Current strategies to minimize SCI with TAAA repairs, Endo and Open: Updated status of intercostal embolization as preconditioning to prevent ischemia (MIS²ACE):

Progress of the PAPAartis RCT

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PAPAartis fighting spinal cord injury

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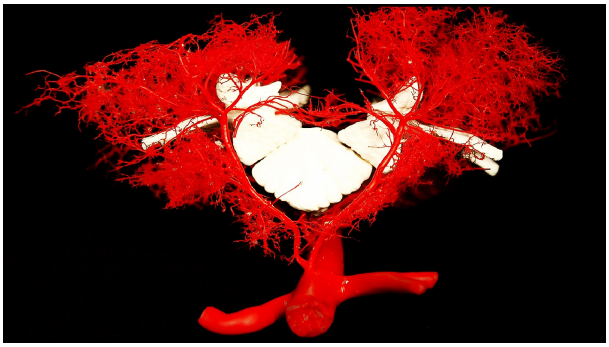
The author declares no conflict of interest

The presented work is part of the Heisenberg focus project 'Spinal Cord Protection' for Aortic Surgery funded by the German Research Foundation (DFG) and the PAPAartis RCT is funded by the EU Horizon 2020 program



Rationale for MIS²ACE

Identification of the Collateral Network

→ ***lead to the concept of staged ‚re-routing' of arterial blood flow to avoid sudden ischemic insults***

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→ ***lead to the concept of staged ‚re-routing' of arterial blood flow to avoid sudden ischemic insults***

→ ***regional arteriogenesis***

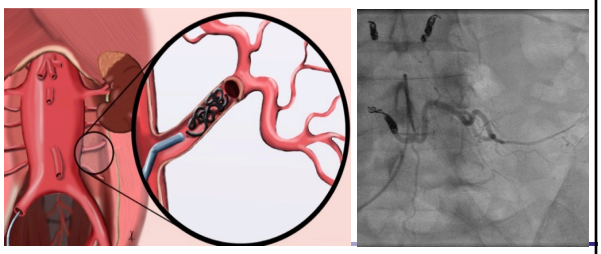
Staged repair significantly reduces paraplegia rate after extensive thoracoabdominal aortic aneurysm repair

Christian D. Etz, MD, PhD,[a] Stefano Zoli, MD,[a] Christoph S. Mueller, MS,[a] Carol A. Bodian, DrPH,[b] Gabriele Di Luozzo, MD,[a] Ricardo Lazala, MD,[a] Konstadinos A. Plestis, MD,[a] and Randall B. Griepp, MD[a]

Open surgery, staged repair:
SCI reduction from 15% to 0%

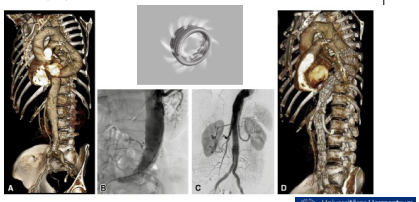
Technique of MIS²ACE

Staged ‘segmental artery (S²)’ occlusion = MIS²ACE



First-in-man endovascular preconditioning of the paraspinal collateral network by segmental artery coil embolization to prevent ischemic spinal cord injury

Christian D. Etz, MD, PhD,[a] E. Sebastian Debus, MD, PhD,[b] Friedrich-Wilhelm Mohr, MD, PhD,[a] and Tilo Kölbel, MD, PhD[b]



Universitäres Herzzentrum Hamburg

Preliminary clinical evidence for MIS²ACE

Ischaemic preconditioning of the spinal cord to prevent spinal cord ischaemia during endovascular repair of thoracoabdominal aortic aneurysm: first clinical experience

Demographics		N (%)
Sex	Male	43 (75)
Age, years	Mean±SD	69.0±7.5
Cardiovascular risk factors		
Hypertension		57 (100)
Chronic pulmonary disease		19 (33)
Smoker		39 (68)
Coronary artery disease		22 (38)
Diabetes mellitus		21 (36)
Renal insufficiency	GFR <60 mL/min/1.73 m²	20 (35)
	Mean GFR±SD (mL/min/1.73 m²)	68.9±19.3
Peripheral artery disease		10 (17)
BMI, kg/m²	Mean±SD	27.7±5.1
Aneurysm characteristics		
Crawford classification	Type I	5 (8.8)
	Type II	12 (21.1)
	Type III	27 (47.3)
	Type IV	13 (22.8)
Maximal aortic diameter, mm	Mean±SD	62.7±8.8
Previous repair of the aorta		
Thoracic aorta	Open repair	5 (8.7)
	Open and endovascular repair	2 (3.5)
Abdominal aorta	Open repair	3 (5.2)
	Median interval between 2 staged procedures (years)	6.5 (0.5-18)
Aetiology		
Atherosclerotic		54 (94.7)
Dissection		3 (5.3)

MIS²ACE – PRELIMINARY CLINICAL EVIDENCE
The Leipzig Experience

Sept 2014 – Dec 2017 (N=57, 39 type II or III)

		1 session	2 sessions	3 sessions	4 sessions	5 sessions
Patients (n)		22	24	7	3	1
Coiling of the inferior mesenteric artery (n)		20	2	1	0	0
Coiled SA (n)	Total	188	96	23	7	5
	Median (range)	3 (1-6)	3 (0-6)	2 (0-5)	2 (1-2)	5
Procedure time, min	Mean±SD	112.7±47.3	112.4±53.5	67.7±45	82.5±40.4	215
Radiation time, min	Mean±SD	36.7±15.6	32.2±18.7	21.7±12.2	24±3.6	59
Contrast, ml	Mean±SD	101±44.4	100.7±57.1	68.7±28	63.7±18	174

NEUROLOGICAL COMPLICATIONS

None of the fifty-four patients alive after the complete exclusion of their aneurysm developed spinal cord ischaemia. One patient developed dysarthria due to a post-interventional minor stroke. She recovered completely before discharge on the tenth postoperative day.

Evolution of MIS²ACE

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... largest publicly funded RCT in aortic aneurysm repair

- 17 (+14) Aortic Reference Centres
- prospectively collect contemporary real-world data on SCI incidence (type I, II, III; open + endo)
- comparing ‚staged' vs. ‚institutional' approach
- evaluating effectiveness of MISACE:
  – SCI protection *& endoleak type II prevention*

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5 year duration | 500 participants | 31 recruiting sites in 9 countries

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733203 and the German Research Foundation.

DFG

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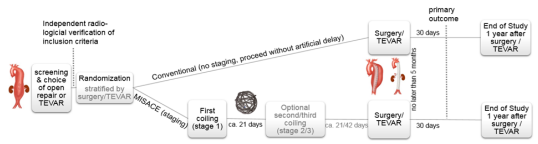
Trial duration

First patient in to last patient out (months): 40
Duration of the entire trial (months): 46
Recruitment period (months): 24



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1. CH: Bern
2. DE: Freiburg
3. DE: Hamburg
4. DE: Leipzig
5. FR: Bordeaux
6. FR: Lille
7. IT: Bologna
8. IT: Milan
9. NL: Maastricht
10. PL: Zabrze
11. SE: Malmö
12. SE: Örebro
13. UK: Liverpool
14. US: Houston
15. US: Philadelphia
16. DE: Munich
17. DE: Warsaw

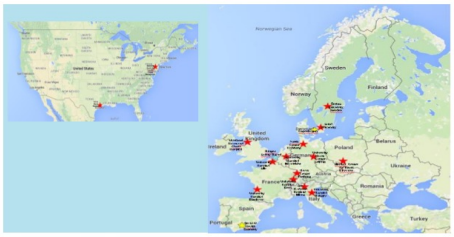

Figure 10 - Participating centres PAPA-ARTIS (EU, Switzerland and the US). Red stars represent recruitment centres and the yellow stars represent the radiology core lab (Copenhagen, WP6) and the health economics group (Grenada, WP3).

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1: Aachen
2: Bern
3: Essen
4: Freiburg
5: Hamburg (UKE)
6: Hanover (MHH)
7: Heidelberg
8: Innsbruck
9: Leipzig
10: Munich
11: Münster
12: Nuremberg
13: Vienna
14: Regensburg

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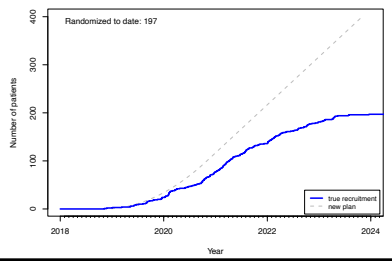
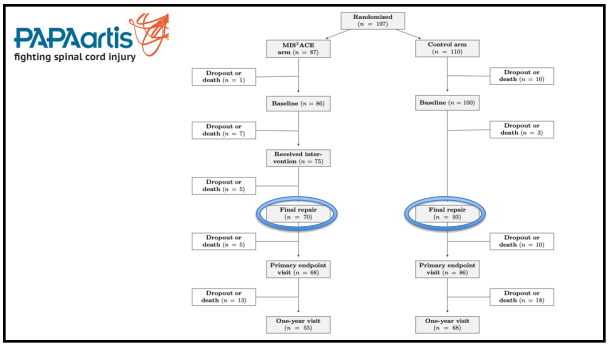
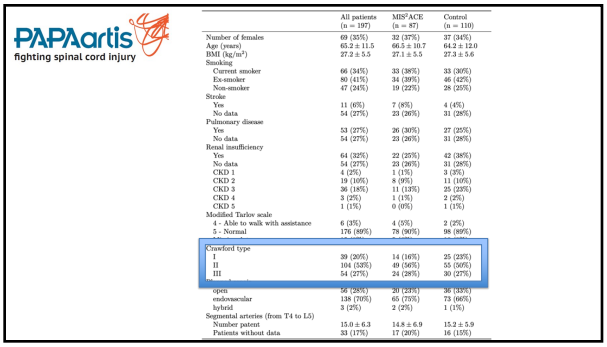
Status of the RCT

Recruitment in PAPAartis (2024–11–13)







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	All patients (n = 197)	MIS²ACE (n = 87)	Control (n = 110)
Number of females	69 (35%)	32 (37%)	37 (34%)
Age (years)	65.2 ± 11.5	66.3 ± 10.7	64.2 ± 12.0
BMI (kg/m²)	27.2 ± 5.5	27.1 ± 5.5	27.3 ± 5.6
Smoking			
Current smoker	66 (34%)	33 (38%)	33 (30%)
Ex-smoker	80 (41%)	34 (39%)	46 (42%)
Non-smoker	47 (24%)	19 (22%)	28 (25%)
Stroke			
Yes	11 (6%)	7 (8%)	4 (4%)
No data	54 (27%)	23 (26%)	31 (28%)
Pulmonary disease			
Yes	53 (27%)	26 (30%)	27 (25%)
No data	54 (27%)	23 (26%)	31 (28%)
Renal insufficiency			
Yes	64 (32%)	22 (25%)	42 (38%)
No data	54 (27%)	23 (26%)	31 (28%)
CKD 1	4 (2%)	1 (1%)	3 (3%)
CKD 2	19 (10%)	8 (9%)	11 (10%)
CKD 3	36 (18%)	11 (13%)	25 (23%)
CKD 4	3 (2%)	1 (1%)	2 (2%)
CKD 5	1 (1%)	0 (0%)	1 (1%)
Modified Tarlov scale			
4 - Able to walk with assistance	6 (3%)	4 (5%)	2 (2%)
5 - Normal	176 (89%)	78 (90%)	98 (89%)
Crawford type			
I	39 (20%)	14 (16%)	25 (23%)
II	104 (53%)	49 (56%)	55 (50%)
III	54 (27%)	24 (28%)	30 (27%)
open	56 (28%)	20 (23%)	36 (33%)
endovascular	138 (70%)	65 (75%)	73 (66%)
hybrid	3 (2%)	2 (2%)	1 (1%)
Segmental arteries (from T4 to L5)			
Number patent	15.0 ± 6.3	14.8 ± 6.9	15.2 ± 5.9
Patients without data	33 (17%)	17 (20%)	16 (15%)

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> 115 MIS²ACE procedures performed

	Session I	Session II	Session III
Number of patients	75	32	9
Dosis area product (Gy × cm²)	148 ± 142	693 ± 3127	137 ± 136
Duration of session (hours)	1.9 ± 0.9	1.8 ± 0.9	2.0 ± 1.3
Number of occluded SA (not pairs)	3.0 ± 2.2	2.9 ± 1.8	2.8 ± 1.7
> 7 pairs occluded	0	0	0
Number of sessions terminated early	5	2	1
Number of sessions with complications	2	2	0

Zero MIS²ACE induced severe Cx (i.e. paraparesis)

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NEXT (and final) STEPS

Final results to be presented
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