

The Polish Interventional Cardiology TAVI Survey (PICTS): 10 years of transcatheter aortic valve implantation in Poland. The landscape after the first stage of the Valve for Life Initiative

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ABSTRACT

INTRODUCTION Few studies assessed the development of transcatheter aortic valve implantation (TAVI) in Poland since its introduction in 2008. Effects of the Valve for Life Initiative in the country have not been reported.

OBJECTIVES The aim of the study was to investigate TAVI adoption and practice in Poland in the years 2008 to 2019.

PATIENTS AND METHODS The Polish Interventional Cardiology TAVI Survey (PICTS) analyzed reports of TAVI activity in all 23 TAVI centers. It consisted of 94 questions and encompassed the following topics: 1) characteristics of centers; 2) the annual number of TAVI procedures in the years 2008 to 2019; 3) pre-, intra-, and postprocedural management of patients; and 4) a list of TAVI team members. It was obligatory to answer all questions. The registry survey was published online.

RESULTS Since 2008, 102 certified operators have performed a total of 6910 procedures. In 2019, the annual number of TAVI reached 1550 (40.38 implants per 1 000 000 inhabitants). Among patients aged 65 years and older, TAVI penetration rate was 18.65% in 2019. Inoperable and high-risk patients were treated in all centers, while 18 also treated medium- and 5 treated low-risk individuals. The rate of transfemoral implantations increased to 93.5% of all procedures.

CONCLUSIONS The survey highlighted a slow increase in the rate of TAVI adoption in Poland. We found a significant treatment gap in patients with severe aortic stenosis. Remarkable regional variations in TAVI experience exist among Polish TAVI centers. Further multinational cooperation is warranted to tackle the identified limitations in access to this life-saving procedure.

INTRODUCTION Degenerative aortic stenosis (AS) is the most common valvular heart disease in European countries. The burden of this disease on public health and healthcare resources

is expected to rise due to population aging observed in developed countries. Valve replacement is the only effective treatment for patients with symptomatic AS with otherwise poor prognosis,

WHAT'S NEW?

In the last 2 decades, transcatheter aortic valve implantation (TAVI) has been introduced to treat aortic stenosis (AS) safely and effectively in the group of patients at high, intermediate, and even low surgical risk. However, variations in regulatory, economic, and social circumstances influence disparity in TAVI adoption and practice in Europe. The Polish Interventional Cardiology TAVI Survey (PICTS) highlighted a slow rate of TAVI adoption in Poland in comparison with other countries of the European Union. It also demonstrated wide variations in experience, volume, and practice among Polish TAVI centers. Intensive healthcare, economic, and scientific planning is needed to address the growing need to save lives of patients with severe AS in Poland.

as no medical therapy modifies the progression of the disease. In the last decade, transcatheter aortic valve implantation (TAVI) has been introduced to treat patients with AS safely and effectively.¹⁻³ However, differences in regulatory, economic, and social circumstances cause disparities in TAVI adoption and practice in Europe.⁴ Few studies assessed TAVI development in Poland, the sixth most populated country of the European Union. Also, there is a paucity of data on TAVI activity and practice in the countries of Central and Eastern Europe.⁴⁻⁷ We sought to address this gap by evaluating the progress and status of TAVI in Poland using a national web-based survey. The specific aims of the study were to analyze the adoption of TAVI in Poland and to detect differences among Polish centers in practice and decision-making. Since 2015, Poland has been one of the beneficiaries of the Valve for Life Initiative of the European Association of Percutaneous Cardiovascular Intervention (EAPCI), which provided resources for the education of physicians, patients, and healthcare authorities. The long-term aim of the Valve for Life Initiative is to reduce disparities across Europe and increase the availability of effective treatment for valvular heart disease. The Valve for Life Initiative in Poland has been extended into 2020 because, despite its success, there is still an unmet need for wider access to timely valve replacement even in the high-risk group.⁸ The current publication is a continuation of the first report published in 2017.⁷

PATIENTS AND METHODS The survey investigated TAVI practice in Polish centers. It consisted of 94 single- and multiple-choice questions focused on the following topics: 1) characteristics of TAVI centres in Poland; 2) the annual number of TAVI procedures in the years 2008 to 2019; 3) pre-, intra-, and postprocedural management of patients; and 4) a list of TAVI team members in the participating center. It was obligatory to answer all questions with the possibility to comment on any of them. The survey was published online (<https://picts.pl>), and formal invitations were sent to all Polish TAVI teams to participate. Responses were collected electronically by the end of December 2020.

The study complies with the Declaration of Helsinki. As the research protocol of this prospective, observational study did not involve any patient data, it did not require additional approval of an ethics committee.

We defined the penetration rate as a measure of actual TAVI use relative to its potential use in patients with symptomatic severe AS at prohibitive, high, medium, and low surgical risk, who could potentially be treated with TAVI. The number of annual potential TAVI candidates was estimated using the already published model.⁹ Reports of the Polish Central Statistical Office were used to estimate the number of inhabitants aged 65 years and older for TAVI penetration analysis as well as to calculate an annual number of TAVI implants per 1 000 000 inhabitants.

Statistical analysis Continuous and categorical variables are presented as numbers and percentages. The TAVI forecast was performed using the Auto-Regressive Integrated Moving Average (ARIMA) model using stationary R^2 as a goodness-of-fit measure. All data analyses were conducted using the SPSS statistical software, version 22.0 (SPSS Inc., Chicago, Illinois, United States).

RESULTS All 23 Polish TAVI sites participated in the study: 1 institute, 14 university hospitals, 6 community hospitals, and 2 private hospitals (FIGURE 1). Following the European Society of Cardiology (ESC) guidelines¹⁰ and recommendations of the Polish position paper,³ 23 multidisciplinary Transcatheter Heart Teams have been established, with 105 operators, including 59 interventional cardiologists and 46 cardiothoracic surgeons. The centers differed in terms of TAVI volume. Since 2008, 4 centers performed more than 500, while 10 centers performed less than 200 procedures in total (FIGURE 2). In 2019, 5 centers performed more than 100 TAVIs and 8 performed less than 50.

Between 2008 and 2019, the cumulative number of TAVI procedures performed in Poland was 6910. The annual TAVI volume growth rate was positive during all years, and in 2019 it increased by 23% (to 1550 procedures) as compared with the previous year (FIGURES 3, 4A and 4B). The annual number of TAVI procedures per 1 000 000 inhabitants rose from 0.21 (1.55 in individuals aged ≥ 65 years) in 2008 to 40.38 (223.12 in individuals aged ≥ 65 years) in 2019 (FIGURE 4A and 4B). The 5-year forecast of TAVI procedures in Poland was calculated using the ARIMA (0,2,2) model based on historical data from the years 2008 to 2019 and following autocorrelation function plots. The projected number of TAVI procedures in 2024 was 3663 (lower control limit, 3486; upper control limit, 3839; FIGURE 3).

Based on the recently published algorithm,⁹ we assessed the number of TAVI-eligible patients in 2019. Among patients aged 65 years and older who could not qualify for surgical aortic valve

FIGURE 1 Geographic distribution of 23 transcatheter aortic valve implantation centers in Poland in 2019

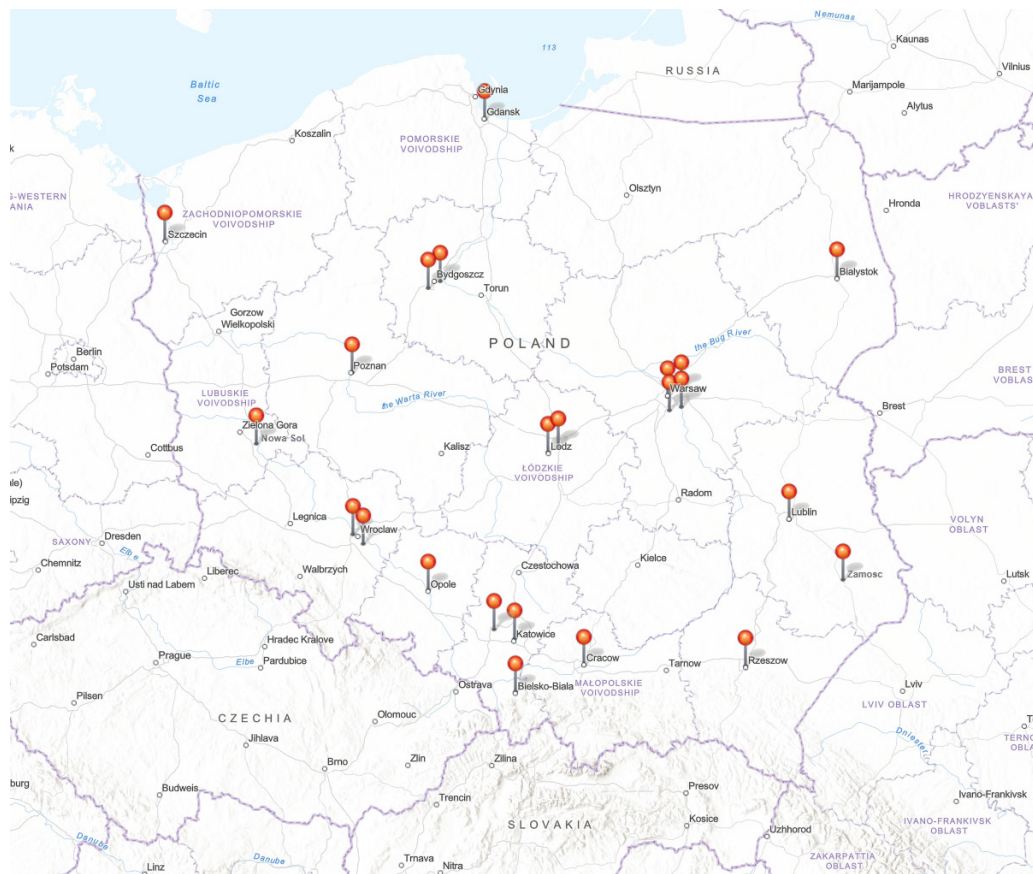
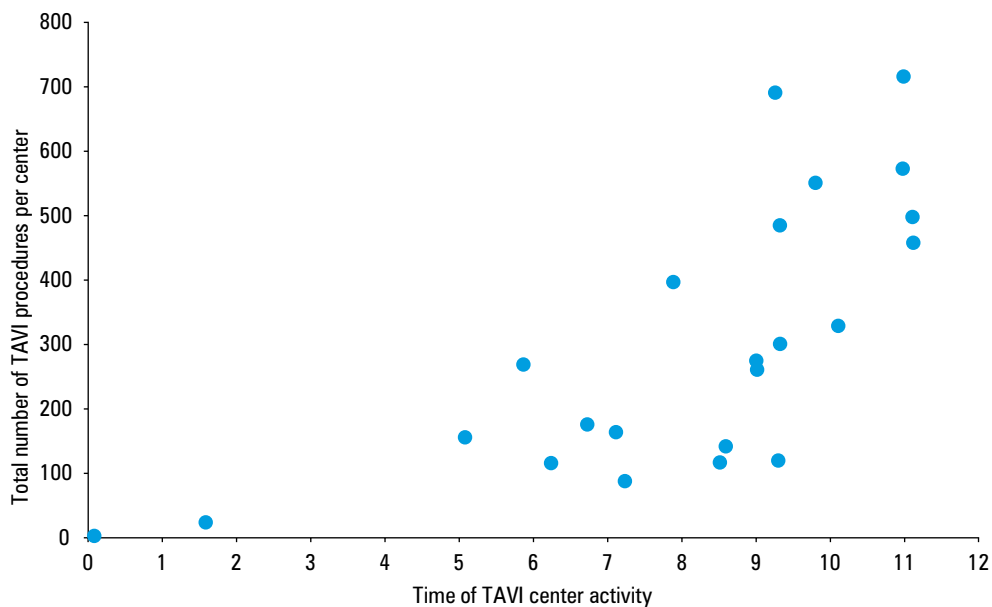


FIGURE 2 Total cumulative number of transcatheter aortic valve implantation (TAVI) procedures performed in Polish centers depending on their activity time



replacement (SAVR) in 2019, the TAVI penetration rate was 18.65% (Supplementary material, *Table S1*).⁹

All centers performed TAVI in inoperable and high-risk patients (Society of Thoracic Surgeons [STS] score >8). Medium-risk patients were referred for TAVI in 18 centers, while low-risk patients (STS score <4) were offered transcatheter treatment in 5 centers.

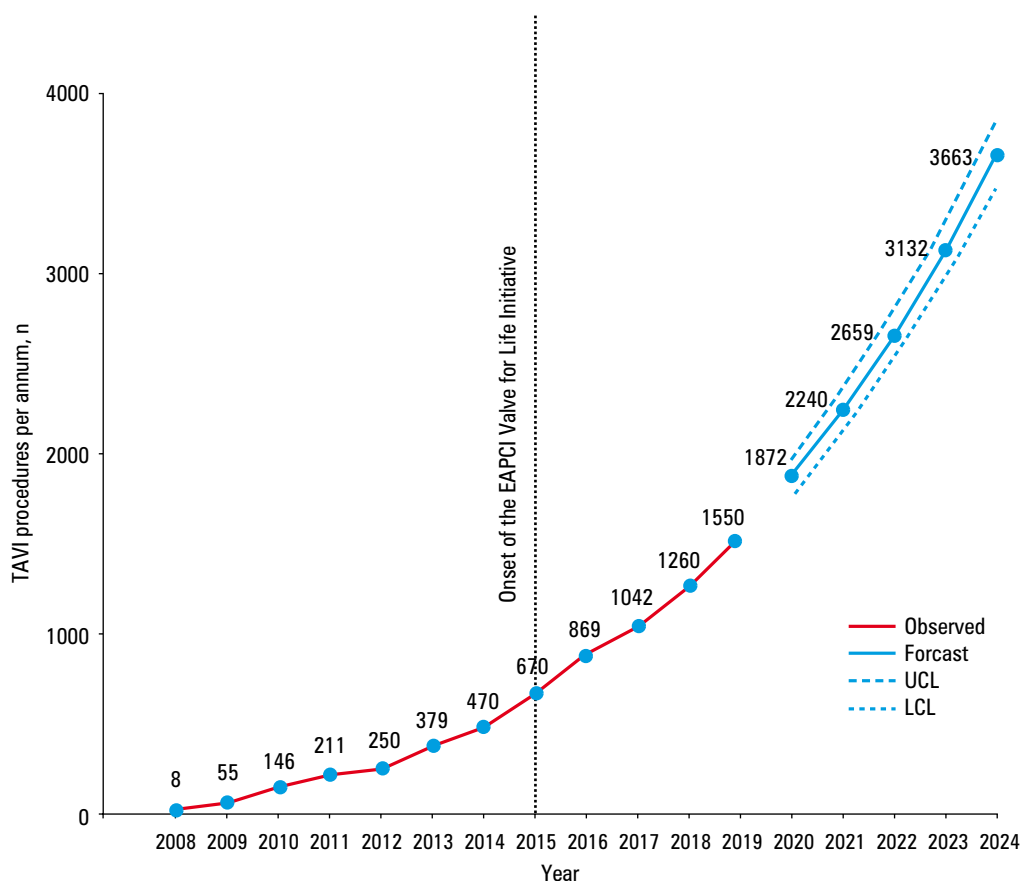
TAVI-specific multislice computed tomography imaging of the heart and peripheral vessels was mandatory in all centers as part of preprocedural

planning. Transesophageal echocardiography was routinely used in 7 hospitals.

If a patient was diagnosed with significant coronary artery disease, a strategy of preventive percutaneous coronary intervention (PCI) of main vessels was used by default in all centers. In 3 of them, such patients were referred for simultaneous PCI during TAVI procedure, and only 4 centers decided to postpone PCI in such circumstances.

In patients with coronary artery disease scheduled for TAVI via the femoral approach using surgical cutdown or closure devices, 19 centers

FIGURE 3 Temporal changes in the volume of transcatheter aortic valve implantation (TAVI) procedures in Poland in the years 2008–2019 and forecast analysis of TAVI procedures in Poland in the years 2019–2024; Auto-Regressive Integrated Moving Average (ARIMA) (0,2,2) model, stationary $R^2 = 0.568$; $R^2 = 0.994$ Abbreviations: EAPCI, European Association of Percutaneous Cardiovascular Intervention; LCL, lower control limit



allowed for dual antiplatelet therapy (DAPT) to be maintained during TAVI. In patients referred for the procedure via the transapical access, 5 centers allowed for DAPT, 7 recommended aspirin only, and 10 stopped antiplatelet therapy before the TAVI procedure.

In 2019, transfemoral access was the default approach in all centers and it was used in 93.5% of the procedures. Proportions of the alternative routes are presented in [FIGURE 5](#).

All TAVI teams adopted the Core Valve/ EvolutR systems (Medtronic, Minneapolis, Minnesota, United States). The SAPIEN XT/3 systems (Edwards Lifesciences, Irvine, California, United States) were introduced in 17 out of 23 centers, Accurate Neo (Boston Scientific, Marlborough, Massachusetts, United States) in 11, Portico (Abbott Vascular, Redwood City, California, United States) in 8, Lotus (Boston Scientific) in 6, and MyVal (Meril Life Sciences Pvt. Ltd., Vapi, Gujarat, India) in a single center. The Hydra valve (Vascular Innovations, Nonthaburi, Thailand) and ALLEGRA bioprosthesis (New Valve Technology, Hechingen, Germany) were used within clinical trials in 1 and 2 centers, respectively. Before its discontinuation, Engager (Medtronic) was used in 10 centers.

During 11 years of TAVI activity, the most frequently used systems were Core Valve/ EvolutR (57.7%), followed by SAPIEN XT/3 (27.1%) and Accurate (6.9%). In 2019, the proportions of TAVI systems used to treat AS were as follows: EvolutR (58.4%), SAPIEN 3 (20.9%), Accurate (11.4%), Portico (8.9%), and Lotus (0.4%) (Supplementary material, [Table S2](#)).

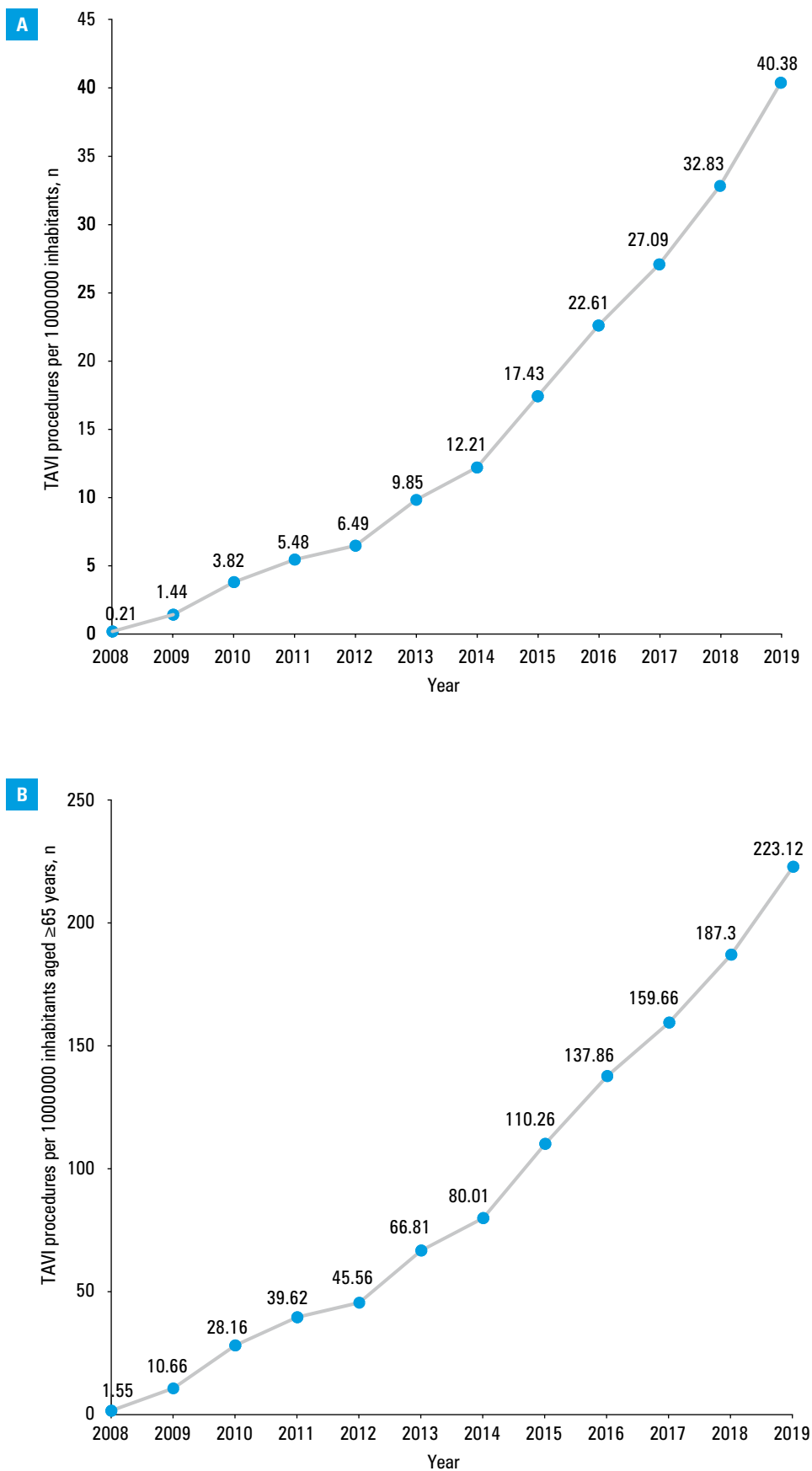
Periprocedural antibiotic prophylaxis was routinely implemented in 20 (91%) centers, 17 (77%) used local anesthesia as a default approach, and 15 (68%) performed routine TAVI without the use of aortic balloon valvuloplasty.

Percutaneous closure devices were used for the transfemoral approach in 13 (59%) centers: all these teams used the ProGlide Suture-Mediated Closure Systems (Abbott Vascular, Redwood City, California, United States), while a single center also used the Prostar XL Percutaneous Vascular Surgical System (Abbott Vascular). The Manta Vascular Closure Device (Teleflex, Morrisville, North Carolina, United States) was introduced in 3 centers in 2019.

Based on the PICTS reports from 2018, among all TAVI centers in Poland, 18 patients (1.43% of TAVI procedures) required urgent conversion to SAVR or surgical intervention due to complications during the index hospitalization. Among patients without evidence of new conduction system abnormalities, in 3 (13.5%) centers the operators removed the right ventricular electrode in the operating room, 10 (45.5%) teams left it for 24 hours, while in 9 (41%) centers, the operators maintained the electrode for 2 days after the procedure.

The antithrombotic regimens prescribed after TAVI varied between the centers: 2 of them (9%) recommended routine single antiplatelet therapy, 20 (91%) recommended DAPT, and none advised oral anticoagulant therapy in patients without other indications. In patients with atrial fibrillation, vitamin K antagonists or novel oral anticoagulants alone were prescribed in 4 (18%) centers, while a combination therapy with single antiplatelet therapy was used in the remaining 18 (81.8%).

FIGURE 4 The annual number of transcatheter aortic valve implantation (TAVI) procedures per 1 000 000 inhabitants (A) and per 1 000 000 inhabitants aged 65 years and older (B) in the years 2008–2019 in Poland

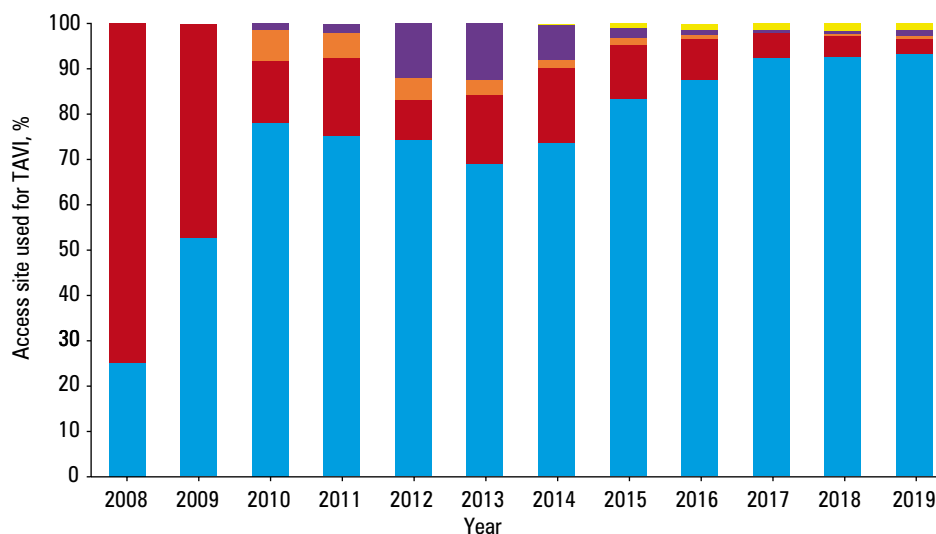


Continuation of DAPT for 3 months was recommended in 12 (54.5%) centers, for 6 months in 9 (41%) centers, and 1-year therapy was recommended in a single center (4.5%).

Structured follow-up of patients varied between the centers. A TAVI-oriented clinic has

been established in a single hospital. Cardiology clinics were responsible for the follow-up in 8 (36.4%), cardiac surgery clinics in 5 (22.7%), while a hybrid scheme of follow-up in cardiac surgery and cardiology clinics was used in 9 (41%) centers.

FIGURE 5 Temporal changes of vascular access site use for transcatheter aortic valve implantation (TAVI) in Poland in the years 2008–2019



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Transcarotid							1	6	11	14	20	21
Direct aortic			2	4	30	47	36	15	11	6	7	19
Subclavian			10	12	12	13	9	11	8	1	7	12
Transapical	6	26	20	36	22	57	77	79	77	56	58	49
Transfemoral	2	29	114	159	186	262	347	559	762	965	1168	1449

DISCUSSION The PICTS analyzed trends in TAVI adoption and practice in Poland since its introduction in 2008 and summarized the experience of TAVI operators. The main findings of the report are outlined below. The number and distribution of the established TAVI centers allow for providing adequate treatment to patients with severe AS. Still, access to treatment remains limited by a yearly number of procedures reimbursed by the national health system. The annual TAVI volume has been increasing since its introduction, but the growth is still suboptimal given the number of patients meeting the clinical and anatomical profile of TAVI eligibility. The development of the Polish TAVI consensus recommendations set the framework for training, certification, and structure of the Heart Teams.³ Accordingly, an adequate number of operators have been trained and certified in the last decade. Centres differ in total TAVI volumes, and the median number of implants per year suggests that in low-volume sites repeated training may be needed to maintain the competence of the operators.

Over the last decade, the rapidly evolving technology transformed a complex transcatheter intervention into a standardized and streamlined procedure. Positive outcomes of clinical trials conducted in all risk groups of patients with severe AS sparked its popularity in developed countries. From the beginning, indications for TAVI have been progressively changing, extending from patients at prohibitive and high surgical risk to moderate- and low-risk individuals. The results of the first randomized trials in inoperable and high-risk patients provided solid evidence for the adoption of TAVI.¹¹⁻¹³ Later studies confirmed that TAVI is not worse compared with surgery in the group of patients at intermediate risk, while the PARTNER III, NOTION, and Evolut Low-Risk trials, as well as a number of registries

opened the door for transcatheter treatment of low-risk patients with AS.¹⁴⁻¹⁸ The ESC updated the guidelines for valve disease in 2017, assigning class I, level B evidence for TAVI treatment for the first time, even in patients at moderate risk if the Heart Team recognizes a contraindication to surgery.¹⁰ The above trials were conducted in the most active American and Western European centers which shared their encouraging experiences with other countries.

The rate of TAVI implementation in Europe varies between the countries, mostly depending on the levels of health spending and reimbursement opportunities. Intensive economic strategies and health policies developed to tackle the main causes of mortality allowed for a faster spread of TAVI to intermediate and low surgical risk groups.¹⁹ In 2017, the annual number of TAVI procedures in Germany reached almost 20 000 (n = 19 752), with the rate of 250 per 1 000 000 inhabitants.^{20,21} In 2015, the number of TAVI procedures in France represented one-third of all aortic valve replacements with an annual number of 6722 procedures, while in 2016 it exceeded 9100 to reach the SAVR volume with 137 implants per 1 000 000 inhabitants.²² The PICTS showed that the numbers of established TAVI centers and operators trained in Poland were sufficient to offer treatment for symptomatic AS patients, meeting the standards of Western European countries. Unfortunately, after a decade of their activity, the annual national rate of TAVI procedures was only 40 per 1 000 000 inhabitants. Based on the model proposed by Durko et al,⁹ the estimated annual number of all candidates for TAVI in Poland in 2019 was 8310, with effective penetration rate of 18.65%. Our forecast analysis predicted that without serious efforts to enhance the availability of TAVI, the situation would not improve in 5 years. A reduction in the access to treatment observed

during the COVID-19 pandemic may further impact this ominous prognosis (FIGURE 3).

The following causes of the slow implementation of TAVI in Poland could be identified. First, the Polish health expenditure as a proportion of the gross domestic product is 6.7%, which is one of the lowest rates in the European region of the World Health Organization.²³ The annual number of procedures per center is limited by contracts with the National Health Fund. Decreasing reimbursement for the intervention only allows for covering the cost of hardware, not reflecting the expenses for patient care or skilled workforce. Reimbursement for the screening of patients with AS does not balance expenditures for the clinical assessment, required imaging, or revascularization. Finally, strategies analyzing the cost-effectiveness of AS treatment are missing in Poland. The EAPCI introduced the Valve for Life Initiative in 2015, boosting the policies of the Polish Cardiac Society framed to tackle the limitations in the access to life-saving treatment of AS. The primary goal of this campaign is to promote knowledge about TAVI among the elderly population and healthcare professionals. The Valve for Life Initiative helps to create an environment for discussion on the optimal treatment selection for patients with severe AS.^{24,25}

The reported distribution of patients based on their risk profile in Polish centers adheres to the current ESC recommendations to provide TAVI to patients at extreme-to-moderate surgical risk. Low acceptance rate of low-risk patients may result from the allocation of the limited resources to higher-risk groups. Multislice computed tomography is the imaging technique of choice for aortic valve and access route assessment in accordance with the European standards.²⁶⁻²⁸ Percutaneous coronary interventions are performed before TAVI in all centers, in keeping with the actual European recommendations for revascularization. The observed practice of performing PCI during TAVI (used in 3 centers) or postponing the procedure (adopted in 4 centers) may reflect the priority given to the treatment of AS and incomplete evidence for the management of coronary artery disease before TAVI.^{29,30} Similarly, limited use of antiplatelet therapy after TAVI and its combination with antithrombotic treatment in patients with atrial fibrillation may explain the existing variations in Polish practice.^{31,32}

In 2019, almost one-third of the centers performed less than 50 procedures in total. Such a result reflects polarization in terms of the experience of the Polish Heart Teams. It also highlights the different levels of experience between the TAVI centers in Western Europe and in Poland. A national TAVI consensus was published in 2017 to stimulate unification of screening, procedural approach, and follow-up practice across the country. Although Poles represent 8.52% of the population of the European Union and 4 TAVI centers performed more than 500 procedures by the end of 2019, few controlled studies

or large-scale registries of this field were conducted in our country.^{7,19,25,28,30} Stimulation of research activity may help to increase the quality and access to advanced AS therapy in Poland.

Interestingly, the survey observed a low reported rate of rescue conversion to SAVR or surgical treatment of in-hospital TAVI complications. With the growing safety profile of TAVI interventions, simplified and early discharge protocols could be proposed in high-volume centers to achieve the best clinical outcomes and to intensify their cost-effectiveness.

In summary, our study confirms the gap in access to life-saving therapies of AS in Poland. Despite the presence of certified TAVI centers, the adoption of this proven technology has been slow in the last decade, with 18% of TAVI-eligible patients having been treated in 2019. Intensive healthcare, economic, and scientific planning is needed to address the growing need for treatment of patients with severe AS. Cooperative efforts on a multinational level are warranted, which could be guided by cooperation with the EAPCI and survey extension to countries of Central and Eastern Europe.

Limitations This was a voluntary observational study and the provided data were not audited locally. The numbers of procedures reported were not validated with registries of national health system administration in the years 2008 to 2013 due to the lack of such reports. Direct comparisons with TAVI adoption practices in countries of Central and Eastern Europe were not presented due to the absence of published reports.

Conclusions The PICTS highlighted a slow increase in the number of TAVI procedures in Poland. When compared with reports from other European countries, our findings point to a large treatment gap in patients with severe AS, including those at high risk of SAVR. Efforts should be made to increase the availability of TAVI to populations considered eligible by the current evidence-based recommendations. In addition, remarkable regional variations in TAVI experience and practice exist among Polish TAVI centers.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/paim.

ARTICLE INFORMATION

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CONTRIBUTION STATEMENT All authors contributed to the study concept, design, and supervision. RP and MD conducted the study and analyzed and interpreted the data. All authors participated in drafting and revising the manuscript and approved its final version.

CONFLICT OF INTEREST None declared.

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