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Case Report

A Case of TAV-in-SAV in a Patient with Structural Valve Deterioration after Surgical Aortic Valve Replacement with the INSPIRIS RESILIA Valve

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The INSPIRIS RESILIA valve is designed to dilate its valve annulus in transcatheter aortic valve-in-surgical aortic valve (TAV-in-SAV), a catheter therapy for biological valve deterioration. RESILIA tissue has improved anti-calcification properties. An 83-year-old man on hemodialysis undergoing surgical aortic valve replacement (SAVR) with a 25-mm INSPIRIS for severe aortic stenosis 22 months ago presented with general malaise. Transthoracic echocardiography revealed severe bioprosthetic stenosis (peak velocity: 3.5 m/s, mean pressure gradient: 32 mmHg, and effective orifice area: 0.45 cm^2) and severely reduced left ventricular function (ejection fraction: 17%). Because redo-SAVR was extremely risky (society of thoracic surgeons [STS] risk score: 31%), the patient underwent transfemoral-TAV-in-SAV using a 26-mm SAPIEN3. Pre- and postoperative computed tomography showed that the internal diameter of the INSPIRIS had expanded from 22.2 mm to 24.2 mm. This case demonstrated the dilatable design of INSPIRIS but not the durability of RESILIA tissue.

Keywords: aortic valve stenosis, transcatheter aortic valve implantation, TAV-in-SAV

Introduction

The INSPIRIS RESILIA aortic valve (Edwards Lifesciences, Irvine, CA, USA), which is a bioprosthetic aortic valve developed for surgical aortic valve replacement (SAVR),[1] is designed to dilate its annulus for transcatheter treatment for structural valve deterioration sis for end-stage renal disease due to autosomal dominant polycystic kidney disease, had a history of SAVR by a 25-mm-INSPIRIS for treating severe aortic stenosis (AS) in the referral hospital. Twenty-two months later, he suffered from general malaise, anorexia, and coughing. Through transthoracic echocardiography (TTE), low left ventricular function and severe aortic prosthetic valve stenosis were suspected, and he was transferred to our hospital. On admission, blood pressure was 89/49 mmHg, pulse rate 59 bpm, and SpO_2 98% (room air). Chest X-ray showed a little bilateral pleural effusion and

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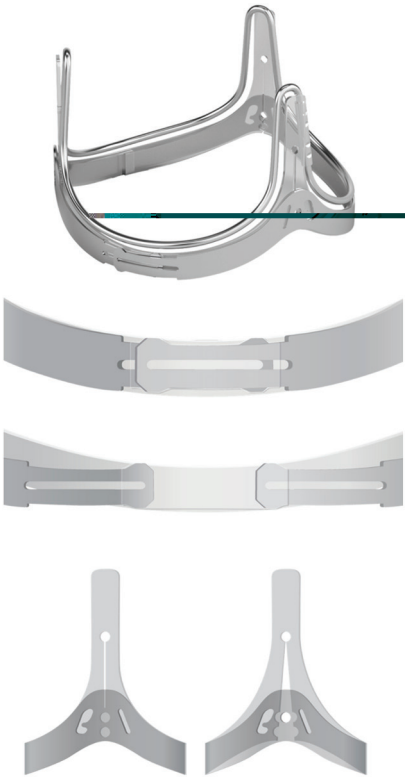

Fig. 1 The INSPIRIS RESILIA aortic valve is designed to dilate its annulus for transcatheter treatment for SVD of SAV.[1] (Courtesy of Edwards Lifesciences Corporation) SVD: structural valve deterioration; SAV: surgical aortic valve

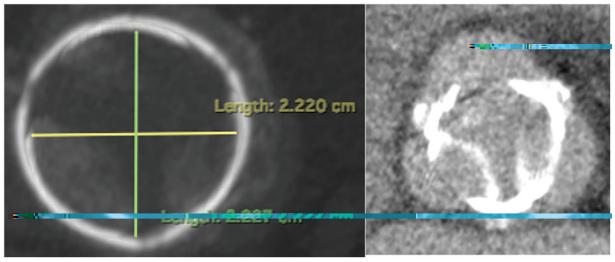

Fig. 2 Preoperative coronary CT revealed the ID of the implanted INSPIRS was 22.2 mm and its leaflets accumulated calcification. CT: computed tomography; ID: internal diameter

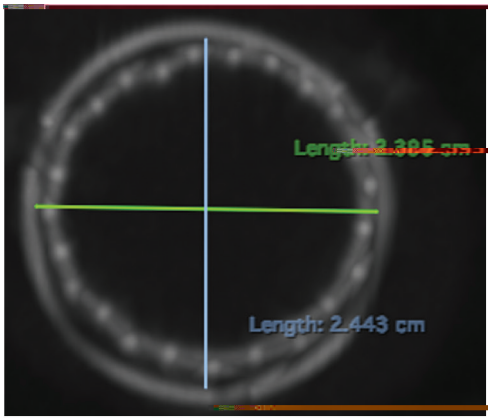

Fig. 3 Postoperative coronary CT revealed the ID was 24.2 mm, dilating by about 2.0 mm from the preoperative ID. CT: computed tomography; ID: internal diameter

no congestion. Blood tests revealed no signs of infection but significantly elevated serum brain natriuretic peptide (4649.4 pg/mL). TTE under the support of dobutamine 3 mcg/kg/min revealed cardiac dilatation and diffused severe hypokinesis of the left ventricle (left ventricular diastolic/systolic diameter [LVDd/Ds]: 67/62 mm, ejection fraction [EF]: 17%). Bioprosthetic valve stenosis was found (effective orifice area [EOA]: 0.45 cm^2, peak velocity [peak V]: 3.5 m/s, and mean pressure gradient [PG]: 32 mmHg). Cardiac computed tomography (CT) revealed that the internal diameter (ID) of the implanted INSPIRIS was 22.2 mm, and its leaflets accumulated calcification (**Fig. 2**). Because the risk of redo-SAVR was extremely high (STS risk score: 31%), TAV-in-SAV was indicated. We obtained informed consent from the patient and his family. The hemodynamics collapse occurred on the next day of admission. Although we planned the patient's surgery 7 days after admission, emergency surgery was performed.

General anesthesia was induced. Cardiopulmonary bypass (CPB) was established before the procedure. A 26-mm SAPIEN 3 (Edwards Lifesciences) was implanted via the right transfemoral artery in the appropriate position using the regular technique. No aortic regurgitation was detected by TTE and aortic angiography. Hemodynamics immediately stabilized, and the CPB was smoothly removed. He was extubated in the intensive care unit 3 hours after the operation. TTE under the support of dobutamine 3 mcg/kg/min revealed slight improvement in cardiac function (LVDd/Ds: 62/57 mmHg, EF: 23%). No peri- and transvalvular regurgitation were detected. Peak V was decreased to 2.3 m/s and mean PG to 13 mmHg. According to cardiac CT, the ID was 24.2 mm, dilating by about 2.0 mm from the preoperative ID (**Fig. 3**). The postoperative course was uneventful, and the patient was transferred to the former hospital on the 6th postoperative day for rehabilitation. After being transferred to the referred hospital, dobutamine was gradually reduced and finished. He received rehabilitation and was discharged from the referred hospital on the 63rd postoperative day. Currently, he attends followed-ups at the referred hospital.

Discussion

INSPIRIS was developed as a novel bioprosthetic valve with long-term durability because of its specific tissue, RESILIA tissue, which prevents the calcification of its leaflets. Due to its high levels of safety and hemodynamics, it has been used worldwide since it gained CE marking in 2016. Another feature of INSPIRIS, the ability to dilate its annulus in TAV-in-SAV, has not been demonstrated in clinical practice. In recent years, an increasing number of TAV-in-SAV has been performed for SVD of surgical aortic valve (SAV). If a small-size surgical valve is implanted, the risk of patient prosthesis mismatch (PPM) is high in TAV-in-SAV, resulting in a possibility of poor prognosis.[2] One of the solutions to avoid PPM in such a case is cracking the SAV by high-pressure ballooning in TAV-in-SAV, that is, balloon valve fracture (BVF). This will enable the implantation of a larger size transcatheter aortic valve (TAV), decreasing the risk of PPM. However, this procedure was technically limited, and some reports indicate its fatal complications, such as annulus rupture and coronary obstruction or embolization by fragments of broken SAV.[3] The INSPIRIS RESILIA valve consists of a splittable polyester band and a dilatable alloy band, delivering a controlled expansion to fit a new TAV. This does not need BVF and may prevent complications with BVF. To the best of our knowledge, there are no reports describing this design in clinical practice, excluding transcatheter pulmonary valve implantation (TPVI).[4] In our case, postoperative CT revealed an ID of 24.2 mm for INSPIRIS, which expanded by 2.0 mm compared to the preoperative ID. This was thought to reflect its dilatable design. Therefore, the INSPIRIS's expandable design may prevent the risk of PPM in TAV-in-SAV.

Several clinical trials have supported its safety, durability, and hemodynamics.[5,6] Bartus et al. reported that none of the 133 patients after SAVR with INSPIRIS experienced SVD during a 5-year observation.[5] However, in our case, early SVD had occurred. We thought it was mainly due to hemodialysis. To the best of our knowledge, there are no reports on the durability of INSPIRIS for patients with hemodialysis. Given this case, the INSPIRIS valves, as well as other bioprosthetic valves, may frequently deteriorate in patients with hemodialysis, although the RESILIA tissue has improved its anti-calcification properties. There are an increasing number of reports about the long-term durability of TAVI valves. However, our previous study revealed the mid-term outcome of TAVI valves in patients with hemodialysis, showing SVD in 14.1% of the cases within 3 years post surgery.[7] There are no reports pertaining to the durability of valve-in-valve in patients with hemodialysis. The TAVI valve, in this case, underwent SVD earlier. Although there was insufficient information about the first surgery (SAVR using INSPIRIS) and the STS score could not be provided at that time, the letter from the referral hospital showed that no cardiac dysfunction was found 17 months after the first surgery, activities of daily living were sufficient, and no other organ dysfunctions were seen. Therefore, the first STS score was not supposed to be so high. On the other hand, he presented low output syndrome 1 month before the second surgery and was in a preshock state at the time of admission to our hospital. For this reason, redo aortic valve replacement was thought to be very risky. Considering the background of this patient, TAV-in-SAV was the best option.

The sizing recommendation for SAPIEN 3 in INSPIRIS is provided by Edwards Lifesciences. A 29-mm SAPIEN 3 is recommended in a 25-mm INSPIRIS. In our case, however, preoperative CT showed that the measured ID of the implanted INSPIRIS was 22.2 mm, smaller than the officially documented ID. In addition, leaflet calcification was observed. Considering that it might not expand as much as expected, we selected a 26-mm SAPIEN 3 and inflated it with a nominal volume. The true ID of the INSPIRIS after expanding was 24.2 mm. The sizing recommendation was a 26-mm SAPIEN 3 when the true ID of the implanted SAV was 22.0 mm to 25.0 mm. Our size selection was thought to be reasonable.

Lee et al. compared SAPIEN 3 and Evolut (Medtronic, Minneapolis, MN, USA) in TAV-in-SAV. SAPIEN 3 was associated with significantly lower rates of postprocedural permanent pacemaker implantation but with smaller postprocedural EOA and higher residual PG compared with Evolut, implanted in the supra-annular position. Although Evolut may be preferred for patients with a small surgical valve size and high risks of PPM,[8,9] we chose a 26-mm SAPIEN 3 valve in the present case, because Evolut was not covered by Japanese health insurance for patients on dialysis.

Conclusion

We showed a case of TAV-in-SAV in a patient who experienced SVD after SAVR with INSPIRIS. This report demonstrated the annulus-dilatable design of

INSPIRIS by pre- and postoperative CT in clinical practice.

Disclosure Statement

None.

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