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RESEARCH

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Long-term outcomes of frozen elephant trunk for aortic dissection: a single-center experience

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Abstract

Background To date a number of papers analysing outcomes of the frozen elephant trunk (FET) in acute aortic dissection has been published. However, there are limited comparative studies on long-term outcomes of FET in acute and chronic aortic dissection. The objective of the study was to analyze the long-term outcomes after FET procedure for aortic dissection (AD).

Methods Between March 2012 and December 2022, a total of 123 FET had been performed for thoracic aortic disease. Patients with aortic dissection ($n=97$) were divided into 2 groups: acute ($n=32$, 33%) and chronic aortic dissection ($n=65$, 67%). Pre-, intra- and postoperative data were retrospectively collected from electronic patient's records, including follow-up data of the analyzed patients.

Results The incidence of stroke was 3.1%. The delirium rate was up to 9.3% in both groups with a prevalence in chronic aortic dissection (CAD) group without significant differences ($P=0.494$). Paraplegia was diagnosed only in CAD patients ($n=2$). Respiratory failure and the rate of renal replacement therapy were similar in the studied groups. Re-sternotomy was required in one (3.1%) patient with acute AD and 5 (7.7%) patients with chronic AD ($P=0.416$). Overall 30-day mortality in the entire cohort, acute and chronic AD was 13 (13.4%), 7 (21.9%) and 6 (9.2%), respectively ($P=0.097$). The overall survival rate at 60 months for the entire cohort, acute and chronic AD was 64.1 ± 5.9%, 62.3 ± 9.1%, 66.5 ± 7%, respectively ($P=0.265$). Freedom from unintended distal aortic re-intervention at 60 months for the entire cohort of patients, acute and chronic AD was 74.2 ± 1.5%, 100%, 65.3 ± 2%, respectively ($P=0.355$).

Conclusions Our experience showed acceptable long-term outcomes after the FET procedure including mortality and re-intervention rate in patients with aortic dissection regardless of acuity of the dissection.

Trial registration The study has been registered in Australian and New Zealand Clinical Trial Registry (ACTRN 12618001329257) on August 7, 2018.

Keywords Aortic dissection, Frozen elephant trunk, Survival, Re-intervention

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Background

Until recently, open surgery has a priority in the treatment of the thoracic aortic pathology. For a long period of time, the 'conventional elephant trunk' has remained the 'gold standard'. Frozen elephant trunk (FET) technique which combines the conventional aortic arch surgery and endovascular repair of the proximal segment of the descending aorta provides one-stage thoracic aortic repair aiming to simplify the open surgery and intending to reduce the re-intervention rate and/or minimize the potential complications during the second-stage intervention [1]. Owing to its advantages, utilization of this technique has gained popularity over the past decades for both aneurysm and aortic dissection (AD) [2]. The main goals of the FET in AD patients are to close intimal tears in the distal arch and/or proximal descending aorta, to direct the blood flow in the true lumen (TL), and to initiate false lumen thrombosis at least along the hybrid graft.

This technique is included in the aortic surgeon armamentarium, which is reflected in current guidelines for the diagnosis and management of aortic disease. Numerous studies analysing outcomes of the FET in acute aortic dissection (AD) allowed considering this procedure in these settings (recommendation IIB, class C) [3].

There are yielded study data related to outcomes in acute AD. At the same time, chronic AD is not a well-studied issue and various authors published different early and especially late outcomes [4–7]. To date, there are limited data on long-term outcomes of the FET including survival and re-intervention rates in acute and chronic aortic dissection. Taking this into account, the objective of the study was to analyze long-term outcomes of the FET in patients with aortic dissection.

Methods

Ethical statement

The study was approved by the local Ethics Committee of Cardiology Research Institute (Protocol no. 167, dated February 14, 2018). Informed written consent was obtained from all patients. Study reporting was conducted in accordance with the Strengthening the Reporting of OBservational studies in Epidemiology statement [8].

Study population

This retrospective single-centre study included the analysis of patient characteristics, procedural and postoperative data from hospital records with prospective patient follow-up.

Between March 2012 and December 2022, a total of 123 FET had been performed for thoracic aortic disease, including 97 patients with AD divided into 2 groups: acute (n=32, 33%) and chronic aortic dissection (n=65, 67%).

We used two types of commercially available hybrid grafts: the E-vita open plus (Jotec GmbH, Hechingen, Germany), and the MedEng hybrid graft (MedEng, Penza, Russia), both with a diameter of 22–28 mm and a length of 150 mm.

The indications for the FET procedure for acute AD were intimal tears in the aortic arch and/or proximal part of the descending aorta with or without propagation of the dissection into the supra-aortic vessels redargless of the ascending and aortic arch diameter.

The indications for the FET procedure for chronic AD were intimal tears in the aortic arch and/or proximal part of the descending aorta with the increase of the arch/descending aorta of >5 cm; and unsuitable anatomy for TEVAR.

End-points

The primary end-point was all-cause mortality and re-intervention rates. The secondary end-points included postoperative complications (stroke and spinal cord ischemia, respiratory failure requiring prolonged lung ventilation, acute kidney injury requiring renal replacement therapy, and re-sternotomy for bleeding).

Definition

Thirty-day mortality (or early mortality) was defined as all-cause death within 30 days of the index intervention. Late mortality was defined as deaths occurring 30 days after the surgery.

Postoperative stroke was defined as a focal or global neurologic deficit lasting for >72 h and confirmed postoperatively by means of computed tomography (CT). Stroke severity was assessed according to the modified 'Rankin scale' [9]. Transient neurological deficit was defined as a postoperative neurological deficit with a negative brain computed tomography scan and complete resolution at discharge. Delirium was diagnosed in case of a new onset of symptoms like illusions, confusion, cerebral excitement in the postoperative period. Spinal cord injury (SCI) was defined as a permanent event in case of irreversible neurological deficit (paraplegia) and reversible neurological symptoms (paraparesis) at discharge, respectively. SCI was graded according to the Tarlov scoring system [9]. Respiratory failure was defined as prolonged lung ventilation>72 h in the postoperative period or the need for a tracheostomy. Temporal (permanent) renal replacement therapy was defined as the need for renal replacement therapy less (more) than 90 days after surgery.

Aortic imaging

Computed tomography was used as the basic imaging modality. Pre-, postoperative and follow-up cross-sectional aortic images were available along the entire aorta.

All measurements were taken using electrocardiography-gated CT. The analysis was performed using the 64-slice scanner Discovery NMCT 570c (GE Healthcare, Milwaukee, WI, USA) with an angiographic spatial resolution ranging from 0.6 to 1.25 mm. The adopted CT protocol included unenhanced, arterial, and delayed data acquisition. The arterial phase was acquired after the intravenous injection of 80–100 mL of non-ionic iodinated contrast at 5 mL/s, followed by a 50 mL bolus of saline solution. Delayed-phase scans were obtained 120–180 s after contrast injection. All measurements were taken in multiplanar reconstruction, always in the plane perpendicular to the manually corrected local aortic center line. Analysis and assessment of the images were based on the consensus between two experienced investigators.

Surgical technique

The FET procedure conduction has been described in detail previously [5]. In brief, during cardiopulmonary bypass (CPB), the body temperature was cooled down to 25–28 °C. When the target temperature was achieved, lower body circulatory arrest with antegrade cerebral perfusion with a flow rate of 8–10 mL/kg/min was initiated. After the aortic arch opening, visual assessment of the aortic lumen was performed followed by the implantation of the hybrid graft into the true lumen of the descending aorta. We did not use a guidewire during graft implantation. The graft was fixed to the aorta in Z2 or Z3 depending on patient's anatomy and the technical complexity of the surgery. When distal anastomosis was completed, lower body perfusion was started. During rewarming period re-implantation of the supra-aortic vessels was performed, preferably using the island technique. Then, the lower body circulatory arrest was stopped and CPB was reinstituted. The proximal aortic reconstruction and, if necessary, concomitant cardiac procedures were performed. Cerebrospinal fluid drainage and pressure monitoring were not performed perioperatively. The sequence of the surgical steps during the operation was the same for all patients.

Follow-up

Follow-up was performed according to the institutional database, supplemented by individual patient records. Clinical and CT follow-ups were performed for all patients upon discharge, at 6 and 12 months after surgery, and annually thereafter. No patients were lost to follow-up. The follow-up time was calculated from the date of the most recent patient visit including CT scan. The median [1st to 3rd quartile] follow-up duration was 25 [2–45] months.

Statistical analysis

Statistical calculations were performed using Medcalc 14.8.1 (Medcalc Software, Belgium). Normality was tested using the Shapiro-Wilk test. Continuous data were described as median with the respective 25th and 75th percentiles. Baseline as well as intraoperative characteristics and postoperative outcomes were compared using the Mann–Whitney U-test for continuous variables and the $\chi 2$ test for categorical variables (the Fisher exact test was used when necessary due to the small cell sizes). Survival curves were estimated using the Kaplan–Meier method comparing differences between groups with the log-rank test. Using univariate logistic regression analysis, significant preoperative and procedural variables for early and late mortality were initially identified ($P<0.05$), and included in the final multivariate logistic regression model to determine the independent risk factors. P-value <0.05 was considered statistically significant.

Results

Preoperative data of both groups are detailed in Table 1. There were no significant differences between acute and chronic patients in most variables. However, there were significantly higher rates of emergent and urgent surgery as well as haemopericardium causing cardiac tamponade in acute patients. At this time, comparison of malperfusion rate between the analyzed groups found it only in acute patients (myocardial ($n=1$) and lower limb ($n=1$) malperfusion) versus none in chronic patients. Nevertheless, the difference between the groups did not reach statistical significance ($P=0.096$). By and large, underlying pathology and comorbidities of the patients were similar in analyzed groups.

Intraoperative data are shown in Table 2. Ischemic times including the duration of the cardiopulmonary bypass, cardiac arrest, antegrade cerebral perfusion as well as the duration of the surgery did not reach significant differences between the groups. However, the lower body circulatory arrest time was significantly longer in chronic patients ($P=0.033$).

Concomitant procedures were performed in 23 (23.7%) patients and included coronary bypass grafting ($n=9$), aortic valve replacement ($n=2$) and Bentall procedure ($n=12$).

The mean distal landing zone was T9 (T8; T10) in the entire cohort without differences in analyzed groups ($P=0.708$).

There were no differences between patients with acute and chronic AD in early postoperative period. Details are summarized in Table 3.

The overall incidence of stroke was 3.1% ($n=3$). Acute patients had ischaemic stroke with a score of 6 (dead) according to the 'Rankin scale'. Two chronic patients had a haemorragic permanent neurological deficit with

Table 1 Demographics and preoperative data

Variable	Acute AD (*n*=32)	Chronic AD (*n*=65)	Total (*n*=97)	*P*-value
Age, years	55.9 ± 1.8	54.9 ± 1.4	55.3 ± 1.1	0.539
Male, n (%)	27 (84.4%)	47 (72.3%)	74 (76.3%)	0.199
Type A, n (%)	21 (65.6%)	31 (47.7%)	52 (53.6%)	0.101
Type B, n (%)	8 (25%)	27 (41.5%)	35 (36.1%)	0.117
Type nonA-nonB, n (%)	3 (9.4%)	7 (10.8%)	10 (10.3%)	0.839
Emergent surgery, n (%)	11 (34.3%)	0	11 (11.3%)	**< 0.001**
Urgent surgery, n (%)	22 (68.7)	0	22 (22.7%)	**< 0.001**
Malperfusion, n (%)	2 (6.3%)	0	2 (2.1%)	0.096
Haemopericardium, n (%)	3 (9.4%)	0	3 (3.1%)	**0.029**
Hypertension, n (%)	25 (78.1%)	59 (90.8%)	84 (86.6)	0.097
Diabetes mellitus, n (%)	1 (3.1%)	1 (1.5%)	2 (2.1%)	0.672
COPD, n (%)	1 (3.1%)	8 (12.3%)	9 (9.3%)	0.164
Creatinine, mg/dl	111 [87.5;114]	96 [84;112]	99 [85; 117]	0.288
Marfan syndrome, n (%)	0	3 (4.6%)	3 (3.1%)	0.285
LVEF, %	65 [61.5;65]	59 [57;62]	63 [60;66]	**0.007**
Redo cardiac surgery, n (%)	1 (3.1%)	7 (10.8%)	8 (8.2%)	0.225
Redo aortic surgery, n (%)	0	3 (4.6%)	3 (3.1%)	0.285

AD: aortic dissection; COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction

Table 2 Intraoperative data

	Acute AD (*n*=32)	Chronic AD (*n*=65)	Total (*n*=97)	*P*-value
CPB, min	225 [187; 272.5]	205 [172; 251]	213 [180; 255]	0.323
Cardioplegic arrest, min	167.5 [139.5; 217.5]	150 117.5;195]	160 [122; 200]	0.079
Lower body circulatory arrest, min	32 [26.5; 44.5]	35 [28; 44]	31 [25; 43]	0.848
uACP time, min	55 [41.5; 65.5]	58 [48; 75]	58 [45; 73]	0.276
Duration of the surgery, min	435 [360; 525]	410 [360; 472]	420 [330; 485]	0.915
Coronary artery bypass grafting, n (%)	2 (6.3%)	7 (10.8%)	9 (9.3%)	0.494
Aortic valve replacement, n (%)	0	2 (3.1%)	2 (2.1%)	0.413
Bentall procedure, n (%)	5 (15.6%)	7 (10.8%)	12 (12.4%)	0.378
Distal landing zone, mean thoracic vertebrae	9 [8; 10]	9 [8; 10]	9 [8; 10]	0.708

AD: aortic dissection; CPB: cardiopulmonary bypass; uACP: unilateral antegrade cerebral perfusion

Table 3 Postoperative data

	Acute AD (*n*=32)	Chronic AD (*n*=65)	Total (*n*=97)	*P*-value
Stroke, n (%)	1 (3.1%)	2 (3.1%)	3 (3.1%)	0.991
TND, n (%)	1 (3.1%)	0	1 (1%)	0.311
Delirium, n (%)	2 (6.3%)	7 (10.8%)	9 (9.3%)	0.494
Paraplegia, n (%)	0	2 (3.1%)	2 (2.1%)	0.413
Paraparesis, n (%)	2 (6.3%)	0	2 (2.1%)	0.096
Respiratory failure, n (%)	13 (40.6%)	17 (26.2%)	30 (30.9%)	0.154
Renal replacement therapy for AKI, n (%)	9 (28.1%)	13 (20%)	22 (22.7%)	0.380
Re-sternotomy, n (%)	1 (3.1%)	5 (7.7%)	6 (6.2%)	0.416
30-day mortality, n (%)	7 (21.9%)	6 (9.2%)	13 (13.4%)	0.097

AD: aortic dissection; AKI: acute kidney injury; TND: transient neurological deficit a score of 3 (moderate disability) and 5 (severe disability). The delirium rate was up to 9.3% with a prevalence in CAD group without a significant difference (P=0.494). In two (6.3%) acute patients there were signs of reversible spinal cord injury (paraparesis). The other two (3.1%) chronic patients had paraplegia. According to the Tarlov scoring system, one patient had a score of 0 (no lower extremity movement), another patient had a score of 1 (lower extremity motion without gravity).

Respiratory failure requiring tracheostomy and the rate of dialysis due to AKI were similar in the studied groups. Re-sternotomy for bleeding was required in one (3.1%) acute and five (7.7%) chronic patients (P=0.416).

Overall 30-day mortality in the entire cohort, acute and chronic AD was 13 (13.4%), 7 (21.9%) and 6 (9.2%), respectively (P=0.097). The causes of death in AAD were multiple organ failure (n=4), postoperative visceral malperfusion (n=1), myocardial infarction (n=1), and uncontrolled bleeding (n=1). In patients with chronic dissection, the causes of death were multiple organ failure (n=6), uncontrolled bleeding (n=1), and abdominal aortic rupture (n=1).

The overall survival rates at 60 months for the entire cohort, acute and chronic AD were 64.1±5.9%, 62.3±9.1%, 66.5±7%, respectively (P=0.265) (Fig. 1).

In acute AD group the cause of late death was heart failure (n=1). In CAD patients the causes of late mortality irrespective to aortic disease was stroke (n=3), cancer (n=2), heart failure (n=2), and unknown (n=1). The aortic-related death occurred in 1 patient at 47 months after surgery due to distal stent-graft-induced new entry (dSINE).

During follow-up there were no indications for proximal aortic re-interventions. Freedom from unintended distal aortic re-intervention at 60 months for the entire cohort of patients, acute and chronic AD was 74.2±1.5%, 100%, 65.3±2%, respectively (P=0.355) (Fig. 2).

Three (9.4%) patients with acute AD received a planned endovascular procedure to enhance the false lumen thrombosis. Also, three (4.6%) patients with chronic AD underwent unintended endovascular downstream aortic re-interventions. In those patients indications for the re-intervention were negative remodelling of the thoracoabdominal aorta (n=2) and dSine (n=1) (Fig. 3).

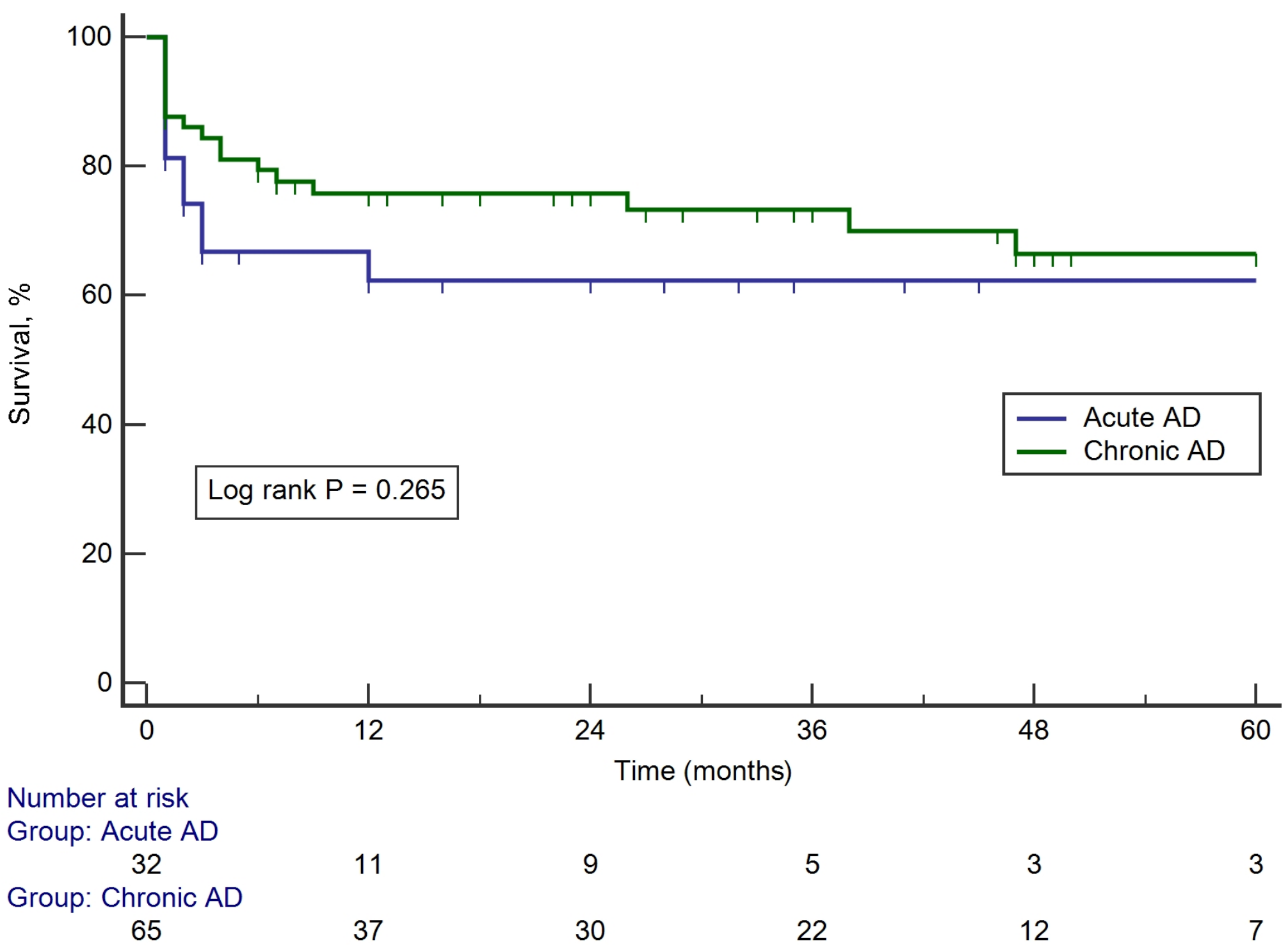

Fig. 1 Kaplan–Meier survival curves for patients with acute and chronic aortic dissection after the frozen elephant trunk procedure

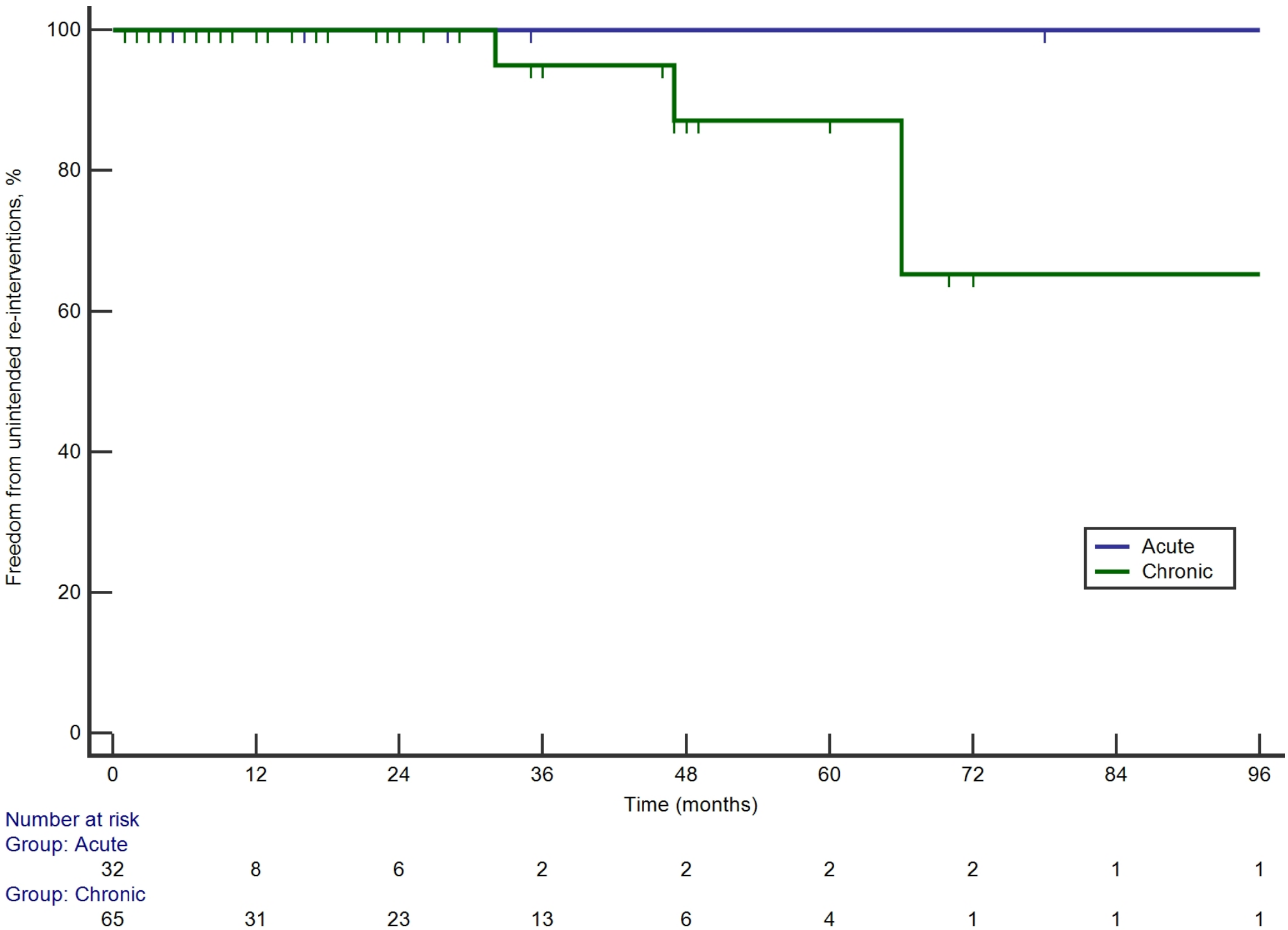

Fig. 2 Kaplan–Meier freedom from re-intervention curves for patients with acute and chronic aortic dissection after the frozen elephant trunk procedure

– type B chronic aortic dissection (preoperative image), second line – 12 months after the FET. Thrombosed false lumen thrombosis along the descending aorta, persistent stable.

dissection of the abdominal aorta, third line – 24 months after the FET, forth line – 47 months after the FET. dSINE at the distal landing zone of a hybrid graft (asterisk), fifth line – early postoperative period after hybrid visceral-renal debranching with endovascular repair.

Among the number of preoperative and procedural variables, univariate analysis revealed that coronary artery disease (OR 3.27, 95% CI 1.27–9.04; $p=0.012$) and aortic dissection extension down to abdominal aorta (OR 9.33, 95% CI 0.98–90.77; $p=0.04$) were independent risk factors of early mortality. Multivariate regression model showed no risk factors.

According univariate analysis for late mortality, the independent predictors were coronary artery disease (OR 59, 95% CI 5.78–14.64; $p=0.002$), prolonged lung ventilation (OR 18.8, 95% CI 2.62–36.01; $p=0.011$), and acute type B aortic dissection (OR 9.5, 95% CI 1.04–77.18; $p=0.032$). These variables were included into final multivariate regression model. This analysis showed that the only independent risk factor for late mortality was coronary artery disease (OR 223.9, 95% CI 10.38–267.1; $p=0.003$).

Discussion

The surgical treatment of aortic dissection is still a surgical challenge. Among the different approaches, FET technique is a viable option for the treatment of aortic dissection mostly due to the likelihood of a single-stage procedure in selected cases [10]. This procedure is associated with acceptable early- and mid-term results [11–13]. According to the literature, in-hospital mortality is up to 15% [14, 15], and the 5-year survival rate exceeds 80% [12]. At the same time, the need for distal aortic re-interventions is up to 30% [16]. Despite a number of papers providing encouraging early - and mid-term results after the FET, there is a lack of comparative studies regarding long-term outcomes in patients with acute and chronic dissection after FET.

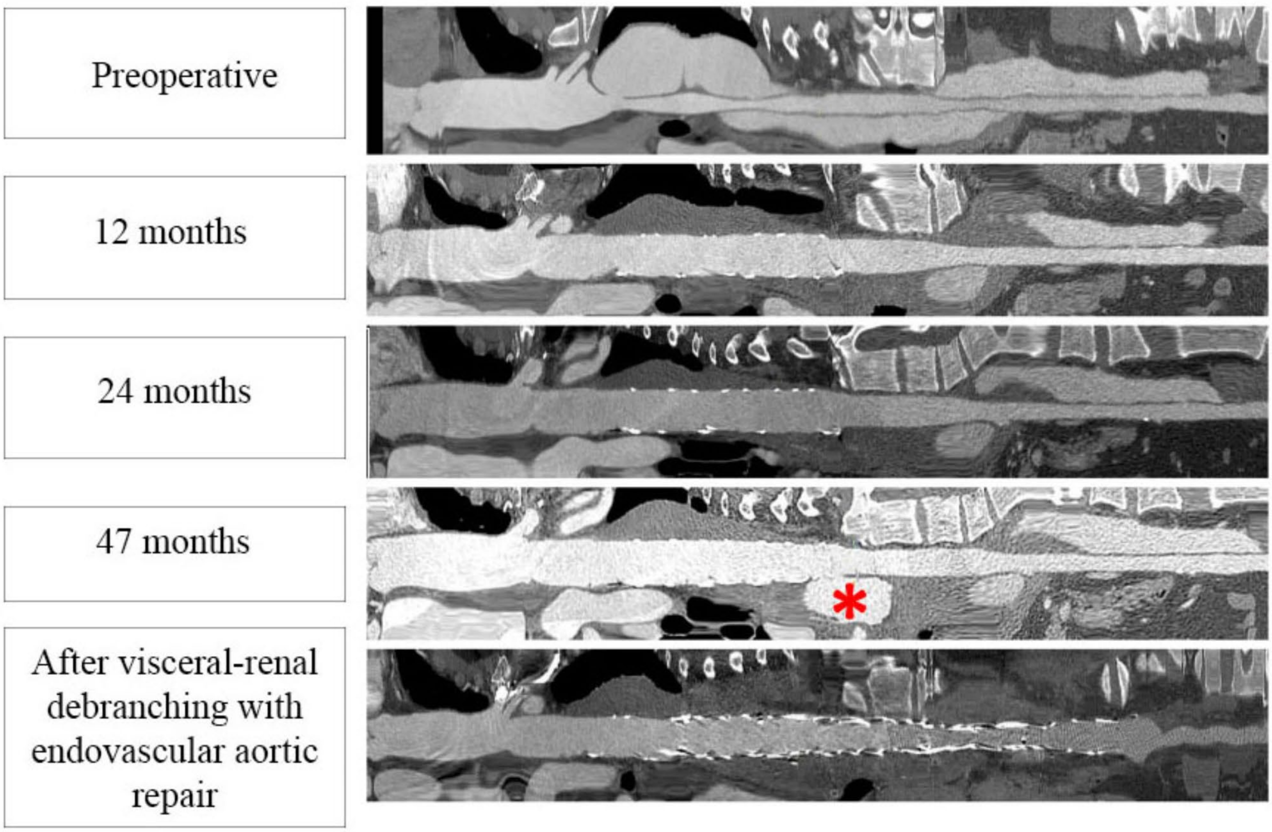

Fig. 3 Three-dimension reconstruction CT scans of the thoracoabdominal aorta. First line

According to our data, the overall 5-year survival rate after the FET for aortic dissection is 64% without a significant difference between acute (62%) and chronic (66%) dissections. Our findings regarding the long-term mortality are in line with the previous reports. In the study published by Jakob et al. [17], the estimated survival rates in acute and chronic AD at 7 years were 55% and 74%, respectively. Later Essen group [18] reported survival rates of 67% and 74% in acute and chronic AD, respectively. And the overall 8-year survival was 60%. Liakopoulos et al. [19] presented similar results at 5 years after the FET procedure. Analyzing aforementioned data, it is worth noting that centre-dependent deviations in surgical management including cerebral perfusion strategy and arterial cannulation site, probably do not impact on the outcomes. Presumably, the overall postoperative outcomes depend on the patient's profile more than on variations in surgical treatment.

Another indicator that reflects long-term safety of FET is the re-intervention rate. Distal aortic re-interventions are common after FET surgery with the incidence up to 33% [2, 20]. According to Shrestha et al. [21], chronic AD is more prone to late reoperations compared to acute AD. Similarly, Leone et al. [22] reported that patients with acute AD received a significantly lower rate of reoperation at a 5-year follow-up. It could be explained by changes in the structural properties of the intimomedial membrane in chronic patients which became thicker and stiffer [23]. However, Wu et al. [24] did not find a difference between acute and chronic settings.

Given the conflicting data, there is a need to clarify possible causes of distal re-intervention in chronic aortic dissection. One of the causes of distal re-intervention may be a decreased rate of the false lumen thrombosis resulting in negative enlargement of the downstream aorta. At the same time, our previous study did not reveal a significant difference for the complete false lumen thrombosis rate at a 2-year follow-up in acute and chronic AD [25]. We speculate that a relatively low distal landing zone (mean T9) plays a role in similar incidence of complete false lumen thrombosis in both settings.

Another possible reason for the re-intervention after the FET is dSINE. This potentially lethal phenomenon occurs more frequently in chronic dissections (6–60%) compared to acute dissections (2.9–15%) [23, 26, 27]. However, our study showed superior results compared to the published data presenting dSINE incidence in 3.1% of CAD patients.

To date, predisposing factors for dSINE are the subject to discussion. In addition to aortic wall fragility, FET stent-graft oversizing and spring-back force due to the device stiffness are known as major risk factors [2, 23, 26]. Compliance mismatch with disturbances in stress-strain distributions between the covered and uncovered descending aorta is a possible mechanism, which is responsible for dSINE [28]. Taking this into consideration, the individual selection of the proper stent-graft size in chronic aortic dissection is crucial. Kreibich et al. [29] use the smallest possible FET hybrid graft in chronic setting while Murana et al. [23] consider an oversizing ratio between 10 and 20% at the distal landing zone effective in prevention of endoleaks and graft migration. Our strategy of the FET hybrid graft selection is based on the true lumen diameter or, rarely, with 0–10% oversizing.

The rates of unplanned distal aortic re-interventions after FET for different reasons including dSINE are up to 11% in acute [10] and 28.5% in chronic AD [26]. Our results are in line with the literature but our incidence of unintended aortic re-operations is lower than the one reported in the previous studies.

We believe that the risk of reoperations should be taken into account in each patient. Any possible measures should be considered to prevent re-interventions after FET for the sake of improved outcomes.

There are several limitations of this study. It is a single-center study with a relatively small sample size. Due to its retrospective nature, potential bias and confounders could not be completely excluded. Along with this, the data were all collected prospectively in the institutional database. Moreover, due to the limited data on long-term outcomes after the FET in patients with aortic dissection, this study adds valuable knowledge on this issue.

Conclusions

Our experience showed acceptable long-term outcomes including mortality and re-intervention rates after the FET procedure in patients with AD, regardless of the dissection acuity. Further evidence-based studies are strongly required to assess the long-term outcomes after the FET.

Abbreviations

AD	Aortic dissection
CAD	Chronic aortic dissection
CPB	Cardiopulmonary bypass
CT	Computed tomography
dSINE	Distal stent–graft–induced new entry
FET	Frozen elephant trunk
SCI	Spinal cord injury

Author contributions

Conceptualization, B.K. and D.P.; methodology, B.K. and D.P.; formal analysis, D.P.; investigation, D.P.; resources, B.K.; data curation, B.K.; writing—original draft preparation, D.P.; writing—review and editing, B.K. and E.K.; visualization, D.P.; supervision, B.K.; project administration, B.K.; All authors have read and agreed to the published version of the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the Strengthening the Reporting of OBservational studies in Epidemiology recommendations, and approved by local Ethics Committee of Cardiology Research Institute, Tomsk National Research Medical Centre (Protocol no. 167, dated February 14, 2018). Informed consent was obtained from all subjects involved in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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