



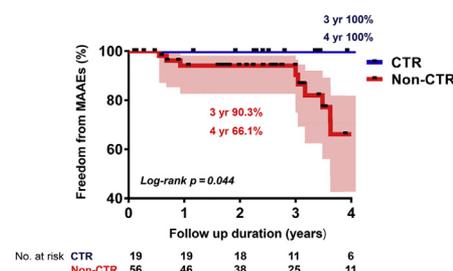
Complete Thoracic Aorta Remodeling After Endovascular Aortic Repair: A New Therapeutic Goal for Chronic DeBakey IIIb Aneurysms

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To introduce complete thoracic aorta remodeling as a new therapeutic target of thoracic endovascular aortic repair for chronic DeBakey IIIb aneurysms, and analyze the predictors for complete thoracic aorta remodeling. From 2012 to 2017, 75 patients underwent thoracic endovascular aortic repair for chronic DeBakey IIIb aneurysms. Complete thoracic aorta remodeling was defined as thoracic false lumen thrombosis with false lumen diameter <5 mm down to T-10 level. Major adverse aortic events were defined as aortic-related mortality, open conversion, and false lumen recanalization after thoracic false lumen thrombosis. Of the 75 patients included in this study, 60 (80.0%) demonstrated thoracic false lumen thrombosis; among them, overall mortality, open conversion, or false lumen recanalization after thoracic false lumen thrombosis occurred in two (3.3%), one (1.7%), and five (8.3%) patients, respectively. Nineteen (25.3%) of 75 patients who demonstrated complete thoracic aorta remodeling had no major adverse aortic events during follow-up. The number of visceral branches from the false lumen and residual intima tears were significant risk factors for complete thoracic aorta remodeling (HR 0.627, $p = 0.041$ and HR 0.754, $p = 0.042$). In chronic DeBakey IIIb aneurysms, complete thoracic aorta remodeling may be the ideal target for endovascular treatment rather than false lumen thrombosis. Additional procedures to eliminate the obstacles to complete thoracic aorta remodeling (number of visceral branches from the false lumen and residual intimal tears) and close follow-up after thoracic false lumen thrombosis may be needed to achieve the optimal outcome.

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Keywords: Chronic DeBakey IIIb, Aortic dissection



Comparison of cumulative curve of freedom from MAAEs stratified by TFT and CTR.

Central Message

Since thoracic false lumen thrombosis alone cannot guarantee the long-term durability of TEVAR for chronic DeBakey IIIb aneurysms, complete thoracic aorta remodeling may be the new ideal target.

Perspective Statement

In the era of endovascular treatment, thoracic endovascular aortic repair is an important treatment in chronic DeBakey IIIb aneurysms. However, the long-term prognosis of endovascular treatment is uncertain and aortic-related complications are frequent even after false lumen thrombosis. In chronic DeBakey IIIb aneurysm, a new therapeutic target is needed rather than false lumen thrombosis.

Abbreviations: CDIIIb, chronic DeBakey IIIb; CI, confidence interval; CT, computed tomography; CTA, computed tomography angiogram; CTR, complete thoracic aorta remodeling; DTA, descending thoracic aorta; FL, false lumen; FLP, false lumen procedure; IQR, interquartile range; MAAE, major adverse aortic event; OAR, open aortic repair; TEVAR, thoracic endovascular aortic repair; TFP, thoracic false lumen partial thrombosis; TFT, thoracic false lumen thrombosis; TL, true lumen

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INTRODUCTION

Thoracic false lumen thrombosis (TFT) is an important prognostic factor for favorable aortic remodeling after thoracic endovascular aortic repair (TEVAR),^{1–4} and persistent patency of the false lumen (FL) has demonstrated a negative prognosis after TEVAR in cases of chronic DeBakey IIIB (CDIIIB) aneurysm.^{4,5} Various markers, including TFT and aortic diameter and volume, have been used to evaluate the aortic remodeling and predict the prognosis after TEVAR for a CDIIIB aneurysm.⁵ Since the recanalization of the FL and aorta-related complications frequently occur even after TFT, none of these markers are good candidates for the therapeutic goal of TEVAR. There are several reasons why TFT is not an ideal target and why complications often occur after TFT. These include endoleak and stent-induced new entry tear; in addition, distal intimal tears and visceral branches arising from the FL can pressurize the thoracic FL following TFT. Thereafter, recanalization of the FL can occur, and a pressurized FL thrombosis may be observed. Therefore, the false lumen procedure (FLP) developed in our institution attempts to improve the rate of TFT and prevent a pressurized FL.⁶ Although TFT is an important indicator for evaluating a successful TEVAR, the presence of a TFT alone cannot guarantee the long-term prognosis of endovascular treatment in cases of a CDIIIB aneurysm. Because of this, we introduced complete thoracic aorta remodeling (CTR) as a new therapeutic target for CDIIIB aneurysms in order to optimize the outcome of endovascular treatment in CDIIIB patients.

The aims of this study were as follows. First, we aimed to determine the frequency of CTR. Second, we analyzed the relationship between CTR and potential influencing factors. Finally, we specifically investigated whether the modifiable factors were related to the achievement of CTR.

METHODS

Patient Population and Data Collection

This study was approved by the Institutional Review Board of Gangnam Severance Hospital, Yonsei University College of Medicine (Yonsei Institutional Review Board no 0.3-2012-0259). The need for individual patient consent was waived. A retrospective review of the Gangnam Endovascular Aortic Registry identified 99 patients who underwent endovascular treatment for CDIIIB aneurysms between 2012 and 2017. Patients whose FL thrombosis was already achieved in a preoperative imaging study or patients without a stent graft were excluded. A total of 75 patients were enrolled in this study (Fig. 1). Chronic aortic dissections were defined as those persisting for longer than 3 months after the diagnosis of acute aortic dissection.⁷ Spinal cord ischemia was defined as any new lower extremity motor and/or sensory deficit not attributable to intracranial pathologic features, peripheral neuropathy, or neuropraxia. Demographics, comorbidities, procedure-related details, and complications were collected from the medical records.⁸ Stroke was defined as any neurologic deficit lasting >24 hours that was confirmed by imaging and documented by a neurologist.⁸

Indication and Treatment Method

TEVAR is the preferred treatment for CDIIIB aneurysms with suitable anatomy at our institution. Indications for TEVAR include newly developed aneurysms, intractable back pain, and aneurysmal degeneration (maximal thoracic aneurysm diameter >55 mm or a documented growth rate of 5 mm in 6 months, as observed in serial computed tomography [CT] angiograms [CTA]) as described in our previous study.^{6,8} In our institution, the aim of TEVAR in CDIIIB patients is to cover as much of the

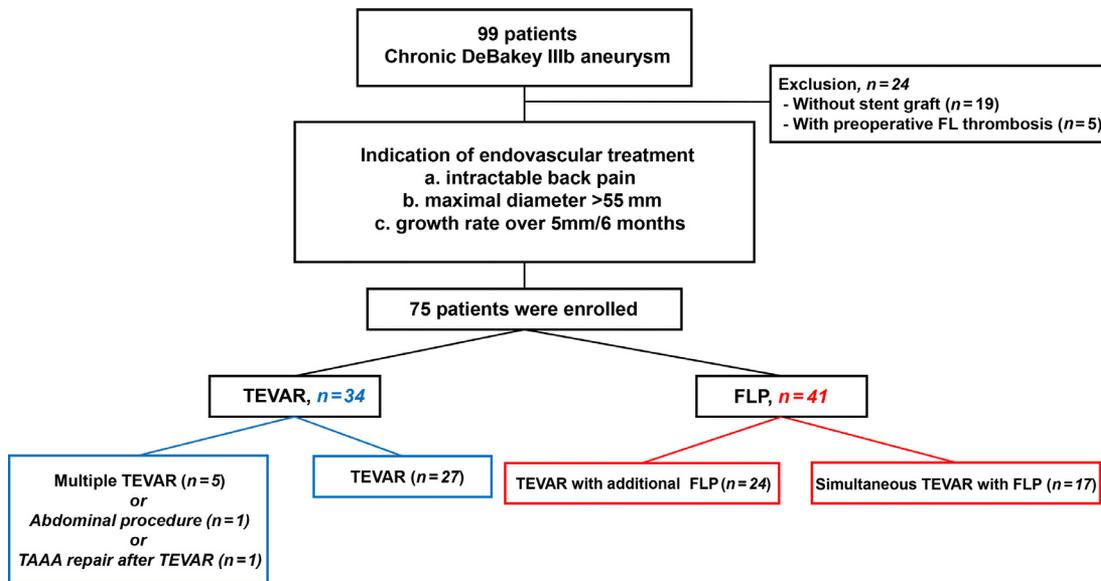


Figure 1. Treatment algorithm and study design.

FL, false lumen; FLP, false lumen procedure; TAAA, thoracoabdominal aorta aneurysm; TEVAR, thoracic endovascular aortic repair.

length of the thoracic aorta as possible.^{6,8} Indications for additional FLP include (1) patent FL or (2) a lack of TFT in the descending thoracic aorta at 6 months after initial TEVAR. FLP was performed with commercialized materials such as the Amplatzer Vascular plug (AGA Medical, Golden Valley, MN), Nester coils (Cook Medical Inc, Bloomington, IN), or embolization glue (33% *N*-butyl cyanoacrylate mixed with lipiodol), and these materials are inserted into the FL to block retrograde FL flow via residual intimal tears, visceral branches, or intercostal arteries.⁶ A Viabahn stent graft (W.L. Gore & Associates., Flagstaff, AZ) was also inserted into the visceral branch to maintain the flow to the organ and block retrograde flow from intimal tears within the visceral branches (Video 1).

We performed simultaneous TEVAR and FLP when the FL was not excessively large (2 or 3 of the largest vascular plugs are insufficient to fill out the FL space), in which case the materials used for occlusion would be insufficient, and when the physician felt that unfavorable aortic remodeling was likely because of multiple reentries below the celiac axis, visceral reentries, or intercostal arteries from the FL.

Remodeling Analysis

The degree of FL thrombosis was analyzed using precontrast, arterial, and delayed-phase postoperative CTA. After the procedures (TEVAR or FLP) were completed, the degree of FL thrombosis was evaluated via delayed-phase CTA and classified as either thoracic FL partial thrombosis (TFP) if both flow and thrombi were present or as TFT if no flow was observed.^{6,8} We defined “TFT” as FL thrombosis down to the T-10 level. We defined “CTR” as TFT with FL diameter <5 mm down to the T-10 level.

We measured the diameter of the thoracic aorta at the origin of the left subclavian artery (LSA), pulmonary bifurcation (PA) level, and celiac artery (CA). Three patients underwent open aortic repair (OAR) after TEVAR. In these patients, the imaging studies prior to the OAR were evaluated. Postoperative CT scans were obtained in the arterial phase and with delayed-contrast imaging to assess the presence of endoleaks and FL patency. CT was performed at 1, 6, and 12 months after the procedure and yearly thereafter.^{6,8}

Major Adverse Aortic Events

Major adverse aortic events (MAAEs) included aortic-related mortality, open conversion, and FL recanalization after TFT. Although there was no any aortic-related complications or contiguous reinterventions after CTR achievement, reinterventions for residual abdominal dissection or distal thoracic aorta were frequently needed for achieving CTR. Since the objective of this study was to evaluate whether therapeutic goals (CTR or TFT) guarantee long-term prognosis or not, the reintervention events were not included in the definition of MAAEs. Furthermore, in contrast with redo open surgery in the era of OAR, the planned percutaneous reintervention needs to be considered from another angle because the risk of procedure is much lower than redo open surgery.

Modifiable Factors

Many factors related to the prognosis of CDIIb aneurysms have been reported.^{6,8} However, many of these factors cannot be corrected by the current treatment options. For example, underlying disease, preoperative aortic diameter, or chronicity of aortic dissection (during the interval from diagnosis to initial procedure) are not correctable. Therefore, we focused on the factors modifiable by treatment, and we analyzed predictors for CTR among these factors.

Statistical Analysis

Categorical variables were summarized using frequencies and percentages and compared using Fisher's exact test or chi-square tests. Continuous variables with a normal distribution were presented as the mean \pm standard deviation, whereas those variables not normally distributed were presented using the median and interquartile range (IQR). Continuous variables were compared by independent *t* tests or Mann-Whitney U tests. The Shapiro-Wilk test was used for testing for normality of the distributions.

The cumulative curve of MAAEs was constructed for time-to-event variables using Kaplan-Meier estimates, and comparisons were made using the log-rank test. Cox hazards proportional regression was used for analyzing the factors related to CTR. Covariates were selected on the basis of their significant association ($P < 0.2$) with CTR in the univariate Cox regression model. Multivariate Cox regression models were constructed using a backward approach with $P < 0.05$ required for the final model entry. Assessment of the proportional hazards assumption was conducted by plotting Schoenfeld residuals vs time. All statistical tests were 2-tailed, and $P < 0.05$ was considered statistically significant. Statistical analyses were performed using SPSS for Windows, version 22.0 (IBM Corp, Armonk, NY) and GraphPad Prism for Windows, version 5.01 (GraphPad Software, CA).

RESULTS

Patient Demographics and Baseline Characteristics

From 2012 to 2017, 75 patients underwent TEVAR for CDIIb aneurysms were enrolled. The overall mean age was 58.2 ± 12.1 years. Approximately 80% of patients in the overall cohort were men. Thirty-six patients (48%) had CDIIb aneurysms, and 39 patients (52%) had residual CDIIb aneurysms after initial type A repair. Two patients (2.7%) had Marfan syndrome. The median duration from dissection onset to intervention was 11.9 months. Female sex was significantly predominant, and the interval from diagnosis to procedure was significantly shorter in the CTR group (Table 1). Preoperative total and FL diameters at LSA, PA, and CA levels were significantly smaller in the CTR group. The remaining baseline characteristics were not significantly different between CTR and non-CTR groups (Table 1).

Procedural Details and Postoperative Outcomes

The median follow-up duration was 36.9 months and completeness of follow-up regarding major adverse aortic events was 63.5% in entire cohort (Table 2).⁹ Full coverage of descending

Table 1. Baseline Characteristics of Entire Cohort

Baseline characteristics	Entire cohort (N = 75)*	CTR (N = 19)*	Non-CTR (N = 56)*	P Value
Age, y	58.2 ± 12.1	57.5 ± 12.6	58.5 ± 12.0	0.772
Male sex	59 (78.7)	9 (47.4)	50 (89.3)	<0.001
HTN	62 (82.7)	17 (89.5)	45 (80.4)	0.578
DM	6 (8.0)	2 (10.5)	4 (7.1)	>0.999
CRF	2 (2.7)	0 (0.0)	2 (3.6)	0.991
Smoking	39 (52.0)	7 (36.8)	32 (57.1)	0.206
CAOD	5 (6.7)	0 (0.0)	5 (8.9)	0.414
COPD	3 (4.0)	1 (5.3)	2 (3.6)	>0.999
Marfan syndrome	2 (2.7)	2 (10.5)	0 (0.0)	0.102
Previous aortic surgery	39 (52.0)	6 (31.6)	33 (58.9)	0.072
Interval from diagnosis (mo)	11.9 (4.1–31.4)	4.1 (3.2–10.7)	16.7 (5.4–38.5)	0.001
LSA pretotal	47.4 ± 11.5	39.7 ± 11.1	50.0 ± 10.5	<0.001
LSA prefalse	28.7 (12.3–38.9)	15.6 (4.3–20.4)	32.6 (20.5–41.0)	<0.001
PA pretotal	44.8 ± 9.7	38.2 ± 8.8	47.1 ± 9.0	<0.001
PA prefalse	27.3 ± 12.6	18.1 ± 10.1	30.4 ± 11.8	<0.001
CA pretotal	36.7 ± 5.9	33.1 ± 6.0	37.9 ± 5.4	0.002
CA prefalse	22.9 ± 6.4	18.8 ± 8.3	24.3 ± 4.9	0.011

CAOD, coronary artery occlusive disease; COPD, chronic obstructive pulmonary disease; CRF, chronic renal failure; DM, diabetes mellitus; HTN, hypertension; LSA, left subclavian artery level; PA, pulmonary artery bifurcation level.

*Values expressed as mean ± standard deviation or median [interquartile range] for continuous data or number (percent) for categorical data. CA; celiac artery level.

thoracic aorta with a stent graft was performed in 58 patients (77.3%). Thirty-four patients underwent TEVAR, and the other 41 patients underwent TEVAR and additional FLP (Fig. 1 and Table 2). The median follow-up and imaging follow-up durations were 36.9 and 23.9 months, respectively. There was no in-hospital mortality. Three patients (4%) died after discharge. One of the 3 mortalities was aortic-related and was due to an aorto-esophageal fistula; the others were due to intraventricular hemorrhage not associated with the aortic disease or procedure, or underlying coronary artery occlusive disease. Three patients underwent OAR after TEVAR due to a continuously enlarging dissecting aneurysm. TFT was achieved in 60 patients (80.0%). There was no aortic-related mortality, open conversion, or FL recanalization in CTR

patients. In contrast, 1 aortic-related mortality, 3 open conversions, and 5 FL recanalizations were observed in non-CTR patients (Table 2). Although TFT (n = 60) was achieved after TEVAR, open conversion, and FL recanalization occurred in 1 (1.7%), and 5 (8.3%) patients, respectively. In TFP patients (n = 15), 3 patients (20%) demonstrated MAAEs during follow-up (Table 3).

New Therapeutic Goals

To compare the reliability of TFT and CTR as a therapeutic goal, cumulative curves of freedom from MAAEs stratified by TFT and CTR were analyzed. Regarding freedom from MAAEs, the TFT group was not demonstrably superior to the TFP group

Table 2. Operative Outcome and Procedure-Related Details

Outcomes and details	Entire cohort (N = 75)*	CTR (N = 19)*	Non-CTR (N = 56)*	P Value
Mortality	3 (4.0)	0 (0.0)	3 (5.4)	0.725
Open conversion	3 (4.0)	0 (0.0)	3 (5.4)	0.725
Proximal endoleak	8 (10.7)	0 (0.0)	8 (14.3)	0.189
TFT	60 (80.0)	19 (100)	41 (73.2)	0.028
Recanalization of FL	5 (6.7)	0 (0.0)	5 (8.9)	0.414
Full coverage of DTA	58 (77.3)	13 (68.4)	45 (80.4)	0.449
FLP	41 (54.7)	10 (52.6)	31 (55.4)	>0.999
Reinterventions	32 (42.7)	8 (42.1)	24 (42.9)	>0.999
Thoracic	29 (38.7)	7 (36.8)	22 (39.3)	>0.999
Abdominal	3 (4.0)	1 (5.3)	2 (3.6)	
Follow-up duration [†]	36.9 (25.4–49.3)	40.6 (28.2–53.2)	34.5 (21.7–48.5)	0.210
Imaging follow-up duration	23.9 (9.5–38.6)	26.2 (22.5–35.2)	18.8 (8.3–38.5)	0.111

CTR, complete thoracic remodeling; DTA, descending thoracic aorta; FL, false lumen; FLP, false lumen procedure; TFT, thoracic false lumen thrombosis.

*Values expressed as mean ± standard deviation or median (interquartile range) for continuous data or number (percent) for categorical data.

[†]Completeness of follow-up regarding major adverse aortic events was 63.5%.²²

Table 3. Major Adverse Aortic Events Stratified by TFT

Variables	TFT (N = 60)	TFP (N = 15)
Overall mortality	2 (3.3)	1 (6.7)
Aortic-related mortality	0 (0.0)	1 (6.7)
Open conversion	1 (1.7)	2 (13.3)
Recanalization of FL	5 (8.3)	0 (0.0)
MAAEs	6 (10.0)	3 (20.0)

CTR, complete thoracic remodeling; FL, false lumen; MAAEs, major adverse aortic event; TFP, thoracic false lumen partial thrombosis; TFT, thoracic false lumen thrombosis.
*Values expressed number (percent).

(4-year freedom from MAAEs: 78.5% vs 63.5%; log-rank $P = 0.085$, Fig. 2A). However, the CTR group demonstrated superior freedom from MAAEs to the non-CTR group (4-year freedom from MAAEs: 100% vs 66.1%; log-rank $P = 0.044$, Fig. 2B).

Predictors for CTR

CTR appears to be an attainable therapeutic goal based on the results of our study, in which CTR was achieved in 19 patients (25.3%) after endovascular treatment. In the analysis of the influencing factors for achievement of CTR using Cox hazards proportional regression, the interval from diagnosis to procedure was the only significant factor, and less chronicity of CDIIIb aneurysm was related to a higher probability of CTR (hazard ratio, HR [95% confidence interval, CI]: 0.998 [0.997–1.000], $P = 0.048$, Table 4). Among the modifiable factors, the number of visceral branches from the FL and residual intimal tears were significant, and fewer visceral branches and residual intimal tears were related to a higher probability of CTR (HR [95% CI]: 0.627 [0.400–0.982], $P = 0.041$ and 0.754 [0.575–0.990], $P = 0.042$, respectively; Table 5).

DISCUSSION

TFT has been considered as the most important surrogate marker and prognostic factor for aortic remodeling. However, FL

recanalization, open conversion, and aortic-related mortality have frequently occurred after TFT. Previous studies regarding the long-term outcome after OAR^{10–12} demonstrated that 5-year overall survival, freedom from contiguous reoperation, and freedom from any aortic reoperation were 65.3–73%, 97.2%, and 86.7%, respectively. Although the follow-up duration was relatively short in our study, 4-year freedom from MAAEs was less than 80% in TFT patients and 100% in CTR patients. TFT as a therapeutic goal in patients with endovascular treatment may not result in a long-term outcome superior to OAR. The difference between postprocedural CDIIIb aneurysms after TEVAR and OAR was the presence of residual FL. The authors observed this difference and subsequently hypothesized that FL thrombosis and resorption of thrombosed FL, which was defined as CTR in this study, improved the long-term outcome of CDIIIb aneurysm patients after TEVAR. Indeed, there were no MAAEs during follow-up (Table 3).

Interestingly, female sex was associated with a favorable tendency for CTR in the risk factor analysis (Table 4) and comparison of baseline characteristics (Table 1). These results are concordant with other studies that demonstrated differences in clinical outcome between female and male patients.^{13–17} However, Fukui et al reported that there was no difference in either early or long-term outcome between male and female patients.¹⁸ This discrepancy in the results may be because features of aortic dissection in Western countries differ from those in east Asia,¹⁴ and pathologic studies in animal models displayed sex differences.¹⁶ In summary, there may be geographical and sex differences in aortic dissection, and further study is needed in terms of genetic and pathologic studies.

The chronicity of CDIIIb aneurysms, the number of residual intimal tears, and visceral branches from an FL were significantly related to aortic remodeling (CTR) (Tables 4 and 5). The thickened and stiff intimal flap involved in chronic dissection has been well demonstrated as obstacles to aortic remodeling.^{6,8} Furthermore, the chronicity of CDIIIb aneurysms is also associated with FL aneurysmal changes. Therefore, a stiff and thick intimal flap and

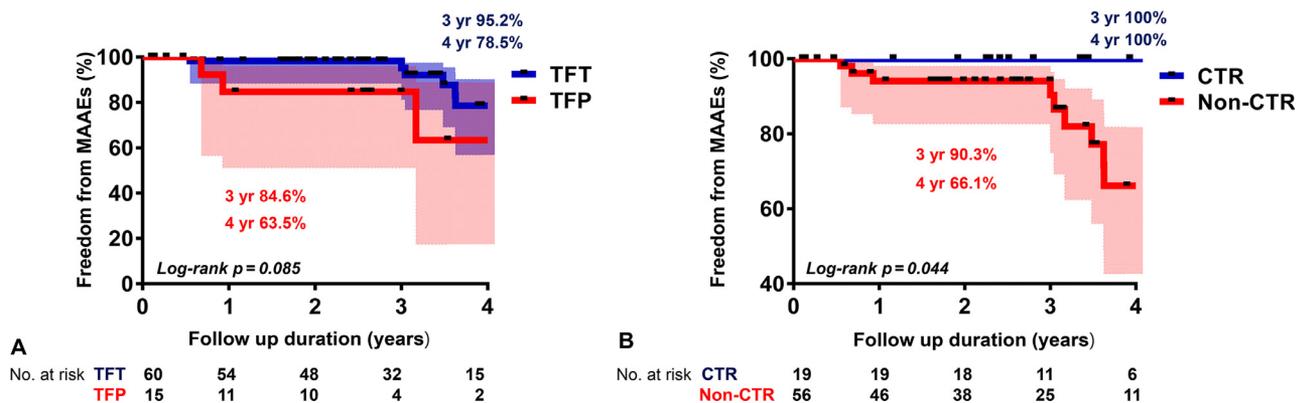


Figure 2. (A) Cumulative curve of freedom from MAAEs comparing thoracic false lumen (FL) thrombosis (TFT) vs thoracic FL partial thrombosis (TFP). (B) Cumulative curve of freedom from MAAEs comparing complete thoracic aorta remodeling (CTR) vs non-CTR. CTR, complete thoracic aorta remodeling; MAAEs, major adverse aortic events; TFP, thoracic false lumen partial thrombosis; TFT, thoracic false lumen thrombosis. Shaded area indicated 95% confidence interval.

Table 4. The Predictors for CTR

Variables*	Cox hazards proportional regression HR (95% CI)	P Value
CA preoperative FL diameter	0.937 (0.869–1.012)	0.097
Interval from diagnosis to procedure	0.998 (0.997–1.000)	0.048
Female sex	2.525 (0.834–7.651)	0.101

*All related factors were considered as covariates for multivariable regression model. CA, celiac artery level; CI, confidence interval; CTR, complete thoracic remodeling; HR, hazards ratio.

Table 5. The Modifiable Factors for Predicting CTR

Variables*	Cox hazards proportional regression HR (95% CI)	P Value
The number of visceral branches from FL	0.627 (0.400–0.982)	0.041
The number of residual intimal tears	0.754 (0.575–0.990)	0.042

CI, confidence interval; CTR, complete thoracic remodeling; FL, false lumen; HR, hazards ratio.

*The only modifiable factors were considered as covariates for multivariable regression model.

enlarged FL seem to be factors affecting poor aortic remodeling. Although the evidence regarding the early intervention in uncomplicated CDIIIb is not conclusive,¹⁹ early endovascular intervention may improve the aortic remodeling and long-term outcome in cases of CDIIIb aneurysms. Residual intimal tears and visceral branches arising from an FL were well-known risk factors for aortic remodeling.^{6,8,20,21} In addition to clinical studies, in vitro fluid dynamic studies have revealed that proximal and distal intimal tears seemed to act as entries and exits into the FL, suggesting that flow enters the FL through residual intimal tears after TEVAR.²²

Considering that most intimal tears occur within the abdominal aorta or visceral branches arising from the FL in CDIIIb aneurysms, additional procedures including FLP or open aortic repair for residual dissection are recommended for CTR and long-term outcome.

LIMITATIONS

There were several limitations in this study. First, this was a retrospective study; the sample size was relatively small, and the follow-up duration was relatively short. However, this study is meaningful, since there was no previous analysis of the 19 CTR patients after TEVAR. Notably, we have introduced CTR as a new therapeutic target. Second, both subjects with residual CDIIIb after type A repair and those with pure CDIIIb were enrolled. However, we believe that residual CDIIIb after type A

repair and pure CDIIIb are not significantly different in terms of fluid dynamics, and they do not differ apart from chronicity of dissection. Last, patients with TEVAR and FLP were combined in our study cohort. However, FLP was considered during the covariates selection, and FLP was not a significant factor for CTR.

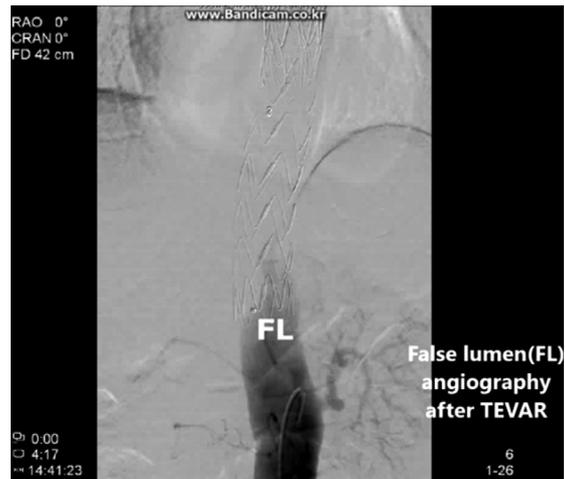
CONCLUSION

In CDIIIb aneurysms, CTR may be the new ideal target of endovascular treatment rather than FL thrombosis. TFT is an important factor related to aortic remodeling and the initial process to CTR. However, TFT alone cannot guarantee the long-term durability of TEVAR for CDIIIb aneurysms.

The number of visceral branches from the FL and residual intimal tears were significant obstacles to achieving CTR. Additional procedures to eliminate the obstacles to CTR and close follow-up after TFT may be needed to achieve the optimal outcome for CDIIIb aneurysms.

SUPPLEMENTARY MATERIAL

The following is the supplementary data to this article:



Video 1. False lumen procedure video. Nester coil insertion (Cook Medical Inc, Bloomington, IN), Viabahn stent graft (W.L. Gore & Associates., Flagstaff, AZ) insertion, and Amplatzer vascular plug (AVP; AGA Medical, Golden Valley, MN) and embolization glue (33% N-butyl cyanoacrylate mixed with lipiodol) insertion were described.

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Video 2. Webcast.

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