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REVIEW

# Frozen Elephant Trunk: An Alternative Surgical Weapon Against Extensive Thoracic Aorta Disease. A Three-Year Meta-Analysis

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**Background** Conventional open total arch replacement is the treatment of choice for surgical aortic arch pathologies. However, it is a two-stage procedure related to high cumulative and interval mortality rates. Hybrid type III aortic arch reconstruction, the so-called ''frozen elephant trunk'' is a one-stage alternative approach.

**Methods** A meta-analysis and detailed review of the literature published from January 2013 until December 2016, concerning frozen elephant trunk hybrid approach was conducted and data for morbidity and mortality rates were extracted.

**Results** Among 989 patients included, the pooled 30-day or in-hospital mortality rate was 5.04% (95%CI = 1.13–10.74), stroke rate was 2.38% (95%CI = 0.13–6.30), and the irreversible paraplegia due to spinal cord injury rate was 0.63% (95%CI = 0.00–2.73). Finally, the pooled cumulative survival at 1 year was remarkably high (86.7%, 95%CI = 81.08–92.90).

**Conclusions** Frozen elephant trunk is a safe alternative to conventional elephant trunk repair for extensive aortic arch pathologies with acceptable short- and mid-term results, avoiding the interval mortality hazard.

**Keywords** Hybrid procedures • Aortic arch • Frozen elephant trunk

## Introduction

The conventional elephant trunk technique, described by Borst in 1983, remains the gold standard of surgical treatment in extensive thoracic aorta disease involving the ascending aorta, aortic arch and the descending aorta [1–3]. Typically, two separate major surgical stages are required, a full sternotomy and a subsequent left lateral thoracotomy or endovascular repair [1]. However, the cumulative and interval mortality rates are significantly high [4,5]. Dake and colleagues [6] introduced endovascular stent-grafts to treat aortic pathology. Hybrid procedures are the combination of conventional open approaches along with endovascular ones. They are an effective alternative surgical approach in extensive aortic pathology management. The frozen elephant trunk (FET) arch repair is one of such hybrid repairs. Proximal aortic replacement via sternotomy combined with antegrade delivery of a stent graft through the transected arch is

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**Table 1** Frozen elephant trunk patients' characteristics.

| Study | Study Period | Total number of patients | Mean age (years) | Males (%) | Prior medical history | Prior surgical history | Indications for treatment | CPB time (min) | Cross clamp time (min) | Ciculatory arrest time (min) | Mean hospital stay (days) | Follow-up (months) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Roselli (2013) [4][*] | 2009-2012 | 17 | Nr | Nr | Nr | Nr | acute type A dissection (100%) | Nr | nr | nr | 20 ± 12 | Nr |
| Ma, Sun et al. (2013) [4][*] | 2003-2012 | 398 | Nr | Nr | Nr | Nr | acute type A dissection (100%) | Nr | nr | nr | Nr | Nr |
| Ius (2013) [4][*] | 2001-2002 | 131 | Nr | Nr | Nr | nr | acute type A dissection (34%), chronic type A dissection (25%), acute type B dissection (2%), chronic type B dissection (8%), aneurysm (3%) | Nr | nr | nr | 18 ± 17 | 42 |
| Xiao (2013) [4][*] | 2008-2011 | 33 | Nr | Nr | Nr | Nr | acute type A dissection (100%) | Nr | nr | nr | 26 ± 11 | 27 |
| Shen (2012[**]) [4][*] | 2010-2010 | 38 | Nr | Nr | Nr | Nr | acute type A dissection (100%) | Nr | nr | nr | 21 ± 13 | 12 |
| Shi (2012[**]) [4][*] | 2007-2010 | 46 | Nr | Nr | Nr | Nr | acute type A dissection (100%) | nr | nr | nr | 19 ± 6 | 14 |
| Leontyev (2013) [2] | 2006-2013 | 51 | 69 ± 10 | 48.9 | 52.9% hypertension, 17.6% diabetes, 11.8% COPD, 3.9% cerebral vasculopathy | 17.6% previous surgery (11.8% thoracic aorta, 5.9% valve, 2% CABG, 2% root, 2% abdominal aorta) | degenerative aneurysm (62.7%), acute type A aortic dissection (15.7%), acute type B aortic dissection (13.7%), downstream aneurysm following acute Type A aortic dissection (3.9%), chronic type A aortic dissection (2%), chronic type B aortic dissection (2%), | 213 ± 66 | 98 ± 38 | 50 ± 14 | Nr | 40.8 ± 4.8 |

**Table 1.** (continued).

| Study | Study Period | Total number of patients | Mean age (years) | Males (%) | Prior medical history | Prior surgical history | Indications for treatment | CPB time (min) | Cross clamp time (min) | Ciculatory arrest time (min) | Mean hospital stay (days) | Follow-up (months) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eusanio (2013) [18] | 2007-2012 | 122 | 61 ± 10 | 86.9 | 86.9% hypertension, 15.6% COPD, 9% coronary artery disease, 5.7% cerebral vasculopathy, 2.5% renal insufficiency, 2.5% diabetes | 56.6% previous cardiac/aortic surgery | residual type A chronic dissection (45.9%), degenerative aneurysm (27%), chronic type B aortic dissection with associated proximal aneurysm (14.8%), acute type A aortic dissection (7.4%), chronic type A aortic dissection (4.1%), acute type B aortic dissection (0.8%) | 237 ± 64 | 153 ± 48 | 64 ± 18 | 15 | Nr |
| Bavaria (2013) [11] | 2005-2012 | 8 | 71.1 ± 8.3 | 63 | 38% prior stroke, 38% chronic lung disease, 38% prior myocardial infarction, 0% chronic renal insufficiency, 75% smoking | 13% redo sternotomy, 13% coronary artery bypass grafting, 13% prior thoracic aortic endograft, 38% abdominal aortic aneurysm (open or EVAR) | aortic arch aneurysm (63%), chronic aortic dissection (38%) | 259 ± 44 | 121 ± 63 | 19 ± 10 | 22.0 ± 9.6 | 30 ± 21 |
| Martinelli (2014) [19] | nr | 5 | Nr | Nr | Nr | nr | acute aortic dissection (60%), chronic aortic dissection (20%), degenerative aneurysm (20%) | Nr | nr | nr | Nr | Nr |

**Table 1.** **(continued).**

| Study | Study Period | Total number of patients | Mean age (years) | Males (%) | Prior medical history | Prior surgical history | Indications for treatment | CPB time (min) | Cross clamp time (min) | Ciculatory arrest time (min) | Mean hospital stay (days) | Follow-up (months) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Narita (2016) [21] | 2008-2014 | 26 | 72.3 ± 7.9 | 80,1 | 30.8% prior ischaemic heart disease, 19.2% prior cerebrovascular disease, 26.9% renal insufficiency, 15.4% pulmonary disease | 34.6% previous ascending aortic aneurysm repair | Nr | Nr | nr | nr | 14,7* | 10.3 ± 10.1* |
| Shrestha (2016) [22] | 2010-2014 | 100 | 59 ± 14 | 65 | 17% renal insufficiency, 12% Marfan syndrome, 11% malperfusion | 28% previous surgery | acute dissection (37%), chronic dissections (31%), aneurysm (32%) | 243 ± 61 | 101 ± 65 | 51 ± 20 | 17 | 37.2 ± 16.8 |
| El-Sayed (2016) [23] | 2013-2015 | 14 | 66 ± 6 | 64 | 71% hypertension, 36% COPD, 29% aortic valve regurgitation | nr | ascending and distal arch aneurysm (57%), ascending, arch and descending aortic aneurysm (43%) | 214 ± 35 | 125 ± 14 | 54 ± 9 | 9 ± 2 | Nr |

Abbreviations: COPD, chronic obstructive pulmonary disease; CABG, coronary artery bypass grafting; nr/Nr, not reported.

*Data extracted from Tian et al. meta-analysis published in 2013 [4].

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achieved in a single stage. Circulatory arrest and selective antegrade brain perfusion are established [7]. This one-stage alternative approach eliminates the interval mortality rate related to the conventional elephant trunk procedure [4,7]. Moreover, it constitutes a solution in fragile patients who cannot safely suffer a second major operation after surviving the first [7]. A detailed meta-analysis and review of the literature published from January 2013 until December 2016, concerning hybrid type III aortic arch reconstruction procedures, the so-called ''frozen elephant trunk'' follows.

# Materials and Methods

## Data Collection

An extensive electronic literature search was undertaken to identify all articles concerning type III hybrid aortic arch repair that were published from January 2013 up to December 2016. The medical literature database ''PubMed'' was systematically searched. Keywords used for the research were ''aortic arch''; ''frozen elephant trunk'' and ''hybrid''. In addition; a snowball process in the reference lists of the eligible articles was performed after retrieving the relevant articles from databases' search.

## Eligibility and Exclusion Criteria

Eligibility criteria were hybrid aortic arch repair via frozen elephant trunk technique, number of patients included equal to, or over, two and the English language. Articles in languages other than English, studies concerning debranching of the aortic arch without or with ascending aorta replacement (type I and II hybrid aortic arch repair) and case reports were excluded. Studies with overlapping populations were also excluded.

## Data Extracted Categories

Data extracted from eligible studies included first author's name and year of publication, study period, total number of patients, mean age, percentage of males, prior medical history, prior surgical history, indications for treatment, cardiopulmonary bypass (CPB) time (minutes), cross-clamp time (minutes), circulatory arrest time (minutes), mean length of hospital stay (days) and follow-up duration (months).

Percentages of patients with outcomes of interest were also extracted. These included, (1) 30-day/in-hospital mortality, (2) stroke, (3) permanent paraplegia, (4) transient neurologic deficit, (5) renal failure and renal failure requiring dialysis, (6) respiratory insufficiency or prolonged ventilation, (7)

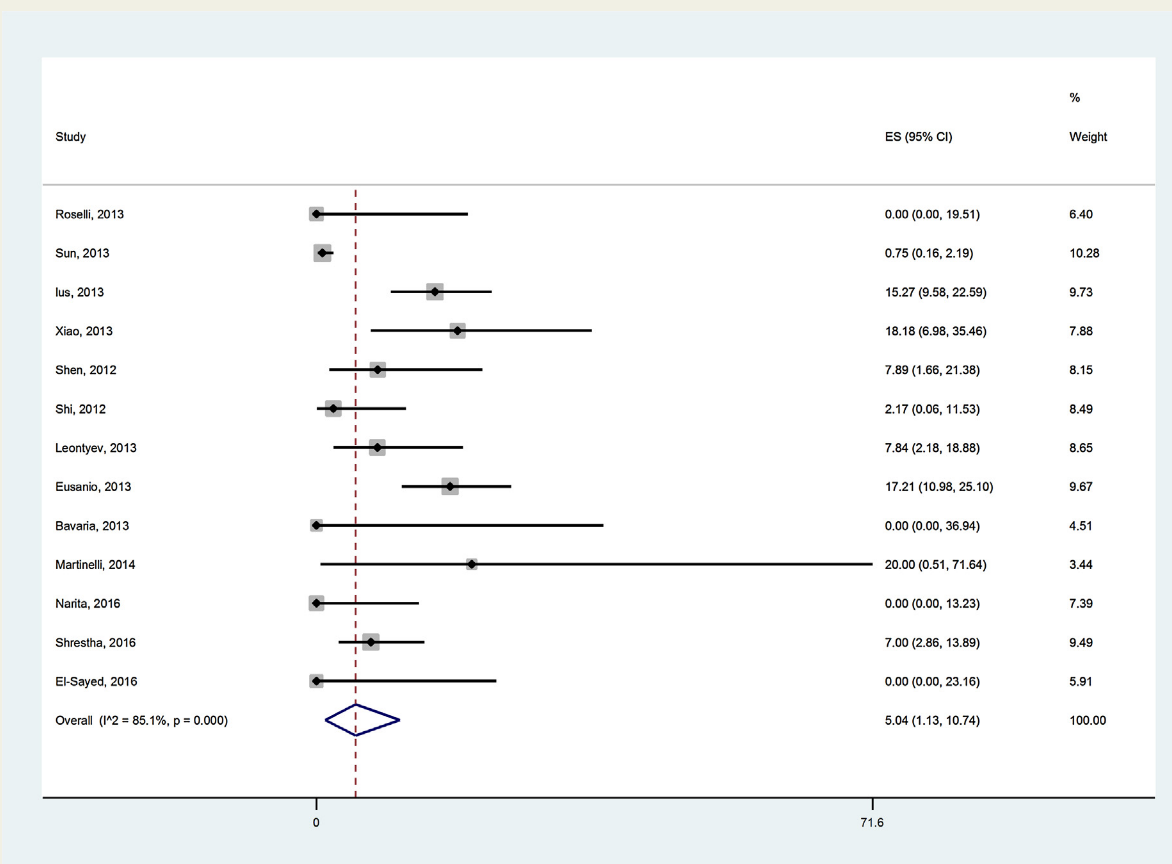


**Figure 1** Forest plot presenting the meta-analysis of 30-day/in-hospital mortality based on event rates for hybrid type III studies included. Event rates in the individual studies are presented as squares with 95% confidence intervals (CIs) presented as extending lines. The pooled event rate with its 95%CI is depicted as a diamond.

reoperation for bleeding, (8) endoleak, (9) late mortality, (10) cumulative survival at 1 year, and (11) reoperation.

## Statistics

As far as the statistical analysis is concerned, STATA statistical software v14 (Stata Corp LP, College Station, TX, USA) was used. Values of the studied outcomes were calculated, expressed as proportions and 95% confidence intervals (95% CIs) and thereafter transformed into quantities according to the Freeman-Tukey variant of the arcsine square root transformed proportion. The pooled effect estimates were calculated as the back-transformation of the weighted mean of the transformed proportions, using DerSimonian-Laird weights of random effects model and expressed as % proportions. A formal statistical test for heterogeneity using the $I^2$ test was performed. Publication bias was assessed using the Egger's test for small-study effects, as well as visual inspection of funnel plots.

However, when the data extracted were scarce due to low number of studies, a meta-analysis would be weak, so the following mathematical formula was used instead to estimate the weighted average of each endpoint adjusted to the number of patients included in each study:

Weighted average = $(n_{1\times1} + n_{2\times2} + \ldots + n_z x_z)/(n_1 + n_2 + \ldots + n_z)$

n = total number of patients included in each study,
x = rate that each endpoint happened.

# Results

The current meta-analysis included 13 studies with a total number of 989 patients. Mean age ranged from 59 to 72.3 years old and the majority of them were males. Significant co-morbidity rates and high percentages of previous cardiac or aortic surgery were noted indicating them as high-risk patients. The most common indication for treatment was acute aortic type A dissection. Mean hospital stay was over 17 days in the vast majority of the studies and the follow-up period ranged from 10.3 to 42 months (thorough data are included in Table 1) Despite the severity of the pathologies, the pooled 30-day or in-hospital mortality rate was 5.04% (95%CI = 1.13–10.74) (Figure 1). This is a quite acceptable outcome. A low enough pooled rate of stroke was reported (2.38% [95%CI = 0.13–6.30]) (Figure 2), as well as a low pooled rate of irreversible paraplegia due to spinal cord injury (0.63% [95%CI = 0.00–2.73]) (Figure 3). Renal failure

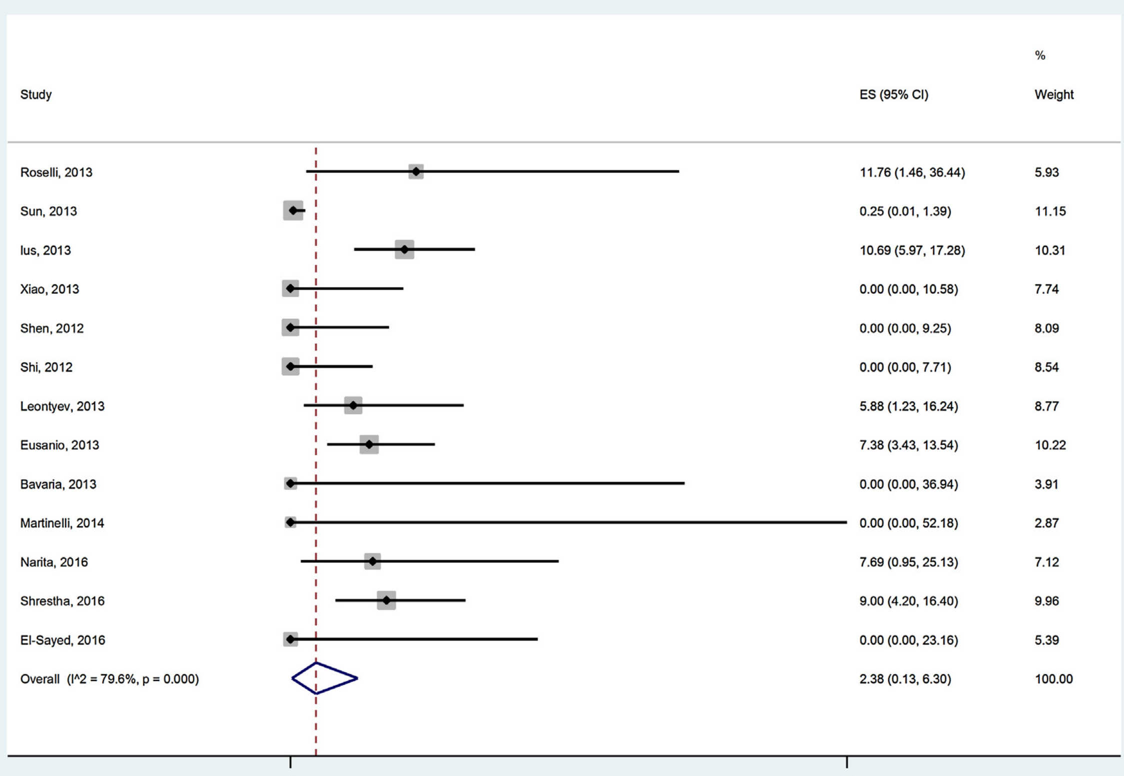


Figure 2 Forest plot presenting the meta-analysis of stroke based on event rates for hybrid type III studies included. Event rates in the individual studies are presented as squares with 95% confidence intervals (CIs) presented as extending lines. The pooled event rate with its 95%CI is depicted as a diamond.

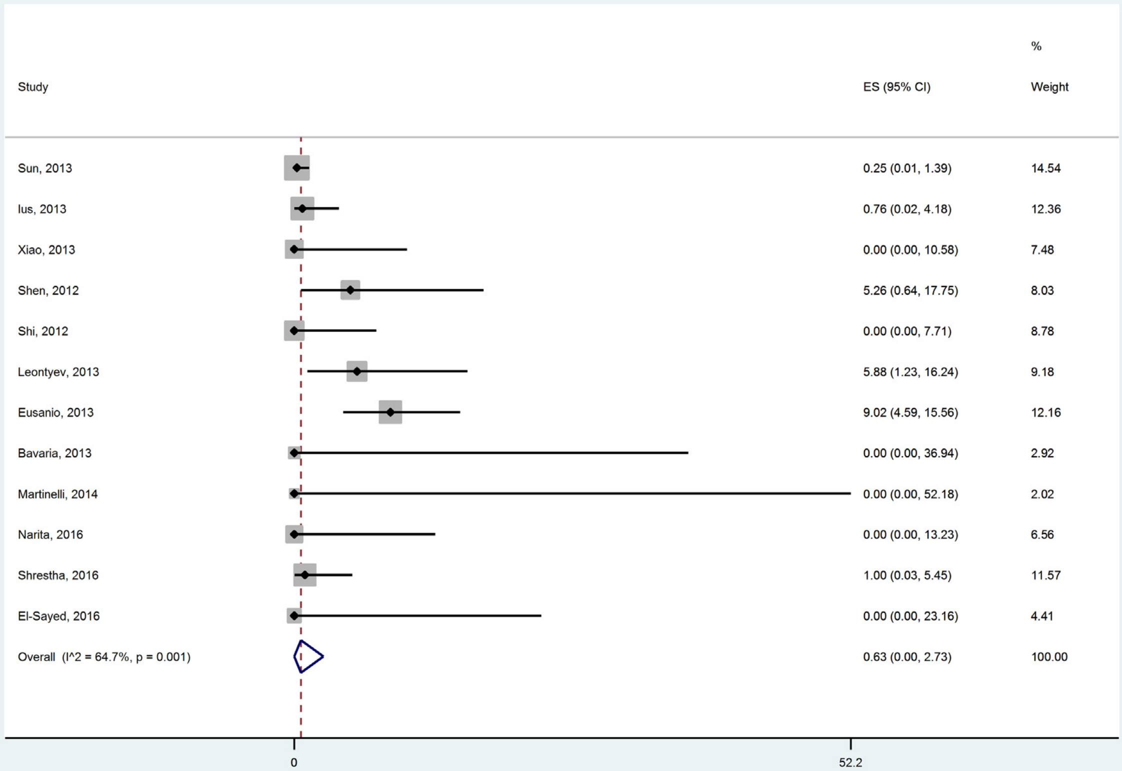


**Figure 3** Forest plot presenting the meta-analysis of irreversible paraplegia based on event rates for hybrid type III studies included. Event rates in the individual studies are presented as squares with 95% confidence intervals (CIs) presented as extending lines. The pooled event rate with its 95%CI is depicted as a diamond.

requiring dialysis occurred in 10.9% of the cases noted. However, a noteworthy weighted reoperation for bleeding rate (7.5%) was reported. Finally, the pooled cumulative survival at 1 year was remarkably high (86.7%, 95%CI = 81.08–92.90) (Figure 4). Table 2 consists of a detailed recording of mortality and morbidity related to frozen elephant trunk procedures.

# Discussion

The beginning date of our study was January 2013. The reason why we chose this date was a meta-analysis already published by Moulakakis et al. [3] including 20 studies, with a total of 1316 patients submitted to type III hybrid aortic arch reconstruction. Consequently, we decided to exclude studies before the aforementioned date which had already been included in Moulakakis's et al.'s study [3]. However, mortality and morbidity results of our meta-analysis proved even better. A 9.5% pooled 30-day or in-hospital mortality rate was reported by Moulakakis et al. Stroke irreversible paraplegia due to spinal cord injury rates were also higher (6.2% and 5% respectively). Renal failure requiring dialysis also occurred more commonly than in our meta-analysis (10.9% vs 19.7%), whereas a similar result to our reoperation for bleeding rate was reported [3].

The FET procedure is a combination of the conventional open aortic arch repair with open endovascular treatment of the descending aorta in a single-stage procedure [8]. Kato [9] first described this modification of the conventional elephant trunk procedure with the deployment of a distal stent graft, whereas Karck [8] gave it the name ''frozen elephant trunk''. Many variations of this approach have been described but its principal concept is delivery of the stent graft into the open aorta under circulatory arrest and suturing it into position [10]. The stent graft is sutured into the arch on its proximal end and fixed endovascularly, or ''frozen,'' in the descending aorta on its distal end [7]. The advantage is that the distal stented portion of the stent graft provides an anastomotic seal at the descending aorta due to expansive radial force [4,10]. However, type III hybrid arch repairs are not classic hybrid arch repair procedures. Circulatory arrest with either selective antegrade perfusion or a combination of antegrade and retrograde cerebral perfusion are required [11,12]. When an extensive aortic pathology affecting the ascending, transverse arch, and descending thoracic aorta or when ''mega-aorta syndrome'' is present, type III hybrid approach (FET) is the optimal hybrid approach [3]. In such cases, cerebrospinal fluid drainage may be used to prevent spinal cord ischaemia in case of extensive aortic repair [13]. Frozen elephant trunk

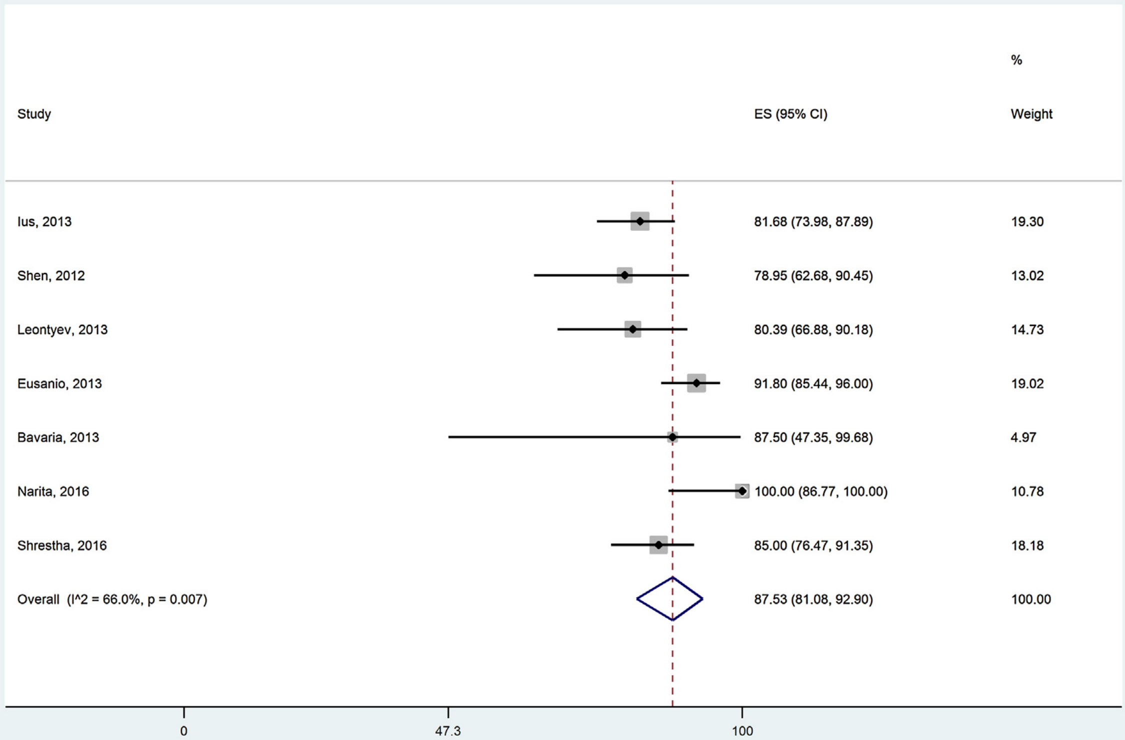


**Figure 4** Forest plot presenting the meta-analysis of cumulative survival at 1-year based on event rates for hybrid type III studies included. Event rates in the individual studies are presented as squares with 95% confidence intervals (CIs) presented as extending lines. The pooled event rate with its 95%CI is depicted as a diamond.

has been used for multifocal degenerative thoracic aneurysms, chronic dissections with aneurysm, and acute extensive (DeBakey I) dissections [7].

Open aortic arch restoration procedure can be performed either by the two-stage elephant trunk approach or by a one-stage open repair via clamshell incision [14]. However, remarkable morbidity and mortality accompany these procedures in high-risk patients, in spite of the advanced cerebral protection perfusion strategies [15,16]. The cumulative mortality of both surgical operations is as high as 30% [5]. Although the classic elephant trunk procedure [1] is the standard of care for extensive disease of the thoracic aorta [4], long periods of deep hypothermic circulatory arrest (DHCA) to reduce cerebral and end-organ dysfunction are required, so it is related to high risk for neurologic complications [13,17]. Long periods of circulatory arrest result in higher risk for stroke and visceral ischaemia, whereas deep hypothermia is related to coagulopathy and subsequent higher risk for bleeding from the distal anastomosis [17]. Even short periods of circulatory arrest have a detrimental effect to higher cognitive function. The longer the DHCA, the higher the incidence of cerebral and other end-organ injury [13]. The interval mortality rate is also an important issue. The longer the duration between the two operations, the higher the mortality rate. Not rarely, these fragile patients fail to come back for the second stage of the conventional procedure [4]. Many important series [12,18] concerning the conventional elephant trunk procedure have shown a mortality rate up to 25% during the interval between the two stages, mostly due to aortic rupture.

By applying the frozen elephant trunk procedure, aortic arch aneurysms extending to the descending aorta can be repaired in a single stage procedure under circulatory arrest [3]. Frozen elephant trunk, performed in one stage, avoids this interval mortality [18]. The key-point of the procedure is direct suturing of the endograft to the aorta and the surgical aortic graft providing with the security of fixation and eliminating the risk of endoleak type I [3,10]. The radial expansion of the stent-graft prevents anastomotic leakages and eliminates the risk of kinking and flapping of the prosthesis. As far as aortic dissection is concerned, intimal tears of the descending aorta are sealed thanks to the compression of the false lumen and expansion of the true lumen, thus preventing further dilation of the proximal descending aorta [4].

However, according to International E-Vita open Registry, FET is related to higher mortality and brain injury rates compared to more conservative management, because of the need for the use of CPB and DHCA [14,18]. Spinal cord injury is a possible complication due to inflammatory response because of the great extent of the operation and due to covering a large aortic segment [4,7]. Consequently, there is an increased risk for paraplegia [18]. According to the International E-vita Open

**Table 2** Results after frozen elephant trunk.

| Study | 30-day, in-hospital mortality (%) | Stroke (%) | Permanent paraplegia (%) | Transient neurologic deficit (%) | Renal failure/ requiring dialysis (%) | Respiratory failure/ prolonged ventilatuion | Reoperation for bleeding (%) | Endoleak (%) | Late mortality (%) | Cumulative survival at 1-year (%) | Reoperation rate (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Roselli (2013) [4]* | 0 | 11.8 | nr (SCI) | Nr | 5.9 | nr | nr | nr | nr | nr | Nr |
| Ma, . . . , Sun (2013) [4]* | 7.8 | 2.5 | 2.5 (SCI) | Nr | 4.3 | nr | 2.5 | nr | nr | nr | Nr |
| Ius (2013) [4]* | 15.3 | 10.7 | 0.8 (SCI) | Nr | 16 | nr | 18.3 | nr | nr | 82 (72% at 5 years) | Nr |
| Xiao (2013) [4]* | 18.2 | 0 | 0 (SCI) | Nr | 3 | nr | nr | nr | nr | nr | Nr |
| Shen (2012**) [4]* | 7.9 | 0 | 5.3 (SCI) | Nr | 0 | nr | 0 | nr | nr | 91 | Nr |
| Shi (2012**) [4]* | 2.2 | 0 | 0 (SCI) | Nr | Nr | nr | 4.3 | nr | Nr | nr | Nr |
| Leontyev (2013) [2] | 7.8 | 11.8 (along with permanent paraplegia) | 11.8 (along with stroke) | 9.8 | 25.5 | 37.3 | 13.7 | nr | Nr | 80.2 ± 5.5 (59.7 ± 10.2% at 5 years) | 17.6 (8/9 TEVAR) |
| Eusanio (2013) [18] | 17.2 | 7.4 | 9 | Nr | 24.6 | 28.7 | 12.3 | nr | 10.7 | 91.7 ± 2.8 (79.1 ± 6.1)% at 3 years) | 23.8 |
| Bavaria (2013) [11] | 0 | 0 | 0 | 25 | 0/0 | nr | 0 | 0 | 13 | 87 | 0 |
| Martinelli (2014) [19] | 20 | 0 | 0 | 0 | 20 | 0 | nr | nr | Nr | nr | Nr |
| Narita (2016) [21] | 0 | 7.7 | 0 | 3.3 | Nr | nr | nr | 26.9 (type II) | 0 | 100 | Nr |
| Shrestha (2016) [22] | 7 | 9 | 1 | 6 | 30/14 | 29 | 10 | nr | 13 | 85 | 22 |
| El-Sayed (2016) [23] | 0 | 0 | 0 | 14 | Nr | nr | 0 | nr | nr | nr | Nr |

Abbreviations: CPB, cardio pulmonary bypass; min, minutes; nr/Nr, not reported; SCI, spinal cord injury; TEVAR, thoracic endovascular aortic repair.

*Data extracted from Tian et al. meta-analysis published in 2013 [4].

**Published -epub- in 2013.

Registry including 274 patients, spinal cord injury happened in 8.0% of them. In spite of partial resolution of paraparesis and paraplegia in 40% of patients, significant complications persisted [4]. On the other hand, permanent or transient spinal cord injury is a rare complication after conventional elephant trunk procedure, ranging from 0.4% to 2.8% [2]. Circulatory arrest, coverage of intercostal arteries, embolisation, and postoperative hypotension are potentially responsible for spinal cord injury after FET procedure [18]. A distal landing zone of T7 or lower, abdominal aortic aneurysm repair history and a core body temperature equal to or over 28 °C during circulatory arrest combined with circulatory arrest time over 45 minutes are strong predictors of spinal cord injury [2,19]. Consequently, deep hypothermia should be established when FET is performed, particularly in cases of prolonged aortic arch surgery [2]. Continuous total brain perfusion with cannulation of the left subclavian artery, lower body perfusion to reduce the duration of circulatory arrest, preventive cerebrospinal fluid drainage, and a mean postoperative arterial pressure over 80 mmHg are additional helpful measures to avoid these complications [7,18,19]. However, paraplegia will still affect some of the patients despite applying these measures [18].

# Conclusions

High-risk patients with complex aortic pathologies can gain profit from hybrid treatment [3]. Frozen elephant trunk is a hybrid aortic arch reconstruction approach with acceptable short- and mid-term results [3,20]. Currently, hybrid procedures are only an alternative to conventional open aortic arch surgery for the treatment of aortic arch pathologies and cannot replace the latter [20]. FET offers the possibility of a single-stage operation for extensive aortic arch pathology repair, avoiding the significant interval mortality rate [4]. A relatively low mortality in patients with extensive thoracic aorta pathology is reported. However, increased rates of postoperative permanent paraplegia due to spinal cord injury are reported, particularly if mild hypothermia ($\geq$28 °C) and prolonged circulatory arrest times ($\geq$45 minutes) are employed [2]. In conclusion, future prospective trials directly comparing open conventional technique with hybrid type III aortic arch reconstruction are required [3].

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