



# Evaluation of the Safety of Total Arch Replacement with Extended Branched Stented Anastomosis Frozen Elephant trunk Repair (EB-SAFER) for Acute Type A Dissection

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### **OBJECTIVE**

■ To reduce the surgical risk of emergency total arch replacement (TAR) for acute type A aortic dissection (AADA), VIABAHN Open Revascularization TEChnique (VORTEC) of the supra-aortic reconstruction during hybrid aortic arch surgery, reported as a Cleveland Clinic

technique, we are performing extended branched stented anastomosis frozen elephant trunk repair (EB-SAFER).

- EB-SAFER; JTCVS Techniques 2023; 17:1-9
- IRB September 24, 2020 (#2020-48)

### **OBJECTIVE**

- EB-SAFER does not require exposure of the cervical artery and has reduced operative time and better surgical outcomes, but long-term patency and arch coarctation are also concerns.
- The purpose of this study was to compare the safety of the branch of EB-SAFER with conventional TAR (CTAR) in AADA where the false lumen is patent.

# **METHODS**

#### Surgical procedure

- From 2016.1 to 2023.8, 102 patients with Type A dissection underwent emergency TAR.
  - retrospective study

#### ■ Conventional TAR group (~2019.12)

- Cervical artery ; graft repair alone
  - Second level sub-bullet

#### **■** EB-SAFER group (2020.1~)

- Cervical artery; Viabahn (Gore Medical, Flagstaff, AZ, USA)
  - sutureless direct branch vessel stent grafting
- Frozen Elephant Trunk ; (Frozenix J Graft(FJG) (Japan Lifeline, Tokyo, Japan)
  - · an oval nitinol stent

# **METHODS**

- After the circulatory arrest, the aortic arch was usually transected circumferentially at Zone1 or 2.
- The FET was deployed to the descending aorta and heated with a cautery to fenestrate it. No need to expose the left subclavian artery.
- The Viabahn was delivered into the Cervical branches through the fenestration.
  - Ankle-Brachial Index (ABI) was measured to evaluate aortic coarctation



**Demographic Characteristics** 

		EB-SAFER	CTAR	p-value
Subjects		63	39	
Age (years)	Mean ± SEM	62.6 ± 12.6	58.3 ± 14.0	0.123
Gender, Male	No. (%)	47 (75)	30 (77)	>0.999
Comorbidities	No. (%)			
Diabetes Mellitus		7 (11)	1 (3)	0.150
Dyslipidemia		22 (35)	8 (21)	0.179
Coronary artery disease		1 (2)	1 (2)	>0.999
Cerebrovascular disease		7 (11)	2 (5)	0.476
COPD		4 (6)	3 (8)	>0.999
Hypertension		49 (78)	31 (80)	>0.999
CKD on HD		0 (0)	0 (0)	NA
Marfan syndrome		0 (0)	2 (5)	0.144
Smoking		34 (54)	18 (46)	0.542

**Demographic Characteristics** 

DeBakey     No. (%)     0.476       I     45 (71)     32 (82)       II     10 (16)     4 (10)       III     8 (13)     3 (8)       Dissection State       Rupture     3 (5)     2 (5)     >0.999       Malperfusion     15 (24)     8 (21)     0.809       Tamponade     5 (8)     5 (13)     0.500       Partial Thrombosis     42(70)     30 (81)     0.245       Severity       Euro score     5.2 (7.6)     2.7 (3.3)     0.270       Japan score     9.5 (7.5)     7.7 (9.1)     0.002       Adjunctive procedure       AVR     3 (5)     0 (0)     0.285       CABG     2 (3)     1 (3)     >0.999       Aortic Root Replacement     2 (3)     1 (3)     >0.999			EB-SAFER(63)	CTAR(39)	p-value
II	DeBakey	No. (%)			0.476
III 8 (13) 3 (8)   Dissection State   Rupture 3 (5) 2 (5) >0.999   Malperfusion 15 (24) 8 (21) 0.809   Tamponade 5 (8) 5 (13) 0.500   Partial Thrombosis 42(70) 30 (81) 0.245   Severity   Euro score 5.2 (7.6) 2.7 (3.3) 0.270   Japan score 9.5 (7.5) 7.7 (9.1) 0.002   Adjunctive procedure   AVR 3 (5) 0 (0) 0.285   CABG 2 (3) 1 (3) >0.999			45 (71)	32 (82)	
Dissection State     Rupture   3 (5)   2 (5)   >0.999     Malperfusion   15 (24)   8 (21)   0.809     Tamponade   5 (8)   5 (13)   0.500     Partial Thrombosis   42(70)   30 (81)   0.245     Severity     Euro score   5.2 (7.6)   2.7 (3.3)   0.270     Japan score   9.5 (7.5)   7.7 (9.1)   0.002     Adjunctive procedure     AVR   3 (5)   0 (0)   0.285     CABG   2 (3)   1 (3)   >0.999	II II		10 (16)	4 (10)	
Rupture   3 (5)   2 (5)   >0.999     Malperfusion   15 (24)   8 (21)   0.809     Tamponade   5 (8)   5 (13)   0.500     Partial Thrombosis   42(70)   30 (81)   0.245     Severity     Euro score   5.2 (7.6)   2.7 (3.3)   0.270     Japan score   9.5 (7.5)   7.7 (9.1)   0.002     Adjunctive procedure     AVR   3 (5)   0 (0)   0.285     CABG   2 (3)   1 (3)   >0.999	<u>                                      </u>		8 (13)	3 (8)	
Malperfusion   15 (24)   8 (21)   0.809     Tamponade   5 (8)   5 (13)   0.500     Partial Thrombosis   42(70)   30 (81)   0.245     Severity   Euro score   5.2 (7.6)   2.7 (3.3)   0.270     Japan score   9.5 (7.5)   7.7 (9.1)   0.002     Adjunctive procedure   3 (5)   0 (0)   0.285     CABG   2 (3)   1 (3)   >0.999	Dissection State				
Tamponade   5 (8)   5 (13)   0.500     Partial Thrombosis   42(70)   30 (81)   0.245     Severity   5.2 (7.6)   2.7 (3.3)   0.270     Japan score   9.5 (7.5)   7.7 (9.1)   0.002     Adjunctive procedure   3 (5)   0 (0)   0.285     CABG   2 (3)   1 (3)   >0.999	Rupture		3 (5)	2 (5)	>0.999
Partial Thrombosis   42(70)   30 (81)   0.245     Severity   5.2 (7.6)   2.7 (3.3)   0.270     Japan score   9.5 (7.5)   7.7 (9.1)   0.002     Adjunctive procedure   3 (5)   0 (0)   0.285     CABG   2 (3)   1 (3)   >0.999	Malperfusion		15 (24)	8 (21)	0.809
Severity     Euro score   5.2 (7.6)   2.7 (3.3)   0.270     Japan score   9.5 (7.5)   7.7 (9.1)   0.002     Adjunctive procedure     AVR   3 (5)   0 (0)   0.285     CABG   2 (3)   1 (3)   >0.999	Tamponade		5 (8)	5 (13)	0.500
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AVR 3 (5) 0 (0) 0.285 CABG 2 (3) 1 (3) >0.999	Japan score		9.5 (7.5)	7.7 (9.1)	0.002
CABG 2 (3) 1 (3) >0.999	Adjunctive procedure				
	AVR		3 (5)	0 (0)	0.285
Aortic Root Replacement 2 (3) 1 (3) >0.999	CABG		2 (3)	1 (3)	>0.999
	Aortic Root Replacement		2 (3)	1 (3)	>0.999

# Result

Surgical Outcome (Technical success: 100%)

		EB-SAFER(63)	CTAR(39)	p-value
Time	Mean ± SEM			
Estimated arch vessel reconstruction		22.7 ± 13.1	63.0 ± 28.3	
Total operation		342.1 ± 87.8	465.2 ± 150.4	
СРВ		204.2 ± 55.9	274.8 ± 94.6	
Cardiac arrest		$142.8 \pm 44.9$	$183.0 \pm 51.6$	
Cerebral perfusion		76.0 ± 25.9	116.8 ± 47.2	
Circulatory arrest		57.2 ± 20.1	67.1 ± 33.2	

Estimated arch vessel reconstruction : Cerebral perfusion - Circulatory arrest CPB : Cardio Pulmonary Bypass

# Result

S <mark>urgical Outcome</mark>	o. (%) EB-SAFER(63)	CTAR(39)	p-value
Blood products			
RBC	2 (6)	10 (8)	<0.001
FFP	6 (6)	10 (7)	
PLT	20 (10)	20 (20)	
Ventilator free days (30)	25 (11)	27 (19)	0.842
ICU free days (30)	23 (12)	21 (18)	0.149
Hospital free days (90)	65 (37)	57 (39)	0.244
Mortality			
30-day	6 (10)	4 (11)	>0.999
In-hospital	7 (11)	6 (16)	0.543
Arch vessel related Complication (m	edian)	34	
Observation period, days	185 (309)	1202 (1980)	
Branch occlusion	0 (0)	1 (3)	>0.999

## Result

Surgical Outcome

No. (%)

**EB-SAFER** 

CTAR

Ankle-Brachial Index (ABI)

Rt, Lt

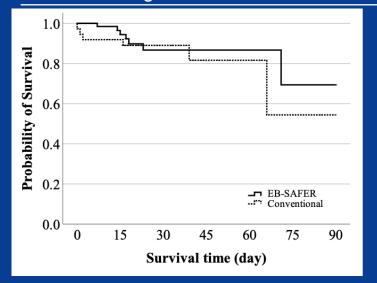
Rt, Lt < 0.9

Coarctation sign: Rt < 0.9 & Lt < 0.9

1.13 ± 0.11 , 1.12± 0.15	
0 (0) 0 (0)	

0 (0) , 0 (0)

0 (0)

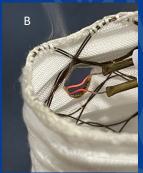


There was no significant difference in survival time between the two groups (P=0.46)

### **Discussion**

- Use self-expandable stent grafts.
- The balloon-expandable type, which is secured by flaring the proximal side during circulatory arrest, carries the risk of arterial injury without fluoroscopy.
- In contrast, the use of self-expandable stent grafts appears to be a simple method that requires attention to only the length from the origin of the subclavian artery to the vertebral artery. It is believed to contribute to long-term patency.
- ABI for assessment of aortic coarctation due to intra-aortic self-expanding stent graft implantation was also normal in the remote period.





A: Post implant view showing VIABAHN inserted in the long axis. The proximal end of the VIABAHN is then secured to the FET with a 5-0 polypropylene thread to prevent long-term migration

B: Fenestrations are created within the oval stent skeleton, and the edges of the polyester material are solidified by thermal cauterization.

### CONCLUSION

- EB-SAFER improved surgical outcomes, including shorter operative time and reduced use of blood products, without worsening long-term survival and branch-related complications.
- This study demonstrated that EB-SAFER is safe and effective, comparable to CTAR, and can be used for AADA with patent false lumen.