



Contents lists available at ScienceDirect

## The American Journal of Surgery

journal homepage: [www.americanjournalofsurgery.com](http://www.americanjournalofsurgery.com)

## Utilization of endovascular and open surgical repair in the United States: A 10-year analysis of the National Trauma Databank (NTDB)

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## ARTICLE INFO

## Article history:

Received 16 March 2019

Received in revised form

21 September 2019

Accepted 23 September 2019

## ABSTRACT

**Background:** Endovascular therapy provides a less invasive alternative to open surgery for critically ill patients who have sustained arterial injuries. The purpose of this study was to evaluate recent trends in the management of arterial injuries in the United States with specific reference to the use of endovascular strategies and to examine the outcomes of endovascular vs open therapy for the treatment of civilian arterial traumatic injuries.

**Methods:** We performed a 10-year (2004–2014) analysis of ACS-NTDB and identified all adult trauma patients who had arterial injuries. Data regarding demographics, injury parameters, endovascular or open vascular repair and outcomes were extracted. Cochran-Armitage trend analysis and multivariate logistic regression analysis were performed.

**Results:** A total of 111,061 patients with arterial injuries were identified and included in our analysis. Mean age was  $39 \pm 19$ y, 82% were male and 79% were white. The most common artery injured was iliac artery followed by brachial artery and thoracic aorta. Overall 6.7% (7434) patients underwent endovascular repair while 38.8% (42,495) had open vascular repair. The rate of endovascular repair increased from 3.1% to 8.9% while the incidence of open vascular repair decreased from 47% to 32% over the study period. Patients in endovascular group had lower ISS compared to patients in open vascular repair group ( $17 + 10$  vs  $24 + 10$ ,  $p < 0.001$ ). Patients who underwent endovascular repair had shorter hospital length of stay (days:  $10 + 17$  vs  $11 + 15$ ,  $p < 0.001$ ), lower mortality (8% vs 14%,  $p = 0.01$ ). On multivariate regression analysis after controlling for confounding variables, endovascular repair was independently associated with improved survival (OR: 2.45 [1.84–4.26],  $p = 0.01$ ).

**Conclusions:** The use of endovascular modalities to repair arterial injuries in the setting of acute trauma is increasing in a dramatic fashion. Endovascular repair of trauma arterial injuries is associated with shorter length of stay and improved survival compared to open vascular procedures.

Published by Elsevier Inc.

## Introduction

In the military setting, vascular trauma historically comprised less than 3%<sup>1–5</sup> of wartime injuries with peak incidence of 15% during the more recent Iraq and Afghanistan conflicts.<sup>6</sup> A prior NTDB analysis reported a 1.6% incidence of civilian vascular trauma.<sup>7</sup> Open vascular repair of peripheral arterial injuries as well as the principle of proximal and distal vascular control has been described for more than 100 years. While vascular stents were

initially conceptualized in 1912, it was not until 1964 that Dotter reported on an “endoluminal splint” to be placed after angioplasty to prevent recoil and dissection.<sup>8</sup> Wide-spread use of metallic stents for cardiovascular interventions did not occur until the late 1990s.<sup>9</sup> Open repair of thoracic aortic injuries was first described in the 1960s<sup>10,11</sup> with endovascular repair first employed in 2005.<sup>12</sup>

As endovascular techniques and tools continue to evolve, minimally invasive endovascular approaches have been adopted for the management of traumatic vascular injury, consequently open repair is not the only option in the vascular trauma toolbox.<sup>13</sup> Embolization with a variety of material is an option for management of bleeding from expendable arteries and in the setting of

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injury to critical arteries, in-line flow can be restored with the use of covered stents. This minimally invasive approach is associated with less morbidity, tissue disruption and blood product utilization,<sup>14,15</sup> with the only absolute contraindication being the inability to cross the area of injury with a wire. In instances where endovascular interventions are not appropriate for definitive management of injury, endovascular balloon occlusion of the aorta (REBOA) and smaller intraluminal occlusion balloons can be used to temporize unstable patients while plans for definitive intervention are enacted. As such, endovascular interventions have seen a surge in utilization in modern trauma centers.

These interventions can be performed in traditional operating rooms, angiography suites and the increasingly common hybrid operating suites. This unique environment, as well as the development of dedicated endovascular trauma services<sup>16</sup> allows for better streamlining of the multi-disciplinary care of the complex trauma patient. Pelvic angiography and angioembolization<sup>17,18</sup> splenic angiography and angioembolization,<sup>19</sup> and thoracic endovascular aorta repair (TEVAR)<sup>20,21</sup> have become increasingly utilized in the setting of traumatic injury, and in the case of TEVAR have become the standard of care for high grade injuries.<sup>22</sup> The purpose of this study was to evaluate trends in management of arterial injuries in the United States. We hypothesize that there is an increase in the endovascular approach and that endovascular procedures have better outcomes compared to open repair in patients with traumatic arterial injuries.

## Methods

A 10-year (2004–2014) retrospective analysis of the American College of Surgeons (ACS) National Trauma Databank (NTDB) was performed and all patients admitted with traumatic arterial injuries identified. The NTDB is the largest registry of trauma patients in the United States. All data are collected annually and subject to continuous screening, logistic checks and audits to improve the quality of the databank. More than 100 data points including demographics, comorbidities, vital signs, injury parameters, diagnoses, procedures, and time to procedure are collected. Although the NTDB is managed by the ACS, the authors of this study are solely responsible for the analyses and conclusions presented in this paper. The NTDB contains only de-identified data and institutional review board (IRB) approval was exempted.

### Inclusion/exclusion criteria

All adult patients (age  $\geq 18$  years) who were admitted with arterial injuries during the study period were included. They were identified using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes. ICD-9-CM procedure codes were used to identify patients who underwent open surgical repair (OSR) or endovascular repair (EVR) of these injuries. Patients with concomitant venous injuries or unspecified arterial injuries were excluded, as were patients who were dead on arrival or transferred from outside institutions.

### Data points

The following data was abstracted for each patient: general demographics (age, gender, race), comorbidities, injury parameters (mechanism of injury, injury severity score [ISS], each body region abbreviated injury scale [AIS]), location of arterial injury, admission vitals (systolic blood pressure [SBP], heart rate [HR], Glasgow coma scale [GCS]), intensive care unit (ICU) admission, ICU length of stay (LOS), hospital LOS, in-hospital complications, mortality and discharge disposition. Patient who underwent endovascular repair

(EVR) were compared to those who underwent open surgical repair (OSR) of their arterial injuries.

### Missing data analysis

Missing data were treated as missing at random (MAR). Variables with missing data included: [Variable (percentage of patients missing these data)] age (2.9%), ED Systolic Blood Pressure (4.8%), ED heart rate (4.7%), ED GCS (4.3%), time to procedure (6.9%). We performed multiple imputations to account for the missing values. The Markov Chain Monte Carlo method was used to perform multiple imputations.

### Statistical analysis

Cochran-Armitage trend analysis was performed to analyze the trend of EVR and OSR over the study period. Multivariate regression was performed to compare outcomes in the two groups. The possible confounding variables including patient demographics, comorbidities, admission vitals, injury parameters, injury severity (global injury severity and each body region injury severity), in-hospital course and hospital level factors were controlled for. Univariate analysis was used to assess the association between each potential dependent variable and the binary outcomes. Variables with a *p*-value less than 0.2 on the univariate analysis were then used in a multivariate logistic regression model. On the multivariate logistic regression analysis, variables were considered significant at a *p*-value less than 0.05. The Hosmer-Lemeshow test and Cox & Snell  $R^2$  were performed to analyze the fitness of the model. In the logistic regression model, the Hosmer-Lemeshow test exceeded 0.05 and the tolerance was greater than 0.1 for all independent variables with a variance inflation factor of less than 10.0. Hosmer-Lemeshow Goodness of fit test  $p = 0.415$ , Cox & Snell  $R^2 = 0.054$ .

Continuous parametric variables are reported as a mean (with standard deviation), continuous non-parametric variables are presented as a median [with interquartile range] while the categorical variables are reported as a proportion. Pearson's chi square test ( $X^2$ ) was used to analyze the differences among categorical variables. Mann-Whitney *U* test and Student's *t*-test were performed to evaluate the differences between the two groups regarding continuous non-parametric and parametric variables, respectively. Alpha was set at 5% and a *p*-value of less than 0.05 ( $p < 0.05$ ) was considered statistically significant in our analysis. All the statistical analyses were performed using the Statistical Package for Social Services (SPSS, version 24; SPSS, Inc., Armonk, NY).

## Results

Over the study period 111,061 trauma patients were admitted with a diagnosis of arterial injury (Table 1). Overall, the mean age was  $39 \pm 19$ y, 82% were male and 79% were white. The iliac artery had the highest injury incidence, followed by the brachial artery and the thoracic aorta. 59% of patients had injuries due to blunt mechanism while 41% were due to penetrating trauma. Only 45% ( $n = 49,929$ ) of the patients underwent a definitive repair of their arterial injuries during the index hospitalization. Overall, 7434 (6.7%) patients underwent EVR while 42,495 (38.3%) underwent OSR. There was significant increase in the use of EVR over the study period; from 3.1% in 2004 to 8.9% in 2014 ( $p = 0.01$ ). The number of patients undergoing OSR decreased significantly during the 10-year period; from 47% in 2004 to 32% in 2014 ( $p = 0.01$ ) (Fig. 1).

Patients in the EVR group were more likely to be older (43y vs 36y,  $p = 0.01$ ), white (84% vs 76%,  $p = 0.01$ ), and male (86% vs 77%,  $p = 0.01$ ) (Table 2). They had a higher SBP (127 mmHg vs 110 mmHg,

**Table 1**  
Overall demographics and injury parameters.

Variables	Patients with arterial injuries (n = 111,061)
Age, mean ± SD	39 ± 19
Male, %	82%
Whites, %	79%
<b>ED Vitals</b>	
SBP, mean ± SD	114 ± 24
HR, mean ± SD	96 ± 17
GCS, median [IQR]	15 [13–15]
<b>Injury Parameters</b>	
ISS, median [IQR]	14[10–26]
Head Injuries, %	31%
<b>Most Common Vessel Injured</b>	
Iliac Artery	24%
Brachial Artery	19%
Thoracic aorta	15%
<b>Mechanism of Injuries, %</b>	
Blunt Injuries	59%
Penetrating Injuries	41%
<b>Comorbidities, %</b>	
Hypertension	22%
Diabetes	8%
COPD	3%
Cardio-vascular disease	5%
Other	13%
<b>ACS Level of Trauma Centers, %</b>	
Level I	68%
Level II	17%
Other	15%
<b>Approach for repair</b>	
Endovascular repair	6.7%
Open surgical repair	38%
Non-operative management	55.3%

$p = 0.03$ ) and a lower HR (95bpm vs 99bpm,  $p = 0.04$ ) at admission compared to patients in the OSR group. Additionally, patients in the EVR group had lower injury severity (ISS: 15 vs 22,  $p = 0.01$ ), were less likely to have a head injury (21% vs 24%,  $p = 0.03$ ) and more likely to be admitted after a penetrating mechanism of injury (44% vs 42%,  $p = 0.03$ ). The mean time to repair was significantly shorter in EVR group vs OSR group (4 h s vs 8 h s,  $p = 0.01$ ). Additionally, there were significant differences in comorbidities between the two groups.

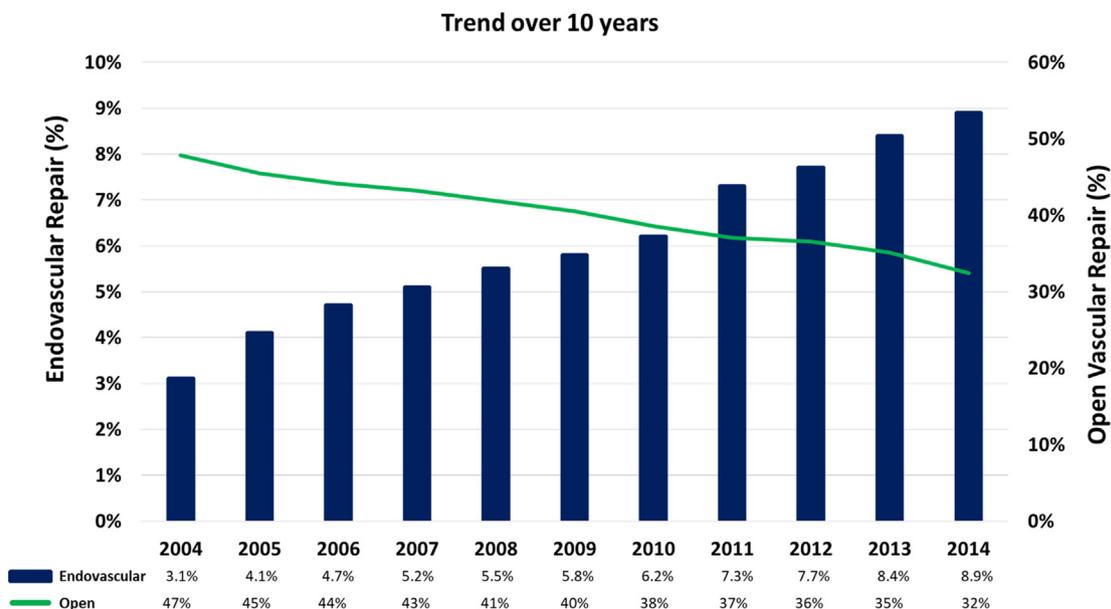
The most common arteries injured in the EVR group were thoracic aorta followed by iliac and femoral arteries while the most common arteries injured in OSR were brachial artery followed by femoral and popliteal arteries. Subgroup analysis of specific location of vascular injury was performed (Table 5). Of the 13,377 patients with femoral arterial injury, 11,895 underwent OSR while 1482 patients (11%) underwent EVR. There were 10,375 patients with iliac artery injuries reported (common, internal and external). OSR was performed in 8072 patients while EVR was performed in 2303 patients (22%). This database did not distinguish between embolization and stenting of the iliac system. Thoracic aortic injuries were present in 6117 patients; 3568 underwent OSR while 2549 (42%) underwent EVR. 3628 axillo-subclavian injuries were reported, with 3289 undergoing OSR and 339 (9%) undergoing EVR.

Patients in the EVR group had lower rates of complications (19% vs 24%,  $p = 0.01$ ), specifically surgical site infections (4% vs 7%,  $p = 0.01$ ) and pneumonia (5% vs 8%,  $p = 0.03$ ) (Table 3). EVR patients were also less likely to be admitted to the ICU (21% vs 31%,  $p = 0.01$ ), had a shorter hospital length of stay (4days vs 8days,  $p = 0.01$ ) and a lower mortality rate (8.8% vs 14.2%,  $p = 0.01$ ). However, there was no difference between the two groups regarding the ICU length of stay ( $p = 0.12$ ) (Table 3).

On regression analysis, after controlling for confounding variables (demographics, comorbidities, admission vitals, injury parameters, ISS), compared to OSR, EVR was independently associated with lower odds of complications and higher odds of survival. No association was found between the approach of repair and ICU admission or SNF/Rehab disposition (Table 4). The same analysis of the anatomic location of injury subgroups yielded similar results (Table 5).

## Discussion

A substantial number of arterial injuries were reported to the ACS NTDB, however fewer than 50% had a reported intervention. As this database review utilized the presence of ICD-9-CM procedure codes to determine whether or not a surgical intervention was performed, this review failed to capture arterial injuries that may have been managed with surveillance and/or medical therapy; i.e. intimal flaps, pseudoaneurysms. Observation is a reasonable course



**Fig. 1.** Trends of Endovascular and Open Surgical repair of arterial injuries (2004–2014).

**Table 2**  
Demographics and injury parameters.

Variables	Open Surgical repair (n = 42,495)	Endovascular repair (n = 7434)	P-value
Age, mean ± SD	36 ± 17	43 ± 20	0.01
Male, %	77%	86%	0.01
Whites, %	76%	84%	0.01
<b>ED Vitals</b>			
SBP, mean ± SD	110 ± 26	127 ± 21	0.03
HR, mean ± SD	99 ± 19	95 ± 18	0.04
GCS, median [IQR]	15 [14–15]	15 [15–15]	0.21
<b>Injury Parameters</b>			
ISS, median [IQR]	22 [13–36]	15 [9–27]	0.01
Head Injuries, %	24%	21%	0.03
<b>Most Common Vessel Injured</b>			
	Brachial (34%) Femoral (28%) Popliteal (21%) Iliac (19%)	Thoracic Aorta (48%) Iliac (31%) Femoral (20%) Brachial (17%)	
<b>Mechanism of Injuries, %</b>			
Blunt Injuries	58%	56%	0.03
Penetrating Injuries	42%	44%	
<b>Comorbidities, %</b>			
Hypertension	18%	25%	0.01
Diabetes	6%	9%	0.03
COPD	2%	5%	0.02
Cardio-vascular disease	2%	4%	0.01
Other	7%	16%	0.01
<b>ACS Level of Trauma Centers, %</b>			
Level I	67%	74%	0.01
Level II	20%	14%	
Other	13%	12%	
<b>Time to repair, hours, median[IQR]</b>	8 [5–31]	4 [2–16]	0.01

**Table 3**  
Outcomes.

Outcomes	Open Surgical repair (n = 42,495)	Endovascular repair (n = 7434)	P-value
Complications, %	24.8%	19.2%	<b>0.01</b>
SSI	7.1%	4.2%	<b>0.03</b>
ARDS	3.1%	2.1%	0.37
Pneumonia	8.3%	5.1%	<b>0.03</b>
Sepsis	3.2%	2.9%	0.25
AKI	5.8%	6.1%	0.31
MI	1.1%	1.0%	0.14
ICU Admission, %	31%	21%	<b>0.01</b>
ICU LOS, days, median[IQR]	3[1–3]	2[1–3]	0.12
Hospital LOS, days, median[IQR]	8[4–11]	4[2–8]	<b>0.01</b>
SNF/Rehab disposition, %	12.4%	10.1%	<b>0.03</b>
Mortality, %	14.2%	8.8%	<b>0.01</b>

**Table 4**  
Multivariate regression analysis for outcomes<sup>a</sup>.

Variables	OR	95% Confidence Interval	P-value
Complications	0.64	0.41–0.86	<b>0.03</b>
ICU Admission	0.96	0.94–2.38	0.35
SNF/Rehab disposition	1.05	0.91–3.18	0.28
Survival	2.45	1.84–4.26	<b>0.01</b>

Reference: Open surgical repair.

<sup>a</sup> Patient demographics, comorbidities, admission vitals, injury parameters, injury severity (global injury severity and each body region injury severity), in-hospital course and hospital level factors.

of action when managing small luminal irregularities in the setting of preserved distal perfusion in a critically ill patient. Without a contraindication to anti-impulse therapy (tight heart rate and blood pressure control), low grade aortic injuries can safely be managed non-operatively.<sup>22</sup> The cohort that did not undergo definitive intervention also includes a portion of patients who did not survive long enough for surgical repair and those who underwent primary amputation. As this is a retrospective review of a

large database, there is likely also an element of incomplete data capture and coding error, however this needs to be considered in the context of the fact that >50% of patients did not undergo either repair.

Of the patients who underwent OSR or EVR, the characteristics of age, gender, and ethnicity were different (Table 1). While the group undergoing EVR was substantially smaller in number than those undergoing OSR, the proportion of those undergoing EVR steadily increased over the 10-year study period. This is likely due to both increasing prevalence of endovascular capabilities for peripheral interventions as well as the FDA approval of TEVAR stent-grafts in 2005. Endovascular repair was used most commonly in TEVAR (42%) followed by iliac artery (22%), femoral artery (11%) and axillo-subclavian arteries (9%).

The mean time to repair was 50% shorter in the EVR vs OSR groups (4h vs 8h). This is counterintuitive and difficult to explain. Our dataset does not have granular timeline detail; it is unclear whether “time to repair” was time from admission to intervention or time from consult of subspecialty service to intervention. Additionally, we did not capture other procedures that were potentially

Table 5

	Total	EVR	OSR	%EVR	OR EVR complication rate	OR mortality rate endovascular repair
Femoral artery	13377	1482	11895	0.110787172011662	0.71[0.51–0.89]	1.99[1.73–4.75]
Iliac artery	10375	2303	8072	0.221975903614458	0.57[0.32–0.74]	2.88[1.93–5.47]
Thoracic aorta	6117	2549	3568	0.41670753637404	0.67[0.48–0.81]	2.89[2.07–6.11]
Axillo-subclavian	3628	339	3289	0.093439911797133	0.88[0.79–0.94]	0.91 [0.85–1.13]

performed during the same trip to the operating room. For example, a patient undergoing TEVAR may simply undergo an isolated endovascular repair, while a patient undergoing an open aortic repair may also require additional exploratory procedures and temporizing measures. Another consideration is the unclear endpoint of “time to repair”; was this the beginning or the end of the case? Was it the time in-line flow was restored?

It has been previously demonstrated at a single institution that time to endovascular hemostasis in the setting of uncontrolled pelvic hemorrhage was markedly different when the patient presented during business hours and after hours, due to the time required to mobilize the specialized teams.<sup>23</sup> While the NTDB does not capture the subspecialty of the endovascular interventionalist, due to credentialing policies at most institutions it is likely that these procedures were performed by physicians who are trained in vascular surgery or interventional radiology. While acute care surgeons have demonstrated competency in basic endovascular technique (REBOA),<sup>24</sup> it is unlikely that they are currently credentialed to perform these more complex endovascular procedures. The variable and sometimes prolonged amount of time required for these consultant providers to evaluate patients and activate their teams after business hours may influence the trauma team's decision to pursue endovascular interventions. Perhaps there is a bias toward consulting interventional radiology or vascular surgery preferentially during business hours, resulting in an artificially decreased time to intervention in this group. A patient who is less severely injured, reflected by their lower ISS, may be deemed to be appropriately stable to wait for a minimally invasive intervention. Trauma surgeons caring for more severely injured or hemodynamically unstable patients may elect to proceed directly to the operating room without involving an additional team. By eliminating the need to activate an out-of-hospital consultant, specialized endovascular trauma services have been demonstrated in a single institution to decrease time to hemostasis in trauma patients.<sup>16</sup>

While those who underwent EVR had a shorter hospital length of stay (HLOS) (days, 10 vs 11,  $p < 0.001$ ) and lower mortality (9% vs 14%,  $p < 0.001$ ), this is likely at least in part due to their lower overall injury burden. On multivariate regression analysis after controlling for patient demographics, comorbidities, admission vitals, injury parameters, injury severity (global injury severity and each body region injury severity), in-hospital course and hospital level factors, EVR was independently associated with improved survival (OR: 2.45[1.84–4.26],  $p = 0.01$ ), however this may not be causative.

The lower complication rate observed in patients undergoing EVR is difficult to interpret. This database review did not capture multiple and repeated operations in the same patient, it simply evaluated overall complication rates. As stated previously, the patients in the EVR group had a lower ISS and consequently likely needed fewer interventions. The higher ISS of the OSR group and presumed increase in required interventions makes them more likely to experience complications. Additionally, while this database contains complications such as fasciotomy, amputation and hematoma there are limited details regarding the patient's clinical course, making it impossible to determine whether those are the direct result of the vascular intervention, the primary injury, or are completely unrelated. Additionally, it is well described that

concomitant venous injury, orthopedic injury and significant soft tissue defect in the setting of arterial injury decrease the likelihood of successful limb salvage.<sup>25</sup> We were also not able to analyze the rates of primary or secondary patency of vascular repairs from the information in this database. Further exploration of vascular trauma specific databases such as the American Association of Surgery for Trauma Prospective Observational Vascular Injury Treatment registry (AAST-PROOVIT)<sup>26</sup> would provide more detailed information regarding vascular complications and outcomes.

While EVR is an increasingly utilized option for repair, it is important to note that there will continue to be injuries better suited to open exploration. Areas of significant flexion or tortuosity i.e. thoracic outlet and popliteal fossa, place stents at high risk for fracture. The smaller caliber of the infrageniculate and infrabrachial vessels makes them poor endovascular targets at high risk of in-stent thrombosis. In this relatively young patient population, in-stent thrombosis has the potential to be particularly dire. These patients lack the arterial collateralization and ischemic preconditioning present in patients with chronic vascular disease, making them especially sensitive to abrupt decrements in arterial flow.<sup>27,28</sup> This should be of paramount consideration in patients with competing injuries, who may have at least temporary contraindications to anticoagulation or antiplatelet therapy. Given that intravascular stents and TEVAR grafts only obtained initial FDA approval in the 1990s<sup>9</sup> and 2000s<sup>12</sup> respectively, there is no long-term patency data available. This certainly must be carefully considered when placing one of these devices in a young patient.

### Limitations

This study is limited by its retrospective nature and the fact that the database used is a sample of voluntarily submitted data, making it prone to missing data and selection bias. There is minimal specific detail in this database regarding vascular injury, making it difficult to draw specific conclusions as detailed above.

### Conclusion

While this study is limited by its large pooled nature and the inability to obtain granular detail about the nature of the injuries and characteristics of the patients, it does demonstrate a growing trend and the acceptance of a valuable new tool in the armamentarium of those who care for the trauma patient. In this study, endovascular repair of arterial injuries was associated with shorter hospital length of stay and improved survival, however, further prospective investigation of the management of these injuries is necessary.

### Declaration of competing interest

None.

### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.amjsurg.2019.09.030>.

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