Vascular Complications in Percutaneous Trans-Femoral TAVI – A single center experience

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Disclosure

- Dr. Ariel Finkelstein - consultation fees from Medtronic Cardiovascular and Edwards Lifesciences.

- All other authors declare having no potential conflict of interest.

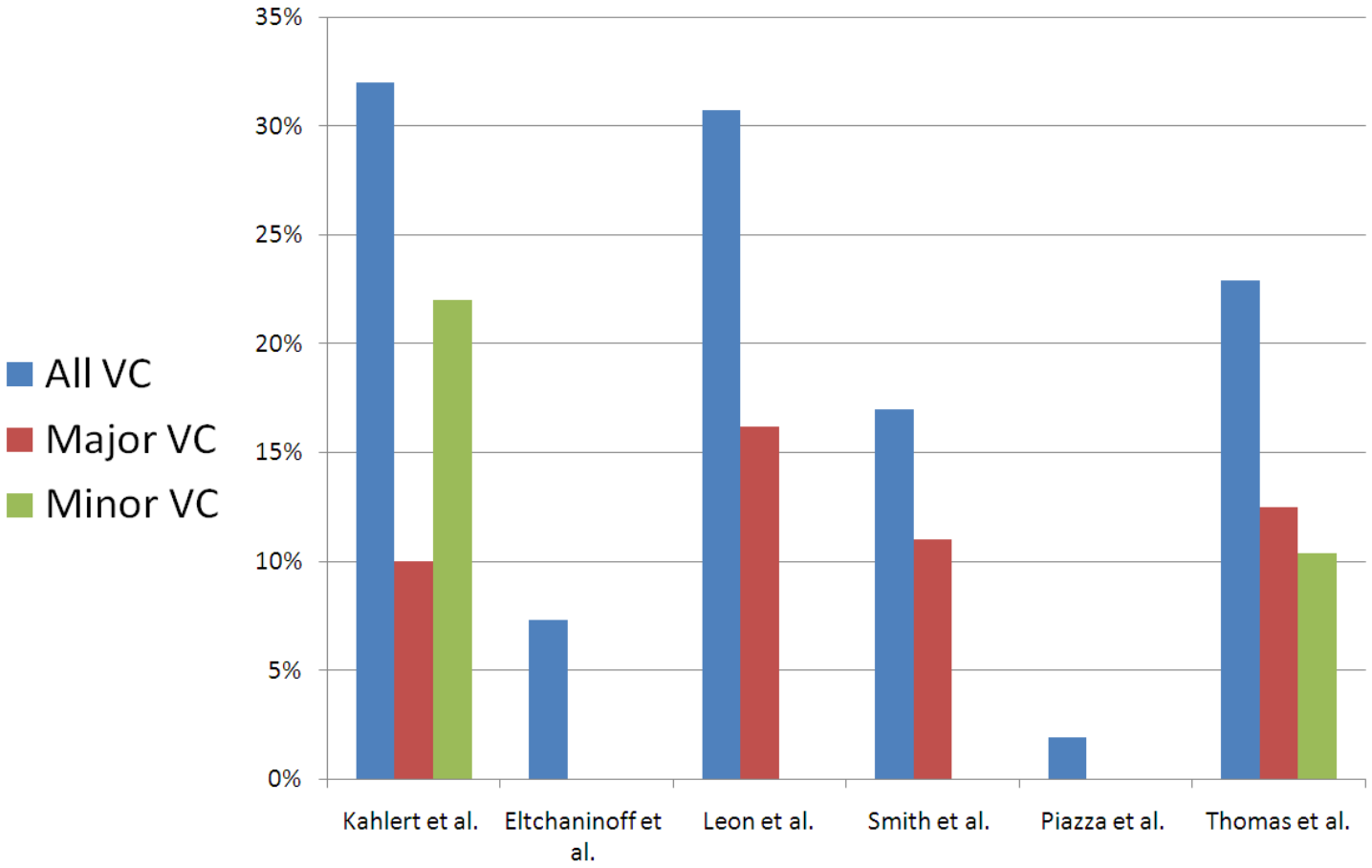
Introduction

- Vascular complications (VC) in TAVI have been associated with a significant increased morbidity and mortality.

- Large variability exists regarding the reported "real-life" occurrence of major and minor VC.

Introduction

- Early TAVI reports regarding VC:



Kahlert et al. *Herz* 2009.
Eltchaninoff et al. *Eur Heart J* 2011.
Leon et al. *N Engl J Med* 2010.
Smith et al. *N Engl J Med* 2011.
Piazza et al. *EuroIntervention* 2008.
Thomas et al. *Circulation* 2010.

Introduction

- Early variability of reported VC rate is partially related to **Different classification** criteria and lack of standardization.

- The Valve Academic Research Consortium (VARC):
  - **VARC-1** – 2011
  - **VARC-2** – 2012

Kappetein et.al, *J Am Coll Cardiol*, 2012

VARC-2 classification

Table 7 Vascular Access Site and Access-Related Complications

Major vascular complications

- Any aortic dissection, aortic rupture, annulus rupture, left ventricle perforation, or new apical aneurysm/pseudo-aneurysm OR
- Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneurysm, hematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) *leading to* death, life-threatening or major bleeding*, visceral ischemia, or neurological impairment OR
- Distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage OR
- The use of unplanned endovascular or surgical intervention *associated* with death, major bleeding, visceral ischemia or neurological impairment OR
- Any new ipsilateral lower extremity ischemia documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram OR
- Surgery for access site-related nerve injury OR
- Permanent access site-related nerve injury

Minor vascular complications

- Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneuysms, hematomas, percutaneous closure device failure) *not leading to* death, life-threatening or major bleeding*, visceral ischemia, or neurological impairment OR
- Distal embolization treated with embolectomy and/or thrombectomy and not resulting in amputation or irreversible end-organ damage OR
- Any unplanned endovascular stenting or unplanned surgical intervention not meeting the criteria for a major vascular complication OR
- Vascular repair or the need for vascular repair (via surgery, ultrasound-guided compression, transcatheter embolization, or stent-graft)

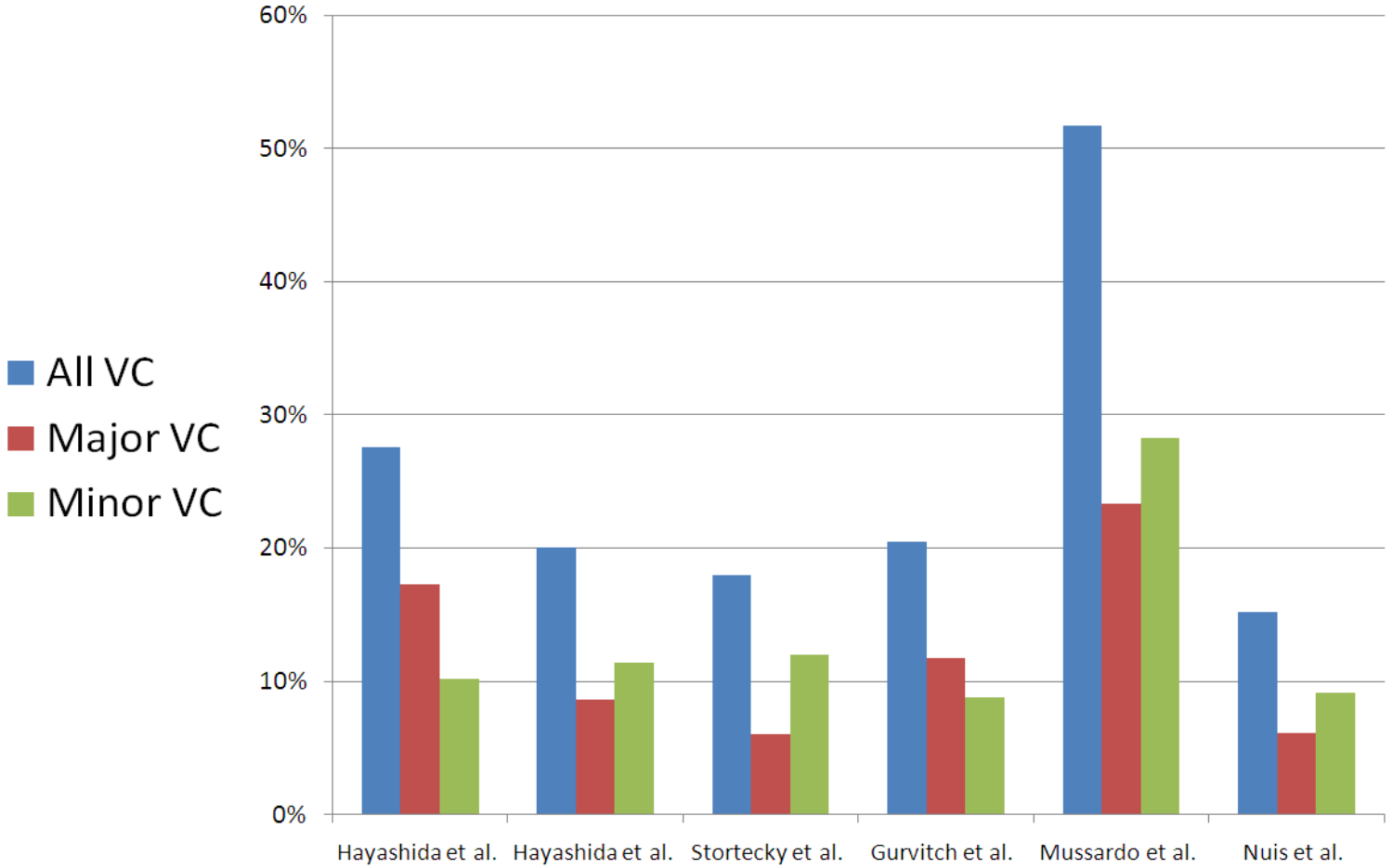
Percutaneous closure device failure

- Failure of a closure device to achieve hemostasis at the arteriotomy site leading to alternative treatment (other than manual compression or adjunctive endovascular ballooning)

*Refers to VARC bleeding definitions.

Introduction

- VC after VARC publication



Hayashida et al. *JACC CI* 2011.
Hayashida et al. *JACC CI* 2012.
Stortecky et al. *JACC CI* 2012.
Gurvitch et al. *EuroIntervention* 2011.
Mussardo et al. *JACC CI* 2012.
Nuis et al. *Am J Cardiol* 2011.

Introduction

- Despite VARC criteria initiation, variability still exists.

- Most reports to date include a mixture of different anatomical access sites and transcatheter approaches.

Objectives

- To describe:
  - **prevalence** of VC
  - **Clinical risk factors** for VC

  associated with trans-femoral TAVI, using the recently updated VARC-2 criteria.

Methods

- **Study population**
  - **Retrospective**, **Single center** analysis
  - First **300** consecutive patients (03/09 – 09/12)
  - Excluded:
    - 7 patients who underwent TAVI via a trans-axillary approach (due to pre-TAVI unfavorable femoral artery angiography).

Methods

- **TAVI procedure**
  - 18F sheaths (for Corevalve system) or 18/19F sheaths (for Edwards Sapien XT system).
  - Prostar XL closure device (Abbott Vascular) was used in all patients, followed by angiography of the femoral artery via the contralateral femoral artery to detect VC.

Methods

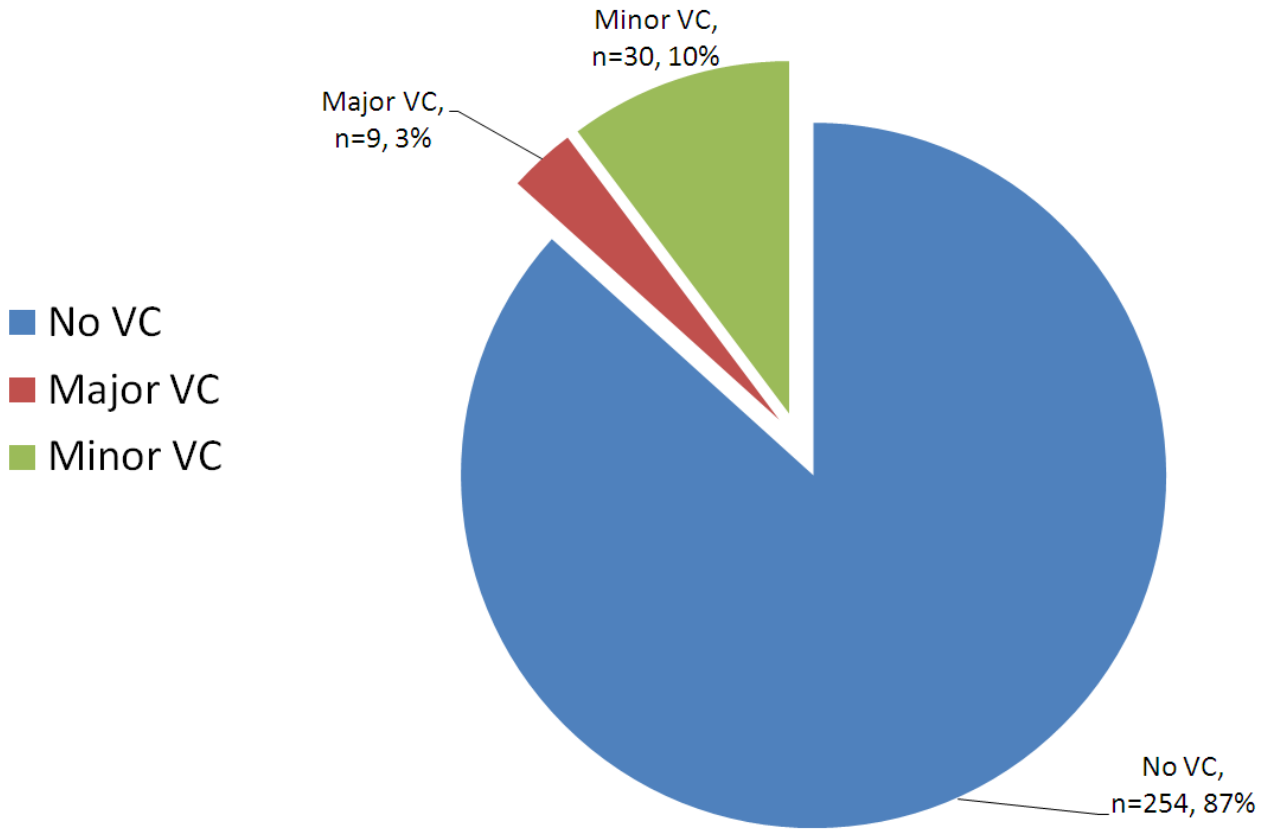
- **Treatment of VC**
  - If *not* referred to emergent vascular surgery, all identified VC were treated during the initial index procedure by balloon angioplasty or with covered stent deployment.
  - Suspected pseudo-aneurysms (PSA): underwent groin ultrasound and a bedside ultrasound-guided thrombin injection.

Results

- **Patient data**
  - The final study population included **293 patients**
    - Mean **age** of **83±5**
    - **61% females**
    - High prevalence of co-morbidities and prior vascular disease
    - **Euroscore** (mean±SD) **25±13**
  - Valve type distribution:
    - **CoreValve** - **83%** (243/293)
    - **Edwards** - **17%** (50/293)
  - **69.3%** underwent TAVI via the Rt. femoral artery (n=203)
  - Mean access site artery diameter: **7.6±1.1 mm**

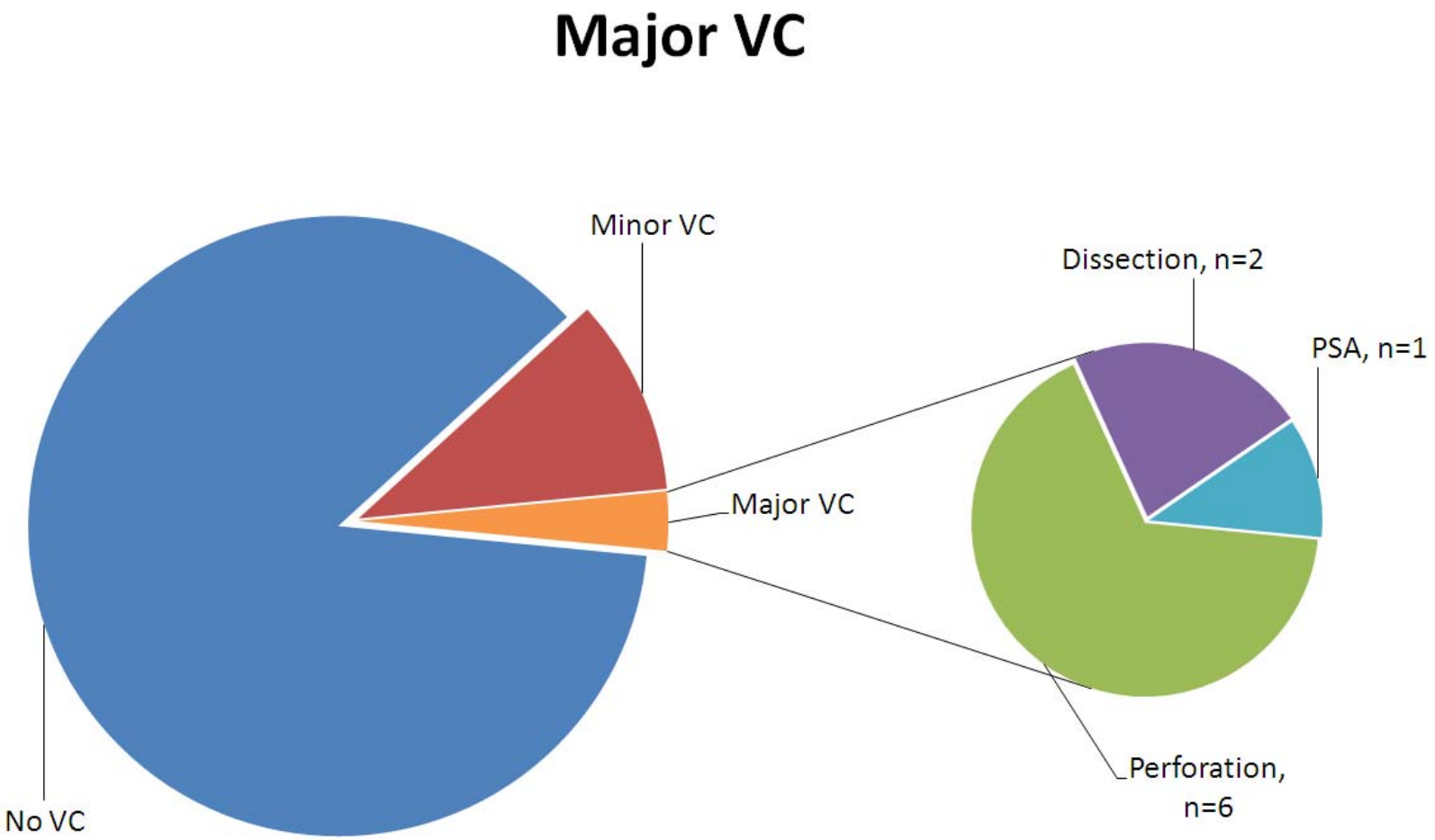
Results

- **Frequency of VC**

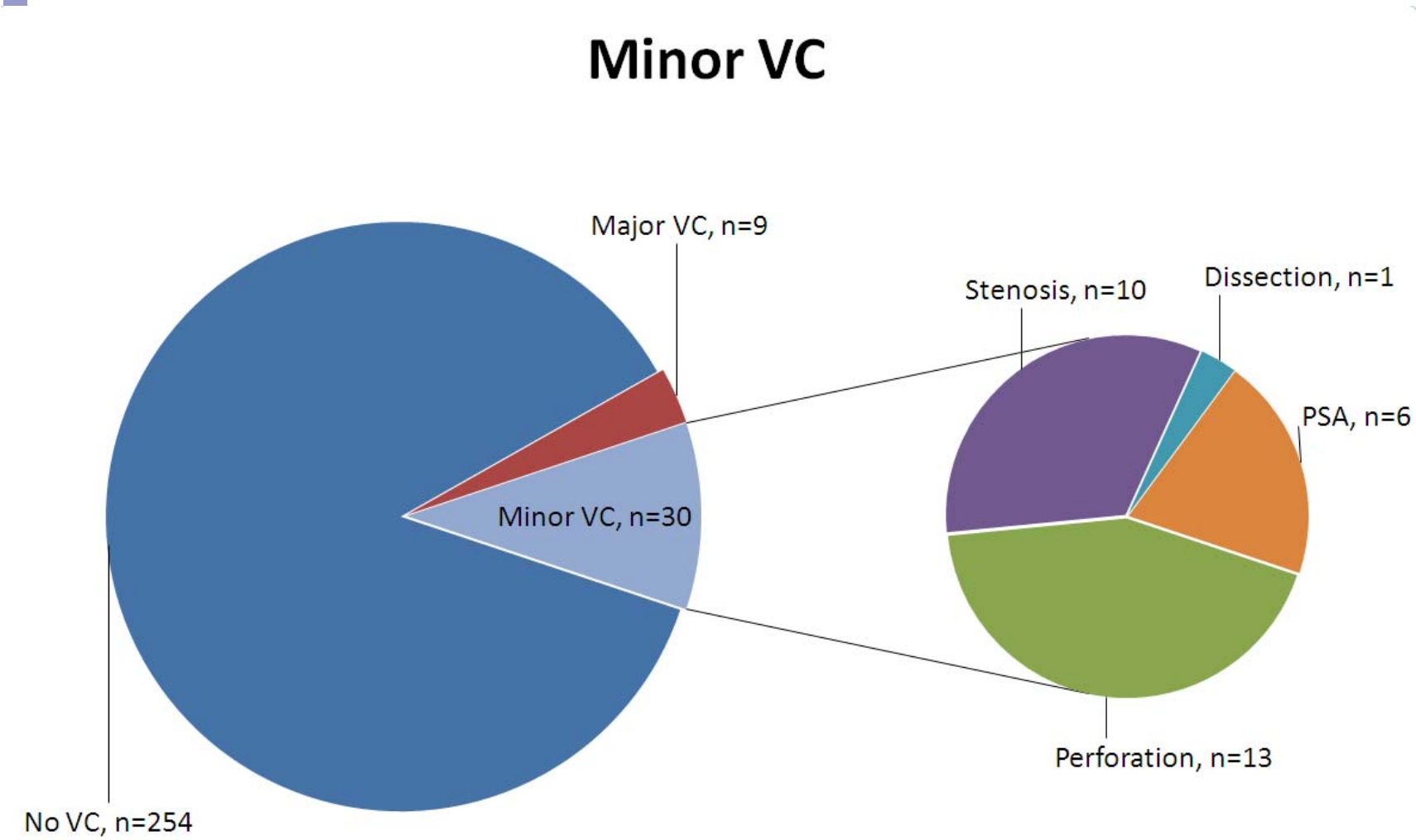


- **All VC encountered were access-site related**

Results


Major VC
Minor VC
Major VC
No VC
Dissection, n=2
PSA, n=1
Perforation, n=6

Results


Minor VC
Major VC, n=9
Minor VC, n=30
No VC, n=254
Stenosis, n=10
Dissection, n=1
PSA, n=6
Perforation, n=13

Results

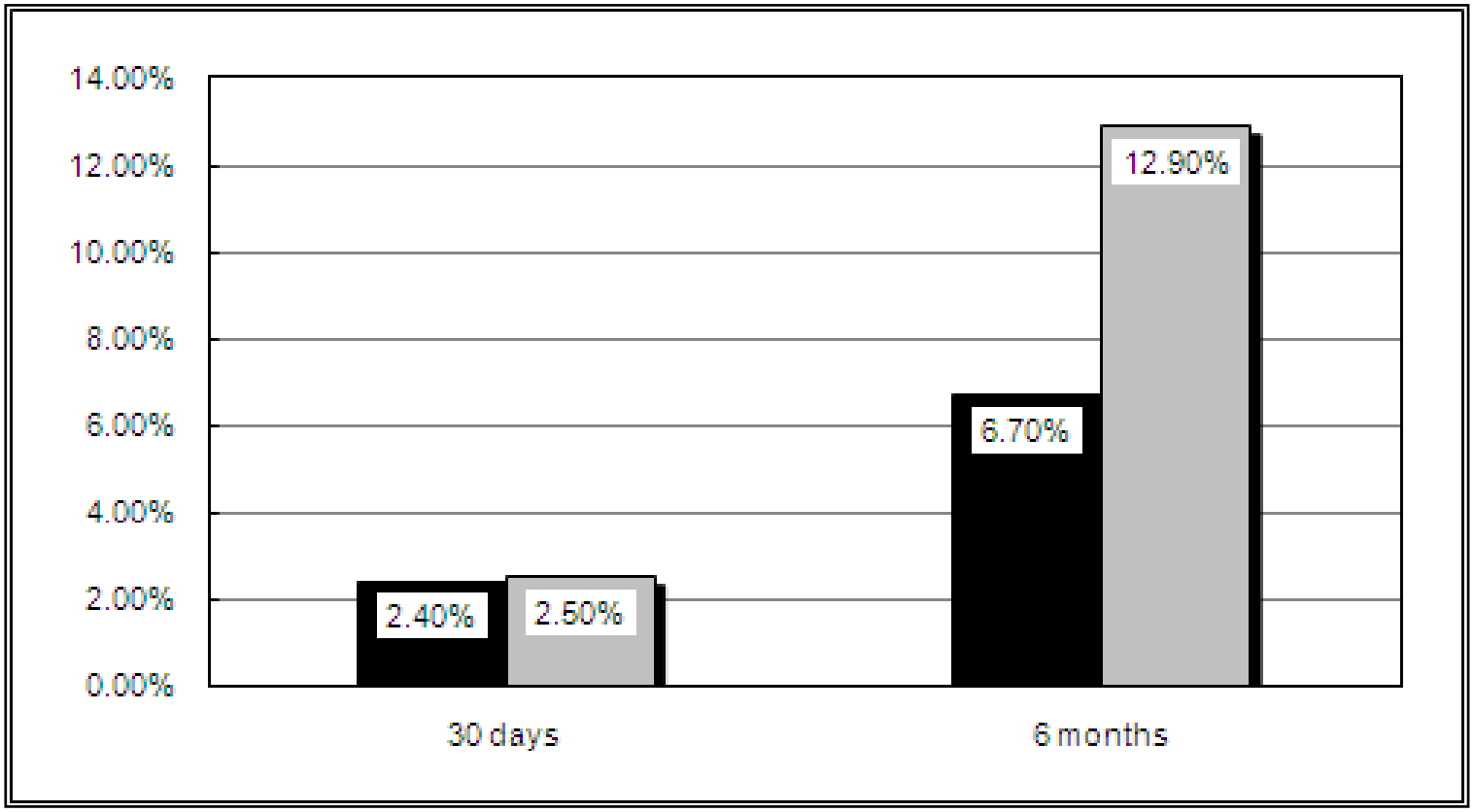
- **Characteristics associated with increased risk for VC**

Variable	OR	95% CI	p Value
Patient			
Female	2.73	1.2-6.1	**0.013**
Weight <71 kg	0.47	0.2-0.9	**0.045**
Height <162 cm	0.21	0.2-0.9	**0.02**
Euroscore >24	2.2	1.1-4.9	**0.02**
Pre-procedural Echo			
Mean pressure gradient > 46 mmHg	2.0	1.01-4.1	**0.04**
Mean AVA <0.7 cm^2	0.5	0.2-0.9	**0.04**
Procedural			
Smaller valve size (23 – 26mm)	0.4	0.2-0.9	**0.03**

OR were calculated for above and below the median for each variable

Results

- **Effect of VC on all-cause mortality**



patients without vascular complications

patients with vascular complications.

Conclusions

- VC occurred in 13% (39/293 patients) of the TAVI procedures, but only 1/4 of those patients (9 patients) had a major VC.

- Female gender and low body mass among other procedural parameters were associated with increased risk of VC.

Conclusions

- Compared to previous publications, we report a relatively lower rate of VC, and these were not associated with increased mortality at 1 month.

- Mortality at 6 months was higher, although non-significant, among patients with VC.

Thank you

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