Suprasternal direct aortic approach transcatheter aortic valve replacement avoids sternotomy and thoracotomy: first-in-man experience†

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Received 12 September 2014; received in revised form 11 November 2014; accepted 20 November 2014

Abstract

OBJECTIVES: Direct aortic deployment of a transcatheter aortic valve eliminates the need to traverse the aortic arch with the valve delivery system, enables placement of large sheaths in the aorta and innominate artery, provides maximal precision during deployment and ensures a safe, conventional surgical aortotomy closure. We describe the initial experience with the Suprasternal Aortic Access System (SuprAA System, Aegis Surgical Ltd, Dublin, Ireland) for direct transaortic/innominate valve delivery.

METHODS: Patients with severe, symptomatic aortic stenosis who were candidates for transcatheter aortic valve replacement (TAVR) via a direct transaortic approach were enrolled in the SuprAA-TAVR First-in-Man Study. Under general anaesthesia, the innominate artery and aortic arch were exposed in each patient, using the SuprAA System via a 2.5-cm incision directly above the sternal notch. The TAVR delivery sheath was positioned and the transcatheter valve deployed routinely under fluoroscopic guidance. Upon sheath removal, haemostasis at the aortotomy site was confidently secured using a double purse-string suture closure. All were extubated immediately. A meta-analysis of the direct aortic approach was done for comparison.

RESULTS: Four male patients (mean 82.5 years) underwent SuprAA-TAVR (2 CoreValve; 2 SAPIEN). Anatomical visualization was excellent and suprasternal valve deployment was accurate regardless of sheath size with 100% Valve Academic Research Consortium-2 procedural success. The average total procedure time was 109.5 min without perioperative wound or vascular complications.

CONCLUSIONS: The SuprAA System provides direct aortic/innominate access without sternal or thoracotomy incision. Patient recovery to normal activity is maximized, sheath size limitations are eliminated and valve deployment is precise. This innovative system creates a new and exciting minimally invasive approach for high-risk patients with aortic stenosis.

Keywords: TAVR • Direct-Aortic • Suprasternal

INTRODUCTION

Since the first patient received a transcatheter aortic valve replacement (TAVR) in 2002 [1], TAVR has been an increasingly frequent option for symptomatic patients at prohibitive or high risk for traditional surgical valve replacement [2–4]. Although a transfemoral (TF) approach is most frequently used, the transapical (TAp), transaortic (TAo) and trans-sub-clavian (TSc) routes are used as clinically and anatomically indicated. Each approach for placement of a catheter-based aortic valve prosthesis has inherent advantages and disadvantages, but the optimum route is the one that maximizes the benefits of TAVR while minimizing the risks associated with the approach.

Bapat described the first direct TAo approach for TAVR in 2010 [5]. TAVR via a partial upper sternotomy or limited right thoracotomy has become an increasingly attractive approach for many patients and surgeons [6]. However, the TAo approach requires at least a partial sternotomy or minithoracotomy with inherently longer recovery and hospital stay when compared with TF [7, 8]. Providing direct access to the aorta and innominate artery without...
sternotomy or thoracotomy may have several advantages. In a manner similar to an extended mediastinoscopy, the Suprasternal Aortic Access (SuprAA) TAVR provides excellent visualization of the ascending aorta and innominate artery for the placement of a transcatheter valve. We describe this technique and our initial clinical experience.

MATERIALS AND METHODS

Procedure

Patients at Clínica de Occidente (Cali, Colombia) with severe, symptomatic aortic stenosis were evaluated and determined to be appropriate candidates for TAO TAVR. After receiving device and procedure approval from the local and Colombian national Institutional Review Board (IRB), we discussed informed consent and conflict disclosures with each patient. At the time of surgery, we positioned the equipment, patient and staff strategically in the hybrid surgical suite for optimal space utilization and safety (Fig. 1A).

During the procedure, the anaesthesiologists and their equipment were placed to the left of the patient’s head, but far away enough to allow room for the surgical team. The cardiologist and transesophageal echocardiography (TOE) machine were positioned to the patient’s left, above the fluoroscopy arm with access to perform the TOE. The perfusionist and bypass machine were located on the patient’s left beside the bank of monitors. The tables for the surgical team and the invasive cardiology team were on the patient’s right. The surgical equipment was closest to the patient until the delivery system was positioned, at which time the interventionist team repositioned for valve deployment (Fig. 1B).

The patient was positioned supine, with arms tucked to the side and head turned to the left. Universal prep and drape was performed exposing the neck, chest, abdomen, right upper extremity and bilateral groins. Central venous access was via the left subclavian vein, leaving the neck free of lines. A roll behind the scapulas elevated the sternal notch. The head and neck were supported as the head was rotated leftwards to maximally expose the supraclavicular mid-line.

The temporary pacemaker was positioned via either sub-clavian or femoral venous access and an arterial angigram catheter positioned via the femoral or radial artery. A transverse mid-line (collar) incision was made above the sternal notch and extended to the sternocleidomastoid muscles. The mid-line fat plane between the sternohyoid muscles inferior to the thyroid isthmus was entered and opened vertically to the pretracheal fascia, enabling the sternohyoid and omohyoid to be liberated laterally.

From the patient’s right side, the surgeon used his/her left index finger in a supinated position to bluntly dissect inferiorly along the pretracheal plane until the aorta and innominate were digitally identified. Blunt dissection was redirected when the aorta and innominate artery were palpated. The surgeon’s left index finger was pronated and the plane between the innominate vein and the origin of the innominate artery was developed.

When the innominate artery was identified, the SuprAA device with the associated obturator was positioned gently but firmly between the strap muscles and into the thoracic inlet while remaining anterior to the innominate artery. The innominate vein and associated mediastinal fat were separated from the anterior surface of the aorta and great vessels, allowing advancement of the SuprAA device further into the antero-superior mediastinum.

The superior tongue-like extension of the SuprAA device (Fig. 2) further enabled the surgeon to lift the innominate vein anteriorly for maximum exposure of the aortic arch and ascending aorta. The SuprAA device provided a generous operative field for confident and safe placement of the valve delivery system.

Identification of the aorta, innominate artery and innominate vein with respect to the bony thoracic inlet on the preoperative CT angiography facilitated optimal selection of the delivery sheath insertion site. A ‘box-in-diamond’ purse-string suture with dual pledget reinforcement was placed in the ascending aorta or innominate artery (Fig. 3). The sutures were secured with individual Rummel tourniquets and an introducer needle placed in the centre of the purse strings allowed passage of the flexible-tipped glide wire into the ascending aorta. The commercially available TAVR delivery system was positioned using fluoroscopy and secured within the purse-string tourniquets. The aortic valve was replaced using either the Corevalve (Medtronic) or the Sapien (Edwards) TAVR prosthesis using a retrograde transcatheter approach.

Upon confirmation of successful placement of the prosthesis, the valve delivery system was removed, leaving only the delivery system. During rapid pacing, the sheath was removed and the tourniquets were tightened for haemostasis. The sutures were tied individually during rapid pacing, using a minimally invasive knot pusher. A soft drain was secured through a separate incision, the mid-line strap muscles reapproximated loosely and the skin closed in two layers.

Meta-analysis

To evaluate the outcomes of patients who had undergone a direct aortic approach, one author reviewed the literature and did a meta-analysis that reported a direct TAO approach for TAVR between January 2002 and August 2014. Two additional reports presented at the 48th meeting of the Society of Thoracic Surgeons in Fort Lauderdale, FL, USA, in January 2012 also were considered in the review. Relevant published studies (n = 110) were identified through a PubMed database search using the keywords transaortic and transcatheter. Only studies reporting a series of 10 or more patients were selected. The data reported in the selected works were critically examined for Valve Academic Research Consortium (VARC)-defined outcomes [9]. Studies were further excluded if a clear VARC-defined outcome for procedural success, 30-day mortality, major stroke, major bleeding or major vascular injury could not be interpreted. Outcomes data from the selected TAO approach studies were compared with the meta-analysis by Généreux et al. of TAVR outcomes data using VARC definitions [10]. Statistical analysis was performed using a two-tailed t-test for at least a 5% level of significance using Microsoft Excel.

RESULTS

Suprasternal approach

Four male patients (ages 77–89) with Society of Thoracic Surgeons (STS) predicted mortality and morbidity greater than 9.4 and 38.9, respectively, underwent SuprAA TAVR (Table 1). One (Patient 1) had previously attempted TF TAVR with valve embolization to the iliac arteries requiring an open aorto-bifemoral bypass graft; 2 patients had a severely tortuous abdominal aorta; 1 patient had size-limiting iliac occlusive disease necessitating an alternate,
non-TF, approach. Two patients received CoreValve prostheses: one via the ascending aorta, one via the innominate artery. Two patients received Sapien XT prostheses, both via the innominate artery. One patient had arteriogram access via the right brachial artery with all remaining procedural vascular access via the femoral vessels. All had left sub-clavian venous access for anaesthesia.

The SuprAA device provided excellent exposure of the aorta and great vessels through a 4-cm suprasternal incision. Patient 3 had experienced previous trauma to the left sternalclavicular joint, leaving a 4-cm ossified mass compromising the thoracic inlet. Despite this, we were able to safely expose the origin of the innominate artery, which was selected for vascular access. Suture placement was intuitively similar to routine aortic cannulation for cardiopulmonary bypass and, on average, took 12.5 min to complete. The innovative design of the SuprAA device facilitated rapid positioning and excellent vascular exposure. The average time from incision to valve deployment was 70 min and the average total procedural time was 109.5 min.

All patients were extubated in the procedure room and recovered in the ICU. Patient 3 suffered a grand mal seizure (a chronic condition) and aspirated while eating breakfast, which led to pneumonia and eventually fatal sepsis and death on Day 15. All other patients were discharged within 7 days post procedure and, at the 30-day follow-up, were without complications. All 4 patients had VARG-2
centres were included in the analysis (Table 2). Most patients received the CoreValve prosthesis (369 vs 294 Sapien and 1 Portico valve). A critical examination of the VARG meta-analysis identified 3519 patients from 16 publications of which less than 1% underwent TAVO TAVR, more than 70% were TF and more than 65% received the Sapien prosthesis.

The difference in 30-day mortality was higher for the TAO approach than for the predominately TF cohort (8.73 vs 7.45%), but the difference did not reach significance. Additionally, there was not a significant difference in the rate of new permanent pacemakers in the comparison. There was, however, a significant advantage seen with regard to procedural success, major stroke, major bleeding and major vascular injury favouring the TAO approach over the primarily TF cohort. There were only 4 (1.14%) reports of thoracic aortic dissection during the TAO procedure. The average length of hospital stay for the TAO cohort was 10.2 days.

**DISCUSSION**

The direct aortic approach done via median sternotomy or right upper parasternal incision appears to be a safe and effective approach for TAVR. However, there are several benefits of avoiding at least partial upper sternotomy or limited thoracotomy to gain direct access to the ascending aorta. The suprasternal placement of the TAVR delivery system and retrograde deployment of the prosthesis help to avoid painful incisions, yet enable the safe placement of large sheaths with the reduced vascular morbidity and lower cerebrovascular complications demonstrated for the TAO approach. The dual purse-string closure of the ‘box-in-diamond’ technique enables a conventional and securely haemostatic closure of the access site and may contribute to the low rate of thoracic aortic dissection and lower risk of major bleeding seen in the TAO cohort. Additionally, when compared with the TA approach, the TAO approach avoids instrumenting the left ventricular apex, which reduces major bleeding complications and ICU and hospital stay, has a better learning curve [11] and avoids long-term reductions in LV dysfunction [12, 13].

Retrograde instrumentation of the aortic arch and stenotic valve contributes to the cerebral embolic events of TAVR [14]. The retroflexing sheath of the TF delivery systems is manipulated through the often atherosclerotic-diseased aortic arch as it is positioned in the ascending aorta. The SuprAA-TAVR approach eliminates the need to instrument the aortic arch with the valve delivery system, which theoretically reduces embolic complications. Avoiding the aortic arch with direct aortic access may contribute to the 50% reduction in incidence of major stroke in the TAO cohort of our analysis.

Precise positioning of the transcatheter prosthesis is crucial to procedural success. Directly placing large sheaths in the aorta and the innominate artery provides maximal precision during valve positioning and deployment. The working distance from vascular access to the aortic valve is less than 12 cm, providing better accuracy and instantaneous control of deployment of the valve. The SuprAA device is connected securely to the procedure table with a ‘quick-connect’ feature. Once secured, the delivery system remains in place.

The SuprAA device also facilitates delivery sheath control with the ‘quick disconnect’ feature. Controlled reorientation of the delivery system within the SuprAA device or redirection of the distal SuprAA device enables precise orientation of the valve and provides support during deployment important for TAOs procedural success as identified in our analysis. Unlike the TF approach, the procedural success with zero to trace aortic insufficiency, no major bleeding or vascular injury, no 30-day stroke and minimal operative blood loss. Patient 4 required permanent pacemaker implantation prior to discharge. All incisions healed with minimal pain (Fig. 4).

**Direct aortic approach**

Of the 110 published articles and 2 oral presentations screened, 5 publications and 1 oral presentation were selected for analysis of direct aortic TAVR. A total of 664 patients from 31 international
The size of the TAo delivery system is not restricted by vascular diameter. Large sheaths are confidently placed in the aorta and innominate artery without the limitations experienced in the femoral and iliac arteries. The reduced rate of major vascular injury for the TAo approach (4.12 vs 11.67%) reflects this advantage. The device provides exceptional exposure of the innominate artery and the aorta for the placement of additional purse-string sutures in the event major bleeding is encountered. Although direct pressure cannot be applied to the cannulation site through the sternum and clavicle, a cotton-tipped instrument or the surgeon’s finger can provide haemostasis should upper partial sternotomy become necessary for vascular control.

Returning these elderly and debilitated patients to an active and normal life without a prolonged hospital stay will demonstrate the benefit to the patient of the SuprAA-TAVR procedure. The complications associated with a sternal or intercostal incision are avoided, resulting in limited pain and improved postoperative pulmonary function. If the femoral vessels are avoided by using radial and sub-clavian vascular access, patients are able to ambulate immediately and should experience an improved recovery, limited ICU care, decreased length of hospital stay and a quicker return to activity. A pilot study is underway to demonstrate this advantage.

The direct aortic access for TAVR seems to have procedural advantages and the early results of the SuprAA-TAVR procedure are encouraging. However, the analysis of the reported literature regarding direct aortic access is a non-randomized summation of data from multiple centres and has inherent limits to its validity. Additionally, we are reporting a very early, single-surgeon experience. As additional centres adopt this approach, careful analysis of VARC success and patient recovery must be critically examined.

Although access-related complications are extremely uncommon, complications similar to those reported for mediastinoscopy, like pneumothorax, wound infections and tracheal injuries, are possible. Vascular injuries are also possible during device placement in the antero-superior mediastinum, even though the SuprAA device is specifically designed to visualize and protect these structures. If the device is placed properly, injury to the phrenic, vagus and recurrent laryngeal nerves is unlikely because the nerves are located posteriorly and laterally.

### ACKNOWLEDGEMENTS

The authors appreciate the editorial assistance of Margaret Alford Cloud (University of North Carolina at Chapel Hill). The clinical study in Cali, Colombia, was sponsored by Aegis, maker of the Suprasternal Aortic Access System, but none of the authors received compensation for the work.

### Table 1: Demographics and procedural outcomes for the first 4 SuprAA-TAVR patients

<table>
<thead>
<tr>
<th>Patient A</th>
<th>Patient B</th>
<th>Patient C</th>
<th>Patient D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>77</td>
<td>89</td>
<td>81</td>
</tr>
<tr>
<td>BSA (m²)</td>
<td>1.88</td>
<td>1.49</td>
<td>1.78</td>
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<tr>
<td>Logistic EuroSCORE</td>
<td>12.67</td>
<td>4.96</td>
<td>10.04</td>
</tr>
<tr>
<td>STS morbidity/mortality</td>
<td>59.908</td>
<td>40.021</td>
<td>49.862</td>
</tr>
<tr>
<td>NYHA class</td>
<td>4</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Previous valvuloplasty</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>CAD</td>
<td>No</td>
<td>LAD stent</td>
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<td>Previous CVA</td>
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<td>No</td>
</tr>
<tr>
<td>LVEF</td>
<td>25%</td>
<td>52%</td>
<td>55%</td>
</tr>
<tr>
<td>Valve type</td>
<td>CoreValve</td>
<td>CoreValve</td>
<td>SAPIEN XT</td>
</tr>
<tr>
<td>Valve size (mm)</td>
<td>31</td>
<td>31</td>
<td>23</td>
</tr>
<tr>
<td>Introducer sheath size (Fr)</td>
<td>18</td>
<td>18</td>
<td>24</td>
</tr>
<tr>
<td>Sheath access vessel</td>
<td>Aorta</td>
<td>Innominate</td>
<td>Innominate</td>
</tr>
<tr>
<td>Arteriogram access</td>
<td>Brachial</td>
<td>Femoral</td>
<td>Femoral</td>
</tr>
<tr>
<td>Pacer access</td>
<td>Femoral</td>
<td>Femoral</td>
<td>Femoral</td>
</tr>
<tr>
<td>Suture placement Time (min)</td>
<td>14</td>
<td>10</td>
<td>17</td>
</tr>
<tr>
<td>Skin to deployment time (min)</td>
<td>86</td>
<td>52</td>
<td>74</td>
</tr>
<tr>
<td>Aortic closure time (min)</td>
<td>6</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Total procedure time (min)</td>
<td>148</td>
<td>89</td>
<td>116</td>
</tr>
<tr>
<td>EBL (ml)</td>
<td>75</td>
<td>50</td>
<td>25</td>
</tr>
<tr>
<td>Length of stay (days)</td>
<td>7</td>
<td>7</td>
<td>15</td>
</tr>
</tbody>
</table>

BSA: body surface area; STS: Society of Thoracic Surgeons; Cr: serum creatinine; NYHA: New York Heart Association; CAD: coronary artery disease; LAD: left anterior descending; CVA: cerebral vascular accident; LVEF: left ventricular ejection fraction; EBL: estimated blood loss.

![Figure 4: Patient 1: (A) 1 h post procedure and (B) 14 days post procedure.](image-url)
### Table 2: Literature analysis of transaortic TAVR with VARC outcomes compared with the largest meta-analysis of TAVR outcomes [6,15-18]

<table>
<thead>
<tr>
<th>Reference</th>
<th>Valve type (CoreValve – Sapien – 0–00 – 01–0)</th>
<th>Number of centres</th>
<th>Number of patients</th>
<th>30-day mortality</th>
<th>Major stroke (VARC)</th>
<th>Major bleeding (VARC)</th>
<th>New permanent pacemaker</th>
<th>Procedure success (VARC)</th>
<th>30-day mortality</th>
<th>Major stroke (VARC)</th>
<th>Major bleeding (VARC)</th>
<th>New permanent pacemaker</th>
<th>Procedural success (VARC)</th>
<th>30-day mortality</th>
<th>Major stroke (VARC)</th>
<th>Major bleeding (VARC)</th>
<th>New permanent pacemaker</th>
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<tbody>
<tr>
<td>Leitman et al. / [10]</td>
<td>98.1% (3,519/3,579)</td>
<td>17</td>
<td>11–93</td>
<td>10</td>
<td>10% (10/100)</td>
<td>0.8% (2/243)</td>
<td>11.1% (39/351)</td>
<td>96.04% (3,377/3,466)</td>
<td>100% (12/12)</td>
<td>0% (0/12)</td>
<td>2.3% (1/44)</td>
<td>12.2% (12/99)</td>
<td>76.8% (243/313)</td>
<td>10% (10/90)</td>
<td>89.5% (326/361)</td>
<td>8.3% (45/546)</td>
<td>11.1% (39/351)</td>
</tr>
<tr>
<td>Soppa G, Roy D, Brecker S, Jahangiri M. Early experience with the transaortic approach for transcatheter aortic valve replacement: a valid alternative to the transapical access in patients with no peripheral vascular option. Eur J Cardiothorac Vasc Surg 2014;19:777–81.</td>
<td>98.1% (3,519/3,579)</td>
<td>17</td>
<td>11–93</td>
<td>10</td>
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<tr>
<td>A.C. Kiser et al. / European Journal of Cardio-Thoracic Surgery</td>
<td>98.1% (3,519/3,579)</td>
<td>17</td>
<td>11–93</td>
<td>10</td>
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</table>

### Funding

Kiser and Stack are founders of Aegis, maker of the Suprasternal Aortic Access System; authors O’Neill and de Marchena are stockholders in Aegis. Aegis sponsored the clinical study in Cali, Colombia. The authors were not compensated or unduly influenced, and had no conflict of interest for the academic work we report.

### Conflict of interest

none declared.

### REFERENCES


Dr C. Huber (Berne, Switzerland): My first question really relates to the way you are approaching the innominate artery. Why not go just one step further and go directly to the carotid? I don’t want to diminish the success of this amazing approach, but why not just move further up to the carotid artery and get even better control? If there is any bleeding, it can be easily controlled; the incision is very small as well, etcetera. Down at the innominate artery, one is faced with the risk of uncontrollable bleeding. If something happens, it is quite challenging to get there and stop the bleeding.

Dr Kiser: It is not as challenging as one may think to have control of the innominate artery at that location. The innominate artery is a much bigger vessel and accommodates the sheath for any valve, with good patency and good flow through the vessel during deployment. I didn’t demonstrate it, but there is an arteriogram demonstrating flow going around the delivery sheath in the innominate artery during valve deployment. Our goal is to access the aorta. In some, we could not do that because of the patient’s anatomy, but the aorta is our objective.

Dr Huber: Transfemoral is being performed percutaneously. We work very hard to also get a transapical approach percutaneous. Looking at your approach, do you think that just a small step is needed in order for it to be performed fully percutaneously as well, by closing the direct access site in the innominate artery with a vascular closure device?

Dr Kiser: It would make me very nervous to do that because it is behind the sternum. Compression of the innominate artery in the location behind the sternum is difficult, unlike the groin where you can compress the vessel. I understand your question, but, as a cardiac surgeon, it would make me very nervous to use a closure device without direct visualization and control of the vessel. I do have great confidence in a purse-string suture to close a vessel, especially an arterial vessel, which gives me the confidence to have them up and moving around 2 hours after the procedure.

Dr Huber: Excellent. Now, the last point is just looking forward. Do you think you can use the same technique to reach into the right atrium and then go from the right atrium transseptally to do a mitral TAVI?

Dr Kiser: I am unable to answer that question. Anything is possible.

Dr Huber: You can use mediastinoscopy or a mediastinal system, go through a small thoracotomy, go into the right atrium, make your purse-string, and then go transseptally and do a mitral valve implantation.

Dr Kiser: That is a great point. As cardiac surgeons, we have to embrace techniques that encourage collaboration with cardiology in some way, shape, or form, and a transsternal incision doesn’t build the relationship with the cardiologist that is necessary in a TAVR program, in an A-fib program, or in a coronary program where you are partnering with a cardiologist. So the less invasive we can be, be it transseptally through the right atrium or without an incision in the chest, the more closely we can work with our colleagues to build the teams that I think helps all the patients, whether it be the transfemoral or transaortic population.