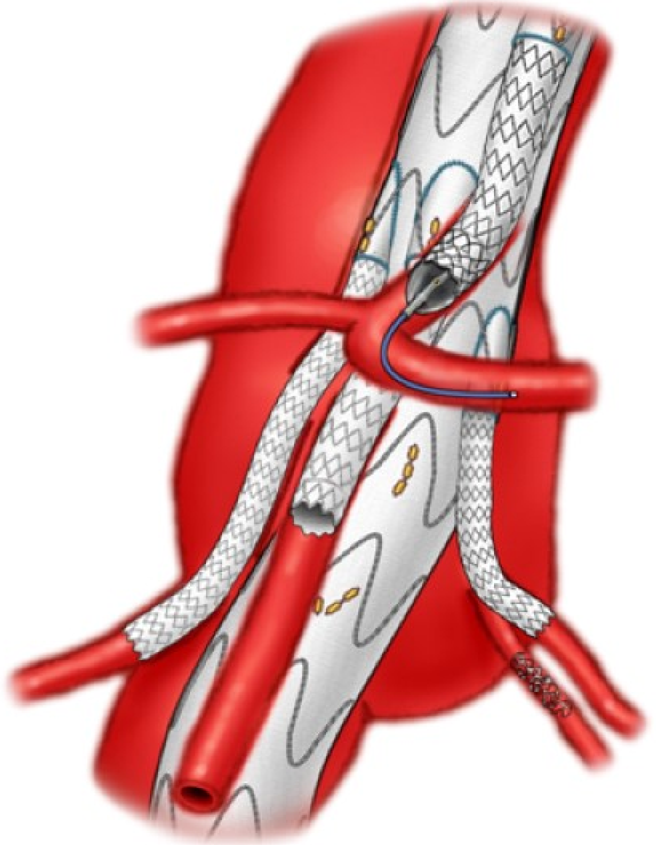
LONGTERM RESULTS OF BRIDGING STENTS IN FENESTRATED & BRANCHED ENDOVASCULAR REPAIR

Gustavo S. Oderich MD
Chair, Vascular and Endovascular Surgery
Professor of Surgery
Director of Aortic Center



Essen, Germany

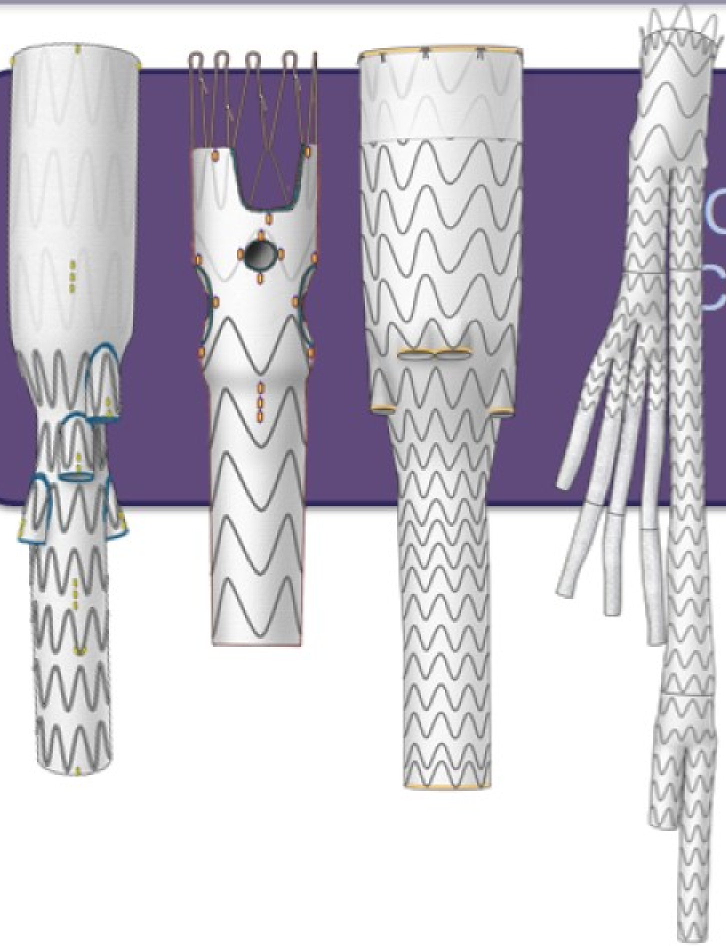
Disclosure

Gustavo S. Oderich

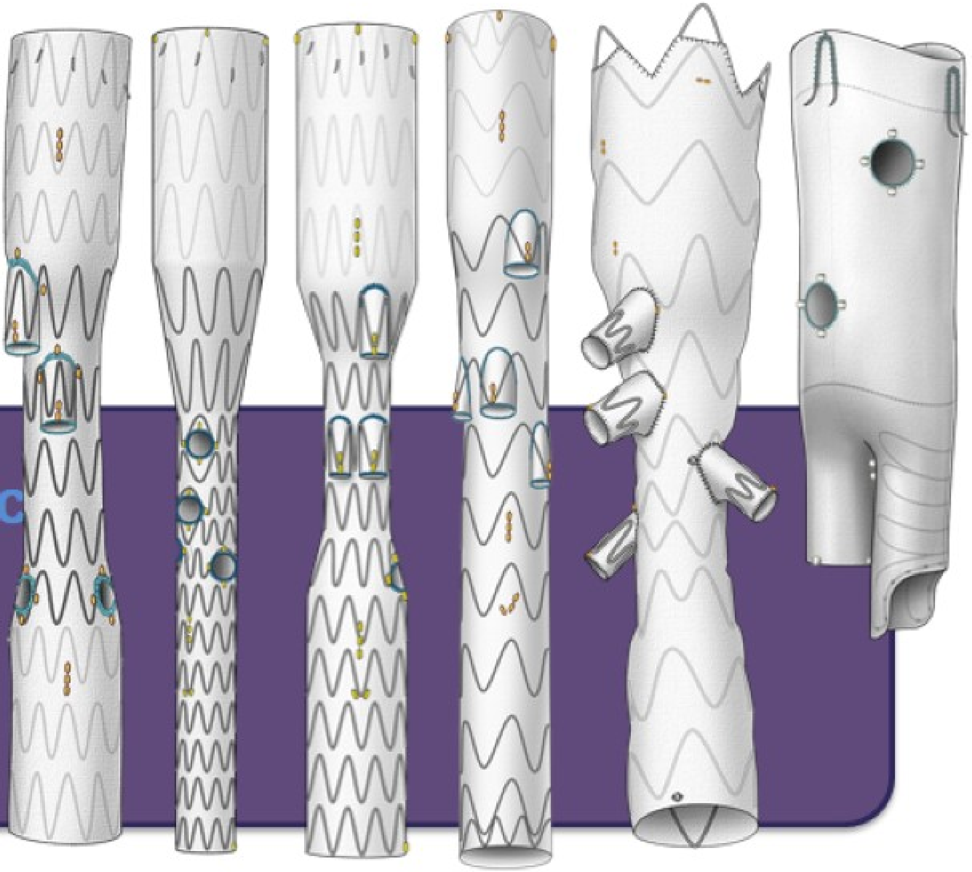
- Consulting: Cook Medical Inc., WL Gore and GE Healthcare
- Research grants: Cook Medical Inc., WL Gore, GE Healthcare

* All consulting fees and grants paid to Mayo Clinic

STENT GRAFT DESIGNS



Off-the-Shelf
Cook t-Branch®
Cook p-Branch®
Gore TAMBE®
Medtronic



Patient Specific
Cook platform
Jotec
Terumo Aorta

FENESTRATED-BRANCHES IN EXTENT I-III TAAAS

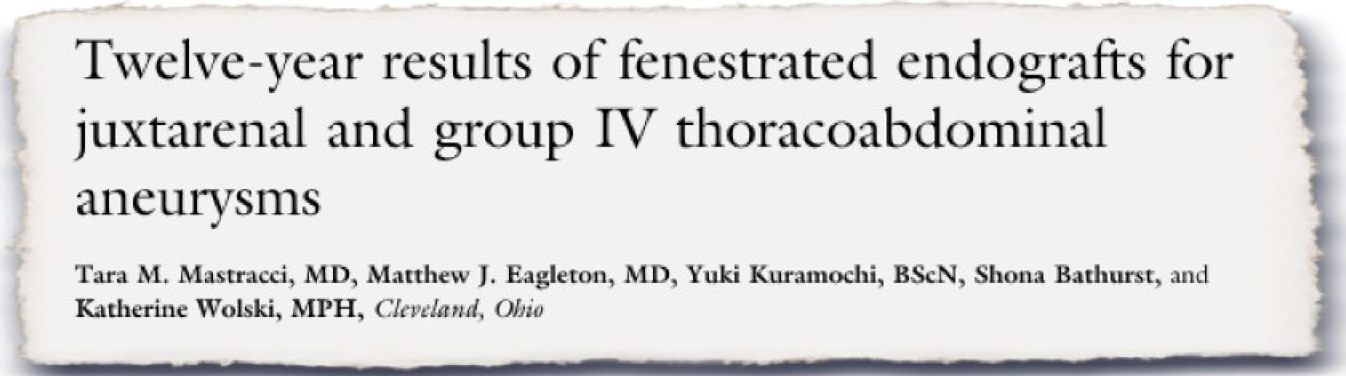
Fenestrated and branched endovascular aneurysm repair outcomes for type II and III thoracoabdominal aortic aneurysms

Matthew J. Eagleton, MD, Matthew Follansbee, BS, Katherine Wolski, MPH, Tara Mastracci, MD, and Yuki Kuramochi, BScN, *Cleveland, Ohio*

2-year Kaplan-Meier Estimates

	Primary patency	Secondary patency
Celiac axis	98%	99%
SMA	97%	99%
R renal artery	**94%**	**99%**
L renal artery	**93%**	**99%**

FENESTRATED-BRANCHES IN PARARENAL AND EXTENT IV TAAAS



Twelve-year results of fenestrated endografts for juxtarenal and group IV thoracoabdominal aneurysms

Tara M. Mastracci, MD, Matthew J. Eagleton, MD, Yuki Kuramochi, BScN, Shona Bathurst, and Katherine Wolski, MPH, *Cleveland, Ohio*

606 patients with 1134 renal fenestrated-branches

	n (Percent)
Renal stent occlusion	**22 (1.9%)**

DIRECTIONAL BRANCHES IN TAAAS

Standard off-the-shelf versus custom-made multibranched thoracoabdominal aortic stent grafts

Charlene C. Fernandez, BS, Julia D. Sobel, BS, Warren J. Gasper, MD, Shant M. Vartanian, MD, Linda M. Reilly, MD, Timothy A. M. Chuter, MD, and Jade S. Hiramoto, MD, *San Francisco, Calif*

133 patients with 235 renal directional branches

CUMMULATIVE EVENT RATE

	(Percent)
Mean follow up (days)	849 + 693
Occlusion or stenosis requiring intervention	**21 (18%)**

RENAL OUTCOMES WITH FENESTRATIONS OR BRANCHES

Mid-term Outcomes of Renal Branches Versus Renal Fenestrations for Thoraco-abdominal Aneurysm Repair☆

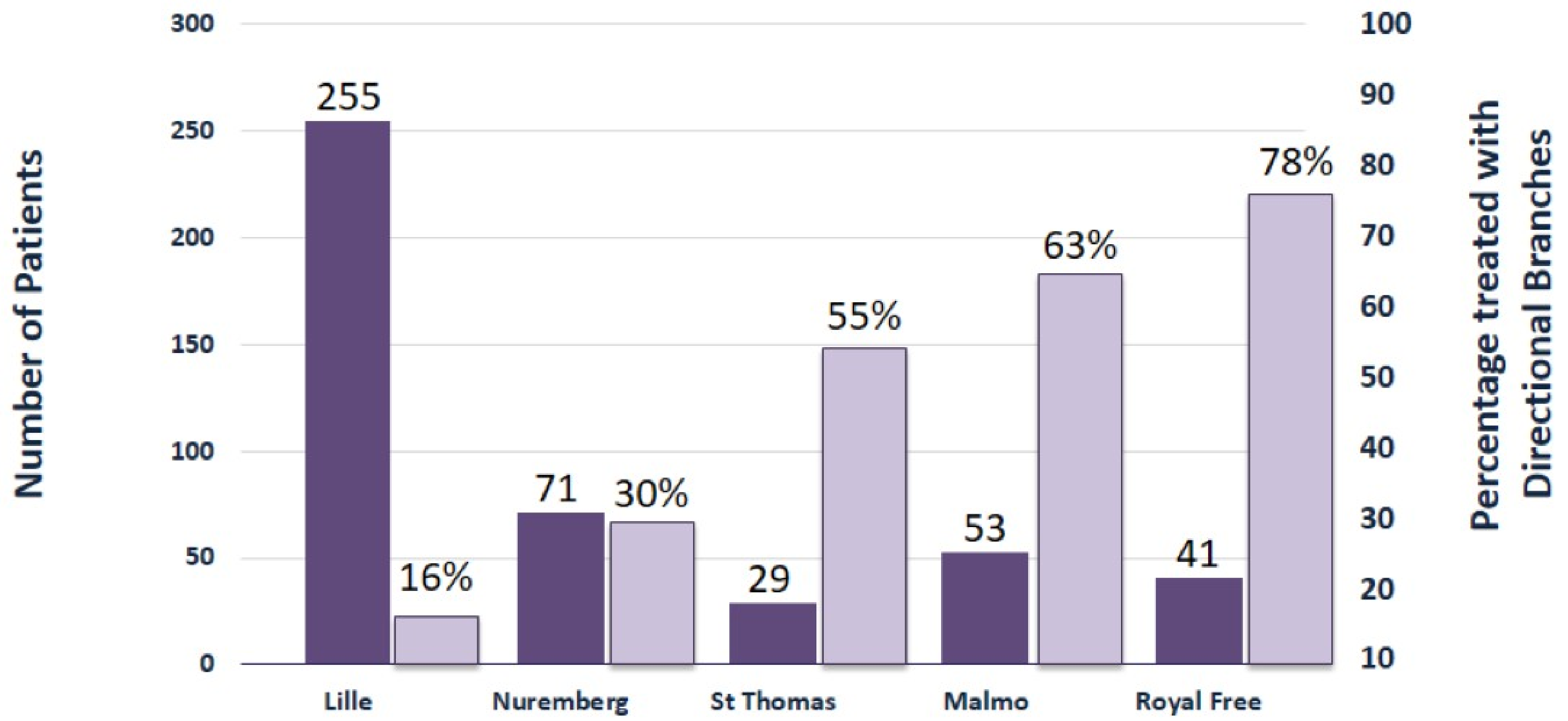
T. Martin-Gonzalez [a], T. Mastracci [b], T. Carrell [c], J. Constantinou [b], N. Dias [d], A. Katsargyris [e], B. Modarai [c], T. Resch [d], E. Verhoeven [e], S. Haulon [a,*]

- 449 patients with 856 renal arteries
  - 445 branches and 411 fenestrations
- Mean follow up, 19 months
- Renal branch stents ~60% self-expandable and 40% BES

2-year freedom from	Fenestrations	Branches	P
Occlusion	**97%**	**90%**	0.01
Reintervention	**99%**	**92%**	0.03
Branch instability	**98%**	**86%**	0.01
>20% decline eGFR	37%	43%	NS
Mortality	82%	73%	NS

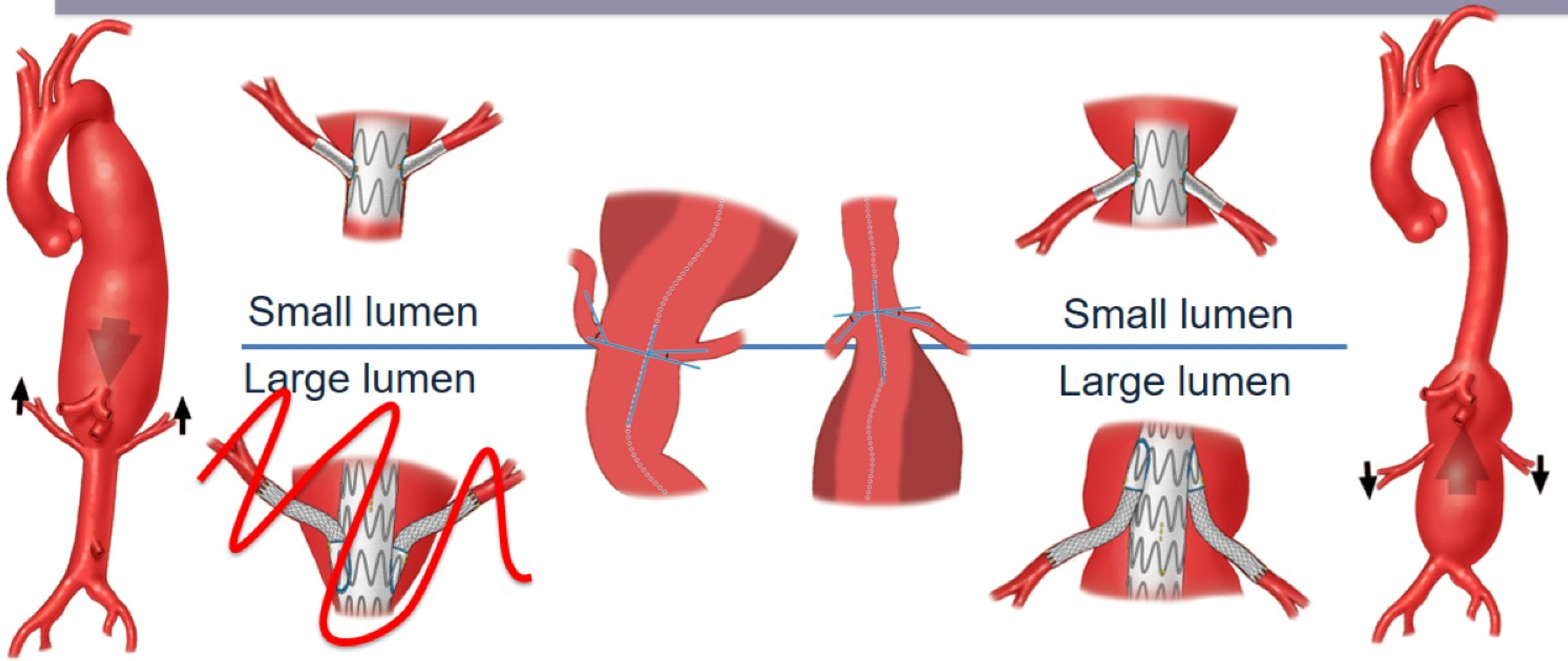
PHYSICIAN PREFERENCE & TYPE OF INCORPORATION

VARIATIONS IN USE OF DIRECTIONAL BRANCHES



Martin Gonzales et al. Eur J Vasc Endovasc Surg 2015

SELECTION OF FENESTRATIONS OR BRANCHES

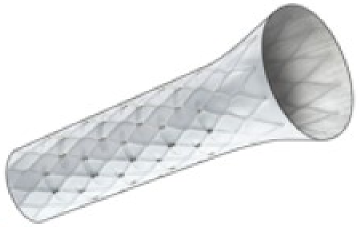


BRIDGING STENT OPTIONS

Self-Expandable

Boston Scientific Wallgraft

Bard Fluency Plus® Flair

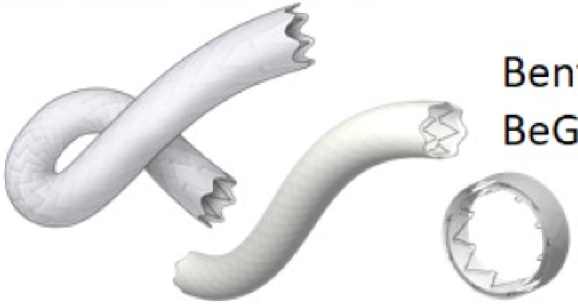


Bard COVERA®

Gore Viabahn®

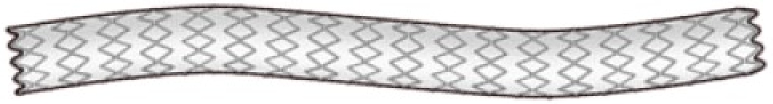
Balloon-Expandable

Atrium Maquet Getinge Icast Covered Stent

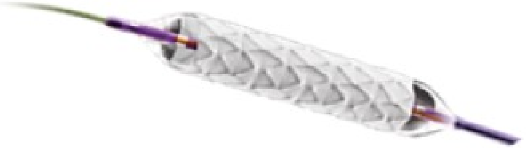


Bentley BeGraft ® and BeGraft Plus®

Gore Viabahn® VBX



Bard LifeStream®



Mendes et al. J Vasc Surg 2015

PROBLEMS WITH F-BEVAR LITERATURE

- Variations on definitions of end-points
- Physician bias towards fenestrations or branches
- Significant variations on selection of bridging stent type
- Underreporting on bridging stent type
- Lack of reporting on key outcomes such as primary patency, target vessel instability, endoleaks and secondary interventions

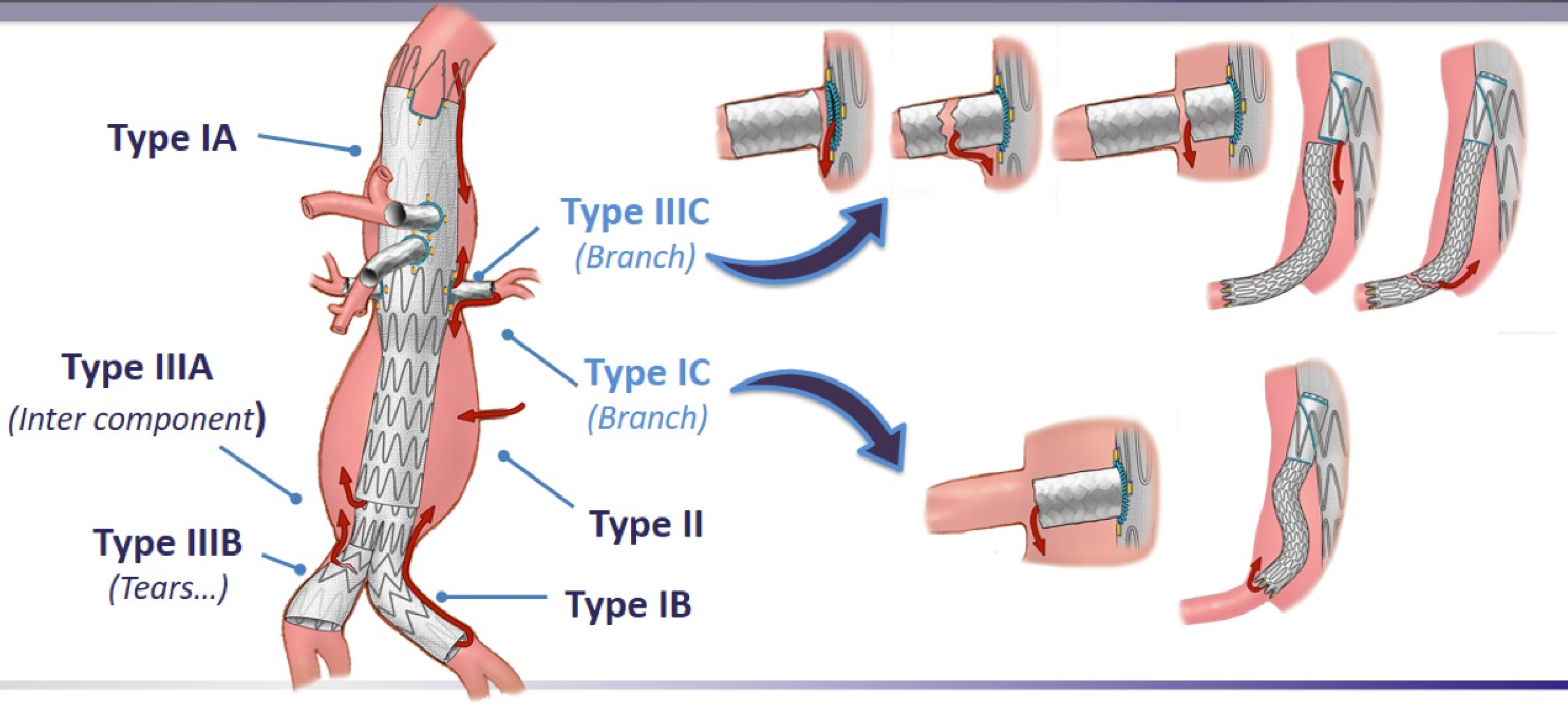
TARGET VESSEL INSTABILITY

Durability of branches in branched and fenestrated endografts

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

- Composite of any branch-related event:
  - Death or aneurysm rupture
  - Occlusion
  - Reintervention for:
    Type IC or IIIC endoleak
    Stenosis or kink
    Disconnection, fracture or integrity issues

REVISED ENDOLEAK CLASSIFICATION (SVS REPORTING STANDARD)



2018 VASCULAR ANNUAL MEETING

Target Artery Outcomes After Branched and Fenestrated Endovascular Repair of Pararenal and Thoracoabdominal Aortic Aneurysms in the US IDE Experience

Darren B. Schneider, Gustavo S. Oderich, Mark A. Farber, Andres Schanzer, Adam W. Beck, Carlos H. Timaran, Matthew P. Sweet, and Emanuel R. Tenorio

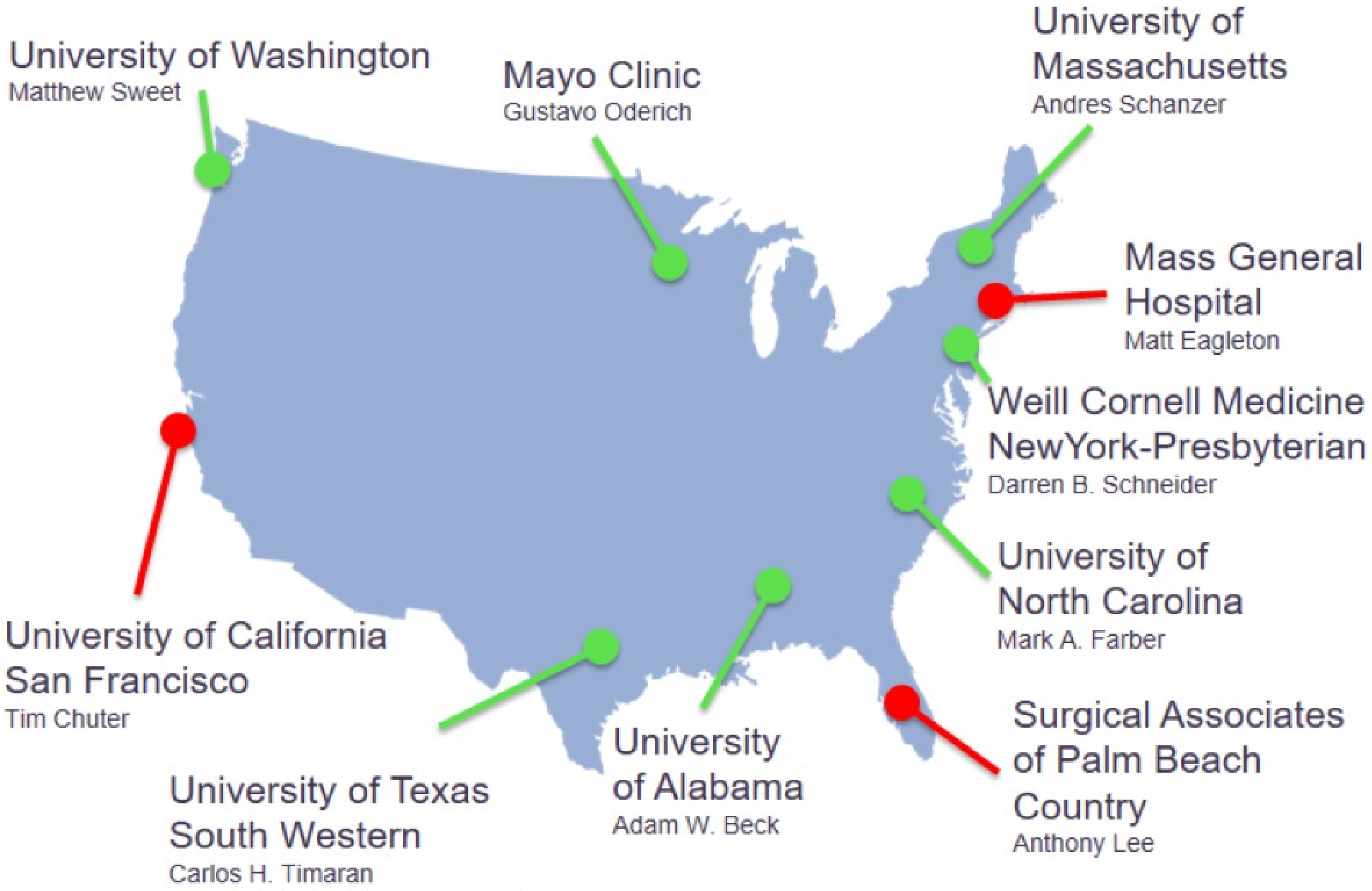
On Behalf of the United States Fenestrated and Branched Research Consortium Investigators

Disclosures

DBS: consulting and research grants from Cook, WL Gore, Endologix and Medtronic; GSO: consulting and research grants from Cook and WL Gore paid to Mayo Clinic; MAF: consulting and research grants from Cook, WL Gore, Endologix and Medtronic; AS: consulting and research grants from Cook; AWB: none; CHT: consulting and research grants from Cook; MPS: none ; ERT: none

US FENESTRATED-BRANCHED CONSORTIUM

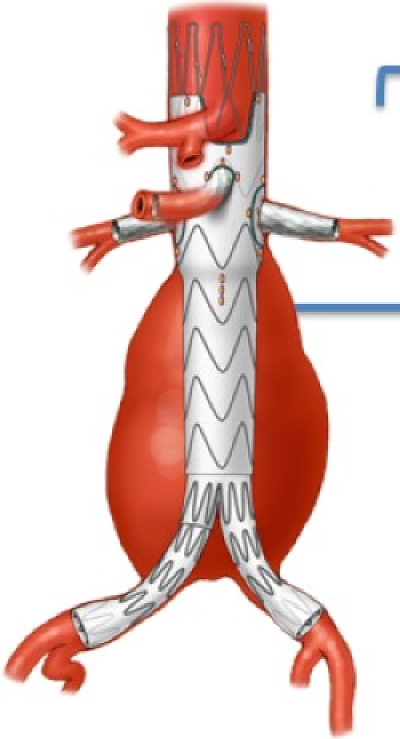
- 10 US sites
- Prospective, physician-sponsored studies
- Monitored, audited
- Similar device design with selective use of fenestrations and branches



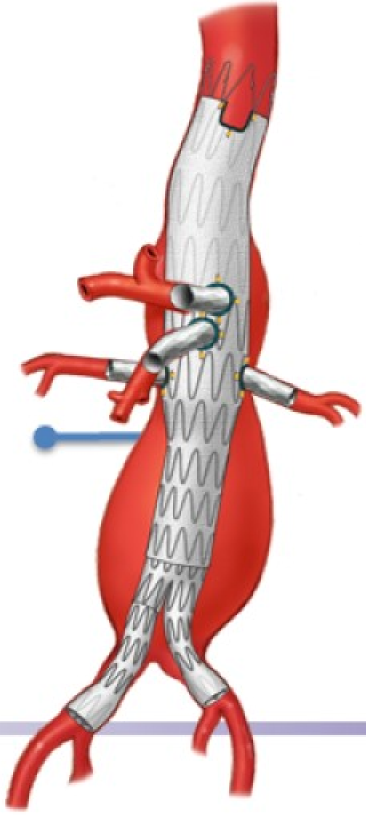
PATIENTS

661 patients enrolled

(January 1st, 2018)



232 pararenal (36%)



221 Extent 4 TAAA (33%)

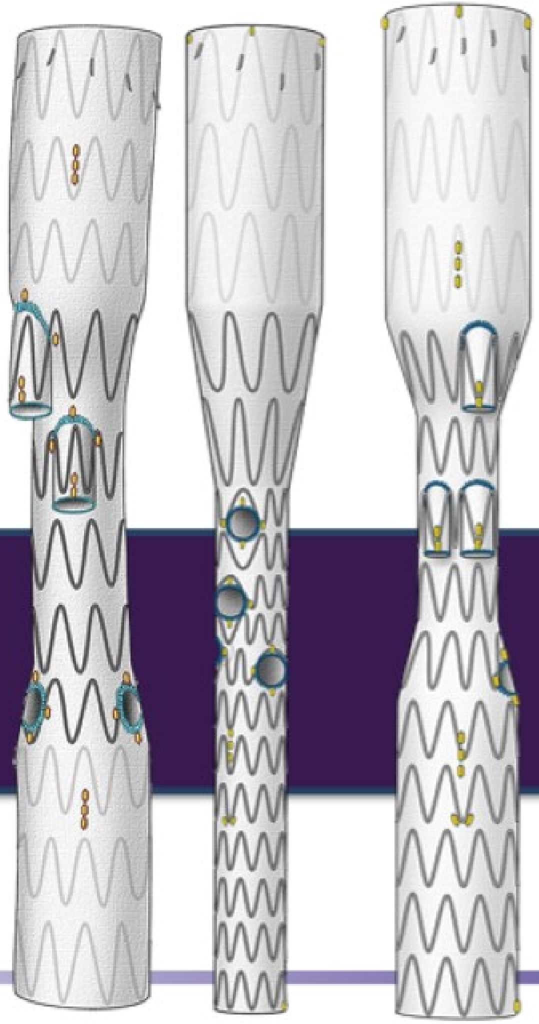
208 Extent 1-3 TAAA (31%)

STENT DESIGN

Off-the-Shelf

Cook t-Branch®

t- Branch = 63 (10%)



Patient Specific

Fenestrations or branches

n = 597 (90%)

SELECTION OF FENESTRATIONS OR BRANCHES

2428 target visceral arteries (3.8/patient)*

	Overall n = 2428	Pararenal n = 801	Type IV n = 881	Type I-III n = 746	P value
	n (Percent) or Mean ± Standard Deviation				
Vessels per patient	3.8±0.6	3.8±0.6	3.8±0.6	3.8±0.7	0.8
Fenestrations	1701 (70)	671 (84)	734 (83)	296 (40)	<0.001
Directional branches	631 (26)	34 (4)	147 (17)	450 (60)	<0.001
Double-wide scallops	96 (4)	96 (12)	0 (0)	0 (0)	<0.001

* All patients with <4-vessels had variant anatomy (e.g. single kidneys, pelvic transplants, celio-mesenteric trunks, etc)

STENT SELECTION FOR FENESTRATIONS

1679 target visceral arteries incorporated with fenestrations (2.5 vessels/ patient)

	Overall n = 1679	Pararenal n = 660	Type IV n = 729	Type I-III n =290	P value
	n (Percent)				
iCAST stent	1648 (98)	649 (98)	715 (98)	284 (98)	0.89
Fluency stent	3 (0.2)	0	2 (0.3)	1 (0.3)	0.36
Viabahn stent	8 (0.5)	1 (0.1)	4 (0.5)	3 (1)	0.17
VBX stent	3 (0.2)	2 (0.3)	0	1 (0.3)	0.31
Others	17 (1)	8 (1.2)	8 (1)	1 (0.3)	0.44
Adjunctive bare metal	470 (28)	153 (23)	234 (32)	83 (29)	0.001

STENT SELECTION FOR DIRECTIONAL BRANCHES

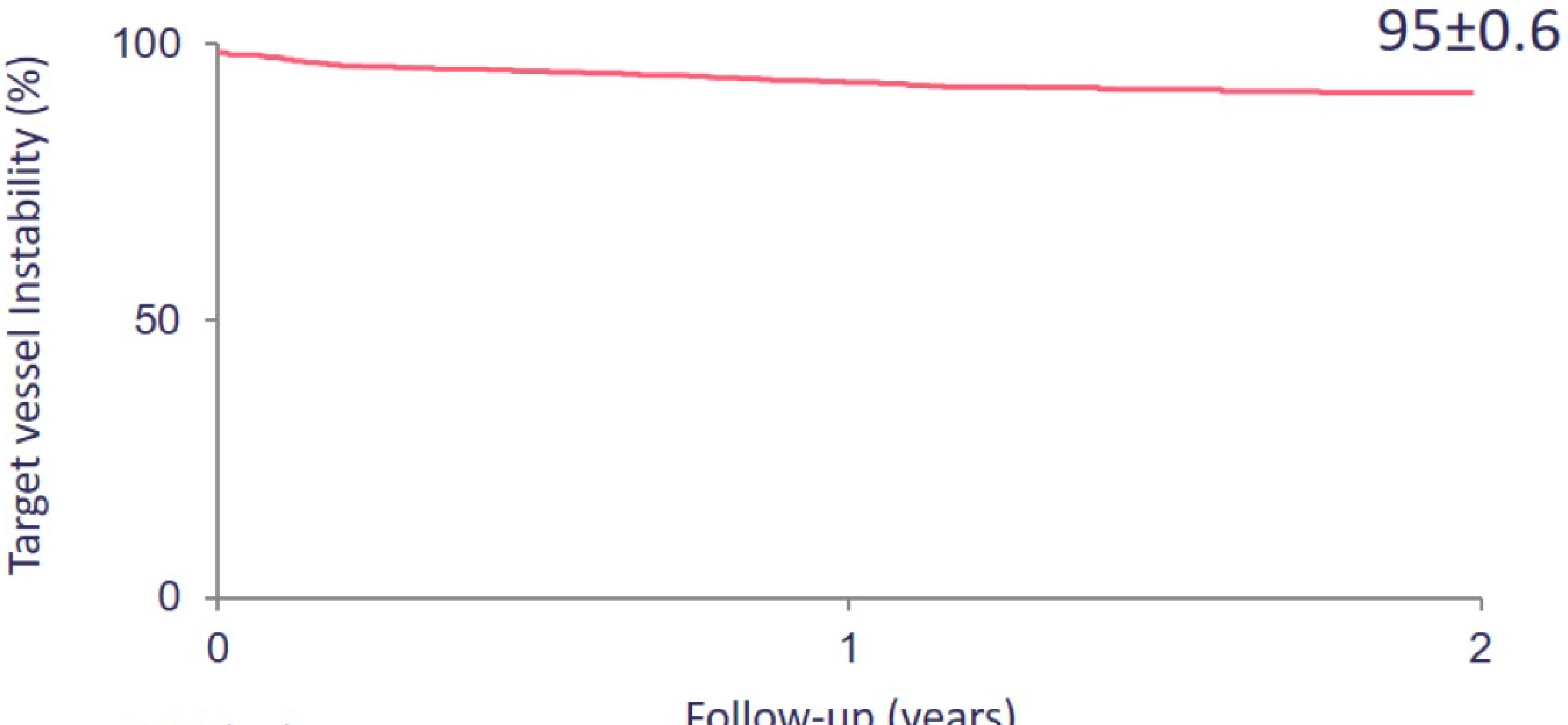
625 target visceral arteries incorporated with branches
(1 vessel/ patient)

	Overall n = 625	Pararenal n = 34	Type IV n = 146	Type I-III n =445	P value
	n (Percent)				
iCAST stent	155 (25)	17 (50)	38 (26)	100 (22)	0.002
Fluency stent	107 (17)	0	27 (18)	80 (18)	0.02
Viabahn stent	282 (45)	16 (47)	76 (52)	190 (43)	0.13
VBX stent	63 (10)	0	0	63 (14)	<0.001
Others	18 (3)	1 (3)	5 (3)	12 (3)	0.9
Adjunctive bare metal	258 (41)	6 (18)	68 (47)	184 (41)	0.009

EARLY OUTCOMES (<30 DAYS)

	Overall n = 661	Pararenal n = 232	Extent IV n = 221	Extent I-III n = 208	P value
	n (Percent)				
Any Mortality	13 (2)	3 (1)	5 (2)	5 (2)	0.82
Any MAE	97 (15)	26 (11)	33 (15)	38 (18)	0.11
EBL >1L	29 (5)	6 (3)	9 (4)	14 (7)	0.10
Acute Kidney injury	36 (5)	7 (3)	14 (6)	15 (7)	0.11
Myocardial infarction	12 (2)	4 (2)	7 (3)	1 (0.4)	0.11
Respiratory failure	20 (3)	2 (1)	10 (5)	8 (4)	0.053
Paraplegia	11 (2)	1 (0.4)	1 (0.4)	9 (4)	<0.001
Stroke	12 (2)	3 (1)	4 (2)	5 (2)	0.68
Bowel ischemia	22 (3)	5 (2)	10 (5)	7 (3)	0.37

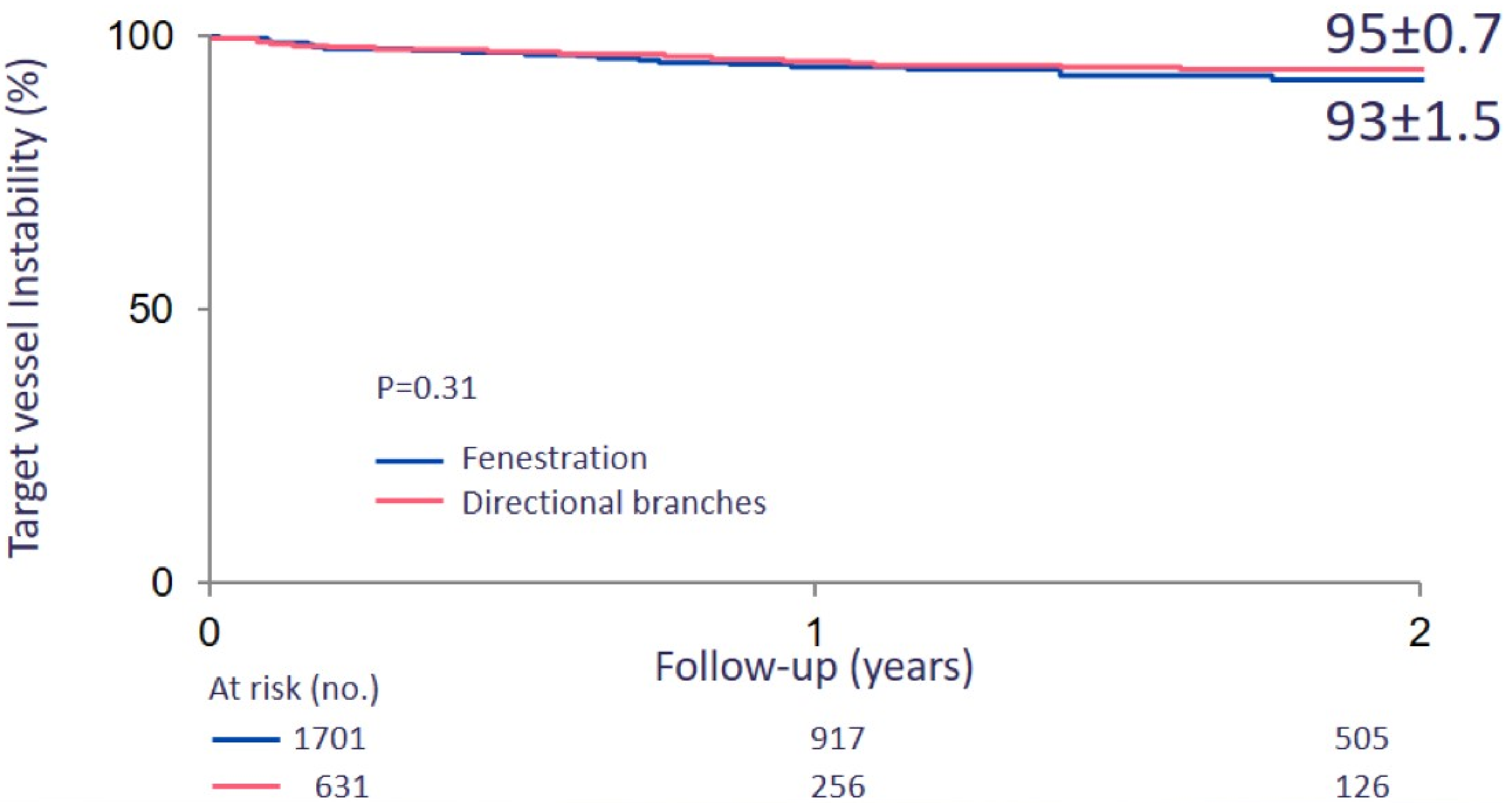
TARGET VESSEL INSTABILITY



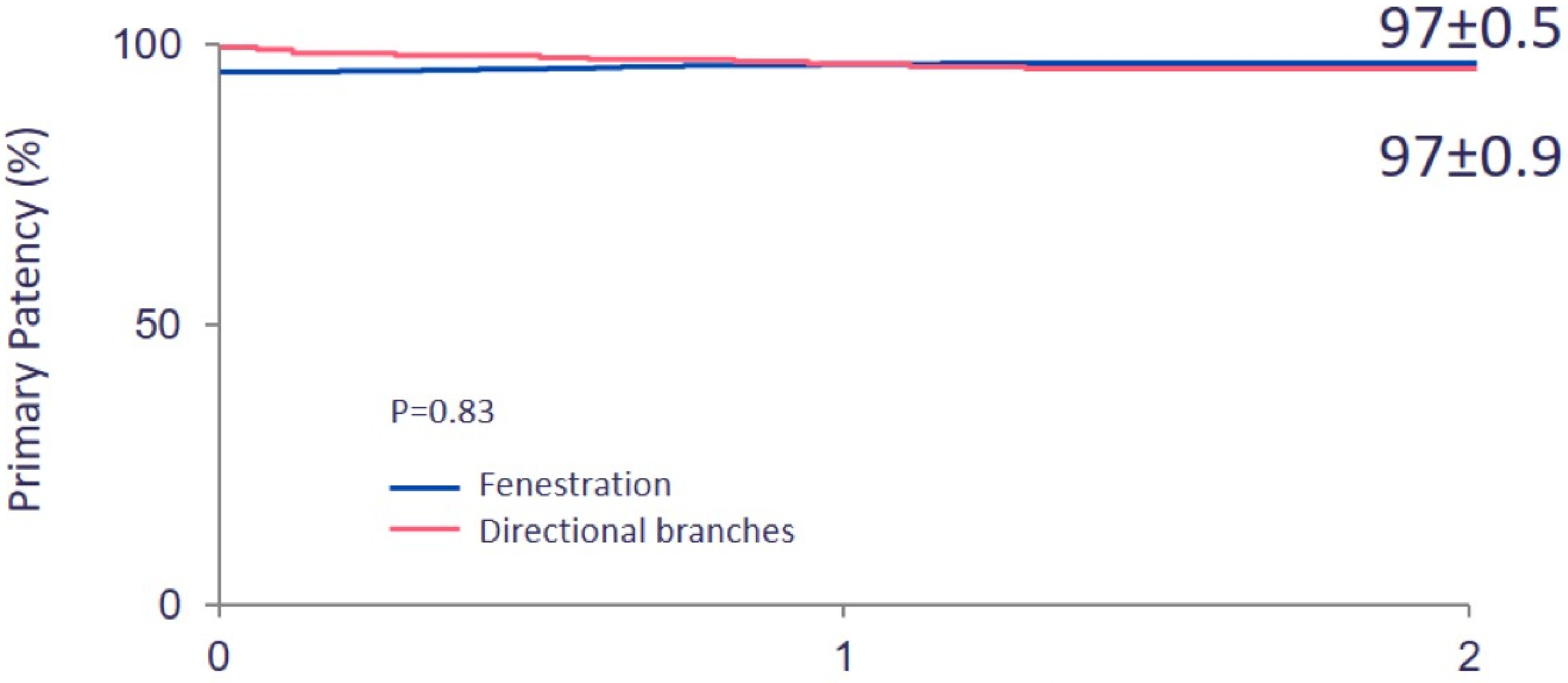
At risk (no.)

2428	1222	662

TARGET VESSEL INSTABILITY FOR FENESTRATIONS vs BRANCHES



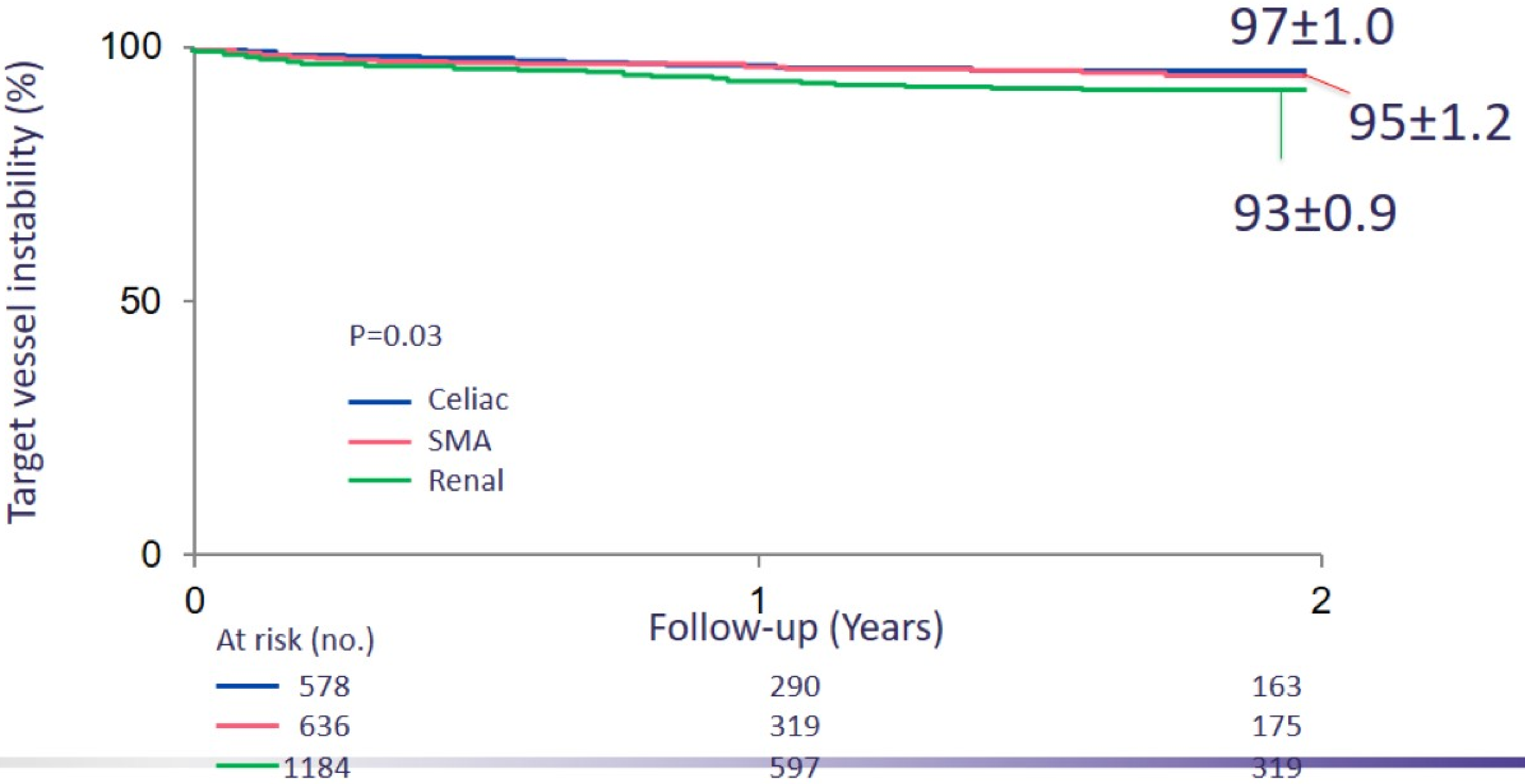
PRIMARY PATENCY FOR FENESTRATIONS vs BRANCHES



At risk (no.)

	0	1	2
Fenestration	1701	935	519
Directional branches	631	264	134

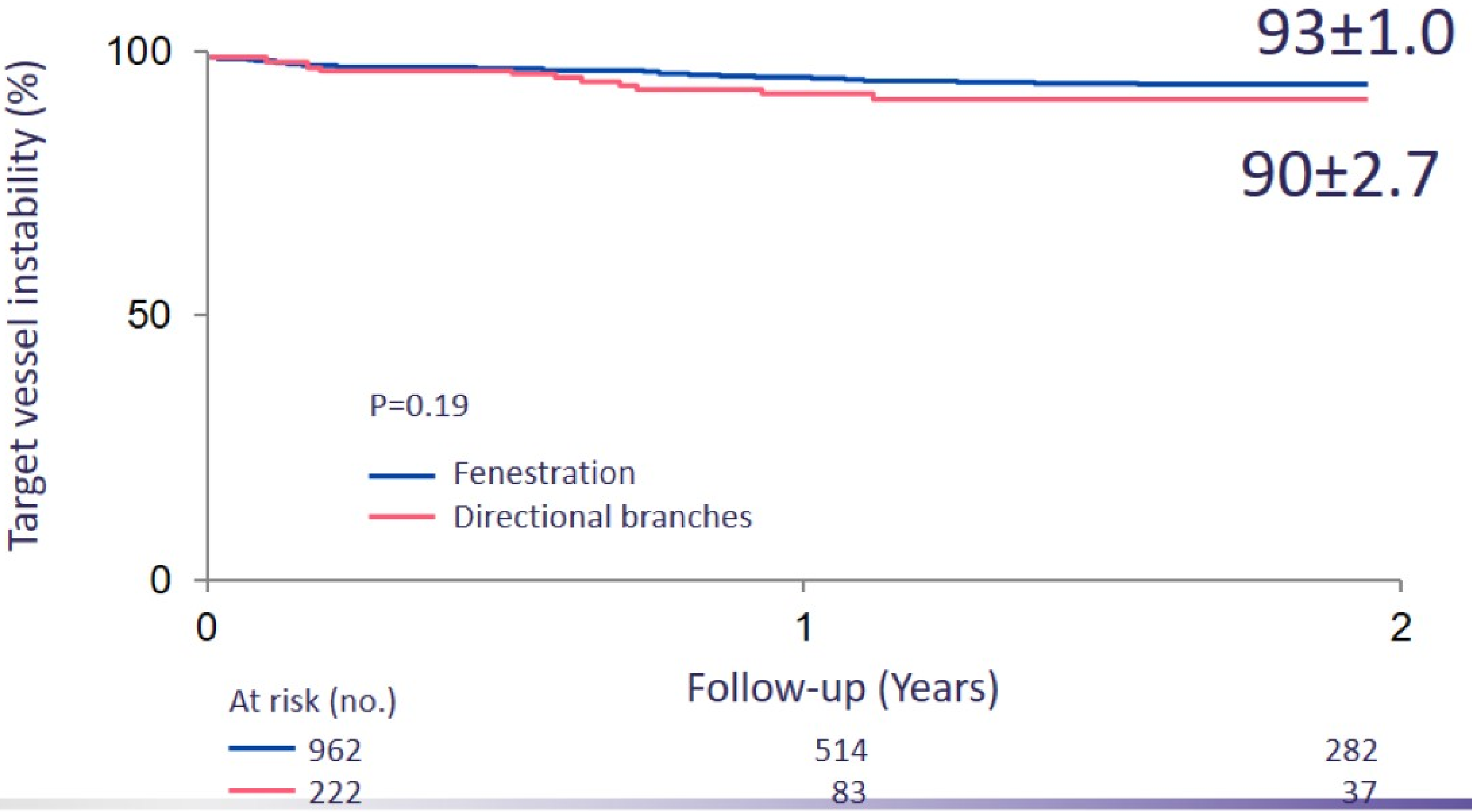
TARGET VESSEL INSTABILITY BY VESSEL



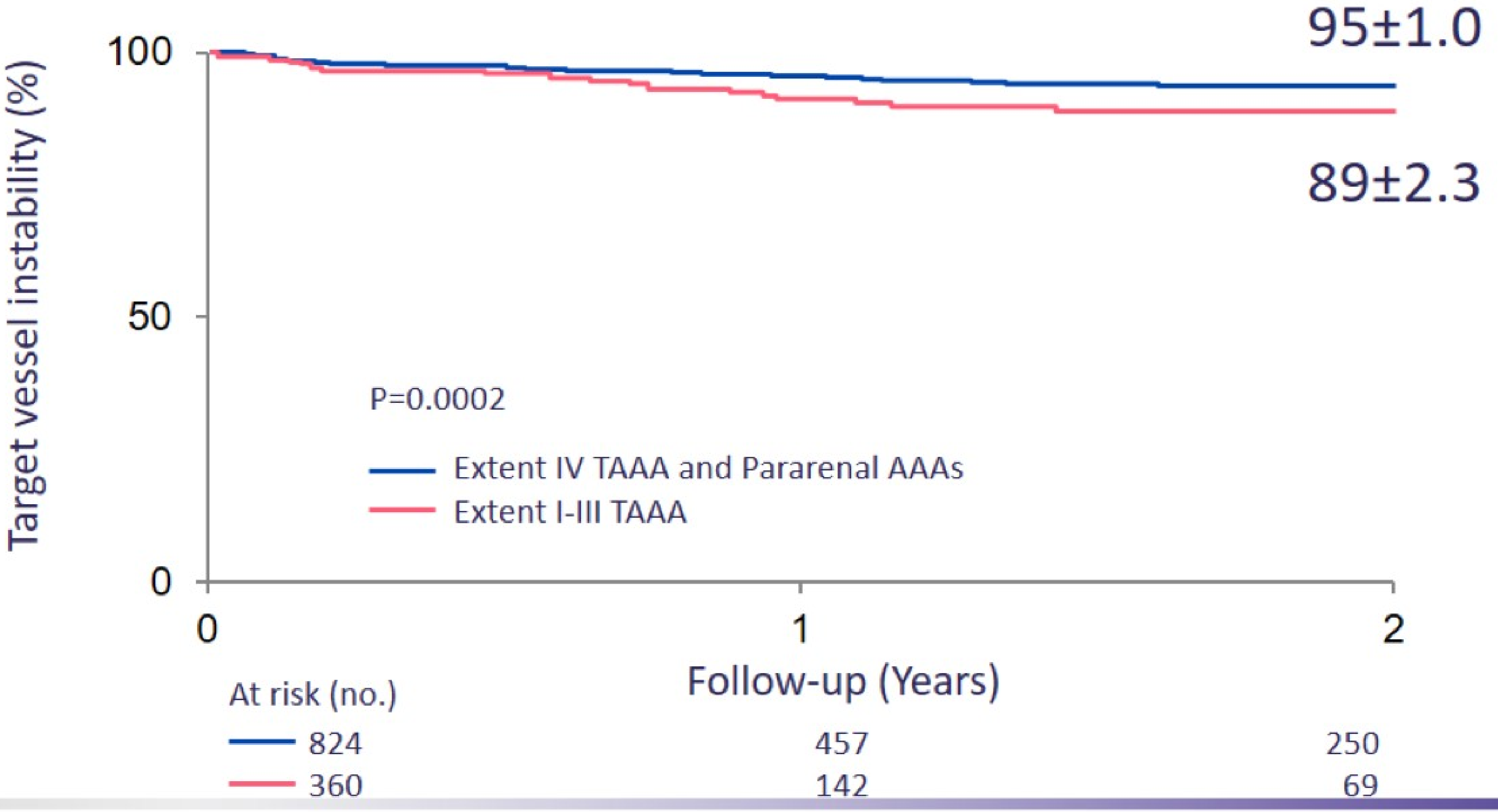
PREDICTORS OF TARGET VESSEL INSTABILITY

	Odds Ratio	95% CI		P value
		lower	upper	
R renal artery	2.001	1.21	3.317	0.0071
L renal artery	1.862	1.11	3.112	0.0176
Chronic Dissection TAAA	3.141	1.69	5.836	0.0003
Celiac Stenosis ≥ 50%	2.181	1.32	3.603	0.0023
Number of target vessels	1.722	1.11	2.682	0.0163

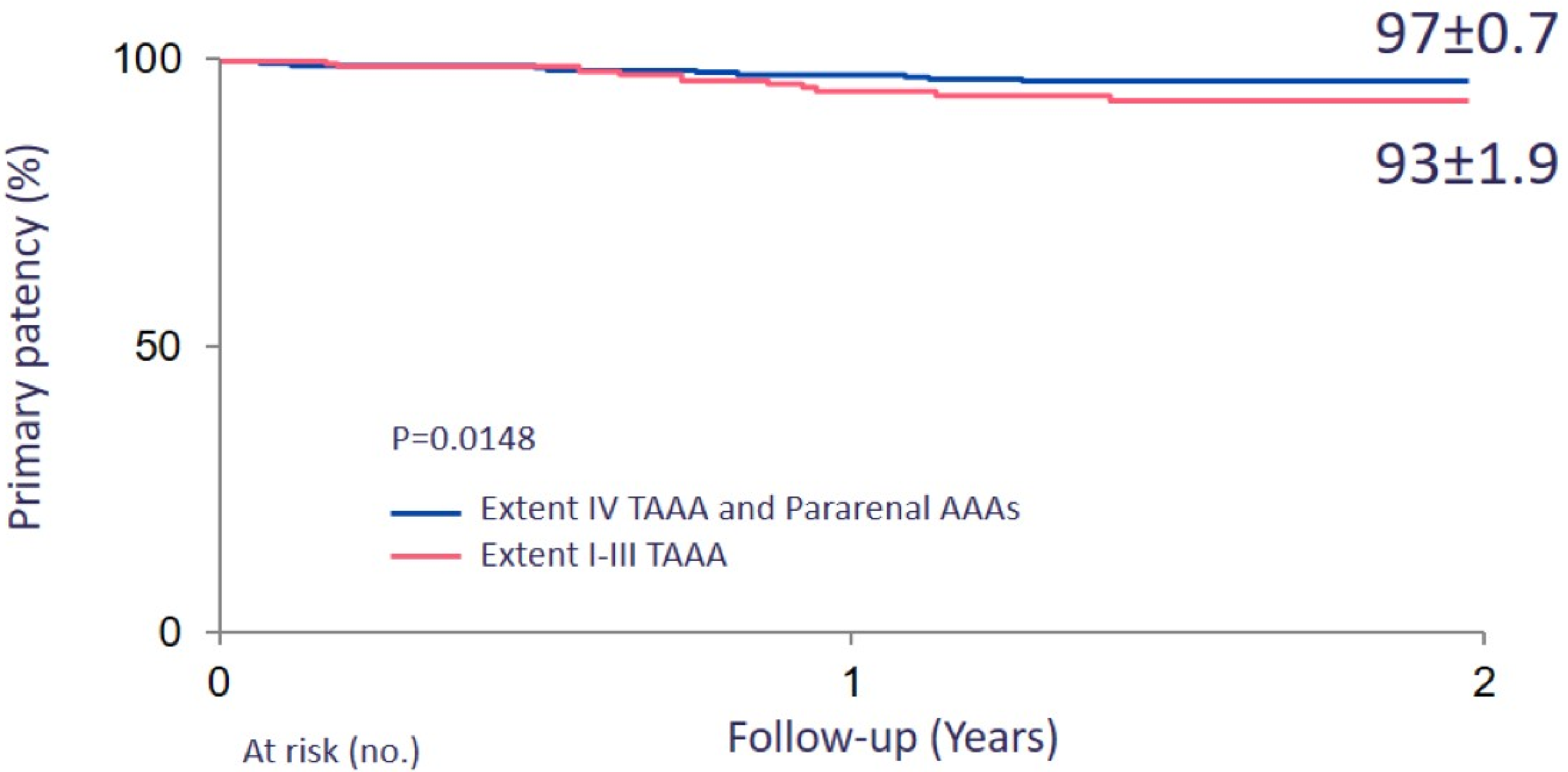
RENAL VESSEL INSTABILITY FOR FENESTRATIONS vs BRANCHES



TARGET VESSEL INSTABILITY BY ANEURYSM EXTENT

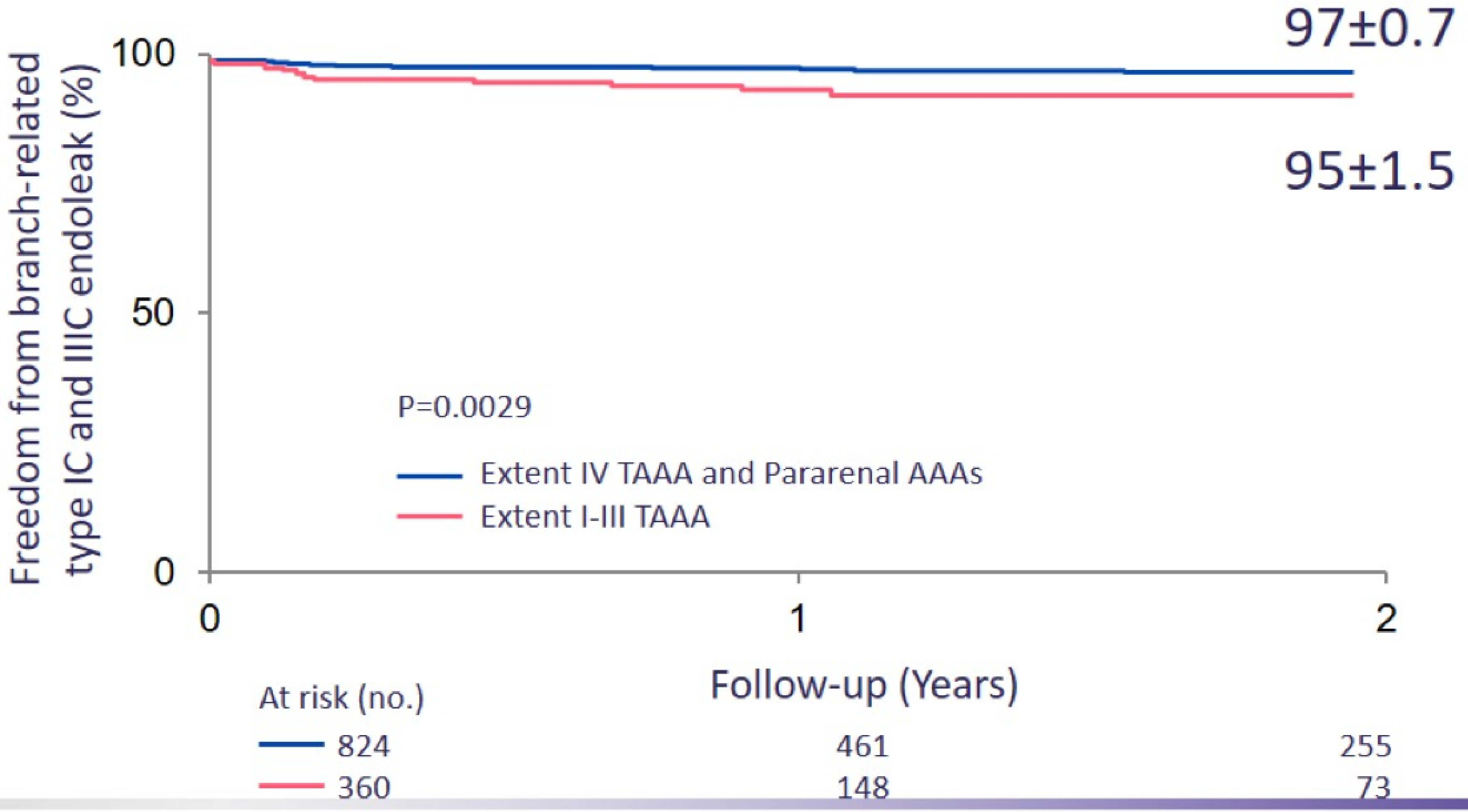


RENAL ARTERY PRIMARY PATENCY BY ANEURYSM EXTENT

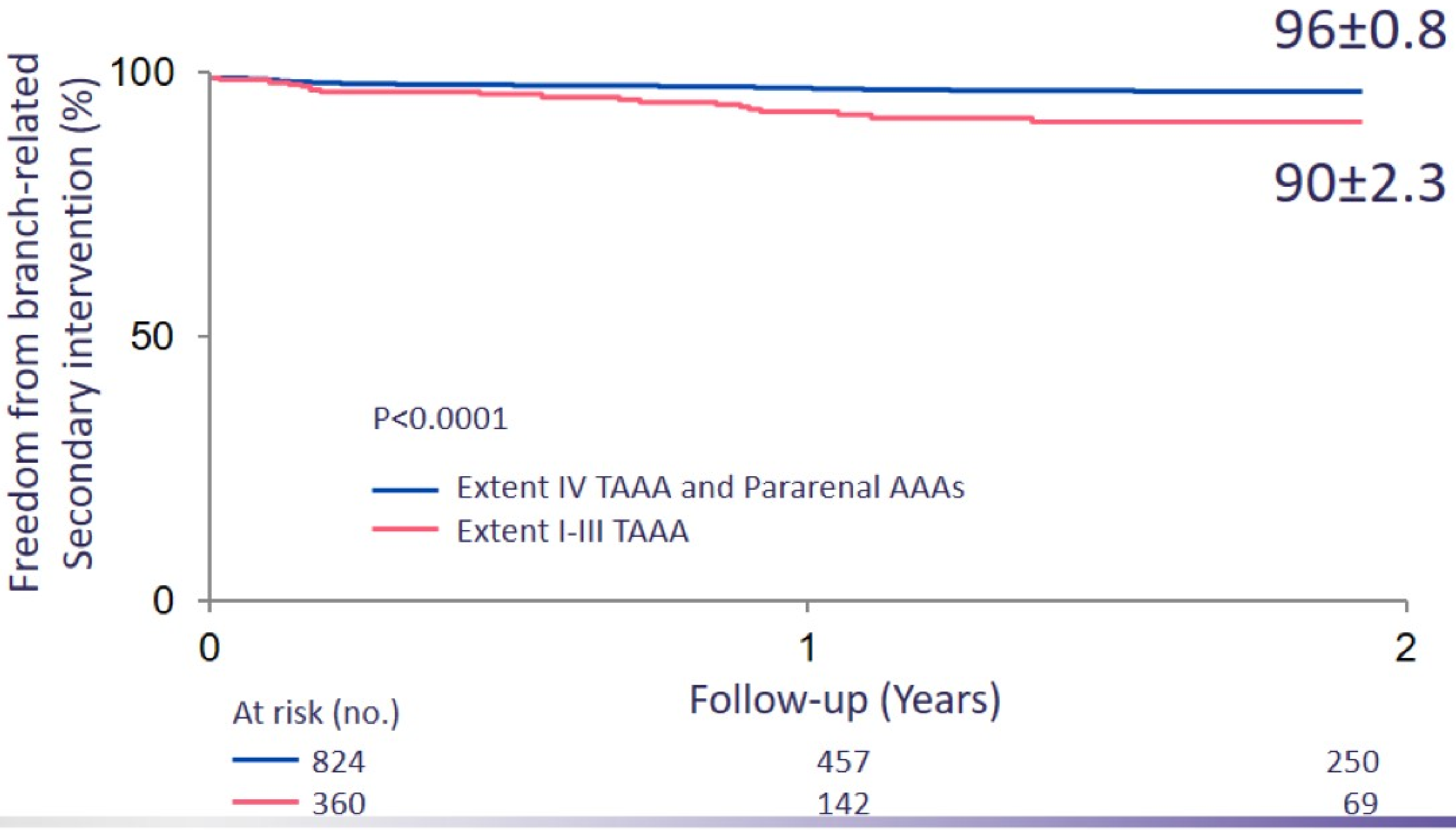


At risk (no.)			
Extent IV TAAA and Pararenal AAAs	824	463	255
Extent I-III TAAA	360	146	74

RENAL ARTERY ENDOLEAK TYPE IC/IIIC BY ANEURYSM EXTENT



RENAL ARTERY REINTERVENTION BY ANEURYSM EXTENT



PREDICTORS OF RENAL VESSEL INSTABILITY

	Odds Ratio	95% CI		P value
		lower	upper	
Number of target vessels	2.1	1.3	3.6	0.005
Extent I-III TAAAs	1.9	1.1	3.3	0.025

AMERICAN ASSOCIATION FOR THORACIC SURGERY
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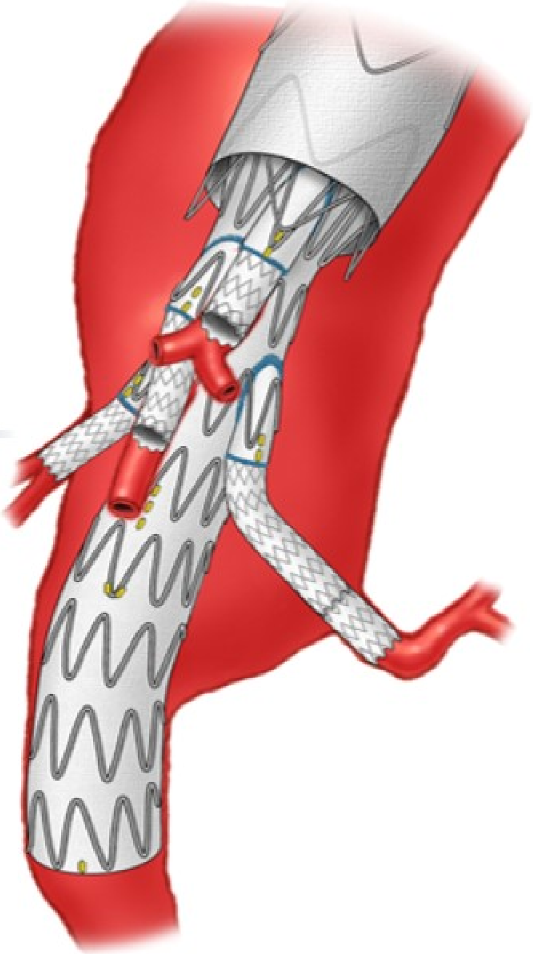
AORTIC
SYMPOSIUM
2018

April 26 - 27, 2018

New York Hilton Midtown
New York, NY, USA

Update on the first 250 patients enrolled in a F-BEVAR prospective, non-randomized study



Gustavo S. Oderich MD, Emanuel Tenorio MD PhD, Jan Hofer RN, Jean Wigham RN, Stephen Cha MS and Thanila A. Macedo MD

Division of Vascular and Endovascular Surgery and Departments of Radiology, Epidemiology and Biostatistics

Journal of Cardiovasc Thoracic Surg 2018 (in preparation)

TYPE OF INCORPORATION

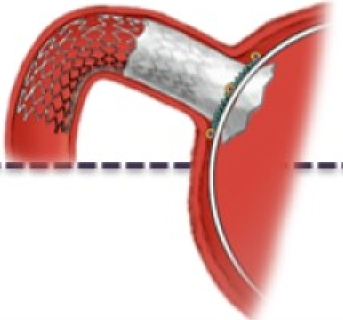
954 renal-mesenteric arteries (3.8/patient)
211 patients (85%) had ≥ 4-vessels

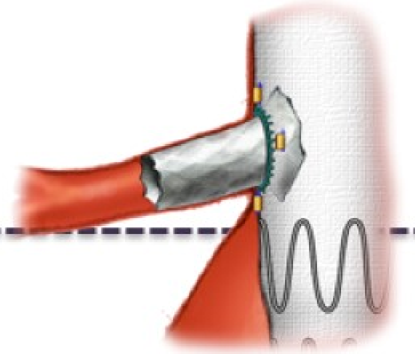
	Overall n = 250	Pararenal n = 91	Type IV n = 63	Type I-III n = 96	P value
	n (Percent) or Mean ± Standard Deviation				
Total target vessels	954	353	246	355	
Vessels per patient	3.9±0.5	3.9±0.5	3.9±0.5	3.8±0.5	0.4
Fenestrations	631 (66)	**308 (87)**	**218 (89)**	105 (30)	<0.001
Directional branches	284 (30)	6 (2)	28 (11)	**250 (70)**	<0.001
Double-wide scallops	39 (4)	39 (11)	0	0	<0.001

CHOICE OF BRIDGING STENT

FENESTRATIONS

Atrium Maquet Getinge Icast
Covered Stent

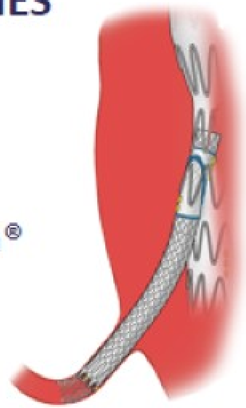




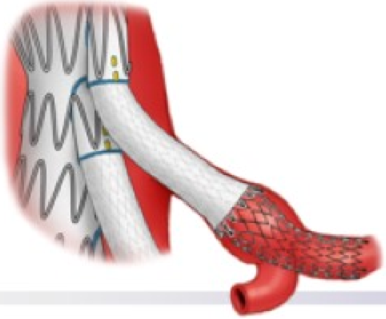
2007 — **Dec-2015** — **Present**

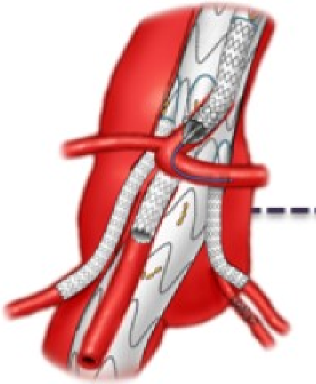
BRANCHES

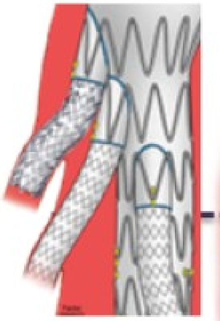
Renals
Viabahn®

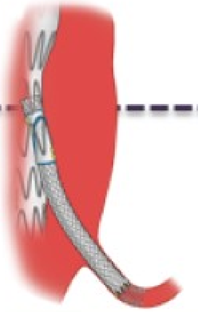


Mesenterics
Fluency®



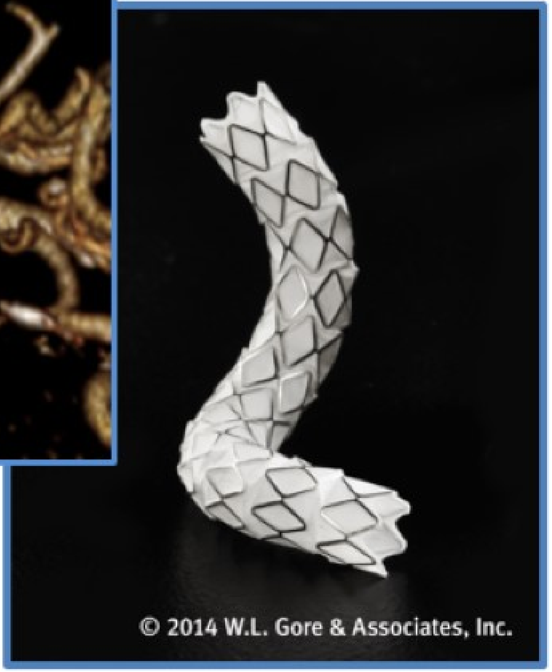




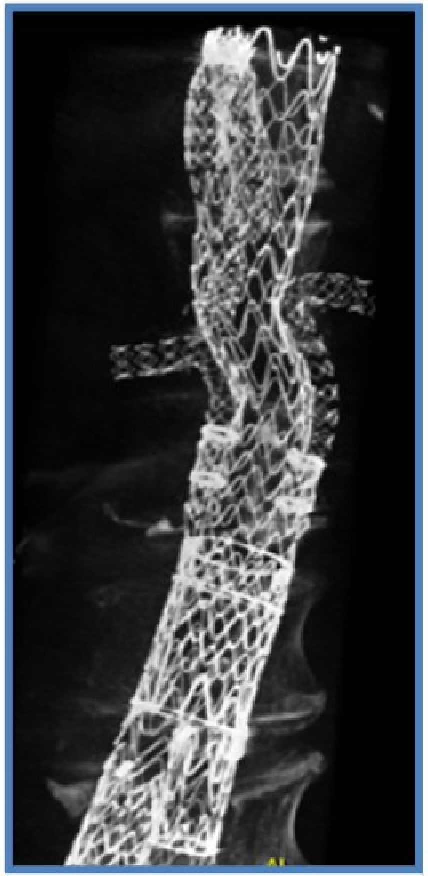


VBX BALLOON-EXPANDABLE STENT-GRAFT

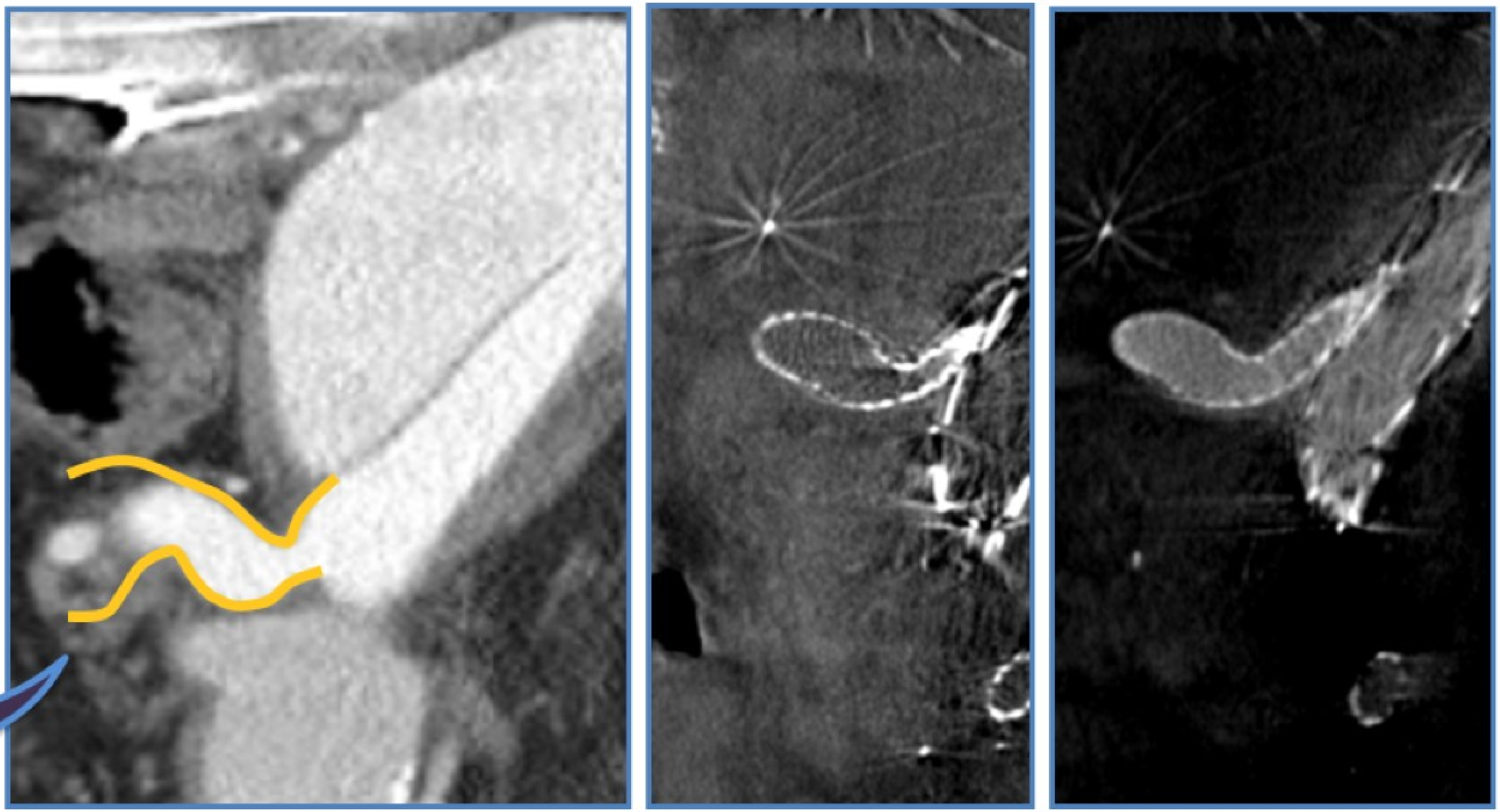
	Viabahn	VBX
Length	5, 7.5, 10-cm	39, 59, 79 mm
Diameter	6-9 mm	5-9 mm (**16**)
Sheath profile	**7-11 Fr**	**7-8 Fr**



FLEXIBILITY

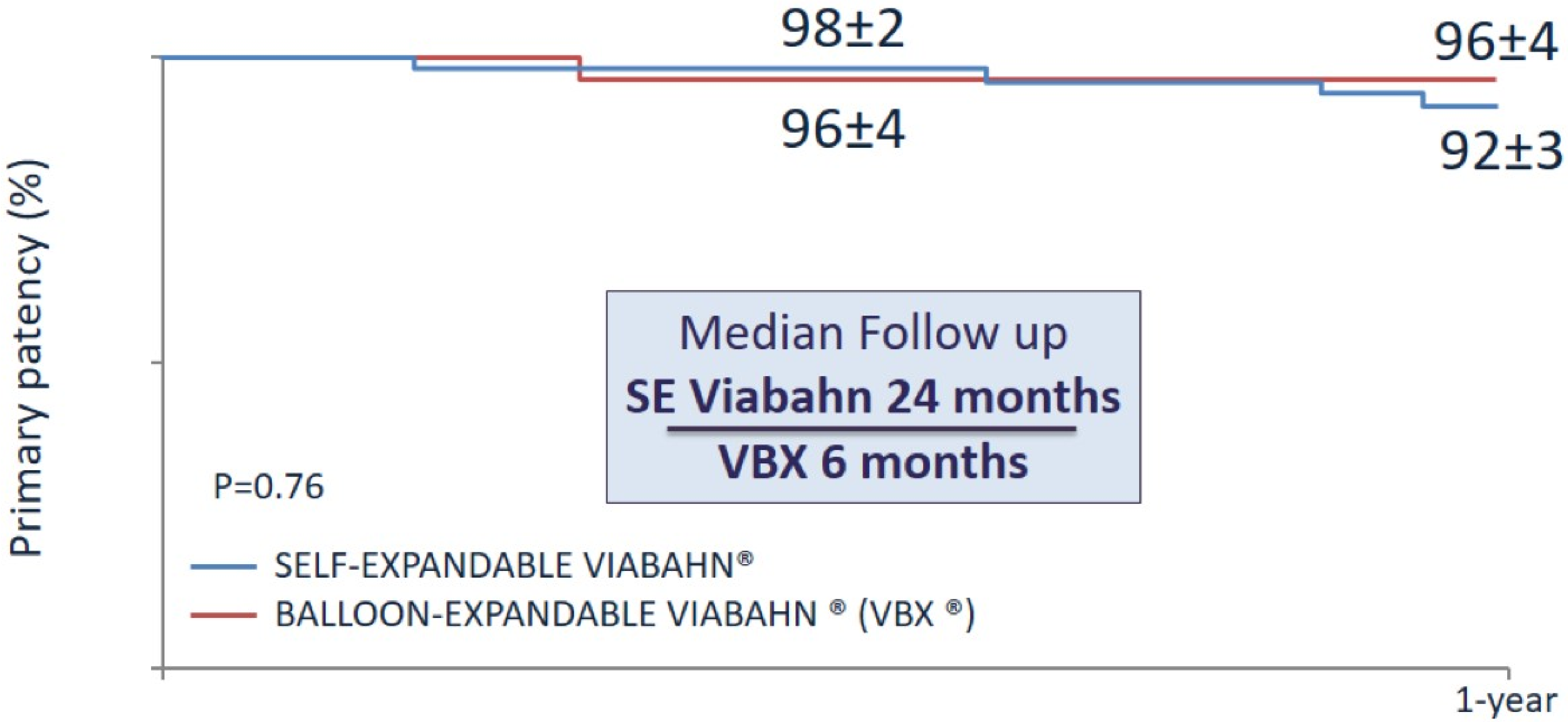


16MM FLARE



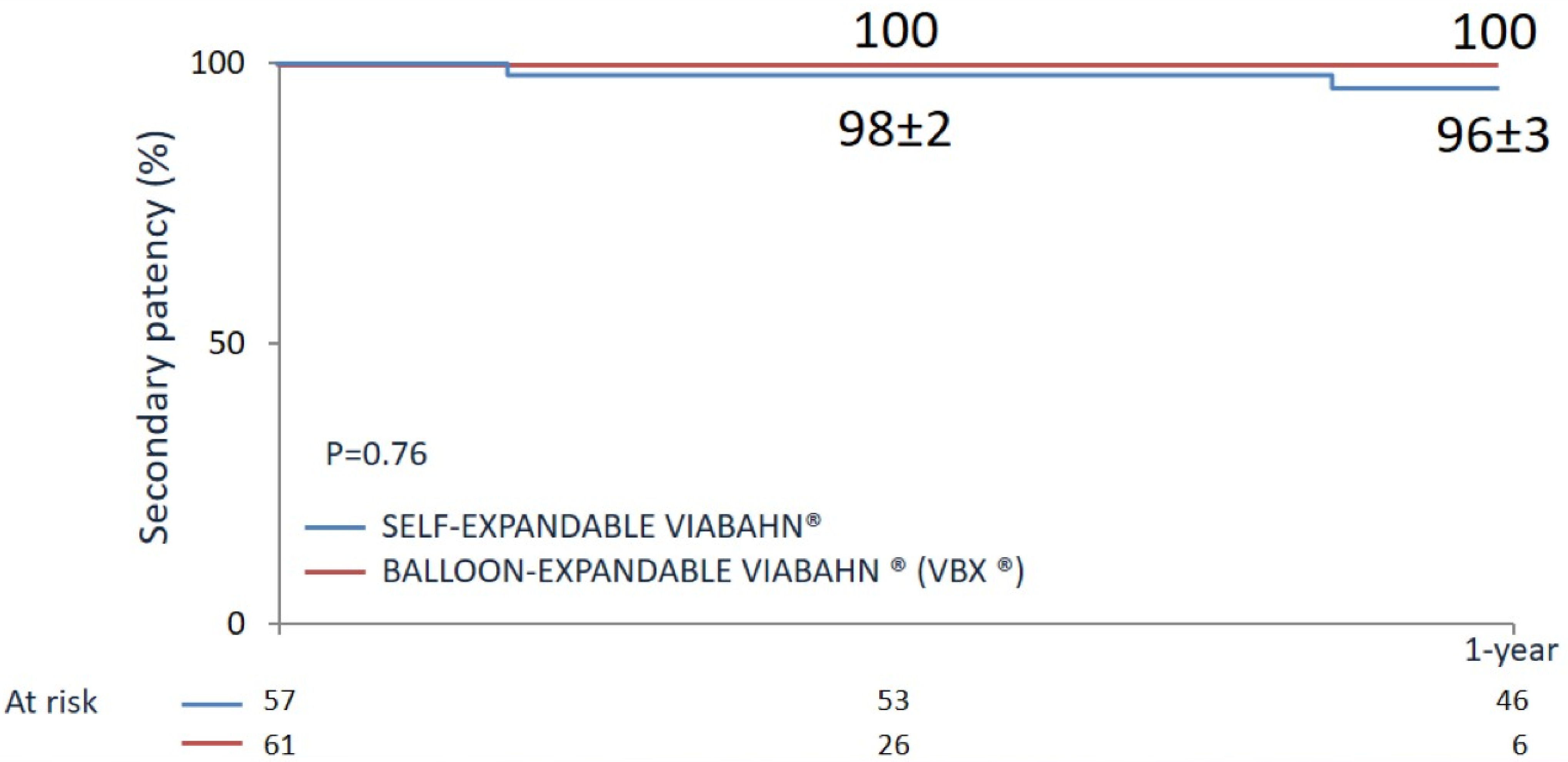
13mm, 8mm

RENAL DIRECTIONAL BRANCHES: PRIMARY PATENCY

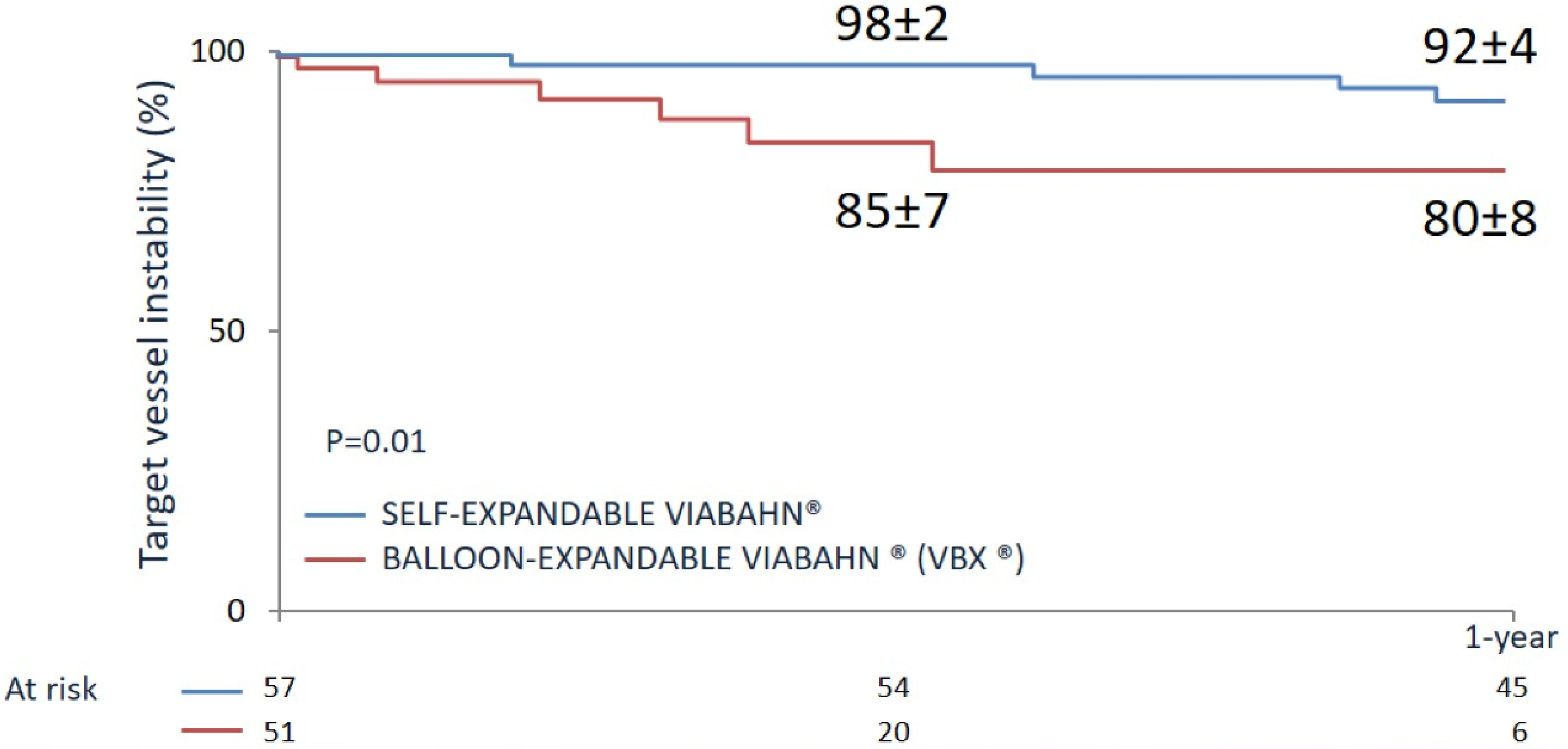


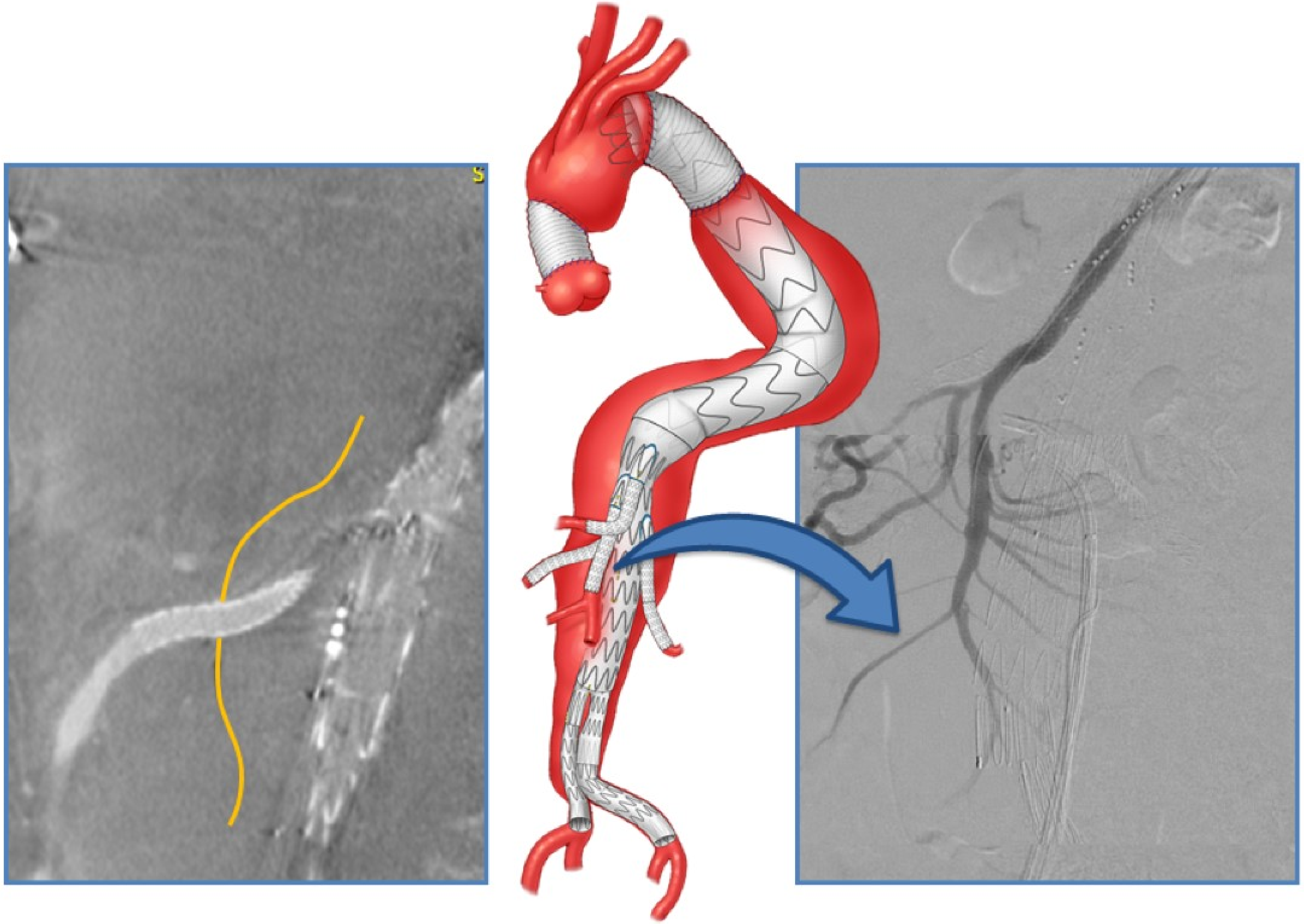
At risk	SELF-EXPANDABLE VIABAHN®	57	54	45
	BALLOON-EXPANDABLE VIABAHN ® (VBX ®)	51	23	6

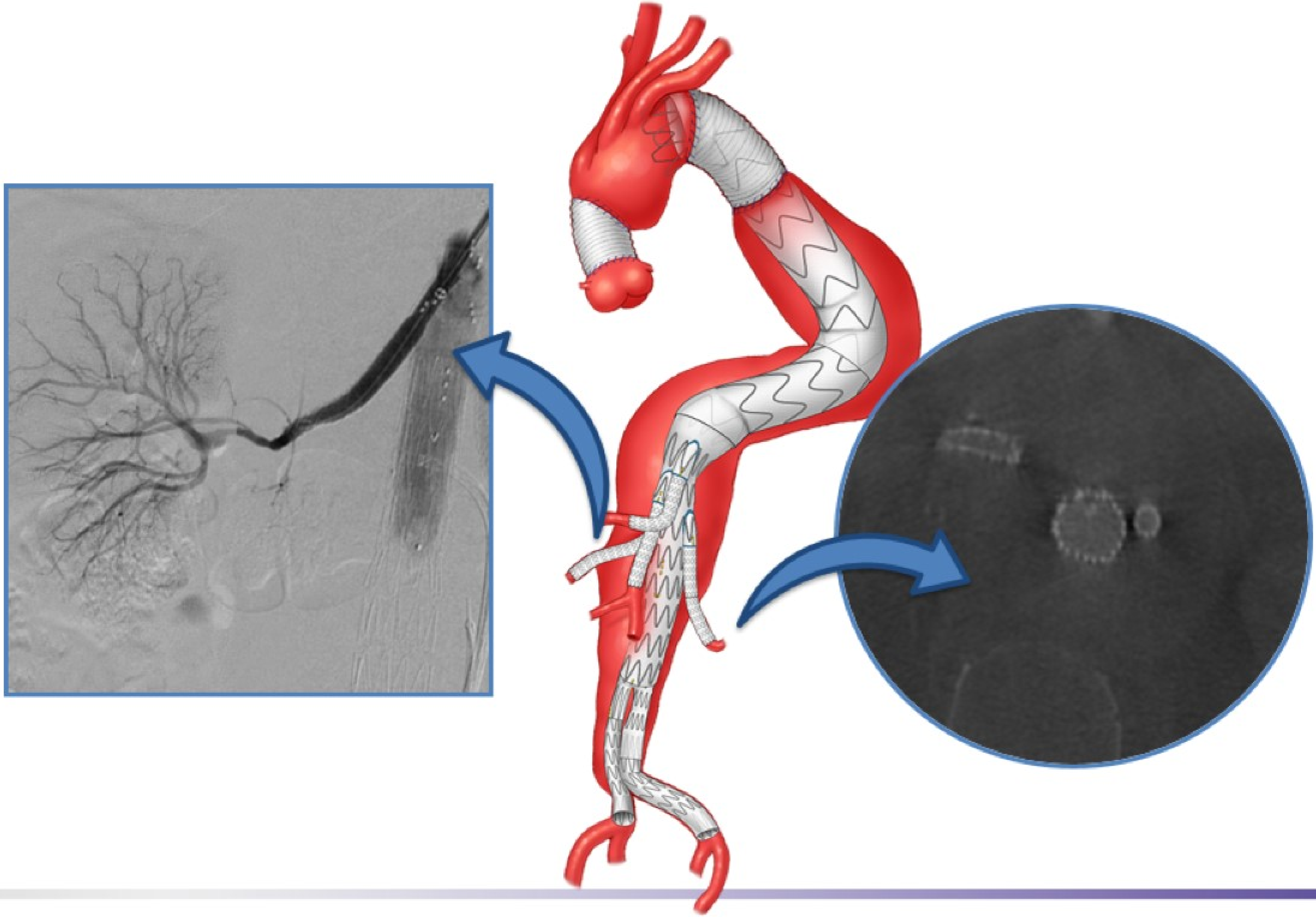
RENAL DIRECTIONAL BRANCHES: SECONDARY PATENCY

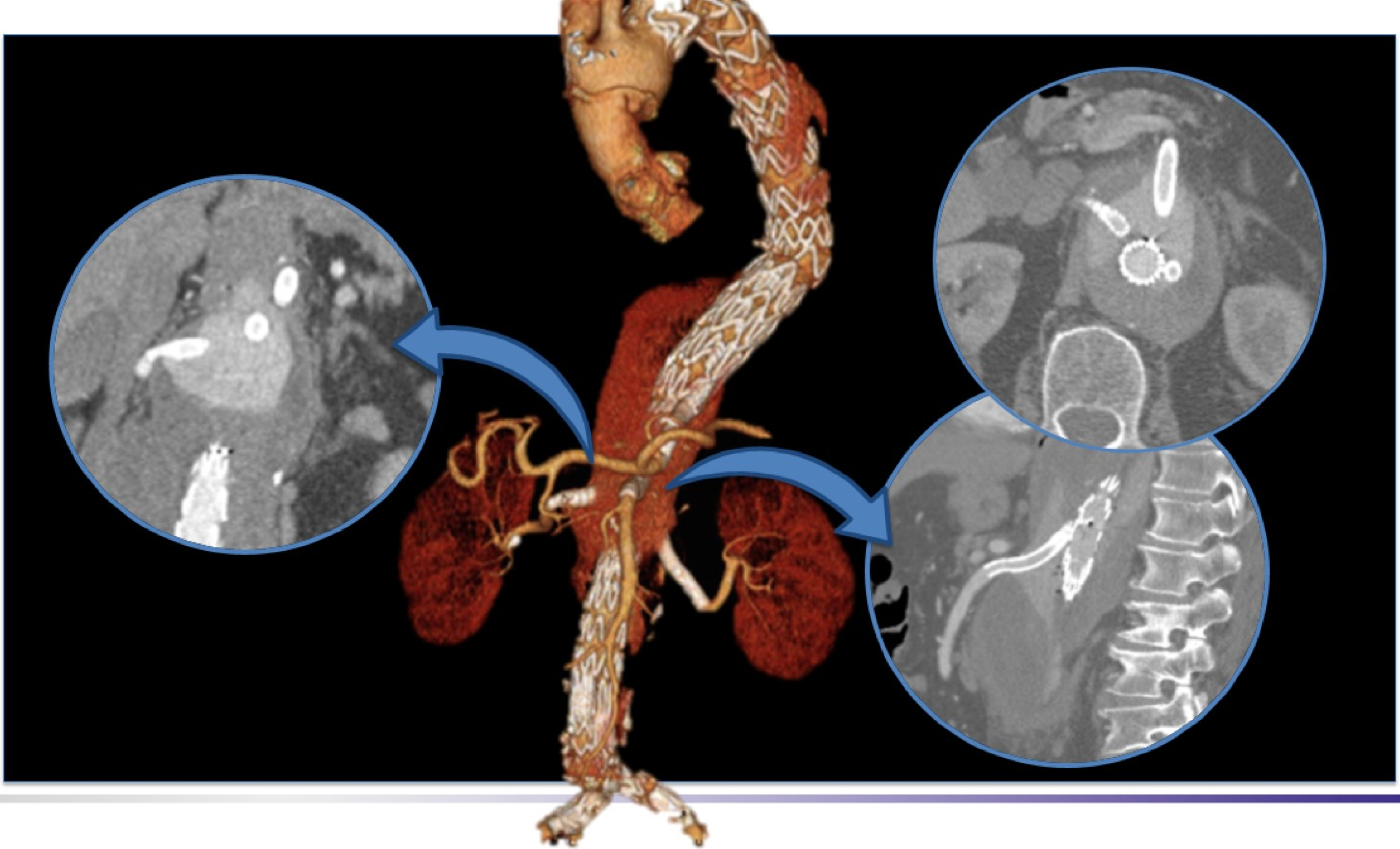


RENAL DIRECTIONAL BRANCHES: INSTABILITY

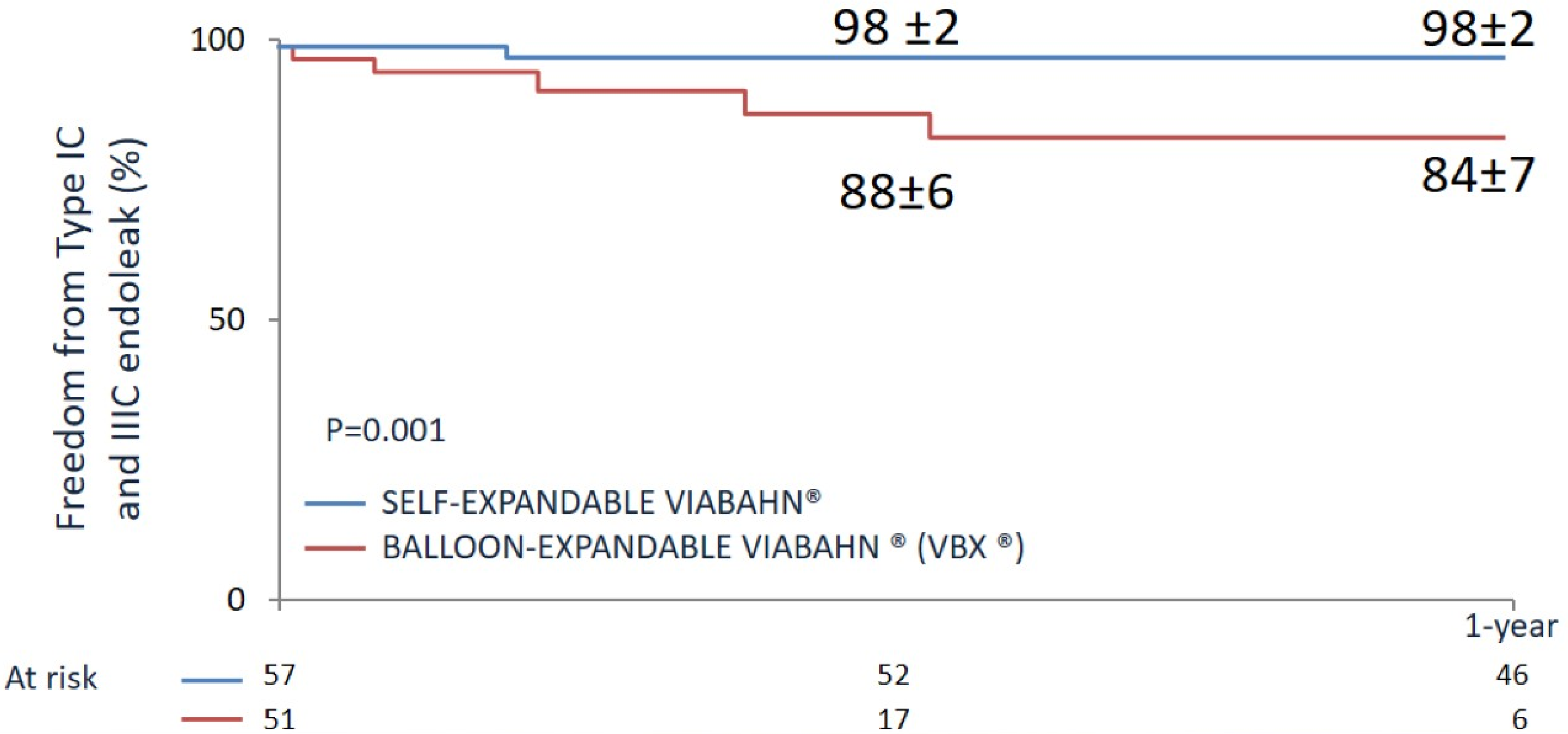




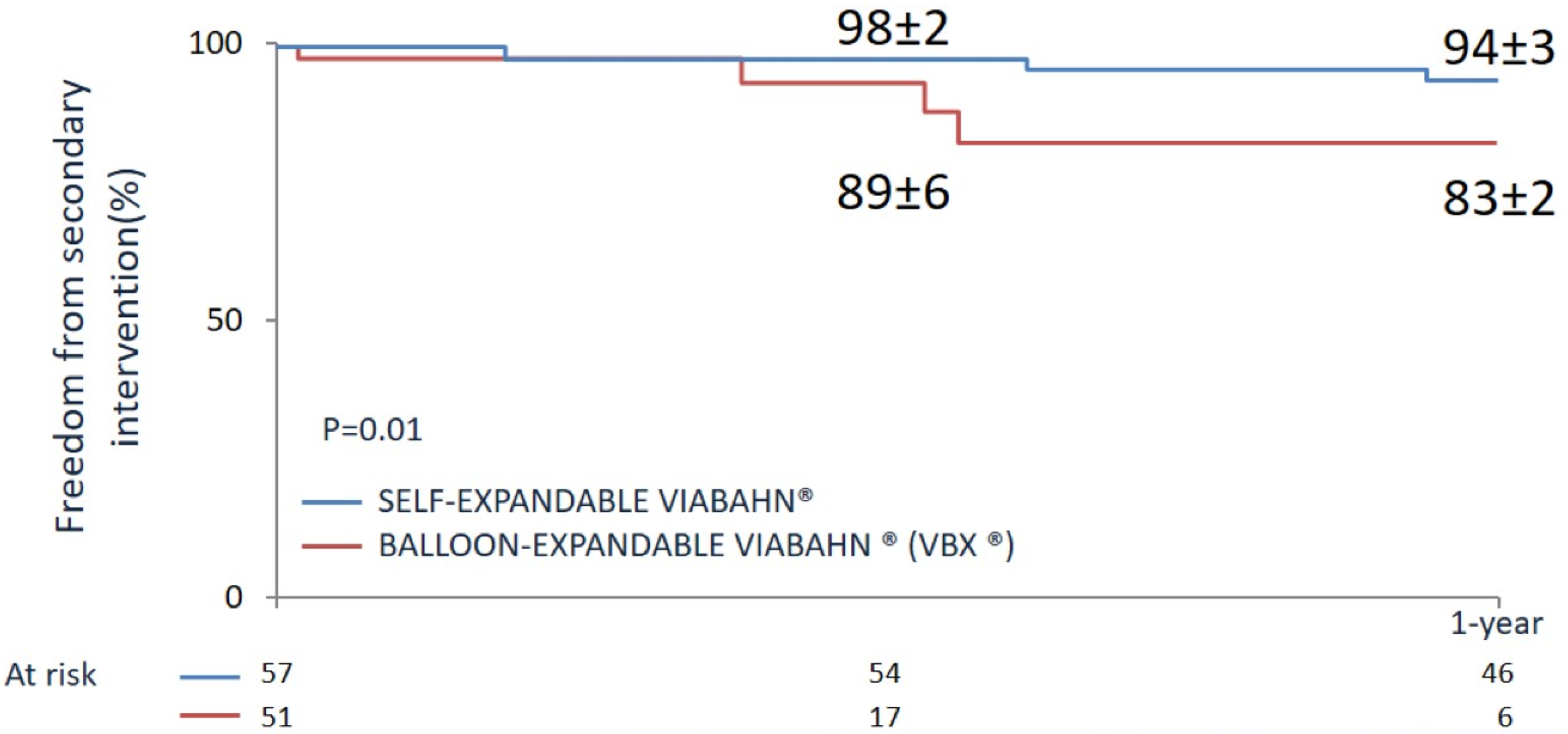




RENAL DIRECTIONAL BRANCHES: TYPE IC AND IIIC ENDOLEAKS



RENAL DIRECTIONAL BRANCHES: SECONDARY INTERVENTIONS



CONCLUSION

- There is controversy on optimal stent design and bridging stent selection
- Fenestrated-branches aligned by balloon-expandable covered stents have consistently shown high patency rates and low rates of target vessel instability
- Although fenestrated branches have shown superior patency in many series, directional branches have an important role and should be considered in patients with proper anatomy
- Early results with newer bridging stent-grafts are promising, but the jury is out on the ideal stent for branch alignment