Structural Heart

The Journal of the Heart Team

ISSN: 2474-8706 (Print) 2474-8714 (Online) Journal homepage: https://www.tandfonline.com/loi/ushj20

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Ryan R. Reeves & Ehtisham Mahmud

To cite this article: Ryan R. Reeves & Ehtisham Mahmud (2017) A Standardized Minimalistic Approach to Transfemoral TAVR: Cooking Up Perfection or Following One Recipe with Different Ingredients?, Structural Heart, 1:3-4, 179-181, DOI: 10.1080/24748706.2017.1363446

To link to this article: https://doi.org/10.1080/24748706.2017.1363446

Accepted author version posted online: 02 Aug 2017.
Published online: 24 Aug 2017.

STRUCTURAL HEART
2017, VOL. 1, NOS. 3–4, 179–181
https://doi.org/10.1080/24748706.2017.1363446

EDITORIAL

A Standardized Minimalistic Approach to Transfemoral TAVR: Cooking Up Perfection or Following One Recipe with Different Ingredients?

Ryan R. Reeves, MD and Ehtisham Mahmud, MD

Sulpizio Cardiovascular Center, UC San Diego Health – La Jolla, California, USA

The rapid evolution in transcatheter aortic valve replacement (TAVR) technique and technology is one of the modern miracles in medicine. In just over a decade, TAVR has become a standard therapy and Class I recommendation for symptomatic aortic stenosis for inoperable and high risk patients.[1] Furthermore, outcomes for the intermediate risk patients are actually superior with transfemoral (TF) TAVR compared to surgical aortic valve replacement (SAVR), largely due to the lower periprocedural morbidity and mortality of the TF approach.[2,3] In this issue of *Structural Heart*, Frangieh and colleagues present a standardized minimalistic approach (MA) towards TF-TAVR with the potential for further improving outcomes using TF access.[4]

The report details the institution of an approach that simplifies preprocedural testing and streamlines intraprocedural steps to shorten procedure time and improve resource utilization. The described MA includes preprocedural protocoled multidetector CT chest and thoracoabdominal imaging, trans-thoracic echocardiography, and invasive coronary angiography. Importantly, the approach includes moderate sedation for the majority of patients without general anesthesia or routine transesophageal echocardiography (TEE). Standard femoral access site technique, preclosure, placement of the E-sheath and valve sizing algorithms for the Sapien S3 (Edwards, Irvine, CA, USA) are described. Subsequent procedural steps including temporary transvenous pacemaker placement, aortic valve crossing, routine balloon aortic valvuloplasty, with or without simultaneous aortography for size assessment, valve delivery, and valve deployment are also described. Final valve assessment is performed with aortography prior to vascular closure.

The report focuses on 300 consecutive patients (80 ± 7 years, 47% female) undergoing TF-TAVR using the Sapien S3 balloon expandable valve by a single operator. The majority of procedures were performed for severe aortic stenosis (aortic valve area 0.7 cm^2, gradient 44 mmHg), in intermediate surgical risk patients (Euroscore II 3.8%, with only 15% of the cohort > high risk score of 10%). It is a relatively healthy cohort of patients with a low prevalence of prior CABG (10%), prior MI (10%), or prior stroke (9%), and median ejection fraction of 60%. Of the entire cohort, 82% were treated with moderate sedation while 18% required intubation. The procedural characteristics included a short procedure time (median 49 minutes), low contrast use (median 100 mL), routine valve predilation (98%) with large balloons, and successful percutaneous vascular closure (98%). High procedural success with moderate/severe aortic insufficiency in 3%, only a single mortality, and no surgical conversion were reported. The in-hospital and 30-day major adverse cardiovascular and cerebrovascular event rates were 7% and 8.3% respectively.

A subanalysis is also presented dividing the overall population into the early (cohort 1 = first year of the MA; n = 120) and late (cohort 2 = after first year of the MA; n = 180) experience of the operator. In cohort 1, the valve deployment position was 50/50 above and below the annular plane. In an effort to reduce permanent pacemaker implantation, in cohort 2, the goal for valve deployment was 3 mm higher than previously recommended. The notable outcome differences between the two cohorts included slightly lower procedure time, fluoroscopy time and contrast use, and a highly significant reduction for new pacemaker implantation (18% to 5.6%) and moderate paravalvular leak (5% to 0.6%) in cohort 2.

The currently reported study focuses on the technique and clinical outcomes of the MA to TAVR. The described technique is fundamentally the same as that in the IFU for the Sapien S3 valve. The major difference in the standardized MA is the substitution of general anesthesia and routine TEE with moderate sedation and surface echocardiography. As reported, this is not only feasible but can be done with high clinical success and without an adverse effect on patient safety outcomes. We do however caution the routine use of large predilation balloons for aortic valvuloplasty prior to valve implantation. It adds an additional step, increases the risk of transient aortic insufficiency, and requires longer rapid ventricular pacing. We and others have restricted this step to aortic stenosis ≤0.7 cm^2 and use undersized balloons of 16–20 mm. After procedural completion, either aortography or surface echocardiography can confirm the absence of aortic insufficiency requiring additional postdilation. An important contribution by the group is the systematic evaluation of the higher valve implant technique with the Sapien S3 resulting in much lower permanent pacemaker rates without compromising valve procedural success, confirming a previous observation.[5] Finally, it is notable that the MA described, although with the Sapien S3, can be utilized for the self-expanding CoreValve (Medtronic, Minneapolis, MN, USA) as well.

CONTACT Ryan R. Reeves, MD rreeves@ucsd.edu Sulpizio Cardiovascular Center, UC San Diego Health – La Jolla, 9434 Medical Center Drive, La Jolla, CA 92037, USA.

From a clinical outcomes standpoint, the rates of major complications in this report are comparable to the larger early observational study of over 1000 patients treated with the Sapien S3, including disabling stroke (1.0–1.3%), pacemaker implantation (10.2–10.7%), major vascular complications (3.0–6.1%) and life threatening-bleeding (3.0–4.6%).[6] However, it is important to recognize that this report with the MA is of a single highly experienced operator, and with a device that has also undergone significant improvement over previous generations. Furthermore, the patient cohort being treated was predominantly intermediate risk, and therefore the same findings may not be extrapolated to higher risk and surgically inoperable patients. No data were provided regarding the number of patients evaluated for TAVR over the study period, or reasons for patient exclusion for TAVR. Therefore, it remains unclear as to the exact number of patients appropriate for the described MA especially those with low coronary heights, significant left ventricular dysfunction, or chronic kidney disease. As an example, in patients with advanced chronic kidney disease, our TAVR work-up includes iliofemoral intravascular ultrasound to evaluate vascular anatomy, TEE to judge annular size for valve selection, and limited coronary angiography to exclude high grade disease.

The group does not report on resource utilization benefits of the MA to TAVR. Apparently, due to reimbursement issues, the average length of stay was 5 days in the described cohort. A smaller report with a less standardized MA by Babaliaros and co-authors noted decreased ICU time, length of stay, and calculated procedure-related costs after initiation of a MA in a high risk or inoperable patient cohort being treated with the first generation Sapien balloon-expandable valve.[7] In our experience, the majority of patients with the MA to TAVR can be discharged by the second day after TAVR and require short to no time in the ICU. Recent ACC NCDR data show that the trend in the United States is shorter length of hospitalization after TAVR, and greater use of the MA to TAVR with moderate sedation increasing 8-fold from 2012 through 2015 (2.2% per year vs. 16.6% per year).[8] Importantly, the potential for a MA in TF-TAVR does not imply that every interventional cardiologist or Cath Lab is well-suited to developing a TAVR program or offer a TAVR procedure. We disagree with the suggestion that following this standardized MA any experienced interventional cardiologist could achieve these high quality results in a standard catheterization lab. This assertion is ambiguous and potentially problematic. The report is missing information on patient selection for the standardized MA and specific decision-making details of the protocol. Appropriately, the protocol is relatively specific in some areas, but subjectivity is present for important decision-making including vascular suitability for access and valve delivery, annular assessment, guidewire choice for delivery sheath placement, optimal valve sizing, and the approach to valve deployment. Additionally, the single operator is a highly experienced, high volume TAVR operator, and this experience cannot be extrapolated to the learning curve for novice or lower-volume operators.

The current report provides a roadmap and goal for every TAVR center. Ultimately with proper patient selection in a systematic manner incorporating the Heart Team, the MA to TAVR can result in superb clinical outcomes and efficient resource utilization. However, attempting a MA for every TAVR candidate does not always result in completion of a MA approach. The ability to establish and execute a plan for escalating care when the procedure does not follow an idealized MA should be in place as even at this experienced center, the MA was abandoned 18% of the time due to the need for endotracheal intubation.[4] Notably, the development of the MA does not improve the life expectancy of the severely ill patient with multiple co-morbidities; therefore, the MA should not change the futility threshold for treating the inoperable or extremely high-risk patient.

Improved in-hospital outcomes are associated with cumulative TAVR volume and while moderate sedation and a percutaneous approach is more commonly applied once higher volumes have been achieved,[9] it appears that the MA is ready for mainstream application; however the subjective holes in a standardized approach are likely best filled with experience. The goal for every great restaurant is to be awarded three Michelin stars, which comes with the label, “exceptional cuisine that is worth a special journey”; to attain this title, the chef must adapt the recipe to the ingredients, or the final product will fall short of expectations. Every TAVR program should strive for such a title, and if TAVR is to be the “pièce de résistance,” the approach will need to adapt to the patient and be ready for unexpected procedural events, for the consequences of falling short may truly be rotten.

Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the writing and content of this article.

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