ORIGINAL ARTICLE

Trends in diagnosis and treatment of aortic stenosis in the years 2006–2016 according to the SILCARD registry

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KEY WORDS

aortic stenosis, mortality, registry

ABSTRACT

INTRODUCTION During the last decade, aortic stenosis (AS) has emerged as one of the most significant concerns in cardiovascular diseases.

OBJECTIVES We aimed to characterize AS patients on the basis of data derived from a local registry.

PATIENTS AND METHODS We used data from the SILesian CARDiovascular (SILCARD) registry, which was developed under the agreement between the Silesian Centre for Heart Diseases in Zabrze and the Silesian branch of the Polish National Health Fund in Katowice to conduct a comprehensive analysis of patients with cardiovascular diseases in Silesian Voivodeship.

RESULTS A total of 15 158 patients hospitalized with a diagnosis of AS between 2006 and 2016 were included (mean [SD] age, 69.87 [11.97] years; male patients, 7644 [50.43%]). Heart failure was reported in 4187 patients (27.62%), and coronary artery disease, in 6217 (41.01%). During the first hospitalization, aortic valve intervention was performed in 2137 patients (14.10%), and during a 12-month follow-up, in 3416 (25.32%). During the first hospitalization, percutaneous coronary intervention (PCI) was performed in 666 patients (4.39%), and coronary artery bypass grafting (CABG), in 1071 (6.71%). At 12-month follow-up, PCI was reported in 560 patients (4.15%), and CABG, in 560 (4.15%). Between 2006 and 2016, 30-day mortality was 4.35% (659 patients) and remained stable throughout the study (5.4% in 2005 vs 4.0% in 2016, $P = 0.28$). The 1-year mortality was 15.88% (2142 patients) and increased from 14.3% in 2006 to 16% in 2015 ($P = 0.07$).

CONCLUSIONS The SILCARD registry has revealed an increase in the number of AS diagnoses. AS has become one of the most critical issues among cardiovascular diseases in Silesian Voivodeship.

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INTRODUCTION With population aging, aortic stenosis (AS) has recently emerged as one of the most significant cardiovascular diseases.[1,2] The broad spectrum of AS symptoms is not only a concern of cardiovascular units but also of intensive cardiac care and internal medicine departments. This makes AS an interdisciplinary issue.[3]

Most commonly, severe AS requires a surgical intervention, but as a high-risk procedure, it excludes patients who are highly vulnerable to periprocedural complications. However, in the last 10 years, percutaneous transcatheter aortic valve implantation (TAVI) was introduced as an alternative to surgery, which allowed treatment of patients with high perioperative risk of complications.[4,5] Such a shift in treatment has significantly changed the physicians' approach by increasing the number of AS patients considered curable.[6] Therefore, the knowledge about AS prevalence and treatment trends over the last decade is essential to establish the most appropriate management strategy.

TABLE 1 *ICD-10* codes for individual cardiovascular diseases

Aortic stenosis	I06.02, I06.0, I35.0, I35.2
Aortic regurgitation	I35.1 I35.11, I35.111, I35.112, I06.111, I06.112, I06.21
Mitral regurgitation	I34.0, I34.1, I05.1, I05.111, I05.112
Mitral stenosis	I05.0, I05.01, I05.2, I05.21, I34.2
Tricuspid valve regurgitation	I36.0, I07.0, I07.01, I07.2,
Heart failure	I50, I51.5, I51.7, J81, R57, I42, I43
Stable coronary artery disease	I25, I20.1, I20.8, I20.9
Unstable angina	I20.0, I24.0, I24.8, I24.9
Myocardial infarction	I21, I22
Atrial fibrillation	I48
Arterial hypertension	I10, I11, I12, I13, I15
Pulmonary embolism	I26
Infective endocarditis	I33, I38, I39
Grown-up congenital heart disease	Q20-Q28
Valvular heart diseases without aortic stenosis	I05, I06.1, I06.8, I06.9, I07, I08, I34, I35.1, I35.8, I35.9, I36, I37

International and local registries seek to identify local health needs.[7] They provide insights into the epidemiology, morbidity, and mortality of patients. In the current study, we extracted data from a local registry to present the characteristics, treatment, and prognosis of AS patients in Silesian Voivodeship in Poland in the last 10 years.

PATIENTS AND METHODS The SILCARD registry was based on the agreement between the Silesian Centre for Heart Diseases in Zabrze and Śląski Oddział Wojewódzki NFZ in Katowice (the Silesian branch of the Polish National Health Fund) to conduct a comprehensive analysis of patients with cardiovascular diseases in Silesian Voivodeship.[8] The inclusion criteria were as follows: each hospitalization at a department of cardiology, cardiac surgery, diabetology, or vascular surgery and hospitalization with a cardiovascular diagnosis at departments of internal medicine or intensive care. The exclusion criteria were hospitalizations of patients living outside Silesian Voivodeship and patients younger than 18 years on admission. All hospitalizations fulfilling the enrollment criteria in the years from 2006 to 2016 were included in the registry. The initial hospitalization was defined as admission for cardiovascular causes, including a potential transfer to another department or hospital. This hospitalization constituted the baseline for follow-up. If the time between hospital discharge and the following admission due to the diagnosed cardiovascular disease was shorter than 1 day, both hospitalizations were treated as one. All data were anonymized. Matching information concerning the individual patient was possible through the hospital register number and encoded national personal identification number (PESEL).

Data analysis was conducted at the Science Department of the Silesian Centre for Heart Diseases and the Department of Biostatistics of the Medical University of Silesia, Katowice, Poland, according to regulations (Security Policy as of September 1, 2015). The individuals involved in data collection and workup signed a confidentiality clause. Data flow was presented previously.[8] The analyses were conducted as follows: 1) according to the first hospitalization of the patient, depending on primary and/or concomitant diagnosis (*International Classification of Diseases, Tenth Revision* [*ICD-10*]), where each next admission was analyzed as an event (analysis of first-time hospitalizations); 2) diagnostic and therapeutic procedures were examined according to the *ICD-9*, presenting all of them together or attributing to each of the patients with a given disease entity. The reported data come from 310 hospital departments and 1863 outpatient clinics. They contain information on 605 920 cardiovascular hospitalizations. In this study, we analyzed the number of hospitalizations, distribution of disease entities, and prognosis up to 12 months in patients with diagnosed AS. The *ICD* classification codes assigned to the individual disease entities are presented in TABLE 1.

Statistical analysis The mortality rate and repeated hospitalizations in a 12-month follow-up were analyzed according to the first hospitalization of the given patient. Descriptive statistics were also applied. Compilations were generated directly from the Oracle database using the SQL Developer tool. The excel spreadsheet was used for graphics development. The obtained data distribution was assessed by the Kolmogorov–Smirnov analysis. For normally distributed values, data were presented as mean with standard deviation (SD), and for nonnormally distributed values, as median with interquartile ranges (25 percentiles, 75 percentiles). Continuous variables were compared using the 1-way analysis of variance. The differences in the number of patients and mortality rate over the years were verified using the Cochran–Armitage trend test.

RESULTS **Hospitalizations of patients with aortic stenosis** Among all 605 920 patients with cardiovascular disease, 15 158 patients (2.5%) were hospitalized with AS diagnosis in the last 10 years, and the rate of patients with diagnosed AS increased from 0.95% in 2006 to 4.64% in 2016 (P <0.001). Most of the AS patients were hospitalized at cardiology units (8268 patients, 54%). The remaining patients were treated at internal medicine departments (4471 patients, 29%), cardiac surgery units (2406 patients, 16%), intensive care units (8 patients, 0.05%), and vascular surgery units (5 patients, 0.03%) (FIGURE 1). The study showed that 44% of patients required urgent hospitalization (data from 2011–2016). Among all patients with AS, 7715 patients (50.9%) were male, and they were younger than women with AS (mean [SD] age, 66 [12] years vs 73 [11] years; P <0.001). The mean (SD) hospital stay for a single patient

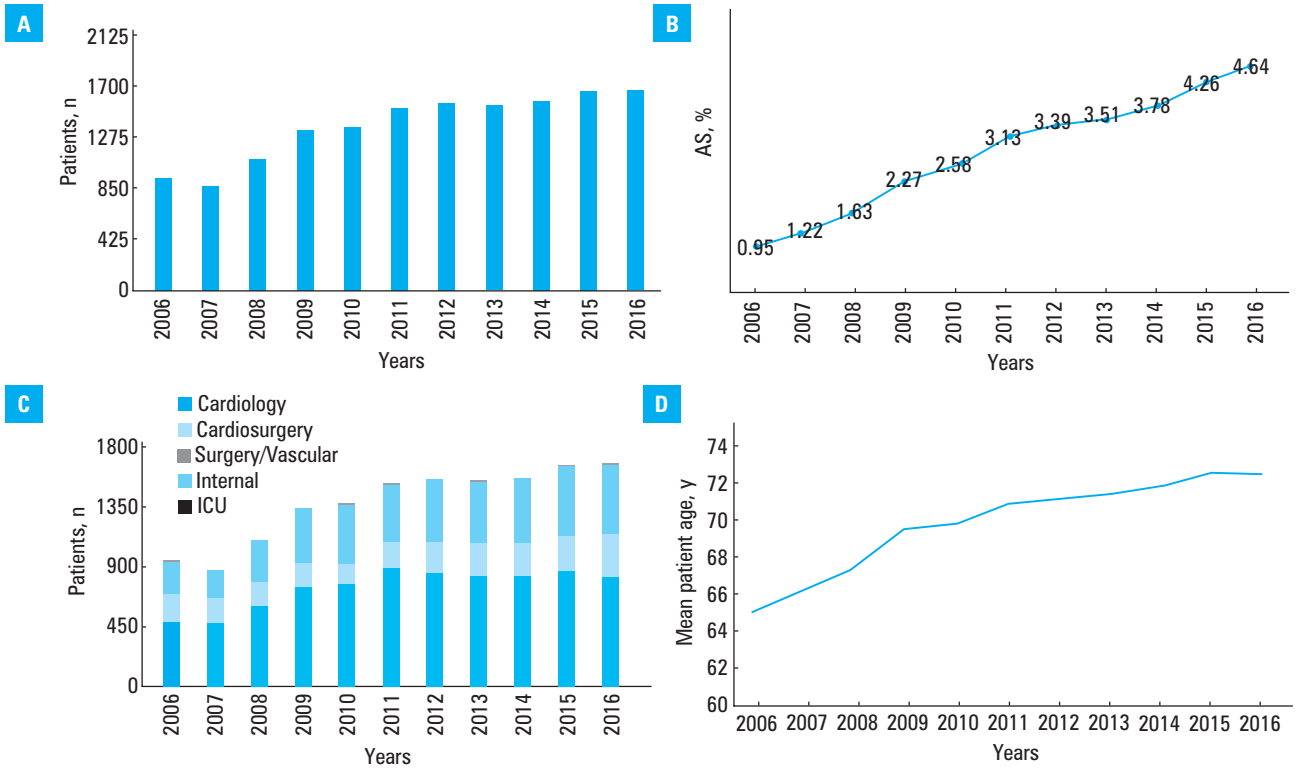

FIGURE 1 Hospitalization trends of patients with aortic stenosis (AS): **A** – number of patients hospitalized with the diagnosis of AS; **B** – percentage of AS among all cardiovascular hospitalizations ($P = 0.02$); **C** – rate of patients hospitalized at departments of cardiology, cardiac surgery, intensive cardiac care (ICU), internal medicine, and vascular surgery; **D** – mean age of patients

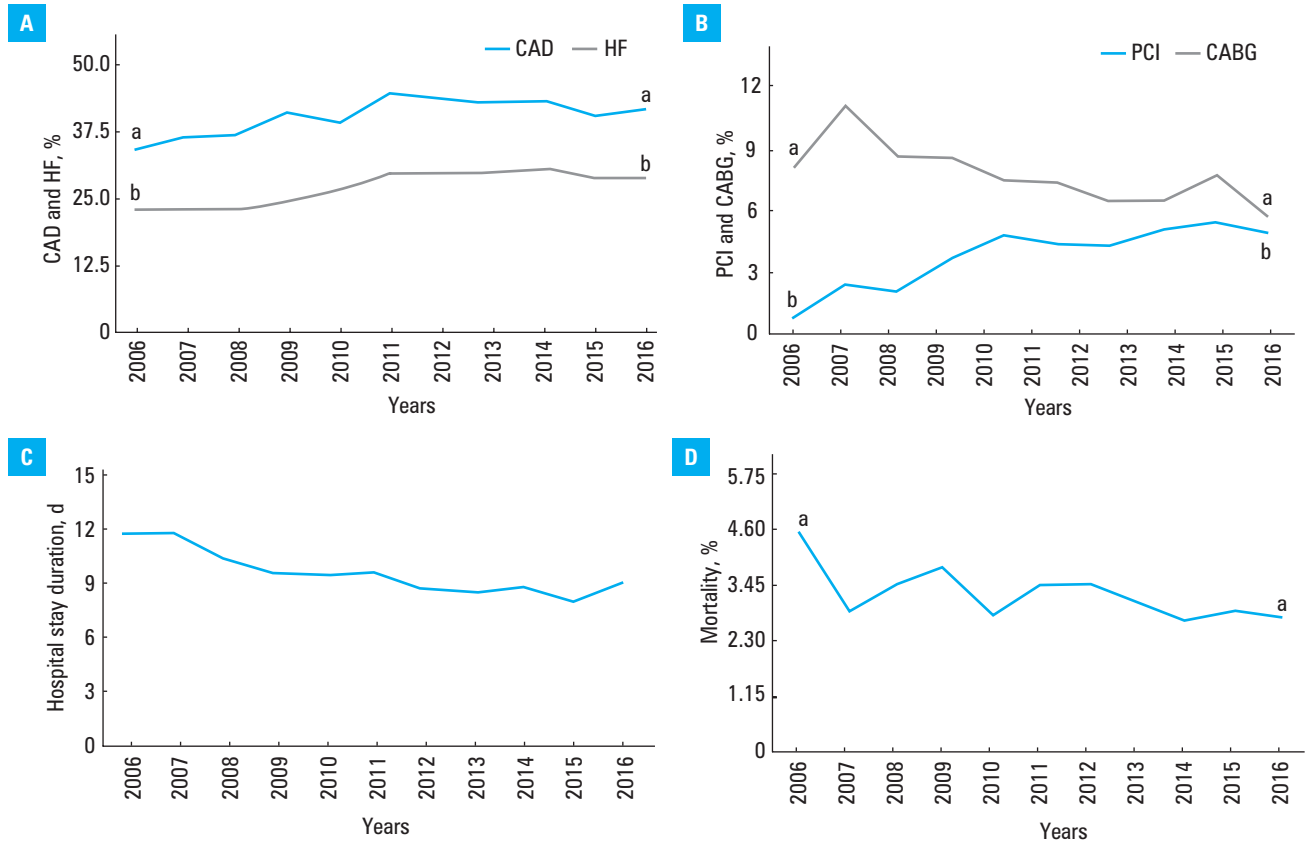

FIGURE 2 Trends for heart failure (HF), coronary artery disease (CAD), myocardial revascularization, length of hospital stay, and in-hospital mortality rate of patients with aortic stenosis (AS): **A** – percentage of coronary artery disease and heart failure coexisting with AS (**a**, **b** $P < 0.01$); **B** – percentage of percutaneous coronary interventions (PCI) and coronary artery bypass grafting (CABG) in patients with AS during the first hospitalization (**a**, **b** $P < 0.01$); **C** – length of hospital stay; **D** – in-hospital mortality (**a** $P = 0.02$)

TABLE 2 Distribution of aortic stenosis hospitalization with concomitant cardiovascular diseases between 2006 and 2016

Disease	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Aortic stenosis	939	875	1100	1343	1366	1522	1564	1542	1577	1661	1669
CAD	323 (34.4)	318 (36.3)	408 (37.1)	550 (41.0)	539 (39.5)	681 (44.7)	684 (43.7)	661 (42.9)	678 (43.0)	675 (40.6)	699 (41.9)
Heart failure	213 (22.7)	202 (23.1)	253 (23.0)	331 (24.6)	365 (26.7)	449 (29.5)	463 (29.6)	464 (30.1)	481 (30.5)	482 (29.0)	484 (29.0)
Pulmonary embolism	2 (0.2)	2 (0.2)	3 (0.3)	2 (0.1)	1 (0.1)	7 (0.5)	2 (0.1)	3 (0.2)	7 (0.4)	12 (0.7)	4 (0.2)
Other valvular diseases	169 (18.0)	156 (17.8)	213 (19.4)	291 (21.7)	304 (22.3)	330 (21.7)	384 (24.6)	324 (21.0)	392 (24.9)	343 (20.7)	325 (19.5)
Congenital heart defect	2 (0.2)	3 (0.3)	5 (0.5)	4 (0.3)	3 (0.2)	5 (0.3)	11 (0.7)	6 (0.4)	5 (0.3)	3 (0.2)	10 (0.6)
Hypertension	333 (35.5)	317 (36.2)	423 (38.5)	534 (39.8)	564 (41.3)	663 (43.6)	640 (40.9)	615 (39.9)	639 (40.5)	631 (38.0)	656 (39.3)
Diabetes	No data	148 (16.9)	206 (18.7)	285 (21.2)	298 (21.8)	356 (23.4)	375 (24.1)	381 (24.7)	408 (25.8)	390 (23.4)	429 (25.7)
COPD	No data	19 (2.2)	22 (2.0)	32 (2.4)	38 (2.8)	53 (3.5)	63 (4.0)	52 (3.4)	64 (4.1)	57 (3.4)	78 (4.7)
Renal insufficiency	No data	48 (5.5)	64 (5.8)	76 (5.7)	111 (8.1)	93 (6.1)	104 (6.6)	117 (7.6)	108 (6.8)	124 (7.5)	127 (7.6)

Data are presented as number (percentage) of patients.

Abbreviations: CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease

was 9.65 (1.24) days, and 492 patients (3.24%) died during hospitalization. The in-hospital mortality rate dropped from 4.5% in 2006 to 3.0% in 2016 ($P = 0.02$) (FIGURE 2).

Concomitant diseases of patients with aortic stenosis Aortic regurgitation was reported in 3877 patients (25.58%); mitral regurgitation, in 615 patients (4.1%); mitral stenosis, in 201 patients (1.32%); and tricuspid valve regurgitation, in 74 patients (0.5%). Heart failure (HF) was reported in 4187 patients (27.62%), and coronary artery disease (CAD), in 6217 patients (41.01%). The number of HF and CAD diagnoses increased over the 10-year period ($P < 0.001$) (FIGURE 2). Hypertension was reported in 6020 patients (39.72%), and other valvular diseases, in 3231 patients (21.32%). Diabetes was found in 3425 patients (22.6%); renal insufficiency, in 485 (3.2%), and chronic obstructive pulmonary disease, in 1015 (6.7%). Pulmonary embolism was diagnosed only in 45 patients with AS (0.3%). The distribution of hospitalizations for AS with concomitant cardiovascular diseases is presented in TABLE 2.

Interventions on the aortic valve During the first hospitalization, an intervention on the aortic valve was performed in 2137 patients (14.10%). The rate dropped from 20.9% in 2006 to 10.1% in 2010 and increased again to 17.6% in 2016 ($P < 0.001$). During the first 12 months after the initial hospitalization, the interventions on the aortic valve were performed in 3416 patients (25.32%) and remained stable over 10-year follow-up. However, the percentage of surgical treatments dropped from 20.34% in 2006 to 16.54% in 2016 ($P < 0.02$). The remaining 13 017 patients (85.88%) were only on optimal medical therapy between 2006 and 2016.

Myocardial revascularization During the first hospitalization, coronary angiography was performed in 5702 patients (37.62%), and percutaneous coronary intervention (PCI), in 666 patients (4.39%). PCI rates increased from 2.6% in 2006 to 5.0% in 2016 ($P < 0.001$) (FIGURE 2). A total of 1071 patients (6.71%) underwent coronary artery bypass grafting (CABG). The rate dropped to 4.3% in 2010, but in 2016 it returned to the level observed in 2006 (7.8%). At 12-month follow-up, coronary angiography was performed in 1623 patients (12.06%), and PCI, in 560 patients (4.15%). PCI rates increased from 1.0% in 2006 to 4.9% in 2015 ($P < 0.001$). CABG was performed in 560 patients (4.15%), and CABG rates decreased from 8.1% in 2006 to 5.8% in 2015 ($P < 0.001$) (FIGURE 2).

Other procedures Cardiac pacemakers were implanted in 239 patients (1.58%), and either implantable cardioverter-defibrillator implantation or cardiac resynchronization therapy (CRT) therapy was performed in 34 patients (0.22%) during the first hospitalization. At 12 months after the initial hospitalization, 77 patients (0.57%) required either ICD or CRT implantation.

Prognosis of aortic stenosis patients Among 13 489 AS patients hospitalized between 2006 and 2015, 1551 patients (11.50%) were hospitalized due to heart failure symptoms, 274 patients (2.03%) due to myocardial infarction, and 244 patients (1.81%) due to stroke. The 1-year mortality rate was 15.88% (2142 patients), and it increased during the follow-up from 14.3% in 2006 to 16% in 2015 ($P = 0.07$). On the other hand, the 30-day mortality rate for all AS patients hospitalized between 2006 and

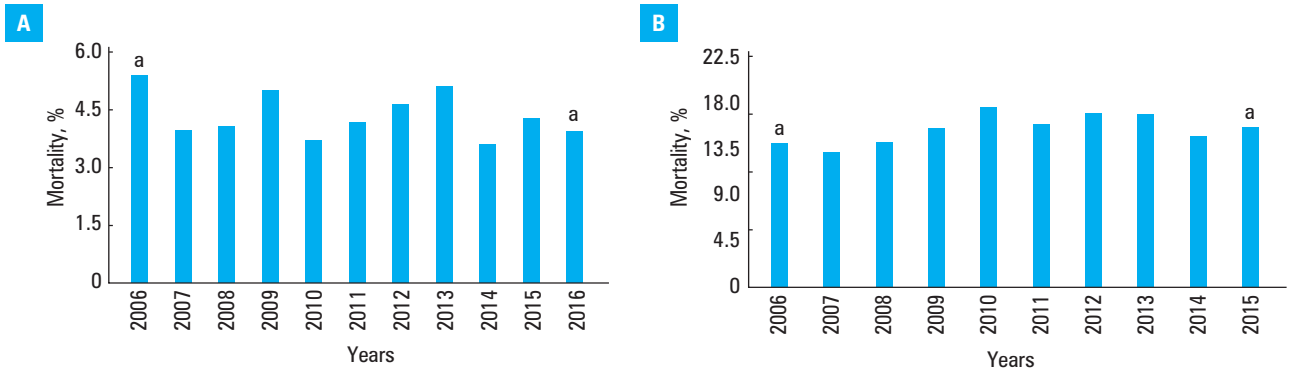

FIGURE 3 Mortality of patients with aortic stenosis; **A** – 30-day mortality (**a** $P = 0.28$); **B** – 1-year mortality (**a** $P = 0.07$)

2016 was 4.35% (659 patients), and it did not decrease over the follow-up (5.4% in 2006 vs 4.0% in 2016, $P = 0.28$) (FIGURE 3). In patients older than 70 years, the 1-year mortality rate dropped from 20.73% in 2006 to 15.20% in 2016. However, during the 10-year follow-up, mortality was higher in patients older than 70 years compared with younger patients (8601 [20.5%] vs 6557 [8.7%], $P < 0.001$). Furthermore, the 1-year mortality rate was lower in women than in men (2384 patients [7.93%] vs 4173 patients [9.24%], $P < 0.001$).

DISCUSSION We presented for the first time the prevalence and trends in the treatment of patients with AS in Poland over the 10-year follow-up. These data are important in that they provide insights into the epidemiology of AS. Such data are essential for defining the local health needs and planning interventions. Our results show that 15158 of AS patients were hospitalized in the years between 2006 and 2016. The data significantly expands on a previous Scottish report on AS prevalence, which was also based on the *ICD-10* classification.[9]

Our results revealed an equal distribution of AS between men and women, which is in contrast to previous American and Japanese reports showing that women were less likely to have AS than men.[10,11] Previous studies showed that AS prevalence and mortality rate are higher in women than in men in an age group of patients older than 65 years.[11] In our report, the 1-year mortality rate was slightly higher in men than in women and was higher for older patients. In Silesian Voivodeship, the rate of patients diagnosed with AS increased almost 5-fold over the 10-year follow-up. This cannot be explained by a longer life expectancy, as it has not changed significantly in the recent years, and the mortality rate from cardiovascular diseases has remained at the same level.[8] Thus, such a growing trend in AS diagnoses may be caused by a more detailed analysis of hospitalized patients, probably due to a broad application of echocardiography in both ambulatory and in-hospital care. The SILCARD data showed a significant increase in the rate of AS diagnosis at internal medicine departments where the application of echocardiography has significantly increased over the last years.

Almost one-third of AS patients were reported to present symptoms of HF. Since the *ICD-10* classification does not distinguish patients with or without severe AS, the reported HF symptoms might have represented the AS population with the poorest prognosis. It was previously documented that the incidence of heart failure in AS patients increased the 5-year mortality rate for both moderate and severe AS.[12] The SILCARD registry provided data on the rate of patients subjected to aortic intervention, and on this basis, it might be suspected that around 25% of patients had significant AS. Interestingly, the rate of AS related to interventions did not change but the number of procedures increased over the 10-year follow-up. The number of aortic interventions represents all procedures performed on the aortic valve, from balloon valvuloplasty to surgical aortic valve replacement and TAVI. As the number of TAVI procedures has been increasing in Poland, the presented data supposedly reflect future population needs.[13]

AS has a significant impact on the patient's prognosis, especially in the presence of another cardiovascular comorbidity.[14,15] For example, coexistent CAD was shown to worsen prognosis of AS patients.[16,17] According to the SILCARD registry, half of the patients had been diagnosed with CAD, but only around 10% required percutaneous or surgical revascularization. Interestingly, the number of PCIs increased over the follow-up. It may be explained by the increased number of TAVI procedures which are accompanied by percutaneous revascularization of CAD. The management of significant CAD in patients with AS is safe and improves their outcomes, both in those referred for aortic valve replacement plus CABG or for TAVI plus PCI.[16,18,19] From the standpoint of disease prevention, appropriate control of common cardiovascular risk factors in middle age decreased AS and atherosclerosis prevalence in older age.[20,21] However, the prevention should address a broad spectrum of cardiovascular risk factors, since aggressive lipid-lowering therapy alone is not enough. It decreases the number of CAD incidents and reduces the number of coronary

revascularizations in AS patients, but it does not have any impact on AS prevalence.[22]

Although the number of patients with diagnosed AS has increased over the last decade, the 30-day in-hospital mortality rate has dropped. One-year mortality rate was still high and was maintained at a level of around 15%, but it should be considered given aging and a growing rate of coexisting extracardiac diseases. Furthermore, these proportions were large compared with data from other publications. A Japanese registry reported that untreated AS was associated with a mortality rate of 6.7% at 16-month follow-up.[23] AS patients in the SILCARD registry probably had different clinical characteristics at baseline compared with other registries, which might have impacted their general prognosis. The registry mostly involved patients with symptomatic AS, excluding those with poor clinical symptoms but an increased risk of adverse events.[24] As mentioned below, the SILCARD registry also has significant limitations, which might have affected the results. Nevertheless, further detailed studies are needed to identify the cause of death in AS patients in Silesian Voivodeship in Poland.

Study limitations The AS diagnosis was based only on the *ICD* codes reported to the National Health Fund. The codes represent the primary cause of hospitalization and, according to Polish regulations, the reporting of coexisting diseases is not mandatory. Furthermore, the order of reported diagnoses is subjective, and some of the important comorbidities may not be recorded in the registry. Moreover, the reporting based on the *ICD* classification does not help identify severe AS, which has the most significant impact on prognosis. Also, some patients with AS might have been lost to follow-up or they might have continued treatment in centers that are not covered by the SILCARD registry. Finally, AS could be underdiagnosed or overdiagnosed in challenging cases, such as low-flow low-gradient AS. All these limitations must be considered when drawing conclusions from our data.

Conclusions According to the SILCARD registry, the number of diagnosed AS patients is increasing. Our data show that AS has become one of the most critical problems among cardiovascular diseases in Silesian Voivodeship. Although the number of aortic valve interventions has increased, the 1-year mortality rate remains high. This leaves a considerable space for developing measures to meet local health needs.

CONTRIBUTION STATEMENT TR conceived the concept for the study. TR, TG, and ZG prepared the manuscript. MH and DC analyzed the data. MZ, WW, and MG were involved in data collection. MZ and MG coordinated funding for the project. All authors edited and approved the final version of the manuscript.

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