Self-expandable bridging stent-grafts for F/BEVAR in TAAA: long-term outcomes and evolution

Gioele Simonte
Vascular and Endovascular surgery Unit
Santa Maria della Misericordia University Hospital
Perugia,Italy

Speaker name: Gioele Simonte

X I have the following potential conflicts of interest to report:

- ☐ Receipt of grants/research support:
- *X* Consultant for Artivion, Penumbra, Shockwave, Cordis, Scitech
- ☐ Participation in a company sponsored speakers‘ bureau
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company

☐ I do not have any potential conflict of interest for this presentation

Durability of branches in branched and fenestrated endografts

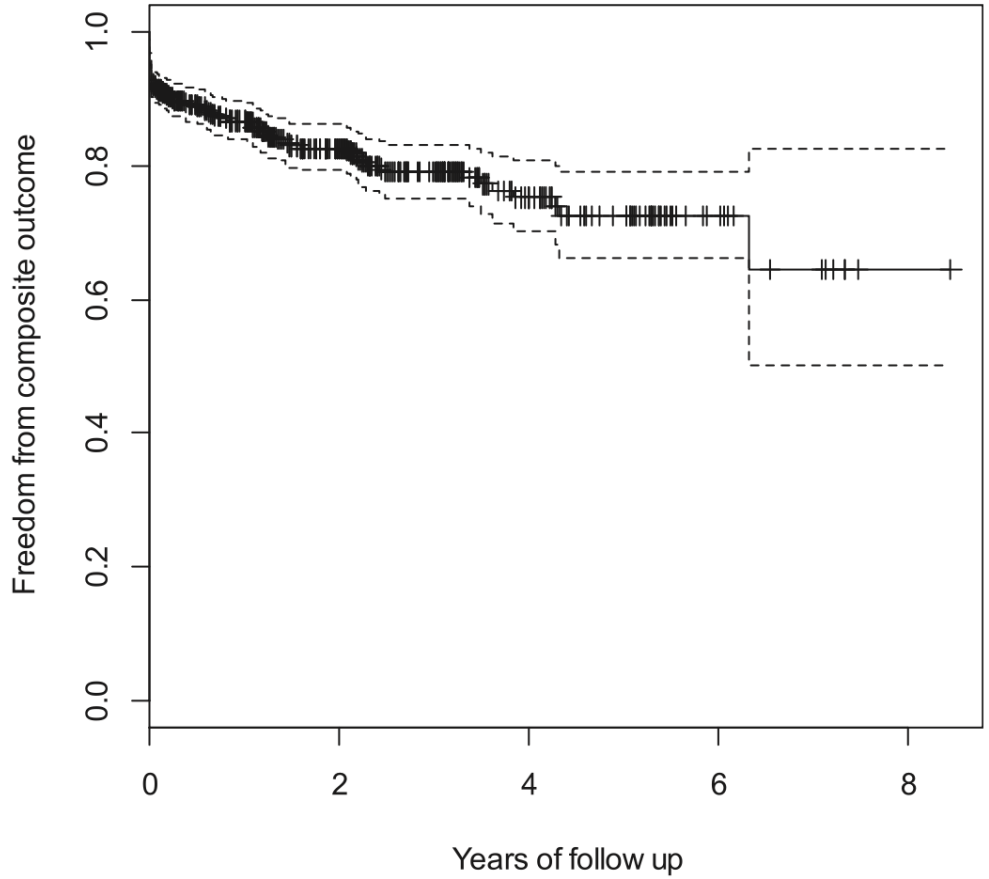
(J Vasc Surg 2013;57:926-33.)

Tara M. Mastracci, MD, Roy K. Greenberg, MD, Matthew J. Eagleton, MD, and **Adrian V. Hernandez, PhD,**
Cleveland, Ohio

1679 TVVs

3 years mean follow up

Freedom from TVV instability 84%@ 5 yrs



Year of follow-up	0	1	2	3	4	5	6	7	8
Patients at risk	615	377	258	157	74	51	39	9	1

Fate of target visceral vessels in fenestrated and branched complex endovascular aortic repair

Aaron Thomas Fargion, MD,[a] Davide Esposito, MD,[a] Sara Speziali, MD,[a] Raffaele Pulli, MD,[a] Enrico Gallitto, MD,[b,c] Gianluca Faggioli, MD,[b,c] Mauro Gargiulo, MD,[b,c] Luca Bertoglio, MD,[d] Germano Melissano, MD,[d] Roberto Chiesa, MD,[d] Gioele Simonte, MD,[e] Giacomo Isernia, MD,[e] Massimo Lenti, MD,[e] *and* Carlo Pratesi, MD,[a] on behalf of the Italian Multicentre Fenestrated and Branched (IMF&B) Study Group, *Florence, Bologna, and Perugia, Italy*

J Vasc Surg. 2023 Sep;78(3):584-592.e2.

591 pts receiving F/BEVAR

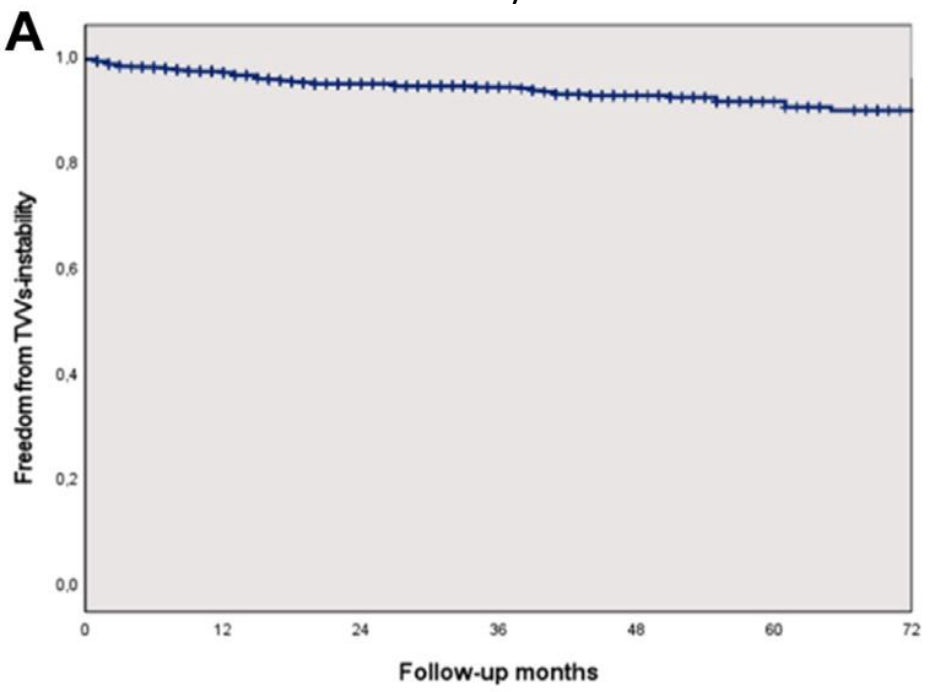
2008-2019

1991 TVVs

mean follow up 25 months

Freedom from TVV instability 90%@ 5 yrs

Freedom from TVV instability



Follow-up months	0	12	24	36	48	60
TVVs at risk	1824	980	677	479	304	182
Estimated rates	1	.966	.944	.938	.922	.900
Standard error	0	.005	.007	.007	.009	.014

Fate of target visceral vessels in fenestrated and branched complex endovascular aortic repair

Aaron Thomas Fargion, MD,[a] Davide Esposito, MD,[a] Sara Speziali, MD,[a] Raffaele Pulli, MD,[a] Enrico Gallitto, MD,[b,c] Gianluca Faggioli, MD,[b,c] Mauro Gargiulo, MD,[b,c] Luca Bertoglio, MD,[d] Germano Melissano, MD,[d] Roberto Chiesa, MD,[d] Gioele Simonte, MD,[e] Giacomo Isernia, MD,[e] Massimo Lenti, MD,[e] *and* Carlo Pratesi, MD,[a] on behalf of the Italian Multicentre Fenestrated and Branched (IMF&B) Study Group, *Florence, Bologna, and Perugia, Italy*

J Vasc Surg. 2023 Sep;78(3):584-592.e2.

Table IV. Risk factors for target visceral vessel (*TVV*)-related type IC/IIIC endoleaks at Cox regression model

	Univariate		Multivariate		
	Log rank	*P* value	HR	95% CI	*P* value
Early vs late experience	4.246	.039	1.767	0.847-3.685	.129
Extent of aneurysm disease	25.021	<.001	3.899	1.924-7.900	<.001
Type of TVV	3.322	.068	1.085	0.506-2.323	.835
TVV ∅ ≥ 7 mm	6.864	.009	1.640	0.736-3.652	.226
Graft configuration	.105	.746			
CMD vs OTS	.268	.605			
Type of BSG	2.694	.101	1.101	0.633-1.915	.733
BSG relining	12.148	<.001	1.501	0.812-2.773	.195

BSG, Bridging stent graft; *CI*, confidence interval; *CMD*, custom-made device; *HR*, hazard ratio; *OTS*, off-the-shelf.

Fate of target visceral vessels in fenestrated and branched complex endovascular aortic repair

Aaron Thomas Fargion, MD,[a] Davide Esposito, MD,[a] Sara Speziali, MD,[a] Raffaele Pulli, MD,[a] Enrico Gallitto, MD,[b,c] Gianluca Faggioli, MD,[b,c] Mauro Gargiulo, MD,[b,c] Luca Bertoglio, MD,[d] Germano Melissano, MD,[d] Roberto Chiesa, MD,[d] Gioele Simonte, MD,[e] Giacomo Isernia, MD,[e] Massimo Lenti, MD,[e] *and* Carlo Pratesi, MD,[a] on behalf of the Italian Multicentre Fenestrated and Branched (IMF&B) Study Group, *Florence, Bologna, and Perugia, Italy*

J Vasc Surg. 2023 Sep;78(3):584-592.e2.

Table V. Risk factors for target visceral vessel (*TVV*) primary patency loss at Cox regression model

	Univariate		Multivariate		
	Log rank	*P* value	HR	95% CI	*P* value
Early vs late experience	.108	.742			
Extent of aneurysm disease	7.805	.005	.925	0.440-1.945	.838
Type of TVV	6.407	.011	2.848	1.108-7.319	.030
TVV $\emptyset \leq 6$ mm	3.807	.051	.644	0.274-1.513	.312
TVV preoperative stenosis >50%	.043	.836			
Graft configuration	38.524	<.001	8.883	3.750-21.043	<.001
CMD vs OTS	16.646	<.001	.735	0.365-1.479	.388
Type of BSG	1.020	.313			
BSG relining	4.713	.030	.887	0.448-1.758	.732

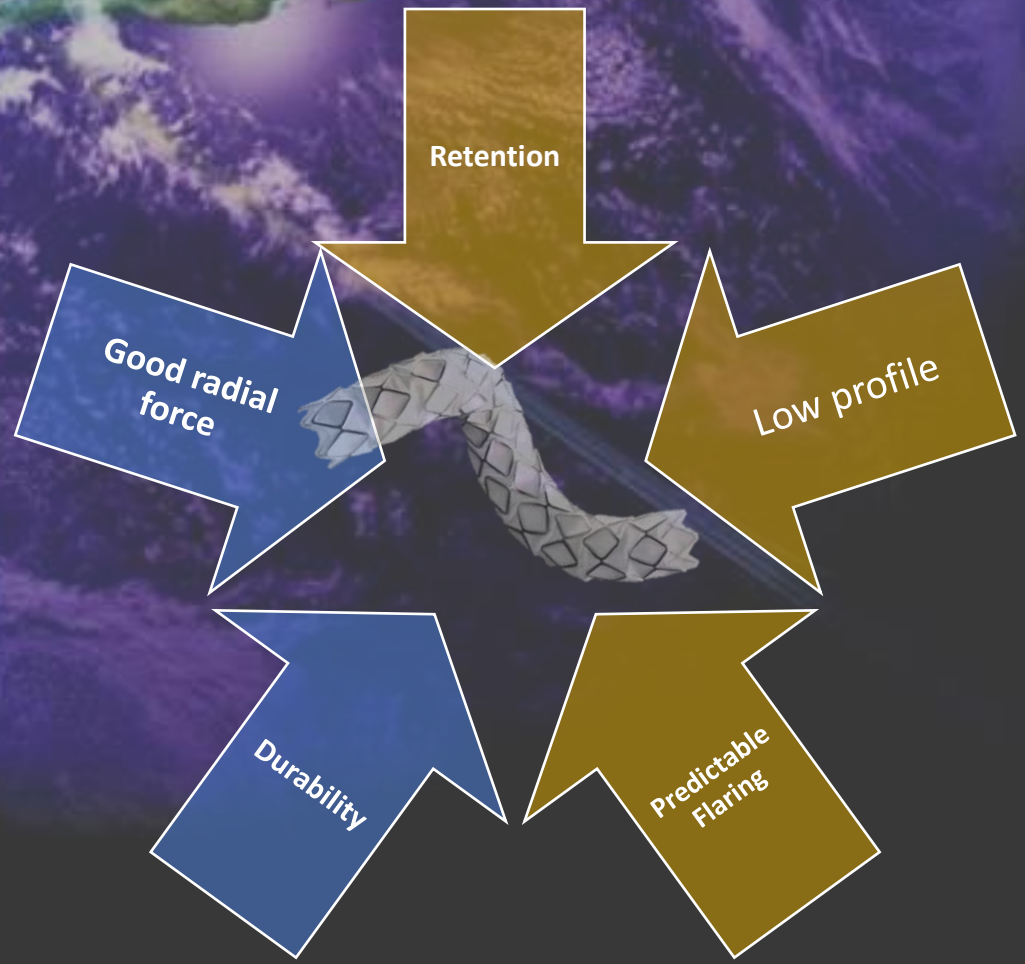
BSG, Bridging stent graft; *CI*, confidence interval; *CMD*, custom-made device; *HR*, hazard ratio; *OTS*, off-the-shelf.

B-EVAR

- BeSG
- SeSG

F-EVAR

- BeSG



THE 26TH INTERNATIONAL EXPERTS SYMPOSIUM

CRITICAL ISSUES

IN AORTIC ENDOGRAFTING

MARCH 21 & 22 2024

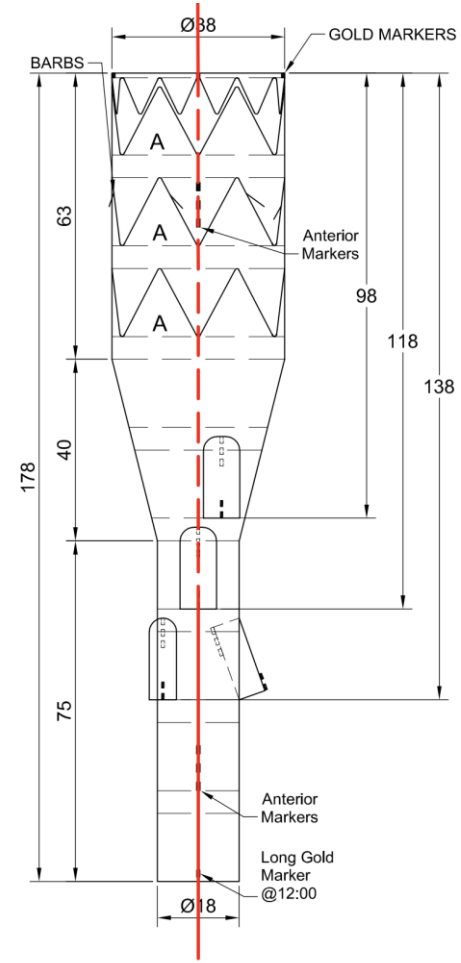
COPENHAGEN/MALMÖ

SCANDIC TRIANGELN, MALMÖ

Still waiting for the perfect device...

B-EVAR

F-EVAR

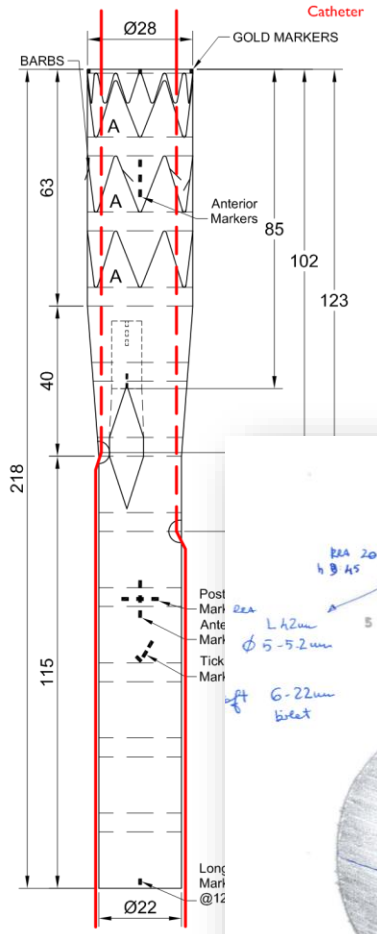


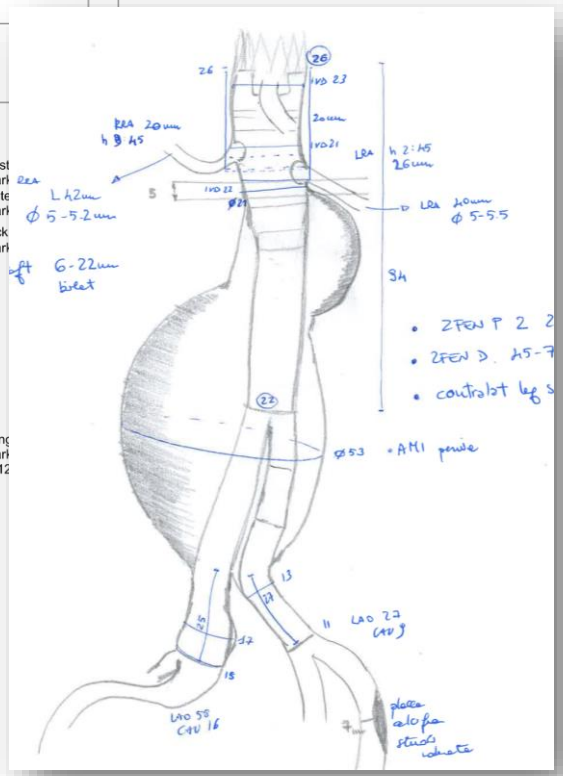
Do what you can, with what you have, where you are

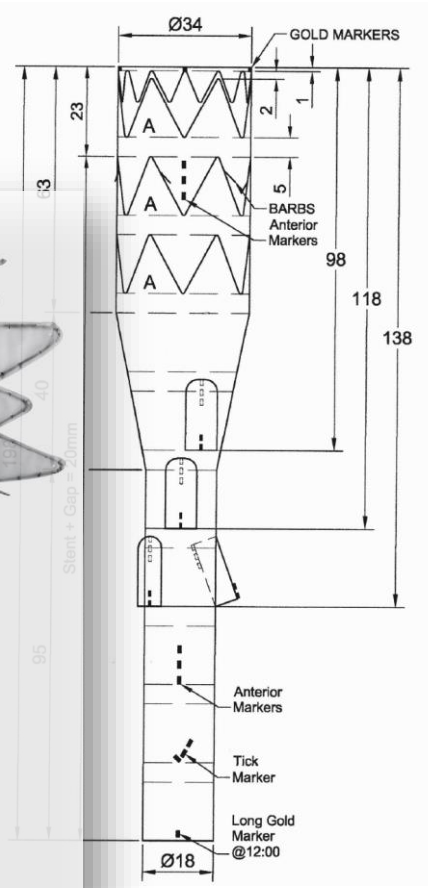
Theodore Roosevelt

THE 26TH INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES
IN AORTIC ENDOGRAFTING
MARCH 21 & 22 2024
COPENHAGEN/MALMÖ
SCANDIC TRIANGELN, MALMÖ

Will an ideal bridging stent ever exist?







Balloon expandable

Self expandable

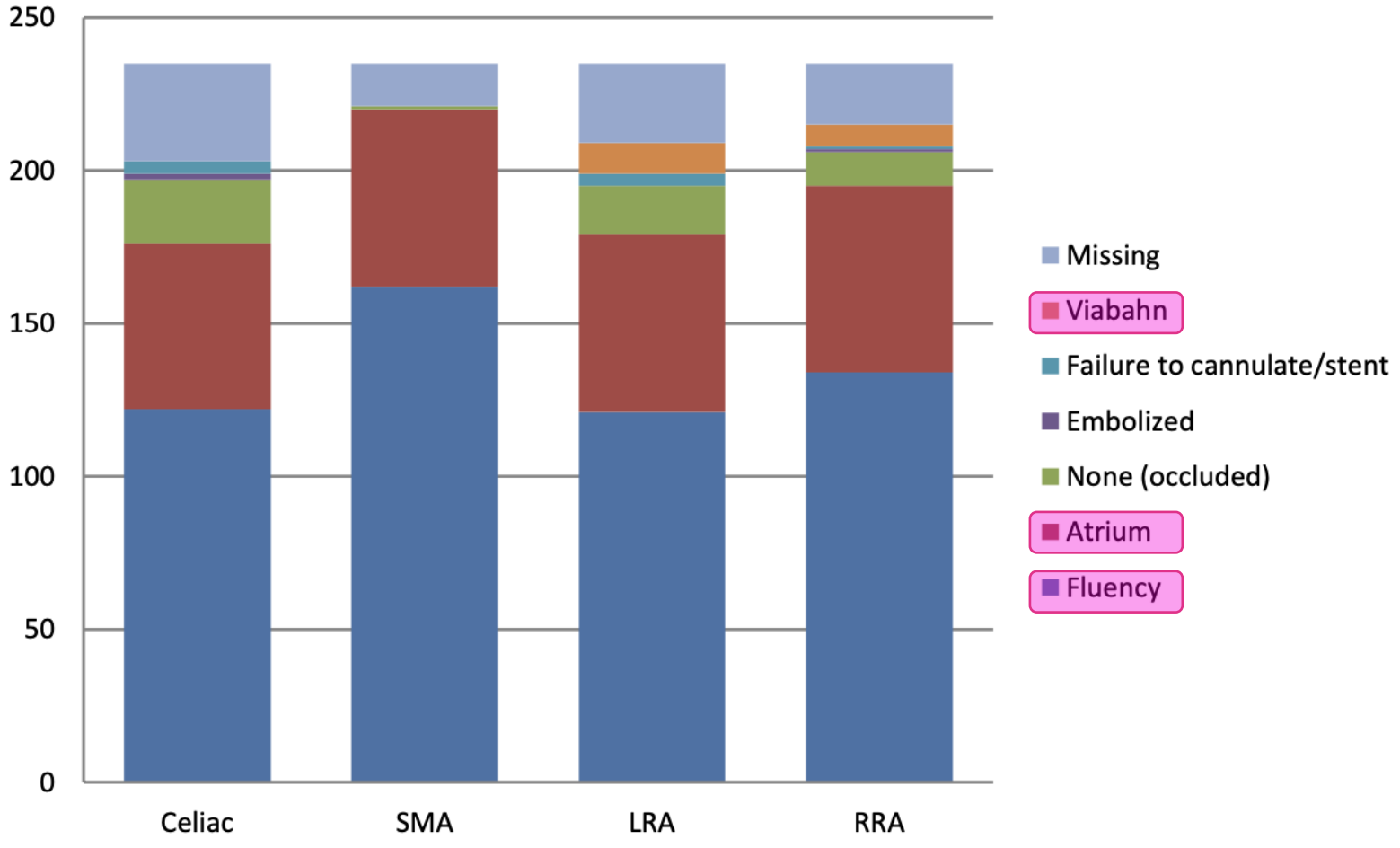
Editor's Choice — Effect of Branch Stent Choice on Branch-related Outcomes in Complex Aortic Repair☆

T.M. Mastracci [a,*], T. Carrell [b], J. Constantinou [a], N. Dias [c], T. Martin-Gonzalez [d], A. Katsargyris [e], B. Modarai [b], T. Resch [c], E.L.G. Verhoeven [e], M. Burnell [f], S. Haulon [d]

Eur J Vasc Endovasc Surg (2016) 51, 536—542

940 TVVs

old generation devices



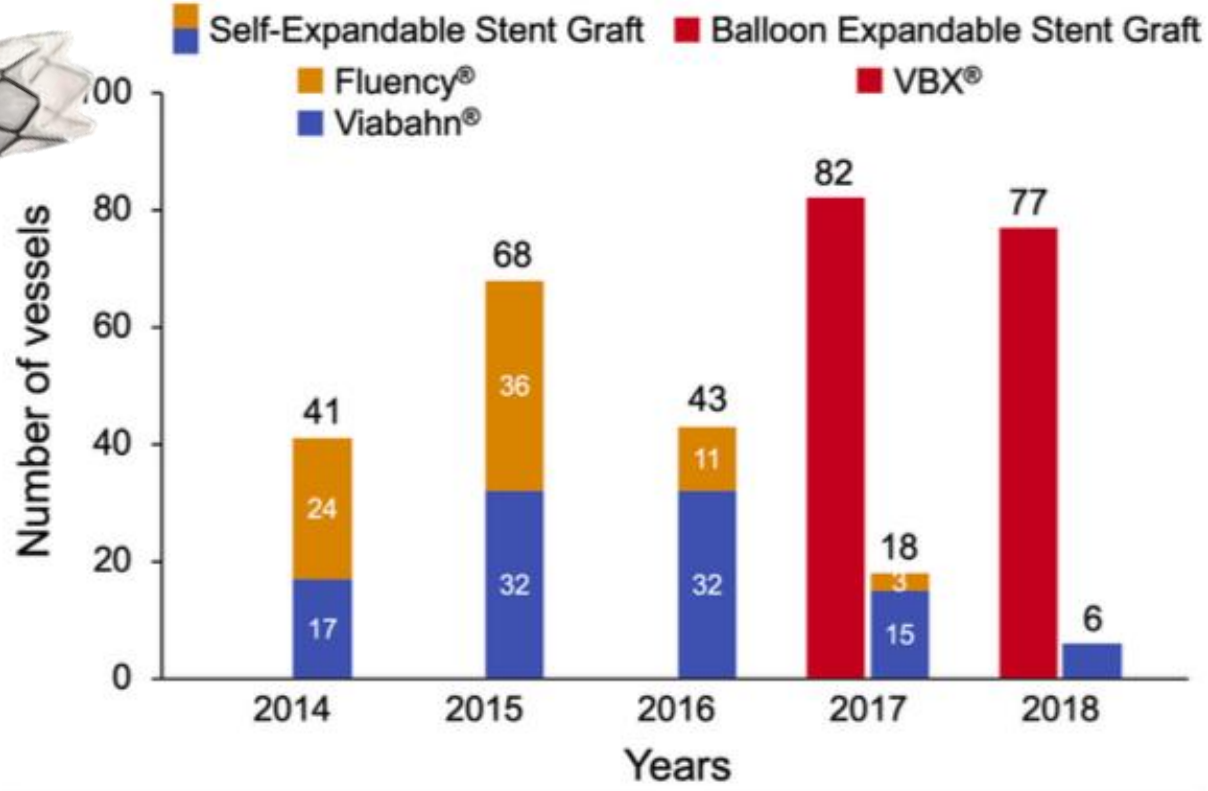
Outcomes of directional branches using self-expandable or balloon-expandable stent grafts during endovascular repair of thoracoabdominal aortic aneurysms

Emanuel R. Tenorio, MD, PhD, Jussi M. Kärkkäinen, MD, PhD, Bernardo C. Mendes, MD, Randall R. DeMartino, MD, Thanila A. Macedo, MD, Alisa Diderrich, RN, Jan Hofer, RN, *and* Gustavo S. Oderich, MD, *Rochester, Minn*

(J Vasc Surg 2020;71:1489-502.)

335 TVVs in
126 pts

2014-2018

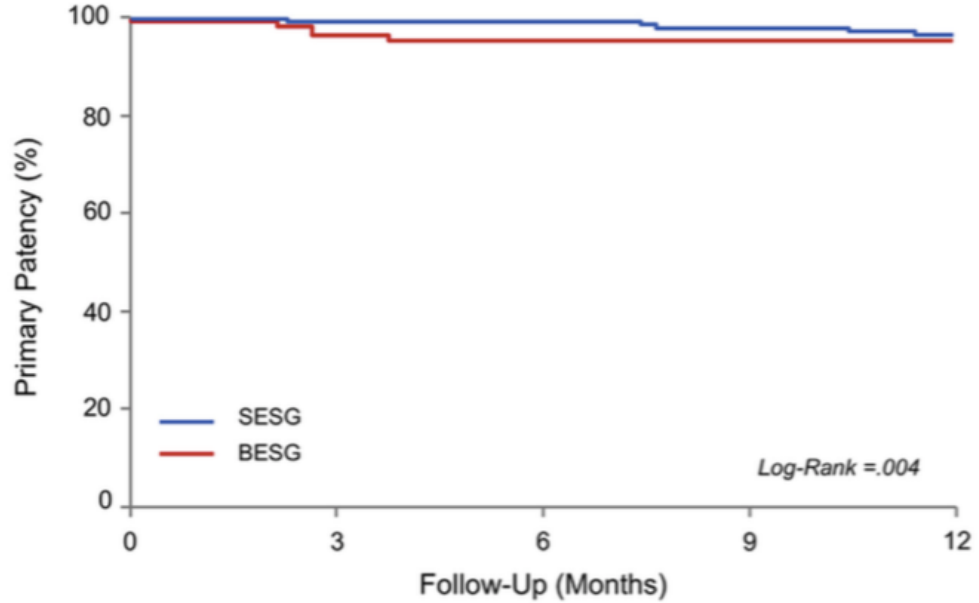


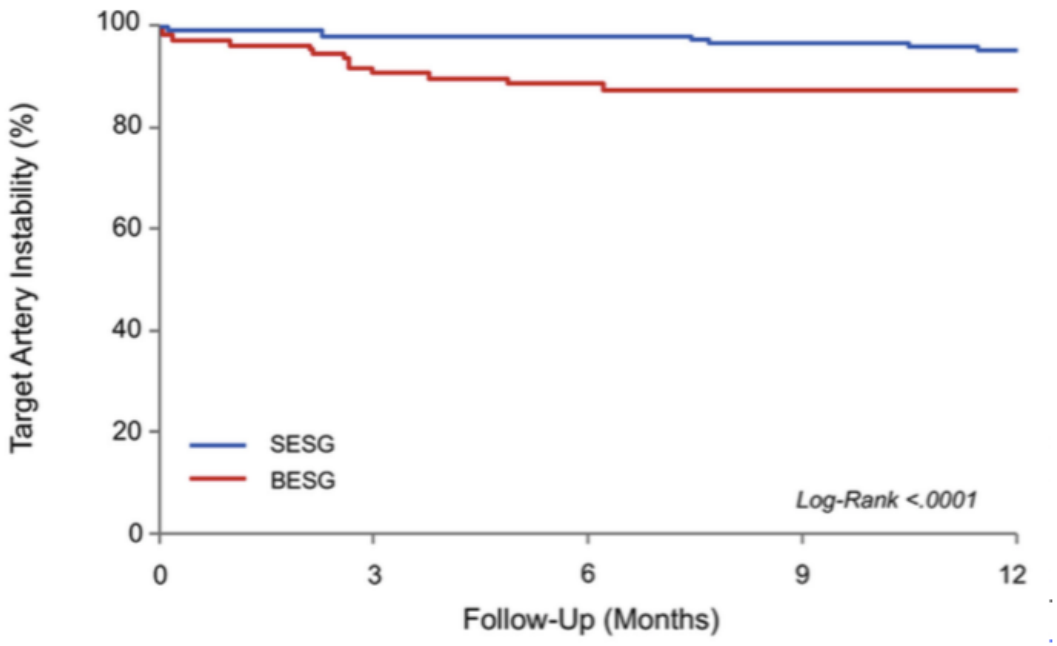
Mean follow-up:
23 months SESG Vs
8 months BESG

Outcomes of directional branches using self-expandable or balloon-expandable stent grafts during endovascular repair of thoracoabdominal aortic aneurysms

Emanuel R. Tenorio, MD, PhD, Jussi M. Kärkkäinen, MD, PhD, Bernardo C. Mendes, MD, Randall R. DeMartino, MD, Thanila A. Macedo, MD, Alisa Diderrich, RN, Jan Hofer, RN, *and* Gustavo S. Oderich, MD, *Rochester, Minn*

(J Vasc Surg 2019;■:1-14.)





«primary patency, freedom from TAI, and freedom from type IC or type IIIC endoleaks was lower for BESGs compared with SESGs»

THE 26TH INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES
IN AORTIC ENDOGRAFTING
MARCH 21 & 22 2024
COPENHAGEN/MALMÖ
SCANDIC TRIANGELN, MALMÖ

Meta-analysis of Comparative Studies Between Self- and Balloon-Expandable Bridging Stent Grafts in Branched Endovascular Aneurysm Repair

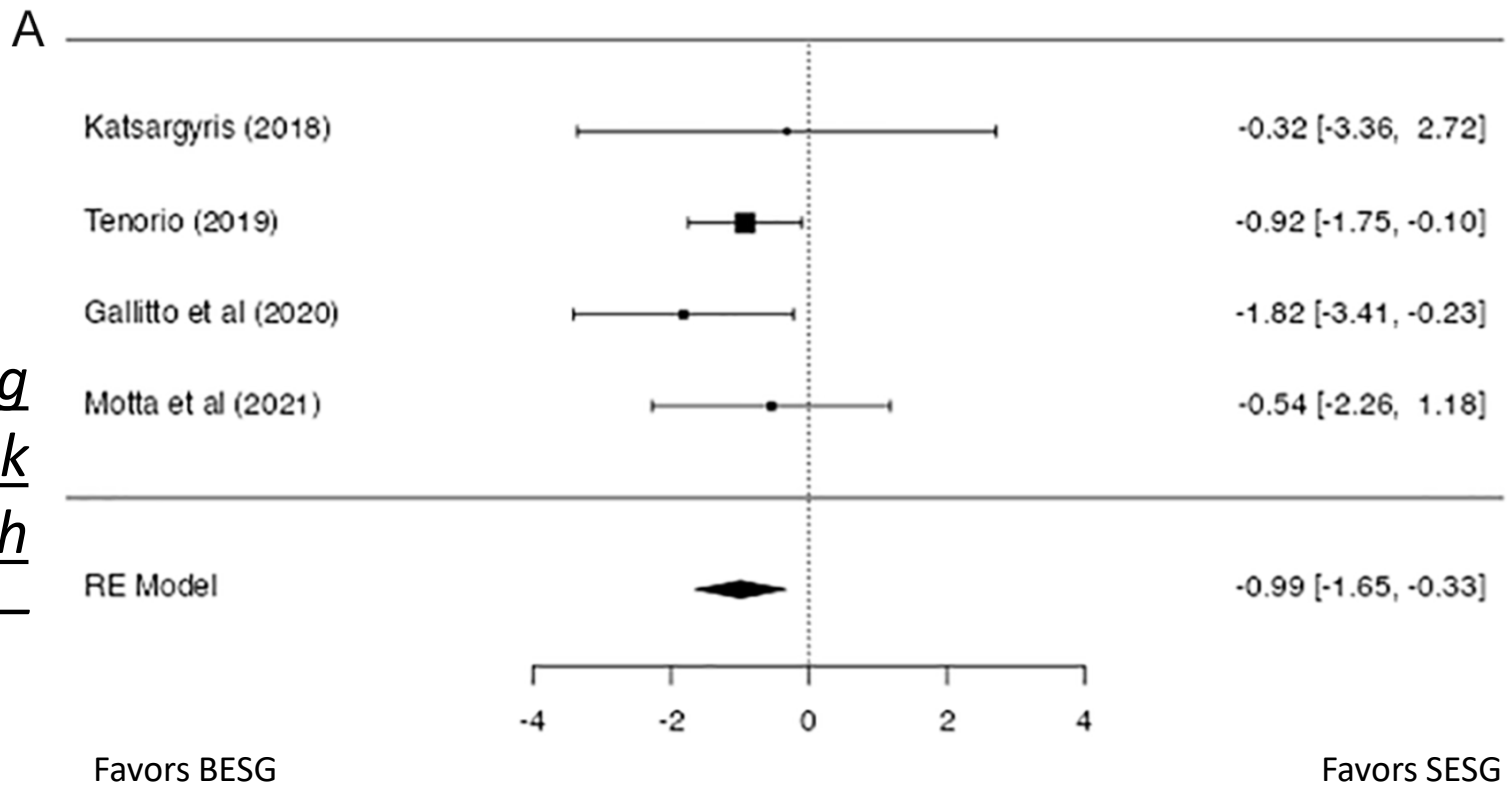
Journal of Endovascular Therapy
2023, Vol. 30(3) 336–346

Petroula Nana, MSc[1,2*], Konstantinos Spanos, PhD[1,2*], Alexandros Brodis, PhD[3], Giuseppe Panuccio, MD[2], George Kouvelos, PhD[1], Christian-Alexander Behrendt, PhD[2], Athanasios Giannoukas, PhD[1], and Tilo Kölbel, PhD[2]

Author	Date	Study period
Mastracci et al[9]	2016	2012–2019
Katsargyris et al[20]	2018	2015–2017
Tenorio et al[10]	2019	2014–2018
Gallitto et al[21]	2020	2010–2019
Motta et al[11]	2021	2012–2019

«TVs being revascularized using SESG stents presented lower risk for instability in comparison with BESG (OR, 0.99; 95% CI, 0.33–1.65, p=.003»

Freedom from TV instability



New generation devices

B-EVAR

SOLARIS®
SELF-EXPANDING

Covera™ Vascular
Covered Stent

BeGraft+
peripheral

GORE
VIABAHN®
VBX

THE 26TH INTERNATIONAL EXPERTS SYMPOSIUM

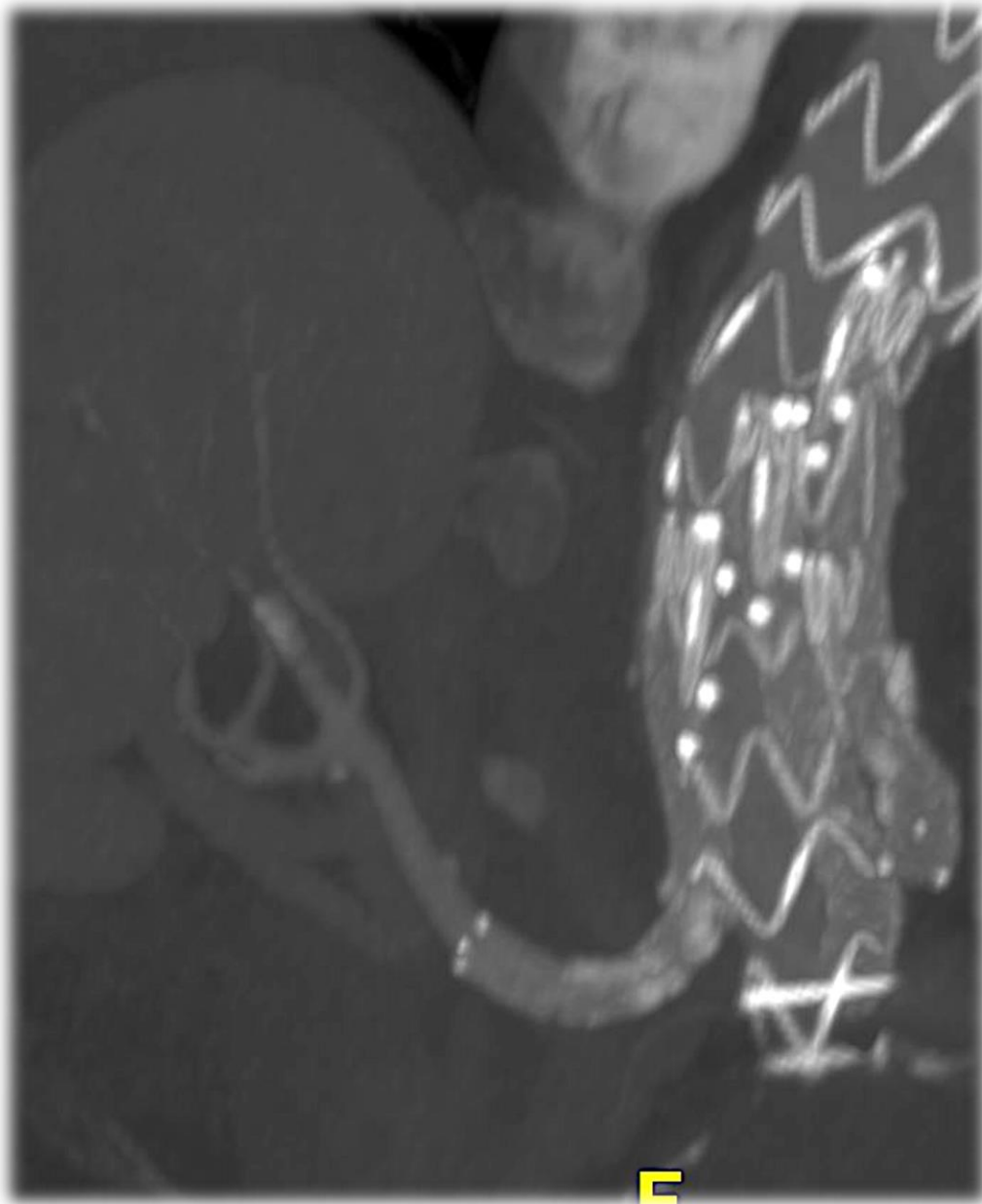
CRITICAL ISSUES

IN AORTIC ENDOGRAFTING

MARCH 21 & 22 2024

COPENHAGEN/MALMÖ

SCANDIC TRIANGELN, MALMÖ



New generation SE devices

SOLARIS®
SELF-EXPANDING

Launched in 2016
CE mark in late 2019

Covera™ Vascular
Covered Stent

CE mark in late 2017

Comparison of self- and balloon-expandable bridging stent-grafts in branched endovascular aortic repair (COVIBRI study)

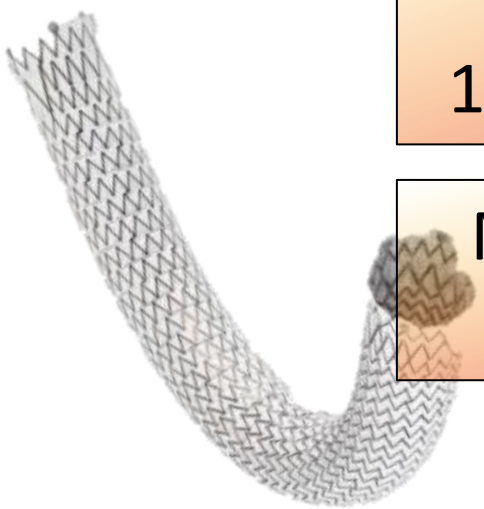
Mattia Migliari, MD,[a] Nicola Leone, MD,[a] Gian Franco Veraldi, MD,[b] Gioele Simonte, MD, PhD,[c] Roberto Silingardi, MD,[a] Timothy Resch, MD, PhD,[d] *and* Stefano Gennai, MD,[a] Study collaborators, *Modena, Verona, and Perugia, Italy; and Copenhagen, Denmark*

J Vasc Surg. 2023 Dec 26:S0741-5214(23)02438-2.

345 TVVs in 106 pts receiving BEVAR

220 Self expandable
Vs.
125 Balloon expandable

Median follow up 13.9 months



	Covera plus (n = 220)	Viabahn ballon-expandable VBX (n = 125)	*P* value
CT	53	33	.981
SMA	63	34	
LRA	49	27	
Right renal artery	54	30	
Accessory vessel	1	1	
Crawford aneurysm type			<.001
I	2	18	
II	56	40	
III	67	10	
IV	70	51	
V	25	6	
Aneurysm diameter, mm	63.0 (59.5-70.0)	66.0 (60.0-74.0)	.137
Rupture	11	7	.810
Urgent	43	23	.795

CT, Celiac trunk; *LRA*, left renal artery; *SMA*, superior mesenteric artery. Values are number or mean (interquartile range). The χ^2 test was used to compare the two groups in terms of target visceral vessel, aneurysm type, rupture state, and urgency. The *t* test was used to compare the mean aneurysm diameter between the groups.

Comparison of self- and balloon-expandable bridging stent-grafts in branched endovascular aortic repair (COVIBRI study)

Mattia Migliari, MD,[a] Nicola Leone, MD,[a] Gian Franco Veraldi, MD,[b] Gioele Simonte, MD, PhD,[c] Roberto Silingardi, MD,[a] Timothy Resch, MD, PhD,[d] *and* Stefano Gennai, MD,[a] Study collaborators, *Modena, Verona, and Perugia, Italy; and Copenhagen, Denmark*

J Vasc Surg. 2023 Dec 26:S0741-5214(23)02438-2.

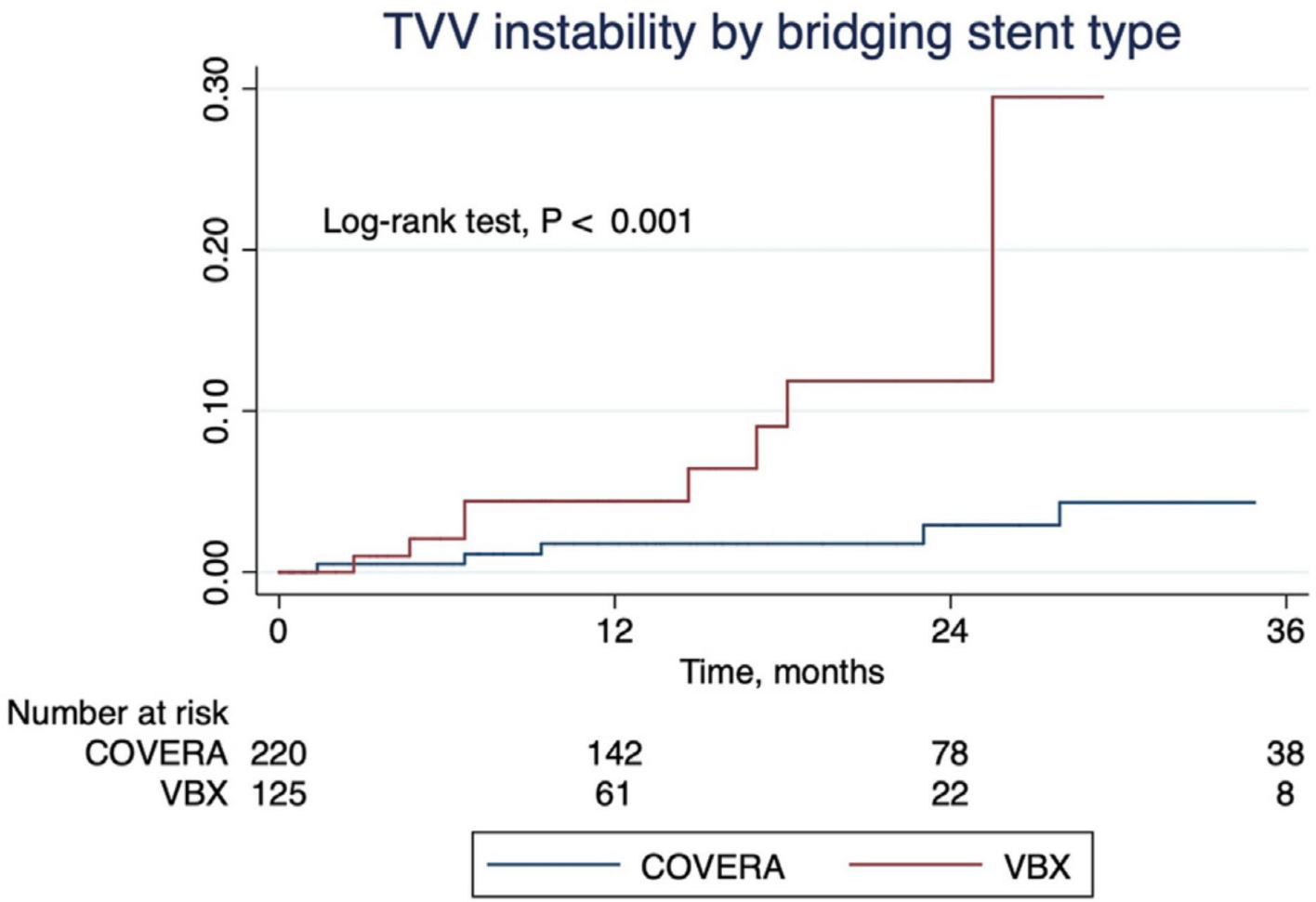


Fig 1. Kaplan-Meier analysis showing a significantly increased risk of target vessel instability in the VBX cohort. *TVV*, target visceral vessel.

«The Viabahn balloon-expandable VBX seemed to perform worse than Covera Plus, being more prone to TVV instability despite a significantly shorter follow-up»

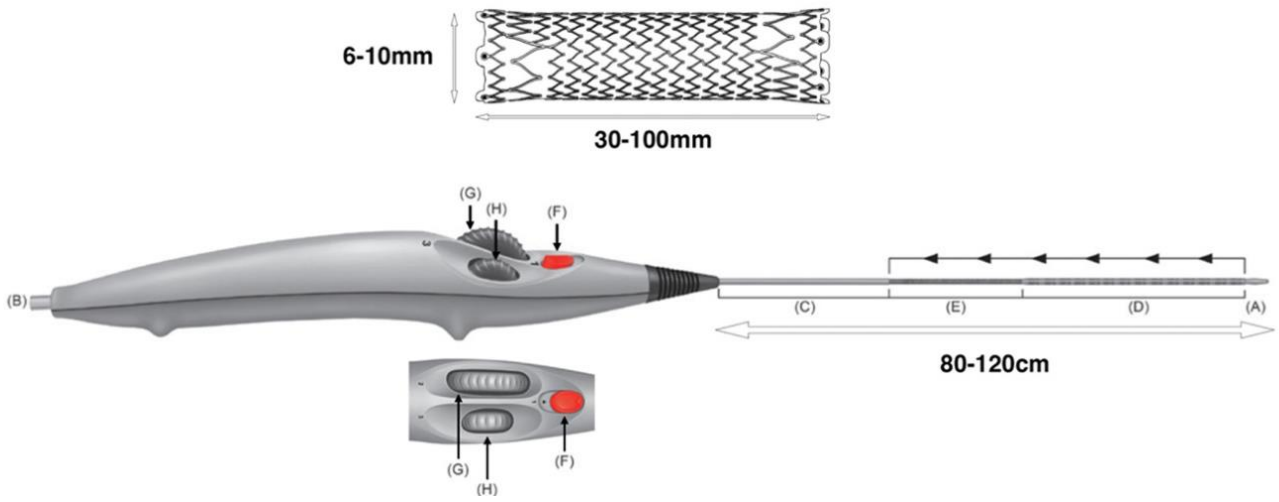
THE 26TH INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES
IN AORTIC ENDOGRAFTING

Midterm results on a new self-expandable covered stent combined with branched stent grafts: Insights from a multicenter Italian registry

Luca Bertoglio, MD,[a] Alessandro Grandi, MD,[a] Gian Franco Veraldi, MD,[b] Raffaele Pulli, MD,[c] Michele Antonello, MD,[d] Stefano Bonvini, MD,[e] Giacomo Isernia, MD,[f] Raffaello Bellosta, MD,[g] Francesco Buia, MD,[h] *and* Roberto Silingardi, MD,[i] on behalf of the COBRA Registry Collaborators,
Milan, Verona, Bari, Padua, Perugia, Brescia, Bologna, and Modena, Italy

708 target vessels in 284 pts receiving BEVAR

Median follow up 32 months



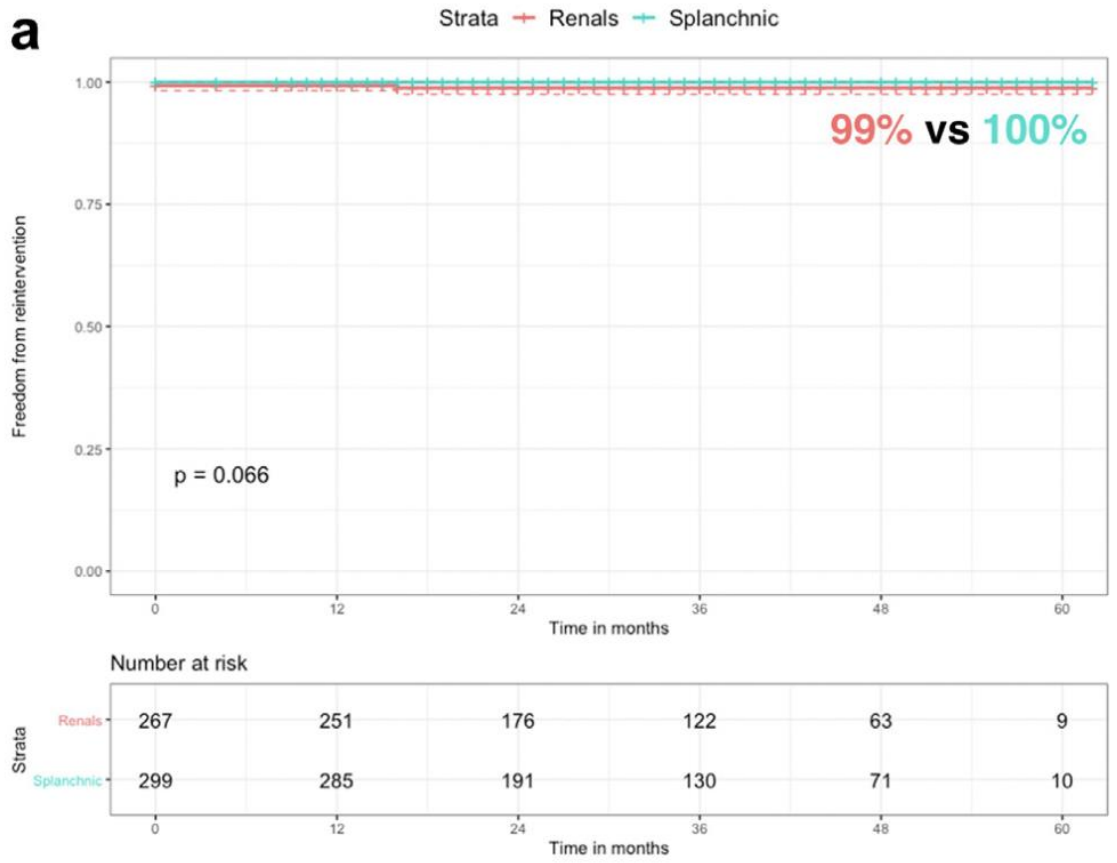
THE 26TH INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES
IN AORTIC ENDOGRAFTING

Midterm results on a new self-expandable covered stent combined with branched stent grafts: Insights from a multicenter Italian registry

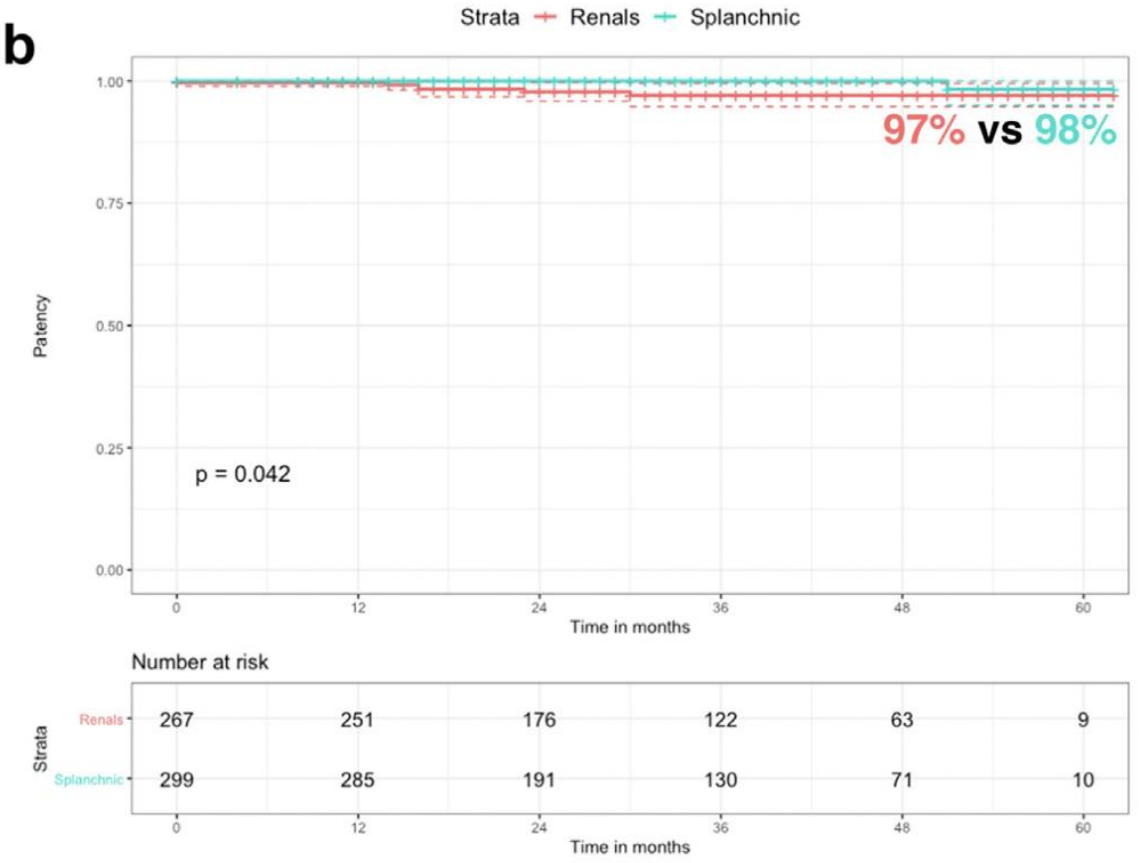
Luca Bertoglio, MD,[a] Alessandro Grandi, MD,[a] Gian Franco Veraldi, MD,[b] Raffaele Pulli, MD,[c] Michele Antonello, MD,[d] Stefano Bonvini, MD,[e] Giacomo Isernia, MD,[f] Raffaello Bellosta, MD,[g] Francesco Buia, MD,[h] *and* Roberto Silingardi, MD,[i] on behalf of the COBRA Registry Collaborators,
Milan, Verona, Bari, Padua, Perugia, Brescia, Bologna, and Modena, Italy

(J Vasc Surg 2023;77:1598-606.)

Freedom from reintervention



Primary patency

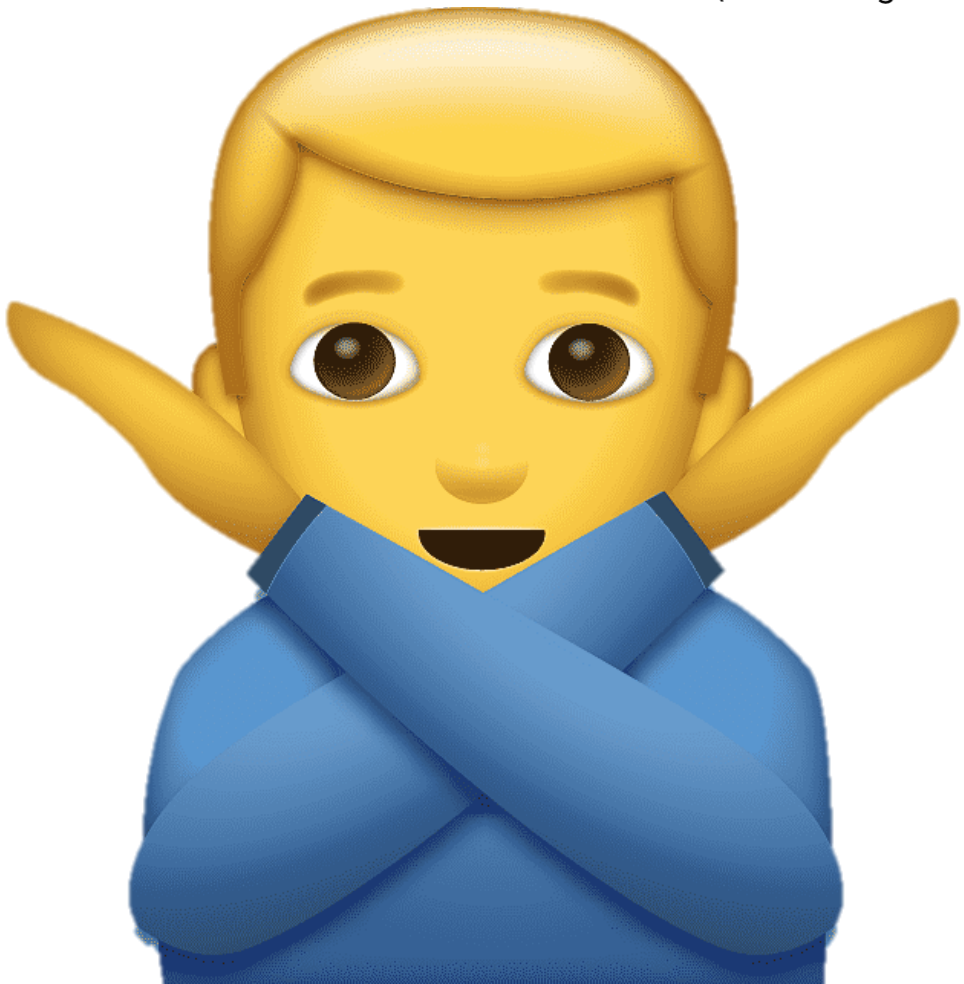


Midterm results on a new self-expandable covered stent combined with branched stent grafts: Insights from a multicenter Italian registry

Luca Bertoglio, MD,[a] Alessandro Grandi, MD,[a] Gian Franco Veraldi, MD,[b] Raffaele Pulli, MD,[c] Michele Antonello, MD,[d] Stefano Bonvini, MD,[e] Giacomo Isernia, MD,[f] Raffaello Bellosta, MD,[g] Francesco Buia, MD,[h] *and* Roberto Silingardi, MD,[i] on behalf of the COBRA Registry Collaborators,
Milan, Verona, Bari, Padua, Perugia, Brescia, Bologna, and Modena, Italy

(J Vasc Surg 2023;77:1598-606.)

Transfemoral with steerable sheath. Although the use of a complete transfemoral approach using steerable sheaths is gaining more and more attention in the endovascular field owing to its lower stroke and embolization rates, it makes device selection even more significant.[26-29] In the present cohort, all four device failures, as well as two distal stent migrations, happened in branches bridged through transfemoral access with steerable sheaths. It is possible that the acute curvature of the steerable sheath through which the stent graft was advanced interfered with the delivery mechanism, making it undeployable with the wheels owing to the excessive friction. A lower profile (6F) delivery system is expected to be released on the market and new tests would be necessary to judge the covered stent deliverability through transfemoral access; in the meantime, delivery via a transfemoral approach is not recommended according to the authors' experience with this covered stent. As the transfemoral approach gains more traction, further studies on the transfemoral delivery of covered stents through a steerable sheath may shed some light on which ones should be used owing to low complication rates.



THE 26TH INTERNATIONAL EXPERTS SYMPOSIUM

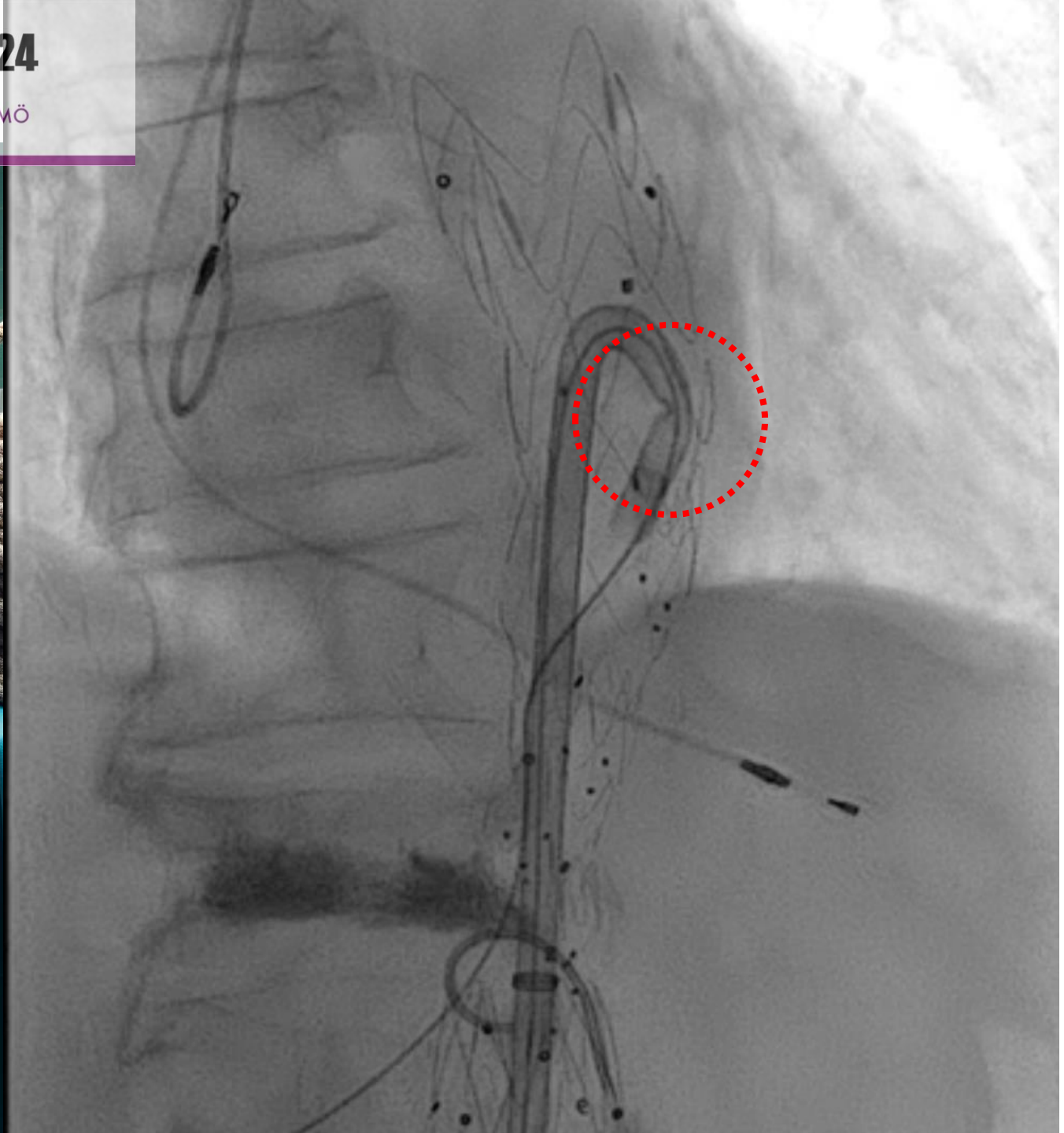
CRITICAL ISSUES

IN AORTIC ENDOGRAFTING

MARCH 21 & 22 2024

COPENHAGEN/MALMÖ

SCANDIC TRIANGELN, MALMÖ



THE 26TH INTERNATIONAL EXPERTS SYMPOSIUM

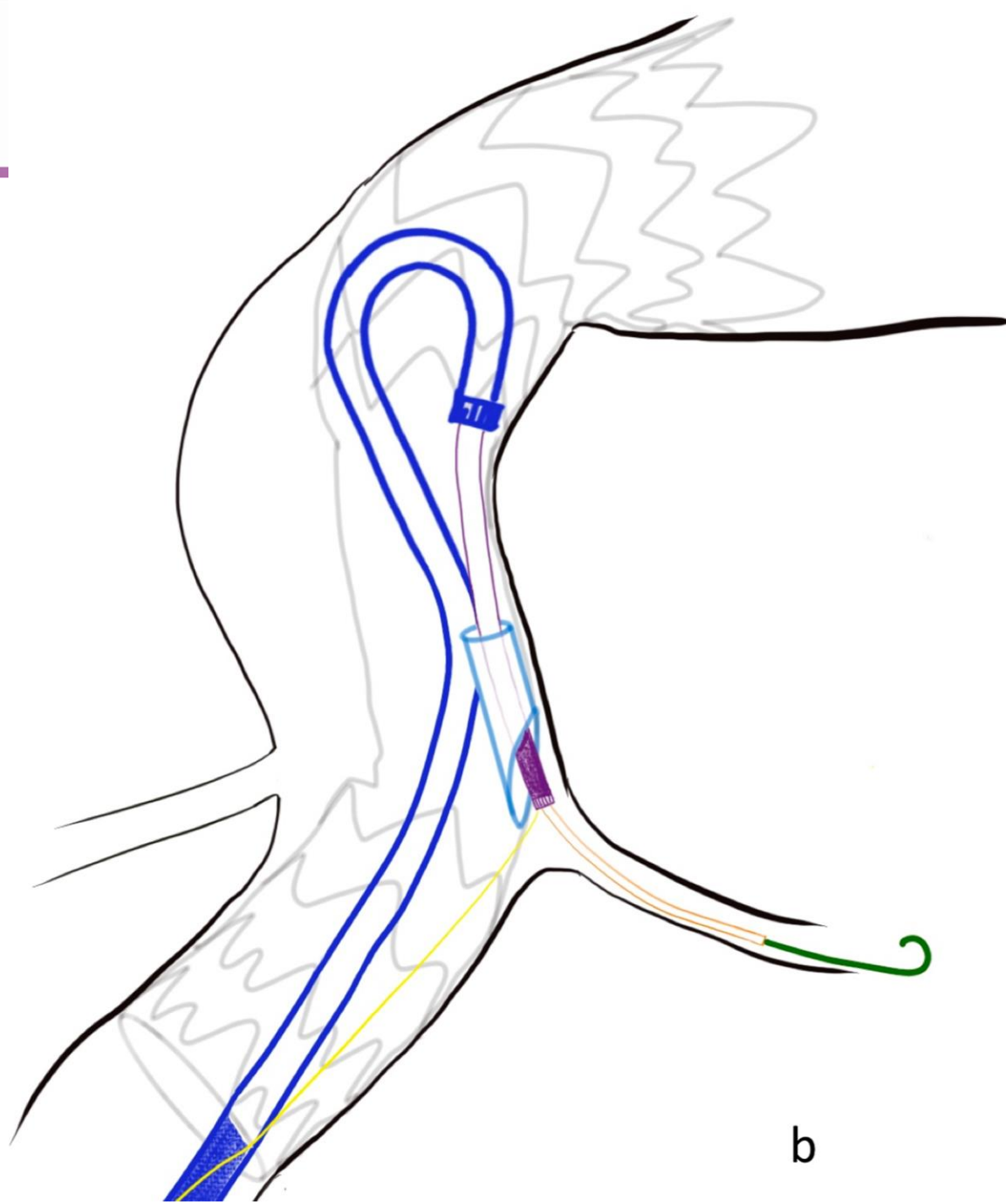
CRITICAL ISSUES

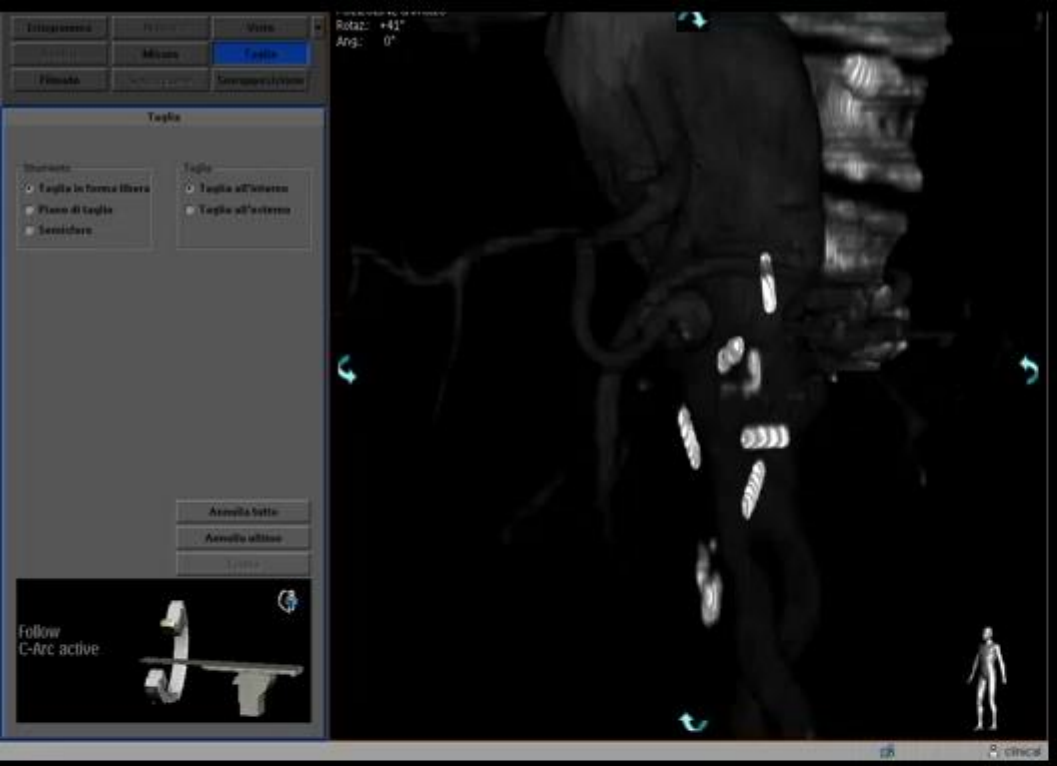
IN AORTIC ENDOGRAFTING

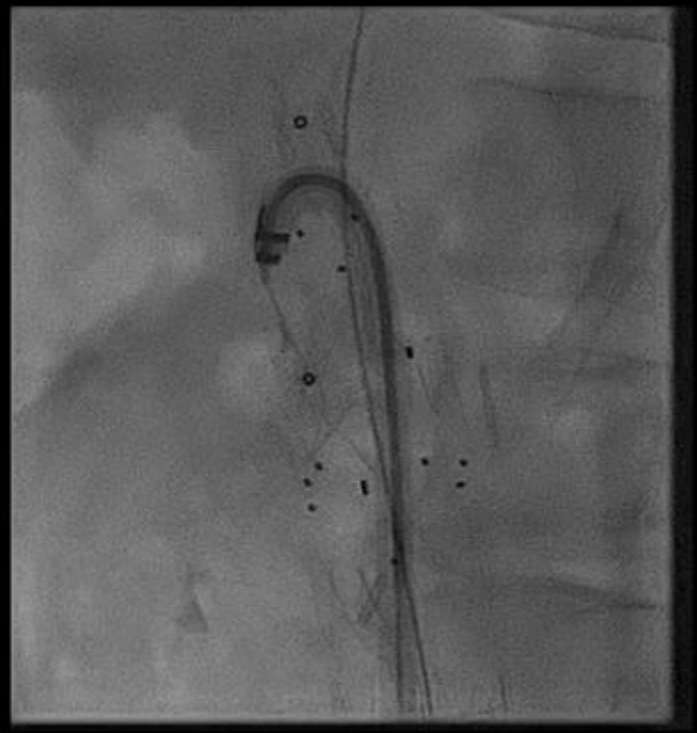
MARCH 21 & 22 2024

COPENHAGEN/MALMÖ

SCANDIC TRIANGELN, MALMÖ





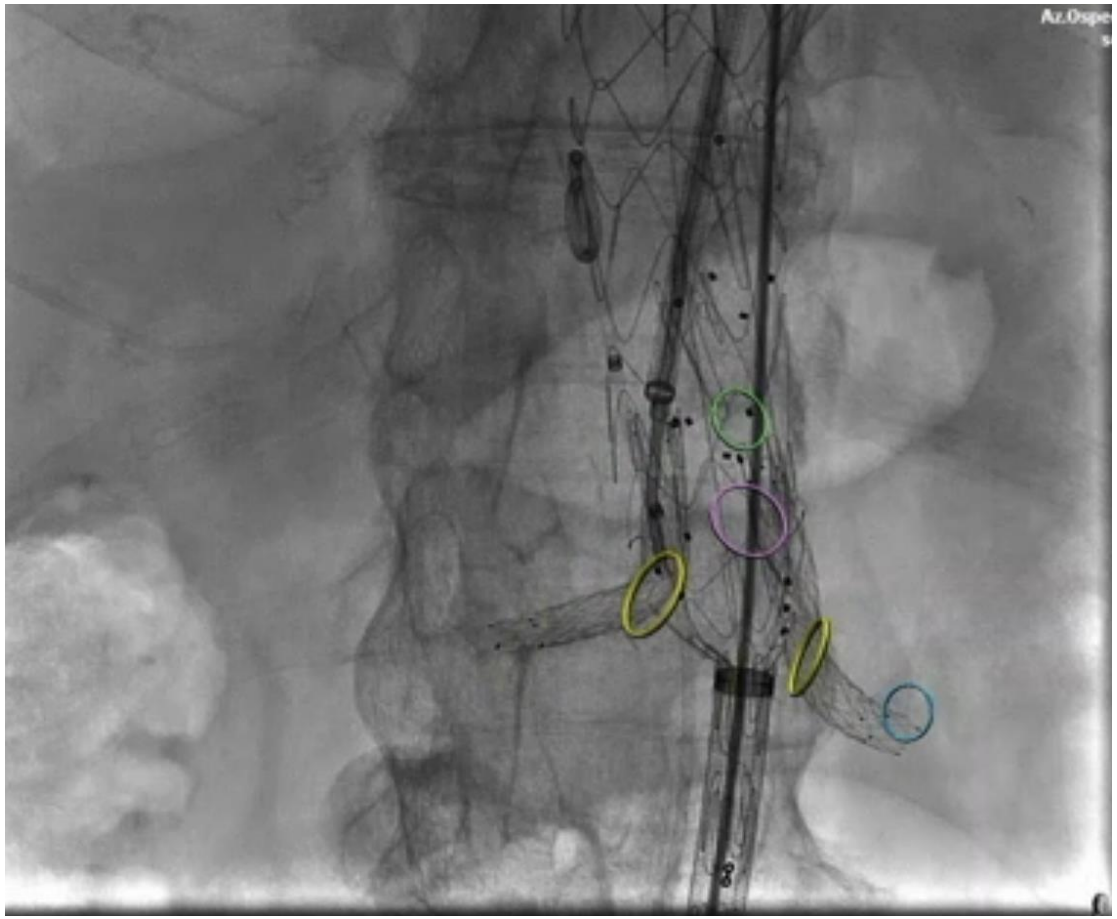


THE 26TH INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES
IN AORTIC ENDOGRAFTING
MARCH 21 & 22 2024
COPENHAGEN/MALMÖ
SCANDIC TRIANGELN, MALMÖ

Single center experience with the Solaris stentgraft in complex aortic repair

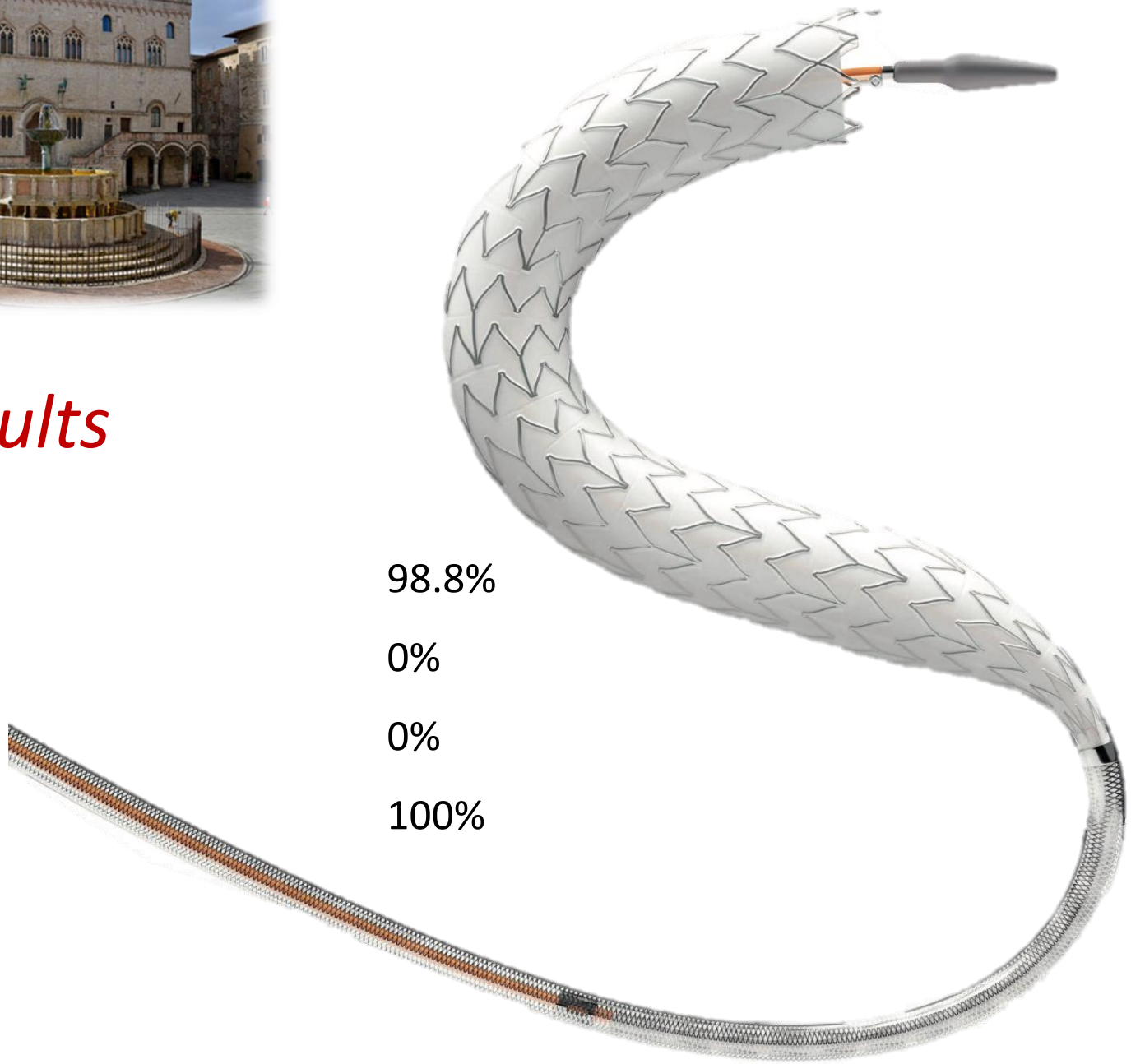
Nov 2021 - March 2024

***87 TVV** preserved using Solaris stent-grafts though inner branches*



Peri-operative results

- Intraop Technical success rate 98.8%
- 30d Stent-related reintervention 0%
- 30d Fracture/disconnection 0%
- 30d Freedom from stents occlusion 100%



Short-term results

Mean follow up 8.1 +/- 5.3 months

- Stent-related reintervention 0%
- Fracture/disconnection 0%
- Freedom from stents occlusion 98.8%

Conclusions

SESG perform better in BEVAR over time

Further improved results expected for new generation devices

Performances in inner branches to be analyzed apart

Competition is good,
Use the right stent for the right TVV