CoreValve Dislocation
Breaking the Wave of Enthusiasm?

Philipp Kahlert, MD; Holger Eggebrecht, MD, FESC; Raimund Erbel, MD, FESC

The natural history of all substantial innovative medical procedures generally follows the same archetype. A new, potentially revolutionary treatment approach for a certain disease is introduced and initial first-in-men, feasibility, and safety studies are conducted by expert operators in highly specialized centers and selected patients. Given promising initial results, this triggers a wave of mounting enthusiasm and a flurry of activity in this field with transfer into the real world until previously unanticipated or not reported problems or complications are recognized that may act as wavebreakers, resulting in a deceleration or even decline in the stream of exuberance. Such complications usually lead to a change of mood and a state of reconsideration with calls for caution and for training programs, the enthusiasm settling down to a healthy, realistic steady state. Necessarily, problems are addressed and techniques refined, taking the procedure to the next, matured level.

This archetype may be readily transferred to the setting of transcatheter aortic valve implantation (TAVI). Being a revolutionary approach for the treatment of severe aortic valve stenosis by offering—for the first time—a definite, catheter-based interventional treatment option for nonsurgical and high-risk patients, TAVI has jubilantly entered the clinical arena in an unprecedented fashion. Introduced only recently in 2002 in France with the first implantation in Germany in 2005, feasibility, safety, and efficacy of this novel technique have been demonstrated first for the balloon-expandable (Edwards Sapien, Edwards Lifesciences Inc, Irvine, Calif) and a little later for the self-expandable (Medtronic CoreValve, Medtronic, Inc, Minneapolis, Minn) bioprosthesis. Meanwhile, both devices are commercially available in Europe, and an ever-increasing number of patients are being treated with these devices with remarkable clinical results. Just recently, the superiority of transfemoral TAVI over optimal medical therapy including adjunct balloon aortic valvuloplasty has been strikingly proven for the balloon-expandable prosthesis in the multicenter, randomized clinical Placement of Aortic Transcatheter Valves (PARTNER) trial, showing a compelling number of only 5 patients needed to be treated to prevent 1 death within the first year. Given these results, TAVI is already established in the armamentarium for treating nonsurgical patients with severe aortic stenosis and anticipated to continue its ride on the wave of enthusiasm in the future.

Nevertheless and despite all exuberance, it must not be forgotten that TAVI is a very complex and technical demanding interventional procedure requiring high catheter skills and training. In addition, it has also to be cautiously noted that TAVI still is a nascent technology with only 2 commercially available devices in their early generations.

At present, the most important challenge during the TAVI procedure is to achieve an exact valve positioning within the native aortic valve annulus, which is fundamental for procedural success and optimal outcome. This crucial step, however, is currently aggravated by the impossibility to reposition or even retrieve the stent valve once deployed. The Edwards valve is implanted using balloon inflation under rapid right ventricular burst pacing in a single-shot fashion, whereas implantation of the Medtronic CoreValve prosthesis is performed stepwise under monitoring with multiple small-volume aortic root angiograms. During deployment, the catheter system must be pulled back constantly to achieve an optimal position at the desired landing zone because the prosthesis is basically pushed out of its constraining capsule for ≈5 cm during unsheathing, thereby moving toward the ventricle because of its tendency to occupy the largest space available. This may either lead to a too-deep position when not pulled back enough, resulting in an increased rate of novel pacemaker implantation as well as significant aortic regurgitation or to dislocation of the prosthesis in the ascending aorta when pulled too hard or when the valve is ejected from the annulus as a result of frequent premature ventricular beats; this description already points to the need for experience, advanced catheter-skills, and intensive training.

In the enthusiasm for TAVI, such technical device shortcomings and associated complications are sometimes forgotten. Therefore, the courageous report of such a complication by Geißbüscher et al in this issue of Circulation: Cardiovascular Interventions is important and timely, serving as a wave-breaking word of caution. In this retrospective study, the authors evaluate the incidence and management of periprocedural CoreValve dislocation into the ascending aorta in a population of 212 consecutive patients treated by a surgical team at a high-volume German TAVI center using both valve types. Observing an incidence of 10%, they show that this complication is frequent. Additionally demonstrating that valve dislocation is associated with an increased risk for...
other peri-interventional complications and also for death, they also show that it should not to be taken with a pinch of salt, but seriously.

To begin with, the authors report the following rescue strategies in case of dislocation: As long as the prosthesis is only partially deployed, it can usually be withdrawn into the access sheath and retrieved, then reccrimped, reloaded, and again implanted. As demonstrated by Geisbüsch et al, this rather standard maneuver is possible in most patients. However, it should be noted that there also are rare cases of failure, for example, if a rather steep aortic arch impedes retraction of the partially released prosthesis into the descending aorta, and that there might be at least the theoretical risk of aortic dissection. When dislocation occurs once the prosthesis is fully deployed, the dislodged prosthesis should be retracted using a snare catheter, and a second prosthesis should be implanted in the native annulus after placement of the dislodged valve within the ascending aorta (“in-series valves”) or in even more distal parts such as the descending aorta.

The report by Geisbüsch et al also shows that these interventional rescue strategies fortunately are successful in the majority of cases (95%), at least acutely. However, data on mid- and long-term outcome are sparse, and some questions remain unanswered, such as the issue on the duration of antiplatelet therapy after implantation of 2 valves in the same or near the same anatomic position, which prolongs the time for endothelialization.13

On the contrary, the authors clearly demonstrate that these rescue interventions—though feasible—are not only challenging, time-consuming, and require special expertise, but are also associated with an increased risk for other peri-interventional complications such as renal failure and also for an adverse patient outcome, with 30-day-mortality being markedly increased in patients with CoreValve dislocation than in patients without (9.9% versus 21.5%, P=0.024).

Hence, prevention of dislocation is of utmost importance. Geisbüsch et al highlight the following anatomic and procedural risk factors for dislocation: a mismatch between native annulus and prosthesis size, specifically the use of an undersized valve; an unfavorable anatomy such as a horizontal off-take of the aortic root from the left ventricle; insufficient valvular calcification as found in 1 patient with isolated aortic regurgitation, raising the question of patient selection and indication; the occurrence of frequent premature ventricular beats during implantation, which may lead to ejection of the valve from the native annulus as a result of postextrasystolic potentiation of the ventricular contraction; a too-short duration of rapid pacing during postdilatation; and inadvertent delivery device retraction. In addition, the degree of subvalvular septal hypertrophy may also be taken into account, favoring implantation of the balloon-expandable stent valve.

Consequently, dislocation may be prevented by the following strategies: A careful patient selection with exclusion of patients with an unsuitable anatomy for CoreValve implantation identified by meticulous and precise preinterventional screening using computed tomography and echocardiography, the use of slow right ventricular pacing at 100 to 140 min⁻¹ during stepwise valve release to avoid ejection of the prosthesis from the annulus by ventricular extrasystoles, a sufficiently long period of rapid right ventricular burst pacing during postdilatation in case of insufficient expansion, and careful observance whether both hinges are detached from the delivery catheter before retraction. Not surprisingly, operator experience is also important to prevent dislocation, as indicated by the learning curve described by Geisbüsch et al. The authors observed no dislocation in their proctored cases, followed by a 12% dislocation rate in their first, 10% in their second, and only 3% in their third year. These data point to the need for a close team approach between experienced interventional cardiologists and dedicated cardiac surgeons, the CoreValve pioneers reporting a dislocation incidence of 3% for comparison.14

The frequent occurrence of valve dislocation and its association with an adverse patient outcome shows us that we are still in a very early stage of TAVI, with only 2 commercial prostheses in their early generations available. It teaches us that valve dislocation must be avoided and should imperatively stimulate future research on increasing safety of the TAVI procedure, presenting a clear plea to the industry to further refine their devices. In the case of the Medtronic CoreValve prosthesis, the difficulty in maintaining a stable position at the desired landing zone has just recently been addressed by a new-generation delivery system (AccuTrak, Medtronic, Inc, Minneapolis, Minn) that promises enhanced control and accuracy for more precise positioning. However, further innovations and developments with particular focus on a repositionable and even retrievable design are even more desired under the assumption that these features provide reliable safeguards for dislocation and malpositioning. First studies of the Sadra Lotus Valve (Sadra Medical, Inc, Los Gatos, Calif) and the Direct Flow Medical percutaneous valve (Direct Flow Medical, Inc, Santa Rosa, Calif) have therefore received major interest,15,16 and many more devices are to come.

In summary, the high incidence of CoreValve dislocation and its relevant clinical implications, presented by Geisbüsch et al in this issue of Circulation: Cardiovascular Interventions, show us that this complication must be taken seriously. Not unlike vascular access site complications in the earlier days of TAVI that resulted not only in an improved patient selection but also lead to the development of transapical and transsubclavian TAVI as well as to a refinement of devices by a relevant profile reduction, device dislocation clearly presents another wave-breaker, propelling the need for further improvement of this young technology. Moreover, particular training and a team approach between interventional cardiologists and cardiac surgeons are needed to provide safe and optimal patient care. Nevertheless, water will always find its way. TAVI has already proven its value as a substantial armamentarium in the treatment of severe aortic valve stenosis. Addressing current limitations, the enthusiasm for TAVI will continue to flow on an even higher, matured level. With further technical refinements and development of next-generation devices featuring repositionability and retrievability, it is most likely that—with increasing safety—this catheter-based, interventional procedure will indeed broaden
its way toward application in younger, lower-risk patients, as widely anticipated.

**Disclosures**

Dr Eggebrecht is a clinical proctor for Edwards Lifesciences, Inc, and Medtronic, Inc.

**References**


6. Kahlert et al. CoreValve Dislocation


12. Kahlert et al. CoreValve Dislocation


15. Kahlert et al. CoreValve Dislocation


17. Kahlert et al. CoreValve Dislocation


20. Kahlert et al. CoreValve Dislocation


CoreValve Dislocation: Breaking the Wave of Enthusiasm?
Philipp Kahlert, Holger Eggebrecht and Raimund Erbel

doi: 10.1161/CIRCINTERVENTIONS.110.959692

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circinterventions.ahajournals.org/content/3/6/523

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation: Cardiovascular Interventions can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation: Cardiovascular Interventions is online at:
http://circinterventions.ahajournals.org//subscriptions/