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EDITORIAL COMMENTARY

Percutaneous edge-to-edge repair for degenerative mitral regurgitation: A journey to the edge of the bell-shaped curve

Patrick M. McCarthy, MD

ACD

See related article on pages 2743-50.

The report in this issue of the *Journal* by Taramasso and colleagues[1] is a welcome addition, as most reports of MitraClip (Abbott Vascular, Santa Clara, Calif) outcomes have been in the cardiology literature. Taramasso and colleagues[1] report excellent outcomes in a high-risk surgical population (78.5 ± 10.8 years; 71% New York Heart Association functional class III or IV; mean Society of Thoracic Surgeons [STS] score 12% ± 10%) with severe degenerative mitral regurgitation (DMR). Their results mirror the US MitraClip experience presented to the Food and Drug Administration panel with a low procedural risk (2% in-hospital mortality), low morbidity, no clip embolization, a very high procedural "success" rate (98%), and short stay relative to conventional surgery.[2] DMR frequently is seen with an anatomically difficult lesion to treat with the MitraClip; however, there was a reasonable reduction in mitral regurgitation to grade II or less in 91.5% of patients. The 1-year survival (89% ± 5.2%), New York Heart Association functional class (93% I or II), and 6-minute walk (mean improvement of 48 meters) were favorable. Initial trials in the United States included low- and medium-risk patients, the type of patients in the middle of the bell-shaped curve of patients treated with surgery, and reflected a strategy (and hubris) to compete directly with conventional heart surgery. These trials, principally the Endovascular Valve Edge-to-Edge Repair High Risk Study (EVEREST) and the continued access protocol, took a long time to execute as the tactics evolved and the target patient population shifted to the sickest patients on

From the Cardiac Surgery Division, Bluhm Cardiovascular Institute, Northwestern University Feinberg School of Medicine, Chicago, Ill.
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Address for reprints: Patrick M. McCarthy, MD, Division of Cardiac Surgery, Northwestern University Feinberg School of Medicine, Northwestern University, 201 East Huron St, Suite 11-140, Chicago, IL 60611-2908 (E-mail: pmccart@nmh.org).
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the edge of the bell-shaped curve. Ultimately, the clip can improve DMR, but it does not reduce it as much as does conventional mitral repair, so it was judged safe but less effective. The Food and Drug Administration recently approved MitraClip in the high-risk DMR population, and multiple publications have reported favorable outcomes.[3-5]

So, just how far out on the curve are these MitraClip candidates? Taramasso and colleagues[1] at San Rafaele provide perspective. Their 48 patients with DMR were only 2% of those treated (2370 patients) with surgical mitral valve repair. Only 5.6% of patients undergoing mitral valve surgery listed in the STS database have a score greater than or equal to 12, and of these 85% underwent replacement, not repair.[2] Another 116 patients underwent MitraClip implantation for functional mitral regurgitation, which is the target population for the US Clinical Outcomes Assessment of the MitraClip Therapy Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation (COAPT) Trial.[6] According to Taramasso and colleagues (personal communication), although they did not track all patients that were screened for the MitraClip, they estimated that only 1 in 4 were treated, and in only 4 of the 48 was there a commissural lesion. The STS database is an excellent tool to risk stratify patients in the middle of the bell-shaped curve; however, patients may have many unusual comorbidities that are not collected by the STS database. These have been described by the Valve Academic Research Consortium[7] and include such medical conditions as cirrhosis, radiation heart disease, "hostile" chest, and extensive aortic calcification or atherosclerosis. Some surgeons have rightly been concerned that the MitraClip studies include patients with a low STS score. As an example, however, 1 patient presented to the Food and Drug Administration panel had multiple sclerosis, was hemiplegic from a previous stroke, and was assisted by a wheelchair yet had a calculated STS score less than 2.[2] The STS score cannot predict the likelihood of good functional recovery. A reasonable concern is that we may apply the MitraClip in patients whose conditions are futile, and their quality of life will be so limited that there is no meaningful improvement. The outcomes from San Rafaele are reassuring, because quality of life and New York Heart Association functional class improved significantly for the majority of patients.

MitraClip is much safer than surgery for these very high-risk patients, so will patient selection gradually migrate back toward the center of the bell shaped curve, as transcatheter aortic valve replacement is evolving? It seems unlikely in the near term and midterm. The surgical treatment of DMR is one of the greatest success stories in cardiac surgery, and as a result of stepwise improvements in surgical techniques and care, we are now able to achieve extremely low mortality and morbidity, a high rate of durable repair, and excellent functional outcomes.[8] A host of new technologies are now being developed to mimic mitral valve repair or to perform transcatheter mitral valve replacement; however, this is a formidable problem compared with transcatheter aortic valve replacement.[9] For the distinctive subset of patients with DMR, the risk-to-benefit ratio for a new device to compete with mitral surgery is not attractive, and functional mitral regurgitation is a more practical target.

The value of this study is to acknowledge that this is an option for patients on whom we would not want to operate. It has achieved a reasonable degree of success for patients who meet the anatomic criteria, the risks are low, and recovery is quite good. As surgeons accumulate experience, we will prepare for the emerging transcatheter approaches.

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