Transcatheter aortic valve implantation. Expert Consensus of the Association of Cardiovascular Interventions of the Polish Cardiac Society and the Polish Society of Cardio-Thoracic Surgeons, approved by the Board of the Polish Cardiac Society and National Consultants in Cardiology and Cardiac Surgery

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Abstract

Patients with severe symptomatic aortic stenosis have a poor prognosis with medical management alone, and surgical aortic valve replacement can improve symptoms and survival. In recent years, transcatheter aortic valve implantation (TAVI) has been demonstrated to improve survival in inoperable patients and to be an alternative treatment in patients in whom the risk of surgical morbidity or mortality is high or intermediate. A representative expert committee, summoned by the Association of Cardiovascular Interventions of the Polish Cardiac Society (ACVI) and the Polish Society of Cardio-Thoracic Surgeons, developed this Consensus Statement in transcatheter aortic valve implantation. It endorses the important role of a multi-disciplinary "TAVI team" in selecting patients for TAVI and defines operator and institutional requirements fundamental to the establishment of a successful TAVI programme. The article summarises current evidence and provides specific recommendations on organisation and conduct of transcatheter treatment of patients with aortic valve disease in Poland.

Key words: clinical expert consensus document, aortic stenosis, aortic valve replacement, heart team, TAVI team, high-risk patients, percutaneous valve therapy, structural heart disease, transcatheter aortic valve implantation, transcatheter aortic valve replacement

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INTRODUCTION

Valvular heart disease is a major public health problem in developed countries. Aortic valve stenosis (AS) is its most common form, affecting more than 5% of the population aged > 65 years [1]. AS is a chronic disease, associated with poor prognosis when left untreated. Depending on the severity of symptoms, the mean survival of patients with a significant AS is two to five years [2]. Conservative treatment or balloon valvuloplasty do not prolong life in symptomatic patients.

Surgical aortic valve replacement (SAVR) represents a well-documented standard of treatment of AS, performed either with conventional or minimally invasive approaches. SAVR outcomes are favourable but depend on the patient's age and the presence of concomitant diseases, factors defining the overall procedural risk as low, intermediate, high, very high, or prohibitive [3]. The prevalence of AS is predicted to rise along with the ageing population, leading to the enlargement of high- or prohibitive-risk groups of patients. Currently, 33% of them are estimated to be either disqualified from SAVR or not considered as potential candidates for such treatment [4].

With these patients in mind, a French cardiologist, Alain Cribier, implemented an endovascular treatment of aortic valve disease with the use of a stented bioprosthesis in 2002. Since then, multiple registries and clinical trials have confirmed the safety and efficacy of transcatheter aortic valve implantation (TAVI, also transcatheter aortic valve replacement: TAVR). Its outcomes have improved with rapid technological advances and growing experience of operators, invasive cardiologists, and cardiac surgeons [5–8]. TAVI has become the treatment of choice in prohibitive-risk patients and the preferred approach to patients with high risk of conventional heart surgery, following the criteria set by the Joint European Society of Cardiology (ESC) and European Society of Cardio-Thoracic Surgeons (EACTS) Guidelines on the management of valvular heart disease [9].

The results of the latest clinical trials and growing experience of Polish cardiology and cardiac surgery centres point to beneficial outcomes in patients in whom the high risk of SAVR is a consequence of the porcelain aorta, previous coronary artery bypass grafting (CABG), prior chemotherapy or chest radiotherapy, osteoporosis, and other comorbidities [10]. In addition to AS, TAVI allows for an alternative treatment of patients with significant aortic valve regurgitation as well as a dysfunctional, aortic or mitral, bioprosthesis [11]. The number of indications to TAVI in the high-risk patient group is steadily growing. Since the pioneering Alain Cribier's procedure, TAVI has been performed in more than 200 thousand patients worldwide. The first TAVI in Poland was conducted using transapical access in Krakow on 25 November 2008, followed by a transfemoral implantation in Zabrze on 22 December 2008. In the years 2008–2016, 3058 TAVI procedures were performed in Poland, with 869 implants completed in 2016 (penetration rate: 22.6 TAVI/million population) [12].

Encouraging results of this novel therapy in prohibitive-, high-, and moderate-risk patients in Poland were possible thanks to the combination of several factors: full support and growing experience of national scientific societies, the introduction of dedicated TAVI programmes in centres with established invasive cardiology and cardiac surgery departments, as well as the organisation of integrated TAVI teams in each of them [13–22]. The role and indications to SAVR in the future will most probably reflect growing TAVI demand. Novel surgical bioprostheses are being introduced, with improved anti-calcification solutions and technical innovations which facilitate rapid deployment in a setting of a minimally, sternum-sparring operation. Sutureless valves, which are similar to TAVI devices in their design, have been shown to offer excellent short and long-term durability, yet they remain underutilised due to reimbursement issues [23–26].

A representative expert committee, summoned by the Association of Cardiovascular Interventions of the Polish Cardiac Society (ACVI) and the Polish Society of Cardio-Thoracic Surgeons, developed this Consensus Statement in TAVI. The article summarises current evidence and provides specific recommendations on the organisation and conduct of transcatheter treatment of patients with aortic valve disease in Poland. It does not replace the present or future ESC and EACTS guidelines and should be referred to in agreement with these publications. This document was fully approved by the Board of the Polish Cardiac Society and the Board of the Polish Society of Cardio-Thoracic Surgeons and National Consultants in Cardiology and Cardiac Surgery.

DEFINITION OF TAVI/TAVR

A therapeutic procedure performed to normalise blood flow and its effective pressure gradient across the aortic valve in patients with acquired, significant aortic valve degeneration. The procedure also applies to diseases of mitral or tricuspid valves, as well as their degenerated bioprostheses, in high- or prohibitive-risk patients, in whom conventional surgery is prone to failure or an occurrence of serious complications. The decision on patient qualification to TAVI and the choice of access is made by a dedicated group of experts, the TAVI team, which includes a cardiologist and a cardiac surgeon experienced in TAVI procedures.

TAVI OUTCOMES

The safety and efficacy of TAVI in patients with a symptomatic and significant aortic stenosis were assessed in registries and randomised multicentre clinical trials. Until now, they provided evidence for clinical utility of TAVI in patients with a prohibitive, high, and intermediate risk of conventional cardiac surgery.

TAVI in prohibitive-risk patients

The PARTNER 1 cohort B trial compared outcomes of conservative treatment with a transfemoral TAVI using a balloon-mounted aortic valve bioprosthesis in symptomatic patients with a significant AS, who had been disqualified from conventional cardiac surgery based on the prohibitive risk of SAVR. The mean age of patients was 83 years. The mean Society of Thoracic Surgeons (STS) risk was 12.1 ± 6.1% in the conservative group vs. 11.2 ± 5.8% in the TAVI group, while the mean logistic EuroSCORE was 30.4 ± 19.1% vs. 26.4 ± 17.2%, respectively. Patients were refused surgery if the predicted 30-day risk of death or irreversible morbidity with surgery exceeded 50%. The mortality after one year was 50.7% with medical treatment compared with 30.7% with TAVI (p < 0.001) [6]. At five-year follow-up, the mortality rates were 93.6% and 71.8%, respectively (p < 0.001). Five-year rates of cerebral stroke were comparable in both treatment groups (18.2% i 16.0%, p = 0.56) [27]. The study proved prohibitive-risk patients, who used to

be qualified to medical treatment, achieved better short- and long-term survival with TAVI.

A non-randomised CoreValve US Pivotal Trial Extreme Risk Iliofemoral Study assessed TAVI using self-expanding bioprosthesis in non-operable patients. The mean age was 83.2 years, STS risk score 10.3%. The one-year composite endpoint (all-cause mortality and cerebral stroke) occurred in 26% of patients, with 24.3% one-year mortality and 4.3% one-year stroke rates [28].

TAVI in high-risk patients

The randomised PARTNER 1 trial, cohort A, compared the effectiveness of SAVR with TAVI using balloon-mounted bioprosthesis implanted using a transfemoral or a transapical access, in symptomatic patients with severe AS and high risk of conventional cardiac surgery (defined as STS ≥ 10%). The mean population age was 84 years; the mean STS score was 11.7 ± 3.5% in the SAVR group and 11.8 ± 3.3% in the TAVI group. The mean logistic EuroSCORE was 29.2 ± 15.6% and 29.3 ± 16.5%, respectively. Analysis of one- and five-year mortality showed comparable outcomes in surgical and TAVI groups (26.8% and 24.2% vs. 62.4% and 67.8%, p < 0.76). Stroke rates were similar in both treatment groups in a five-year observation (11.3% and 10.4%, p = 0.61) [8, 29].

The CoreValve US Pivotal High-Risk Trial compared SAVR and TAVI using self-expandable bioprosthesis in patients with severe and symptomatic AS. All patients were high risk, defined as the estimated 30-day mortality ≥ 15%. The mean patient age was 83 years, STS 7.4%. One-year mortality was significantly higher in the surgical group than in TAVI (19.1% vs. 14.2%, p < 0.04), with a non-significant trend to a higher one-year stroke rate after surgery (12.6% vs. 8.8%, p = 0.1) [5]. Three-year mortality was comparable in both treatment groups (39.1% vs. 32.9%, p = 0.07), but the three-year stroke rate was significantly higher in the SAVR group (19.0% vs. 12.6%, p = 0.03) [30].

TAVI in intermediate risk patients

The PARTNER 2 randomised clinical trial compared SAVR with TAVI in intermediate-risk patients with symptomatic, severe AS (STS 4–8%). The mean age was 81 years, and STS was 5.8% in each group. The composite endpoint (all-cause mortality and stroke) did not differ between SAVR and TAVI [31]. In the transfemoral TAVI group, the risk of composite endpoint occurrence was significantly smaller in comparison to the SAVR group (HR = 0.79, p = 0.05, intention-to-treat) [7]. The SURTAVI randomised clinical trial compared SAVR with TAVI with the use of a self-expanding bioprosthesis. The mean age of patients was 79 years, and STS was 4.5%. At 24 months the estimated incidence of the primary endpoint (a composite of death from any cause or disabling stroke) was 14.0% in the SAVR group and 12.6% in the TAVI group. Surgery was associated with higher rates of acute kidney injury, atrial fibrillation, and transfusion

requirements whereas TAVR had higher rates of residual aortic regurgitation and the need for pacemaker implantation [32]. Edwards Sapien 3 and Medtronic CoreValve EvolutR bioprostheses have received a Conformité Européenne (CE) mark as well as acceptance of the America Food and Drug Administration (FDA) for the transcatheter treatment of intermediate-risk patients with severe aortic valve stenosis.

TAVI in low-risk patients

Reflecting the real-world expansion of TAVI procedures into low-risk patients, the cohort was assessed in clinical studies. In a pilot, randomised, clinical NOTION trial, SAVR was compared to TAVI in all-comers with symptomatic, severe AS. Their mean age was 79.1 years. 81.8% of patients were classified as low risk (STS < 4%). Two-year mortality and stroke rates were comparable in the two treatment arms (9.8% vs. 8.0%, p = 0.54 and 5.4% vs. 3.6%, p = 0.46, respectively) [33, 34]. With these results in mind, data of the prospective German GARY registry observed a comparable mortality in high-risk patients undergoing SAVR and TAVI, while a lower mortality was reported in SAVR vs. TAVI in low-risk patient groups [31].

Three large, randomised, clinical trials were initiated in 2016 with the aim to compare SAVR with TAVI in low-risk patients with severe, symptomatic AS: PARTNER 3, using the Edwards Sapien 3 system (STS < 4%, age ≥ 65 years, NCT02675114), Medtronic Transcatheter Aortic Valve Replacement in Low-Risk Patients using the Medtronic EvolutR system (STS < 3%, no age limits, NCT02701283), and NOTION-2 using Symetis, Boston Lotus and St. Jude/Abbott Portico systems (all-comers, NCT02825134). Early results of these trials are expected to be announced in 2019.

TAVI in specific indications

Although mostly used in patients with significant aortic stenosis, transcatheter aortic valves have been successfully used to treat other forms of valvular diseases. Indeed, the first TAVI procedure was performed by a transseptal puncture, under local anaesthesia, in a patient with a regurgitant, bicuspid aortic valve (BAV). Due to increased risk of prosthesis malposition, residual paravalular leaks (PVL) or transprosthetic high gradient in challenging anatomy other than tricuspid aortic valve stenosis, patients with these indications were not included in randomised trials. Current evidence for TAVI in BAV, degenerated aortic bioprosthesis, pure native aortic regurgitation or low-flow, low-gradient aortic stenosis is based on registry data. Their summary presented below should guide TAVI teams in an individualised approach to such patients based on thorough assessment of procedural risk and the experience of operators.

Bicuspid aortic valve

In low-risk patients with a BAV and in those with concomitant aortopathy, surgical aortic valve replacement is the recommended option for treatment [9, 35]. However, this most com-

mon congenital anomaly affects up to 2% of the population and almost uniquely requires SAVR during a patient lifetime. BAV has been a contraindication to TAVI in most clinical trials, as an asymmetrical BAV orifice may prevent full expansion of the implanted bioprosthesis. In addition, the stress of the calcified raphe on the valve frame is variable, leading to difficulty in appropriate device sizing. All these factors may give rise to the following complications.

— PVL — in low implantations (the device sealing is provided by the BAV orifice located up to 8 mm above the aortic annulus), in very eccentric BAV orifice and in case of unfavourable distribution of calcifications. PVL following TAVI is a risk factor for earlier prosthesis degeneration, which is especially important in younger patients with BAV. High implantation and use of second-generation devices with sealing skirts or their repositionability allow reducing the rate of PVL.

— Annulus rupture: observed mainly in balloon-expandable valves in the presence of bulky, asymmetric calcifications. Cautious use of undersized devices (in comparison to tricuspid aortic valve standards), use of balloon-sizing and self-expandable bioprostheses allow averting this dramatic adverse event.

— Aortic dissection: The vulnerable ascending aorta of BAV patients may be prone to injury during TAVI catheter manipulation. Careful navigation and deflection of the TAVI system away from walls of the aortic arch and the ascending aorta during catheter passage is recommended in these high-risk patients.

— Conduction abnormalities: an asymmetrical calcium distribution, with deposits located in the noncoronary cusp or valve oversizing, compared to an elliptical BAV orifice, increase the risk of new pacemaker implantation [36].

Current registry data provide guidance for the transcatheter treatment of this challenging group of patients. The reported overall survival rate is similar in BAV and tricuspid aortic valve patients. Procedural complications seem to be more frequent in the BAV group, especially in patients receiving first-generation devices. In the largest registry published to-date, conversion to surgery was 2.5% vs. 0.3%, the need for a second valve implantation 7.2% vs. 2.2%, significant PVL 15.9% vs. 10.3% and aortic root injury 4.5% vs. 0% in BAV and tricuspid aortic valve patients, respectively. It is important to note that these differences were not present in patients treated with second-generation devices [37].

In the light of encouraging study results supported by the outcomes of the Polish BAV registry, further multicentre studies are required before the expansion of TAVI to lower-risk patients with an increased proportion of BAV [38, 39]. They should analyse differences between device designs as well their long-term durability in the challenging BAV anatomy. Independently, this group of patients requires careful evaluation of concomitant aortopathy in the decision-making process.

Vale-in-Valve

The use of biologic prostheses for the treatment of aortic stenosis has increased steadily to over 50% in comparison to mechanical valves, obviating the need for lifelong coagulation, but at the cost of the shorter durability of implanted bioprostheses. With increasing life expectancy of an ageing Polish population, the number of patients with surgical valve failure is expected to rise. Although reoperative surgical replacement is the current standard of care, the presence of comorbidities in elderly patients or technical difficulties after previous operations may impact the risk of reoperation [40].

The diversity of surgical aortic bioprosthesis requires knowledge of their design, methods of surgical implantation and specifically, the position of the suture ring in the aortic valve. We recommend considering the following Valve-in-Valve (ViV) aspects during patient screening to TAVI.

1. Type of bioprosthesis dysfunction:
   — stenosis: differentiation between valve stenosis and valve-size mismatch (especially in surgical valves size ≤ 21 mm);
   — regurgitation: differentiation between intravalvular and paravalvular regurgitation.
2. Valve sizing:
   — identification of the prosthesis true inner diameter. It is smaller than the labelled valve size or the inner stent diameter in stented valves, as valve tissue, its calcification or pannus ingrowth may narrow the true lumen. Transoesophageal echocardiography (TEE) and multislice computed tomography (MSCT) are indispensable tools in valve assessment. In addition, available medical software applications are helpful tools in TAVI guidance;
   — valve oversizing reduces the risk of embolisation and PVL at the expense of a higher gradient and earlier dysfunction of TAVI bioprosthesis.
3. Risk of coronary obstruction:
   — stentless valves, narrow sinuses of Valsalva and low coronary ostia are predictors of coronary obstruction by the leaflet of the prosthesis. Aortography during aortic balloon valvuloplasty may help to predict coronary artery closure [41];
   — in high risk of this complication, the use of retrievable devices and low implantation is recommended. Coronary artery wiring with coronary balloon placement may also be beneficial, by allowing to deflect apposing tissues away from the occluded coronary ostium with subsequent stenting.
4. Balloon pre-dilatation is helpful only in select patients without fluoroscopic markers of the bioprosthesis, to detect the level of the reference plane and to assess the risk of coronary obstruction.
5. TAVI prosthesis positioning:
   — a sewing ring of the surgical valve prosthesis is the reference plane for TAVI. Its relationship with fluoroscopic markers is specific to the type of surgical prosthesis;
   — the target TAVI landing zone is located 4–5 mm below the sewing ring;
   — rapid ventricular pacing may help stabilise the TAVI system during implantation and reduce the amount of contrast used.

Based on published ViV registry data, most frequent complications were: valve embolisation (12.4%), pacemaker implantation (7.6%; lower than observed in native TAVI), coronary obstruction (2.2%) and stroke (1.4%). The mean transvalvular gradient after ViV was 15.5 mm Hg, higher than in native TAVI reports of < 10 mm Hg. The mean mortality rate at one year was 15.1%. Factors associated with increased mortality were smaller surgical valves, stenotic dysfunction and transapical approach [42].

Currently available TAVI systems may be used for ViV in the mitral position to treat patients with degenerated mitral bioprostheses or recurrent regurgitation after a complete-ring annuloplasty. Such procedures may be performed transapically or transseptally, depending on patient anatomy, the TAVI prosthesis used and operators'experience. Careful pre-procedural planning with data on previous mitral operation, TEE and MSCT analysis are crucial to assess ViV feasibility, to select the optimal type and size of TAVI bioprosthesis and to agree on its intraprocedural positioning and the degree of over-expansion [43].

Native aortic valve regurgitation

Native aortic valve regurgitation (NAVR) constitutes 10.9% of all native valve disease. The most common causes of NAVR are congenital valve malformations, including BAV, followed by acquired diseases such as infective endocarditis, rheumatic heart disease, vasculitis, radiotherapy, chest trauma or left ventricular assist device valve injury. The clinical course may be acute or chronic, leading to the development of congestive heart failure and pulmonary hypertension, owing to volume overload and left ventricular dysfunction [4].

Transcatheter treatment of NAVR is challenged by several clinical and anatomic factors. Patients presenting with aortic regurgitation are usually younger than patients with AS, due to the different pathophysiology of valve degeneration. Active endocarditis, annuloectasia or aortic dissection may be prohibitive for TAVI. Quick NAVR progression to left and right ventricular failure render patients more complex and vulnerable to treat than in case of degenerative AS. Absence of valvular calcification complicates the anchoring of a bioprosthesis in the aortic annulus, with an increased risk of valve embolisation or PVL. The dilatation of the left ventricle due to volume overload may increase the size of the annulus, exceeding the range of currently available prostheses. The increased

stroke volume and regurgitant jet limit device control during its positioning and implantation.

The choice of bioprosthesis and its sizing requires thorough TEE and MSCT assessment, although the quality of computed tomography may be lowered by accompanying tachycardia. The choice of recapturable self-positioning TAVI systems with feelers, clippers and other fixation mechanism, may be preferred. We advise a patient-specific prosthesis oversizing to provide increased radial force in this native anatomy, careful observation of the bioprosthesis waist during implantation and, in specific cases, the performance of a tug test before the release of a self-expandable prosthesis. Such approach may prevent valve malpositioning, migration or significant paravalvular regurgitation at the expense of increased risk of annulus rupture or valve malposition. Balloon-expandable prostheses have been considered unsuitable for NAVR due to lack of calcification to anchor the prosthesis, yet recent publication of their use with adequate oversizing suggest its safety in highly selected patients [44]. Results of a limited number of heterogenous studies show that TAVI is technically feasible in selected high-risk patients with native pure aortic regurgitation, with acceptable 30-day mortality (8%, CI 4–12%). The occurrence of a second valve implantation and the rate of residual moderate or severe aortic regurgitation were 7% and 9%, respectively [11, 45].

Low-flow low-gradient aortic stenosis with normal ejection fraction

In symptomatic patients with severe AS (aortic valve area [AVA] < 1 cm^2 or index AVA < 0.6 cm^2/m^2) and low peak aortic velocity (< 4 m/s) or low mean Doppler gradient (< 40 mm Hg), the discordance may reflect a low stroke volume index, despite a normal left ventricular ejection fraction (paradoxical low-flow low gradient aortic stenosis [PLF-LGAS]). Such phenomenon has been associated with the presence of small ventricular cavities, severe concentric hypertrophy, increased afterload, restrictive physiology, systolic dysfunction and myocardial fibrosis [9, 46]. Importantly, this group has a higher prevalence of comorbidities, including atrial fibrillation and arterial hypertension, which requires careful differentiation of symptoms and their correlation with results of diagnostic studies:
— a critical review of echocardiography measurements is necessary, with confirmation of the left ventricular outflow tract diameter (TEE or cardiac magnetic resonance), visualisation of leaflet calcification and reduction of their opening, analysis of peak flow velocity, the presence of left ventricular hypertrophy and global strain, not attributable to other diseases;
— MSCT-based aortic valve calcium scoring may support the diagnosis;
— measurement of the natriuretic peptide may confirm the presence of heart failure.

So far studies have reported disparate results regarding the significance and prognosis of this condition. Initial reports showed a poorer prognosis in comparison to patients with high gradient AS, while a recent study has provided evidence for comparable outcomes of PLF-LGAS to that of patients with a moderate AS [47].

Paradoxical low-flow low gradient aortic stenosis was observed in 20.8% of patients treated with TAVI or SAVR in the GARY registry. Reported TAVI outcomes and complication rates were comparable with high gradient AS patients, and significantly better than in low gradient AS and reduced left ventricular function (one-year mortality 22.3% vs. 32.3%, respectively) [48].

Further research is needed to better understand the natural history and impact of SAVR and TAVI in PLF-LGAS. Currently, treatment with SAVR or TAVI should be reserved by the Heart Team for selected symptomatic patients, in whom additional diagnostic studies support the diagnosis.

The durability of transcatheter and surgical aortic bioprostheses

Any treatment of aortic valve disease should offer a high profile of safety and a permanent outcome. The introduction of TAVI began in prohibitive and high-risk patients, whose projected survival is significantly shorter than in intermediate or low-risk patients. Along with the improvement of access to TAVI technology and its spread towards lower-risk groups, maintaining the durability of implanted biological prostheses is of particular importance.

Prosthetic dysfunction may present in the form of its stenosis or insufficiency. Their criteria have been defined by the Valve Academic Research Consortium 2 (VARC-2): a mean pressure gradient > 20 mm Hg, effective orifice area < 1.1 cm^2, Doppler Velocity Index < 0.35 or effective regurgitant orifice area > 0.1 cm^2, presuming an optimal and stable 30-day result of implantation [49]. The long-term significance of a MSCT-derived leaflet calcification or reduced motion in a TAVI bioprosthesis, without accompanying stenosis or regurgitation, is yet unknown [50].

Based on more than 10 years of observation of surgical patients, the following risk factors for premature degeneration of biological aortic valve prostheses have been recognised:
— patient age, male sex, renal failure, chronic inflammatory diseases, immunosuppression;
— endocarditis, thrombosis;
— procedural factors: PVL, annulus-prosthesis mismatch, elliptical shape of the implanted prosthesis [51].

Due to construction similarities, the above factors may also be valid for TAVI systems. The degree of the frame and leaflet folding, the duration of crimping, and the number of system recaptures and post-dilatations may further impact TAVI durability. Based on available registry data, the most common factors responsible for early transcatheter degeneration

are endocarditis, thrombosis, leaflet calcification, late prosthesis migration, and valve distortion during chest compression (in balloon expandable valves) [52]. The recommended imaging follow-up in patients after TAVI and the management of suspected valve thrombosis are described further in the "Post-procedural management" chapter.

In a five-year follow-up of inoperable patients included in the PARTNER 1 trial, the area of transcatheter aortic valves and their mean aortic pressure gradient were intact (1.52 ± 0.28 cm^2 and 10.6 ± 3.9 mm Hg) [27]. Furthermore, in a five-year observation of high-risk patients of the PARTNER 1 trial treated surgically or with TAVI the valve area and the mean aortic pressure gradient were constant since the time of implantation and comparable between treatment groups (1.5 vs. 1.6 cm^2, p = 0.29, 10.6 mm Hg vs. 10.7 mm Hg, p = 0.92, respectively) [29]. Similarly, the CoreValve US Pivotal High-Risk Study observed stable echocardiographic parameters of implanted bioprostheses in a three-year follow-up of high-risk patients, but the results were significantly worse in the surgical group in comparison to TAVI (1.53 cm^2 vs. 1.79 cm^2, p < 0.001 and 11.4 mm Hg vs. 7.62 mm Hg, p < 0.001) [30]. In the SURTAVI study assessing moderate-risk patients, the TAVI group had lower mean aortic-valve gradients and larger aortic-valve areas than did the SAVR group. However, moderate or severe residual paravalvular regurgitation was more common in the TAVI group at one year (15.3% vs. 0.6%, respectively) [32]. Likewise, in a one-year observation of a low-risk patient population included in the NOTION trial, the effective TAVI prosthesis area and the mean aortic pressure gradient remained intact. Echocardiographic parameters were significantly worse in the surgical group in comparison to the TAVI group (1.3 cm^2 vs. 1.6 cm^2, p < 0.001 and 13.0 mm Hg vs. 9.0 mm Hg, p < 0.001, respectively) [34].

An international registry assessing long-term durability of transcatheter aortic valves (VAlve Long-term durability International Data [VALID]) includes the first-generation TAVI systems implanted since 2002. Its results are still pending publication. Expansion of TAVI indications to younger, low- and moderate-risk patients, will depend on evidence of favourable, ≥ 10-year outcomes for this treatment modality.

RISK ASSESSMENT AND TREATMENT OF AORTIC VALVE DISEASES
Risk of a classic cardiac surgical procedure
Deciding on the treatment of aortic valve disease requires assessment of surgical risk associated with the planned procedure. Both ESC and EACS guidelines, along with statements of American scientific societies, recommend using the following risk score calculators in patients with valvular heart diseases: STS score and EuroSCORE II. They are available online at http://riskcalc.sts.org/ and http://www.euroscore.org/, respectively.

Based on results obtained, patients are stratified into four groups of surgical risk:
— low — STS < 4%, EuroSCORE II < 4%;

— intermediate: STS 4–8%, EuroSCORE II 4–8%;
— high: STS ≥ 8%, EuroSCORE II ≥ 8% (or Log EuroSCORE ≥ 20%);
— prohibitive (non-operable): a calculated 30-day risk of mortality and morbidity exceeding 50% [9, 53, 54].

The previously-mentioned randomised clinical trials provided evidence for TAVI safety and efficacy in patients with prohibitive, high, and intermediate risk of SAVR.

Current risk calculators do not include all factors affecting outcomes of cardiac surgery and influencing the decision on the transcatheter treatment of the heart valve disease [55]. Therefore, we recommend inclusion of the following factors or comorbidities:
— heavy calcium burden of the ascending aorta (a porcelain aorta);
— prior chest radiotherapy;
— chest deformations;
— liver diseases;
— osteoporosis;
— patent CABG or their track across the line of the sternum;
— neoplasm;
— frailty.

Currently used risk scales are based on cohorts of patients who underwent SAVR, and they are not specific for rapidly evolving TAVI procedures. Cardiology and cardiac surgery societies should work jointly in the future to provide an accurate definition of risk groups of patients qualified to TAVI.

Patient screening and qualification to TAVI
The complex examination of a patient referred for TAVI can be performed in a referring hospital or a TAVI centre (Fig. 1). Local protocols for patient screening should include [22]:
— clinical data allowing for the STS and/or EuroSCORE risk assessment;
— valid information not covered by contemporary surgical risk scales;
— data on comorbidities and medical history, their course, and potential impact on proposed treatment;
— complete diagnostics of comorbidities, such as coronary artery disease, chronic pulmonary obstructive disease, cancer, and renal failure;
— assessment of cognitive and mental disorders;
— echocardiographic evaluation of:
  • morphology and function of the aortic valve;
  • morphology and function of other heart valves;
  • other structural heart diseases and/or defects;
  • myocardial function;
  • pulmonary artery pressure;
— ultrasound examination of carotid arteries;
— diagnosis of coronary artery disease: invasive or MSCT coronary angiography;
— the MSCT of the heart and peripheral vessels;
— in the presence of contraindications to the MSCT:
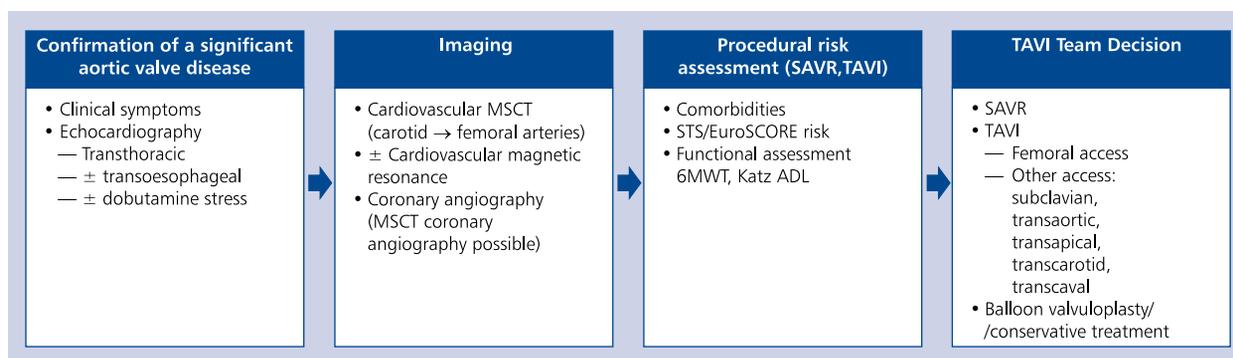
Figure 1. Patient diagnosis and screening for transcatheter aortic valve implantation (TAVI); 6MWT — 6-minute walk test; SAVR — surgical aortic valve replacement; STS — Society of Thoracic Surgeons; Katz ADL — Katz Index of Independence in Activities of Daily Living; MSCT — multislice computed tomography

- magnetic resonance of heart and peripheral arteries;
- three-dimensional (3D) echocardiography;
- peripheral artery angiography or a vascular ultrasound examination.

Echocardiography

Transthoracic and transoesophageal echocardiography, optimally three-dimensional (3D-TTE and 3D-TEE), allow for an accurate analysis of the aortic valve morphology. 3D-TEE-derived parameters reproduce results obtained from the heart MSCT. TEE remains a valuable tool in periprocedural monitoring, supporting decision-making on valve sizing, balloon valvuloplasty, and assessment of PVL [56, 57].

Multislice computed tomography

MSCT is pivotal in patient screening for TAVI and should be performed unless evident contraindications are present. Examination of peripheral arteries allows a decision to be made regarding the optimal access route. It should include assessment of the depth of subcutaneous tissue overlying the artery, diameters, tortuosity, and pattern of calcifications of femoral, iliac, and subclavian arteries and evaluation of the aortic arch morphology. The following MSCT-derived parameters allow us to choose the proper size of bioprosthesis: aortic valve perimeter and area, left ventricular outflow tract diameter, coronary sinus diameter, sino-tubular junction height and diameter (STJ), as well as distances of coronary artery ostia from the plane of the virtual aortic valve annulus.

MSCT allows determination of the optimal C-arm projection during TAVI procedure, significantly reducing the total amount of contrast needed for valve implantation. The MSCT-based analysis of the amount and spatial distribution of aortic annulus and leaflet calcification may limit the frequency of post-implantation PVL in TAVI [58].

We propose the following two-stage computed tomography protocol [19]:
1. Contrast MSCT:
   - range: from carotid arteries to the cardiac apex;
   - electrocardiogram (ECG)-gating: retrospective (optimal) or prospective;
   - slice thickness: < 1 mm.
2. Contrast MSCT angiography: from the thoracic aorta to lower limb arteries (unless the transapical route has already been chosen):
   - if scanning in one setting, allow a 15-s delay between cardiac and abdominal phases (to allow the patient to breathe and ECG gating to turn off);
   - range: base of the heart and down to the lesser trochanter, including the abdominal aorta to common femoral arteries;
   - non-ECG gated;
   - slice thickness: < 1 mm.
3. Intravenous contrast injection protocols: depending on the computed tomography hardware and injection systems, they should be adjusted to the patient body composition and the renal function. Variable injection rates during the MSCT acquisition allow a substantial reduction of the amount of injected contrast medium [59].

MSCT allows quantification of aortic valve calcification, which is a risk factor for the progression of the aortic stenosis, future cardiovascular adverse events, and the need for a pacemaker implantation after TAVI. The amount of calcium in the TAVI device landing zone, defined as a volume or Agatston units, is a predictor of residual PVL [60, 61].

Functional assessment of the aortic valve

Assessment of the severity of the aortic valve disease should be based on the echocardiography, using ESC guidelines criteria [9]. In patients with a suspected low-grade aortic stenosis, a dobutamine stress test echocardiography is recommended to help define both the nature and severity of the disease, and in relation to the left ventricular contractile reserve.
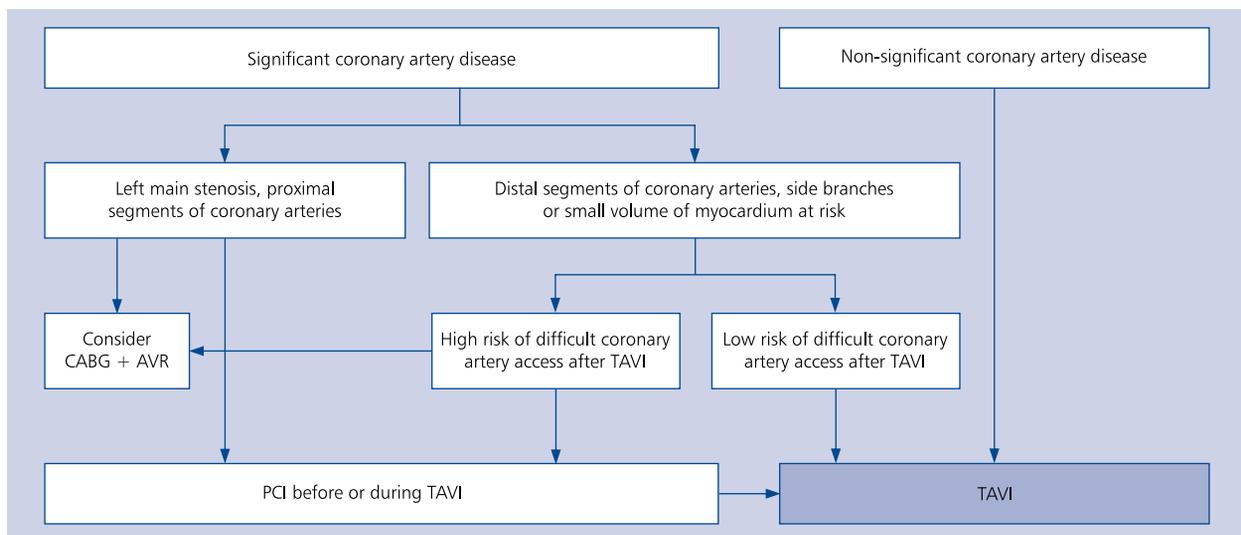
Figure 2. Recommended procedure in patients with diagnosed coronary artery disease, qualified to transcatheter aortic valve implantation (TAVI) by the TAVI team; AVR — aortic valve replacement; CABG — coronary artery bypass grafting; PCI — percutaneous coronary intervention

Morphological assessment of the aortic valve

A precise analysis of the aortic valve anatomy is crucial in a patient qualification pathway to TAVI. MSCT is a gold-standard examination used for the recognition of the aortic valve apparatus and an anatomical relationship between the aortic valve and its surrounding structures. In cases of uncertain or unreliable MSCT results, they should be verified by TEE [38].

Assessment of coronary anatomy and coronary revascularisation

Coronary angiography is recommended in patients qualified to SAVR (I C class of recommendations) [9]. The knowledge of coronary artery anatomy is essential and allows for additional risk and clinical/procedural stratification. Aortic valve replacement combined with CABG improves prognosis in patients with a significant coronary artery disease and may be reconsidered in cases of coexisting multivessel coronary disease [62, 63]. Although coronary artery disease is present in 34–75% of patients qualified to TAVI, its impact on long-term mortality has not been proven [5, 6, 8, 64, 65]. Also, available registry data do not demonstrate short- and long-term benefit of percutaneous coronary intervention (PCI) performed before TAVI [66–70]. These observations may result from variable criteria used for the definition of significant coronary lesions and problems with accurate assessment of fractional flow reserve and the instantaneous wave-free ratio in patients with a significant aortic valve disease [71].

While waiting for more evidence gathered from clinical trials and with further widening of TAVI indications to populations with longer life expectancy, we recommend taking the decision on revascularisation in TAVI Teams, following ESC/EACTS guidelines for the management of valvular heart diseases and myocardial revascularisation. In current clinical practice, angiographically significant stenosis of proximal segments of main coronary arteries, including the left main, depending on a SYNTAX Score II, are treated either with coronary angioplasty or bypass grafting after considering the procedural risk [72]. Ostial coronary lesions require careful stent positioning to avoid its future collision with the implanted aortic valve bioprosthesis. It is of particular importance in patients with a narrow anatomy of coronary sinuses. It should be noted that conditions of PCI after TAVI depend on the type of implanted bioprosthesis and its position relative to ostia of coronary arteries. In patients with advanced coronary artery disease and a high estimated risk of their percutaneous treatment or after its failed attempt, we recommend considering a repeat consultation towards the surgical treatment: SAVR combined with CABG. In patients with a clinically dominant importance of aortic stenosis, revascularisation should not postpone TAVI treatment [72]. The proposed treatment algorithm in patients with coronary artery disease, who are qualified to TAVI, is presented in Figure 2.

Assessment of vascular access

A thorough access site assessment is an indispensable part of the patient screening pathway to TAVI. The imaging should range from all available TAVI access sites to the site of valve implantation. MSCT allows analysis of all currently used TAVI routes, with an accurate definition of vessel diameters, their tortuosity, and patterns of their calcification. Angiography remains inferior in this context while using comparable amounts of contrast agents. In patients with advanced renal

failure, with a high risk of contrast nephropathy, magnetic resonance imaging or, to a lesser extent, vascular ultrasound permit competent analysis of vascular access in TAVI.

Currently, the following access sites are used for TAVI procedures:

4. Transvascular:
   — transfemoral: allowing an entirely percutaneous valve implantation with the subsequent vascular closure of the puncture site;
   — trans-subclavian;
   — transaxillary;
   — transcarotid;
   — transcaval, caval-aortic.
5. Transthoracic:
   — transapical: using a left lateral mini-thoracotomy;
   — transaortic: using a mini-sternotomy or a right lateral mini-thoracotomy.

The common femoral artery is the preferred and most frequently used vascular access site. Published data has proven the presence of the most favourable TAVI outcomes using transfemoral approach. Therefore, the femoral artery is the first-choice access, and its evaluation should be performed in all patients referred to TAVI [7, 73]. Outer diameters of currently used transfemoral TAVI systems do not exceed 8 mm. With the most advanced technology the procedure is possible via femoral arteries with diameters ≥ 5 mm, using percutaneous closure devices or a surgical arterial cut-down, the latter performed after 2–3 cm incision of the overlying skin. Currently, the artery preclosure and the surgical access are equally safe and efficient [74, 75]. Their choice should depend on the experience and preferences of the TAVI centre, considering its outcomes and complication rates [76].

Transfemoral access should be preferred in all TAVI patients. In the case of a very small artery diameter ≤ 5 mm or the presence of extensive atherosclerosis or calcifications, significantly narrowing the vessel lumen, the TAVI team should consider an alternative vascular approach. If no contraindications to general anaesthesia exist, a transthoracic access should be considered [77, 78].

The transapical implantation is performed under general anaesthesia. After minimally-invasive skin cut-down in the fifth or sixth left intercostal space, the apex is visualised and prepared for puncture and guidewire insertion across the aortic valve to the descending aorta. One of the major benefits of the transapical approach is a small distance between the apex and aortic valve, allowing for a stable and controlled valve deployment. However, due to more invasive nature, the transapical approach remains a secondary alternative.

Functional patient assessment

The assessment of physical activity, cognitive function, and nutrition is increasingly used to identify patients with a possibly futile outcome of proposed SAVR or TAVI.

1. Any decrease in the six-point scale Katz Index of Independence in Activities of Daily Living (Katz ADL) leads to an increased risk of procedural complications and a worse long-term outcome in patients undergoing TAVI [79].
2. Similarly, a reduced exercise capacity indicated by the 6-m walking test (6MWT) distance under 150 m or a 5-m walking test duration exceeding 6 s are predictive of poor outcomes after TAVI [80–82].
3. AHA/ACC guidelines on managing patients with valvular heart diseases advocate frailty assessment in addition to global risk scores when assessing procedural risk: the presence of at least two frailty indexes indicates an increased risk of the planned procedure [53].
4. The Mini-Mental Status examination allows detection of disturbances of the cognitive function or dementia.
5. The visual assessment of the patient stature and nutrition, paired with the body mass index, are valuable tools in routine patient assessment before aortic valve replacement and TAVI, allowing prediction of worse procedural and long-term outcome.

The presented scales and indices should be complementary to the general evaluation of the patient referred to TAVI.

Quality of life assessment

Treatment of valvular diseases in elderly patients with multiple comorbidities may not extend their long-term survival but may improve their quality of life (QoL). The recommended QoL scales used in TAVI patients are the heart-failure specific Kansas City Cardiomyopathy Questionnaire (KCCQ) and a general EuroQoL 5-Dimensions 5-Levels Questionnaire (EQ-5D-5L). The observation of QoL changes before and after the intervention allows assessment of the clinical benefit from the treatment. In turn, such analysis will allow a better description and selection of patients with the greatest potential QoL increase after TAVI [83, 84].

Patients unlikely to benefit from TAVI

Despite the growing experience of TAVI centres, advances in technology, and reduction of procedural complications, certain patients receive no benefit from the TAVI treatment regarding their clinical status, QoL, and survival. The PARTNER, FRANCE 2, and TARIS clinical trials identified factors associated with a futile post-TAVI outcome. They are presented in Table 1 [85–89]. In patients with risk factors for poor outcomes after TAVI, the TAVI team should inform the patient and the family about the higher probability of procedural complications and possible suboptimal long-term outcome of TAVI.

Recommendations for treatment of patients with significant aortic valve stenosis

1. The decision on the optimal treatment of patients with a severe, symptomatic aortic valve disease should be

Table 1. Clinical factors predicting poor outcomes after transcatheter aortic valve implantation

Diseases	Factors
Chronic lung diseases	6-minute walk test (6MWT) < 150 m
	Oxygen therapy
Advanced renal failure	Atrial fibrillation
	Renal dialysis
Frailty	Katz ADL < 6
	6-minute walk test < 150 m
Cardiovascular diseases	LVEF < 30%
	Pulmonary hypertension (mean PAP > 25 mm Hg)
	Low-gradient aortic valve stenosis
	Low cardiac output (< 35 mL/m^2)
	Severe degenerative mitral valve regurgitation

Katz ADL — Katz Index of Independence in Activities of Daily Living; LVEF — left ventricular ejection fraction; PAP — pulmonary artery pressure

made by a multidisciplinary TAVI team experienced in patient screening and management during TAVI procedures. It should include at least: two certified TAVI operators (an interventional cardiologist and a cardiac surgeon), an echocardiographer, and an anaesthesiologist [22, 90].

2. Prohibitive-risk patients should be qualified to TAVI first [6, 28, 91].

3. High-risk patients (STS ≥ 8%, EuroSCORE II ≥ 8%, log EuroSCORE ≥ 20%) should be qualified to TAVI first [5, 8, 9, 53].

4. The decision on the treatment strategy of the following groups of patients should depend on the TAVI team:
   — intermediate-risk patients [5, 7–9, 32, 35, 53];
   — patients aged ≥ 85 [5, 8, 9, 53];
   — patients with a degenerated aortic valve bioprosthesis or with a history of previous cardiac operations unamenable to SAVR [42, 92–94];
   — patients with the following risks of cardiac surgery:
      • extensive calcification of the ascending aorta (porcelain aorta);
      • history of chest radiotherapy;
      • chest deformations;
      • liver failure;
      • osteoporosis;
      • active or recent history of cancer;
      • frailty syndrome.

5. Low-risk patients < 75-year-old (STS < 4%, EuroSCORE II < 4%, log EuroSCORE < 10%) should be first referred to the surgical aortic valve replacement [9, 95].

6. In unstable patients with severe aortic stenosis and with high operative risk or awaiting a non-cardiac operation, aortic balloon valvuloplasty should be considered alone, or as a bridge to SAVR or TAVI therapy.

7. In unstable patients already qualified to TAVI, aortic balloon valvuloplasty should be considered as a bridge to a planned TAVI procedure.

8. Aortic balloon valvuloplasty can also be considered as a palliative treatment in patients with multiple risk factors rendering cardiac surgery risk prohibitive and TAVI impossible.

9. Patients with a predicted poor outcome, including < one-year survival, should be qualified to a palliative treatment (conservative or aortic balloon valvuloplasty).

TAVI PROGRAMME
TAVI team

Transcatheter aortic valve implantation was introduced as an alternative treatment to the standard cardiac surgery operation in patients with high-risk of SAVR complications. The process of decision-making in this group of patients in highly complex and requires proper judgement in wide areas of medicine: interventional cardiology, cardiac surgery, echocardiography, radiology, anaesthesiology, and vascular surgery. The support of other specialists is often required; neurologists, gastroenterologists, geriatricians, pulmonologists, nephrologists, and oncologists may participate in patient qualification to optimal therapy. Based on this experience, setup of the TAVI team is essential and obligatory in every TAVI centre [13–15, 17–19, 22, 90, 95–100].

The TAVI team is a multidisciplinary group of specialists overviewing and responsible for the TAVI programme in their centre. Its task is to combine the knowledge of diagnosis, treatment decisions, postoperative care, and rehabilitation in patients with structural heart diseases. Independent TAVI operators — an interventional cardiologist and a cardiac surgeon, all certified by corresponding scientific societies (ACVI and the Polish Society of Cardio-Thoracic Surgeons) — constitute the core part of the team. The group also includes other specialists with skills, experience, and knowledge required to assess patients referred to TAVI objectively. They should be able to decide on the efficient and safe therapy of valvular heart diseases. Also, they should be qualified in the treatment of aortic valve diseases and aortic aneurysm, ensuring high-quality postoperative care. Appointment of such teams, who plan and perform structural heart interventions, significantly improves the outcome of such complex therapy.

The TAVI team includes:
— operators: interventional cardiologists and cardiac surgeons, all certified in TAVI;
— specialists qualified in the imaging of the cardiovascular system (cardiologists experienced in the non-invasive cardiovascular imaging, radiologist);
— nurses engaged in the care of patients qualified to TAVI;
— a cardiologist;
— an anaesthesiologist.

The main role of the TAVI team is a thorough patient assessment, estimation of benefits and risks of all available treatment strategies, and finally, deciding on the optimal destination therapy (conservative treatment, aortic balloon valvuloplasty, SAVR, or TAVI). The TAVI team may define the optimal access, type of anaesthesia, the choice and size of bioprostheses, the role of TAVI operators, and the type of postoperative care and its location in cardiac surgery or cardiology departments. We recommend briefings on the management of potential procedural complications before every procedure. Such a strategy, summing up decisions and describing procedural scenarios, increase the team's preparation for the planned therapy.

TAVI team meetings should be regular in every TAVI centre, with official dates known to referring physicians. Joint decisions should be communicated to the patient, and the physician involved in the treatment process. We recommend designing and using dedicated TAVI templates, simplifying and speeding the patient referral, the risk assessment, and decision making on the TAVI procedure (Appendix 1–3).

Preprocedural management

A member of the TAVI team should provide necessary information to the TAVI patient and the family on preparation for the procedure, its expected outcomes, and risks involved. The timing of the patient admission depends on the clinical status and necessary diagnosis. It should allow planning of the drug therapy and estimation of the degree and type of potential cardiac arrhythmias and abnormalities of the conduction system. If right ventricular pacing is planned during the TAVI procedure in patients with an implantable cardioverter-defibrillator device, we recommend modifications to its settings beforehand.

TAVI procedure

The TAVI procedure is performed by a team of operators: interventional cardiologists and/or cardiac surgeons. All operators involved should be certified in TAVI by their corresponding scientific societies: the ACVI for interventional cardiologists and the Polish Society of Cardio-Thoracic Surgeons for cardiac surgeons.

To increase the safety of the operated patient, we recommend that TAVI be performed jointly by a certified interventional cardiologist and a certified cardiac surgeon.

Choosing the optimal type of anaesthesia, obtaining a safe vascular access, and setting the best C-arm projection for fluoroscopy are the first, crucial stages of the TAVI procedure. If peripheral access is planned in patients with severe atherosclerosis, we recommend the direct assistance of a vascular surgeon during the procedure.

Further, a stiff wire is passed through the aortic valve to the left ventricle, supporting the aortic balloon placement (used during an elective valvuloplasty) and the TAVI system.

The aortic balloon valvuloplasty is performed most frequently during a rapid pacing of the right ventricle, usually at the rate of 160–200 bpm. Such stimulation allows for reducing the systolic pressure in the left ventricle and its stroke volume. Depending on the patient risk profile, the amount of calcification, and the annulus sizing precision, the balloon valvuloplasty may often be skipped [78]. The implantation technique of the aortic bioprosthesis varies with its type and construction. Balloon-expandable valves should be implanted during a rapid pacing of the right ventricle, while such stimulation is optional for self-expandable prostheses. In difficulties of valve stabilisation, fast pacing at the rate of 120–140 bpm may help to achieve an accurate implantation position [11]. After the valve deployment, its location in the surrounding anatomy, and the function and presence of PVL should be assessed by angiography and echocardiography. If the paravalvular regurgitation is severe, the bioprosthesis may be post-dilated with a correctly sized aortic balloon, at the increased risk of valve malposition. If PVL is related to an incorrect valve position, further decisions should be based on precise benefit-risk calculations [89]. The implanted bioprosthesis may be repositioned or sealed by implantation of the second aortic prosthesis in the required aortic position, or managed by surgical intervention.

If TAVI is followed by a haemodynamic patient instability or ECG patterns of acute myocardial ischaemia, we recommend performing an urgent coronary angiography to assess patency of coronary arteries. Their occlusion is a rare but life-threatening complication. It requires immediate action to restore the myocardial blood supply with either percutaneous coronary angioplasty or a relocation of the aortic bioprosthesis. In any sudden worsening of the patient's clinical status, the team should rule out aortic annulus rupture, acute cardiac tamponade, or other major vascular complications that require prompt management. Therefore, we recommend that an interventional cardiologist and a cardiac surgeon be present in the TAVI centre during each TAVI procedure.

The last stages of TAVI are the achievement of full haemostasis at puncture sites, confirmation of stable patient's clinical status and his/her safe transfer to a postoperative, intensive cardiology or cardiac surgery care unit. Any active bleeding at the site of the puncture, arterial dissection, or its occlusion should be promptly managed with peripheral balloons, stents, or stent-grafts sized according to the vessel diameter. In the presence of serious complications, vascular surgery is warranted to save the affected artery.

Post-procedural management

The aims of the post-procedural management are prompt patient mobilisation and autonomy as well as monitoring and treatment of potential procedural complications. The course of postoperative surveillance over TAVI patients differs from cardiac surgery and requires a dedicated care pathway in the

TAVI centre. The most common problems occurring during this phase are: bleeding or vascular complications, cardiac arrhythmias, stroke, and acute heart or respiratory failure.

Patients should remain in the intensive postoperative care unit or the intensive cardiology care unit for at least one night after TAVI. A reasonably quick patient transfer to a step-down unit enables their earlier mobilisation, self-care, and feeding, resulting in shortening the length of hospital stay (LOS). In advanced centres, the mean LOS of an uncomplicated TAVI is 2–5 days for transfemoral approach and 4–7 days for other access sites used [14]. Based on POL-TAVI registry reports, the mean LOS of an uncomplicated TAVI procedure in Poland is seven days.

Cardiac conduction disturbances

Disturbances of the cardiac conduction system are relatively common after TAVI. Such complications are precipitated by the anatomical neighbourhood of the aortic valve and the bundle of His and its branches. Reported postprocedural rates of pacemaker implantation after TAVI range from 17.5% in the German GARY registry, 17.4% in the FRACE-2 registry to 11.0% in the American Transcatheter Valve Therapy Registry [101–105].

Prognostic factors. Known factors of a new-onset cardiac conduction abnormalities after TAVI are:
— male sex;
— the presence of cardiac conduction disturbances before TAVI:
   • right bundle branch block,
   • left anterior hemiblock,
   • atrioventricular block (AVB) type I;
— TAVI in the native aortic valve (unlike the Valve-in-Valve implantation);
— porcelain aorta [106, 107].
   The following risk factors are modifiable:
— the kind of TAVI bioprosthesis (self-expandable > balloon-mounted);
— aortic balloon valvuloplasty;
— the depth of valve implantation below the aortic annulus (≥ 6 mm) [106, 108].

The frequency of new LBBB or pacemaker implantation is significantly higher in patients treated using self-expandable TAVI systems in comparison to balloon-mounted ones (average LBBB rates 48% and 14%, new pacemakers 28% and 6%, respectively) [101, 108]. In the CHOICE randomised clinical trial, 37.6% of patients with self-expandable TAVI bioprosthesis required pacemaker implantation, compared to 17.3% of patients treated with a balloon-mounted bioprosthesis (p < 0.001) [65]. The introduction of newer generation TAVI systems has not lowered the rate of newly implanted pacemakers [102].

Recommendations. Cardiac arrhythmias and conduction disturbances are frequent in populations of patients currently referred to TAVI. Therefore, we recommend that 24-h ECG monitoring and its detailed analysis be performed before the TAVI procedure. Current guidelines do not recommend a prophylactic implantation of pacemakers based on the existence of risk factors for conduction defects. However, early detection of such defects allows shortening of the time needed for decision-making if such complications occur after TAVI [109].

The ESC guidelines on cardiac pacing and cardiac resynchronisation therapy recommend patient observation and monitoring up to seven days before deciding on the implantation of cardiac pacemakers in patients with the occurrence of an advanced or complete AVBs after TAVI (recommendation level 1 C) [110]. In the case of a complete AVB with a low rate escape rhythm, the time of monitoring may be shortened, due to a low probability of recovery. Unfortunately, current registry data indicate that clinical practice does not follow the published guidelines: 33% of pacemaker implantations occur in the first 24 h, and 50% of them in the first 48 h, after TAVI [109, 111].

The occurrence of the sick sinus syndrome with symptomatic bradycardia after TAVI, without a complete AVB, is not an indication for pacemaker implantation. On the contrary, the presence of the new LBBB after TAVI increases the risk of late, advanced AVB by more than three-fold, especially in patients with a QRS duration > 160 ms [112]. Electrotherapy should be considered in this group of patients until new evidence from randomised trials appears [112, 113]. The algorithm of recommended diagnosis and treatment of TAVI-qualified patients with conduction abnormalities is presented in Figure 3.

Bioprosthetic transcatheter valve dysfunction

Recommendations on diagnosis and treatment of thrombotic complications after TAVI are based on empirical data because the frequency of leaflet thrombosis in TAVI devices is not precisely known. In the randomised PARTNER and CoreValve trials the occurrence of leaflet thrombosis was not reported. In two multicentre registries it was observed in 0.76% and 0.61% of patients, most often in the first three months after TAVI [114, 115]. Routine MSCT examination performed in the three months after TAVI allowed for detection of leaflet thrombosis in 6.9% of patients. The recognised predictive factors for transcatheter aortic valve dysfunction were large size of the prosthesis and lack of oral anticoagulation (OAC) after TAVI [116]. Current classification of bioprosthetic valve thrombosis is based on its timing or diagnostic certainty, assessed with clinical, imaging, or pathological criteria (Tables 2 and 3) [117].

For prevention of thromboembolic events after TAVI, European and American cardiology societies recommend dual antiplatelet therapy with aspirin (75–100 mg daily) indefinitely and clopidogrel (75 mg daily) given for 1–6 months. The Canadian Cardiovascular Society supports clopidogrel withdrawal 1–3 months after the procedure, which corresponds to the current clinical practice in Poland. Based on
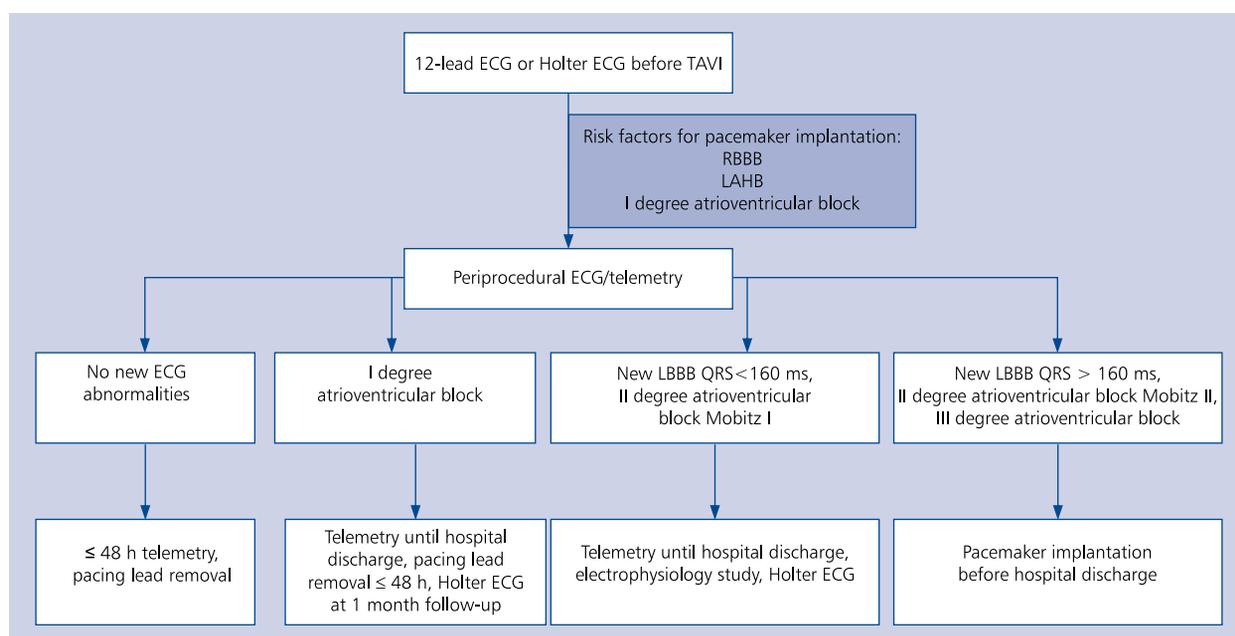
Figure 3. Recommended diagnosis and treatment of conduction abnormalities in patient qualified to transcatheter aortic valve implantation (TAVI); ECG — electrocardiogram; LAHB — left anterior hemiblock; LBBB — left bundle branch block; RBBB — right bundle branch block

Table 2. Temporal classification of bioprosthetic valve thrombosis

Classification	Time of onset after TAVI
Acute	0–3 days
Subacute	4 days – 3 months
Late	3 months – 1 year
Very late	> 1 year

reports of high bleeding rates in patients undergoing TAVI in Poland, its authors recommend individual evaluation of double antiplatelet therapy (DAPT) requirements vs. single antiplatelet therapy (SAPT). They also note that antiplate-

let monotherapy, preferably with aspirin, could minimise bleeding complications, without increasing rates of early dysfunction of TAVI bioprosthesis [118, 119]. In patients with indications to OAC, we recommend a combination of OAC and SAPT (clopidogrel or aspirin) for 1–3 months [13, 14, 17–19, 83, 101, 120].

The recommended antiplatelet and antithrombotic therapy after TAVI, based on comorbidities and patient bleeding risk, is presented in Tables 4 and 5 [121–124]. Publication of randomised clinical trials evaluating optimal antiplatelet and antithrombotic therapy after TAVI (novel oral anticoagulants [NOAC], and their pairing with ticagrelor), the introduction of new stents, as well as the publication of new guidelines on the

Table 3. Classification of bioprosthetic valve thrombosis based on diagnostic certainty

Diagnostic certainty	Clinical symptoms	MSCT	Echocardiography	Pathomorphology
Definite	Regression of new-onset heart failure symptoms after initiation of anticoagulation therapy	Reduced leaflet motion Hypoattenuated leaflet thickening	Visualisation of thrombosis Regression of elevated mean gradient < 10 mm Hg after oral anticoagulation therapy	Evidence of device thrombosis on examination of tissue samples retrieved during cardiac surgery or autopsy
Probable	Acute heart failure symptoms	Reduced leaflet motion	Increase in mean gradient > 10 mm Hg	–
Possible	Stroke or arterial embolism after TAVI, after exclusion of other causes	–	–	–

MSCT — multislice computed tomography; TAVI — transcatheter aortic valve implantation

Table 4. Antiplatelet therapy in patients with sinus rhythm, who are qualified to transcatheter aortic valve implantation (TAVI)

Indications other than TAVI	Therapy	Before TAVI	≤ 3 months after TAVI	> 3 months after TAVI
None	–	SAPT (ASA*) for 48 h	SAPT (ASA*)	Lifelong SAPT (ASA*)
Coronary artery disease	SAPT (ASA*)	SAPT (ASA*)	SAPT (ASA*)	Lifelong SAPT (ASA*)
Elective PCI before TAVI	DAPT[1]	SAPT (ASA*) for 5–7 days	SAPT (ASA*)/DAPT[1] if PCI soon after TAVI	Lifelong SAPT (ASA*)
ACS before TAVI	DAPT[2]	SAPT (ASA*) for 5–7 days/DAPT[2]	SAPT (ASA*)/DAPT[2]	DAPT[2] < 6 months, followed by lifelong SAPT (ASA*)

ACS — acute coronary syndrome; ASA — acetylsalicylic acid; DAPT — double antiplatelet therapy; PCI — percutaneous coronary intervention; SAPT — single antiplatelet therapy; *Preferred: (1) DAPT for 1 to 6 months following PCI, depending on the type of stent used as well as the risk of thrombosis and bleeding. Potent P2Y12 inhibitors (prasugrel, ticagrelor) should not be used. Reduce to SAPT 5–7 before TAVI. If possible, defer TAVI > 1 month after PCI; (2) DAPT for 3 to 6 months following PCI. Potent P2Y12 inhibitors (prasugrel, ticagrelor) should not be used. Reduce to SAPT 5–7 before TAVI. If possible, defer TAVI until DAPT termination

Table 5. Antiplatelet and antithrombotic therapy in patients with atrial fibrillation (AF), who are qualified to transcatheter aortic valve implantation (TAVI)

Indications other than TAVI	Therapy	Before TAVI	≤ 3 months after TAVI	> 3 months after TAVI
AF	VKA/NOAC	VKA: stop (INR 1.0–1.3), LMWH bridging may be considered. NOAC: stop 48–72 h before TAVI, depending on agent and creatinine clearance. LMWH bridging in very high stroke risk	VKA Consider LMWH bridging until therapeutic INR achieved	VKA/NOAC[1]
AF + elective PCI before TAVI	VKA/NOAC + DAPT[2]	VKA: stop (INR 1.0–1.3), LMWH bridging may be considered. NOAC: stop 48–72 h before TAVI, depending on agent and creatinine clearance. LMWH bridging in very high stroke risk + SAPT (ASA*) for 5–7 days	VKA Consider LMWH bridging until therapeutic INR achieved + SAPT (ASA*)/consider DAPT[2] if PCI soon after TAVI	VKA/NOAC[1] + SAPT ≤ 6 months after TAVI
AF + ACS before TAVI	VKA/NOAC + DAPT	VKA: stop (INR 1.0–1.3), LMWH bridging may be considered. NOAC: stop 48–72 h before TAVI, depending on agent and creatinine clearance. LMWH bridging in very high stroke risk + SAPT (ASA*) for 5–7 days	VKA Consider LMWH bridging until therapeutic INR achieved + SAPT (ASA*)/consider DAPT[2] if PCI soon after TAVI	VKA/NOAC[1] + SAPT ≤ 6 months after TAVI

ACS — acute coronary syndrome; ASA — acetylsalicylic acid; DAPT — double antiplatelet therapy; INR — international normalised ratio; LMWH — low molecular weight heparin; NOAC — novel oral anticoagulants; PCI — percutaneous coronary intervention; SAPT — single antiplatelet therapy; VKA — vitamin K antagonists; *Preferred: (1) VKA are preferred due to insufficient NOAC evidence. Until the publication of randomised trials, starting NOAC may be considered 3–6 months after TAVI; (2) DAPT for 1 to 6 months following PCI, depending on the type of stent used as well as the risk of thrombosis and bleeding. Potent P2Y12 inhibitors (prasugrel, ticagrelor) should not be used. Reduce to SAPT 5–7 before TAVI. If possible, defer TAVI > 1 month after PCI; (3) Defer TAVI until DAPT termination, if possible. Otherwise, maintain DAPT for 3–6 months after ACS in patients with high thrombotic risk. Potent P2Y12 inhibitors (prasugrel, ticagrelor) should not be used

use of dual antiplatelet therapy may modify our current recommendations. Nonetheless, we advise taking an individual approach to patients who are qualified to TAVI, considering their increased bleeding and thrombotic risk.
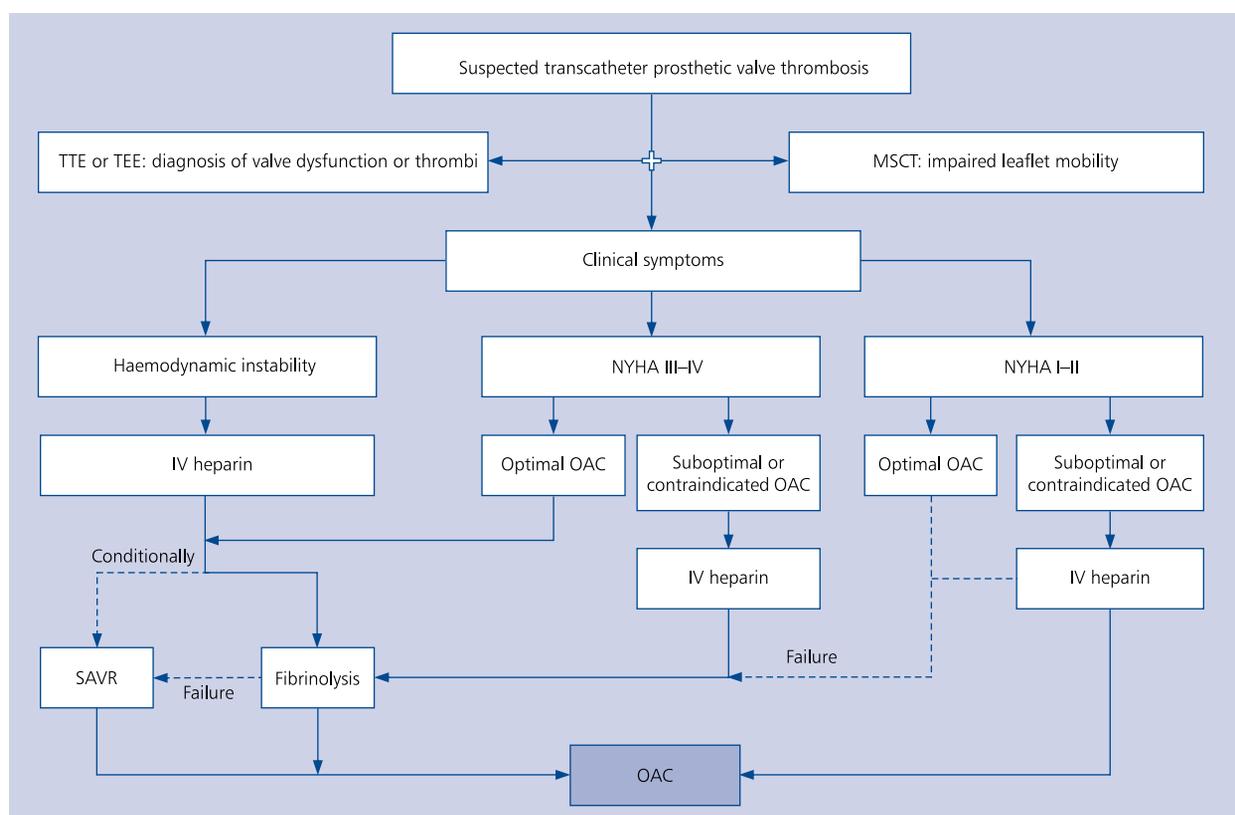
Figure 4. Recommendations on the diagnosis and management of transcatheter aortic valve thrombosis; IV — intravenous; MSCT — multislice computed tomography; NYHA — New York Heart Association functional class; OAC — oral anticoagulation; SAVR — surgical aortic valve replacement; TEE — transoesophageal echocardiography; TTE — transthoracic echocardiography

Management of transcatheter aortic valve thrombosis depends on the severity of heart failure symptoms and evidence derived from echocardiography or MSCT. The proposed algorithm for the diagnosis and treatment of transcatheter aortic valve thrombosis is presented in Figure 4 [117].

Endocarditis. The risk of prosthetic valve endocarditis is present in all patients after SAVR or TAVI. Therefore, primary and secondary prevention is vital in all TAVI patients as indicated in the ESC guidelines for the management of infective endocarditis [125].

Echocardiography follow-up. TTE should be performed in all TAVI patients before hospital discharge, with special attention paid to transvalvular pressure gradient, effective valve area, and degree and location of PVL. Follow-up TTE examinations should be planned at one-month follow-up visit after TAVI and every year thereafter [126]. The intervals should be shorter in patients with increased risk of early bioprosthesis degeneration: high gradient, PVL, renal failure, and at every new onset of heart failure (Fig. 5) [117].

TAVI OPERATORS
TAVI operator requirements
The status of an independent TAVI operator may be given to interventional cardiologists who comply with the ACVI

certification requirements, and to cardiac surgeons who have received TAVI Skill Certificate issued by the Polish Society of Cardio-Thoracic Surgeons, allowing them to perform these procedures using all available access sites.

To guarantee patient safety, we recommend the presence of two certified TAVI operators during the procedure: an interventional cardiologist and a cardiac surgeon. The following, detailed recommendations on TAVI training and skills refer to both operators involved.

Interventional cardiologist
To receive an Independent TAVI Operator Certificate, an interventional cardiologist should fulfil the following criteria:
1. Board-certified specialisation in cardiology.
2. A valid certificate of the Independent Interventional Cardiology Operator issued by the ACVI.
3. The first or the second operator experience of:
   — at least 10 TAVI procedures performed under the supervision of an independent TAVI operator/proctor;
   — followed by at least 20 TAVI procedures performed independently;
   — at least 10 TAVI procedures performed yearly afterwards;
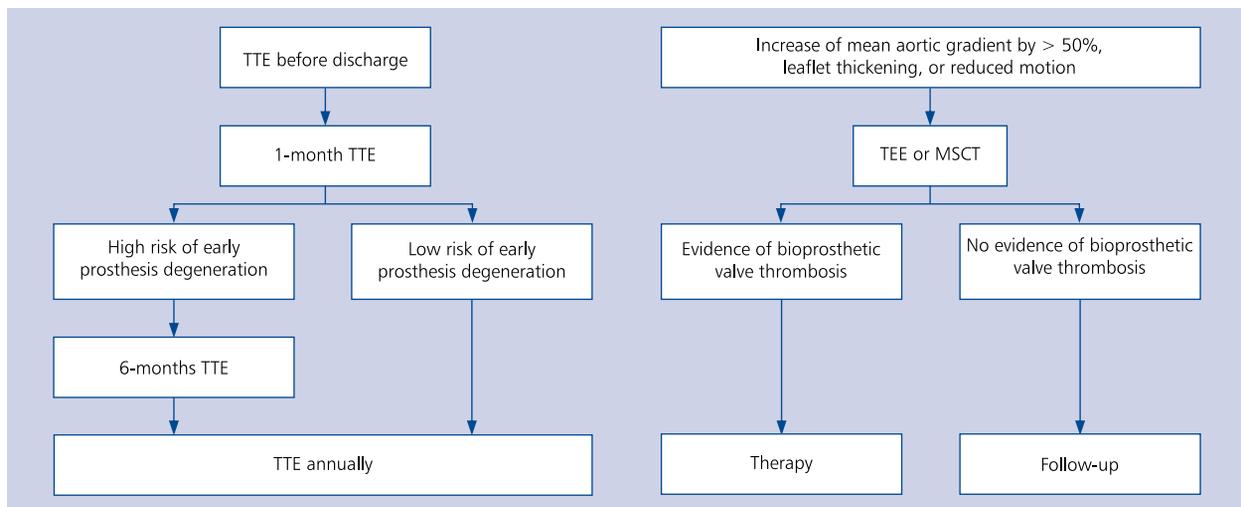
Figure 5. Recommended bioprosthetic valve imaging follow-up after transcatheter aortic valve implantation; MSCT — multislice computed tomography; TEE — transoesophageal echocardiography; TTE — transthoracic echocardiography

— after the total of 50 TAVI procedures performed, the Independent TAVI Operator Certificate becomes permanent.

4. Formal training on the use of available TAVI systems, including tutoring in an experienced TAVI centre. At a minimum, the training should include educational presentations and participation in at least two TAVI procedures performed in a reference TAVI centre.

TAVI is a complex procedure, requiring skilful management of various complications. Therefore, interventional cardiologists should take part in courses and practical training in:
— interventional treatment of structural heart diseases;
— interventional diagnosis and treatment of peripheral artery diseases;
— peripheral artery access site management and closure;
— extracorporeal membrane oxygenation (ECMO) placement and patient management [13, 15, 17, 18, 21, 83, 90, 95, 127–129].

Cardiac surgeon

A cardiac surgeon — an Independent TAVI Operator — should fulfil the criteria defined by the Skill Certificate, issued specifically by the Polish Society of Cardio-Thoracic Surgeons, after the following experience and skills in TAVI have been documented:
— a board-certified specialisation in cardiac surgery;
— operator experience in surgical valve replacement, with the minimum of 300 structural heart operations;
— operator experience in surgical valve reoperations, with the minimum of 25 reoperations;
— ECMO placement and patient management;
— participation in TAVI training, as recommended by the Polish Society of Cardio-Thoracic Surgeons or Euro-

pean societies: EACTS/ESC/ESCVS, or other specialisation courses;
— operator experience in at least 20 TAVI procedures [13, 15, 17, 18, 21, 83, 129–131];
— at least 10 TAVI procedures performed yearly afterwards;
— formal training on the use of available TAVI systems, including a practice in an experienced TAVI centre. At a minimum, the training should include educational presentations and participation in at least two TAVI procedures performed in a reference TAVI centre [90, 95, 127, 128].

TAVI CENTRE

Institutional and operator experience is crucial for securing optimal outcomes in patients referred to TAVI. The introduction of the modern TAVI technology to treat high-risk patients in multispecialty hospitals with established TAVI teams allows reduction of the number of procedural complications in the challenging treatment group. Such a policy ensures optimal decision making during patient referral to TAVI. Also, it guarantees skilful procedural performance and high quality of care during hospitalisation and after the discharge.

The TAVI programme should be conducted in hospitals with accredited interventional cardiology catheterisation labs (class C accreditation awarded by ACVI), with a cardiac surgery department on site.

Moreover, the TAVI centre should fulfil the following criteria [13, 15, 17, 18, 21, 83, 90, 95, 132]:
— perform no less than 1000 coronary angiography and no less than 700 coronary angioplasty procedures in a calendar year;
— perform at least 150 SAVR in a calendar year, including at least 15 SAVR in high-risk patients (STS ≥ 8%, Euro-SCORE II ≥ 8%);

— employ at least two interventional cardiologists and at least two cardiac surgeons, all certified in TAVI by appropriate scientific societies;

— take part in the Polish TAVI Registry, POL-TAVI, with systematic data contribution and monitoring of its completeness (https://poltavi.pl);

— enrol in the Polish Interventional Cardiology TAVI database, administered by ACVI (PICTS, available online: http://aisn.pl) and the TAVI centre address database, managed by the Polish Society of Cardio-Thoracic Surgeons.

TAVI centres should contain the following facilities [13, 15, 17, 18, 21, 83]:

— cardiac catheterisation laboratory or hybrid cath lab/operating room equipped with a fixed table, fluoroscopy system, and pressure monitoring systems;

— the implantation room must have sufficient space to accommodate all personnel involved in TAVI procedure and the necessary anaesthesiology, echocardiography, and cardiopulmonary bypass equipment, which may be used during TAVI;

— cardiac surgery department on site, performing at least 150 SAVR in a calendar year with mortality < 6% and approximately 10% of SAVR reoperations;

— non-invasive cardiology and vascular imaging laboratories:
  • echocardiography lab, performing transthoracic and transoesophageal examinations. Its staff must be trained in imaging of structural heart diseases and their interpretation,
  • access to a vascular laboratory capable of performing vascular imaging examinations and their interpretation,
  • access to a computed tomography laboratory, capable of performing heart and vessel computed tomography imaging and its interpretation;

— catheterisation lab/operating room certified for pacemaker and implantable cardiac defibrillator implantations;

— essential equipment to treat various TAVI complications, such as heart conduction abnormalities, aortic and peripheral artery perforation, cardiac tamponade, and cardiogenic or hypovolaemic shock;

— ECMO availability and TAVI team experience in its implantation and management in life-threatening conditions;

— (Cardiology) Intensive Care Unit or Postoperative Intensive Care Unit present on-site;

— renal replacement therapy available on-site.

To increase standards of TAVI procedure, we recommend:

— integration of ventilation and air conditioning laminar flow diffusers;

— high-output lighting systems for the operating field.

TAVI outcomes

Outcomes of TAVI therapy strongly depend on the institutional experience gained and individual number of procedures performed by TAVI operators. To ensure a high procedural safety profile and quality of care, TAVI centres should aim to achieve the following level of proficiency, including the number of procedures performed and their outcomes levels [13–15, 17, 18, 21, 83, 90, 95, 132]:

— ≥ 40 TAVI procedures per calendar year;

— 30-day all-cause mortality < 5%;

— 30-day stroke (transient ischaemic attack included) < 5%;

— major vascular complications < 3%;

— continuous reporting and integrity of data in the Polish TAVI Registry (POL-TAVI) including short-term and long-term follow-up;

— 80% one-year patient survival rate in the last two years of the TAVI programme in the centre.

TAVI REGISTRIES: ACCESSIBILITY AND SAFETY MONITORING

Transcatheter aortic valve implantation is a novel technology, requiring continuous evaluation of procedural safety as well as short- and long-term treatment outcomes. Multicentre TAVI registries are necessary to establish the efficacy of this therapy in specific indications. Also, they serve to document the TAVI experience in new clinical applications, in patients with different profile risks and treated with an array of TAVI systems. Short- and long-term follow-up should allow assessment of efficacy and safety of the novel therapy, including patient survival, follow-up of implanted bioprostheses for their degeneration, and observation of reintervention rates after TAVI [133]. Registry objectives may also include cost-effectiveness surveillance and comparison of the offered treatment. Registries should meet the set credibility criteria, assessed by internal as well as external monitoring and validation. Such hospital-independent comparisons with healthcare provider reimbursement reports ensure the highest quality assessment of the novel therapy.

Observational data of all patients undergoing TAVI should be submitted and registered in the Polish cardiology and cardiac surgery TAVI Registry (POL-TAVI). Its creation in 2012 was initiated by cardiac surgeons and cardiologists in cooperation with the Ministry of Health and the National Health Fund and supported by the Polish Cardiac Society and The Polish Society of Cardio-Thoracic Surgeons. Since then POL-TAVI has gathered significant demographic data on patient referral, in-hospital success and complications rates, as well as short- and long-term outcomes in Poland [134]. With bi-annual internal and external auditing, it meets strict criteria set for independent national registries.

TAVI COST

The mean cost of TAVI treatment is currently five-times higher than SAVR, a situation driven mainly by the cost of the bioprosthesis. At the same time, the valuation of TAVI procedure and hospitalisation in Poland is lower than in other European Union countries. Based on the experience of many Polish

centres, the current reimbursement scheme, covering solely cardiac surgery departments at small procedural valuation level, does not allow the budget of TAVI hospitalisation to be balanced. Importantly, TAVI saves lives and decreases rehospitalisation rates and the length of hospital stay in patients disqualified from SAVR by TAVI teams [6, 91]. In high- and intermediate-risk patients, shortening the intensive care unit stay and the total duration of TAVI hospitalisation may be beneficial, both clinically and economically.

The growth of Polish TAVI team experience supported by technology advances in imaging and construction of transcatheter valves will result in better diagnosis and selection of patients, with a further reduction of complication rates. So far, the economic superiority of TAVI in Poland has been proven in prohibitive and high-risk patients only. Still, with significantly shorter durations of TAVI procedure, the postoperative care, and the total hospital stay, the cost-effectiveness of TAVI may become competitive to cardiac surgery — providing a lower cost of aortic bioprosthesis and readjustment of the compensation for TAVI hospitalisation. As the number of Polish patients on TAVI waiting lists is increasing, a nationwide quality-adjusted life year (QALY) assessment and cost-effectiveness analysis (CEA) is required to address the above problems [12].

SUMMARY

TAVI is a modern and efficient therapy dedicated to specific groups of patients with aortic valve diseases, especially those at high risk of conventional surgery.

TAVI is a lifesaving treatment for non-operable patients. In high- and intermediate-risk groups, results of TAVI and cardiac surgery are comparable. Early experience indicates the usefulness of this therapy in patients with degenerated aortic bioprostheses. Such remarkable outcomes can be achieved as long as TAVI patients are qualified by dedicated TAVI teams and operated by highly skilled TAVI operators: interventional cardiologists and cardiac surgeons. The situation will be possible with continuous education and shared support present among cardiologists, cardiac surgeons, and other physicians involved in the treatment of patients with structural heart diseases in Poland. In the wake of population ageing, medical, organisational, and economic experts participating in the development of this innovative therapy in Poland should act together to increase the number of TAVI procedures and its cost-effectiveness to average European levels. Such actions should rely on results of non-commercial registries of TAVI quality, accessibility, and safety, including POL-TAVI and the National Registry of Cardiac Surgery Procedures (KROK).

EXPERT CONSENSUS OUTLINE
Current evidence

TAVI is a safe and effective therapy in patients with significant and symptomatic AS:

— prohibitive risk/inoperable patients: TAVI is superior to medical treatment (PARTNER 1 Study Cohort B, CoreValve US Pivotal Trial Extreme Risk Iliofemoral Study);
— high-risk patients: TAVI is non-inferior to SAVR (PARTNER 1 Study Cohort A, CoreValve US Pivotal Trial High-Risk Study);
— intermediate-risk patients: TAVI and SAVR are equally effective. In transfemoral approach, TAVI is superior to SAVR (PARTNER 2 A Study, SURTAVI Study);
— low-risk patients: TAVI is non-inferior to SAVR (NOTION).

TAVI is associated with a better or equal effective orifice area and mean pressure gradient of implanted biological prosthesis than after SAVR across all patient risk groups (PARTNER 1, CoreValve High-Risk, PARTNER 2, SURTAVI, NOTION). These parameters remained unchanged in prohibitive risk (PARTNER 1 Study, five-year follow-up), high-risk (PARTNER 1 Study: five-year follow-up, CoreValve High-Risk Study: three-year follow-up), moderate-risk (SURTAVI, one-year follow-up), and low-risk patients (NOTION, two-year follow-up).

Recommendations for treatment of patients with significant aortic valve stenosis

1. The decision on the optimal treatment of patients with severe, symptomatic aortic valve disease should be made by a multidisciplinary TAVI team experienced in patient screening and management during TAVI procedures. It should include at least: two certified TAVI operators (an interventional cardiologist and a cardiac surgeon), an echocardiographer, and an anaesthesiologist [22, 90].
2. Prohibitive-risk patients should be qualified to TAVI first [6, 28, 98].
3. High-risk patients (STS ≥ 8%, EuroSCORE II ≥ 8%, log EuroSCORE ≥ 20%) should be qualified to TAVI first [5, 8, 9, 53].
4. The decision on the treatment of lower-risk groups of patients should depend on the TAVI team. TAVI should be considered in the following populations:
   — intermediate-risk patients [5, 7–9, 53];
   — patients aged ≥ 85 years [5, 8, 9, 53];
   — patients with a degenerated aortic valve bioprosthesis or a history of previous cardiac operations increasing the reoperation risk [42, 92–94];
   — patients with the following risks of cardiac surgery:
     • extensive calcification of the ascending aorta (porcelain aorta),
     • history of chest radiotherapy,
     • chest deformations,
     • liver failure,
     • osteoporosis,
     • active cancer,
     • frailty syndrome;

5. Low-risk patients < 75 years old (STS < 4%, EuroSCORE II < 4%, log EuroSCORE < 10%) should be first referred to SAVR [9, 95].

6. In unstable patients with severe aortic stenosis and with high operative risk or awaiting a non-cardiac operation, aortic balloon valvuloplasty should be considered alone, or as a bridge to SAVR or TAVI therapy.

7. In unstable patients already qualified to TAVI, aortic balloon valvuloplasty should be considered as a bridge to a planned TAVI procedure.

8. Aortic balloon valvuloplasty can also be considered as a palliative treatment in patients with multiple risk factors rendering cardiac surgery risk prohibitive and TAVI impossible.

9. Patients with a predicted poor outcome, including < 1-year survival, should be qualified to a palliative treatment (conservative or aortic balloon valvuloplasty).

TAVI centres and operators

1. On-site interventional cardiology cath-lab accredited with the ACVI class C.
2. On-site cardiac surgery department.
3. Imaging laboratory (echocardiography and MSCT or magnetic resonance laboratory).
4. ≥ Two TAVI-certified interventional cardiologist employed.
5. ≥ Two TAVI-certified cardiac surgeons employed.
6. ≥ Two anaesthesiologists trained in TAVI employed.
7. Established TAVI team with regular consultation meetings.
8. ≥ 40 TAVI procedures in a calendar year.
9. Participation in the POL-TAVI registry.
10. TAVI centres and operators registered in TAVI databases of the ACVI and the Polish Society of Cardio-Thoracic Surgeons.
11. Independent TAVI operators:
    — interventional cardiologist: a board-certified cardiologist holding a valid Independent TAVI Operator Certificate issued by ACVI,
    — cardiac surgeon: a board-certified cardiac surgeon holding a valid TAVI Skills Certificate issued by the Polish Society of Cardio-Thoracic Surgeons.

TAVI procedure

1. Performed by certified TAVI operators: interventional cardiologists and/or cardiac surgeons. For increased patient safety, TAVI should be performed jointly by a certified interventional cardiologist and a certified cardiac surgeon.
2. Hybrid room or cath-lab in close proximity to a cardiac surgery theatre.
3. ECMO availability, with TAVI team experience in ECMO placement and patient management.
4. Conscious sedation preferred over general anaesthesia.
5. Transfemoral access preferred over other TAVI routes.

Post-procedural care

1. Patient supervision in Intensive Therapy Department or Intensive Coronary Care Unit ≥ 24 h after TAVI.
2. Telemetry ≥ 24 h after TAVI, depending on the presence of cardiac arrhythmias and conduction abnormalities or their risk factors.
3. Direct access to a vascular surgeon, neurologist, radiologist, surgeon for an urgent consultation.
4. Direct access to echocardiography and MSCT imaging.
5. Dedicated diagnostic and therapeutic pathway for patients with cardiac conduction abnormalities.
6. Follow-up visits: at least one-month and one-year after TAVI, every year thereafter (clinical status, QoL, echocardiographic examination).

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APPENDIX 1. TAVI patient referral card

Date				Referring Centre		
PATIENT INFORMATION						
Name				Age		
ID				Weight		
Address				Height		
Phone				BMI		
CLINICAL INFORMATION						
Diagnosis				Symptoms	Vertigo	☐
					Syncope	☐
					Angina CCS	☐
					Dyspnoea NYHA	☐
				Vascular diseases	Ischaemic heart disease	☐
					Previous myocardial infarction	☐
					Previous PCI	☐
					Previous CABG	☐
					Previous stroke	☐
					Significant carotid artery disease	☐
					Significant lower limb artery disease	☐
				Cardiac arrhythmias	Atrial fibrillation	☐
					RBBB	☐
					LBBB	☐
					Pacemaker / ICD / CRT-D	☐
				Structural heart diseases	Heart failure	☐
					Significant aortic valve regurgitation	☐
					Significant mitral valve regurgitation	☐
					Previous aortic valve replacement	☐
					Previous mitral valve replacement	☐
				Other comorbidities	Renal failure	☐
Risk	EuroSCORE II				Chronic pulmonary disease	☐
	STS				Neurologic disease	☐
	Katz ADL				Cancer	☐
	6-minute walk test				Anaemia	☐
Qualified to TAVI	Yes	No	Proposed date	TAVI Team signatures		
	TAVI system			Date		
Route	Transfemoral	Other				
				Interventional Cardiologist	Cardiac Surgeon	

APPENDIX 2. Checklist for TAVI procedure

PATIENT					
Name			Date of birth		
Invasive Cardiologists			Cardiac Surgeons		
ANAESTHESIA					
Anaesthesia	Local ☐		General ☐		
Lines	Arterial ☐		Temporary RV pacing ☐		
	Venous ☐				
TAVI SYSTEM					
Access	Transfemoral R / L ☐		Access	Min. artery diameter	
	Subclavian ☐		Percutaneous ☐	R	L
	Transcarotid ☐		Surgical cutdown ☐		
	Direct aortic ☐				
	Transapical ☐		Tortuosity	Arterial ☐	Aortic ☐
	Transcaval ☐		Calcification	Arterial ☐	Aortic ☐
Valve type	Brand		Aortic annulus	Diameter	
				Area	
	Size			Perimeter	
VALVE IMPLANTATION					
RV pacing required ☐			Aortic valvuloplasty required ☐		
Coronary ostia	RCA ___ mm	LCA ___ mm	Preventive coronary artery wiring required ☐		
Imaging	C-arm projection		TEE required ☐		
PROCEDURAL RISK FACTORS					
CAD	Incomplete revascularisation ☐		PCI required ☐		
Valve positioning	Large, focal calcium deposits (→PVL) ☐				
	Narrow coronary sinuses (→coronary artery occlusion) ☐				
	Narrow STJ (aortic root rupture) ☐				
	Significant mitral valve calcification (aortic root rupture, valve positioning) ☐				
Heart morphology	Bicuspid aortic valve ☐		LVEF < 40% ☐		
	Aortic bioprosthesis ☐		Low left ventricular ejection volume ☐		
	Native aortic valve regurgitation ☐		Significant mitral regurgitation ☐		
	Right ventricle failure ☐		LA thrombi ☐		
	Significant tricuspid regurgitation ☐				
	Significant pulmonary hypertension ☐				
Renal function	Creatinine / eGFR		Type of contrast		
Arrhythmias	Atrial fibrillation ☐		AV block ☐	RBBB ☐	LBBB ☐
Electrotherapy	Pacemaker ☐	ICD / CRT-D (re-programming before RV pacing)			
Respiratory system	Asthma / COPD ☐				
Stature	Obesity ☐	Low height ☐	Scoliosis ☐		
DRUGS					
Previous bleeding ☐					
Antiplatelet drugs	Aspirin ☐	Clopidogrel ☐	Ticagrelor ☐	Other ☐:	
OAC	Acenocoumarol ☐	Warfarin ☐	Rivaroxaban ☐	Dabigatran ☐	

APPENDIX 3. TAVI procedure control chart

Patient Name			TAVI System		
			Valve size		
Age	Sex		Access: transfemoral | other		Side: R | L
STS	EuroSCORE II				
Operators					

PERSONNEL		EQUIPMENT	
☐	Briefing: description of possible procedural risks	☐	TTE, TEE
☐	acute care unit ready for patient admission	☐	Femoral artery occluders
☐	cardiac surgeon, vascular surgeon, invasive cardiologists assisting or on alert	☐	1–2 pigtail catheters
PROCEDURAL STRATEGY		☐	Predilatation aortic balloon: size
☐	Sedation / general anaesthesia	☐	Postdilatation aortic balloon: size
	TEE on standby / continuous	☐	Spare TAVI system
☐	Venous access for temporary pacing carotid, subclavian or femoral	☐	Rescue TAVI system (in valve dislocation): size
☐	Additional arterial line for blood pressure monitoring: radial or femoral	☐	Femoral sheaths (6, 10, 14, 18 F)
☐	C-arm projection (MSCT or 3D-TEE derived)	☐	Guidewires: floppy J-curved and straight, teflon-coated
☐	Coronary artery guidewire protection?	☐	Guidewires: stiff straight and preshaped
☐	Predilitation	☐	Coronary guidewires
☐	RV pacing during valve implantation?	☐	Guiding catheters: AL1, AL2, JR, pigtail, JL, JR, LIMA
PATIENT		☐	Temporary pacing electrode
☐	Identity confirmed	☐	Pacemaker (burst or > 200 bpm capable)
☐	Written informed consent	☐	Pericardiocentesis set
☐	Blood type sampled and cross-matched	☐	ECMO
☐	Blood bags prepared	☐	Cardiac surgery / vascular surgery equipment
☐	Blood morphology	☐	Coronary angiography and PCI equipment
☐	Creatinine, eGFR	☐	Peripheral artery stenting equipment
☐	Antiplatelet drugs, anticoagulation	☐	Endografts
☐	INR, APTT	☐	Cerebral protection systems
☐	LVEF		
☐	Allergies		

FINAL DECISIONS	
☐	TAVI outcome assessment fluoroscopy: position, symmetry, aortography, pressure gradients, echocardiography, ECG
☐	Vascular access closure
☐	Temporary pacing lead removal
☐	Patient clinical status assessment

SUMMARY			
☐	Procedural time	☐	Decision on further intensive care, ambulation and pharmacotherapy
☐	Fluoroscopy time		
☐	Radiation dose	☐	Data backup: procedural reports, anaesthesia charts, cine, pressure recordings, echocardiography, ECG
☐	Contrast volume		

Comments:

Nurse / Medical Technician signatures	Operators signatures