How to reduce vascular complications of TAVI

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Definition of Vascular complications

- VARC-2 consensus statement

- Any complication caused by:
  - Wire
  - Catheter
  - Anything related to vascular access (including LV perforation and pseudoaneurysm)

- Only major vascular complications are considered important clinical end points

- Why is it important?
- Increased mortality in patients with vascular complications
  - OR 2.4 – 8.5
- Prolonged hospitalization
- Increased procedural costs

- Incidence:
- 2 – 17% major vascular complications across the literature
  - Predominantly transfemoral TAVIs

- Prevention, early recognition and prompt treatment are vital

Toggweiler et al. JACC Intv 2013

Patient selection

- Suitable clinical candidate
- Suitable aortic root anatomy
- **Iliac and femoral anatomy**

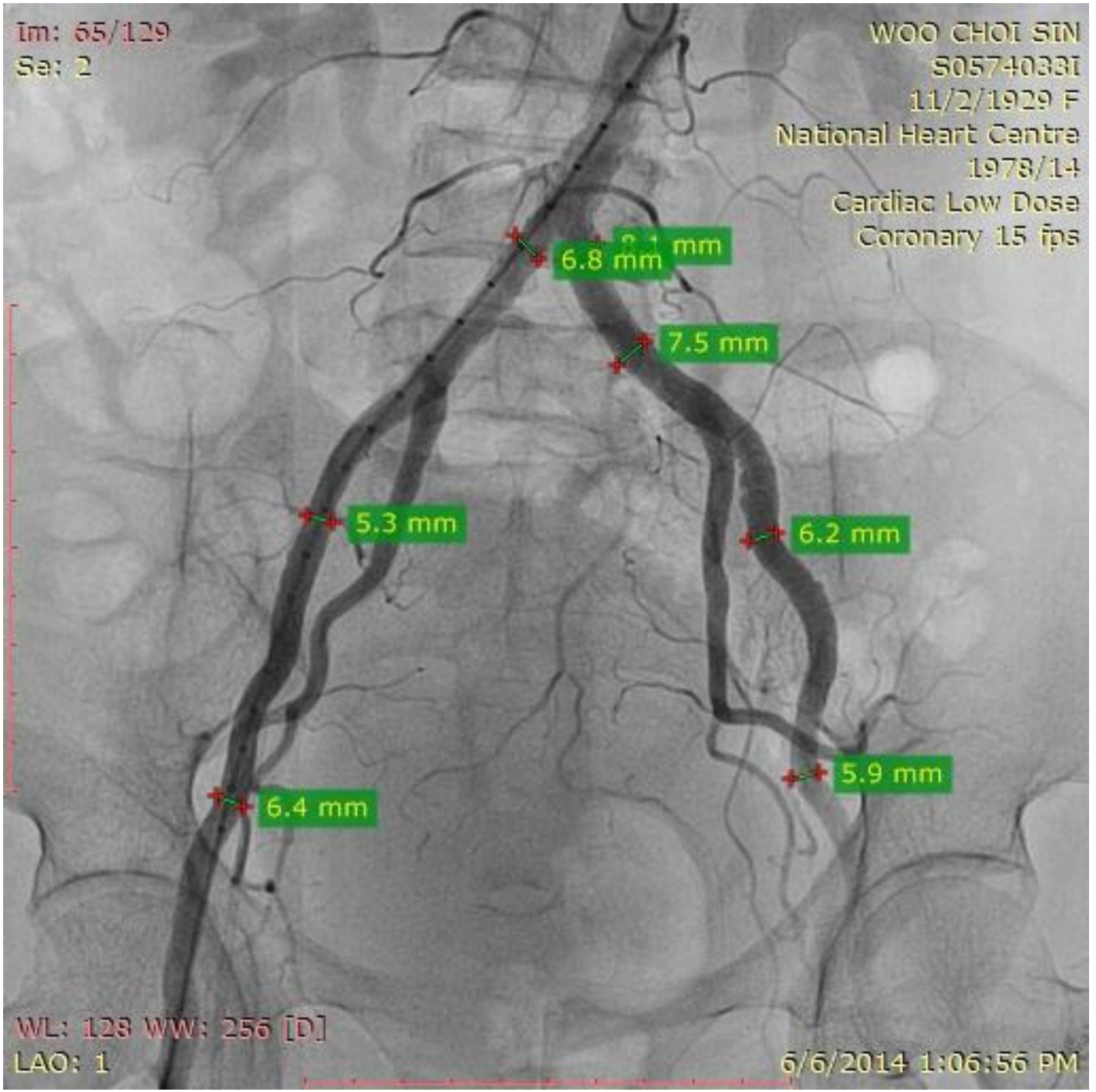
Pre-procedure planning

- Pre-procedure imaging of paramount importance
- Accurate vessel size and calcification assessment critical
- Tortuosity also important to understand but less critical
- Invasive angiography
- CTA (especially with use of centre lines)
- Ultrasonography

Angiography

- Advantages:
  - Easy to perform (during cardiac catheterization)
  - Lower cost (part of cardiac angiography)
  - Lower contrast load (15 – 20ml only)
  - Lower radiation dose

- Disadvantages:
  - No 3-dimensional appreciation of vasculature
  - Qualitative assessment of calcification
  - May miss stenosis/ narrowings due to eccentric plaque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5.3 mm
6.2 mm
5.9 mm
6.4 mm
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CT angiography

- Advantages:
  - Better spatial resolution
  - Enhanced appreciation of vessel size
  - 3-dimensional appreciation of tortuosity
  - Quantitative assessment of calcification

- Disadvantages:
  - Adds cost
  - Increased contrast load (80 – 100ml)
  - High radiation dose

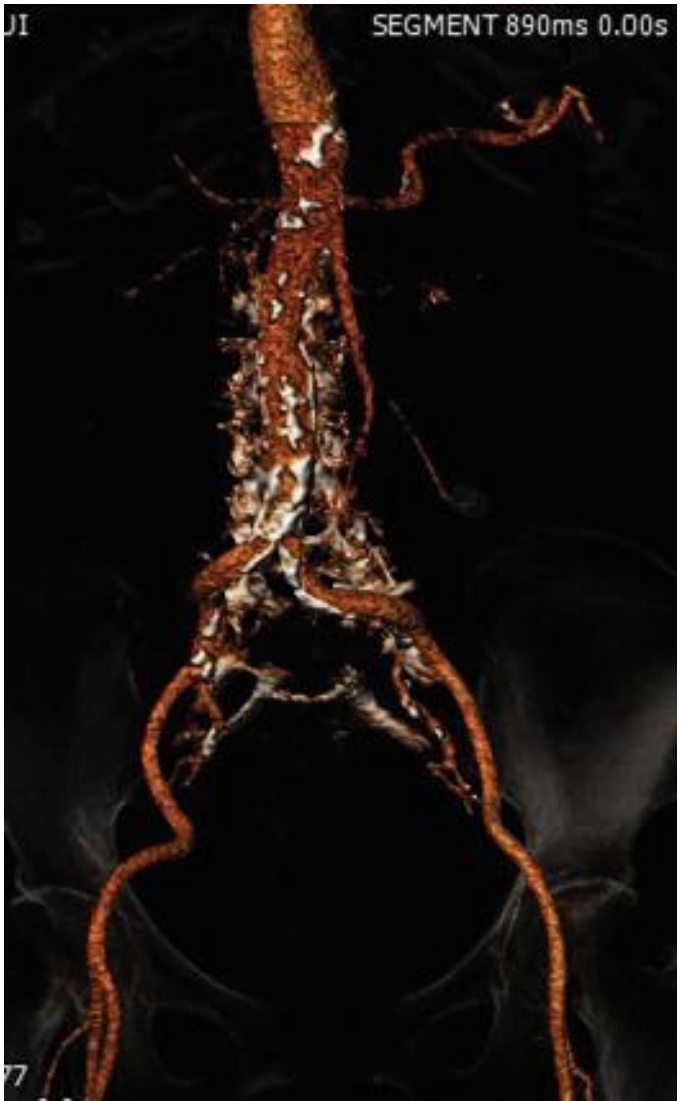
CT angiography

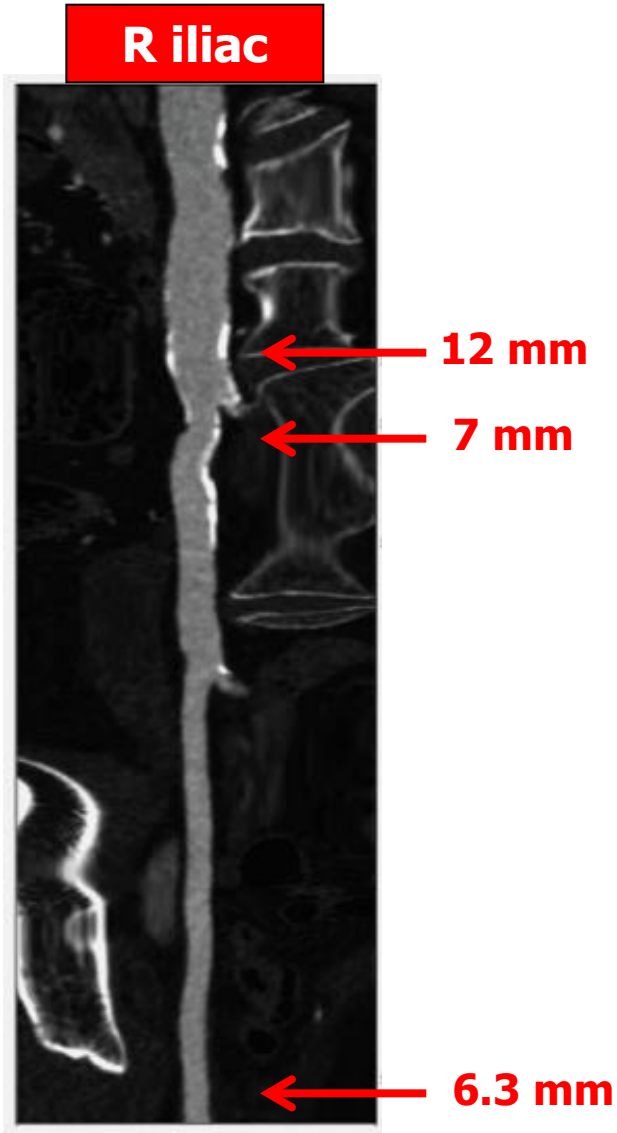
- CTA particularly useful when deploying preclosure devices → helps to assess presence and location of calcium at the CFA

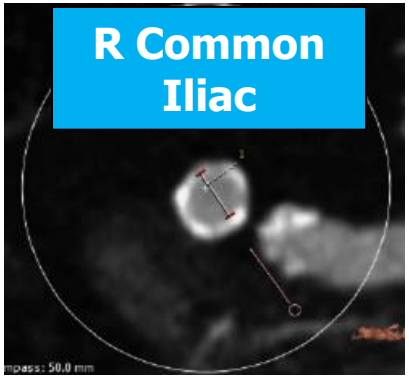
- Also helps to assess for soft unstable plaques and dissections in vasculature

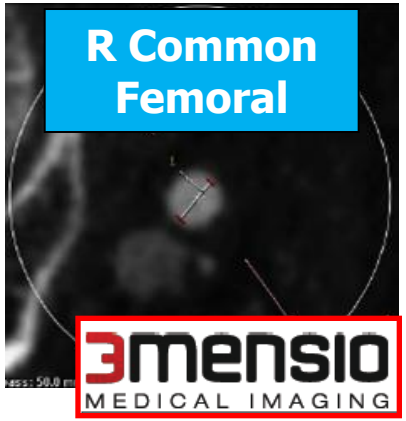
MDCT – Peripheral artery

- **Minimal diameters & Calcifications**



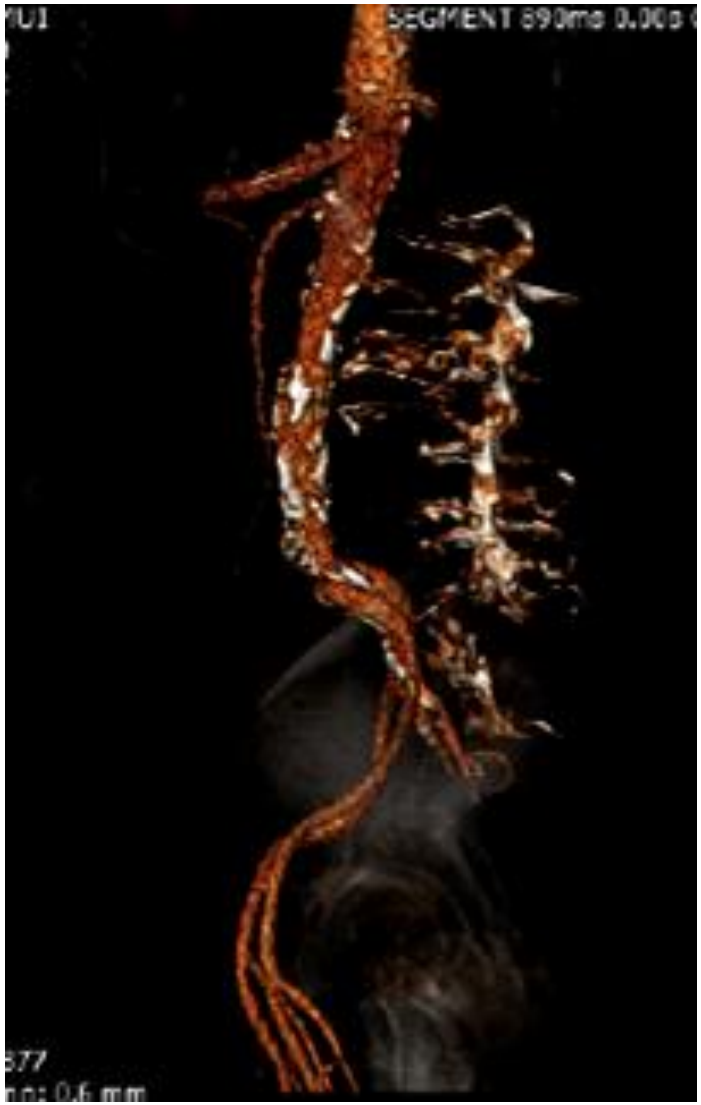


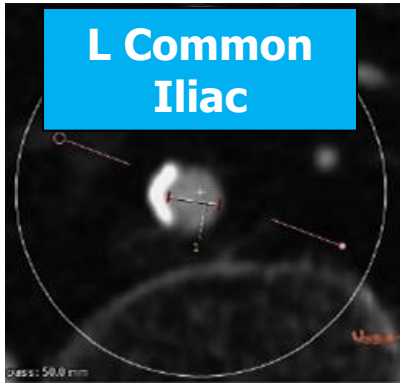




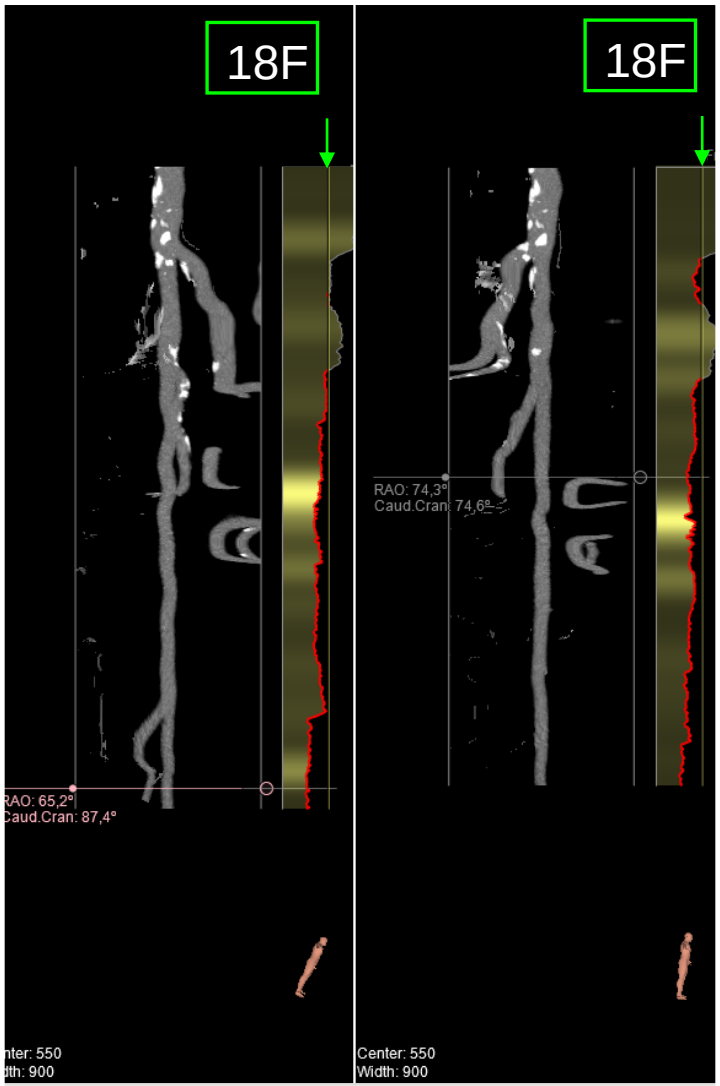
MDCT – Peripheral artery

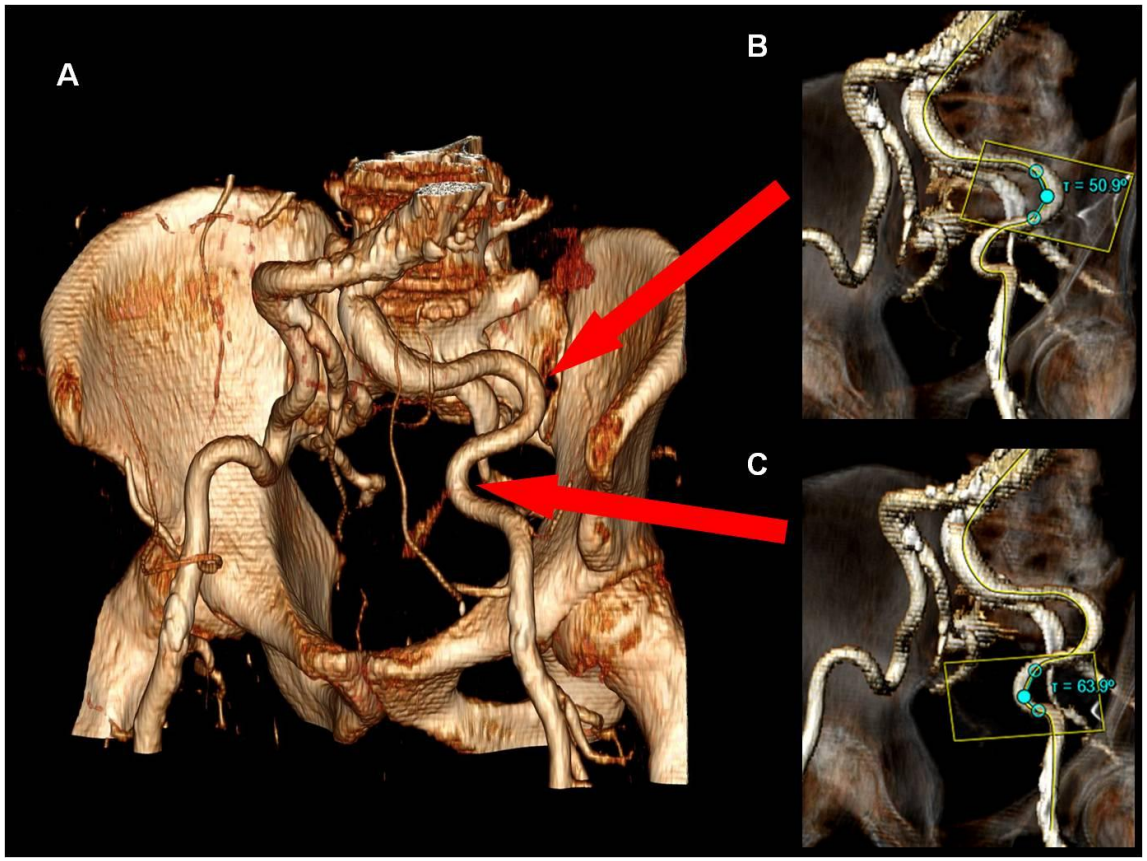
- **Minimal diameters & Calcifications**





1. Lumen diameter
2. Calcification
3. Tortuosity





Complications of the iliofemoral arteries

- Predisposing factors:
- Small vessel size
- Moderate-severe calcification
- Centre experience
- Female gender

- Sheath-to-femoral artery ratio (SFAR) > 1.05 → very strong predictor

- Iliofemoral tortuosity NOT a predictor

Toggweiler et al. JACC Intv 2013
Hayashida et al. JACC Intv 2011

Manufacturer	Sheath	Sheath Internal Diameter, F	Sheath External Diameter, mm
Edwards Lifesciences	RetroFlex 3 introducer sheath	22	8.4
		24	9.2
	NovaFlex introducer sheath	18	7.2*
		19	7.5
	Expandable Sheath	14	5.9*
		16	6.6*
		18	7.2*
		20	7.8*
Cook Medical	Check-Flo Introducer	18	7.2
St. Jude Medical	Ultimum	18	6.8
		20	7.6
		22	8.2
Onset Medical	SoloPath Balloon Expandable Transfemoral Introducer	19	7.3†
		20	7.7†
		21	8†
Gore Medical	DrySheath	16	6.2
		18	6.8
		20	7.5

Table 1 Diameters of the eSheath in its unexpanded and expanded state.

Model	Sheath ID (unexpanded)	Sheath OD (unexpanded)	Sheath OD (expanded)	Loader ID	Compatible NovaFlex+ device	Minimum vessel diameter[a]
916ES23	16F (5.3 mm)	6.7 mm	Up to 8.9 mm	21F	9355NF23 (23 mm THV)	6.0 mm
918ES26	18F (5.9 mm)	7.2 mm	Up to 8.9 mm	21F	9355NF26 (26 mm THV)	6.5 mm
920ES29	20F (6.7 mm)	8.0 mm	Up to 9.9 mm	23F	9355NF29 (29 mm THV)	7.0 mm

ID: inner diameter; OD: outer diameter; THV: transcatheter heart valve.
[a] Minimal vessel diameter requirement.

CoreValve 23mm, 26mm, 29mm, 31mm → all pass through 18F St. Jude or Cook sheath

Minimum vessel diameter ≥ 6.0mm

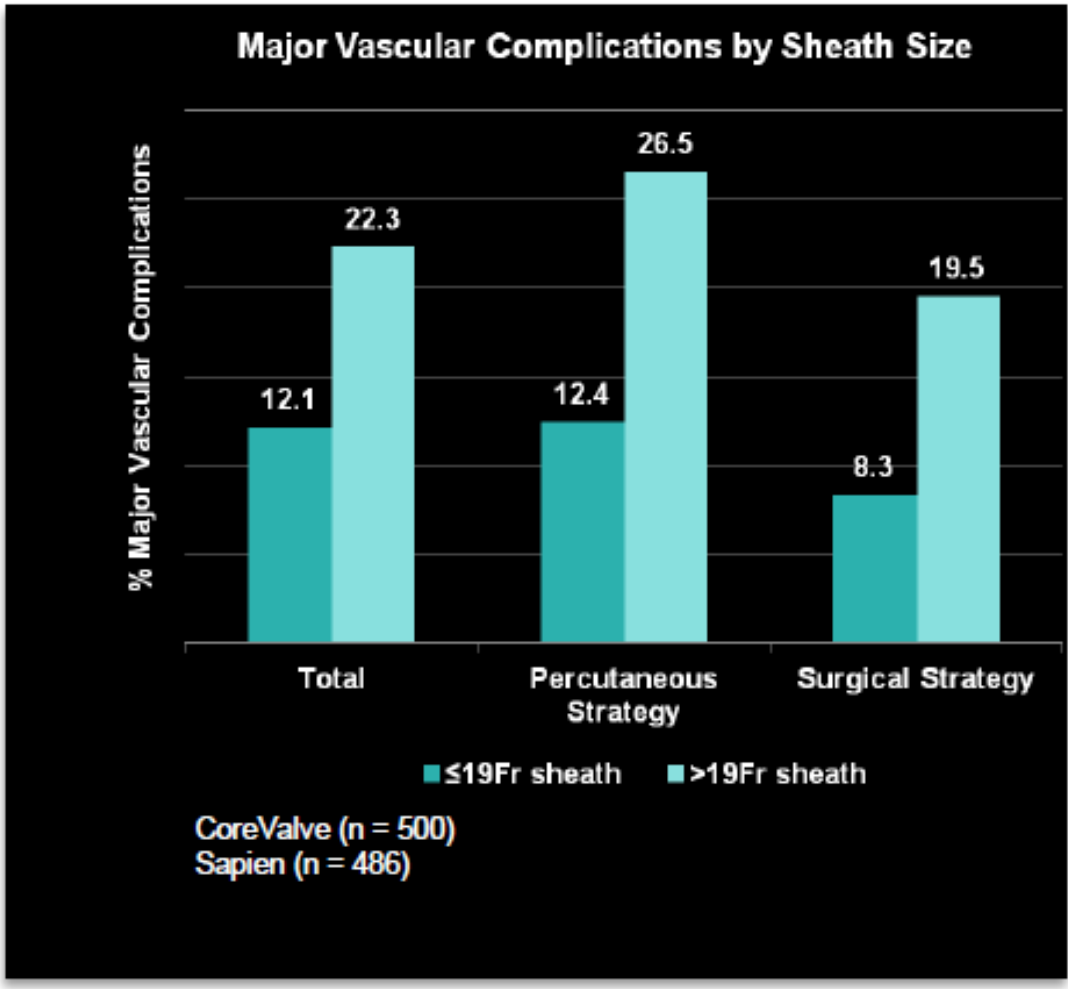
Minimum vessel diameter applies to vessels that are relatively free of calcium

Implications of Sheath Size

Sheath sizes >19Fr lead to more vascular complications

Patients treated with the >19Fr sheath (ID) had:

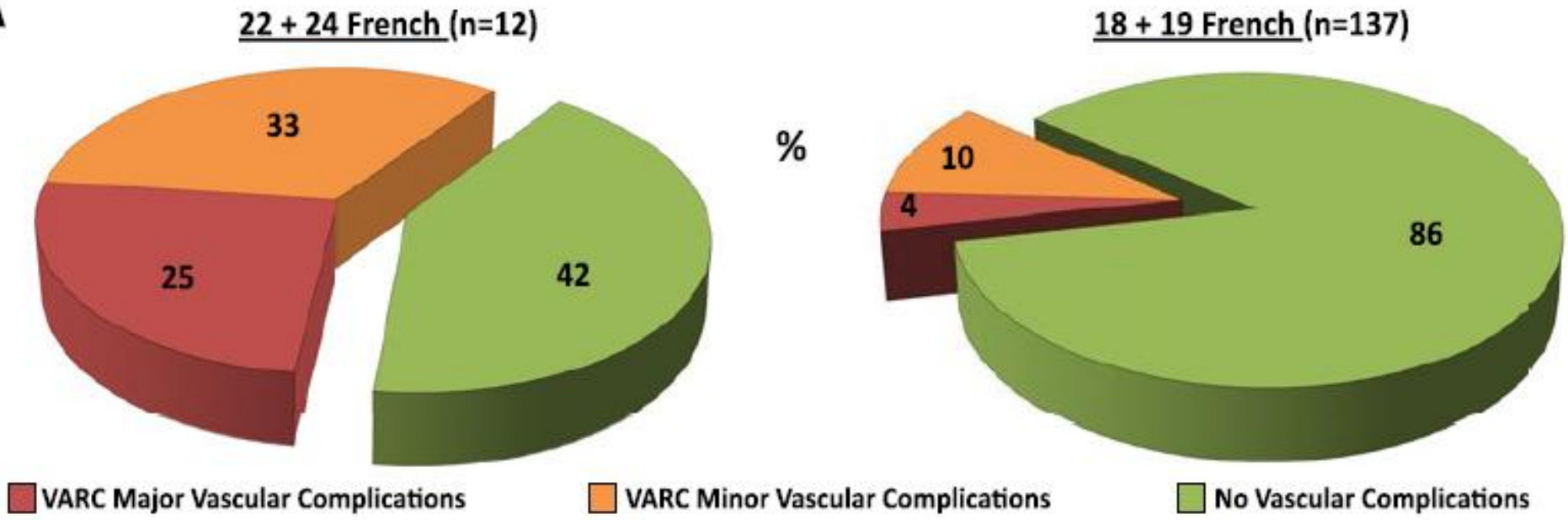
- more vascular complications
  - (22% vs 12%, p < 0.001)
- more bailout interventions for access-related issues
  - (20% vs 10%, p < 0.001)



1. Van Mieghem et al. Am Card. 2011.

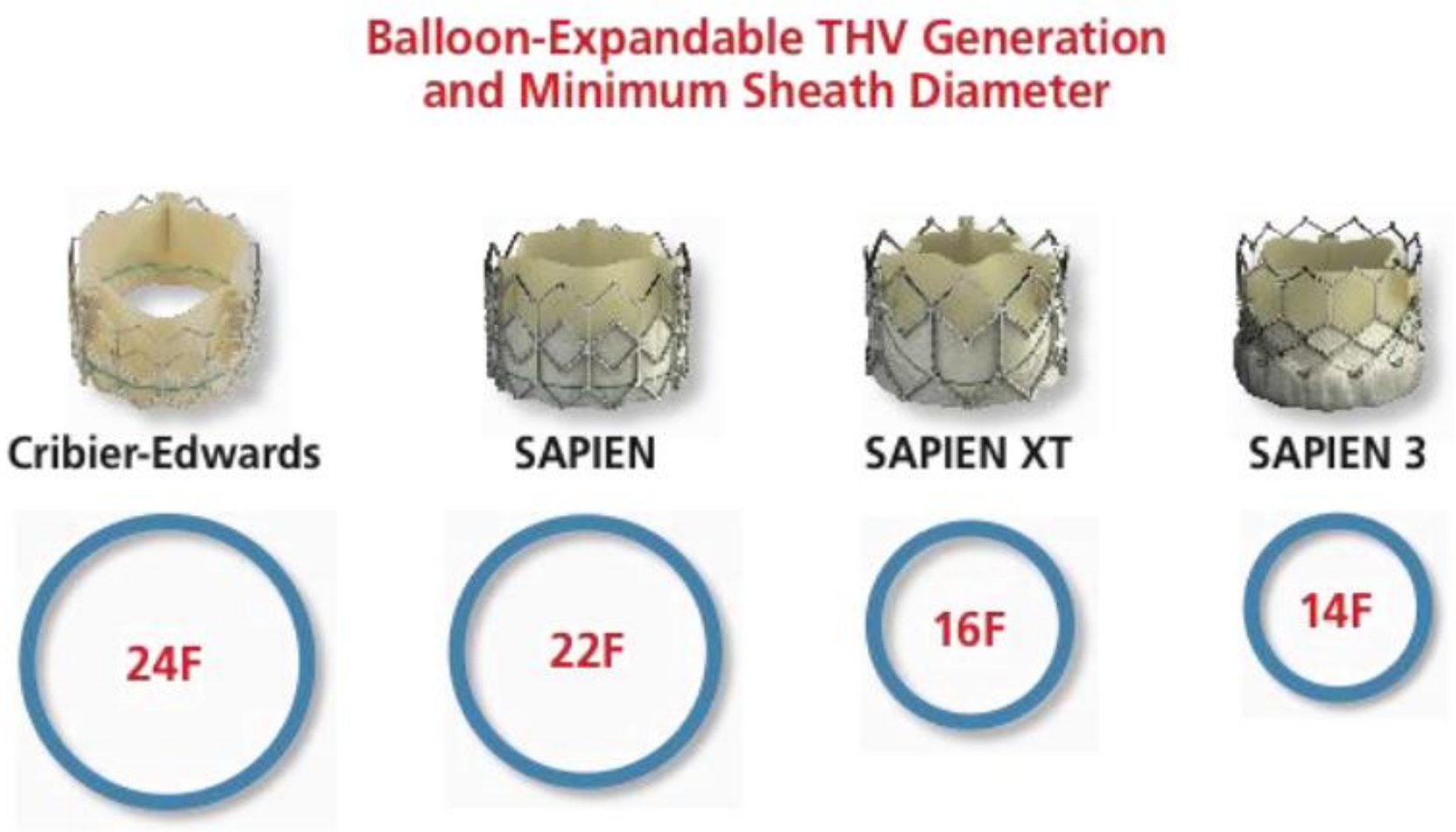
Large vs Small Sheaths
Bern experience

A



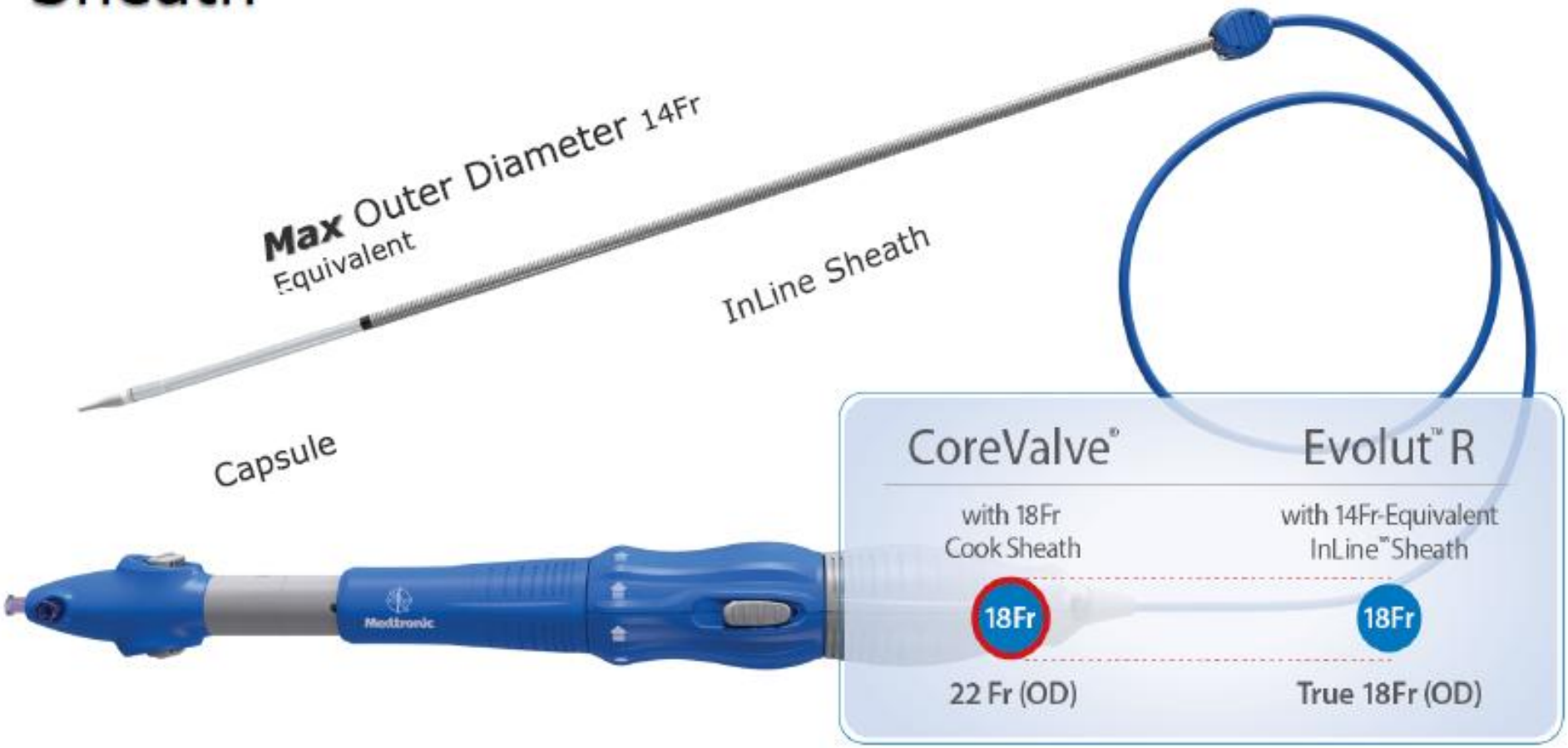
Storecky (Bern) JACC Intv 2012

Lower profile devices will reduce vascular complications



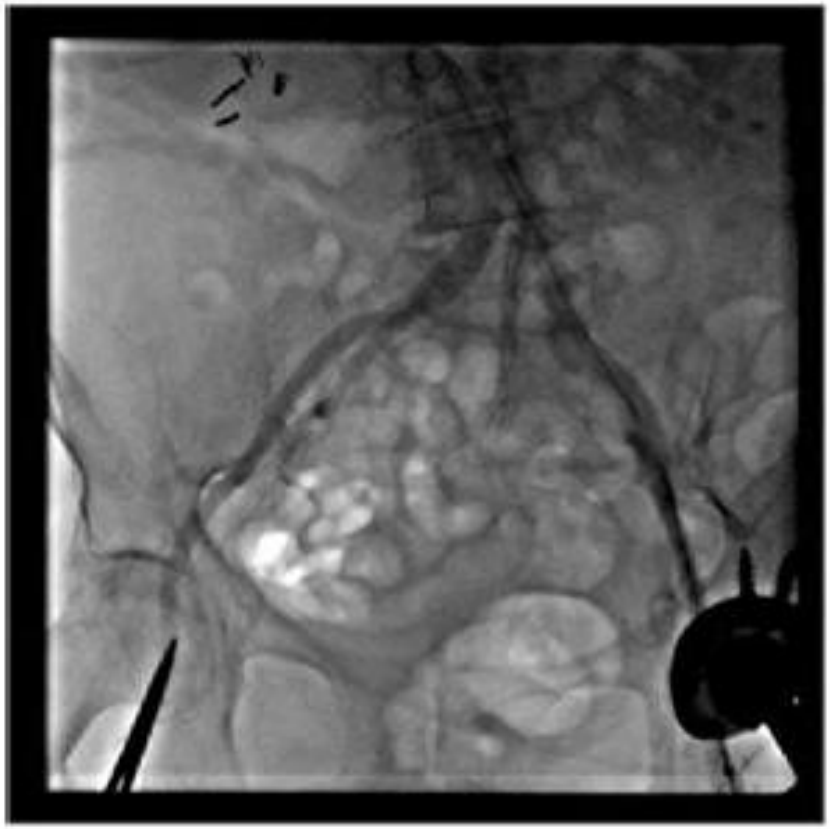
EnVeo R Delivery Catheter

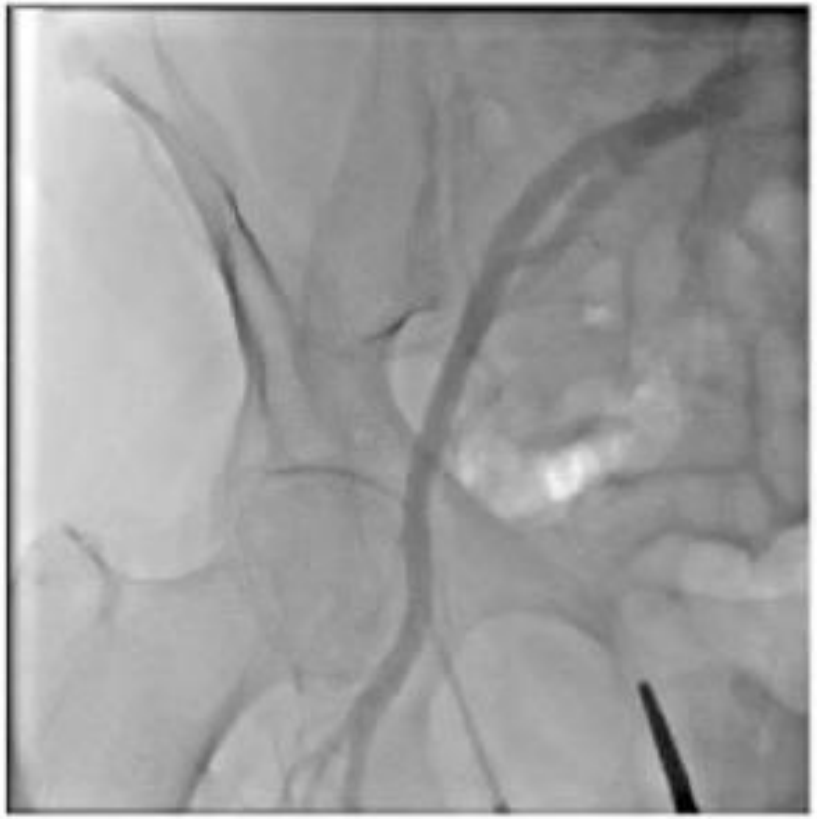
14Fr-Equivalent Delivery Profile with InLine Sheath



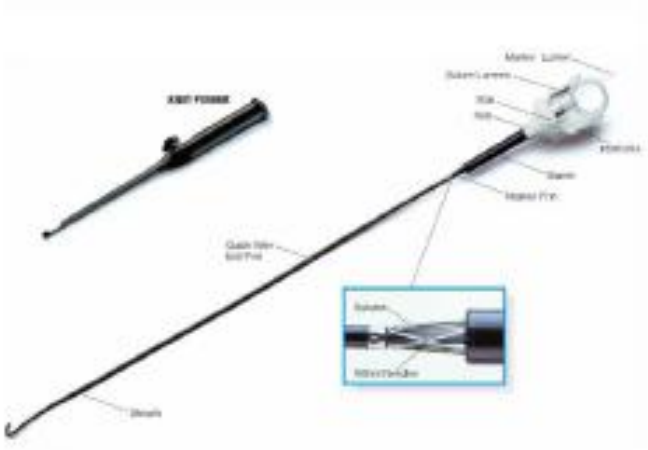
Access techniques – a higher standard for percutaneous access

Crossover injection to localize puncuture site





Be familiar with closure devices



	Proglide	Prostar
Size	6F	10F
Easy to learn	yes	no
Devices	2	1
Pretied	yes	no
Needle entrapment	yes	no
Repeatable	yes	not so much

Be ready to deal with complications

- Iliofemoral dissections:
  - Minor dissections can possible be left alone
  - More complex dissections can be treated with
    - Prolonged balloon inflation
    - Stent placement
    - Covered stent
    - Surgical repair

- Iliofemoral rupture:
  - If ipsilateral wire still in-situ, advance the dilator/ sheath immediately to tamponade rupture site
  - Occlusion balloon (eg Coda balloon) from the ipsilateral/ contralateral access to the distal aorta
  - For small perforation, cross over balloon for 10 min may seal leak
  - Covered stent may seal perforation
  - Many cases will require surgical repair

- Stenosis/ thrombosis:
  - Percutaneous closure can result in stenosis of the CFA → if severe, balloon inflation can help
  - Thrombosis can be treated with thrombectomy (eg Angiojet), angioplasty or surgical revascularization

- Failed Prostar/ Perclose closure:
  - Prolonged manual compression
  - Balloon tamponade
  - Stent implantation
  - Surgical repair

Conclusion:

- Vascular complications still happen as sheaths are still large

- The best treatment is prevention
- Adequate pre-procedure imaging to assess vessel size and calcification is critical

- Upcoming smaller profile devices (Sapien 3, CoreValve Evolut R) will help to reduce vascular complications

- Have equipment ready in the lab in case of vascular complications

- Be ready to consult surgical colleagues for assistance.

Thank you

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