Minimalist Direct Aortic TAVR: Urgently Needed Improvements in Technique – Suprasternal Approach

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Objectives This study sought to identify problems encountered with current approaches to TAVR and provide a solution to key remaining challenges, namely how to effect reductions in the rate of complications, length of stay and cost.

Methods Starting from the premise that direct aortic puncture is a simple and reliable means of access to the aortic valve, 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 suprasternal 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) TAVR procedure for the majority of patients in need of isolated aortic valve intervention with a major reduction in overall procedure cost.

TAVR has increasingly gained acceptance as the preferred treatment for symptomatic or severe aortic stenosis. Globally over 300,000 patients have been treated by TAVR 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 TAVR 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-TAVR 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 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, 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 to be best for alternative access and some may even consider it first choice access. As the principal goal of TAVR access is to secure entry into the ascending aorta, it is believed that direct aortic puncture will ultimately prove to be the most favourable and universally applicable access. 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 DA-TAVR 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-TAVR procedure that are required.

Is DA-TAVR as efficacious as TF?

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

In particular, efficacy and incidence of VARC-2 recognised complications following DA-TAVR 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 TAVR 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 DA-TAVR is employed. These three complications are discussed in the following paragraphs.

Stroke rate is less with DA-TAVR 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-TAVR 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-TAVR. [11]

Hence available evidence is fairly compelling that DA-TAVR is likely associated with a lower incidence of stroke than TF.

Rate of Permanent Pacemaker Implantation (PPI) is less with DA-TAVR 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-TAVR 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-TAVR 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.[12]

This is clearly another very major step forward in the field suggesting that DA-TAVR 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-TAVR

Major vascular complications were observed in 12% of patients in a contemporary series of patients in whom TAVR was performed predominantly (92%) by TF access. [2] 9% of patients undergoing TF TAVR 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.[13] 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.[14] Also, 0% vascular complications were encountered in 50 consecutive patients undergoing DA-TAVR using CoreValve between 2011 – 2012.[15] In the Society of Thoracic Surgeons / American College of Cardiology TVT registry only 3 out of 868 patients (0.3%) undergoing DA-TAVR in United States between 2011 and 2014 exhibited major vascular complications despite that these were extremely high risk patients with multiple co-morbidities.[16] Therefore, there is a realistic expectation of 0% PVC if DA-TAVR 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 TAVR 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 DA-TAVR as experience increases and sheath size diminishes (see below).

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

There is currently no prospective randomised clinical trial (RCT) comparing DA-TAVR with TF-TAVR side-by-side in identically matched patient populations. This is a mixed blessing for despite that DA-TAVR offers a technical solution for universal access, and appears to have much lower incidence of three important complications (stroke, PVC and PPI) DA-TAVR 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 seems inevitable.

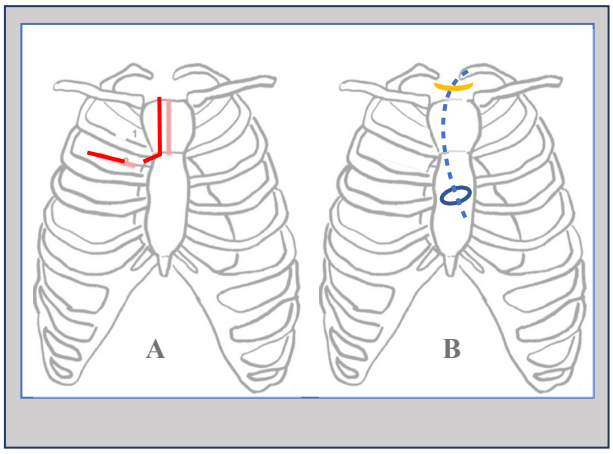

Figure 1 Traditional Painful Mini-sternotomy or Mini-thoracotomy incisions in red (A); Essentially Painless Suprasternal incision in yellow (B). Surface markings of the aortic valve in blue and trajectory of TAVR guidewire and catheter using suprasternal approach in broken blue.

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

1. Change to Suprasternal Incision
2. Eliminate Drains
3. Create Minimalist Clinical Pathway

1. Change to Suprasternal Incision

Suprasternal approach to DA-TAVR virtually eliminates pain.

Aside from the occurrence of complications, pain is the main barrier to early ambulation and quick discharge from hospital when DA-TAVR is employed. However, this can be eliminated if approach to DA-TAVR is modified to suprasternal. How will DA-TAVR 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 TAVR 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.[17]

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 TAVR [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,[18] transcervical thymectomy [19] and transcervical thyroid surgery,[20] discussed in more detail below.

Wirth regard to current approaches to DA-TAVR, 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- TAVR 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. Two devices are set to change the way that DA-TAVR is performed, CoreVista® Retractor (CardioPrecision Ltd., Glasgow, UK) and Aegis Transit™ System (Aegis Ltd, Dublin, Ireland) use a suprasternal (transcervical) incision. Figure 2 shows the CoreVista® Retractor System in a hybrid lab.

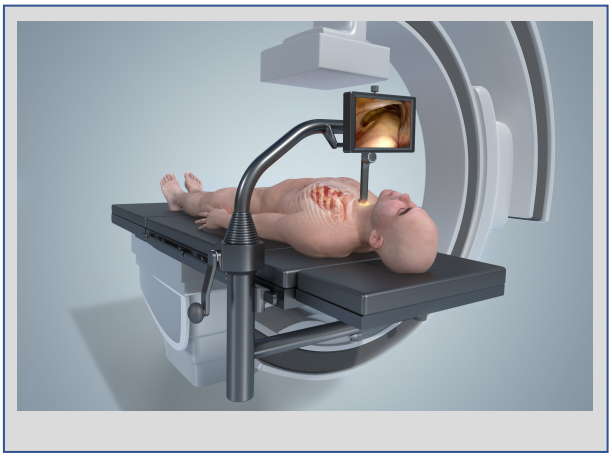

Figure 2 CoreVista® Retractor System in Hybrid Cardiac Catheterisation Laboratory (CardioPrecision Ltd, Glasgow)

These incisions are commonly used for mediastinoscopy [21] transcervical thymectomy [19] and transcervical thyroidectomy [20] and are 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 the majority of patients.

Whilst the Aegis device offers only limited access to the base of the brachiocephalic artery, [22] the CoreVista® Retractor affords access to the entire ascending aorta for TAVR to be performed [23] and the arch, if desired. It has even been used to perform SAVR procedure. [24] This means that site of entry can be accurately located to avoid calcification. Figure 1B shows suprasternal approach and the trajectory or

pathway that the guide wire catheter and device will pass. It is seen to follow the smooth, naturally convex curvature of the ascending aorta to the aortic valve.

Data on suprasternal approach to DA-TAVR is limited. [22, 23, 25] However, early evidence has shown that when suprasternal approach is used patients can be extubated at the end of procedure and discharged within 48 hours (2 days) [25] and this is at the very start of the learning curve**.** In fact, some studies have already shown that suprasternal approaches correlate with shorter length of stay than TF (Hazard Ratio 2.42, p = 0.002). [26] This observation is perhaps not surprisingly, given that the suprasternal incision is already commonly employed in surgeries like mediastinoscopy,[21] transcervical thymectomy [19] and transcervical thyroidectomy [20] where same day discharge (i.e. LOS = 1 day) is the norm.

Suprasternal 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 [18] 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-TAVR is performed by suprasternal route under GA.

2. Eliminate Drains

Minimisation of drains and tubes has been identified as a key element of enhanced recovery in day case procedures by other authors. [27] Drains are unnecessary in suprasternal DA-TAVR.

Leaving 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*. [14]

In contrast, in the suprasternal approach to DA-TAVR, 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 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 lateral segment of the aorta is the preferred entry point for DA-TAVR. [28]

Therefore, suprasternal approach to DA-TAVR avoids the pericardium completely, negating the need for a drain.

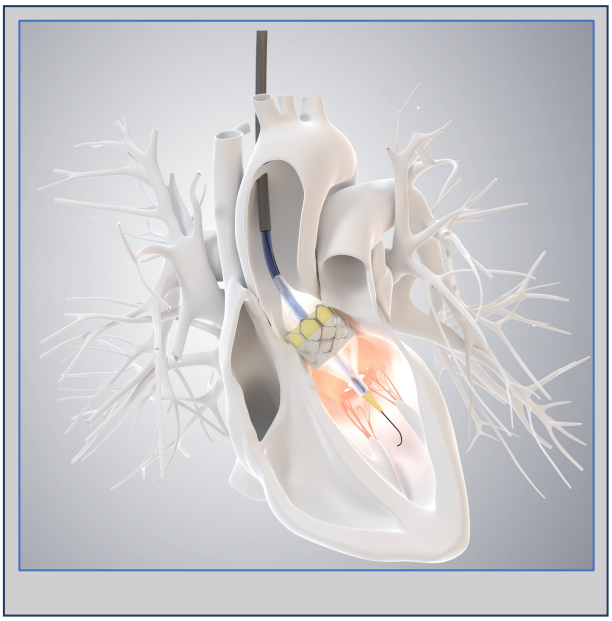

Figure 3 Suprasternal Approach to DA-TAVR using CoreVista® Retractor System; note entry point of catheter and sheath into right supero-lateral portion of aorta.

3. Create Minimalist Clinical Pathway

It should be possible to create a 1 day Length of Stay (LOS) Minimalist Clinical Pathway for suprasternal DA-TAVR. That is better than current 3 day target LOS for TF.

The current trend in TF-TAVR 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).[18] 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. [27] All of these conditions can be easily met with suprasternal approach to DA-TAVR.

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. [27]

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 (suprasternal) incision. Information leaflets on recovery expectations, emergency contact details and follow up schedules are the final key element for same day discharge.[27]

In principle, all of the above steps are deliverable with suprasternal DA-TAVR 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 suprasternal DA-TAVR.

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 TAVR. Outcomes were mapped to Valve Academic Research Consortium-2 (VARC-2) criteria. [5]

TAVR 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 Minimalist Direct Aortic - TAVR as the preferred alternative access approach with results that match if not surpass those associated with TF-TAVR.

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 reconfigure the valve prosthesis differently on the delivery catheter.

With regard to universal applicability, the main cited contraindication to DA-TAVR 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.[28] In fact, DA-TAVR is almost always possible as a suitable 'area of real estate' in the preferred right lateral portion of the aorta is almost invariably present, if the CT scan is studied carefully. As with all TAVR procedures high quality imaging and careful preoperative planning are the keys to success.

It is often stated that continued reduction in French size will cement the future of TF-TAVR. However, reduction in French size also favours DA-TAVR. The average aortic cannula is 22Fr, similar to first generation sheaths (24 Fr) used at the outset with Direct Aortic approach.[28] 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. [30]

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.[31] 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. Suprasternal approach to DA-TAVR 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.

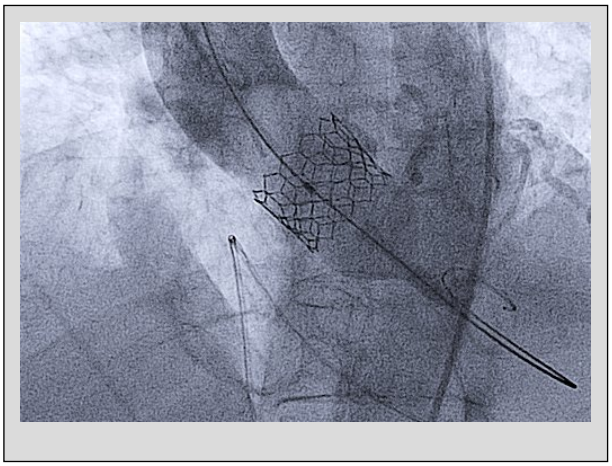

Figure 4 Implantation of SAPIEN S3 by Transcervical Direct Aortic TAVR using CoreVista® Retractor System.

Transcervical or suprasternal DA-TAVR 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 TAVR program managers, there is a realistic prospect that TAVR can become a day case procedure if DA-TAVR is employed in this way.

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