

# The Polish Interventional Cardiology TAVI Survey (PICTS): adoption and practice of transcatheter aortic valve implantation in Poland

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Adv Interv Cardiol 2017; 13, 1 (47): 10–17  
DOI: <https://doi.org/10.5114/aic.2017.66181>

## Abstract

**Introduction:** Few studies have assessed the development of transcatheter aortic valve implantation (TAVI) in Poland since its introduction in 2008, and data on current TAVI activity or practice are missing.

**Aim:** To assess the dynamics of TAVI adoption in Poland and to detect differences among Polish centres in TAVI practice and decision-making.

**Material and methods:** The Polish Interventional Cardiology TAVI Survey (PICTS) was approved by the Polish Association of Cardiovascular Interventions and presented to all 21 national TAVI centres. Between 2008 and 2015 the cumulative number of TAVI performed in Poland was 2189. The annual number of TAVI rose from 8 in 2008 to 670 in 2015 (0.21 to 17.4 implants per million inhabitants, respectively).

**Results:** The median TAVI experience per centre was 80 procedures (95% CI: 38.1–154.6). In 2015 the TAVI penetration rate reached 5.12% of the estimated eligible Polish population. Inoperable and high-risk patients are treated with TAVI in all centres, with 52% of Heart Teams also qualifying medium-risk patients. The rate of transfemoral implantations increased to 83.2% of all procedures in 2015, while transapical implantations decreased to 12%. The frequency of subclavian, direct aortic or transcatheter routes in 2015 was below 3% each.

**Conclusions:** The PICTS survey observed a positive but slow rate of adoption of TAVI in Poland. When compared to Western European countries, our findings highlight a significant treatment gap in high or prohibitive surgical risk patients with severe aortic stenosis. Remarkable variations in TAVI practices among Polish TAVI centres warrant publication of joint national guidelines and recommendations.

**Key words:** heart failure, transcatheter aortic valve implantation, transcatheter aortic valve replacement, aortic valve stenosis, Heart Team, aortic valve regurgitation.

## Introduction

Since the first-in-man procedure performed in 2002, transcatheter aortic valve implantation (TAVI) has become the treatment of choice for inoperable patients and an alternative for high-risk patients with severe, symptomatic aortic stenosis [1, 2]. However, variations in regulatory, economic and social circumstances, as well as disease prevalence, influenced the disparity in TAVI adoption and practice in European countries [3]. So far, few studies have assessed TAVI development in Poland,

and there is a paucity of data on TAVI activity and practice in the countries of Central and Eastern Europe [3–5]. The Association of Cardiovascular Intervention of the Polish Cardiac Society (ACVI) sought to address this gap by assessing the progress and current status of TAVI in Poland through a national web-based survey.

## Aim

Specific aims of the study were to analyse dynamics of TAVI adoption in Poland since its introduction in 2008

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Received: 23.11.2016, accepted: 30.12.2016.

and to detect differences among Polish centres in practice and decision-making in percutaneous aortic valve therapy.

## Material and methods

### Data sourcing

The survey was designed to investigate TAVI activity and practices in Polish interventional cardiology centres. It consisted of 41 single and multiple-choice questions focused on the following topics: 1. characteristics of centres involved in the TAVI programme in Poland; 2. the annual number of TAVI implants from 2008 to 2015; 3. practice of pre-, intra- and post-procedural patient management. It was obligatory to answer all questions with the possibility to comment on any of them. After approval of the questionnaire by the ACVI in January 2016, the survey was published online at the ACVI official website, and formal invitations were sent to all invasive cardiology centres involved in the TAVI programme in Poland to participate. Responses were collected electronically by the end of February 2016.

### Transcatheter aortic valve implantation penetration

We determined TAVI penetration rate as a measure of TAVI use relative to its use in patients with symptomatic severe aortic stenosis at high or excessive surgical risk that could potentially be treated with TAVI [6]. Following the already published methodology, among elderly inhabitants aged  $\geq 75$  years with severe aortic stenosis (3.4%), 75.6% were estimated to be symptomatic, 40.5% were deemed to be inoperable due to excessive surgical risk, and 5.2% were determined to be at high operative risk. 40.3% of inoperable patients and 80% of the high-risk patients were deemed to be potential TAVI candidates. Polish Central Statistical Office reports were used to esti-

mate the size of the elderly population aged  $\geq 75$  years for TAVI penetration analysis as well as to calculate the annual number of TAVI implants per million population and the number of TAVI centres per million population in Poland.

The results are presented in the paper as descriptive statistics.

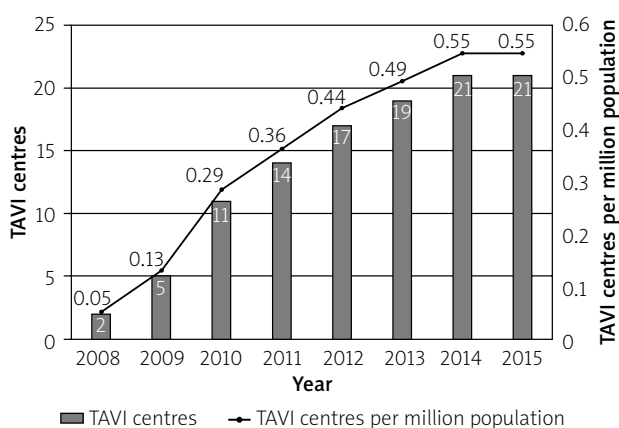
## Results

### Description of centres

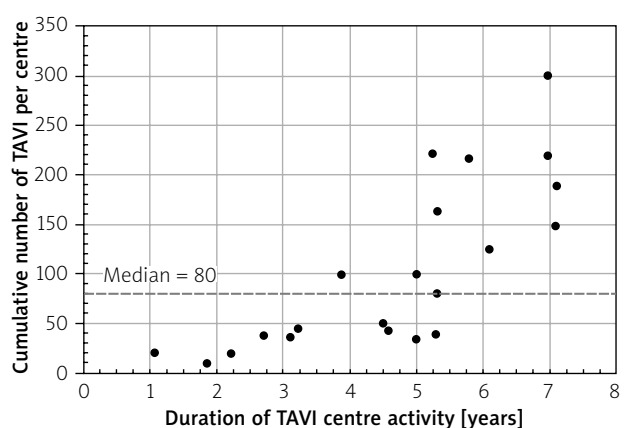
The TAVI programme was introduced in Poland in December 2008 and expanded across 21 centres by the end of 2015 (Figure 1). The number of TAVI centres per million population increased from 0.05 in 2008 to 0.55 in 2015. All of them fully participated in the survey: 15 (71%) university centres, 5 (24%) community hospitals and 1 (5%) private hospital. Following recommendations of the European Society of Cardiology, 21 multidisciplinary Heart Teams involving 46 certified interventional cardiologists were established in all TAVI centres [7]. The distribution of TAVI experience across centres varied widely. The median cumulative number of TAVI implants per centre was 80 (95% CI: 38.1–154.6). From 2008 to 2015, 4 centres performed more than 200 (19%) procedures, 4 centres performed between 100 and 200 procedures (19%), while 13 centres performed less than 100 procedures (62%; Figure 2). The median number of TAVI procedures per centre per annum increased from 4 in 2008 to 24 (95% CI: 13.7–41.4) in 2015. In the last year of survey, 5 centres performed 50–100 procedures (24%), 7 centres 20–49 procedures (33%) and 9 centres fewer than 20 procedures (43%).

### Number of transcatheter aortic valve implantation procedures

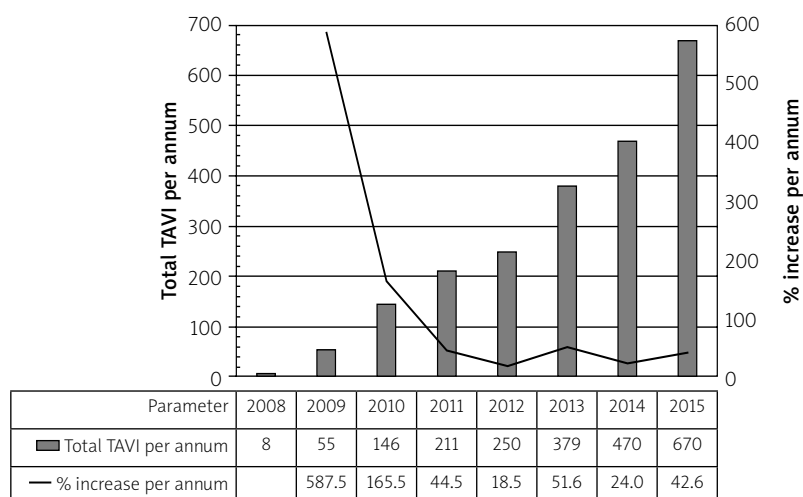
Between December 2008 and December 2015 the cumulative number of TAVI procedures performed in Poland



**Figure 1.** A cumulative number of transcatheter aortic valve implantation (TAVI) centres and number of TAVI centres per million population in Poland from 2008 to 2015



**Figure 2.** The TAVI activity in 21 Polish centres: Cumulative number of TAVI procedures per centre during years of activity (black markers represent single centres, median = 80 procedures, grey line)



**Figure 3.** The TAVI procedures in Poland per annum and percentage of their annual increase

was 2189. The annual number of implantations increased from 8 in 2008 to 670 in 2015. The annual procedural volume growth rate was positive during all years, with a 42.6% increase in 2015 (Figure 3). The annual number of TAVI procedures per million inhabitants rose from 0.21 in 2008 to 17.4 in 2015. The annual number of TAVI implants per million inhabitants aged  $\geq 75$  years increased from 3.2 in 2008 to 247.6 in 2015 (Figures 4 A and B).

#### Transcatheter aortic valve implantation penetration in Poland

Depending on Polish Central Statistical Office reports we estimated the number of potential TAVI candidates in the years from 2008 to 2015. Based on the number of TAVI recipients per annum, we calculated TAVI penetration rates presented in Table I. Consequently, out of 13 076 TAVI eligible patients in 2015, 670 were treated with TAVI, leading to a 5.12% penetration rate in 2015.

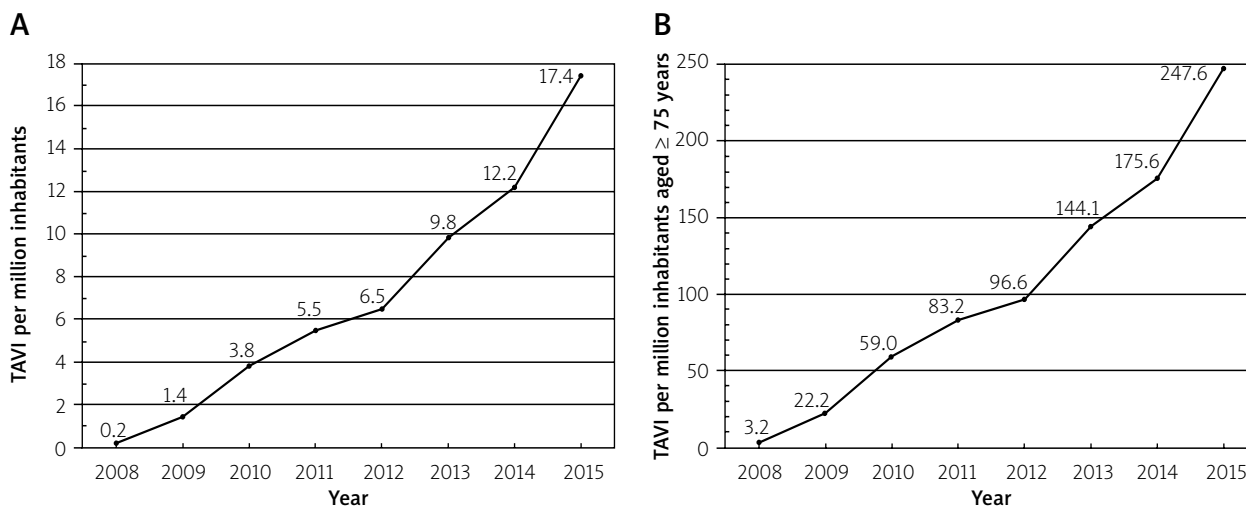
#### Transcatheter aortic valve implantation pre-procedural management

##### Risk

All Polish centres perform TAVI in inoperable and high-risk patients (Society of Thoracic Surgeons – STS score  $> 8$ ). Medium risk patients (STS 4–8) are qualified for TAVI in 10 centres (52%), while low-risk patients (STS  $< 4$ ) are offered transcatheter treatment in 1 centre (5%).

##### Imaging

Multislice computed tomography (MSCT) is the imaging modality performed in all Polish centres to assess aortic valve anatomy before TAVI. In addition, transoesophageal echocardiography is concomitantly used in the majority of hospitals (66%). Assessment of the vascular access route for TAVI is based on MSCT in 95% of centres, with angiography alone being used in one centre only (5%).



**Figure 4.** The TAVI procedures per annum in Poland from 2008 to 2015: **A** – TAVI implants per million inhabitants. **B** – TAVI implants per million inhabitants aged  $\geq 75$  years

**Coronary artery disease**

Coronary angiography is routinely performed in all centres as a part of pre-procedural planning. If patients are diagnosed with significant coronary artery disease, the strategy of preventive percutaneous coronary angioplasty of main vessels (PCI) is used by default in all centres. Nineteen percent of them may qualify such patients for simultaneous PCI during TAVI session, and only 14% of centres may decide on postponing PCI in such circumstance. After PCI with drug-eluting stent (DES), the recommended deferral of TAVI is 1 month in 71% of centres, 3 months in 24% and 6 months in 5% of centres.

In patients with coronary artery disease scheduled for TAVI with a femoral approach using surgical cutdown or closure devices, 95% of centres allow dual antiplatelet therapy (DAPT) to be maintained during TAVI. In patients qualified for transapical access, 60% of centres allow for DAPT, 35% recommend aspirin only and 5% withhold antiplatelet therapy on the day of the TAVI procedure.

**Transcatheter aortic valve implantation procedure**

**Prophylactic antibiotic therapy**

Routine use of periprocedural antibiotic therapy is advocated in 71% of centres. The remaining centres reserve antibiotic therapy for patients with additional indications.

**Anaesthesia**

Local anaesthesia for TAVI is used in 62% of centres. Since 2008, 12.6% of patients have been treated with TAVI under local anaesthesia. In 2015 the rate of such procedures reached 20.6%.

**Choice of access sites**

The transfemoral route is the default TAVI option in all Polish centres. Transapical access implantations have been performed in 95% of centres, followed by direct aortic (62%) and subclavian routes (48%). Only 3 centres have performed transcarotid TAVI in the last 2 years of the survey (14%). The rate of transfemoral implantations increased to 83.4% of all procedures in 2015, while the use of transapical access decreased to 11.8%. The frequency of the subclavian, direct aortic or transcarotid route for TAVI in 2015 was below 3% each (Figure 5).

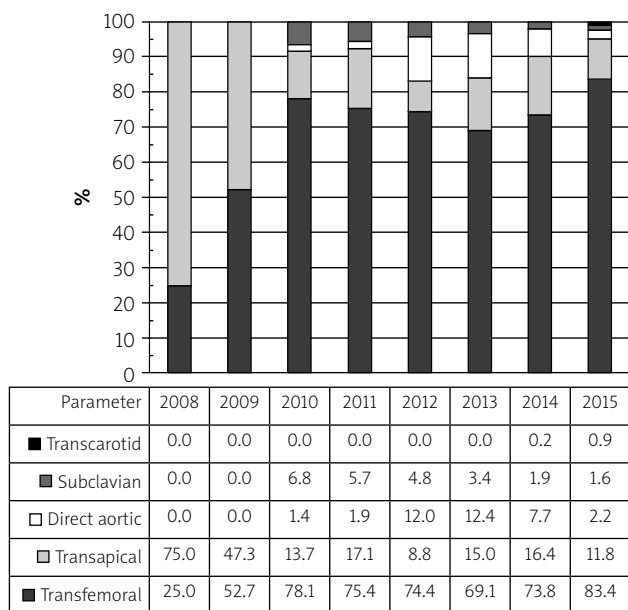
**Use of closure devices**

Percutaneous closure devices are used for the transfemoral TAVI approach in 43% of centres. Perclose ProGlide Suture-Mediated Closure Systems (Abbott Vascular, Redwood City, CA, USA) is used by 29% of centres and a single Prostar XL Percutaneous Vascular Surgical Systems (Abbott Vascular, Redwood City, CA, USA) in 33% of centres. Since the beginning of the TAVI programme

**Table 1.** Temporal changes of TAVI penetration in Poland in 2008–2015

Year	Total population	Population aged ≥ 75	Severe AS (3.4%)	Symptomatic severe AS (75.6%)	Ineligible for SAVR		Eligible for SAVR		TAVI eligible (80%)	Total TAVI eligible	TAVI procedures performed	TAVI penetration (%)
					Ineligible for SAVR (40.5%)	TAVI eligible (40.3%)	Eligible for SAVR (59.5%)	High risk (5.2%)				
2008	38135876	2357644	80160	60601	24543	9891	36058	1500	11391	8	0.07	
2009	38167329	2411888	82004	61995	25108	10119	36887	1535	11653	55	0.47	
2010	38200037	2472267	84057	63547	25737	10372	37811	1573	11945	146	1.22	
2011	38538447	2536957	86257	65210	26410	10643	38800	1614	12257	211	1.72	
2012	38533299	2587905	87989	66520	26940	10857	39579	1646	12503	250	2.00	
2013	38495659	2630496	89437	67614	27384	11036	40230	1674	12709	379	2.98	
2014	38478602	2676211	90991	68789	27860	11227	40930	1703	12930	470	3.63	
2015	38437239	2706427	92019	69566	28174	11354	41392	1722	13076	670	5.12	

AS – aortic stenosis, SAVR – surgical aortic valve replacement, TAVI – transcatheter aortic valve implantation.



**Figure 5.** Temporal changes of access site use during TAVI in Poland per annum

in Poland percutaneous closure devices have been used in 31.6% of patients (Perclose Proglide 3.8%, Prostar XL 27.8%). In 2015, closure devices were used in 28.1% of patients (Perclose Proglide 10.4%, Prostar XL 17.7%).

#### ***Aortic balloon valvuloplasty before transcatheter aortic valve implantation***

Sixty-seven percent of centres consider TAVI without the use of aortic balloon valvuloplasty. As a result, 31% of patients were treated with direct TAVI in 2015.

#### ***Transcatheter aortic valve implantation post-procedural management***

##### ***Right ventricular electrode removal after transcatheter aortic valve implantation***

In patients without evidence of new conduction system abnormalities, 48% of centres maintain the right-ventricular electrode for 2 days after the TAVI procedure, 38% remove it after 24 h and 4% discard it in the hybrid room.

##### ***Double antiplatelet therapy or anticoagulation after transcatheter aortic valve implantation***

The antithrombotic regimens prescribed after TAVI include DAPT in 81% and single antiplatelet therapy in 19% of centres. No centre is currently mandating oral anticoagulation therapy for TAVI indication only. In all patients with standard indications for anticoagulation, a single antiplatelet agent is prescribed in combination. Antiplatelet therapy is recommended for 3 months in 56% of responding centres, while a 6-month regime is supported by 44% of them.

## **Discussion**

The Polish Interventional Cardiology TAVI Survey (PICTS) survey is the first report of TAVI adoption and practice in Poland since its introduction in 2008. The main findings are as follows: 1. The number of TAVI centres per million population is 0.05 with substantial variation in the number of TAVI implants per centre across Poland: the median cumulative number of TAVI implants per centre was 80 (95% CI: 38.1–154.6); 2. The annual number of TAVI procedures per million population increased from 0.21 in 2008 to 17.4 in 2015; 3. TAVI remains greatly underutilised with an estimated weighted penetration rate of 5.12% in 2015; 4. A vast majority of patients are treated with TAVI using the transfemoral route, with the rate of 83.4% in 2015; 5. A broad divergence of procedural TAVI practices exists between national centres in Poland.

Organisation of Polish centres built around TAVI therapy adheres to current guidelines and recommendations with Heart Teams, interventional cardiology and cardiac surgery departments established in all of them [7, 8]. Although their number reached an average of Western European nations such as France, the United Kingdom and Denmark, the experience of Polish centres with median 24 TAVI performed in 2015 is below the European average of 41 procedures in 2011 [3]. We observed substantial variation of TAVI implantations per centre in Poland, with 19% of centres performing 50–100 procedures and 33% of centres performing fewer than 20 implants in 2015. Eleven centres performed fewer than 50 procedures in total despite their long activity (Figure 2). The causes of such restraints were beyond the scope of the study. As all centres reported long patient waiting lists, TAVI quota and reimbursement limits may be the likely causes of the slow progress rate.

Despite a positive growth of procedural volume from 2008 to 2015, we found that the latest annual number of 17.1 TAVI procedures per million population in Poland is 10 times lower than in Germany, 3 times lower than in Sweden, twice as low as in Ireland and half of the Western European average reported in 2011 [9–11]. Similarly, the estimated TAVI penetration rate of 5.12% in Poland in 2015 is lower than in any Western European country except for Portugal in 2011 [3]. According to our estimates, the number of TAVI eligible patients in Poland was 13 076 in 2015. The published estimated number of new TAVI candidates each year in Poland, under current indications, was 1220 [6]. In contrast, the number of TAVI procedures performed in Poland in 2015 was 670. Based on preliminary reports, the European Association of Percutaneous Interventions (EAPCI) introduced the Valve for Life initiative in Poland in 2015 “to enhance awareness concerning inequality of patient access to the lifesaving indications of TAVI therapy [...] with the goal of increasing the treatment of severe valvular heart disease by 20% by 2020” [12]. Our survey observed a 42.6% increase of TAVI procedures in Poland in 2015 in comparison to 2014.

Patient risk distribution in Polish centres resembles current European practice with universal acceptance of TAVI in patients with extreme and high risk, but also in selected medium risk patients [13]. The MSCT is the imaging technique of choice for aortic valve and vascular access route assessment, reflecting current guidelines and concordance with European standards [8, 14, 15]. Coronary revascularisation procedures (PCI) in patients qualified for TAVI in Poland are performed before the procedure in all centres according to the actual European recommendations for revascularization [16]. The observed practice of PCI during TAVI used in 19% of centres or postponing PCI after TAVI present in 14% of centres may reflect the preference given to the treatment of aortic stenosis and incomplete evidence for management of coronary artery disease before TAVI [16, 17]. Variations in practice of maintaining dual antiplatelet therapy before TAVI using the transapical approach may mirror difficult decision-making in high-risk patients.

Contrary to recent reports of the German AQUA Registry of transapical use in 22.3% of patients qualified for TAVI, the number of Polish patients treated transapically decreased to 11.8% of all procedures in 2015, while the transfemoral approach was predominant in Poland from 2009 onwards [10]. The factors influencing such changes may be technology advances in the design of femoral delivery systems and supportive long-term results of TAVI procedures in medium-risk patients using transfemoral access [18]. Infrequent use of alternative access sites (subclavian, direct aortic, transcarotid) may have been limited by the facilitated transfemoral approach and relatively low procedural volume in Polish centres.

The observed predominant use of surgical femoral artery cutdown over suture-based closure devices may be explained by assumed avoidance of vascular complications and bleeding as well as the decreasing cost of the procedure. Also, TAVI operators need thorough experience in using closure systems, which is possible to achieve with a high number of implantations. The reported preference of Prostar XL over Proglide use in Polish centres depends on local practice. Current conflicting reports on the safety of closure device use in TAVI suggest the need for further research in this field [19, 20].

The relatively large proportion of patients treated with direct valve implantation may represent the process of simplifying the TAVI procedure to increase its safety, but more evidence for such an approach is needed [21]. In fact, 33% of Polish centres perform aortic valvuloplasty during TAVI.

The DAPT after TAVI is currently recommended in most centres, while more evidence is needed on anti-thrombotic therapy [22]. There is a broad range of recommended duration of DAPT across national centres, with no consensus present also in a European survey in which 53% of centres supported a 3-month and 19% a 6-month DAPT after valve implantation [13].

The survey has the following limitations, which should be considered when interpreting the results. Although the study was fully addressed by all Polish TAVI centres, the answers were provided mostly by interventional cardiologists and may not be fully representative of the whole multidisciplinary team community. The numbers of TAVI procedures reported were not validated with registries of the national health system administration in the years 2008–2013 due to the lack of such reports. The causes of the low TAVI penetration rate were not surveyed in the study and further research in this field is warranted. The estimates of TAVI use are likely to have included patients treated for off-label indications, such as patients at lower surgical risk, which may have affected the estimates of TAVI penetration. Direct comparisons to TAVI adoption practices in countries of Central and Eastern Europe were not described due to the absence of published reports.

## Conclusions

The PICTS survey highlighted a positive but relatively slow rate of adoption of TAVI in Poland. When compared to Western European countries, our findings point to a large treatment gap in high or prohibitive surgical risk patients with severe aortic stenosis. In addition, remarkable regional variations in TAVI growth exist among Polish TAVI centres. Currently, the EAPCI Valve for Life campaign addresses the problem with multidirectional actions aiming to offer improved care to Polish patients. Finally, substantial discrepancies between practices of centres point to the need for publication of joint national guidelines and recommendations.

## Impact on daily practice

Until now temporal changes of TAVI adoption and practice in countries of Central and Eastern Europe have remained largely unreported. The PICTS study highlights a slow rate of TAVI adoption in Poland in comparison to countries of Western Europe. We observed significant improvements of TAVI penetration after the introduction of the EAPCI Valve for Life campaign in Poland. The survey demonstrated wide variations in TAVI practice among Polish centres, calling for publication of joint TAVI practice guidelines.

## Acknowledgments

The authors would like to thank the leaders of Polish TAVI Heart Teams for their help in providing datasets used in the PICTS study and their support given to the Valve-for-Life programme:

- Sławomir Dobrzycki, Paweł Kralisz, Marek Frank, Tomasz Hirnle, Medical University of Białystok, Białystok;
- Paweł Buszman, Marcin Dębiński, Wojciech Domaradzki, Marek Cisowski, American Heart of Poland, Bielsko-Biała;

- Wojciech Pawluszak, Dr Antoni Jurasz Memorial University Hospital, Bydgoszcz;
- Robert Romanek, Maurycy Missima, 10<sup>th</sup> Military Research Hospital, Bydgoszcz;
- Dariusz Ciećwierz, Dariusz Jagielak, Medical University of Gdansk, Gdańsk;
- Andrzej Ochata, Wojciech Wojakowski, Grzegorz Smolka, Radostaw Parma, Marek Deja, Medical University of Silesia, Katowice;
- Dariusz Dudek, Jarostaw Trębacz, Paweł Kleczyński, Robert Sobczyński, Bogustaw Kapelak, Jagiellonian University Medical College, Kraków;
- Jarostaw Wójcik, Andrzej Madejczyk, Janusz Stążka, Medical University of Lublin, Lublin;
- Michał Kidawa, Bogdan Jegier, Andrzej Walczak, Michał Krejca, Medical University of Lodz, Łódź;
- Jerzy Sacha, Jacek Kaperczak, Regional Medical Center, Opole;
- Maciej Lesiak, Marek Grygier, Marcin Mistowski, Marek Jemielity, Poznan University of Medical Sciences, Poznań;
- Piotr Olszówka, Kazimierz Widenka, 2<sup>nd</sup> District Hospital, Rzeszów;
- Jarostaw Gorący, Maciej Lewandowski, Mirosław Bryczyński, Pomeranian Medical University, Szczecin;
- Wojciech Wąsek, Grzegorz Suwalski, Military Institute of Medicine, Warsaw;
- Robert Gil, Tomasz Pawłowski, Piotr Suwalski, Central Clinical Hospital of the Ministry of the Interior and Administration, Warsaw;
- Janusz Kochman, Zenon Huczek, Radostaw Wilimski, Medical University of Warsaw, Warsaw;
- Adam Witkowski, Zbigniew Chmielak, Maciej Dąbrowski, Krzysztof Kuśmierski, Institute of Cardiology, Warsaw;
- Marcin Protasiewicz, Marek Jasiński, Wrocław Medical University, Wrocław;
- Krzysztof Reczuch, Artur Telichowski, Jacek Skiba, Clinical Military Hospital, Wrocław;
- Krzysztof Wilczek, Piotr Chodór, Marian Zembala, Medical University of Silesia, Zabrze;
- Andrzej Kleinrok, Tomasz Smyk, Łukasz Tułcecki, Pope John Paul II Hospital, Zamość.

## Footnotes

RP and MD contributed equally to this study. Study concept, design and supervision: all authors. Conduct of the study: RP, MD. Analysis and interpretation of data: RP, MD. Drafting and revision of the manuscript: all authors. Approval of the final version of the manuscript: all authors.

## Conflict of interest

The authors declare no conflict of interest.

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