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on Endovascular Therapeutics

The customizable solution for short necks

Looking for durability in elective patients

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Disclosure – Speaker name Prof. Mauro Gargiulo

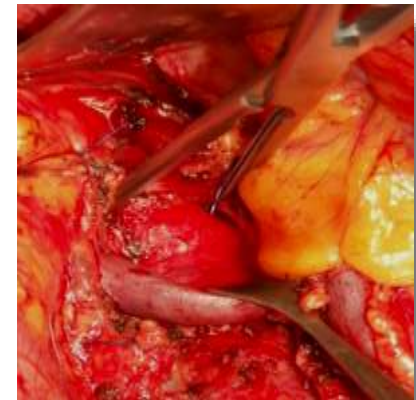
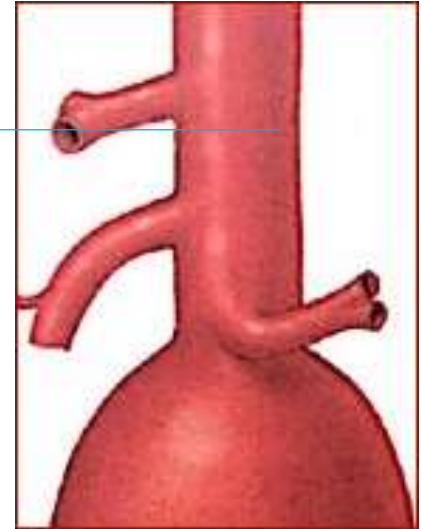
I have the following potential conflicts of interest to report:

X Consulting : Cook Medical

- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company

J-AAAs

- ✓ AAAs extending to renal arteries without ostia involvement
- ✓ Infrarenal neck length < 5 mm
- ✓ Approximately 15% of AAAs
- ✓ Open Repair: Suprarenal aortic cross clamping required



J-AAAs - Open Repair

Juxtarenal aortic aneurysm repair

Vincent Jongkind, MD,^{a,b} Kak K. Yeung, MSc,^{b,c} George J.M. Akkersdijk, MD,^a David Heidsieck, BSc,^b Johannes B. Reitsma, MD,^d Geert Jan Tangelder, MD,^c and Willem Wisselink, MD,^b *Hoofddorp and Amsterdam, The Netherlands*
JVS, 2010

First author	Year	N	Age, mean y	Male %	JAA diameter, mean cm	Pre-op renal failure %	SVC %	Renal art procedures %	Cold renal perfusion	Renal ischemia time, mean min	Peri-op mortality %	New onset dialysis %	Postoperative renal dysfunction %
Crawford	1986	94	68 ^a	91 ^a	NS	20 ^a	92 ^a	14 ^a	—	19 ^a	7.4	5.3	16 ^a
Poulias	1992	38	66	100	NR	16	0	16	—	NR	5.3	13	NS
Allen	1993	31	NR	NR	NS	NR	39	23	selective	26	0	3.2	NR
Nypaver	1993	32	NR	NR	NR	NR	45	1	selective	NR	2.4	NR	NR
Taylor	1994	23	66	78	6.3	1	8	1	—	21 ^a	0	4.0	NS
Schneider	1997	23	62	92	6.6	4	0	0	—	23	0	0	26
Jean-Claude	1999	122	71	80	NR	22	1	0	selective	28, 35 ^b	NS	5.7	39
Guilini	2000	56	67	91	6	7	0	NS	—	20	3.6	1.8	14
Sasaki	2000	13	70	72	NS	0	8	21	—	44 ^c	0	0	38
Ayari	2001	24	NR	NR	NR	38	29	8	—	NS	4.2	0	NS
Sarac	2002	138	72	67	6.4	20	31	27	selective	32, 25 ^b	5.1	5.8	28
Bicknell	2003	44	70	84	NS	NR	41	0	—	26	4.5	0	14
Shortell	2003	112	72	78	6.2	13	82	12	—	NS	6.3	3.6	13
Komori	2004	2	69	85	NS	2	0	NS	—	38 ^c	0	0	NS
Kudo	2004	18	66	56	NR	0	0	0	—	31	0	0	33
Chiesa	2006	81	69 ^a	NS	NS	9	1 ^a	0	selective	27	1.2	6.2	22
Pearce	2007	134	71	74	5.9	27	19	26	—	30	3	4.5	14
Wahlgren	2007	38	71	29	6	8	8	0	—	30	5.3	5.3	5
Knott	2008	126	74	78	6.3	17	21	12	selective	23	0.79	4.0	18
Sharp	2008	52	70	56	6	10	0	NS	—	27	0	0	NS
Yeung	2008	23	70	78	6.7	52	0	22	routine	37	0	0	0

JAA, Juxtarenal aortic aneurysm; NR, data is not retrievable specifically for non-ruptured JAA; NS, data is not stated in the article; SVC, supravisceral aort

	Median	Range
Renal Ischemia time (min)	27	19 - 44
	Median	95% C I
30-day mortality (%)	3	2 - 4
Post-operative renal dysfunction (%)	18	0-39
Post operative dialysis (%)	3	2 - 4

Results of standard suprarenal fixation endografts for abdominal aortic aneurysms with neck length ≤ 10 mm in high-risk patients unfit for open repair and fenestrated endograft

Enrico Gallitto, MD, Mauro Gargiulo, MD, Antonio Freyrie, MD, Claudio Bianchini Massoni, MD, Rodolfo Pini, MD, Chiara Mascoli, MD, Gianluca Faggioli, MD, and Andrea Stella, MD, *Bologna, Italy*

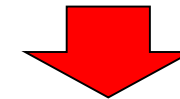
(J Vasc Surg 2016;64:563-70.)

Outcomes of endovascular aneurysm repair performed in abdominal aortic aneurysms with large infrarenal necks

Mauro Gargiulo, MD, PhD,^a Enrico Gallitto, MD, PhD,^a Helene Wattez, MD,^b Fabio Verzini, MD, Claudio Bianchini Massoni, MD,^a Diletta Loschi, MD,^c Antonio Freyrie, MD, PhD,^a and Stephan Haulon, MD, PhD,^b *Bologna and Perugia, Italy; and Lille, France*

(J Vasc Surg 2017; 66:1065-72)

Severe Neck = 3
< 10 mm
> 28
< 120°
> 50%



1° choice FEVAR



FEVAR for J-AAAs



✓ **FEVAR** is currently considered a valid alternative to OR of jAAAs in high-risk patients

✓ Studies comparing FEVAR vs OR reported **lower 30-day mortality for FEVAR**

✓ Long term benefits of FEVAR vs OR are largely unknown

Post operative Complications	FEVAR 368 pts (%)	OR 1164pts (%)	RR
30-day mortality	1.4	3.6	1.03
Renal worsening	14.9	20.0	1.06
Dialysis	1.4	1.4	ns
Reinterventions	15.0	3.0	.087

Nordon EJVS, 2009

Aim

To evaluate

early & long term outcomes of **FEVAR** in **j-AAAs**

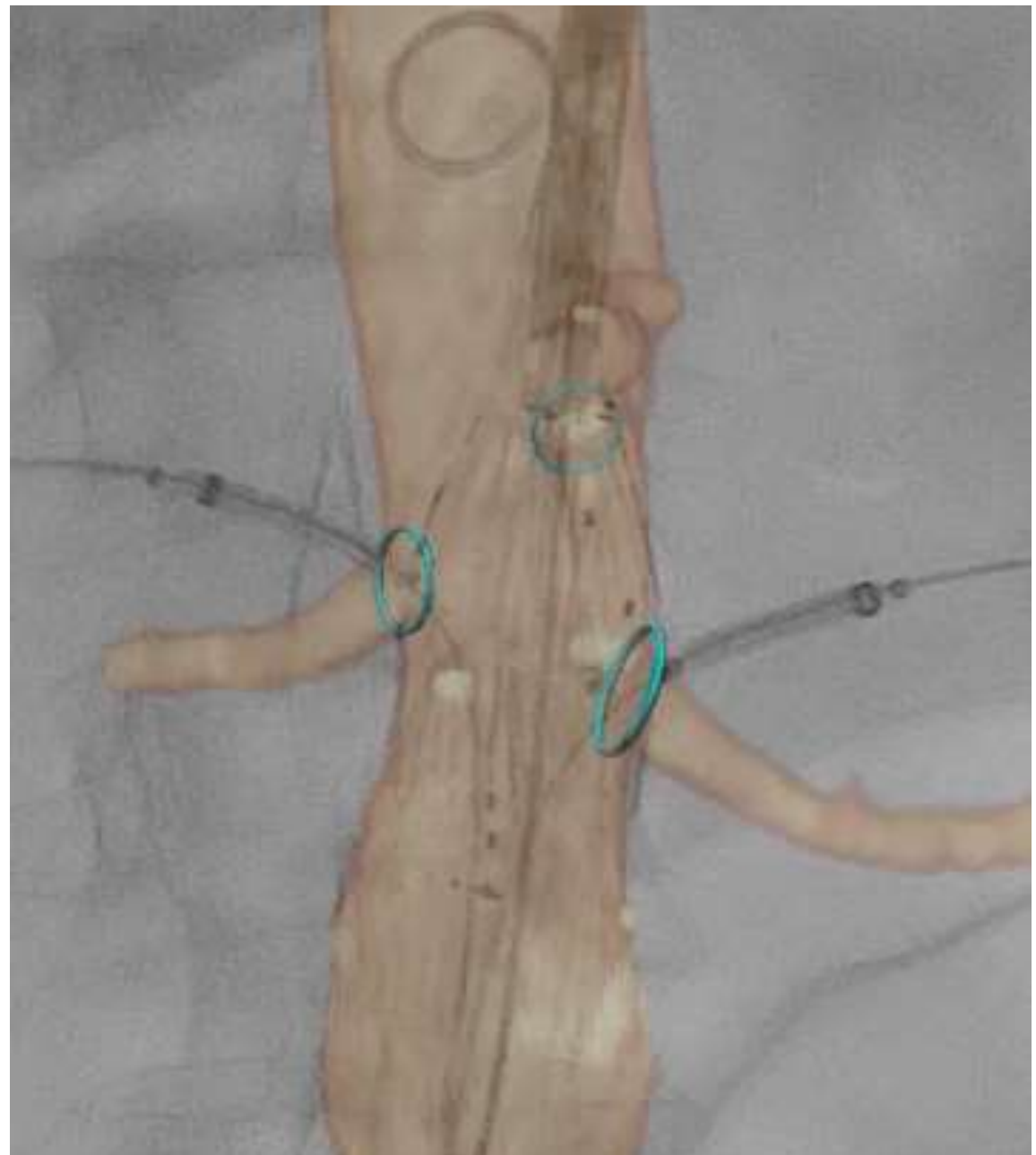
Treated 2008-2017



Methods

- ✓ 2008 – 2017
- ✓ j-AAAs
- ✓ FEVAR - Cook Zenith Platform
- ✓ Prospectively enrolled
- ✓ Retrospective analysis

Pre, intra & post-procedural data



Indication for FEVAR in j-AAAs

- ✓ Asymptomatic
- ✓ High surgical risk patients

SVS reporting standard

- ✓ Aneurysm diameter $\geq 55\text{mm}$

- ✓ Para-visceral aortic angles $< 60^\circ$

- ✓ Iliac artery and TVVs anatomical feasibility

Clinical

Morphological



Endpoints

Early

- ✓ Technical success

TVVs-patency

No type I-III EL, iliac leg stenosis/occlusions

24-hour survival

- ✓ Renal function worsening

Reduction of baseline GFR $\geq 30\%$

- ✓ 30-day mortality

Late

- ✓ j-AAAs shrinkage

Diameter reduction $\geq 5\text{mm}$

- ✓ Freedom from reinterventions

- ✓ TVVs-patency

- ✓ Renal function worsening

- ✓ Survival



Results

✓ 2008 - 2017

	n	%
J-AAAs	66	37
P-AAAs	35	19
T-AAAs	80	44
Total	181	100

✓ Mean diameter $58 \pm 6\text{mm}$

Preoperative Features	n	%
Male	62	94
Hypertension	62	94
Dyslipidemia	45	68
Diabetes	8	12
Chronic Obstructive Pulmonary Disease (COPD)	22	33
Coronary Artery Disease (CAD)	24	36
Atrial fibrillation	11	17
BMI ≥ 31	9	14
Peripheral Artery Occlusive Disease (PAOD)	8	12
Chronic Renal Failure (CRF)	20	30
Previous laparotomy	15	23
Cerebral – Vascular Insufficiency (CVI)	13	20
ASA III / IV	52 / 14	79 / 21



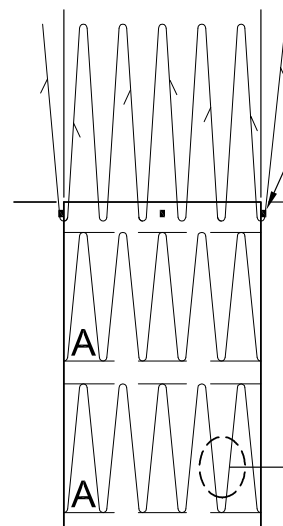
Results

FEVAR configuration	n	%
1 fen	2	3
2 fen	22	33
3 fen	27	41
4 fen	15	23
Total	66	100

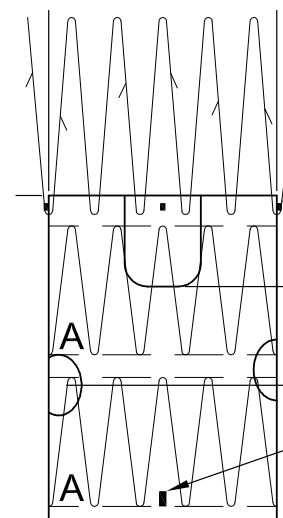
✓ **Overall TVVs** **236**

Fen & scallop

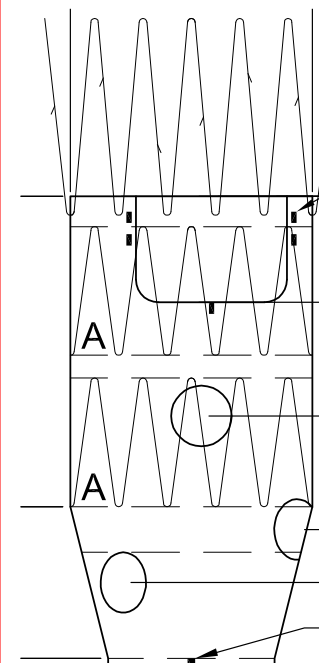
✓ Mean TVVs / patient 3.6 ± 1



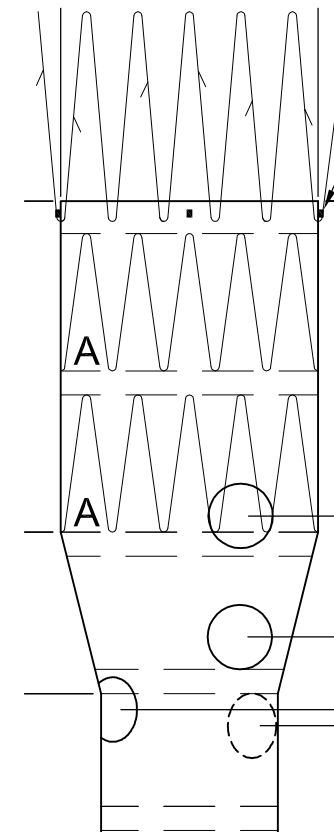
3%



33%



41%

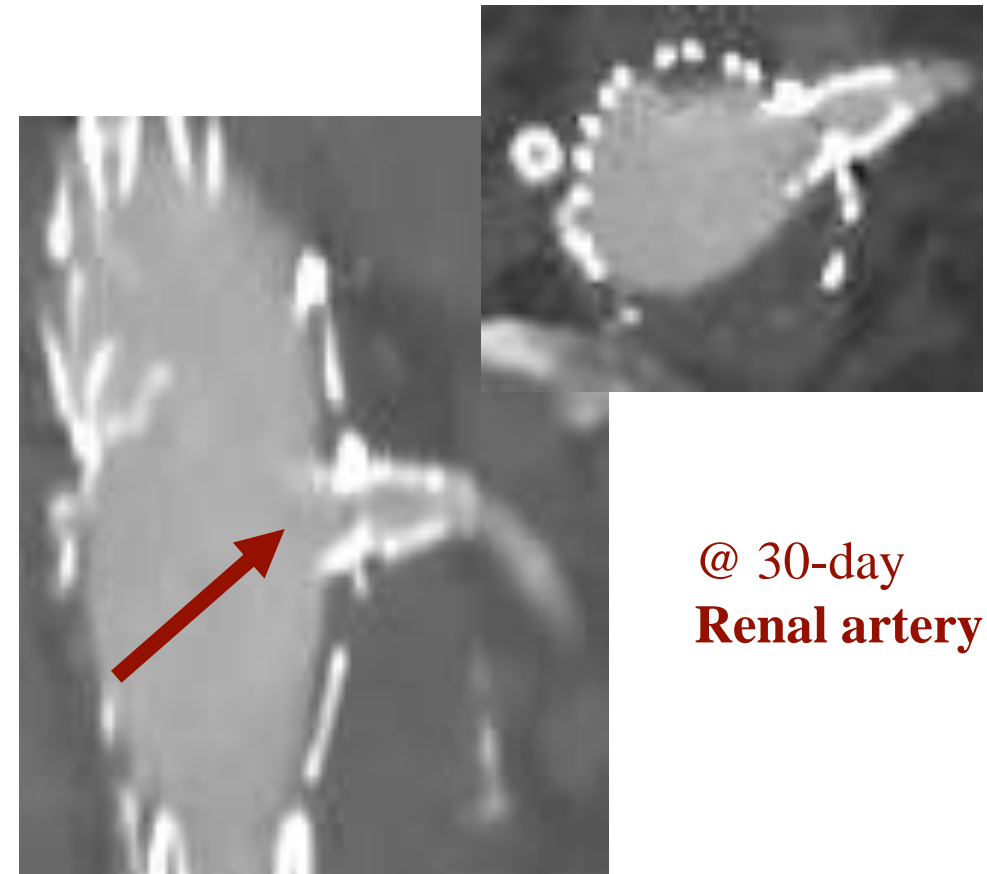
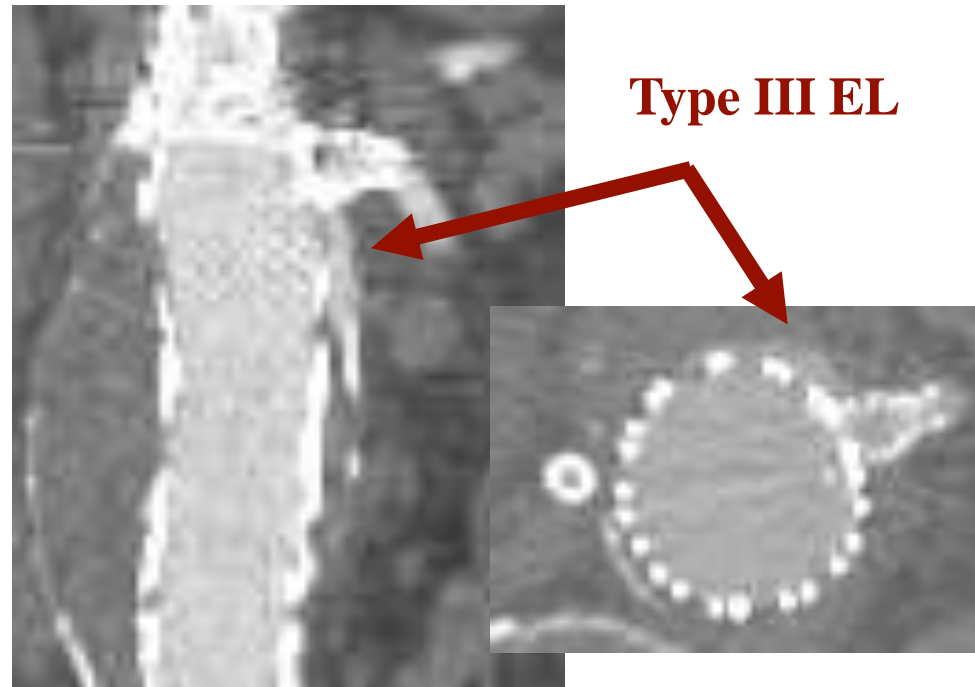


23%



Results

Early outcomes	n	%
Technical success	65	98.4



Results

Early outcomes	n	%
Technical success	65	98.4
30-day morbidity		
Cardiac	3	5
Pulmonary	4	6
Acute splanchnic ischemia	0	-
Renal function worsening	7	10
Dialysis	1*	1.5
30-day mortality	1*	1.5

* The same patient, case series #10



Results

✓ Renal function worsening

Post operative	n	%
Renal function worsening	7/66	10
✓ 3/7 (42%) had preoperative CRF		
✓ 3/20 (15%) with preoperative CRF had post operative renal function worsening		

@ 30-day	n	%
Returned to baseline	4/7	57
Persisted (no dialysis required)	2/7	29
Dialysis & death	1/7	14



Results - Follow up

- ✓ Mean 46 ± 22 months
- ✓ Range 6 - 120 months

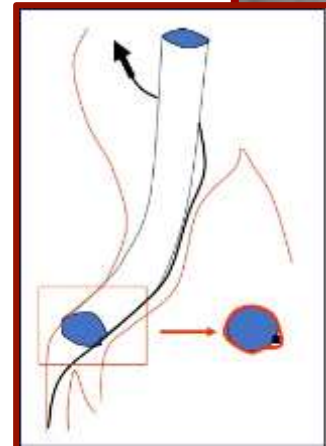


Results - Follow up

✓ J-AAA sac evolution

	n	%
Shrinkage	42	64
Stability	22	33
Increase	2	3

✓ Type II EL – reinterventions by trans-limb approach



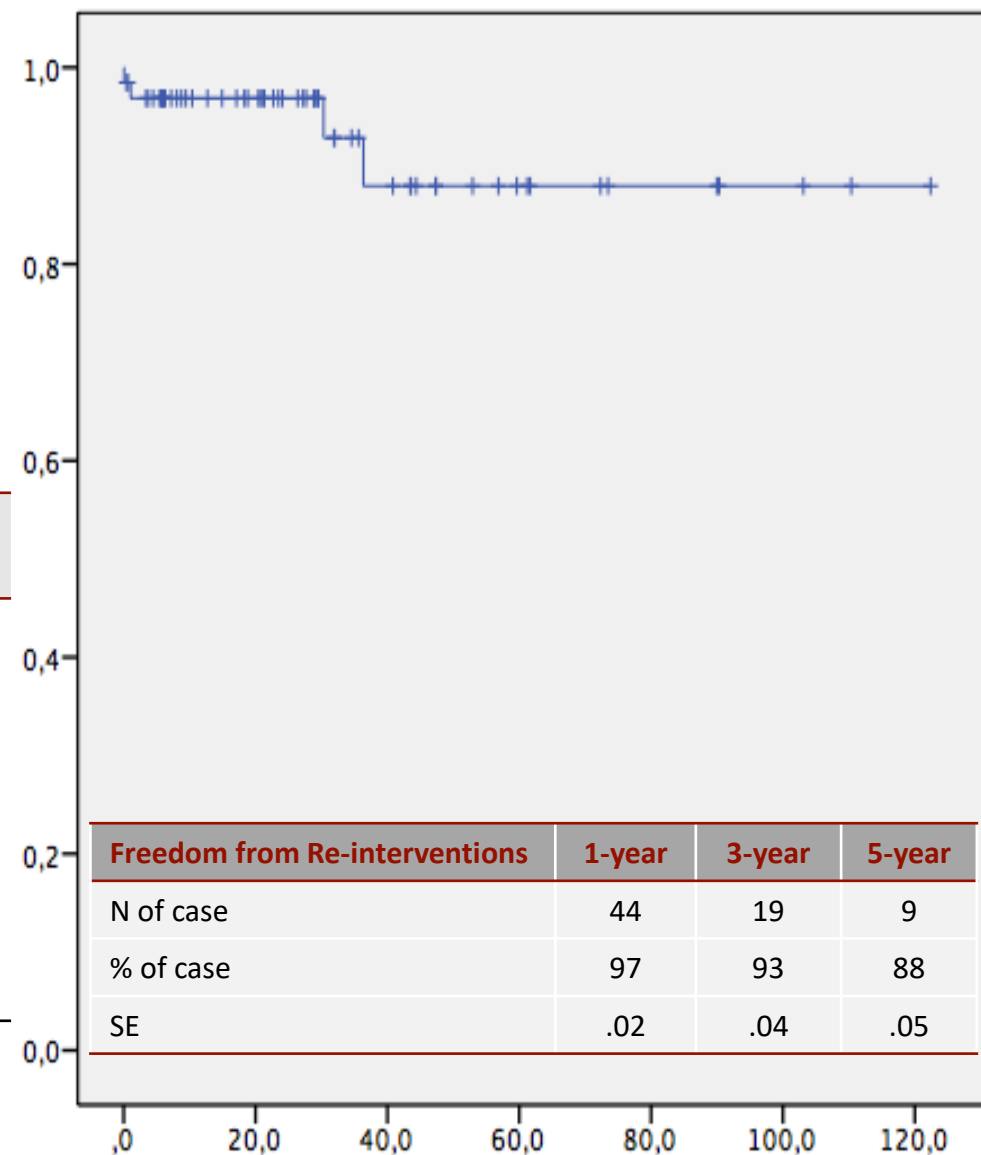
Results - Follow up

✓ Freedom from re-interventions

88% @ 5-year

n	Cause	Timing	Reintervention	Results
1	CFA* occlusion	1-day	CFA* arterectomy	solved
2	ELIII	30-day	Renal stentgraft relining	sealed
3	ELII	30-month	Sac embolization	sealed
4	ELII	36-month	Sac embolization	sealed

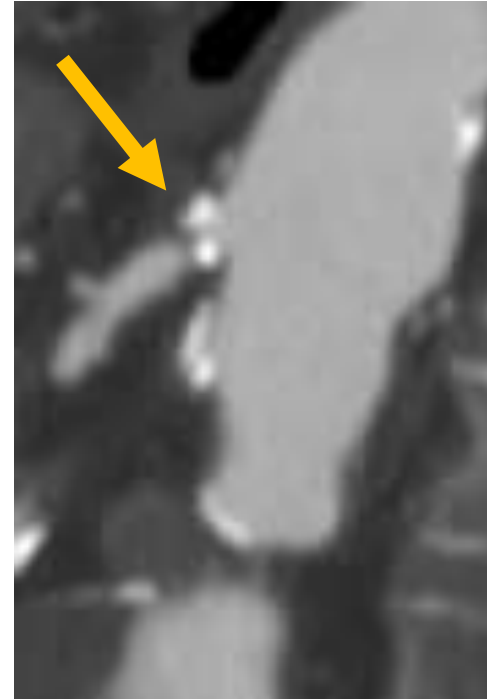
* Common femoral artery dissection



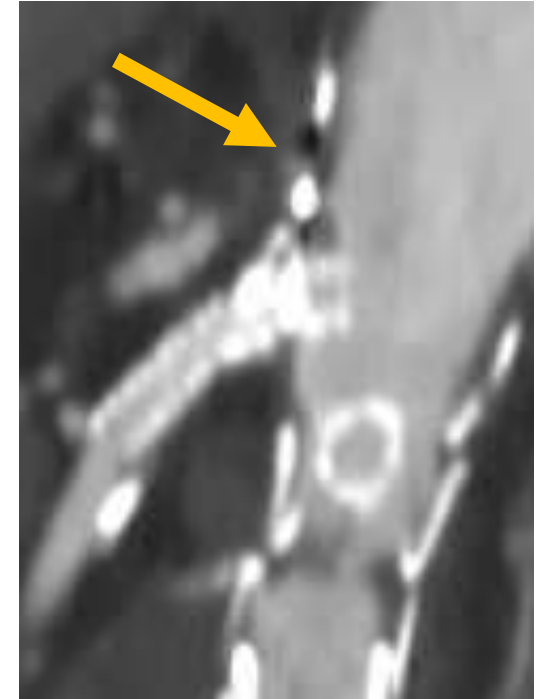
Results - Follow up

✓ TVVs 236

Occlusion	n	%
Celiac Trunk	1	0.4
Superior mesenteric artery	0	-
Renal Artery	0	-
EL I – III	0	-



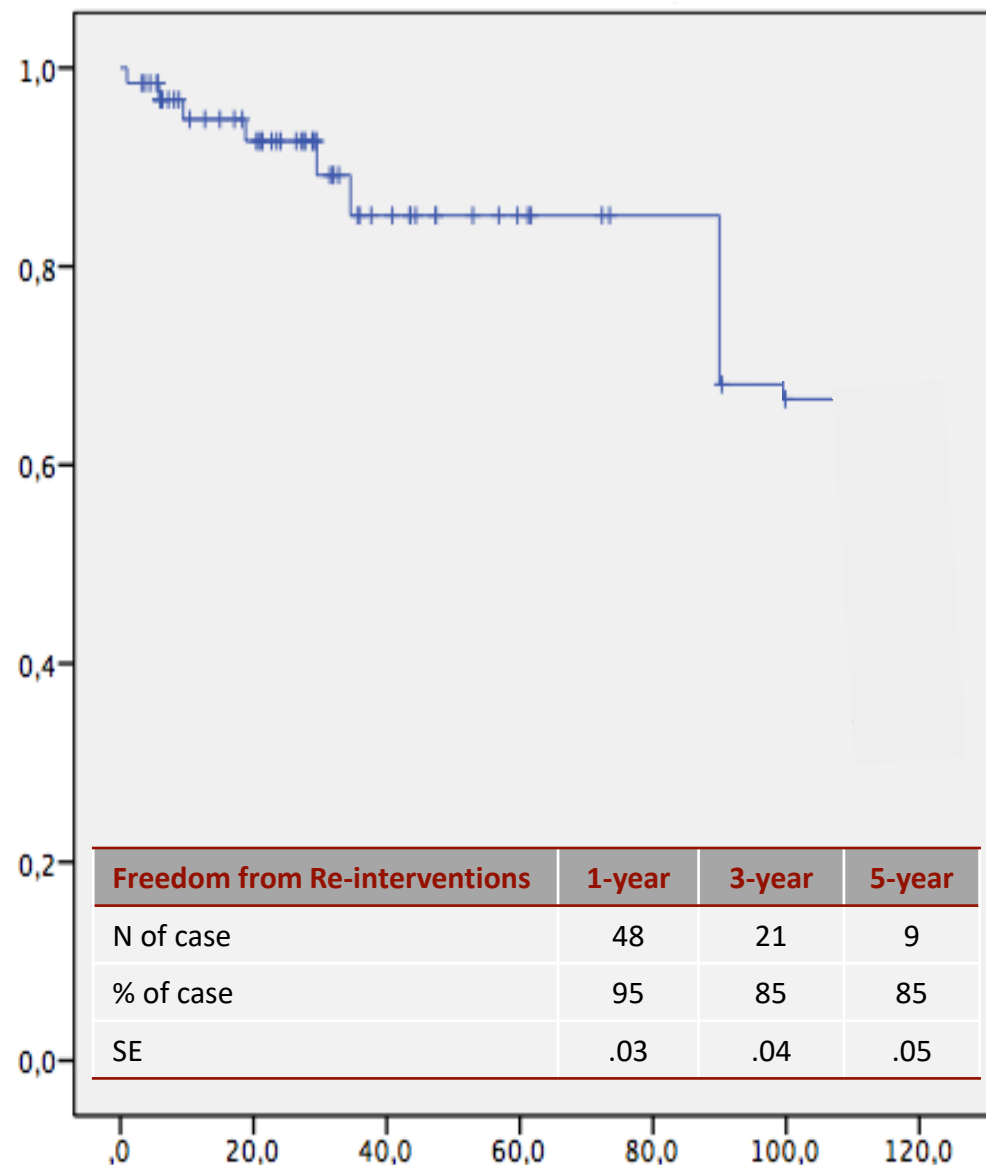
Pre-operative



@ 24-month

Results - Follow up

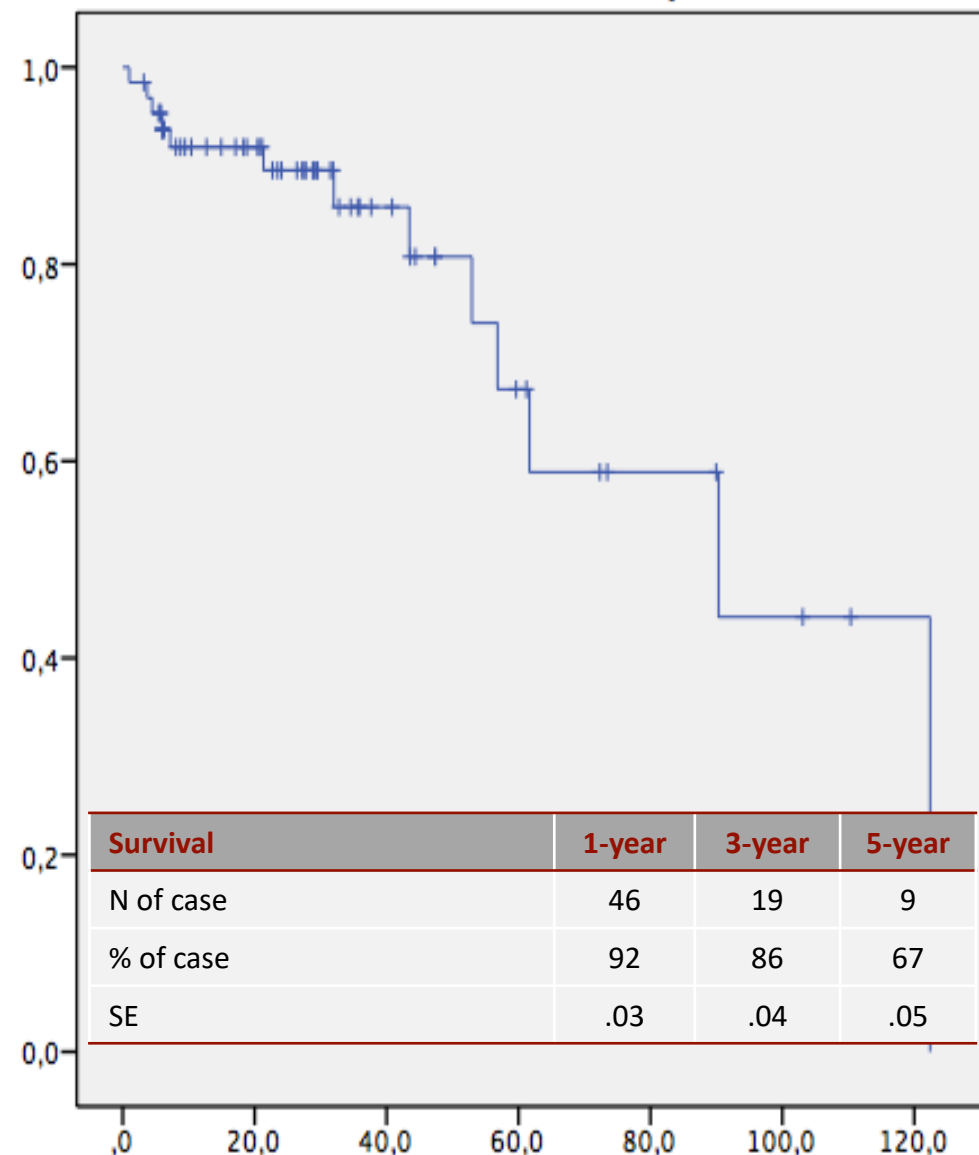
✓ Freedom from renal function worsening
85% @ 5-year



Results - Follow up

✓ Survival
67% @ 5-year

Cause of Mortality	n	%
Cancer	3	23
Cardiac	4	31
MOF/Sepsis	2	15
Pulmonary	2	15
Stroke	1	8
Unknow	1	8
Overall	13	100



Results - Follow up

✓ Risk factors for overall **Mortality**

Univariate	p
BMI \geq 31	.048
COPD	.006
Preoperative chronic renal failure	.044
F-up renal function worsening	.050

Multivariate	p	HR	95% CI
BMI \geq 31	.303	2.6	0.4 - 16.4
COPD	.021	5.3	1.3 - 21.9
Preoperative chronic renal failure	.471	1.7	0.4 - 7.21
F-up renal function worsening	.999	.00	.00



Literature experience (>50 cases)

Authors	Journal - Year	Mean FU (months)	Estimated 3y-Survival (%)	AAA-related mortality (n)
O'Neill	EJVS - 2006	19	79	0
Semmens	JET - 2006	15	-	0
Verhoeven	EJVS - 2010	24	75	0
Amiot *	EJVS - 2010	15	86	0
Kristmundsson	JVS - 2009/14	60	76	5
Vallabhaneni *	Circulation - 2012	6	89	0
Oderich	JVS - 2014	37	90	0
Roy *	BJS - 2017	34	79	0
Katsargyris	JVS - 2017	20	83	0.5
Our experience	-	46	86	0

F. up 6 - 60 months

✓ 3-y Survival: 75 – 90%

✓ AAA-related Mortality: 0 – 0.5 %

* Multicenter experience

Literature experience (>50 cases)

Authors	Journal - Year	Estimated 3-y TVVs patency (%)	Estimated 3-y FF Endoleaks (%)	Estimated 3-y FFR (%)
O'Neill	EJVS - 2006	-	-	-
Semmens	JET - 2006	-	-	-
Verhoeven	EJVS - 2010	93	-	90
Amiot *	EJVS - 2010	-	-	-
Kristmundsson	JVS - 2009/14	91	-	70
Vallabhaneni *	Circulation - 2012	95	-	70
Oderich	JVS - 2014	97	63	78
Roy *	BJS - 2017	90	85	80
Katsargyris	JVS - 2017	99	-	90
Our experience	-	99	94	93

F. up 6 – 60 months

✓ 3-y TVVs patency: 90 – 99%

✓ 3-y FFR: 70 – 90 %

* Multicenter experience

The customizable solution for short necks

Looking for durability in elective patients

Conclusion

- ✓ **FEVAR** is safe & effective for j-AAAs @ early / long-term follow-up
- ✓ **SMA** fenestrations & stenting in 64% of cases
- ✓ **Low** rate of TVVs occlusion during follow-up
- ✓ Pre-operative **COPD** could reduce long term survival
- ✓ According with high technical success, the 30-day & follow-up results, FEVAR could be considered as the first line treatment for j-AAAs in high surgical risk patients in presence of anatomical feasibility