Mortality Early And 3-5 Years After Endo Repair Of Juxtarenal And Complex AAAs In The US Aortic Research Consortium (ARC) Registry Is Less Than That Reported For Comparable Open Repairs

Andres Schanzer, MD

November 19th, 2024
Veith Symposium, New York, NY

Disclosures

- Cook Medical, Phillips Imaging, Cryolife
  - Research grants
  - Case proctor
  - Consult

All compensation goes to UMass Memorial Foundation and none to me personally.

Editor's Choice – Comparison of Open Surgery and Endovascular Techniques for Juxtarenal and Comp… AneurySm Study (UK…

mortality rate did not hold the assumption of proportional hazards owing to a reversal of treatment effect direction during the follow up period (Fig. 4). Specifically, there is a peri-operative survival benefit for endovascular techniques but a later disadvantage. This crossover of direction occurred at 10.3 months for EVAR *vs.* OSR and 12.1 months for FEVAR *vs.* OSR. Statistically, non-proportional hazards were confirmed with an assessment of Schoenfeld residuals against the rank of time giving a p value of $< .001$. Like to the late all cause mortality results, the overall survival benefit with OSR over endovascular techniques was not seen in the 0 — 4 mm neck length group. For these patients, overall survival between EVAR *vs.* OSR and FEVAR *vs.* OSR was equivalent at 3.5 years of follow up. Kaplan—Meier graphs showing comparative overall survival data for the six subgroups are presented in Figure 5. Comparative analysis results by subgroup are presented in Table 5 and the

Conclusion: FE… proves notably… neck length), … with comparable midterm survival. For patients with short neck (5 — 9 mm) and complex neck (≥ 10 mm) AAAs, overall survival was worse in endovascularly treated patients compared with OSR despite relative peri-operative safety. This warrants further research and a re-appraisal of the current clinical application of endovascular strategies, particularly in patients with poor general survival outlook owing to comorbidity and age.

Eur J Endovasc Surg. 2024

Editor's Choice – Comparison of Open Surgery and Endovascular Techniques for Juxtarenal and Complex Neck Aortic Aneurysms: The UK COMPlex AneurySm Study (UK-COMPASS) — Peri-operative and Midterm Outcomes

Srinivasa R. Vallabhaneni [a,b,*], Shaneel R. Patel [a,b], Bruce Campbell [c,d], Jonathan R. Boyle [e,f], Andrew Cook [f], Alastair Crosher [f], Sophie M. Holder [f], Michael P. Jenkins [f], David C. Ormesher [f], Anna Rosala-Hallas [f], Richard J. Jackson [f]

n=366 FEVAR

2024

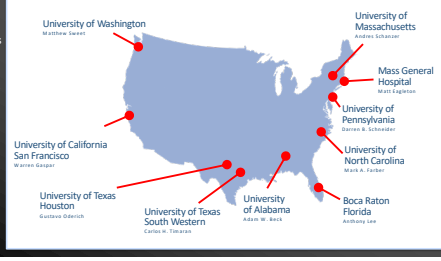
n=621 FEVAR

2008

UNITED STATES AORTIC RESEARCH CONSORTIUM

- 10 US sites
- Prospective, physician-sponsored studies
- Independent monitoring, FDA audited
- Similar device design with selective use of fenestrations and branches

United States F/BEVAR Aortic Research Consortium (ARC)



	Total n=3453	TAAA (1-5) n=2357	Complex AAA n=1096	p-value
Age at index procedure, mean (std)	73.5 (8.3)	72.8 (8.6)	75.1 (7.5)	<0.0001
Male sex	2423 (70)	1546 (66)	877 (80)	<0.0001
Race (can select more than one)				
White	2954 (86)	1962 (83)	992 (91)	<0.0001
Black	278 (8.1)	226 (9.6)	52 (4.7)	<0.0001
Asian	36 (1.0)	22 (0.9)	14 (1.3)	0.35
American Indian or Alaska Native	13 (0.4)	7 (0.3)	6 (0.6)	0.37
Native Hawaiian or Pacific Islander	2 (0.1)	2 (0.1)	0 (0)	0.99
Other/unknown	91 (2.6)	71 (3.0)	20 (1.8)	0.043
Hispanic ethnicity	77 (2.2)	63 (2.7)	14 (1.3)	0.010
Comorbidities				
CAD	1647 (48)	1062 (45)	585 (54)	<0.0001
COPD	1211 (35)	809 (34)	402 (37)	0.19
Renal failure requiring dialysis	61 (1.8)	53 (2.3)	8 (0.7)	0.002
Diabetes	523 (15)	334 (14)	189 (17)	0.019
Hypertension	3169 (92)	2176 (92)	993 (91)	0.06
Current tobacco use	933 (27)	624 (27)	309 (28)	0.3
Prior EVAR	531 (16)	304 (13)	227 (24)	<0.0001
Technical success	3327 (97)	2259 (96)	1068 (98)	0.030
ICU LOS days, mean (std)	3.3 (5.4)	3.8 (6.0)	2.0 (3.4)	<0.0001
Total LOS days, mean (std)	6.4 (9.4)	7.2 (9.3)	4.8 (9.4)	<0.0001

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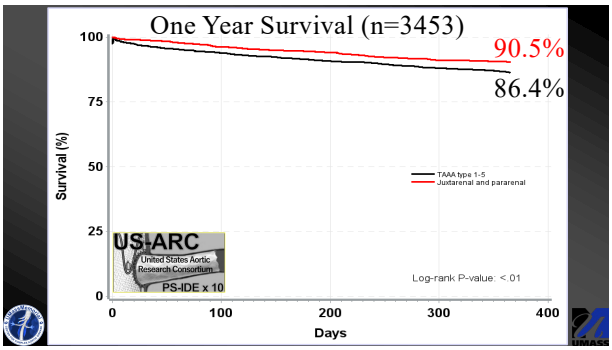
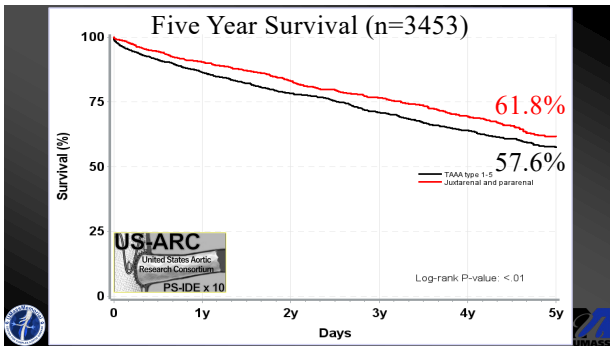
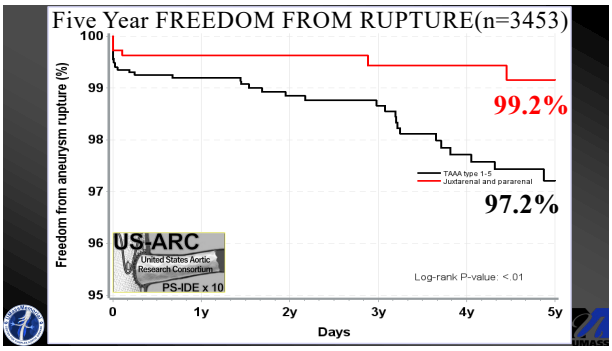
30-day or in-hospital mortality (n=3481)

30-Day Mortality (11/13/24): 101/3481 =

2.9%







1,681 Patients / 6,349 Target Vessels

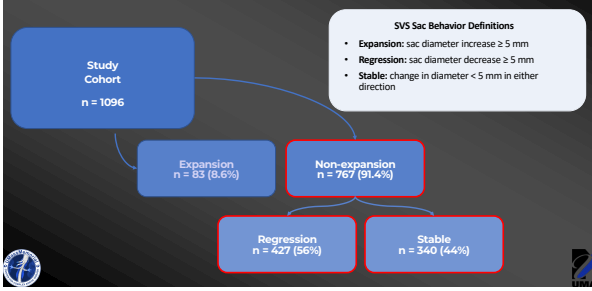
Mid-term Renal and Mesenteric Artery Outcomes During Fenestrated and Branched Endovascular Aortic Repair for Complex Abdominal and Thoracoabdominal Aortic Aneurysms in the United States Aortic Research Consortium

Emanuel R. Tenorio, MD, PhD, Andres Schanzer, MD,† Carlos H. Timaran, MD,‡ Darren B. Schneider, MD,§ Bernardo C. Mendes, MD,‖ Matthew J. Eagleton, MD,¶ Mark A. Farber, MD,# Federico Ezequiel Parodi, MD,# Warren J. Gasper, MD,** Adam W. Beck, MD,†† Matthew P. Sweet, MD,‡‡ Ying Huang, MD, PhD,* Gustavo S. Oderich, MD,*§§ and on behalf of the U.S. Fenestrated and Branched Aortic Research Consortium§§*

Renal target artery stents 5-year Kaplan-Meier Estimates (%)	Fenestration n = 2166	Branch n = 989	P value
Primary patency	94±1	83±3	<.001
Secondary patency	97±1	89±2	<.001
Freedom from target vessel Instability	88±2	80±2	.001

Tenorio E et al. Ann Surg 2023

Juxta/Para Sac Behavior (n = 1096)



United States Aortic Research Consortium

- Thoughts
  - Largest dataset of F/BEVAR in the world
  - FDA audited
  - Outcomes superior to open repair

Open Surgical Repair of Complex AAA in Large Single Center Studies

Author (Reference)	n	30-day Mortality	Renal failure	Dialysis
Giulini et al (Eur JVES 2000)	56	3.6%	-	2%
Ayri et al (Ann Vas Sur 2001)	53	11%	-	-
Sarac et al (J Vasc Surg 2002)	138	5.1%	22%	3%
Shortell et al (J Vasc Surg 2003)	112	6%	12%	3%
Bicknell et al (Eur JVES 2003)	44	6.8%	-	-
Kudo et al (J Vasc Surg 2008)	18	0	17%	5.6%
Chiesa et al (J Vasc Surg 2006)	119	7.6%	18%	5.8%
West et al (J Vasc Surg 2006)	243	2.5%	22%	2%
Knott et al (J Vasc Surg 2007)	126	0.8%	22%	1%
	1202	**4.2%**	**19%**	**3.8%**

Open vs Fenestrated Repair for Complex AAA in the United States

Review of NSQIP Database on Juxtarenal Aneurysms

	Open Repair n = 598	Fenestrated Repair n = 629 patients
Mean age	73	71
30-day mortality	**4.5%**	**2%**
Dialysis	**6%**	**2%**
Return to OR	9%	-
Re-intervention	-	17%
Branch pa	-	93%

2x↑ mortality
3x↑ dialysis

Linsen et al. J Vasc Surg 2012

Systematic Review of Open vs Fenestrated Repair for Complex AAA

Systematic	Open Repair (n = 1164)		Fenestrated Endografts (n = 368)		RR (95% CI)	P value
30-day mortality	**3.6%**	2.7-4.9	**1.4%**	0.4-3.1	1.03 (1.01-1.04)	.02
Renal impairment	**20%**	17.9-22.5	**15%**	11.5-18.7	1.01 (1.01-1.12)	.03
Dialysis	1.4%	0.8-2.3	1.4%	0.5-3.1	1.00 (0.99-1.01)	1
Primary endoleak	-	-	6%	3.1-7.8	-	-
Vessel patency			97%	95.4-97.8	-	-
Re-intervent			**15%**	11.5-18.7	0.87 (0.83-0.91)	.0001

2x↑ mortality
5x↓ reinterventions

Nordon et al. Eur J Vasc Surg 2009

Outcomes of Open Surgical Repair and Fenestrated Repair of CAAAs in the SVS VQI

	Age <65				Age 65-75			
	FEVAR	OSR	OR (95% CI	P value	FEVAR	OSR	OR (95% CI	P value
30-day mortality	0.9%	2.1%	0.40(0.07-1.44)	.22	**2.2%**	**5.0%**	0.50(0.30-0.79)	.004
Dialysis	1.3%	2.6%	0.51(0.14-1.43)	.24	**1.2%**	**5.4%**	0.60(0.35-0.89)	<.001
Cardiac complications	**0.4%**	**5.0%**	0.15(0.03-0.47)	.005	**2.5%**	**7.6%**	0.42(0.28-0.62)	<.001
Pulmon compli				002	**2.5%**	**12%**	0.29(0.28-0.62)	<.001
Any co				001	**8%**	**23%**	0.38(0.26-0.42)	<.001

For age > 65
2x↑ mortality
3x↑ dialysis, cardiac, pulmonary complications

Rastogi et al. Eur J Vasc Endovasc Surg 2023

Clinical Investigation

ENDOVASCULAR THERAPY

Long-Term Propensity-Matched Comparison of Fenestrated Endovascular Aneurysm Repair and Open Surgical Repair of Complex Abdominal Aortic Aneurysms

Giovanni Tinelli, MD, PhD[1], Simona Sica, MD[1], Jonathan Sobocinski, MD, PhD[2], Zoé Ribreau, MD[2], Chiara de Waure, MD, MSc, PhD[3], Marco Ferraresi, MD[4], Francesco Snider, MD[1], Yamume Tshomba, MD[1], and Stéphan Haulon, MD, PhD[2]

Abstract

Purpose: This study investigated the long-term outcomes of patients treated with fenestrated and branched endovascular aneurysm repair (F-BEVAR) or open surgical repair (OSR) for complex abdominal aortic aneurysms (c-AAAs). Complex abdominal aortic aneurysms are defined as aneurysms that involve the renal or mesenteric arteries and extend up to the level of the celiac axis or diaphragmatic hiatus but do not extend into the thoracic aorta. This study compares with a propensity-score matching the outcome of these procedures from 2 high-volume aortic centers. **Materials and Methods:** All patients with c-AAAs undergoing repair in 2 centers between January 2010 and June 2016 were included. The long-term imaging follow-up consisted in a yearly computed tomography angiography (CTA) in the F-BEVAR group. Yearly abdominal ultrasound examination and 5-year CTA were performed in the OSR group. The primary endpoints were long-term mortality, aneurysm-related mortality, and chronic renal decline (CRD), defined as estimated glomerular filtration rate reduction to <60 mL/min/1.73 m² or >20%de novo dependence on permanent dialysis in patients with normal or abnormal preoperative renal function, respectively. Secondary endpoints included aortic-related reinterventions, target vessel occlusion, proximal aorta degeneration, access-related complications, graft infection, and the composite endpoint of clinical failure during follow-up. **Results:** After 1:1 propensity matching, 102 consecutive patients who underwent F-BEVAR and OSR, respectively, were included. The median follow-up was 67 months. There was no significant difference in long-term overall mortality (40.2% vs 36.3% [P=0.40] and aneurysm-related mortality (6.8% vs 5.8%; p=0.30), in the F-BEVAR and OSR groups, respectively. During follow-up, late renal function decline occurred in 27 (27.8%) versus 46 patients (47.4%) in the F-BEVAR and OSR groups, respectively (p<.0.01). During follow-up, 23 reinterventions (23.5%) were performed in the F-BEVAR group, and 5 (5.1%) in the OSR group (p<.0.01). **Conclusions:** No differences in overall and aneurysm-related mortality were observed. Chronic renal decline was significantly higher after OSR, while the reintervention rate was higher in the F-BEVAR group. These long-term results reflect the outcomes of a complex procedure performed by a single experienced operator in 2 high-volume centers, and followed with a strict surveillance imaging follow-up.

Tinelli et al. Eur J Vasc Endovasc Surg 2024

Open vs Fenestrated Repair for Complex AAA in France

Review of 2 High Volume Centers on CAAA

	Open Repair n = 102	Fenestrated Repair n = 102 patients	p-value
Long-term overall mortality	36.3%	40.2%	**0.40**
Aneurysm-related mortality	5.8%	6.8%	**0.30**
Late renal function decline	**47.4%**	27.8%	<0.01
Reinterventions	5.1%	**23.5%**	<0.01

2x↑ renal function decline
4x↓ Reinteventions

Tinelli et al. Eur J Vasc Endovasc Surg 2024

2019 ESVES AAA guidelines

	Recommendation	Class	Level
95	In patients with CAAAs, **open repair or complex endovascular repair should be considered** based on patient status, anatomy, local expertise, team experience and patient preference	IIa	C
96	In complex endovascular AAA repair, **FB-EVAR** should be considered the **preferred option** when feasible	IIa	C
97	In complex endovascular AAA repair, parallel grafts, endo-stables, in situ fenestrations may be considered in the **emergency setting** when fenestrated grafts are not indicated or available or as a bail out, ideally restricted **to ≤2 parallel grafts**	IIa	C
98	In patients with CAAAs, **new techniques or concepts** (EVAS, in situ, etc) **are not recommended as first line of treatment**	III	C
99	In patients with **ruptured CAAAs, open repair or complex endovascular repair** (with PMEGs, off the shelf or parallel grafts) may be considered based on patient status, anatomy, local experience, team experience and patient preference	IIa	C

Wanhainen A, et al. Eur J Vasc Endovasc Surg 2019

CLINICAL PRACTICE GUIDELINE

2022 ACC / AHA Guideline for the Diagnosis And Management of Aortic Disease

Complex Abdominal Aortic Aneurysms

INTACT

- Repair is recommended when diameter is ≥ 5.5-cm in men and ≥ 5-cm (Class 1)
- In **low-moderate risk** patients with suitable anatomy for **open or endo** repair, **shared decision making is recommended** weighting risks/ benefits of each option **(Class 1)**
- In **high risk patients** with CAAAs and suitable anatomy, **FB-EVAR is reasonable** over open repair **(Class 2a)**

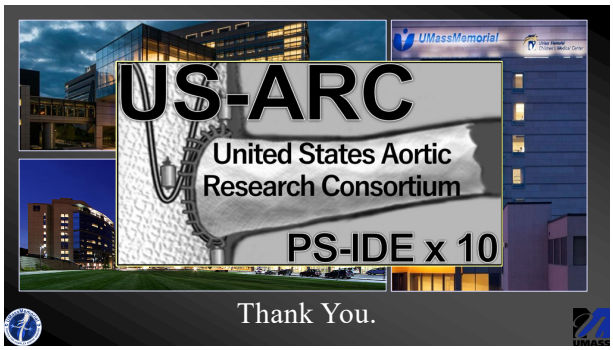
RUPTURED

- In patients with Ruptured AAA and **suitable anatomy, EVAR is recommended** over open repair **(Class 1)**
- **In stable patients with CAAAs endovascular repair is reasonable** in centers with expertise and access to devices **(Class 2b)**

Isselbacher E et al. Circulation and JACC 2022

Conclusions

- F/BEVAR is associated with lower morbidity and mortality compared to open surgical repair for complex AAA, despite being used in older and higher risk patients
- Limitations of F/BEVAR are important to acknowledge: secondary intervention, limited access, regulatory hurdles, cost, and need for surveillance
- While open and endovascular repair are valuable, it's time to stop starting and ending every talk with, "Open repair is the gold standard." Because it no longer is.
- The US ARC has established a higher level of evidence supporting use of FB-EVAR in most patients with cAAA (and TAAAs)


UMassMemorial
US-ARC
United States Aortic
Research Consortium
PS-IDE x 10
Thank You.
UMASS