Kardiologia Polska 2016; 74, 3: 224–230; DOI: 10.5603/KP.a2015.0161 ISSN 0022–9032

ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Comparison of mid-term results of transcatheter aortic valve implantation in high-risk patients with logistic EuroSCORE ≥ 20% or < 20%

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Abstract

Background: Transcatheter aortic valve implantation (TAVI) is an established treatment method in selected high-risk patients with severe aortic stenosis. However, data on which patients gain most benefit from this procedure is still limited. According to the European consensus document, TAVI is recommended for high-risk patients with logistic EuroSCORE (log ES) ≥ 20%. To date, little is known about TAVI outcomes in patients with log ES < 20%.

Aim: To evaluate outcomes of TAVI in high-risk patients with log ES ≥ 20% in comparison with high-risk patients with log ES < 20%.

Methods and results: Of 93 patients who underwent TAVI at our institution between January 2009 and December 2011, we identified 59 (63.4%) patients with log ES ≥ 20% (Group 1) and 34 (36.6%) patients with log ES < 20% (Group 2). The mean log ES was 30.9 ± 9.7% in Group 1 and 12.7 ± 4.9% in Group 2 ($p < 0.01$). Significant differences were found between the two groups in regard to age (82.9 ± 5.9 vs. 78.7 ± 7.8 years, $p = 0.001$), left ventricular ejection fraction (51.5 ± 14% vs. 60.4 ± 9.6%, $p = 0.002$), pulmonary artery systolic pressure (56 ± 11 vs. 49 ± 10.6 mm Hg, $p = 0.02$), and glomerular filtration rate (51.3 ± 18.4 vs. 60.6 ± 16.6 mL/min/m^2, $p = 0.02$). Survival rates at 1 and 2 years were 76.6% and 69.0% in Group 1 and 89.0% and 83.6% in Group 2 (p = NS). However, cardiovascular mortality at 1 and 2 years was higher in Group 1 compared to Group 2 (21.4% and 28.6% vs. 8.1% and 10.8% in Groups 1 and 2, respectively).

Conclusions: The results of this study demonstrate that at 2 years of follow-up, TAVI in high-risk patients with log ES ≥ 20% was associated with a higher cardiovascular mortality compared to high-risk patients with log ES < 20%.

Key words: aortic valve stenosis, transcatheter aortic valve implantation, logistic EuroSCORE

Kardiol Pol 2016; 74, 3: 224–230

INTRODUCTION

Transcatheter aortic valve implantation (TAVI), performed for the first time in 2002, is widely used in the treatment of selected patients with severe degenerative aortic stenosis (AS). In patients with haemodynamically significant AS, TAVI was shown to significantly improve exercise capacity and increase survival compared to medical treatment [1–5].

Determination of the operative risk is of major importance when selecting patients with significant AS for surgical aortic valve replacement (AVR) or TAVI. Risk scores most commonly used for this purpose include the Society of Thoracic Surgeons (STS) Risk Score and the logistic EuroSCORE (log ES), replaced by the EuroSCORE II in 2012 [6, 7]. While these risk scores were designed for the evaluation of surgical risk, no risk scores

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Received: 24.02.2015 **Accepted:** 02.07.2015 **Available as AoP:** 19.08.2015

have been specifically developed for the evaluation of TAVI procedural risk. In routine clinical practice, patients with low to moderate surgical risk are referred for surgical AVR, and high risk patients are referred for TAVI. According to the 2008 joint position statement of the European Association for Cardio-Thoracic Surgery (EACTS), the European Society of Cardiology (ESC), and the European Association of Percutaneous Cardiovascular Interventions (EAPCI), TAVI is indicated in patients with log ES ≥ 20% or STS > 10%, while lower risk patients should be referred for surgical valve replacement [8]. According to the 2012 ESC guidelines on the management of valvular heart disease, the decision regarding the treatment approach in patients with AS should be made by the Heart Team [9]. The superior role of the Heart Team has been highlighted due to the fact that available risk scores do not include many clinical and anatomical factors associated with a significant increase in the operative risk. For this reason, the Heart Team often selects TAVI also in patients with log ES < 20% in whom concomitant conditions make the actual operative risk higher that estimated using the cardiac surgical risk scores.

In previously published studies, TAVI outcomes were mostly compared between patients deemed not to be candidates for surgery due to log ES ≥ 20% or STS ≥ 10% and moderate risk patients (log ES < 20% or STS < 10%) [10–13]. In these reports, it has not been stated whether the patients with log ES < 20% were deemed not to be candidates for surgical treatment. Thus, it is unclear what is the effect of log ES on TAVI outcomes in high-risk or inoperable patients. The aim of the present study was to compare TAVI outcomes in patients with log ES ≥ 20% or < 20% who were selected for TAVI by the Heart Team due to concomitant conditions that were not included in the log ES algorithm but were associated with a significant increase in the operative risk.

METHODS

Transcatheter aortic valve implantation procedures have been performed at the National Institute of Cardiology in Warsaw-Anin since January 2009. Patients with severe symptomatic AS with valve area < 1.0 cm^2 and mean transvalvular pressure gradient > 40 mm Hg are selected for the procedure. All candidates for TAVI underwent routine laboratory testing, invasive or multidetector computed tomography (CT) coronary angiography, transthoracic echocardiocardiography (TTE), transoesophageal echocardiocardiography (TEE), CT of the lower limbs, aorta and the aortic valve, spirometry, gastroscopy, carotid Doppler ultrasound, and neurology evaluation. Aortic valve anatomy and diameter were evaluated by TTE, TEE, and CT. The importance of specific diagnostic modalities when selecting patients for TAVI, contraindications to this procedure, the criteria of prosthetic valve selection, and selection of the access route have been described previously [14].

All patients selected for TAVI were not considered suitable candidates for surgical valve replacement by the Heart Team. The reason for inoperability was high operative risk, i.e. log ES ≥ 20%, or in patients with log ES < 20%, the presence of concomitant conditions that significantly increased the risk of surgical valve replacement. The patients were divided into two groups: Group 1 with log ES ≥ 20%, and Group 2 with log ES < 20%. Reasons for selecting TAVI in the latter group were detailed in 'Results'.

The patients were implanted with a balloon-mounted Edwards Sapien valve (Edwards Lifesciences, Irvine, CA, USA), currently available in a modified from as Sapien XT valve, or a CoreValve device (Medtronic CoreValve, Irvine, CA, USA). Details of the TAVI procedure were reported previously [14]. Following TAVI, all patients underwent outpatient follow-up at the National Institute of Cardiology in Warsaw. Follow-up visits were scheduled at 1 and 6 months after the procedure, followed by every 12 months. Follow-up was censored in case of the patient's death.

Statistical analysis

Continuous variables were shown as mean values ± standard deviation, and categorical variables as percentage frequencies. Comparison of selected pre- and postprocedural clinical, haemodynamic, and echocardiographic variables was performed using the Student t test for paired samples. Independent groups were compared using the χ^2 test. Survival probability was determined separately in Group 1 and Group 2. Survival differences were shown using cumulative Kaplan-Meier curves, and the significance of survival differences between the two groups was evaluated using the log-rank test. $P < 0.05$ was considered statistically significant. Statistical analysis was performed using the STATISTICA data analysis software system, version 10 (StatSoft, Inc. 2011, www.statsoft.com).

RESULTS

Since January 2009 till the end of 2011, 93 inoperable patients with symptomatic degenerative AS were selected for TAVI at the National Institute of Cardiology. Most patients were women (n = 60, 64.5%). Overall, the mean age was 81.3 ± 7.1 years (range 54–91 years). Preprocedurally, echocardiography showed the mean peak aortic gradient of 99.03 ± 23.3 mm Hg and the mean aortic valve area of 0.66 ± 0.13 cm^2. The mean log ES was 25.3 ± 12.4%. Group 1 included 59 (63.4%) patients with log ES ≥ 20%, and Group 2 included 34 (36.6%) patients with log ES < 20%. The mean log ES was 30.9 ± 9.7% (range 20–59.2%) in Group 1 compared to 12.7 ± 4.9% (range 2.86–19.27%) in Group 2 ($p < 0.01$).

The most common causes of inoperability in patients with log ES < 20% included advanced osteoporosis with previous spine compression fractures in 14 (41.2%) patients, advanced chronic obstructive pulmonary disease (COPD) in 13 (38.2%) patients, and porcelain aorta in 5 (14.7%) patients. Other

Table 1. Baseline clinical and echocardiographic patient characteristics

Variable	Group 1 (log ES ≥ 20%) N = 59	Group 2 (log ES < 20%) N = 34	P
Age [years]	82.9 ± 5.9	78.7 ± 7.8	0.01
Women	37 (62%)	22 (64%)	NS
Logistic EuroSCORE	30.9 ± 9.7%	12.7 ± 4.9%	< 0.001
Society of Thoracic Surgeons Risk Score	9.7 ± 4%	5.0 ± 2%	< 0.001
Peak aortic gradient	95.5 ± 27.4	104.2 ± 18.6	NS
Coronary artery disease	39 (66%)	19 (55.9%)	NS
Previous myocardial infarction	15 (25.4%)	7 (20.6%)	NS
Previous PCI	16 (27.1%)	11(32.4%)	NS
Previous CABG	8 (13.6%)	4 (11.8%)	NS
Left ventricular ejection fraction	51.5 ± 14%	60.4 ± 9.6%	0.002
NYHA class II	14/59 (23.7%)	6/34 (17.6%)	NS
NYHA class III	40/59 (67.8%)	25/34(73.5%)	NS
NYHA class IV	5/59 (8.5%)	3/34 (8.8%)	NS
Pulmonary artery systolic pressure [mm Hg]	56 ± 11	49 ± 10.6	0.02
Diabetes	14 (23.7%)	7 (20.6%)	NS
Previous stroke/transient ischaemic attack	7 (11.9%)	2 (5.9%)	NS
Glomerular filtration rate	51.3 ± 18.4	60.6 ± 16.6	0.02
Atrial fibrillation	22/59 (37.3%)	12/34 (35.3%)	NS

CABG — coronary artery bypass grafting; NYHA — New York Heart Association; PCI — percutaneous coronary intervention

reasons for which the patients were not considered suitable candidates for surgery included previous chest radiotherapy, previous stroke with a neurological deficit, previous cardiac surgery, morbid obesity, and significantly limited mobility. Of note, some patients had multiple comorbid conditions that significantly increased the operative risk.

Compared to Group 2, patients in Group 1 were older (82.9 ± 5.9 vs. 78.7 ± 7.8 years, p = 0.009), had lower left ventricular ejection fraction (LVEF; 51.5 ± 14% vs. 60.4 ± 9.6%, p = 0.002), higher pulmonary artery systolic pressure (56 ± 11 vs. 49 ± 10.6 mm Hg, p = 0.02), and worse renal function (glomerular filtration rate: 51.3 ± 18.4 vs. 60.6 ± 16.6 mL/min/m^2, p = 0.02). Comparison of the two groups is shown in Table 1.

30-day outcomes

Transcatheter aortic valve implantation was successfully performed in 92 (98.9%) patients. In 1 case, a 90-year-old patient in Group 1, implantation of an Edwards Sapien valve was not possible due to a tortuous course of and calcifications in the femoral artery which precluded insertion of a appropriately-sized vascular sheath. The procedure was concluded with aortic valve balloon valvuloplasty that resulted in a significant reduction of the aortic gradient.

Of the remaining 92 patients, 48 (52.2%) had a CoreValve device implanted, and an Edwards Sapien or Sapien XT valve was used in 44 (47.8%) patients. When selecting the approach route, a transvascular approach via the femoral or subclavian artery was considered first, followed by a possibility of valve implantation via the transapical approach. The decision regarding the approach route was based on CT angiography findings. Most patients were treated using a transvascular approach, including via the femoral artery in 66 (71.0%) patients and vie the subclavian artery in 9 (9.7%) patients. The transapical approach was used for aortic valve implantation in 18 (19.3%) patients. No difference in the choice of the access route was found between the two groups. Table 2 summarises the types of valves used and the access routes in both groups.

Table 2. Access route and the type of implanted aortic valve

	Group 1	Group 2	P
Access route	N = 59	N = 34	
Femoral artery	40 (67.8%)	26 (76.5%)	NS
Subclavian artery	4 (6.8%)	5 (14.7%)	NS
Transapical approach	15 (25.4%)	3 (8.8%)	NS
Valve type	N = 58	N = 34	
Edwards Sapien/ /Sapien XT	33/59 (56.9%)	11/34 (32.4%)	0.04
CoreValve	25/59 (43.1%)	23/34 (67.6%)	0.04

Immediately after the procedure, the peak aortic gradient by echocardiography decreased from 95.5 ± 27.4 to 16.47 ± 8.15 mm Hg in Group 1 (p < 0.001) and from 104.2 ± 18.6 to 17.16 ± 7.44 mm Hg (p < 0.001) in

Group 2. Moderate perivalvular aortic regurgitation was observed postprocedurally in 4 (6.8%) patients in Group 1 and 1 (2.9%) patients in Group 2 (p = NS).

At 30 days after the implantation, overall 7/93 (7.5%) patients died, including 5/59 (8.5%) in Group 1 and 2/34 (5.9%) in Group 2 (p = NS). All deaths were cardiac deaths according to the VARC-2 definition [15]. Two deaths in Group 1 occurred during TAVI, including one due to myocardial infarction caused by occlusion of the left main coronary artery by a calcified valve leaflet and one due to a vascular complication. One death occurred at 8 days after TAVI due to pulseless electrical activity in a patient with LVEF of 20%, and two sudden deaths occurred several days after hospital discharge. In Group 2, aortic annulus rupture occurred in 1 patient during TAVI who died despite immediate surgery, and the other death was a sudden cardiac death due to ventricular fibrillation at 1 day after the procedure.

Major vascular complications according to the VARC-2 definition occurred after TAVI in 16 (17.2%) patients, including 10/59 (16.95%) patients in Group 1 and 6/34 (17.6%) patients in Group 2 (p = NS). Transfusion of > 3 units of blood due to anaemia after the procedure was required in 4 (6.8%) patients in Group 1 and 1 (2.9%) patient in Group 2 (p = NS). One transient ischaemic attack was observed but no strokes occurred. In addition, 1 patient in Group 1 with pulmonary hypertension and a history of COPD developed respiratory failure that lasted several months and required ventilator therapy for several weeks.

Pacemaker implantation was necessary following TAVI in 21/93 (22.6%) patients. In all cases, the indication for pacing was the development of left bundle branch block associated in with first degree atrioventricular block seen after TAVI. Pacemaker implantation was needed in 5/44 (11.4%) patients with an Edward Sapien or Sapien XT valve, compared to 16/48 (33.3%) patients with a CoreValve device (p = 0.02).

Long-term outcomes

The mean duration of follow-up was 24.8 ± 14.5 months (range 0–54 months). Overall, 23/59 (39.0%) patients in Group 1 and 7/34 (20.6%) patients in Group 2 died, including 19/59 (32.2%) patients in Group 1 and 4/34 (11.8%) patients in Group 2 between 30 days after the procedure and the end of follow-up. Cardiovascular death occurred in 12/19 (63.2%) patients in Group 1 and in 2/4 (50.0%) patients in Group 2. One-year survival in Group 1 was 76.6%, and 2-year survival was 69.0%, compared to 89.0% and 83.6%, respectively, in Group 2. Cardiovascular mortality rates at 1 and 2 years of follow-up were significantly higher in Group 1 compared to Group 2 (21.4% and 28.6% vs. 8.1% and 10.8%, respectively, p = 0.02). Kaplan-Meier survival curves for freedom from death and freedom from cardiovascular mortality in Groups 1 and 2 are shown in Figures 1 and 2.

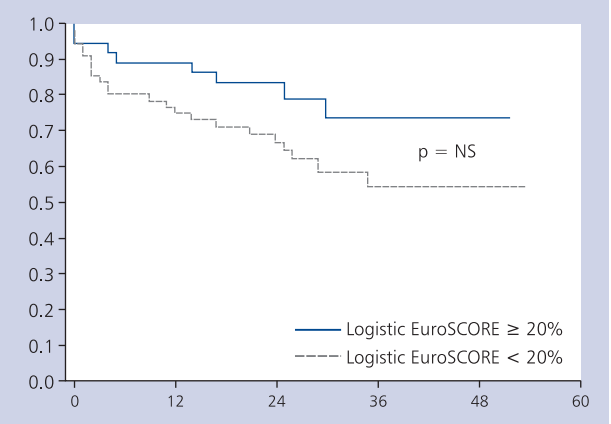

Figure 1. Kaplan-Meier survival curves for freedom from all-cause mortality during follow-up (months) among patients with logistic EuroSCORE ≥ 20% and < 20%

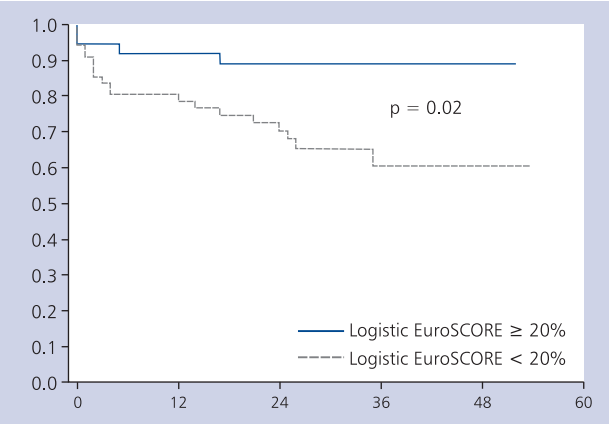

Figure 2. Kaplan-Meier survival curves for freedom from cardiovascular mortality during follow-up (months) among patients with logistic EuroSCORE ≥ 20% and < 20%

DISCUSSION

Although TAVI has been used for just more than 10 years, the method has been widely accepted and is commonly used in the treatment of selected patients with symptomatic AS. Initially, only patients considered definitively unsuitable for surgical treatment and high surgical risk patients were referred for TAVI but recently, also moderate risk patients became treated with TAVI in many centres. It is currently debated whether moderate risk patients should be treated surgically or some of them, especially older patients, might be better treated with TAVI. Increasing use of TAVI in older moderate risk patients is based on registry data showing that outcomes of TAVI in moderate risk patients are superior compared to those in high surgical risk patients [3, 16–18]. It is also known that surgical outcomes in older patients are worse than in younger patients [19, 20]. Recently, a randomised trial

comparing surgical treatment to TAVI in high and moderate risk patients has been reported, showing a significantly lower mortality at 1 year in the TAVI group compared to surgically treated patients [21].

The aim of our study was to compare TAVI outcomes in patients with log ES ≥ 20% and < 20%. Log ES was below 20% in more than one third of patients (36.6%) referred for TAVI in our centre which means that these patients were not selected for surgical AVR due to concomitant conditions that were not included in the risk scores. The mean log ES in Group 1 was 30.9 ± 9.7% compared to more than twofold lower value of 12.7 ± 4.9% in Group 2. However, other concomitant conditions were considered significant enough to affect the decision of the Heart Team regarding further treatment approach.

Immediate outcomes

In our study group, 30-day mortality was similar in both study groups. Our outcomes are also similar to outcomes reported in other studies. In a metaanalysis that included more than 3000 patients treated with TAVI, 30-day mortality ranged from 1.7% to 14.3%, mean 7.8% [22]. Results of a large multicentre registry in the United States have been published recently. This study included 41 centres with 489 inoperable patients with severe AS. The mean patient age was 83.2 years, and the mean log ES was 22.6%, similarly to our study. All patients had a CoreValve device implanted, and 30-day mortality was 8.4% [23]. In several studies that included moderate risk patients, an association between log ES and 30-day mortality was found. In a study in 165 patients, Tamburino et al. [10] found that 30-day mortality after TAVI was 15.6% in those with log ES ≥ 20% but much lower (2.4%) in those with log ES < 20%. Similar results were reported by Wenaweser et al. [13] who divided 389 patients treated with TAVI into three groups depending on the operative risk by the STS risk score: low risk patients with STS < 3%, moderate risk patients with STS 3–8%, and high risk patients with STS > 8%. Low risk patients were significantly younger. It was found that 30-day mortality was related to the STS risk score and was 2.4%, 3.9%, and 14.9%, respectively, in low, moderate, and high risk patients. The authors then selected those patients who had their aortic valve implanted via the transfemoral approach and showed best outcomes in the low risk subgroup, with 30-day mortality of 0% compared to 3.5% in the moderate risk subgroup and 14.7% in the high risk subgroup. In our study, we found no difference in 30-day mortality between the two groups. The rate of complications was also similar in both study groups. In both studies cited above, a high 30-day mortality of about 15% among high risk patients was notable. In our study, 30-day-mortality among patients with log ES ≥ 20% was lower at 8.5%. It seems that these results may be explained by a low number of patients included in our study.

Long-term outcomes

In our study, overall mortality was 28.4% at 1 year and 35.2% at 2 years. In the historic PARTNER study, 2-year mortality was 43.3% in the inoperable cohort and 33.9% in the high surgical risk cohort [1, 24]. Our results are very similar to those reported by Toggweiler et al. [25] who found that 1-year survival after TAVI was 83%, 2-year survival was 74%, and 5-year survival was 35%. In the multicentre United States registry cited above, 1-year mortality among inoperable patients was 24.3% [23]. Tamburino et al. [10] found that at 1 year after TAVI, mortality in the log ES ≥ 20% group was 25.7% compared to 6.8% in the log ES < 20% group. In the study by Wenaweser et al. [13], mortality at 1 year was 10.1% vs. 16.1% vs. 34.5%, respectively, in patients with STS score risk of < 3%, 3–8%, and > 8%. In our study, we did not find a difference in overall mortality during long-term follow-up but cardiovascular mortality rate was significantly higher among patients with log ES ≥ 20% compared to those with log ES < 20%. Our findings confirm the importance of risk scores for predicting long-term TAVI outcomes in inoperable or high surgical risk patients and clearly show that the outcomes of TAVI are better in patients with lower log ES values.

At the 2014 ACC Scientific Sessions, a study was reported that randomised high risk patients with severe AS to two groups: 390 patients with log ES of 17.7 ± 13.1 were referred for percutaneous implantation of a CoreValve device, and 357 patients with log ES of 18.6 ± 13.0 were referred for surgical valve replacement. At 1 year, a significantly lower mortality was found in the TAVI group (14.2%) compared to the surgical group (19.1%) [21]. It was the first randomised study that showed lower mortality following TAVI compared to surgical treatment. Currently, two other randomised trials are underway, the Surgical Replacement and Transcatheter AorticValve Implantation (SURTAVI) study evaluating the CoreValve device, and the Placement of AoRtic TraNscathetER (PARTNER 2) study evaluating the SAPIEN XT valve. Results of these studies will allow determination of the role of TAVI in the management of moderate surgical risk AS patients.

CONCLUSIONS

The results of this study demonstrate that at 2 years of follow-up, TAVI in high-risk patients with log ES ≥ 20% was associated with a higher cardiovascular mortality compared to high-risk patients with log ES < 20%. (??)

Conflict of interest: *none declared*

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Cite this article as: Chmielak Z, Witkowski A, Dąbrowski M et al. Comparison of mid-term results of transcatheter aortic valve implantation in high-risk patients with logistic EuroSCORE ≥ 20% or < 20%. Kardiol Pol, 2016; 74: 224–230. doi: 10.5603/KP.a2015.0161.

Porównanie wyników średnioterminowych przezcewnikowej implantacji zastawki aortalnej u chorych z grupy wysokiego ryzyka z logistic EuroSCORE ≥ 20% i z logistic EuroSCORE < 20%

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Streszczenie

Wstęp: Przezcewnikowa implantacja zastawki aortalnej (TAVI) jest ustaloną metodą leczenia wybranych chorych ze zwężeniem zastawki aortalnej. Według wspólnego stanowiska ekspertów, Europejskiego Towarzystwa Torakochirurgów i Kardiochirurgów, Europejskiego Towarzystwa Kardiologicznego i Asocjacji Interwencji Sercowo-Naczyniowych, opublikowanego w 2008 r. TAVI powinno się wykonywać u chorych z grupy wysokiego ryzyka chirurgicznego z logistic EuroSCORE (log ES) ≥ 20%. Istnieje natomiast niewiele doniesień na temat TAVI u pacjentów z grupy wysokiego ryzyka chirurgicznego, ale z log ES < 20%.

Cel: Celem pracy było porównanie wyników TAVI u chorych z log ES ≥ 20% z rezultatami uzyskanymi u pacjentów z log ES < 20%, którzy ze względu na inne choroby współtowarzyszące zostali ostatecznie zdyskwalifikowani z leczenia operacyjnego.

Metody i wyniki: W okresie od stycznia 2009 do grudnia 2011 r. TAVI wykonano u 93 chorych, którzy zostali podzieleni na dwie grupy. Grupę 1 stanowiło 59 (63.4%) pacjentów z log ES ≥ 20%, a grupę 2 — 34 (36,6%) osób z log ES < 20%. Średnia wartość Log ES wynosiła 30,9 ± 9,7% w grupie 1 oraz 12,7 ± 4,9% w grupie 2 (p < 0,001). Chorzy z grupy 1 byli starsi (82,9 ± 5,9 *vs*. 78,7 ± 7,8 roku; p = 0,01), charakteryzowali się niższą frakcją wyrzutową lewej komory (51,5 ± 14% *vs*. 60,4 ± 9,6%; p = 0,002), wyższym ciśnieniem skurczowym w tętnicy płucnej (56 ± 11 *vs*. 49 ± 10,6 mm Hg; p = 0,02) oraz gorszą funkcją nerek (GFR 51,3 ± 18,4 *vs*. 60,6 ± 16,6 ml/min/m^2; p = 0,02). Przeżycie po roku i po 2 latach było porównywalne i wynosiło 76,6% i 69,0% oraz 89,0% i 83,6% odpowiednio w grupie 1 i 2 (p = NS), natomiast częstość występowania zgonów sercowych po roku i po 2 latach była istotnie wyższa w grupie 1 (21,4% i 28,6%) niż w grupie 2 (8,1% i 10,8%) (p = 0,02).

Wnioski: Wyniki niniejszej pracy pokazują, że częstość występowania zgonów sercowych w okresie 2-letniej obserwacji po TAVI jest wyższa u chorych z grupy wysokiego ryzyka chirurgicznego z log ES ≥ 20% niż u pacjentów zdyskwalifikowanych z leczenia chirurgicznego przez Zespół Sercowy, ale z log ES < 20%.

Słowa kluczowe: zwężenie zastawki aortalnej, przezcewnikowa implantacja zastawki aortalnej, logistic EuroSCORE

Kardiol Pol 2016; 74, 3: 224–230

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Praca wpłynęła: 24.02.2015 r. **Zaakceptowana do druku:** 02.07.2015 r. **Data publikacji AoP:** 19.08.2015 r.