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ORIGINAL ARTICLE

Outcomes of total arch repair using frozen elephant trunk for type I aortic dissection: a retrospective study

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Abstract:
Objectives: The study aimed to evaluate the outcomes of total arch repair in patients with type I aortic dissection.
Methods: A total of 117 patients who underwent total arch repair over a period of 27 years were enrolled and divided into two groups: 75 patients who underwent total arch replacement (TAR) and 42 who underwent total arch repair using the frozen elephant trunk (FET) technique. Univariate and multivariate analyses of outcomes were performed between the two groups.
Results: There was no significant difference in permanent cerebral dysfunction (5.3% vs. 9.5%) and temporary cerebral dysfunction (4.0% vs. 2.4%) between the TAR group and FET group. The 30-day and in-hospital mortality of TAR group vs. FET group were 6.7% vs. 0% (P=0.158) and 10.7% vs. 0% (P=0.049), respectively. The overall survival was significantly higher in the FET group (log rank P=0.034). The long-term survival and aortic event free survival rates were not significantly different between the two groups. The independent risk factors for hospital mortality were age (P=0.046), preoperative hemodialysis (P=0.003), malperfusion of the carotid artery (P=0.032), and mediastinitis (P=0.017).
Conclusions: Total arch repair in patients with type I aortic dissection using FET was beneficial by reducing the in-hospital mortality and improving long-term survival rate.

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Key words: total arch repair; Type I aortic dissection; frozen elephant trunk.

Introduction

Total aortic replacement (TAR) is a surgical treatment with curative intent for aortic arch aneurysm and has been regard as the gold standard treatment for patients with this condition[1-4]. On the contrary, TAR is one of the highly invasive cardiovascular surgeries; therefore, the perioperative risk of morbidity and mortality are high particularly in patients with aortic dissection. Perioperative stroke is one of the major complications of TAR, and once it occurs, it will affect patients' long-term quality of life adversely leading to late mortality.

Recently, technical advances in aortic surgery using stent graft have been made, and various industrial devices have been used. Then, thoracic endovascular aortic repair (TEVAR) has become a less invasive surgical strategy for high risk patients with distal aortic arch or descending thoracic aortic aneurysm[5]. Furthermore, TEVAR has been selected in patients with complicated acute type-B aortic dissection to close the primary intimal tear, preventing progressive enlargement or rupture of the false lumen[6]. In 2002, Yamaki et al. reported a technique involving the placement of a covered stent graft as an elephant trunk concomitant with aortic arch replacement in patients who underwent Stanford type-A aortic dissection[7]. Previously, the covered stent graft procedure had to be performed by hand; recently, the open stent graft proce-

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dure, also known as the frozen elephant trunk (FET) technique, has been commercially available.

We reported that the early and long-term outcomes of total arch replacement for patients with both true aortic arch aneurysm and aortic dissection, and that the in-hospital mortality or postoperative neurologic dysfunction rate was satisfactory[8]. Furthermore, we have recently used the FET technique in patients with DeBakey type I aortic dissection to further improve the operative outcome.

This study aimed to evaluate the outcomes of total arch repair for patients with type I aortic dissection and to assess if these patients can benefit from FET technique concomitant with total arch repair.

Patients and Methods

One hundred and seventeen patients who underwent total arch repair over a period of 27 years (from September 1989 to December 2016) for aortic dissection were enrolled in this study. Those procedures were performed in two hospitals: 20 patients underwent total arch replacement in Tsukuba Medical Hospital (Tsukuba, Ibaraki, Japan), which was performed by a single cardiovascular surgeon before December 2001, and 97 patients underwent total arch replacement in Hirosaki University Hospital, which was performed by board-certified attending surgeons since 2002. TAR was performed in selected patients with Stanford type-A aortic dissection with an entry on the transverse arch and DeBakey type I aortic dissection. We divided all 117 patients into two groups: 75 who underwent total arch replacement (TAR) and 42 who underwent total arch repair using the FET technique. Patients who underwent aortic arch repair with hemi-arch replacement, partial aortic arch replacement, and aortic root surgery were excluded. Those who underwent TEVAR with translocation of the arch vessels without using cardiopulmonary bypass (CPB) were also excluded. This study was approved by the Ethics Committee of Hirosaki University Graduate School of Medicine, and the requirement for an informed consent was waived.

To evaluate the presence of systemic atherosclerotic disease, a contrast-enhanced computed tomography of the chest and abdomen was performed prior to surgery. We focused on the possible presence of an abdominal aneurysm, iliofemoral occlusive disease, or protruding atheroma in the aorta.

Surgical technique

Surgery was performed through a median sternotomy as we had previously reported in all cases[8]. The arterial cannulation site was determined based on the area of aortic dissection in preoperative CT and the presence of malperfusion. Perfusion during CPB either through the femoral artery or axillary artery or through both arteries was performed in most of the patients. Aortic cannulation of the ascending aorta or left ventricular apex was performed as an alternatives in selected patients. In cases of a malperfusion of the unilateral or bilateral common carotid artery (CCA), isolated selective cerebral perfusion (SCP) was established using a SCP cannula just after starting CPB by exposing the common carotid artery through a lateral neck skin incision.

Under moderately hypothermic circulatory arrest (HCA) at a bladder temperature of 25℃ to 28℃, the aorta was incised and antegrade SCP was initiated. SCP cannulae were inserted through the orifices of arch vessels. The total SCP flow ranged from 10-15 ml/Kg/min adjusted to maintain a perfusion pressure of 30- 50 mmHg. Antegrade cold crystalloid cardioplegic solution was administered after the establishment of cerebral perfusion.

Since 2010, we have used FET in selected patients who had DeBakey type I aortic dissection with patent false lumen. The diameter size of the FET was determined based on the diameter of the true lumen of the proximal descending thoracic aorta measure by preoperative CT image. Before November 2014, we used hand-made stent graft made of UBE woven graft and Z-stent or Matsui-Kitamura stent. Since December 2014, we used J Graft open stent graft^{TM} (Japan Lifeline Co., Ltd, Japan) as a commercially available open stent graft.

The end of the FET was placed at the straight portion of the descending thoracic aorta at the level of the aortic root. After open distal anastomosis of a trifurcated graft, the proximal anastomosis was performed and coronary perfusion was restarted. Finally, the arch vessels were reconstructed individually using a trifurcated graft.

Evaluation of the aortic remodeling after FET implantation

The proximal anastomotic level of the FET was indicated at the level of the open distal anastomotic site, which is described as follows: zone 0, ascending aorta; zone 1, between the brachiocephalic artery and left CCA; zone 2, between the left CCA and left subclavian artery; and zone 3, distal aortic arch. The maximum diameter of the thoracic aorta was measured using enhanced CT performed in the last follow up. The distal end of the FET was determined by measuring the thoracic vertebrae level on the sagittal view of the CT scan.

Statistical analysis and long-term follow-up

We investigated the long-term event by reviewing patients' -medical records or by interviewing the patients over the phone. The mean follow-up period was 50.3 ± 43.3 months. A univariate analysis of the two groups was performed using unpaired t-test or chi square test. We defined temporary cerebral dysfunction as temporary paresis or paralysis that resolved before hospital discharge, while permanent dysfunction was defined as residual paresis or paralysis at the time of discharge. Hospital mortality included operative death within 30 days after surgery. The independent risk factors for hospital mortality were examined in total cases by a conducting a multivariate logistic regression analysis of risk factors with p values less than 0.30 in the previous univariate analysis. Long-term survival and aortic event free survival rates were estimated using the Kaplan-Meier method. Statistical analysis was performed using IBM SPSS Statics Version 25.0 for Microsoft Windows (IBM Japan, Tokyo, Japan).

Results

The preoperative patients' characteristics are shown in Table 1. Between the two groups, sex and mean age were not significantly different. In the FET group, the incidence of emergency surgery was significantly high (95.2%, P=0.001) due to the occurrence of complications such as shock (11.9%), cardiac tamponade (9.5%), and malperfusion of the coronary artery (7.1%), carotid artery (26.2%) or lower extremities (9.5%).

The postoperative outcomes are shown in Table 2. There was no statistical difference in operation time, CPB time, SCP time, open distal time and cardiac arrest time between the two groups. The incidence rates of concomitant reconstruction of the common carotid artery (11.9%, P=0.022) and extra-anatomic femoral bypass (1.3%, P=0.015) were significantly higher in the FET group. The incidence rates of intraoperative bleeding and re-exploration for bleeding were not different between the two groups. The incidence rates of permanent and temporary cerebral dysfunction in the TAR vs. FET groups were 5.3% vs 9.5% (P=0.455) and 4.0% vs. 2.4% (P=1.000), respectively. Paraplegia

Table 1. Preoperative Patients' Characteristics

Groups	TAR	FET	P value
Number of patients	75	42	
Gender, men	41 (54.7%)	24 (57.1%)	0.796
Gender, women	34 (45.3%)	18 (42.9%)	
Age	61.9 ± 12.3	60.1 ± 12.2	0.436
Age older than 70 years old	23 (30.7%)	9 (21.4%)	0.282
Emergency operation	51 (68.0%)	40 (95.2%)	0.001
Shock	20 (26.7%)	5 (11.9%)	0.062
Redo operation	5 (6.7%)	0 (0.0%)	0.158
Cardiac tamponade	17 (22.7%)	4 (9.5%)	0.076
Malperfusion			
Coronary artery	2 (2.7%)	3 (7.1%)	0.251
Carotid artery	15 (20.0%)	11 (26.2%)	0.440
Bowel ischemia	1 (1.3%)	0 (0.0%)	
Lower extremities	0 (0.0%)	4 (9.5%)	0.015
Hypertension	51 (68.0%)	36 (85.7%)	0.035
Diabetes	4 (5.3%)	3 (9.5%)	0.700
Renal dysfunction, serum creatinine>1.4mg/dl	11 (14.7%)	6 (14.3%)	0.955
Hemodialysis required	2 (2.7%)	0 (0.0%)	0.536
Abdominal aortic aneurysm	9 (12.0%)	1 (2.4%)	0.093
Marfan syndrome	3 (4.0%)	0 (0.0%)	0.552

Values are expressed as mean ± standard deviation

was reported in one patient from the FET group. The 30-day mortality and in-hospital mortality of the TAR group vs. FET group were 6.7% vs. 0% (P=0.158) and 10.7% vs. 0% (P=0.049), respectively. The causes of in-hospital death were as follows: multiple organ failure (2), mediastinitis (2), postoperative bleeding (1), preoperative malperfusion of visceral artery (1), concomitant malperfusion in the coronary and carotid artery (1) and rupture of the abdominal aortic aneurysm (1). The overall mortality in the TAR group was significantly higher (18.7%, P=0.011), while the overall aortic event rate was not significantly different between the two groups (P=0.653). In the TAR group, long-term death was reported in six cases, of whom two died of aortic event, two had malignancy, and one had senile deterioration. On the contrary, none of the patients in the FET group died due to aortic event during follow-up; graft infection was the only cause of death in the FET group.

The demographic characteristics of patients who underwent the FET procedure and aortic remodeling are shown in Table 3. During the mean follow-up of 689 days, the maximum diameter of the aortic arch of the residual portion was significantly reduced (P<0.001), while that of the distal descending thoracic aorta remained un-changed (P=0.986). No stent graft-induced new entry or stent graft migration occurred during this period.

The univariate and multivariate risk factors for in-hospital mortality are shown in Table 4. Age older than 70 years (P=0.046), preoperative hemodialysis (P=0.003), preoperative malperfusion of the carotid artery (P=0.032), and postoperative mediastinitis (P=0.017) were the independent risk factors.

The FET group had higher long-term survival rate than the TAR group (log rank P=0.034) (Fig 1-A). The incidence of aortic event was not significantly different between the two groups (log rank P=0.737) (Fig 1-B).

Table 2. Postoperative Patients' Outcomes

Groups	TAR	FET	P value
Number of patients	75	42	
Operation time, minutes	557 ± 175	538 ± 123	0.528
Cardiopulmonary bypass time, minutes	269 ± 72	257 ± 53	0.336
Selective cerebral perfusion time, minutes	151 ± 44	164 ± 37	0.097
Open distal anastomosis time, minutes	78 ± 24	74 ± 16	0.337
Cardiac arrest time, minutes	136 ± 49	134 ± 32	0.797
Concomitant operation			
coronary artery bypass grafting	2 (2.7%)	3 (7.1%)	0.348
aortic valve replacement	2 (2.7%)	0 (0.0%)	0.536
common carotid artery reconstruction in neck	1 (1.3%)	5 (11.9%)	0.022
Extra-anatomical bypass to the femoral artery	0 (0.0%)	4 (1.3%)	0.015
Intraoperative bleeding (ml)	2050 ± 2555	1397 ± 1217	0.201
Minimum rectal temperature, (℃)	24.6 ± 2.3	25.4 ± 2.1	0.078
Intensive Care Unit stay, days	11.7 ± 19.3	6.9 ± 4.2	0.109
Mechanical ventilation more than 48 hours	26 (34.7%)	20 (47.6%)	0.075
Reexploration for bleeding	4 (5.3%)	3 (7.1%)	0.700
Mediastinitis	4 (5.3%)	2 (4.8%)	1.000
Pneumonia	3 (4.0%)	5 (11.9%)	0.133
Hemodialysis required	5 (6.7%)	8 (19.0%)	0.063
Permanent cerebral dysfunction	4 (5.3%)	4 (9.5%)	0.455
Temporary cerebral dysfunction	3 (4.0%)	1 (2.4%)	1.000
Paraplegia	0 (0.0%)	1 (2.4%)	0.359
Operative mortality within 30 days	5 (6.7%)	0 (0.0%)	0.158
Hospital mortality	8 (10.7%)	0 (0.0%)	0.049
Overall mortality during follow-up	14 (18.7%)	1 (2.4%)	0.011
Overall aortic events during follow-up	4 (5.3%)	1 (2.4%)	0.653

Values are expressed as mean ± standard deviation

Discussions

In the surgical treatment of type I aortic dissection, replacement of an aorta with primary intimal tear is a fundamental procedure; hence, hemiarch replacement has been regarded as the standard procedure worldwide. Based on the report of an international registry of acute type-A aortic dissection, which enrolled 1,732 patients, hemiarch replacement has been performed in 51.7% of 811 patients with type I aortic dissection from 2010 to 2016, while total arch replacement was performed less frequently in 22.1%[9]. Meanwhile, branched graft for the reconstruction of the arch vessels was only employed in 10.1% of the patients with type I aortic dissection, while the elephant trunk procedure and FET were employed in only 6.1% and 1.2%, respectively. According to that registry, in-hospital mortality has been decreasing, but still high at 12.2% possibly because antegrade cerebral perfusion with HCA was performed in only 50.8%[9]. A previous study conducted a single-center analysis to compare the outcomes of hemiarch and total arch replacement with unilateral or bilateral antegrade cerebral perfusion with HCA, which reported an in-hospital death associated with TAR of 33% vs. 15% in the hemiarch group; moreover, TAR was found to be the only independent risk factor for operative death.

According to the Japanese survey of surgical results of acute type-A aortic dissection, the in-hospital mortality after aortic arch replacement

Table 3. Demographics of frozen elephant trunk and aortic remodeling

Group	FET
Follow up period (days)	689 ± 517
FET length (cm)	10.4 ± 2.1
FET proximal anastomosis sites (n)	
Zone 0	1
Zone 1	7
Zone 2	20
Zone 3	14
FET distal end level (n)	
Th 4	3
Th 5	15
Th 6	13
Th 7	9
Th 8	2
Home-made stent graft	25
Stent graft diameter (mm)	27.4 ± 2.4
MK stent	3
Z stent	22
J-Open stent graft	17
Stent graft diameter (mm)	26.4 ± 1.7
Stent length 60mm	10
90mm	7
Maximal diameter of aortic arch (mm)	
preoperative	36.3 ± 4.7
postoperative	31.9 ± 4.3
p value of pre vs. postoperative diameter	<0.001
Maximal diameter of descending thoracic aorta (mm)	
preoperative	30.8 ± 2.9
postoperative	30.8 ± 4.7
p value of pre vs. postoperative diameter	0.986
Stent graft induced new entry	0
Stent graft migration	0

FET, Frozen elephant trunk; Th, Thoracic vertebrae, Values are expressed as mean ± standard deviation

has been improving every year, and the in-hospital mortality associated with TAR was 9.1% compared with the 9.2% in-hospital mortality associated with ascending aorta replacement reported in 2013[1]. In our study, the total in-hospital mortality associated with TAR and total aortic repair using FET cases for aortic dissection was 6.8% (8/117 cases), which also improved compared with the values reported in our previous study using the data from 1987 to 2006[8]. In this study, no in-hospital death occurred in the FET group. We presume that the reasons why the in-hospital mortality rate improved were as follows: the use of brain protection method and hemostasis at the open distal anastomotic site when the FET was used. Antegrade SCP with HCA has become a widely used method for cerebral protection, because it allows effective cerebral oxygenation and cerebral artery velocity, resulting in a reduced incidence of cerebral dysfunction compared with deep hypothermia with circulatory arrest or retrograde cerebral perfusion[10-12]. Furthermore, in patients with complicated carotid artery malperfusion,

Table 4. Risk factors for hospital death

Risk factors	Univariate *P* value	Multivariate *P* value
Preoperative factors		
Age older than 70 years old	0.125	0.046
Diabetes mellitus	0.270	
Hemodialysis required	0.084	0.003
Malperfusion of carotid artery	0.072	0.032
Malperfusion of coronary artery	0.199	
Shock	0.290	
Operative factors		
Use of frozen elephant trunk	0.158	
Coronary artery bypass grafting	0.199	
Operative time longer than 8 hours	0.155	
Cardiopulmonary bypass time longer than 6 hours	0.054	
Postoperative factors		
Hemodialysis required	0.094	
Mediastinitis	0.021	0.017

cerebral perfusion was performed by directly exposing the unilateral or bilateral common carotid artery through a lateral neck skin incision. Using SCP cannula, cerebral perfusion was initiated in 11.9% of the patients just after the CPB by exposing the carotid artery, and then systemic cooling was performed. To avoid brain ischemia, we increased the cerebral perfusion flow rate if the regional brain saturation dropped significantly during systemic cooling. Okita et al. had reported the efficacy of direct perfusion of the carotid artery in reducing cerebral complications in patients with preoperative brain malperfusion[13].

TAR is the surgical treatment with curative intent for type I aortic dissection to prevent distal aortic malperfusion or reoperation of the aortic arch in the long-term. FET implantation have been performed in selected patients with DeBakey type I aortic dissection with patent false lumen since 2009. The purpose of this procedure was to secure hemostasis at the open distal anastomotic site, improve blood flow into the true lumen, and promote thrombosis and reverse remodeling of the false lumen. During long-term follow-up, none of the patients from the FET group underwent reoperation due to enlargement of residual distal aortic arch; moreover, a significant reverse remodeling of the aortic arch was reported in this study. Although the residual distal arch aneurysm or descending thoracic aorta will possibly enlarge during the long-term follow-up, TEVAR can be performed if the FET had already been implanted. Reexploration for bleeding was performed in 5.3% of the patients from the FET group, but the bleeding did not originate from the anastomotic site. The incidence of paraplegia in the FET group was 2.4% (1 case), and this was the complex case of acute Stanford type-A aortic dissection with chronic type-B aortic dissection. The rate of paraplegia was about 4% in TAR using FET as treatment for aortic dissection[14-16].

It remains controversial whether TAR can be regarded as the standard procedure for acute type I aortic dissection. The significant

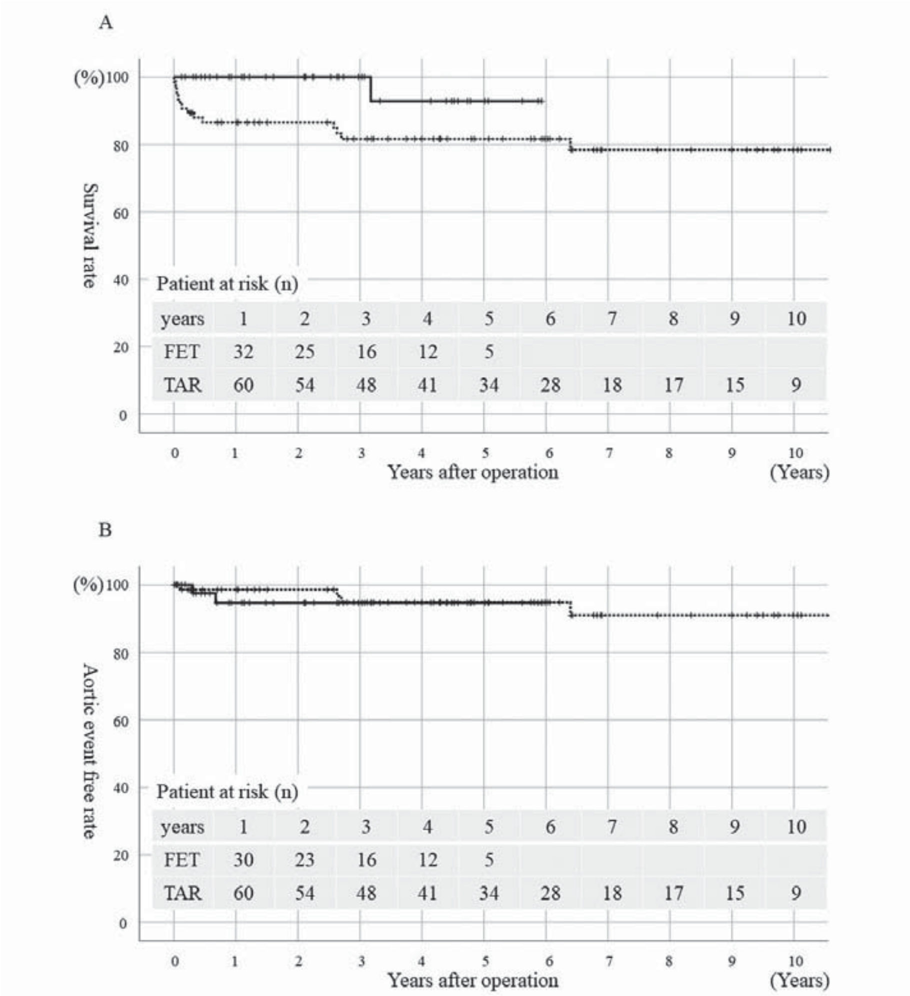

Figure 1 The long-term survival rate (A) and aortic event free survival rate (B) between the frozen elephant trunk (FET) group (solid line) and TAR group (broken line) are shown. The FET group had significantly higher long-term survival rate than the TAR group (log rank P=0.034). Aortic event rate was not significantly different between the two groups (log rank P=0.737).

risk factors for in-hospital death were age, CPB time, brain malperfusion, renal failure, cerebrovascular event, ruptured aneurysm, and emergency surgery[17-20]. In our study, age older than 70 years, preoperative hemodialysis, malperfusion of the carotid artery, and mediastinitis were predictors for hospital mortality. The significant difference in overall survival rate was due to the increased number of early postoperative death within 1 year in the TAR group. Vallabhajosyula et al. reported that the concomitant surgical technique for type I aortic dissection with lower operative mortality (13%) is hemiarch replacement with antegrade TEVAR as it promotes false lumen thrombosis in the area where the stent graft has been implanted[21]. We also agree that TAR for type I aortic dissection is not always beneficial for extremely high-risk patients; actually, six cases of hemiarch replacement and seven cases of partial aortic arch replacement were performed during the study period.

This study has several limitations. Firstly, this is a retrospective study, and the patients assigned to the two treatment groups were not selected through random sampling. Secondly, the preoperative risk factors could not be adjusted; hence, the mortality or morbidity rate might be over- or underestimated.

Conclusions

In conclusion, total arch repair using FET was beneficial for the patients with type I aortic dissection as it reduced the in-hospital mortality and improved the survival rate. Additionally, total arch repair using FET would reduce residual thoracic aortic events in the long-term.

Conflict of Interest Statement

All authors have no conflicts of interest directly relevant to the content of this article.

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