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EDITORIAL COMMENT

Percutaneous Mitral Repair

A Potential "Standard" for Functional Mitral Regurgitation?*

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In this issue of *JACC: Cardiovascular Interventions*, Nickenig et al. (1) present the safety and effectiveness outcomes of the Cardioband Percutaneous Mitral Repair System in patients with chronic functional mitral regurgitation (FMR). The 6-month results using this novel transcatheter mitral annuloplasty band in 31 FMR patients are presented. All these patients had moderate to severe FMR with heart failure and a depressed ejection fraction. Procedural success rate was near 100% and there were no periprocedural deaths. The 30-day mortality was 5% and the 6-month mortality was 9.7%. The Cardioband annuloplasty device seems to have an acceptable safety profile, similar to other percutaneous mitral devices.

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In terms of effectiveness, the AP (septal-lateral) diameter of the dilated FMR mitral orifice was greatly decreased and appeared to be stable at 6 months. Furthermore, patients with 3 or 4+ mitral regurgitation was also significantly reduced from 77% to 11% after the procedure and was maintained at 6 months. Finally, New York Heart Association functional class, 6-minute walk test, and Minnesota quality of life evaluations were also improved. The authors concluded in this feasibility trial that transcatheter mitral annuloplasty with the Cardioband device demonstrated a favorable safety profile and resulted in improvement in heart failure symptomatology.

Therapeutic approaches to FMR patients are fraught with difficulty. FMR patients have numerous medical problems, of which mitral regurgitation may be only one among the multitude of causes of their heart failure. These patients have a primary disease of the ventricle and not of the mitral valve. FMR may be a marker of the severity of the underlying ventricular disease, as well as causative in mortality. Furthermore, FMR patients do not have a predictable swift mortality course but rather do "poorly slowly." Therefore, FMR interventions to remove mitral regurgitation cannot be expected to have quick and dramatic mortality effects, rather the "standard" for these therapies must more impact heart failure and quality of life.

The authors are to be congratulated on this initial experience with one of the first percutaneous direct annuloplasty devices for FMR. Indirect percutaneous mitral annuloplasty, generally via the coronary sinus, has lacked effectiveness and has not been adopted widely for patients with FMR. The Cardioband device has attempted to recreate the "surgical standard" for mitral annuloplasty in FMR patients.

However, what is the "standard" for medical versus surgery versus emerging percutaneous therapies for FMR remains unanswered. There are numerous nonrandomized trials of mitral surgery for FMR, which have "safe" 30 day-mortalities similar to the presented series. These surgical "direct" annuloplasty series have not shown a definitive impact on mortality and, unfortunately, have had a wide range of FMR recurrence rates. Also, at surgery a complete rigid ring is generally favored as opposed to a partial flexible band for FMR, because complete rings seem to have lower FMR recurrence rates. The Cardioband device would be considered a partial, flexible band.

Fundamentally, one may ask to what degree must FMR be reduced to have an "impact" on mortality and heart failure. For example, is reducing 4+ FMR to

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2+ regurgitation "good enough" or should the "standard" be that FMR is extinguished to zero? Hopefully the ongoing COAPT (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation) study will help our thinking about this "standard." Last, the 6-month follow-up for FMR patients may not be enough to assess the impact upon heart failure, hospitalizations, and mortality. In many surgical series, 6 months postoperative is when significant FMR begins to recur and does not stabilize for 12 to 24 months. Unfortunately, what is the "standard" for FMR and whether this will be different for percutaneous FMR approaches remains unclear.

This series has shown that a percutaneous intervention to implant a direct mitral annuloplasty band can be accomplished safely and technically. Only time will tell whether this type of device or intervention is potentially "good enough" for FMR patients and will become a standard of FMR therapy. What is certain is this device and/or future devices are greatly needed as therapeutic options for these complicated FMR patients.

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