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The Cardioband System for Treatment of Secondary MR

Technology that presents a promising alternative to traditional surgery.

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Chronic mitral regurgitation (MR) presents unique management challenges, especially with regard to functional (or secondary) MR (FMR). In primary MR, intervention is required in the presence of symptoms or even earlier in selected cases. Repair of the valve in primary MR is generally preferable to replacement.[1,2] However, in FMR, which is the consequence of the left ventricle dysfunction with normal mitral leaflets, the indications and type of intervention (ie, valve repair vs replacement) are less established.

Medical therapy (including revascularization) and resynchronization, when applicable, are the foundation of treatment for FMR. Mitral valve surgery has debatable benefit in the setting of FMR; furthermore, any benefit of surgical intervention may be offset by associated morbidity and mortality. As a result, there is interest in developing percutaneous mitral interventions that can serve as a viable alternative.

Performing percutaneous repair of the valve using the MitraClip device (Abbott Vascular) has been shown to be a feasible approach to induce reverse left ventricular remodeling, improve symptoms, and reduce hospitalizations for heart failure.[3,4] The potential clinical applicability and viability of this technique is currently being studied in clinical trials. Early studies with MitraClip suggest that it has a role in FMR, although questions remain about which patients would benefit from valve repair and whether interventions that leave future options open should precede its use.

More recently, the Cardioband system (Valtech) has become available in Europe with CE Mark approval, and a study is planned in the United States (Figure 1).[5] The Cardioband system, in essence, mimics open heart repair principles, insofar as the objective is to reduce the size of the annulus by placing an annuloplasty ring around it. Using this reconstruction system, the left atrium is accessed through the fossa ovalis via the right atrium using a transseptal approach. An annuloplasty band is implanted using anchors (instead of sutures) along the posterior annulus. Then, after implant deployment, a size adjustment tool is introduced over

Figure 1. The Cardioband delivery system and implant.

the wire to decrease the size of the annulus. Because the procedure is performed in real time under beating heart conditions and solely in the left atrium, it is associated with an excellent safety profile.

CLINICAL RESULTS WITH CARDIOBAND

The Cardioband was recently studied in 50 patients from seven sites in Europe (mean age, 71 years; 39 were men). The mean EuroSCORE was 7.5, and 84% had New York Heart Association (NYHA) class III or IV heart disease at baseline. Thirty-one of the cases had ischemic etiology. Notable medical history included 32% with previous coronary artery bypass graft surgery, 22% with chronic obstructive pulmonary disease, 76% with moderate-to-severe renal failure, 24% with severe pulmonary hypertension, and 78% with atrial fibrillation. Major safety events at 30 days of follow-up are summarized in Table 1.

TABLE 1. REPORTED MAJOR SAFETY EVENTS AT 30 DAYS

30-Day Events*	All Patients (N = 50) Experiencing Events (%)
Death† • Hemorrhagic stroke‡ • Need for elective mitral operation	2 (4%) • 1 (2%) • 1 (2%)
Ischemic attack	1 (2%)
Major bleeding complications	1 (2%)
Renal failure	2 (4%)
Myocardial infarction	0 (0%)
Respiratory failure	0 (0%)
Cardiac tamponade	1 (2%)

*Based on VARC-2 guidelines.
†There was one additional compassionate death in the intent-to-treat analysis.
‡Hemorrhagic stroke was determined to be a contributor to but not primary cause of death.

In the study, 91% of patients achieved MR ≤ 2+ and 65% had MR ≤ 1+ at 12 months, as determined by the core lab. There was a mean 30% reduction in anterior-posterior dimension at the time of discharge compared with baseline. Notably, there was functional improvement noted in the 6-minute walk test at 6 months ($P < .01$) and 12 months ($P < .05$), as well as in the Minnesota Living with Heart Failure questionnaire and NYHA classification at 6 months ($P < .01$ for both) and 12 months ($P < .01$ for both) (Figures 2 and 3).

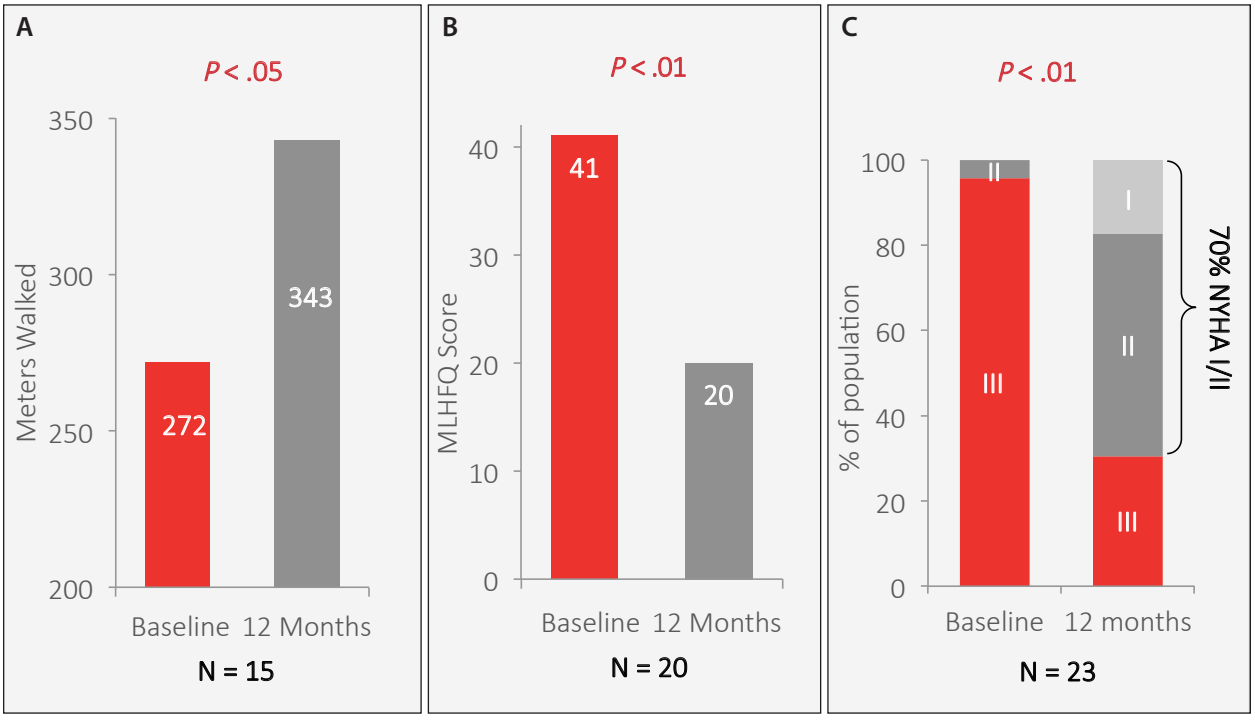

Figure 2. Functional improvement at 12 months, including 6-minute walk test (A), Minnesota Living with Heart Failure questionnaire (MLHFQ) (B), and New York Heart Association (NYHA) class (C).

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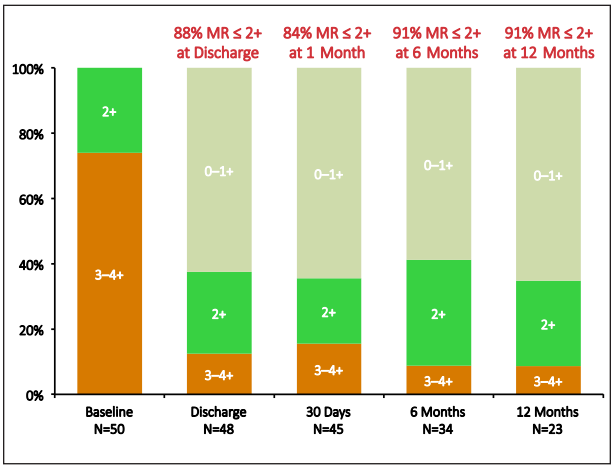

Figure 3. Outcomes for 91% of patients with MR ≤ 2+ at 12 months by core lab. Note: where core lab data from Paul Grayburn, MD, with Baylor University were not available, clinical site data were used.

This study demonstrated the feasibility of transcatheter annuloplasty to treat FMR, as the safety profile was similar to other transcatheter mitral procedures. There was also a high success rate of implantation, and patients demonstrated significant improvement in clinical outcomes.

FUTURE DIRECTIONS

In primary MR, mitral valve repair has several benefits over replacement, as it offers better long-term outcomes. In FMR, there is insufficient evidence to know if percutaneous procedures are viable and, if they are, whether repair or replacement provides superior outcomes.[6] To date, more than 30,000 patients have undergone valve repair using percutaneous approaches, but fewer than 100 patients have undergone percutaneous valve replacement. It is likely that these approaches will prove complementary, with repair likely being applied at an earlier stage of the disease in patients with less advanced valve lesions.

There may be cases in which it would be advantageous to combine the use of several percutaneous devices and techniques, reproducing what is done surgically. For example, Cardioband may be combined with chordal repair or MitraClip use in some primary MR cases. In select cases of FMR, such as when severe valve tethering is present, the Cardioband device could be used to, in effect, stabilize the results of MitraClip, similar to the way annuloplasty is used in conjunction with surgery. Early results with combining these techniques are promising, but this strategy will need to be studied more extensively.

FMR is a challenging entity and is currently an unmet need. Cardioband may represent an adjunctive treatment that leaves open a variety of future options should they become necessary. Compared with the edge-to-edge technique, for instance, percutaneous annuloplasty has the theoretical advantage of allowing for subsequent percutaneous valve replacement in case of failure. Although the current results of Cardioband are promising, more data and longer follow-up are needed to confirm its safety and efficacy and to evaluate the durability of the results. In addition, randomized studies should be performed to establish its clinical benefit. If longer-term experience confirms the current results, Cardioband may be considered a viable option for percutaneous intervention at an earlier stage, when treatment directed toward the valve is more likely to have long-term benefit. ■

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