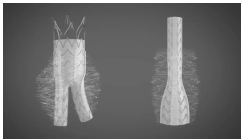


VEITH SYMPOSIUM
Connecting The Vascular Community

A RCT Shows The Advantages Of IMA And Lumbar Embolization

The Next Generation Of EVAR Endografts Must Prevent Endoleaks: How Can It Be Done !



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Disclosure

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Speaker name:
Dominique Fabre
I have the following potential conflicts of interest to report:
Consulting for Affluent Medical

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Endoleak is a long term factor of mortality!

Long-term age stratified survival following endovascular and open abdominal aortic aneurysm repair

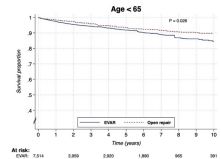


Fig 1. Inverse probability weighted 10-year survival for endovascular aneurysm repair (EVAR) versus open aneurysm repair patients aged less than 65 years old.

Varkevisser JVS 2022

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Endovascular Aneurysm Repair With Selective IMA embolization: Prospective RCT

- 2 groups:
- EVAR + IMA EMBOLIZATION
- VS
- EVAR

Endovascular Aneurysm Repair With Selective IMA Embolization for Preventing Type II Endoleak: A Prospective Randomized Control Trial

Endovascular Aneurysm Repair With IMA Embolization for Preventing Type II EL: A Prospective RCT.
Samura M, Morikage N, Otsuka R, Mizoguchi T, Takeuchi Y, Nagase T, Harada T, Yamashita O, Suehiro K, Hamano K.
Ann Surg. 2020

Clinical outcomes

the incidence of T2EL is lower in the embolization group number needed to treat = 4.1
The aneurysmal sac shrunk significantly more in the embolization group (5.7 vs 2.8mm; P = 0.037), and the incidence of aneurysmal sac growth related to T2EL was significantly lower in the embolization group

Variables	Embolization (n = 53)	Nonembolization (n = 53)	P	ARR (95% CI)	NNT (95% CI)
Follow-up period, mo	29.3 ± 20.9	25.2 ± 11.0	0.76		
Presence of T2EL, (%) (n/32)	10 (25.7%)	24 (45.3%)	0.09	23.3% (8.41–40.0%)	33 (24–155)
Quantity of T2EL, (%) (n/32)	0	1 (2.9%)			
IMA	0	1 (3.0%)			
IMA + L4a	0	4 (12.9%)			
Other IMA, L4a + IMA or IMA	0	1 (3.0%)			
Aneurysm diameter change, mm	-4.3 ± 3.5	-2.9 ± 4.7	0.02		
Aneurysm growth, 2 (mm) related to T2EL	1 (2.7%)	9 (16.6%)	0.01	13.9% (3.89–26.9%)	6.5 (3.0–27.6)
Quantity of T2EL, (n) related to T2EL	0	4 (8.9%)			
IMA, IMA + L4a	1 (1.9%)	1 (2.7%)			
Other IMA	0	1 (2.7%)			
Secondary intervention related to T2EL	0	1 (2.7%)	1.00		

IMA indicates inferior mesenteric artery; ARR, absolute risk reduction; CI, confidence interval; IMA, inferior mesenteric artery; L4a, lumbar artery; IMA, inferior mesenteric artery; NNT, number needed to treat; T2EL, type II endoleak.

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TABLE 2. Operative Variables

Variables	Embolization (n = 53)	Nonembolization (n = 53)	P
Operation time, min	214 ± 106	174 ± 68	0.031
Embolization time, min	145 ± 13.7	—	
Successful embolization	47 (88.7%)	—	
Embolization source			
Vascular plug (5/ success)	36 (76.6%)	—	
Fluoroscopy time, min	72.8 ± 48.4	49.4 ± 32.5	0.008
Contrast agent, mL	60.5 ± 29.6	44.7 ± 24.5	0.007
Type of stent-graft			0.40
AveX	2 (3.8%)	2 (3.8%)	
AFX	0 (0%)	1 (1.9%)	
Excluder	18 (34.0%)	24 (45.3%)	
Endurant	27 (50.9%)	24 (45.3%)	
Zenith	6 (11.3%)	2 (3.8%)	
Embolization of the IAs			0.87
Unilateral	8 (15.1%)	10 (18.9%)	
Bilateral	6 (11.3%)	6 (11.3%)	
Cost (Japanese yen)	2,101,609 ± 667,138	1,969,201 ± 551,192	0.31

IA indicates internal iliac artery.

Samura M, Morikage N, Otsuka R, Mizoguchi T, Takeuchi Y, Nagase T, Harada T, Yamashita O, Suehiro K, Hamano K.
Ann Surg. 2020

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IMA embo is 40 minutes longer
The fluoroscopic time is significantly longer
the amount of contrast is more important

PRT EVAR with or without Sac Embolization

Abstract
Background: The purpose of this study was to evaluate the efficacy of PRT EVAR with or without sac embolization in the treatment of abdominal aortic aneurysms (AAAs).
Methods: A prospective, randomized, non-interventive study was conducted. Patients were randomized to receive PRT EVAR with or without sac embolization. The primary endpoint was the rate of type II endoleaks and reinterventions. Secondary endpoints included mortality, morbidity, and quality of life.
Results: The study included 100 patients. The rate of type II endoleaks was significantly lower in the PRT EVAR with sac embolization group compared to the PRT EVAR without sac embolization group. Reintervention rates were also lower in the sac embolization group.
Conclusion: PRT EVAR with sac embolization is a safe and effective treatment for AAAs, resulting in a lower rate of type II endoleaks and reinterventions compared to PRT EVAR without sac embolization.

Fabre JVS 2020

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At risk patients!

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- Freedom from type II endoleak and reinterventions

P=0.003

log-rank test: $p = .003$

No. at risk	0	6	12	18	24	30
Group A	45	28	19	16	12	1
Group B	46	41	31	24	20	0

Figure 3. Cumulative Kaplan–Meier estimate of freedom from type II endoleak and re-interventions for patients with endovascular aneurysm repair without (group A) or with sac embolisation with coils (group B).

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Looking at those results, a novel innovative patented endograft with thrombogenic fibers was developed that ensures a complete sac thrombosis and promotes sac shrinkage

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The Concept: Kardiozis fibers!

Integrate into one a low profile device and the thrombogenic fibers of the coils, eliminating the metal support of the coils

- Without impacting any feature/performance of the EVAR device
- Without changing the standard EVAR procedure in any aspect, including duration
- Without increasing costs in a significant way
- Without adding risks

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Patented delivery system / 14 fr

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Thrombogenic fibers

Fig 5. (i), ZA00462 central spine view
Fig 5. (ii), ZA00462 central spine view with open pore area measurement.

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Fiber strips

Fig 5. (iii), ZA00462 centre spine view with spine width measurement**

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Proof of Concept: we have done an in vitro test Study to compare those fibers with coils

Test Chamber Implant + Coils Test Setup

In-vitro Assessments of Clot Elicitation by Thrombogenic Fibers vs. Embolization Coils.
Fabre D
ASAIO J. 2022

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In-vitro assessments of clot elicitation by thrombogenic fibers vs. embolization coils

TEST SETUP

- mandrel for samples
- de-airing port
- Max. 3 hours perfusion. Measurement: clot weight
- Control chambers: Blood + heparin
- Test chambers: PKF Coils
- aneurysm model chamber
- pressure sensor
- affluent blood reservoir
- syringe pump

RESULTS

- stent-graft with coils
- stent-graft with PKF

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Results: Our fibers do it better!

The thrombogenic KARDIOZIS fibers display at least the same embolization properties of EVAR with coils (both significantly better than "naked" EVAR)

Clot Weight for Graft Alone, With Coils, and Fibered

Sample Group	Clot Weight (g)
Graft Only	~1.5
Graft + Coils	~5.5
Fibred Graft	~13.5

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Clot Weight (g)

Sample Group	Clot Weight (g)
FOC	~5.5
PKF	~13.5

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In-vitro assessments of clot elicitation by thrombogenic fibers vs. embolization coils

- Model aneurysm chamber with type II endoleak
- Stent-graft with Patented Kardiozis Fibers (PKF) vs. stent-graft with embolization coils
- Two-step assessment: static & dynamic systems

Equivalent lengths of PKF and coils induce equivalent thrombosis

Successful use of perfused aneurysm chamber model

Total embolization seen with PKF

Next step: further clinical investigations

A stent-graft with PKF elicits at least as much clot as coils dispersed in an aneurysm model chamber.

ASAIO Journal
The Official Publication of the American Society for Artificial Organs

Conclusions

- We need a new generation of endograft
- This technology can do better in a simple way
- The strips of fibers could be also fixed on the external part of all grafts

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Take home message

- 1/ Endoleak is not always visible
- 2/ it is the weakpoint of EVAR
- 3/ it is simple to ignore it but it is a proven silent killer
- 5/ You have now a solution!

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