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Review Article

Left Ventricular Outflow Tract and Transcatheter Mitral Valve Replacement Obstruction and TMVR: Predictors, Evaluation, and Solutions

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ABBREVIATIONS

ABSTRACT

In this issue of *Structural Heart*, high-impact presentations from Transcatheter Valve Therapies 2023 are reviewed. Dr Jaffar Khan provided updates on the current understanding of left ventricular outflow tract obstruction in the field of transcatheter mitral valve replacement, highlighting known predictors of obstruction, a generally agreed-upon strategy for preprocedure assessment, and a host of management strategies in various stages of development and study.

CTA, computed tomography angiography; LVOT, left ventricular outflow tract; LVOTO, left ventricular outflow tract obstruction; TMVR, transcatheter mitral valve replacement; ViMAC, valve in MAC (mitral annular calcification); ViR, valve in ring; VIV, valve in valve.

Introduction

Briefly, during transcatheter mitral valve replacement (TMVR), implantation of a transcatheter heart valve results in displacement of the anterior mitral leaflet into the left ventricular outflow tract (LVOT) toward the basal interventricular septum, such that the corridor is narrowed. Much has been learned from the work of the preceding decade regarding the incidence and outcome effects of LVOT obstruction (LVOTO), relevant predictors, the development of an algorithmic preprocedure evaluation strategy, and advances in management options both prior to and at the time of TMVR. Particularly as numerous dedicated TMVR prostheses, the majority of which have a closed cell design, progress toward commercial availability and a move away from the relative widespread use of off-label aortic prostheses feels imminent, an understanding of these anatomic features is paramount to procedural success.

LVOTO remains a feared and catastrophic complication of TMVR. While LVOTO is not the sole driver of outcomes in TMVR, and much has

been said regarding the comorbidity and frailty of early cohorts, particularly those patients treated with valve in mitral annular calcification (MAC) (ViMAC), its presence remains vexing. Of the first 116 patients treated in the TMVR in the MAC Global Registry, 11.2% (n = 13) experienced LVOTO with hemodynamic compromise, 11 of whom subsequently died.1 However, these data represent the earliest broad experience of TMVR and are reported from numerous centers with a small per-center case load. As understanding of the anatomic relationships, risk factors, and sizing algorithms has grown, it would be expected that LVOTO risk would decrease over time. Compared to valve in valve (ViV), in which the native mitral anterior leaflet is surgically absent, valve in ring (ViR) and ViMAC have a demonstrably higher rate of LVOTO, though the incidence of LVOTO is variably reported between 10% and 40%,^{2,3} depending on the registry evaluated. Data from the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry evaluating over 900 patients treated with TMVR from March 2013 to June 2017 (ViV [n = 680], ViR [n =

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Figure 1. (a) Gated cardiac CTA assessment of the LVOT in long access following insertion of a hypothetical valve within the previously defined mitral annulus in a patient with previous TAVR. The total height of the valve frame is simulated by the blue outline, while the shorter, pink lines define the covered portion of the prosthesis cage. The white and blue tulips markers at the basal septum define the LVOT area plane for the (b) neo-LVOT (blue), measuring 142.7 mm², and (c) skirt neo-LVOT (white), measuring 364.3 mm².

Abbreviations: CTA, computed tomography angiography; ES, end systole; LVOT, left ventricular outflow tract; MPR, multiplanar reformat; TAVR, transcatheter aortic valve replacement.

123], or ViMAC [n = 100]) report that LVOTO occurred considerably more frequently with ViMAC cases and, to a lesser extent, ViR (ViMAC 10%, ViR 4.9%, MViV 0.7%; p < 0.001).³ What's more, in-hospital and 30-day mortality curves all follow a similar trajectory, stratified by case type (ViV 6.3%, ViR 9%, ViMAC 18%; p = 0.004; ViV 8.1%, ViR 11.5%, ViMAC 21.8%; p = 0.003), and prospective data from the mitral implantation of transcatheter valves trial maintains this finding out to 2 years.⁴ While it is clear that numerous factors dictate procedural success and short- and long-term outcomes following TMVR, LVOTO at the time of implant remains a primary driver and remains a prominent cause of screen failure in TMVR trials, ranging from 5% to 44% of anatomic exclusions depending on series, etiology, and the evaluating center.^{5–7}

Predictors

To better understand the patient-specific factors behind an individual case, a detailed assessment of the mitral annulus and landing zone on cardiac-gated CTA is performed, typically at the end systole, using multiplanar reconstruction software (i.e., Circle, Circle Cardiovascular Imaging; 3mensio, Pie Medical Imaging). Careful analysis of the annular structures-whether that be a surgical prosthesis, ring, or advanced MAC-is crucial to understanding how the valve will sit upon deployment. Next, the LVOT must be evaluated at baseline and following the implant of a transcatheter prosthesis, which may be accurately simulated using the software platforms mentioned above, to understand and mitigate the risk of LVOTO (Figure 1a-c). The predicted "neo-LVOT," the space created between the septum and the displaced anterior mitral leaflet, is the smallest area measured on the CTA following positioning of the hypothetical valve. Truly, it is not possible to know the prosthesis landing zone with certainty, and some assumptions are made during this analysis, though, generally, a 20% atrial/80% ventricular placement is used. Through this, operators may visualize the relative relationships that "will exist" following a valve implant.

In addition to this "fixed" LVOTO caused by a reduced neo-LVOT, there is also a risk of "dynamic" LVOTO as a result of systolic anterior motion (SAM) of the anterior mitral leaflet. A long anterior leaflet with redundant, lax chordae predisposes to SAM after TMVR (Figure 2).

Considerable work has been done to understand and validate the ex vivo computed tomography analysis of transcatheter valve implantation. Early data published in 2018 analyzing 38 patients treated with TMVR, 7 of whom developed LVOTO defined as an increase in hemodynamic gradient by 10 mmHg, had an average predicted neoLVOT of 114.0 \pm



Figure 2. Displacement of a long, billowy anterior mitral valve leaflet by the cage of the transcatheter heart valve may result in dynamic LVOT obstruction, mimicking SAM type physiology.

Abbreviations: LVOT, left ventricular outflow tract; SAM, systolic anterior motion.



Figure 3. SESAME involves traversing the interventricular septal long access with a penetrative wire, which is then snared and externalized. Electrocautery is applied to slice the muscle bulk, increasing the LVOT area by creating a "valley" for blood flow through the septum, which enlarges during healing due to tension from the circumferential fibers of cardiac muscle.

Abbreviations: NHLBI, National Heart Lung and Blood Institute; SESAME, septal scoring along the midline endocardium.

63.0 mm². However, a receiver operator curve analysis of this small cohort revealed a predicted neo-LVOT area <189.4 mm² was extremely predictive of LVOTO with 100% sensitivity and 96.8% specificity.⁸

Further, among 194 patients in the TMVR Registry with preprocedural CT undergoing TMVR (ViV, 107 patients; ViR, 50 patients; ViMAC, 37 patients), Yoon et al. described 26 patients who developed LVOTO and evaluated several fixed anatomic predictors. Some, such as aortomitral angle (sensitivity 46.2, specificity 41.1, p = 0.92), left ventricular mass index (sensitivity 65.4, specificity 61.1, p = 0.02), relative wall thickness (sensitivity 96.2, specificity 38.9, p = 0.001), and left ventricular end diastolic dimension (sensitivity 88.5, specificity 53.3, p < 0.001), were not particularly discerning. However, in keeping with previous findings, a predicted neo-LVOT <170 mm² was 96.2% sensitive and 92.3% specific (p < 0.001) for predicting LVOTO. Additionally, the measurement of mitral annular to interventricular septal (IVS) distance was a reasonably strong predictor, 84.6% sensitive and 95.8% specific (p < 0.001). Particularly as the current practice of using open cell prostheses led to the development of strategies to modify the native anterior mitral leaflet (more below), such that blood may flow through the open cells in the LVOT, understanding the potential interaction between the valve cage and IVS is relevant. Even in circumstances in which successful modifications are performed to accommodate TMVR and LVOT flow hemodynamics are normal following implant, it has been hypothesized that contact of the valve cage with the IVS may alter local laminar flow patterns in the LVOT and may contribute to hemolysis. Based on these data, a predicted neo-LVOT under 170 to 200 mm² is now broadly accepted as inhospitable for TMVR and necessitates modification. There was some initial consideration that this cut point may be overly conservative and result in a high false-positive rate. To that end, there is increased traction to the notion that there is no measure of LVOT area

that would be "too large," and this circumstance is one in which, universally, more is better, which has led to a broader acceptance of adjunctive procedural modifications to optimize LVOT area around the time of TMVR, particularly in ViR and ViMAC patients.

While it is true that all anatomic relationships within the heart have dynamism throughout the cardiac cycle, the motion of the residual elements of the native anterior mitral leaflet may result in dynamic outflow obstruction. Though well understood to be a contributing factor to outcomes following mitral valve surgery and septal myectomy, understanding how to manage a long or redundant native anterior leaflet in the setting of TMVR is in its early phases.^{9,10} Reports describe an overhanging anterior leaflet interacting with, or impinging on, the leaflets of the prosthesis, which may lead to dysfunction. More to the topic at hand, a large, billowy native leaflet may result in dynamic outflow obstruction, as may be seen in a patient with hypertrophic cardiomyopathy-type LVOTO in the setting of systolic anterior mitral leaflet motion. As this is particularly dependent on loading conditions, postimplant LVOT hemodynamics may be normal or only slightly increased from baseline, and severe LVOTO may arise in follow-up.¹¹

As the field proliferates, an understanding of the fixed and dynamic anatomic players that give rise to LVOTO following TMVR has taken shape. Knowing the catastrophic effect LVOTO plays in the outcomes following TMVR, honing our tools and skills to modify these becomes critical to procedural success and safety, as well as broader care delivery.

Management

Leveraging detailed knowledge of the aforementioned anatomic contributors, as well as the transcatheter prosthesis construction and device specifications, the interventionalist now has numerous strategies for the management of LVOTO risk in the preprocedural and intraprocedural period, which may be tailored to the individual patient's anatomy and operator, or site-specific skill sets. Acute salvage strategies for severe LVOTO and cardiovascular collapse are extremely limited, and great care should be taken to mitigate this risk, including multiple preparatory procedures if needed.

Despite appropriate preprocedural planning, if LVOTO does occur with associated cardiovascular collapse, mechanical circulatory support may be required. Typically, an intraventricular, transaxial flow pump such as Impella (Abiomed) is used to bypass the level of obstruction and support perfusion. Medical management focuses on appropriate left ventricular volume loading, avoidance of chronotropic and inotropic agents, and use of peripheral vasopressors to support the standard blood pressure. Addressing any aortic valve contributor to the LVOTO is often low-hanging fruit, and, as mentioned below, operators should be prepared to perform TAVI in a bailout situation if they do not intend to perform antecedent aortic valve replacement. Alcohol septal ablation (ASA) is an additional bailout strategy, desiring to induce a myocardial akinesis at the treated site. However, the full effects of ASA are not realized immediately, and local tissue edema may result, which could theoretically worsen obstruction, though this is not well understood. Though these techniques and others have been used in bailout situations, they are invariably less effective when performed acutely and under duress.

As we take stock of the mechanisms by which LVOT area may be increased, it is helpful to lump the techniques into three "buckets": interventricular septal reduction therapies, modification of the anterior mitral leaflet, and changes in the design of dedicated prostheses. Often, and particularly in ViMAC cases, an individual patient may require multiple procedures to facilitate TMVR, and complex cases should be reserved for centers with broad experience in managing these patients.

Typically performed in advance of TMVR, septal reduction strategies are aimed at debulking the muscular mass and limiting the contractility of the basal IVS. ASA is a well-established procedure to percutaneously debulk the IVS using ethanol-induced, controlled myocardial infarction. After engagement of the left main coronary, angiography is used to

identify an appropriate septal perforator. The vessel is wired, and a small caliber, over-the-wire balloon is used to occlude proximal flow. Echocardiographic contrast administration via the balloon lumen can be used to localize the subtended myocardium fed by the vessel. Once satisfied with the location, dehydrated alcohol is administered at a concentration of approximately 0.1 mL per 1 mm of septal thickness, which is generally less than reported treatment algorithms for hypertrophic cardiomyopathy patients (2 to 4 mL).¹² While there is no set standard, cardiac CT reassessment is performed at around 1 month to assess for LVOT enlargement following ASA, which is a generally agreed-upon time course to reassess any pre-TMVR septal modification strategy. The procedure is associated with high rates of complete heart block (10.5% in large series) and, less frequently, ventricular septal defect, though it is generally well tolerated.¹² However, these data represent the ASA experience in hypertrophic cardiomyopathy patients, which carries several intrinsic differences to the pre-TMVR cohort. Wang et al. published a series of 27 patients undergoing ASA prior to TMVR. In their cohort, median increase in neo-LVOT surface area post-ASA was 111.2 mm², though pacemaker rate was 16.5%, with 10/27 patients (27%) having a predicting neo-LVOT area persistently <200 mm².¹³ Although demonstrably effective at debulking the septum, the relatively high rate of complete heart block and inadequate LVOT area enlargement leave something to be desired. It is worth noting, however, that ASA may be used as a bailout strategy in these circumstances to render the septal myocardium hypo- or akinetic acutely. This may be temporarily satisfactory to support cardiac performance while the extended-term benefits of ASA take effect.

Additional strategies to address the septal component of LVOTO have been reported. Percutaneous radiofrequency ablation (septal bipolar ablation of noncoronary subtended myocardium to prevent outflow tract obstruction) has shown promise and has been demonstrated to be effective in patients with hypertrophic cardiomyopathy; however, in the pre-TMVR patient population, it is associated with a very high pacemaker rate approaching $100\%^{14,15}$ and, for this reason, has not been widely adopted. Similarly, the percutaneous intramyocardial septal radio-frequency ablation technique was studied in 200 patients in China from 2016 to 2020 with hypertrophic cardiomyopathy. At a median follow-up of 19 months, maximal septal thickness was reduced from a mean of 24 to 13.3 mm (p < 0.001), and LVOT gradients decreased from 79 to 14 mmHg (p < 0.001). However, the 30-day major adverse cardiovascular event rate was 10.5% with 2 in-hospital deaths and 19 patients (9.5%) with pericardial effusion requiring management. Notably, there were no permanent pacemaker implants.¹⁴ Overall, these techniques may have a role but require further study in the pre-TMVR population before adoption.

A different septal debulking strategy, electrosurgical septal myotomy, also called septal scoring along the midline endocardium, involves separating the septal muscle bulk in the longitudinal dimension (Figure 3) and is performed routinely by high-volume operators in the originating centers. A penetrative wire is burrowed through the basal to midseptum and then snared in the ventricular apex, electrified using standard electrocautery tools, and pulled through the muscle into the ventricular cavity.¹⁶ The resulting "cut" slowly pulls apart as the circumferential fibers of the left ventricular myocardium, which then scars and fibrose, creating a valley for blood flow through the LVOT. While still investigational, data on the effectiveness and safety of the technique is forthcoming and shows great promise.

At the time of TMVR, LVOTO risk mitigation typically focuses on modification of the anterior mitral leaflet. Intentional LAMPOON Procedure (laceration of the anterior mitral leaflet to prevent left ventricular outflow tract obstruction), during which the anterior leaflet is intentionally penetrated and cut using electrocautery, flays the mitral leaflet in such a way as to allow blood to flow through the open cells of the transcatheter prosthesis in the LVOT¹⁷ (Figure 4a-d). As the height of the skirt of the transcatheter prosthesis is uniformly known, CT assessment of the "skirt neo-LVOT" allows for estimation of the LVOT area after LAMPOON. A predicted skirt neo-LVOT area <150 mm² is associated with a significant risk of LVOTO obstruction, and TMVR is not



Figure 4. LAMPOON is performed at the time of TMVR. (a) As seen in the three dimensional en face projection prior to transcatheter heart valve and the two dimensional three chamber view following implantation, (b) the anterior mitral leaflet is sliced from the base to the tip to allow for maximal splay, though nonlaminar flow is still observed as blood flows through the open cells of the valve cage. (c and d) The open position of the mitral leaflet against the valve cage can be clearly seen in CTA reconstructions and is necessary to prevent LVOT obstruction in this patient, given the small predicted neo-LVOT (61 mm²).

Abbreviations: LAMPOON, laceration of the anterior mitral leaflet to prevent left ventricular outflow tract obstruction; TMVR, transcatheter mitral valve replacement. recommended without preemptive septal modification. However, for dedicated transcatheter mitral valve designs with completely closed cells, the benefits of LAMPOON are limited to the prevention of SAM. Certain TMVR valves are designed to anchor on the mitral leaflets, and the suitability of these valve designs in combination with leaflet modification strategies are yet to be tested. Given the high screen failure rate for clinical trials due to LVOTO, future generations of these valves may have open cells facing the LVOT to allow adjunctive LAMPOON and increase LVOT flow.

Finally, concomitant aortic valve disease may be addressed as part of an LVOTO management plan. Elevation in the aortic gradient may serve to compound LVOTO following TMVR, particularly in those patients with borderline sizing measurements on CTA. Even a moderately elevated aortic valve gradient, which, in isolation, may not warrant treatment, may cause clinically significant outflow obstruction when coupled to a degree of LVOTO. To that end, transcatheter aortic valve implant (TAVI) could be considered in patients with elevated resting aortic valve gradients above 20 to 25 mmHg, as long as it is anatomically feasible, though this approach requires individualization. Further, if hemodynamically significant LVOTO occurs after TMVR in a patient with an elevated resting aortic valve gradient, TAVI may be performed urgently as a bailout strategy. To that end, in patients not treated prior to TMVR, sizing measurements for TAVI are recommended in case an urgent bailout is unexpectedly encountered.

As the collective understanding of preprocedural workup and assessment has grown, with an ever-growing armament of management strategies, published algorithms have been created to help guide the care of these complex patients. Based on the neo-LVOT, anterior mitral leaflet length, and skirt neo-LVOT, a generally accepted care pathway has developed for the management of LVOTO risk, as clearly outlined in the recent 2023 JACC State of the Art Review by Eleid et al.¹⁸ Generally, if there is predicted risk of LVOTO, consider using a valve with a smaller footprint in the left ventricle if possible, and/or one or a combination of septal and leaflet modification strategies. Individualized decisions must be made regarding the necessary steps to ensure the safety of the TMVR procedure, particularly for ViMAC cases, and a careful, upfront discussion with the patient to outline this process is crucial to understanding and satisfaction.

Summary

TMVR is an effective therapy and an increasingly available option to treat those patients for whom surgical mitral valve replacement is not offered. However, the risks of TMVR remain considerable, particularly in cases of ViMAC, and the management of LVOTO risk remains a primary concern. Much work has been done to understand the preparatory CT analysis, anatomic predictors, management strategies, and general care pathways to complete these procedures effectively and with a high degree of safety. However, particularly as the complement of dedicated transcatheter mitral prostheses continues to grow, which largely obviates the use of leaflet management strategies such as LAMPOON, septal modification strategies are of increasing importance. As highlighted at Transcatheter Valve Therapies 2023, many strategies exist in various stages of evaluation and practice, each with technical considerations and risk profiles. Given the catastrophic nature of postimplant LVOTO, operators should employ a "belts and suspenders" approach with these patients to optimize the LVOT area to the degree possible. While certain minimum requirements are generally agreed upon at this time, as the field moves from nascency to more enlightened understanding, aggressive preparatory LVOT modification should be considered routinely and balanced against the procedural risks to optimize the LVOT in every patient.

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