

Research Article

Distal Stent Graft-Induced New Entry Prophylaxis for Chronic Type B Aortic Dissection

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Abstract

Background: Oversizing is a risk of retrograde type A aortic dissection and distal stent graft-induced new entry in chronic type B aortic dissection after thoracic endovascular aortic repair. Although oversizing of $\leq 5\%$ suppresses retrograde type A aortic dissection, but distal stent graft-induced new entry is controversial. As distal stent graft-induced new entry mostly develops asymptotically, it can go unnoticed and affect outcomes without ongoing follow-ups. Herein, we examined the effect of preventing distal stent graft-induced new entry by performing follow-up computed tomography in all patients treated with thoracic endovascular aortic repair for chronic type B aortic dissection

Methods: All patients who underwent initial thoracic endovascular aortic repair for chronic type B aortic dissection between April 2012 and December 2023 were included. The oversizing rate was determined by dividing the distal diameter of the stent graft by the true lumen diameter. An oversizing rate of 100-105% was defined as the same-size group (S Group) and 106% or more as the oversize group (O Group).

Results: In the O and S groups, which did not show a significant difference in patient background other than oversize, distal stent graft-induced new entry occurred more often in the O group, although no significant difference was observed (44% vs. 0%; $p=0.066$).

Conclusions: Although there was no significant difference, size selection of $\leq 105\%$ was associated with distal stent graft-induced new entry suppression. Continuous and careful follow-up is required after TEVAR for patients with chronic type B aortic dissection.

Keywords: TEVAR, RTAD, d-SINE, cTBAD

INTRODUCTION

Background

Retrograde type A aortic dissection (RTAD) and distal stent graft-induced new entry (d-SINE) are important complications after thoracic endovascular aortic repair (TEVAR) surgery for chronic type B aortic dissection (cTBAD)¹⁻⁶. Since RTAD has a lethal prognosis, adequate measures must be taken at the time of surgical planning. Oversizing and the use of bare stents are considered risk factors for RTAD^{7,8}. Appropriate intervention is necessary because d-SINE causes rapid expansion of the aortic false lumen and poses the risk of aortic rupture⁹. The true lumen of the descending aorta in patients with cTBAD is often narrow and meandering. Therefore, it is difficult to select the appropriate size of the stent graft, and even the smallest diameter of the stent graft will be oversized, especially in patients with a highly narrowed true lumen. In addition, the distal side of the stent graft is often placed in the dissecting inner membrane, where the risk of d-SINE is potentially high¹⁰⁻¹³. In addition, d-SINE often occurs asymptotically, and a diagnosis may not be made unless a doctor suspects it and performs contrast-enhanced computed tomography (CT)¹⁴. Reflecting on this situation, follow-up after TEVAR is mandatory in Japan by the Japanese Committee for Stentgraft Management.

What is already known

Excessive oversizing (greater than 5%) on the central side is a risk factor for RTAD^{15,16}. On the other hand, Xiang *et al.* examined the association between excessive (greater than 5%) oversizing on the distal side and d-SINE and showed that oversizing did not affect the occurrence of d-SINE^{15,16}.

What is unknown

However, Xiang *et al.* excluded patients who did not undergo continuous follow-up CT¹⁶. As mentioned above, d-SINE is difficult to detect unless physicians implement continuous CT follow-up¹⁴. Previous studies may have underestimated the relationship between oversizing and d-SINE. In fact, some studies have shown that d-SINE may increase owing to excessive oversizing¹⁷⁻¹⁹. Therefore, the results of previous studies are inconsistent with the conclusion that there is no relationship between oversizing and d-SINE.

Purpose

We conducted a single-center retrospective cohort study to clarify the relationship between distal oversizing and d-SINE.

MATERIAL AND METHODS

Design

This single-center retrospective cohort study included patients who underwent TEVAR for cTBAD between April 2012 and December 2023.

Ethics

The Research Ethics Committee of Kameda General Hospital approved this study (Approval Number: 22-006). Patient consent for data acquisition was obtained through opt-outs in accordance with Japan's laws and guidelines.

Study setting

Kameda Medical Center is a tertiary medical institution located in rural Japan. We have a track record of performing TEVAR in 20 cases per year. In Japan, follow-up after TEVAR is mandatory at each medical institution according to the Japanese Committee for Stent Graft Management. For this reason, the Kameda Medical Center follows up patients who have undergone TEVAR every 3 months, 6 months, and yearly thereafter; a simple CT scan is performed at every follow-up and a contrast-enhanced CT scan is performed when an enlarged aneurysm is observed.

Patient population

All patients who underwent initial TEVAR for cTBAD between December 2012 and December 2023 were included, and the observation period was from December 2012 to April 2024. These cases were observed retrospectively from the preoperative period to the end of the observation period or until the onset of the outcome. No exclusion criteria were established.

Variables

Outcome

The occurrence of d-SINE was defined as the primary outcome. d-SINE was diagnosed by a physician using contrast-enhanced CT. The history of the discovery of d-SINE includes detection using contrast-enhanced CT at postoperative follow-up and detection using contrast-enhanced CT at chronic dissecting aortic rupture. The secondary endpoints were the incidence of paraplegia and death within 30 days.

Exposure

The oversizing rate was determined by dividing the peripheral diameter of the stent graft by the true lumen diameter. Excessive (greater than 5%) oversizing was considered exposure. The oversizing rate of 100-105% was in the same size group (S group), and 106% or more was in the oversize group (O group).

Other

From electronic medical records, age, sex, dyslipidemia, hypertension, diabetes, cardiovascular disease, chronic obstructive pulmonary disease, chronic kidney disease, and connective tissue disease were obtained as background information for the patients, and stent graft diameter and length were obtained as information at the time of surgery.

Bias source

As this was a descriptive study, imbalances in patient attributes between the groups were not corrected.

Study size

As this was an observational study, we did not design the sample size in advance and included all cases that could be collected within the study period.

Statistical analysis

Descriptive statistics of the patient attributes and outcomes in groups O and S were obtained. The median and IQR are shown for continuous variables, and the number of occurrences and their percentages are shown for categorical variables. The Mann–Whitney U test was used to compare groups of continuous variables, and Fisher’s exact probability test was used to compare groups of categorical variables.

The survival time to event occurrence was analyzed between the groups. Kaplan-Meier curves were drawn for groups O and S, and comparisons between the groups were performed using a log-rank test.

RESULTS

During the period, 24 patients underwent the first TEVAR for chronic type B aortic dissection.

The preoperative patient backgrounds of both groups are shown in Table 1. There were no significant differences between the S and O groups, except for the oversizing rate.

Table 1

	Samesize(N=6)	Oversize(N=18)	p	test	Missing
Age (median [IQR])	65.00 [60.75, 67.75]	66.00 [62.25, 70.75]	0.764	nonnorm	0
Gender = male (%)	4 (66.7)	15 (83.3)	0.568	exact	0
Observation_length (median [IQR])	1116.50 [999.75, 1399.75]	1172.00 [857.75, 3201.00]	0.594	nonnorm	0
DL = yes (%)	1 (16.7)	1 (5.6)	0.446	exact	0
HTN = yes (%)	6 (100.0)	15 (83.3)	0.546	exact	0
DM = yes (%)	2 (33.3)	0 (0.0)	0.054	exact	0
CAD = yes (%)	1 (16.7)	2 (11.1)	1	exact	0
COPD = no (%)	6 (100.0)	18 (100.0)	NA	exact	0
CKD = yes (%)	1 (16.7)	3 (16.7)	1	exact	0
CTS = yes (%)	1 (16.7)	0 (0.0)	0.25	exact	0
Oversize_rate (median [IQR])	101.50 [100.00, 103.75]	119.50 [112.25, 139.00]	<0.001	nonnorm	0
SG_size (median [IQR])	29.00 [26.50, 30.75]	31.50 [28.00, 36.25]	0.169	nonnorm	0
SG_length (median [IQR])	127.50 [100.00, 159.50]	150.00 [111.75, 159.50]	0.613	nonnorm	0
Zone (%)			0.749	exact	0
0	0 (0.0)	1 (5.6)			
1	0 (0.0)	3 (16.7)			
2	1 (16.7)	5 (27.8)			
3	2 (33.3)	3 (16.7)			
4	3 (50.0)	6 (33.3)			
Th (median [IQR])	9.50 [7.50, 10.00]	7.50 [7.00, 9.00]	0.162	nonnorm	0

The risk factors for d-SINE, which have been identified in previous studies, were not significantly different in terms of connective tissue disorders and short stent graft length but were more common in the J group.

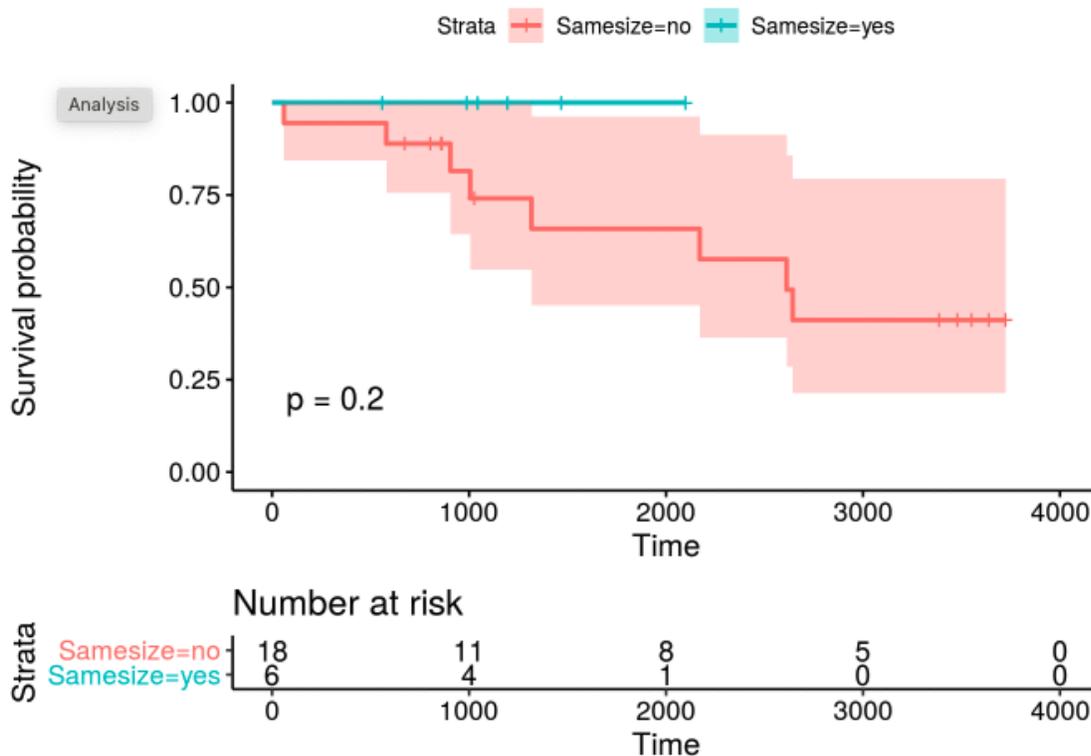
Although the difference was not significant, d-SINE was more common in the O group (44% vs. 0%; $p=0.066$) (Table 2). In addition, the occurrence of paraplegia, a secondary endpoint, and death within 30 days did not occur in both groups.

Table 2

	Samesize(N=6)	Oversize(N=18)	p	test	Missing
SINE = yes (%)	0 (0.0)	8 (44.4)	0.066	exact	0
Paraplegia = no (%)	6 (100.0)	18 (100.0)	NA	exact	0
mortality_30d = 0 (%)	6 (100.0)	18 (100.0)	NA	exact	0

In Figure 1, we present the Kaplan-Meier curve divided into the O and S groups. In the O group, the KM curve was lower than that in the S group, and the time to event occurrence tended to be shorter; however, the difference was not statistically significant (log-rank test, $p = 0.2$).

Figure 1



DISCUSSION

There was no significant difference other than the oversizing rate between the O and S groups, but d-SINE was more common in the O group, although the difference was not statistically significant.

Xiang *et al.* showed that there is no association between excessive peripheral oversizing (greater than 5%) and d-SINE but excluded patients who did not undergo continuous CT follow-up¹⁶. d-SINE often develop asymptotically, and studies without continuous follow-up may have underestimated the relationship between oversizing and d-SINE.

Therefore, in this study, all patients who underwent initial TEVAR for cTBAD during the relevant period were regularly followed up with CT. Although there was no significant difference, d-SINE was more common in the O group. These results may have differed from those of previous studies, in that all cases were followed up using regular CT scans.

In previous studies, the follow-up of all patients after TEVAR was incomplete, and data such as those of this study, in which the follow-up results of all cases were measured, are scarce.

Although larger epidemiological studies are required, the results of this study indicate that an oversizing of 5% or more may contribute to the development of d-SINE. Because d-SINE is asymptomatic, it is easily overlooked and detection is delayed unless the physician is aware of it and continues to follow up, during which time the pseudo-lumen can expand rapidly and lead to a fatal prognosis¹⁴.

There is a possibility that d-SINE can be suppressed by suppressing the oversizing rate to 105% in TEVAR; however, there are cases where oversizing is unavoidable for anatomical reasons, especially due to highly narrowed true cavities 11. In such cases, it is necessary to take measures such as increasing follow-up. In addition, measures such as the PETTICOAT snowshoe technique may be effective²⁰.

Limitation

This was a medium-term retrospective cohort study conducted at a single hospital, and it is difficult to generalize the results because of the small number of cases.

The results of this study suggest a non-significant association between distal oversizing and d-SINE. It is necessary to consider the possibility of preventing, early detection, and treatment of d-SINE by selecting a size of 100-105% of the peripheral diameter and conscious follow-up of cases with oversizing.

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DECLARATIONS

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Declaration of Conflicting Interests: None declared

Ethical Approval: The ethics committee of Kameda Medical Center approved this study (REC number: 22-006)

Informed Consent: According to Japanese ethical guidelines, written informed consent was waived in this study as only pre-existing medical information was used.

Data Availability: As the study was approved by the ethics committee with the condition of not disclosing personally identifiable information, data sharing that could potentially identify individual participants is not possible. However, the datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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