



## First experience of transatrial transcatheter valve implantation in patients with bioprosthetic mitral valve dysfunction

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We present three cases of successful transatrial transcatheter valve-in-valve implantation in patients with bioprosthetic mitral valve dysfunction. Patients with a high surgical risk, with severe heart failure due to bioprosthetic mitral valve dysfunction, were implanted with transcatheter prostheses using the transatrial approach. Transesophageal echocardiography and fluoroscopy-guided transcatheter mitral prosthetic valve positioning was performed. With a cardiac pacing at 180 bpm, a transcatheter valve was implanted. The transcatheter valves functioned properly after surgery. The patients were discharged in satisfactory condition.

**Keywords:** mitral valve, transcatheter valve implantation, valve-in-ring, valve-in-valve.

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**Relationships and Activities:** none.

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The widespread use of bioprosthetic mitral valve (MV), which are less durable than mechanical ones, leads to a natural increase in the number of reoperations for its dysfunction [1].

Repeated on-pump heart valve replacement is still the preferred treatment for biological prosthesis dysfunction. Data on valve reoperation in elderly patients (80 years and older) showed poorer results compared with younger groups of patients, thus confirming that they have an increased risk of mortality and complications, despite well-performed surgery [2-5]. Therefore, minimally invasive technologies should be a priority when treating this group of patients. The development of transcatheter valve replacement opened up new frontiers in the treatment of elderly patients with severe comorbidities. In particular, transcatheter valve replacement in case of bioprosthetic valve dysfunction (valve-in-valve technique) is associated with a lower surgical risk. The valve-in-valve procedure in elderly multimorbid patients is regularly used in large centers with good clinical outcomes [6-8]. The valve-in-valve procedure can be performed by transapical or transseptal transfemoral approaches, but each of them is associated with a number of negative aspects. Novel and promising technique is the transatrial approach through the left atrial (LA) lateral wall through right minithoracotomy [9].

In this work, we present a case series of successful transcatheter valve replacement in patients with structural bioprosthetic mitral valve dysfunction using a transatrial approach.

### Material and methods

**Patients.** First seventy-three-year-old patient was admitted with complaints of shortness of breath on exertion and sometimes at rest, lower limb edema, right upper quadrant pain. Eight years ago, bioprosthetic MV replacement was performed (UniLine № 28) due to mitral stenosis. In the postoperative period, myocardial infarction was recorded. Percutaneous transluminal coronary angioplasty with circumflex artery stenting was performed. According to postoperative echocardiography, left ventricular (LV) ejection fraction (EF) was 33%. Heart failure has progressed over the past 2 years. According to transthoracic echocardiography (Figure 1 A, B), the LA size is 5,0×6,3 cm; area — 30,0 cm<sup>2</sup>. Mitral bioprosthesis. Prosthetic leaflets are thickened, sclerosed, and open with limitations. Signs of prosthesis dysfunction. Peak LA/LV diastolic gradient was 23 mm Hg, the mean — 12 mm Hg, opening area =1,0 sm<sup>2</sup>. Grade 0-1 regurgitation. A decrease in global LV contractility (EF, 31%). Pulmonary hypertension (estimated systolic pressure, 68 mm Hg).

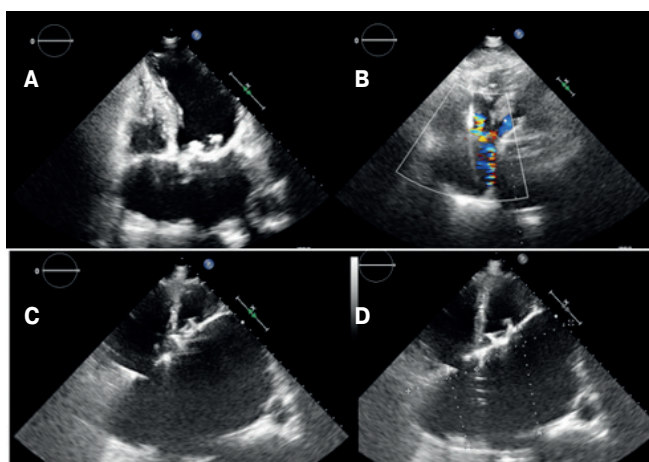
Second seventy-five-year-old patient was admitted with complaints of shortness of breath on exertion and sometimes at rest. For rheumatic MV disease, bioprosthetic MV replacement was performed (UniLine № 26). She has been feeling well for 10 years, but over the past year she has begun to notice a progressive decrease in exercise tolerance. According to echocardiography, at admission, the LA was significantly increased (6,3×6,8 cm). Peak LA/LV diastolic gradient was 27 mm Hg, the mean — 9-10 mm Hg, opening area =1,6-1,7 sm<sup>2</sup>. Grade 2-3 mitral regurgitation. Diffuse LV myocardial hypokinesia (EF, 44%). Pulmonary hypertension (estimated systolic pressure, 63 mm Hg).

Third eighty-year-old patient was admitted with complaints of shortness of breath on exertion and sometimes at rest. For rheumatic MV stenosis, bioprosthetic MV replacement was performed (PERICARBON MORE № 28). After surgical treatment, an echocardiography was performed annually. Over the past four years, there was a progression of MV bioprosthetic stenosis and HF symptoms to functional class III-IV. According to echocardiography (Figure 1 C, D), pronounced dilatation of both atria (area, RA — 40 cm<sup>2</sup>; LA — 79 cm<sup>2</sup>; volume — 656 ml) and right ventricle, signs of prosthesis dysfunction. Prosthetic leaflets are compacted, inactive, grade 0-1 regurgitation. Peak LA/LV diastolic gradient — 13 mm Hg, the mean — 8 mm Hg, opening area =1,02 sm<sup>2</sup>.

Upon admission to the department, the condition of patients was assessed as severe, due to circulatory decompensation. According to auscultation data, all patients have a characteristic pronounced blowing systolic murmur over the entire heart region.

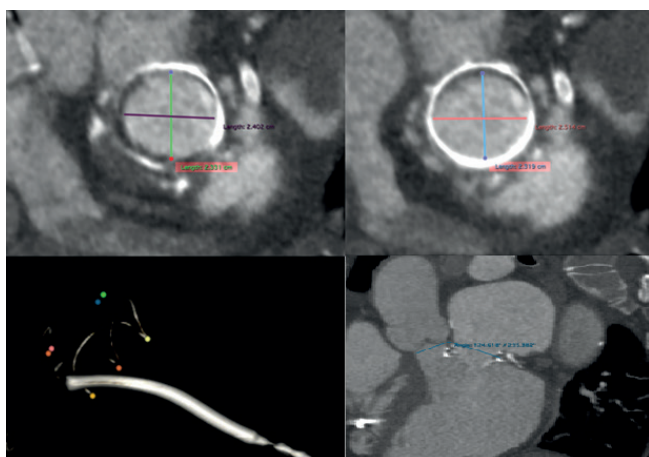
Given the extremely high risk of repeated cardiac surgery (all patients had an STS score >8%) using a standard approach (median sternotomy), transcatheter MV replacement (using the valve-in-valve technique) using the transatrial approach.

**Prosthesis selection.** In order to select the required size of transcatheter prosthesis, all three patients underwent multislice computed tomography with measurement of the internal prosthesis diameter (UniLine № 28; UniLine № 26; PERICARBON MORE № 28) (Figure 2). In accordance with the obtained true internal diameters (first patient, 23,3 mm; second patient, 24,6 mm; third patient, 26,3 mm), the balloon-expandable prosthesis “MedLab CT” (NPP MedInzh, Penza, Russia) with a diameter of 23, 25, 27 mm was chosen. When selecting a prosthesis, we were guided by the recommendations, according to which the transcatheter prosthesis diameter should be 10-15% larger than the internal diameter of bioprosthesis. The risk of LV outflow

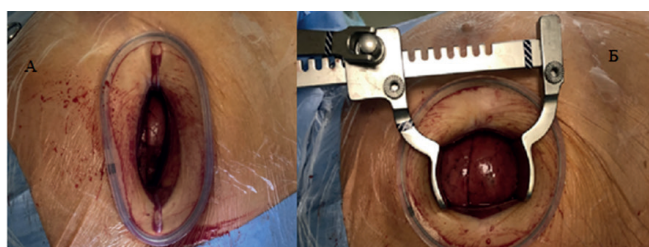


**Figure 1.** Echocardiography.

**Note:** **A.** Prosthetic leaflets are thickened, sclerosed, and open with limitations; **B.** Grade 0-1 regurgitation; **C.** Prosthetic leaflets are compacted; **D.** Dilation of both atria.



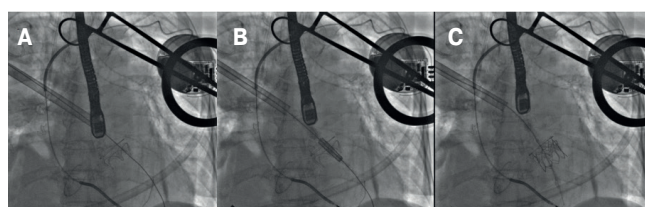
**Figure 2.** Computed tomography. Measurement of the inner bio-prosthetic diameter and the mitral aortic angle.



**Figure 3.** Access to LA roof.

**Note:** **A** — thoracotomy along the 4<sup>th</sup> right intercostal space. **B** — soft tissue retractor in the 4<sup>th</sup> right intercostal space.

tract obstruction was also assessed by measuring the mitral-aortic angle. All three patients had a mitral-aortic angle was  $>110$  degrees. Therefore, the obstruction risk was low.



**Figure 4.** Transcatheter prosthetic valve implantation.

**Note:** **A** — fluoroscopy- and TEE-guided prosthetic valve placement; **B** — implantation of the MedLab CT prosthesis № 23; **C** — final view.

**Abbreviation:** TEE — transesophageal echocardiography.

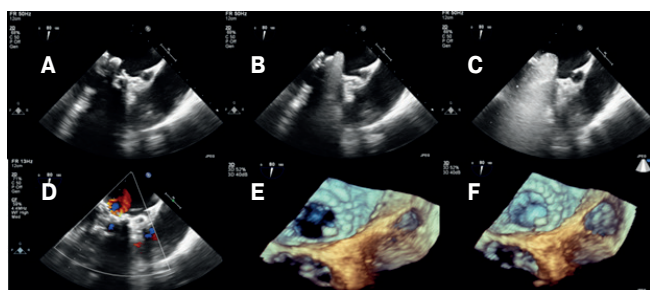
**Surgery stage.** The operation was performed in a hybrid operating room. A small incision was made in the right fourth intercostal space, crossing the midaxillary line (Figure 3).

A soft tissue retractor and a standard minimally invasive retractor were used to access the surgical site. The pericardium was opened 3-4 cm above the phrenic nerve. A temporary pacing lead was placed through the jugular access to the right ventricular apex. A purse-string suture was applied to LA roof. LA puncture was performed using Seldinger technique with purse-string sutures. A 6 Fr introducer (Terumo, Belgium) was installed, through which a ZIPwire 0,035 in $\times$ 180 cm hydrophilic guidewire (Boston Scientific, USA) was inserted into the LA cavity and then into the LV. Then a Pigtail Optitorque 6 Fr catheter (Terumo, Belgium) was inserted, through which a Amplatz Super-stiff 0,035 in $\times$ 260 cm guidewire (Boston Scientific, USA) was inserted into the LA. The SuperStiff guidewire was passed through the mitral prosthesis into the LV (Figure 4 A). The MedLab CT prosthesis was inserted through the port, which was placed in MV prosthesis projection under the guidance of fluoroscopy and transesophageal echocardiography (TEE) (Figure 4 A, Figure 5 A, B, C). The stent-prosthesis was implanted with pacing a rhythm of 160 bpm (Figure 4 B, C, Figure 5 C, E, F). All patients had a port removed after TEE assessment. Purse-string sutures are tied.

## Results

In the third patient, due to severe RA dilatation, the right LA contour isolation without using artificial circulation was impossible. The femoral vessels were cannulated. After the start of artificial circulation, LA isolation became technically possible.

In the first patient, TEE revealed a paraprosthetic fistula of 0,6 $\times$ 0,7 cm. After implantation of the prosthesis, the fistula was occluded with an Amplatzer Vascular PLUG II device (Abbott) with a good hemodynamic result (Figure 6).



**Figure 5.** TEE during stent-prosthesis implantation.

**Note:** A, B — TEE-guided prosthesis placement; C — implantation of the MedLab CT prosthesis; D — regurgitation spreads in several streams with insignificant volume; E, F — stent-prosthesis in the mitral site, LA view (3D reconstruction).

**Abbreviations:** LA — left atrium, TEE — transesophageal echocardiography.

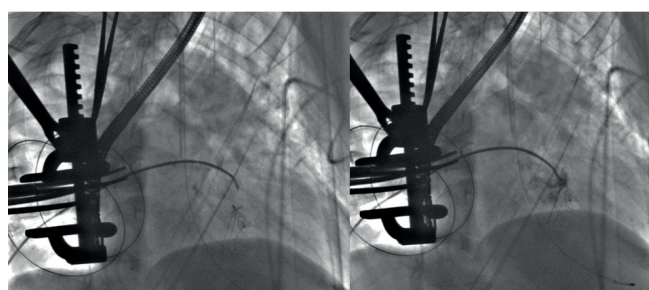
According to TEE, the first patient has a peak gradient on the prosthesis of 8–9 mm Hg, the mean — 4–5 mm Hg. The mitral valve opening area according to Doppler ultrasound was 3,19 cm<sup>2</sup>. Grade 1–2 regurgitation with insignificant volume.

In the second patient, immediately after the procedure, a peak gradient on the prosthesis was 8 mm Hg, the mean — 5 mm Hg. The mitral valve opening area according to Doppler ultrasound was 2,0 cm<sup>2</sup>. Grade 1 regurgitation. The third patient also had a satisfactory immediate result of surgical treatment: peak LV/LA diastolic pressure gradient of 6–8 mm Hg, the mean — 3–5 mm Hg. Grade 1 regurgitation with insignificant volume.

#### Postoperative period

The early postoperative period was uneventful. Mechanical ventilation no more than 7 hours; vasotonic support during the first day. Patients were transferred from the intensive care unit on the second day after surgery. Warfarin was prescribed as antithrombotic therapy with the target international normalized ratio of 2,5–3,5. In the postoperative period, a significant improvement in the clinical condition of patients was noted: a decrease in edema, relief of heart failure. The body temperature did not rise. However, due to the high risk of infection, antibiotic therapy was carried out for 7 days (intravenous infusion of 2 g ceftriaxone).

According to the echocardiography at discharge, in the third patient, LVEF was 41%. In the MV site with stent-prosthesis, peak diastolic gradient was 10 mm Hg, the mean — 6 mm Hg, the MV opening area according to Doppler ultrasound — 3,0 cm<sup>2</sup>. Grade 1 regurgitation with insignificant volume. Grade 1 tricuspid regurgitation with insignificant volume. The estimated pulmonary artery systolic pressure was 39 mm Hg, while the mean pulmonary artery pressure — 26,3 mm Hg.



**Figure 6.** Fistula occlusion with Amplatzer Vascular PLUG II (Abbott).

In the first patient, LVEF was 51% at discharge. In the MV site with stent-prosthesis, peak diastolic gradient was 9 mm Hg, the mean — 4 mm Hg, the MV opening area according to Doppler ultrasound — 2,9 cm<sup>2</sup>. Grade 1 mitral regurgitation with insignificant volume. Grade 1 tricuspid regurgitation with insignificant volume. The estimated pulmonary artery systolic pressure was 39 mm Hg.

In the second patient, LVEF was 46% at discharge. In the MV site with stent-prosthesis, peak diastolic gradient was 9 mm Hg, the mean — 4 mm Hg, the MV opening area according to Doppler ultrasound — 2,7 cm<sup>2</sup>. Grade 1 mitral regurgitation with insignificant volume. Grade 1 tricuspid regurgitation with insignificant volume.

#### Discussion

Repeated on-pump heart valve replacement is the method of choice in patients with dysfunction of bioprosthetic mitral valve and provides good immediate and long-term outcomes [1, 2].

The benefits of using biological or mechanical prostheses are still debated, and despite the development of novel valve types, bioprosthetic valves still have limited durability with a relatively high risk of reoperation [1, 3–7].

Nonetheless, bioprosthesis use has increased in the older age group over the past decade due to favorable clinical outcomes in the elderly, but despite all efforts to prevent structural valve degeneration and increase valve life, there is a risk of re-surgery. Recent publications on reoperations in elderly patients have shown higher mortality than in younger age groups, confirming that this population has an increased risk of surgical mortality and morbidity with a risk of poor outcome, despite well-performed surgery [2–5].

Transcatheter valve implantation has opened new frontiers in cardiac surgery, making it possible to implant stent valves with less surgical risk in elderly multimorbid patients with bioprosthetic dysfunction. The valve-in-valve procedure has been used with good clinical outcomes [6, 10].

Transapical transcatheter prosthetic implantation basically follows the same rules as the standard TAVI. However, there are several important points: first, the guidewire must be passed through the bioprosthesis and inserted into the LA or right inferior pulmonary vein with care so as not to damage the atrium and fragile pulmonary vessels. Second, valvuloplasty should not be performed due to the potential risk of calcium embolism [11]. The first successful transcatheter prosthetic implantation in a patient with mitral bioprosthetic dysfunction was performed in 2009 [12] using a transapical approach. However, the transapical approach has some specific technical limitations, as, for example, in the case of LV apex calcification as a result of prior surgery, as well as potential complications, including myocardial rupture, LV apical aneurysm, arrhythmias, LV apex hypokinesia or akinesia, especially in patients with initially low LVEF [12].

The technique of transcatheter implantation through a transfemoral venous access requires transesophageal echocardiography guided transseptal puncture. This method requires maximum flexion of catheter delivery system, and therefore there is a high risk of inferior vena cava rupture [13]. A common problem associated with transseptal puncture is the presence of a large atrial septal defect requiring an occluder.

At first, attempts of transcatheter implantation using the transatrial approach were unsuccessful due to the impossibility of placing transcatheter valve coaxially inside the bioprosthesis. However, since 2012 there have been works that describe cases of successful implantation [11]. We believe that this approach should have a number of advantages. The first is an antegrade passage, which eliminates the risk of thickened leaflets and calcium obstructing the device passage. From the same access, it is possible not only to perform a quick and safe artificial circulation in case of a failure of the transcatheter MV implantation with ventricular fibrillation. It is also theoretically possible to combine an on-pump transcatheter procedure and tricuspid valve repair, as successfully reported by Lee TC, et al. [14].

The results of using the transcatheter MV implantation were evaluated in two large international registries: Valve-in-valve international data registry (n=660) [15] and International multicentre registry of TMVR (n=322) [16].

Considering whether a valve-in-valve procedure or repeated open heart surgery can be challenging. All patients should be evaluated by a multidisciplinary team prior to the procedure, including interventional cardiologists, cardiac surgeons, cardiologist, anesthesiologist, and cardiac imaging specialist. The Euroscore and STS score systems

can be used to estimate predicted mortality from surgery. The main inclusion and exclusion criteria for the valve-in-valve procedure are similar to those suggested for standard transcatheter aortic valve implantation (TAVI) [17, 18].

Hemodynamic disorders (regurgitation or stenosis) have a significant impact on valve-in-valve outcomes [19]. In terms of valve size, bioprostheses with small bore diameter show a higher incidence of patient-prosthesis mismatch, which affects hemodynamic outcome and decreases survival [19-22].

During the valve-in-valve procedure in patients with frame-mounted bioprosthetic dysfunction, fixation is provided due to radial forces. Therefore, not only stenosis, but also insufficiency due to impaired prosthetic valve leaflets become treatable. In case of dysfunction of a frameless prosthetic dysfunction, the feasibility assessment of valve-in-valve procedure is carried out according to standard TAVI rules, when pronounced calcification is required for the procedure success. In the case of paravalvular fistulas, the valve-in-valve procedure should not be used because there is usually no significant change in regurgitation severity [19]. However, some case reports show possibility of paravalvular fistula reduction by implantation of separate devices (Edwards SAPIEN 3). Thrombosis and valvular infective endocarditis are contraindications to the valve-in-valve procedure because the affected tissue is not removed during the procedure. However, one successful case of a valve-in-valve procedure for endocarditis in an inoperable patient had a favorable outcome [20].

Preoperative evaluation of a bioprosthesis in a patient requires multimodal cardiac imaging. Echocardiography is used to assess the etiology and severity of stenosis or insufficiency, and to rule out paravalvular fistulas and active endocarditis.

The ideal transcatheter valve placement is influenced by the fluoroscopy image and the design of bioprosthesis. Angiography is not required and the procedure can be performed on patients with impaired renal function under TEE and fluoroscopic guidance.

The level of frame-mounted bioprosthetic ring during fluoroscopy should be used as a reference level for transcatheter valve fixation [23-25]. If, during implantation, fluoroscopy shows an hourglass shape, this may disrupt the operation of bioprosthetic valves and should be avoided [23]. It is easy to position the fluoroscopic device perpendicular to the frame-mounted bioprosthesis, since the metal frame of most existing prostheses is radiopaque. Although there may be differences in

the radiopaque markings. Frameless prostheses do not have radiopaque landmarks and the procedure can be technically challenging and more similar to TAVI.

Currently, there are no guidelines for balloon valvuloplasty for prosthetic MV dysfunction during valve-in-valve procedures [26].

The risk of LV outflow tract obstruction during valve-in-valve procedures is not a major problem, since low-profile transcatheter valves are implanted into the bioprosthetic ring, and not into the native MV with the risk of anterior leaflet prolapse. The risks of obstruction the valve-in-valve procedure persist in the case of a small LV size, acute mitral-aortic angle, pronounced interventricular septal hypertrophy. The risk of LV outflow tract obstruction can be predicted using multislice computed tomography reconstruction (Figure 2).

With mitral valve-in-valve procedures, the risk of postoperative high gradients is lower compared to aortic valve-in-valve procedures because the bioprosthetic MV has a larger diameter. The presented case series confirms these conclusions.

## Conclusion

Given the accumulated experience, transcatheter techniques may increasingly replace conventional procedures, reducing the need for open re-surgery, especially in high-risk patients. The cases we have described have demonstrated the technical feasibility and safety of this technology. Therefore, we consider transcatheter valve implantation as an alternative to standard reoperation after a comprehensive patient assessment.

**Relationships and Activities:** none.

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