

Rescue valve-in-valve implantations in second generation transapical transcatheter aortic valve prostheses

Arnaud Van Linden · Johannes Blumenstein ·
Thomas Walther · Helge Möllmann · Won Keun Kim ·
Christian Hamm · Jörg Kempfert

Received: 22 August 2012 / Accepted: 26 October 2012 / Published online: 6 November 2012
© Springer-Verlag Berlin Heidelberg 2012

Sirs:

The largest worldwide experience with transcatheter aortic valve implantation (T-AVI) for the treatment of elderly high-risk patients with severe aortic stenosis is based on the use of the self-expandable Medtronic CoreValve[®] and the balloon-expandable Edwards SAPIEN[™] prostheses [1–5]. In October 2011, two second-generation T-AVI prostheses have obtained CE-mark approval for the transapical (TA) approach: the Symetis ACURATE TA[™] and the JenaValve[™]. Both are porcine valves on a self-expandable nitinol stent with unique stepwise implantation features. Details of both devices and initial promising outcome have been published recently [6, 7]. Although malpositioning is rare with both devices, it may occur and might lead to suboptimal hemodynamical results (paravalvular leak). We report two cases where malpositioning of each, an ACURATE TA[™] and a JenaValve[™], resulted in severe paravalvular aortic regurgitation followed by implantation of an Edwards SAPIEN[™] prosthesis as a bail-out maneuver.

The first patient was an 80-year-old woman with severe aortic stenosis at NYHA functional class III who received JenaValve[™] implantation. Her logistic EuroSCORE was 30 % and had a history of stroke. Left ventricular ejection fraction (LVEF) was 55 %, mean preoperative transvalvular

gradient was 50 mmHg and the effective aortic valve orifice area (EOA) was 0.9 cm².

The second patient was a 79-years-old man with severe aortic stenosis at NYHA functional class III who received an ACURATE TA[™] prosthesis. He had a previous CABG procedure in 1991 with patent grafts and logistic EuroSCORE was 36 %, LVEF was 60 %, mean preoperative transvalvular gradient was 56 mmHg and EOA was 0.7 cm². Both the patients were discussed in an interdisciplinary heart team and the indication for T-AVI was based on risk profile and individual preoperative patient status.

Both procedures were performed under general anesthesia in a modified hybrid cath-lab. Standard transapical approach was performed [8] and previously to implantation of the prosthesis, a balloon valvuloplasty was performed. The JenaValve[™] (size 23) and ACURATE TA[™] (size M) were implanted by stepwise unsheathing with a short episode of rapid ventricular pacing. After complete deployment of the valve, transesophageal echocardiography (TEE) and angiography were performed for functional valve assessment. In both cases, imaging revealed a significant paravalvular leak resulting in aortic regurgitation >2⁺ (Fig. 1). The mechanism of paravalvular leakage seemed to be a situation where one of the “guiding feelers” of the JenaValve[™] had not been placed properly behind the corresponding native cusp in the first patient and a too high position of the ACURATE TA[™] valve in the second patient. Direct re-balloon did not significantly reduce the regurgitation in both cases. All members of the interdisciplinary heart team agreed that the aortic regurgitation had to be treated and could not be accepted. Conversion to conventional aortic valve replacement via sternotomy using cardio pulmonary bypass would have been an option, but implanting a balloon-expandable SAPIEN[™] prosthesis

A. Van Linden (✉) · J. Blumenstein · T. Walther ·
W. K. Kim · J. Kempfert
Department of Cardiac Surgery, Kerckhoff-Klinik Heartcenter,
Benkestr 2–8, 61231 Bad Nauheim, Germany
e-mail: van-linden@gmx.de

H. Möllmann · W. K. Kim · C. Hamm
Department of Cardiology, Kerckhoff-Klinik Heartcenter,
Bad Nauheim, Germany

Fig. 1 Malpositioning of the ACURATE TA™ (a) and the JenaValve™ (b) leading to severe paravalvular aortic regurgitation

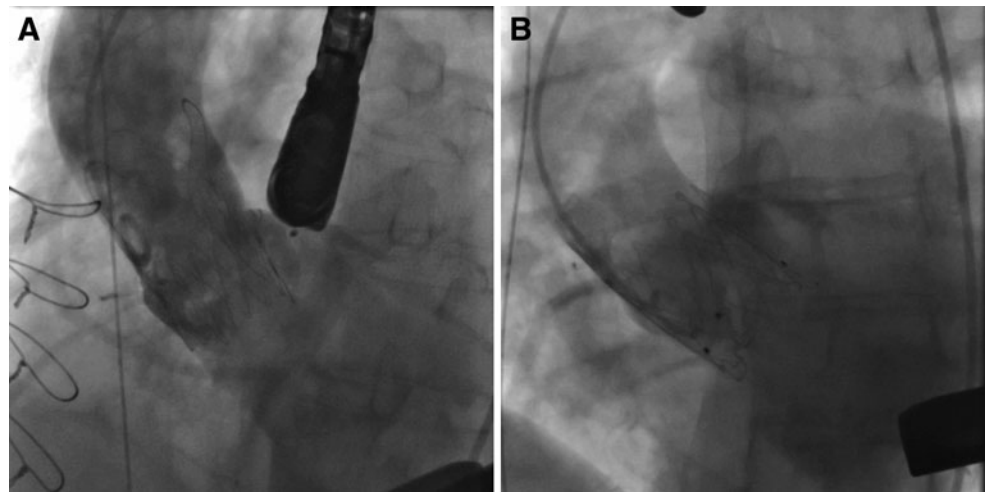
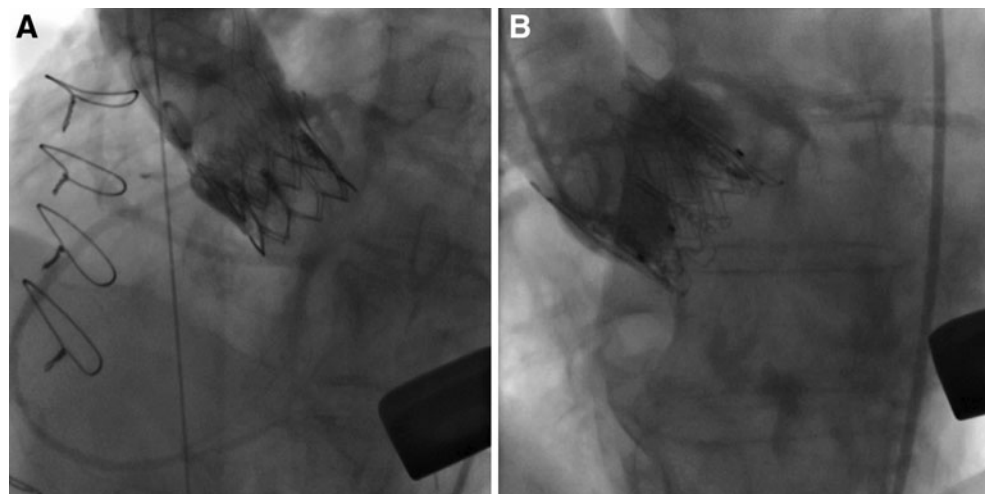


Fig. 2 Final result of the valve-in-valve rescue procedure. SAPIEN™ in ACURATE TA™ (a) and SAPIEN™ in JenaValve™ (b) without any relevant aortic regurgitation or coronary flow impairment



as valve-in-a-valve (VinV) seemed to be the less invasive option, although a valve-in-valve with the ACURATE TA™ and the JenaValve™ had never been performed to that day.

In both patients, a 26 mm SAPIEN XT™ prosthesis was chosen and crimped in a standard fashion. Subsequently, the SAPIEN™ prosthesis was deployed in a pronounced stepwise fashion using the radiopaque landmarks of the initially implanted prostheses, respectively. Angiography and TEE after SAPIEN™ VinV implantation revealed no relevant aortic regurgitation and good valve function (Fig. 2). Both patients had an uneventful postoperative course and were discharged in good clinical conditions. Both patients who underwent 1-year follow-up examination and were in good clinical condition both in NYHA functional class I. Echo follow-up demonstrated good hemodynamic function of the prostheses. Mean gradient for the SAPIEN™ within the JenaValve™ was 10 mmHg with an EOA of 1.75 cm², and for the SAPIEN™ within the ACURATE TA™ was 8 mmHg with an EOA of 2.03 cm², respectively.

The concept of implanting second prosthesis as valve in valve, as a rescue option for severe aortic regurgitation after T-AVI has been published previously [9]. This experience was based on SAPIEN™ into SAPIEN™ prosthesis implantation. To our knowledge these are the first reports on a SAPIEN™ prosthesis that was implanted inside other and younger generation T-AVI prostheses. The incidence of malpositioning with these two second-generation devices is very low as the recent CE-mark approval trials have showed [6, 7]. This might be due to the stepwise implantation technique, which eases a reproducible implantation. Nevertheless, in these two described cases severe aortic regurgitation occurred due to a slightly very high position of the initial prostheses. Aortic regurgitation based on incomplete deployment of the nitinol stent can easily be treated by re-ballooning. In case of partial malpositioning, however, re-ballooning is not sufficient. The slightly lower implantation of a balloon-expandable SAPIEN™ prosthesis under these circumstances seems to lead to good hemodynamic valve function even after mid-term follow-up.

In summary, valve-in-valve implantation of a SAPIENTM prosthesis inside an ACURATE TATM or a JenaValveTM prosthesis seems to be an adequate rescue option for severe aortic regurgitation after implantation of these second-generation T-AVI prostheses.

References

1. Leon MB, Smith CR, Mack M et al (2010) Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 363:1597–1607
2. Piazza N, Wenaweser P, van Gamen M et al (2010) Relationship between the logistic EuroSCORE and the society of thoracic surgeons predicted risk of mortality score in patients implanted with the corevalve revalving system—a Bern-Rotterdam study. *Am Heart J* 159:323–329
3. Smith CR, Leon MB, Mack MJ et al (2011) Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 364:2187–2198
4. Thomas M, Schymik G, Walther T et al (2010) Thirty-day results of the SAPIEN aortic bioprosthesis European outcome (SOURCE) registry: a European registry of transcatheter aortic valve implantation using the Edwards SAPIEN valve. *Circulation* 122:62–69
5. Zahn R, Gerckens U, Grube E et al (2011) Transcatheter aortic valve implantation: first results from a multi-centre real-world registry. *Eur Heart J* 32:198–204
6. Kempfert J, Treede H, Rastan AJ et al (2012) Transapical aortic valve implantation using a new self-expandable bioprosthesis (ACURATE TA): 6-month outcomes. *Eur J Cardio-Thorac Surg: Off J Eur Assoc for Cardio-thorac Surg* [Epub ahead of print]
7. Treede H, Mohr FW, Baldus S et al (2012) Transapical transcatheter aortic valve implantation using the JenaValve system: acute and 30-day results of the multicentre CE-mark study. *Eur J Cardio-Thorac Surg: Off J Eur Assoc for Cardio-thorac Surg* 41:e131–e138
8. Walther T, Mollmann H, van Linden A et al (2011) Transcatheter aortic valve implantation transapical: step by step. *Semin Thorac Cardiovasc Surg* 23:55–61
9. Kempfert J, Rastan AJ, Schuler G et al (2011) A second prosthesis as a procedural rescue option in trans-apical aortic valve implantation. *Eur J Cardio-Thorac Surg: Off J Eur Assoc for Cardio-thorac Surg* 40:56–60