Percutaneous Mitral Balloon Valvuloplasty: Worldwide Trends

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Since its introduction in 1984, percutaneous mitral balloon valvuloplasty (PMV) has established itself as the procedure of choice for patients with severe symptomatic rheumatic mitral stenosis, providing excellent immediate, intermediate, and long-term results. PMV today is considered to be the procedure of choice in symptomatic patients with severe rheumatic mitral stenosis and suitable mitral valve anatomical features.[1–3] Before the advent of PMV, most patients with symptomatic mitral stenosis were treated with surgical mitral commissurotomy, either open or closed.[1] In the case of moderate or severe mitral stenosis, one has to assess the anatomical features of the mitral valve meticulously with regard to the feasibility and safety of PMV.[3] The most widely used echocardiographic parameter is the Wilkins score,[4] which takes into consideration the anatomical features of the leaflet, the commissures, and the subvalvular apparatus. The scoring system assigns a point value from 1 to 4 for each of the following: (1) valve calcification, (2) leaflet mobility, (3) leaflet thickening, and (4) subvalvular apparatus degeneration. A mitral valve with a score of <8 to 9 with no more than moderate mitral regurgitation is deemed the best candidate for percutaneous balloon mitral valvuloplasty (PBMV). In patients with a score of >9 to 10, especially with more than moderate mitral regurgitation, surgical therapy should be advised, except in cases with serious comorbidities. A simpler echocardiographic classification for the stenotic mitral valve was introduced by the Iung and Cormier score.[5] This score is unique for taking the length of the chordae into consideration. A novel quantitative parameter, described by Nunez et al,[6] included the ratio between the commissural areas/the maximal excursion of the leaflets from the annulus in diastole. Independent predictors of outcome were assigned a point value proportional to their regression coefficients: mitral valve area $\leq$1 cm^2,[2] maximum leaflet displacement $\leq$12 mm,[3] commissural area ratio $\geq$1.25,[3] and subvalvular involvement.[3] Three risk groups were defined: low (score of 0–3), intermediate (score of 5), and high (score of 6–11), with observed suboptimal PMV results of 16.9%, 56.3%, and 73.8%, respectively. The use of the same scoring system in the validation cohort yielded suboptimal PMV results of 11.8%, 72.7%, and 87.5% in the low-, intermediate-, and high-risk groups, respectively (P<0.0001). Long-term outcome was predicted. The model improved risk classification in comparison with the Wilkins score (net reclassification improvement, 45.2%; P<0.0001). Long-term outcome was predicted by age and postprocedural variables, including mitral regurgitation, mean gradient, and pulmonary pressure.[6]

Severe mitral regurgitation after mitral balloon valvuloplasty is a major complication of this procedure. This complication confers an adverse prognosis and frequently requires intensive treatment and urgent mitral valve surgery. Although some morphologic features of the mitral valve might increase the risk of severe regurgitation, echocardiographic evaluation with the Wilkins mitral valve score has been unable to predict it. We described a new echocardiographic score that can predict the development of severe mitral regurgitation after mitral balloon valvuloplasty with the double balloon and the Inoue balloon techniques.[7,8] This score takes into account the distribution (even or uneven) of leaflet thickening and calcification, the degree and symmetry of commissural disease, and the severity of subvalvular disease. Thus, echocardiography could identify patients with a high risk of developing severe mitral regurgitation after percutaneous mitral valvulotomy using this proposed mitral regurgitation echocardiographic score. This new score can help assess the probability of this complication before the procedure to anticipate the likelihood that surgical repair may be needed. In addition, it could conceivably be used to select patients for modified procedures that might be developed to minimize this complication.[7,8]

Although there has been a steady decline in the incidence of rheumatic heart disease in industrialized nations, rheumatic mitral stenosis still causes significant mortality and morbidity worldwide. This is particularly true in nations with a significant number of immigrants from regions with endemic rheumatic

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heart disease. The incidence and prevalence of rheumatic mitral stenosis is declining in the United States and the world.[9,10]

In this issue of the *Journal of the American Heart Association* (*JAHA*), the article by Desnos et al reported a progressive decrease in the number of PMVs performed per year.[11] Furthermore, in this population originating mainly from a European country, they reported that patients presenting for PMV have become older and have less favorable mitral valve anatomical features for PMV. Despite significant trends in increased age and less favorable anatomical conditions, the safety of the technique improved, and its efficacy was maintained.[11] They speculate that the good results obtained in this population, despite the less favorable anatomical features, may be because of the operator's experience in improving the technique and more careful patient selection. Furthermore, the multifactorial nature of the prediction of immediate results can also play a role in the improved post-PMV results in these suboptimal patients.[12,13]

The findings of this article are in agreement with previous studies showing similar PMV trends in the United States and Europe.[9–13] We previously reported 7.5% decreased use during the past decade, with a concomitant increase of procedure complication rate of 15.9%, and increased age in a study from 13-year data (from 1998 to 2010) of the nationwide inpatient sample, a subset of the Healthcare Cost and Utilization Project sponsored by the Agency for Healthcare Research and Quality.[9] The mean age of the patients increased from 58.4±16.7 years in 1998 to 62.9±17.0 years in 2010 ($P<0.001$ for trend). Vascular complications occurred in 1.7% of these patients. In prior studies, mortality rates of 0% to 3% have been reported and are usually related to vascular complications.[1] The increased procedural complication rates were accompanied with an increased age and burden of comorbidities and a significant increase in cost, in patients undergoing PMVs with suboptimal anatomical features. Cardiac complications occurred in 4.5% of these cases. Complete heart block requiring permanent pacemaker implantation (<0.5%) and pericardial tamponade (0.6%) accounted for the rest. During admission, 5.8% of patients required open-heart surgery. Postprocedure neurological events (strokes or transient ischemic attacks) accounted for 2.8%. Overall, there was an annual 0.4% ($P=0.001$) increase in procedural complication rate from 1998 to 2010.

There has been a steady down trend decline in the use of PMV in the United States and worldwide in concordance with the downward trend in the incidence of mitral stenosis. The procedure nowadays is increasingly being performed on patients with higher comorbidities and increased age.[9–13] Operators play an important role in reducing the length of stay and the risk of death and complications. These trends support the guidelines on valvular heart disease that strongly recommend that mitral balloon valvuloplasty should be performed in higher-volume centers with skilled and experienced operators. As the use rate of PMV is gradually decreasing over years, these centers would not only play a pivotal role in reducing the complication rate but would also be indispensable toward providing and maintaining adequate volume required for physician training.

In patients with suboptimal mitral valve anatomical features, PMV results are less gratifying. The risk of surgical mitral valve replacement (MVR) in patients with severe mitral annular calcification (MAC) is high. Patients with MAC are frequently an elderly high-risk population with multiple comorbidities and a high risk of cardiovascular death and all-cause mortality.

Transcatheter MVR (TMVR) has recently emerged as an exciting new frontier in the field of cardiac structural interventions. The experience with TMVR remains at an early stage. There have been important challenges in the development of this technology, including the complexity of the mitral valve anatomical features, involving a saddle oval shape, the subvalvular apparatus, the interaction with the left ventricular outflow tract, and the aortic valve, as well as the large size of TMVR devices and large catheters for implantation. At this stage of development, all of these limit the delivery approach to transapical in most cases.

Several patients worldwide with severe MAC have been treated successfully with TMVR (transcatheter mitral valve replacement) using the balloon-expandable Sapien aortic transcatheter valves.[14] The TMVR in MAC Global Registry is a multicenter registry that collects data on outcomes of these procedures. A total of 116 patients with extreme surgical risk and severe MAC underwent TMVR; 106 had a procedure date >1 year before data lock and were included in the analysis. Their mean age was 73±12 years, and 68% were women. The mean Society of Thoracic Surgeons score was 15.3±11.6%, and 90% were in New York Heart Association functional class III or IV. The 30-day and 1-year all-cause mortality rates were 25% and 53.7%, respectively. Most patients who survived 30 days were alive at 1 year (49 of 77 [63.6%]), and most (71.8%) were in New York Heart Association functional class I or II. Left ventricular outflow tract obstruction with hemodynamic compromise is a worrisome complication of this technique and occurred in 13 patients (11.2%). Although the procedure could be performed, it was associated with a higher in-hospital mortality. The 30-day all-cause mortality was 25% (cardiovascular, 13%; noncardiovascular, 12%). There were 28 deaths between 31 days and 1 year after TMVR, and 49 patients were alive at 1 year. The 1-year all-cause mortality was 53.7% (cardiovascular, 23.5%; noncardiovascular, 30.2%). However, landmark analysis after 30 days showed that most patients who survived the 30-day postprocedural period remained alive at 1 year.

Echocardiographic data at 1 year were available in 34 patients. Mean left ventricular ejection fraction was

58.6±11.2%, mean mitral valve area was 1.9±0.5 cm^2, mean mitral gradient was 5.8±2.2 mm Hg, and 75% had zero or trace mitral regurgitation. The authors concluded that TMVR with balloon-expandable aortic valves in patients with extreme surgical risk and severe MAC is feasible, but it is associated with high 30-day and 1-year mortality. Nevertheless, the role of TMVR in patients with MAC requires further evaluation in clinical trials.

Patients with mitral valve disease who are too high risk for heart surgery may be candidates for less invasive, catheter-based (percutaneous) options, such as TMVR. Several types of TMVR devices in carefully selected patients as part of clinical studies have been used. Three of these valves are currently undergoing randomized clinical trials, including the Tendyne valve, the CardiaAQ-Edwards, and the Intrepid percutaneous mitral valve replacement (PMVR).[15]

Disclosures

None.

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