injury/condition of subject, or a history of a cerebral vascular accident within the 2 preceding months. No specific Injury Severity Score (ISS) constituted exclusion criteria.

Definitions. BTAI was classified as described by Azizzadeh et al.[3] Grade I injury was confined to the intima, grade II was confined to the media and associated with an intramural hematoma, grade III had a pseudoaneurysm, and grade IV represented frank aortic rupture with blood inside the pleural cavity. Patients were also graded using the ISS, an anatomic system that provides an overall score for patients with multiple injuries.[20]

Follow-up. All survivors were entered into the RESCUE trial follow-up protocol consisting of a physical examination, adverse event evaluation, a CTA or magnetic resonance angiogram at 1, 6, and 12 months and annually thereafter for 5 years. Multiple view chest x-rays will also be acquired at 1, 3, and 5 years to assess for device integrity.

Statistical analysis. Descriptive statistics were reported for the study cohort using the Statistical Analysis Software (SAS) v. 9.2 (SAS Institute, Cary, NC).

RESULTS

Fifty patients were enrolled from 69 patients screened at 20 centers, most of which were level I trauma centers. The number of patients enrolled at each site ranged from one to five. Reasons for screen failure included the following: surgical treatment pursued (two); medical treatment pursued (two); device of the appropriate size was not available (four); unable to obtain informed consent (two); patient died just after being consented (one); patient declined to participate in study (one); insurance would not cover (one); and six patients who did not meet inclusion or exclusion criteria, including aortic diameter less than 15 mm (one), proximal landing zone distance $<$20 mm (one), contraindication to anticoagulants (one), patient was pregnant (one), patient had a nonsurvivable injury or condition (one), and procedure occurred more than 30 days after injury (one). All patients but one completed 1-month follow-up, including one patient who died within 30 days. No patient was lost to follow-up.

Table I. Demographics and medical history

Demographics	
Age	
Mean age ± SD	41 ± 17
Median age (range)	39.5 (18-76)
Male, % (m/n)	76% (38/50)
Ethnicity: Hispanic or Latino	20% (10/50)
Race	
White	68% (34/50)
Black or African American	20% (10/50)
Asian	4% (2/50)
Other or not available	8% (4/50)
Medical history	
Hypertension	24% (12/50)
Chronic obstructive pulmonary disease	4% (2/50)
Renal insufficiency	0% (0/50)
Congestive heart failure	2% (1/50)
Myocardial infarction	0% (0/50)
Coronary artery bypass grafting	0% (0/50)
Stroke/cerebrovascular accident	0% (0/50)
Paraplegia	2% (1/50)
Paraparesis	0% (0/50)
Bleeding disorder	0% (0/50
Diabetes	2% (1/50)
Gastrointestinal conditions	2% (1/50)
Other important medical condition	46% (23/50)

SD, Standard deviation.

Table II. Injury characteristics

Extent of overall injuries	
Assigned injury severity score	
Mean ± SD	38 ± 14
Median (range)	35 (13-75)
Extent of aortic injury	
Grade I: 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)
Associated traumatic injuries	
Head injury	48% (24/50)
Neurologic deficits	12% (6/50)
Long B1 fracture	38% (19/50)
Pelvic fracture	40% (20/50)
Scapula fracture	8% (4/50)
Unstable C/T/L spine fractures	14% (7/50)
Abdominal injury[a]	58% (29/50)
Lung injury	70% (35/50)
Rib fracture	64% (32/50)
Sternum fracture	6% (3/50)
Other	50% (25/50)

SD, Standard deviation.
[a]Solid organ, bowel, bladder, or diaphragm injury.

Patient population

Mean age was 41 ± 17 years (18-76). Seventy-six percent (38/50) were male. Demographics and medical history of the study group are shown in Table I. The mean ISS was 38 ± 14 (13-75). Motor vehicle collisions accounted for most injuries (60%), followed by motorcycle accidents (22%), pedestrian injury by vehicles (10%), falls (4%), and other mechanisms (4%). Injury characteristics are presented in Table II. The extent of aortic injury was classified as grade I in 18% (9/50), grade II in 12% (6/50), grade III in 68% (34/50), and grade IV in 2% (1/50), respectively. Indications for intervention were BTAI in the proximal descending thoracic aorta (aortic isthmus) in 84% (42/50) and in the distal half of the descending thoracic aorta in 16% (8/50). Anatomic characteristics are presented in Table III. The mean diameter at the proximal landing zone was 24.3 ± 3.9 mm, with a range of 18 to 35 mm, whereas the mean diameter at the distal landing zone was 22.5 ± 4.1 mm with a range of 18 to 34 mm. The mean maximum descending thoracic aorta diameter was 26.5 ± 6.6 with a range of 18 to 42 mm.

Procedural data

After the initial trauma survey, patients were stabilized, evaluated for concomitant injury, and the timing of the TEVAR was determined based on the discretion of the operator and trauma surgeon. Fifty-one Medtronic Valiant Captivia thoracic stent grafts (Medtronic, Inc) (Fig) and a single Talent thoracic stent graft (Medtronic, Inc) were implanted in the 50 patients within a median of 1.0 days following injury (mean, 1.8 ± 4.0; 0-23 days). Two patients each received two stent grafts; one received a Talent stent graft as a second device because of the emergent nature of the case and the lack of availability of an appropriately sized Valiant graft (Medtronic, Inc) at the site. All but one of the stent grafts placed in the proximal position were proximal bare spring configurations; a closed web tapered graft was placed in the proximal position in one patient. Investigators reported 100% delivery and deployment success of the stent graft in this study population, and no finding of misaligned deployment was made by the core laboratory. There were no reports of aortic perforation, retrograde type A dissection, or conversions to open surgery.

All endovascular exclusions were performed under general anesthesia using a fixed fluoroscopic imaging system or C-arm in the operating room or an endovascular suite. Ninety-eight percent (49/50) of patients received stent grafts implanted via a femoral (46/50) or iliac (3/50) approach by an open or percutaneous technique; an aortic conduit was required in one patient. Systemic heparinization was used in 80% (40/50) of patients prior to introduction of the stent graft. Median blood loss was 50 mL (10-900). Median fluoroscopy and operative times were 8 minutes (3-66) and 91 minutes (35-311), respectively. Median contrast material used was 110 mL (31-230). Two patients had preoperative insertion of a cerebrospinal fluid drainage catheter. The left subclavian artery was covered in 58% of patients (29/50), with complete coverage in 20 and partial coverage in nine patients. Fifty-four percent (28/52) of implanted Valiant grafts were 26 mm or less in size (Fig). Mean oversizing was 10%. Median intensive care unit stay and hospital stay were 6 days (1-108) and 12 days (1-147), respectively.

Primary end point

The primary objective for this study was to assess the safety of Valiant Captivia in subjects with BTAI determined

Table III. Anatomic characteristics (core laboratory reported)

Category	
Distance from left subclavian artery to injury	
No.	50
Mean ± SD, mm	15.0 ± 9.4
Median (range), mm	13.5 (0-36)
Aortic diameter 20 mm proximal to injury	
No.	50
Mean ± SD, mm	24.3 ± 3.9
Median (range), mm	23.5 (18-35)
Maximum descending thoracic artery diameter	
No.	50
Mean ± SD, mm	26.5 ± 6.6
Median (range), mm	25.5 (18-42)

SD, Standard deviation.

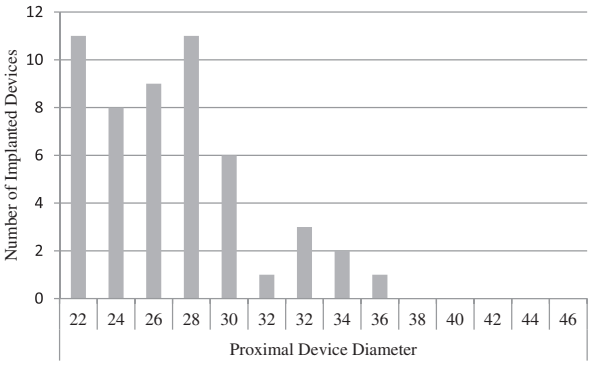

Fig. Distribution of stent graft diameters.

by the 30-day all-cause mortality. Four subjects died within 30 days of the index procedure, resulting in an all-cause 30-day mortality rate of 8.0% (Table IV). Two of these deaths (patients 018-001 and 059-002) were considered by the CEC to be aortic-related. One of the two deaths (patient 059-002) was adjudicated to be related to the aortic injury, device, and procedure because of the ill-defined nature of the available data.

Early deaths

Patient 018-001. A 22-year-old male, thrown from a horse into a tree, arrived with bilateral hemothoraces and a myocardial contusion (ISS = 30, grade III aortic injury). The patient underwent prompt and successful TEVAR, with the postprocedural aortogram demonstrating successful exclusion of BTAI and no extravasation or endoleak. While the left-sided hemothorax subsided after TEVAR, the patient expired on the next day from continued right-sided massive hemothorax. An autopsy was performed on this patient and showed no evidence of an additional aortic injury. The CEC adjudicated this death to be related to the aortic injury and unrelated to the device or procedure.

Patient 182-001. A 68-year-old male blind pedestrian was hit by a motorcycle and presented to the hospital with a BTAI and several comorbidities including traumatic brain injury (ISS = 50, grade III aortic injury). The patient underwent prompt and successful TEVAR but died the next day from the brain injury. The CEC adjudicated the death as unrelated to the aortic injury, device, or the procedure.

Patient 344-033. A 23-year-old male in a motorcycle accident presented to the hospital with a right hemopneumothorax, deformities in both legs, and multiple fractures of the femur. (ISS = 29, grade III aortic injury). The patient underwent prompt and successful TEVAR and expired on day 5 from cardiac arrhythmia. The death was adjudicated by the CEC as unrelated to the aortic injury, device, or procedure.

Patient 059-002. A 67-year-old female, with a history of atrial fibrillation and recent pulmonary embolus on coumadin, was admitted after a motor vehicle accident with a BTAI associated with distal dissection into the abdominal aorta, subarachnoid hemorrhage, T1 spinal fracture, bilateral hemothoraces, liver laceration, and other abdominal injuries (ISS = 34, grade III aortic injury). She underwent successful TEVAR exclusion with angiographic documentation of no endoleaks and expected false lumen perfusion in the abdominal aorta. Two subsequent CTAs (including one performed 1 week prior to her demise) revealed the stent graft to be in good position with no endoleak and with formation of a hematoma in the false lumen. One week after discharge to an acute care facility, the patient experienced sudden unexplained death on day 22. The patient had a history of atrial fibrillation and subtherapeutic anticoagulation, however, because of the lack of autopsy, the cause of death was undetermined. Because of the ill-defined nature of the relationship between this patient's death and the device, procedure, and aortic injury and because of the limited information available, the CEC conservatively adjudicated this death to be related to all three.

Secondary end point results

The secondary end points of this trial were to evaluate the safety and effectiveness of the device by assessing the outcomes of the procedure and/or the occurrence of device-, procedure- , or aortic-related adverse events and aortic-related mortality within 30 days (Table V).

The 30-day CEC adjudicated aortic-related mortality was 4.0% (2/50). In addition, six patients (12%) had seven nonfatal procedure- and/or aortic-related adverse events (Table VI) within 30 days. Other than the death of patient 059-002 (Table IV), there were no device-related adverse events. The single nonfatal aortic-related adverse event is discussed below under neurologic outcomes. Six other patients had procedure-related adverse events within 30 days as listed in Table VI, including four access site complications and two cases of arm ischemia and claudication requiring carotid-to-subclavian bypass. The two patients with arm ischemia and claudication had partial and complete coverage of the left subclavian artery, respectively. After 30 days, two procedure-related adverse events occurred, including one case of arm ischemia requiring bypass. The other event involved a loss of radial pulse

Table IV. Early deaths

Patient	*Time to death, days*	*Cause of death site reported*	*Death relatedness site reported*	*Death relatedness adjudicated by CEC*	*ISS score*
018-001	1	Hemothorax	Not related	Aortic injury related	30
182-001	1	Traumatic brain injury	Not related	Not related	50
344-033	5	Arrhythmia	Not related	Not related	29
059-002	22	Complications of multiple blunt force injuries	Not related to procedure; relatedness to device and aortic injury not evaluable	Device related, procedure related, aortic injury related	34

CEC, Clinical Events Committee; *ISS,* Injury Severity Score.

Table V. Study end points

Primary end point	
All-cause mortality (30 days)	8% (4/50)
Secondary end points	
Procedure- and/or aortic injury-related adverse events (30 days)	12% (6/50)
Aortic injury-related mortality (30 days)	4% (2/50)
Technical success	
Successful delivery and deployment of the stent graft	100% (50/50)

that was not treated. Both patients with ischemia and loss of radial pulse had intentional complete coverage of the left subclavian artery.

Endoleaks and reinterventions

The core laboratory reviewed the intra- and postoperative imaging of all enrolled patients, finding no endoleaks. Furthermore, no stent graft migration, kinking, twisting, fracture, or loss of stent graft integrity or patency was observed. No secondary endovascular reintervention or conversion to open surgery occurred.

Neurologic outcomes

Upon admission, six (12%) patients had neurologic deficit attributable to associated head injury. One patient presented with preoperative paraplegia. No patient had a preprocedural history of stroke.

There were no cases of spinal cord injury or embolic stroke related to the TEVAR procedure. One patient experienced aortic rupture with free extravasation during the procedure prior to device introduction (340-004). The stent graft successfully excluded the grade IV aortic injury with planned partial coverage of the left subclavian artery; however, the patient suffered anoxic brain injury attributable to the periprocedural hypotensive state. The anoxic brain injury was considered as an aortic-related adverse event. The patient was discharged to home, and in the follow-up period beyond 30 days, developed bowel ischemia secondary to extended bowel obstruction and expired on day 169 because of an infection.

DISCUSSION

Since the introduction of commercially available stent grafts in 2005, TEVAR has been increasingly used as a primary treatment option for BTAI. TEVAR has shown significant promise and efficacy in various studies.[3,6-18,21] In 2008, the American Association for the Surgery of Trauma (AAST) reported on a prospective multicenter trial evaluating the management of BTAI, confirming the increased utilization of TEVAR as the primary approach in up to 65% of patients.[14] In comparison to earlier reports of results within open surgery, the same authors found a significant reduction in the early operative mortality rates from 22% with open surgery to 13% using TEVAR, as well as a reduction in spinal cord injury from 8.7% with open surgery to 1.6% using TEVAR.[15] While timing improved by delaying the repair of BTAI and advancements in open surgical techniques such as distal aortic perfusion have contributed to improved BTAI outcomes overall, TEVAR was clearly instrumental in reducing morbidity and mortality in this complex patient cohort. These improved outcomes have contributed to a paradigm shift from open surgery toward off-label use of TEVAR in BTAI treatment, whether as a bridge or for definitive treatment.

The RESCUE trial prospectively investigated the outcomes of TEVAR in multiple centers using the Medtronic Valiant Captivia stent graft (Medtronic, Inc) in patients with BTAI to support potential FDA approval for BTAI indications. RESCUE was designed as a descriptive study focused on safety outcomes. The primary end point of the RESCUE trial was 30-day all-cause mortality and was shown to be 8.0% (4/50). This result is within the expected mortality rate of 0%-15% as reported in the literature[3,7,9,11,13,14] and compares favorably to the 13% mortality rate reported in the 2008 AAST2 study.[15] It is noteworthy that RESCUE was a purely TEVAR trial, while the AAST2 cohort consisted of patients treated by both open and endovascular techniques. Moreover, the RESCUE investigators were selected from high-volume centers experienced in TEVAR, having surpassed the learning curve, while some groups included in the AAST report may have been relatively new to the technology. Recent clinical practice guidelines purely based on TEVAR studies for BTAI quote mortality rates of approximately 9%.[18,22]

The secondary end points were the safety and effectiveness of the device as assessed by the incidence of nonfatal adverse events within 30 days related to the device, procedure or aorta, and aortic-related mortality. By these criteria, the Medtronic Valiant Captivia (Medtronic, Inc) was shown to be a safe device. Although one death was

Table VI. Detail on adverse events (excluding those in Table IV that led to a death within 30 days)

Patient	*Adverse event*	*Days after procedure*	*Serious?*	*Related to device, procedure, or aortic injury?*	*Action taken*
Adverse events ≤ 30 days, related to the device, procedure, or aortic injury					
005-003	Focal dissection of the common femoral artery	0	Yes	Procedure	Thrombectomy and Dacron patch
340-001	Hematoma	0	No	Procedure	None
340-004	Anoxic brain injury (rupture just prior to procedure)	0	Yes	Aortic injury	Initial stent graft placement
340-004	Iliac vein laceration	0	Yes	Procedure	Surgical repair
325-003	Erythema at groin incision	4	No	Procedure	Medication
325-002	Peripheral ischemia	7	Yes	Procedure	Carotid-to-subclavian bypass
112-004	Arm claudication	30	Yes	Procedure	Carotid-to-subclavian bypass
Additional serious adverse events > 30 days, reported to date, related to the device, procedure, or aortic injury					
344-002	Upper limb ischemia	36	Yes	Procedure	Carotid-to-subclavian bypass
325-003	Lack of palpable pulse in arm	39	No	Procedure	None
340-004	Bowel infection (leading to death at 169 days)	167	Yes	Unrelated	None

adjudicated as related to the device, procedure, and aorta, the conservative approach stemmed from little or no information being available about the cause of death. There were no nonfatal device-related adverse events and 100% delivery and deployment success was achieved. The latter observation is particularly noteworthy given the younger age of patients with BTAI and the challenges associated with the narrow radius of curvature of the aortic arch, the severe angulation seen in zones II and III, the hyperdynamic hemodynamics, and the significant variations in the intravascular volume status and the small diameters of the thoracic aorta predisposing to stent graft oversizing and collapse in this patient population.[12,23]

Twelve percent (6/50) of patients enrolled in RESCUE experienced seven nonfatal adverse events within 30 days. Six of the seven events were procedure-related, four of which access vessel-related, including surgical site hematoma, erythema, iliac vein laceration, and femoral artery dissection, the latter two requiring local vascular repair. Another two patients developed arm ischemia and claudication within 30 days (and one-third developed similar symptoms at day 36), an expected delayed complication associated with partial or complete coverage of the left subclavian artery, which was performed in 58% (29/50). This result is commensurate with recent reports of 41%[24] and 61%[25] left subclavian arterial coverage.

One patient had an aortic-related adverse event, anoxic brain injury because of prolonged perioperative hypotension attributable to the development of active aortic hemorrhage during the induction of general anesthesia at the time of the procedure. Otherwise, there were no new neurologic events compared with an incidence of paraplegia rates seen with open surgical repair as high as 19%.[26]

Patients with an aortic transection usually have a high incidence of associated chest trauma, which can negatively impact the performance of a left-sided thoracotomy. During an open aortic repair procedure, the left lung has to be deflated requiring the patient to rely entirely on the right lung for oxygenation, or, alternatively, necessitates that the patient be placed on cardiopulmonary bypass. Furthermore, in case of significant left-sided rib fracture and associated pulmonary contusion, avoidance of a thoracotomy can result in decreased pulmonary complications. The latter advantage has been described in TEVAR procedures performed in patients with thoracic aneurysms or aortic dissections and associated pulmonary disease.

Limitations of this study include the lack of randomization of patients, the short period of follow-up to date, and the selection of institutions experienced with TEVAR. However, further follow-up is in progress and will be reported when the data become available. Since longer-term safety and effectiveness of TEVAR is well-established in the treatment of aneurysms, this article focuses on the primary end point of the trial (ie, 30-day mortality associated with the treatment of BTAI).

It may also be somewhat controversial that TEVAR treatment was selected for the 18% of patients in this study with grade I aortic injury. The decision to enroll these subjects in the RESCUE trial was made by the on-site investigators and the corresponding trauma surgeons according to their considerable experience with such patients. Although there are controversies whether this group of patients may be managed watchfully with serial imaging, many physicians prefer early TEVAR in patients with concomitant head injuries, allowing early elevation of systemic and cerebral perfusion pressures with vasopressors. In RESCUE, the decision to treat subjects with grade I aortic injuries was because of uncertainty regarding progression of the injury based on serial imaging and the presence of either hypotension with dropping blood pressure, long intimal tears, or competing injuries.

CONCLUSIONS

TEVAR using the Medtronic Valiant Captivia (Medtronic, Inc) was a safe and effective approach for primary

treatment of BTAI. Both primary and secondary end points of RESCUE compare favorably to the body of literature on BTAI. Long-term follow-up will be required to determine the effectiveness and longevity of stent grafts in this complex patient population.

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AUTHOR CONTRIBUTIONS

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Additional material for this article may be found online at www.jvascsurg.org.

Appendix (online only). RESCUE investigators

Principal investigator	*Site*	*City*	*Patients enrolled*
Rodney A. White, MD	Harbor UCLA	Torrance, Calif	5
Ali Azizzadeh, MD	Memorial Hermann Heart and Vascular Institute	Houston, Tex	5
Alan H. Matsumoto, MD	University of Virginia Medical Center	Charlottesville, Va	5
Omaida C. Velazquez, MD	University of Miami Jackson Memorial Hospital	Miami, Fla	4
Joshua Rovin, MD	Cardiac Surgical Associates Bayfront Medical Center	St. Petersberg, Fla	3
Joseph V. Lombardi, MD	Cooper Health System	Camden, NJ	3
Ernest Moore, MD Robert Allen, MD	Denver Heath	Denver, Colo	3
Robert Hieb, MD	Medical College of Wisconsin Froedtert Hospital	Milwaukee, Wisc	3
Bart E. Muhs, MD	Yale New Haven Hospital	New Haven, Conn	3
G. Chad Hughes, MD	Duke University Medical Center	Durham, NC	2
Francios Dagenais, MD	Institut Universitaire de Cardiologie et de Pneumologie de Québec	Québec, QC	2
Himanshu J. Patel, MD	Regents of the University of Michigan	Ann Arbor, Mich	2
Clifford J. Buckley, MD	Scott and White Memorial Hospital	Temple, Tex	2
Robert J. Feezor, MD	University of Florida	Gainesville, Fla	2
Marc L. Schermerhorn, MD	Boston, Mass	Boston, Mass	1
Ali Khoynezhad. MD	Cedars Sinai Medical Center	Los Angeles, Calif	1
JeanM, Panneton, MD	Sentara Norfolk General Vascular & Transplant Specialists	Norfolk, Va	1
John P. Pigott, MD	Toledo Hospital Jobst Vascular Center	Toledo, Ohio	1
William D. Jordan, MD	University of Alabama Hospital	Birmingham, Ala	1
Nirman Tulsyan, MD	Vascular Research Institute Morristown Memorial	Morristown, NJ	1