



Changing trends in aortic valve procedures over the past ten years—from mechanical prosthesis via stented bioprosthesis to TAVI procedures—analysis of 50,846 aortic valve cases based on a Polish National Cardiac Surgery Database

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Background: Aortic valve replacement (AVR) is one of the most common surgeries performed in cardiac surgery operating rooms. We present actual, real life trends from the last 10 years for AVR interventions based on a multicentre National Registry of Cardiac Surgery Database.

Methods: The study population consisted of all 50,846 consecutive adult patients who underwent AVR between January 2006 and August 2016 in all cardiac surgery units in Poland. The main outcome measures were changes in the number of valves, characteristics of valves, operative details, and in-hospital mortality. Analysis consisted of all aortic valve (AV) procedures, including isolated AV surgery, combination procedures and patients who had a prior valve operation.

Results: In last 10 years, the number of procedures increased by 46%. Isolated surgical AVR was performed in 61.2%, AVR + coronary artery bypass grafting (CABG) in 23.9%, AVR + mitral valve replacement (MVR) in 7%, and transcatheter aortic valve implantation (TAVI) in 2.3% of patients. The mean patient age increased significantly from 61.4 years in 2006 to 66.1 years in 2016. Aortic stenosis was diagnosed in 73.4%, severe aortic insufficiency in 15.8% of cases. The most common valve pathology was calcification. Congenital valve dysfunction was diagnosed in 3.7% of cases. There was a 33.7% increase of bioprosthesis, and the most common implanted bioprosthesis was the Hancock II. The most common implanted mechanical prosthesis was the St. Jude Medical Mechanical Valve. In-hospital mortality decreased significantly over the 10-year period in all AV procedures from 10.9% in 2006 to 8.3% in 2016. Mean in-hospital mortality was: 4.0% in isolated surgical AVR, 5.4% in TAVI, 6.8% in AVR + CABG, 9.8% in AVR + MVR, 17.2% in AVR + MVR + CABG.

Conclusions: In the last ten years, the number of AV procedure has doubled. Mortality was significantly lower with all types of AV procedure despite very rapid aging of AVR patients. TAVI procedure rapidly grew

in popularity. There is significant increase in the use of bioprosthesis.

Keywords: Aortic valve replacement (AVR); bioprostheses; mechanical prosthesis; transcatheter aortic valve implantation (TAVI); heart valve prosthesis

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Introduction

Aortic valve (AV) pathology is the most common type of heart disease in industrialized countries. In contrast to other common types of heart disease, including coronary artery disease (CAD), heart failure or hypertension, conservative medical therapy is insufficient, and progressive disease often requires interventions (1).

The prevalence of AV pathology increases with aging and in recent years the number of AV procedures have also increased (2). However, older age is associated with a higher frequency of comorbidity with increased risks associated with interventions (1). Surgical aortic valve replacement (AVR) is still the gold standard for treatment of AV pathology, however transcatheter aortic valve implantation (TAVI) offers a new treatment option for patients considered high risk for surgery (3).

Therefore, with the worldwide growth in AV procedures, herein we present changes in 10-year observations for AV pathology intervention/treatment trends, regarding patient characteristics, AV pathology, type of procedure, type of implanted prosthesis, technical issues and outcomes based on 50,846 cases from a multicentre Poland registry.

Aim

The aim of the study was to assess and characterize changes in trends in AVR in Poland in the last ten years.

Methods

The study population consisted of 50,846 consecutive adult patients (over the age of 18 years) who underwent AVR between January 2006 and August 2016 in all cardiac surgery units in Poland. The analysis consisted of all AV procedures, including isolated AV surgery, combination procedures and patients who had a prior valve operation. Operative mortality was defined as death within 30 days

after the procedure.

The authors had full access to the data, take responsibility for its integrity, and have read and agree to the manuscript as written.

This study will only collect retrospective data information that has been recorded in Polish National Cardiac Surgery Database that is obligatory in Poland. The Polish Society of Cardiothoracic Surgeons approved the research project. All the data has been anonymized. Because of the size of the research group and approval from the Polish Society of Cardiothoracic Surgeons, no patients informed consent was needed.

Study databases

Data for this study was collected retrospectively based on the standardised form of the Polish National Database of Cardiac Surgery Procedures (KROK).

The data collected included age, gender, body mass index (BMI), ejection fraction (EF), previous percutaneous coronary intervention (PCI), Canadian Cardiovascular Society (CCS) class, New York Heart Association (NYHA) class, smoking status, diabetes mellitus (DM), arterial hypertension, hypercholesterolaemia, asthma, chronic obstructive pulmonary disease (COPD).

On the basis of the form of the National Database of Cardiac Surgery (KROK), a computer database was built for further statistical analysis.

Missing data

We excluded patients if records for outcomes (i.e., mortality/survivors) were missing. The completeness of each record was counted: records were only analysed where the percentage of complete data was higher than 90%. Records that were lower than 90% were excluded from analysis. Almost all the data collected was more than 90% complete.

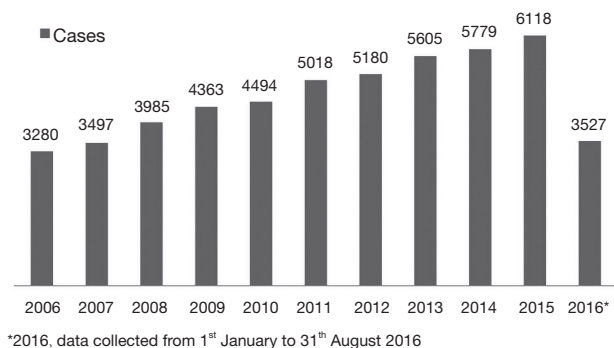


Figure 1 Number of procedures performed in each year (data complete 100%).

Statistical analysis

Descriptive statistics were performed, and all data were expressed as mean \pm standard deviation. Continuous variables were checked for normal distribution with the Shapiro-Wilk test. To assess the differences between two continuous variables, Student's *t*-test (for normally distributed values), or the Mann-Whitney U-test (for non-normally distributed values) were applied. Statistical analysis was performed with STATISTICA 10.0 (StatSoft, Tulsa, OK, USA). A two-sided P value <0.05 was considered statistically significant.

Results

Patient characteristics

Among 247,364 consecutive adult patients who underwent cardiac surgery procedures during the study period, 50,846 underwent an AV procedure (20.6%). Each year, the number of procedures increased significantly from 3,280 cases performed in 2006 to 6,118 cases performed in 2015 (Figure 1). Patients' mean age increased significantly during 10 years of observation, from 61.4 years in 2006 to 66.1 years in 2016 ($P<0.001$) (Figure 2). Detailed patient characteristics are presented in Table 1.

AV pathology

Aortic stenosis was observed in 73.4% of cases (99% data complete), and aortic insufficiency in 80.3% of cases, in whom trivial stenosis was observed in 19.7%, mild stenosis in 22.4%, moderate stenosis in 22.3% and severe stenosis in 15.8% of cases (98% data complete). The most common

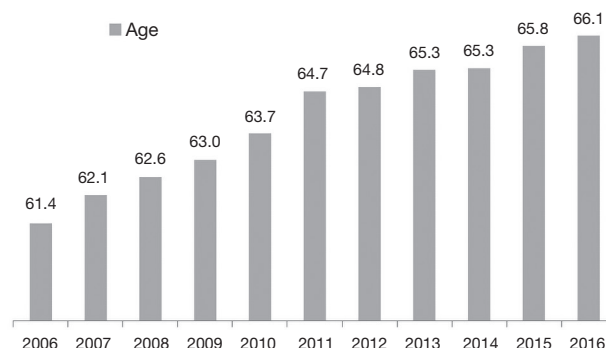


Figure 2 Mean patient age ($P<0.000001$) (data complete 100%).

AV pathology was calcific degeneration observed in 44.9% of cases. Other types of valve pathology are presented in Figure 3.

Procedure

The most common procedure was isolate surgical AVR in 61.2% patients, followed by AVR + coronary artery bypass grafting (CABG) in 23.9% of patients, AVR + mitral valve replacement (MVR) in 7% of patients and TAVI in 2.3% of patients. Detailed data are presented in Figure 4.

There were significant changes in the type of procedures performed each year ($P<0.001$). The highest increase was observed in the TAVI procedure, from 0% in 2006 to 8.3% in 2016. The highest decrease was observed in AVR + MVR, from 10.5% in 2006 to 4.7% in 2016. Detailed data of all procedures, including all other procedures performed during this time are presented in Figure 5. Elective procedures were performed in 78.2% cases and 4.39% procedures were reoperations.

Type of prosthesis

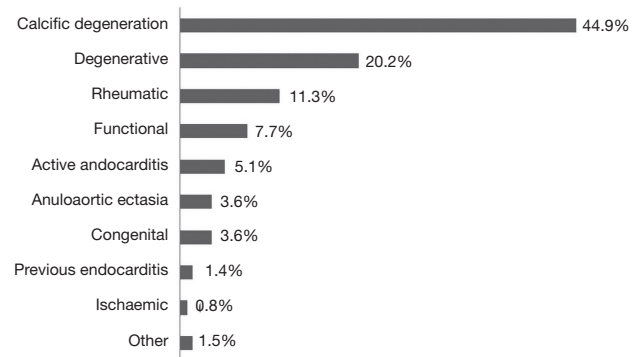
From 2006 to 2016, AVR was performed in 94.8% of cases, TAVI in 2.3%, AV repair in 1.5%, homografts in 0.3% and others in 1.1% of cases. The proportion of prosthetic valves changed from 71.8% mechanical prosthesis *vs.* 27.1% biological prosthesis in 2006 to 26.4% mechanical prosthesis *vs.* 60.8% biological prosthesis in 2016. The TAVI procedure had a rapid growth in last four years, from 1.2% in 2012 to 8.8% in 2016. These results were statistically significant ($P<0.001$) (Figure 6).

During the 10-year observation, the most commonly

Table 1 Patient characteristics

Variables	Results	Data complete
Age	Mean: 64.27 ± SD 12.27 Range, 18–100 years	100%
Sex	Female 37.7% Male 62.3%	100%
EF (%) (4)	Mean: 52.7 ± SD 11.8 Range, 10–93	81.4%
BMI (kg/m ²)	Mean: 27.87 ± SD 4.58 Range, 12.50–57.78	96.1%
CCS		98.1%
CCS 0	24.1%	
CCS 1	26.2%	
CCS 2	33.9%	
CCS 3	13.8%	
CCS 4	1.9%	
ACS	0.2%	
NYHA		98.3%
NYHA 0	3.7%	
NYHA 1	8.7%	
NYHA 2	42.8%	
NYHA 3	38.1%	
NYHA 4	6.4%	
Acute HF	0.3%	
Hyperlipidemia	43.3%	98.2%
Hypertension	70.3%	98.3%
Diabetes type 2		98.3%
Without treatment	0.5%	
On diet	3.8%	
Only oral medications	12.3%	
Insulin	7.7%	
No DM type 2	75.6%	
Previous MI	12%	93.1%
COPD	7.7%	91%
Smoking		90.7%
Active smoker	10.2%	
Former smoker (<1 month without smoking)	40.1%	
Never smoking	49.5%	

EF, ejection fraction; BMI, body mass index; CCS, Canadian Cardiovascular Society; NYHA, New York Heart Association; HF, heart failure; DM, diabetes mellitus; MI, myocardial infarction; COPD, chronic obstructive pulmonary disease.

**Figure 3** Type of valve pathology.

used prosthesis was the Hancock II bioprosthesis implanted in 19.9% of patients. The second most common was the Saint Jude Mechanical prosthesis and the third most common was the ATS Medical mechanical prosthesis. All other mechanical and biological prostheses used during this study are presented in *Figure 7*. The most common size of implanted prosthesis was 23 mm (34.8%), followed by 21 mm (27.77%) and 25 mm (19.43%). All other valve sizes used between 2006–2016 are presented in *Figure 8*.

Hospitalization

Mean time on ICU was 3.25 days, and mean hospitalization time was 13.04 days. Detailed procedure characteristics and hospitalization data are presented in *Table 2*. In-hospital mortality significantly decreased ($P=0.034$) from 10.9% in 2006 to 8.3% in 2016.

Throughout the observation period, in-hospital mortality was: 4.0% in isolated surgical AVR, 5.4% in TAVI, 6.8% in AVR + CABG, 9.8% in AVR + MVR, 17.2% in AVR + MVR + CABG, and 11.6% in other procedures (*Figure 9*).

Discussion

We present contemporary real-life trends in AV procedures over the last ten years in Poland, one of the biggest countries of central Europe, where every year more than 27,000 procedures are performed in 37 centres (6).

Currently, surgical AV procedures are the second most commonly performed cardiac surgery procedures and the number of procedures are likely to increase over time (6,7). Over the course of the study period, more than 20% of procedures (50,846 cases) in Poland were AV procedures. The absolute number of patients undergoing AV

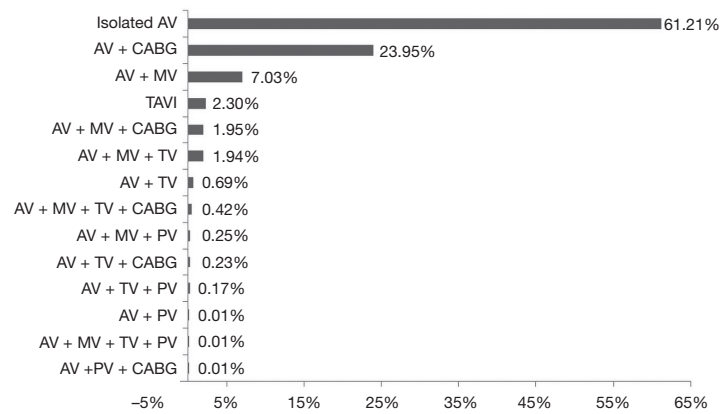


Figure 4 All AV procedures performed from 2006–2016 (100% complete data). AV, aortic valve; CABG, coronary artery bypass grafting; MV, mitral valve; TAVI, transcatheter aortic valve implantation; TV, tricuspid valve; PV, pulmonary valve.

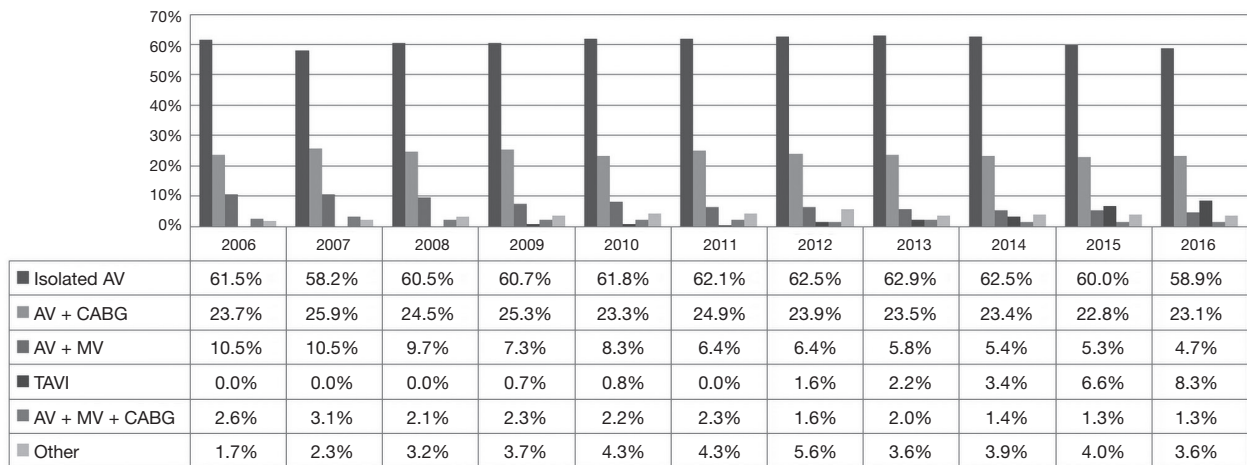


Figure 5 Characteristics of all AV procedures performed from 2006–2016 (100% complete data). AV, aortic valve; CABG, coronary artery bypass grafting; TAVI, transcatheter aortic valve implantation; MV, mitral valve.

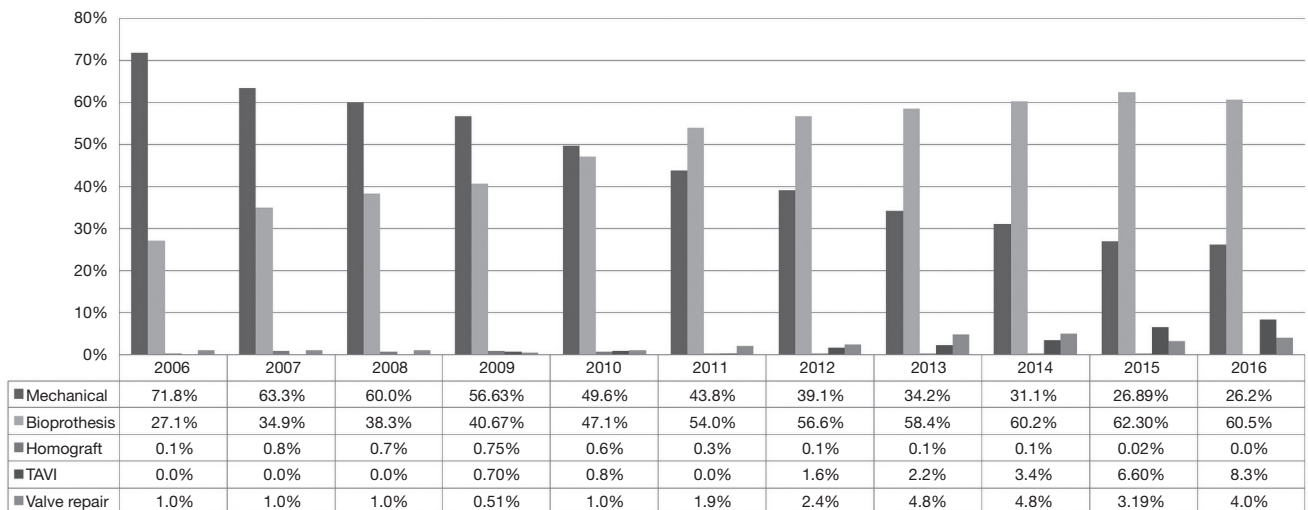


Figure 6 Proportion of all implanted prostheses in each year (97% complete data). TAVI, transcatheter aortic valve implantation.

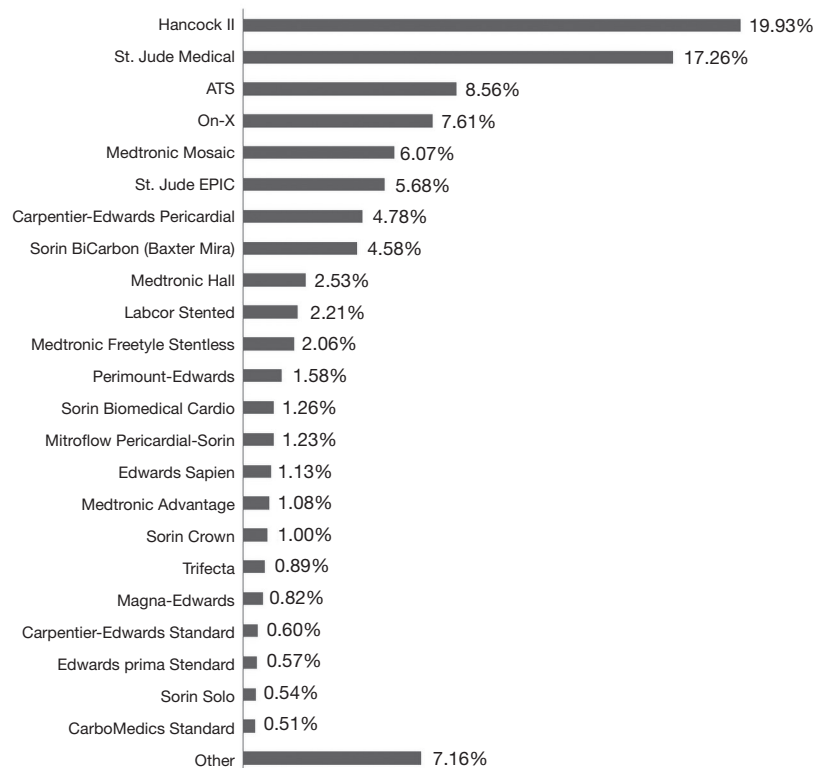


Figure 7 Types of all implanted prostheses from 2006–2016 (97% complete data).

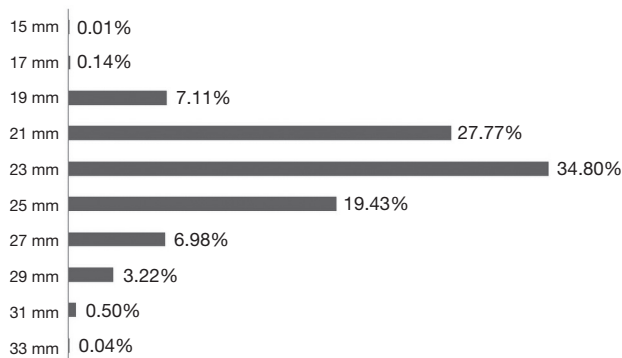


Figure 8 Prosthesis valve size.

procedures in each year increased significantly from 3,280 cases performed in 2006 to 6,118 cases performed in 2015. Similar trends are also observed all over the world (7).

AV disease is the most common acquired valvular disease in elderly patients (8). Currently in Poland, the expected life expectancy of the population of 60 years old is 19 years for men and 21 years for women. In the aging population,

it is reasonable to expect that the number of patients seeking treatment for AV disease will also increase in the coming years (2). In our observations, the mean patient age increased significantly from 61.4 years in 2006 to 66.1 years in 2016. However, Polish patients seems to be younger than American patients undergoing these procedures during a similar time period (7). With the aging of patients, there is also an increased risk of coexisting disease. In our study, in the last ten years, the most common comorbidities was hypertension (70.3%), hyperlipidaemia (43.3%) and DM type 2 (23.4%), diseases that are significant risk factors for heart disease and postoperative complications (2,7-11).

Aortic stenosis was observed in 73.4% of cases. The mean transaortic gradient was 80.72 mmHg and was twice as high as the current mean gradient eligible for surgery (1). Severe aortic insufficiency was observed in 15.8% of cases. It should be noted that the mean EF was 52.7%, therefore we may assume that most of the patients undergoing operations had good left ventricular hemodynamic function. Unfortunately, in our database, there was no information on the prevalence of mixed AV disease, and

Table 2 Procedure characteristics and hospitalization in AV procedures performed from 2006–2016

Variables	Results	Data complete
Procedure status	Elective: 78.2%	90.2%
	Non-elective: 17.8%	
Reoperations	4.39%	100%
Procedure in ECC	99%	96.7%
ECC time (5)	Mean: 120.18 ± SD 58.7	93.9%
	Range, 10–1,105	
ACC time (5)	Mean: 82.5 ± SD 35.3	78.3%
	Range, 0–517	
Time on ICU	Mean: 3.25 ± SD 6.76	90.9%
	Range, 0–273	
Hospitalization (day)	Mean: 13.04 ± SD 13.7	99.1%
	Range, 0–643	
In hospital mortality	5.62%	100%
Time of death after surgery (day)	Mean: 10.4 ± SD 20.8	93.1%
	Range, 0–641	

AV, aortic valve; ECC, extracorporeal circulation; ACC, aortic cross clamp.

therefore information on the reason for the AV procedure is incomplete.

Intraoperative examination showed the most common AV pathology was valve calcification present in 44.9% of patients and degenerative dysfunction in 20.2% of patients. The prevalence of congenital AV disease was 3.6% and was nearly twice as high as figures described in the literature (12,13). The higher prevalence of bicuspid valves in our study is due to the fact that we present intraoperative examinations, while other studies present mostly results of echocardiography examinations, underestimating case of bicuspid valves (14).

Isolated surgical AVR was performed in 61.2% of cases, and the remainder were combined procedures: CABG + AVR was performed in 23.95% of cases and AVR + MVR was performed in 7.1% of cases. TAVI was only performed in 2.3% of cases. Overall, the number of TAVI procedures may seem low during a 10-year observation period, however the TAVI procedure was first performed in Poland in 2008 (15), six years after first TAVI implantation in the world. From 2008, the TAVI procedure has rapidly grown in popularity from <0.01% cases in 2008 to 8.3% in 2016. In contrast to the TAVI growing trend, the

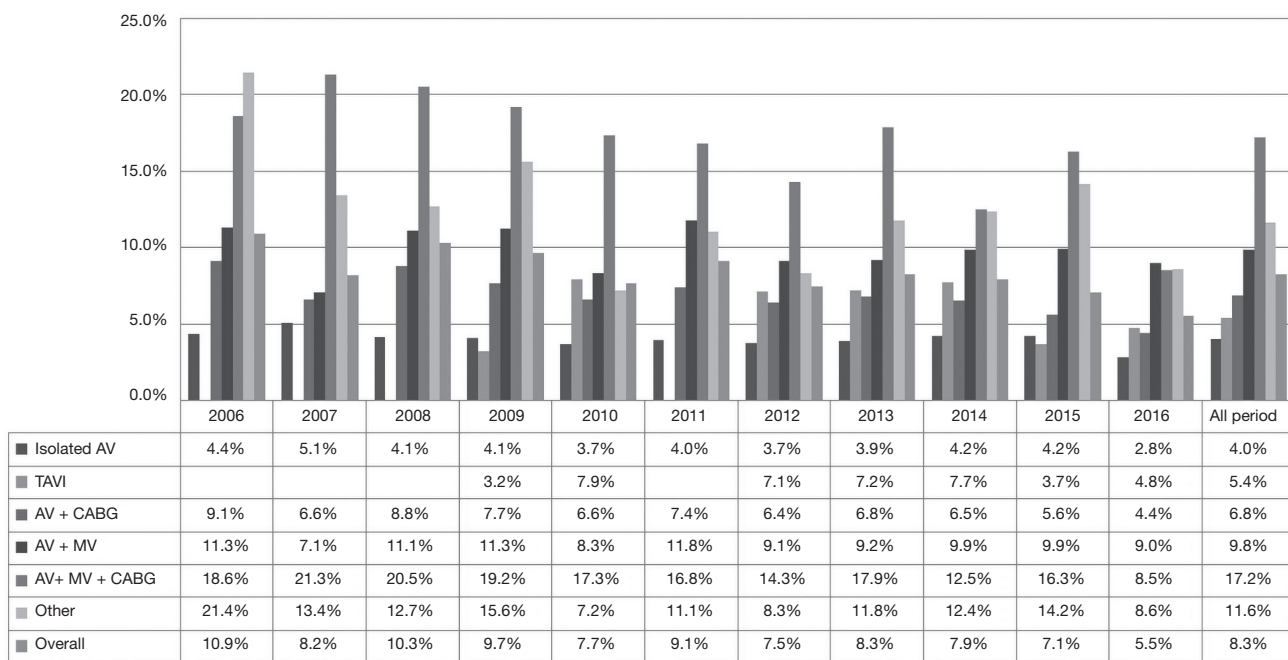


Figure 9 In-hospital mortality in AV procedures from 2006–2016. AV, aortic valve; TAVI, transcatheter aortic valve implantation; CABG, coronary artery bypass grafting; MV, mitral valve.

10-year period saw a 1.6% decrease in the number of isolated surgical AVR from 60.5% in 2008 to 58.9% in 2016. This figure likely represents a stable trend, indicating that the number of indications for the TAVI procedure is increasing. It should be highlighted, that in Poland, for economic reasons, TAVI procedure are reserved only for high risk patients. However, based on the rapidly increase in the rate of TAVI procedures must nowadays in Poland must be treated not as an alternative option for surgical AVR, but as an equal treatment option in high risk patients. In the future, the use of TAVI may overtake that of surgical AVR as the frequency of implanted biological valves is increasing, while mechanical valve implantation is decreasing. However in Poland, surgical AVR still remains the standard treatment options for moderate and low risk patients. This is in contrast with current ESC/EACTS guidelines for AV disease treatment (16). Techniques modification and continuous development of TAVI prosthesis and the publication of several randomized trials, comparing surgical and TAVI treatments, not only in elderly high-risk patients, but also in intermediate and low risk patients (16-18). The results of The PARTNER 3 (19) and EVOLUT (20) were superior or comparable following surgical AVR among patients with severe aortic stenosis at low surgical risk.

The current study presents a changing proportion of mechanical *vs.* bioprosthetic valves from 71.8% *vs.* 27.1% in 2006 to 26.4% *vs.* 60.8% in 2016, respectively. An increased rate of bioprosthetic valve implantation has been observed in the last decade (4,7,21). However, other databases present higher percentages of implanted procedures in each year. Brown and colleagues (4) reported a 78.4% rate of bioprosthetic valve implantation in 2006, Dunning and colleagues (21) 78% in 2009 and Thourani and colleagues (7) 83.8% in 2010. Compared to the present study, the percentage of implanted mechanical valves in Poland is still very high. However, the cited studies present results only for isolate AVR, not in all AV procedures as is the case in the present study. Therefore, from our clinical observations, the overall percentage of implanted bioprosthetic valves in surgical AVR should be higher. The guidelines of the American College of Cardiology and the American Heart Association state that despite a slight advantage of mechanical valves, the increase in bioprosthetic valve implantation is likely due to an older patient population undergoing surgical AVR, perceived improvements in valve durability, and a desire to avoid short-term and long-term anticoagulation, if possible (7,22-24).

Our study shows that in current cardio-surgical practice

the role of homografts is marginal, constituting 0.8% of cases. Homografts were implanted more commonly in previous years, likely due to acceptable long term results (25). However, homograft implantation technique is difficult and current bioprosthetic valves have similar outcomes (26). Preservation of the native valve, rather than mechanical valve use may be advantageous, allowing the avoidance of anticoagulation and fewer complications of the operated valve (5,11,23).

From near fifty thousand AV prostheses implanted in the last ten years in Poland, the most common implanted prosthesis was the Hancock II (bioprosthesis), and the second most common was the St. Jude Mechanical Valve (mechanical prosthesis). Our study shows that in Poland, where there are more than 38 cardiac surgery centres, the prosthesis market is huge with a lot of different therapeutic valve options available (23,24,27-30). However, the current study did not examine the effect of valve type on operative outcomes.

Our study also showed that small aortic prostheses, size 15–19 mm, were implanted only in 7.25% of cases. According to the study, this group is a high risk of postoperative PPM (31). The most common implanted prostheses were medium-sized (21–25 mm) implanted in 85% of cases. Although the current study did not examine the effect of prosthesis size and prevalence of postoperative PPM.

In the last ten years, in-hospital mortality significantly decreased for all AV procedures. Importantly, in-hospital mortality reductions were observed even in older patients' groups. Advances in pre- and post-operative care have led to the possibility that an increasing number of elderly patients can be operated on safely and with a satisfactory outcome (9,32). In isolated surgical AVR, mean in-hospital mortality was 4.0% and was higher than results from American or British databases (7,21). The mean in-hospital mortality in the TAVI group was 5.4%. However, these results are not comparable due to the differences in patient populations included in the studies. In surgical AVR patients, the mean patient age was lower compared to patients undergoing TAVI and the mean Euroscore should be much lower.

Study limitations

This study has several limitations. The most important limitation is the lack of Euroscore or STS results. In the last ten years, the Euroscore was replaced by the Euroscore II. Additionally, in Poland different centres replaced the Euroscore at different times. Therefore, Euroscore results in our database are not comparable and were not analysed

to avoid misleading the reader. Additionally, in our database there too many instances of absence of any Euroscore data. Secondly, in some cases medical data were incomplete. However, the size of the sample (n=50,846) suggests that a few instances of incomplete data would not have a statistically significant effect on the outcomes. Thirdly, this study has all of the limitations associated with the collection of data from 37 centres.

Conclusions

- (I) This study demonstrates a 46% increase in the number of patients undergoing all types of AV procedure in Poland over a 10-year period. The most common procedure was isolated surgical AVR, performed in 61.2% of cases.
- (II) From 2008, the TAVI procedure rapidly grew in popularity to 8.3% in 2016.
- (III) The mean patient age increased significantly as well as the number of cases performed every year.
- (IV) The most common valve pathology was valve calcification; congenital valve dysfunction was only diagnosed in 3.7% of patients.
- (V) In last ten years, there was significant increase in the use of bioprosthesis.
- (VI) In last ten years, in-hospital mortality significantly decreased for all AV procedures from 10.9% in 2006 to 8.3% in 2016.

Acknowledgments

None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The Polish Society of Cardiothoracic Surgeons approved the research project (No. 002,10.11.2018). All the data has been anonymized. Because of the size of the research group and approval from the Polish Society of Cardiothoracic Surgeons, no patients informed consent was needed.

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