Journal of Integrative Cardiology Open Access | ISSN 2674-2489

Journal of Integrative Cardiology Open Access

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Research Article

Mid-Term Clinical and Morphological Outcomes After Thoracic Endovascular Aortic Repair for Complicated Type B Aortic Dissection

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ARTICLE INFO

Article history:
Received: 1 May, 2020
Accepted: 14 May, 2020
Published: 23 June, 2020

Keywords:
Type B
aortic dissection
remodeling
endovascular
repair

ABSTRACT

Background: Complicated type B aortic dissections require surgery or thoracic endovascular aortic repair (TEVAR). In this study, we sought to explore the early and mid-term clinical efficacy of TEVAR treatment for Stanford complicated type B aortic dissection.

Methods: From January 2012 to October 2017, the medical records and the aortic imaging data of 172 consecutive patients treated by TEVAR were retrospectively reviewed for statistical analysis. Aortic remodeling was evaluated based on the preoperative and one-year postoperative followed-up aortic CTA scan results. We analysed the diameters of the total aortic lumens, True and False lumens diameter and the thrombosis status at different five levels along the descending aorta.

Results: The primary technical success rate was 97%, and the clinical success rate was 94.8%. At 1-year of aortic CTA follow-up after TEVAR, the true lumen diameter at the stented descending thoracic aorta increased significantly, the false lumen diameter significantly reduced. The remodeling process was stable with mild changes of true lumen increase and false lumen reduction at the unstented distal part of the descending thoracic and the abdominal aorta.

Conclusion: This study confirmed that TEVAR treatment for complicated type B aortic dissection has a low mortality rate of mid-term follow-up outcomes. TEVAR stabilizes the size of the aorta and precipitates in FL thrombosis. However, FL in the abdominal aorta still patented and must be carefully observed for further long-term events.

Introduction

Aortic dissection is a critical cardiovascular disease related to high mortality and morbidity rates [1]. In Stanford TBAD, the dissection is known to involve the level beneath the LSA until the distal regions of the aorta, which does not involve the aortic arch or the ascending aorta. Usually classified as acute subacute or chronic phases, depending on the onset of symptoms. Another essential classification of TBAD based on the presence or absence of complications, which allows us to distinguish between complicated and uncomplicated TBAD. It is important for the estimation of in-hospital death in CTBAD patients, which was near 50%, compared to only 10% in un-CTBAD patients. Classically the definition of the acute complications are marked as aortic rupture, refractory pain, despite the persistence of uncontrolled hypertension with adequate medical treatment, rapidly increases in the mean aortic diameter more than 0.5cm per year, or aortic enlargement more than 5.5cm, acute hoarseness, signs of malperfusion such as visceral or limb ischemia, and acute renal failure. However, some of these terms required further clarification. Complications such as aortic rupture into the pleural cavity will result in an immediate large amount of hemothorax, leading to severe hypovolemic shock and death.

In 1999, Dake *et al*. study was the first clinical trial described the medical use of implanted stent-grafts for the management of the aortic aneurysm patients who expected as a high risk for open surgery management [2]. At present, this technology has been increasingly applied to CTBAD due to a favourable result when compared to standard open surgery. Closure of the primary entry tear may promote the formation of thrombus in the

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http://dx.doi.org/10.31487/j.JICOA.2020.03.03

FL, leading to the degradation and re-expansion changes in the TL, these late effect changes are known as aortic remodeling.

Probably it can prevent the late degenerations of the aneurysm or rupture of the dissected aortic segment as it was detected earlier in 20 to 50% of patients who applied OMT [3, 4]. There were numerous clinical trials reported the remodeling process of the aorta after TEVAR treatment [5-7].

The aortic remodeling changes, and its effectiveness in preventing late aortic events are still not fully described. Therefore, our study retrospectively analysed the aortic database of CTBAD patients who underwent TEVAR treatment, to seek out the main characteristics and the beneficial effects of the aortic remodeling after TEVAR treatment.

Methods

I Study Design and Patients

The current study was approved by the institutional review board of our hospital, in the Declaration of Helsinki, and compliance with the Health Insurance eligible and responsibility Act regulations. The Institutional Review Board conceded the requirement for distinct patients' consent. The aortic database and the medical record of 172 patients who underwent TEVAR treatment for CTBAD (DeBakey 3b aortic dissection) Between January 2012 and October 2017 were the target group of this retrospective study. The CTBAD was previously defined as any occurrence the following symptoms or signs: relapsed or refractory pain, malperfusion, aortic rupture, abnormal neurological signs, shock, refractory hypertension, and early aortic dilation or expansion, either at the presentation time or during the hospitalization stay [8-10]. All patients underwent de-novo stenting for the proximal thoracic descending aorta. All patients were being confirmed with the diagnosis of CTBAD by the preoperational thoracoabdominal aorta CTA (Discovery CT750 HD; GE Healthcare, Milwaukee, WI, USA). We excluded the patients who were managed by open surgery due to the aortic condition as they were not appropriate for TEVAR treatment.

II TEVAR Procedure Details

In this study, 141 (82%) patients underwent TEVAR treatment in the acute setting of CTBAD (<14 days of the onset of the symptoms), while 31 (18%) patients were in the sub-acute stage (≥14 days and ≤90 days). The endograft-systems delivery performed via the femoral artery in most cases, only in 7 (4.2%) cases performed through the iliac artery. In all patients, TEVAR procedure completed under the guidance of the Digital subtraction angiography (DSA) imaging systems (Allura XpraFD10, Philips Medical Systems Inc., Best, The Netherlands; GE Healthcare Innova IGS 530, BUC CEDEX, France.). The mean implanted endograft-stents diameter was 31.52±2.33 (ranged between 28 and 40 mm), and the mean length was 164.74 ± 22.65 (ranged between 80 and 200) mm. All endograft-stents were oversized by 5% to 10% according to the decision made by the operators.

The operations conducted under local anesthesia were 143 (83.1%) cases and general anesthesia in 29 (16.9%) cases. The endograft-stents brands were Valiant TM stents (n=85 (49.4%) (Medtronic Endovascular, Santa Rosa, California, USA), Relay (n= 39 (22.7%) (Bolton Medical, Sunrise Florida, USA), Hercules TM stent (n=42 (24.4%) (MicroPort Scientific Corporation, Shanghai, China), E-Vita Thoracic (n=4 (2.3%) (JOTEC, Hechingen, Germany), Hemasheild (n=1 (0.6%) (German Healthcare Export Group, Germany), and Lifetech Scientific (n=1 (0.6), (Lifetech Scientific (Shenzhen) Co., Ltd. China). Details of TEVAR endograft brands are listed in (Table 1). The prescribed medications after patients discharged from the hospital were routinely based on patients' general cardiovascular risk factors. All patients were advised to perform the follow-up after TEVAR at first and the sixth month, then once per year.

III Assessment of the Aortic Remodeling

Assessments of the aortic lumens remodeling based on the aortic CTA scan results obtained at the closet time preoperatively and at after one-year of TEVAR follow-up. Aortic remodeling changes were evaluated at five different levels along the aorta; level A was at the mid-point of the aortic arch on the maximum transverse image, level B at the proximal descending aorta about 2cm beyond the origin of the LSA, level C at the pulmonary artery bifurcation, level D at the hiatus aorticus on the diaphragm, and level E at the celiac trunk origin. All of the obtained axial images data transferred then to the workstation by Fujifilm's medical imaging and information Management system, SYNAPSE PACS (Picture Archiving and Communication System). For accurate diameters measurements, all lumens were measured on a cross-sectional level in a perpendicular position to the intimal flaps at each of these five levels.

Successful introduction and placement of the stent-graft system without open surgical management, death ≤ 24 h, type I or III endoleaks, or obstruction of the graft-stent is defined as the primary technical success [11]. Primary clinical success defined as the succeeded deployment of the delivered graft-stent to the intentional position without type I or type III endoleaks, aortic aneurysm expansion, stent infection, thrombosis, ruptured aortic aneurysm, transferring to open surgical management or death from dissection-related treatment [12].

Statistical Analysis

Collected data statistically analyzed by IBM SPSS statistics version 25.0 (SPSS, Chicago, Illinois, USA). The categorical variables displayed as frequencies with percentages and analyzed by using the chi-square test or Fisher's exact test if necessary. Normally distributed continuous variables presented as means and their standard deviations. The difference in the aortic diameter measurements before and at one-year post-TEVAR treatment, at different levels was compared by paired-samples T-test.

Results

I Patient Demographic Characteristics

Demographic parameters and the aortic dissection features are listed in (Table 1). The mean age was 52.19±10.53 years; male patients are 142(82.6%) cases. TEVAR procedure performed in the acute stage of CTBAD was observed in 141 (82%) cases, sub-acute stage in 31 (18%) cases. All of the patients presented with DeBakey 3b aortic dissections. Patients treated by TEVAR due to rupture in 23 cases, limb or visceral ischemia in 61 cases, persisting pain in 104 cases, uncontrolled hypertension in 33 cases, diameter > 4cm in 19 cases or malperfusion in 25 cases. No adjunctive procedures required such vessels bypass or stenting of the renal artery, superior mesenteric artery or iliac artery. All

TEVAR procedures completed by single graft-stent implanted in the proximal segment of the descending thoracic aorta in every patient with a median diameter of 32 mm ranged between (28, 40) mm, and a median length of 160 ranged between (80, 200) mm. Complete coverage of the LSA was required in 5 (2.9%) patients, managed by isolated left common carotid to left subclavian artery bypass operation.

Table 1: Patients' Demographic Features and aortic dissection characteristics.

Variables	N=172	Variables	N=172
Acute CTBAD n (%)	141 (82.0%)	Aortic rupture, no (%)	23 (13.4%)
Subacute CTBAD n (%)	31 (18.0%)	Malperfusion, no (%)	25 (14.5%)
Age years old (M ± SD)	52.19 ± 10.53	L/V ischemia, no (%)	61 (35.5%)
Male no. (%)	142 (82.6%)	Persisting pain, no (%)	104 (60.5%)
BMI kg/m^2, (median)	26.14 ± 2.20	Uncontrolled HTN, no (%)	33 (19.2%)
HTN, no (%)	141 (82.0%)	A.D > 4cm, no (%)	19 (11.0%)
Smokers, no (%)	68 (39.6%)	General anesthesia, no (%)	29 (16.9%)
DM, no (%)	11 (6.4%)	Local anesthesia, no (%)	143 (83.1%)
CAD, no (%)	10 (5.8%)	Covered LSA, no (%)	5 (2.9%)
CVD, no (%)	3 (1.7%)	Covered LCCA, no (%)	0 (0%)
CT involved, no (%)	61 (35.5%)	Graft diameter, median(R)	32 (12)
SMA involved, no (%)	29 (16.9%)	Graft length, median(R)	160 (120)
LRA involved, no (%)	31 (18.0%)	Valiant thoracic, n (%)	85 (49.4%)
RRA involved, no (%)	10 (5.8 %)	Relay, n (%)	39 (22.7%)
LIA involved, no (%)	52 (30.2%)	Microport, n (%)	42 (24.4%)
RIA involved, no (%)	47 (27.3%)	JOTEC GmbH, n (%)	4 (2.3%)
NTL Branches, no (%)	24 (14.0%)	Life technology Scientific	1 (0.6%)
Pleural effusion, no (%)	77 (44.8%)	Hemasheild platinum, n (%)	1 (0.6%)

Data with normal distribution are presented as frequencies with their percentages or means ± SD, and median with the range if not normally distributed. CTBAD: Complicated Type B Aortic Dissection; M: Mean; SD: Standard Deviation; BMI: Body Mass Index; HTN: Hypertension; DM: Diabetes Mellitus; CAD: Coronary Artery Disease; CVD: Cerebrovascular Disease; CT: Celiac Trunk; SMA: Superior Mesenteric Artery; LRA: Left Renal Artery; RRA: Right Renal Artery; LIA: Left Iliac Artery; RIA: Right Iliac Artery; NTL: Narrow True Lumen; L/V: Limb or Visceral; A.D: Aortic Diameter; LSA: Left Subclavian Artery; LCCA: Left Common Carotid Artery.

II Early Events

In this study, two patients have been confirmed with retrograde type-A dissection, and they were transferred to for treatment by open surgery. Type-I endoleaks were recorded in three patients just after stent-graft deployment repeated aortic angiography, and they were treated conservatively with close observation. The 30-day mortality rate was 2 (1.2%). One patient died of cardiac arrest after two days from TEVAR at the admission word. Another patient died of a ruptured abdominal aortic aneurysm on the 4th day after TEVAR operation (Table 2).

Table 2: Early and late events after TEVAR.

Variables	N=172	Variables	N=172
Early events		Retrograde type A dissection	2 (1.2%)
Type-I endoleak	3 (1.7%)	Aortic enlargement	10 (5.8)
Type-II endoleak	0 (0.0%)	Ulcer-like projection	0 (0.0)
Type-III endoleak	0 (0.0%)	Type-I endoleak	3 (1.7%)
Retrograde type A dissection	2 (1.2%)	Type-II endoleak	0 (1.2%)
Organ failure	0 (0.0%)	Type-III endoleak	0 (0.0%)
Stroke	2 (1.2%)	**Late death**	
30-days death	2 (1.2%)	Aortic related	1 (0.6%)
Late events		Aortic unrelated	2 (1.2%)
Aortic rupture	3 (1.7%)	Unknown	1 (0.6%)

Normally distributed data are presented as frequencies with their percentages, and median with the range if were not normally distributed.

III Late Events

Late events included retrograde dissection, aortic enlargement, aortic rupture, ulcer-like projection, type-I and-II endoleaks, and late death illustrated in (Table 2). During one year of follow-up results, there were four deaths recorded in this study. There was one case of aortic-related death due to ruptured false lumen on the descending aorta at the presenting time. The other three deaths were categorized as unrelated to the aortic dissection (cardiac-related death in two cases). The aetiology in one death could not be determined (Table 2).

IV Analysis of the Imaging Data

Overall, 172 patients, only 166 patients were available for the 1-year aortic CTA follow-up analysis. In the mid aortic arch (A level), the total aortic diameter did not change significantly compared to before TEVAR.

At the 1-year follow-up, the TLD at the levels (B and C) of the stented segment of the descending thoracic aorta increased significantly after TEVAR procedure; also, the mean reduction of the FLD was extremely significant. Almost in the included 166 patients, complete disappearance of the FL was observed in 21 (12.7%) and 22 (13.3%) cases respectively, complete thrombosis was observed in 128 (77.1%) and 117(70.5%) cases, at both levels B and C respectively. At the aortic hiatus level (D level) just beneath the stent area, The TLD and the FLD showed fewer changes effect than the proximal and mid aortic levels. However, in this level, 48(28.9%) cases the FL still patent, and 65 (39.2%) cases were partially thrombosed, the complete thrombosis observed in 42 (25.3%) cases. And only 11(6.6%) cases observed as complete obliteration. Compared with the value of preoperative CTA results, the TLD and FLD in the abdominal aorta at the celiac trunk (level E) demonstrated mild remolding changes. In this level, 87 (52.4%) cases FL still patent, and 64 (38.6%) cases were in partial thrombosis process; complete thrombosis was detected in 11 (6.6%); only 4 (2.4%) had complete obliteration. All aortic measurements are listed in (Table 3). Preoperative and postoperative False Lumen Status are listed in (Table 4).

Table 3: Aortic diameters of different aortic levels (n=166).

Aortic (level)	Preoperative	Post-operative	P-Value
Mid-aortic arch (A)	35.05±3.19	35.27±3.07	0.065
True lumen measurements			
Proximal level (B)	19.78±5.48	29.23±2.85	<0.001
Pulmonary bifurcation (C)	17.32±5.92	26.62±3.26	<0.001
Hiatus aorticus (D)	14.79±5.45	23.01±4.18	<0.001
Celiac trunk (E)	12.54±4.58	17.22±4.57	<0.001
False lumen measurements			
Proximal level (B)	18.54±6.27	3.57±5.67	<0.001
Pulmonary bifurcation (C)	15.49±6.87	3.40±5.42	<0.001
Hiatus aorticus (D)	13.64±5.63	9.34±4.30	<0.001
Celiac trunk (E)	11.98±4.47	9.42±4.31	<0.001

Data are displayed as estimated measured means ± SD in mm obtained from preoperative aortic CTA and follow up one year.

Table 4: Before and one-year postoperative False Lumen Status at Different Aortic levels (n =166).

Lumen Status	Level B	Level C	Level D	Level E
Preoperative				
Patent	140(84.3%)	141(84.9%)	121(72.9%)	154(92.8%)
Partial thrombosis	23(13.9%)	15(9.0%))	30(18.1%)	9(5.4%)
Complete thrombosis	3(1.8%)	10(6.0%)	15(9.0%)	3(1.8%)
Complete Obliteration	0(0%)	0(0%)	0(0%)	0(0%)
Post-operative				
Patent	6(3.6%)	9(5.4%)	48(28.9%)	87(52.4%)
Partial thrombosis	11(6.6%)	18(10.8%)	65(39.2%)	64(38.6%)
Complete thrombosis	128(77.1%)	117(70.5%)	42(25.3%)	11(6.6%)
Complete Obliteration	21(12.7%)	22(13.3%)	11(6.6%)	4(2.4%)

Data are displayed as frequencies with their percentages.

Discussion

Stanford type B aortic dissection is a critical cardiovascular disease; it classified into complicated and uncomplicated TBAD. Complicated TBAD treatment by TEVAR hit an earlier closure effect of the entry tear, which may lead to TL expansion and thrombosis or regression of the FL effects. Over the past decade, both the morbidity and mortality rates for TBAD have been reduced significantly [13]. In the current years, TEVAR treatment for acute TBAD with complications has been developed with acceptable clinical-outcomes and has generally replaced the traditional open surgery choice for the treatment of TBAD.

In this study, we aimed to investigate the influence of TEVAR on early and late clinical outcomes in CTBAD. Formerly, the ratio of the early events in CTBAD and un-CTBAD patients managed by TEVAR procedure were ranged between 2.4% to 33.3% and 8.3%, in complicated and uncomplicated cases, respectively [12, 14, 15]. In our study, early event rates after TEVAR were 5.2%, of which there were two (1.2%) early deaths. In previous trials, the rate of early death in patients with CTBAD treated with TEVAR has ranged from from3% to 13.3% [12, 14, 15]. Therefore, the rate of early death and the early events in our study sample were consistent with those of prior studies [16, 17]. As for the late events, Aortic enlargement (5.8%) was the most common findings. Aortic enlargement in some conditions may be related to the rupture of the aorta in patients with TBAD; this is a vital late adverse event marked as one of the main causes of late death [18, 19]. In our study, there were one out of six (16.7%) patients died of the related aortic cause, which was consistent with those of the previous studies [20, 21].

Computed tomography is an important investigation which is preferred in preparation for TEVAR intervention, especially to estimate the size of the stent-graft, deployment site and access sites all important considerations evaluated. CT is also important in the post-procedure follow-up of AD patients [22]. There were several studies which have illustrated the aortic remodeling progression or even the complete loss of the false lumen after entry closure by TEVAR procedure; this dramatic alteration may represent the ‘‘healing’’ of the aortic dissection

[6, 23-25]. The coverage of primary intimal tear by TEVAR operation may expand the TL, prevent an antegrade of blood flow into the FL by closing the entry tears at the dissected layers of the aortic wall. In this study, only patients with CTBAD (DeBakey 3b aortic dissection) were involved in this study to maintain the homogeneity of the study sample as far as acceptable. The morphological data of the aorta during a mid-term follow-up were statistically analysed for the assessment of post-TEVAR aortic remodeling outcomes, when performed in the acute or subacute stages, and may not contain patients in the chronic stages.

The description of the MOTHER database study included 1010 cases, of which 114 cases were in the acute TBAD; the mean follow-up was 2.2 years; the conclusion reported that when performing TEVAR treatment for both thoracic aortic aneurysm and TBAD seems to offer remarkable mid-term protective effect from aortic-related mortality [26]. However, this protective effect seems to depend on the high rate of re-intervention of the aorta, which must be the focus of future training and equipment development.

We found a beneficial aortic remodeling effect after TEVAR. In the thoracic area, a significant increase of the TLD, and a reduction of the FLD were detected. The descending thoracic aorta not only achieved complete FL thrombosis but in 22 of 166 cases had a complete loss of the FL. These findings are similar to previously reported trials [27, 28]. However, TEVAR eliminates the original anatomical problem by closing the FL; yet, it only occurs at the covered level by the stent-graft. Meanwhile, in our study, there was a mild increase in the TLD and a slow reduction of the FLD at the level of the hiatus aorticus.

The abdominal aorta at the celiac trunk level, compared with the levels mentioned above B to D level respectively, the TLD showed a gradual increase and decrease in the FLD. Although the abdominal aorta was stable during the follow-up time, it was less stable than the covered thoracic part. At the hiatus aorticus level, there was a significant increase in the change of the partial and complete FL thrombosis compared with to its status at preoperative time, this evidently proves progressive growth over time of partial or complete FL thrombosis from the LSA to the celiac trunk level post-TEVAR treatment in patients with CTBAD. Previous studies such as Andacheh *et al*. detected an increase of the infrarenal aorta post-TEVAR treatment in the aortic dissection that reached into the abdominal aorta. Maximal TLD of the Infrarenal artery had been increased significantly post-TEVAR operation; also, there was a decrease in the FLD [29]. One more study, Sigman *et al*. reported an expansion within the true lumen and failed false luminal progression in the thoracic region, there were no clear changes in the abdominal aortic part. However, they evaluated both the diameter and the volume of the aortic lumens, and the follow-up was only 14.4 months [30].

We expected to consider the fact that abdominal aortic repair after the closure of the entry located at the proximal aortic segment beyond the LSA is not needed since there was no luminal increase up to a massive abdominal aortic aneurysm. In a condition that complete coverage of the aorta at the thoracic region by an extended stent-graft covering until the level of the celiac trunk, although it may result in loss of the FL at these critical levels, and this could add more stability of the aorta, but it may lead to vital complications such as spinal cord ischemia.

Most of the technical approaches were completed in the acute settings. Performing an implanted proximal stent-graft in the subacute phase possibly offer an additional aortic remodeling and therefore may diminish the risk of spinal cord ischemia. In our study group, coverage of the LSA was performed in 5 cases (3%). These patients did not complain from any symptoms of paraplegia or acute limb ischemia during the admission time and after discharging from the hospital.

Limitations

First, in our study, the follow up was only up to one year. Therefore, it was not long enough. And this is maybe due to most patients chose to perform their imaging investigations at their local area's hospitals. So, all CTA scans after time more than 1-year may perform in their regional hospitals, that we could not obtain their CTA scan data. The study sample is not large enough to obtain more obvious details about the aortic remodeling process; it may need a larger sample. Hence, a multicentre prospective follow-up of recent patients is required.

Conclusion

In conclusion, a reduction in the mortality rates balanced the increase rate of reinterventions expected from the endovascular treatment. Our study remodeling findings suggested that in all patients with type B aortic dissection should receive endovascular treatment because it can be treated effectively with TEVAR. In patients with CTBAD, TEVAR resulted in remodeling of the aortic part in the thorax area, and the majority of the patients had a complete loss of the FL in Proximal and mid-segment of descending thoracic aorta. Besides that, the size of the Proximal descending thoracic aorta is stabilized by TEVAR, which is usually the largest part of the aorta. At the part of the aorta in the abdominal region, the FL still patented and needs to be closely monitored for long-term intervention, as it is the part that is most likely to become an aneurysm and may be exposed to aortic rupture.

Conflicts of Interest

None.

Abbreviations

FL: False Lumen
TEVAR: Thoracic Endovascular Aortic Repair
CTBAD: Complicated Type B Aortic Dissection
CTA: Computed Tomography Angiography
TL: True Lumen
TLD: True Luminal Diameter
FLD: False Luminal Diameter
AD: Aortic Dissection
LSA: Left Subclavian Artery
TBAD: Stanford Type B Aortic Dissection
OMT: Optimal Medical Therapy
DSA: Digital Subtraction Angiography
HTN: Hypertension
LCCA: Left Common Carotid Artery
SD: Standard deviation
BMI: Body Mass Index
SMA: Superior Mesenteric Artery

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