One-Stage Off-Pump Transapical Mitral Valve Repair and Aortic Valve Replacement

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Transcatheter aortic valve implantation (TAVI) is routinely performed in high-risk patients presenting with severe symptomatic aortic valve stenosis. The use of TAVI in patients with symptomatic pure aortic regurgitation (AR) is less common because of the limited number of devices specifically designed for this pathology. Nowadays, the only device specifically approved for use in pure aortic insufficiency is the Jena Valve (Jena Valve Technology, Munich, Germany), currently available only for the transapical approach.2

Transcatheter mitral valve repair has been also proposed with the use of different technologies. Recently, transapical off-pump mitral valve repair with neochord implantation (TOP-MINI) using the NeoChord DS 1000 device (NeoChord, Eden Prairie, MN) has been shown to be feasible and safe for repairing degenerative mitral valve disease.3-5 Unlike TAVI and other percutaneous devices, transapical off-pump mitral valve intervention with Neochord implantation is approved not just for high-surgical-risk candidates.

Two-stage treatment of aortic valve stenosis and mitral regurgitation (MR) using transcatheter techniques has already been described. Here, we present the first-in-humans 1-stage transapical off-pump concomitant aortic valve implantation and mitral valve repair in a patient experiencing pure AR and degenerative MR.

A 78-year-old man with severe AR and MR in New York Heart Association functional class III despite optimal medical therapy was referred to our institution. He presented systemic arterial hypertension and moderate 2-vessel coronary artery disease. Preoperative transesophageal echocardiography confirmed the presence of severe AR and severe MR with severe calcifications of the posterior mitral annulus and annular portion of the posterior mitral leaflet (Figure 1 and Movies I–III in the online-only Data Supplement). His left ventricular ejection fraction was 67%, with initial signs of ventricular dilatation (left ventricle end-diastolic volume, 86 mL/m²).

The patient’s comorbidities evidenced a moderate risk for conventional operation (Euroscore II, 3.07%), but this strategy was considered technically challenging, mainly because of the severe mitral annulus calcifications. Hence, the heart team considered a better approach to treat simultaneously both valve pathologies through a transapical access: implantation of a Jena Valve followed by Neochord implantation. The patient gave his informed consent, and the procedure was approved by the local ad hoc committee (administration representative, health technology assessment representative, geriatricians, ethics committee representative, and surgeons).

The transapical access TAVI procedure was performed under general anesthesia in the standard fashion,2 and a 25-mm Jena Valve was implanted. Despite apparent good positioning of aortic prosthesis, a moderate to severe postprocedural regurgitation resulting from paravalvular leak (PVL) was observed. Considering undersizing of the prosthesis as the main cause responsible for this complication, we attempted 3 unsuccessful balloon dilatations to obtain an overexpansion of the Jena Valve nitinol stent. Finally, a valve-in-valve implantation of a 29-mm Edwards Sapien 3 (Edwards Lifesciences, Irvine, CA) prosthesis was performed. At angiographic control, the final result was excellent, and only trivial PVL was observed (Figure 2 and Movies IV–VI in the online-only Data Supplement). Subsequently through the same apical access, the NeoChord device was inserted into the left ventricle, and under live 2- and 3-dimensional transesophageal echocardiography guidance, 3 pairs of Neochords were implanted on the prolapsing posterior mitral leaflet.6 Final NeoChord length and tension were achieved under 2- and 3-dimensional transesophageal echocardiography color Doppler evaluation, obtaining mild residual MR (Figure 3 and Movies VII and VIII in the online-only Data Supplement).

The patient did not required blood transfusions, and the total procedure time was 180 minutes. He was transferred to the intensive care unit in good hemodynamic condition with only mild inotropic support. Postprocedural recovery was uncomplicated, with the onset of a single episode of atrial fibrillation requiring intravenous infusion of amiodarone that was determined to be a transient atroventricular block. Temporary epicardial pacemaker in addition to infusion of dopamine (4 gamma Kg min) for 12 hours allowed prompt return to sinus rhythm. The patient’s hospital stay was

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uneventful, and he was discharged 8 days later to a rehabilitation center. At discharge, transthoracic echocardiography revealed good aortic gradients (peak gradient, 23 mmHg; mean gradient, 9 mmHg), trivial PVL, and mild residual MR. Good left ventricular function (left ventricular ejection fraction, 42%), similar to the preoperative finding, was also described.

At the 6-month follow-up, the patient was in good clinical conditions (New York Heart Association class I). On transthoracic echocardiography, aortic gradients decreased (peak gradient, 13 mmHg; mean gradient, 7 mmHg), AR remained trivial, MR was mild (Figure 4 and Movies IX and XI in the online-only Data Supplement), and left ventricular function had improved (left ventricular ejection fraction, 52%).

Comment

Combined surgical treatment of aortic and mitral valve pathologies presents an increased risk of mortality compared with isolated valve correction. When surgical candidates are treated, the reported perioperative mortality rates may range from 5% to 18%. In octogenarians, mortality can be as high as 24%. Even when mitral valve repair is performed instead of mitral valve replacement, perioperative and follow-up outcomes are still burdened with higher event rates compared with single valve surgery.

The use of transcatheter techniques in this subset of patients has already been shown to be safe and feasible. Unfortunately, in all reported cases, transcatheter therapy has been applied only in patients experiencing aortic stenosis and MR with a 2-stage approach.

The possibility of treating aortic and mitral valve pathologies simultaneously with the use of transcatheter techniques with a 1-stage approach is fascinating. To the best of our knowledge, this is the first study reporting successful treatment of pure AR and degenerative MR using 1-stage transcatheter approach.

The most critical aspect of this procedure is the selection of the left ventricular entry site. Neochord conventional access is performed in the fifth to sixth intercostal space to reach the posterior-lateral apex. This approach allows crossing of the mitral valve directly and implantation of the Neochords on the papillary muscles, mimicking real mitral valve anatomy. This posterior-lateral access is not considered the best approach for transapical access TAVI, but in this specific case, it did not prevent us from correctly reaching the aortic root because of the great flexibility of the unsheathed Jena Valve delivery system. Consequently, it should be considered the preferred entry site for this combined procedure.

In this case, a 1-stage combined treatment was performed. The procedure sequence (TAVI first and transapical off-pump mitral valve intervention with Neochord implantation second) was extremely important for the success of the intervention because Neochords are anchored in the myocardial muscle after the definitive closure of the apical purse strings. A staged approach would increase the surgical risk as a result of apical adhesions and could cause Neochord rupture or distortion during the introduction of the Jena valve delivery system, even in a different left ventricular entry site. Moreover, in this case, AR correction would not reduce MR resulting from degenerative mitral valve disease with posterior mitral leaflet flail. In case of conventional surgery, this patient would have received a double valve procedure at the same time. So similarly, we performed a double minimally invasive procedure as a single-session treatment.

The present case report demonstrates the feasibility of combined transapical TAVI and TOP-MINI procedure in patients with concomitant AR and degenerative MR. It may be considered an alternative technique in very selected patients deemed at high risk for or inoperable for conventional surgery. However, we need larger studies with longer follow-up to assess its long-term efficacy.

As far as the TAVI procedure is concerned, the PVL after Jena Valve implantation was probably explained by an erroneous choice of prosthesis dimension rather than an incorrect prosthesis positioning. After implantation of a valve-in-valve Edwards Sapien 3 prosthesis, the Jena Valve was pushed toward the aortic wall, obliterating the PVL. Thus, scrupulous measurements of aortic annulus and sinotubular junction diameters are mandatory to choose the right valve size, especially for the Jena Valve. It is an auto-expandable prosthesis, and its anchoring mechanism is guaranteed by clipping the aortic leaflets between the feelers and the basis of the device. Therefore, in cases of an intermediate annular dimension and particularly in cases of pure AR, it is preferable to choose the larger prosthesis to increase its radial force.

In conclusion, the present case shows the feasibility, safety, and efficacy of a 1-stage transapical off-pump procedure to repair a degenerative mitral valve with Neochord implantation and the transcatheter replacement of a purely regurgitant aortic valve.

Disclosures

Drs Gerosa, Pittarello, Colli, Zucchetta, and Manzan received travel grants from Neochord, Inc. Dr D’Onofrio is proctor for Edwards Lifesciences. The other authors report no conflicts.

References

Figure 1. Preoperative transesophageal echocardiography (TEE). 
A, Two-dimensional TEE color Doppler showing severe aortic regurgitation (AR) and concomitant moderate mitral regurgitation (MR; Movie I in the online-only Data Supplement). B, Two-dimensional TEE color Doppler showing moderate MR (Movie I in the online-only Data Supplement). C, Two-dimensional TEE. Morphological evaluation of the mitral valve shows severe calcification of the posterior leaflet with P2 segment prolapse and normal tricuspid morphology of the aortic valve without the presence of valvular calcifications (Movie II in the online-only Data Supplement). D, Preoperative anatomic reconstruction of the mitral valve. Three-dimensional transesophageal echocardiography showing an important prolapse of the posterior leaflet (P1, P2, and P3 segments; Movie III in the online-only Data Supplement).
Figure 2. Preoperative, intraoperative, and postoperative aortography. A, Preoperative aortography showing severe aortic regurgitation (AR; Movie IV in the online-only Data Supplement). B, Aortography after the Jena Valve implantation showing the presence of severe AR (Movie V in the online-only Data Supplement). C, Aortography after Sapien 3 implantation into the Jena valve (rescue valve-in-valve procedure) showing the presence of mild residual AR (Movie VI in the online-only Data Supplement).

Figure 3. Final result of aortic valve and mitral valve procedure. A, Two-dimensional transesophageal echocardiography (TEE) and color Doppler showing correct aortic prosthesis function with minimal residual paravalvular leakage (Movie VII in the online-only Data Supplement). B, Two-dimensional TEE and color Doppler showing mitral valve function after tensioning of the Neochords with mild residual mitral regurgitation (Movie VII in the online-only Data Supplement). C, Three-dimensional TEE showing the final anatomic result of the repaired mitral valve (Movie VIII in the online-only Data Supplement).
Figure 4. Echocardiographic results at the 6-month follow-up of aortic valve and mitral valve procedures. A, Two-dimensional transesophageal echocardiography (TEE) and color Doppler showing correct aortic prosthesis function with a trace of residual paravalvular leakage (Movie IX in the online-only Data Supplement). B, Two-dimensional TEE and color Doppler showing mitral valve function after tensioning of the Neochords with mild residual mitral regurgitation (Movie X in the online-only Data Supplement). C, Three-dimensional TEE showing the final anatomic result of the repaired mitral valve (Movie XI in the online-only Data Supplement).
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