Management of patients after heart valve interventions. Expert opinion of the Working Group on Valvular Heart Diseases, Working Group on Cardiac Surgery, and Association of Cardiovascular Interventions of the Polish Cardiac Society

Edyta Płońska-Gościniak[1], Wojciech Wojakowski[2], Tomasz Kukulski[3], Zbigniew Gąsior[3], Marek Grygier[4], Katarzyna Mizia-Stec[5], Tomasz Hirnle[6], Maria Olszowska[7,8], Lidia Tomkiewicz-Pająk[7,8], Jarosław D Kasprzak[9], Piotr Suwalski[10], Monika Komar[7,8], Stanisław Bartuś[11], Piotr Pysz[2], Magdalena Mizia-Szubryt[5], Tomasz T Hryniewiecki[12]

Review Committee: Andrzej Gackowski[8], Danuta Sorysz[11], Andrzej Szyszka[13], Andrzej Tomaszewski[14], Krzysztof Gołba[15], Robert Olszewski[16]

Reviewers (on behalf of the Polish Cardiac Society): Maciej Lesiak[17], Bożena Sobkowicz[18], Romuald Cichoń[19]

[1]Department of Cardiology, Pomeranian Medical University, Szczecin, Poland
[2]Department of Cardiology and Structural Heart Diseases, Medical University of Silesia, Katowice, Poland
[3]Department of Cardiology, Congenital Heart Disease and Electrotherapy, School of Health Sciences in Zabrze, Medical University of Silesia, Katowice, Poland
[4]1st Department of Cardiology, Poznan University of Medical Sciences, Poznań, Poland
[5]Department of Cardiology, School of Medicine in Katowice, Upper-Silesian Medical Centre, Medical University of Silesia, Katowice, Poland
[6]Department of Cardiac Surgery, Medical University of Bialystok, Białystok, Poland
[7]Department of Cardiac and Vascular Diseases, Institute of Cardiology, Jagiellonian University Medical College, Kraków, Poland
[8]John Paul II Hospital, Kraków, Poland
[9]1st Department and Chair of Cardiology, Bieganski Hospital, Medical University, Łódź, Poland
[10]Clinical Department of Cardiac Surgery, Central Clinical Hospital of the Ministry of Interior and Administration, Warszawa, Poland
[11]Department of Cardiology and Cardiovascular Interventions, University Hospital, Kraków, Poland
[12]Department of Acquired Cardiac Defects, National Institute of Cardiology, Warsaw, Poland
[13]1st Department of Cardiology, Poznan University of Medical Sciences, Poznań, Poland
[14]Department of Cardiology, Medical University of Bialystok, Białystok, Poland
[15]Department of Cardiac Surgery, Medical University of Warsaw, Warszawa, Poland
[16]2nd Department of Cardiology, Poznan University of Medical Sciences, Poznań, Poland
[17]Department of Cardiology, Medical University of Lublin, Lublin, Poland
[18]Department of Electrocardiology and Heart Failure, Medical University of Silesia, Katowice, Poland
[19]Cardiology and Internal Medicine Clinic, Military Institute of Medicine, Warszawa, Poland

Correspondence to:
Monika Komar, MD, PhD,
Department of Cardiac and Vascular Diseases,
Institute of Cardiology,
Jagiellonian University Medical College,
Prądnicka 80, 31–202 Kraków, Poland,
phone: +48 600 533 798,
e-mail: moni_s@interia.pl

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INTRODUCTION

This document aims to systematize the recommendations for the management of adult patients after surgical and percutaneous valve interventions in acquired valvular heart disease. In recent years, the number of patients after transcatheter repair or implantation of the aortic, mitral, and tricuspid valves has increased significantly. At the same time, there has been considerable development of surgical techniques, including minimally invasive approaches. The number of patients undergoing these procedures is rising substantially as well. Greater accessibility of modern diagnostic and therapeutic methods, along with novel indications for interventions, also increases the patient population. Proper management of these patients after the procedure is essential to achieve the best possible long-term outcomes of interventional treatment of valvular heart disease.

Table 1. Echocardiographic parameters for the assessment of mitral/tricuspid valve after the valve repair procedure

- Length and height of the leaflets coaptation of the repaired valve, leaflet tenting area
- The presence and severity of regurgitation (quantitative methods: vena contracta, effective regurgitant orifice area (EROA) by proximal isovelocity surface area (PISA), regurgitant volume and a regurgitant fraction (2D/3D + Doppler)
- Evaluation of valve morphology (annulus and leaflets), artificial tendinous chords, the position of papillary muscles (depending on the procedural technique)
- Assessment of peak diastolic velocity as well as the mean gradient
- Assessment of left ventricular dimensions and ejection fraction (LVEF), as well as select right ventricular (R) dimensions and functional parameters, e.g. tricuspid annular plane systolic excursion (TAPSE)
- Calculation of right ventricular systolic pressure (RVSP) in the presence of tricuspid regurgitation

Table 2. Echocardiographic probability of pulmonary hypertension (PH)

Peak tricuspid regurgitation velocity, m/s	Other "pulmonary hypertension echo signs" present[a]	Echocardiographic probability of pulmonary hypertension
≤2.8 or not measurable	No	Low
≤2.8 or not measurable	Yes	Intermediate
2.9–3.4	No	
2.9–3.4	Yes	High
>3.4	Not required	

[a]Echocardiographic indices of pulmonary hypertension (at least 2 from different categories required). Category A: Right ventricle/left ventricle basal diameter ratio >1.0; Flattening of the interventricular septum in short axis parasternal wiev; Category B: Right ventricular outflow Doppler acceleration time <105 ms and/or mid-systolic notching; Early diastolic pulmonary regurgitation velocity >2.2 m/s; Category C: pulmonary artery diameter >25 mm; inferior vena cava diameter >21 mm with reduced respiratory collapse <50%; end-systolic right atrium area >18 cm^2

FOLLOW-UP OF PATIENTS AFTER CARDIAC VALVULAR INTERVENTIONS

Follow-up after surgical mitral and tricuspid valve repair

Patients undergoing mitral or tricuspid valve repair require intraoperative transesophageal echocardiography (TEE) and a subsequent transthoracic echocardiographic examination (TTE) before the hospital discharge. Considering long-term care of patients, it is critical to provide a detailed description of the procedural methods in the medical records, including information on the type and size of the annuloplasty ring [1] and all other surgical details relevant for follow-up imaging and possible future interventions. The armamentarium of surgical techniques for valve repair is wide and dependent, among others, on the type of pathology (i.e. whether the regurgitation is primary or secondary) and on the mechanism of regurgitation (type I — annular dilatation, leaflet perforation; type II — leaflet prolapse; type III — leaflet restriction). The techniques include implantation of an artificial valve ring or artificial tendinous chords, resection or plication of the leaflet, as well as suturing or percutaneous clipping of the leaflets [2–7].

The postoperative follow-up should be performed in the first 30 days at the cardiac surgery department, followed by early postoperative TTE within 2–3 months as part of visits at cardiology clinics.

During the first outpatient TTE examination after cardiac surgery, the pleural and pericardial cavities should be examined to assess the presence of fluid that may accumulate due to postpericardiotomy syndrome. Table 1 summarizes the most important post-procedural echocardiography parameters that should be assessed. An accurate assessment of cardiac chamber size and function is essential. A detailed description of the morphology and function of the mitral and tricuspid valve is required. If there is a residual regurgitation, it should be reported taking into account full quantification, i.e.: vena contracta (VC) measurements, calculation of effective regurgitation orifice area (EROA) by proximal isovelocity surface area (PISA), regurgitant volume (assessing the aortic flow vs left ventricular stroke volume) using either two- or three-dimensional (2D or 3D) evaluation.

The aim of the valve repair is to restore the largest possible leaflet coaptation surface. Therefore, the assessment of the leaflet coaptation by measuring the coaptation length, height, and leaflet tenting area, as well as implanted ring adherence to the native cardiac tissue with regard to possible dehiscence, is especially important. The echocardiographic probability of pulmonary hypertension should also be evaluated (Table 2).

Outpatient evaluations should be performed at least annually unless the patient's condition requires more frequent monitoring [8]. Patients with functional mitral regurgitation secondary to left ventricular enlargement and dysfunction, for whom optimization of guideline-recommended treatment of heart failure is essential for survival, require special attention. Similar rules apply to all patients with left or right ventricular dysfunction after cardiac surgery according to general recommendations. Patients requiring anticoagulant therapy should be monitored for blood cell counts, coagulation parameters, kidney, and liver function.

Echocardiographic signs suggesting pulmonary hypertension (PH) parameters from at least two different categories are needed to determine the probability of PH are:

- A category: right ventricular/left ventricular basal diameter ratio >1.0; flattening of the interventricular septum in parasternal short axis view;
- B category: right ventricular outflow Doppler acceleration time <105 ms; Early diastolic pulmonary regurgitation velocity >2.2 m/s; pulmonary artery diameter >25 mm
- C category: inferior vena cava diameter >21 mm with decreased inspiratory collapse <50%; right atrial area (end-systole) >18 cm^2.

Follow-up after surgical repair of the aortic valve due to chronic aortic regurgitation

The etiological factors of aortic regurgitation (AR) are leaflet dysfunction, abnormalities in the anatomy of the aortic

complex (aortic opening, aortic bulb, size of the sinotubular junction), and pathologies in the proximal part of the ascending aorta. In recent years, the number of valve repair procedures in chronic aortic insufficiency has increased. These procedures must be tailored to the type of pathology and, due to difficulty level, require vast operator experience. For this reason, current recommendations of the European Society of Cardiology propose that aortic valve repair (AVRep) should be considered only in specialized centers with extensive experience. This explains a lower class of recommendations as compared to the previous edition of the guidelines [8].

Despite downgrading the recommendation, experienced cardiac surgeons will continue to perform these procedures, and the number of patients requiring monitoring after such procedures is expected to increase. Monitoring an AVRep patient after surgery requires knowledge of the surgical procedure including the specific surgical technique. Of note, the choice of the procedure depends on the center's experience, the coexistence of aortic aneurysm, characteristics of the valve leaflets, expected survival time, and finally the possibility of using anticoagulant therapy. In experienced centers, complex aortic valve repair (e.g. subcommissural annuloplasty in type Ic aortic regurgitation, leaflet plication in type II aortic regurgitation, annuloplasty or ring placement in the case of aortic annulus dilatation) and replacement of the aortic bulb while preserving the patient's native valve are increasingly performed (David's procedure — valve reimplantation, Yacoub procedure — bulb remodeling) and offer excellent long-term outcomes [8, 9].

The intraoperative TEE examination after the restoration of circulation is mandatory. It determines the effectiveness of the procedure and helps predict the possible risk of regurgitation recurrence. In the intraoperative evaluation, the presence of asymmetric regurgitation, greater than trace (usually moderate or severe), obliges cardiac surgeons to reoperate. The type of reintervention depends on the direction of the regurgitant jet (consistent/opposite to the initial echocardiographic image). In the case of a residual central regurgitant jet found in the intraoperative examination, the degree of regurgitation should be determined — optimally in the TEE transgastric view. The presence of regurgitation, with EROA ≥10 mm^2 and VC width ≥3 mm, is an indication for reintervention. The choice of procedure depends on the size of the aortic annulus (>25 mm — annuloplasty is indicated) and possible restriction of the leaflets (re-repair or replacement of the valve) [9].

Echocardiographic parameters indicative of good immediate surgical outcome and predictive for durable AVRep, are

- Absence of residual regurgitation (or minimal central jet aortic regurgitation);
- Effective coaptation height ≥9 mm;
- Leaflet coaptation ≥4 mm;
- Aortic valve annulus <25 mm;
- No leaflet restriction;
- Mean transvalvular gradient <10 mm Hg [8, 9].

Cardiology associations did not recommend any specific schedule of follow-up echocardiographic examinations after AVRep. It seems reasonable to perform TTE monitoring like in patients with implanted bioprostheses — one month and 12 months after the procedure, and then annually. The new onset of symptoms indicative of valve dysfunction represents a specific urgent indication for an echocardiographic evaluation. An open international registry to evaluate medical and surgical outcomes of aortic valve insufficiency and ascending aorta aneurysm (AVIATOR) proposes a format for preoperative, intraoperative, and postoperative echocardiographic examination reports [10].

Patients who undergo thoracic endovascular aortic repair (TEVAR) without aortic valve intervention constitute a separate group. In these cases, the first clinical and imaging examination should take place one month after the procedure to exclude early complications. Subsequent evaluations are performed after 6 or 12 months, and then annually. In stable patients, after endovascular repair of the thoracic aorta due to aortic aneurysm, in the absence of endoleak in the first 24 months, the intervals between subsequent imaging examinations can be extended to 2 years. After aortic surgery, with a stable course of disease during the first year, longer intervals between follow-up examinations may be sufficient [8].

Chest computed tomography (CT) is the examination of choice for patients who underwent thoracic aorta surgery and the most widely used diagnostic tool, ensuring optimal visualization. Magnetic resonance imaging (MRI) also plays an increasingly important role. In patients with nitinol stent grafts, MRI must be supplemented with a chest X-ray to visualize the metallic stent struts. In the case of stainless-steel prostheses, MRI is associated with intense artifacts. TEE is reserved for patients with severe renal dysfunction [8, 11].

Follow up after surgical implantation of prosthetic cardiac valves

The follow-up of patients with prosthetic heart valves (PHV) should involve [1, 8, 12]:

- Assessment of the general condition with particular attention to blood pressure, presence of heart failure, heart rate, as well as identification of the occurrence of arrhythmias or conduction disturbances;
- Monitoring the quality of anticoagulant therapy (acenocoumarol or warfarin) with the international normalized ratio (INR) values (obligatory in patients with a mechanical prosthesis);
- Echocardiographic assessment of cardiac chambers as well as the structure and function of the prosthesis.

The outpatient evaluation should be performed within 30 days, and then annually unless the patient's condition requires more frequent monitoring. Clinical judgment dictates whether more frequent visits are required, particularly if the patient has comorbidities, heart failure during

cardiac surgery as well as in the case of patients undergoing emergency surgery in infective endocarditis (IE). The INR should be assessed frequently to ensure maintenance within the recommended target range, depending on the implanted prosthesis and patient clinical characteristics (every 4 weeks and 1 week after every change in drug dose).

Echocardiography should be performed within the first three months after surgery. The obtained detailed description of the prosthetic valve function, the assessment of the dimensions and function of the cardiac chambers, as well as evaluation of the other valves, should serve as a reference in the further follow-up. In the early postoperative period, up to 30 days, the presence of effusion in the pericardial and pleural cavities should be excluded.

TTE/TEE should be performed whenever symptoms and/or suspected valve dysfunction appear. In a patient with a surgically or transcatheter implanted bioprosthesis, it is recommended to perform a follow-up TTE after 1 year, and then every year, according to the European Society of Cardiology (ESC) 2021 guidelines. TEE is indicated in the case of a non-diagnostic TTE image and in each case of suspected valve dysfunction. There are currently no indications for regular TTE monitoring in asymptomatic patients with mechanical prostheses, although patients with an ascending aortic dilatation and after mitral valve replacement should be monitored annually to control tricuspid regurgitation and right ventricular function.

The evaluation of PHV function should take into account the type of prosthesis and its size, as well as the function of the heart chambers, in particular the left ventricular ejection fraction. Importantly, all available windows should be used to minimize the impact of acoustic shadowing from PHV structure (also related to Doppler flow signal), including TEE as needed. Elevated transvalvular gradients require a complete diagnostic workup of suspected PHV obstruction. In case of doubt, one should use the manufacturer's data for a specific type of the implanted prosthesis [12], which provides the value of effective orifice area (EOA). The measured EOA value should not differ from the reference value for a given size of the prosthesis by more than 0.25 cm^2. Significant PHV stenosis is characterized by EOA smaller than reference by more than 0.35 cm^2. Difficulties may arise in differentiating the valvular stenosis from the so-called patient-prosthesis mismatch (PPM) which occurs usually when a PHV that is too small for the patient's body size is implanted in the aortic position [12, 13]. EAVCI recommends echocardiographic indicators for differential diagnosis (Table 3), as well as performing exercise echocardiography in patients with elevated resting gradients [12, 14, 15]. It should be noted, however, that exercise stress testing is safe in asymptomatic patients and in those with biological PHV, whereas it is contraindicated in suspected endocarditis or blockage of the valve disc.

Table 3. Essential echocardiographic parameters in the comprehensive evaluation of prosthetic valve function

- Peak velocity, m/s
- Mean gradient, mm Hg
- Effective regurgitant orifice area (EROA) and indexed effective orifice area cm^2/m^2
- Doppler velocity index (DVI)
- Systolic acceleration time (AT) — evaluation of the aortic valve prosthesis
- Ejection time (ET) — evaluation of the aortic valve prosthesis
- Pressure half time in mitral valve assessment
- Regurgitant jet evaluation (transvalvular, paravalvular and "physiologic" regurgitation)

Echocardiography is essential to define the presence, location, and severity of PHV regurgitation. The echocardiographic evaluation must discriminate physiological from pathological regurgitant flow and define intra- or periprosthetic regurgitation. The origin and direction of the jets should be evaluated, with quantification of regurgitation.

TEE (preferably by 4D/4D color flow) should follow TTE to precisely diagnose and quantify PHV dysfunction in suspected valve leak or obstruction (e.g. due to thrombus, pannus, or vegetation). Cinefluoroscopy must be performed in suspected blockage of the mechanical valve disc. The interpretation of echocardiographic parameters of prosthetic aortic and mitral valve function at rest, during the exercise test, and in the long-term follow-up is presented in Table 4.

Follow-up after transcatheter edge-to-edge mitral valve repair (TMVR)

Currently, two transcatheter edge-to-edge repair systems (MitraClip, Abbott Vascular, Santa Clara, CA, US and PASCAL, Edwards Lifesciences, Irvine, CA, US) are available in

Table 4. Selected echocardiographic parameters of prosthetic aortic and mitral valve function

Position of the prosthesis	Parameter	Normal	Possible stenosis	Significant stenosis
Mitral position	Peak velocity, m/s	<1.9	1.9–2.5	≥2.5
	Mean gradient, mm Hg	≤5	6–10	≥10
	Exercise-induced increase in mean pressure gradient, Δmm Hg	<5	5–12	>12
	Increase in mean pressure gradient in long-term follow-up evaluation, Δmm Hg	<3	3–5	>5
Aortic position	Peak velocity, m/s	<3	3–3.9	≥4
	Mean gradient, mm Hg	<20	20–34	≥35
	Exercise-induced increase in mean pressure gradient, Δmm Hg	<10	10–19	≥20
	Increase in mean pressure gradient in long-term follow-up evaluation, Δmm Hg	<10	10–19	≥20

Poland. The principle of both procedures is similar. The aim of patient monitoring after the edge-to-edge repair is to assess both the early and late procedural success rate and effectiveness, as well as to monitor the progression of heart failure [8]. It is important to assess the position, orientation, and stability of the clip, the size of the iatrogenic atrial septal defect, as well as to determine residual/new regurgitant jets and evaluate the severity of tricuspid regurgitation and left and right ventricular function. It is also of utmost importance to assess the occurrence of single leaflet detachment. Intraoperatively, before the clip is released from the delivery system presence, significant mitral stenosis should be evaluated since it is associated with a poorer prognosis. In the long-term follow-up, the diastolic transvalvular pressure gradient and mitral valve orifice area are also assessed.

While the visual exclusion of mild regurgitation is not difficult, to assess severe regurgitation and/or multiple regurgitant jets it is necessary to integrate many quantitative and semi-quantitative parameters (PISA radius, VC width, regurgitant jet area, length, volume, E wave velocity, analysis of the mitral and pulmonary venous inflow patterns, the intensity of the continuous wave [CW], Doppler regurgitant jet signal, the forward stroke volume of the LV). This is because residual regurgitant jets run in many directions and planes and they often cross each other. Assessment of pulmonary venous flow is useful since flow reversal is an indirect sign of significant regurgitation. In practice, the EROA calculation is of little use in evaluating the regurgitation after MitraClip implantation. If the obtained echocardiographic measurements are unreliable, then TEE or magnetic resonance imaging should be performed.

Comparative echocardiographic assessment before, during, and after the MitraClip procedure, allows for the ongoing monitoring of the reverse cardiac remodeling. When assessing the severity of right ventricular systolic dysfunction and functional tricuspid regurgitation, the magnitude of pulmonary hypertension should be considered. For this purpose, it is reasonable to use tricuspid annular plane systolic excursion (TAPSE)/right ventricular systolic pressure (RVSP) ratio, reflecting the ventricular-pulmonary coupling. The values of the quotient <0.31 are associated with poor long-term prognosis, which should be taken into consideration when planning for the next stage of surgical treatment, e.g. clipping the tricuspid valve.

Postoperative ASD usually does not induce a relevant interatrial shunt. Left-to-right shunts are most common and typically bear no hemodynamically significant consequences. Right-to-left shunts, especially in patients with right heart dysfunction, are associated with an increased risk of paradoxical embolism. In some patients, especially with concomitant right ventricular dysfunction, iatrogenic ASD may be a significant clinical problem, exacerbating the symptoms of right ventricular failure (see: Management of complications after cardiac valve interventions). In these patients, the standard assessment should include Qp/Qs ratio measurements using Doppler (Qp — pulmonary blood flow, and Qs — systemic blood flow) or an invasive saturation monitoring. The echocardiography examination after edge-to-edge repair should be treated as an examination of a patient with severe compensated heart failure. Patients treated with transcatheter mitral valve repair (TMVR) should undergo a periodic echocardiographic evaluation with a similar frequency of visits and for the same indications as for patients with heart failure with reduced ejection fraction.

Patients after transcatheter procedures should be evaluated at discharge. Outpatient monitoring is recommended during one month after the procedure, with TTE examination (or TEE in some patients) after 1 year and then annually. The first post-operative examination performed within 30 days of MitraClip implantation should be the starting point for comparative evaluation performed during subsequent follow-up visits.

It is not uncommon for patients considered for edge-to-edge repair procedures to wear cardiac implantable electronic devices (CIED): implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy-pacemaker (CRTP), or cardiac resynchronization therapy-defibrillator (CRTD). While assessing the right ventricular function and tricuspid regurgitation, attention should be paid to the potential CIED-mediated tricuspid regurgitation, and in the case of the febrile state, a potential lead-dependent IE. In patients with worsening heart failure, electrical storm occurrence or progression of ventricular dysfunction is important to assess cardiac chamber dimensions, the restriction of mitral leaflet motion and severity of residual mitral and tricuspid regurgitation, echocardiographic signs of volume/pressure overload (measurement of the inferior vena cava diameter), as well as to assess the unfavorable remodeling.

Follow-up after transcatheter aortic valve implantation (TAVI)

The patients after percutaneous transcatheter aortic valve implantation should be followed up regarding the prosthetic valve leak and obstruction/restenosis. The likelihood of paravalvular regurgitation after TAVI is low [8]. It has been further reduced to 0%–2% with newer transcatheter heart valve designs. While mild paravalvular leak (PVL) does not affect the prognosis of patients after TAVI, moderate/severe PVL is associated with a worse prognosis. Predictors of a paravalvular leak include undersizing, the presence of massive calcifications or incidence of the bicuspid aortic valve, and finally, incorrect positioning of the prosthesis. In the case of very low valve implantation, a supraskirtal regurgitation may occur, which is often difficult to differentiate from a typical leak. Transvalvular regurgitation can occur in the presence of valve malapposition, deformation, degeneration, thrombosis, perforation, or infective endocarditis (IE).

Both TTE and TEE remain the preferred methods of assessing the size of PVL, notwithstanding their limita-

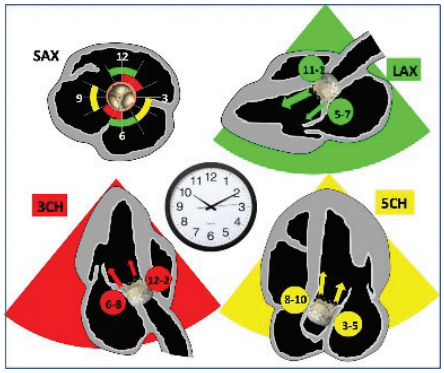

Figure 1. The methodology of paravalvular leak assessment in standard transthoracic echocardiographic examination projections after transcatheter aortic valve implantation procedure

Abbreviations: 3CH, apical three-chamber view; 5CH, apical five-chamber view; LAX, parasternal long-axis view; SAX, parasternal short-axis view

tions. When assessing PVL, attention should be paid to color-coded Doppler signals in standard transthoracic and transesophageal projections. It is necessary to visualize the prosthesis in all available projections to minimize the influence of the artifact on the quality of the color-coded Doppler signal. Anterior PVL is more visible in the apical 3-chamber view during TTE, while posterior PVL are best visualized in the mid-esophageal and transgastric view during TEE. The methodology of PVL assessment in 4 standard transthoracic views is presented in Figure 1. The PVL grading should be comprehensive and include quantitative and semi-quantitative measurements, including the assessment of diastolic flow in the descending aorta. A quick method of assessing the PVL significance is the evaluation of PVL circumferential extent, defined as the sum of PVL orifice circumference(s) divided by the valve circumference. If the extent exceeds >20% (a cutoff >30% is proposed in some sources) the PVL is severe. If the PVL has been assessed on echocardiogram as greater than mild and there are discrepancies between the clinical symptoms and the PVL severity, MRI may be necessary.

Echocardiographic examination after the TAVI procedure, besides the PVL assessment, should also report the resting transvalvular gradient, as well as the function of both ventricles and atrioventricular valves. Early post-TAVI TTE is crucial for follow-up evaluation of the implanted prosthesis, representing baseline hemodynamics. The increasing mean gradient in consecutive examinations may indicate valve thrombosis or degeneration. A comprehensive evaluation of the prosthesis failure mechanism can be performed using TEE and CT. The evaluation of transvalvular gradients should be supplemented with the calculation of the EOA and EOAi of the valve. The increase in the transvalvular gradient may be caused by valve thrombosis, leaflet degeneration, or IE. Notably, in the first months after surgery, the increase in transvalvular gradient may be due to improved LV systolic function and an increase in left ventricular output. In this situation, the opening of the valve, measured as EOA, is normal and stable. In the first years after TAVI, the increase in transvalvular gradients with a concomitant decrease in EOA is usually caused by valve thrombosis (which is uncommon after >3 years). Diagnostics should then be extended to include TEE and possibly CT. In later years, the increase in transvalvular gradients and the decrease in EOA are mainly due to valve degeneration.

After TAVI, the first follow-up examination should be performed at discharge, then after 30 days, 1 year, and then every 1–2 years after the procedure with specific evaluation of the prosthesis function, assessment of potential PVL, left ventricular (LV) function, and the severity of mitral regurgitation if present. In asymptomatic patients with adequate function of the implanted prosthesis, preserved LV systolic function without concomitant valvular disease, subsequent evaluations should be performed as in other patients with bioprostheses and in every case of patient-reported cardiac symptoms. More and more experts recommend TTE every 1–2 years based on the current data.

Echocardiography is an essential component of cardiac evaluation and therefore should be performed on all consecutive follow-up visits. Concomitant functional mitral regurgitation often regresses after TAVI, but its course in individual patients is difficult to predict, which should prompt a mitral regurgitation jet assessment at each subsequent visit. Mixed etiology mitral regurgitation may not be reduced after TAVI procedure, and therefore determining patients' eligibility for the next stage procedure — e.g. edge-to-edge repair — might be necessary. Patients with degenerative mitral valve disease and coexisting mitral stenosis will require more frequent visits to monitor the progression of the disease. If necessary, the decision for the next-stage surgical treatment is made.

MANAGEMENT OF COMPLICATIONS AFTER CARDIAC VALVE INTERVENTIONS

Complications of valve surgery — prevention and treatment

Complications associated with surgical treatment of valvular heart disease can be divided into two groups.

The first group includes complications that may follow any classic cardiac surgery procedure. These are associated with using cardiopulmonary bypass and surgical access. The use of extracorporeal circulation can initiate a systemic inflammatory response syndrome (SIRS), which in the case of prolonged surgery, may cause kidney and lung injury, intestinal ischemia, coagulation disorders, vascular endothelial dysfunction, and hemolysis.

To reduce the intensity of this unfavorable phenomenon, the duration of extracorporeal circulation should be shortened. Therefore, hybrid procedures facilitate minimally invasive approaches, where instead of complex procedures, such as e.g. surgical aortic valve replacement (SAVR)

and coronary artery bypass grafting (CABG), the treatment is divided into stages — the first is percutaneous coronary intervention and the next minimally invasive aortic valve replacement. In the case of CABG, it is possible to eliminate the extracorporeal circulation (Off-Pump Coronary Artery Bypass Grafting, OPCAB). Extracorporeal removal of inflammatory mediators is possible with adsorption filters. Infection and impaired wound healing are considered important complications of surgical access. Mediastinitis is known to be the most severe form of infection with a very high mortality rate. Minimally invasive accesses, for example, right-sided mini-thoracotomy for mitral valve surgery or upper mini-sternotomy for aortic valve interventions, as well as proper preprocedural preparation of the patient (elimination of inflammatory foci before the surgery), reduce the incidence of these complications.

The second group of complications include those directly related to a specific valve procedure, including conduction disturbances and a paravalvular leak.

Postoperative conduction disturbances

Postoperative atrioventricular block (AVB) after mitral valve procedures occurs in 24% of patients and intraventricular conduction disturbances occur in 15% of patients. Conduction disturbances in most cases resolve spontaneously before the patient's discharge from the hospital, but about 4% of patients after mitral valve surgery require implantation of a permanent pacemaker. Factors such as prolonged duration of myocardial ischemia, damage to the artery supplying the atrioventricular node, large size of implanted valvular prosthesis, and simultaneous ablation of the atrial fibrillation substrate are associated with an increased risk of conduction disturbances [16].

The risk of atrioventricular block after SAVR is over 10%, and the prevalence of intraventricular conduction disturbances is approximately 8.5%. Roughly 1.5% of patients require permanent pacemaker implantation. Risk factors associated with permanent pacemaker implantation include the history of cardiac arrhythmias, bicuspid aortic valve, aortic valve regurgitation, female sex, prolonged extracorporeal circulation, previous cardiac surgery, or myocardial infarction [17]. New-onset significant conduction disturbances are common after TAVI (see: Complications after transcatheter valve interventions) [18].

Tricuspid valve procedures are associated with a high risk of permanent conduction blocks. This is due to the anatomical proximity of the stimulus-conduction system. Twenty-one percent of patients after valve replacement surgery and over 9% of patients after repair surgery are qualified for permanent pacemaker implantation [19]. The factors increasing that risk are heart ischemia time exceeding 60 minutes and simultaneous operation on the mitral valve [20].

Implant the largest possible prosthesis to avoid the PPM phenomenon is a common risk factor for the occurrence of postoperative conduction disturbances, which is difficult to avoid. Patient-prosthesis mismatch (PPM) essentially is a concept of a relatively small effective orifice area in relation to the patient's body size. Severe PPM after aortic prosthesis implantation, defined as the indexed effective orifice area (EROAi) <0.65 cm^2/m^2, and PPM after mitral prosthesis implantation, defined as EROAi <1.2 cm^2/m^2, could have a possible adverse effect on long-term survival [21, 22].

Post-operative paravalvular leak

Paravalvular leaks (PVLs) have been shown to be a major complication that results from insufficient sealing between the native annular tissue and the outer aspect of the prosthesis. Based on the literature, the prevalence of PVL after surgical aortic valve replacement (SAVR) is 2%–10% and 7%–17% in the case of mitral prosthesis implantation. A significant leak can lead to heart failure, hemolytic anemia, as well as IE.

The configuration of the native aortic annulus, which consists of three deep interconnected arches, is a factor contributing to the incomplete valve adherence. PVLs are often the result of significant tension between the non-compliant ring of the prosthesis and the arches of the native aortic annulus. This problem can be mitigated by placing sutures through the aortic wall that secures the valve in a single plane. The choice of prosthesis is also important. Valve implantation due to IE is also a risk factor for a PVL. Patients with mechanical prostheses with a non-compliant metal ring bear the highest PVL risk. Some stented bioprostheses have a more compliant ring with marked arches, which reduces tension. Stentless bioprostheses eliminate the risk of PVL almost entirely. PVLs observed after surgical mitral valve interventions are most often a result of the injury to the delicate heart tissue caused by the sutures holding the valve. This is due to the much higher pressures affecting the valve in the left venous outlet and prior IE [23]. The indication for reoperation is any hemodynamically or hematologically significant PVL unless percutaneous closure is feasible.

Factors increasing the risk of PVL after transcatheter aortic valve implantation are valve undersizing, incorrect valve positioning, and massive calcification of the native valve [24].

Repeat valve surgery (reoperation)

Cardiovascular diseases are the leading cause of mortality in Poland. The occurrence of these diseases is undoubtedly related to the aging of the population and the increasing access of patients to diagnostic tools, health promotion programs, and specialist care.

Data from the Society of Thoracic Surgeons National Database report indicate that the number of patients receiving bioprosthetic valves increased to over 78% in comparison to mechanical valves [25]. Similar data were also obtained in Europe and in the Polish National Register of Cardiac Surgery Procedures, the relationship between the number of implanted mechanical and tissue valves has

changed over the decade in favor of bioprostheses [26]. Young patients with a more active lifestyle often choose biological valves, therefore, accepting the risk of future reoperation. Nevertheless, the dysfunction of the prosthesis does not only concern biological valves [26].

Common indications for valve reinterventions include

- Recurrence of the pathology after primary valve repair;
- Degeneration of the bioprosthesis — the most common cause for reoperation;
- Prosthetic valve dysfunction, prosthetic heart valve thrombosis, pannus (mechanical and biological prostheses);
- Significant paravalvular leak;
- IE.

The most important risk factors for reoperated patients are [26, 27]:

- The patient's age at the time of reintervention;
- Female sex;
- Infective endocarditis;
- Left ventricular failure;
- Reduced ejection fraction;
- Multivessel coronary artery disease;
- History of multiple valve surgery;
- Reoperation type (elective, urgent, emergency).

Median sternotomy remains the standard approach for reinterventions. Re-do sternotomy carries a risk of right ventricular trauma or intraoperative bleeding, as well as the risk of inadvertent trauma to a patent coronary graft. Reoperations require careful preparation, including not only the assessment of indications but also the development of a management strategy. Computed tomography of the chest remains indispensable for overall imaging of the chest; hence, it primarily assesses relationships between mediastinal structures and the sternum. If the right ventricle or the aorta adheres to the sternum, an alteration of the reoperation strategy and technique should be considered. In such patients, cardiopulmonary bypass before repeat sternotomy seems a valid option to render cardiac reoperation safer. This implies the need for peripheral cannulation. The femoral vascular access site is the most frequently used.

The development of minimally invasive techniques has also resulted in major changes in current surgical practices in cardiac reoperations. Minimally invasive procedures, such as mini-sternotomy or mini-thoracotomy, reduce the risk of pericardial and pleural adhesions. Thus, performing cardiac reoperation in patients with previous cardiac surgery using a minimally invasive technique reduces the procedural risk of reintervention. In patients with patent coronary grafts, it is possible to perform the reoperation via lateral mini-thoracotomy or using a thoracoscopic approach. In patients who have undergone valve surgery and are eligible for surgical revascularization, it is possible to perform the procedure using a minimally invasive technique through the left-sided lateral mini-thoracotomy approach (MIDCAB) [28]. Among other surgical strategies, a hybrid approach should also be considered, combining minimally invasive cardiac surgery and interventional cardiology. An example of this are percutaneous coronary interventions within coronary artery bypass grafts.

In the case of aortic bioprosthesis dysfunction in prohibitive surgical risk patients, with contraindications to reoperation, the technique of transcatheter valve implantation — TAVI valve-in-valve (ViV) is a new and preferred strategy [29]. It can be also performed in dysfunctional mitral and tricuspid bioprostheses.

Reoperation is recommended not only in patients with valve dysfunction but also in those affected by the progression of valve disease after previous cardiovascular surgery, most often coronary surgery. Despite the development of minimally invasive and endovascular techniques, reoperations are still high-risk procedures that require careful assessment of indications and the scope of surgery. The rapid growth of technology and diagnostic imaging decreases the risk of reintervention in many patients. A summary of the most important indications and recommendations on the management of prosthetic valve dysfunction according to the 2021 ESC/EACTS Guidelines for the management of valvular heart disease is presented in Table 1 [8].

Complications after transcatheter valve interventions

Complications after TAVI: The main goal of the TAVI procedure is to stretch and widen the valve orifice and improve blood flow into the aorta, which can be achieved in almost all patients. An effective treatment leads to a detectable improvement in the patient's condition including the improvement of exercise tolerance, reduction of dyspnea, elimination of syncope, relief of angina, and above all, improved survival and quality of life [1, 8, 30].

Due to the low invasiveness of the procedure, replacing general anesthesia with local anesthesia, and the fact that, unlike the surgical option, TAVI does not require opening the chest or use of extracorporeal circulation, the patient can be quickly mobilized and rehabilitated. The risk of periprocedural death is low and, in most patients, it does not exceed 1.0%–1.5%. The incidence of periprocedural myocardial infarction is extremely rare. The risk of conversion to open-heart surgery due to perioperative complications is low and does not exceed 0.3%.

Transcatheter aortic valve implantation (TAVI) is associated with a risk of periprocedural stroke (1.5%–4.0%); however, it is lower than that of Surgical Aortic Valve Replacement (SAVR). The risk of this complication appears to be reduced with the use of periprocedural cerebral vascular protection systems, especially in patients with a high risk of stroke associated with TAVI procedure (bicuspid valve, massive calcification of the aortic valve or the aortic arch, ViV procedures). An appropriate periprocedural pharmacotherapy with antiplatelet or anticoagulant agents seems to play an important role in patients with indications for anticoagulation, though that role requires further research.

Another life-threatening complication is cardiac tamponade, which may be caused by the left ventricular injury (due to guidewire) or aortic annular rupture. The risk factors include, inter alia, undersizing and massive native valve calcifications, especially in the area of the left coronary aortic valve leaflet and the aortic apparatus. If rapid ventricular pacing is used during the procedure, tamponade may be caused by the introduction of the pacing lead into the right ventricle.

Undersizing may result in the migration of the valve either into the left ventricle or to the ascending aorta. A rare but serious complication is damage to the mitral apparatus with rupture of papillary muscle or tendinous cords usually due to intraprocedural aortic valvuloplasty or careless manipulations in the left ventricle with guidewires or the delivery system. Another very rare serious complication is the formation of a ventricular septal defect.

Due to the nature of vascular access and the introducer diameters, vascular complications and the associated bleeding complications most commonly occur at the access site (3%–8%). As a consequence of the recent technological progress, a significant reduction of system size, as well as the contemporary percutaneous closure technologies and increasing experience of operators, such complications are less frequently observed. In the periprocedural period, conduction disturbances (left bundle branch block, atrioventricular blocks including complete block) may appear or increase, which in some patients (8%–25%) requires pacemaker implantation. The risk of pacemaker implantation is greater in patients with pre-existing conduction disturbances.

The technique of the procedure itself (the depth of prosthesis implantation), severe native valve calcifications, and the type of bioprosthesis used (higher risk for self-expanding bioprosthesis, lower for balloon-expandable valves) are also of immense importance in terms of the occurrence of this complication. New valve generations and improved implantation techniques have reduced the risk of PPM.

Contrast-induced nephropathy (CIN) is one of the leading causes of hospital-acquired, transient acute kidney injury (AKI), especially in patients with previous chronic kidney disease. Proper hydration of the patient in the periprocedural period, avoiding prolonged hypotension and the use of as little iso-osmolar contrast media as possible during the procedure minimizes the risk of this complication. The occurrence of periprocedural arrhythmias (mainly atrial fibrillation), although similarly to AKI observed less frequently than after SAVR, requires treatment following the current recommendations, as well as the implementation of an anticoagulant regimen. In less than 5% of patients, depending on the type of prosthesis, moderate or severe PVL is observed post-TAVI (see: Follow-up after transcatheter aortic valve implantation), which worsens the prognosis. Modern prostheses are designed to reduce the risk of this complication by the addition of external sealing skirts.

Complications after transcatheter mitral valve repair (TMVR)

Among several approaches to transcatheter mitral valve repair; in Poland, the most popular technique is transcatheter edge-to-edge-approach (TEER).

Determining patients' eligibility for TMVR should be consistent with the consensus recommendations developed in centers with expertise in both surgical and percutaneous treatment of mitral valve disease by experienced multidisciplinary teams. Notably, medical therapy must be optimized, and CRT-D use considered [1, 8, 31, 32].

Periprocedural complications of transcatheter edge-to-edge repair procedures with the MitraClip and PASCAL systems include periprocedural death (less than 1%), bleeding at the vascular access site of various severity (up to approximately 5%–8% in total), single leaflet detachment (less than 2%), complete clip detachment or embolization (<0.05%), leaflet perforation, mitral chordal rupture, cardiac perforation followed by pericardial tamponade (mainly the left atrium or its appendage), thrombus formation within the left atrium, stroke, and TIA, as well as kidney failure. Conversion to emergency cardiac surgery is extremely rare (<0.5%).

Clip placement requires an interatrial transseptal puncture, which due to the relatively large delivery system and guiding catheter creates an iatrogenic atrial septal defect (iASD). It may close spontaneously or remain patent after the procedure (incidence of 50%–85% after 30 days and <30% after 12 months). In the event of acute respiratory failure, it is recommended to close the iASD immediately after the TMVR procedure with an adequate, dedicated occluder. The long-term approach to postprocedural ASD is controversial. The data from the registries are contradictory and demonstrate both the beneficial effect of left atrial decompression on symptoms and prognosis, as well as an increased risk of worsening heart failure and poorer prognosis.

Complications of edge-to-edge procedures result from the procedural technique itself, and their incidence decreases significantly with a proper candidate selection by a multidisciplinary team, as well as with the increasing experience of the operators and centers.

Valve-in-valve — transcatheter valve implantation for failing surgical bioprostheses

Valve-in-valve (ViV) TAVI emerged in 2007 and since then has become an established treatment option for surgical bioprosthetic valve deterioration. The 2019 STS/ACC TVT Registry reported a significant increase in the number of ViV-TAVI procedures (over 4 500 procedures were performed in the USA) [33]. This is due to the more frequent use of biological prostheses in younger patients and an increased risk of reoperation in patients previously undergoing SAVR (comorbidity, presence of coronary bypass grafts). ViV procedures are most frequently performed on malfunctioning surgically implanted aortic valve bi-

oprostheses (stented and scentless valves, homografts), and more and more often, also on mitral and tricuspid bioprostheses (stented valves).

In the case of ViV procedures in the aortic position, transfemoral access is favored over alternatives. In ViV transcatheter mitral valve replacement the transseptal approach has emerged as the preferred option, but trans-apical access is also viable, whilst ViV tricuspid valve replacement is performed via internal jugular and femoral approaches [34].

The pre-procedural preparation process includes (1) TTE (assessment of the pathology mechanism; quantitative assessment of the gradient and/or degree of regurgitation; comparison of parameters obtained immediately after SAVR allows to distinguish prosthesis-patient mismatch [PPM] from degeneration); (2) TEE (PVL and infective endocarditis); (3) CT of the heart with contrast medium and CT angiography of the aorta (access assessment, accurate measurements of coronary height from the aortic valve annulus, aortic root dimensions, orientation of the bioprosthetic commissures and sizing of the prosthesis); (4) coronary angiography; (5) reviewing the SAVR procedural data (verification of the surgical technique, residual gradient after SAVR, as well as valve type and dimensions).

It is very important to establish the "true internal diameter," which depends on how the valve leaflets are mounted in the stent frame, as well as the type of animal tissue (bovine vs. porcine). The mechanism of bioprosthesis dysfunction is important, as in stented bioprostheses stenosis is dominant, while in stentless, regurgitation. The technique of the procedure is similar to TAVI in a native aortic valve, but prior knowledge of the characteristics of the previously implanted bioprosthesis is necessary (stent cells as the orientation point the top of the stent or a marker within the prosthesis) [35]. This information can be obtained from the "Valve in Valve App" developed by V. Bapat (ViV aortic and ViV mitral).

The most important limitation of ViV-TAVI procedures is a risk of an elevated residual gradient after transcatheter valve implantation in small size degenerated surgical bioprostheses. Depending on the initial anatomy of the aortic valve region (e.g., the depth, width, and height of the sinuses) and the type of bioprosthetic surgical aortic valve (e.g., externally or internally mounted leaflets), ViV-TAVI may be associated with an increased risk of coronary obstruction in some patients, as well as the consequent need for PPM implantation, which remain important issues. Therefore, pre-procedural planning with a thorough angio-CT analysis, with the measurement of the valve-to-coronary orifice distance (VTC) is crucial. In patients who are at risk of iatrogenic coronary obstruction (VTC < 4 mm), coronary protection of the coronary ostia and eventual stent implantation in case of coronary flow impairment, as well as BASILICA (Bioprosthetic or native Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstructions during TAVR) procedure have been suggested as potential strategies for alleviating the risk.

Another issue is the preservation of future access to the coronary vessels after ViV-TAVI, which may be of particular importance in this group of patients due to the relatively long life expectancy compared to the general TAVI population. The appropriate orientation of the transcatheter aortic valve (TAV) in relation to the previously implanted surgical aortic valve is of great significance. There are numerous studies describing the self-expanding valves implantation technique that allows minimizing the phenomenon of commissural misalignment.

ViV-TAVI in degenerated surgical bioprosthetic valves has been performed in Poland since 2010 and constitutes approx. 2% of all TAVI procedures. Recently published data from the Polish Transcatheter Aortic Valve-in-Valve Implantation (ViV-TAVI) Registry from 14 participating centers and covering a total of 130 procedures showed high procedural effectiveness of ViV-TAVI, especially since second-generation transcatheter heart valves (bioprostheses that can be repositioned and/or with an additional sealing skirt) were introduced [36].

In summary, ViV TAVI procedures have emerged as a safe and effective alternative to SAVR reoperation, provided that patients are carefully selected, and the procedure is planned. A regular echocardiographic follow-up is necessary due to the possible degeneration of the bioprosthesis [8, 37].

Transcatheter management of paravalvular leaks

The PVL is found in several to over a dozen percent of patients with surgically implanted heart valve prostheses, and even in several dozen percent of patients with percutaneously implanted aortic valve prostheses (especially the first-generation valves, as the likelihood of paravalvular regurgitation has been reduced with newer heart valve designs) (see: Follow-up after transcatheter aortic valve implantation, and Post-operative paravalvular leak). The occurrence of PVL is directly linked to the presence of extensive calcifications of the native aortic annulus (the device landing zone) and/or inflammation-related destruction of the surrounding tissues, which prevents the prosthesis from adhering tightly to the annulus. A majority of PVLs occur within the first year from valve implantation; however, about 25% are discovered later, which may be due to the "smoldering" infection in the tissues surrounding the prosthesis. Reoperation is recommended if the paravalvular leak provokes heart failure symptoms and/or causes hemolysis requiring repeated blood transfusions [8, 38, 39].

When assessing a patient with a prosthetic valve in TTE, a careful examination technique is required to eliminate the limitations resulting from the presence of acoustic shadows that increase the risk of underestimating or even overlooking a PVL. An important indirect sign of a large PVL, especially in mitral valve prostheses, is a high transvalvu-

lar mean pressure gradient resulting from the increased transvalvular flow. TEE is helpful for definitive diagnosis. Irregular shape of the PVL channel with frequently oblique course, presence of multiple PVLs at the same prosthesis or coexistence of mitral and aortic PVLs in patients after double valve surgery necessitate multifactorial echocardiography assessment, in selected cases supplemented by cardiac magnetic resonance data (regurgitation fraction) [13, 40–42].

The role of transcatheter paravalvular leak closure (TPVLC) in the management of PVL is increasing, and it was granted class IIa recommendation in both the 2021 ESC [8] and 2020 American College of Cardiology and American Heart Association (AHA/ACC) guidelines [38]. Sealing PVL with occluders is performed from transvenous, transarterial, or transapical access (depending on the location of the PVL). The device is selected on the basis of echocardiographic (mainly 3-dimensional TEE) characteristics of the PVL channel [43] and in some cases, supplemented with CT data. Due to high surgical risk and frequent recurrence of PVL after surgical correction (up to 20% in long-term follow-up), the reoperation should be reserved for patients in whom PVL coexists with active IE, significant dysfunction or degeneration of the prosthetic valve, its mechanical instability or other concurrent indications for surgical treatment. Verification of TPVLC effectiveness should include both echocardiography and monitoring of hemolysis (reticulocytosis, unconjugated bilirubin, and lactate dehydrogenase [LDH]) to exclude the possibility of incomplete closure of PVL, which may exacerebate the hemolysis after TPVLC.

Pharmacotherapy after TPVLC is not standardized. In patients who require chronic anticoagulation therapy, the treatment is continued after the procedure, with the addition of antiplatelet drugs in some cases. In patients not receiving chronic oral anticoagulant treatment, dual antiplatelet therapy (aspirin + clopidogrel) is usually prescribed for 6 months.

MANAGEMENT OF SPECIFIC CLINICAL SITUATIONS AFTER CARDIAC VALVE INTERVENTIONS

Management of anticoagulant and antiplatelet therapy after prosthetic valve implantation

Over the past 50 years, around 4 million prosthetic heart valves have been implanted. Every year 300 000 prosthetic heart valve replacements are done worldwide, and the number is growing [44]. The surgical procedure remains the only effective treatment for the majority of patients with severe valvular heart disease.

Patients with mechanical prostheses

The latest guidelines for the management of valvular heart disease, published in 2021 and developed by the Task Force for the management of valvular heart disease of the ESC and the European Association for Cardio-Thoracic Surgery (EACTS), recommend lifelong treatment with VKA guided by the INR in all patients with mechanical prostheses (class IB). These guidelines are mainly based on observational data and expert opinion, as only a few randomized trials have been conducted so far. Factors influencing the prosthesis thrombogenicity include altered blood flow, activation of the blood coagulation caused by the surgical procedure, and exposure to artificial valve surfaces (sutures, components of the prosthetic heart valve). Currently, the most used VKAs are warfarin (half-life of 40 hours) and acenocoumarol (half-life of 8-11 hours). Attempts to use oral anticoagulants that are not-vitamin K antagonists have failed. Currently, the use of NOACs in patients with mechanical heart valves is contraindicated (class III B) [8].

VKA therapy in clinical practice is challenging as it is associated with several limitations, including the slow onset of action, prolonged activity after drug withdrawal, narrow therapeutic window, and variable dose response due to multiple interactions with other therapeutics or food. Treatment with VKA should be initiated on the first postoperative day in combination with bridging therapy with therapeutic doses of either unfractionated heparin (UFH) or off-label use of low-molecular-weight heparin (LMWH) until therapeutic INR is obtained.

INR is used to assess and monitor the effectiveness of VKA therapy. It is recommended to target a median INR value rather than a range to prevent viewing extreme values in the target range as a valid target INR. Target INR should be based not only upon prosthesis thrombogenicity but also on patient-related risk factors [8, 44]. Low-thrombogenicity mechanical heart valves are Carbomedics, Medtronic Hall, ATS, Medtronic Open-Pivot, St Jude Medical, Sorin Bicarbon, and high-thrombogenicity mechanical heart valves are Lillehei-Kaster, Omniscience, Starr-Edwards (ball-cage), Bjork-Shiley. Target INR in patients with mechanical prostheses without risk factors and with risk factors, such as a mitral or tricuspid valve replacement, previous thromboembolism, atrial fibrillation (AF), left ventricular systolic dysfunction, coagulation disorders, or older generations of prostheses are presented in Table 1 [8].

Patient education plays an important role in achieving stable anticoagulation. The guidelines emphasize the role of INR self-monitoring. The use of INR self-monitoring is associated with a lower rate of VKA-related complications in all ages. A study comparing the effectiveness of self-monitored vs in-clinic INR tested anticoagulation along with high patient compliance, demonstrated the safety of both methods after the implantation of the On-X mechanical heart valve in the aortic position. Hence, the guidelines recommend INR self-monitoring (class I B) for patients treated with VKA, provided that adequate training and quality control are performed. The addition of low-dose (75–100 mg) acetylsalicylic acid (ASA) to VKA may lower the incidence of thromboembolism at the cost of bleeding and may be occasionally necessary, usually in

Table 5. Recommendations on management of prosthetic valve dysfunction according to 2021 European Society of Cardiology (ESC)/European Association for Cardio-Thoracic Surgery (EACTS) Guidelines for the management of valvular heart disease [8]

Thrombosis of mechanical prosthetic valve	Class	Level
Urgent or emergency valve replacement is recommended for obstructive thrombosis in critically ill patients without serious comorbidity	I	B
Fibrinolysis (using recombinant tissue plasminogen activator 10 mg bolus + 90 mg in 90 min with UFH or streptokinase 1 500 000 U in 60 min without UFH) should be considered when surgery is not available or is a very high risk, or for thrombosis of right-sided prostheses.	IIa	B
Surgery should be considered for large (>10 mm) non-obstructive prosthetic thrombus complicated by embolism.	IIa	C
Bioprosthetic valve thrombosis		
Anticoagulation using a VKA and/or UFH is recommended in bioprosthetic valve thrombosis before considering re-intervention.	I	C
Anticoagulation should be considered in patients with leaflet thickening and reduced leaflet motion leading to elevated gradients, at least until resolution.	IIa	B
Hemolysis and paravalvular leak		
Reoperation is recommended if a paravalvular leak is related to endocarditis or causes hemolysis requiring repeated blood transfusions or leading to severe heart failure symptoms.	I	C
Transcatheter closure should be considered for suitable paravalvular leaks with clinically significant regurgitation and/or hemolysis in patients at high or prohibitive surgical risk.	IIa	B
Decision on transcatheter or surgical closure of clinically significant paravalvular leaks should be considered based on patient risk status, leak morphology, and local expertise.	IIa	C
Bioprosthesis failure		
Reoperation is recommended in symptomatic patients with a significant increase in transvalvular gradient (after exclusion of valve thrombosis) or severe regurgitation.	I	C
Transcatheter, transfemoral valve-in-valve implantation in the aortic position should be considered by the Heart Team depending on anatomic considerations, features of the prosthesis, and in patients who are at high operative risk or inoperable.	IIa	B
Transcatheter valve-in-valve implantation in the mitral and tricuspid position may be considered in selected patients at high risk for surgical reintervention	IIb	B
Reoperation should be considered in asymptomatic patients with significant prosthetic dysfunction if reoperation is low risk.	IIa	C

Abbreviations: UFH, unfractionated heparin; VKA, vitamin K antagonists

the setting of acute coronary syndrome and arterial stent implantation. Thus, the addition of antiplatelets to VKAs should be reserved for rare and carefully selected patients at very high risk of thromboembolism where the benefits exceed the risks (class IIa C).

In case of VKA overdose, major or life-threatening bleeding, and in patients requiring urgent surgery, the VKA should be discontinued, and 10 mg vitamin K should be administrated by slow i.v. infusion and if needed, repeated every 12 hours. Until the anticoagulation effect is reversed, the administration of prothrombin complex concentrates (PCC) and/or fresh frozen plasma (FFP) should be initiated according to body weight and pre-treatment INR. The efficacy should be monitored by reassessment of INR at 30 min and every 46 hours until normalization. In asymptomatic patients with INR >10, VKA must be discontinued, and oral vitamin K should be administered, while the INR values must be monitored on a daily basis for 2 weeks. Multiple randomized controlled trials in patients with INR between 4.5 and 10 suggest no difference in the incidence of bleeding with vitamin K vs. placebo. Thus, in such patients, VKA should be stopped temporarily, and a low dose of oral vitamin K (1–2 mg) can be considered individually, balancing the risks. Asymptomatic patients with INR <4.5 require cautious dose reduction and/or omission of one or more doses [8].

The anticoagulation strategy should be carefully considered in patients with prosthetic valves before elective non-cardiac surgery. It is recommended that oral anticoagulant therapy should not be interrupted before minor, low-risk procedures, such as cataract surgery or teeth extraction. In major surgical procedures, it is recommended to temporarily discontinue VKA therapy until INR <1.5 is achieved with the use of unfractionated heparin bridging or the use of low molecular weight heparin (LMWH) monitored and titrated to therapeutic doses (class I C) [8].

Patients with surgically implanted bioprosthetic valves

The incidence of thromboembolic events in patients with biological prostheses appears to be highest in the first 3 months after surgery. Lifelong oral anticoagulation, after surgical implantation of a bioprosthetic valve, is recommended only in patients who have other indications for anticoagulant therapy. Recent studies have shown that NOACs are not inferior to VKA. According to current recommendations, VKA administration should be considered for the first 3 months after the procedure in all patients with mitral or tricuspid biological heart valves (class IIa B). Either ASA (75–100 mg/day) or VKA monotherapy should be considered for 3 months after surgical implantation of an aortic bioprosthesis (class IIa B). NOACs rather than VKAs are recommended 3 months after surgical bioprosthesis implantation in patients with atrial fibrillation (class IIb C) [8].

Patients with transcatheter bioprosthetic valves

Lifelong antiplatelet therapy with a single agent is recommended after TAVI in patients with no baseline indication

Table 6. Target international normalized ratio for mechanical prostheses

Prosthesis thrombogenicity	No risk factors	≥1 patient-related risk factor
Low	2.5	3.0
Medium	3.0	3.5
High	3.5	4.0

for oral anticoagulant therapy (class I B). This recommendation was based on (1) a meta-analysis of three studies where a significant increase in major or life-threatening bleeding was observed with administration of dual antiplatelet therapy (DAPT) compared to monotherapy; (2) the latest POPular TAVI trial, which has demonstrated a significant reduction in bleeding and thromboembolic complications with the use of ASA alone compared to DAPT strategy. Therefore, a single antiplatelet therapy is recommended unless there are concomitant indications for DAPT (ACS, stent implantation).

There is a lack of data on the management of antithrombotic therapy after the implantation of the transcatheter mitral valve, but due to the increased risk of thrombus on the valve leaflets, manufacturers recommend VKA for up to 6 months in the absence of other indications for anticoagulation [8].

Patients after surgical mitral and tricuspid valve repair

Observational data show a comparable risk of thromboembolism with ASA or VKA use after mitral valve repair, though randomized data are lacking. High incidence and recurrence of new-onset AF, increased tendency to the thrombosis on the components of the repair systems and a relatively high proportion of ASA-resistant patients make VKA the preferred therapeutic strategy in the initial 3-month postoperative period. VKA should be considered in the first 3 months after mitral and tricuspid valve repair — class IIa C [8].

Patients after surgical aortic valve repair and aortic reconstruction

Due to a small number of such procedures, there are no clear guidelines for the management of this group of patients. Isolated reports from the literature indicate that in patients with aortic regurgitation who underwent aortic valve replacement, whilst maintaining the native valve, anticoagulation was not routinely administered. Monotherapy with a low dose of ASA (75–100 mg/day) should be considered for the first 3 months after the abovementioned interventions — class IIa C [8].

Patients after transcatheter mitral and tricuspid valve repair interventions

Optimal anticoagulation protocol for patients after edge-to-edge valve repair has not been standardized. It is recommended to use a loading dose of clopidogrel before or immediately after the procedure. Instead of clopidogrel, ASA can also be administered in a loading dose of 325 mg. After the procedure, clopidogrel at a dose of 75 mg/day or ASA 75–100 mg/day should be used for at least 6 months [45, 46].

A significant percentage of patients eligible for transcatheter repair of the mitral and tricuspid valves have AF and, therefore, indications for oral anticoagulation. Depending on the risk of bleeding in these patients, it seems advisable to add single antiplatelet therapy or a dual therapy of short duration.

Optimal management after valve interventions in pregnancy

In 2018, the European Society of Cardiology updated its guidelines for the management of women with cardiovascular disease during pregnancy. Pregnant women with mechanical heart valves belong to class III of the modified classification of the World Health Organization (mWHO) with regard to their risk of cardiac events during pregnancy, which represents a significantly increased risk of maternal mortality or severe morbidity, with a maternal cardiac event rate of 19%–27% [8, 47]. Women with mechanical heart valves should receive pre-pregnancy counseling and should be managed by a multidisciplinary care team during pregnancy and childbirth., i.e. the Pregnancy Heart Team. Follow-up visits during pregnancy should be performed every 1 to 2 months in an expert center with a Pregnancy Heart Team.

Different anticoagulation regimens should be carefully discussed before pregnancy. The patient should be informed that the use of VKA is the most effective way to prevent valve thrombosis and is the safest treatment for the mother. The dose-related increased risk of embryopathy, fetopathy, fetal loss, and fetal bleeding associated with the use of VKA should also be presented [48]. It is also necessary to inform the patient about a higher risk of valve thrombosis associated with the use of LMWH. The patient should understand that strict adherence to therapeutic recommendations is essential for successful pregnancy outcomes, irrespective of the treatment regimen. The choice of an anticoagulant depends on the dose of VKA necessary to obtain the therapeutic INR value [8, 47, 49].

If the VKA dose is low (warfarin <5 mg/day, acenocoumarol <2 mg/day), the continuation of VKA therapy throughout the entire pregnancy should be considered. The INR check should be determined weekly or every 2 weeks. An intra-hospital conversion to LMWH may be considered during the 6^{th}–12^{th} week of pregnancy under close monitoring antyXa level and after full disclosure of the associated risks is provided to the mother. The treatment of LMWH in the first trimester should take place in the hospital.

In women taking high-dose VKA (warfarin >5 mg/day, acenocoumarol >2 mg/day) discontinuation of VKA be-

tween weeks 6 and 12 of pregnancy and replacement with adjusted-dose intravenous UFH with APTT monitoring or subcutaneous administration of LMWH with strict anti-Xa monitoring should be considered. Initial doses of LMWH enoxaparin are 1 mg/kg and 100 IU/kg in case of dalteparin, administered subcutaneously twice daily. Doses should be adjusted according to the anti-Xa level at the time of maximum drug effect. Measuring anti-Xa levels shortly before the administration of the next dose should be considered. It is recommended to monitor the anti-Xa level daily in a hospital setting until reaching the target anti-Xa level, followed by a weekly anti-Xa concentration assessment. For patients with mechanical heart valve prosthesis, recommended peak anti-Xa levels are at 1.0–1.2 U/ml (mitral and right-sided valves) or 0.8–1.2 U/ml (aortic valves) after 4 to 6 hours since drug dose administration and anti-Xa level before the next drug dose should be at >0.6 U/ml [8, 50]. If UHF is administered, once stable APTT values have been achieved, the intensity of anticoagulation should be monitored by the APTT level weekly, aiming at a reference range at least 2 times greater than the control. However, the use of UHF infusion for 6 weeks is difficult for practical reasons (labile APTT values, the need for 24/7 infusion, and the risk of infectious complications). After the patient had provided written informed consent, continuation of VKA administration should also be considered. VKA is the preferred anticoagulant in the second and third trimesters.

Regardless of the dose, it is recommended to discontinue VKA at week 36 and initiate unfractionated heparin infusion which should be monitored with APTT or use low-molecular-weight heparin with anti-Xa measurements. It is recommended to start the infusion of unfractionated heparin and adjust the dose (based on the APTT) 36 hours before the planned cesarean section in all patients. The infusion should be stopped 4–6 hours before the delivery and then restarted 4–6 hours after delivery if no bleeding has occurred [8, 50]. It should be emphasized that adjustments in anticoagulation regimens in pregnant women with mechanical valve prostheses should be implemented in the hospital setting.

Management of valve thrombosis after prosthesis implantation

Hemorrhagic and thromboembolic complications in patients with implanted valve prostheses account for 75% of all postoperative complications. Increased risk of thromboembolic events, both in the perioperative period and in long-term follow-up, is observed in patients with at least one of the following factors: age over 65, atrial fibrillation, heart failure, and low cardiac output syndrome, previous stroke, as well as the presence of common comorbidities such as hypertension, diabetes, renal failure, cancer, anemia, and coagulation disorders [51].

Obstructive prosthetic valve thrombosis should be suspected in every patient who presents with recent dyspnea or a thromboembolic event regardless of the type of prosthetic valve. The diagnosis should be confirmed by TTE and TEE, fluoroscopy, or CT [13]. When the echocardiographic assessment of a mechanical prosthesis is challenging, fluoroscopy can be a very useful diagnostic tool to demonstrate reduced valve leaflet mobility or immobilization of the mechanical prosthesis disk.

Management of mechanical prosthetic valve thrombosis either with pharmacological or surgical strategy is associated with a substantial risk of complications. Anticoagulation is the first-line treatment and should be initiated immediately in all patients until the thrombus is resolved [8].

Fibrinolytic therapy carries a higher risk of bleeding, systemic embolism, as well as thrombosis recurrence than surgery [13]. Urgent valve replacement is recommended in obstructive prosthetic thrombosis in severe condition patients without contraindications to surgery. The management of nonobstructive mechanical prosthetic valve thrombosis depends on the presence of thromboembolic complications as well as the size of the thrombi. Surgery should be considered for large (>10 mm) non-obstructive mechanical prosthetic valve thrombus, complicated by embolism, or persistent thrombus despite optimal anticoagulation [8, 52]. Anticoagulation therapy with VKA and/or UFH is the treatment of choice in biological prosthesis thrombosis [8].

Patients' eligibility for non-cardiac procedures after valve interventions

Patients who underwent valvular interventions may be at increased risk of perioperative cardiovascular complications during non-cardiac surgery. The risk can vary depending on the type and effectiveness of prior valve procedures, as well as the type of non-cardiac surgery [53].

Routine classification of non-cardiac surgeries into three risk groups: (low risk: <1%, moderate risk: 1%–5%, and high risk: >5%) should also be used in patients who underwent valvular interventions [54, 55].

Clinical and echocardiographic evaluation is recommended for all patients who underwent valve intervention, undergoing elective non-cardiac surgery associated with intermediate or high risk [53, 54]. In the overall assessment of patients after valvular intervention, the main issues are the evaluation of hemodynamic stability, assessment of clinical symptoms and investigating their relation to prior valve intervention, the risk assessment of non-cardiac surgery, as well as cardiac complications depending on the type of non-cardiac procedure. In patients after valvular intervention, with symptomatic heart failure or arrhythmias, apart from clinical and echocardiographic evaluation, appropriate pharmacological treatment is recommended, if necessary, before non-cardiac surgery [55, 56].

In patients with a history of a previous surgical correction of a heart defect or implantation of an artificial valve, non-cardiac surgery can be performed without

additional risk unless there is evidence of valvular or ventricular dysfunction. In current practice, the main issue is the necessity to modify the anticoagulant treatment regimen in the perioperative period — oral anticoagulants are temporarily replaced by UFH or LMWH in therapeutic doses [53, 56].

In patients with mechanical prostheses, bridging with UFH or LMWH before non-cardiac surgery carries a risk of perioperative bleeding, while temporary discontinuation of anticoagulation leads to a significant increase in the risk of thromboembolic complications, including valve thrombosis [57]. Therefore, anticoagulant treatment in patients with mechanical prostheses undergoing elective non-cardiac surgery requires detailed individual evaluation supported by other specialists if necessary [57, 58]. Discontinuation of oral anticoagulant treatment is not recommended for minor surgical procedures (e.g. dental, cataract surgery, skin incisions). where bleeding is usually minor and can be easily controlled.

Major surgeries require temporary discontinuation of oral anticoagulant therapy to achieve an INR of <1.5 and bridging therapy with UFH or LMWH at therapeutic doses. Fondaparinux should not be routinely used for perioperative bridging therapy but may play a role in patients with a history of heparin-induced thrombocytopenia [58].

Coronary artery disease after valve interventions

In the immediate postoperative period after valve surgery, interventional treatment of coronary artery disease is limited only to urgent interventions, i.e. in the case of acute coronary syndromes. In such situations, percutaneous revascularization is favored. In selected patients, revascularization may be performed as the next stage of a planned hybrid treatment after the valve intervention [8].

In long-term management of patients after percutaneous valve procedures, due to the baseline characteristics of this group (often elderly patients with multiple comorbidities), a decision whether to perform coronary angiography must be made individually and often depends on the diagnosis of acute coronary syndromes. If revascularization is indicated, percutaneous coronary intervention is preferred. In certain situations, cardiac reoperation must be considered; however, it is associated with a high surgical risk.

In patients after percutaneous aortic valve implantation, catheter access to coronary arteries may be difficult. This is due to the design of the implanted valve and the anatomical conditions — valve stent may extend over ostia of the coronary vessels. Additionally, when percutaneous coronary intervention is required, coaxial positioning of the guide catheter may be challenging. Such patients may benefit from referral to an experienced center, where the intervention can be safely performed. The above-mentioned difficulties have become the reason for modifying the design of new-generation TAVI valves and improving the methods of their implantation.

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