Operative Repair or Endovascular Stent Graft in Blunt Traumatic Thoracic Aortic Injuries: Results of an American Association for the Surgery of Trauma Multicenter Study

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Introduction: **The purpose of this American Association for the Surgery of Trauma multicenter study is to assess the early efficacy and safety of endovascular stent grafts (SGs) in traumatic thoracic aortic injuries and compare outcomes with the standard operative repair (OR).**

Patients: **Prospective, multicenter study. Data for the following were collected: age, blood pressure, and Glasgow Coma Scale (GCS) at admission, type of aortic injury, injury severity score, abbreviate injury scale (AIS), transfusions, survival, ventilator days, complications, and intensive care unit and hospital days. The outcomes between the two groups (open repair or SG) were compared, adjusting for presence of critical extrathoracic trauma (head, abdomen, or extremity AIS >3), GCS score ≤8, systolic blood pressure <90 mm Hg, and age >55 years. Separate multivariable analysis was performed, one for patients without and one for patients with associated critical extrathoracic injuries (head, abdomen, or extremity AIS >3), to compare the outcomes of the two therapeutic modalities adjusting for hypotension, GCS score ≤8, and age >55 years.**

Results: **One hundred ninety-three patients met the criteria for inclusion. Overall, 125 patients (64.9%) were selected for SG and 68 (35.2%) for OR. SG was selected in 71.6% of the 74 patients with major extrathoracic injuries and in 60.0% of the 115 patients with no major extrathoracic injuries. SG patients were significantly older than OR patients. Overall, 25 patients in the SG group (20.0%) developed 32 device-related complications. There were 18 endoleaks (14.4%), 6 of which needed open repair. Procedure-related paraplegia developed in 2.9% in the OR and 0.8% in the SG groups (p = 0.28). Multivariable analysis adjusting for severe extrathoracic injuries, hypotension, GCS, and age, showed that the SG group had a significantly lower mortality (adjusted odds ratio: 8.42; 95% CI: [2.76–25.69]; adjusted p value <0.001), and fewer blood transfusions (adjusted mean difference: 4.98; 95% CI: [0.14–9.82]; adjusted p value = 0.046) than the OR group. Among the 115 patients without major extrathoracic injuries, higher mortality and higher transfusion requirements were also found in the OR group (adjusted odds ratio for mortality: 13.08; 95% CI [2.53–67.53], adjusted p value = 0.002 and adjusted mean difference in transfusion units: 4.45; 95% CI [1.39–7.51]; adjusted p value = 0.004). Among the 74 patients with major extrathoracic injuries, significantly higher mortality and pneumonia rate were found in the OR group (adjusted p values 0.04 and 0.03, respectively). Multivariate analysis showed that centers with high volume of endovascular procedures had significantly fewer systemic complications (adjusted p value 0.001), fewer local complications (adjusted p value p = 0.033), and shorter hospital lengths of stay (adjusted p value 0.005) than low-volume centers.**

Conclusions: **Most surgeons select SG for traumatic thoracic aortic ruptures, irrespective of associated injuries, injury severity, and age. SG is associated with significantly lower mortality and fewer blood transfusions, but there is a considerable risk of serious device-related complications. There is a major and urgent need for improvement of the available endovascular devices.**

Key Words: **AAST multicenter study, Traumatic thoracic aorta, Open repair versus endovascular repair, Outcomes.**

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The diagnosis and management of traumatic thoracic aortic (TA) injuries have undergone some major changes in the last few years. The replacement of chest X-rays by routine computed tomography (CT) scan for screening purposes in high-speed deceleration injuries has resulted in the earlier and more frequent diagnosis of TA injuries.[1,2] Angiography has largely been replaced by CT scan for the definitive diagnosis of TA ruptures. The introduction of beta blockers has reduced the risk of in-hospital free rupture.[3,4] In selected cases, delayed definitive repair under more optimal conditions has reduced mortality.[5–8] The concept of nonoperative management in selected high-risk, elderly patients with small aortic tears is in the early explorative stages with encouraging results.[9,10] The introduction of angiographically placed stent grafts (SGs) is revolutionizing the definitive management of these injuries.

Although endovascular SG placement was initially used in high-risk multiple injuries or elderly patients, in many centers it has now become the initial procedure of choice,

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even in young or low-risk patients. The reported experience with this procedure is very limited and almost all published series include small numbers of retrospectively collected cases. The purpose of the present study was to evaluate the current practices in the surgical community, compare early outcomes between open surgical management and endovascularly placed SGs in patients with traumatic TA injuries, and identify the group of patients who might benefit from each of the techniques.

PATIENTS AND METHODS

This was an American Association for the Surgery of Trauma (AAST) multicenter, prospective study with 18 participating trauma centers. The study protocol was prepared and approved by the Multi-Institutional Trials Committee of the AAST. Each center obtained approval from its own institutional review board. The data collection sheet included the following fields for each patient: age, gender, mechanism of injury (motor vehicle injury, auto vs. pedestrian, motorcycle, fall from height, other mechanism), initial clinical presentation (blood pressure, Glasgow Coma Scale [GCS], need for emergency endotracheal intubation), injury severity score (ISS), body area (head, chest, abdomen, extremity) abbreviate injury scale (AIS), method of diagnosis of the aortic rupture (CT scan, angiography, transesophageal echocardiogram, magnetic resonance imaging), type of aortic rupture (intimal tear, aneurysm, dissection), site of injury, type of definitive management (operation with clamp and sew or bypass, angiographically placed stent), and time from injury to completion of the therapeutic procedure. The decision for open or endovascular repair was surgeon's preference. The outcomes included survival, ventilator days, intensive care unit (ICU) and hospital stay, blood transfusions, and complications. The following complications were recorded: procedure-related paraplegia, pneumonia, adult respiratory distress syndrome (ARDS), urinary tract infection (UTI), graft infection, deep venous thrombosis, renal failure, femoral or iliac or brachial artery thrombosis on tear or aneurysm, device endoleak, and other. Standardized definitions of pneumonia, ARDS, septicemia, UTI, graft sepsis, DVD, and renal failure were used by all participating centers. The patients were followed up until discharge or death. Data were entered into an Excel spreadsheet and analyzed using SPSS 12.0 for Windows (SPSS, Inc., Chicago, IL).

For the analysis, the following continuous risk factors were dichotomized using clinically relevant cut-points: age, ≤55 years versus >55 years; systolic blood pressure (SBP), <90 mm Hg versus ≥90 mm Hg; GCS score, ≤8 versus GCS score >8; AIS, ≤3 versus >3.

The primary outcome measure analyzed was in-hospital mortality. Secondary outcomes included complication rates, ventilator days, units of blood transfusions, ICU, and hospital length of stay.

Outcomes were compared between the two therapeutic modalities for the total study population, for patients with and for patients without major extrathoracic trauma as defined as head, abdomen, or extremity AIS >3 using bivariate and multivariable analysis. For bivariate analysis, the χ^2 or two-tailed Fisher's exact test was used to compare proportions and the Student's *t* test or Mann-Whitney rank-sum test was used to compare the means of two groups.

The logistic regression analysis was used to compare the dichotomous outcomes including mortality and complications between two study groups adjusting for presence of major extrathoracic trauma, GCS score ≤8, SBP <90 mm Hg, and age >55 years. Adjusted odds ratio, 95% confidence intervals and *p* values were derived.

Analysis of covariance using the original data and rank data were conducted to compare the continuous outcomes including units of blood transfusions, ventilation days, ICU length of stay, and hospital length of stay between the two groups. Adjusted mean difference and its 95% confidence interval of each outcome between the operative repair (OR) group and the SG group were derived. Parametric and nonparametric adjusted *p* values were derived for the comparisons.

In the analysis that compared the outcomes between the two study groups for the entire study population, the factors used for adjustment included presence of major extrathoracic trauma, GCS score ≤8, SBP <90 mm Hg, and age >55 years. In the stratified analysis comparing the outcomes between the two modality groups among patients with major extrathoracic trauma or among patients without major extrathoracic trauma, the factors used for adjustment included hypotension, GCS score ≤8 and age >55 years.

Further analysis was performed to compare the outcomes between low-volume and high-volume centers. Participating centers were classified as low or high volume centers according to the number of procedures performed. Centers with less than 15 procedures performed were classified as low-volume centers (center <15) and centers with 15 or more (center ≥15) procedures performed were classified as high-volume centers. Outcomes were compared between these two groups of centers using bivariate analysis followed by multivariable analysis adjusting for presence of severe extrathoracic trauma, GCS score ≤8, SBP <90 mm Hg, and age >55 years, using the same approach as for the comparison of outcomes between the two therapeutic modalities.

RESULTS

During the 26-month study period, 193 patients from 18 participating centers were entered into the study. The average number of cases was 10.7 per center, with the largest three trauma centers contributing 42.5% of all cases (average of 27.3 patients). The most common mechanism of injury was motor vehicle crashes (MVCs; 67.7%), followed by motorcycle injuries (13.0%), falls from height (7.3%), auto versus pedestrian (AVP) (6.3%), and other blunt mechanisms (5.7%). Most patients were male (75.6%) and the mean age was 40.2 years (range 11–85) (Table 1). The clinical condition of the patients at admission is shown in Table 1. Overall, 31 (16.1%)

Table 1 **Comparison of Patient and Injury Characteristics Between Patients Who Had Operative Repair (OR) and Patients Who Had Endovascular Stent Graft (SG)**

Characteristic	All Patients (N = 193)	Operative Repair (N = 68)	Endovascular Stent Graft (N = 125)	*p*
Gender				0.211
Percent (n) male	75.6 (146)	80.9 (55)	72.8 (91)	
Age				
Mean ± SD (n)	40.2 ± 18.7 (192)	34.1 ± 17.4 (68)	42.2 ± 18.1 (124)	<0.001
Percent (x/n) >55 yr	20.3 (39/192)	13.2 (9/68)	24.2 (30/124)	0.071
Percent (x/n) >70 yr	10.4 (20/192)	4.4 (3/68)	13.7 (17/124)	0.044
Mechanism of injury				
Percent (x/n) MVC	67.7 (130/192)	66.2 (45/68)	68.5 (85/124)	0.737
Percent (x/n) motorcycle	13.0 (25/192)	16.2 (11/68)	11.3 (14/124)	0.336
Percent (x/n) fall from height	7.3 (14/192)	5.9 (4/68)	8.1 (10/124)	0.774
Percent (x/n) auto vs. pedestrian	6.3 (12/192)	4.4 (3/68)	7.3 (9/124)	0.544
Percent (x/n) other mechanism	5.7 (11/192)	7.4 (5/68)	4.8 (6/124)	0.524
Hypotension at admission				0.207
Percent (x/n) yes	16.1 (31/193)	20.9 (14/67)	13.8 (17/123)	
GCS				0.923
Percent (x/n) ≤8	25.8 (49/190)	25.4 (17/67)	26.0 (32/123)	
ISS				0.826
Mean ± SD (n)	39.5 ± 11.7	38.9 ± 11.8	39.4 ± 11.3	
AIS				
Percent (x/n) head AIS >3	18.9 (36/190)	16.4 (11/67)	20.3 (25/123)	0.511
Percent (x/n) abdomen AIS >3	19.5 (37/190)	16.4 (11/67)	21.1 (26/123)	0.432
Percent (x/n) extremity AIS >3	9.5 (18/190)	4.5 (3/67)	12.2 (15/123)	0.083
Any severe associated injury				0.103
Percent (x/n) yes	39.2 (74/184)	31.3 (21/67)	43.4 (53/122)	
Diagnostic technique				
Percent (x) CT scan	93.3 (180)	86.8 (59)	96.8 (121)	0.013
Percent (x) angio	8.3 (16)	13.2 (9)	5.6 (7)	0.066
Percent (x) TEE	1.0 (2)	1.5 (1)	0.8 (1)	1.000
Percent (x) surgery	1.6 (3)	4.4 (3)	0.0 (0)	1.000
Type of TA injury				
Percent (x/n) intimal tear	20.5 (38/185)	19.7 (13/66)	21.0 (25/119)	0.832
Percent (x/n) aneurysm	58.4 (108/185)	57.6 (38/66)	58.8 (70/119)	0.869
Percent (x/n) dissection	25.4 (47/185)	28.8 (19/66)	23.5 (28/119)	0.431
Location of TA injury				
Percent (x/n) ascending	3.6 (4/111)	10.0 (4/40)	0 (0/71)	—
Percent (x/n) distal SCA	74.5 (82/110)	69.2 (29/39)	77.5 (55/71)	0.343
Percent (x/n) descending	21.8 (24/110)	20.5 (8/39)	22.5 (16/71)	0.806
Hours from injury to procedure				
Mean ± SD (n)	54.6 ± 101.6	67.6 ± 136.0	48.1 ± 77.6	0.416

x, number of events; n, number of subjects at risk for the derivation of the percent.

The *p* values for categorical variables were derived from two-tailed χ^2 test or Fisher's exact test; *p* values for continuous variables were derived from Student's *t* test or Mann-Whitney *U* test.

were hypotensive and 49 (25.8%) had a GCS score ≤8 at admission. The mean ± SD ISS was 39.5 ± 11.7 and 59 patients (30.6%) had critical extrathoracic injuries (head, abdomen, or extremely AIS >3). The most common type of aortic injury was an aneurysm (58.4%), followed by dissection (25.4%) and intimal tear (20.5%) (Table 1).

Overall, 68 patients (35.2%) were managed with open repair and 125 (64.8%) with endovascular stenting. The demographic, clinical, and injury characteristics of the two groups are shown in Table 1. The mechanisms of injury, the mean ISS and GCS score and the incidence of critical extrathoracic trauma (AIS >3) were similar in the two groups. However, patients in the endovascular group were significantly older (mean age 42.2 vs. 34.1 years, $p = 0.001$), and more likely to be older than 70 years old (13.2 vs. 4.4%, $p = 0.044$) (Table 1).

Of the 68 patients with open surgery, 57 (83.8%) had the aortic repair performed under some type of bypass and the remaining 11 (16.2%) with the clamp and sew technique. The commercially available devices used for the endovascular stenting are shown in Table 2.

Outcomes: All Patients

The overall mortality was 13.5%; 23.5% in the open repair and 7.2% in the endovascular repair group ($p = 0.001$) (Table

Table 2 Definitive Management of TA Injuries

	Percent (x/n)
Operative repair (N = 68)	
Clamp and sew	16.2 (11/68)
Bypass	83.8 (57/66)
Endovascular stent graft (N = 117)	
TAG (Gore)	78.6 (92/117)
Zenith (Cook)*	16.2 (19/117)
Talent (Medtronic)	3.4 (4/117)
Vanguard (Boston)	1.7 (2/117)

* Zenith (Cook) approved by FDA only for abdominal aortic aneurysms.

3). Multivariable analysis adjusting for age >55 years, GCS score ≤8, hypotension at admission, and critical extrathoracic injuries, showed a significantly lower adjusted mortality in the endovascular group (adjusted odds ratio = 8.42; 95% CI: 2.76–25.69; $p < 0.001$) (Table 4). No statistically significant differences were found in the ICU or hospital length of stay and ventilator days between the two groups, based on both the bivariate and multivariable analysis (Tables 3 and 5). However, the endovascular group required significantly fewer blood transfusions (adjusted mean difference [OR-SG]: 4.98 units; 95% CI: 0.14–9.82; adjusted p value = 0.046).

The incidence of any systemic complication was 50.0% in the open repair and 42.4% in the endovascular group (adjusted odds ratio:1.41; 95% CI: 0.75–2.34; $p = 0.29$, adjusted for age >55 years, hypotension and GCS score ≤8 at admission and major extrathoracic injuries) (Tables 3 and 4). There was no significant difference in the incidence of specific complications (pneumonia, ARDS, septicemia, UTI, deep venous thrombosis, renal failure, and graft sepsis) between the two groups (Table 3).

The incidence of procedure-related paraplegia was 2.9% in the open repair group and 0.8% in the endovascular group (adjusted p value = 0.28). The one paraplegia case in the endovascular group was the result of stent collapse and thrombosis of the thoracic aorta. This patient also developed permanent renal failure requiring chronic hemodialysis. The two cases of paraplegia in the open repair group occurred in the bypass subgroup.

Overall, 25 patients (20.0%) in the endovascular repair group developed 32 device-related complications. The most common complication was an endoleak (18 cases, 14.4%). Nine endoleaks were successfully managed with the deployment of a second SG and six needed conversion to open repair. All six patients survived. The remaining three endoleaks were successfully observed. There were 14 other serious device-related complications, which included four access vessel injuries (iliac or femoral or brachial artery tears or thrombosis), four occlusions of the left subclavian artery, two strokes, one para-

Table 3 Outcomes by Therapeutic Modality

Outcome	All Patients (N = 193)	Operative Repair (N = 68)	Endovascular Stent Graft (N = 125)	Odds Ratio (95% CI)	p*
Mortality					
Percent (x) died	13.0 (25)	23.5 (16)	7.2 (9)	3.97 (1.65 to 9.56)	0.001
Any systemic complications					
Percent (x) yes	45.1 (87)	50.0 (34)	42.4 (53)	1.36 (0.75 to 2.46)	0.311
Complications					
Percent (x/n) paraplegia†	1.6 (3/193)	2.9 (2/68)	0.8 (1/125)	3.76 (0.33 to 42.21)	0.284
Percent (x/n) pneumonia	33.0 (63/191)	35.8 (24/67)	31.5 (39/124)	1.22 (0.65 to 2.28)	0.540
Percent (x/n) ARDS	15.4 (29/188)	18.2 (12/66)	13.9 (17/122)	1.37 (0.61 to 3.08)	0.442
Percent (x/n) septicemia	14.4 (27/188)	14.9 (10/67)	14.0 (17/121)	1.07 (0.46 to 2.50)	0.870
Percent (x/n) UTI	18.6 (35/188)	20.9 (14/67)	17.4 (21/121)	1.26 (0.59 to 2.67)	0.550
Percent (x/n) graft sepsis	0.5 (1/187)	1.5 (1/67)	0.0 (0/121)	—	0.358
Percent (x/n) DVT	4.8 (9/188)	6.0 (4/67)	4.1 (5/121)	1.47 (0.38 to 5.68)	0.723
Percent (x/n) renal failure	9.1 (17/187)	10.4 (7/67)	8.3 (10/120)	1.28 (0.46 to 3.54)	0.630
Outcome	**Mean ± SD (n) [Median]**	**Mean ± SD (n) [Median]**	**Mean ± SD (n) [Median]**	**Mean Difference (95% CI)**	**p‡**
Ventilation days	9.2 ± 11.0 [5]	10.0 ± 14.3 [5]	8.8 ± 8.8 [5]	1.24 (−2.09 to 4.57)	0.893
ICU days	13.4 ± 12.0 [9]	14.0 ± 15.1 [9]	13.1 ± 10.0 [9]	0.89 (−2.73 to 4.51)	0.522
Hospital days	23.2 ± 32.2 [19]	27.3 ± 50.3 [21]	21.0 ± 14.6 [17]	6.30 (−3.42 to 16.02)	0.990
Blood transfusion units	10.3 ± 16.7 [6]	12.0 ± 19.1 [7]	9.5 ± 15.3 [5]	2.50 (−2.63 to 7.63)	0.095

* χ^2 test or two-sided Fisher's exact test.
† Procedure related.
‡ Student's t test or Mann-Whitney U test.

Table 4 **Adjusted Odds Ratio for Mortality and Complications (Operative Repair vs. Endovascular Stent Graft)**

Outcome	Adjusted Odds Ratio (95% CI)*	Adjusted *p**
Deaths	8.42 (2.76 to 25.69)	<0.001
Any systemic complications	1.41 (0.75 to 2.34)	0.290

* Multivariable analysis adjusting for severe extrathoracic trauma (any head or abdomen or extremities AIS >3, GCS score ≤8, SBP <90 mm Hg, and age >55 years).

Table 5 **Adjusted Mean Differences for Continuous Outcomes (Operative Repair vs. Endovascular Stent Graft)**

Outcome	Adjusted Mean Difference (95% CI)*	Adjusted *p**	Adjusted *p* on Rank*
Ventilation days	1.66 (−1.76 to 5.09)	0.339	0.850
ICU days	1.28 (−2.41 to 4.98)	0.495	0.706
Hospital days	4.77 (−5.33 to 14.86)	0.352	0.861
Blood transfusion units	4.98 (0.14 to 9.82)	0.044	0.046

* Multivariable analysis adjusting for any severe extrathoracic trauma (any head or abdomen or extremities AIS >3, GCS score ≤8, SBP <90 mm Hg, and age >55 years).

plegia, one occlusion of the left common carotid artery, one partial collapse of the SG, and one infection at the vascular access site (Table 6). The device-related complications of each of the commercially available devices are shown in Table 6.

Outcomes in Patients With No Critical Extrathoracic Injuries

There were 115 patients who had no critical extrathoracic injuries (head, abdomen, or extremity AIS >3 were excluded). The mortality rate in this group of patients was 12.2%; 23.9% in the open repair; and 4.3% in the endovascular group. Multivariable analysis adjusting for hypotension, GCS score ≤8 and age >55 showed that the mortality was significantly higher in the open repair group (adjusted odds ratio:13.08; 95% CI: 2.53–67.53; $p = 0.002$). No significant differences were found in ICU and hospital days, ventilator days and complication rates. However, the transfusion need was significantly lower in the endovascular group (adjusted mean difference [open repair minus endovascular repair]: 4.45, 95% CI: 1.39–7.51; $p = 0.005$). Tables 7 to 9 provide the findings of the comparisons.

Outcomes in Patients With Critical Extrathoracic Injuries

There were 74 patients with critical extrathoracic injuries (head, abdomen, or extremity AIS >3). The overall mortality was 13.5%; 23.8% in the open repair group and 9.4% in the endovascular group (Table 10). Multivariable analysis adjusting for hypotension, GCS score ≤8 and age >55 showed a significantly lower mortality in the endovascular group (adjusted odds ratio: 5.68; 95% CI: 1.09–29.45; adjusted *p* value = 0.039) (Table 11). The adjusted ICU and hospital stays, ventilator days, and blood transfusions, were similar in both groups. However, the incidence of pneumonia was significantly lower in the endovascular group (adjusted odds ratio: 3.49; 95% CI: 1.13–10.82; $p = 0.030$). Tables 11 and 12 provide the details of the comparisons of specific outcomes between the two treatment groups.

High- Versus Low-Volume Centers

Multivariate analysis adjusting for critical extrathoracic injuries, GCS, hypotension, and age showed no difference in mortality outcomes between low and high-volume centers. However, high-volume centers had a significantly shorter hospital length of stay and a strong trend toward fewer systemic complications (Tables 13). Further multivariate analysis which included only the endovascular procedures showed significantly fewer systemic complications (adjusted *p* value 0.001), fewer local complications (adjusted *p* value = 0.033), and shorter hospital length of stay (adjusted *p* value 0.005) in high-volume centers (Table 14).

DISCUSSION

The diagnosis and management of traumatic TA injuries have undergone some major changes in the last few years. The replacement of chest X-rays and angiography by CT angiography, the introduction of beta blockers and delayed operation in selected cases, the liberal use of bypass techniques, the nonoperative management of selected cases and endovascular interventions have contributed to an earlier diagnosis and reduction of mortality and serious complications. The advancement of endovascular techniques and devices is revolutionizing our approach to traumatic TA injuries. The theoretical advantages of this technique are numerous: the

Table 6 **Stent Graft Related Complications**

	All (n = 125)	Gore (n = 89)	Cook (n = 17)	Odds Ratio (95% CI)	*p*
Endoleak, % (n)	13.6 (17)	10.1 (9/89)	29.4 (5/17)	0.27 (0.08 to 0.94)	0.047
Any stent graft related complications, % (n)	18.4 (23)	15.7 (14/89)	35.3 (6/17)	0.34 (0.11 to 1.08)	0.087
Any stent graft related complications, endoleak excluded, % (n)	4.8 (6)	5.6 (5/89)	5.9 (1/17)	0.95 (0.10 to 8.70)	1.000

The *p* values were derived from two-tailed Fisher's exact test.

Table 7 Comparison of Outcomes Between Operative Repair and Endovascular Stent Graft Patients Without Major Extrathoracic Injuries

Outcome	All Patients (N = 115)	Operative Repair (N = 46)	Endovascular Stent Graft (N = 69)	Odds Ratio (95% CI)	p^*
Mortality					
Percent (x) died	12.2 (14)	23.9 (11)	4.3 (3)	6.91 (1.81 to 26.43)	0.002
Any systemic complications					
Percent (x) yes	43.5 (50)	45.7 (21)	42.0 (29)	1.16 (0.55 to 2.46)	0.701
Complications					
Percent (x/n) paraplegia†	1.7 (2/115)	2.2 (1/46)	1.4 (1/69)	1.51 (0.09 to 24.78)	1.000
Percent (x/n) pneumonia	30.7 (35/114)	26.1 (12/46)	33.8 (23/68)	0.69 (0.30 to 1.58)	0.380
Percent (x/n) ARDS	16.1 (18/112)	20.0 (9/45)	13.4 (9/67)	1.61 (0.58 to 4.44)	0.354
Percent (x/n) septicemia	12.4 (14/113)	15.2 (7/46)	10.4 (7/67)	1.54 (0.50 to 4.73)	0.450
Percent (x/n) UTI	17.9 (20/112)	19.6 (9/11)	16.7 (11/66)	1.22 (0.46 to 3.22)	0.694
Percent (x/n) DVT	4.5 (5/112)	4.3 (2/46)	4.5 (3/66)	0.95 (0.15 to 5.59)	1.000
Percent (x/n) renal failure	4.5 (5/112)	8.7 (4/46)	6.1 (4/66)	1.48 (0.35 to 6.23)	0.715
Outcome	**Mean ± SD (n) [Median]**	**Mean ± SD (n) [Median]**	**Mean ± SD (n) [Median]**	**Mean Difference (95% CI)**	**$p^‡$**
Ventilation days	8.0 ± 11.0 (n) [5]	9.4 ± 14.9 (n) [4]	7.1 ± 7.4 (n) [5]	2.39 (−2.42 to 7.19)	0.768
ICU days	11.9 ± 11.9 (n) [8]	13.0 ± 15.8 (n) [7]	11.2 ± 8.5 (n) [9]	1.82 (−3.32 to 6.96)	0.587
Hospital days	22.9 ± 39.6 (n) [16]	29.5 ± 60.2 (n) [18]	18.5 ± 13.3 (n) [15]	10.97 (−7.36 to 29.31)	0.605
Blood transfusion units	7.4 ± 8.6 (n) [5]	10.2 ± 10.5 (n) [7]	5.6 ± 6.4 (n) [4]	4.65 (1.16 to 8.14)	0.008

* χ^2 test or two-sided Fisher's exact test.
† Procedure related.
‡ Student's *t* test or Mann-Whitney *U* test.

Table 8 Adjusted Odds Ratio for Mortality and Complications in Patients Without Major Extrathoracic Injuries (Operative Repair vs. Endovascular Stent Graft)

Complication	Adjusted Odds Ratio (95% CI)*	Adjusted p^*
Deaths	13.08 (2.53 to 67.53)	0.002
Any systemic complications	1.15 (0.52 to 2.52)	0.732

* Multivariable analysis adjusting for GCS score ≤8, SBP <90 mm Hg, and age >55 years.

Table 9 Adjusted Mean Differences for Continuous Outcomes in Patients Without Major Extrathoracic Injuries (Operation vs. Stent Graft)

	Adjusted Mean Difference (95% CI)*	Adjusted p^*	Adjusted p on Rank*
Ventilation days	2.22 (−2.10 to 6.55)	0.311	0.565
ICU days	2.33 (−2.76 to 6.48)	0.426	0.885
Hospital days	7.03 (−8.18 to 22.24)	0.362	0.838
Blood transfusion units	4.45 (1.39 to 7.51)	0.005	0.004

* Multivariable analysis adjusting for GCS score ≤8, SBP <90mm Hg, and age (≤55 vs. >55 years).

procedure can be performed under local anesthesia, there is no need to open the chest cavity, the blood loss is minimal and the risk of paraplegia is minimized.

The initial experience with endovascular SG in nontraumatic abdominal and TA pathologies has been very encouraging.[11–16] The early morbidity and mortality were impressively low and many vascular surgeons and interventional radiologists declared that the days of open surgery were over. However, subsequent larger and prospective randomized studies with long-term follow-up showed less impressive results and expressed skepticism and caution. The EVAR trial[12] randomized 1,082 patients, aged 60 years or older, with abdominal aortic aneurysm, and assigned them into an open repair or endovascular repair group. Although there was an initial postoperative benefit and fewer aneurysm-related deaths in the endovascular group (4% vs. 7%), after 4 years the all-cause mortality did not differ between the two treatment groups (28%). The incidence of postoperative complications within 4 years of randomization was 41% in the endovascular group and 9% in the open repair group (p <0.0001). After 12 months of randomization there was no difference in health-related quality of life. The need for re-intervention within the first 4 years was 20% in the endovascular group and 6% in the open repair group (p <0.0001). The hospital costs were much higher in the endovascular group.

The experience with endovascular SG in traumatic TA injuries is still very limited and early. Since the publication of

Table 10 Comparison of Outcomes Between Operative Repair and Endovascular Stent Graft in Patients With Associated Major Extrathoracic Injuries

	All Patients (N = 74)	Operative Repair (N = 21)	Endovascular Stent Graft (N = 53)	Odds Ratio (95% CI)	P*
Mortality					
Percent (n) died	13.5 (10)	23.8 (5)	9.4 (5)	3.00 (0.77 to 11.72)	0.135
Any systemic complications					
Percent (n) yes	45.9 (34)	57.1 (12)	41.5 (2)	1.88 (0.68 to 5.22)	0.224
Complications					
Percent (x/n) paraplegia†	1.4 (1/74)	4.8 (1/21)	0.0 (0/53)	—	0.284
Percent (x/n) pneumonia	35.6 (26/73)	55.0 (11/20)	28.3 (15/53)	3.10 (1.07 to 8.98)	0.034
Percent (x/n) ARDS	13.9 (10/72)	10.0 (2/20)	15.4 (8/52)	0.61 (0.12 to 3.16)	0.716
Percent (x/n) septicemia	18.3 (13/71)	15.0 (3/20)	19.6 (10/51)	0.72 (0.18 to 2.96)	0.746
Percent (x/n) UTI	16.7 (12/72)	20.0 (4/20)	15.4 (8/52)	1.38 (0.36 to 5.20)	0.727
Percent (x/n) DVT	5.6 (4/72)	10.0 (2/20)	3.8 (2/52)	2.78 (0.36 to 21.21)	0.307
Percent (x/n) renal failure	12.7 (9/71)	15.0 (3/20)	11.8 (6/51)	1.32 (0.30 to 5.90)	0.705
Outcome	**Mean ± SD (n) [Median]**	**Mean ± SD (n) [Median]**	**Mean ± SD (n) [Median]**	**Mean Difference (95% CI)**	**p‡**
Ventilation days	11.1 ± 10.9 [8]	11.2 ± 13.2 [7]	11.1 ± 10.0 [9]	0.05 (−5.72 to 5.82)	0.659
ICU days	15.9 ± 11.9 [12]	15.6 ± 13.6 [13]	16.0 ± 11.4 [12]	−0.38 (−6.71 to 5.95)	0.725
Hospital days	23.7 ± 15.6 [22]	21.8 ± 15.2 [21]	24.5 ± 15.9 [23]	−2.75 (−11.04 to 5.54)	0.520
Blood transfusion units	15.5 ± 24.6 [8]	16.2 ± 32.8 [6]	15.2 ± 21.4 [8]	1.01 (−12.92 to 14.94)	0.527

* χ^2 test or two-sided Fisher's exact test.
† Procedure related.
‡ Student's *t* test or Mann-Whitney *U* test.

Table 11 Adjusted Odds Ratio for Mortality and Complications in Patients With Associated Major Extrathoracic Injuries (Operative Repair vs. Endovascular Stent Graft)

Outcome	Adjusted OR (95% CI)*	Adjusted p*
Death	5.68 (1.09 to 29.45)	0.039
Any systemic complication	2.17 (0.70 to 6.09)	0.179
Pneumonia	3.49 (1.13 to 10.82)	0.030

* Multivariable analysis adjusting for GCS score ≤8, SBP <90 mm Hg, and age >55 years.

Table 12 Adjusted Mean Differences for Continuous Outcomes in Patients With Associated Major Extrathoracic Injuries (Operative Repair vs. Endovascular Stent Graft)

Outcome	Adjusted Mean Difference (95% CI)*	Adjusted p*	Adjusted p on Rank*
Ventilation days	0.31 (−5.67 to 6.28)	0.919	0.712
ICU days	−0.06 (−6.57 to 6.44)	0.985	0.693
Hospital days	−2.54 (−11.17 to 6.10)	0.560	0.520
Blood transfusion units	4.99 (−8.53 to 18.50)	0.463	0.404

* Multivariable analysis adjusting for GCS score ≤8, SBP <90 mm Hg, and age >55 years.

the first trauma case treated with an endovascular SG in 1997,[17] many case reports and small retrospective studies have been published.[18–27] A systemic review by dePoll et al.[28] of all published literature up to January 2006 showed only 284 patients from 62 centers with traumatic TA rupture treated with endovascular repair. Only 15 of the 284 cases were analyzed prospectively. One of the major problems with small retrospective series is the risk of publication bias because of the inclination to publish mostly successful cases. The current prospective study addresses this concern and provides a more accurate picture of the strengths and problems of the two therapeutic approaches.

Endovascular repair was initially recommended for high-risk patients with multiple injuries or severe comorbid conditions.[29] Open repair is still considered as the gold standard for younger and low-risk trauma patients. However, the present study shows that endovascular treatment has become the procedure of first choice in the majority of cases, even in very young and low-risk patients. About 65% of all patients, 60% of patients with no major extrathoracic injuries and 57% of patients ≤55 years old and no major extrathoracic trauma, were managed with SG.

The long-term results with endovascular repair are not known. The available studies are small and the follow-up very limited. The mean follow-up in the existing survivors up to 2006 was only 15 months.[28] In older ages, the thoracic

Table 13 Adjusted Odds Ratio Between Small and Large Centers (Centers <15 Procedures vs. Centers ≥15 Procedures) for Mortality and Complications in Endovascular Stent Graft Patients

Outcome	Adjusted OR (95% CI)*	Adjusted *p**
Deaths	0.23 (0.04 to 1.27)	0.092
Any systemic complications	3.88 (1.69 to 8.91)	0.001
Any local complications	2.70 (1.08 to 6.71)	0.033

* Multivariable analysis adjusting for any severe extrathoracic trauma (head or abdomen or extremities AIS >3, GCS score ≤8, SBP <90 mm Hg, and age >55 years).

Table 14 Adjusted Mean Differences Between Small and Large Centers (Centers <15 Procedures vs. Centers ≥15 Procedures) for Continuous Outcomes in Endovascular Stent Graft Patients

Outcome	Adjusted Mean Difference (95% CI)*	Adjusted *p**	Adjusted *p* on Rank*
Ventilation days	0.311 (−2.79 to 3.41)	0.843	0.581
ICU days	1.392 (−2.130 to 4.91)	0.435	0.430
Hospital days	7.10 (1.79 to 12.42)	0.009	0.005

* Multivariable analysis adjusting for any severe extrathoracic trauma (head or abdomen or extremities AIS >3, GCS score ≤8, SBP <90 mm Hg, and age >55 years).

Table 15 Comparison of Procedure-Related Paraplegia Rates Between the Previous AAST Study[22] and Present Study

	Previous AAST Study[22]		Current Study		*p*
	Number of Patients	Paraplegia (%)	Number of Patients	Paraplegia (%)	
Overall	207	8.7	193	1.6	0.001
Clamp and sew	73	16.4	11	0.0	0.15
Bypass	134	4.5	57	3.5	0.76
Endovascular	—	—	125	0.8	—

aorta becomes ectatic and tortuous and theoretically, there is a risk of device failure. In addition, the long-term mechanical properties of the device are not known. It has been suggested that in the worst scenario, endovascular stenting may serve as a bridge for a definitive procedure.[18] Although this might be true for certain types of complications, such as endoleaks or stent migration, other potentially catastrophic complications such as acute thrombosis or emboli may occur with no warning.

The reported early results with endovascular repair of traumatic TA injuries are encouraging. The overall mortality in the 284 cases reported up to 2006 was 5.6% and the procedure-related mortality was 1.5%.[28] The current study confirms these findings. When compared with OR, endovascular repair had a lower mortality rate; overall, in patients with associated major extrathoracic injuries and patients with "isolated" TA injuries.

One interesting finding in this study was the low incidence of procedure-related paraplegia in the OR group (2.9%). This is significantly lower than the reported paraplegia of 8.7% in the AAST multicenter study of 207 thoracic aorta repairs[30] (Table 15). This might be attributed to the higher rate of bypass techniques used in this present study than the previous AAST study (84 vs. 65%). However, in the clamp and sew technique none of the patients developed paraplegia, in comparison with the 16.4% reported in the previous AAST study.[30] This finding supports the view that paraplegia may occur regardless of which accepted technique is used.[31]

The incidence of major adverse events associated with SG placement is considerable. Overall, 20% of patients developed device-related complications. Some of the complications were iatrogenic injuries to the access vessels. This problem is directly related to the large diameter of the introducer sheaths, which may require the creation of specialized access, such as iliac conduits.[32,33] Future improvement in the endovascular devices and physician training will minimize access-related complications.

Endoleaks remain another common device-related problem. This occurred in 18 patients (14.4%), 9 of which were successfully managed with the deployment of a second or third SG. The long-term implications of multiple SG in the thoracic aorta are unknown. The proper sizing of the device is critical in avoiding complications such as endoleaks or collapse of the prosthesis. The current practices recommend oversizing the SG by 10% to 20% for optimal deployment.[18,20,28] This is not always possible because the commercially available devices come in a limited range of sizes. The average diameter of the thoracic aorta, proximal and distal to the ruptured site, in patients with trauma is 19 mm.[28] The most commonly used devices are available in sizes ranging from 22 mm to 46 mm. The variable anatomy of the thoracic aorta may be a significant problem that might result in endoleaks. Borsa et al.[34] reported that in many patients with traumatic thoracic aorta rupture, the angle between the left subclavian artery and the aorta distal to the ruptured site can be up to 90 degrees. This may result in poor alignment of the device with the inner surface of the aortic arch. Excessive oversizing of the SG to address this problem may result in collapse of the device.[19,20,35,36] This type of problem resulted in a catastrophic complication of paraplegia and permanent renal failure in one of the patients in the current study. A more sophisticated design of curved prostheses, which addresses the specific anatomic needs of each individual patient is an exciting possibility which may reduce complications.

Endovascular procedures in trauma, especially in the presence of complex associated injuries, require a sophisticated multidisciplinary team approach and experience with the technique. The current study demonstrated that high-volume centers had significantly fewer systemic and local complications and shorter hospital lengths of stay than lower-volume centers. It might be advisable that these procedures be performed in selected centers of excellence which monitor their results through the quality improvement process.

CONCLUSION

Surgeons seem to prefer endovascular repair over open repair for blunt traumatic TA, even in young and low-risk patients without major associated injuries. Endovascular repair is associated with significantly lower mortality and fewer blood transfusions than open repair, but there is a considerable risk for serious device-related complications. There is a major and urgent need for improvement in the available endograft devices. Open repair is associated with a very low incidence of procedure-related paraplegia, which is not significantly higher than that with endovascular repair. Higher volume centers have better outcomes with endovascular techniques. The lack of long-term results with endovascular SG, especially in young patients, is of major concern and it might be prudent to be cautious with the liberal use of this endovascular technique until we learn more about the long-term behavior of these devices.

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DISCUSSION

Dr. Kenneth L. Mattox (Houston, Texas): Since the very earliest papers on thoracic aortic injury presented to this association, controversy has existed. This paper adds to the historic and continuing debate.

These data are very compelling and join many others, reports from individual hospital experience, in supporting continued development of new technology for treatment of most injuries to the proximal descending thoracic aorta.

During the time of this study, only one FDA-approved device existed. The smallest size of this device was 26 millimeters in diameter, too large for most young trauma patients whose average diameter is 18.5 millimeters in diameter.

Twenty-one percent of the stent grafts used in this study were off-label or custom devices. The one paraplegia in the stent group occurred with an approved device and in the case where a too-large of a graft was used in a very small aorta, causing infolding and aortic thrombosis.

I welcome the report of this complication because most centers are under-reporting this known complication and it has only appeared in the literature this past year.

Close analysis of this paper reveals both significant cautions and tremendous support. First in the area of diagnoses. This report did not present any data relating to the significant national and international concern that stent grafts are increasingly being inserted for minimal injuries that would never have undergone operation during historic time when open procedures were the only option.

Twenty-point-five percent of the injuries were described in the paper as merely having an "intimal tear." Do you have any means of assessing whether or not these were so trivial as to actually have required no treatment at all?

With only 8.3 percent of the diagnoses being made by arteriography and an astounding 96.8 percent of the injuries of the endovascular group being made by CT scan, is it possible that some of these images were artifacts or merely VOMIT? In such a case, an endograft might have been inserted in a normal aorta.

I am aware of at least one case, and probably more, where a case in this particular report was presented at another meeting by a thoracic surgeon. The CT scan showed an almost non-injury and at the time of the arteriogram of the graft insertion there was no injury to the aorta. The stent graft was deployed.

All the papers in the literature and those you see here, except for two cases in this series, were to the descending thoracic aorta. Injuries to the ascending arch and distal thoracic aorta still exist. Stent graft reports are not forthcoming.

Six of the 18 endoleaks required open repair, 30 percent. Both the number of endoleaks and the percent requiring open repair is too high.

The cost issues the authors cite as being much higher in the endovascular group, especially the need for additional endograft insertion for endoleaks, open repair, and the need for lifelong follow-up, the details of this higher cost absolutely must be analyzed.

The timing of the operation in these injuries averaged 54.6 hours, thus supporting the suggestion that delayed repair has become a new standard.

The terminology "dissection" was used in the paper. It was the diagnosis in 25.4 percent of the patients undergoing endovascular procedures.

We all know what a dissecting hematoma from cystic medial necrosis represents pathologically. I am aware of not one paper that describes the pathologic findings of a dissection described on CT scan, not one.

The continued need for open expertise will, obviously, occur. Patients with complex injury and repeat surgery and major complications are going to continue to require open procedures.

As less complex injuries are going to be managed with the endograft, those patients requiring open procedures in the future are going to have more complex injuries, greater number of procedures, related complications, and a higher mortality.

In the future, how are we going to train the open aortic surgeon? This will represent an entirely different cohort and this association has a responsibility to develop those risk adjustments for those future open cases.

The access site vascular injury was reported in this paper. This, too, has been underreported in series across the country. This has to be addressed and the so-called iliac artery on a catheter has to disappear.

It appears that in this study the comparison to the previous AAST report is significantly different and needs to be analyzed.

The long-term fate of the aortic stent grafts is unknown. Many issues in this paper are disconcerting and the greatest of these is use of endografts in minor injuries.

I would suggest that until many of these technical issues are addressed the use of endovascular stenting for thoracic aortic injuries must be on a tight IRB and FDA-approved protocol. I would recommend that this association join the thoracic associations in making that recommendation.

Dr. Mark A. Malangoni (Cleveland, Ohio): Thank you. I enjoyed your paper very much. I wonder if you could elaborate on the outcomes of some of the problems such as subclavian artery occlusions, carotid artery occlusions, and operations that were necessary because of endoleaks.

Did any of the patients who developed occlusion require anything specific? And what happened to those patients who had endoleaks and required a later operation? I would suspect that this was technically quite difficult.

Dr. Demetrios Demetriades (Los Angeles, California): Thank you very much, Dr. Mattox, for the very thoughtful comments and questions and I will respond in a mixed order.

It seems that the introduction of the endovascular repairs has revolutionized the way these injuries are managed. You saw very clearly that the mortality in early, the early mortality, this dramatically, not a little bit, dramatically lowered blunt and open repair.

And many surgeons will have the mentality, look, I fix a problem now and I worry later on if there is any complication. It might be wrong. The other thing is you showed 65 percent of these cases were managed by open repair.

When they analyze very young people, all very low risk people, 60 percent, almost two-thirds, were managed with the open, with the endovascular technique.

But like you, Dr. Mattox, I'm concerned, very concerned, about two things. Number 1 is the high incidence of device-related complications. Twenty percent is very high. And the industry needs to step up their efforts to improve this.

Again, as you correctly pointed out, a lot of these devices are really customized. Only one company has stent grafts specifically for thoracic aortic problems.

Another company, Cook, has these stent grafts for thoracic aorta available in Europe and Australia but not in the states. And I believe that in the near future we are going to see a significant improvement in these devices.

For example, now there is work to produce the curved stent graft. With the curved stent graft you will reduce the incidence of endoleaks. You will have a better position and a lot fewer endoleaks.

Now there is significant effort to produce smaller diameter introducer sheets. So hopefully it will reduce the incidence of injuries to the iliac vessels and the femoral vessels.

Now, there is work to produce branch stent grafts or grafts with small orifices. So this hopefully will reduce the need to occlude the subclavian or the carotid artery.

So, the second big concern is the lack of long-term results. We do not know what is going to happen. That's a huge concern. You put this stent graft in a 25-year old person.

Many years later his aorta will become dilated and tortuous. How is this device going to behave? Is it going to stay there or is it going to fall apart? We do not know. We need a follow-up, long-term follow-up.

Now, Dr. Mattox suggests that this should be done, the procedure should be done after IRB approval. I think it's difficult to stop the tide. As you show, 65 percent of surgeons think that this is the acceptable standard of care.

However, I would suggest that we maintain a national registry. We have all these cases treated with stent devices and we follow them up in the long-term to see any complications. I think this is the most appropriate way.

Now, minor lesions detected on the CT scan but not on the angio I think is fair to these cases that interventional radiologist goes in, he says, you know, I cannot see anything but I'm here and I might as well deploy a stent graft.

I think this is completely unacceptable. It puts the patient at significant risk, 20 percent. And it puts the physician at the significant medical/legal problem.

AAST, Number 1, the first one, the first one, the study published by Dr. Fabian, when you compare it with our results, the overall incidence of paraplegia, it's dramatically lower, 8.7 percent in the first study; 1.6 percent in the current study.

What are the possible explanations for that? Number 1, I think in the second study people used a lot of endovascular grafts so this pushed down the paraplegia rate.

Number 2, Dr. Fabian made the strong point about the 30-minute collapsed. Now, people are more educated now. And perhaps they did the collapse technique only for fairly easy cases where they are confident that that is going to be shorter than 30 minutes.

Number 3, now maybe with the delayed operations the patients are better resuscitated and perhaps this contributed to the lower incidence of paraplegia.

And, finally, I want to go to Dr. Malangoni's comments about the complications, subclavian artery occlusion. Well, they say, the books say that occlusion of the subclavian artery is tolerated quite well.

We know from trauma that if you ligate the subclavian artery, 25 percent of your patients will go to have a significant problem. So we are concerned. If, by chance, you have a dominant vertebral artery on the right side and you occlude it, there is a risk of stroke. It happened here. So, we are quite concerned.

In two of these cases there was a bypass between carotid and subclavian to address the problem. Endoleaks, it was 6 cases needed to be converted to open repair. All of them were done electively, semi-electively. And none of them developed any serious problems.