Editorial

Cardioband for the treatment of secondary mitral regurgitation: a viable percutaneous option?

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Secondary mitral regurgitation (MR) remains a vexing clinical problem associated with a doubling in the risk of mortality, for patients with both ischemic and non-ischemic cardiomyopathy (1). Observational studies have failed to demonstrate a consistent clinical benefit to mitral valve (MV) surgery for secondary MR, which is reflected in the major Societal Guidelines on the management of valvular heart disease (2,3). Given the high rate of MR recurrence after MV repair, MV prosthesis-related complications, and the inherent operative risk in this patient population, less invasive percutaneous treatments for secondary MR therapy have been developed (4). The Cardioband mitral repair system (Valtech Cardio, Or Yehuda, Israel) is one such catheter-based device that functions as a percutaneous annuloplasty band. Utilizing a transvenous and transseptal approach, the Cardioband is implanted on the posterior mitral annulus from the anterolateral to the posteromedial commissure, with intraprocedural adjustment to reduce the septolateral diameter of the mitral annulus and restore leaflet coaptation.

Nickenig *et al.* recently reported the 6-month outcomes of 31 patients enrolled in the Cardioband feasibility trial. The patients had a mean age of 71.8±6.9 years, a mean left ventricular ejection fraction of 34%±11%, and a mean EuroSCORE II of 8.6%±5.9% (5). At baseline, 22.6% had moderate (2+) and 77.4% had severe (3–4+) MR. Technical success was achieved in 93.6% of patients, and there were no in-hospital deaths or major complications. At 6- month follow-up, available in 22 patients, there was none or mild MR present in 54.5% of the patients, moderate MR in 31.8%, and severe MR in 13.6%, when compared with baseline (P<0.001). Significant improvements were noted in the New York Heart Association functional class, 6-minute walk test, and quality of life assessment. Survival at 6 months was 90.3%, with 10 (32.3%) of patients requiring rehospitalization for heart failure. In summary, the feasibility trial showed the Cardioband to be safe and efficacious in decreasing secondary MR severity and symptoms of heart failure, with improvement in functional parameters and quality of life, at early follow-up. Nevertheless, a few points of interest merit further discussion.

While the Cardioband was successful in reducing the overall severity of MR, moderate or greater MR persisted in 45.4% of patients at 6 months, and one-third of patients required hospitalization for heart failure. This is similar to the prevalence reported after surgical MV repair, and is a predictor of increased mortality and cardiac complications (6,7). As with surgical mitral restrictive annuloplasty, the Cardioband reduced the septolateral diameter of the mitral annulus (3.67±0.47 *vs.* 2.41±0.44 cm, P<0.001), but did not address the coexisting geometric subvalvular distortions. Persistent MR after MV repair is the result of continued left ventricular remodeling and dilatation, which perpetuates posterolateral and apical papillary muscle displacement, mitral leaflet tethering by the chordae tendinae, and incomplete systolic mitral valve closure (8,9). Data suggests that in the setting of left ventricular dilatation and secondary MR, a 1.5-fold increase in annular size may be tolerated prior to exacerbation of the MR regurgitant volume, reinforcing the importance of subvalvular dysfunction (10). It should also be noted that due to the anatomic fixation of the anterior mitral leaflet to

the intervalvular fibrosa, a restrictive annuloplasty displaces the posterior annulus anteriorly, increasing tethering and inhibiting the proper mechanics of the posterior leaflet (11). Thus, the development of a percutaneous approach targeting both the annular and subvalvular components of the MV apparatus may be preferable, as this has been associated with improved surgical MV repair durability (12). Alternatively, a transacatheter edge-to-edge repair or MV replacement may be performed, although these techniques are also under early clinical investigation for use in secondary MR (6).

With this in mind, it begs the question: is there role for minimally invasive valve surgery (MIVS) in this population? The patients included in the Cardioband feasibility trial constituted a high-risk surgical group, with a predicted operative mortality of 8.6%, and a high prevalence of New York Heart Association functional class III or IV symptoms, advanced renal insufficiency, and pulmonary hypertension. When compared with a conventional median sternotomy, MIVS via a hemisternotomy or thoracotomy is associated with reduced surgical trauma, less post-operative morbidity, and a faster recovery in high risk patients, with a possible mortality reduction in the elderly (13). In patients with chronic kidney disease, MIVS has been shown to decrease the incidence of post-operative acute kidney injury, and increase mid-term survival, when compared with median sternotomy (14). Minimally invasive MV surgery for secondary MR and left ventricular systolic dysfunction has been performed with an operative mortality of 0–2.8%, and has been successfully utilized in complex MV and subvalvular repair in the form combined ring annuloplasty and papillary muscle approximation (15-17). Given the growing data supporting the safety and feasibility of MIVS in high-risk patients, and the overestimation of MIVS surgical risk by the EuroSCORE II, it is tempting to hypothesize that a minimally invasive approach to MV intervention may be plausible in the population represented by the Cardioband trial (18). Nevertheless, given the complexity of secondary MR and the learning curve of MIVS, these operations are typically only performed in high-volume MV Centers of Excellence.

A less invasive percutaneous MV intervention is most appealing in the secondary MR population, of whom 50%–70% are denied surgery based upon risk factors such as left ventricular systolic dysfunction, age, co-morbidities, and MR severity (19,20). The Cardioband feasibility trial adds to the armamentarium of MV interventions for secondary MR, and was shown to be safe and effective in the short-term. However, the high prevalence of persistent MR, and the complexity of the MV apparatus raises some concerns. Follow-up beyond 1-year will be critical as left ventricular remodeling is completed, which may impact MR severity and clinical outcomes. Finally, future studies comparing the Cardioband to medical therapy or surgical MV intervention via sternotomy or MIVS, and in potential combination use with MitraClip percutaneous MV repair, are warranted.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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