Aortic stenosis (AS) is the most common valvular heart disease and untreated has bleak prognosis. The only effective method of treatment is valve replacement, surgical (SAVR) or transcatheter (TAVI). With increased life expectancy and aging of the population more elderly people require invasive treatment. Therefore, a greater knowledge of predictors of the mortality is needed and remain a crucial aspect of maintaining safety when choosing more adequate AS treatment option: TAVI or SAVR.

Aims of the study

1) Analysis and comparison of long- term outcomes in patients undergoing surgical and transcatheter aortic valve implantation.
2) Identification of predictors determining bleak long-term prognosis after surgical and transcatheter aortic valve implantation.
3) Assessment and comparison of early and late outcomes of aortic stenosis treatment.
4) Comparison of patients characteristics qualified for TAVI and SAVR.
5) Assessment of modification of eligibility criteria for the treatment of aortic stenosis over the years.

Materials and methods

A retrospective analysis of 1,229 patients with advance AS, comprising TAVI (n=211), *SAVR (n=556)* from January 2014 to July 2018 in single center in Poland was performed. The baseline characteristics and occurrence of postprocedural complications were collected and analyzed. Likewise, long-term mortality (6-, 12- and 24- months after procedure) were reported. Afterwards, to identify risk factors of poor outcomes, the impact of clinical and echocardiographic characteristic, blood test results as well as postprocedural complications on long term mortality was investigated.

The protocol of the study was approved by Regional Bioethical Committee at the National Institute of Cardiology (registered under the number 1836).

Results

Baseline characteristic of patients

A total of 1,129 of patients underwent aortic valve replacement in our hospital from January 2014 to July 2018. Among them, 556 were assigned to isolated SAVR and 211 were referred to TAVI. TAVI patients were older, had higher EuroScore II score and more comorbidities. Chronic kidney disease, chronic coronary syndrome, pulmonary diseases and diabetes were observed more frequently in patients qualified to TAVI compared to SAVR. No significant differences in baseline characteristic of patients qualified for both methods of treatment was found in the recent years.

Periprocedural complications

After surgical treatment, requirement of red blood cells (RBC) transfusion was observed significantly more frequently then after TAVI (55.8% vs 36%). Second the most common complication after surgery was post pericardiotomy syndrome (48.7% SAVR vs. 4.2% TAVI), that in 23 (5.7%) of patients caused cardiac tamponade. Arrythmias occurred more frequently after SAVR then TAVI (42,3% SAVR vs. 37,4% TAVI). New onset of atrial fibrillation (NOAF) was reported substantial often after SAVR then after TAVI (287-51.6% SAVR vs. 16-17.5% TAVI). Otherwise, not only atrioventricular block, but also left bundle branch block was described more often after TAVI (AV block 17 (3.1%) SAVR vs. 16 (7.5%) TAVI; LBBB 15 (7.1%) TAVI vs. 11 (2.0%) SAVR). The necessary of pacemaker implantation was more common after TAVI (10.4% vs. 2.9%).

Local complications such as ecchymosis and hematomas (4.3% SAVR vs. 36% TAVI) were the most common complication after TAVI and occurred the most often in the puncture site (31 of patients). Moreover, hematoma in pleura cavity (2 people- 2.6%) and retroperitoneum (1 patient- 1.3%) were described. Furthermore, major vascular complications include pseudoaneurysm (6- 40%), arteriovenous fistula (2- 13.3%), vascular dissection (2- 13.3%), vascular avulsion (2- 13.3%), vascular obstruction (1- 6.67%), valvular occlusion (1- 6.67%) occurred after TAVI. Besides, one case of subclavian artery thrombosis (6.67%), in patient, who underwent direct aorta approach for TAVI, was reported. In compered to SAVR, significant paravalvular regurgitation was observed more frequently after TAVI (2,8% vs. 0,2%). Additional post dilatation (3-50%), closure paravalvular leak with occluder (1- 16,67%), valve in valve procedure (1- 16,67%) was used as a treatment strategy. In one patient (1- 16,67%), the treatment was not necessary. After TAVI patients had a higher risk of stroke than patients surgically treated. The incidence of valve dislocation was 0,9% and the conversion to conventional SAVR was essential. In-hospital and 30 days mortality were significant higher after TAVI (in hospital: 2,1% SAVR vs. 6,2% TAVI; 30-days: 1,2% SAVR vs. 4,7% TAVI).

Analysis of comparable groups of patients qualified for TAVI and surgical treatment showed that patients after TAVI procedures were significantly more often exposed to vascular complications and a new left bundle branch block than patients treated with cardiac surgery. Patients after cardiac surgery more often required infusion of catecholamines, RBC transfusion and reoperation. In addition, acute kidney injury, NOAF and post-pericardiotomy syndrome were observed significant more common after SAVR. Interestingly, the greater risk of stroke and the pacemaker implantation in patients after TAVI have not been confirmed.

Long term outcomes

The overall 6-month mortality was significantly lower in surgical group than TAVI (3.2% SAVR vs. 11% TAVI). This observation was also confirmed in 12-month (4.7% SAVR vs. 14.5% TAVI) and 24-month observation (6.1% SAVR 25.4% TAVI). Interestingly, propensity score model revealed no difference in the survival after TAVI and SAVR. However, there was a trend of higher mortality in the TAVI group compared to the SAVR (P= 0.053) during the 24-month follow-up.

Predictors of mortality

Univariate analysis revealed that the following predictors were associated with 6-month mortality after TAVI:

- patient-related risk factors: higher EuroSCORE II (HR 1.116; 95% CI 1.037-1.201; p=0.007), heart failure classified in New York Heart Association as NYHA IV (HR 4.67; 95% CI 1.045-20.87; p=0.44), elevated red blood cell distribution width (RDW) (HR 1.09; 95% CI 1.03-1.14; p= 0.023), increased glucose level (HR 1.09; 95% CI 1.03- 1.14; p= 0.023) and increased right ventricular systolic pressure (RVSP) (HR 1.048; 95% CI 1.022-1.075; p= 0.0003).
- procedure-related risk factors: prolonged catecholamines infusion (HR 5.94; 95% CI 2.62- 13.49; p<0.0001), RBC transfusion (HR 2.53; 95% CI 1.11-5.78; p= 0.027), reoperation (HR 7.20; 95% CI. 2.44- 2123; p= 0.0003), respiratory failure (HR 13.52; 95% CI 5.64- 32.37; p<0.0001), AKI (HR 4.274; 95% CI 1.756- 10.40; p= 0.001), NOAF (HR 4,71; 95% CI 2,06- 10,76; p= 0,0002), infections (HR 3.33; 95% CI 1.47- 7.55; p= 0.004), disorders of consciousness (HR 7.04; 95% CI 3.04- 16.31; p<0.0001), prolonged hospitalization time (HR 1.028; 95% CI 1.014-1.042; p= 0.002).

In addition to above, the negative impact of heart failure classified in NYHA as III, mean cell hemoglobin concentration (MCHC) (HR 4.49; 95% CI 1.05- 19.2; p = 0.043), significant paravalvular leak (HR 4.58; 95 CI 1.39- 15.12; p= 0.006) and NOAF (HR 4.2401; 95 CI 2.039–8.816; p= <0.0001) on 12-month survival was observed after TAVI.

Univariate analysis showed that the following predictors were related with 6-month mortality after SAVR:

- patient-related risk factors: higher Euroscore II (HR 1.154; 95%CI 1.021-1.304; p= 0.022); mean cell hemoglobin (MCH) (HR 0.786; 95% CI 0.649- 0.952; p= 0.014) and concomitant tricuspid regurgitation (HR 7.636; 95% CI 1.28-45.70; p= 0.026)
- procedure-related risk factors: prolonged catecholamines infusion (HR 3.059; 95% CI 1.186- 7.892; p= 0.021), RBC transfusion (HR 6.482; 95% CI 1.490- 28.190; p= 0.013), reoperation (HR 7.93; 95% CI 3.07- 20.46; p <0.0001), respiratory failure (HR

13.71; 95% CI 5.14- 36.55; p<0.0001), AKI (HR 3.763; 95% CI 1.494- 9.479; p= 0.005), disorders of consciousness (HR 6.194; 95% CI 2.401-15.979; p= 0.0002), postoperative stroke/TIA (HR 8.899; 95% CI 2.576- 30.745; p= 0.0005)

Predictive factors of 12-month mortality after SAVR:

- patient-related risk factors: elderly age (HR 1.053; 95% CI 1.009- 1.098; p= 0.019), chronic obstructive pulmonary disease (HR 3.118; 95% CI 1.176- 8.270; p= 0.022), higher EuroSCORE II (HR 1,156; 95% CI 1,045- 1,279; p= 0,005), lower mean corpuscular hemoglobin concentration (MCHC) (HR 0.711; 95% CI 0.561- 0.981; p=0.038); mean platelet volume (MPV) (HR 1,443; 95% CI 1,009- 2,063; p= 0,045) and concomitant tricuspid regurgitation (HR 4,78; 95% CI 1,74- 12.99; p= 0,002)
- procedure-related risk factors: prolonged catecholamines infusion (HR 3.150; 95% CI 1.430- 6.942; p= 0.004), RBC transfusion (HR 6.252; 95% CI 1.877- 20.82; p= 0.003), reoperation (HR 8.03; 95% CI 3.64- 17.69; p <0.0001), respiratory failure (HR 12.85; 95% CI 5.58- 29.59; p <0.0001), AKI (HR 3.241; 95% CI 1.499-7.008; p= 0.003), infections (HR 2.633; 95% CI 1.145- 6.056; p= 0.023), disorders of consciousness (HR 6.280; 95% CI 2.849- 13.84; p <0.0001), prolongated time of hospitalization (HR 1.013; 95% CI 1.007- 1.019; p <0.0001), postoperative stroke/TIA (HR 8.446; 95 CI 2.909- 24.52; p= <0.0001)

Multivariate analysis identified postprocedural respiratory insufficiency as the independent predictor of 6- and 12-month mortality in both groups of patients. For TAVI, the predictors of 6 and 12-month mortality were: elevated EuroSCORE II risk score (HR 1.195; 95% CI 1.078- 1.324; p= 0.0007), RDW (HR 1.327; 95% CI 1.110- 1.586; p= 0.0019) and NOAF (HR 6.141; 95% CI 1.691- 22.294; p= 0.0058). For SAVR, the independent predictors of 12- and 24-month mortality were: postoperative bleeding defined as necessity of RBC transfusion (HR 4.772; 95% CI 1.066- 21.37; p= 0.041) as well as history of stroke/TIA (HR 5.743; 95% CI 1.568- 21.039; p= 0,008) and COPD (HR 3.380; 95% CI 1.049- 10.896; p= 0.041). The elevated EuroSCORE II was associated with 24-month mortality in this group of patients (HR 1.155; 95% CI 1.038- 1.284; p= 0.008).

Conclusions

- No significant differences regarding prognosis for up to 24 months between SAVR and TAVI in groups of consecutive patients in propensity score model were found.
- Independent predictive factors of late mortality specific for SAVR were:
  - 12- month mortality: stroke/TIA, COPD and RBC transfusion
  - 24- month mortality: the above-mentioned factors and the increased estimated surgery risk in the EuroSCORE II (>4%)
- Independent risk factors of 6- and 12- month mortality after TAVI were elevated EuroSCORE II risk, NOAF and the increased red blood cells distribution.
- Independent predictive factor of 6-, 12- and 24- month mortality after both procedures were the postprocedural respiratory failure.
- In comparision to TAVI, he higher incidence of post-pericardiotomy syndrome, new onset of atrial fibrillation, RBC transfusion and prolonged catecholamines infusion were reported after SAVR. Vascular complications, especially at the puncture site, intraventricular conduction disturbances (mainly new LBBB) and paravalvular leaks were specific postprocedural complication for TAVI.
- Patients assigned to TAVI were older, had higher EuroSCORE II score and more comorbidities.
- No significant differences in baseline characteristic of patients qualified for both methods of treatment in the recent years were found.

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