

Spinal ischemia session

How many stages is enough?

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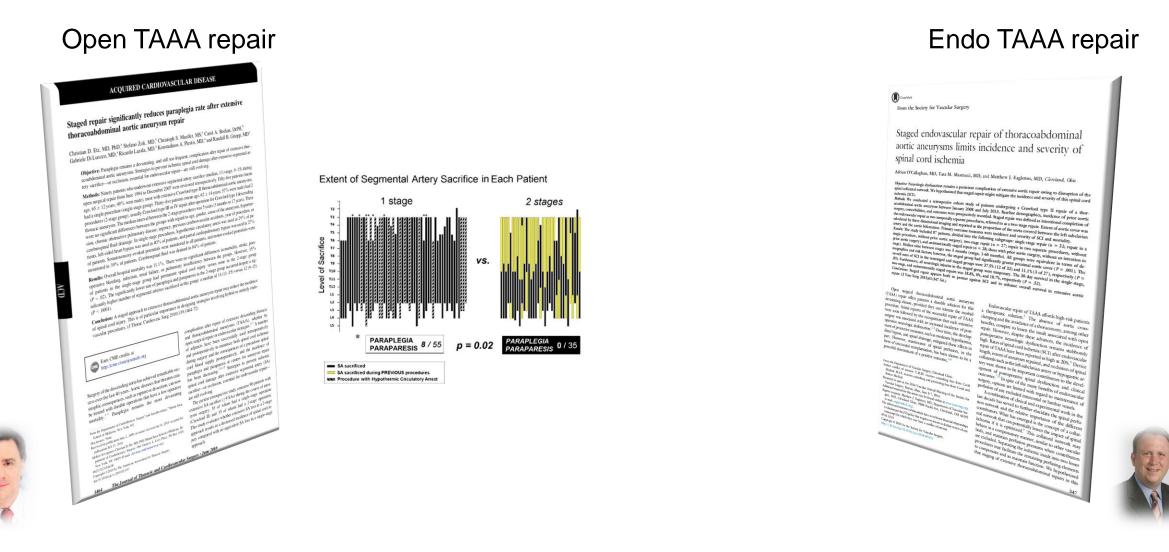
Disclosures

- Co-PI / research coordinator for thoracic and abdominal aortic stent graft trials (Cook[®], Cardinal health, TrivascularTM, Medtronic, Gore[®])
- Participated as a lecturer at symposia hosted by Cook[®], Cardinal health, Jotec Gmb, Gore[®].
- Consultant for Cook®, Jotec Gmb, Cardinal health

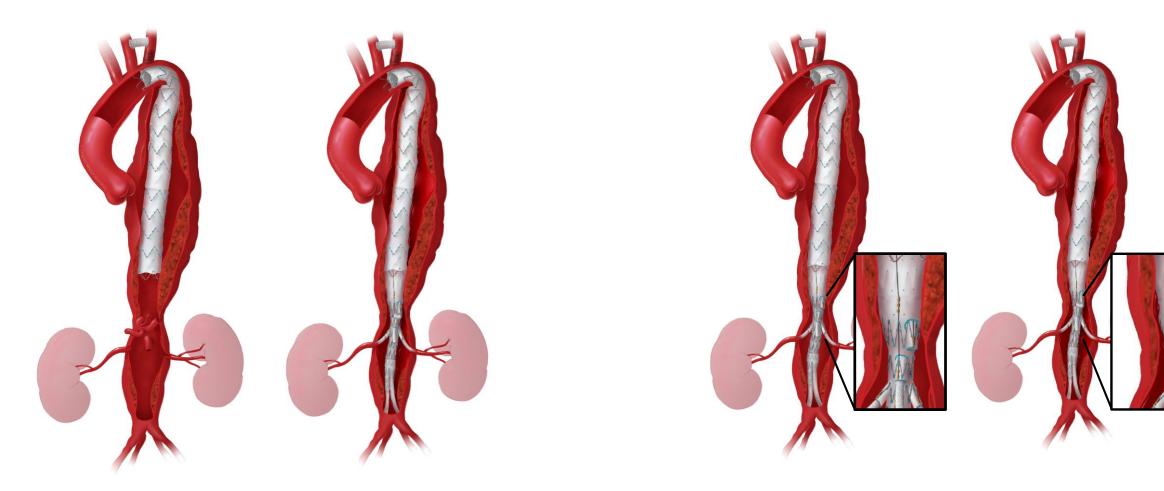




Spinal preconditioning with procedural staging



Two steps staging protocols: TEVAR first / TASP

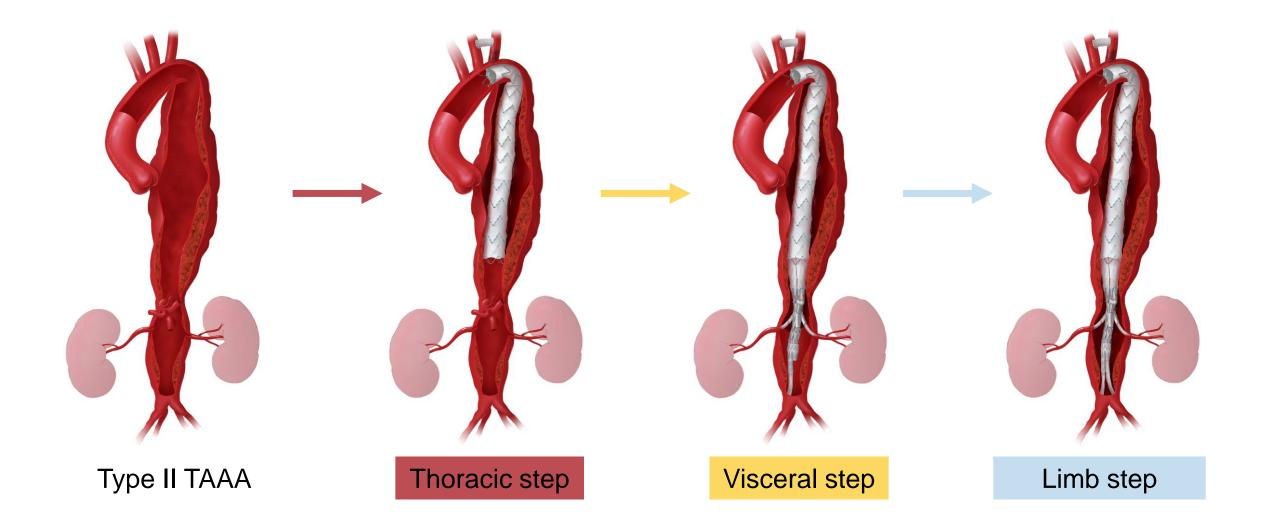


Temporary Aneurysm sac perfusion (TASP)

Proximal stent-grafting

Harrison SC et al. J Vasc Surg 2012

Three-step staged protocol





Only therapeutic CSFD drainage in elective cases

- No prophylactic / preoperative CSFD
- Only therapeutic / postoperative CSFD
- Automated drainage



Liquogard Monitoring: < 10 cmH₂O; max flow 20 mL/h



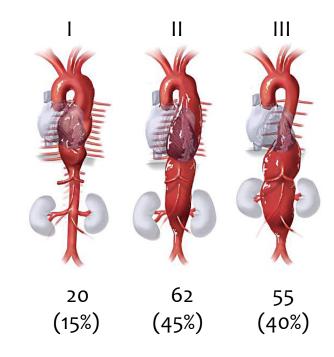


Updated Type I-II-III TAAA elective experience

137 cases (Jan. 2013 – December 2021)

Age (years)	73 (IQR 68 – 78)
Male	72%
Hypertension	92%
Smoking	74%
Hyperlipemia	64%
Diabetes	12%
$CAD \ge 1 (SVS/AAVS)$	56%
$COPD \ge 1 (SVS/AAVS)$	75%
Renal \geq 1 (SVS/AAVS)	47%
Renal stage <u>></u> II	86%
II (GFR 60-89 mL/min)	39%
III (GFR 30-59 mL/min)	43%
IV (GFR 15-29 mL/min)	5%
V (GFR < 15 mL/min)	4%

Crawford Classification



Mean diameter: 61 (IQR 55-68) Post-dissecting= 33 (24%)





Mortality / Spinal cord ischemia results

Mortality 7.3% - Permanent paraplegia 3.6%

Outcome	Type I (n=20)	Type II (n=62)	Type III (n=55)	Overall (n=137)
In-hospital mortality	2	1	3	6 (4.4%)
Intersurgical death*	1	3	0	4 (2.9%)
Permanent SCI	0	3	2	5 (3.6%)
Temporary SCI	4	10	5	19 (13.9%)

*All aneurysms > 8 cm: 3 ruptures and 3/4 CMD devices





Literature waiting time rupture / death

During the waiting time of CMDs

CLINICAL RESEARCH STUDIES				Apra and Major Branches Eur J Vanic Endovasic Surg (2020) 60, 44 - 48
From the Society for Vascular Surgery The risk of aneurysm rupture and target visceral vessel				Aneurysm Rupture and Mortality During the Waiting Time for a Customised Fenestrated/Branched Stent Graft in Complex Endovascular
				Aortic Repair
fenestrated/Dictar Faggioli, MD. Paolo Spath, NO, and Mauro Cargiulo, NO, and Andre Cargiulo, Andre Cargiulo, NO, and Andre Cargiulo, Andre Cargiulo, Andre Cargiulo, Andre Cargiulo, Andre Cargiulo,	Gallitto et al.		Katsargyris et al.	A unelin Katagini ", Vanali Uhbupkense, Palio Mangues de Marino, Balazs Botos, Eric L. Verhoeven In univers el vincula ad fotoseolar Sogers Pracelius Medical University Riverborg, Gerenal Hospital Narenborg, Germany
Sterner moliuate ludvense events occurring during the laid period	(n=141)		(n=906)	WHAT THIS PAPER ADDS Treatment of antic pathology by customised fenestrated/branched endovascular aneurysm repair (F/BEVAR) can be disped by weral factors including decision making time, graft plan design, manufacturing and delivery of the steet graft. The consequences of this delay are not well described in the literature. This single centre waiting time for contender FARS and the prevalence of aneurysm repture and complexitient.
ASSTRACT Objective: The deleticities of this study and the standard standard standard standard study and the standard s	5 (3.8%)	Ruptures	16 (1.8%)	walling time for outsmixed //FEWA. The study suggests that aneurysm rupture and complications during the relatively rate, but more common in patients with larger aneurysm. Potential measures to reduce the waiting time and the risk of rupture are proposed.
default main (MV) device any anyority to plant 3. compared some plant in anyone and the extension of the end	2 (1.4%)	Un-related death	22 (2.4%)	Objective: Treatment of complex acritic pathologies with outcomised fenestrated/branched stent grafts (F/ EVAN) is associated with a longer waiting time to the procedure. This study aimed to investigate the prevainer al anexymm nature and morality during the waiting time for a fenestrated/branched stent grafts (F/ Methods: All patients with a parameni (PAA), thoraco-abdominal (TAAA), or aortic arch anexymm planned to be ref r/BiVAR with the procedure allowed and December 2018 were included. Patients planned 65:110 (underwise the procedure of F/BiVAR during the study and and //BiVAR for exclusioned for the direct of F/BiVAR during the study and (FAX) and ensures the procedure of a funding for F/BiVAR during the study and //BiVAR for exclusioned for the direct of F/BiVAR during the study and and the study and the study and (FAX) and the startymm, in = 200 for f/BiVAR during the study and the study.
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Conclusions in our division reasons reasons for particular and reactive reaction in the concentration of the conc	6 (5.2%)	Any intersurgical death	38 (4.2%)	and a soft also metanome and integer and and the waiting time waiting titem waiting time waiting time waiting time waiting time waiting
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Literature waiting time rupture / death

During the waiting time of CMDs

CLINICAL RESEARCH STUDIE From the Society for Vascular Surgery The risk of aneurysm rupture and target visceral vessel occlusion during the lead period of custom-made fenestrated/branched endograft

"...diameter may be at higher risk of rupture. Measures to reduce the risk of rupture during the waiting time might include the use of off the shelf devices for larger aneurysms."

"...there is a **high risk** of both rupture in **aneurysms** >70 mm ... These factors should be considered in the indication for custom-madefenestrated/branched endograft repair."

Eur J Vasc Endovasc Surg (2020) 60, 44 48

Aneurysm Rupture and Mortality During the Waiting Time for a Customised Fenestrated/Branched Stent Graft in Complex Endovascular Aortic Repair

Pablo Marques de Marino, Balazs Botos, Eric L. Verhoe

by several factors including decision making time, graft plan design, manufact e stent graft. The consequences of this delay are not well described in the literature. This sing provides further insight into the prevalence of aneurysm rupture and complications d energy proves turner imagine must be prevented by suggests that aneurysm rupture during the ore common in patients with larger aneurysms. Potential n

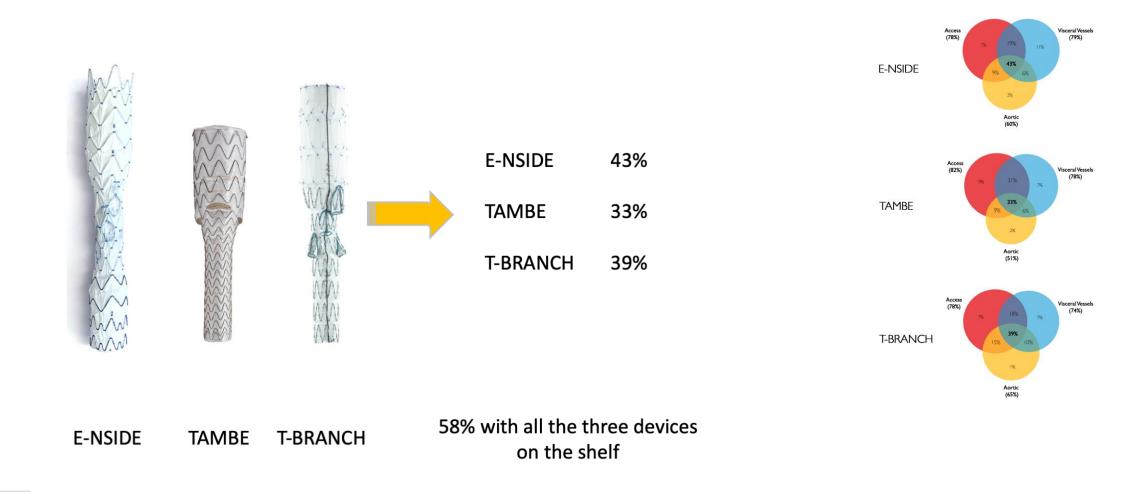


New off-the-shelf TAAA devices

58% of TAAAs are treatable within IFUs

OFF-THE-SHELF MULTIBRANCHED STENT-GRAFT

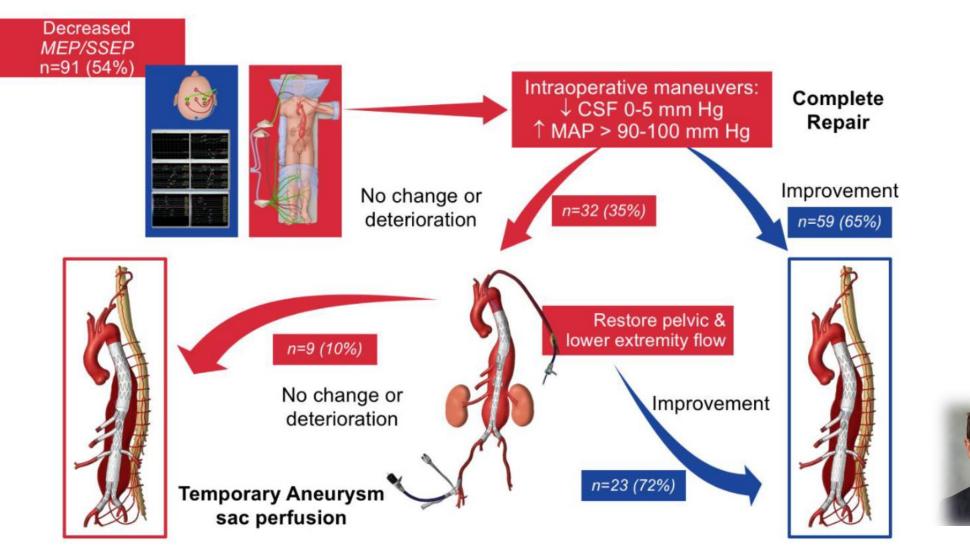
OVERALL FEASIBILITY





Selective staged procedures based on MEP /SEPs

TEVAR first in 18% of the cases + selective TASP in 10% of the cases with 96% of CSFD





Banga et al. J Endovasc Ther 2016 Tenorio. Ann Surg 2021

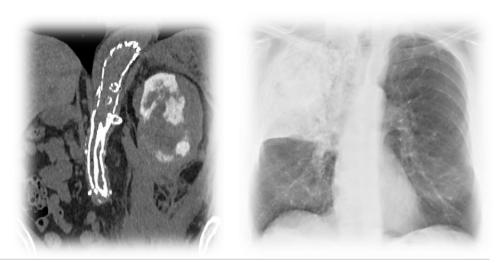
Spinal cord postoperative possible triggers

No aneurysm exclusion during the more complex step

Final sac exclusion without precipitating SCI factors:

- Hypotensive state
- Anemia
- Cardiopulmonary complications





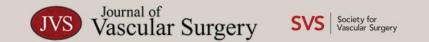




Identify high-risk patients subgroups requiring staging



	Overall (n=596)
ТААА	252 (42%)
Туре І	32 (14%)
Туре II	103 (45%)
Type III	96 (42%)
Type V	21 (8%)
Complex Abdominal	334 (56%)
Type IV	89 (27%)
JAAA	124 (37%)
Pararenal	121 (36%)
Visceral aortic patch	10 (2%)
Elective	521 (86%)
Urgent / Emergent	75 (13%)
Ruptured	16 (21%)
Symptomatic	11 (15%)
> 8 cm	48 (64%)



FULL LENGTH ARTICLE | ONLINE FIRST

Role of historical and procedural staging during elective fenestrated and branched endovascular treatment of extensive thoraco-abdominal aortic aneurysms

Luca Bertoglio, MD $\[LocalCondot]$ Andrea Kahlberg, MD • Enrico Gallitto, MD • ... Mauro Gargiulo, MD • Roberto Chiesa, MD • On behalf of the Italian Multicenter Fenestrated and Branched (IMF&B) study's group • Show all authors

Published: November 30, 2021 • DOI: https://doi.org/10.1016/j.jvs.2021.11.056



Cohort selection criteria (240 extensive TAAA)

INCLUSION

- Extensive TAAA (Crawford/Safi Type I, II, III and V)
- Elective

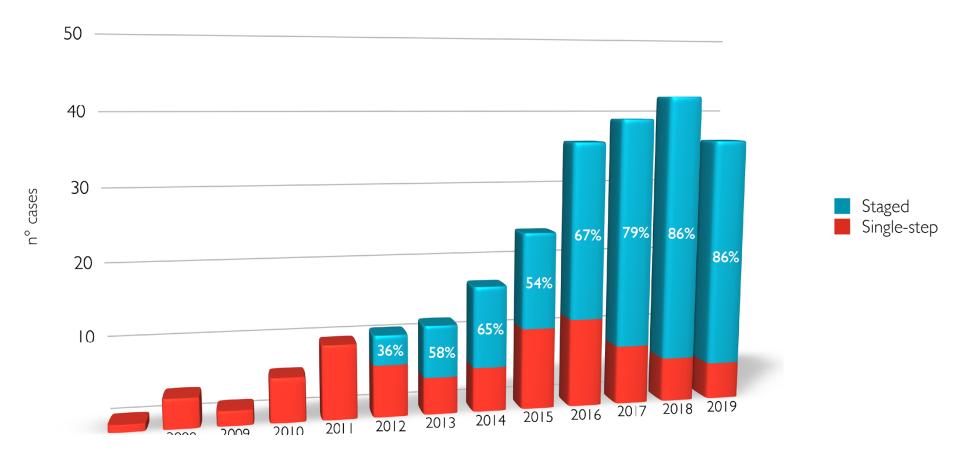
EXCLUSION

- Complex abdominal aneurysms (juxtarenal, pararenal and type IV)
- Ruptured
- Visceral aortic patch in previous TAAA open repair

Preoperative risk factors	Overall n=240
Age, years	73 (68-77)
Male	183 (76%)
Hypertension (grade ≥1)	232 (97%)
Smoking habit (grade ≥1)	171 (72%)
Diabetes (grade ≥1)	65 (27%)
Hyperlipidemia (grade ≥1)	155 (65%)
Renal status (grade ≥1)	82 (34%)
Pulmonary status (grade ≥1)	161 (67%)
Cardiac status (grade ≥1)	110 (46%)
Brain status (grade ≥1)	65 (27%)
SVS score, points	8 (6-12)
ASA score = 4	103 (43%)
Aneurysm diameter, mm	63 (58-70)
Post-dissecting	34 (14%)
Connective tissue disorders	8 (3%)

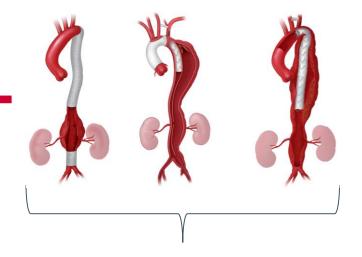
Cohort procedural staging: 136 (57%)

Elective extensive TAAA per year performed with a staged approach



Previous aortic surgery = historical staging

Preoperative status	Overall n=240
LSA stenosis >75% or occlusion	6 (3%)
Any thoracic or abdominal aortic surgery	136 (57%)
Branched endovascular arch	1 (1%)
Frozen elephant trunk	9 (4%)
Thoracic endovascular repair	25 (10%)
Open thoracic repair	12 (5%)
Open thoraco-abdominal	13 (5%)
Open abdominal repair	89 (37%)
Abdominal endovascular repair	13 (5%)
Any HA stenosis >75% or occlusion	37 (15%)
Bilateral iliac occlusive disease	14 (6%)



EVAR TEVAR Open AAA Open DTA FET

Spinal cord ischemia: Uni- and Multivariable analysis

Only p values <.01

Outcome	Univariable analysis	Multivariable analysis			
	Risk factor	P value	OR	95%Cl	P value
	Female gender	.051			
	Pulmonary status ≥1	.047			
Spinal Cord complications Grade = 3 (Permanent)	Previous thoracic or abdominal aortic repair	.002	0.02	0.001 - 0.461	.014
	Any LSA or HA stenosis>75% or occlusion	.047	17.27	1.7 - 175.8	.016
	Bilateral iliac occlusive disease	.008	10.14	1.05-98.32	.046
	Procedural staging	.036	0.01	0.021 - 0.7	.019
	Red blood cells transfusion visceral stage	.021	1.37	1.07 - 1.76	.014
	Any postop. renal complications	<.001	6.49	1.20 - 35.0	.030

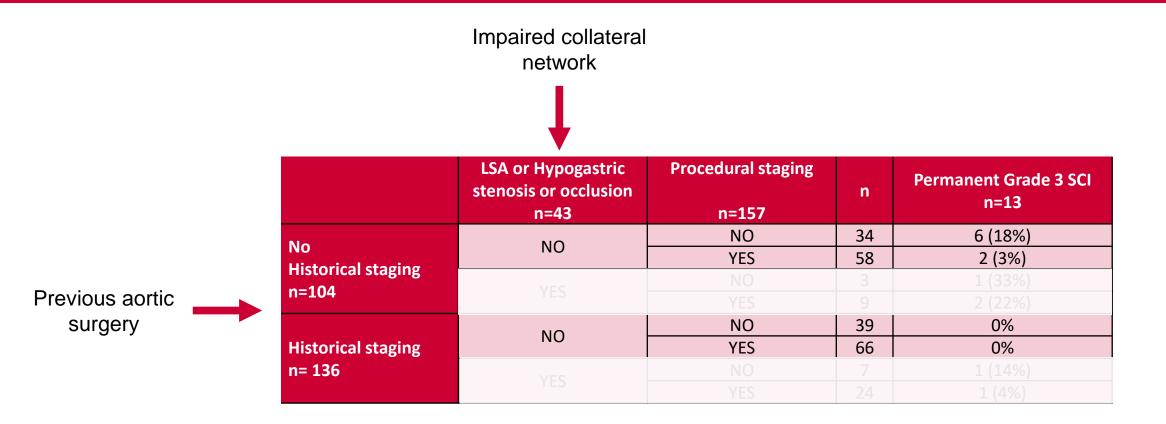
Procedural staging in historical staged patients

	No Hi	storical stagin n=104	g	Historical staging n=136			
	No Procedural Staging n=37	Procedural Staging n=67	p value				
Hypertension (grade ≥1)				44 (96%)	90 (100%)	.046	
Diabetes (grade ≥1)	9 (25%)	18 (27%)	.050				
Pulmonary status (grade ≥1)				27 (59%)	68 (76%)	.043	
Brain status (grade ≥1)				7 (15%)	28 (32%)	.041	
TAAA V extent	6 (16%)	3 (5%)	.042				
Any LSA or HA stenosis >75% or occlusion	3 (8%)	9 (13%)	.421	7 (15%)	24 (27%)	.134	
Bilateral iliac occlusive disease	3 (8%)	6 (9%)	.931	2 (4%)	3 (6%)	.815	
Any preoperative CSFD	18 (49%)	39 (60%)	.277	28 (61%)	45 (51%)	.280	
Any Mortality	3 (8%)	5 (8%)	.906	3 (7%)	7 (8%)	.791	
Any systemic complication ≥1	19 (51%)	27 (40%)	.277	24 (52%)	39 (43%)	.328	
Any temporary or permanent SCI	9 (24%)	9 (13%)	.160	7 (15%)	15 (17%)	.828	
Permanent grade 3 SCI	7 (19%)	4 (6%)	.040	1(2%)	1 (1%)	.626	
Cerebrovascular complications	1 (3%)	4 (6%)	.456	0%	5 (6%)	.103	
Cardiac complications	4 (11%)	7 (10%)	.954	8 (17%)	13 (14%)	.653	
Pulmonary complications	8 (22%)	13 (19%)	.787	15 (33%)	20 (22%)	.190	
Renal complications	15 (41%)	17 (25%)	.109	10 (22%)	19 (21%)	.933	
Bowel complications	1 (3%)	4 (6%)	.456	1 (2%)	2 (2%)	.986	
Number of RBC transfusion	1 (0-2)	2 (1-7)	.005	1 (0-4)	3 (0-5)	.071	

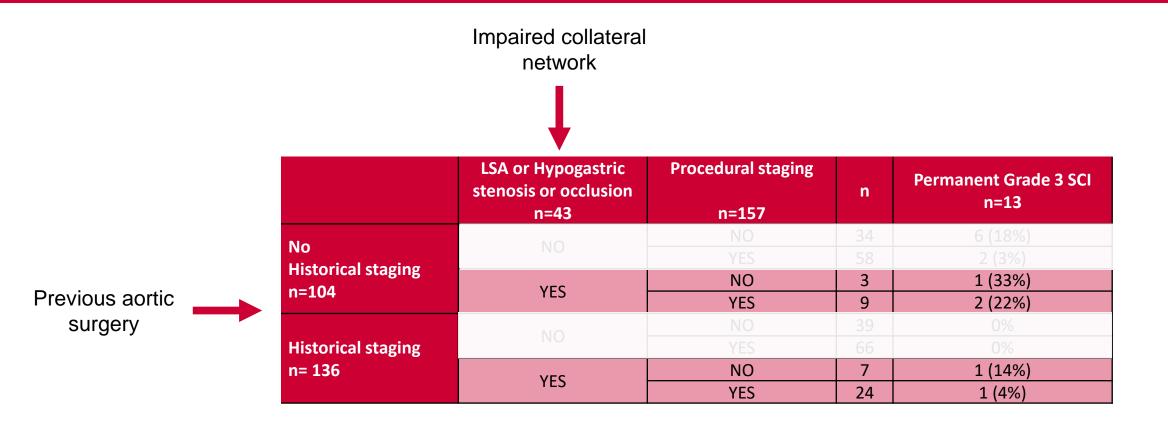
Procedural staging in historical staged patients

	No Historical staging n=104			Hist	orical staging n=136	
				No Procedural Staging n=46	Procedural Staging n=90	p value
Hypertension (grade ≥1)				44 (96%)	90 (100%)	.046
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Role of collateral network impairment



Role of collateral network impairment



Staged vs Multistaged (unpublished data)

157 patients

	Two	stages	Three stages	
	+ TEVAR + TASP		+ TEVAR	P value
			+ TASP	
	n=77	n=45	n=35	
Preoperative risk factors				
Diabetes	27 (35%)	4 (9%)	17 (49%)	<.001
ASA score = 4	26 (34%)	28 (62%)	9 (26%)	.004
TAAA I extent	20 (26%)	0%	5 (14%)	.002
Any aortic previous aortic surgery	50 (65%)	22 (49%)	18 (51%)	.413
Any preoperative CSFD	43 (56%)	33 (73%)	10 (29%)	<.001
30-day outcomes				
Clinical success	60 (78%)	32 (71%)	28 (80%)	.932
Any Mortality	6 (8%)	5 (11%)	1 (3%)	.768
In-hospital	4 (5%)	3 (7%)	0%	.693
Intersurgical	2 (3%)	2 (4%)	1 (3%)	.996
Any MAE <u>></u> 1	30 (39%)	23 (51%)	13 (37%)	.711
Any spinal cord ischemia	13 (17%)	6 (13%)	5 (14%)	.997
Permanent spinal cord deficit	2 (3%)	2 (4%)	1 (3%)	.996
Cerebrovascular complications	4 (5%)	3 (7%)	2 (7%)	.575
Cardiac complications	10 (13%)	5 (11%)	5 (14%)	.999
Pulmonary complications	14 (18%)	12 (27%)	7 (20%)	.898
Renal complications	12 (16%)	18 (40%)	6 (17%)	.016
Bowel complications	2 (3%)	2 (4%)	2 (6%)	.974
Number of RBPC transfusion	2 (0-4)	5 (2-10)	2 (1-5)	.004



AN RAFFAELE

- Vascular Surgery



Conclusions – How many Stages???

- Both historical and planned procedural staging were associated with a reduction of permanent SCI
- No additional benefit was observed when a procedural staging was performed in patients with historical staging <u>and</u> intact collateral network

- The number of stages should be influenced by the collateral network status and by the use of prophylactic CSFD use









Procedural staging in historical staged patients

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