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Impact of Closure Device Type in Short- and Long-Term Outcomes after TAVI: Results from EVERY-TAVI Registry

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Potential conflicts of interest

Speaker's name: Julinda Mehilli

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

Honorarium: ABBOTT VASCULAR, DAIICHI SANKYO and ELI-LILLY, EDWARDS LIFESCIENCES, TERUMO

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Background

Outcomes of TAVI procedures continue to improve with increasing experience of operators and technical improvements of prostheses platforms.

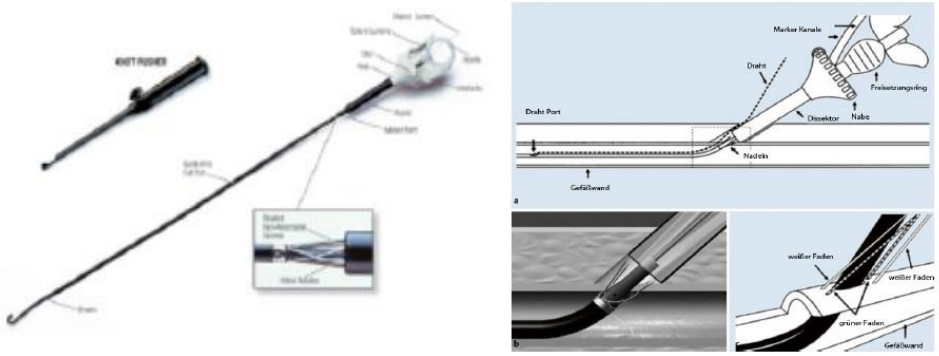
Vascular and bleeding complications at the TAVI-access site are frequently observed and involve 20% to 30% of TAVI patients.

Therefore, implementation of strategies for achieving an adequate haemostasis at the TAVI access-site might further increase the safety of these procedures

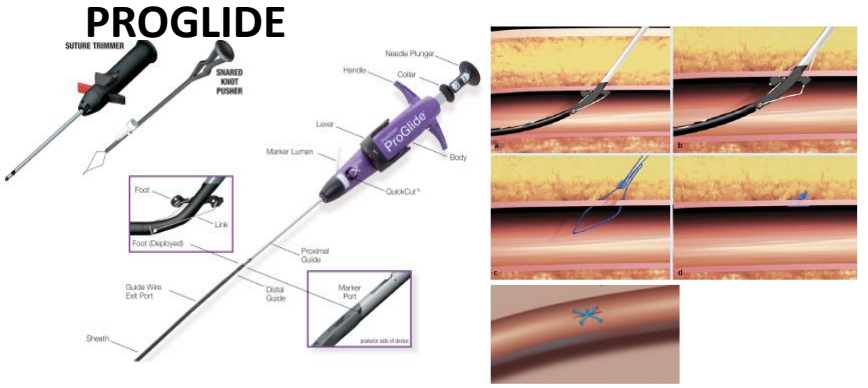
Suture Mediated Closure Devices

Two suture mediated closure device (SMCD) techniques are frequently used to minimal-invasively achieve access-site haemostasis

PROSTAR XL



PROGLIDE



While only few data about clinical safety and efficacy with SMCD after TAVI exist, comparison between the two strategies are lacking

Study Aim and Methods

Aim: to comparatively assess performance of two preclosure techniques in patients undergoing trans-femoral TAVI.

Primary outcome of interest:

- Incidence of vascular complications according to VARC-2 definition

Secondary outcomes of interest:

- Incidence of bleeding complications according to VARC-2 and BARC definition
- Mortality at 30-day and 1-year follow-up
- Incidence of closure device failure

Data collection: Demographics, clinical and procedural data were collected prospectively as a part of national quality control

Definitions of Clinical Endpoints

BARC Bleeds

Table 3. Bleeding Academic Research Consortium Definition for Bleeding

Type 0: no bleeding

Type 1: bleeding that is not actionable and does not cause the patient to seek unscheduled performance of studies, hospitalization, or treatment by a healthcare professional; may include episodes leading to self-discontinuation of medical therapy by the patient without consulting a healthcare professional

Type 2: any overt, actionable sign of hemorrhage (eg, more bleeding than would be expected for a clinical circumstance, including bleeding found by imaging alone) that does not fit the criteria for type 3, 4, or 5 but does meet at least one of the following criteria: (1) requiring nonsurgical, medical intervention by a healthcare professional, (2) leading to hospitalization or increased level of care, or (3) prompting evaluation

Type 3

- Type 3a
  - Overt bleeding plus hemoglobin drop of 3 to <5 g/dL* (provided hemoglobin drop is related to bleed)
  - Any transfusion with overt bleeding
- Type 3b
  - Overt bleeding plus hemoglobin drop ≥5 g/dL* (provided hemoglobin drop is related to bleed)
  - Cardiac tamponade
  - Bleeding requiring surgical intervention for control (excluding dental/nasal/skin/hemorrhoid)
  - Bleeding requiring intravenous vasoactive agents
- Type 3c
  - Intracranial hemorrhage (does not include microbleeds or hemorrhagic transformation, does include intraspinal)
  - Subcategories confirmed by autopsy or imaging or lumbar puncture
  - Intraocular bleed compromising vision

Type 4: CABG-related bleeding

- Perioperative intracranial bleeding within 48 h
- Reoperation after closure of sternotomy for the purpose of controlling bleeding
- Transfusion of ≥5 U whole blood or packed red blood cells within a 48-h period†
- Chest tube output ≥2L within a 24-h period

Type 5: fatal bleeding

- Type 5a
  - Probable fatal bleeding; no autopsy or imaging confirmation but clinically suspicious
- Type 5b
  - Definite fatal bleeding; overt bleeding or autopsy or imaging confirmation

Mehran et al., Circulation 2011

VARC-2 Bleeds

Table 5 Bleeding

Life-threatening or disabling bleeding

- Fatal bleeding *(BARC type 5)* OR
- Bleeding in a critical organ, such as intracranial, intraspinal, intraocular, or pericardial necessitating pericardiocentesis, or intramuscular with compartment syndrome *(BARC type 3b and 3c)* OR
- Bleeding causing hypovolaemic shock or severe hypotension requiring vasopressors or surgery *(BARC type 3b)* OR
- Overt source of bleeding with drop in haemoglobin >5 g/dL or whole blood or packed red blood cells (RBCs) transfusion >4 units* *(BARC type 3b)*

Major bleeding (BARC type 3a)

- Overt bleeding either associated with a drop in the hemoglobin level of at least 3.0 g/dl or requiring transfusion of two or three units of whole blood/RBC, or causing hospitalization or permanent injury, or requiring surgery AND
- Does not meet criteria of life-threatening or disabling bleeding

Minor bleeding (BARC type 2 or 3a, depending on the severity)

- Any bleeding worthy of clinical mention (e.g. access site hematoma) that does not qualify as life-threatening, disabling, or major

*Given that one *unit* of packed RBC typically will raise the hemoglobin concentration by 1 g/dl, an estimated decrease in hemoglobin will be calculated.

VARC-2 Vascular complications

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)

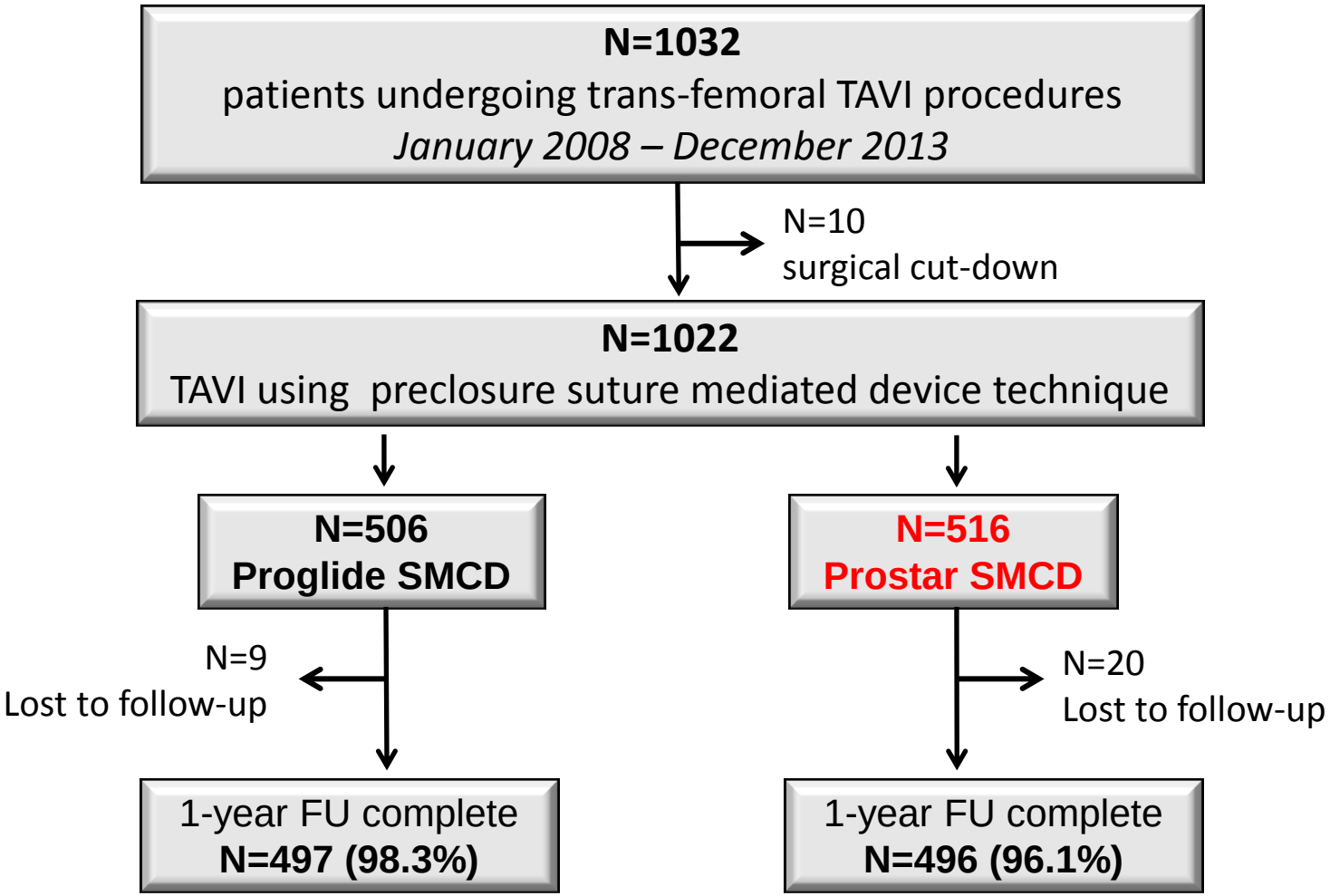
Percutaneous closure device failure

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

Kappetein et al., J Am Coll Cardiol 2012

Study Population

Population – subset of the on-going EVERY-TAVI registry :



Participating centers:

- Munich University Clinic, Ludwig-Maximilians University, Munich, Germany
- Herzzentrum, Bad Segeberger Kliniken, Bad Segeberg, Germany

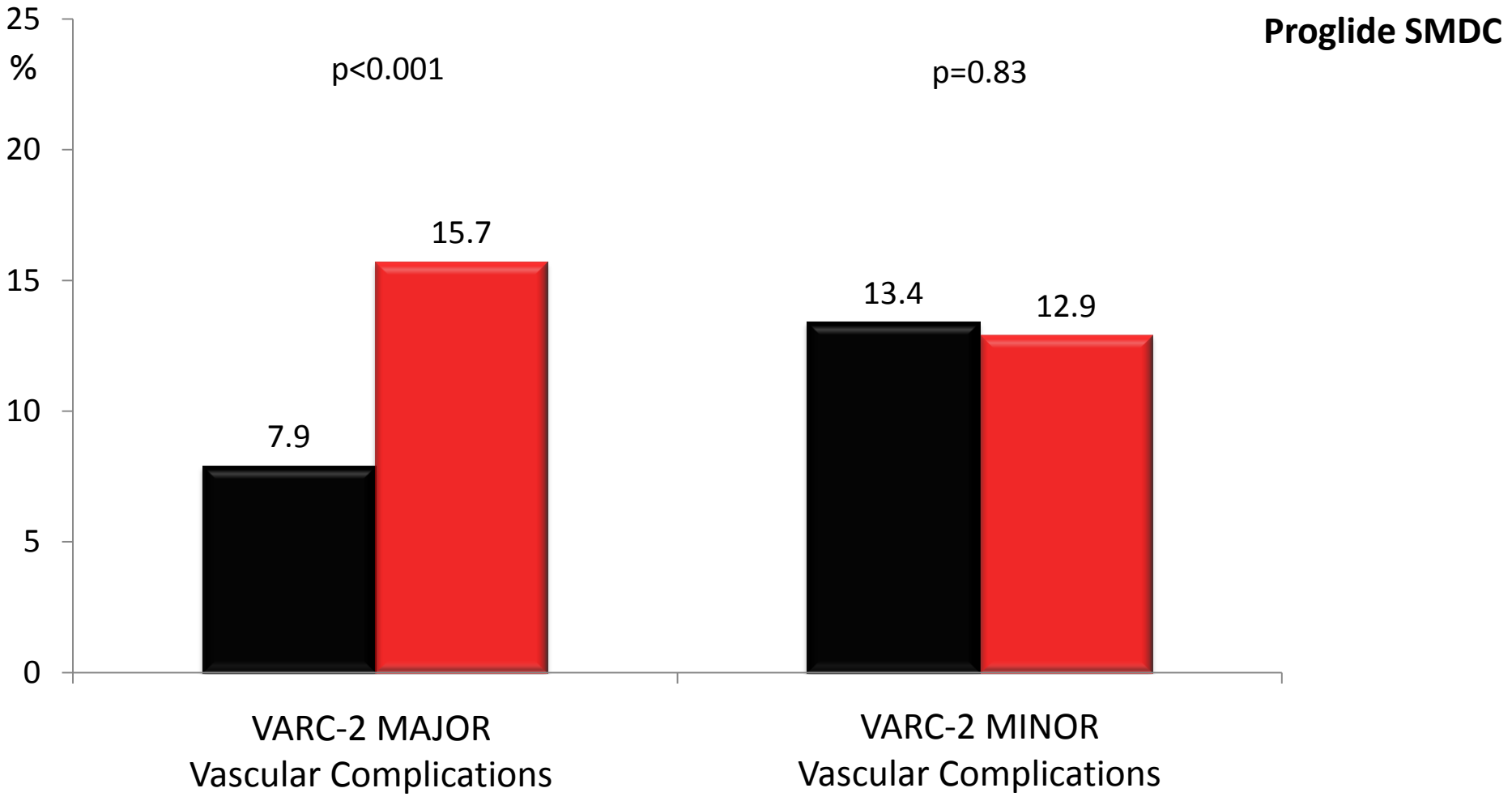
Key Baseline Characteristics

	Proglide SMCD n=506	Prostar SMCD n=516	p-Value
Age, yrs	84.6±7.3	81.2±7.1	0.15
Women, %	57.5	55.8	0.58
LogEuroscore, %	21.2±14.0	21.9±12.1	0.38
Diabetes, %	24.7	23.0	0.53
Chronic kidney disease, %	30.6	42.2	<0.001
Coronary artery disease, %	66.6	54.9	<0.001
History of stroke, %	12.1	9.9	0.31
Peripheral vascular disease, %	10.9	10.5	0.88
COPD,%	10.3	14.3	0.05
Malignancies, %	17.8	17.4	0.88
Persistent atrial fibrillation, %	38.5	27.9	<0.001
Baseline haemoglobin, g/dl	12.22±1.85	12.07±1.73	0.19

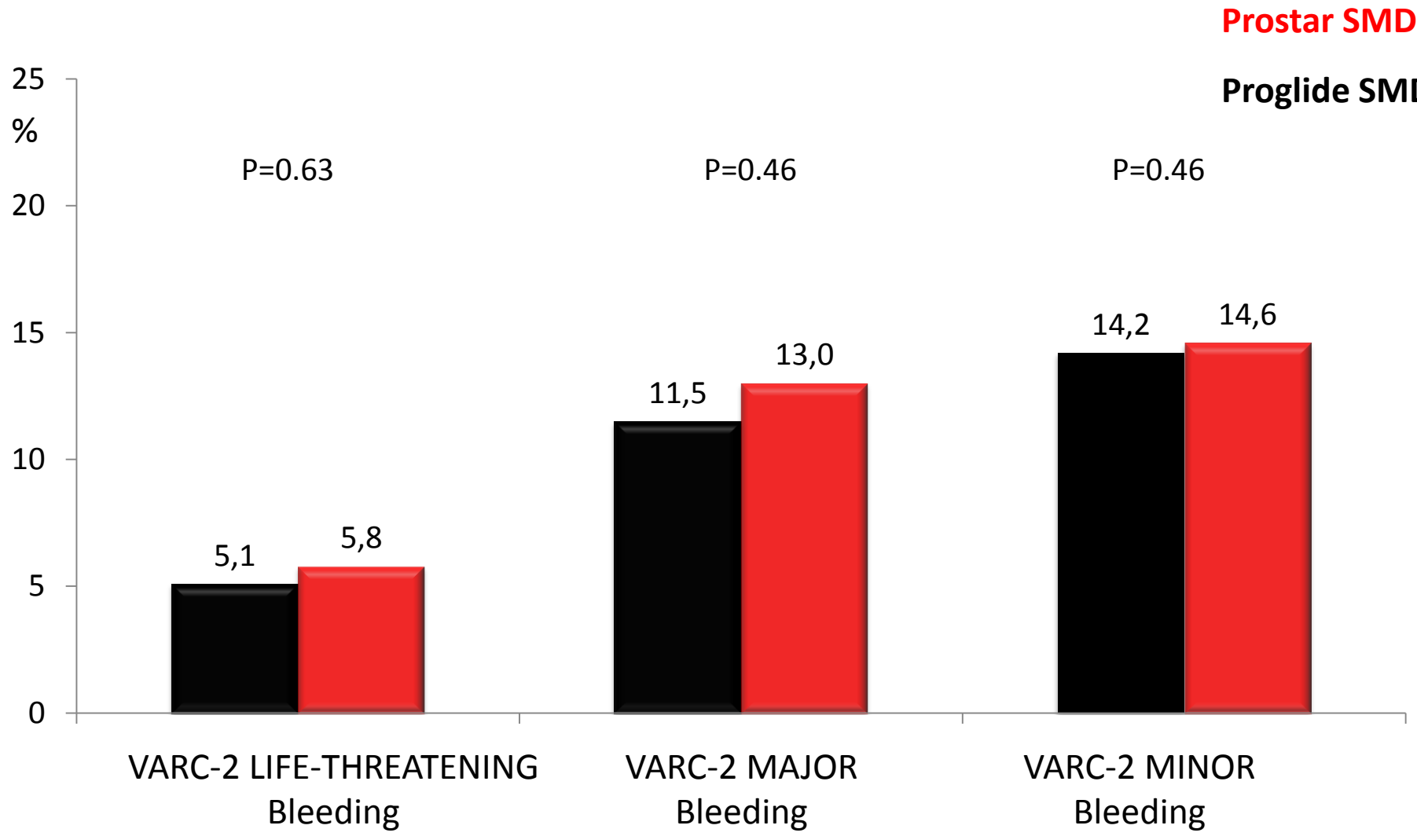
Key Baseline Characteristics

	Proglide SMCD n=506	Prostar SMCD n=516	p-Value
Implanted prosthesis, %			<0.001
Sapien XT	51.0	34.7	
CoreValve	49.0	65.3	
Sheath size, %			<0.001
16F	9.5	12.0	
18F	76.7	85.1	
20F	13.8	2.9	
Prosthesis size, %			0.08
23	11.3	12.6	
26	40.3	46.7	
29	44.1	38.0	
31	4.3	2.7	
Diameter AFC access site, mm	8.7±5.3	8.4±1.9	0.22
Severe tortuosity of iliac artery, %	5.6	0.9	<0.001
Severe calcification of access site, %	32.1	13.8	<0.001

VARC-2 Vascular Complications Primary Outcome of Interest



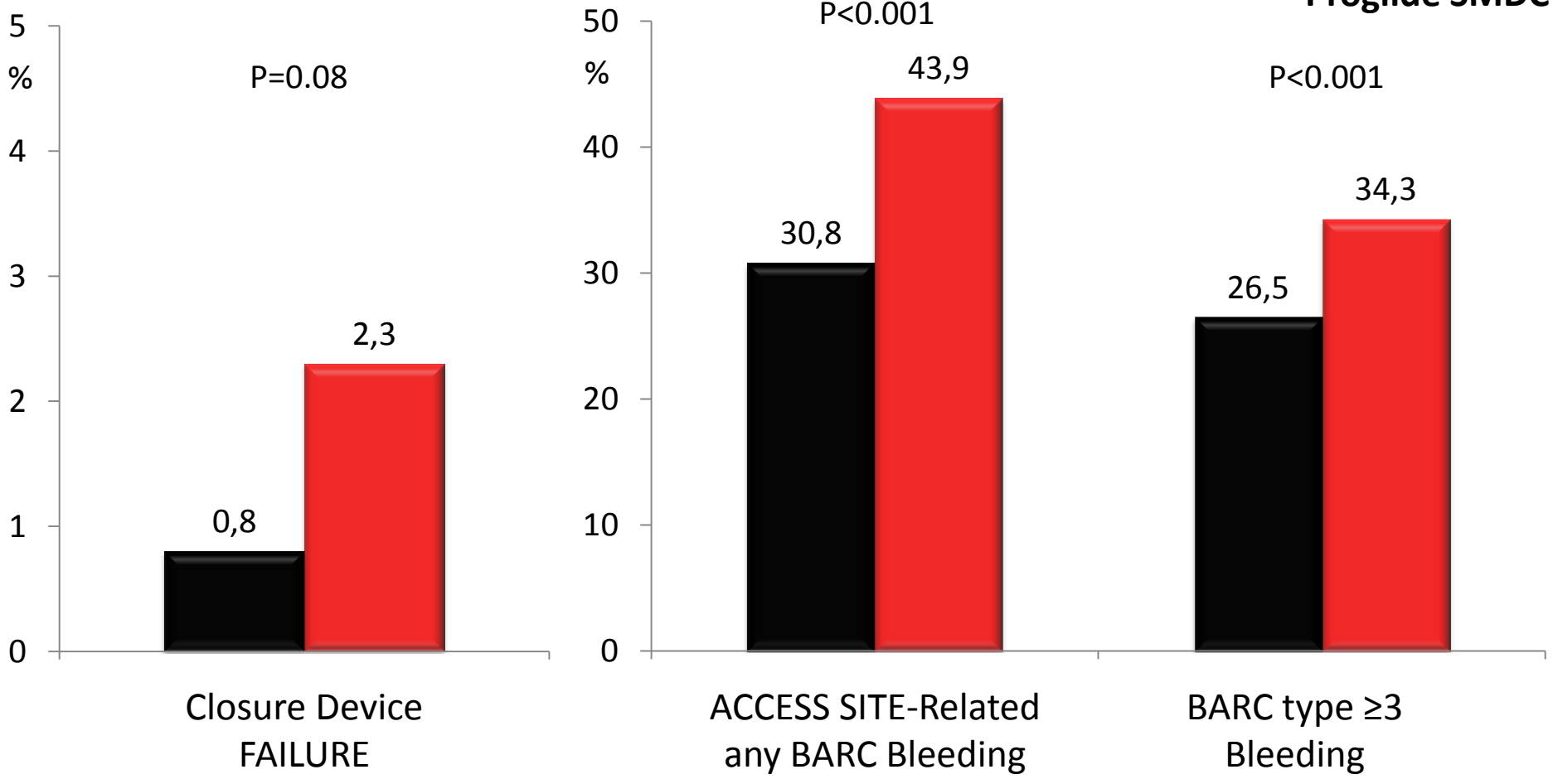
VARC-2 Bleeding Complications Secondary Outcome of Interest



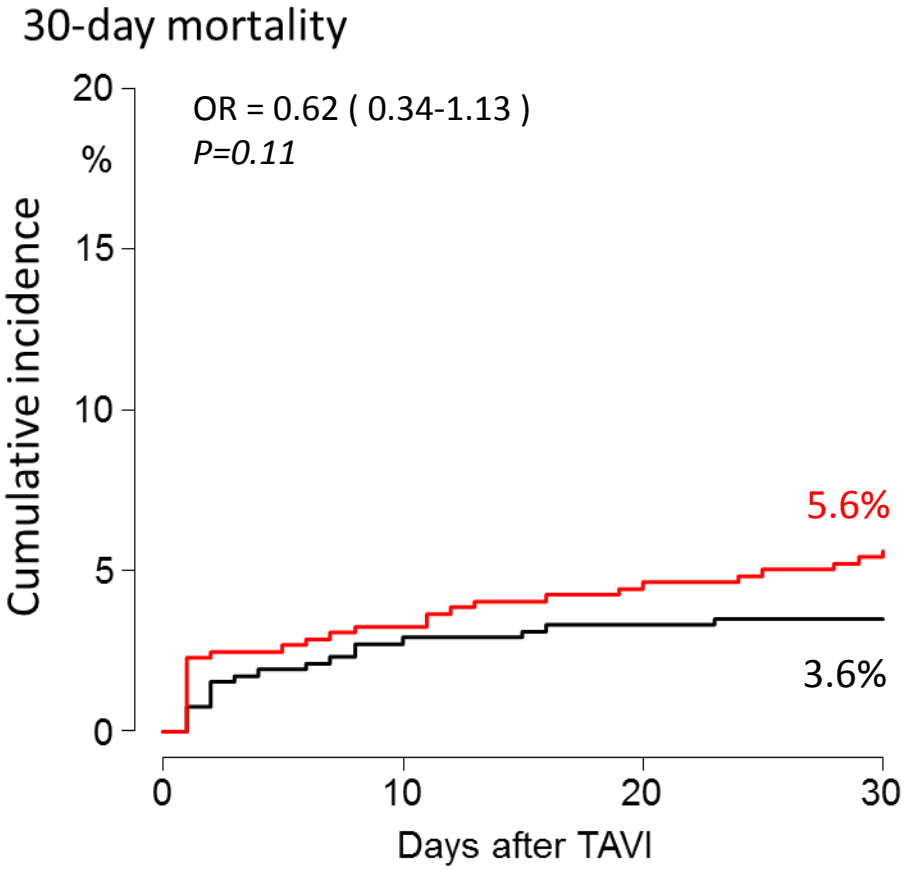
SMCD Failure and BARC Type Bleeding
Secondary Outcomes of Interest

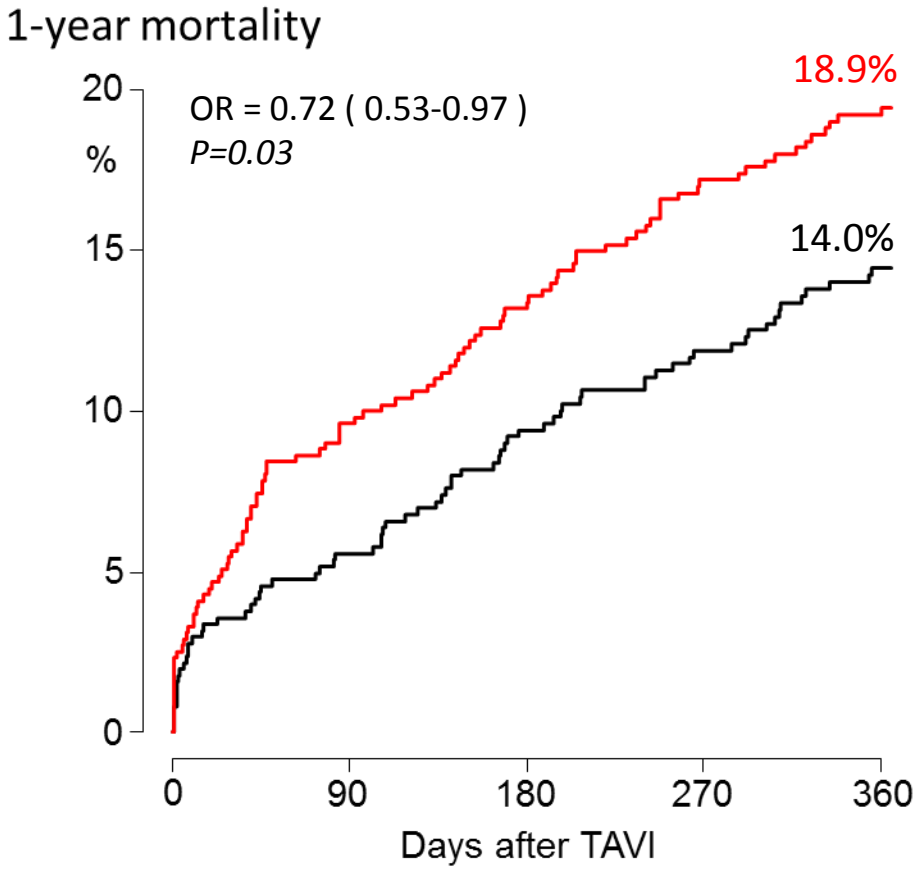
Prostar SMDC

Proglide SMDC



All-cause Mortality
Secondary Outcome of Interest

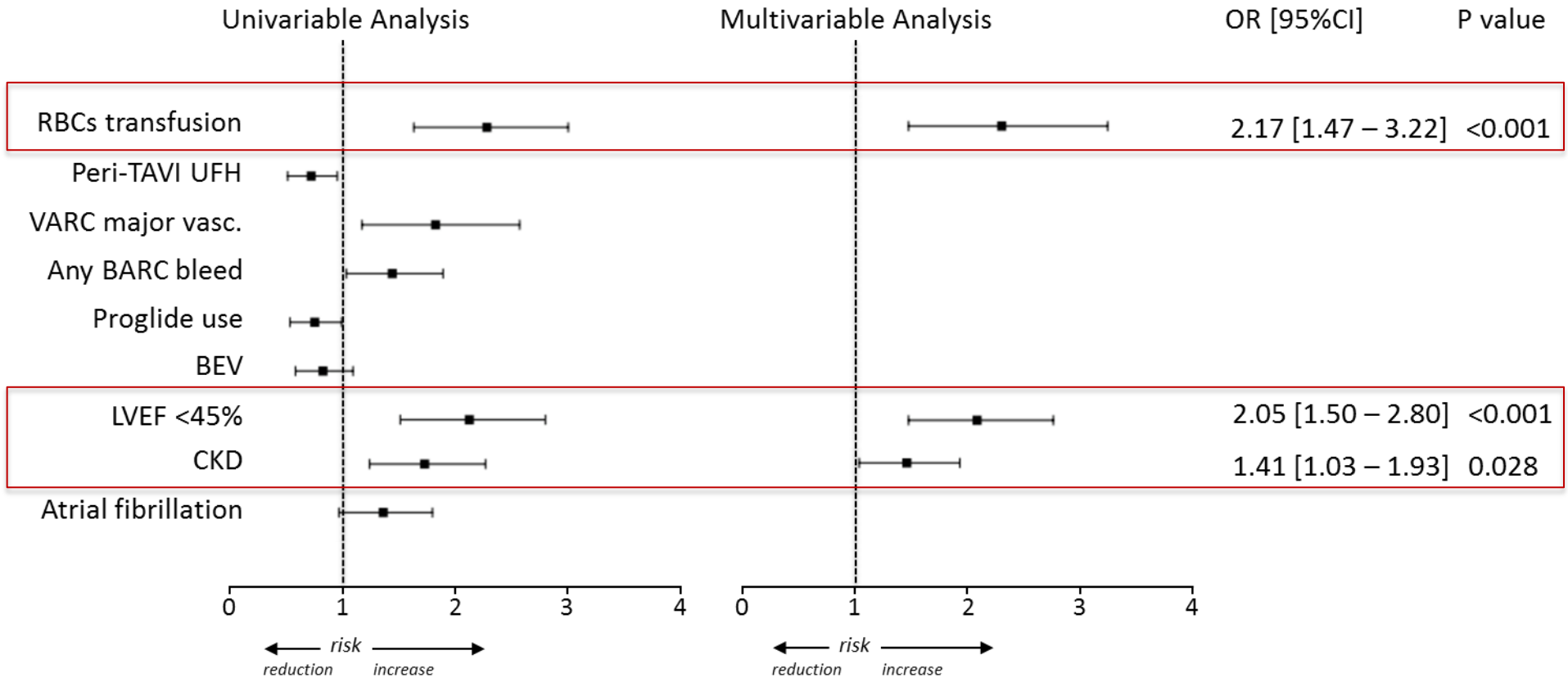




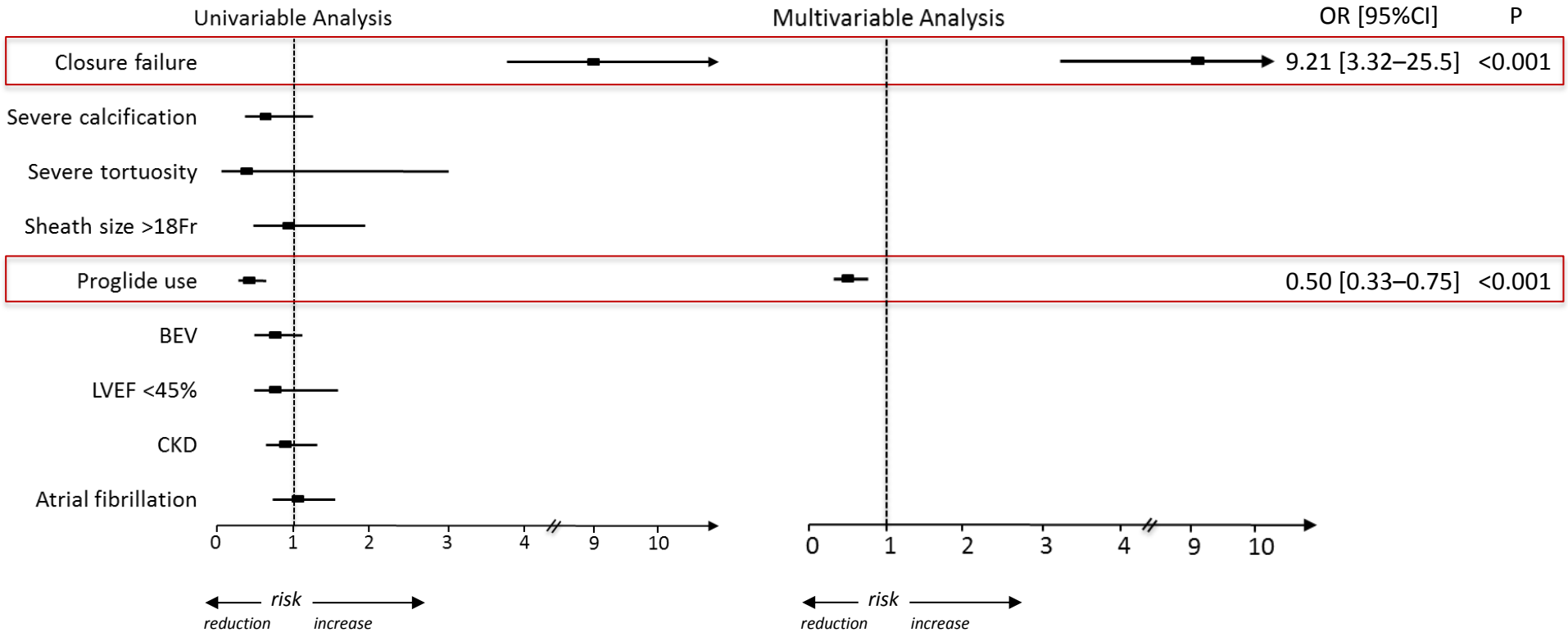
Prostar SMDC

Proglide SMDC

Predictors of One-Year Mortality



Predictors of VARC-2 Major Vascular Complications



Summary

In the large EVERY-TAVI registry, compared to Prostar SMCD preclose technique, use of Proglide SMCD preclose technique is associated with lower risk of access site vascular complications in patients undergoing trans-femoral TAVI procedure. It remains the only independent predictor of reduced vascular complications.

Although, Proglide SMCD preclose technique technique was associated with lower mortality, the type of strategy used for achieving access site haemostasis does not independently predict mortality one-year after TAVI procedure.

Limitations

1. Non-randomized comparison
2. Retrospective adjudication of events (for TAVIs 2008-2012) due to changes in definitions.

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Thank you!