Supplementary material

Pyłko A, Dąbrowski M, Kowalik I, et al. Analysis of complications in transfemoral transcatheter aortic valve implantation: a single-center study. Pol Arch Intern Med. 2024; 134: 16696. doi:10.20452/pamw.16696

1. Definitions of periprocedural complications according to the Valve Academic Research Consortium-2 consensus document.

Minor vascular complication: access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneurysms, haematomas, percutaneous closure device failure) not leading to death, life-threatening or major bleeding, visceral ischaemia, or neurological impairment OR distal embolization treated with embolectomy and/or thrombectomy and not resulting in amputation or irreversible endorgan 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) OR percutaneous closure device failure or a failure to achieve haemostasis at the arteriotomy site leading to alternative treatment (other than manual compression or adjunctive endovascular ballooning).

Major vascular complication : 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, haematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) leading to death, lifethreatening or major bleeding, visceral ischaemia, or neurological impairment OR distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible endorgan damage OR the use of unplanned endovascular or surgical intervention associated with death, major bleeding, visceral ischaemia or neurological impairment OR any new ipsilateral lower extremity ischaemia 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 bleeding: any bleeding worthy of clinical mention (e.g. access site haematoma) that does not qualify as life-threatening, disabling, or major.

Major bleeding: overt bleeding either associated with a drop in the haemoglobin 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 bleeding.

Life-threatening bleeding: fatal bleeding OR bleeding in a critical organ, such as intracranial, intraspinal, intraocular or pericardial necessitating pericardiocentesis, or intramuscular with compartment syndrome OR bleeding causing hypovolaemic shock or severe hypotension requiring vasopressors or surgery OR overt source of bleeding with drop in haemoglobin ≥5 g/dl or whole blood or packed red blood cells (RBCs) transfusion ≥4 units.

Periprocedural myocardial infarction: new ischaemic symptoms (e.g. chest pain or shortness of breath) or new ischaemic signs (e.g. ventricular arrhythmias, new or worsening heart failure, new ST-segment changes, haemodynamic instability, new pathological Q-waves in at least two contiguous leads, imaging evidence of new loss of viable myocardium or new wall motion abnormality) AND elevated cardiac biomarkers (preferable CKMB) within 72 h after the index procedure, consisting of at least one sample postprocedure with a peak value exceeding 15× as the upper reference limit for troponin or 5× for CK-MB. If cardiac biomarkers are increased at baseline (>99th percentile), a further increase in at least 50% post-procedure is required AND the peak value must exceed the previously stated limit ≤72 h after the index procedure.

Periprocedural stroke: acute episode of a focal or global neurological deficit with at least one of the following: change in the level of consciousness, hemiplegia, hemiparesis, numbness, or sensory loss affecting one side of the body, dysphasia or aphasia, hemianopia, amaurosis fugax lasting ≥24 h; OR the neurological deficit resulting in death.

Cardiovascular mortality: death due to proximate cardiac cause (e.g. myocardial infarction, cardiac tamponade, worsening heart failure). Death caused by non-coronary vascular

conditions such as neurological events, pulmonary embolism, ruptured aortic aneurysm, dissecting aneurysm, or other vascular disease. All procedure-related deaths, including those related to a complication of the procedure or treatment for a complication of the procedure. All valve-related deaths including structural or non-structural valve dysfunction or other valve-related adverse events. Sudden or unwitnessed death

Table S1. Determinants of risk of death - multivariable Cox proportional hazards regression.

	HR [95% CI]	P value
All-cause death		
Sex (male vs female)	0.724 [0.490 – 1.069]	0.10
Age	1.019 [0.992 – 1.048]	0.17
Group (early vs late)	0.779 [0.523-1.159]	0.22
Chronic obstructive pulmonary disease	1.597 [1.013-2.517]	0.04
Creatinine clearance	1.421 [1.038 -1.944]	0.03
Cardiac death		
Sex (male vs female)	1.397 [0.881-2.214]	0.16
Age	1.012 [0.980 – 1.045]	0. 48
Group (early vs late)	0.511 [0.323 -0.807]	0.004
Creatinine clearance	1.469 [1.304 -2.088]	0.03

Table S2. Determinants of risk of composite endpoints - multivariable logistic regression.

	OR [95% CI]	P value
Composite endpoint - any vascular complication (major or minor vascular complications)		
Sex (male vs female)	1.286 [0.783 -2.110]	0.32
Age	1.020 [0.984 -1.058]	0.27
Group (early vs late)	0.459 [0.281 – 0.751]	0.002
Composite endpoint - life-threatening bleeding, major vascular complication, or death at one month		
Sex (male vs female)	0.980 [0.627 -1.532]	0.93
Age	1.032 [1.00 – 1.066]	0.05
Group (early vs late)	0.480 [0.314 – 0.733]	<0.001
Creatinine clearance	1.847 [1.251 -2.726]	0.002
Aortic valve area calculated using the continuity equation	0.244 [0.059 -0.998]	0.05