SOLACI
SOCIEDAD LATINOAMERICANA DE CARDIOLOGIA INTERVENCIONISTA

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In partnership with tct

Complicaciones Vasculares

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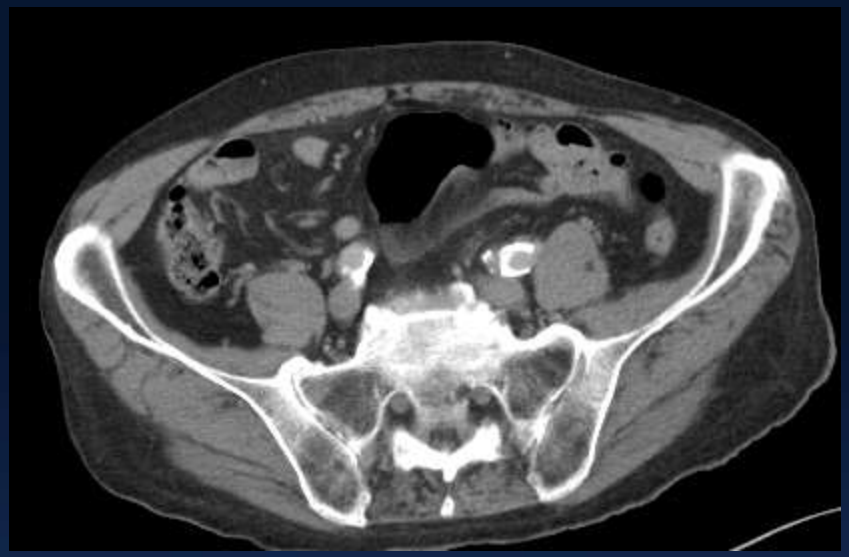
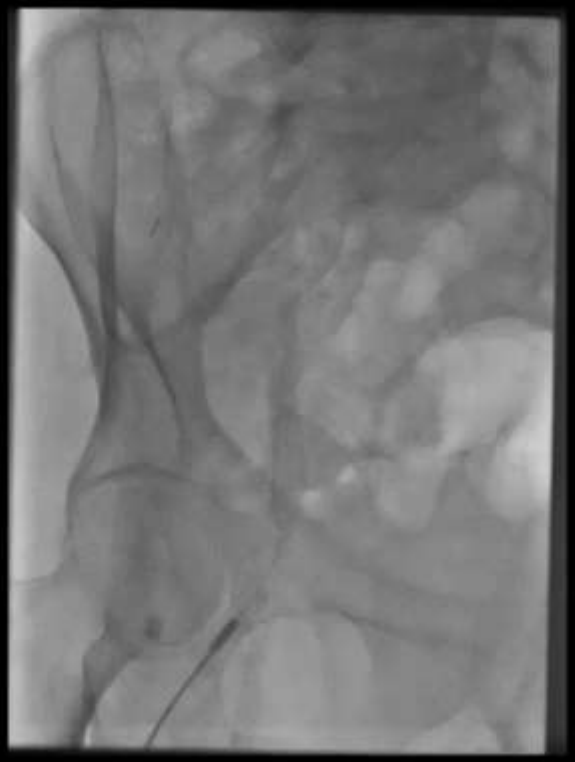
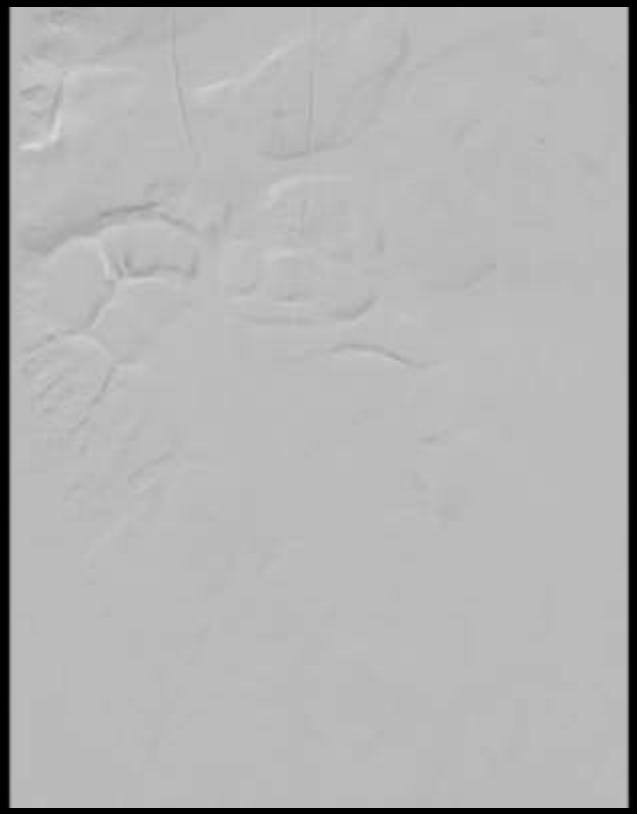
Let's Start with a Case

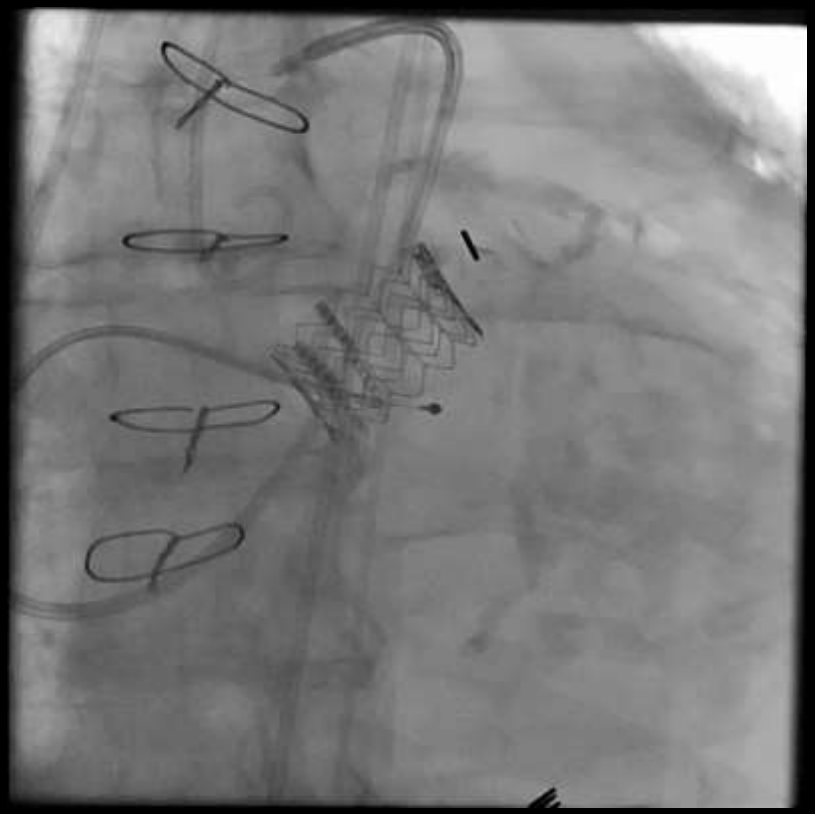
- **79 yo male with severe AS, NYHA class III with an episode of unresponsiveness and cyanosis on 5/17/13.**
  - Risk factors: HTN / / dyslipidemia / CAD / COPD
  - Previous revascularization: CABG 1990 – Bare metal stent 1/20/13
- **Small cell lung carcinoma s/p XRT and chemo / Collapsed left lung**
- **Evaluation**
  - ECHO: EF 55%, AVA 0.99 cm^2, grad 21 mmHg, V_{max} 307.3 cm/sec
  - Cardiac cath: 5/23/13 Patent graft to lateral wall. Patent LIMA. Occluded SVG to RCA. Occluded native coronaries.
  - LIMA crosses midline.
- **STS Score 5.4**
- **Cohort : B – Clinically inoperable**
- **Proposed approach: TF 26 mm SAPIEN valve (annulus= 2.3 cm)**

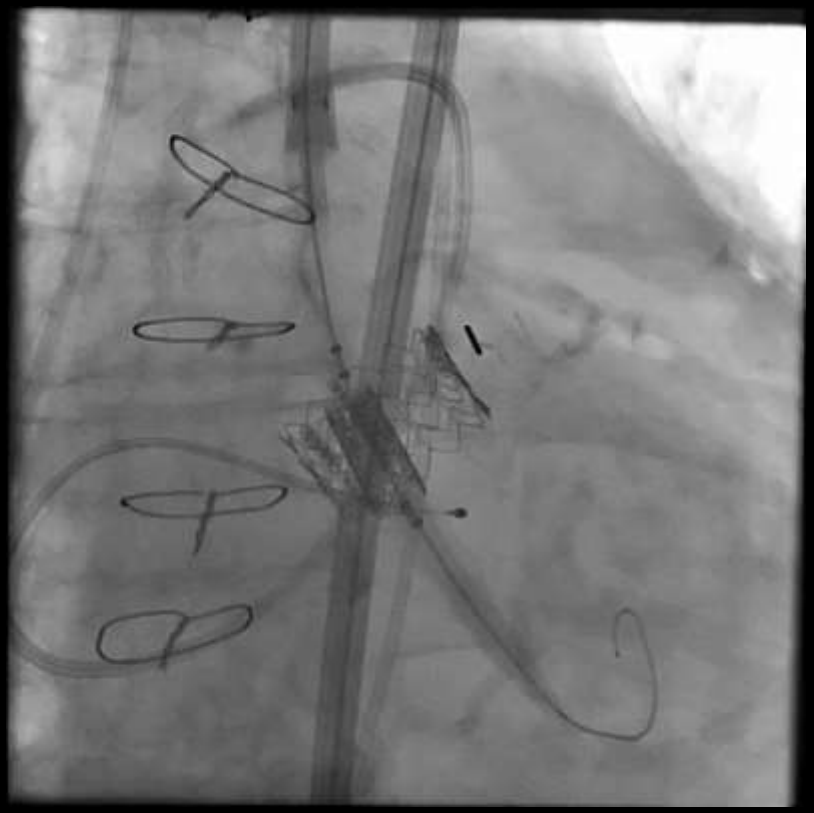
CT Scan

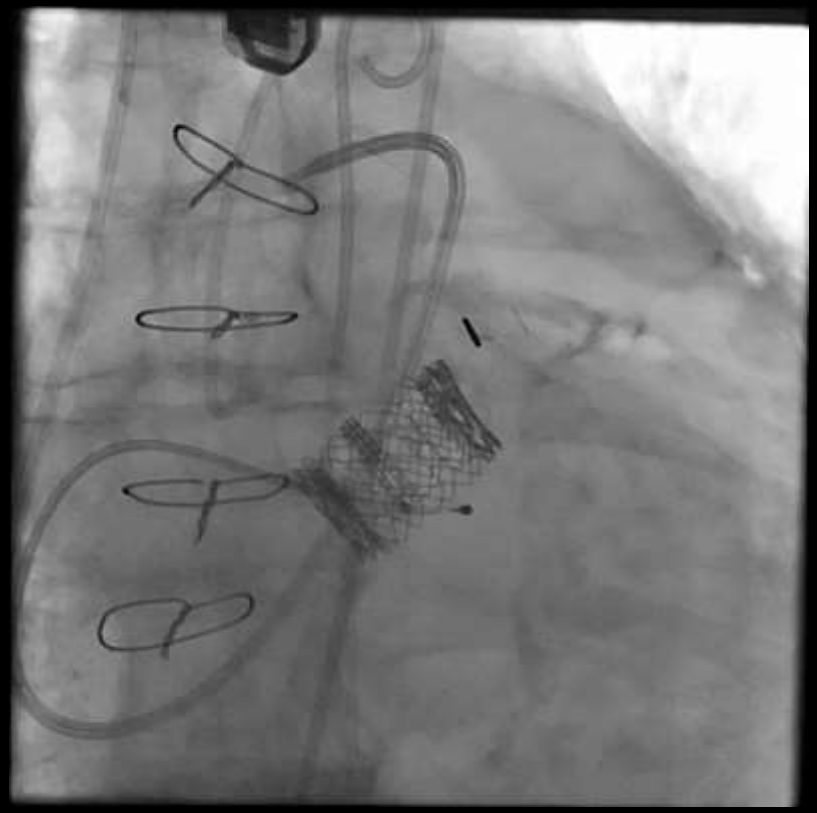




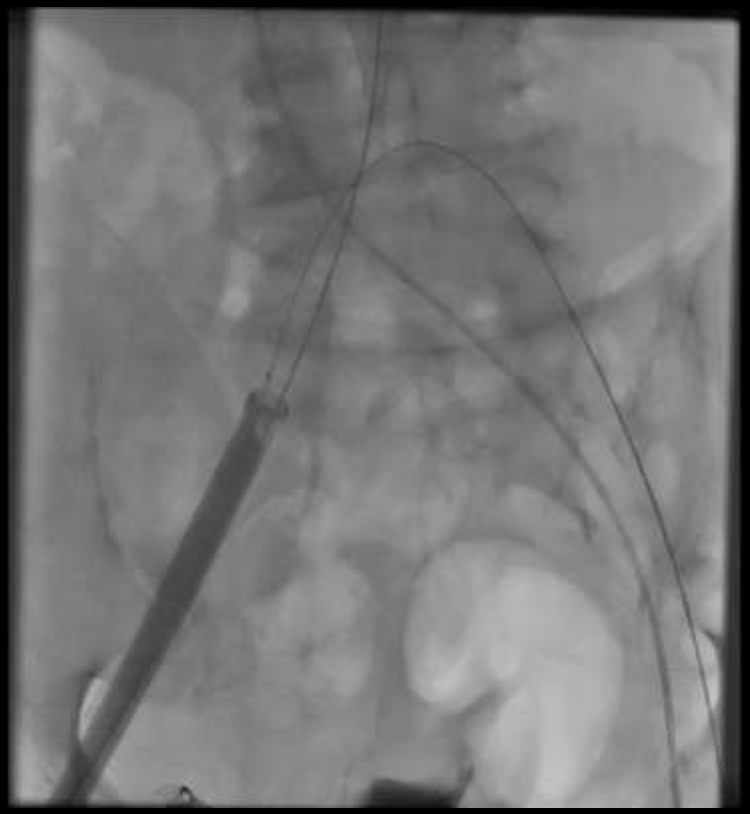


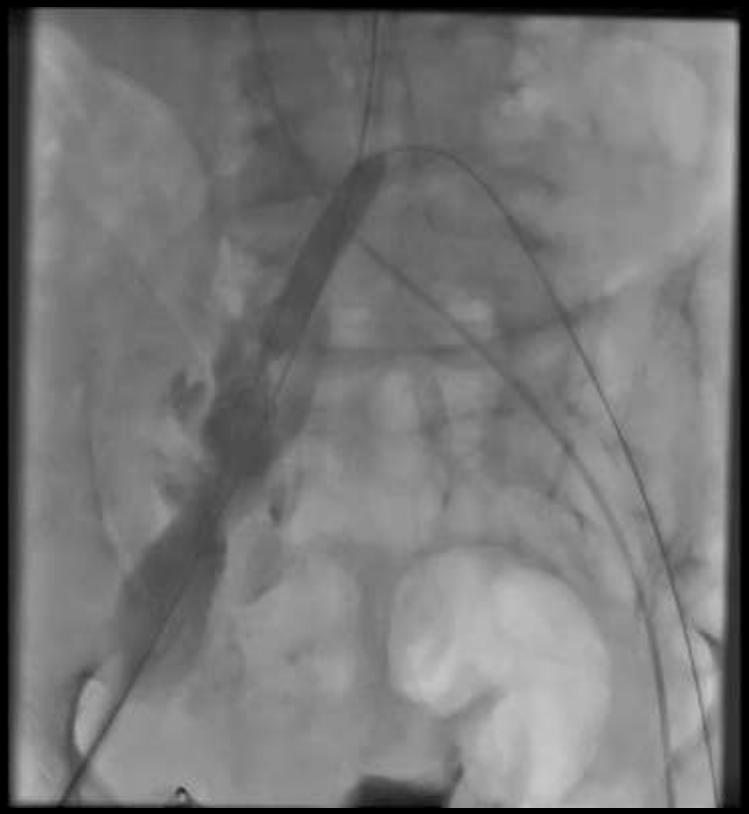


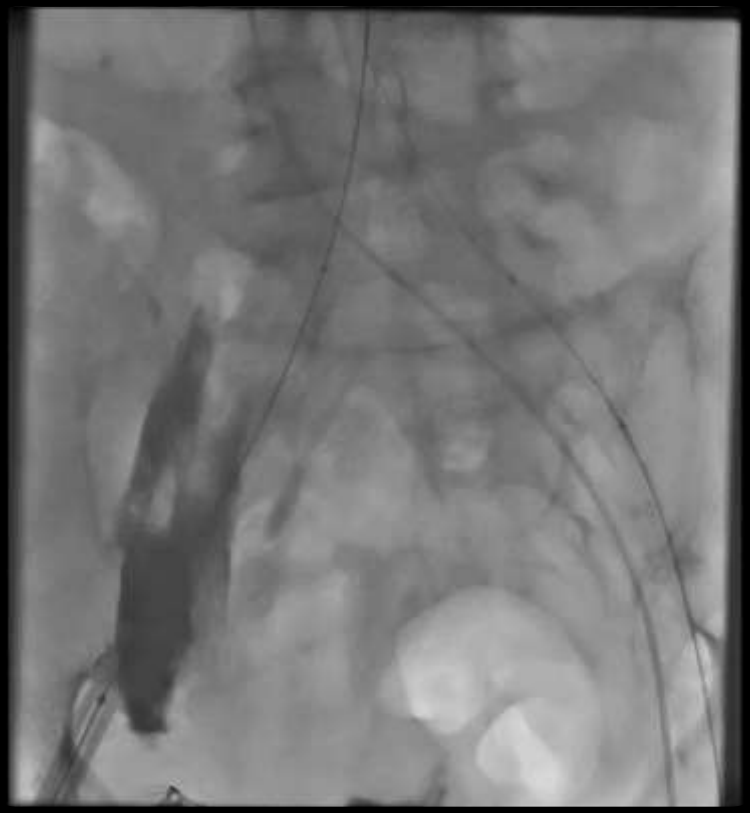


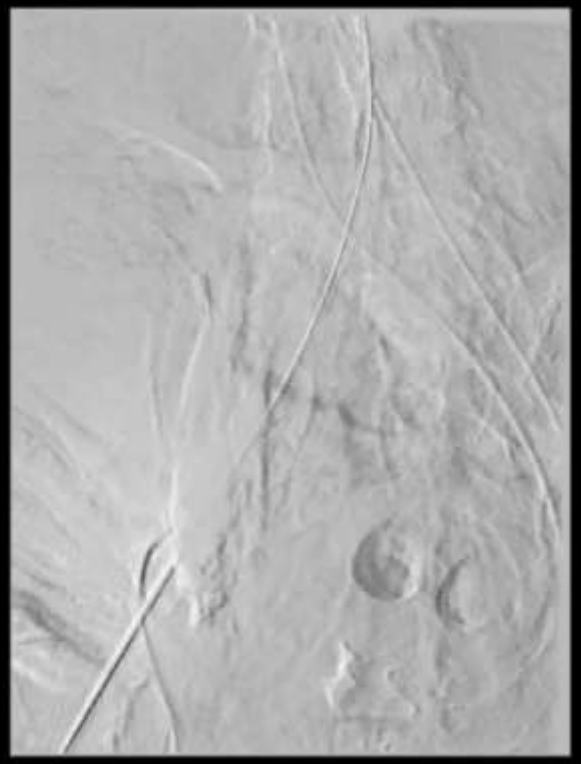


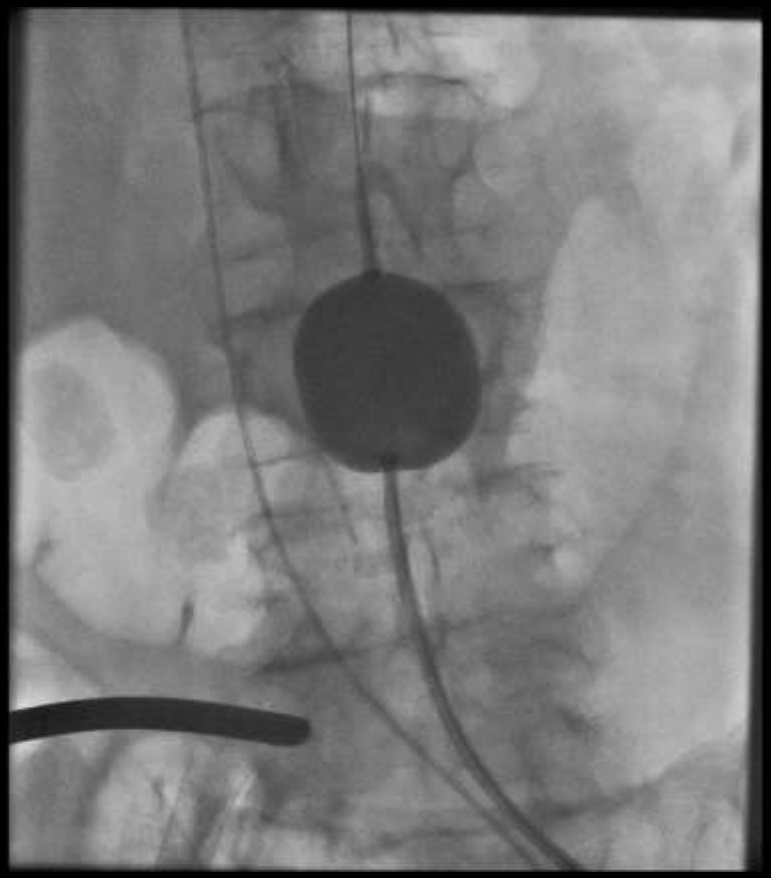
Y… La Cosa se Pone Interesante







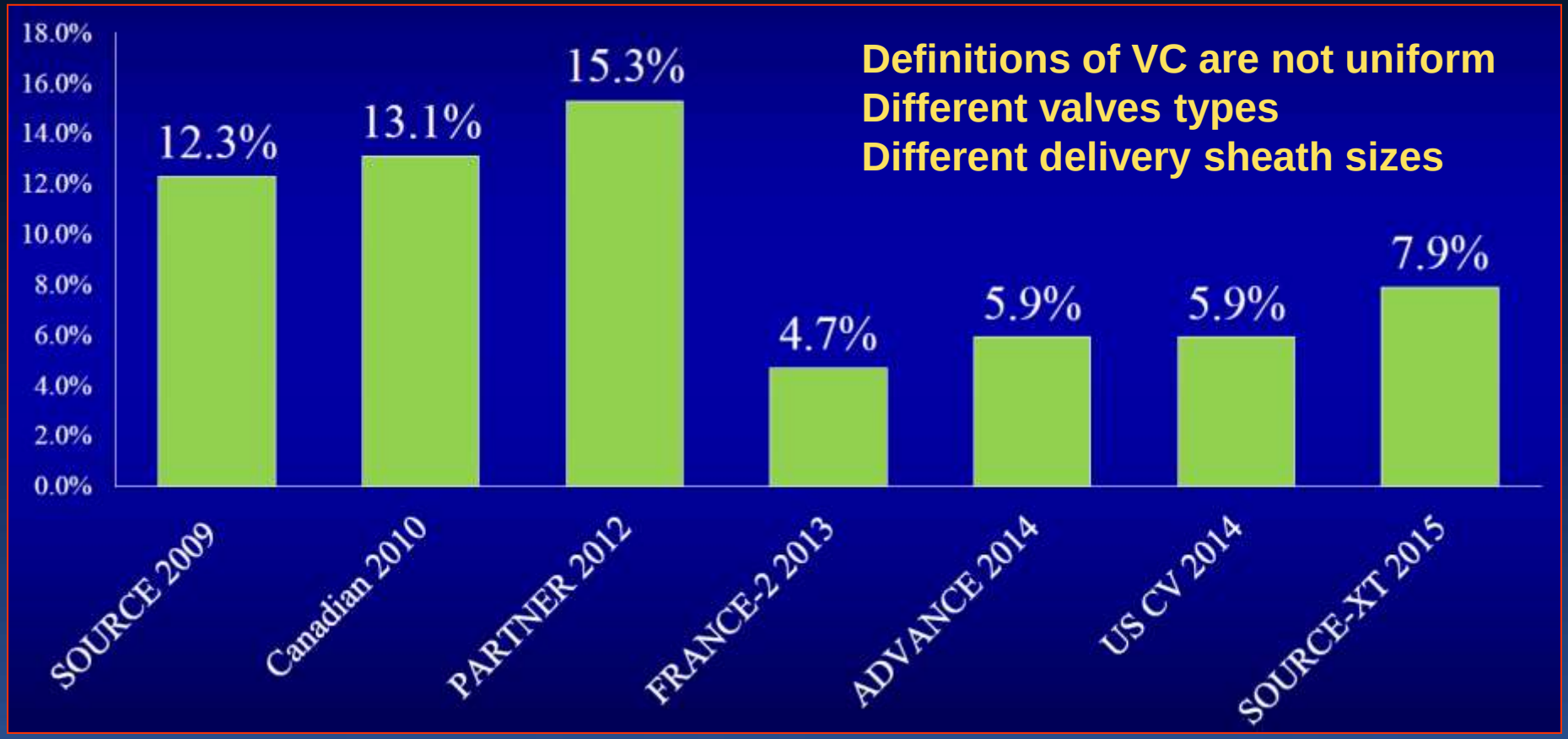




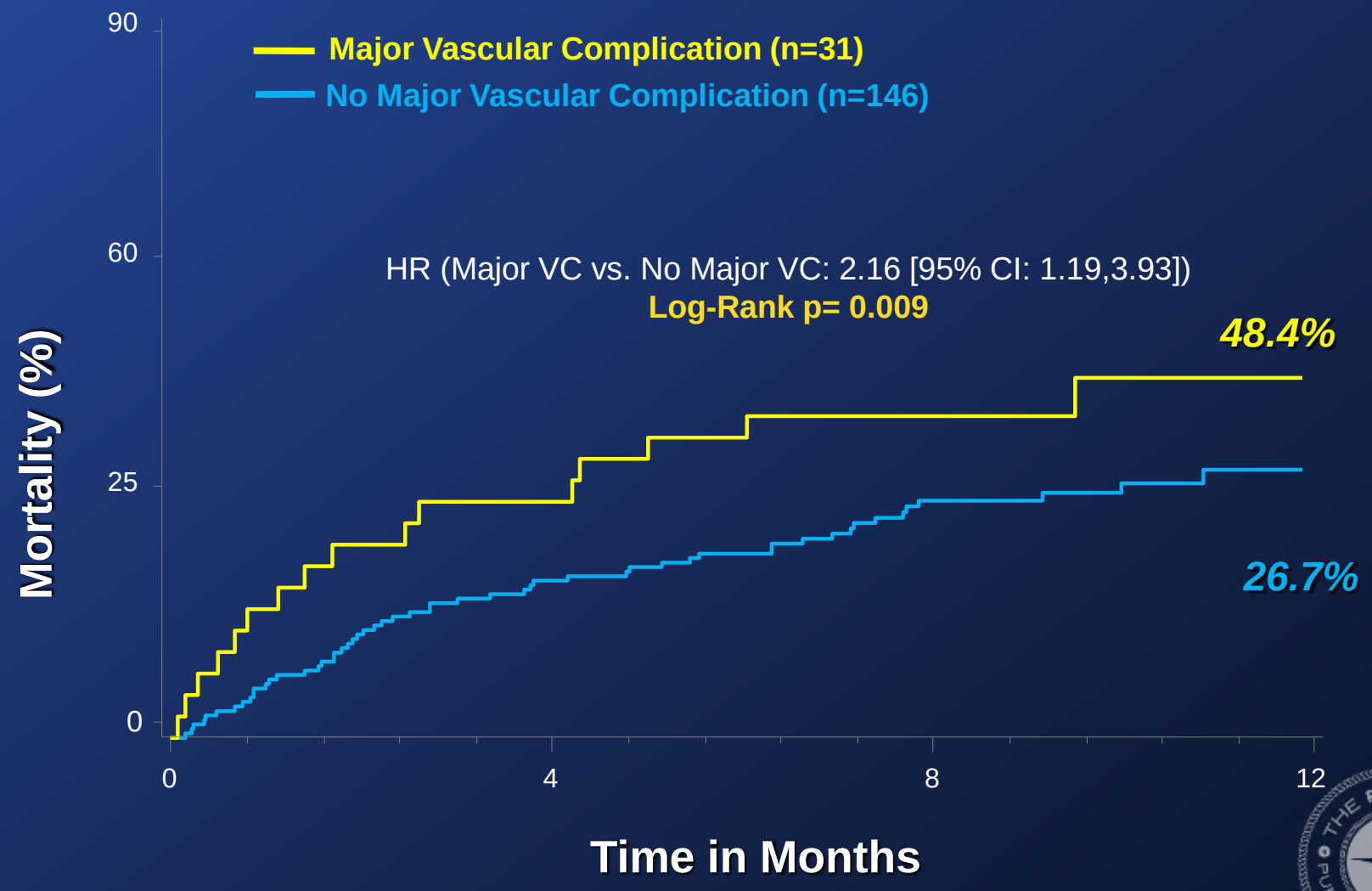
Vascular Complications with Percutaneous Approach

	N	Sheath size	Procedural success	Major vascular complications	30-day mortality	Vascular access	Vascular closure
Griese *et al.*	162	18F	93.9%	4.3%	5.6%	Percutaneous	Double proglide
Borz *et al.*	162	16F/18F/ 19F	NA	8.0%	5.6%	Percutaneous	Prostar-XL
Kahlert *et al.*	94	18F/19F/ 22F/24F	NA	12%	NA	Percutaneous	Proglide
Genereux *et al.*	56	22F/24F	94.6%	14.3%	7.1%	Percutaneous	Prostar-XL
Sharp *et al.*	49	18F/22F/ 24F	NA	14.2%	NA	Percutaneous	Prostar-XL
Nakamura *et al.*	140	22F/24F	82.1%	15.0%	2.9%	Percutaneous	Proglide
Hayashida *et al.*	142	18F/19F/ 22F/24F	90.7%	8.6%	8.6%	Percutaneous	Prostar-XL

Vascular Complications in Major RCTs and Registries



Mortality with Major Vascular Complications in PARTNER 1B (TF)

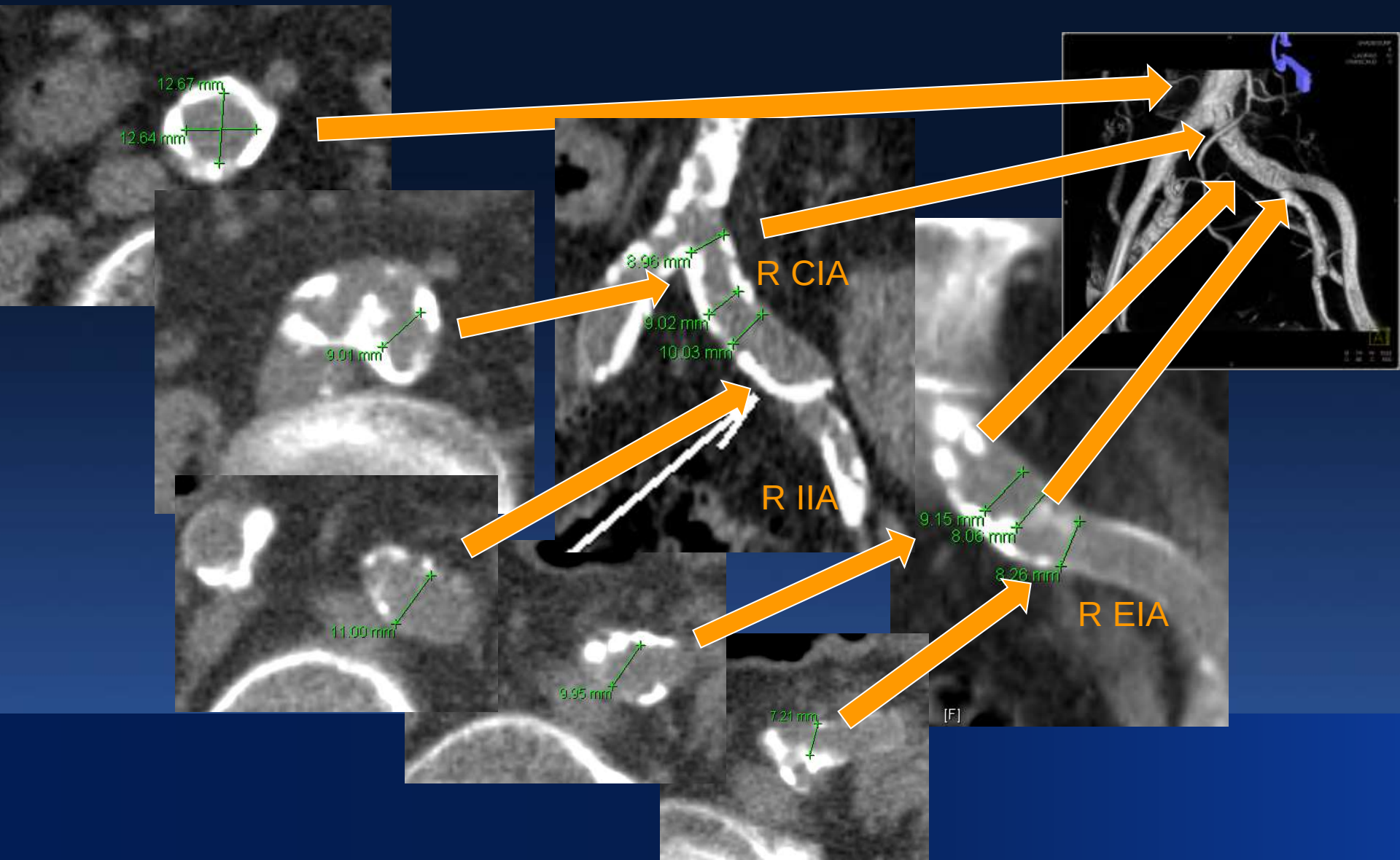


Généreux et al. *JACC* 2012

How to Prevent Complications?

- **Large vascular access has become common in the new era of structural heart disease interventions and percutaneous LVADs**
  - The cardiologist should be fully familiar with closure
- **Planning and Strategy**
  - Non-invasive assessment of iliofemoral axis
  - Studies carefully reviewed by entire team with focus on vessel size, tortuosity, pathology and calcification (especially at bifurcations)
- **Perfect access technique is critical**
  - Ultrasound guided
  - Micropuncture
- **Closure**
  - Contralateral balloon occlusion technique
  - Percutaneous closure with 2 proglide devices

Careful Evaluation of Iliofemoral Arteries



Tortuosity

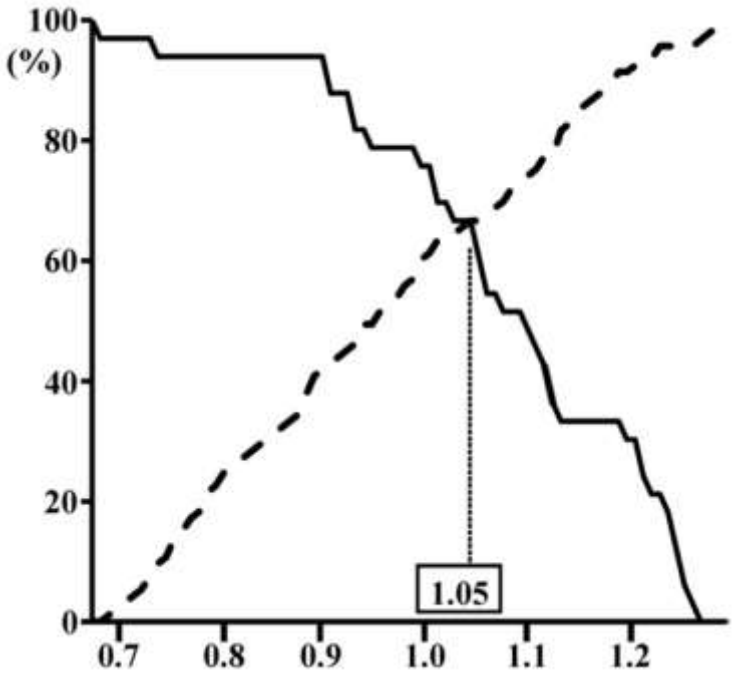

Ø 13.7 mm
Ø 10.1 mm
Ø 10.3 mm
Ø 10.4 mm
Ø 7.2 mm
Ø 7.5 mm
Ø 7.5 mm
Ø 8.3 mm
Ø 9.3 mm
Ø 9.0 mm
Ø 9.8 mm

Transfemoral Aortic Valve Implantation

New Criteria to Predict Vascular Complications

- **Sheath to Femoral Artery Ratio (SFAR)**
  - Sheath OD / FA diameter

Variable	P	OR (95% CI)
Early center experience	0.023	3.66 (1.17–11.49)
SFAR	0.006	186.20 (4.41–7,855.11)
Femoral artery calcification	0.026	3.44 (1.16–10.17)



The specificity and sensitivity curve identified the threshold SFAR of 1.05 as predictive of vascular complications

Hayashida et al. JACC Intv 2011;4:851–

Transfemoral Aortic Valve Implantation

New Criteria to Predict Vascular Complications

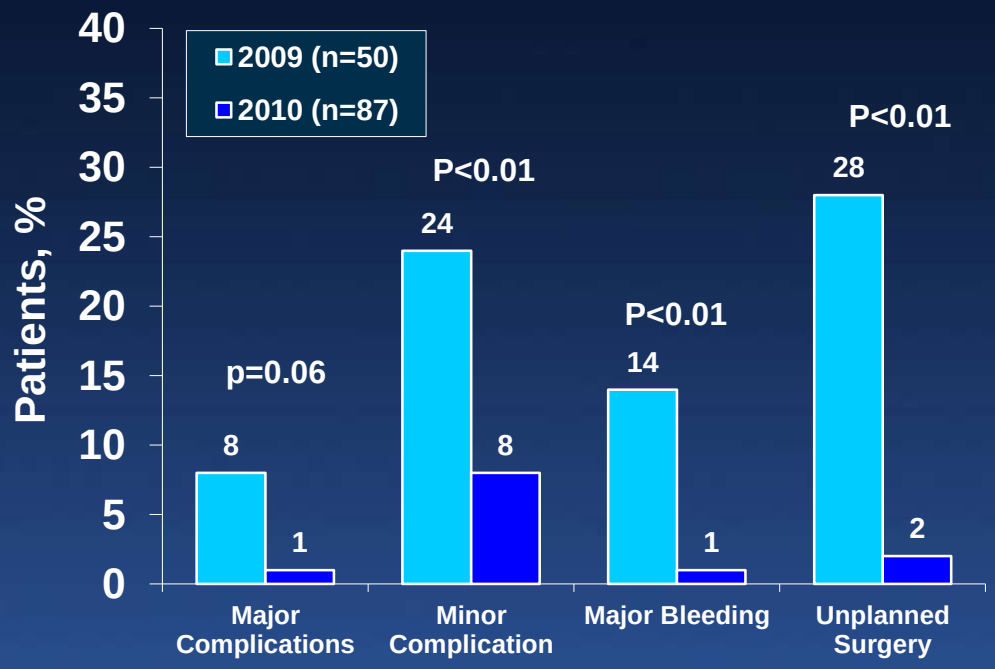
- Sheath to Femoral Artery Ratio (SFAR)
  - Sheath OD / FA diameter

Variables	SFAR ≥1.05 (n = 55)	SFAR <1.05 (n = 72)	p Value
Any vascular complication	23 (41.8%)	12 (16.7%)	**<0.001**
VARC Major	17 (30.9%)	5 (6.9%)	**0.001**
VARC Minor	6 (10.9%)	7 (9.7%)	0.827
Femoral artery complication	15 (27.3%)	9 (12.5%)	**0.035**
Iliac artery complication	11 (20.0%)	2 (2.8%)	**0.002**
In-hospital mortality	11 (20.0%)	5 (6.9%)	**0.033**
30-day mortality	10 (18.2%)	3 (4.2%)	**0.016**

Hayashida et al. JACC Intv 2011;4:851– 8

Access Technique, Closure, and Vascular Outcomes

Systematic MDCT screening, smaller sheaths, U/S or fluoro-guided and "Preclosure"

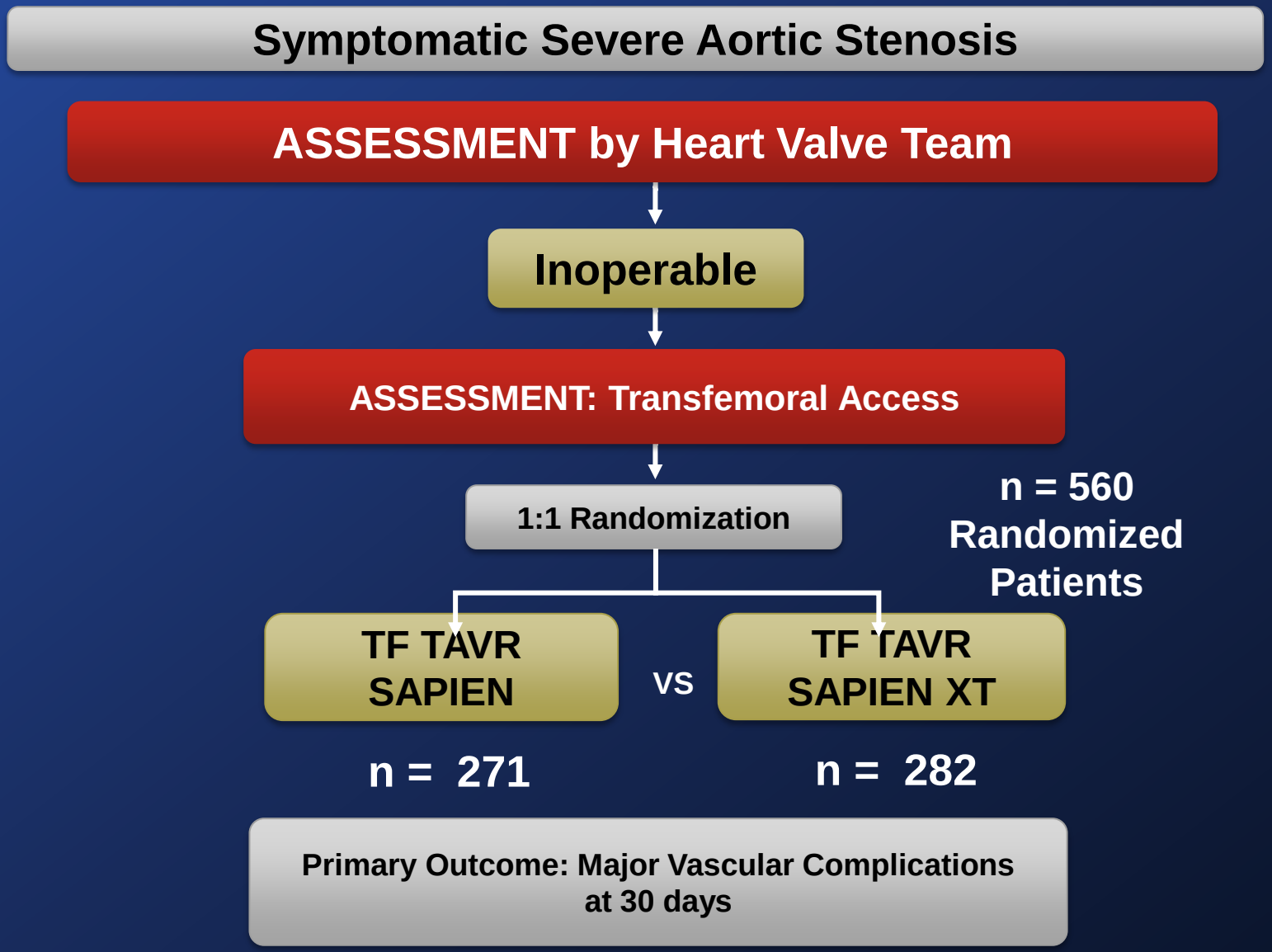


Toggweiler S, et al. *JACC* 2012;59:113-118


2012Apr19
Depth
Gain
Near
Far
L/R
CPD
4.6

The PARTNER II Inoperable Cohort

As-Treated Population Study Flow



Sheath Size Comparison

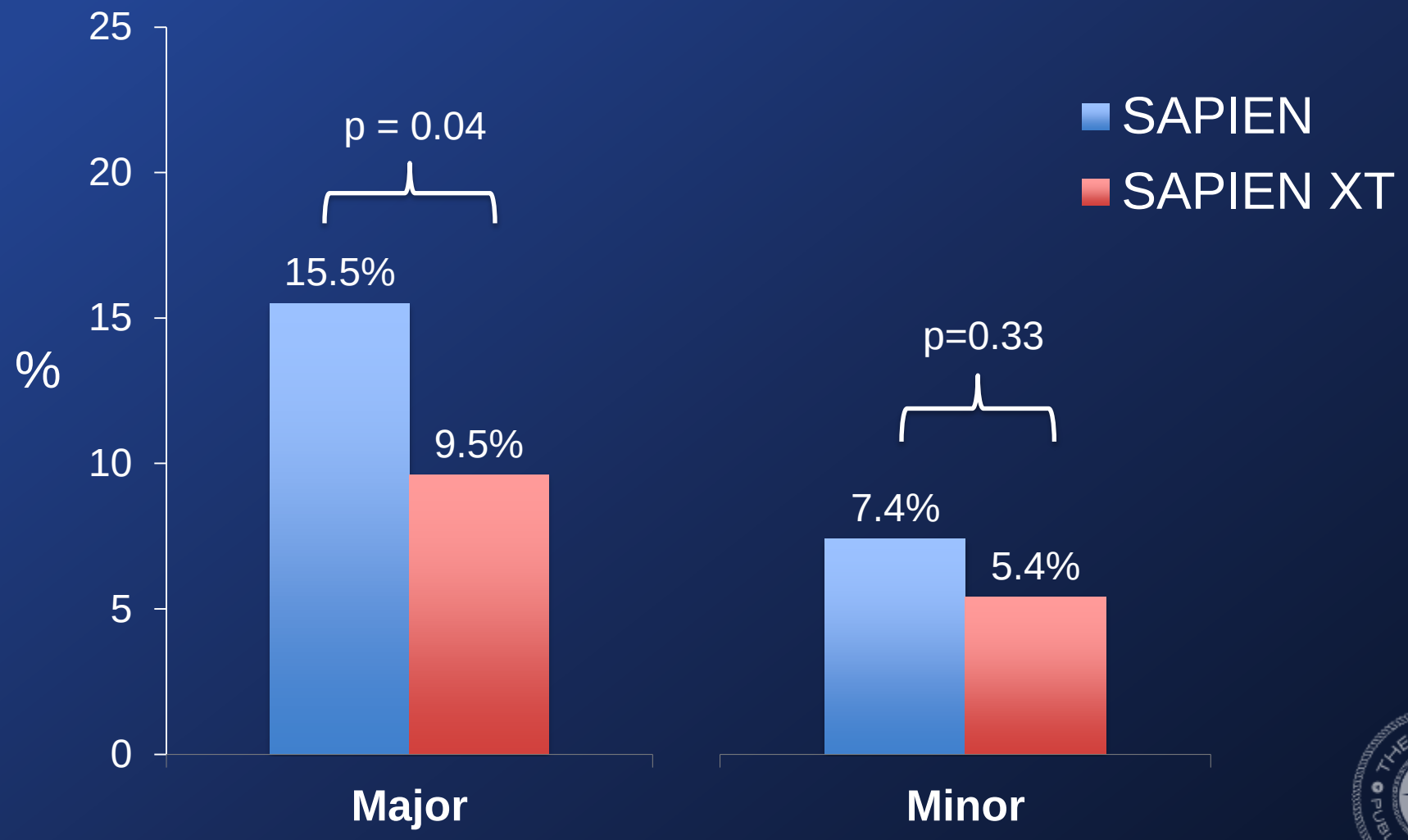
Valve	Valve Size	Sheath ID	Sheath OD	Minimum Vessel Diameter
SAPIEN THV	23mm	22F	25F (8.4mm)	7.0mm
SAPIEN XT THV	23mm	18F	22F (7.2mm)	6.0mm
SAPIEN THV	26mm	24F	28F (9.2mm)	8.0mm
SAPIEN XT THV	26mm	19F	23F (7.5mm)	6.5mm

33% reduction in CSA

RetroFlex 3

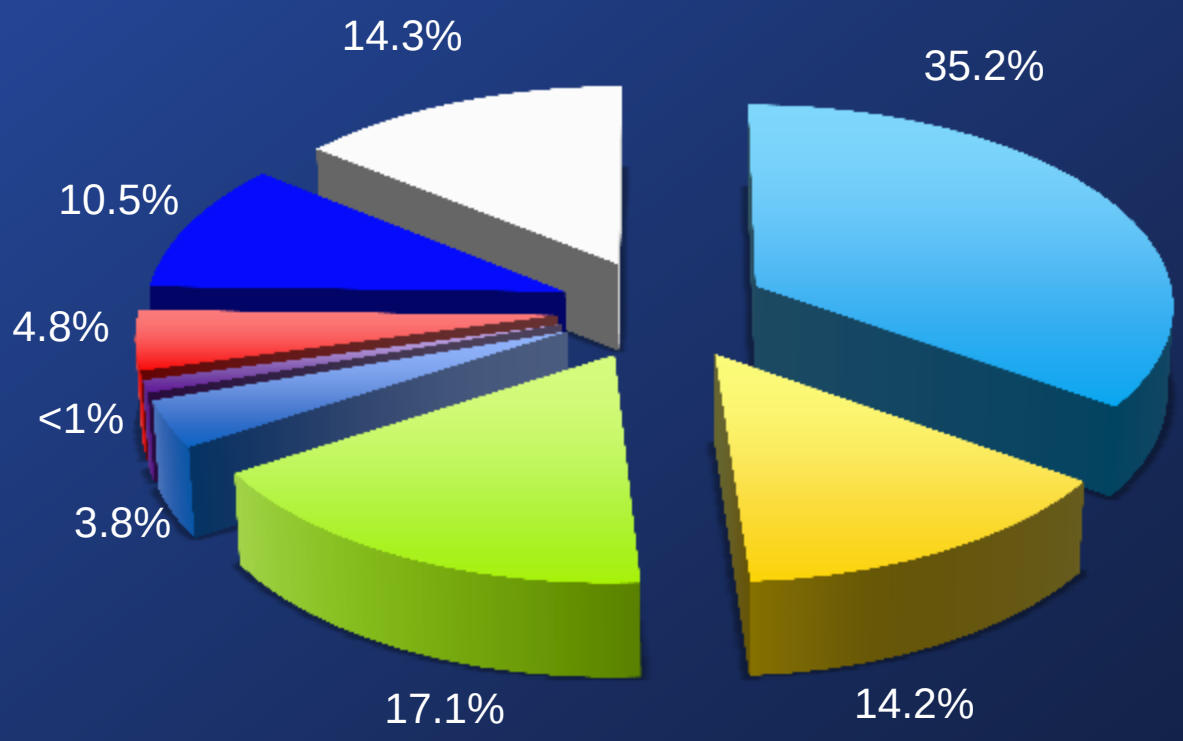
NovaFlex

Partner II Inoperable Cohort Vascular Complications



Pichard ACC 14

Vascular Complications Subtypes (105/553 patients)



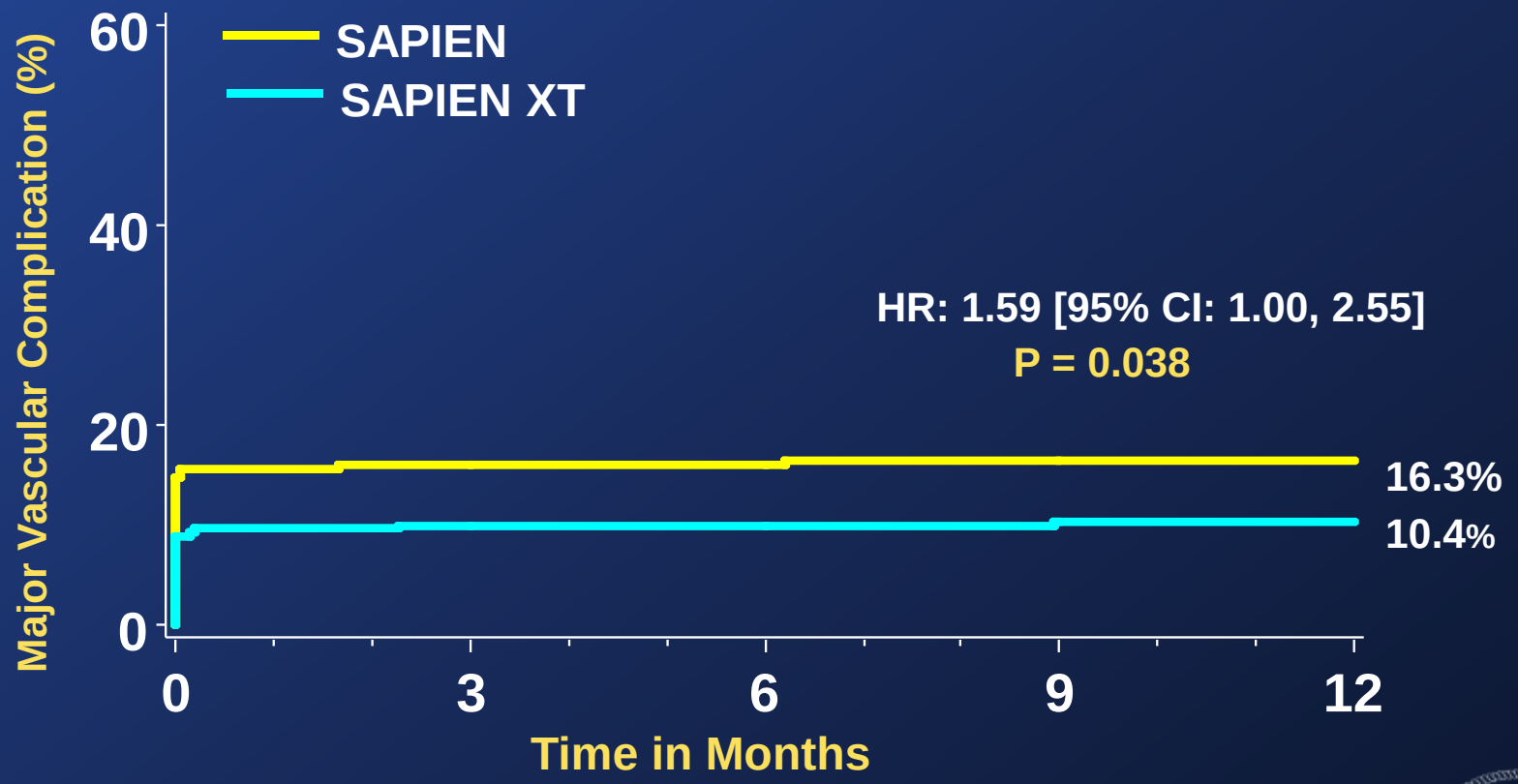
n=105

- Dissection
- Perforation
- Hematoma
- Stenosis
- Arterio-Venous fistula
- Failure of percutaneous access site
- Access site infection
- Misc. access site complications

Most Frequent

Pichard ACC 14

1 Year Major Vascular Complication Rates by Device Type



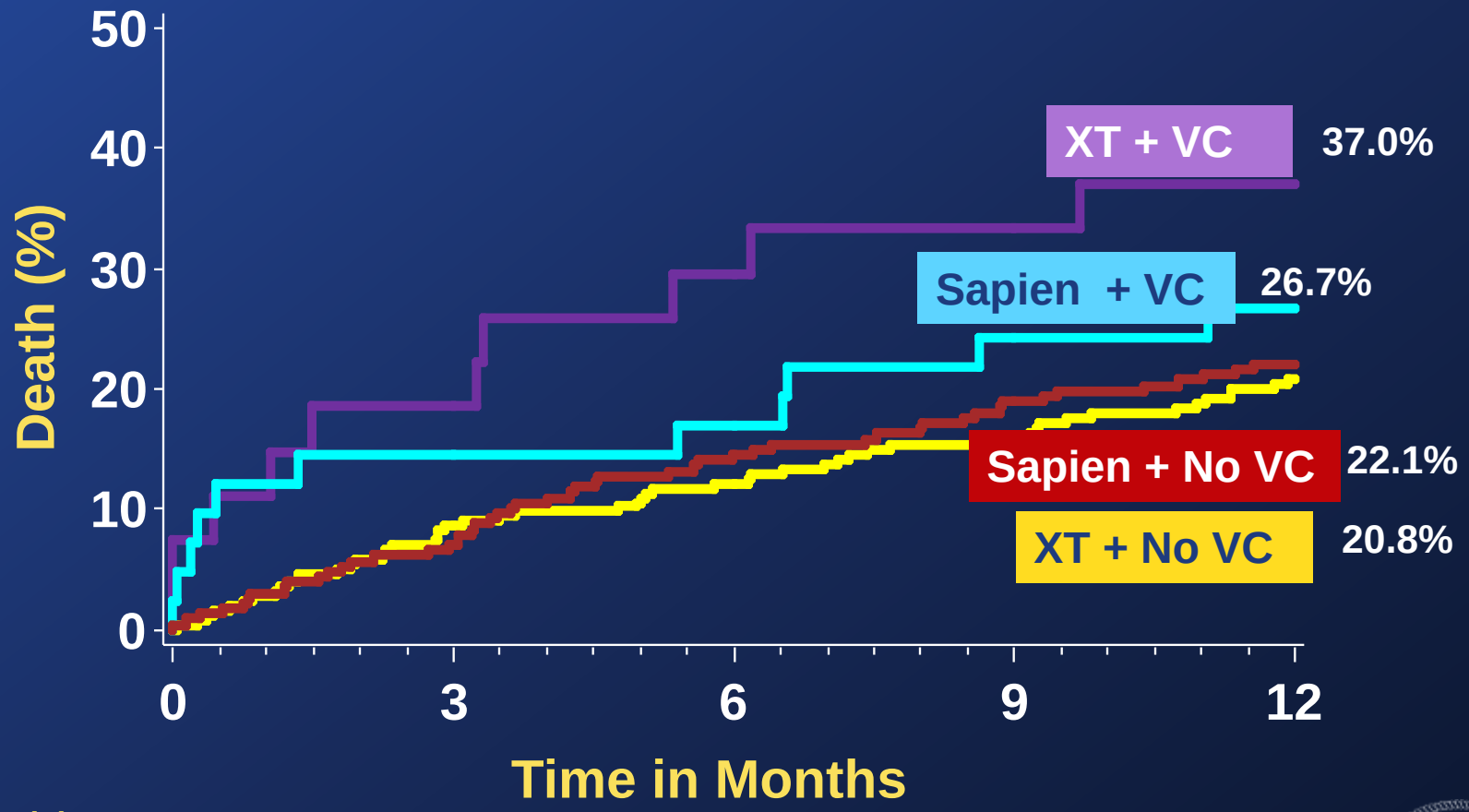
Number at risk:

SAPIEN	271	210	192	180	170
SAPIEN XT	282	232	223	214	199

Pichard ACC 14

1 Year Mortality and Major Vascular Complications by Valve Type

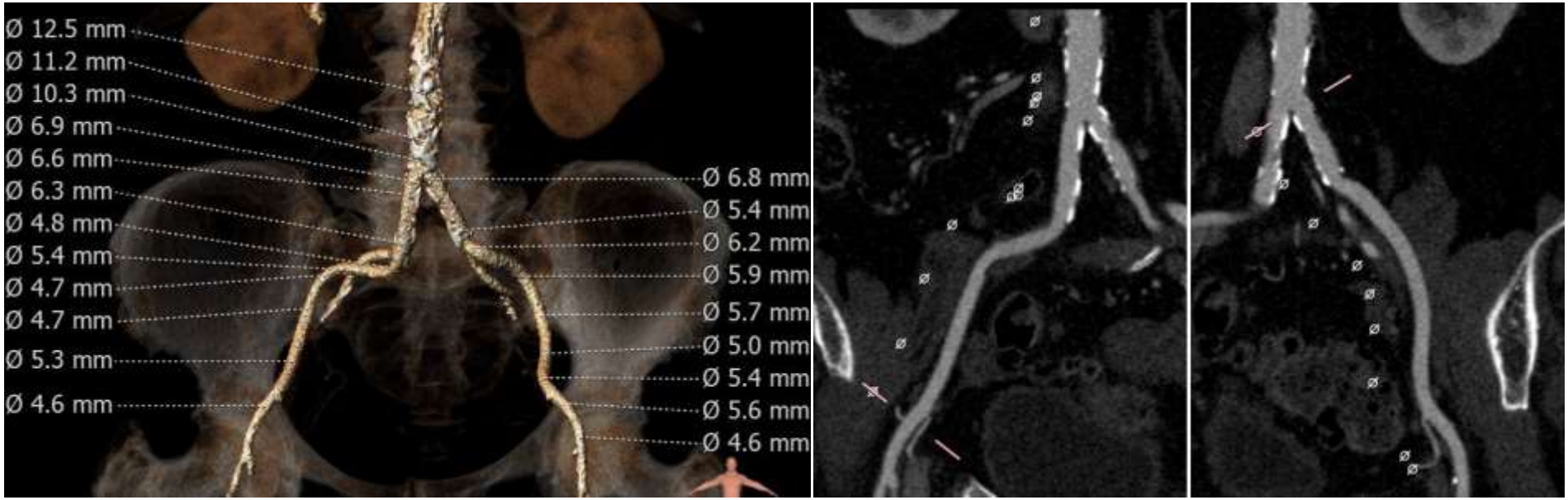
Pichard ACC 14



Number at risk:

Group 1	27	22	19	18	17
Group 2	255	233	224	216	200
Group 3	42	35	34	31	30
Group 4	229	211	193	182	172

Small Size – No Calcium



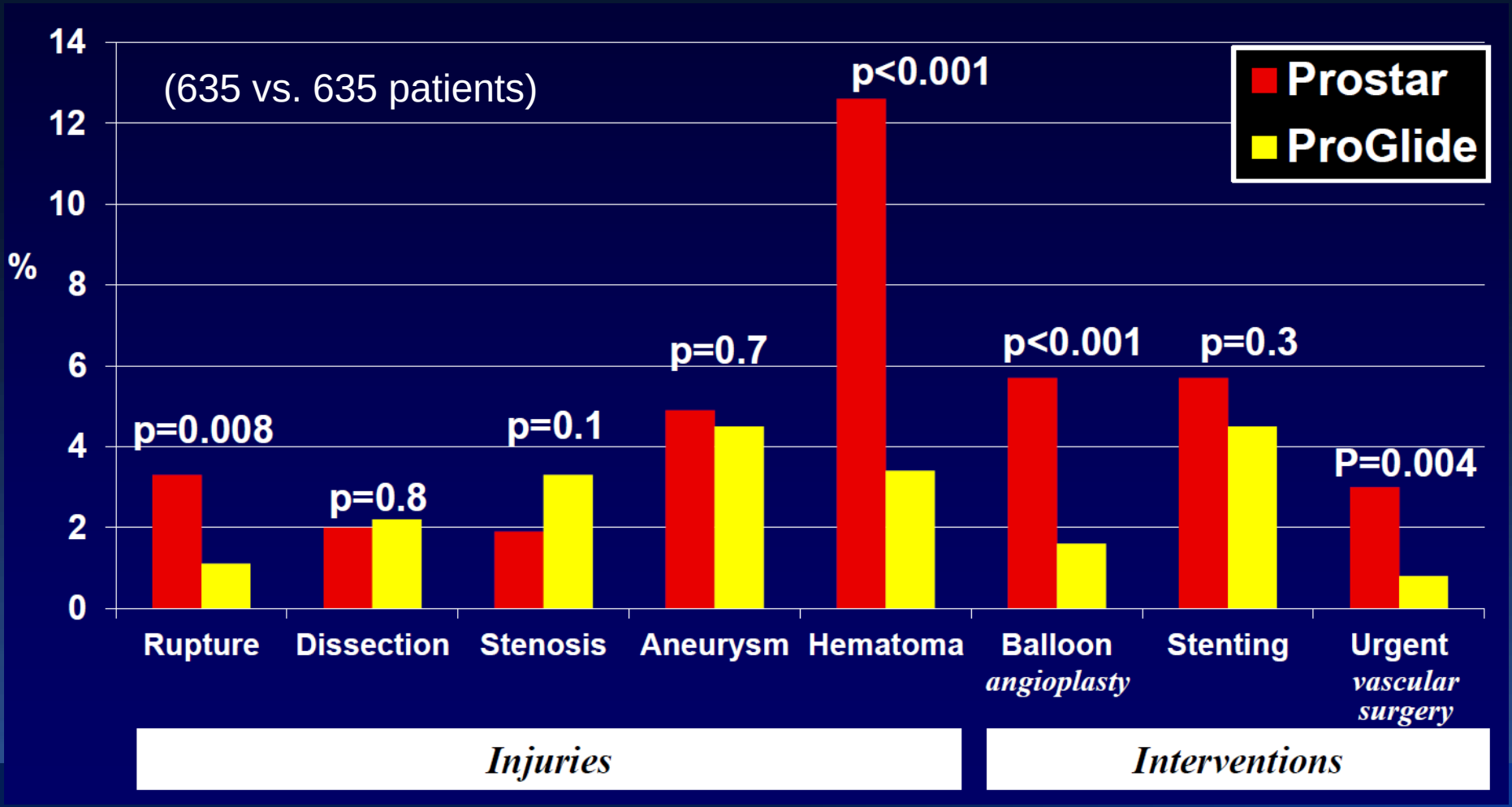
SoloPath Sheath

Crossover Balloon Occlusion Technique for Percutaneous Closure

- Withdraw the large sheath until positioned in external iliac artery
- Crossover using a Contra or Omniflush catheter
- Advance stiff glidewire into lumen of large sheath
- Advance and inflate an appropriately sized peripheral balloon (usually 7 x 40 mm)
- Tighten the ProGlide® sutures as you pull the large sheath
- Perform final angiogram

Genereux P, et al. JACC Intv, 2011; 4:861-867

Prostar vs. Proglide



Barbash IM EuroPCR 2015

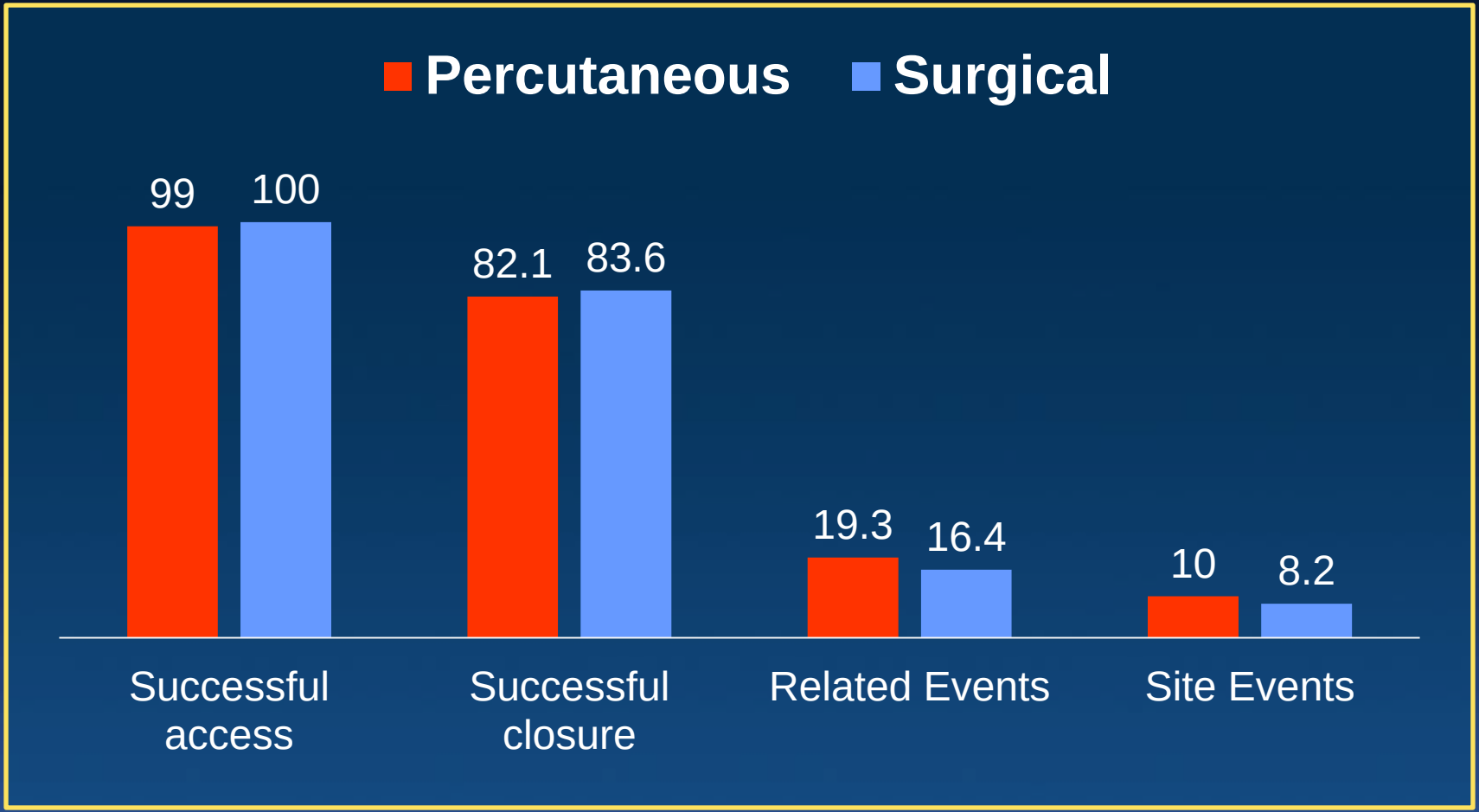
Surgical Cut-down vs. Percutaneous Closure

Cedars-Sinai Experience

- Observational data
- n=274 patients, treated Nov 2007 – May 2012
- Surgical cut-down (n=134)
  - **Primary closure method from 2007-2011**
  - **All these patients enrolled in PARTNER I**
- Preclosure with 2 ProGlide devices (n=140)
  - **Primary closure method since 2011**
  - **Enrolled in Partner I, Partner II and commercial**

Nakamura M et al. CCI 2014;84:293-300

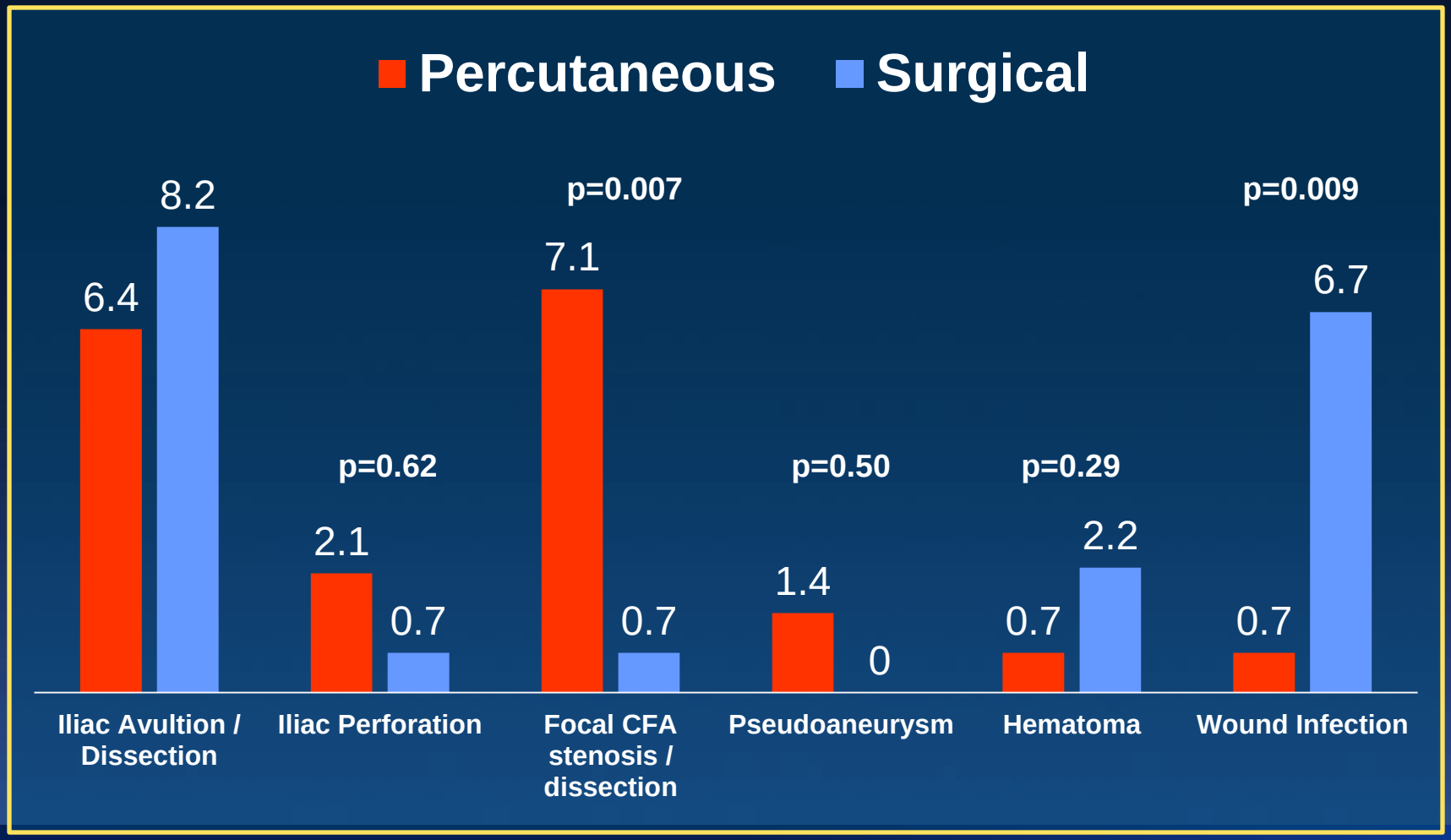
Cedars Sinai Experience



Nakamura M et al. CCI 2014;84:293-300

Cedars Sinai Experience

Acute Success



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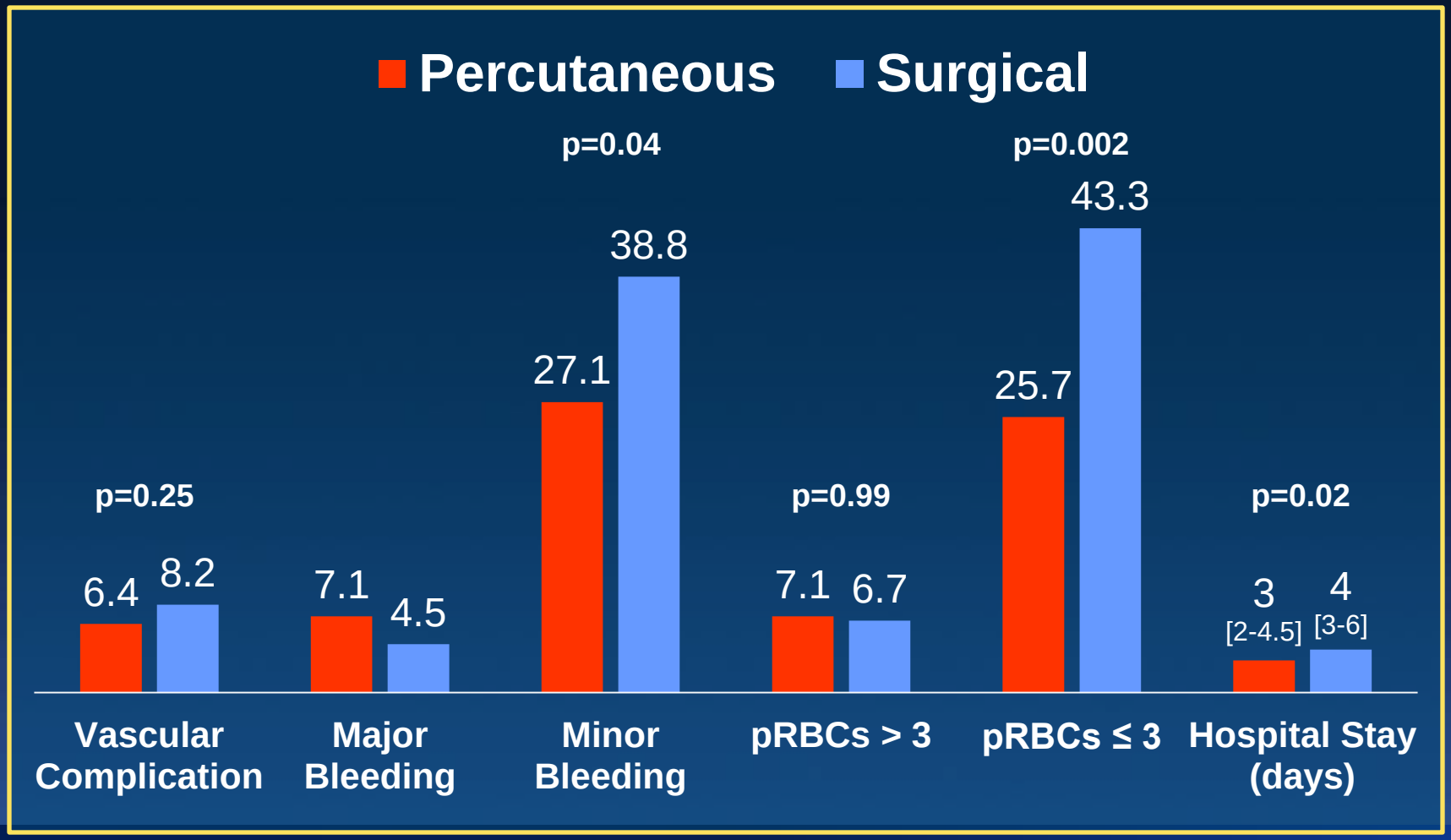
Cedars Sinai Experience

In-Hospital Outcomes



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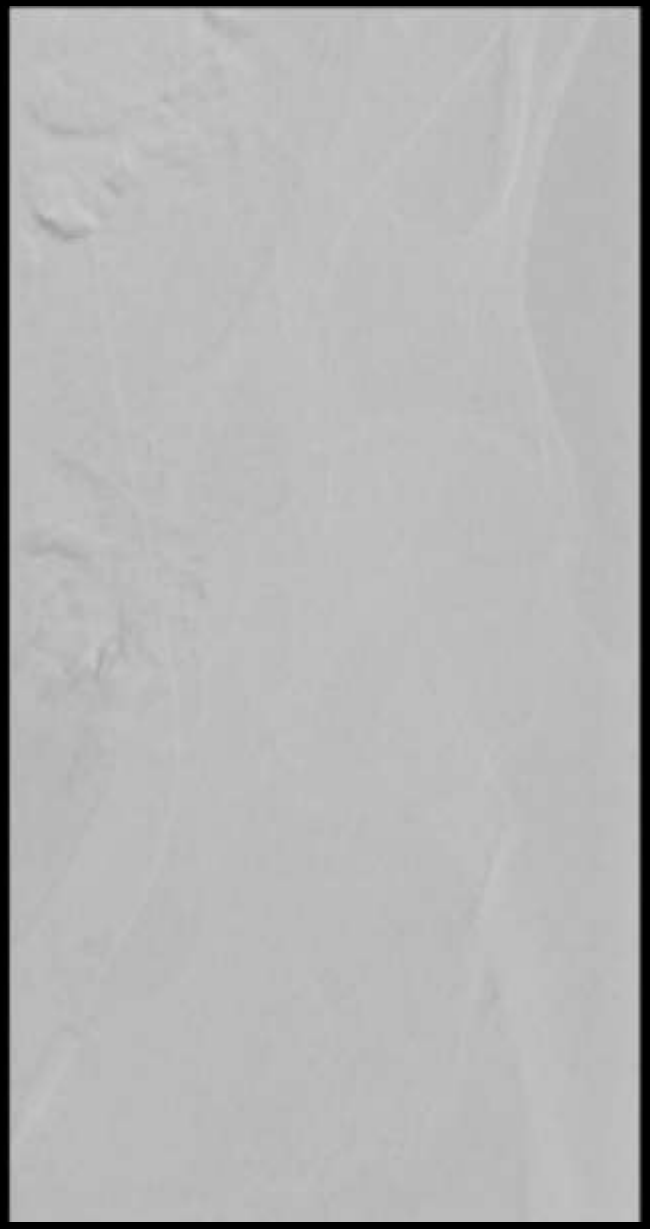

Not All Vascular Complications Occur in the Primary Access Site

Up to 25% of vascular complications can originate from the secondary access site → Consider radial

Allende R et al. AJC 2014

Conclusions

- Vascular complications after TF TAVR are frequent and associated with unfavorable clinical outcomes
- Substantial decrease in vascular complication rates
  - New device generations
  - Smaller delivery systems
  - Better screening and increased operator experience
- Always be prepared