# Early Thoracic Endovascular Aortic Repair of Uncomplicated Type B Thoracic Aortic Dissection: An Aorta Team Approach

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## Abstract

**Background**   Although uncomplicated Type B aortic dissection (uTBAD) is traditionally treated with optimal medical therapy (OMT) as per guidelines, recent studies, performed primarily in interventional radiology or surgical operating rooms, suggest superiority of thoracic endovascular aortic repair (TEVAR) over OMT due to recent advancements in endovascular technologies. We report a large, single-center, case control study of TEVAR versus OMT in this population, undertaken solely in a cardiac catheterization laboratory (CCL) with a cardiologist and surgeon. We aimed to determine if TEVAR for uTBAD results in better outcomes compared with OMT.

**Methods**   This was a retrospective chart review of all patients with uTBAD during the last 13 years, with 46 cases (TEVAR group) and 56 controls (OMT group).

**Results**   In the TEVAR group, the procedure duration of 2.5 hours resulted in 100% procedural success for stent placement, with 63% undergoing protective left subclavian artery bypass, 0% mortality or stroke, and a lower readmission rate (1 vs. 2%; $p = 0.04$ in early TEVAR cases), but a longer length of stay (12.9 vs. 8.5 days: $p = 0.006$). The risk of all-cause long-term mortality was markedly reduced in the TEVAR group (RR = 0.38; $p = 0.01$), irrespective of early (<14 days) versus late intervention. On follow-up computed tomography imaging, the false lumen stabilized or decreased in 85% of cases, irrespective of intervention timing.

**Keywords**
► aneurysm
► aortic dissection
► endovascular repair
► thoracic aorta

**Conclusion**   TEVAR performed solely in the CCL is safe and effective, with lower all-cause mortality than OMT. These data, in collaboration with previous data on TEVAR in different settings, call for consideration of an update of practice guidelines.

## Introduction

Thoracic aortic dissection, a life-threatening diagnosis, has an incidence of 2.0 to 6.0 cases per 100,000 people per year, with roughly one-third of these cases involving the descending thoracic aorta (Type B).[1] Thoracic aortic dissection Type B (TBAD) is associated with a 10% mortality rate within the first 30 days and 30% mortality at 2 years.[2,3] TBAD is classified as uncomplicated and complicated based on high-risk features. Complicated TBAD is a process that needs immediate intervention with surgery or thoracic endovascular aortic repair (TEVAR). TEVAR in acute complicated TBAD has been shown to be highly effective in inducing complete false lumen thrombosis, false lumen obliteration, or both.[3–7] However, uncomplicated TBAD (uTBAD) is currently treated with aggressive medical management, and intervention is reserved for those who fail optimal medical therapy (OMT). Recent studies have challenged this treatment strategy, creating a clinical equipoise of TEVAR for all uTBAD versus TEVAR reserved for those who fail OMT.[8,9] These trials (INSTEAD [investigation of stent grafts in aortic dissection],[10] INSTEAD XL [investigation of stent grafts in aortic dissection with extended length of follow-up],[11] and ADSORB [acute dissection stent graft or best medical treatment][12]) and other publications[13–16] have demonstrated the superiority of TEVAR plus OMT over OMT alone in terms of aortic remodeling, all-cause mortality, aorta-specific mortality, and progression of disease in early subacute TEVAR (14–90 days) and acute TEVAR (<14 days of symptom onset).[13–17]

Whereas the previous studies were performed primarily in interventional radiology or vascular surgery operating rooms, the current study was carried out to evaluate the safety and outcome of TEVAR performed for uTBAD solely in the hybrid rooms of the cardiac catheterization laboratory (CCL) by interventional cardiology in partnership with a cardiothoracic surgeon, both working side by side, as a model of the aorta team approach.

## Materials and Methods

This retrospective case-control study was conducted with the approval of the Aurora Health Care Institutional Review Board. The need for individual patient consent for inclusion in this study was waived by this board due to its retrospective nature. A retrospective chart review of all patients with uTBAD diagnosed between January 1, 2005, and January 1, 2018, was performed. Patient charts were identified for initial review utilizing International Classification of Diseases 9 and 10 procedure and diagnostics codes for TEVAR and thoracic aortic dissection, respectively. The cardiac catheterization procedure log was also reviewed for patients who had undergone a TEVAR prior to this period. Patients younger than 18 years and those with a prior aortic intervention were excluded from review. All TEVAR procedures were performed after the U.S. Food and Drug Administration granted device approval in 2005.

TBAD was defined as aortic dissection distal to the last great vessel of the aortic arch, left subclavian artery, or aberrant right subclavian artery. Uncomplicated was defined as patients who, at the time of presentation, had none of the following evidence of perfusion deficits (neurological, cardiac, renal, or gastrointestinal): recurrent or uncontrolled chest pain, aortic rupture, pending aortic rupture, or hemodynamic instability. Patients were divided into study groups based on treatment: TEVAR with medical therapy (TEVAR group) or medical therapy alone (OMT group). The medical charts were reviewed for date of diagnosis, demographics, comorbidities, procedural data, and follow-up. The review identified 46 patients who underwent TEVAR for uTBAD. Twenty patients had intervention during the acute phase which was defined as within 14 days of diagnosis. Fifty-six patients identified with uTBAD did not undergo any aortic intervention and received standard medical therapy alone.

### Patient Treatment and Procedure

Treatment was determined with the consensus of an aorta team (interventional cardiologist and cardiothoracic surgeon) and the patient or the patient's health care proxy. Informed consent was obtained prior to the procedure. Prior to intervention, patients were optimized for heart rate and blood pressure control as per hospital protocol.

Patients underwent general anesthesia or monitored anesthesia care according to the decision of the anesthesiologist. The interventional cardiologist obtained percutaneous access via the left common femoral artery for pigtail catheter placement. The surgeon performed a cut down on the opposite common femoral artery to gain access for TEVAR stent deployment. Left subclavian artery protection in all cases was decided prior to TEVAR deployment. Patients requiring left subclavian artery protection underwent the procedure a few days before or at the time of TEVAR. Most patients undergoing left subclavian artery protection had carotid-subclavian bypass. Intravascular ultrasound was utilized prior to deployment of the endograft to confirm true lumen position. Procedural success was defined as deployment of the endovascular stent graft without the need for repeat intervention during index hospitalization. Patients were followed for postprocedural complications and further medical optimization via medical record review.

### Definitions

Chronicity of dissection was labeled as either acute (<14 days) or nonacute. Hypertension was defined as patients already taking antihypertensive medications or having a prior diagnosis. Other definitions were:

- Resistant hypertension: the taking of three or more antihypertensive medications.
- Hyperlipidemia: prior diagnosis or taking a cholesterol-lowering medication.
- Tobacco use: any smoking history prior to index diagnosis/hospitalization.
- Coronary artery disease/myocardial infarction: any prior coronary disease on cardiac catheterization, electrocardiogram findings indicative of prior myocardial infarction, or previously listed in the medical record.
- Aortic valve disease: any history of aortic stenosis, aortic regurgitation, bicuspid valve, or prior aortic valve intervention.

- High risk syndromes: Marfan, Ehlers–Danlos, Loeys–Dietz, Turner, familial thoracic aortic aneurysm and dissection.

The reported left ventricular ejection fraction was obtained from echocardiography performed ± 90 days from the index diagnosis/hospitalization. Incidental finding was defined by the patient undergoing imaging for a reason other than ruling out acute pathology of the chest.

For all identified patients, chest computed tomography angiography (CTA) measurements were reviewed and remeasured for standardization. Follow-up CTA at 1 year or more postintervention was reviewed for comparison. Given the retrospective nature of the study, not all CTAs included the abdomen and pelvis; therefore, dissection length was limited to just the thoracic cavity. Additionally, all false lumen and true lumen measurements were taken from the thoracic cavity at the point of maximal or minimal diameter 90 degrees to the dissection flap in the transaxial plane. The number of abdominal vessels originating from the false lumen was included when distal imaging was available. Stabilization or improvement of the aorta was defined as no further aortic dissection progression or false lumen dilation on follow-up CTA.

Procedural duration was defined as the time from start to stop of anesthesia. Length of stay for controls was limited to the index hospitalization. For the TEVAR group, we combined length of stay from the index diagnosis hospitalization with the additional length of stay if the patient was brought back for intervention.

Death and time of death were limited to events reported in the institutional or shared institutional electronic health record. Survival was determined by last time seen alive as documented.

### Statistics

Mean ± standard deviation and median and range were used to describe continuous variables; absolute numbers and percentage frequencies were used for categorical factors. For continuous variables, differences between groups were evaluated by use of a 2-sample $t$-test or nonparametric Mann–Whitney $U$-test depending on the distribution of variables. Categorical variables were compared by the Fisher exact test or $\chi^2$ test. Time-to-event curves were calculated by the Kaplan–Meier method and compared by log-rank test on an intention-to-treat basis. Cox proportional hazards regression models were used to estimate hazard ratios and 95% confidence intervals. All tests were two-tailed and $p < 0.05$ was considered statistically significant. JMP statistical analysis software (SAS Institute, NC) was utilized for statistical analysis.

### Results

Baseline characteristics of the TEVAR and the OMT groups are listed in ►**Table 1**. The mean age of all patients was $67 \pm 15$ years, and 51% were male. The TEVAR group was younger ($61.0 \pm 13.4$ vs. $71.6 \pm 14.5$ years, $p = 0.0002$), less likely to be Caucasian, more likely to have prior history of aortic disease and drug use, and had a higher body mass index.

Procedural and hospitalization data are listed in ►**Table 2**. TEVAR patients were more likely to have a longer index hospitalization ($12.9 \pm 6.4$ vs. $8.5 \pm 8.1$ days, $p = 0.006$). However, the TEVAR group had a trend for reduced hospitalization 1 year after diagnosis. This trend became significant when only acute TEVAR interventions were compared with the the group ($1.0 \pm 1.8$ vs. $2.2 \pm 2.4$ hospitalizations, $p = 0.046$).

Comparison of acute with nonacute TEVAR intervention did not show a statistical difference in procedure time, left subclavian protection, procedural success, postprocedural complications, length of stay, repeat hospitalizations 1-year post-procedure, endoleak and/or aortic progression, or mortality (►**Table 3**). However, there was a trend toward fewer repeat interventions with TEVAR done in the acute phase (4.8 vs. 16%, $p = 0.205$).

Kaplan–Meier methodology for survival (►**Fig. 1**) showed the separation of the TEVAR and OMT groups that continued out to the completion of the review at just under 13 years ($p = 0.006$). Long-term survival at 10 years was significant (54 vs. 33%, $p < 0.05$). Mortality with TEVAR compared with the OMT group (13 vs. 34%, $p = 0.013$) was significantly reduced. This correlated with a relative risk of 0.38, a relative risk reduction of 62%, and a number of patients needed to treat to prevent one death of only 5.

### Discussion

The current study adds additional evidence to the recent literature in support of endovascular repair for acute and chronic uTBAD, a pathology that primarily has been treated medically despite a high likelihood of poor outcomes (►**Table 4**).[5,11,16,18] TEVAR performed solely in the CCL showed a good safety profile and improved mortality over OMT alone. TEVAR done in the CCL by an interventional cardiologist and a cardiothoracic surgeon as cooperators had similar success, safety, feasibility, and favorable remodeling to TEVAR performed in other clinical settings, indicating the triumph of the aorta team approach in the CCL. The superior survival data of intervention over medical therapy from the current study along with the aforementioned studies challenge current treatment algorithms and guidelines. As such, a review of current practice guidelines for possible changes that more accurately reflect these recent findings should be considered.

This single-center experience shows that utilizing an aorta team approach resulted in safe and effective TEVAR in the CCL. TEVAR, regardless of time to intervention, resulted in lower mortality, which is similar to what was seen in other studies (►**Table 4**). A higher incidence of left subclavian artery protection was seen in the current study compared with others, except for the ADSORB trial (►**Table 5**). Stroke and other neurological complications were similar. Length of stay was longer than in the INSTEAD trial, but this is likely due to the frequency of patients undergoing a left subclavian bypass surgery, which was usually done 2 to 5 days before TEVAR.

**Table 1** Demographic and clinical characteristics of patients treated with thoracic endovascular aortic repair (TEVAR) and optimal medical treatment

| Basic characteristics | TEVAR ($n = 46$) | | Medical treatment ($n = 56$) | | *p*-Value |
|---|---|---|---|---|---|
| | *n* | % | *n* | % | |
| Age (y) | 61.0 ± 13.4 | | 71.6 ± 14.5 | | **0.0002** |
| Male sex | 26 | 57 | 26 | 46 | 0.3098 |
| White race | 29 | 63 | 48 | 86 | **0.0078** |
| BSA | 2.04 ± 0.29 | | 2.39 ± 3.91 | | 0.553 |
| BMI | 30.8 ± 8.2 | | 26.8 ± 6.6 | | **0.0094** |
| HTN | 32 | 70 | 55 | 98 | **0.0001** |
| BP medications | 1.8 ± 1.8 | | 3.1 ± 1.5 | | **0.0002** |
| Resistant HTN | 15 | 33 | 38 | 68 | **0.0005** |
| Diabetes | 5 | 11 | 10 | 18 | **0.0118** |
| HLD | 20 | 43 | 35 | 63 | 0.0546 |
| Cr (serum) | 1.12 ± 0.49 | | 1.44 ± 1.21 | | 0.1179 |
| COPD | 4 | 9 | 5 | 9 | 0.9671 |
| Tobacco use | 35/45 | 78 | 42 | 75 | 0.744 |
| Drug use | 4/40 | 10 | 0/48 | 0 | **0.0106** |
| CAD/MI | 5 | 11 | 3 | 5 | 0.3033 |
| Atrial fibrillation | 1 | 2 | 2 | 4 | 0.6738 |
| LVEF | 60.6 ± 13.7 | | 58.4 ± 12.9 | | 0.5561 |
| Prior AV disease | 13 | 28 | 7 | 13 | **0.0458** |
| High risk syndrome | 0 | 0 | 1 | 2 | 0.2719 |
| Incidental finding | 7/41 | 17 | 9/35 | 26 | 0.3576 |

Abbreviation: AV, aortic valve; BSA, body surface area; BMI, body mass index; BP, blood pressure; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; HLD, hypersensitivity lung disease; HTN, hypertension; LVEF, left ventricular ejection fraction; MI, myocardial infarction.
Note: Data presented as mean ± standard deviation or *n* (%).

**Table 2** Procedural variables stratified according to early thoracic endovascular aortic repair (TEVAR; <14 days) versus late TEVAR

| | Acute TEVAR (<14 days) | | Nonacute TEVAR | | *p*-Value |
|---|---|---|---|---|---|
| | *n* | % | *n* | % | |
| Time to TEVAR (days) | 5.9 ± 3.1 | | 638 ± 1045 | | **0.0049** |
| Procedural duration (min) | 159 ± 58 | | 151 ± 50 | | 0.6261 |
| Left SCA protection | 14/21 | 67 | 15/25 | 60 | 0.8499 |
| Procedural success | | 100 | | 100 | |
| Paraplegia | 1 (resolved) | | 1 (resolved) | | |
| CVA within 30 days | | 0 | | 0 | |
| Length of stay (days) | 12.1 ± 4.1 | | 13.6 ± 7.9 | | 0.4248 |

Abbreviations: CVA, cerebrovascular accident; SCA, subclavian artery.
Note: Data presented as mean ± standard deviation unless otherwise stated.

TEVAR previously was shown to stabilize and promote aortic remodeling, which was also seen in our data. Recurrent admissions for those medically treated are likely secondary to the aortic progression along with evaluation for urgent or emergent intervention. Further, physician concern for worsening aortic disease likely establishes a lower threshold for admission versus outpatient management. The time to intervention did not result in any difference in mortality when subdivided into acute and nonacute groups. However, there was a trend toward repeat interventions in the nonacute group, 4 to 1, respectively, $p = 0.205$. This finding merits further investigation given the limitations imposed by the

**Table 3** Outcomes of thoracic endovascular aortic repair (TEVAR) versus optimal medical treatment only

| | TEVAR | | Optimal medical treatment | | p-Value |
|---|---|---|---|---|---|
| | n | % | n | % | |
| Hospitalizations within 1 y | 1.5 ± 1.8 | | 2.2 ± 2.4 | | 0.087 |
| Hospitalizations within 1 y (acute) | 1.0 ± 1.8 | | 2.2 ± 2.4 | | **0.046** |
| Mortality | 6/40 | 13 | 19/56 | 34 | **0.013** |
| | RR = 0.38 | | RRR = 61.7% | | NNT = 4.8 |
| | Acute TEVAR | | Nonacute TEVAR | | |
| | n | % | n | % | |
| Hospitalizations within 1 y | 1.0 ± 1.8 | | 1.8 ± 1.9 | | 0.149 |
| Endoleak/aortic progression | 6/21 | 29 | 5/25 | 20 | 0.498 |
| Repeat intervention | 1/21 | 4.8 | 4/25 | 16 | 0.205 |
| Mortality | 4/21 | 19 | 2/25 | 8 | 0.267 |

Abbreviation: NNT, number needed to treat; RR relative risk; RRR, relative risk reduction; TEVAR, thoracic endovascular aortic repair.
Note: Data presented as mean ± standard deviation unless otherwise stated.
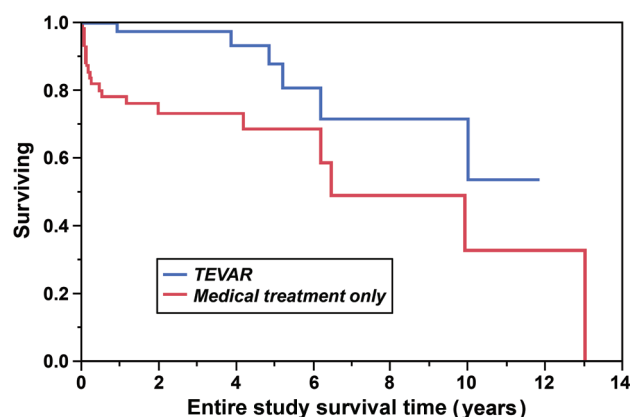


**Fig. 1** Kaplan–Meier survival curve: thoracic endovascular aortic repair (TEVAR) versus medical treatment only, $p = 0.0061$.

The baseline patient characteristics were similar to those in prior studies, with the exception of a slightly higher percentage of female patients in the current study. Additionally, aside from Qin et al,[16] there are not many pure uTBAD with TEVAR treatment studies. Most of the literature combines data from complicated cases or strictly treats with medical therapy.[2]

Advancement in imaging has led to more accurate and intricate measurement, allowing the identification of new high-risk features. Techniques such as volumetric expansion comparison may prove to be a more beneficial measurement, improving follow-up comparison and decreasing interreader variability. Recommended follow-up with repeat imaging is critical for long-term outcomes.[1,2,4–11,18–25]

### Study Limitations

There are several limitations secondary to the retrospective nature of the study, limiting data collection at the time of the procedure as well as long-term follow-up. Additionally, utilizing two electronic medical record systems along with dependence on scanned data prior to electronic medical record initiation must be considered. Many individuals did not have follow-up computed tomographic

current study's sample size. Early TEVAR did result in a significantly lower rehospitalization rate (1 vs. 2%; $p < 0.05$), and a larger sample may prove significantly higher repeat intervention rates in the nonacute TEVAR group, creating another line of evidence in favor of early intervention.

**Table 4** Comparison of mortality in studies evaluating thoracic endovascular aortic repair versus optimal medical therapy in treatment of uncomplicated Type B aortic dissection

| | Intervention arm | | Control arm | | p-Value |
|---|---|---|---|---|---|
| | n | % | n | % | |
| Tsai et al (IRAD)[5] | | 15.50 | | 29.00 | **0.018** |
| Instead XL, >14 d[11] | | 11.10 | | 19.30 | 0.13 |
| ADSORB, <14 d[18] | 0/30 | | 1/31 | | Not powered |
| Qin et al (2016)[16] | | 10.80 | | 14.30 | **0.01** |
| Current study | 6/46 | 13 | 19/56 | 34 | **0.0125** |

Abbreviation: IRAD, International Registry of Aortic Dissection.

**Table 5** Comparison of procedural characteristics and post-thoracic endovascular aortic repair (TEVAR) complications across the studies in patients undergoing TEVAR

|  | n (cases/controls) | Procedure time (min) | LSCA protection (%) | LOS (days) | CVA (%) | Paraplegia/paraparesis |
|---|---|---|---|---|---|---|
| INSTEAD[10,11] | 72/68 | 108 | 2.9 | 8 | 1.4 | 4.2 |
| ADSORB[12] | 30/31 | N/A | 60 | N/A | N/A | N/A |
| Qin et al[16] | 184/154 | N/A | 7.6 | 11.1 | 0.5 | 0 |
| Lou et al[7] | 87/172 | N/A | N/A | N/A | 0 | 3.5 |
| Current study | 46/56 | 150 | 63 | 12.9 | 0 | 4.3 |

Abbreviations: CVA, cerebrovascular accident; LOS, length of stay; LSCA, left subclavian artery; N/A, not applicable.

imaging, which makes the assessment of true stability/remodeling in the TEVAR group and subanalysis based on the timeliness of intervention difficult. Due to the nonrandomized nature of this study, the findings need to be considered with caution due to selection bias. It is reasonable to expect that patients who were healthier and had better surgical risk were more likely to be offered TEVAR, which could at least in part, contribute to the lower all-cause mortality observed in the TEVAR group. In this study, age, hypertension, diabetes, and hyperlipidemia were lower in the TEVAR group than the OMT group but other comorbidities were not significantly different. The smaller sample size and single-center nature also may limit the generalizability of our study findings. However, our study provides real-world data on the feasibility and effectiveness of TEVAR performed exclusively in a CCL setting.

## Conclusion

In patients with uTBAD, TEVAR can be safely and successfully performed in the CCL under the direction of an aorta team with better survival and favorable remodeling as compared with OMT. The benefit of TEVAR was seen in both acute and late presentations of uTBAD. This study adds to the current literature in favor of TEVAR as a preferential therapy for uTBAD and may suggest a revision of current treatment guidelines for uTBAD.

Conflict of Interest
The authors declare no conflict of interest related to this article.

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