A novel modification of frozen elephant trunk technique: unique protocol from one institution

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Abstract. – OBJECTIVE: We aim to present a novel surgical technique of Frozen Elephant Trunk (FET) to treat complex thoracic aortic diseases in one stage and report its short-term outcomes.

PATIENTS AND METHODS: Between December 2019 and 30 April 2021, twenty-five patients underwent FET operation at Viet Duc University Hospital. The mean age of the patients was 55.9 (±9.9, range 33-72) years. Eighteen (72%) of the patients were men. Thoracic aortic aneurysm was presented in three (12%) patients. Among seventeen (68%) of the patients undergoing the aortic dissection, eleven (44%) were treated acute type A aortic dissection. Type A intramural hematoma was presented in three (12%) patients. Four (16%) of the patients had undergone previous aortic operations, four (16%) of them had Marphan syndrome and two (11.1%) of them had stage 3 chronic kidney disease. All patients underwent FET procedure by unique protocol. Brain protection was achieved by antegrade bilateral selective cerebral perfusion and moderate hypothermia (28°C) in all cases; besides cerebral tissue oximetry monitoring was used to control brain oxygenation.

RESULTS: There were no perioperative deaths, and all patients are still alive during mild-term follow-up period. Sixteen (88.9%) patients received isolated FET, while a Bentall procedure during FET was performed in two (8%) patients and right coronary artery bypass was in one (4%) case. The duration of cardiopulmonary bypass, cross-clamping, circulatory arrest, and total operation were 176.7 (±48.1, range 102-330), 106 (±39.8, range 63-205), 32.7 (±9.6, range 20-58), and 365.6 (±53.6, range 270-480) min, respectively. There was no bleeding following surgery. Prolonged ventilation required tracheotomy was documented in two (8%) patients, hemodialysis caused acute renal failure was in five (20%) patients, cerebral shock was in one (4%) patient, and type 1A endoleak in 2 (8%) patients.

CONCLUSIONS: Our modification of FET technique was feasible, effective, and safe, with good postoperative outcomes.

Key Words:
Thoracic aortic disease, Frozen elephant trunk, Modified frozen elephant trunk, Aortic dissection, Aortic aneurysm.

Introduction

For the treatment of complex thoracic aortic disease, Borst at al[1] first described elephant trunk technique in 1983. It was considered as a revolution at that time, but this technique still had many disadvantages, such as the difficulty in making deep distal anastomosis, the high risk of nerve injury, the difficulty in stopping bleeding especially in acute aortic dissection, the risk of thrombus formation between descending aorta and graft, and the need of second stage in the future. Through the time, the Borst' technique underwent many improvements and one of the last modifications was hybrid technique[2]. The apply of hybrid technique helps to simplify the operation, thereby, solving the disadvantages of classic technique with better postoperative results[2-4]. However, the usage of special devices, known to be E-vita OPEN PLUS Hybrid Stent Graft, Thoraflex™ Hybrid Prosthesis Thoraflex and branches graft makes the cost of treatment to be so high, with the unavailability of these devices everywhere and any time, especially in the developing countries. For using branches graft, we had to make more anastomosis, which took the time and was not easy in acute aortic

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dissection. Roselli et al[4] introduced the endovascular resolution for the left subclavian artery and the hemi-arch technique to maintain brachiocephalic trunk and carotid artery, but this technique was not universal, cannot be used in cases in which intimal tear is located between brachiocephalic trunk and left carotid artery, and is not easy to make with high cost and risk of endoleak. From these aspects, since September 2019 at Viet Duc University Hospital (Hanoi, Vietnam), we modified the hybrid frozen elephant trunk (FET) technique that was implemented in our clinical practice. In this study, we describe a novel surgical technique of FET to treat complex thoracic aortic diseases in one stage.

Patients and Methods

Patients

Between December 2019 and 30 April 2021, 25 consecutive patients underwent FET operation at Department of Cardiovascular and Thoracic Surgery, Viet Duc University Hospital (Hanoi, Vietnam), one of the oldest and largest surgical public hospitals in Vietnam. All patients were indicated with FET procedure by unique protocol. The data were collected from the management system of hospital's medical record.

Viet Duc Operative Protocol and FET Modification

The indications for the FET technique were followed by the consensus of the European Association for Cardio-Thoracic surgery and the European Society for Vascular Surgery about thoracic aortic pathologies involving the aortic arch[5], and included chronic thoracic aortic dissection, acute or chronic type B dissection when endovascular treatment was contraindicated, chronic aneurysm of the thoracic aorta, and chronic aneurysm of the distal arch. The FET technique was also indicated in acute type A aortic dissection, especially when the tear was localized in the aortic arch, in cases of distal malperfusion, and in young patients.

Operation was started with right subclavian artery cannulation, middle sternotomy, and using one venous canular to right atrium. All the aortic arch branches were dissected. Bypass went on and left carotid artery was ligated at the origin; after that it was cut and started selective perfusion. The left subclavian artery was ligated at origin. We then cut this artery from the origin to make anastomosis between the artery and the 8-mm vascular Dacron graft. Hypothermia (28°C) was applied.

Aorta was clamped and cardioplegia using Custodiol solution was performed. When the rectal temperature reached 28°C, the head was put down, and circulator arrest was started. The brain protection was achieved by bilateral perfusion (right side: through main cannula of right subclavian artery and clamping of brachiocephalic trunk, in the left side: through selective left carotid artery cannula), and controlled by cerebral tissue oximetry monitoring. Stent graft without be stent was anterogradely delivered in the aortic arch and descending aorta just below origin of brachiocephalic trunk by direct vision (Figure 1A). The size of the stent graft was measured before operation based on multislice computed tomography images, and we did not perform the oversized stent graft.

The aortic wall over stent graft was cut as the same as hemi art technique and the wall of the aortic arch just below origin of brachiocephalic trunk was fixed to stent graft, using teflon felt, to prevent endo leak (Figures 1A and B). The anastomosis between Dacron graft with stent graft and aortic arch was performed, using "hemi-arch technique" with continuing suture line and bioglue. In the case with acute aortic dissection, the Teflon felt was routinely used. Then, the perfusion starts again, and the body warms up. If the aortic root was normal, ascending aorta would be replaced using "sandwich technique" with a same Dacron graft (Figure 1B). If the aortic root was needed to treat, Bentall or David' procedure was preferred.

After de-airing, aortic clamp was removed and anastomosis between subclavian 8 mm Dacron graft and ascending aorta prothesis were made in place of aortic root drainage. The perfusion of left carotid artery was ended and was implanted into subclavian artery graft end to side (Figure 1C). Operation was finished routinely.

Statistical Analysis

Data were sorted, cleaned, coded and entered into Epidata 3.1 and analyzed using Stata version 15.0 statistical software. Descriptive statistics, such as frequency, percent, mean, standard deviation and interquartile range were used to summarize preoperative, intraoperative and postoperative parameters.

Results

Preoperative main clinical parameters of the patients are shown in Table I. Among twenty-five patients, the mean age was 55.9 (±9.9, range 33-

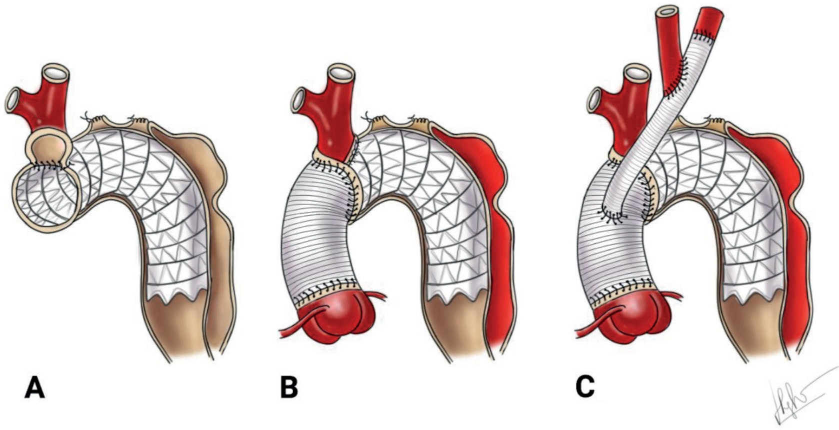

Figure 1. The FET modification in stages at Viet Duc University Hospital. **A**, Delivery of stent graft. **B**, Ascending aorta and hemi-arch replacemen. **C**, Aorta-left carotid and subclavian extra-anatomic bypas

72) years. Eighteen (72%) of the participants were men. Thoracic aortic aneurysm was presented in three (12%) patients. Among seventeen (68%) of the patients undergoing the aortic dissection, eleven (44%) were treated acute type A aortic dissection. Type A intramural hematoma was presented in three (12%) patients. Four (16%) of the patients undergone previous aortic operations, four (16%) of them had Marphan syndrome and two (11.1%) of them had stage 3 chronic kidney disease. Limb malperfusion was present in four (16%) of the patients, and preoperative recurrent laryngeal nerve compression in two (8%) of them.

Intraoperative characteristics of the patients are revealed in Table II. Fourteen (56%) patients underwent emergency operation. Arterial cannulation in most cases (n = 11, 61.1%) was performed through right axillary artery; in the cases with limb malperfusion, we preferred to cannulate right axillary artery and femoral artery in the side of ischemia through 8 mm Dacron prothesis end to side. For venous return, mono-cannula routine-

Table I. Preoperative parameters.

Preoperative parameters	Patients (N = 25)
Age	
Mean ± Standard deviation – yr	55.9±9.9
Range – yr	33-72
Sex – No. (%)	
Male	18 (72.0)
Female	7 (28.0)
Hypertension – No. (%)	14 (56.0)
Type 2 diabetes mellitus – No. (%)	5 (20.0)
Stage 3 chronic kidney disease – No. (%)	2 (8.0)
Marphan' syndrome – No. (%)	4 (16.0)
Previous operation on thoracic aorta – No. (%)	4 (16.0)
Recurrent laryngeal nerve compression – No. (%)	2 (8.0)
Limb malperfusion – No. (%)	4 (16.0)
Indication for FET – No. (%)	
Acute aortic dissection type A	11 (44.0)
Chronic aortic dissection type A	6 (24.0)
Acute intramural hematoma type A	3 (12.0)
Thoracic aortic aneurysm	3 (12.0)
Aortic root aneurysm	2 (8.0)

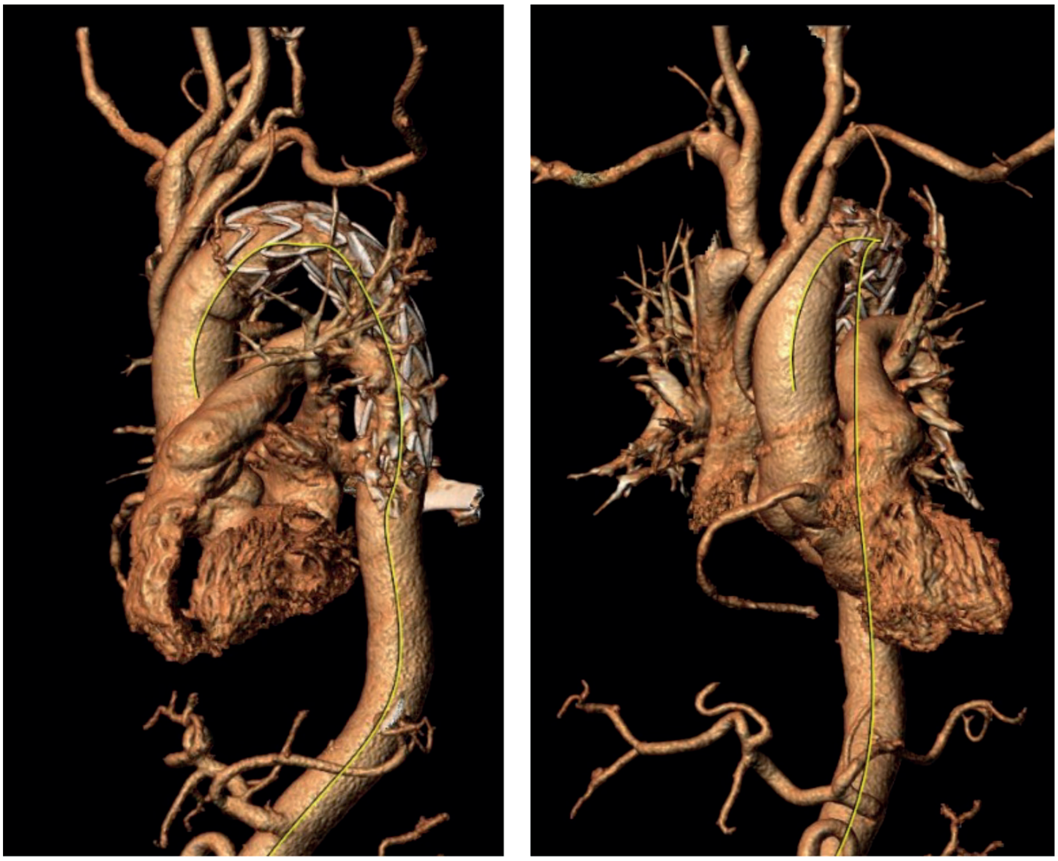

Figure 2. Images of MSCT with 3D reconstruction.

ly was used in all patients, while for brain protection bilateral antegrade perfusion and middle hypothermia (28°C) were maintained. Masimo SET® apparatus was used for the brain regional oximetry monitoring. Extra-anatomic bypass was performed routinely to create new left brachiocephalic trunk by using an 8 mm Dacron prosthesis. Common sizes of stent graft were 30 mm and 32 mm, with 12 (48%) patients and 9 (36%) patients, respectively. The most common length of stent graft was 200 mm (n = 16, 64%). Supracoronary aortic replacement was performed in 23 (92%) patients. The durations of cardiopulmonary bypass (CPB), cross-clamping, circulatory arrest, and total operation were 176.7 (±48.1, range 102-330), 106 (±39.8, range 63-205), 32.7 (±9.6, range 20-58), and 365.6 (±53.6, range 270-480) min, respectively.

Table III presents postoperative parameters and complications. There was no in-hospital mortality. Regarding the neurological complication, only one (4%) patient had cerebral shock. There was no patient with spinal cord ischemia, recurrent never faulty, phrenic never faulty and bleeding. Hemodialysis for acute renal failure was present in 5 (20%) patients, while two (8%) patients had prolonged mechanical ventilation and tracheotomy. One (4%) patient underwent second intervention after 3 months. All patient under follow-up and presented after 1, 3, and 6 months since hospital discharge. There was no dead in follow-up period. Figure 2 revealed the images of MSCT with 3D reconstruction after operation. Results of CT scan in follow-up period are shown in Table IV.

Discussion

This study aims to evaluate the most up-to-date results of the modified FET application at our institution since 2019. This preliminary analysis mainly focused on the feasibility in the modified FET application associated with our newly developed surgical procedure. To date, we have not documented any in-hospital mortality, as well as during follow-up time, while early mortality rates in various centers around the world were approximately 9-16%[2,6-9]. This can be explained by the

Table II. Intraoperative parameters.

Intraoperative parameters	Patients (N = 25)
Emergency operation – No. (%)	14 (56.0)
Location of arterial cannula – No. (%)	Patients (N = 18)
Brachiocephalic trunk	3 (16.7)
Axillary artery	11 (61.1)
Femoral artery	2 (11.1)
Axillary and femoral artery	2 (11.1)
	Patients (N = 25)
Operative time	
Mean ± Standard deviation – min	365.6±53.6
Range – min	480–270
Cardiopulmonary bypass time	
Mean ± Standard deviation – min	176.7±48.1
Range – min	330–102
Cross-clamping time	
Mean ± Standard deviation – min	106.0±39.8
Range – min	63-205
Body's temperature (°C)	28
Circulatory arrest time	
Mean ± Standard deviation – min	32.7±9.6
Range – min	58–18
Size of vascular prothesis – No. (%)	
24 mm	2 (8.0)
26 mm	11 (44.0)
28 mm	6 (24.0)
30 mm	6 (24.0)
Size of stent graft – No. (%)	
26 mm	1 (4.0)
28 mm	3 (12.0)
30 mm	12 (48.0)
32 mm	9 (36.0)
Length of stent graft – No. (%)	
200 mm	16 (64.0)
150 mm	7 (28.0)
170 mm	1 (4.0)
185 mm	1 (4.0)
Operation in aortic rood and ascending aorta – No. (%)	
Bentall procedure	2 (8.0)
Supracoronary aortic replacement	23 (92.0)

fact that we selected patients who were not too severe for performing modified FET technique, and the sample size of patients undergoing this technique was relatively small.

For severe cases, or elderly patients (>75 years old), we indicated a simple method with the short operative time, such as the ascending aorta replacement alone or partial aortic arch replacement. Then, the patient was followed up until the FET was indicated in phase 2. There were four patients in the study who underwent FET in phase 2 and all of them had a favorable outcome.

Nerve complications, especially central nervous system, are major complications of thoracic aortic surgery, which is an important indicator to evaluate the safety of the technique. It is widely reported that these rates of brain injury and paralysis from a spinal cord injury range from 8.8-15.2% and 5.6-8.8% respectively, particularly, higher risk in the patients with acute type A aortic dissection[6,8-10]. In the current study, no patient was with major neurological complications, such as brain death or spinal cord paralysis. One patient had cerebral infarction and nine patients had agitation after surgery, that was treated conservatively. It is possible that, as mentioned above, the patient's indications for modified FET are that the condition is not too severe and the age is not too old. Paralysis from spinal cord ischemia was known as a classic complication of FET[2,10]. Several authors[8-10] suggested that stent grafting beyond the T8 thoracic vertebrae could increase the risk

Table III. Postoperative parameters and complications.

Preoperative parameters	Patients (N = 25)
In-hospital mortality* – No. (%)	0 (0.0)
Cerebral shock – No. (%)	1 (4.0)
Spinal cord ischemia – No. (%)	0 (0.0)
Recurrent nerve palsy – No. (%)	0 (0.0)
Bleeding required reoperation – No. (%)	0 (0.0)
Red blood cell transfusion above 5 units – No. (%)	0 (0.0)
Malperfusion required intervention or surgery – No. (%)	0 (0.0)
Haemodialysis – No. (%)	5 (20.0)
Tracheostomy – No. (%)	2 (8.0)
Mechanical ventilation time	
Mean ± Standard deviation – day	12.6±13.2
Range – day	1–59
Intensive care unit time	
Mean ± Standard deviation – day	21.5±18.9
Range – day	7–90
Length of hospital stay	
Mean ± Standard deviation – day	58.2±92.7
Range – day	17-90
Second-stage TEVAR – No. (%)	1 (4.0)

*In-hospital mortality or early death was defined as 'death due to any cause within 30 days of surgery or during hospitalization'.

of spinal cord paralysis, yet a multi-center ARCH study did not find this correlation[11]. The most common length of the stent graft in our patients was 200 mm (77.8%). However, because Stent graft was delivered in the aortic art and descending aorta just below origin of brachiocephalic trunk, it is higher compared to other authors', which is located lower to the left subclavian artery. Spinal cord injury was not found in this study, which could be explained by the small number of patients, stable hemodynamics before operation, and short circulatory arrest time. Recurrent laryngeal nerve injury is a common complication with a fairly high rate of 13.2-19.8%[6-9], while the rate of phrenic nerve paralysis was reported to be 4.4%[9]. However, we also did not encounter any patients with these complications following operation because among present technique we did not make the anastomosis at the level of the left subclavian artery.

Postoperative hemostasis is a difficult task for conventional techniques in the aortic arch surgery, especially in acute dissection. Distal anastomosis located in the level of brachiocephalic trunk, using "Hemi-arch" technique. This position is not too deep, so it is easier to perform, easier to stop bleeding, and has less risk of nerve damage. It is noticeable that we have no difficulty in hemosta-

Table IV. CT scan results during follow-up time.

Preoperative parameters	Patients (N = 25)
CT before discharge – No. (%)	23 (92.0)
A follow-up visits at one month after surgery – no. (%)	20 (80.0)
A follow-up visits at three months after surgery	18 (72.0)
Endoleak type IA – No. (%)	2 (8.0%)
False lumen thrombosis	
Proximal 1/3 descending aorta – No. (%)	23 (92.0)
Middle 1/3 descending aorta – No. (%)	17 (68.0)
Distal 1/3 descending aorta – No. (%)	9 (36.0)

sis, no cases are indicated for reoperation due to bleeding, as well as there are no cases requiring a large blood transfusion (>5 units). Meanwhile, we recognize the bleeding rates in other modified FET procedures are quite high, which was documented to be 18.9-25%[6,9].

Acute renal failure requiring dialysis after surgery accounted for 22.2% of all patients and occurred in patients with acute aortic dissection. There were two patients with stage III chronic kidney disease who underwent elective surgery and both of them did not need dialysis after surgery. Our result agrees with the previous reported study by Liakupoulos et al[6] and Kremer et al[9]. There are four patients requiring prolonged mechanical ventilation and tracheostomy. In general, the duration of mechanical ventilation, ICU time and hospital stay corresponds to the severity of the disease, consistent with previous evidence[6,8,9].

Post-operative computed tomography revealed two patients with endoleak type IA from the brachiocephalic artery stem. After that, we modified our technique and started pressing the aortic wall to the stent graft in left half of perimeter of brachiocephalic trunk by suture and felt (Figure 1B), and no further cases. Several authors[12-14] have encountered a similar situation and also have their own improvements to avoid this complication. Our postoperative rate of false lumen thrombosis after FET surgery around the stent-graft was 88.9%. This figure was lower compared to 93-99% in previous reports, with progressively decreasing rates in the downstream aortic segments[12-14]. In our study, there is one case who needs second-step intervention due to the lower aneurysm; however, herein our patients with endoleak have not received further intervention due to the economic difficulties and have been continuing to be monitored.

Several important limitations need to be acknowledged in the present analysis. This study was a small, retrospective study with not long enough follow-up period after discharge. The survey sample was done from only one medical surgical institution in the North of Vietnam. In the future, the authors will have larger data after routine implementation at the current institution with a longer, more accurate follow-up period.

Conclusions

At Viet Duc University Hospital, we propose a modified technique of FET for treating complex thoracic aortic diseases in one stage, which is easy to implement, cost-effective and gives good and safe initial results.

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Author Contributions

Conceptualization, SHDP; Data curation, SHDP, STN, TNV, HQD and UHN; Formal analysis, SHDP, STN and LHV; Writing – original draft, SHDP; Writing – review and editing, SHDP, STN, LHV, TNV, TDN, LVP, HQD and UHN. All authors have read and agreed to the final version of the manuscript.

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Data Availability Statement

All the data that support the findings of this study are available from the corresponding author on reasonable request. Requests for access to these data should be made to Dr. Son Hong Duy Phung (Email: hongsony81@yahoo.com).

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