JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 9, NO. 7, 2016

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER

Letters

TO THE EDITOR

New Less Invasive Approach for Direct Aortic Transcatheter Aortic Valve Replacement Using Novel CoreVista Transcervical Access System

We report the results of a first-in-man application of a newly developed approach for direct aortic (DA) transcatheter aortic valve replacement (TAVR) using a novel device system (CoreVista, CardioPrecision Ltd., Glasgow, United Kingdom) designed to provide access to the ascending aorta from a short transverse incision in the neck.

DA-TAVR is currently emerging as a valid alternative in patients who are not eligible for the less invasive transfemoral (TF) approach. However, similar to the transapical approach, it is harnessed by the drawbacks related to the trans-sternal surgical access, which increases hospital length of stay and possible complications, jeopardizing its potential advantages over other techniques.

This new technology finds its inspiration in the experience with transcervical thymectomy, a procedure allowing complete thymus gland resection within a regimen of same- or next-day discharge with an exceptional reduction in post-procedure recovery time and risk/severity of complications compared with the traditional median sternotomy approach (1). The feasibility of the transcervical DA approach was first tested in a human cadaveric model and, after adequate validation of and training on this model, first-in-man procedures were performed.

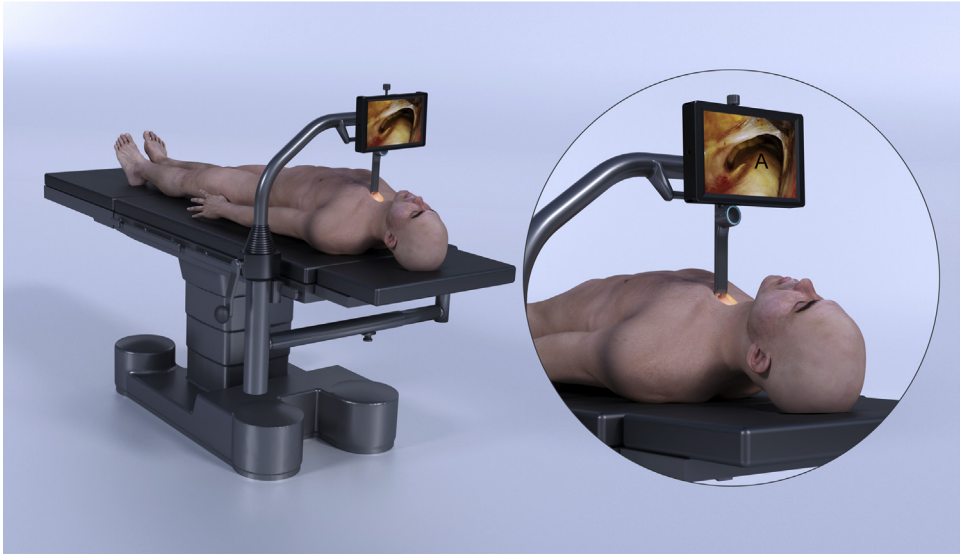
Two patients with symptomatic isolated aortic stenosis (Society of Thoracic Surgeons risk: 11.2% and 6.7%) were selected to undergo TAVR using the new DA approach. Written informed consent was obtained. Routine TAVR pre-operative work-up was performed.

The CoreVista device system comprises a lifting frame that affixes to the catheterization laboratory/surgical table, a small retractor equipped with a set of lights to illuminate different zones of the operating field in step with the procedure, and a high-definition monitor that is positioned above the incision in the line of sight of the operator for optimal visualization during the procedure (**Figure 1**). With the patient under general anesthesia for a brief period, a short transverse incision was made in the skin crease of the neck, the retractor portion of the device was introduced, and the manubrium was elevated. Using the programmed sequential illumination system, superficial tissues were mobilized, and fatty remnants of the thymus gland in close relation to the left brachiocephalic vein were dissected and/or mobilized to display the pericardium, which was then opened to expose the entire ascending aorta (**Figures 2A and 2B**). A suitable entry point was identified, and DA-TAVR was performed in conventional fashion under fluoroscopy (**Figures 2B and 2C**) using a 26-mm CoreValve self-expanding prosthesis (Medtronic Inc., Minneapolis, Minnesota). The wound was then closed, and valve performance was assessed using transesophageal echocardiography (**Figure 2D**).

Primary outcomes were evaluated according to the latest Valve Academic Research Consortium-2 criteria (2). TAVR was successful in both patients, with the absence of procedural or periprocedural mortality, and with correct positioning of a single valve prosthesis in the proper anatomic location and intended performance of the prosthetic heart valve (no prosthesis-patient mismatch, mean aortic valve gradient of 7 and 4 mm Hg, and valve area of 1.45 and 1.60 cm^2, respectively, with no aortic regurgitation in either case). The patients were extubated on the table. No periprocedural myocardial infarction, stroke, acute kidney impairment, or other complication occurred. Patients experienced only minor discomfort from the neck wound and required acetaminophen analgesia only. Patients were mobile early and were discharged in sinus rhythm on days 2 and 3 after intervention without a pacemaker. Dyspnea and functional status progressively improved with no symptom recurrence. Echocardiographic re-evaluation at 30 days demonstrated no change in valve position, mean aortic valve gradient of 9 and 7 mm Hg, and valve area of 1.78 and 1.31 cm^2, respectively, with no aortic regurgitation in either case.

The small retractor device with built-in illumination system allowed easy access and visualization of the ascending aorta for TAVR to be performed. High-definition on-screen visualization of the field provided much-enhanced visualization of the aorta and

FIGURE 1 CoreVista Transcervical Access System (CardioPrecision Ltd.)



Exposure of the ascending aorta (A) for transcervical direct aortic transcatheter aortic valve replacement.

related structures, allowing safe aortic exposure to be achieved.

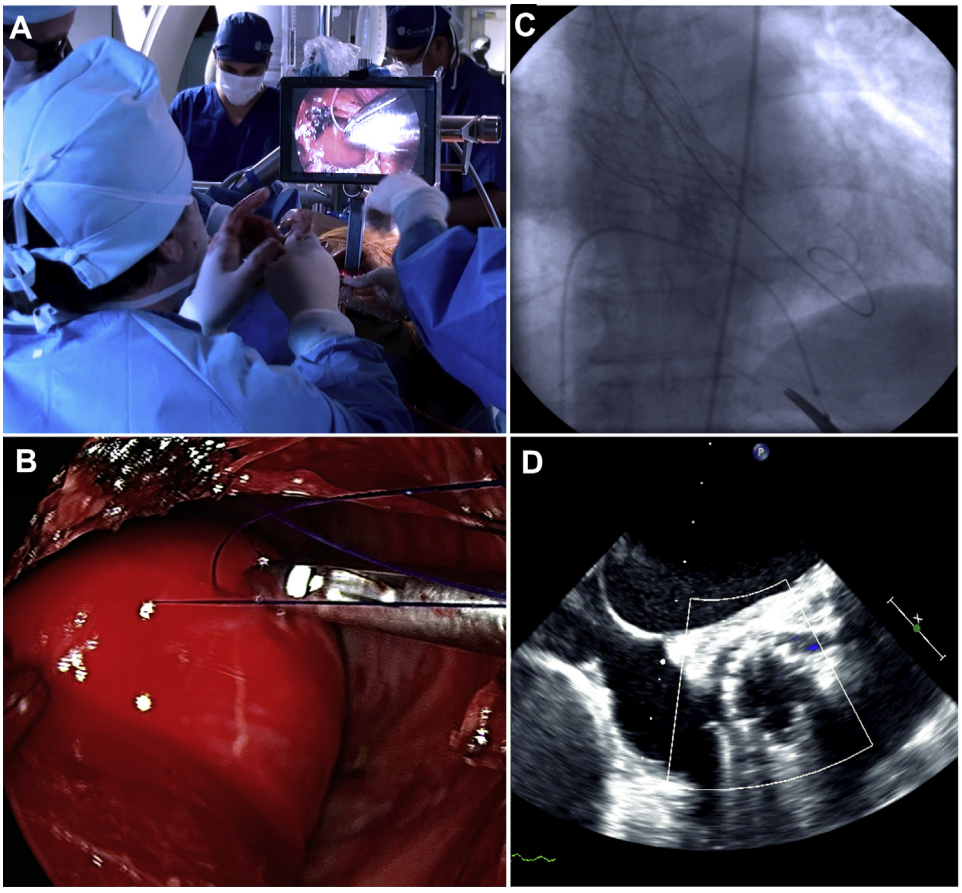
Recently, Kiser et al. (3) described a suprasternal approach enabling TAVR without direct chest access. This technique exploits principles of mediastinoscopy to obtain access to the aorta or brachiocephalic artery via a device that is advanced into the mediastinum from the neck underneath the innominate vein and provides a working lumen for the surgeon to perform TAVR. However, the actual aorta was accessed in only 1 of 4 procedures, these procedures being performed via the brachiocephalic artery. Conversely, our approach relies on the combination of sternal elevation and tailored illumination, thereby providing space and exposure for actual deep dissection of pre-tracheal planes under high-definition visualization beyond the level of the brachiocephalic artery to the ascending aorta. Placement of aortic purse strings, aortic catheter insertion, and other steps of the standard DA-TAVR procedure are therefore greatly facilitated by this new device with good access for control of bleeding in case of complications.

The technique described here is considered suitable for all devices currently on the market that are configured for transfemoral delivery, including the SAPIEN, Evolut R, Portico, Symetis, JenaValve, Lotus, and DirectFlow devices, thus permitting device and delivery route to be tailored precisely to individual patient pathology and physician device preferences.

Interestingly, the transcervical route would also be amenable to the increasingly frequent category of post-coronary artery bypass graft procedures, as it overcomes concerns raised in the published data about potential graft injury during sternal re-entry in standard DA-TAVR (4), being centered on a suprasternal dissection and a progressive careful exposure of the ascending aorta from the thoracic inlet.

Clearly, this was a feasibility study comprising 2 cases and a single operator experience, and despite the encouraging results, more confirmatory data are needed to assess the effectiveness of this approach in clinical practice. Nevertheless, the prospect of a procedure that circumvents chest disruption or trans-sternal access, enabling a rapid recovery and a same- or next-day discharge clinical pathway, would constitute a revolutionary advancement in the treatment of aortic valve disease, reinvigorating the potential for TAVR to be a single-day procedure for all patients. Indeed, by also embracing the emerging minimalist policy in the post-operative management of TF-TAVR, which aims to turn TAVR into a single-day procedure (5), transcervical DA-TAVR might become a valid ally of TF-TAVR in unsuitable patients. Their combination might allow a dramatic reduction in length of stay and perioperative costs in the most challenging patients, rendering the procedure financially competitive to surgical AVR and therefore viable also in low-risk patients. Indeed, transcervical DA-TAVR might be considered an equivalent of TF-TAVR

FIGURE 2 Transcervical DA-TAVR Procedural Steps



(A) Exposure of the ascending aorta via a transcervical incision; accurate anatomic exposure is greatly facilitated by on-screen visualization. The aorta is seen in the center of a high-definition screen. **(B)** Precise placement of purse-string sutures at an optimally selected entry point in the aorta for transcervical direct aortic transcatheter aortic valve replacement (DA-TAVR); instruments are easily manipulated and clearly visualized on the screen. **(C)** DA-TAVR performed under fluoroscopic guidance. **(D)** Transesophageal echocardiogram of the implanted CoreValve prosthesis (Medtronic).

in terms of clinical management and post-operative care, but applied in cases of unfavorable peripheral vascular anatomy. This would circumvent the major drawbacks of the currently available alternatives to TF access, such as the transcarotid or trans-subclavian route, which have similar limitations related to peripheral vascular disease and unsuitable vascular access.

We truly believe that the transformation of DA-TAVR into a sternotomy/thoracotomy-free procedure will allow new avenues in the clinical management of aortic valve disease and in the selection of the most adequate approach during a TAVR workup, realizing the potential for TAVR to be a single-day procedure for all patients and therefore financially viable for all patients requiring aortic valve replacement.

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http://dx.doi.org/10.1016/j.jcin.2016.01.035

Please note: This study was sponsored by CardioPrecision Ltd. Dr. Dapunt and Dr. Luha are based at the Medical University of Graz, Austria. Dr. Dapunt is a consultant and proctor for Medtronic and Livanova. Dr. Sutherland receives consulting fees and holds stock in CardioPrecision Ltd. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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Immediate Invasive Strategy for Patients With Both New Ischemic Electrocardiographic Changes and Troponin Elevation

We read with great interest the recent publication by Milosevic et al. (1) on the RIDDLE-NSTEMI (Randomized Study of Immediate Versus Delayed Invasive Intervention in Patients With Non-ST-Segment Elevation Myocardial Infarction) trial, and we congratulate the investigators on their important contribution to clarify the optimal timing of invasive management in non-ST-segment elevation acute coronary syndromes (NSTEACS). They conclude that an immediate (<2 h) is superior to a delayed (2 to 72 h) invasive strategy at mid-term follow-up, mainly because of a decrease in the risk for new myocardial infarction before catheterization. Certainly, though guidelines recommend early invasive management, how early it must be according to patient characteristics within the wide spectrum of NSTEACS remains a matter of controversy. Indeed, the results of RIDDLE-NSTEMI could modify clinical practice, performing early cardiac catheterization. This policy might entail logistic constraints for many institutions and health care systems. The very low rate (3%) of patients with nonsignificant coronary stenosis found in RIDDLE-NSTEMI, however, is unusual. For example, in the ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) trial, including moderate- and high-risk NSTEACS, the rate of nonobstructive coronary artery disease was 8.8% (2). Furthermore, the introduction of high-sensitivity troponins has increased the number of procedures under the suspicion of NSTEACS as well as the number of patients with troponin elevation and normal angiographic results, which could be as high as 20% (3,4). The final diagnosis of these patients is challenging, but probably many of them do not actually have NSTEACS (5). In the high-sensitivity troponin era, the indiscriminate implementation of the RIDDLE-NSTEMI conclusions might trigger unnecessary very early catheterization, which will probably translate into a spurious benefit in terms of ischemic events. In our opinion, Milosevic et al. should underscore the selective inclusion criteria of their study; enrolled patients required both new ischemic electrocardiographic changes and troponin elevation. What differentiates RIDDLE-NSTEMI from other trials is the approximate 80% rate of new ST-segment depression and 20% rate of new T-wave inversion in its population. Therefore, to clarify the message, the conclusions of the study should be modified to state that in patients with NSTEACS with both new ischemic electrocardiographic changes and troponin elevation, the policy of immediate invasive management is superior to a delayed invasive strategy.

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http://dx.doi.org/10.1016/j.jcin.2016.01.019

Please note: This work was supported by the Ministry of Economy and Competitiveness through the Carlos III Health Institute: RETICS RD12/0042/0010, FEDER; Health Research Fund FIS PI 11/01595. The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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