Case Report

Salvaging Lowermost Deployment of an ACURATE Device During Transcatheter Aortic Valve Replacement with Balloon and Lasso Pull Techniques

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Transcatheter aortic valve replacement (TAVR), also known as transcatheter aortic valve implantation (TAVI), is being used with increasing frequency in patients with severe aortic stenosis at high or prohibitive surgical risk. A number of devices are becoming available for TAVR, and competence in using them is mandatory to maximize the safety and efficacy of TAVR, while individualizing device selection in keeping with patient features. The ACURATE TF is a novel promising device for transfemoral TAVR. However, its peculiar features may require additional maneuvers in case of complications. We hereby report the case of a patient undergoing transfemoral TAVR with the ACURATE TF device, in whom lowermost deployment was complicated by massive aortic regurgitation. With two separate remedial actions, the balloon pull and lasso techniques, we were able to pull back the device and significantly reduce post-TAVR aortic regurgitation. Awareness of this complication and the possible use of these two techniques may increase the safety and efficacy of TAVR with this and other new devices. © 2015 Wiley Periodicals, Inc.

Key words: aortic stenosis; complication; transcatheter aortic valve implantation; transcatheter aortic valve replacement

INTRODUCTION

The landmark results of randomized trials and their pooled analysis in favor of transcatheter aortic valve replacement (TAVR) in patients with severe aortic stenosis but high or prohibitive surgical risk have ushered a new era of minimally invasive therapy for structural heart disease.[1–4] Further improvements in the risk-benefit profile of TAVR may be achieved by widening the interventionists' armamentarium with new devices for TAVR, which may eventually enable the tailoring of device and procedure choice to the specific patient features. [5]

The ACURATE device (Symetis, Ecublens, Switzerland) is a self-expandable prosthetic valve with porcine pericardial leaflets and a nitinol frame with several connected elements: three stabilization arches which reside in the aorta, an upper crown which enables supra-annular anchoring, a central waist which captures the native valve leaflets, and a lower crown which rests in contact with the upper left ventricular outflow tract.

Additional Supporting Information may be found in the online version of this article.

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Conflict of interest: Dr. Biondi-Zoccai has consulted for Direct-Flow.

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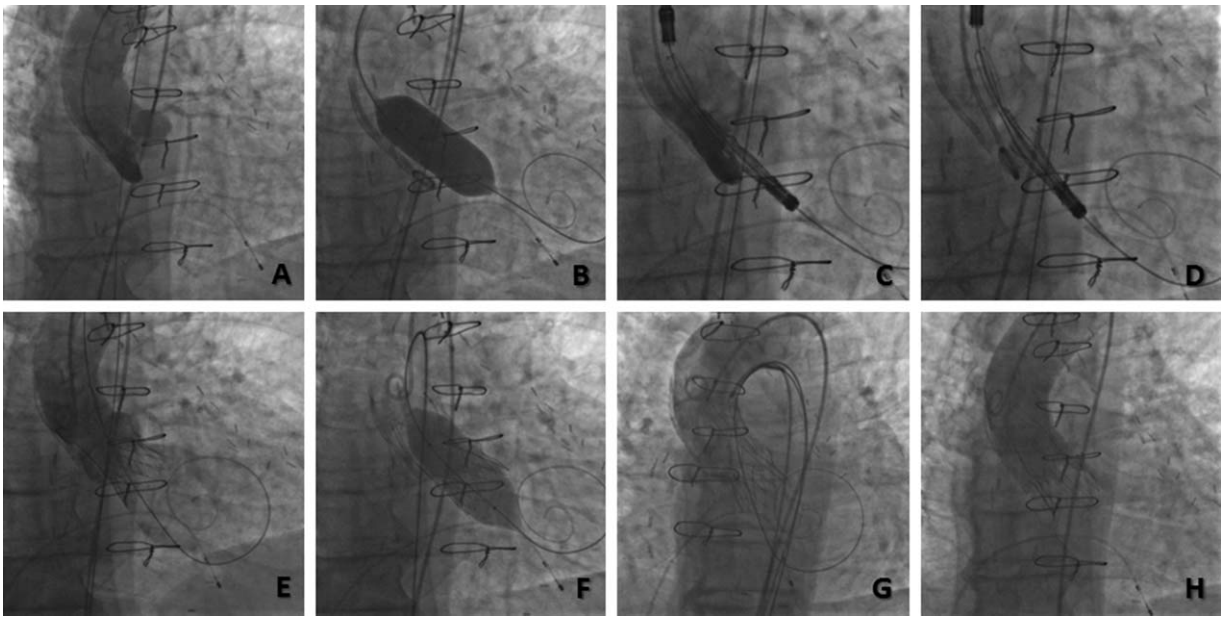

Fig. 1. Correction of low deployment of a Symetis ACURATE device during transcatheter aortic valve replacement with balloon pull and lasso techniques. Panel A: baseline aortography; panel B: balloon valvuloplasty; panels C and D: progressive phases of device deployment (in retrospect positioned too low); panel E: aortography showing the device deployed too low with ensuing severe aortic regurgitation; panel F: post-dilation with pulling of the balloon shaft to pull back the device, according to the balloon pull technique; panel G: lasso technique to grab the distal portion of the device and pool it backwards even more, after having created a lasso by crossing one of the valve stabilization arches with an exchange-length guidewire and externalizing it; panel H: final aortography showing substantial improvement in aortic regurgitation.

In addition, an external skirt reduces the risk of paravalvular leak. It can be implanted from both the transapical (ACURATE TA) and transfemoral route (ACURATE TF). [6–8] While its use for transapical TAVR is quite established, the experience so far with transfemoral TAVR using the ACURATE device is more limited. Hence, there is a paucity of reports on which type of complications can occur when using this device, and which remedies should be adopted when facing such complications.

We hereby report the case of a patient undergoing transfemoral TAVR with the ACURATE device, complicated by lowermost deployment and massive aortic regurgitation, which were successfully managed with two *ad hoc* techniques.

CASE

A 79-year-old gentleman with severe aortic stenosis but high surgical risk was referred to our institution for transcatheter aortic valve replacement (TAVR). After heart team consensus and preprocedural computed tomographic analysis, TAVR was planned via the left transfemoral route and an ACURATE M device was chosen. Device size was based on computing valve diameter, area and diameter, leading to the choice of an M sized ACURATE TF device, which is recommended for valves with a 23–25 mm diameter, 415–491 mm^2 area, and 72–79 mm perimeter, thus avoiding oversizing or undersizing

Briefly, after positioning a 0.035" Safari guidewire (Boston Scientific, Natick, MA, USA) and predilating with a 22 $\times$ 40 mm VACS II balloon (Osypka, Rheinfelden-Herten, Germany), the ACURATE M device was deployed, in three steps, as recommended. However, inadvertently, the device was deployed with a low seating (Fig. 1; Supporting Information Fig. 1, Video 1). In retrospect, we believe that two factors simultaneously played a role. First, this was one of the first cases we performed with this device at our center. Despite a large experience with other TAVR devices (>200 cases performed by a single operator) and the presence of an external proctor experienced with this device, it is likely that the valve was unintentionally positioned too low (i.e. mis-positioned). In addition, we found that in the present case the valve did jump forward a little bit, possibly because of adverse geometry or aortic calcifications.

Given the presence of significant aortic regurgitation likely due to the suboptimal deployment with paravalvular leak, post-dilation was performed with a 23×40 mm Valver balloon (Balton, Warsaw, Poland).

Unfortunately significant regurgitation persisted. In light of the high operative risk contraindicating surgical conversion, additional measures were adopted to improve the valve position. [9] First, we used a balloon pull technique, by inflating again the 23 × 40 mm Valver balloon in the ACURATE device and then exercising a progressively stronger traction on the balloon shaft while maintaining the balloon inflated and ongoing rapid pacing.

Then, as the ACURATE device cannot be snared with a standard goose neck snare (as by design it lacks any specific element which can be grasped with a goose neck snare), we crossed one of the valve stabilization arches of the device with a 0.035" exchange-length Emerald guidewire (Cordis, Miami, FL) brought it backwards, and then snared it in the abdominal aorta with a 5 mm goose neck snare (ev3, Plymouth, MN) and finally externalized it outside the patient, forming a lasso. Such lasso was then very forcefully pulled to move upward the valve with such dedicated lasso technique, without rapid pacing.

Notably, we tried to minimize the risk of pooling the valve too high by performing the balloon and the lasso pull techniques in several subsequent steps, and with repeated, multiple and progressively more forceful attempts. The position of the device was also appraised repeatedly by visual inspection in comparison to the bony landmarks. Eventually, both maneuvers improved the seating of the valve despite causing a slight rotation of the same in comparison to the annulus. Thus, a final standard balloon post-dilation was performed during rapid pacing with the Valver balloon to ensure coaxial alignment of the valve with the ascending aorta. At the end of the procedure only moderate residual aortic regurgitation was disclosed. The subsequent hospital stay was also uneventful, and 1-month follow-up showed similarly favorable results for valve gradients and further improvements in aortic regurgitation, which proved mild at both transthoracic and transesophageal echocardiography (Supporting Information Fig. 2, Video 2).

DISCUSSION

The increasing prevalence of severe aortic stenosis poses important challenges to clinicians as often patients with this condition are very old or with multiple comorbidities. The introduction of TAVR has provided an appealing alternative to surgery for high risk subjects and a superior option in comparison to medical therapy to those with prohibitive risk [1–4]. While the bulk of evidence is limited to two devices, new second-generation devices are being introduced in clinical practice with promising results [5].

The ACURATE device is among the most promising TAVR devices, given the combination of self-expanding nitinol structure, porcine leaflets, and presence of a PET skirt to improve positioning and seal [6,7]. As with any device, however, only the buildup of experience, including both successful and unsuccessful or complicated cases, may lead to improved early and long-term results. Indeed, other potentially favorable features of this device include the possibility of optimizing commissural alignment, and the ensuing reduced risk of coronary obstruction [10], with potential applications also to pure aortic regurgitation [11], and the minimization of microembolization, [6] despite the need of post-dilation in more cases than with other devices (especially the Sapien device, Edwards, Irvine, CA). [12]

We hereby expand the still limited evidence base on transfemoral implantation of the ACURATE device by reporting on a complication we faced when implanting transfemorally an ACURATE device at the beginning of our experience with this device, but when our expertise with TAVR was already established (more than 200 cases performed with the CoreValve device, Medtronic, Minneapolis, MN, USA). Indeed, despite the purported lower risk of paravalvular leak, thanks to the PET skirt, we had to face an acute and massive aortic regurgitation. We successfully managed this with the sequential use of the balloon pull and lasso techniques, finally achieving a significant reduction in the severity of aortic regurgitation. Indeed, our remedial actions originally expand those established already with other devices, and thus may prove useful also when performing TAVR with devices which are similar but not identical, or even altogether different, from the ACURATE. [9,13–15]

Of course, the limitations inherent to the present case report should also be borne in mind, and other strategies, either preventative or therapeutic, could be envisioned to minimize or solve lowermost implantation of an ACURATE device complicated by massive aortic regurgitation. In particular, prevention of such occurrence should always be favored as even more established remedial actions (e.g. post-dilation) can be associated with life-threatening complications (e.g. annulus rupture). [13] In addition, given the peculiarities of the procedure, only small parts of it were actually filmed and archived in cineangiography, and thus the provided Videos highlight only some of the key procedural steps.

In conclusion, lowermost deployment of an ACURATE device can be complicated by massive aortic regurgitation. Use of the balloon pull and lasso techniques can be beneficial and substantially improve paravalvular leak. Awareness of this complication and

the possible use of these two techniques may increase the safety and efficacy of TAVR with this and other new devices.

REFERENCES

1. Makkar RR, Fontana GP, Jilaihawi H, Kapadia S, Pichard AD, Douglas PS, Thourani VH, Babaliaros VC, Webb JG, Herrmann HC, Bavaria JE, Kodali S, Brown DL, Bowers B, Dewey TM, Svensson LG, Tuzcu M, Moses JW, Williams MR, Siegel RJ, Akin JJ, Anderson WN, Pocock S, Smith CR, Leon MB, PARTNER Trial Investigators. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. N Engl J Med 2012;366: 1696–1704.
2. Kodali SK, Williams MR, Smith CR, Svensson LG, Webb JG, Makkar RR, Fontana GP, Dewey TM, Thourani VH, Pichard AD, Fischbein M, Szeto WY, Lim S, Greason KL, Teirstein PS, Malaisrie SC, Douglas PS, Hahn RT, Whisenant B, Zajarias A, Wang D, Akin JJ, Anderson WN, Leon MB, PARTNER Trial Investigators. Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med 2012;366:1686–1695.
3. Adams DH, Popma JJ, Reardon MJ, Yakubov SJ, Coselli JS, Deeb GM, Gleason TG, Buchbinder M, Hermiller J Jr, Kleiman NS, Chetcuti S, Heiser J, Merhi W, Zorn G, Tadros P, Robinson N, Petrossian G, Hughes GC, Harrison JK, Conte J, Maini B, Mumtaz M, Chenoweth S, Oh JK, US. CoreValve Clinical Investigators. Transcatheter aortic-valve replacement with a self-expanding prosthesis. N Engl J Med 2014;370:1790–1798.
4. Biondi-Zoccai G, Peruzzi M, Abbate A, Gertz ZM, Benedetto U, Tonelli E, D'Ascenzo F, Giordano A, Agostoni P, Frati G. Network meta-analysis on the comparative effectiveness and safety of transcatheter aortic valve implantation with CoreValve or Sapien devices versus surgical replacement. Heart Lung Vessel 2014;6:232–243.
5. Agarwal S, Tuzcu EM, Krishnaswamy A, Schoenhagen P, Stewart WJ, Svensson LG, Kapadia SR. Transcatheter aortic valve replacement: Current perspectives and future implications. Heart 2015;101:169–177.
6. Erdoes G, Huber C, Basciani R, Stortecky S, Windecker S, Wenaweser P, Carrel T, Eberle B. The self-expanding Symetis Acurate does not increase cerebral microembolic load when compared to the balloon-expandable Edwards Sapien prosthesis: A transcranial Doppler study in patients undergoing transapical aortic valve implantation. PLoS One 2014; 9:e108191
7. Möllmann H, Diemert P, Grube E, Baldus S, Kempfert J, Abizaid A. Symetis ACURATE TF^{TM} aortic bioprosthesis. EuroIntervention 2013; 9:S107–S110.
8. Maeda K, Kuratani T, Torikai K, Mizote I, Ichibori Y, Onishi T, Nakatani S, Sakata Y, Toda K, Sawa Y. New self-expanding transcatheter aortic valve device for transfemoral implantation-early results of the first-in-Asia implantation of the ACURATE Neo/TF(TM) system. Circ J 2015; 79:1037–1043.
9. Laborde JC, Brecker SJ, Roy D, Jahangiri M. Complications at the time of transcatheter aortic valve implantation. Methodist Debakey Cardiovasc J 2012;8:38–41.
10. Camboni D, Holzamer A, Flörchinger B, Debl K, Endeman D, Zausig Y, Maier LS, Schmid C, Hilker M. Single institution experience with transcatheter valve-in-valve implantation emphasizing strategies for coronary protection. Ann Thorac Surg 2015; 99:1532–1538.
11. Wendt D, Kahlert P, Pasa S, El-Chilali K, Al-Rashid F, Tsagakis K, Dohle DS, Erbel R, Jakob H, Thielmann M. Transapical transcatheter aortic valve for severe aortic regurgitation: Expanding the limits. JACC Cardiovasc Interv 2014;7:1159–1167.
12. Kempfert J, Meyer A, Kim WK, Van Linden A, Arsalan M, Blumenstein J, Möllmann H, Walther T. Comparison of two valve systems for transapical aortic valve implantation: A propensity score-matched analysis. Eur J Cardiothorac Surg, in press.
13. Nombela-Franco L, Barbosa Ribeiro H, Allende R, Urena M, Doyle D, Dumont E, Delarochellière R, Rodés-Cabau J. Role of balloon postdilation following trancatheter aortic valve implantation. Minerva Cardioangiol 2013; 61:499–512.
14. Ussia GP, Barbanti M, Sarkar K, Aruta P, Scarabelli M, Cammalleri V, Immè S, Pistritto AM, Gulino S, Mulè M, Deste W, Cannata S, Tamburino C. Transcatheter aortic bioprosthesis dislocation: Technical aspects and midterm follow-up. EuroIntervention 2012; 7:1285−1292.
15. Sheiban I, Infantino V, Bollati M. Buddy balloon to deliver a percutaneous aortic valve device: A percutaneous shoehorn? Catheter Cardiovasc Interv 2009;74:805–807.