

# Trends in isolated aortic valve replacement in middle-aged patients over the last 10 years: epidemiology, risk factors, valve pathology, valve types, and outcomes

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## KEY WORDS

aortic valve, aortic valve replacement, biological valve, mechanical valve, transcatheter aortic valve implantation

## ABSTRACT

**BACKGROUND** Valve prosthesis selection in aortic valve replacement (AVR) is particularly difficult in middle-aged patients (60–70 years old).

**AIMS** We described changes in trends and outcomes of AVR in middle-aged patients over the last 10 years, based on the real-life single-center data from the Polish National Registry.

**METHODS** A total of 4912 consecutive adult patients who underwent any type of isolated aortic valve surgery between 2006 to 2016 were included. The main outcome measures were changes in the number of procedures, characteristics, surgical details, and in-hospital mortality.

**RESULTS** Out of all 4912 AVR procedures performed, 1531 patients (31.2%) were between 60 and 70 years of age. The share of aortic valve prosthesis in the overall number of replacements changed between 2006 and 2016 for mechanical valves (MV) from 98.3% to 15.2% and for biological valves (BV) from 0% to 81.8% ( $P < 0.001$  for both comparisons). In the BV group, stented valves were implanted in 92.6%. The most common MV was the St. Jude Medical Mechanical Heart Valve (St. Jude Medical, Saint Paul, Minnesota, United States) and most common BV was the Carpentier-Edwards Perimount Magna (Edwards Lifesciences, Irvine, California, United States). The most common prosthesis size was 23 mm. There were no significant differences in body mass index and comorbidities between the patients with MV and BV. The overall in-hospital mortality was 3.46% (3.33% in the MV group and 3.69% in the BV group;  $P = 0.85$ ).

**CONCLUSIONS** In the last 10 years, one-third of aortic valve replacements were performed in patients between 60 and 70 years of age. We observed rapidly changing trends in the type of implanted valve prostheses.

**INTRODUCTION** Aortic valve disease is a common heart condition, which – if progressive – requires intervention. Over the last decade, the once predominant surgical aortic valve replacement (SAVR) has been replaced by the transcatheter aortic valve implantation (TAVI). Currently, TAVI may be performed in older patients considered intermediate- or high-risk for conventional surgery.<sup>1-3</sup>

However, the real world studies have shown excellent outcomes of SAVR in low-risk, intermediate-risk, and high-risk patients. To ensure excellent long-term results with improved long-term mortality and morbidity rates, appropriate selection of valve prosthesis in SAVR is essential.

The valve prosthesis selection process is the most difficult in middle-aged (borderline)

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Received: April 17, 2019.

Revision accepted: May 29, 2019.  
Published online: May 29, 2019.  
Kardiologia Polska 2019; 77 (7-8): 688-695  
doi:10.33963/KP.14854

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## WHAT'S NEW?

Between 2006 and 2016 in Poland, one-third of aortic valve surgeries were performed in patients between 60 and 70 years of age. In this group of patients, the selection of prosthesis type is very difficult due to the lack of clear recommendations. The European Society of Cardiology / European Association for Cardio-Thoracic Surgery guidelines for patients between 60 and 65 years and American Heart Association / American College of Cardiology guidelines for patients between 60 and 70 years contain ambiguous recommendations as to prosthesis type selection. Therefore, we describe real-life changes in trends and outcomes of aortic valve replacement in middle-aged patients over the last 10 years. We observed rapidly changing trend in the type of implanted prostheses. The prevalence of biological valve prosthesis implantation has increased from 0% in 2006 to 81.8% in 2016. The most common implanted mechanical valve was the St. Jude Medical Mechanical Heart Valve (St. Jude Medical, Saint Paul, Minnesota, United States), and the most common bioprosthetic valve was the Carpentier-Edwards Perimount Magna (Edwards Lifesciences, Irvine, California, United States). The short-term mortality was comparable in patients receiving mechanical and biological valves.

patients between 60 and 70 years of age due to the lack of clear recommendations. The most current guidelines, European Society of Cardiology/European Association for Cardio-Thoracic Surgery (ESC/EACTS) guidelines<sup>1</sup> (class IIa recommendation) for patients between 60 and 65 years of age and American Heart Association/American College of Cardiology (AHA/ACC) guidelines<sup>2</sup> (class IIa recommendation) for patients between 60 and 70 years of age, contain ambiguous recommendations as to the selection of the valve prosthesis type.

Both valve prosthesis types, mechanical valves (MV) and biological valves (BV), have disadvantages and advantages.<sup>1,2,4-7</sup> In borderline patients, many factors are considered, including prosthesis parameters and patient preferences. Therefore, in middle-aged patients, the selection of valve prosthesis type is difficult and requires complex decision making.<sup>7</sup>

In this study, we presented real-time-related trends in isolated aortic valve replacement in patients between 60 and 70 years of age based on a large cohort of 1531 cases. Ten-year trends were assessed by comparing patient characteristics, risk factor distribution, aortic valve pathology, valve types, surgical outcomes, and in-hospital mortality.

**METHODS** Out of 4912 consecutive adult patients who underwent any type of isolated aortic valve surgery, we selected 1531 patients (31.2%) who were aged between 60 and 70 years.

The selected cohort of 1531 consecutive adult patients underwent isolated aortic valve surgery between January 2006 and August 2016 in a single center, which is the largest cardiac surgery department in Poland. Patients after previous cardiac surgery were excluded from

the study. All patients who had aortic valve replacement were divided into 2 groups, those with MV, and those with BV, to enable comparisons between the 2 groups. The in-hospital mortality was defined as death within 30 days from the index operation, or later if the patient was still hospitalized.

**Study database** Data for the study was collected retrospectively based on the standardized form of the National Registry of Cardiac Surgery (*Krajowy Rejestr Operacji Kardiologicznych* – KROK).

The data collected included age, gender, body mass index (BMI), ejection fraction, Canadian Cardiovascular Society class, New York Heart Association class, smoking, diabetes mellitus, arterial hypertension, hypercholesterolemia, creatinine clearance, chronic obstructive pulmonary disease, extracorporeal circulation, aortic cross clamp, and mortality.

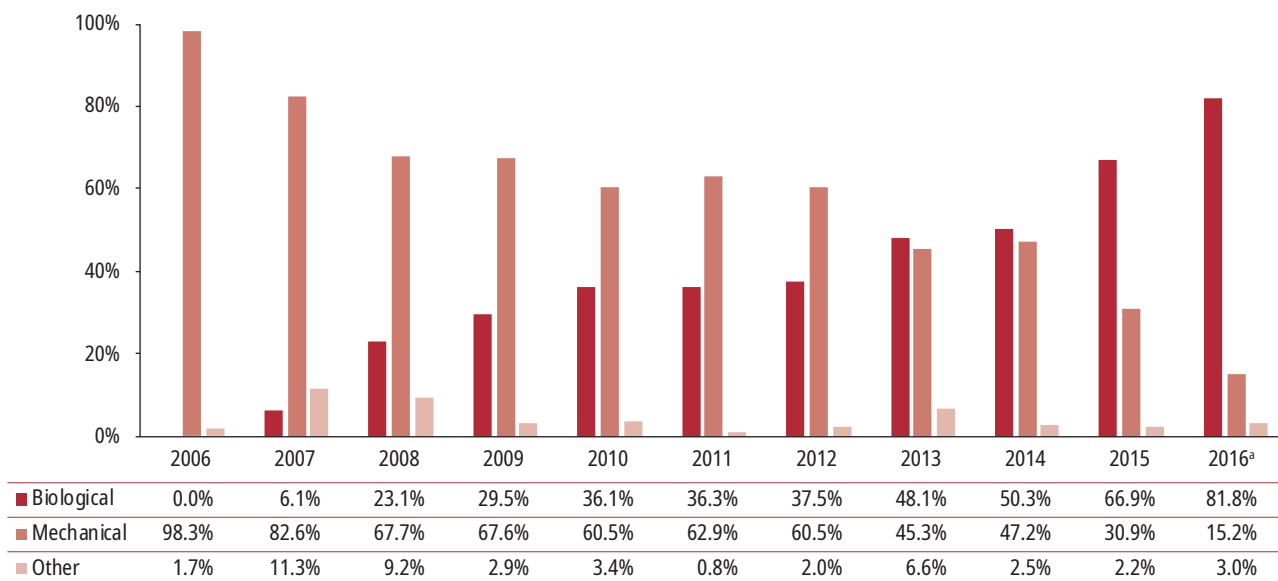
Based on the KROK form, a computer database was created for further statistical analysis. The completeness of each record was validated.

**Missing data** We excluded patients whose mortality/survival records were missing. Patients with missing data were excluded in the denominator when reporting the prevalence of binary (yes/no) risk factors and the type of implanted valve prosthesis. We analyzed only those records in which the percentage of complete data exceeded 95%. Records with completeness level below 95% were excluded from the analysis. The completeness of each record was validated.

**Statistical analysis** All descriptive statistics data were expressed as mean (SD) or median (interquartile range, IQR) unless stated otherwise. For continuous variables, the normality of distribution was verified with the Shapiro–Wilk test. To assess the differences between 2 continuous variables, the *t* test (for normally distributed values), or the Mann–Whitney test (for nonnormally distributed values) were used. Categorical variables were expressed as counts and percentages. To assess the differences between 2 categorical variables, the  $\chi^2$  test was used. The statistical analysis was performed with the STATISTICA 12.0 software (StatSoft, Tulsa, Oklahoma, United States). A 2-tailed *P*-value of less than 0.05 was considered statistically significant.

**RESULTS** Out of 4912 consecutive adult patients who underwent isolated aortic valve surgery in the last 10 years, 1531 patients were aged between 60 and 70 years (31.2%).

**Aortic valve pathology** Severe symptomatic aortic stenosis was observed in 69.1%, while clinically significant aortic insufficiency was present in 14.7% of patients. Combined aortic



**FIGURE 1** Proportion of all implanted prosthesis in each year from 2006 to 2016 (99.5% complete data).

**a** Data collected from 1st January to 31st August 2016

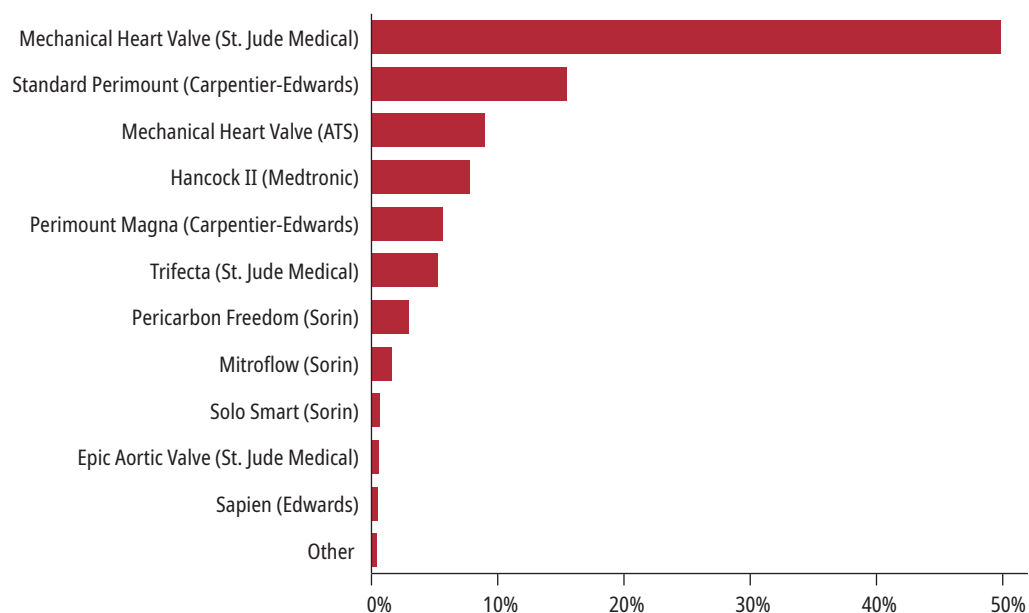
valve disease was diagnosed in 16.2% of patients (99.5% data complete).

The most common aortic valve pathology was calcific degeneration, observed in 62.8% of patients.

**Valve prosthesis** Between 2006 and 2016, MV were implanted in 56.9% of patients and BV in 39.0%. Other types of procedures represented 4.1% of cases (99.4% data complete). Among BV, 92.6% of implanted prostheses were stented valves. The share of aortic valve prosthesis in the overall number of replacements changed between 2006 and 2016 for MV from 98.3% to 15.2% and BV from 0% to 81.8% ( $P < 0.001$  for both comparisons) (FIGURE 1).

Out of all implanted valves, the most commonly implanted valve prosthesis was the St. Jude Medical Mechanical Heart Valve, which was used in 49.9% of patients, followed by the standard Carpentier-Edwards Perimount valve, used in 15.5% of patients, whereas the third most common valve prosthesis type was the ATS Medical Mechanical Heart Valve (ATS Medical Inc., Minneapolis, Minnesota, United States), used in 9.0% of patients (94.8% complete data) (FIGURE 2). The most common prosthesis size was 23 mm, accounting for 35.5% of all valve prostheses.

**Patient characteristics, surgical details, hospitalization, short-term outcomes** Elective procedures were performed in 88.7% cases.



**FIGURE 2** Aortic valve prostheses implanted between 2006 and 2016 (96% complete data)

Comparisons between the groups with MV and BV in terms of patient characteristics, procedures and short-term outcomes are shown in

**TABLE 1.** The overall in-hospital mortality rate was 3.46% (3.33% in the MV group and 3.69% in the BV group;  $P = 0.85$ ) (FIGURE 3).

**TABLE 1** Patient characteristics (continued on the next page)

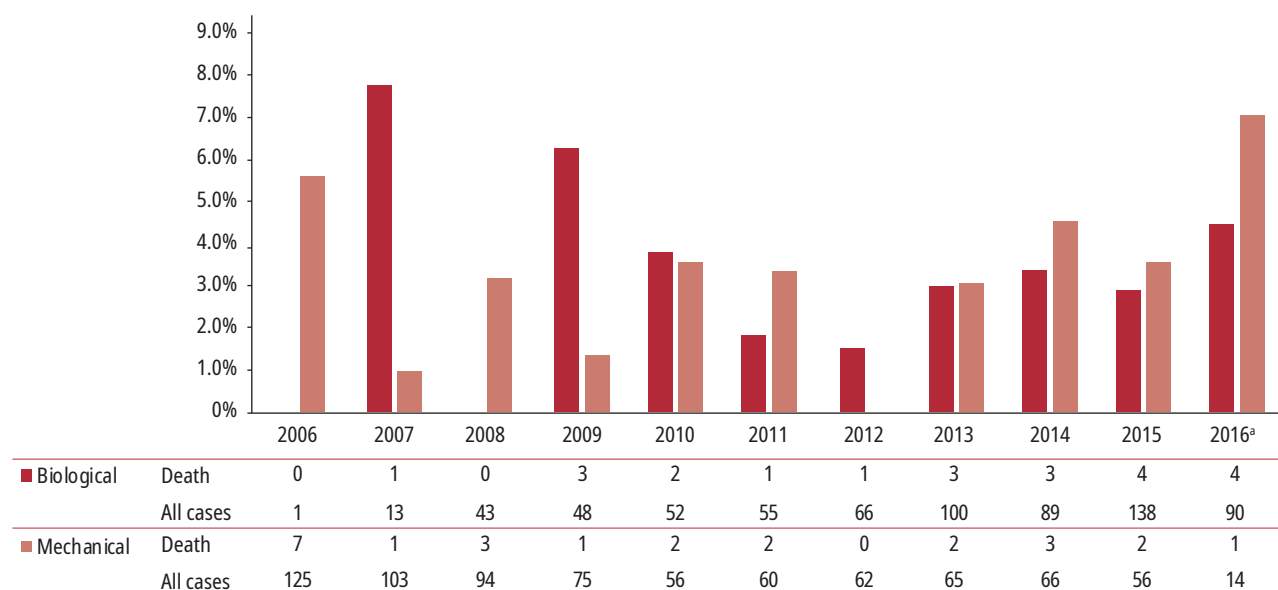
Parameter		Mechanical valve	Biological valve	<i>P</i> value	Complete data
Age, y	Mean (SD)	64.5 (2.8)	65.9 (2.5)	<0.001	100%
	Median (IQR)	65 (63–68)	65 (62–68)		
Sex	Female	1084 (38.8)	877 (45.8)	0.006	100%
	Male	1711 (61.2)	1038 (54.2)		
EF, %	Mean (SD)	52.6 (10.4)	54.2 (10.5)	0.003	94.3%
	Median (IQR)	58 (47.2–62.0)	55 (48.7–60.2)		
BMI, kg/m <sup>2</sup>	Mean (SD)	29.0 (3.9)	29.1 (4.0)	0.07	99.3%
	Median (IQR)	29.0 (25.6–32.8)	27.9 (25.3–31.0)		
CCS	0	186 (6.7)	213 (11.2)	0.004	99.5%
	1	890 (32.0)	600 (31.5)		
	2	1293 (46.5)	898 (47.1)		
	3	339 (12.2)	170 (8.9)		
	4	62 (2.2)	15 (0.8)		
NYHA class	0	11 (0.4)	6 (0.3)	0.002	99.5%
	1	250 (9.0)	251 (13.1)		
	2	1221 (43.9)	942 (49.2)		
	3	1086 (39.0)	645 (33.7)		
	4	211 (7.6)	71 (3.7)		
	Acute HF	3 (0.1)	0		
Hyperlipidemia		1091 (39.2)	684 (37.0)	0.4	99.6%
Hypertension		2310 (83.0)	1578 (85.3)	0.3	99.6%
T2D treatment	No treatment	3 (0.1)	9 (0.5)	0.04	99.6%
	Dietary treatment	95 (3.4)	54 (2.9)		
	Oral medications only	340 (12.2)	301 (16.3)		
	Insulin	223 (8.0)	196 (10.6)		
	No T2D	2124 (76.3)	1282 (69.3)		
Kidney function	CC >85 ml/min	247 (63.2)	148 (55.1)	0.051	44.9%
	CC >50 and <85 ml/min	122 (31.1)	110 (41.0)		
	CC <50 ml/min	14 (3.8)	9 (3.4)		
	Dialysis	7 (1.9)	1 (0.5)		
COPD		78 (2.8)	51 (2.7)	0.87	99.5%
Atrial fibrillation		356 (12.8)	183 (9.6)	0.004	99.5%
Smoking status	Active smoker	281 (10.1)	217 (11.4)	<0.001	99.5%
	Former smoker (<1 month without smoking)	651 (23.4)	248 (13.0)		
	Never smoking	1849 (66.5)	1440 (75.6)		

**TABLE 1** Patient characteristics (continued from the previous page)

Parameter		Mechanical valve	Biological valve	P value	Complete data
Valve prosthesis size, mm, median (IQR)		23 (21–25)	23 (21–23)	0.9	99.5%
Valve prosthesis size	17 mm	17 (0.6)	0 (0.0)		
	19 mm	292 (10.5)	112 (5.9)		
	21 mm	784 (28.2)	642 (33.7)		
	23 mm	968 (34.8)	713 (37.4)		
	25 mm	528 (19.0)	345 (18.1)		
	27 mm	147 (5.3)	76 (4.0)		
	29 mm	39 (1.4)	19 (1.0)		
	31 mm	3 (0.1)	0 (0.0)		
ECC time, min	Mean (SD)	115 (39.7)	110 (32.9)	0.13	98.6%
	Median (IQR)	106 (90–125)	106 (90–132)		
ACC time, min	Mean (SD)	74.0 (22.6)	70 (17.5)	0.02	98.2%
	Median (IQR)	71 (69–72)	69 (67–70)		
Hospitalization, d	Mean (SD)	11.0 (9.2)	14.4 (15.9)	0.87	100%
	Median (IQR)	10 (10–11)	10 (9–11)		
In-hospital mortality		109 (3.9)	57 (3.0)	0.47	100%

Data presented as number (percentage) unless indicated otherwise.

Abbreviations: ACC, aortic cross clamp; BMI, body mass index; CC, creatinine clearance; CCS, Canadian Cardiovascular Society; COPD, chronic obstructive pulmonary disease; ECC, extracorporeal circulation; EF, ejection fraction; HF, heart failure; IQR, interquartile range; NYHA, New York Heart Association; T2D, type 2 diabetes

**FIGURE 3** In-hospital mortality rates in patients after biological and mechanical valve replacement from 2006 to 2016

a Data collected from January 1 to August 31, 2016

**DISCUSSION** Aortic valve disease is one of the most common heart conditions.<sup>1,2,8</sup> The mortality rate after initial presentation with aortic valve symptoms is almost 25% per year.<sup>9</sup>

Due to population aging, the number of aortic valve replacement procedures will increase, and this trend can already be seen worldwide.<sup>4,10</sup> Current AHA/ACC guidelines recommend SAVR for

aortic stenosis in low- and moderate-risk patients (class I recommendation).<sup>8</sup> In high-risk patients, however, SAVR and TAVI (class I recommendation) are equally recommended.<sup>2</sup>

In clinical practice, TAVI is only performed in selected patients of older age and those considered high-risk for conventional surgery because of its complexity, limited availability, and associated high cost.<sup>3,11</sup> Despite rapid development of TAVI in recent years, SAVR is still more available, less expensive, and provides excellent results, with acceptable survival rates and quality of life (regardless of surgical risk level), and with low postoperative complication rates.<sup>4,12</sup> A large variety of valve prostheses are currently available on the market. Therefore, to ensure the best long-term results, a valve prosthesis must be carefully selected, and all decisions made with caution, having considered patient preferences. Aortic valve prostheses may be divided into 2 categories of MV and BV.<sup>5,13</sup> The MV, which are entirely made of pyrolytic carbon, offer longer durability with a lower risk of reoperation.<sup>14,15</sup> Their disadvantages include high risk of thromboembolism and major bleeding, as well as the need for oral anticoagulation.<sup>14,15</sup> In contrast, BVs do not require oral anticoagulation and are associated with lower risk of major bleeding.<sup>6,7,14,15</sup> However, they are less durable, which limits their use, particularly in younger patients.<sup>6,7,14,15</sup>

The current American and European guidelines specify that patient age affects the recommendations. In patients under 60 years of age, with no contraindications to warfarin therapy, MV is recommended (ESC/EACTS and AHA/ACC guidelines, class IIa recommendation).<sup>1,2</sup> BVs are recommended in older patients, namely, those over 65 and 70 years of age (ESC/EACTS and AHA/ACC guidelines, class IIa recommendation).<sup>1,2</sup>

The absence of a clear recommendation for patients between 60 and 70 years of age means that the choice in this group is divided (borderline) between MVs and BVs. Our study on real-world data shows that over 31% of borderline patients required SAVR and that the total number of borderline patients increased every year. Therefore, from both clinical and practical viewpoint, it is important to present actual, real trends in AVR surgery, as the absence of clear recommendations affects more than one-third of all candidates for aortic valve replacement.

Our study showed a rapid change in the type of valve prosthesis implanted in middle-aged patients. In 2006, MV were predominant, implanted in 98.1% of isolated aortic valve replacements. However, this trend has rapidly reversed over the last 10 years. In 2016, a BV was chosen in 81.8% of cases, whereas an MV was chosen in only 15.2% of cases. Similar trends have also been reported over the last decade in the global prosthesis market.<sup>4,10,16</sup> Our results are in line with those from other national database studies investigating patients who underwent isolated surgical

aortic valve replacement. In 2006, Brown et al<sup>10</sup> reported a BV implantation rate of 78.4%; Dunning et al<sup>16</sup> in 2009 reported a BV implantation rate of 78%, while Thourani et al<sup>4</sup> reported a BV implantation rate of 83.8% in 2010. Therefore, the BV implantation rates increase with the age of populations included in those studies.

A large meta-analysis comparing clinical outcomes of SAVR in middle-aged patients between the MV and BV groups, showed equal survival, but higher thromboembolism and major bleeding rates with MV as compared with BV in a follow-up of up to 15 years.<sup>5</sup> The largest differences between the 2 valve prostheses were observed in a 20- and 25-year follow-up.<sup>5</sup> However, one study reported nonsignificant differences in 20- and 25-year outcomes in patients below 60 years of age.<sup>15</sup>

In contrast to MVs, BVs are associated with higher reoperation rates due to structural valve deterioration, which is a major obstacle, especially in younger patients.<sup>5,17,18</sup> However, this disadvantage currently seems to be of lesser importance for several reasons. First, some studies suggest that reoperation-associated mortality rate is low and acceptable, and may actually be lower than mortality rate associated with major bleeding caused by anticoagulant treatment.<sup>5,19</sup> Additionally, the durability of new generation BVs with good hemodynamic parameters is comparable with that of MVs.<sup>7,18</sup> Furthermore, a valve-in-valve procedure using TAVI may be used in high-risk patients undergoing reoperation after an initial BV implantation.<sup>20</sup>

In our study, the mean age in the MV group was slightly lower than that reported in other studies.<sup>5</sup> Importantly, unlike in other databases, our group was comparable with the general population in terms of sex, ejection fraction, BMI, and other comorbidities.<sup>4,16</sup> There were no significant differences in BMI or other comorbidities, such as hypertension, hyperlipidemia, or diabetes mellitus, which may have clinical impact on short-term mortality or morbidity rates.<sup>1,2,5</sup> The in-hospital mortality rate was similar between the MV (3.5%) and BV (3.7%) groups, but remained high, especially when compared with the data from the Society of Thoracic Surgeons National Database.<sup>10</sup> However, upon comparison with the nationwide data for SAVR from KROK (where the overall in-hospital mortality rate was 4.0% [unpublished data presented at the meeting of the Club of Polish Cardiac Surgeons on May 2019]), our institutional mortality rate seems to be moderate.

The slight increase in mortality observed in the recent years also deserves a comment. One might speculate that the shift in patient risk profile seen in the last decades is the underlying cause. Arguably, cardiac surgeons in Poland may face more difficult and worse prepared patients than their colleagues from West Europe. In our center, the percentage of patients considered not eligible for surgery upon the assessment by the heart team

is relatively low (<2% of all cases), putting surgeons under pressure. Additionally, over 10% of all AVR procedures are done as urgent or emergency surgery, in which a patient is not properly prepared for surgery. This increases the risk of perioperative complications and reflects the issue of underdiagnosis in this population. Unfortunately, a thorough analysis of preoperative risk was beyond the scope of the current study due to the lack of EuroSCORE or the STS risk scores, which is a limitation of this analysis. That notwithstanding, it should be underlined that in Poland, the availability of TAVI is still limited due to procedural cost, reserving it for very old or extreme-risk patients only, whilst the remaining ones are managed with open surgery.

The most common valve prosthesis size was 23 mm in both the MV and BV groups and comparable to the general AVR group.<sup>4,16</sup> A smaller size, less than 21 mm, which is associated with a higher risk of post-operative prosthesis mismatch, was only implanted in 8.2% of patients.<sup>21-23</sup> The current study did not examine the effect of the size of valve prosthesis on the prevalence of postoperative prosthesis mismatch.

Unfortunately, we found no information about the frequency and types of valve prostheses implanted in different counties in national databases. Such information would have been of interest to the global community of cardiac surgeons. In our opinion, this data may differ due to economic differences in individual countries and differing valve prices. Based on the KROK (unpublished data as described above), in Poland, over the last 10 years, the most commonly implanted MV was the St. Jude Medical Mechanical Heart Valve and the most common BV was the Hancock II (Medtronic). These results showed that in countries with more than 38 cardiac surgery centers, there is a significant variability of valve prosthesis options for middle-aged patients. However, we did not assess the effect of valve type on surgical outcomes.

**Study limitations** This study was a retrospective review of a single center database (KROK). We assessed only short-term mortality rates, up to 30 days following discharge from the hospital. Because of missing data, we did not analyze other serious events such as stroke or major bleeding. Due to the strict inclusion criteria (more than 95% complete data), parts of data were missing, therefore, the EuroSCORE II and the Society of Thoracic Surgeons were not calculated.

**Conclusions** In the last 10 years, one-third of aortic valve surgeries were performed in patients between 60 and 70 years of age. In this group of patients, we observed rapidly changing trends in the type of implanted valve prosthesis. The proportion of implanted BV increased from 0% in 2006 to 81.8% in 2016. The most common

implanted MV was the St. Jude Medical Mechanical Heart Valve and the most common BV was the Carpentier-Edwards Perimount Magna valve. The short-term mortality was comparable in patients receiving MV and BV.

## ARTICLE INFORMATION

**CONTRIBUTION STATEMENT** GF and RL contributed equally to the manuscript and are co-primary authors. The authors had full access to the data, take responsibility for its integrity, and have read and agree to the manuscript as written.

**CONFLICT OF INTEREST** None declared.

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**HOW TO CITE** Filip G, Litwinowicz R, Kapelak B, et al. Trends in isolated aortic valve replacement in middle-aged patients over the last 10 years: epidemiology, risk factors, valve pathology, valve types, and outcomes. *Kardiol Pol.* 2019; 77: 688-695. doi:10.33963/KP.14854

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