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LETTER TO THE EDITORS

Interventional options for severe aortic regurgitation after transcatheter aortic valve implantation: balloons, snares, valve-in-valve

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Sirs:

Transcatheter aortic valve implantation (TAVI) is a novel treatment option for elderly, co-morbid patients with severe symptomatic aortic stenosis considered in-operable or at high-risk for conventional surgery [1, 2]. Currently available TAVI prostheses lack retrievability. Therefore, implantation at the accurate position within the aortic annulus is often technically demanding even for experienced operators. Malplacement may cause acute severe paravalvular leakage which is poorly tolerated and associated with adverse clinical outcome [3, 4]. We report the case of a patient with large anatomy of the aortic annulus, in whom malplacement of Medtronic/CoreValve prosthesis at a too-low position in the left ventricular outflow tract (LVOT) resulted in severe acute aortic regurgitation. Corrective bail-out strategies are discussed.

An 85-year-old male patient presented with worsening dyspnea NYHA class III due to severe aortic valve stenosis and moderately depressed left ventricular function (ejection fraction 40%). The mean transvalvular gradient was 45 mmHg. The aortic orifice area measured using transesophageal echocardiography was 0.8 cm^2. Due to advanced age, moderate dementia, and general frailty (logistic EuroSCORE II 3.25%), the risks associated with conventional open surgery were deemed too high, and the patient was considered for TAVI. Pre-interventional imaging revealed a rather large anatomy of the aortic annulus which measured 29 × 25 mm (perimeter 85 mm, mean diameter 27.1 mm) on computed tomography. As this diameter exceeded the size range that could be treated with the TAVI prostheses available at the time of initial presentation (April 2011), the patient was treated with balloon valvuloplasty to improve symptoms. Symptoms, however, recurred after 4 months, and the patient was now scheduled to undergo TAVI with the recently available 31 mm Medtronic/CoreValve prosthesis, which is designed for treating annular diameters of up to 29 mm.

Under anesthetist-controlled conscious sedation, percutaneous access to the right common femoral artery was gained and a single 6F Proglide device (Abbott Vascular) was deployed in a pre-close fashion for later access closure. An 18F vascular sheath was inserted uneventfully. After crossing the aortic valve, valvuloplasty with a 22 mm balloon (Z-Med II, PFM) was performed under rapid right ventricular pacing at 180/min. Then, a self-expanding 31 mm Medtronic/CoreValve prosthesis was advanced over an Amplatz SuperStiff guidewire which was placed in the left ventricular apex. Under repeat angiographies, the prosthesis was deployed in a stepwise fashion. However, the prosthesis migrated in a position too low into the LVOT, resulting in severe paravalvular aortic regurgitation (Fig. 1, movie 1). Simultaneous pressure measurements showed equalization of diastolic aortic and left ventricular end-diastolic pressure. Options were contemplated: the valve appeared well-expanded under fluoroscopy, but too

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low in the LVOT. Therefore, an initial attempt of pulling the valve upwards was undertaken using an 8F Judkins right guiding catheter and a 20 mm Amplatz gooseneck snare (EV3, Plymouth, USA). Under continuous pulling tension, the valve could be retracted into a higher position within the annulus, significantly improving the degree of regurgitation; however, the valve relapsed into the too-low position after release of tension (Fig. 2, movie 2). Balloon dilatation with a 28 mm balloon was performed under rapid pacing to approve apposition of the valve within the annulus, but regurgitation remained unchanged (Fig. 3, movie 3). Then, the decision was made to implant a second 31 mm Medtronic/CoreValve prosthesis within the first prosthesis ("valve-in-valve"). The second prosthesis was implanted in a higher position (Fig. 4, movie 4). After deployment, regurgitation was reduced to only trace (Fig. 5, movie 5). Hemodynamics were significantly improved (Fig. 6).The patient was stable throughout the entire procedure. Echocardiography documented only trace regurgitation and the patient was discharged, 5 days after the procedure. At the 30-day follow-up, the patient remains well alive with significant improvement of symptoms. Aortic regurgitation is still trace with a mean transvalvular gradient of 8 mmHg on echocardiography.

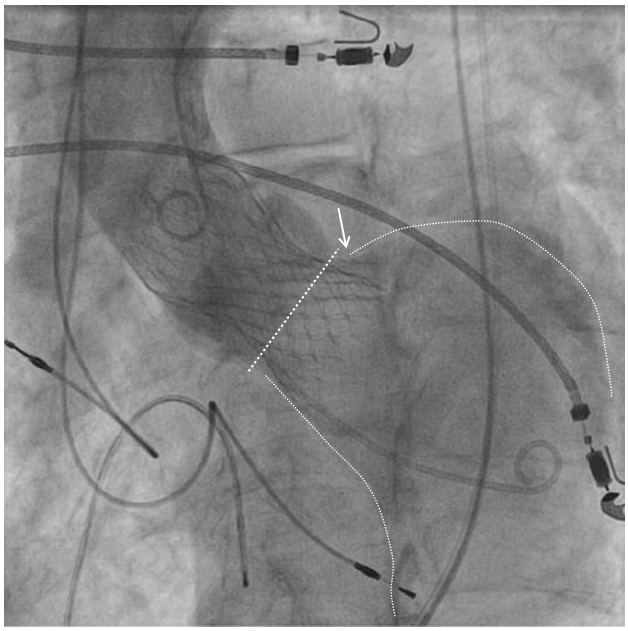

Fig. 1 Angiography after valve implantation showing a too-low position of the prosthesis into the left ventricular outflow tract, resulting in severe paravalvular (*arrow*) regurgitation. *Line* depicts the level of the aortic annulus

Transcatheter aortic valve implantation has been rapidly embraced as a novel treatment option for patients with symptomatic severe aortic valve stenosis. Recent randomized studies have documented the superiority of TAVI over standard medical treatment in patients who cannot undergo open surgery due to severe co-morbidities [1]. In patients deemed at high surgical risk, results of TAVI were at least not inferior to open valve replacement [2].

Aortic regurgitation (AR) is a main drawback of TAVI. Mild to moderate AR is usually well-tolerated after TAVI.

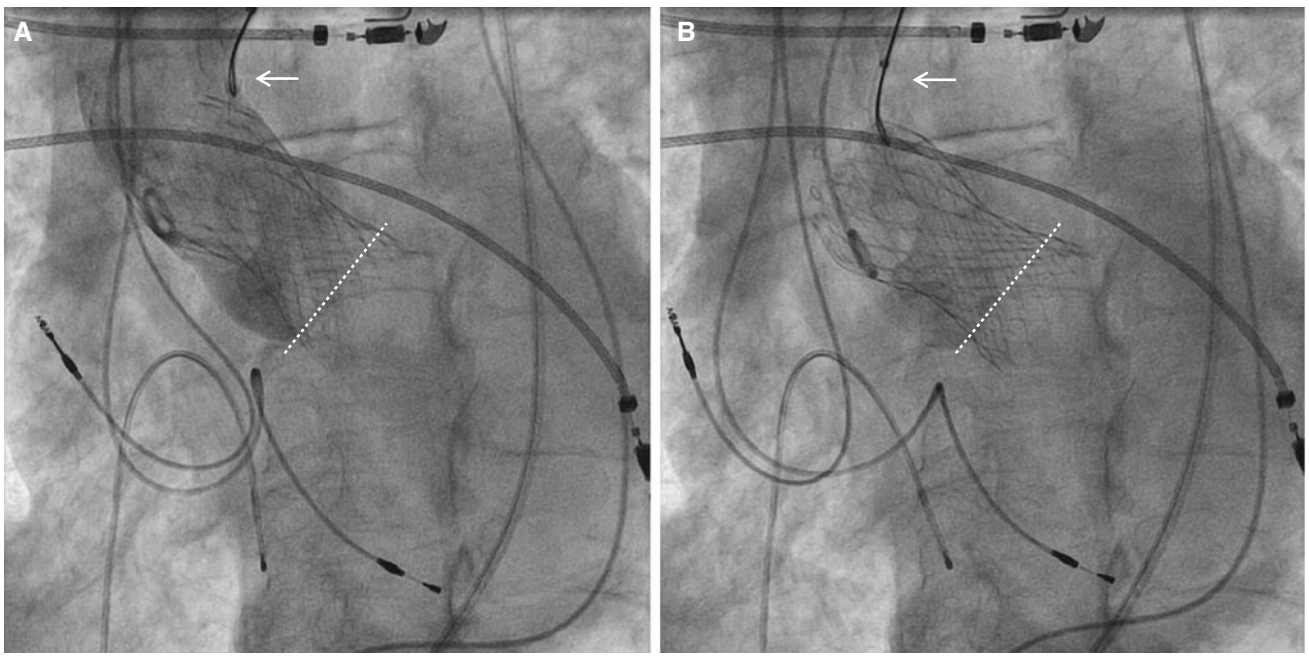

Fig. 2 Upwards pulling of the prosthesis by a loop snare attached to one of the frame loops (*arrow*) resulting in an optimal position with diminished regurgitation (**a**). After release of tension (*arrow*), the valve migrates back into the too-low position (**b**)

However, acute severe AR after TAVI is poorly tolerated and has significant impact on post-procedural survival [3]. Central regurgitation can often be observed when the stiff guidewire is still in place, but will diminish immediately after wire withdrawal. Rarely, primary defects of the valve tissue can cause central regurgitation. In most cases, AR after TAVI is related to paravalvular leakage due to insufficient sealing of the aortic annulus. This can be caused by prosthesis/annulus mismatch (too large annulus), device malpositioning (too high, too low), or severe calcifications of the native valve resulting in gap formations or incomplete expansion of the self-expandable nitinol stent frame. In our case, the valve prosthesis was obviously malpositioned too low into the LVOT resulting in paravalvular leakage through the uncovered cells of the prosthesis. Several percutaneous techniques have been described trying to avoid acute conversion to open surgery which portends particular risks in these elderly co-morbid patients currently referred for TAVI [5–7]. Interventional options include balloon dilatation to achieve better expansion of the valve stent frame, pulling the valve upwards into a higher position by a loop snare [8–10], or implantation of a second valve prosthesis inside the first one ("valve-in-valve") [5, 6, 11], which can also be used for paravalvular AR after malplacement of the prosthesis too high outside of the annulus into the ascending aorta. For the Medtronic/CoreValve prosthesis, snaring devices attached to one of the two frame loops have been successfully used via a transfemoral or transbrachial approach to correct a position too low in the LVOT [8–10]. During such a snaring maneuver, blood pressure should be continuously monitored for a rise in diastolic pressure. Particular care must be taken not dislodging the valve out of the aortic annulus into the ascending aorta by pulling too brisk. In the present case, the valve could be mobilized to a higher position, but after release of snaring tension the valve relapsed into previous, low position again. Therefore, valve-in-valve implantation of a second Medtronic/CoreValve prosthesis was performed, almost completely abolishing AR.

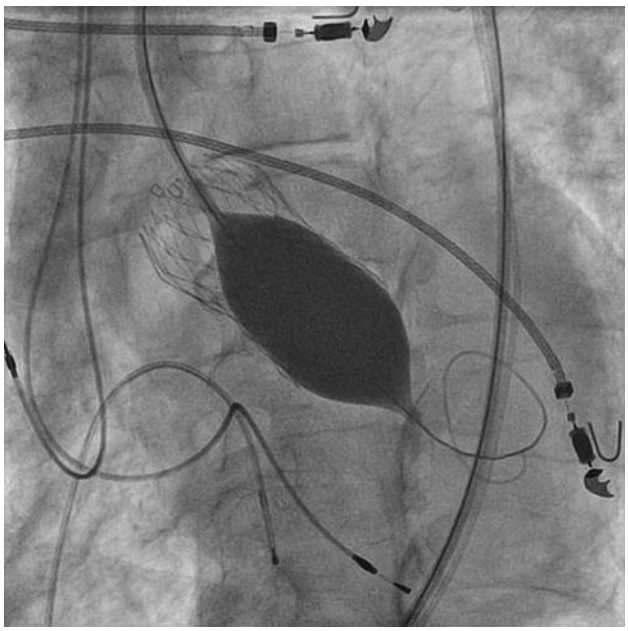

Fig. 3 Balloon dilatation of the implanted valve

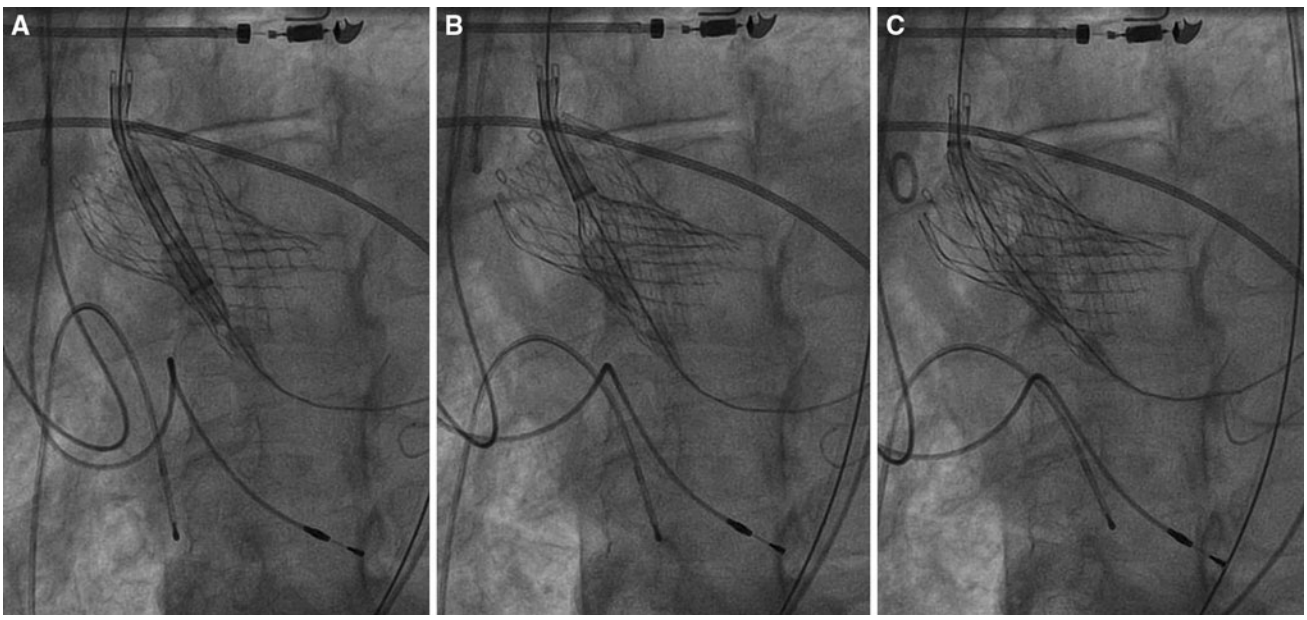

Fig. 4 Stepwise implantation of the second (valve-in-valve) Medtronic/CoreValve prosthesis at a higher position (**a–c**)

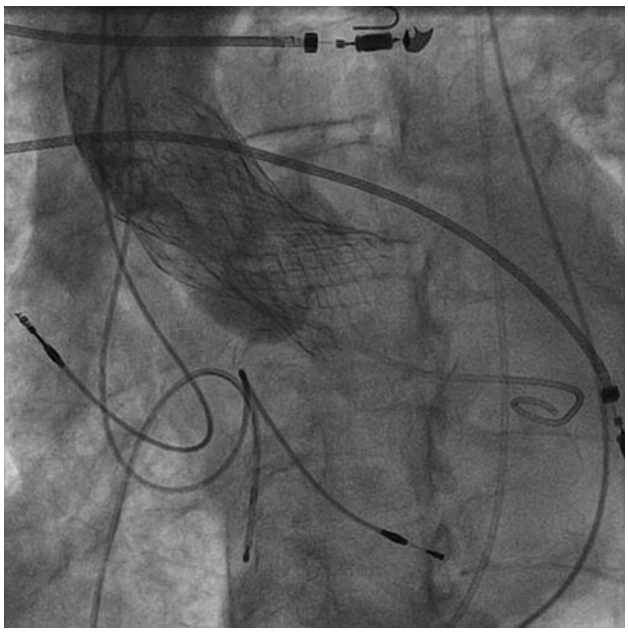

Fig. 5 Final result showing only trace transvalvular regurgitation

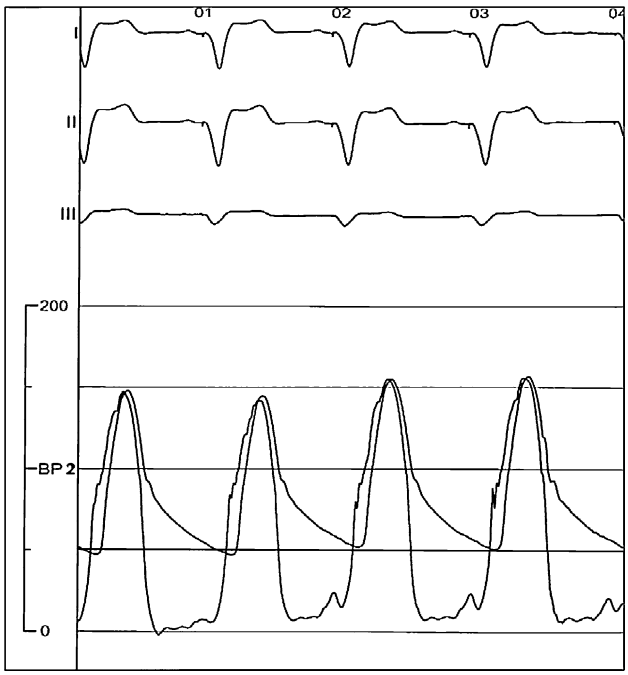

Fig. 6 Final hemodynamic result showing a good separation of diastolic aortic pressure and left ventricular end-diastolic pressure

Implantation of a second valve into a TAVI prosthesis has been successfully used as a bail-out concept for treating severe paravalvular leakage after Medtronic/CoreValve–TAVI [5, 11] and has also been performed for misplaced, leaking Edwards Sapien valves [12]. In the Italian Medtronic/CoreValve registry, valve-in-valve implantation of a second prosthesis for severe paravalvular leakage was required in 24 (3.6%) out of 663 patients in total [4]. In these 24 patients, implantation of a second valve was performed without 30-day mortality or stroke [4]. Transvalvular gradients were not increased in second-valve patients. Although acute effects were so far favorable, data on the long-term outcome of valve-in-valve implantation of two Medtronic/CoreValve prostheses are scarce. Concerns mainly relate to valve durability and thrombotic/embolic events. So far, anecdoctal case reports have shown no structural deterioration of valve function up to 3 years after valve-in-valve TAVI [6, 11], which was recently supported by the larger Italian Medtronic/CoreValve registry showing no differences in mean transaortic gradients at 1-year follow-up (10.5 ± 5.2 mmHg in valve-in-valve patients vs. 10.1 ± 4.2 mmHg; $p = 0.838$) [4, 10]. In this registry, no differences in clinical outcomes at 1 year were observed between patients with and without valve-in-valve implantation [4].

In summary, severe paravalvular aortic regurgitation represents a major complication of TAVI and is poorly tolerated. For Medtronic/CoreValve prosthesis implanted too low into the LVOT, percutaneous techniques exist to correct paravalvular regurgitation. If other maneuvers fail (retraction by snaring, balloon dilatation), a valve-in-valve procedure should be considered.

Conflict of interest Holger Eggebrecht is a trainer for transcatheter aortic valve implantation (TAVI) for Medtronic/CoreValve and clinical proctor for Edwards Lifesciences. Mirko Doss is a clinical proctor for Edwards Lifesciences.

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