The Comparison between Frozen Elephant Trunk Technique and Conventional Total Arch Replacement, a Single-center Study

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ABSTRACT

Objective: The advantage of the frozen elephant trunk technique (FET) is treating the aortic pathology extending from the aortic arch to the descending aorta in a one-stage operation. This study aimed to determine the early and long-term outcomes of total arch replacement with the frozen elephant trunk technique compared to conventional total arch replacement (cTAR).

Materials and Methods: This study was a single-center, retrospective cohort study. Patients who underwent aortic arch replacement between January 2009 and December 2020 were enrolled and divided into two groups. 32 patients underwent the FET and 47 patients underwent cTAR. Outcomes and survival analysis were compared.

Results: The 5-year survival for FET and cTAR were 87.27% and 82.55% and the aortic-related mortality was not significantly different (HR 0.97, 95%CI 0.22-0.43). Aortic re-intervention was significantly lower in the FET group accounting for 3.57%, while there was 39.1% in the cTAR group. FET significantly reduced aortic re-intervention compared with cTAR (HR 0.09, 95%CI 0.01-0.81). There were no differences in the incidence of stroke between the two groups. However, FET patients had significantly increased risks of paraplegia by 21% when compared to cTAR (Risk difference +0.21, 95%CI 0.02-0.40).

Conclusions: The FET technique had comparable early outcomes in terms of mortality, renal function, postoperative bleeding, and recurrent laryngeal nerve injury. Even though FET had a significant risk of postoperative paraplegia, FET reduced the aortic re-intervention rate without increasing aortic-related death.

Keywords: Aortic arch; Frozen elephant trunk technique; Conventional total arch replacement (Siriraj Med J 2022; 74: 778-786)

INTRODUCTION

One advantage of aortic arch replacement with frozen elephant trunk technique (FET) over conventional total arch replacement (cTAR) is that it allows treatment of the aortic pathology extending from the aortic arch to the descending aorta in a single operation.[1,2] In some cTAR operations, the aortic pathology lies in the descending aorta or there is residual disease present after the initial operation. Thus, requiring a possible second aortic intervention to manage the remaining aortic disease.[3-6]

Another advantage is that the distal anastomosis between the native aortic tissue and prosthetic graft can be achieved more proximally than in cTAR regardless of the location of the distal diseased aorta. In FET, the

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anastomosis can be completed within Ishimaru's aortic zone 0 to zone 3.[7,8] Therefore, this technique doesn't require dissection of the para-aortic tissue toward the distal part of each zone of the aortic arch, resulting in a decrease in the circulatory arrest time and a decrease in the incidence of recurrent laryngeal nerve injury.[9,10]

Despite many advantages of using FET, the incidence of spinal cord ischemia (SCI) or post-operative paraplegia should be considered. The incidence of SCI is significantly more frequent in a patient with longer stent coverage, prolonged circulatory arrest time, and postoperative hemodynamic instability.[9]

Therefore, this study aimed to determine the early and long-term outcomes of aortic arch replacement with FET compared with cTAR. Upon the hypothesis that FET is non-inferior to a conventional technique, the outcomes were also determined in aspects of aortic-related mortality and aortic re-intervention.

MATERIALS AND METHODS

Patients

A retrospective cohort study was conducted at Maharaj Hospital, Faculty of Medicine, Chiang Mai University, Thailand, and was approved by the Research Ethics Committee no.4 of Faculty of Medicine, Chiang Mai University. (SUR-2021-08696, Research ID: 8696) Patients 18 years old or older who underwent aortic arch replacement between January 2009 and December 2020 were enrolled in this study. The operation included both emergency and elective surgery. The etiology of aortic disease included acute and chronic aortic dissection, dissection variants, and aneurysms. There were no differences in operative techniques in all patients even at different emergency levels or with different aortic etiology. The other aortic arch operation (hemiarch replacement, partial arch replacement) was excluded from the study. Also, patients who underwent total arch replacement via thoracotomy were excluded from the study.

The 79 cases of aortic arch replacement included in this study were divided into two groups: patients who underwent aortic arch replacement with the FET technique, FET group (n=32, 43.2%); and patients who underwent total arch replacement using a conventional technique, cTAR group (n=47, 56.8%).

Operative technique and procedure

Conventional total arch replacement

The operation was performed via median sternotomy. Cardiopulmonary bypass was set up with arterial inflow via central, peripheral, or both-site cannulation. Venous drainage was obtained from a two-stage venous cannula that was inserted via the right atrial appendage. Cardiopulmonary bypass was run via a roller pump with the non-pulsatile flow. Myocardial protection was performed by selective, antegrade, and retrograde perfusion with cold Bretschneider's solution (Custodiol® Essential Pharmaceuticals, LLC). Deep hypothermia (20-24°C) concurrent with selective antegrade cerebral perfusion was used as a neuroprotective strategy during circulatory arrest with near-infrared spectroscopy (NIRS) monitoring.

All specific details of the surgical technique are defined as a total arch replacement. The distal anastomosis was performed with complete transection of the proximal descending aorta (Ishimaru's zone 3).[7] Then the distal part of the commercial or self-made quadrifurcated graft was anastomosed to the descending aorta with a 3-0 polypropylene running suture. This was followed by anastomosis of the left subclavian artery, left common carotid artery, and a brachiocephalic branch with 5-0 polypropylene. In addition, a proximal anastomosis was connected to the residual good pathological ascending aorta with 3-0 polypropylene running sutures.

Frozen elephant trunk technique

The initial approach and cardio-pulmonary bypass technique were similar to cTAR. The stent graft devices used for FET included the commercial hybrid stent graft (E-vita open plus (Jotec® Inc., Germany), Thoraflex™ hybrid (Vascutek Terumo, Scotland, UK)) or non-commercial stent graft. In non-commercial devices, the stent graft (Relay® plus NBS (Vascutek Terumo, Scotland, UK), Valiant™ Captivia (Medtronic, Minnesota, USA), Zenith TX2® or Zenith Alpha™ (Cook® medical, Indiana, USA) was deployed either in an antegrade or retrograde fashion. The distal anastomosis was from Ishimaru's aortic arch zone 0 to zone 3 and running continuous sutures with 3-0 polypropylene between the prosthetic graft and native aortic tissue with a stent graft inside. The aortic arch branches were debranched and reimplanted proximally to the distal anastomosis arch zones or sequence anastomosed to quadrifurcated grafts, similar to conventional total arch replacement.

Concomitant procedures

Concomitant procedures included aortic valve replacement in 14 patients, aortic root surgery in 16 patients, and coronary artery bypass grafting in 12 patients.

Spinal drainage and post-operative management

Spinal fluid drainage was selectively used in patients that underwent FET and needed long stent coverage in the descending aorta beyond the T9 vertebra level or when the total stent graft length was longer than 200 mm. Cerebrospinal fluid (CSF) drainage was initiated when the CSF pressure was more than 10 mmHg. The spinal fluid drainage catheter was removed postoperatively on day 3 after confirmation of no existing neurological deficit. Target postoperative mean arterial pressure was 80 to 100 mmHg. If the patient developed paraplegia and spinal cord ischemia was diagnosed, spinal fluid drainage was initiated in patients without prior placement and the target means arterial pressure was raised above 100 mmHg. Intravenous corticosteroids and mannitol were used as adjunct treatments for spinal cord ischemia.

Follow-up

In the follow-up periods, hypertension and dyslipidemia were controlled by medical treatment. The first-line drug was beta-blockers and statins. Patients were also advised to quit smoking. Computed tomography angiography (CTA) of the aorta was the first choice for both techniques.

Definition

Mortality was defined as aortic-related death after the operation. Aortic re-intervention was defined as any re-operation for aortic surgery (including endovascular or/and open aortic surgery) after the first operation. Stroke was defined if there was any brain lesion identified in the brain CT corresponding to the symptoms. Paraplegia was defined as a new impairment in the neurologic function of the lower extremities which occurred after the operation. Acute kidney injury was defined if the postoperative creatinine level increased > 0.5 mg/dL compared to the pre-operative level or a new post-operative renal replacement therapy. The recurrent laryngeal nerve injury was defined as a post-operative vocal cord paralysis resulting in hoarseness, aspiration, and voice change.

Statistical analysis

Statistical analyses were performed using STATA software, version 16.1. The sample size was calculated by test-comparing two independent means based on studies in which the outcomes were similar to this study.[9]

Continuous data were analyzed by T-test analysis for normal distribution and Ranksum test for non-normal distribution. Categorical data were analyzed by Fisher's exact test. A propensity score for adjustment was calculated using the following parameters: age, sex, hypertension, current smoker, aortic etiology, emergency surgery, CSF drainage, and lowest body temp. The differences in propensity score between the two groups were shown in Table 1.

Aortic-related death and freedom from aortic re-intervention were calculated using the Kaplan–Meier method. Differences in these rates between both groups were analyzed using the log-rank test. Independent survival and aortic re-operation predictors were identified using multivariable Cox regression analysis and adjusted with propensity scores. Binary risk regression analysis was used to identify the post-op adverse outcome between the two study groups. Logistic regression analysis was used to identify the independent risk factors.

In all statistical tests, differences between the groups were considered significant at $p<0.05$.

RESULTS

Patient demographics

In Table 1, the comparison revealed the patients in the FET group were older than the cTAR group. However, the overall underlying diseases in both groups were comparable. Most of the aortic pathologies in cTAR were acute and chronic aortic dissection. In the FET group, aortic aneurysms represented most of the aortic pathologies. In concomitant procedures, an aortic root procedure was performed more frequently in the cTAR group.

The operative data showed no differences between the two groups' total operation time, cardiopulmonary bypass time, aortic cross-clamp time, and lower body circulatory arrest time. The mean total length of the stent graft in FET was 179.4±38.9 millimeters.

Aortic-related mortality

The mortality was lower in the FET group accounting for 4 cases (12.5%), while there were 9 cases (19.2%) in the cTAR group. The 5-year survival for FET and cTAR was 87.27% and 82.55%. The Kaplan-Meier curves and hazard ratio (HR) showed no significant difference between the two groups (Fig 1).

Aortic re-intervention

Aortic re-intervention was lower in the FET group accounting for 3.57%, while there was 39.1% in the cTAR group. 5-year re-intervention free for FET and cTAR were 93.75% and 55.61%. The median re-intervention time for cTAR was 5.42 years. The Kaplan-Meier curves and HR showed that FET had significantly reduced aortic re-intervention when compared to cTAR (Fig 2).

In the cTAR group, 9 patients underwent thoracic endovascular aortic repair (TEVAR) for re-intervention due to an aneurysmal change of the distal aorta and the

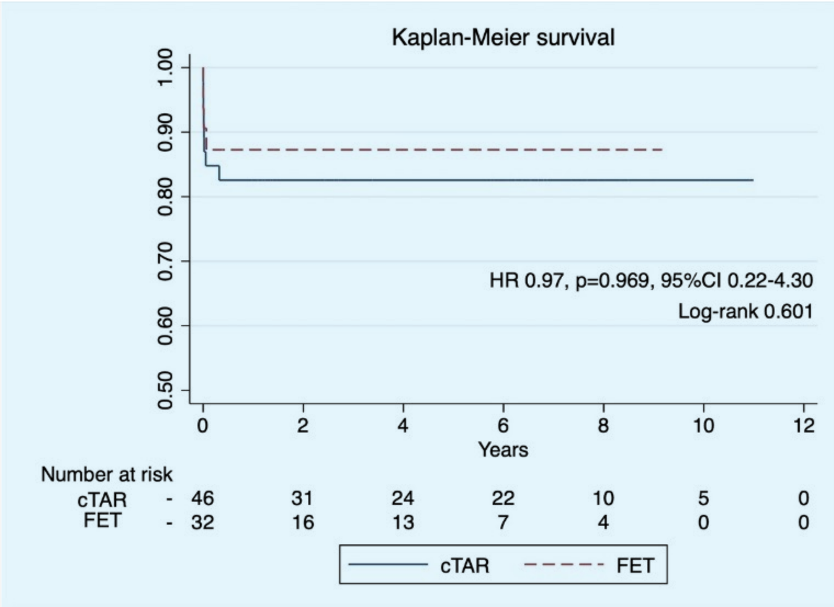
TABLE 1. Baseline characteristics and operative data.

	FET (n = 32)	cTAR (n = 47)	P
Male, n (%)	21 (65.6)	27 (57.5)	0.311
Age (year, mean ± SD)	65.1±9.2	56.0±10.0	<0.001
Current smoker, n (%)	22 (68.8)	22 (46.8)	0.044
Hypertension, n (%)	30 (93.8)	35 (74.5)	0.025
Diabetes Mellitus, n (%)	2 (6.3)	3 (6.4)	0.678
CAD, n (%)	6 (18.8)	6 (12.8)	0.338
CVA, n (%)	2 (6.3)	1 (2.1)	0.358
LVEF<50%, n (%)	3 (9.4)	7 (14.9)	0.359
eGFR (ml/min, mean ± SD)	65.6±15.7	74.5±21.6	0.058
Renal replacement therapy, n (%)	1 (3.2)	0 (0)	0.397
Etiology, n (%)			0.004
Acute dissection	5 (15.6)	19 (40.4)	
Chronic dissection	5 (15.6)	15 (31.9)	
IMH	2 (6.3)	0 (0)	
PAU	1 (3.1)	0 (0)	
Fusiform aneurysm	14 (43.8)	8 (17.0)	
Saccular aneurysm	5 (15.6)	5 (10.6)	
Maximum aortic diameter (mm, mean ± SD)	57.5±10.4	52.8±1.76	0.185
Emergency surgery, n (%)	4 (12.5)	18 (38.3)	0.010
Re-sternotomy, n (%)	4 (12.5)	9 (19.2)	0.323
Concomitant procedure, n (%)			
CABG	7 (21.9)	5 (10.6)	0.148
Valve surgery	4 (12.5)	10 (21.3)	0.244
Aortic root surgery	2 (6.3)	14 (29.8)	0.009
Operation time (min, mean ± SD)	403.4±119.4	379.4±118.4	0.382
CPB time (min, mean ± SD)	262.1±52.4	237.6±83.5	0.192
Aortic cross-clamp time (min, mean ± SD)	154.3±57.1	141.5±58.9	0.398
Lower body circulatory arrest time (min, mean ± SD)	55.1±46.4	44.3±26.2	0.233
Lowest body temperature (°C, mean ± SD)	22.3±1.9	23.9±2.6	0.007
Total length of stent graft (mm, mean ± SD)	179.4±38.9	-	-
CSF drainage, n (%)	11 (36.7)	1 (2.2)	<0.001
Propensity score* (mean ± SD)	0.62±0.27	0.24±0.23	<0.001

Abbreviations: FET, Frozen elephant trunk technique; cTAR, Conventional total arch replacement; CAD, Coronary artery disease; CVA, Cerebrovascular accident; LVEF, left ventricular ejection fraction; eGFR, estimated glomerular filtration rate; IMH, Intra-mural hematoma; PAU, Penetrating aortic ulcer; CABG, Coronary artery bypass grafting; CPB, Cardio-pulmonary bypass; CSF, Cerebrospinal fluid.

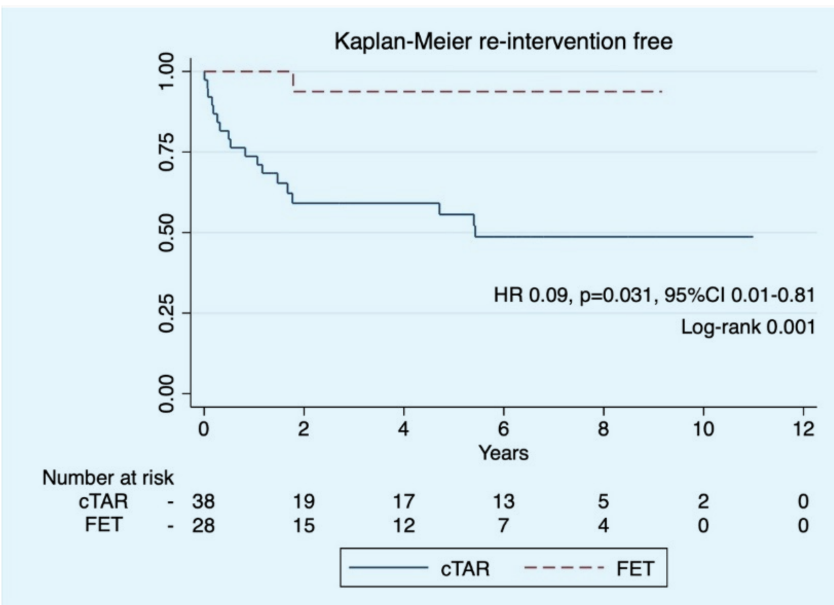
*A propensity score was calculated by age, sex, hypertension, current smoker, aortic etiology, emergency surgery, CSF drainage, and lowest body temp.

Statistically significant at p<0.05



FET, Frozen elephant trunk technique; cTAR, Conventional total arch replacement
P < 0.05: statistically significant different.

Fig 1. Kaplan-Meier for freedom from aortic-related death.



FET, Frozen elephant trunk technique; cTAR, Conventional total arch replacement
P < 0.05: statistically significant different.

Fig 2. Kaplan-Meier for freedom from aortic re-intervention.

remaining patients underwent open surgery. One patient in the FET group underwent re-intervention upon which TEVAR was performed due to type IB endoleak.

Postoperative outcomes

Postoperative outcomes are summarized in Table 2. The incidence of stroke was similar in both groups, but paraplegia was significantly higher in the FET group. FET patients had a significantly increased risk of paraplegia by 21% when compared to cTAR (Risk difference +0.21, p=0.029) (Table 3). Of all 5 paraplegic patients in the FET group, 3 cases were undergoing pre-operative spinal drainage. And 2 cases were undergoing spinal drainage after the patients had post-operative paraplegic symptoms. Only 1 patient was fully recovering from paraplegia within 1 year after intensive re-habitation, and other patients demonstrated varying degrees of neurological improvement. The prognostic risk factors for postoperative paraplegia in the FET technique were explored and listed in Table 4. Furthermore, the incidence rate of recurrent laryngeal nerve (RLN) injury was comparable between the two groups.

DISCUSSION

Open surgical repair has remained the gold standard for treating aortic arch pathology since 1975, following the publication of the case series by Griepp and colleagues.[11,12] The classic elephant trunk (ET) basic principle provides a length of tubing into the descending aorta to facilitate further distal aortic procedures. ET also facilitates and

TABLE 2. Post-operative outcomes.

	FET (n = 32)	cTAR (n = 47)	P
Stroke, n (%)	4 (13.8)	6 (13.0)	0.593
Paraplegia, n (%)	5 (17.2)	0 (0)	0.007
AKI, n (%)	14 (48.3)	16 (34.8)	0.179
Need renal replacement therapy, n (%)	2 (6.9)	4 (8.7)	0.573
Tracheostomy, n (%)	2 (7.1)	2 (4.4)	0.589
Recurrent laryngeal nerve injury, n (%)	0 (0)	3 (6.5)	0.234
Re-operation due to bleeding, n (%)	4 (13.8)	8 (17.0)	0.487

Abbreviations: FET, Frozen elephant trunk technique; cTAR, Conventional total arch replacement; AKI, Acute kidney injury.
Statistically significant at p<0.05

TABLE 3. Binomial (Risk) regression adjusted with propensity score for the adverse outcome of Frozen elephant trunk technique versus total arch replacement.

	Univariable			Multivariable		
	RD	p	95% CI	RD	p	95% CI
Stoke	-0.01	0.926	-0.15, 0.16	0.11	0.350	-0.12, 0.33
Paraplegia	**0.17**	**0.015**	**0.03, 0.31**	**0.21**	**0.029**	**0.02, 0.40**
Re-op bleeding	-0.03	0.702	-0.19, 0.13	0.12	0.432	-0.18, 0.43
New AKI	0.13	0.246	-0.09, 0.36	0.18	0.258	-0.13, 0.50
New RRT	-0.02	0.744	-0.14, 0.11	0.07	0.596	-0.19, 0.34
Prolong ventilator	-0.09	0.371	-0.29, 0.11	-0.18	0.306	-0.52, 0.16
Tracheostomy	0.03	0.625	-0.08, 0.14	0.01	0.971	-0.18, 0.19
RLN injury	-0.06	0.075	-0.13, 0.01	-0.01	0.371	-0.04, 0.02
	RR	**p**	**95% CI**	**RR**	**p**	**95% CI**
Stoke	1.05	0.926	0.32, 3.43	1.97	0.356	0.45, 8.41
Paraplegia	-	-	-	-	-	-
Re-op bleeding	0.81	0.710	0.26, 2.45	1.57	0.512	0.41, 6,09
New AKI	1.38	0.240	0.80, 2.39	1.39	0.286	0.75, 2.57
New RRT	0.79	0.781	0.15, 4.05	1.72	0.600	0.22, 13.29
Prolong ventilator	0.72	0.394	0.33, 1.54	0.70	0.442	0.28, 1.73
Tracheostomy	1.64	0.609	0.24, 11.01	1.37	0.789	0.13, 14.01
RLN injury	-	-	-	-	-	-

Abbreviations: RD; Risk difference, RR; Risk ratio, Re-op, Re-operation; AKI, Acute kidney injury; RRT, Renal replacement therapy; RLN, Recurrent laryngeal nerve.
Statistically significant at p<0.05

TABLE 4. Prognostic risk factor of paraplegia in frozen elephant trunk technique by logistic regression.

	Univariable			Multivariable*		
	OR	p	95%CI	OR	p	95%CI
Age >60 years	4.23	0.207	0.45, 39.81	7.78	0.403	0.06, 957.9
Male	2.83	0.363	0.30, 26.64	0.67	0.836	0.02, 27.91
LVEF <50	1.94	0.575	0.19, 19.55	1.58	0.510	0.06, 38.19
Dissection cause	0.47	0.426	0.07, 3.01	0.97	0.977	0.09, 10.87
Aneurysm cause	2.54	0.325	0.39, 16.20	1.04	0.977	0.09, 11.66
Fusiform type	1.92	0.492	0.29, 12.47	0.77	0.831	0.08, 7.83
Saccular type	1.93	0.575	0.19, 19.56	1.37	0.789	0.13, 14.37
Aortic Diameter >50 mm	0.71	0.726	0.11, 4.61	0.25	0.265	0.02, 2.89
Re-sternotomy	1.50	0.729	0.15, 14.83	1.43	0.762	0.14, 15.02
Emergency operation	1.67	0.591	0.26, 10.73	3.58	0.636	0.02, 70.82
Pre-op spinal drainage	1.47	0.740	0.14, 14.58	0.33	0.513	0.01, 9.06
Aortic clamp >3 hours	0.82	0.870	0.08, 8.06	0.31	0.572	0.01, 17.67
Circulatory arrested >1 hours	0.62	0.684	0.06, 6.02	0.27	0.613	0.01, 41.38
Stent graft length >200 mm	1.06	0.948	0.15, 7.54	0.47	0.699	0.01, 20.9

Abbreviations: OR; Odd ratio, LVEF; left ventricular ejection fraction, pre-op; Pre-operative.
*Multivariable was calculated in an exploratory model based on the risk factor of paraplegia including age, sex, type of emergency, aortic disease etiology, pre-operative spinal drainage, operative time, aortic clamp time, and length of the stent.
Statistically significant at $p < 0.05$

shortens clamping time during the second opening of the thoracoabdominal aortic surgery.[2,3] The FET technique was developed from ET by using a stent graft to replace the tubing graft in descending aorta.[13] In acute type A aortic dissection, FET is recommended for treating the entry tear in the distal arch or the proximal part of the descending aorta.[4] In acute and chronic type B aortic dissection when the endovascular repair is in the presence of an inadequate proximal landing zone, FET is the preferred procedure.[3,4]

In this study, the results showed that operative-related mortality was comparable between the FET and cTAR. Similar to Hirano, et al.[9] studied FET and cTAR and found that there was no difference in operative mortality between the two techniques (FET 5.3%, cTAR 2.6%, p=0.500). A meta-analysis by Preventza et al.[14] focused on the mortality rate in FET procedures in which overall mortality was 8.8%. Kremer, et al.[15] found that FET operative mortality was 13.2%, which was close to this study's aortic-related mortality result.

The FET was developed to decrease the incidence of re-operation, but FET still had occurrences of aortic reintervention. Ius F, et al.[16] found that at 1-, 5- and 10-year freedom from distal aortic re-operation were 81 ± 4, 67 ± 5, and 43 ± 13%, respectively for the FET procedure. Nonetheless, in this study, the aortic re-intervention rate was significantly lower in the FET group compared to the cTAR group. The difference in the pathology of aortic disease is also the factor in the difference in re-intervention. The patients who had aortic dissection had a high incidence of aortic reintervention.[4,13] Ius F, et al.[16] also found that chronic aortic dissection was identified as an independent risk factor for distal aortic operation (odds ratio (OR) = 3.8; 95% CI 1.5-9.3; p = 0.004). In this study, the cTAR might had a higher re-intervention rate because it had a higher incidence of aortic dissection.

Additionally, there was no significant difference in the incidence of stroke, acute kidney injury, and re-operation due to postoperative bleeding. The meta-analysis by Preventza and colleagues[14] reported a 7.6% stroke rate, similar to another meta-analysis, which found no difference between FET and ET in the stroke (6.5% vs. 9.7%).

Even though there was no statistically significant difference, the result showed the incidence of RLN injury was low in the FET group (FET 0%, cTAR 6.5%). The most frequent distal aortic anastomosis site in this study was Ishimaru's zone 3 in cTAR and Ishimaru's zone 1 in FET. The difference in anastomosis site location may be the reason why the incidence of RLN injury was higher in the cTAR group. Similar to the previous study results by Hirano et al showed that recurrent nerve injury was low in the FET group (9.2%) compared with the cTAR group (25.6%).[9]

With an average stent length of 179.4 millimeters for FET in this study, FET patients had a significantly increased risk of paraplegia by 21% when compared to those who underwent cTAR. A meta-analysis study by Preventza, et al[14] showed that the overall rate of spinal cord ischemia was 7.6% with 95% CI 2.9% to 12.3%. They found that when the spinal cord coverage beyond T8 or stent length was more than 150 millimeters, patients had a higher incidence of spinal cord ischemia when compared to those with a stent length of 100 millimeters (11.6% vs 2.5%). Furthermore, Hirano et al[9] also found that chronic dissection or spinal drainage had high OR for paraplegia.

Several limitations in this study warrant mentioning. First, this study was a retrospective cohort study and there was heterogeneity in patient characteristics such as aorta pathology differences. However, statistical methods were used to correct this confounding factor and unequal baselines were adjusted to be properly statistically compared. In addition, the most frequent sites of distal aortic anastomosis in the FET group were in Ishimaru's zone 3. However, over the last two years, as the FET operative strategy evolved, a more simplified distal aortic anastomosis was performed at zone 2 or more proximally. Therefore, the outcomes of the FET group may differ from the initiation of the study to the present time.

CONCLUSION

The FET technique had comparable early outcomes in terms of mortality, renal function, postoperative bleeding, and recurrent laryngeal nerve injury. However, the incidence of postoperative paraplegia increased. The FET technique had favorable outcomes that reduced the aortic re-intervention rate without increasing aortic-related death. Therefore, treatment methods and strategies should be carefully selected according to the patient's risk factors.

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