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Research article

Risk of d-SINE in Aortic Dissection

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Abstract

Background: Distal stent graft-induced new entry (d-SINE) following total arch replacement using a frozen elephant trunk (TAR FET) or following thoracic endovascular aortic repair (TEVAR) for chronic type B aortic dissection (cTBAD) has been previously reported. Risk factors for d-SINE include oversizing ratio, and stent graft (SG) peripheral angle. We compared the risk factors of d-SINE in cTBAD patients in the TAR FET and TEVAR groups.

Methods: Patients who underwent TAR FET with Frozenix or TEVAR for cTBAD between December 2012 and March 2021 were included. There were eight patients in the TAR FET group (mean age, 61 years) and 15 in the TEVAR group (mean age, 66 years).

Results: d-SINE was occurred on six patients from the TAR FET group and three from the TEVAR group (75.0% vs. 26.3%, p=0.074). The oversizing ratio did not differ significantly between the TAR FET and TEVAR groups (118% vs. 126%, p=0.331). The peripheral angle of the SG was significantly increased (p=0.047) in the TAR FET group (30°) as compared to the TEVAR group (18°). As compared to the TEVAR group, the SG diameter was also considerably smaller in the TAR FET group (26 mm vs. 31 mm, p=0.007), and the SG length was significantly shorter in the TAR FET group (86 mm vs. 140 mm, p=0.023).

Conclusion: Careful planning and appropriate intervention with TEVAR are necessary when performing TAR FET with Frozenix for the management of cTBAD.

Keywords

Distal stent graft-induced new entry, total arch replacement using a frozen elephant trunk, thoracic endovascular aortic repair, chronic type B aortic dissection

Introduction

Distal stent graft-induced new entry (d-SINE) following total arch replacement using a frozen elephant trunk (TAR FET) or thoracic endovascular aortic repair (TEVAR) is a common complication of chronic type B aortic dissection (cTBAD) 1—12. Some risk factors for this complication include the oversizing ratio and the stent graft (SG) peripheral angle1,6-10. Few studies have compared TAR FET and TEVAR.

Although TAR FET or TEVAR is the standard procedure for cTBAD at our hospital, d-SINE occurred frequently in the TAR FET group. As a result, we felt it was necessary to conduct a risk analysis to assess the appropriateness of TAR FET treatment. In this study, we evaluated the risk of d-SINE in cTBAD patients in the TAR FET and TEVAR groups and discussed the presence of risk factors unique to the TAR FET group.

Patients and Methods

This single-center, retrospective cohort study was conducted at a rural acute-care hospital in Japan that performs several surgeries for cTBAD annually. In all cases, TAR with FET was performed with a median incision, circulatory arrest at 26°C, and selective cerebral perfusion. Frozenix was used to place an open stent graft from Zone 0-2. All patients underwent TEVAR via the femoral artery approach.

Patients who underwent TAR FET or TEVAR for cTBAD or dissecting aortic aneurysm between December 2012 and March 2021 were included in this study. These patients were regularly followed up during the study period to obtain relevant information. Patients who underwent multiple TAR FETs or TEVARs during the follow-up period and those with a healthy landing zone at the end of the SG were excluded as dissecting aortic aneurysms. The study centers did not transfer patients to other hospitals for cTBAD or follow-up, except in the case of death, and cTBAD was treated with long-term outpatient follow-up.

Variables

The following information was obtained from medical records retrospectively: type of TAR FET or TEVAR, oversizing ratio within the first postoperative week, angle of the peripheral end of the SG relative to the actual aortic cavity, as well as diameter and length of the SG on CT images. The oversizing ratio was calculated by dividing the diameter calculated from the circumference of the true lumen on the preoperative CT by the SG diameter used. The angle of the SG was defined as the angle created by the intersection of the straight line connecting the center point of the peripheral end of the SG to the center point of the 2 cm portion of the true lumen centrally and the straight line connecting the center point of the 5 cm portion peripherally to the true lumen. This analysis was performed using EndoSize® software (Therenva SAS, Rennes, France) (Image 1). The presence or absence of d-SINEs was determined during the follow-up period.

Image

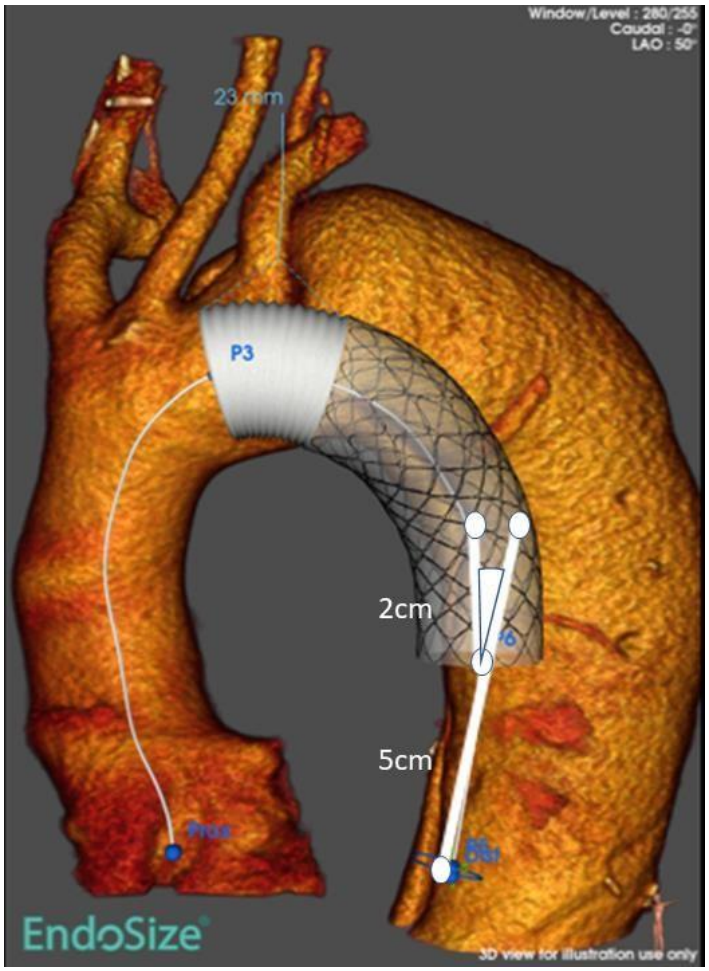

Image 1: Measurement of stent graft angle.

The angle of SG was defined as the angle created by the intersection of the straight line connecting the center point of the peripheral end of SG to the center point of the 2 cm portion of the central part of the true lumen and the straight line connecting the center point of the 5 cm portion of the peripheral part of the true lumen. This analysis was performed using EndoSize® software (Therenva SAS, Rennes, France).

Comparison

We used the TEVAR group as an axis of comparison with the TAR FET group and evaluated the same items that were measured.

Statistical Analysis

Statistical analyses between the two groups were performed. Continuous variables were denoted as mean ± standard deviation, while categorical variables were denoted as percentages. The differences in proportions were evaluated using the chi-square test ($\chi 2$ test) or Fisher's exact test, while the differences in means were assessed using the Student's t-test. Univariate analysis was performed to identify the risk factors of d-SINE. The significance level was set at $p < 0.05$ in this study.

Results

Twenty-three patients were included in the analysis (Figure 1). Preoperative patient backgrounds for both groups are shown in Table 1. Of the 23 patients, eight were in the TAR FET group (8 Frozenix) and 15 were in the TEVAR group (9 cTAG, 2 Relay, 2 Zenith, and 2 Valiant). The mean observation period was 4.12 years. There were no statistically significant differences in patient characteristics such as sex or operative age. The overall incidence of d-SINE was 35% (8/23), higher in the TAR FET group at 75% (6/8) compared to 26.7% (3/15) in the TEVAR group.

Oversizing ratios were not significantly different between the TAR FET (118%) and TEVAR groups (126%) are shown in Table 2. The angle of the SG peripheral end (TAR FET group 30°, TEVAR group 18°, p=0.047), SG diameter (TAR FET group 26 mm, TEVAR group 31 mm, p=0.007), SG length (TAR FET group 86 mm, TEVAR group 140 mm, p=0.023) were significantly less angulated, smaller, and shorter, respectively, in the TAR FET group as compared to the TEVAR group.

Table 1: Baseline characteristics

	TAR FET (n=8)	TEVAR (n=15)	p-Value
Sex (female)	2 (25%)	2 (13.2%)	0.9
Age (years)	61±12	66.33±9	0.231
Dyslipidemia	4(50%)	2(13%)	0.159
Hypertension	8(100%)	14(93.3%)	1
Diabetes	1(12.5%)	1(6.7%)	1
CAD	1(12.5%)	1(6.7%)	1
COPD	8(100%)	15(100%)	1
CKD	3(37.5%)	4(26.7%)	0.951
CTS	0(0%)	1(6.7%)	1

CKD: Chronic Kidney Disease, COPD: Chronic Obstructive Pulmonary Disease, CTS: Connected Tissue Disease, SINE: Stent graft Induced New Entry

Table 2: Operative outcome

Perioperative outcome	TAR FET (n=8)	TEVAR (n=15)	p-Value
SINE	6 (75.0%)	4 (26.3%)	0.074
Paraplegia	1（12.5%)	0	0.084
Oversize rate (%)	118±16	126±22	0.331
Post angle (°)	30±16	18±12	0.047
SG size	26±2	31±5	0.007
SG length	86±19	140＋59	0.023

SINE: Stent graft Induced New Entry

Discussion

Descriptive statistics were obtained for patients with cTBAD who were divided into two groups, namely the TAR FET and TEVAR groups. d-SINE predominantly occurred in 75% of patients in the TAR FET group, compared to 20% in the TEVAR group.

Previous reports have indicated that the incidence of d-SINE in TAR FET for cTBAD ranged between 13.7 and 36.4%1,2,4, and that the incidence of d-SINE in TEVAR for cTBAD ranged between 12.9 and 50.0%7-9. Therefore, the incidence of d-SINEs in the TAR FET group for cTBAD in the current study was significantly higher.

Additionally, previous studies have identified oversize ratios, SG angle, SG size, and SG length as risk factors for d-SINE1,6-10.

In order to avoid the risk of spinal cord ischemia, the peripheral end of the SG is limited to the central part of Th8 when performing TAR-FET for cTBAD 13. However, if the SG is too short, its peripheral end may come into contact with the descending aortic flexure, thus increasing the risk of d-SINE6. On the other hand, when performing TEVAR for cTBAD, it is recommended that the peripheral end should be located in a straight portion of the descending aorta at least 20 mm peripherally from the entry, and that the oversizing rate should be 110-120% of the true lumen diameter13. A comparison of implantation positions between our two groups also revealed that, although there were differences between the TAR FET and TEVAR groups, neither group deviated from the guideline range.

The higher incidence of d-SINE in the TAR-FET group, despite not deviating from the guidelines, is a concern. This could be explained by the fact that the TAR FET group tends to be too angled at the end of the SG as they must be placed above Th8 due to spinal cord ischemia considerations6. This is an anatomical limitation of TAR FET and is considered a risk factor for d-SINEs in cTBAD6.

Kreibich et al. evaluated Thoraflex with a polyester prosthesis and Nitinol stent and E-vita OPEN NEO with a PTFE prosthesis and Nitinol stent and showed that Thoraflex has a stiff peripheral end and may be a potential reason for the occurrence of d-SINE4. Our institution uses Frozenix, the only available polyester vascular prosthesis and Nitinol stent in Japan. Furutachi et al. reported that the spring back force of Frozenix might affect d-SINE1. The difference in structure may affect d-SINE more than the difference in materials, and improvements in Frozenix are awaited. Hence, TAR FET for cTBAD has a high risk of d-SINE and may require a treatment strategy that considers secondary TEVAR.

After this study, we modified the TAR FET plan for cTBAD, selected a device size of 100-105%, limited the device to the central Th8 to avoid contact with the spinal cord ischemia, and aggressively performed TEVAR in angled cases to prevent d-SINE.

This study has a few limitations. Since this was a single-center retrospective study, the possibility of bias cannot be ruled out as TAR FET and TEVAR typically involve different patient backgrounds, and generalizability to other centers remains an issue. A larger sample size and a multicenter retrospective study are warranted to discuss the reliability and validity of the treatment.

Conclusion

Due to the high risk of d-SINE and anatomical limitations when performing TAR FET for cTBAD, careful follow-up and additional appropriate treatment with TEVAR are necessary.

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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.

References

1) Furutachi A, Osaki J, Koga K, et al. (2022). Late outcomes of the frozen elephant trunk technique for acute and chronic aortic dissection: the angle change of the FROZENIX by "spring-back" force: Gen Thorac Cardiovasc Surg

2) Berger T, Graap M, Rylski B, et al. (2022). Distal aortic failure following the frozen elephant trunk procedure for aortic dissection: Front. cardiovasc. med

3) Kreibich M, Siepe M, Berger T, et al. (2021). The Frozen Elephant Trunk Technique for the Treatment of Type B and Type Non-A Non-B Aortic Dissection: Eur J Vasc Endovasc Surg

4) Kreibich M, Bunte D, Berger T, et al. (2020). Distal stent graft-induced new entries after the frozen elephant trunk procedure: Ann Thorac Surg

5) Hohri Y, Yamasaki T, Matsuzaki Y, et al. (2020). Early and mid-term outcomes of frozen elephant trunk using spinal cord protective perfusion strategy for acute type A aortic dissection: Gen Thorac Cardiovasc Surg

6) Yamane Y, Katayama K, Furukawa T, et al. (2020). Mid-term results of frozen elephant trunk technique for chronic aortic dissection: Ann Vasc Dis

7) J ang H, Kim MD, Kim GM, et al. (2017). Risks factors for stent graft-induced new entry after thoracic endovascular aortic repair for Stanford type B aortic dissection: J Vasc Surg

8) Canaud L, Gandet T, Sfeir J, et al. (2019). Risk factors for distal stent graft-induced new entry tear after endovascular repair of thoracic aortic dissection: J Vasc Surg

9) Pantaleo A, Jafrancesco G, Buia F, et al. (2016). Distal stent graft-induced new entry: an emerging complication of endovascular treatment in aortic dissection: Ann Thorac Surg.

10) Ouchi T, Kato N, Kato H, et al. (2020). Relevance of aortic dissection chronicity to the development of stent graft-induced new entry: Ann Thorac Surg

11) Li Q, Ma WG, Zheng J, et al. (2019). Distal Stent Graft-Induced New Entry After TEVAR of Type B Aortic Dissection: Experience in 15 Years: Ann Thorac Surg

12) Zhao Y, Yin H, Chen Y, et al. (2018). Restrictive bare stent prevents distal stent graft-induced new entry in endovascular repair of type B aortic dissection: J Vasc Surg

13) JCS Joint Working Group. (2013). Guidelines for diagnosis and treatment of aortic aneurysm and aortic dissection (JCS 2011): Circ J

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