French National (Real World) Comparison Of Results Of F/EVAR And Open Repair (ORFEVAR Trial) For The Treatment Of Complex AAA (Juxtarenal, Suprarenal And Type IV TAAAs): Do We Need A RCT?

AURC

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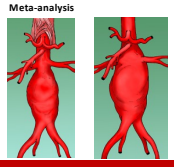
Disclosures

- Proctor For Cook
- Consultant for Philips

Is there a need for studies comparing FEVAR and OR?

- **UK-COMPASS Trial**
- **French WINDOWS Trial**
- **Meta-analysis**



FEVAR:

↘ early postoperative mortality

↗ reintervention rate

Mid-term and long-term results???

Recommendation 120			Changed
For patients with a complex abdominal aortic aneurysm and standard surgical risk, open or endovascular repair should be considered based on patient fitness, anatomy, and patient preference.			
Class	Level	References	ToE
IIa	C	Patel et al. (2022),[305] Antoniou et al. 92021),[302] Patel et al. (2021),[303] Doonan et al. (2019)[304]	

YES

There is a need for a randomized study

Is a randomized study realistic?

Surgeons/centers developed specific expertise in OR or FEVAR

NO

Expected difficulties in consenting patients

Realistic: prospective comparative multicenter cohort, with a propensity score to minimize bias

ORFEVAR Trial

- prospective non-randomized comparative cohort study, 29 University Centers
- Objective, primary outcome:
  To compare the cost effectiveness incremental ratio at 36 months of FEVAR and OR for CAAA.
- Grant: 820 000 euros, French ministry of Health (PRME)
- Review board approval 2021 (CPP Ouest IV: 06/21_3)

Study population

Complex degenerative asymptomatic AAA (short neck, juxtarenal, suprarenal and type IV)

Diameter > 50 mm

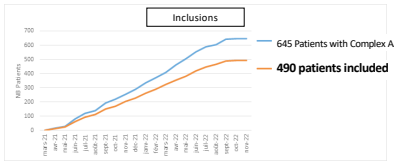
Exclusion criteria

- Extended TAAAs
- Dissecting, infected, ruptured or painful AAA
- History of abdominal aortic
- CHIMPS, hybrid
- Life e

High surgical risk patients

Patients anatomically unsuitable for FEVAR

- Shaggy aorta, < 4 mm main renal artery



215 OR

275 FEVARS

Demographic data

	OR (215)	FEVAR(275)	p
Age (available data : 215/275)	69.3 (±7.4)	73.3 (±7.7)	<0.001
Diabetes mellitus (available data : 195/243)	24 (12.3%)	47 (19.3%)	0,047
Tobacco usage (available data : 196/242)	108 (55.1%)	109 (45.0%)	0,036
COPD (available data : 182/222)	16 (8.8%)	36 (16.2%)	0,027
Past history of stroke (available data : 191/233)	14 (7.3%)	38 (16.3%)	0,005
Hostile abdomen (available data : 193/232)	1 (0.5%)	12 (5.2%)	0,006
GFR (CKD-EPI) (available data : 176/221)	77.5 [62-89.5]	71 [55-85]	0,005
ASA Score (available data : 180/233)			0,004
I	3 (1.7%)	1 (0.4%)	
II	76 (42.2%)	64 (27.5%)	
III	98 (54,4%)	162 (69.5%)	
IV	9 (2.2%)	6 (2.6%)	

Anatomical data

	OR	FEVAR	p
Mean aneurysm diameter (available data : 124/176)	58 [52.5-68.5]	56 [53-62]	0,349
Juxtarenal/ Suprarenal/ Type IV	Under analysis		

Intraoperative data, OR group

Proximal anastomosis (data available for 159 patients)	
Infrarenal	114 (74.0%)
Bevelled anastomosis integrating ≥ 1 renal artery	23 (14.9%)
Suprarenal	10 (6.5%)
supramesenteric	7 (4.6%)

Intraoperative data, FEVAR group

FEVAR group	
Type of stentgraft (data available for 205/275 patients)	
Fenestrated Cook	155 (75.6%)
Fenestrated Anaconda	46 (22.4%)
Branched Cook	1 (0.5%)
Fenestated and branched Cook	3 (1.5%)
Proximal border of the stent graft (data available for 177/275 patients)	
Above the CA:	159 (89,8%)
<5 cm above the CA	120 (67.8%)
5-10cm above the CA	27 (15.2%)
>10 cm above the CA	12 (6.8%)
Below de CA	18 (10.2%)

Preliminary early results

	OR	FEVAR	P
30-day mortality (available data: 202/236)	**4.5%**	**3.4%**	?

Preliminary early results

	OR	FEVAR	P
Any complication (available data: 206/236)	33.0%	30.5%	?
Major complication* (available data: 204/228)	7.4%	7.5%	?

*: death, MI, prolonged mechanical ventilation, dialysis, bowel ischemia necessitating resection, stroke, paraplegia)

	OR	FEVAR	P
Any early reintervention** (available data: 199/228)	9.6%	6.6%	?
Major reintervention:** (available data: 204/228)	3.0%	3.1%	?

**SVS criteria

Preliminary early results

	OR	FEVAR	P
Primary technical success (available data: 202/231)	91.6%	91.8%	?
Primary clinical success (available data: 201/231)	89.5%	91.3%	?

	OR	FEVAR	P
Lenght of hospital stay (available data: 167/177)	8 (7-12)	4 (3-6)	?
Lenght of intensive care unit stay (available data: 152/146)	4 (2-6)	1 (1-2)	?

Conclusion

- prospective comparative multicenter cohort, with a propensity score to minimize bias
- Primary outcome: cost-effectiveness ratio
- 490 patients, 215 OR, 275 FEVARS
- Final short term and mid term results are still awaited