Reply to letter to the editor: Warning: Potential risks and limitations of preemptive alcohol septal ablation before transcatheter mitral valve replacement

To the Editor,

We would like to thank the authors for their great interest and comments on our article titled, "Tip-to-base LAMPOON to prevent left ventricular outflow tract obstruction in a valve-inring transcatheter mitral valve replacement: First LAMPOON procedure in Turkey and first LAMPOON case for transseptal Myval[™] implantation," which has recently published in Anatol J Cardiol 2021; 25: 363-7 (1).

Although preemptive alcohol septal ablation (ASA) was used in some patients to prevent LVOTO during transcatheter mitral valve replacement (TMVR), we believe that this method should not be used as a first-line therapy and should not be evaluated as an alternative method to LAMPOON procedure (2-4). Preemptive ASA may only be a supportive treatment modality to LAMPOON procedure, especially in a small subset of patients with very small ventricles where the covered skirt of the transcatheter valve causes left ventricular outflow tract obstruction (LVOTO) despite the usage of LAMPOON procedure (4). Although preemptive ASA looks like a less invasive method, we believe that it is not a benign procedure and may be harmful for these patients. In a very recently published article, Wang et al. (2) evaluated clinical outcomes of preemptive ASA in 30 patients who were candidates for TMVR. Among 30 patients, only 20 underwent mitral valve replacement (14 transseptal, 3 transatrial, 1 transapical, 1 transseptal with LAMPOON, and 1 treated with surgery). Two (6.7%) patients who underwent ASA immediately died before TMVR owing to total occlusion of the coronary arteries and new-onset atrial fibrillation that caused hemodynamic compromise. In addition, insufficient neo-LVOT remodeling and the permanent pacemaker rates following ASA were found to be very high (13.6% and 16.7%, respectively) (2). On follow-up, 10 (37%) still had a neo-LVOT under 200 mm² (2). Moreover, the Achilles' heel of this procedure is that it needs a long waiting period, and some patients cannot tolerate this period and can die during the 4 or 6 weeks of waiting process. Patients who do not have an engageable septal perforator or who have had prior CABG and an occluded left main coronary artery are also not eligible for preemptive ASA therapy. There is also a risk of development of late ventricular septal defect after preemptive ASA if the septum thickness is relatively low (5).

We did read the article which was recently published by Tiwana et al. (3) carefully and referred by the authors in their letter. However, that study did not evaluate the clinical outcomes of ASA before TMVR as only 3 of the 40 patients underwent preemptive ASA in the study population (3). The main objective of Tiwana et al. (3) was to evaluate outcomes of commercial TMVR for annular rings and calcification using contemporary techniques. The authors recommend an algorithm for TMVR by using the reference figure of Tiwana et al. (3) in their letter. However, that figure only represents the selection criteria of the patients included in the study empirically (3). Therefore, that figure should never be used by implanting physicians as a guide as these criteria were created empirically over time; and thus, not all patients in the study were subject to the same selection criteria. ASA also was not as commonly performed for prophylaxis in the cohort of Tiwana et al. (3) because of concerns with its associated morbidity and mortality following an early death owing to malignant arrhythmia 3 days post ASA in a patient planned for TMVR (3). Therefore, we do not agree with the authors and do not recommend using these criteria as an algorithm for prevention of LVOTO in TMVR. Moreover, in the study by Tiwana et al. (3), 1 of 3 patients developed acute LVOTO despite preemptive ASA.

In our case, there were multiple anatomic risk factors for LVOTO during TMVR as the patient had a very elongated anterior leaflet (31.5 mm), a small ventricular cavity, and a perpendicular AMA. We also calculated the predicted neo-LVOT using virtual 26-mm Myval found as 169 mm², which confers an increased and prohibitive risk of LVOTO according to observational studies (<170-190 mm²) (6-8). The neo-LVOT area, measured using a computed tomography simulated valve, predicts LVOT obstruction from TMVR (8). This assumes the anterior leaflet covers any open valve stent cells (9). We also agree that measuring "skirt neoLVOT" especially after TMVR is very useful approach. However, the term "skirt neoLVOT" mainly represents the residual area after TMVR and anterior leaflet resection either by surgery or transcatheter LAMPOON procedure (9). Because the protruding fabric skirts on the transcatheter heart valves may still obstruct the LVOT, emergency ASA as an adjunctive therapy may be required despite anterior leaflet modification (9). Nevertheless, no gradient was observed after LAMPOON and TMVR in our patient. The pre-procedural calculation of "skirt" neoLVOT is usually done with only the atrial skirt of the valve simulated, that is, with a height of 10 mm for a 26-mm Edwars valve. However, it can be different according to valve type and size, and further studies are required to validate the most appropriate cut-off values (9). In the study of Tiwana et al. (3), the cut-off values as 200 mm² and 150 mm² were selected empirically and should not be used until validation by prospective studies with computational fluid hemodynamics (3, 9).

As our main aim was to present the results of the first LAMPOON procedure in Turkey, we did not discuss adjunctive or alternative techniques in our case report (1). However, we agree with the authors' comments that there are other methods such as preemptive ASA, radiofrequency ablation of the interventricular septum, mechanical splitting of the anterior leaflet, the POULEZ

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technique, and the kissing-balloon technique (10). Nevertheless, only LAMPOON for TMVR has been investigated in a prospective, independently adjudicated multi-center clinical trial (11).

One additional contribution we would make to the authors' comments is to underline the transcatheter balloon assisted translocation of anterior leaflet (BATMAN) procedure, which may be a future alternative for the LAMPOON procedure (12). BATMAN is a new technique to prevent LVOTO from TMVR by deploying the transcatheter heart valve from the apex through a perforation of the anterior mitral valve leaflet. Nevertheless, it is a transapical approach and carries the risks of uncontrolled balloon dilatation of the anterior mitral valve leaflet, including extension of the tear superiorly into the aorto-mitral curtain or laterally to avulse the trigone from the annulus (13). However, a variation of this technique to allow application in patients with a transseptal approach is under investigation and may be useful, especially for valve in ring procedures (12).

We agree with the use of smaller balloons to dilate the atrial septum. However, we could not take any risk of valve entrapment in this patient as emergent valve replacement was required under intraaortic balloon support after the LAMPOON procedure (1). Finally, we once again wish to thank our friends for their important comments on our original article. Nevertheless, implanting physicians should also recognize the potential complications and risk of therapeutic failure associated with preemptive ASA in these patients who are often extremely sick and at risk of death.

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