Transcervical Direct Aortic TAVI: Urgently Needed Improvements to Alternative Access

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Objectives This study sought to identify problems encountered with alternative access for TAVI and provide a solution to key challenges, namely how to effect reductions in the rate of complications, length of stay and cost for all patients in need of TAVI.

Methods Starting from the premise that direct aortic puncture is the simplest and most reliable means of access to the aorta, the author explains how key changes in technology, technique and clinical pathway can bring about improvements in stroke rate, PPI rate and PVC rate with attendant reduction in length of stay and cost.

Results Clinical papers reviewed provide strong evidence to suggest that three key practice changes (1) adoption of transcervical approach, (2) elimination of drains and (3) use of a minimalist clinical pathway should be capable of effecting major reductions in rates of stroke, permanent pacemaker implantation (PPI) and peripheral vascular complications (PVC) with attendant reduction in length of stay and overall cost.

Conclusion Use of the new CoreVista® technology along with simple changes in technique and clinical pathway should be capable of delivering a day case (i.e. LOS = 1 day) TAVI procedure for the majority of patients in need of isolated aortic valve intervention with a major reduction in overall procedure cost.

TAVI has increasingly gained acceptance as the preferred treatment for symptomatic or severe aortic stenosis. Globally over 300,000 patients have been treated by TAVI to date and double-digit compound annual growth in procedure numbers is anticipated over the next decade. Significant improvement in results and relative freedom from peri-procedural complications together with sustained enthusiasm from physicians and their patients for a less invasive alternative to surgery have fuelled this change in practice. [1]

On a practical level, with few exceptions most centres have adopted a 'femoral first' approach to TAVI with a preference for conscious sedation as the default, these choices being driven substantially by cardiologists who take comfort from decades of experience with femoral access under conscious sedation and no compelling reason to change. [2]

TF-TAVI especially when performed under conscious sedation (CS) with a minimalist clinical pathway that avoids intensive care is capable of delivering discharge from hospital within 3 days (72 hours) in 23% of patients. [3] However, mean length of stay remains highly variable with *circa* 7.5 days length of stay still being reported in some contemporary papers despite the TF access & CS strategy outlined above. [2]

For patients deemed unsuitable for TF approach, a smorgasbord of alternative access options are available with enthusiasts seeming to favour one or other approach but a common thread throughout the literature that no one route reigns superior above all others. A number of excellent reviews have outlined the main advantages and disadvantages of each approach.[4] However, there is no clear consensus on first choice alternative access and seemingly no alternative access that is universally applicable. Mostly, alternative access is thought to be inferior to TF in terms of invasiveness and rates of the most commonly encountered complications, at least that is current thinking.

The premise of this paper is that amidst all this confusion the simplest and most obvious of all approaches will prove superior for alternative access. As the principal goal of TAVI access is to secure uncomplicated entry into the ascending aorta, it is believed that direct aortic puncture will likely be the most favourable, least morbid and most universally applicable access route if this can be done minimally invasively. Moreover there is evidence that such an approach is feasible in almost ***all*** patients, including but not limited to those patients currently turned down for TF. However, urgent changes to the historic DA-TAVI procedure are needed if it is to emerge as a realistic alternative to TF. This paper outlines key questions to be asked of the access route and changes to the DA-TAVI procedure that are required to achieve this goal.

Is DA-TAVI as efficacious as TF?

In terms of efficacy, historical studies have consistently demonstrated that mortality and freedom from VARC-2 recognised complications[5] are at least as good with DA-TAVI as TF-TAVI, especially once appropriate risk adjustment has been made to properly account for the multiple co-morbidities typically encountered in the patient population undergoing DA-TAVI.

In particular, efficacy and incidence of VARC-2 recognised complications following DA-TAVI from ROUTE registry were similar or better than results from contemporary studies using SAPIEN valve and TF access despite the presence of significant co-morbidities in the former patient group and 25% being documented unsuitable for TF access.[6] The same was true of efficacy and incidence of VARC-2 complications in ADVANCE DA registry where 35% were

charted as having unfavourable TF access using CoreValve.[7]

By way of possible explanation, direct aortic puncture avoids manipulation of the arch, navigation of the thoraco-abdominal aorta, and of course avoids the femoral vessels which is especially important in the presence of hostile ileo-femoral anatomy whatever the cause.

Complications

Complications remain a major cost driver in TAVI programs worldwide. In the original PARTNER trial 49% of patients had one or more complications.[8] Therefore, a systematic reduction in the frequency of complications has economic merit as well as clinical importance. Three complications deserve special consideration because of their extreme importance and also because of their potentially much lower frequency when a less invasive DA-TAVI is employed. These three complications are discussed in the following paragraphs.

Stroke rate is less with DA-TAVI than TF

Incidence of the most feared of all complications, stroke, occurred in only 1.0% and 1.1% in ROUTE and ADVANCE DA registries, respectively. This is noticeably less than the incidence of "all strokes" reported in the TF cohort of PARTNER II (4.2% at 30 days and 6.9% at one year) [9] and SURTAVI (2.6% at 30 days, 5.5% at one year) where 94% of procedures were performed TF,[10] despite that these latter studies were conducted on the supposedly lower risk patient group labelled "intermediate risk".

There is no prospective randomised comparison of DA and TF sufficiently powered to look at stroke *per se*. However, the low incidence of stroke has been a consistent finding in DA-TAVI from the outset. Indeed, prior to embarking upon the ROUTE registry, Romano reported 1 delayed stroke out of 94 (1.0%) consecutive patients undergoing DA-TAVI. [11]

Stroke rates with the often favoured subclavian and carotid access routes are noticeably higher than with TF or DA. The French trans-carotid TAVI registry reported 30-day stroke rate of 6.3% [12]. Data from the recent trans-axillary / trans-subclavian approaches have shown a 30-day stroke rate of between 6 and 7.5% [13,14,15] which is much greater than the commonly cited 2% risk of stroke that attends contemporary TF TAVI. [16]

Based on available evidence there is, therefore a compelling expectation that a less invasive DA-TAVI will be associated with lower incidence of stroke than trans carotid, trans axillary / trans subclavian and even trans femoral.

Rate of Permanent Pacemaker Implantation (PPI) is less with DA-TAVI than with TF

Another key driver for extended length of stay and cost of care is the need for permanent pacemaker implantation (PPI). PPI rates were 8.1% at 30 days in TF cohort of PARTNER II [9] and 28.3% at 30 days in SURTAVI. [10] Need for permanent pacemaker in DA-TAVI was 8.8% and 14.5% at 30 days in ROUTE and ADVANCE DA registries, respectively i.e. rates were comparable for SAPIEN but much less for CoreValve using DA access.

However, it has since been shown that omitting the BAV pre-dilatation step in DA-TAVI using SAPIEN can virtually eliminate the need for peri-procedural PPI implantation. The occurrence of complete AV block requiring PPI was observed in 0% of patients where this step was omitted, compared with 5.0% when pre-dilation was performed. A borderline trend towards even fewer procedural complications in general was also observed in the group of patients where the valve was implanted directly.[17]

This is clearly another very major step forward in the field suggesting that DA-TAVI with SAPIEN avoiding BAV pre-dilatation step can almost eliminate peri-procedural PPI a strategy that can undoubtedly diminish overall cost and length of stay.

0% Rate of Peripheral Vascular Complications (PVC) is possible with DA-TAVI

Major vascular complications were observed in 12% of patients in a fairly contemporary series of patients in whom TAVI was performed predominantly (92%) by TF access. [2] 9% of patients undergoing TF TAVI in the German Quality Assurance Registry on Aortic Valve Replacement suffered PVC, a dataset comprising 17,919 patients over two calendar years 2013 and 2014.[18] Therefore, PVC remains a significant problem with TF access.

A notable feature of DA access route is that several authors have shown that with careful execution of the procedure a 0% access site complication rate is achievable with Direct Aortic access using SAPIEN XT and CoreValve in equal numbers and in a similar population of patients and notably using the old 24Fr/26Fr Ascendra sheath.[19] Also, 0% vascular complications were encountered in 50 consecutive patients undergoing DA-TAVI using CoreValve between 2011 – 2012.[20] In the Society of Thoracic Surgeons / American College of Cardiology TVT registry only 3 out of 868 patients (0.3%) undergoing DA-TAVI in United States between 2011 and 2014 exhibited major vascular complications despite that these were extremely high risk patients with multiple co-morbidities.[21] Therefore, there is a realistic expectation of 0% PVC if DA-TAVI is employed in the manner outlined in this paper.

In addition to morbidity associated with PVC it is estimated that major vascular complication add $27,000 and a related phenomenon, major bleeding adds $43,000 incremental cost to the overall cost of the TAVI procedure.[8] Hence the systematic avoidance of peripheral vascular complications can have a major impact on the economics of the procedure at a program level.

Therefore, it is to be anticipated that PVC or access site complications will diminish to almost 0% with a DA-TAVI as experience increases and sheath size diminishes (see below).

What changes are required for Minimalist DA-TAVI to be ready for 'Prime Time'?

There is currently no prospective randomised clinical trial (RCT) comparing DA-TAVI with TF-TAVI side-by-side in identically matched patient populations. This is a mixed blessing for despite that DA-TAVI offers a technical solution for universal access and appears to have much lower incidence of three important complications (stroke, PVC and PPI) DA-TAVI in its current form suffers from some major drawbacks that urgently need to be addressed. Once these have been addressed and operators have become skilled in the new techniques an RCT would be an obvious next step.

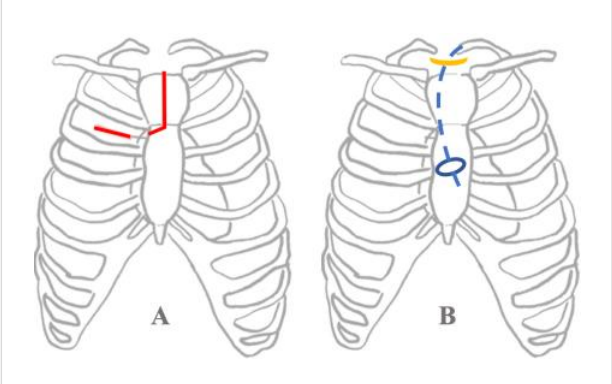

Figure 1. Traditional Painful Mini-sternotomy or Mini-thoracotomy incisions in red (A); Essentially Painless Transcervical incision in yellow (B). Surface markings of the aortic valve in blue and trajectory of TAVI guidewire and catheter using transcervical approach in broken blue.

To be ready for 'prime time', DA-TAVI procedure requires three key changes in practice listed below and discussed in the following paragraphs:

1. Change to Transcervical Incision
2. Eliminate Insertion of Chest Drains
3. Create Minimalist Clinical Pathway

1. Change to Transcervical Incision

Transcervical approach to DA-TAVI virtually eliminates pain.

Aside from the occurrence of complications, pain is the main barrier to early ambulation and quick discharge from hospital when DA-TAVI is employed. However, this can be eliminated if approach to DA-TAVI is modified to transcervical. How will DA-TAVI compare with TF when pain is taken out of the equation?

First of all it should be stated that TF is not without pain. Pain was experienced by 87% of patients following TF TAVI with mean worst level of pain 6.2 on a numeric rating scale (NRS) from 0 to 10. It is pertinent that related problems i.e. bleeding or oozing at the femoral access site was seen in 45% of patients and haematoma was observed in 19%.

Moreover, when one considers the effect of pain on early ambulation it is pertinent that despite that it is reported that 87% of patients can be 'mobilised' on the evening of TF procedure, the actual mobilisation activities contributing to this figure include dangling legs over the side of the bed, standing on the spot or sitting in a chair. In actual fact, only 6 out of 54 patients (11%) were able to properly ambulate.[22]

Difficulty progressing patients owing to femoral access site discomfort together with bleeding, oozing or haematoma formation may explain why the minimum expected length of stay in the current literature is still 3 days (72 hours) for TF TAVI, [3] despite that minimum anticipated length of stay for many more invasive procedures in modern surgical practice is only 1 day. Obvious examples of the latter include laparoscopic cholecystectomy,[23] transcervical thymectomy[24] and transcervical thyroid surgery,[25] discussed in more detail below.

Wirth regard to current approaches to DA-TAVI, it is recognised that opening the chest by mini-sternotomy or mini-thoracotomy is exquisitely painful. It really doesn't matter if the incision is large or small, with or without rib spreading, chest incisions are intrinsically painful. Moreover, pain is exacerbated by the act of breathing making it difficult if not impossible for these patients to mobilise early become enrolled in fast track protocols. Herein lies a fundamental flaw of DA- TAVI using existing mini-sternotomy or mini-thoracotomy incisions (Figure 1).

However, new technology means that it is no longer obligatory to open the chest in order to access the aorta. CoreVista® (CardioPrecision Ltd., Glasgow, UK) uses a transcervical incision to provide access to the aorta through a short incision in the skin crease of the neck. Figure 2 shows the CoreVista® Retractor System in a hybrid lab.

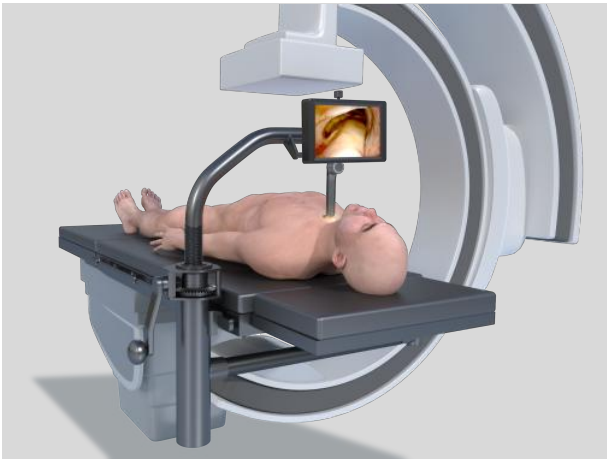

Figure 2. CoreVista® in Hybrid Cardiac Cath. Laboratory

This incision is commonly used for mediastinoscopy[26] transcervical thymectomy[24] and transcervical thyroidectomy [25], and is essentially pain free, requiring Acetaminophen analgesia on discharge from hospital at most. Furthermore, being located off the chest, whatever limited discomfort the patient experiences is unaffected by breathing and surgical

closure of the entry site facilitates certain haemostasis making early ambulation possible in majority of the patients.

A competitor device (Aegis Surgical) that is no longer commercially available experienced limited early success but suffered from only providing a very limited access to the base of the brachiocephalic artery,[27] whereas CoreVista® affords access to the entire ascending aorta for TAVI to be performed.[28] Indeed the versatility of CoreVista has allowed the device to also be used to perform totally endoscopic, uniportal SAVR procedure.[29] Unfettered access to the entire ascending aorta means that site of entry can be accurately located to avoid calcification. Figure 1B shows transcervical approach and the trajectory or pathway that the guide wires, catheter and device will pass. This is seen to follow the smooth, natural curvature of the ascending aorta to the aortic valve with no inflection points along its course.

Recent descriptions of transcervical brachiocephalic access without the benefit of this new device have provided very encouraging clinical outcomes in a sizeable number of patients (n = 84 patients in the larger series) owing to the small neck incision.[30,31] However, the utility of the described access without CoreVista is constrained by the anatomical origin of the brachiocephalic artery from the aortic arch after the latter has commenced its course posteriorly and to the left, which means that a catheter inserted into the transcervical brachiocephalic artery has to bend through two inflections points over a very short distance on its way to the aortic valve, thus limiting the manoeuvrability of catheters delivered in this way.

Data on transcervical approach to DA-TAVI was until recently limited to a few studies with small patient numbers.[27, 28, 32] Nonetheless, evidence from these studies demonstrated that when transcervical approach was used patients can be extubated at the end of procedure and discharged within 48 hours (2 days)[32] and this very encouraging result was demonstrated at the very start of the learning curve**.** In fact, some studies have already shown that transcervical approaches correlate with shorter length of stay than TF (Hazard Ratio 2.42, p = 0.002).[33] This observation is perhaps not surprisingly, given that the transcervical incision is already commonly employed in surgeries like mediastinoscopy,[26] transcervical thymectomy [24] and transcervical thyroidectomy[25] where same day discharge (i.e. LOS = 1 day) is the norm.

Transcervical approach using conscious sedation (CS) has been considered but GA *per se* is not a contraindication to same day discharge. Indeed many more complex procedures such as laparoscopic cholecystectomy [23] as well as the three transcervical procedure outlined above (mediastinoscopy, thymectomy, thyroidectomy) are routinely performed under GA with same day discharge.

In principle, therefore it should be possible to eliminate pain and achieve early ambulation and same day discharge if DA-TAVI is performed by transcervical route under GA.

2. Eliminate Insertion of Chest Drains

Minimisation of drains and tubes has been identified as a key element of enhanced recovery in day case procedures by other authors.[34] Drains are unnecessary in transcervical DA-TAVI.

Leaving chest drain(s) *in situ* at the end of the procedure obligates a period of watchful waiting until the drain(s) meets certain arbitrary criteria for removal. This potentially unnecessary precaution delays early progress towards extubation and recovery when time is of the essence if same day discharge is to be achieved.

Once the pericardium is opened it makes sense to place a drain as small amounts of fluid can easily impede diastolic filling causing cardiac tamponade. However, if the pericardium is not opened and the aortic cannulation site is dry there is no reason to place a drain. To some extent it is possible to avoid opening the pericardium when the aorta is approached through mini-sternotomy but never with mini-thoracotomy and in practice a chest drain is always left *in situ*.[19]

In contrast, in Transcervical DA-TAVI, the pericardial sac that encases the ascending aorta is easily identified where it is reflected off the vessel just a few cm caudal to the lower border of the left brachiocephalic (innominate) vein. Careful blunt exposure of the right supero-lateral border of aorta from above leaves several cm^2 of exposed vessel for sheath insertion without even touching the pericardium (Figure 3). This right supero-lateral segment of the aorta is the preferred entry point for Transcervical DA-TAVI.[35]

Therefore, Transcervical DA-TAVI can avoid the pericardium completely, negating the need for a drain.

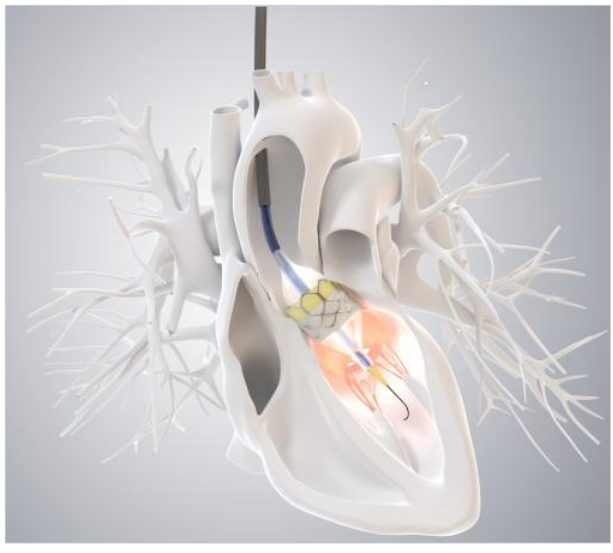

Figure 3 Transcervical DA-TAVI using CoreVista®. Note: (i) entry point of catheter into right supero-lateral portion of ascending aorta, (ii) smooth, gently curved trajectory to the aortic valve, (iii) absence of any inflections along this path.

3. Create Minimalist Clinical Pathway

It should be possible to create a one day length of stay (LOS) Minimalist Clinical Pathway for transcervical DA-TAVI. That is better than current 3 day target LOS for TF.

The current trend in TF-TAVI favours conscious sedation and protocolised minimalist strategy for recovery. However, general anaesthesia (GA) *per se* is not a barrier to minimalist recovery or same day discharge. As explained above, a multitude of surgical procedures are routinely performed under GA as day case procedures. Rather, it is pain and the attendant need for strong analgesia that primarily mandates these patients' admission to intensive care.

In a UK study of almost 9,000 patients undergoing laparoscopic cholecystectomy under GA, a staggering 80% of elective cases were performed as day cases (i.e. LOS 1 day).[23] To achieve same day discharge key elements of the enhanced recovery include minimisation of drains and tubes (as outlined above), carbohydrate drinks and fluids for up to 2 hours before surgery, avoidance of hypothermia, individualised fluid balance, early mobilisation, early return to eating and drinking and early discharge planning.[34] All of these conditions can be easily met with transcervical approach to DA-TAVI.

For same day discharge after laparoscopic cholecystectomy patients usually discharge from hospital with simple analgesics like Acetaminophen and are advised to take them pre-emptively. Additional medications may be required to counteract the effect of analgesia/ anaesthesia, such as anti-emetics, laxatives and proton pump inhibitors.[34]

Increasingly skin glues are also used as 'dressings' to render the wound waterproof enabling the patient to shower freely once they get home. Skin glues may also be applied to the transcervical (transcervical) incision. Information leaflets on recovery expectations, emergency contact details and follow up schedules are the final key element for same day discharge.[34]

In principle, all of the above steps are deliverable with transcervical DA-TAVI performed under GA. Taken together these data suggest that it is possible to design a minimalist pathway that is capable of delivering same day (1 day LOS) after transcervical DA-TAVI.

Case Report using CoreVista® System

A 84 year old male with symptomatic (NYHA class III) degenerative aortic stenosis, considered a candidate for TAVI on account of frailty but with hostile femoral anatomy underwent Transcervical Direct Aortic TAVI. Outcomes were mapped to Valve Academic Research Consortium-2 (VARC-2) criteria.[5]

TAVI was successfully performed via the transcervical access and a 26mm SAPIEN S3 valve prosthesis was implanted in correct final position (Figure 4). Only one valve was used and there was no migration or ectopic deployment. Mean gradient was 14mmHg with no aortic regurgitation, no myocardial infarction, no new onset AF, no pacemaker, no stroke, no life threatening / major / minor bleeding, no major vascular complication, no access related vascular injury, no renal injury, no evidence of new coronary obstruction and no repeat procedure. The patient was discharged on dual anti-platelet therapy and found to be NYHA class I without complication at 30 day follow up.

Conclusions

In summary, simple changes in technology, technique and clinical pathway can position Transcervical Direct Aortic TAVI as the preferred alternative access, surpassing trans-subclavian / trans-axillary, or trans-carotid approaches with results that match or even better TF-TAVI.

These changes in practice should be easy to achieve for an operator of average skill and extended team of dedicated and experienced healthcare professionals. Direct aortic puncture is the obvious strategy when TF is unsuitable, it is appropriate for all valve types and there is no need to change polarity of the valve prosthesis on the delivery catheter.

With regard to universal applicability, the main cited contraindication to DA-TAVI is porcelain aorta. However, detailed study of the distribution of calcium in such cases has shown that the often cited porcelain aorta is not actually a contraindication to DA approach.[35] In fact, DA-TAVI is almost always possible as a suitable 'area of real estate' in the preferred right supero-lateral portion of the aorta is almost invariably present, if the CT scan is studied carefully. As with all TAVI procedures high quality imaging and careful preoperative planning are the keys to success.

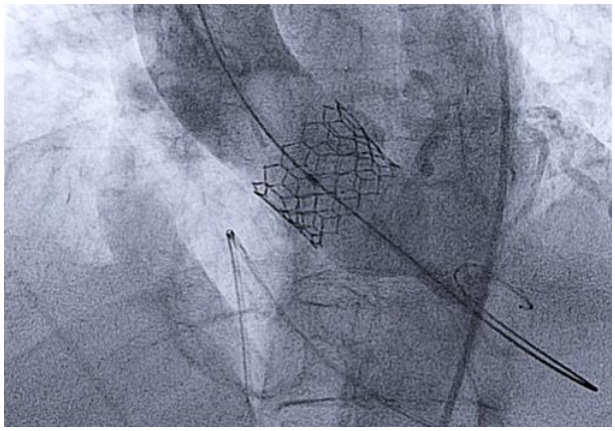

Figure 4 Implantation of SAPIEN S3 by Transcervical Direct Aortic TAVI using CoreVista®.

It is often stated that continued reduction in French size will cement the future of TF-TAVI. However, reduction in French size also favours DA-TAVI. The average aortic cannula is 22Fr, similar to first generation sheaths (24 Fr) used at the outset with Direct Aortic approach.[36] The latest Edwards Commander eSheath is only 14Fr. Furthermore, conventional practice has been to place two concentric purse string sutures in much the way one would place sutures

around an aortic perfusion cannula. However, with reduction in French size the need for two concentric purse strings with Teflon reinforcement may be unnecessary and simpler closure may be preferable and less likely to cause problems if the aorta is fragile. For example, two simple square stitches placed orthogonally to each other with inverse obliquities combines simplicity with effectiveness for smaller aortic cannula sizes.[37]

With regard to procedure time, It has been shown that procedure times of DA and TF almost identical once proficiency has been reached. However, fluoroscopy time and contrast usage are much higher with TF.[38] Procedure times were very similar in ROUTE and ADVANCE DA, 107.0 ± 30.7 and 98.3 ± 45.6 min. but actual experience and proficiency was limited to just 5 cases for operator entry into the study. Transcervical approach to DA-TAVI will be a lot faster because there is no time spent opening and closing the chest, controlling bleeding from the incision site and placing drains. As shown by Henn et al, speed will also increase significantly with operator experience.

Transcervical DA-TAVI has not yet been done in sufficient numbers to draw firm conclusions but evidence outlined above strongly points towards much improved outcomes on a par with TF or better if the steps outlined above are adopted. Importantly for cost conscious TAVI program managers, there is a realistic prospect that TAVI can become a day case procedure for all patients if Transcervical DA-TAVI is employed as the first choice for alternative access.

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