

Transcervical Aortic Valve Surgery: The Least Invasive Option

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INTRODUCTION

Continued pressure for optimization of clinical outcomes in cardiac surgical patients and for a cost-effective management of their postoperative care, has fostered in the recent years ever increasing interest for Minimally Invasive Approaches (**MIS**) and given new impulse to the development of alternative strategies aimed at obtaining better outcomes in terms of length of hospital stay, recovery and return to work activities for cardiac procedures. On the surgical front, inspired by the revolutionary results of laparoscopic procedures in general surgery, which basically determined a transformation in the management of several interventions into a day surgery practice, several surgeons attempted to propose alternative strategies to perform valve or coronary surgery avoiding massively invasive incisions of sternotomy or thoracotomy. For Surgical Aortic Valve Replacement (**SAVR**) initial attempts to avoid median sternotomy were proposed in the early 90's by Cosgrove and Sabik who described a parasternal approach [1]; then in 1998 by Gundry and colleagues described a partial sternotomy in a reverse 'J' fashion

from the sternal notch into the 4th right intercostal space, later modified [2]. More recently, a 5-7cm Right Anterior Thoracotomy (**RAT**) in the line of the ribs has been proposed to achieve access to the aortic valve without splitting the sternum [3] with encouraging results [4]. However, meta-analysis of studies comparing conventional and MIS approaches despite showing a general improvement in clinical outcomes such as mortality, complication rates and blood loss [5,6], failed to reveal a major impact on the outcome variables reflecting actual early recovery from surgery, such as hospital Length of Stay (**LOS**) or Intensive Care Unit (**ICU**) stay [7,8] and did not reproduce the revolutionary achievements of laparoscopic surgery in terms of patient recovery, hospital stay and complication rate.

In parallel, on the interventional cardiology front, Transcatheter Aortic Valve Replacement (**TAVR**) is continuously achieving more and more consensus with progressive expansion of its indications, technological advancements and reduction in complication rates and postoperative management [9,10]. From the invasiveness standpoint, TAVR, especially if performed via Transfemoral (**TF**) access, seems to represent a clearly less invasive approach to SAVR by avoiding any kind of chest disruption. Additionally, a prospect of day-case or next-day discharge has been shown to be achievable in around 20% of patients undergoing TAVR in Europe with concomitant economic benefits [11]. In North America, the 3M TAVR Study (Multidisciplinary, Multimodality, but Minimalist Approach to Transfemoral Transcatheter Aortic Valve Replacement) is currently recruiting patients to test the feasibility and efficacy of next day discharge [12]. Early results from next day discharge using this methodology have been encouraging [13]. Furthermore, the concept of minimalist approach is progressively affirming as demonstrated by recent trials [14-16].

However, TAVR is still harnessed by a number of drawbacks and complications mainly related to paravalvular leaks, high rate of atrio-ventricular blocks requiring pace-maker implantation, stroke and, specifically for TF approaches, major and minor vascular complications with an incidence ranging between 15-25% across studies [17], [18]. These points restrict the widespread application of TF-TAVR and rule out patients with small, tortuous or calcified ileo-femoral vessels, patients with extensive disease of the abdominal aorta, thoracic arch or ascending aorta (in whom manipulation of wires or advancement of stiff catheters may dislodge atheroma) and obese patients where access via the groin may be technically challenging, more prone to haematoma formation and potentially more at risk of endocarditis. Conversely, the other available alternatives for TAVR access, namely the Transapical (**TA**) and Direct Aortic (**DA**) approaches, are hurdled by ventricular puncture-related complications [19] and share the same range of drawbacks related to major incisions of the sternum or lateral chest wall [20].

Against this background, a novel access to aortic structures which completely avoids median sternotomy or chest disruption has been conceived and developed. The aim of this novel technology is to unify the conventional surgical and interventional options for aortic valve replacement by providing a common pathway for the two approaches to be performed in a controlled and truly

minimally invasive fashion, according to patient's characteristics and eliminate complications associated with current state of the art for 'least invasive SAVR' and 'least invasive TAVR'. Indeed, the new route provides access to the aortic valve by the upper thoracic inlet to the mediastinum by means of a specifically designed device, the CoreVista® system (CardioPrecision Ltd, UK) which combines an action of sternal elevation and a tailored sequenced illumination, enabling an effective visualisation of mediastinal structures on a High Definition (**HD**) monitor. This system provides exposure, visualization, surgical access and space for manoeuvre to comfortably perform surgical procedures on the aorta, related anatomical structures and aortic valve. This approach has been proved to be suitable for both Surgical Aortic Valve Replacement (**SAVR**) and Transcatheter Aortic Valve Replacement (**TAVR**) constituting a radically less invasive access route for aortic valve replacement, as providing access to either the intrapericardial or extrapericardial ascending aorta, in accordance to the procedure to be performed. This technique would therefore represent a route to perform alternatively SAVR or TAVR circumventing on a side the drawbacks related to median sternotomy and surgical complications, and on the other the restrictions related to vascular or ventricular access.

DEVELOPMENT OF LEAST INVASIVE APPROACH

The ideal Minimally Invasive Surgical (**MIS**) approach should provide a direct anatomical route to the organ to be addressed with ease of repair or reconstruction of the structures encountered during the surgical access. As an example, the significant consensus and success achieved by minimally invasive right thoracotomy for mitral surgery mainly relies in the anatomical topography and localization of the thoracic access in relation to the mitral valve, which provides a direct view of the target being situated at a relatively short distance from the incision. The angle of view from the thoracotomy access, despite the variability of chest conformation and depth, provides visualization of the valve plane in a straight line, maintaining the geometrical references and the native configuration and symmetry of the structure when imaged with telescopes. In this setting, the length of the minimally invasive instruments would compensate for the distance of the heart in respect to the incision, as the route to the target is not hurdled by oblique angles. Conversely, the median sternotomy approach requires manipulation and rotation of the heart by means of pericardial suspension to achieve an adequate visualization of the valve and the complications related to the sternal incision, as sternal non-union, deep sternal wound infection, post-operative mediastinitis or osteomyelitis are considered the most daunting in cardiac surgery constituting a significant burden on both clinical outcome and resource expenditure [21]. Similarly, an ideal approach to aortic valve should combine ease of access and prevention of access-related complications. On the basis of these demands, we developed an approach enabling an enhanced en face view of the aortic valve, similar to mitral valve in MIS mitral surgery, through a small essentially painless incision in the neck. Importantly, the region of skin access is well circulated area and therefore characterized by fast healing with low risk of wound infection and limited or no analgesic requirement.

The clinical benefits of such approach will be apparent to those surgeons familiar with the general thoracic surgical operation, Transcervical Thymectomy (**TCT**) [22], proposed by Cooper et al in 1988 which aimed to circumvent the complications encountered in the traditional median sternotomy approach for thymectomy, including potential for deep sternal wound complications, chest and respiratory morbidity and bleeding with consequent reflection in prolonged hospital stay [23,24]. Since then, a good amount of evidence has accumulated worldwide on TCT showing not only feasibility and effectiveness, but also improved clinical outcomes with Length of Stay ranging between 1 and 2 days [25-28] and relatively low risk of largely non-serious adverse events such as pleural effusion, wound seroma / other minor wound problem, and simple pneumothorax, all occurring with a cumulative incidence ranging between 2% and 6% [27,29]. The significant stepchange in thymectomy clinical management sensed by Cooper was further developed by Shrager et al. who implemented a protocol to discharge patients on the day of surgery as a routine practice [30]. We therefore hypothesize that adopting the same approach for aortic valve access would potentially reproduce the same clinical outcomes and related benefits for cardiac surgery patients. However, TCT was performed using a simple, unlit retractor with the surgeon wearing a headlight and looking through a small transverse incision in the neck [22], which, despite providing a direct angle of view of the aorta, is inadequate to reach deeper planes and to offer a safe exposure to manipulate the aorta and aortic valve. For these reasons a novel access system has been developed to address the need for an effective illumination inside the chest cavity and adequate visualisation of mediastinal structures (CoreVista®, CardioPrecision Ltd, UK). The device was designed to create a comfortable operating environment for transcervical surgery or cardiovascular interventions to be performed from a seated position through a perfect combination of retraction, illumination and visualisation at every stage of the procedure.

INDICATIONS

The indications for aortic valve replacement are well known [31]. Transcervical route is meant to be utilized in candidates for SAVR, Direct Aortic (**DA**) TAVR, Transapical (**TA**) and TF-TAVR and might be considered as both an alternative or an adjunct in cases of absolute or relative contraindications to these interventions. For example, in the context of SAVR, the increasingly frequent category of post CABG cases might pose daunting conditions and challenging intraoperative issues related to difficulties in re-entry or unexpected injury to venous or arterial grafts lying in front of the aorta. This eventuality hurdles not only full sternotomy standard procedures but also partial sternotomy in the context of direct aortic TAVR [20]. Interestingly, using the transcervical route, which is centred on a suprasternal dissection and a progressive careful exposure of the ascending aorta from above, the chance of encountering previous grafts is expected to be very low. On the other side, TF, DA and TA access for TAVR, is harnessed by major and minor vascular complications, drawbacks associated to partial sternotomy or thoracotomy and issues related to ventricular puncture, respectively, which often affect and invalidate the general outcome of the procedure [32]. Transcervical approach could be similarly applied not

only to TF, but also TA and DA TAVR candidates, circumventing the restrictions and setbacks of these approaches.

As the transcervical route is suitable for both TAVR or SAVR, case selection should focus primarily on (i) the pathology of the aorta and aortic valve and the suitability of SAVR or TAVR to optimally address such pathology and (ii) anatomical considerations regarding access.

In this context, high quality imaging is essential for good case selection, as for TAVR in general. A set of multiple imaging modalities, including 3D transesophageal echocardiography, Multislice CT scan (**MSCT**) and Magnetic Resonance (**MRI**), is affirming as a keystone in every step of aortic valve replacement including the assessment of peripheral vasculature, the aortic root and the annulus [33]. MSCT is considered crucial in this setting as allowing 3D reconstruction and accurate imaging of femoral access, annulus and leaflet calcification, aortic root configuration and, especially for TAVR, permitting decision-making on the best suitable vascular access, preimplantation device selection and sizing and post implantation assessment [34]. Recently, several investigators are highlighting the clinical significance of MRI in this context and the initially suggested use of this technique as a procedural guidance [35] has been translated into reality in some preliminary animal studies [36,37].

In any case, all the described advances developed for TAVR are actually applicable for virtually any other modality of AVR and might provide a valid adjunct for the preoperative planning and postoperative assessment of transcervical procedures as well, and in particular to select the most appropriate technique to be used (SAVR vs TAVR) through this route and the actual suitability of the neck and chest anatomy for the procedure itself.

PATHOLOGY OF THE ASCENDING AORTA, AORTIC VALVE AND OTHER CONSIDERATIONS: SAVR VERSUS TAVR

The different conditions encountered in aortic pathology deserve a careful consideration with regard to the best suitable approach to be adopted. Both surgical and transcatheter techniques can be performed through the transcervical route, but selection of the most appropriate strategy is important to optimize clinical outcomes.

In the common clinical practice, the anatomical findings of patients undergoing AVR often show severely calcified aortic annulus and leaflets. A surgical approach in these cases, enabling an actual excision of the calcified valve leaflets and decalcification of the aortic annulus, permits the implantation of a bioprosthesis with a significant increase in the orifice area. A four-five times increase of the valve area in respect to the preoperative estimated measurement can be obtained, with significant reflex on the aortic hemodynamics. Surgical valve excision and prosthetic replacement indeed result in a substantially greater hemodynamic benefit in comparison to than seen with TAVR prostheses of similar size post implantation, and, especially in patients with heavily calcified native valve, SAVR with sutureless valves enable larger effective orifice

area [38] in comparison with transcatheter valves [39,40], and warrant superior outcomes. Indeed a recent study from Biancari et al. comparing large cohorts of patients undergoing sutureless valve implantation versus TAVR patients matched for age and preoperative clinical characteristics, demonstrated significantly reduced in-hospital mortality, incidence of mild to moderate paravalvular leaks and need for permanent pacemaker in the sutureless group [41]. Similarly, in cases of bicuspidy the choice between SAVR and transcatheter approach should drift towards the surgical option as the anatomical variability and the geometrical constraints of a bicuspid valve are not amenable for TAVR. Additionally extensive calcification [42] and eccentric annulus geometry [43] are considered contraindications to TAVR due to risk of paravalvular leaks and major complication [44-46]. In case of regurgitant valves, often presenting in concomitancy with aortic root dilation, the applicability of the current TAVR devices has several limitations, being mainly designed for the treatment of calcific aortic stenosis, and the transcatheter approach is not recommended [47]. Infective endocarditis is also considered a purely surgical indication, considering the mandatory need for complete excision of infected leaflet tissue. The transcervical route enables a suitable exposure and access to perform a standard SAVR. From our experience implantation of sutureless valve rather than stented conventional prosthesis is recommended for ease and timing of the procedure, but both the valves type can be successfully implanted.

No restrictions to the transcervical approach apply for proper TAVR candidates and in relation to the conventional and novel TAVR indications [48]. Moreover, the transcervical route carries the above-described advantage of avoiding several of the TAVR-related complications.

In this context it is important to consider the eventuality of a porcelain aorta which is a common contraindication for SAVR as impeding a safe aortic clampage and closure of aortotomy demanding for transcatheter approach. However, if a suitable soft spot is identified on preoperative imaging, extensive aortic calcification might become a surmountable hurdle as the transcervical route would allow to switch during surgery according to the actual intraoperative findings and to select the most appropriate strategy.

SUITABILITY FOR TRANSCERVICAL ACCESS

TAVR can probably be performed by the transcervical route in most patients, whatever their anatomy. For SAVR, based upon experience of the transcervical thymectomy operation, females of average build are ideal candidates for the transcervical approach as they have more pliable chest for elevation of sternum and therefore for optimal exposure.

A largely 'vertical' aorta, centred behind the sternum wherein the aortic valve is located 12 cm or less from the proposed cervical incision makes for the easiest exposure for SAVR. However, horizontality of the aorta, more lateral position of the aorta and greater distance of the native valve from the incision are not absolute contraindications.

For SAVR, detailed radiological examination of the aorta from femorals to aortic valve is required for planning cannulation strategy for cardiopulmonary bypass. Despite retrograde perfusion with femoral CPB is generally considered safe and has been recently proposed by Drews et al. as a valid adjunct also in high-risk TAVI patients, normally affected by peripheral vascular disease (70% in the reported study) [49], in case of extensive calcification or intimal flaps retrograde flow is inadvisable. In such case central cannulation can be performed directly into the aortic arch between the origins of the brachiocephalic and left common carotid and the cannula led out of the left side of the wound out of the way of the surgeon.

CONTRA INDICATIONS

Limited neck extension appears to be the main contraindication. Patients weighing over 250 pounds or who are excessively obese are more challenging. However, as is often the case in minimally invasive surgery, these patients arguably have the most to gain from least invasive intervention as they are often even less attractive for open surgical procedures.

Surgical Technique

Transcervical surgical device and special equipment

The CoreVista® Transcervical Access System apparatus (Figure 1) comprises a robust lifting frame that attaches to each side of the operating table; a retractor to be engaged underneath the sternum and equipped with a set of lights sequenced to illuminate different zones of the operative field in step with the surgical procedure, the light sequence being delivered through an optical switch mounted on the rear surface of the retractor; and a High Definition (**HD**) surgical monitor that it is positioned immediately above the incision (behind a sterile cover) in the natural line of sight of the surgeon.

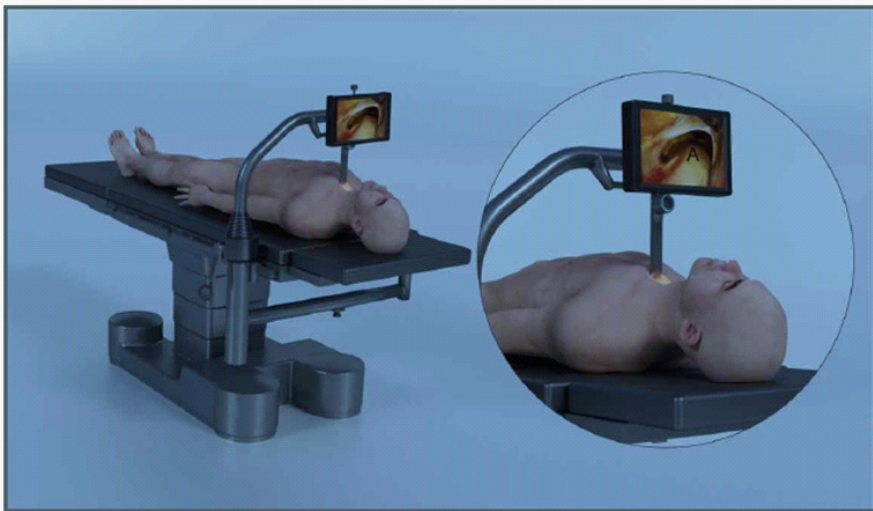


Figure 1: CoreVista® Transcervical Access System (Cardio Precision Ltd, UK). Reprinted from Journal of American College of Cardiology Cardiovascular Intervention Apr 11;9(7), Dapunt OE, Luha O, Ebner A, Sonecki P, Spadaccio C, Sutherland FW, New Less Invasive Approach for Direct Aortic Transcatheter Aortic Valve Replacement Using Novel CoreVista® Transcervical Access System, page 751, doi: 10.1016/j.jcin.2016.01.035. Copyright JACC Cardiovasc Interv (2016), with permission from Elsevier.

This provides the operator with a magnified view of the aorta and related structures in high definition (Figure 2). A 5mm thoracoscope is used to enhance visualisation and the image displayed on the surgical monitor in the direct line of sight of the surgeon for optimal hand-eye coordination.

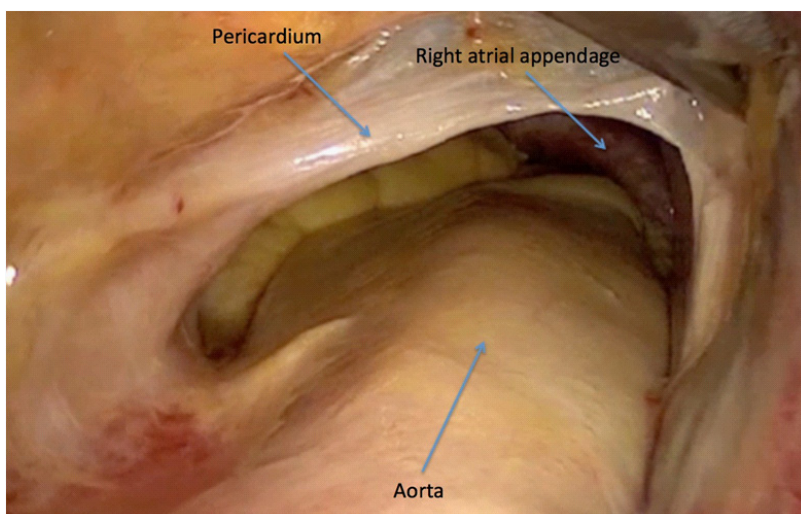


Figure 2: Operator's View of Aorta.

MIS instruments are required. Scanlan International Inc. (St Paul, MN, USA) and Delacroix-Chevalier (Paris, France) provide a range of instruments suitable for MIS cardiac surgery, some based on the original Heart Port mechanism of action. A surgical set should contain at least the following key instruments: transthoracic (Chitwood) clamp, MIS forceps, knife, 11 blades, strongly curved scissors, lightly curved scissors, rongeurs, minimally invasive needle drivers (Ref.9009-640, Scanlan International Inc., St Paul, MN), MIS aortic and venous cannulae, cardioplegia delivery needles and vents (Medtronic Inc, St Paul, MN).

For purse string suture for TAVR and valve guiding / implanting sutures for SAVR, standard length 75 cm sutures are suitable. 90 cm sutures are also available according to individual surgeon preference but are considered unnecessary by the authors. The choice of 16mm or 23 mm needles is also according to individual surgeon preference although paradoxically the larger needle can be easier to use in the restricted space. (see below). A knot pusher is required to tie knots. Alternatively, Corknot device (LSI Solutions, NY, USA) can be used to reduce time taken to tie.

Operating Room Setup

For SAVR, the operating room setup comprises the CoreVista® Transcervical Access System (Cardio Precision Ltd, UK) secured to the operating table and the theatre personnel organized in order to have the surgeon at the head of table and the assistant on his left side. Ventilator and anaesthesiologist stand aside of the surgeon with eventual second assistant at the top left of the table. Scrub nurse and instruments table are conveniently located at the right side of the patient, while perfusion machine and its operator are situated along the left side of the patient with the aim to allow ample space of manoeuvre around the patient's right side for unobstructed passage of instruments from scrub nurse to surgeon and vice versa or, in the case the surgeon needs to rapidly move to convert the procedure in a full median sternotomy, the operator has free access to the patient's right side. In fact, in-built safety feature of the system allows the retractor to be swiftly removed and lifting apparatus swung easily out of the way for conventional access (Figure 3).

For TAVR, the setup is essentially the same. The C arm is brought into the field from the left side and the principal operators (cardiologist and cardiac surgeon) stand at the head of the table.

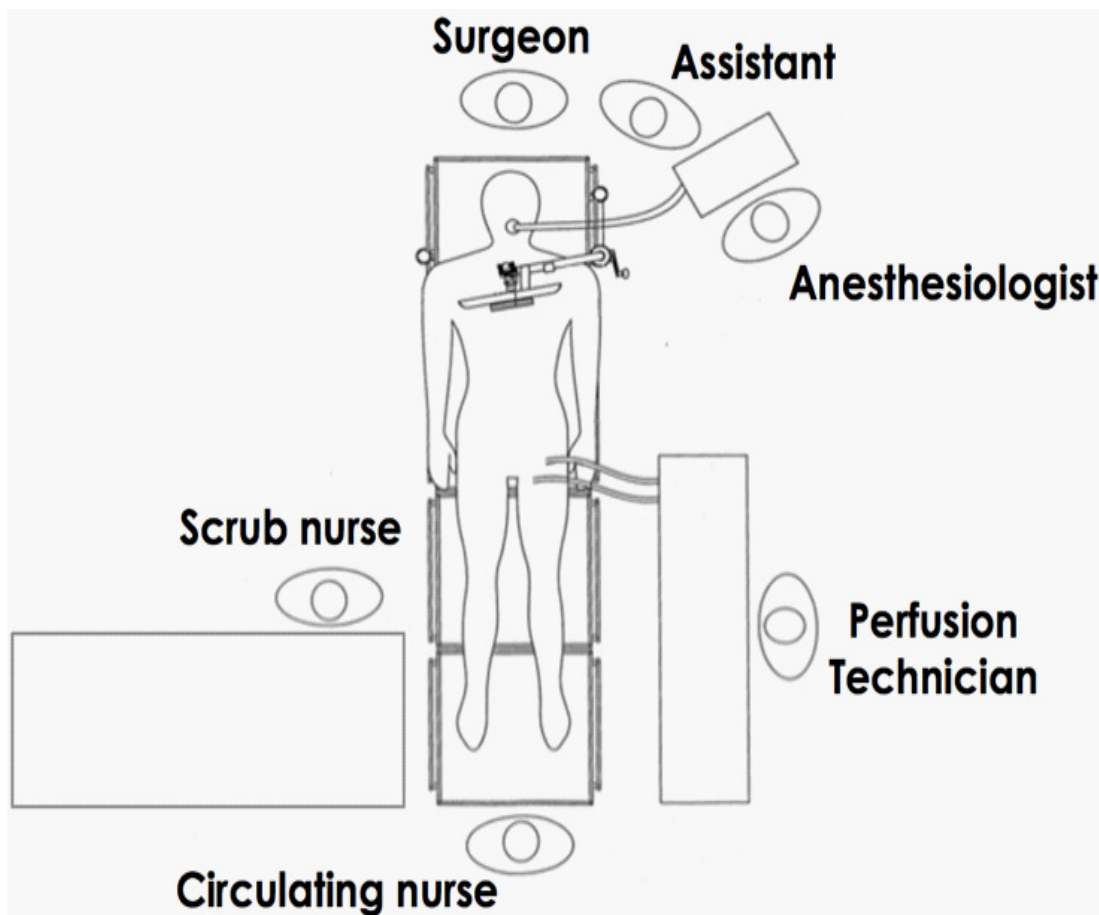


Figure 3: Operating Room Setup.

Surgical Steps and Procedure

The procedure is normally carried out under general anaesthesia and endotracheal intubation. After patient positioning and prepping a skin crease incision is performed in the neck about 2 cm above the sternal notch (Figure 4).

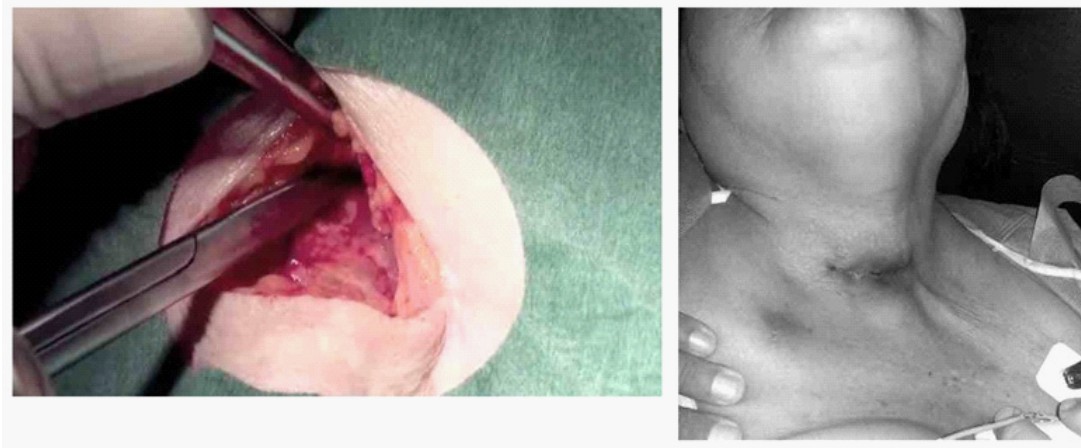


Figure 4: Location of Incision.

Recognition of anatomical landmarks is important to obtain an adequate access without risk of injuring important structures. Initial mobilization of the soft tissue is performed, and the retractor system engaged underneath the sternum (Figure 5).

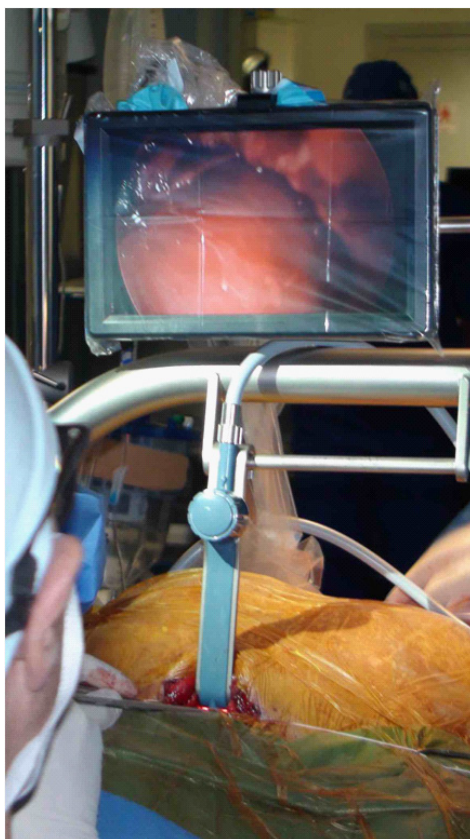


Figure 5: CoreVista® Retractor *in situ*.

Initial dissection is then directed under the sternum, identification of strap muscles attaching to posterior surface of sternum is important and dissection should be carried out staying above them to protect left brachiocephalic (innominate) vein. The thoracoscope is introduced and progressively advanced into the wound providing direct vision to the HD monitor embedded in the CoreVista® system. The telescope is secured in position with an extra arm frame with an angle parallel to the main direction towards aorta and digital zoom is then used to augment visualization during the procedure. Pericardium is opened where it is reflected off the ascending aorta caudal to the left brachiocephalic vein. This reflection can be immediately inferior to the vein or up to 4 cm beyond the lower margin of the vein but is usually much closer and is optimally opened with scissors rather than cautery. It is possible to dissect free the innominate vein and obtain access both anteriorly and posteriorly going below the vein. However, it should be considered that, especially if performing the procedure on cardiopulmonary Bypass (**CPB**), the innominate vein will collapse, and would normally tend to hang down across the operative field. Therefore, it is advisable to work anterior to the vein. Pericardium should be opened with scissors and the incision extended to left and right to expose the ascending aorta using the sequenced illumination and HD visualisation provided by the device. Pericardium will be held up by attachment to posterior surface of the sternum. If performing SAVR on CPB, a purse string suture is placed in the ascending aorta using minimally invasive instruments for insertion of a long cardioplegia delivery cannula and instillation of cold blood cardioplegia. Insertion site should be the same of future aortotomy. Cardiopulmonary Bypass (**CPB**) is established by femoro-femoral cannulation and aorta is cross-clamped using transthoracic (Chitwood) clamp inserted percutaneously at the 3rd intercostal space. Application of the clamp is performed under clear direct vision from the neck, a significant advantage over use of the clamp in mitral procedures. Ventilation should be stopped and clamp passed anterior to the superior vena cava under vision with jaws convex surface oriented cranially i.e. facing the surgeon. The handle of the clamp may be pivoted around the skin port in an upward direction and secured with a silk tie to the frame in order to depress the jaws of the clamp on the aorta and improve access to the aortic root. Cardioplegia is then given through the aortic root, the aorta is incised with long knife and aortotomy transversely extended with MIS scissors. Care should be taken to locate aortotomy high in ascending aorta to avoid complications when closing.

The main pulmonary artery is readily accessible for venting. Alternatively the aorta can be vented through the aortic root. CO₂ may be instilled into the wound according to surgeon preference. However, the authors recommend displacing air from the heart chambers and chest at the end of the valve implant procedure prior to closing the aortotomy.

The native valve is excised and valve sized with appropriate sizers. Both sutureless or standard valve can be implanted according to the manufacturer's instructions under high definition visualisation of the operative field on-screen. Sutureless valve is clearly easier and ideally suited to this minimalist approach. Guiding sutures are easily placed in a precisely analogous fashion to the implanting sutures of a conventional valve replacement.

Of note, movement of needle holder while placing annulus sutures should be performed in the cranio-caudal plan parallel to the main straight line of vision as no conventional rotation is allowed. Needle should be placed as a spike to capture the native annulus from below and pushed forwards allowing the curve of the needle to make path through the annulus with sequential stitches placed around a clock face. For this reason use of larger needles is suggested as paradoxically easier to direct through the native annulus. Needle can easily slid along the surface of scope until it drops off the end into view and then used accordingly. It is important to keep the scope between the needle and the target tissue, to avoid that the needle holder shaft from obstructing the view. This technique ensures a clear view of the aortic wall throughout. Also, the surgeon should pay close attention to the organisation of sutures and use of one of the commercially available suture organizers is useful to avoid time consuming tangles (Figure 6).

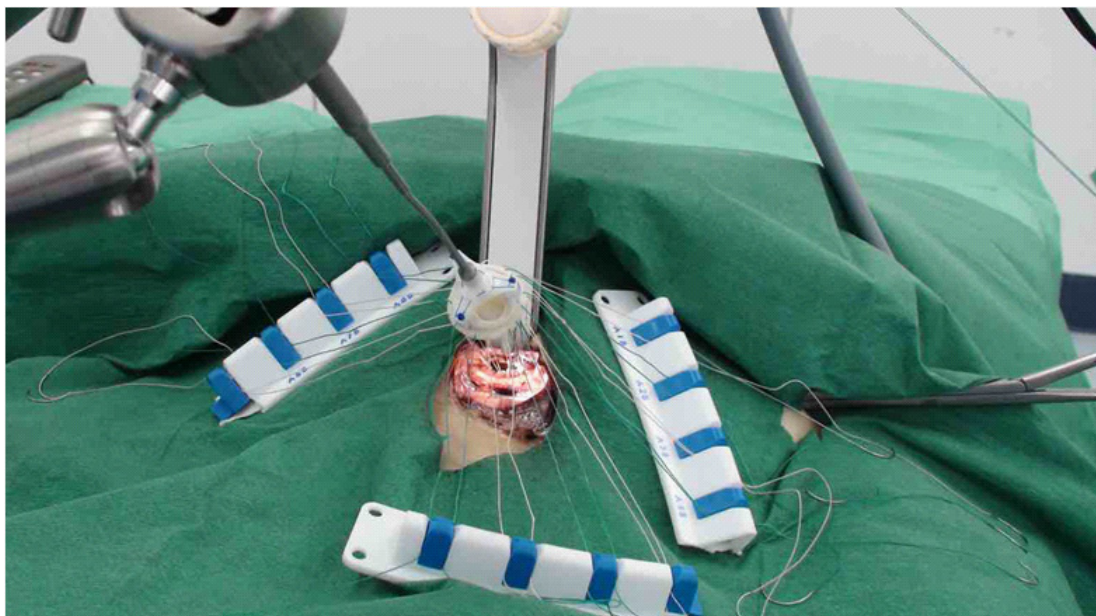


Figure 6: Organisation of Sutures for Conventional Valve Replacement Procedure.

The aorta is closed with running Prolene sutures in conventional fashion. Usually it can be hand tied as 8-10 cm inside the wound under direct vision using the light from Retractor device. The left side of the heart is de-aired in conventional fashion through a cannula placed in the ascending aorta and procedure completed routinely. Neck incision is anatomically closed in layers using absorbable sutures.

If performing TAVR, a similar neck dissection is performed. Aorta is approached at a higher level with or without pericardial opening. Preliminary work in cadavers has demonstrated that the optimal access point to the aorta, typically located anterolaterally at a distance of at least 6cm from the aortic annulus, is readily accessible via this route and easily visualised on screen (Figure 7). Illumination is optimized using the in-built light switching system and a purse string

in the ascending aorta is placed to provide access to the delivery device. Direct Aortic (DA) TAVR procedure routinely performed under fluoroscopic and echographical guidance. After assessment of success of the procedure, the delivery device is removed and the purse string tied. Careful inspection of the aortic entry site permits avoidance of postprocedural bleeding. Neck incision is then anatomically closed in layers as above described.

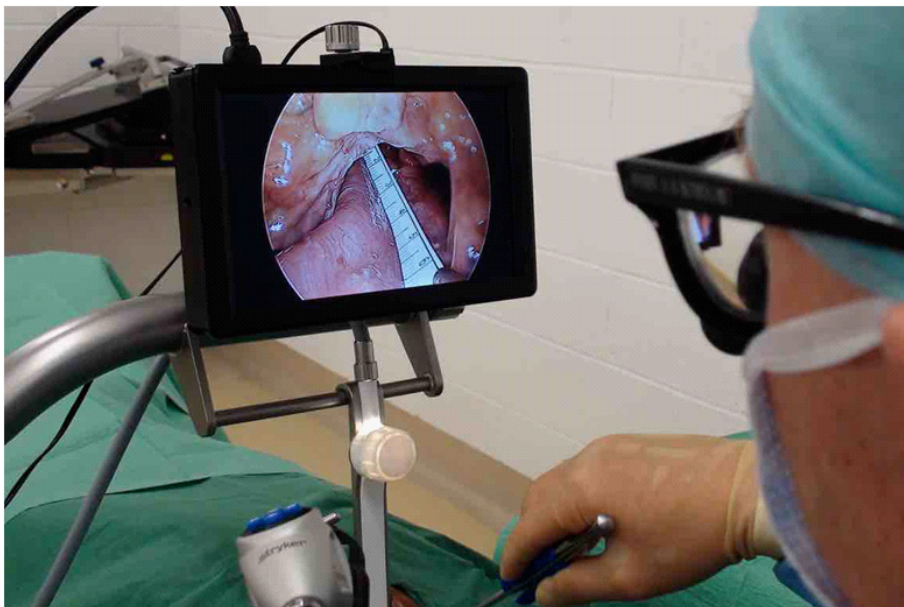


Figure 7: Selection of Optimal Site of Entry for Direct Aortic TAVR.

PRELIMINARY ACTIVITY, TRAINING AND CLINICAL RESULTS

Surgical Aortic Valve Replacement (SAVR)

The surgical procedure was developed and iteratively improved through repeated experimentation and practice on cadavers starting from a simple transverse (skin crease) incision in the neck. The Thiel's embalming technique [50] of soft cadaver fixation was used for the model of training as providing a convenient fixation of cadavers with optimal preservation of colour, consistency and flexibility of tissues. This method allowed to accurately simulating every step of the procedure including mediastinal dissection, exposure, removal and replacement of an aortic valve through the mentioned transcervical access. A detailed step-by-step operative plan capturing every step of the new procedure was developed, a training program for the surgical team was implemented and two surgeons were extensively trained before embarking on first human case.

Procedural steps necessary to accomplish SAVR using this approach were identified, with key steps of the procedure, device settings and modes of use optimized according to the temporal progression of the surgical phases of the operation.

The operative steps were subjectively classified for training purposes into (i) operative manoeuvres that are routinely practiced in minimally invasive cardiac surgery or entail only minor variation from standard surgical practice and (ii) major variations from normal practice that merit specific training. Examples of major departures from standard practice include the initial setup and installation of the device system on the operating table; the incision, mobilisation of soft tissues and insertion of the specialised retractor device, intra-thoracic dissection and exposure of the ascending aorta and importantly use of sequenced illumination on the CoreVista® Retractor to optimise illumination of different zones of the surgical field at different stages of the operative procedure. Training of the surgeon encompassed use of the device and all steps of the new procedure but placed particular emphasis on steps of the procedure that were considered major variations from normal surgical practice, as outlined above. No step was considered too difficult to be learnt or taught to an accomplished cardiac surgeon of average skill.

Fifteen cadavers underwent transcervical aortic valve replacement. Successful valve implantation was defined as secure location of a prosthetic valve (mechanical, biological or sutureless) in the aortic root, unrestricted opening and closure of the valve leaflets, patent coronary ostia and secure closure of the aortotomy as dynamic modes of valve assessment were not possible in the cadaver model.

Valve implantation was completed successfully in all fifteen cadavers according to the criteria above defined with no need of sternotomy. Although replacement with conventional sutured valve prosthesis was clearly achievable in cadavers, the procedure appeared particularly well suited to use with one of the new sutureless valve technologies.

Experience achieved in cadavers was transferred into a comprehensive step-by-step guide to the procedure, taking account of the real-life scenario in living patients and the requirements of an on-pump cardiac operation. In parallel, theatre set up, materials and human resource allocation within the operating room were identified and used to inform anaesthesiologists and theatre personnel prior to first clinical case.

At time of writing first case has been performed by Dapunt et al. [51]. A 63 year old female with symptomatic critical aortic stenosis (STS risk 11%) was selected to undergo the procedure. Coronary angiography showed normal coronary arteries but heavily calcified aortic valve. Transoesophageal echocardiography demonstrated mean gradient 47 mmHg, valve area 0.5 cm² and mild aortic regurgitation. CT showed extensive calcification of the valve leaflets, especially non-coronary leaflet and a functionally bicuspid valve owing to fusion between right and left coronary cusps demanding surgical AVR. CT scan with MPR 3D planar reconstructions was also used to define spatial an anatomical relation between neck and cardiac structures. According to our previous experimental cadaveric work, a distance of 12-15 cm from neck incision to the aortic valve plane over a straight line was suitable to easily perform the procedure. In this patient neck incision-to-aortic valve was measured as 13 cm. Ethics committee approval and informed consent were obtained.

The surgeon operated through the cervical incision using on-screen HD visualisation and a 23mm Medtronic ENABLE sutureless valve prosthesis was implanted. Access, delivery and deployment of sutureless valve prosthesis were successfully achieved using the novel access system and surgical procedure. Transoesophageal echocardiography confirmed correct position of the valve in the proper anatomical location with a mean gradient of 6 mmHg and aortic valve area of 2.5 cm². The patient experienced an uncomplicated course in the immediate postoperative period.

Transcatheter Aortic Valve Replacement (TAVR)

A similar process of training was developed for TAVR and two patients with symptomatic aortic stenosis (STS risk 11.2% and 6.7%) were selected to undergo TAVR using the new system [52]. Written informed consent was obtained. Both patients had normal coronary angiograms. Preoperative transoesophageal echocardiography showed severe aortic stenosis with mean gradients of 42 mmHg and 54 mmHg, aortic valve area of 0.6 cm² and 0.55 cm² with mild and trace aortic incompetence respectively. Preoperative planning was completed by CT scans in order to provide more detailed information on the landing zone. Both aortic valves were severely calcified with a perimeter derived annular diameter measured 22.4 mm and 21.0 mm, annular angulation 530 and 610, and optimal calculated projection angles for the procedure LAO 120 Cranial 140 and LAO 130 Cranial 20, respectively.

The procedure entailed the same steps described above with initial neck dissection, sternal elevation, mobilisation of fatty remnants of the thymus gland in close relation to the left brachiocephalic vein and exposure of the aorta. After a suitable entry point was identified a double purse string suture was placed and DA-TAVR was performed in routine fashion under fluoroscopy using Corevalve self-expanding transcatheter aortic valve prosthesis (Medtronic Inc., Minneapolis, MN). Valve performance was assessed using transoesophageal echocardiography, the device removed and aortic purse string was tied. The neck incision was closed anatomically in layers. TAVR implantation using 26mm Corevalve self expanding prosthesis was successful in both patients according to the latest VARC criteria [53] with absence of procedural or peri-procedural mortality, correct positioning of a single valve prosthesis in the proper anatomical location and intended performance of the prosthetic heart valve (no prosthesis-patient mismatch, mean aortic valve gradients of 7 mmHg and 4 mmHg and valve area 1.45 cm² and 1.60 cm² with no aortic regurgitation in either case). Patients were extubated on the table and did not experience major complications as peri-procedural myocardial infarction, stroke, acute kidney impairment, or other minor complication. Minor discomfort from the neck wound was addressed with Acetaminophen only and patients were mobilised early. Discharge occurred in sinus rhythm on days 2 and 3 after intervention without pacemaker. At 30 days follow-up dyspnoea and functional status progressively improved with signs of clinical improvement in both patients. Echocardiographic re-evaluation at follow-up showed no change in valve position, and demonstrated a mean aortic valve gradients of 9 mmHg and 7 mmHg and valve area 1.78 cm² and 1.31 cm², respectively with no aortic regurgitation in either case (Figure 8).

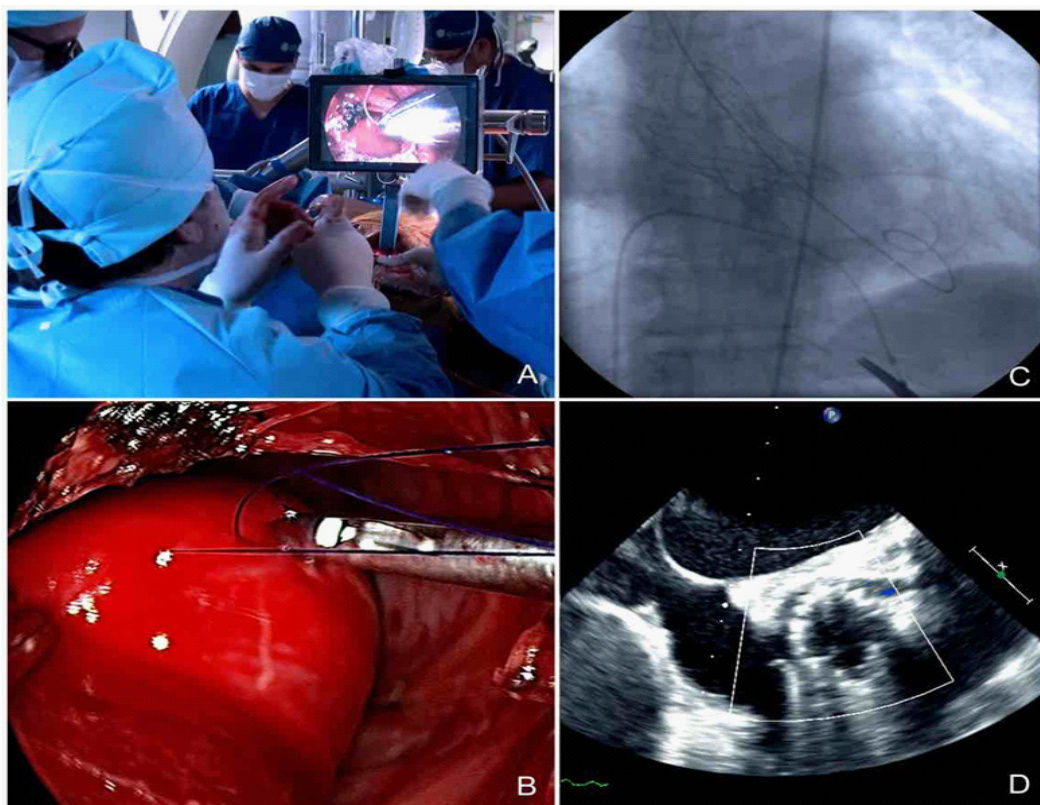


Figure 8: TAVR procedural steps.

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CONCLUSIONS

The transcervical approach is a radically less invasive route to perform alternatively SAVR and TAVR according to patient's characteristics, while circumventing the current complications of these approaches. The aim of this novel technology is to unify the conventional surgical and interventional options for aortic valve replacement, in order to offer to the patients an optimized outcome, which is based on the possibility to select the most appropriate strategy, avoiding at the same time all its major drawbacks. The transcervical route not only enables to perform AVR in a controlled minimally invasive fashion avoiding the current morbidities associated to both SAVR and TAVR, but on the basis of the surgical experience with other transcervical procedures, is expected to significantly shorten the recovery time. However, more experience in the clinical use of the procedure is required for its widespread diffusion.

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