ABSTRACT: An inverted Edwards SAPIEN 23 mm valve was implanted in a 14-year-old patient with Ebstein’s anomaly who received a Medtronic Mosaic 25 mm valve 8 years earlier and presented with significant progressive symptoms related to severe valvular regurgitation and moderate stenosis. The procedure was performed via the femoral vein using the RetroFlex 3 system and predilation of the tricuspid valve, under transesophageal echocardiographic guidance. The patient had an immediate drop in right atrial and trans-tricuspid pressures with mild regurgitation, and had stable results on short-term follow-up.

Key words: transcatheter, intervention, tricuspid, bioprosthesis, revalvulation

Case Description

A 14-year-old boy was diagnosed since early life with Ebstein’s anomaly causing severe tricuspid regurgitation. He received a surgical replacement of the tricuspid valve when 6 years old with a Medtronic Mosaic bioprosthesis (Medtronic, Inc) together with atrial septal defect closure and right ventricular plication. The nominal size of the prosthesis was 25 ± 0.5 mm external diameter, 22.5 ± 0.5 mm internal diameter, and 18 ± 0.5 mm height. The surgical procedure required right ventricular plication and epicardial Medtronic dual-chamber pacemaker implantation for complete atrioventricular block. Seven years later, the patient started reporting progressive dyspnea on exertion, easy fatigability, chest discomfort related to hyperdynamic precordium at rest, and loss of appetite, followed by exercise-induced chest pains. Follow-up assessments documented moderate tricuspid stenosis with severe regurgitation and marked limitation of leaflet motion. The case was discussed at the medico-surgical rounds and the indication for valve replacement was decreed. Because of the elevated surgical risk, a percutaneous approach was favored.

Procedural Details

The valved stent was obtained following approval from Health Canada, Special Access Programme. A written informed consent was obtained from the parents, with the patient’s assent. The procedure was performed under general anesthesia, with fluoroscopic and transesophageal echocardiographic (TEE) guidance. Access was obtained via the right femoral vein, and the right femoral artery was cannulated for blood pressure monitoring. Left subclavian venous access was obtained for angiographic guidance. Initial hemodynamic study yielded a 20 mm Hg gradient between the right atrium and the right ventricle, the tricuspid annulus measured 20 mm by fluoroscopy and 19 mm by TEE, which was consistent with computed tomography scan measurements (Figure 1). On fluoroscopy, the Mosaic valve is basically radiolucent, with 3 radiopaque metallic eyelets at the level of the valve comissures, which were utilized as landmarks together with the aid of TEE.

The stenotic bioprosthetic valve was crossed by a floatation catheter and a super-stiff Amplatz wire was seated in the left pulmonary artery. A 22 Fr RetroFlex 3 delivery system (Edwards Lifesciences) was used; the valved stent was prepared by crimping over the balloon using a mechanical tool that ensures symmetrical compression of the SAPIEN device. The balloon was previously tested to a maximum diameter of 23 mm in a way that a predetermined volume of the pump syringe would be delivered during deployment without exceeding the nominal preset balloon diameter. The RetroFlex system was passed to the right atrium and curved to enter the right ventricle through the stenotic valve, which failed despite several manipulations with various flexing degrees. Consequently, a valvuloplasty was performed via the other femoral vein using an 18 mm x 4 cm Z-MED balloon (B. Braun). Following valvuloplasty, the RetroFlex system was able to cross the bioprosthesis, and the suitable position was determined by the combination of TEE guidance and the radio-opaque landmarks on the Mosaic bioprosthesis (Figure 1). During balloon inflation, a rapid left ventricular pacing at 220 beats/min was performed using his pacemaker, together with controlled apnea. The valve was successfully deployed using the slow inflation technique to allow repositioning of the prosthesis as it tends to displace distally. A stable position was assured by a small proximal waist and a distal flair adhering...
SAPIEN in Tricuspid Position

Following deployment and termination of ventricular pacing, the right atrial mean pressure dropped immediately to 7 mm Hg, with mild central regurgitation noted on TEE, and no perivalvular leak (Figure 3). The total procedure time was 155 minutes, with fluoroscopic time of 38.3 minutes, radiation exposure of 1985 mGy, and radiopaque contrast solution of 1 mL/kg. Following the intervention, the pacemaker battery was changed surgically. The patient was subsequently transferred to the pediatric intensive care unit to be extubated a few hours later. On the following day, SAPIEN prosthesis position was intact and its function was unchanged by fluoroscopy and echocardiography. The peak transvalve pressure gradient was 8 mm Hg, with a mean of 4 mm Hg. The patient was discharged from the hospital on the third day on daily antiplatelet dose of aminosalicylic acid. On follow-up 10 days and 2 months later, the patient reported freedom of all previously experienced symptoms.

Discussion

This is the second pediatric case to receive a percutaneous tricuspid SAPIEN valve (the first was with an Edwards Carpentier bioprosthesis), the fourth pediatric case using either SAPIEN or Melody valves, and one of the first few cases to receive a SAPIEN valve in the tricuspid position. In our case, the percutaneous route was based on the estimated surgical difficulties and the potential complications inherent to the dissection, the proximity to the right coronary artery, and the complex extraction of the in situ prosthesis on a surgically-plicated right ventricle. In an Ebstein’s anomaly requiring tricuspid valve replacement, the functional right ventricle is typically small in size, often a bipartite with severely underdeveloped right ventricular apex. The SAPIEN valve was preferred in our case because of its shorter axial size compared to the Medtronic Melody valve (14 mm for the 23 mm valve and 16 mm for the 26 mm valve). As the inserted SAPIEN valve is nearly fully covered by the pre-existing Mosaic valve hard structure, there is essentially no chance that the SAPIEN stent would perforate the myocardium in the future. Although never reported, a longer stent could hypothetically represent such a risk. In addition, the SAPIEN valve has a sturdier structure (stainless-steel frame) as opposed to the Melody stent (platinum-iridium frame), which is prone to fracture as reported for the valve in the right ventricle to pulmonary artery conduit position. The Melody-valved stent fractures are thought to be caused by external compression in the retrosternal position. One might argue that in the tricuspid position, a Melody valve may be at a lower risk, as there are no reports of fracture in the short series, neither in the tricuspid position nor within a right atrium to right ventricle conduit.

In a 15-case series using the Melody valve system to palliate right atrioventricular valve defect, 10 were in the tricuspid position, and 5 in a right atrium to right ventricle conduit. Among the tricuspid position cases, 7 required postdilatation, which did not seem to cause significant regurgitation.

The first use of the SAPIEN valve in the tricuspid position was via a transatrial approach in an elderly patient. The jugular approach was favored in one report using the SAPIEN system and in 4 out of 15 in a Melody valve case series having an aligned route to the tricuspid valve. In our case, we preferred the femoral approach because of the large sheath size, and also because the in situ prosthetic valve orientation was not particularly oriented to favor the jugular approach. With the availability of the flexible catheters that can align the valved stent in a coaxial position to the dysfunctional valve, the SAPIEN delivery system may be fit for either delivery approach. Nevertheless, selection of the approach should be tailored to each case considering the structural anatomy, body habitus, and the type of valve used. There is, however, a practical limitation to the RetroFlex system despite its flexing capability. In fact, the delivery catheter, which is designed to spouse the sharp curve of the aortic arch, was difficult to slide over the wire in a dilated right atrium when the flex capability was used. This was particularly felt in trying...
to cross the stenotic degenerated valve in our case. The prolifera-
tion was therefore necessary. A different balloon delivery system, which
would typically advance over a long delivery sheath, might have been
easier to advance over the wire across the stenotic lesion, bearing in
mind that the main advantage we were seeking for our patient was
the valve itself for its particular characteristics described above.

Another particularity of using the SAPIEN system in the
right heart position is the fact that the valve must be loaded in
a reverse orientation compared to the aortic position. This
may represent some technical challenges as addressed
previously where a retrograde loading technique was performed on
the NovaFlex delivery system following a few successful bench
testing.

This was not required in our case since a 22 Fr sheath
was therefore necessary. A different balloon delivery system, which
would typically advance over a long delivery sheath, might have been

easier to advance over the wire across the stenotic lesion, bearing in
mind that the main advantage we were seeking for our patient was
the valve itself for its particular characteristics described above.

Another particularity of using the SAPIEN system in the
right heart position is the fact that the valve must be loaded in
a reverse orientation compared to the aortic position. This
may represent some technical challenges as addressed
previously where a retrograde loading technique was performed on
the NovaFlex delivery system following a few successful bench
testing. This was not required in our case since a 22 Fr sheath
was therefore necessary. A different balloon delivery system, which
would typically advance over a long delivery sheath, might have been

easier to advance over the wire across the stenotic lesion, bearing in
mind that the main advantage we were seeking for our patient was
the valve itself for its particular characteristics described above.

Another particularity of using the SAPIEN system in the
right heart position is the fact that the valve must be loaded in
a reverse orientation compared to the aortic position. This
may represent some technical challenges as addressed
previously where a retrograde loading technique was performed on
the NovaFlex delivery system following a few successful bench
testing. This was not required in our case since a 22 Fr sheath
was therefore necessary. A different balloon delivery system, which
would typically advance over a long delivery sheath, might have been

easier to advance over the wire across the stenotic lesion, bearing in
mind that the main advantage we were seeking for our patient was
the valve itself for its particular characteristics described above.

Conclusion

We report the successful implantation of an inverted Edwards
SAPIEN valve to treat severe dysfunction of a Mosaic bioprosthet-
ic valve in a teenager. The limited worldwide experience offers an
encouraging alternative to open-heart surgery. Nevertheless, new
developments may become necessary in the future in a search for
dedicated material.

Acknowledgment. We thank Dr Suzanne Vobecky, the
patient’s surgeon, for her support and for providing surgical
back-up during the procedure. We also thank Dr Marie-Josée
Raboisson for TEE guidance.

References

2. Iscan Z, Vural K, Bahar I, et al. What to expect after tricuspid valve replacement? Long-
3. Sung K, Park PW, Park KH, et al. Is tricuspid valve replacement a catastrophic opera-
5. Rizzoli G, Vendramin I, Nesseris G, et al. Biological or mechanical prosthesis in the
valve as a right ventricle to pulmonary artery conduit. Prosthetic experience. Eur J
aortic valve prosthesis for calcified aortic stenosis: first human case description. Circula-
10. Bekerjian R, Chotwannop P, Katus HA. Successful transcatheter antegrade valve-
in-valve implantation of a SAPIEN XT valve into a degenerated mitral valve prosthesis.
11. Shafer U, Freker C, Busse C, Kuck KH. Transjugal and transseptal treatment of a
degenerated mitral valve prosthesis with a balloon-expandable biological valve. Heart
Lung Circ. 2012 Jun 1 (Epub ahead of print).
14. Gewillig M, Dubois C. Percutaneous re-revalvulation of the tricuspid valve. Catheter
15. Kenny D, Hijazi ZM, Walkk K. Transcatheter tricuspid valve replacement with the Ed-
SAPIEN valve in a tricuspid bioprosthesis without fluoroscopic landmarks. EuroInterv-
18. McElhinney DB, Cheatham JP, Jones TK, et al. Stent fracture, valve dysfunction, and
right ventricular outflow tract reintervention after transcatheter pulmonary valve im-
plantation: patient-related and procedural risk factors in the US Melody Valve T rial.
transcatheter pulmonary valve in patients with a dysfunctional right ventricular outflow