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EDITORIAL

Left Atrial Appendage Closure and TAVR – A Matter of Timing and Patient Selection

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Transfemoral transcatheter aortic valve replacement (TAVR) is the accepted treatment of choice for elderly patients at higher operative risk with symptomatic severe aortic valve stenosis (AS).[1,2] Apart from age, co-morbidities and frailty characterize contemporary high-risk TAVR candidates. As such, approximately one third of these patients have atrial fibrillation (AF), which is associated with a two-to-threefold higher early and late mortality rate.[3] Therefore, anticoagulation is indicated in many such TAVR patients.

Clinically significant bleedings are relatively frequent after TAVR, especially in the early post-procedure phase (approximately one in ten), but are also non-negligible beyond 1 month after the procedure.[4,5] Furthermore, elderly patients under consideration for TAVR often have a high bleeding risk according to the HASBLED score (comprised of Hypertension, Abnormal renal/liver function, Stroke, history of or predisposition to Bleeding, Labile international normalized ratio, Elderly (> 65 years), and Drugs/alcohol).[6] In a combined TAVR cohort of 978 patients from Rotterdam and Bern, 90% of patients had a HASBLED score of ≥ 2 and 43% ≥ 3 corresponding to annual bleeding risks of at least 4 and 6% respectively (unpublished data). Accordingly, high-risk TAVR patients are at high risk of both complications of atrial fibrillation and bleeding.

Transcatheter left atrial appendage closure (LAAC) has emerged as an alternative to long-term warfarin therapy in terms of stroke prevention with a favorable safety profile including less (non-procedure related) major bleeding, hemorrhagic stroke and mortality.[7] With this background in mind it makes total sense to at least explore the feasibility of concomitant TAVR and LAAC. In this issue of *Structural Heart*, Gilhofer et al,[8] confirmed the safety of combined TAVR with the Lotus transcatheter heart valve and LA appendage occlusion with the Watchman LAAC device (both Boston Scientific Corporation, Natick, MA, USA) in 10 patients. Procedural and clinical outcome were reassuringly similar to a cohort of patients undergoing isolated Lotus TAVR or Watchman LAAC. These findings echo another Swiss experience in 52 patients.[9] However, how can we reconcile this practice of combined TAVR and LAAC with (1) current trends of "minimalist TAVR"; (2) the entity of hypo-attenuation and reduced motion/subclinical leaflet thrombosis; (3) the emergence of non-vitamin K/direct oral anticoagulants (NOAC/DOAC).

Minimalist TAVR. Many centers have streamlined TAVR to a less-than-1-hour procedure under local anesthesia avoiding additional instrumentation like transesophageal echo, deep venous access or urinary catheters.[10] Adding LAAC to TAVR will definitely complicate the procedure flow because LAAC is still predominantly performed under general anesthesia and transoesophageal echocardiography (TOE) guidance. The implementation of intracardiac echocardiography (ICE) instead of TOE may preclude the requirement for general anesthesia but would require an additional skill set and add significant cost.[11] Also, most operators would favor TAVR first and LAAC second suggesting a transseptal puncture under full anticoagulation that may impose inherent risk to the procedure.

Subclinical leaflet thrombosis. Recently, multislice computed tomography (MSCT) studies have identified transcatheter heart valve leaflet hypo-attenuation (HALT/HAM), at times accompanied by concomitant reduced motion.[12] This entity was observed more often in patients receiving (dual) antiplatelet therapy than OAC, and seemed to resolve with OAC. Replacing OAC with ad-hoc LAAC after TAVR might expose patients to an early increased risk of HALT/HAM. Some data suggest a favorable outcome with a 3-month OAC regimen after (surgical) aortic valve replacement with a bioprosthesis and current American College of Cardiology and American Heart Association guidelines recommend oral anticoagulation for the first 3 months after such procedures (Class IIa recommendation).[13] Whether this would also hold true for TAVR and whether a 3-month course of OAC would prevent HALT/HAM remains elusive. The clinical relevance of this MSCT finding is still controversial and definitely requires further research. Nevertheless, it seems prudent to keep OAC in the post-TAVR regimen until the HALT/HAM enigma has been cleared.

NOAC/DOAC. Vitamin K antagonists (VKA) may no longer be the preferred OAC for AF. Indeed, various NOAC/DOAC have a favorable safety and efficacy profile as compared to VKA and are now approved for clinical use.[14] Large international randomized trials are evaluating NOAC/DOAC vs. VKA based regimens after TAVR in patients with AF (ENVISAGE TAVI AF (NCT02943785) and ATLANTIS (NCT02664649)). The question is whether NOAC/DOAC as compared to VKA will be associated with less bleedings early and later after TAVR. Finally, it deserves mentioning that current evidence of the clinical efficacy of LAAC has been derived in comparison to VKA. How LAAC compares to NOAC/DOAC remains uncertain, even more so in TAVR patients in whom the subclinical leaflet thrombosis issue lingers.

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To conclude, in general LAAC is an attractive option in the armamentarium for patients with atrial fibrillation who are at risk for major bleeding or do not tolerate conventional oral anticoagulant therapy. Catheter-based LAAC has proven feasible in combination with a TAVR procedure. However, further adoption in our clinical practice needs confirmation in larger studies and in more centers. Issues including the optimal technical procedure, role of anticoagulation, and use of NOAC/DOACS require elucidation. For now, a deliberate, multidisciplinary approach to the individual, with reflection on risk assessment and timing, seems appropriate when deciding whether to perform LAAC and TAVR in a single procedure.

Disclosure statement

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References

1. Nishimura RA, Otto CM, Bonow RO, et al. 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines. *J Am Coll Cardiol*. 2017;70:252–289. doi:10.1016/j.jacc.2017.03.011.
2. Baumgartner H, Falk V, Bax JJ, et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J*. 2017;38:2739–2791. doi:10.1093/eurheartj/ehx391.
3. Tarantini G, Mojoli M, Urena M, Vahanian A. Atrial fibrillation in patients undergoing transcatheter aortic valve implantation: epidemiology, timing, predictors, and outcome. *Eur Heart J*. 2017;38:1285–1293. doi:10.1093/eurheartj/ehw456.
4. Vranckx P, Windecker S, Welsh RC, Valgimigli M, Mehran R, Dangas G. Thrombo-embolic prevention after transcatheter aortic valve implantation. *Eur Heart J*. 2017;38:3341–3350. doi:10.1093/eurheartj/ehx390.
5. Genereux P, Cohen DJ, Williams MR, et al. Bleeding complications after surgical aortic valve replacement compared with transcatheter aortic valve replacement: insights from the PARTNER I Trial (Placement of Aortic Transcatheter Valve). *J Am Coll Cardiol*. 2014;63:1100–1109. doi:10.1016/j.jacc.2013.10.058.
6. Honda YYM, Araki M, Tada N, et al. Impact of HAS-BLED score to predict trans femoral transcatheter aortic valve replacement outcomes. *Catheter Cardiovasc Interv*. 2018. doi:10.1002/ccd.27596.
7. Reddy VY, Doshi SK, Kar S, et al. 5-year outcomes after left atrial appendage closure: from the PREVAIL and PROTECT AF Trials. *J Am Coll Cardiol*. 2017;70:2964–2975. doi:10.1016/j.jacc.2017.10.021.
8. Gilhofer TS, Obeid S, Luescher TF, Binder, RK. Simultaneous transcatheter aortic valve implantation and left atrial appendage occlusion versus both interventions as stand-alone procedures. *Struct Heart*. 2018;2:this issue.
9. Attinger-Toller A, Maisano F, Senn O, et al. "One-stop shop": safety of combining transcatheter aortic valve replacement and left atrial appendage occlusion. *JACC Cardiovasc Interv*. 2016;9:1487–1495. doi:10.1016/j.jcin.2016.04.038.
10. Barbanti M, Webb JG, Gilard M, Capodanno D, Tamburino C. Transcatheter aortic valve implantation in 2017: state of the art. *EuroIntervention*. 2017;13:AA11–AA21. doi:10.4244/EIJ-D-17-00567.
11. Berti S, Pastormerlo LE, Santoro G, et al. Intracardiac versus transesophageal echocardiographic guidance for left atrial appendage occlusion: the LAAO Italian multicenter registry. *JACC Cardiovasc Interv*. 2018;11:1086–1092. doi:10.1016/j.jcin.2018.05.008.
12. Chakravarty T, Sondergaard L, Friedman J, et al. Subclinical leaflet thrombosis in surgical and transcatheter bioprosthetic aortic valves: an observational study. *Lancet*. 2017;389:2383–2392. doi:10.1016/S0140-6736(17)30757-2.
13. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association task force on practice guidelines. *J Am Coll Cardiol*. 2014;63:2438–2488. doi:10.1016/j.jacc.2014.02.537.
14. Siontis KC, Yao X, Gersh BJ, Noseworthy PA. Direct oral anticoagulants in patients with atrial fibrillation and valvular heart disease other than significant mitral stenosis and mechanical valves: a meta-analysis. *Circulation*. 2017;135:714–716. doi:10.1161/CIRCULATIONAHA.116.026793.