Original Article

Surgical Strategies for Type B Aortic Dissection by Frozen Elephant Trunk

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The timing and choice of surgical method for type B aortic dissection, is still a topic of much debate. We performed total arch replacement using frozen elephant trunk (TAR-FET) as a means of preventing distant aortic events, such as retrograde type A aortic dissection (RTAD). We conducted analysis of 142 patients with acute type B dissection who were admitted between January of 2010 and July of 2017. Fifty-five cases required surgical intervention to treat enlargement of the false lumen diameter and ULP formation 2 weeks after the onset of symptoms. 17 TAR-FET were performed with a mean of 42±26 days period from onset to surgery. There were no complications of RTAD or paraplegic, and 90% of patient demonstrated aortic event free survival (5 years) and false lumen reduction ratio of 35%. Based on our analysis, using TAR-FET properly avoids serious complications like RTAD, and is a viable treatment option for type B dissection. (This is a translation of J Jpn Coll Angiol 2018; 58: 151–157.)

Keywords: TAR-FET, TEVAR, aortic dissection, type B, entry closure

Introduction

In recent years, the utility of entry closure using stent grafts has been recognized for conditions ranging from early subacute to chronic type B dissection.[1,2] However,

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there is also a lack of consensus across facilities with respect to the surgical treatment strategy to be followed; it depends on the preference of the surgeon. Although rare, there is a possibility of enlargement of the aortic diameter in isolated disease and Stanford A type dissection if the aorta in the ascending arch is large. There is also a possibility of retrograde type A aortic dissection (RTAD) arising from aortic intimal injuries owing to stent grafts.[3] Thus, choosing a treatment based on patient background and entry position of the tear to the aortic lumen is necessary to avoid aortic events in isolated diseases and to achieve favorable surgical results.

In this study, patients who were determined as not requiring surgery for acute disease were classified into the uncomplicated type B aortic dissection group. To promote remodeling by early entry closure in such patients with acute exacerbation (those with ulcer-like projection [ULP] formation and enlargement of the diameter of the aneurysm), the site of entry and anatomical requirements were evaluated. Two weeks or more after the onset of symptoms, the appropriateness of performing either the total arch replacement using frozen elephant trunk (TAR-FET) or thoracic endovascular aortic repair (TEVAR) technique was considered, after which proactive surgical intervention was performed. The validity of the treatment plan was then verified.

Patient Population and Methods

Patient population

The study population comprised 142 patients who were urgently transported to our institution between January 2010 and July 2017 and were diagnosed with acute aortic dissection (Stanford B) based on results of computed tomography (CT). Patients requiring surgery for acute disease owing to a ruptured aorta and impaired organ perfusion were classified into the complicated type B aortic dissection group (n = 8).

In patients in the uncomplicated type B aortic dissection group, who did not require surgery for acute disease, the diameter of the aneurysm increased, and new ULPs appeared during the course of regular follow-up (between 2

weeks and 1 year after onset). Consequently, 55 patients required surgery. TAR-FET was performed using open stents in 17 patients. In the subgroup of elderly patients who were deemed unable to tolerate open-heart surgery, 16 patients underwent TEVAR landing in Zone 2. Comparative analysis was then performed for the 2 groups.

Methods

All of the aforementioned patients were admitted to the intensive care unit (ICU) and underwent strict antihypertensive management under invasive arterial pressure monitoring according to the guidelines for the diagnosis and treatment of aortic aneurysm and aortic dissection. Contrast-enhanced CT was performed 1, 7, and 14 days after admission to evaluate the development of new ULPs, rapid enlargement of the largest aortic diameter (<5 mm/week), ruptures (impending rupture), reoccurring dissections, and organ ischemia. If any of the aforementioned were observed, surgical intervention was performed.

TAR-FET was performed on (i) patients aged ≤ 75 years with a large diameter spanning from the ascending aorta to the arch region; (ii) patients with patent false lumens and entry via the distal arch; (iii) patients with aneurysm type disease (Cambria type III)[4]; and (iv) patients with new or rapid enlargement of ULPs in the arch and descending thorax during conservative treatment, with aortic dissection and aneurysmal diameter enlargement in isolated disease considered for patients with rapid enlargement. TEVAR was performed in patients for whom the main entry was in the distal arch, there was no dissection at the central end of the central landing zone, and a landing could be secured at a level that was not ≥ 2 cm distal from the left subclavian artery or without causing left subclavian artery occlusion. FROZENIX® open stents (Japan Lifeline, Tokyo, Japan) were used for all patients, and the TEVAR device used was C-TAG® (GORE, Tokyo, Japan). Surgery was performed in the supine position under general anesthesia. The left subclavian artery and perfusable femoral artery in the true lumen not covered by dissection on either the left or right side were exposed, and a 9-mm aortic graft was anastomosed to provide a route for blood supply (**Fig. 1a**). After median sternotomy was performed and the bladder temperature decreased to 28°C, the left subclavian artery was triple ligated. The perfusion pressure of the left subclavian artery was maintained above a mean value of 60 mmHg. At that stage, lower body circulatory arrest was established, the aorta was dissected, and selective antegrade cerebral perfusion was performed (**Fig. 1b**). A FROZENIX® stent was placed under the guidance of transesophageal echocardiography while keeping the patient's head down to prevent pneumatic embolism and to observe debris and the status of the

dissecting cavity. A balloon for blood vessel occlusion was inserted into the FET to close the lumen. The lower body was perfused again from the femoral artery at a flow rate of 2.4 L/min/m², and lower body circulatory arrest was terminated. At the distal end, the unstented portion was everted to cover the aortic wall and form a stump (**Fig. 1c**). Subsequently, a four-branched aortic graft was set, and continuous anastomosis was performed. The antegrade lower body blood supply was resumed from the aortic graft and warming of the entire body began. The proximal side of the aortic graft was continuously anastomosed near the sinotubular junction of the ascending aorta. After completing central anastomosis, the aortic blockade was released, and the cervical branch was reconstructed under an on-pump beating condition. Lastly, an aortic graft anastomosed to the left subclavian artery was guided into the mediastinum via the left second intercostal space and reconstructed via a vascular–vascular prosthesis anastomosis to complete the procedure (**Fig. 1d**).

When selecting the FET size, a size of 90% of the aortic outer diameter was selected if the true lumen was displaced into the false cavity and the exact diameter could not be determined[5]; if the true lumen size was preserved, a size 2–3 mm larger than the diameter measured from the circumference of the true lumen was chosen. Ultimately, the size was determined using a transesophageal echo and sizer during surgery.

Evaluation of changes in the status of the false lumen (remodeling)

The results of the TAR-FET group were the clinical endpoints. Thrombosis of the false lumen was evaluated using contrast-enhanced CT before and one year after surgery, and changes in the diameters of the descending aorta (true lumen and false lumen) and thoracoabdominal aorta were measured for remodeling. The patient background, aortic diameter, and results in the TAR-FET group and Zone 2 TEVAR group were evaluated and compared.

Statistical analysis was performed using JMP Version 12 (SAS Institute Inc., Cary, NC, USA). Continuous data are presented as means ± standard deviation. Categorical variables were analyzed using the Chi-square or Fisher's exact tests. Continuous variables were analyzed using t-tests or Mann–Whitney U tests. Differences were considered statistically significant if the p-value was <0.05.

Results

Perioperative results

The patients comprised 12 males and 5 females with a mean age of 69.4±9.7 (range: 55–85) years. The mean time from onset to surgery was 41.8±25.9 (range: 13–121) days. The site of entry was the distal arch
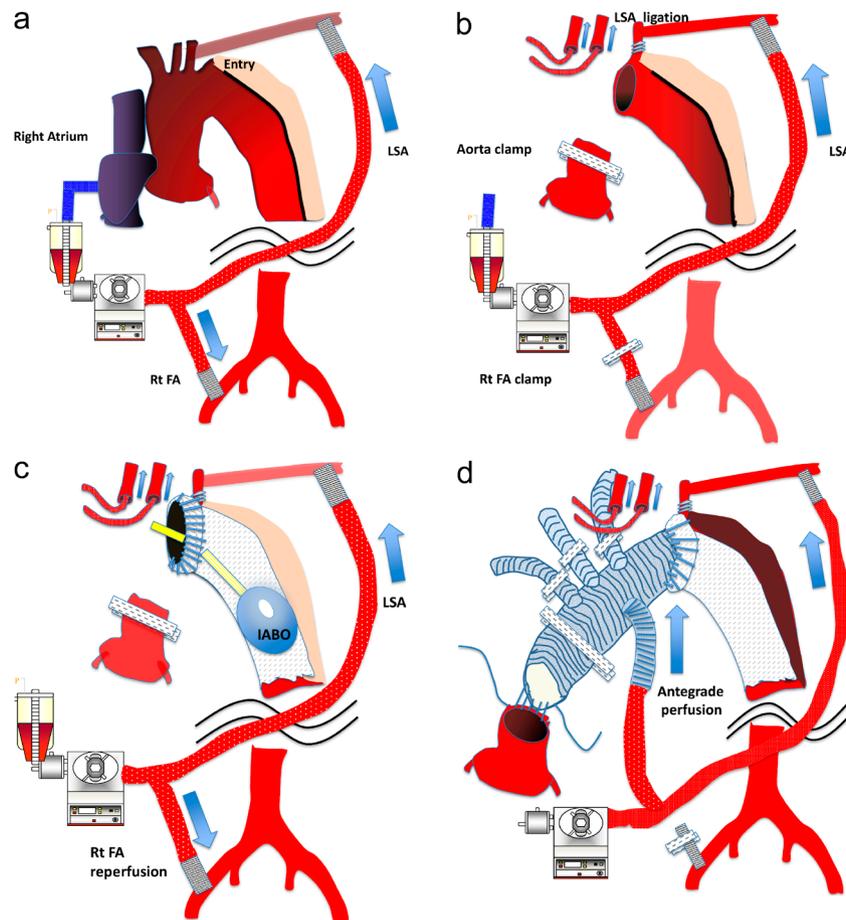
Fig. 1 (**a**) Initially, arterial return cannulas are placed in the left subclavian artery and unilaterally in the femoral artery, and a median sternotomy is performed. Unicaval venous cannulas are inserted through the right atrium. Subsequently, cardiopulmonary bypass (CPB) is initiated, and core cooling is performed to achieve a bladder temperature of 28°C. (**b**) The ascending aorta is cross-clamped, and a cold crystalloid cardioplegic solution is injected into the aortic root to achieve cardiac arrest. The brachiocephalic and left carotid arteries are selectively cannulated, and the left subclavian artery is clamped. Perfusion from the femoral artery is discontinued after establishing selective cerebral perfusion at a rate of 1.2 L/min/m². (**c**) Next, the aortic arch is transected between the left carotid and left subclavian arteries, and FROZENIX is deployed through this transection site into the intended distal landing portion under transesophageal echocardiography (TEE) guidance. Immediately after placement, the proximal side of FROZENIX is cut to align the edge with the transected aortic arch. A intraaortic balloon is inserted inside FROZENIX at the distal landing position and inflated while reperfusing the visceral arteries and lower body from the femoral artery at a rate of 2.4 L/min/m². An anastomotic stoma is created by sewing together the dissected aorta and the varied non-stent part using external running sutures, after which the stoma is anastomosed to a 4-branched graft. (**d**) Next, an arterial return cannula is connected to the 4-branched graft, antegrade perfusion to the visceral arteries and lower body is restarted, and core rewarming is initiated. During rewarming, the proximal ascending aortic stoma is anastomosed to the 4-branched graft using standard techniques, and coronary artery perfusion is restarted. Finally, 3 neck vessels are reconstructed using branches of the 4-branched graft in the mediastinum.

just below the left subclavian artery in 12 patients; in the remaining 5 patients, there was development of new ULPs of the thrombo-occlusive type with unclear entry or rapid expansion of ULPs. Ten patients had patent false lumen.

Endoleaks and dissecting cavities had clots in all patients, and entry closure was confirmed by postoperative CT. There were no hospital deaths or deaths owing to isolated disease in the TAR-FET group. The mean observation

Table 1 Patient's characteristics and operative profiles

No	Age (Yr)	Sex	Period (Day)	Concomitant surgery	Crawford type	entry; LSA	False lumen patency	Ope indication	4branch J-GRAFT size (mm)	FROZENIX diameter (mm)	FROZENIX stent length (mm)
1	79	F	45		IIIb			Involving aneurysm 60 mm s/p Type A DA	30	33	120
2	69	F	59		IIIb			Arch dilatation 49 mm	30	31	120
3	69	M	54		IIIa	○	○	Arch dilatation 48 mm	30	31	90
4	61	M	22		IIIb	○	○	Arch dilatation 52 mm	30	31	120
5	56	M	46		IIIb	○	○	ULP formation, shaggy	26	29	90
6	74	M	46		IIIa			Involving aneurysm 55 mm	22	31	120
7	75	M	15		IIIb	○	○	Arch dilatation 55 mm	24	25	120
8	77	M	13		IIIa			Arch ULP enlargement	22	29	90
9	59	M	19		IIIa	○	○	Arch ULP enlargement	24	25	90
10	55	M	17	CABG (LITA-LCX)	IIIb	○	○	Arch dilatation 53 mm	28	29	120
11	81	M	36		IIIa			Involving aneurysm 58 mm	26	25	120
12	73	M	43		IIIa	○	○	ULP formation, shaggy	28	33	120
13	69	M	68		IIIb	○		Arch dilatation 53 mm	28	33	90
14	81	F	27	AVP+TAP	IIIb	○	○	Involving aneurysm 49 mm	26	25	120
15	85	M	37		IIIa	○	○	ULP formation, shaggy Ao	28	33	90
16	58	F	121		IIIa	○		ULP enlargement 51 mm	22	29	90
17	59	F	42	TAP	IIIb	○	○	Aggravated to Type A DA 48 mm	30	31	90

CABG: coronary artery bypass grafting, LITA: left internal thoracic artery, LCX: left circumflex coronary artery, AVP: aortic valve repair, TAP: tricuspid annuloplasty, Ao: aorta, DA: aortic dissection

Table 2 Evaluation of thrombosis rate of false lumen at each site in TAR-FET. It is examined by contrast CT of follow-up after discharge and one year later. 18 of 35 cases involve Stanford A dissection

	PreDischarge No (%)	Follow up No (%)
Stent graft level		
Complete thrombosis	30/35 (87)	34/35 (93)
Partial thrombosis	5/35 (12)	1/35 (6)
Patent	0/35	0/35
Distal descending thoracic aorta		
Complete thrombosis	26/35 (75)	30/35 (87)
Partial thrombosis	9/35 (25)	5/35 (12.5)
Patent	0/35	0/35
Abdominal aorta		
Complete thrombosis	2/35 (6)	0/35
Partial thrombosis	4/35 (12.5)	6/35 (18)
Patent	29/35 (81)	29/35 (81)

Table 3 Aortic remodeling after TAR-FET (pulmonary arterial bifurcation level). There were significant true lumen expansion and false lumen constriction

	Preoperative	Follow up	P-value
Descending aorta, mm	34.9±9.6	34.3±9.1	0.49
True lumen, mm	19.5±9.1	29.5±4.1	<0.001
False lumen, mm	16.4±6.2	5.9±6.6	<0.001
Thoracoabdominal aorta	27.5±3.3	28.5±4.3	0.09

Table 4 Comparison of results between TAR-FET and Zone 2 landing TEVAR

Parameter	TAR-FET (N=17)	Zone 2 landing TEVAR (n=16)	P-value
Age (Yr)	67.4±9.9	76.1±10	0.02
Ascending–arch diameter (mm)	46±8.4	37±3.1	0.001
Early mortality	0	0	np
Stroke	0	1	np
Spinal cord injury	0	1	np
Late mortality	0	0	np
Additional operation	0	2	np
Endoleak or new tear	0	2	np

period was 15.8 ± 9.7 months. The follow-up rate was 100%. Although the hospitalization period was prolonged owing to postoperative pneumonia in one patient, all patients were discharged. Cerebral infarction and paraplegia were not observed. None of the patients required additional treatment owing to complications such as distal stent graft-induced new entry (SINE). The mean duration of surgery was 310 ± 54 min, mean cardiopulmonary bypass duration was 147 ± 40 min, and mean duration of lower body circulatory arrest was 12 ± 3.3 min. Three patients underwent concomitant surgery (one patient underwent coronary artery bypass, one patient underwent

aortic valvuloplasty, and 2 patients underwent tricuspid annuloplasty). The mean duration of an ICU stay was 2.0 ± 1.2 days. The indwelling FROZENIX® stent length was 90 mm in 8 patients and 120 mm in 9 patients. All graft lengths were set to 200 mm (**Table 1**). The mean landing zone on the peripheral side was 7.4 ± 1.2 levels in the thoracic spine.

Status of false lumen
High thrombosis was present at the end of the stent in the segment where FET was indwelt, with similar trends observed at the end of descending thoracic aorta (**Table 2**). At the level of the celiac artery, 81% of patients were patent.

Remodeling
When aortic remodeling was evaluated, remodeling of the false lumen was significant at the level of the thoracic descending aorta distal to the segment where FET was indwelt (**Table 3**).

Comparison with TEVAR landing in Zone 2
Subsequently, we performed a retrospective comparison of the 17 patients who underwent TAR-FET at our institution and 16 patients who underwent TEVAR in Zone 2 covering the left subclavian artery. Compared with the TEVAR group, the mean age was significantly lower (67 vs. 76 years; p = 0.02) and the maximum diameter of the ascending arch was significantly larger in the TAR-FET group (46 mm vs. 37 mm; p = 0.001). There were no hospital deaths or deaths owing to isolated disease in either of the groups; there were no differences in the additional treatments associated with cerebral infarction, paraplegia, or aortic events in either of the groups (**Table 4**).

Discussion

Indications
The efficacy of TEVAR in patients with uncomplicated type B disease within one year of onset was demonstrated in the INSTEAD XL study, and early adoption of the procedure is now conducted at many institutions.[1] However, there is an ongoing debate as to whether open surgery or TEVAR should be selected for central repair of the arch area in patients with acute exacerbation of uncomplicated type B aortic dissection.[6,7] Debranching + TEVAR is required for patients with type B dissection with arch entry[8]; however, total arch aortic replacement must be evaluated in patients with ascending arch enlargement. The possibility of the occurrence of RTAD should be considered if the landing zone approaches the central side. The incidence of RTAD is only 1.3%, and the mortality rate is at 42%, which is extremely high.[9] There is no guarantee that performing TEVAR in patients with RTAD would prevent

isolated dissection-related complications.[10] TAR-FET has been reported as a valuable tool for the treatment of the same sites.[11] We mainly performed TAR-FET in patients who were not indicated for TEVAR (i.e., those who were outside the scope of our institutional recommendations and required debranching + TEVAR or those at increased risk for RTAD).

There are several reasons supporting early adoption of TAR-FET. First, many patients with distal arch entry and patent false lumens have an isolated disease for which intervention is required.[12] Second, there are individual differences in changes occurring in patients with rapid expansion of the distal arch and ULP, and there have been cases of thrombo-occlusion type distal arch and ULP in the thoracic descending aorta resulting in multiple sudden ruptures and death within 7 days of conservative treatment or follow-up under observation. Reutersberg et al. reported that 33% of patients in the uncomplicated type B aortic dissection group at the time of admission progressed to complicated type disease. The mortality rate in patients in the aforementioned group is significantly higher than that in patients without progression within 14 days (12.5% vs. 0%; P 1/4, 0.02).[13] Considering the complications observed in patients with isolated disease, active and early intervention should be performed for patients at high risk as described above.

Methods
We used the FET technique with the aim of achieving minimally invasive TAR. The associated advantages include a shorter duration of surgery by simplifying distal anastomosis and a shorter duration of lower body circulatory arrest with the usage of intra-aortic balloon occlusion. Additional advantages of TAR-FET are as follows: no risk of RTAD, perfusion below the descending aorta can be performed under direct visual supervision, and valve replacement and coronary artery bypass operation can be performed simultaneously. We were able to perform minimally invasive TAR in 3 out of 17 patients. Notably, there are certain disadvantages, such as uncertain peripheral landing (iatrogenically occurring peripheral new entry and SINE owing to TEVAR performed for Stanford type B aortic dissection and bending of aortic grafts), the use of cardiopulmonary bypass, circulatory arrest (TAR is needed for cardiopulmonary bypass and circulatory arrest, whereas TEVAR is not), cooling of the entire body, lower body circulatory arrest, and spinal cord disorders associated with spinal cord ischemia.[8,11] Adjustments were made to overcome these drawbacks. First, a longer FET was selected (90–120 mm) and was placed parallel to the descending thoracic aorta to prevent interference with the aortic wall. Through these measures, we aimed to prevent SINE on the peripheral side. Numerous studies have

reported that this treatment is often prolonged, resulting in a collapse of the intercostal artery network and development of myelopathy (4%–11%).[6,14,15] By comparison, even if the duration of the treatment is long, the incidence of spinal cord disorders associated with TEVAR is low at approximately 0.9%–2.9%.[16,17] No spinal cord disorders were reported in the 98 patients included in our study who had type A dissection or true aneurysm, indicating that the hypothesis that a longer stent length can result in a high incidence of spinal cord injury (SCI) cannot be proven based on this causal relationship alone.

A high perfusion rate of the left subclavian artery is said to be crucial for preventing paraplegia[18]; our department's policy is to maintain the mean perfusion pressure for the left subclavian artery above 60 mmHg. In addition, after FET insertion, the balloon for occlusion is used from the central side, and lower body perfusion is started at a high flow rate of 2.4 L in an antegrade manner. Anastomosis for stump formation is started; however, if the false lumen is patent in a patient, initiation of lower body perfusion becomes challenging. In such cases, after stump formation is started to close the false lumen, reperfusion is re-started, if possible, to reduce the duration of lower body ischemia as much as possible. If conventional rates of spinal cord infarction are acceptable, conventional hypothermia alone may suffice and high flow rate perfusion may not be required. However, even for open-heart surgery, by reducing the duration of spinal cord ischemia as much as possible, we were able to improve the rates of incidence of spinal cord infarction close to those observed when TEVAR is performed. Because the results showed that no patients developed spinal cord infarction and all were successfully treated, our method is considered appropriate. Although we typically perform TAR using elephant trunks and two-stage TEVAR at our institution, we encountered a case in which it was difficult to gain access from the thigh owing to rupture or bending of the elephant trunk prior to transitioning for TEVAR by dividing the treatment in two.[19,20] Although one-stage TAR-FET was performed thereafter, there were other 4 patients for whom two-stage TEVAR was performed after the FET expanded over the entire length of the descending thorax. All patients had good access to the FET and were treated without complications.

Remodeling

Sun et al.[21] performed TAR combined with FET in patients with RTAD that progressed to acute disease within 2 weeks of onset and reported false lumen thrombosis of the aorta to the level of the diaphragm owing to false lumen thrombosis (65%) up to the lower end of the FET in 94% of patients. In Europe, using E-vita, Pacini et al.[22] reported false lumen thrombosis and remodeling at a favorable FET site and in the thoracic region in patients with chronic type B dissection. Even after using FROZENIX®, high thrombosis (87% immediately after surgery and 93% 1 year after surgery) was observed at the level of the end of the stent in the FET indwelling section, and significant remodeling was achieved with a mean reduction of 65% in the false lumen at the level of the descending thoracic aorta peripheral to the FET indwelling portion. Based on these reports, if TAR-FET is performed for acute exacerbation of uncomplicated acute type B dissection, good aortic remodeling is promoted although the results do not differ significantly from those observed for TEVAR. The consequences of late aortic events in isolated disease—especially the onset of new peripheral tears—and of residual reentry into the abdominal area require further investigation.

Conclusion

Selecting a treatment (TAR-FET or TEVAR) for patients with acute exacerbation of uncomplicated type B aortic dissection based on age, entry site, and aortic diameter resulted in good early and mid-term results. In particular, for performing TAR-FET at the subacute stage, aortic remodeling with entry closure is promoted and if the procedure is performed correctly, an aorta with a wide arch can be reconstructed without complications such as SCI and SINE.

Disclosure Statement

None of the authors have conflicts of interest to report.

Additional Remarks

Conference name: The 58th Annual Meeting of Japanese College of Angiology
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Additional Note

The original article was published in The Journal of Japanese College of Angiology Vol. 58 (2018) No. 9; however, errors in reference numbers were detected after the publication. The erratum was published in Vol. 59 (2019) No. 9 of the same journal. This translation reflects the corrections.

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