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AORTIC VALVE REPLACEMENT AFTER PREVIOUS TAVI

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Endovascular surgery for aortic valve defects has proven itself well in elderly patients with severe comorbidities competing with the underlying disease. However, the risk of dysfunction resulting from structural degeneration of bioprosthetic heart valve and prosthetic valve endocarditis remains high. Repeated surgeries are associated with complications, but open surgery is the only method of treatment in this group of patients. **Objective:** to describe a series of reinterventions for prosthetic valve dysfunction occurring after TAVI. **Material and methods.** From 2015 to 2022, at the Department of Emergency Surgery for Acquired Heart Diseases (Head, Professor R.M. Muratov), Bakulev Research Center for Cardiovascular Surgery, 6 reoperations were performed in patients who had previously undergone transcatheter aortic valve implantation (TAVI). The average age of patients at the time of TAVI and at the time of reoperation was 70.6 years (62–83) and 74.3 years (70–84), respectively. The EuroSCORE II predicted risk of mortality at the time of reintervention was 42.2% (21.7–87.6). The mean time to reoperation was 42 months. Indications for reoperation were early active prosthetic endocarditis (4 cases) and structural valve degeneration (2 cases). **Results.** At the hospital stage, 1 patient died of acute heart failure; the operation was performed for vital indications in conditions of extreme initial severity. In three patients, the early postoperative period was uneventful. One patient required intra-aortic balloon counterpulsation (IABP) due to heart failure, and 1 patient was implanted with permanent pacemaker. The average time of hospitalization was 14 days. Patients with active prosthetic endocarditis received a 6-week course of antibiotic therapy. The function of the implanted valves was satisfactory. **Conclusions.** Aortic valve replacement after previous TAVI is an emergency operation and represents the only way to treat valve dysfunction. Under active prosthetic endocarditis, timely surgery can save this patient cohort.

Keywords: valve replacement, infective endocarditis, TAVI.

INTRODUCTION

When choosing a surgical technique for aortic stenosis, it has been shown that open surgery is indicated in young patients, amidst infective endocarditis and the risk level according to STS and EuroSCORE II scales is below 4%. Whereas in the presence of multivessel coronary artery disease, atrioventricular valve pathology, aortic aneurysm, interventricular septal hypertrophy requiring myomectomy and the risk degree according to the same scales more than 4%, comorbid pathology, gross post-radiation changes in the mediastinal organs, risk of injury to functioning shunts during resternotomy may be a preference for transcatheter aortic valve replacement (TAVR, also called transcatheter aortic valve implantation, TAVI).

With the accumulation of experience in TAVR procedures, the disadvantages and contraindications have been identified. Absolute contraindications include the absence of specially trained cardiac surgical service, life expectancy <1 year, and low likelihood of improving the quality of life after TAVR due to severe concomitant pathology. Anatomical features such as narrow or wide aortic annulus (<18 mm or >29 mm) and left ventricular thrombus are also important. Unfavorable aortic root anatomy, asymmetric calcinosis with a high risk of

coronary ostial obstruction, aortic atheromatosis with unstable plaques and a high risk of systemic embolism may also be contraindications.

The TAVI procedure was originally intended to be minimally invasive and to maximize safety for patients with high surgical risk. However, the incidence and extent of acute complications during valve implantation, such as coronary ostial obstruction, rupture of the aortic annulus, atrioventricular block, paraprosthetic fistulas, stroke, myocardial infarction and complications occurring at various times after surgery on the side of the implanted valve: secondary valve thrombosis, dysfunction due to compression and prosthetic endocarditis do not make this technique the gold standard when choosing the type of surgery for aortic valve (AV) stenosis.

MATERIALS AND METHODS

From 2015 to 2022, 6 patients were re-operated at the Department of Emergency Surgery of Acquired Heart Defects, Bakulev Research Center for Cardiovascular Surgery (led by Prof. R.M. Muratov) after earlier TAVR. The average age of patients at the time of TAVR was 70.6 years (62–83), at the time of reoperation was 74.3 years (70–84). The predicted EuroSCORE II mortality risk at the time of reintervention was 42.2%

(21.7–87.6). Women/men were 4/2. The mean time to perform reoperation from the time of primary surgery was 42 months (8–144) (see Table). The indication for surgery in 4 cases was early active prosthetic valve endocarditis (PVE), in 2 cases structural degeneration of the valve.

The main symptoms in patients were dyspnea at minimal physical exertion, prolonged increase in body temperature up to 38.5 °C, loss of body weight, and severe weakness. All patients had severe heart failure (HF) with lower limb edema and enlarged liver. One patient was operated for vital indications due to progressive HF.

All patients were examined by standard methods. Cardiac ultrasound found that in patients with PVE,

there were overlaps and vegetations on the prosthetic leaflets with formation of grade 2–3 mitral regurgitation. In patients with prosthetic degeneration, valve leaflets were limited in mobility, thickened and calcified with formation of transvalvular peak and mean gradient and significant regurgitation. In one case, in a patient with the CoreValve aortic valve, when it was difficult to confirm an infectious lesion using transesophageal echocardiogram (TEE) due to its structural features (high nitinol framework), 18F-FDG PET/CT was performed to confirm the diagnosis of PVE, which showed the presence of pathological hypermetabolism in the bioprosthetic aortic valve projection (see Fig. 1). To exclude malfor-

Table

Clinical characteristics of reoperated patients, n = 6

Patient / Age	TAVR system	Age at TAVR (years)	Age at re-operation (years)	Post-TAVR period (months)	ES 2 (%)	Concomitant pathology
1. 70 years	Edwards Sapien-23	65	70	60	19.9	MFA, COPD
2. 84 years	Core Valve-26	83	84	8	36.5	MFA, stage 4 CKD, diabetes, HBP
3. 73 years	Edwards Sapien-29	72	73	8	87.6	Stage 4 CKD. Benign prostatic hyperplasia
4. 75 years	MedLAB-27	73	75	24	24.8	Pulmonary fibrosis, HBP
5. 70 years	Boston Scientific Acurate neo-25	69	70	11	23.5	Mastectomy, radiotherapy
6. 74 years	CoreValve-23	62	74	144	38.1	Surgery artificial circulation and ECMO history

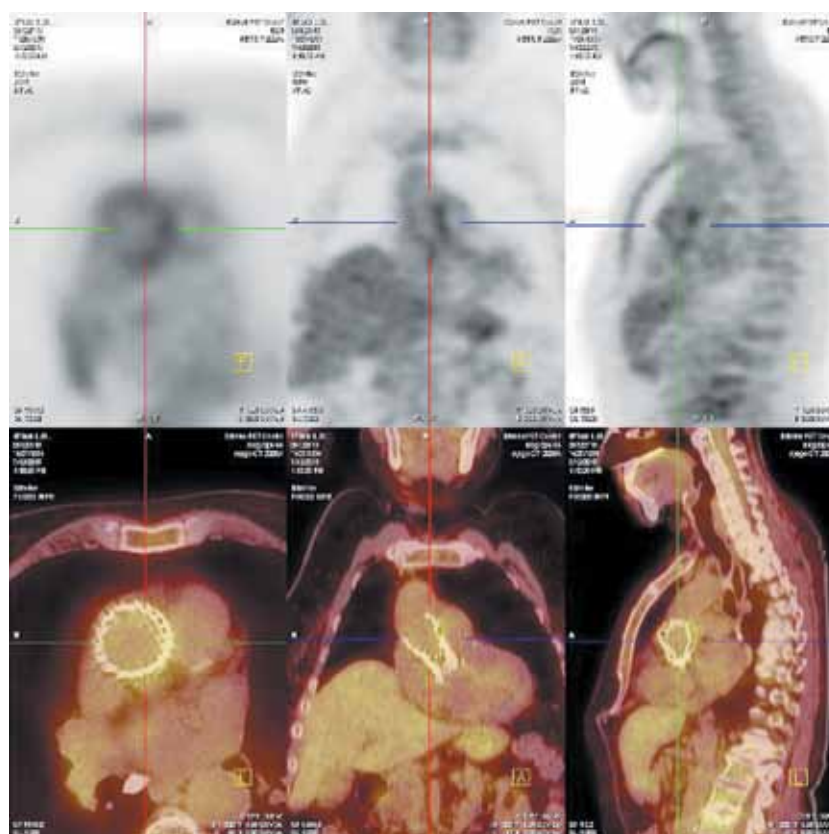


Fig. 1. 18F-FDG PET-CT imaging, pathological hypermetabolism in the bioprosthetic aortic valve projection

mation and cerebral mycotic aneurysm, brain MRI was performed in case of infective PVE.

CHARACTERISTICS OF SURGICAL INTERVENTIONS

All operations were performed under hypothermic cardiopulmonary bypass (28 °C). In five cases, the operation was performed through a full median sternotomy, in 1 case a J-ministernotomy along the 4th intercostal space was used. Myocardial protection in all patients was performed by administration of 2 liters of Custodiol solution. The average cardiopulmonary bypass (CPB) time was 197.5 minutes and aortic clamping time was 141.7 minutes.

Patient 1. Diagnosis: postoperative Edwards Sapien-23 TAVR by transapical access condition. Bioprosthetic aortic valve stenosis and failure on the background of structural degeneration (Fig. 2). Stage IIb heart failure (HF). New York Heart Association (NYHA) functional

class IV. Operation: AV replacement with BioLAB-20 bioprosthetic valve. CPB lasted for 116 minutes. Aortic clamping lasted for 76 minutes. The postoperative period was uneventful; the patient was discharged on day 8.

Patient 2. Diagnosis: postoperative CoreValve 26 TAVR condition, stenting of the left anterior descending artery (LADA). Early prosthetic AV endocarditis, active phase. Infective mitral valve (MV) endocarditis with grade 2 regurgitation. Stent restenosis in the LADA. Stage IIb HF. NYHA functional class IV. Operation: AV replacement with Karboniks-22 mechanical prosthetic valve, MV replacement with Karboniks-28 mechanical prosthetic valve, coronary artery bypass grafting (CABG-LADA) (see Fig. 3). CPB lasted for 227 minutes. Aortic clamping lasted for 165 minutes. The postoperative period was uneventful; the patient was discharged on day 18.

Patient 3. Diagnosis: postoperative Edwards Sapien-29 TAVR condition. Early prosthetic AV endocarditis,

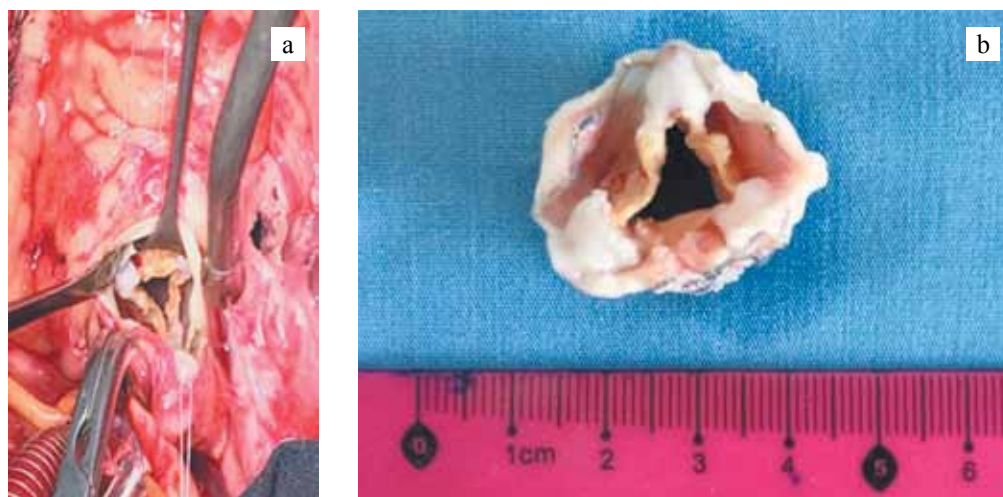


Fig. 2. Structural degeneration of the Edwards Sapien-23 valve: a, intraoperative photo; b, explanted Edwards Sapien-23 valve

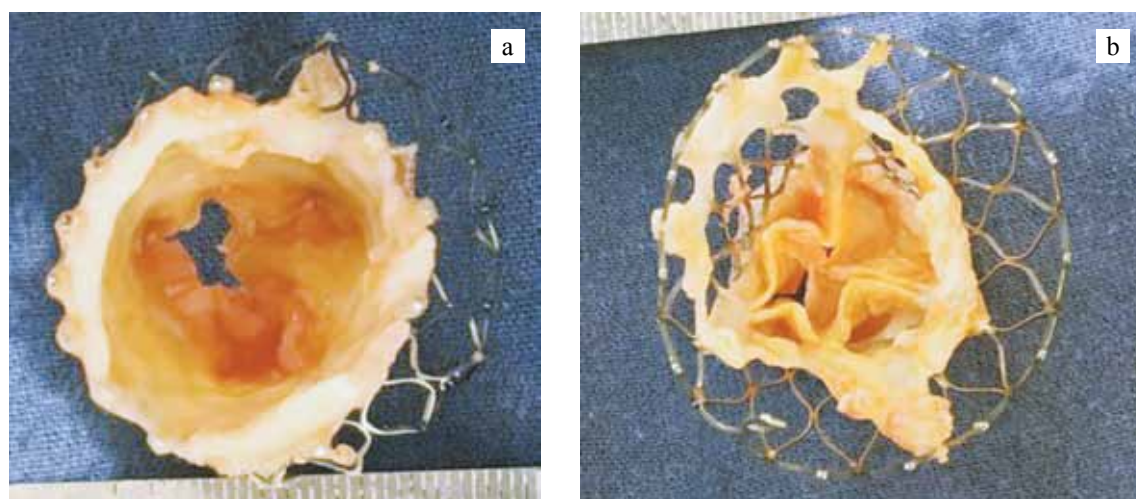


Fig. 3. Prosthetic valve endocarditis affecting the CoreValve 26 stent (vegetation on xenopericardial flaps): a, ventricular surface of the valve; b, aortic surface of the valve

active phase. Grade 3 mitral and tricuspid regurgitation. High pulmonary hypertension. Ascites. Artificial ventilation. Stage IIb HF. NYHA functional class IV. Operation: AV replacement with Karboniks-26, MV repair on a polytetrafluoroethylene strip, tricuspid valve repair according to DeVega procedure (see Fig. 4). CPB lasted for 204 minutes. Aortic clamping lasted for 125 minutes. The patient died from progressive HF in the early postoperative period.

Patient 4. Diagnosis: postoperative TAVI MedLab-KT 27 condition. Early aortic prosthetic valve endocarditis. Aortic regurgitation. Stage IIa HF. NYHA functional class III. Operation: AV replacement with BioLAB-22 bioprosthetic valve from a mini-sternotomy (Fig. 5). CPB lasted for 151 minutes. Aortic clamping lasted for 85 minutes. The postoperative period was uneventful; the patient was discharged on day 9.

Patient 5. Diagnosis: postoperative Boston Scientific Acurate neo-25 condition. Early prosthetic AV endocarditis, active phase. Aortic regurgitation (see Fig. 6). Stage IIa HF. NYHA functional class IV. Operation: aortic root replacement with devitalized allograft, implantation of a dual-chamber pacemaker. CPB lasted for 194 minutes. Aortic clamping lasted for 140 minutes. The postoperative period was uneventful; the patient was discharged on day 16.

Patient 6. Diagnosis: postoperative Mitroflow aortic valve bioprosthesis, AV replacement using CoreValve 23 TAVR technique under ECMO to prevent postoperative complication in the patient with critical hemodynamic disturbance (intraoperative ventricular tachycardia). Structural degeneration of the valve by calcinosis (see Fig. 7). Stage IIa HF. NYHA functional class II. Operation: AV replacement with Karboniks-22 prosthetic valve.

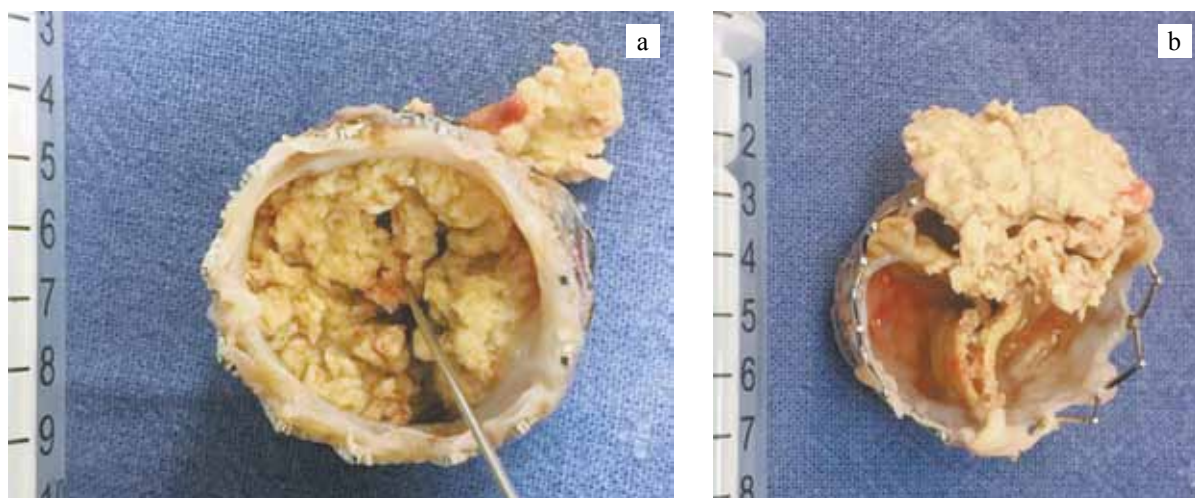


Fig. 4. Prosthetic valve endocarditis affecting the Edwards Sapien-29 valve stent: a, ventricular surface of the valve; b, aortic surface of the valve

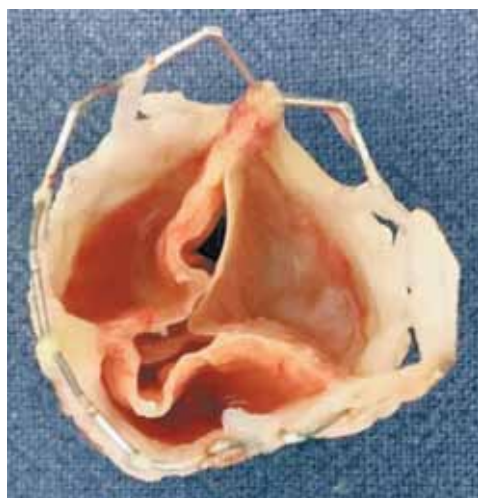


Fig. 5. Explanted MedLAB KT 27 valve stent (flat vegetations on PTFE flaps)

RESULTS

At the hospital stage, 1 patient died of acute HF. Patient #3 with decompensated HF was taken for surgery on vital indications with multi-organ failure. EUROScore II was 87%. To prevent and replenish blood loss during all operations, the Cell-Saver device was used. Blood loss by drains on the first day averaged 500 mL (350–750). Mechanical ventilation lasted for an average of 23 [13 : 682] hours. Prolonged ventilation was performed due to neurological deficit in patient #3 and development of HF. The patient stayed at the ICU for 4.5 (1.3–30) days.

In three patients, the early postoperative period was uneventful. The average time in hospital was 14 days. Patients with active PVE underwent a 6-week course of antibiotic therapy. At the moment of discharge, 3 patients

had sinus rhythm, 1 patient had permanent atrial fibrillation, and 1 patient had a permanent pacemaker. The function of implanted prosthetic valves was satisfactory.

DISCUSSION

The development and implementation of alternative techniques (TAVI, balloon valvuloplasty) for the treatment of AV stenosis in high surgical risk and inoperable patients (STS 7–11%, EuroSCORE II 18–29%) have shown safety and stable outcomes at various times after surgery [1]. However, expansion of indications for transcatheter procedures is often an example of commercial advantage without in-depth discussion of each specific clinical case. The decision to perform them should be made and discussed by a group of physicians from different specialties [2].

A retrospective MedPAR (Medicare Provider Analysis and Review) analysis summarizing data from 2009 to 2015 in patients with isolated AV stenosis showed an

increase in the number of AV interventions by 14.4% per year (from 22,076 in 2009 to 49,362 in 2015). When comparing the number of surgeries performed (traditional AV replacement and TAVI), there is an increasing trend for catheter-based procedures. By the end of the study, such procedures accounted for 46% of all AV interventions. The authors also emphasized a downward trend in in-hospital 30- and 90-day mortality, which were 2.69%, 4.46%, 6.66%, respectively. However, 90-day mortality in the TAVI group remains high at 8.37% and the incidence of infective endocarditis ranges from 2.4% to 2.7% [3].

Infective endocarditis after TAVI is a life-threatening complication with high in-hospital and 1-year mortality. Early diagnosis is of paramount importance in order to initiate appropriate treatment to avoid negative clinical outcomes. According to the TAVI International Registry, the incidence of PVE ranges from 0.3 to 1.2% of patients per year. The authors identified the use of

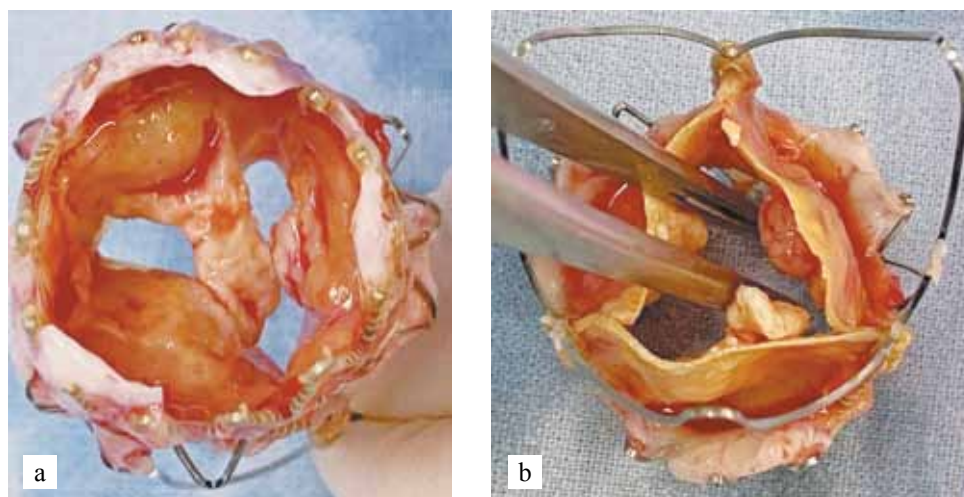


Fig. 6. Prosthetic valve endocarditis affecting the Boston Scientific Acurate neo-25 valve stent: a, ventricular surface of the valve; b, aortic surface of the valve

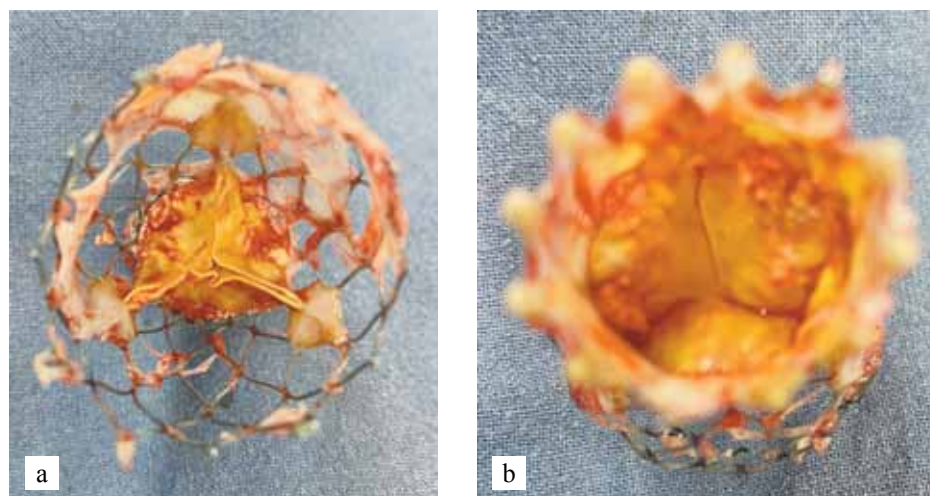


Fig. 7. Structural degeneration of the CoreValve 23 valve stent: a, ventricular surface of the valve; b, aortic surface of the valve

self-expandable stent valves and intubation during surgery as independent predictors. Transfemoral access was performed in 76% of cases. The authors also noted high in-hospital mortality (47%), both at the time of TAVI and at reoperation. These results are associated with the initial severity and age of the patients [4]. Our material describes four clinical cases of early PVE after transcatheter AV implantation, and it should be said that despite certain difficulties in interpreting the diagnosis of “prosthetic valve endocarditis” especially in the case of implanted CoreValve valve, the use of active surgical tactics with the use of conventional surgery, in combination with antibiotic therapy, has shown to be feasible and effective in this severe category of recurrent cases.

A pooled analysis of 61 randomized controlled trials analyzing 8,969 patients, which covered the period from 2012 to 2020, found no significant difference in the endpoint, deaths from cardiovascular causes. A positive effect was observed in surrogate endpoints such as bleeding, postoperative atrial fibrillation impairing quality of life, renal failure, strokes, and length of hospital stay. Meta-analysis demonstrated no significant difference in mortality in the early and mid-term postoperative mortality. Moreover, by year 5, mortality in the TAVI group had increased by 15% (OR 1.11 95% CI 1.01–1.23, $p = 0.04$, $I^2 = 0\%$; $n = 3761$) [5–8]. The early postoperative mortality may be due to the occurrence of events such as strokes (2-year study, OR 0.88, 95% CI 0.67 to 1.16, $p = 0.37$, $I^2 = 48\%$; 6 studies, $n = 6,453$ patients) [5–9], bleeding (reported 64% reduction in major bleeding in favor of TAVI, this trend persists up to year 5 where the value is 20%). By year 5, the observed effect had shifted toward a favorable prognosis for surgical AV replacement.

Regarding surgical aspects, this technique has several technical limitations [10–12], resulting in an increased number of re-interventions (including valve-to-valve) and hospitalizations (see Fig. 8). A PORTICO study [13] showed that the absence of anticoagulant therapy, valve-to-valve procedure, use of a 23-mm transcatheter valve, and high BMI were independent predictors of hemodynamic valve deterioration. This hypothesis is supported by the fact that the problem associated with prosthetic leaflet thrombosis was resolved by long-term warfarin use.

Infective endocarditis, as the most dangerous complication at up to 30 days, shows a significant decrease in the TAVI group; further follow-up shows that this effect has no differences and by year 5 the weighted mean reaches an OR value of 1.34 (95% CI 0.87–2.05, $P = 0.18$, $I^2 = 0\%$; 4 studies, $n = 3,761$) [1, 14–16], and in relative terms, the number of infective endocarditis cases increases by 134%.

However, such data should be alarming and must be treated with some caution. Pooled analysis of 6 cohort studies demonstrated that individuals with early PVE

were younger (73.5 ± 4.2 vs 79.9 ± 3.24 , $P < 0.001$), identified the most significant risk factors as sex OR 1.24 (95% CI 1.15 to 1.33), intubation OR 2.99 (95% CI 2.73 to 3.28), and chronic kidney disease (OR 5.19, 95% CI 4.16 to 6.47). The median time to development of infective endocarditis ranged from 1 month to 9.4 months [17–20]. The analysis demonstrated that only 22.3% were re-operated, the rest (77.7%) were treated conservatively. Overall mortality for the pooled cohort was 38.3%. Mortality in the surgical and antibiotic treatment groups were 16.7% and 37.4% ($P < 0.05$) [21].

CONCLUSION

In order to determine the surgical tactics for degenerative aortic valve defects, in the context of modern realities with the development and wide accessibility of endovascular aids, it is necessary to adhere to the point of view of pragmatism, where the end and means must be justified. In today's era of saturated information flow and patient awareness, indications for the method of choice must be clearly defined. TAVI should be performed in advanced centers for possible elimination of the developed complication. The decision to choose a method should be based on such indicators as durability of the prosthetic valve and life expectancy, rather than the classical approach based on modern risk stratification scales and anatomical features.

Fatal complications such as PVE in this patient cohort are associated with an enormous risk of mortality. However, only a combination of surgical treatment and conservative therapy can provide a predictable outcome and the possibility of cure.

The authors declare no conflict of interest.

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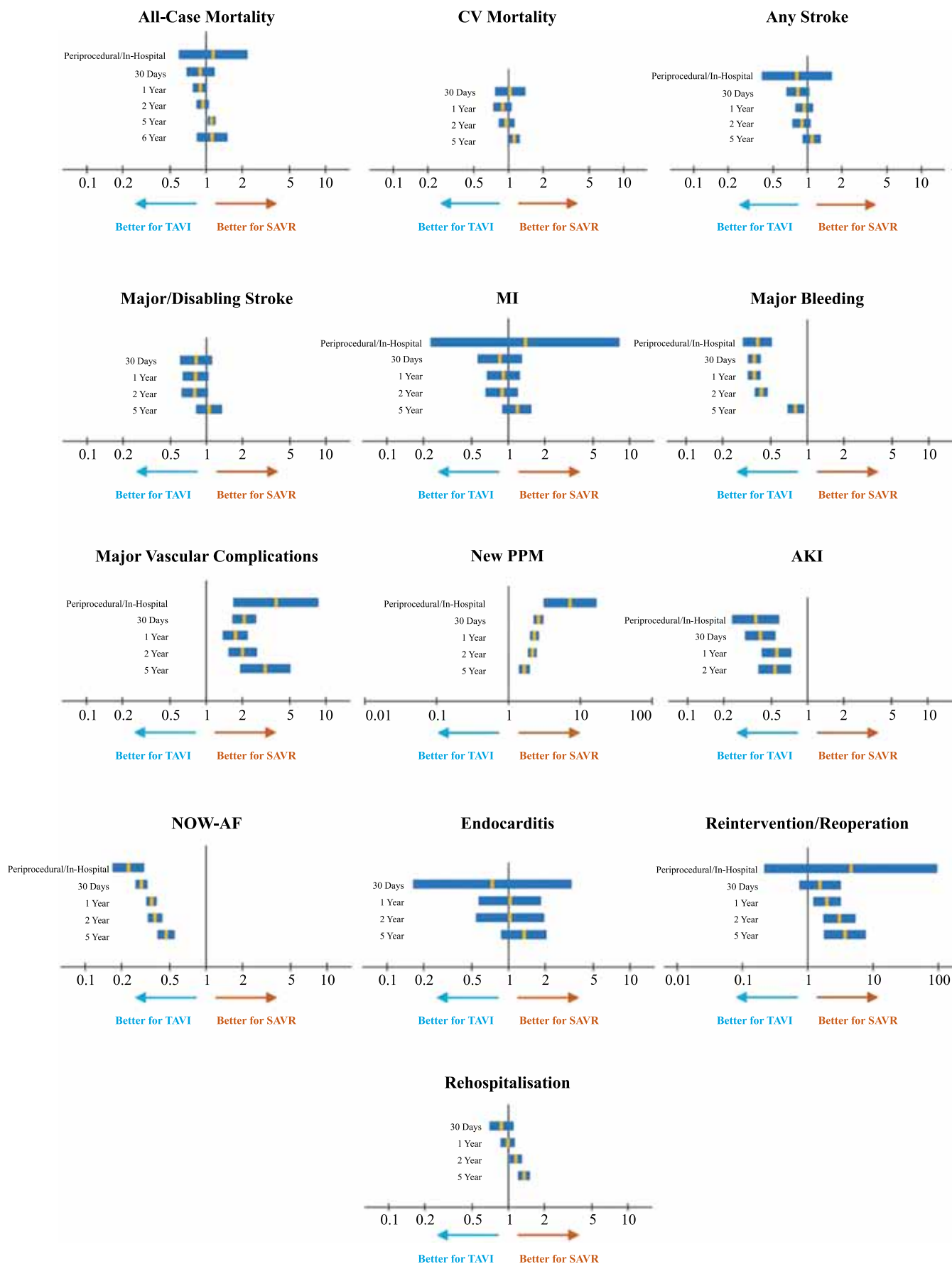


Fig. 8. Data pooled from randomized controlled trials (RCT) results [22]

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