Flexible Versus Nonflexible Mitral Valve Rings for Congestive Heart Failure
Differential Durability of Repair

Martinus T. Spoor, MD; Amy Geltz, RN; Steven F. Bolling, MD

Background—Surgical intervention is playing an increasingly important therapeutic role in congestive heart failure (CHF) patients with ischemia and dilated cardiomyopathy. Their mitral regurgitation (MR) is a result of left ventricular (LV) geometrical distortion. The optimal type of ring for CHF patients with geometric ventricular-based MR is unknown. This study reviewed the results of flexible versus nonflexible complete mitral valve rings in CHF patients with geometric mitral regurgitation.

Methods and Results—Using a prospectively maintained database, patients undergoing mitral valve reconstruction (MVR) with either a flexible or nonflexible complete ring were identified on the basis of preoperative ejection fraction (EF) ≤30% and no primary mitral pathology. These 2 groups of CHF patients with severe geometric MR were then compared in terms of recurrent MR requiring reoperation. Between 1992 and 2004, 289 patients with EF ≤30%, received an undersized complete mitral annuloplasty ring as their MVR procedure. Of these, 170 patients had a flexible complete ring. In follow-up, 16 “flexible” patients (9.4%) required a repeat procedure for significant recurrent geometric MR and CHF (10 replacements, 3 re-repairs, 3 transplants). The average time to reoperation was 2.4 years. In contrast, 119 patients with an EF ≤30% received a MVR using an undersized nonflexible complete ring. Only 3 “non-flexible” patients required a repeat operation, MVR (1), and 2 patients required a transplant. The time to reoperation was 4.0 years. A significant difference in reoperation rates, for recurrent MR, between the 2 groups (P<0.012). There were no differences between groups, in terms of age, ring size used, preoperative EF, LV size, MR grade, or New York Heart Association class.

Conclusions—Patients with CHF having a flexible ring have a higher likelihood of developing recurrent MR requiring reoperation. The use of a nonflexible ring appears to significantly reduce the need for repeat surgical procedures. Further refinement and development of nonflexible ring systems, aimed at LV restoration, deserve ongoing investigation. (Circulation. 2006;114[suppl I]:I-67–I-71.)

Key Words: heart failure • mitral valve regurgitation • surgery

The debate over the efficacy of mitral valve repair versus mitral replacement was renewed in 1995 by Cohn et al,1 who looked at their patients on the basis of ischemic mitral regurgitation (MR). That same year, our group published a group of patients with a mean ejection fraction (EF) of 18% and reported significant improvements in both clinical and echo follow-up with documented improvements in left ventricular (LV) volumes, EF, and hemodynamics.2 Since that time, the surgical results from treating patients with geometric-based mitral valve reconstruction (MVR) have improved dramatically. These improving results have now encompassed sicker groups of patients from numerous centers around the world.3–5 The results of the latest ACORN trial from multiple sites show that these results can now be duplicated with low single-digit mortality rates.

Study Population
This study was approved by the University of Michigan Institutional Review Board before data collection. Using a prospectively maintained single-institution cardiac surgery database, 289 patients were identified. Patients were selected on the basis of having a dilated cardiomyopathy with moderate to severe (3+/4+) or severe (4+/4+) MR. The basis of the dilated cardiomyopathy was ischemic or idiopathic. Patients with ischemic dilated cardiomyopathy had no active untreated ischemia. Patients were selected over a time period from 1992 to 2004. To help eliminate confounding factors, patients were all operated on by a single surgeon (S.F.B.). All patients had geometric based disease of the left ventricle resulting in functional MVR. Patients with valvular-based MV disease (including papillary muscle rupture), active untreated ischemia, concurrent aortic valve procedures, LV restoration procedures, or EF >30% were excluded from the study population.

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Surgical Technique
Standard bicaval cannulation and routing cardiopulmonary bypass techniques were used in all patients. All operations performed via a median sternotomy used standard surgical techniques including cold blood antegrade cardioplegia. Patients with a previous median sternotomy incision were operated on via a right or left anterior thoracotomy. Although standard cardiopulmonary bypass (CPB) techniques were used in the thoracotomy patients and the majority of patients had bicaval cannulation within the chest, the hearts were opened and allowed to beat “empty” while on CPB. An undersized complete ring was used in all patients. As the experience improved with this subset of patients the tendency was to use a flexible ring at the beginning of the series, and a rigid ring almost exclusively since 2000. More recently (since 2000), patients with concurrent atrial fibrillation received an anti-fibrillation procedure either on the left atrium or both atria depending on the chronicity of the atrial fibrillation. In addition, patients with concurrent moderate 2+/+ or greater tricuspid valve regurgitation or a dilated tricuspid valve annulus received a tricuspid valve annuloplasty. Again with increasing experience over time, patients in the early part of the series received a deVega type annuloplasty, whereas patients in the past several years have received an annuloplasty ring. All patients received either a 26- or a 28-mm complete mitral ring. Aggressive heart failure therapy was used in the perioperative period including milrinone and norepinephrine. All patients were discharged on diuretics, digoxin, and angiotensin-converting enzyme inhibitor, acetylsalicylic acid (ASA), and/or spironolactone medications and adjusted as needed by their primary cardiologist.

Follow-Up
All patients were followed-up in the postoperative surgical heart failure clinic as well as by their primary cardiologist. Echocardiograms, when available, were reviewed on a regular basis. Patients with recurrent MR were referred back to their primary cardiac surgeon and they were re-operated on or referred for transplantation or left ventricular assist device (LVAD) therapy when appropriate.

Statistical Analysis
All data were entered prospectively and maintained within a single institution database. Statistical analysis was performed using SPSS Version 12.0 (SPSS Inc.) for Windows (Microsoft Corporation). Continuous data were compared using Student t test for paired and unpaired data when appropriate. Categorical variables were analyzed by χ² and Fisher exact test when appropriate.

The authors had full access to the data and take responsibility for their integrity. All authors have read and agree to the manuscript as written.

Results
The results of this series shows that the initial short-term results are no different between the flexible and nonflexible mitral valve annuloplasty groups and overall the relative rate of complications for this high-risk subset of patients was quite low. The baseline demographics are illustrated in Table 1. It should be noted that the patients in the flexible ring group were older and had more severe symptoms of heart failure, although the differences were not statistically signif-
consider these patients for a repeat valvuloplasty procedure and with our use of nonflexible rings; the number of actual patients in this subgroup has been very low.

**Discussion**

Mitral valve repair is the procedure of choice for geometric LV-based or functional regurgitation compared with mitral valve replacement. Previous surgical teachings have traditionally focused on the high mortality rate associated with mitral valve replacement. Since the mid 1990s, several groups have shown the reproducibility of good short-term MVR results in terms of morbidity and mortality and varying degrees of long-term results.3,6–9 Some of the difficulty in assessing the long-term results of MVR lies in the variety of mitral valve repair techniques used. Some have proposed that a mitral valve ring is not important after a good mitral valve repair whereas others have advocated some form of annular support although the choice of partial versus complete and flexible versus non-flexible rings did not matter.10 Others have shown that the early results in patients with ischemic cardiomyopathy favor repair, whereas the long-term results in the sickest subgroup of patients showed little difference between mitral valve repair or replacement.11 It is important to remember the history of mitral valve repair when discussing mitral valve ring properties. The first generation of mitral rings was developed in the repair of rheumatic valve disease. The decline of this disease in the developed world secondary to better primary prevention resulted in a second generation of repair techniques and rings being devised to treat an increasing proportion of patients with degenerative valve disease. The focus of the investigation of this study was to highlight the unique properties of the next generation of mitral valve repair patients with advanced heart failure who do not have primary mitral valve pathology but have severe functional MVR secondary to geometric changes in the ventricle. The altered geometry of the left ventricle (whether by the development of ischemic or nonischemic cardiomyopathy) results in the loss of function of the valve secondary to excess tethering of the valve leaflets and resultant loss of the zone of coaptation. The resultant vicious spiral of increased MR leads to further maladaptive changes in the left ventricular geometry. The presence of MR is known to be a poor prognostic indicator in patients with ischemic heart disease.12,13 The degree of MR has been associated with differences in outcome even in asymptomatic patients.14 Although our early results with undersized flexible rings were initially encouraging, our overall recurrence rate of MR has been ≈15%, which is similar to results reported by other groups.15 At the same time that we noted a higher incidence in mitral valve procedures in patients with flexible rings placed during their primary mitral valve procedure, more experimental evidence was accumulating about the theoretical benefits of rigid or nonflexible rings in this subgroup of mitral valve patients with heart failure.16 Further evidence of the importance of aggressively treating MR was shown in a recent study showing increased risk of MR in affecting the development of congestive heart failure and increased mortality in patients post myocardial infarction.17 Additionally, autopsy, laboratory, and clinical studies began to appear in the literature showing that the anterior mitral valve leaflet trigone distance was not a permanently fixed distance but was in fact quite dynamic and enlarged over time.18–20 This prompted our switch to the use of nonflexible complete mitral rings to inhibit further dilation of the mitral valve annulus and support the re-established zone of coaptation.

The dissimilar results between the 2 groups cannot be explained by differences between the flexible and nonflexible groups. The 2 groups were very similar preoperatively with the main difference being the tendency to use a flexible ring

**TABLE 4. Repeat Procedures for Recurrent MR**

<table>
<thead>
<tr>
<th>Patients With Additional Procedures</th>
<th>Flexible Ring</th>
<th>Nonflexible Ring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitral valve replacement</td>
<td>10 patients</td>
<td>119 patients</td>
</tr>
<tr>
<td>Left ventricular assist device placement</td>
<td>2 patients</td>
<td>0 patients</td>
</tr>
<tr>
<td>Orthotopic heart transplant</td>
<td>5 patients</td>
<td>0 patients</td>
</tr>
<tr>
<td>Repeat valvuloplasty</td>
<td>4 patients</td>
<td>0 patients</td>
</tr>
</tbody>
</table>

Interval 175 days to 5.3 years (2.8±2 years).

**TABLE 5. Repeat Procedures and Echocardiography Findings for Recurrent MR by Ring Flexibility**

<table>
<thead>
<tr>
<th>Flexible Ring</th>
<th>Nonflexible Ring</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>170</td>
</tr>
<tr>
<td>MV replacements</td>
<td>10</td>
</tr>
<tr>
<td>MV Re-repair</td>
<td>3</td>
</tr>
<tr>
<td>Transplant</td>
<td>3</td>
</tr>
<tr>
<td>Total repeat procedures</td>
<td>16 (9.5%)</td>
</tr>
<tr>
<td>Time to reoperation</td>
<td>2.4 years</td>
</tr>
<tr>
<td>LVIDd at primary operation (mm)</td>
<td>60.4±7</td>
</tr>
<tr>
<td>LVIDs at primary operation (mm)</td>
<td>54.5±13</td>
</tr>
<tr>
<td>Decrease in LVIDd preoperatively at time of second operation (mm)</td>
<td>6.5±12</td>
</tr>
<tr>
<td>Decrease in LVIDs preoperatively at time of second operation (mm)</td>
<td>6.5±13</td>
</tr>
<tr>
<td>Mean gradient at time of second operation (mm Hg)</td>
<td>10±6</td>
</tr>
</tbody>
</table>
early in our experience and the universal use of nonflexible rings in the past several years. It could be argued that the younger patients in the nonflexible ring group, although less symptomatic, were nevertheless considered high-risk and would also have a longer time period after the operation to develop recurrent MR, which was not the case. The differences in outcomes also cannot be explained on the differences in ring size because the 2 groups had undersized and over corrected mitral valve annuloplasty performed. In addition, the fact that the basis of the MVR was in the ventricle meant that no additional mitral valve repair techniques such as leaflet resection, sliding plasty, or the use of Gortex chords was required.

At the time of the second operation, it was noted that in the flexible ring group of patients the return of MR was caused by functional changes in the LV geometry, which produced recurrent MR. The undersized flexible rings were not dehisced, nor did they have high gradients; rather, they were unable to support the posterior mitral annulus over time. The posterior mitral annulus in these patients tended to fall outwards and downward secondary to ongoing LV wall changes producing functional MR as the zone of coaptation was lost. This finding is the basis for changes made in many of the newer mitral annuloplasty ring designs in an attempt to address ongoing changes of LV geometry affecting the ability of the posterior mitral annulus to support a good zone of coaptation. Further support of this concept has recently been published by Alfieri’s group, showing that in finite element model simulations of various mitral rings, conventional rings demonstrating ongoing annular stresses producing regurgitation secondary to changes in the LV geometry.21

One difference between the groups that we noted was the better New York Heart Association functional class of the non-flexible ring group with an associated worse EF. This may be because of the referral pattern of the consultant cardiologists who began to refer patients earlier in their symptomatic or functional disease course based on the initial good surgical results

Study Limitations

This study of the recurrence of MVR after mitral valve annuloplasty represents our changing clinical practice and ongoing refinements in technique and is not a prospective blinded randomized clinical trial. The long-term functional status of all of our patients could not be assessed due to the unique geographic referral pattern of our tertiary mitral valve repair practice. Our loss to follow-up for all patients has been <5%. Patients and their referring cardiologist at time of discharge are instructed to return to us for further surgical consultation as necessary. Although some patients with MR recurrence may have been referred to other institutions, there are few surgeons within our geographic referral area who are willing to operate a second, third, or fourth time on this high-risk subset of heart failure patients because many of these patients are referred to us by these surgeons for their primary operation. In addition, our center is 1 of 2 approved LVAD and transplant programs in the state, so it unlikely that patients would have been referred elsewhere for further LVAD therapy or transplantation. The overall survival of a slightly different of cohort of mitral valve repair patients has been previously published by our group at the University of Michigan. The 500-day survival for nonischemic MVR patients is 82% and for MVR with coronary artery disease is 79%.22 The complex and multifactorial approach to surgical decision-making may have resulted in potential candidates with recurrent MR not being referred for repeat mitral valve surgery or therapy for end-stage heart failure. In addition, a portion of our practice represents referrals from patients from across the United States and these patients may have elected to be referred elsewhere for additional surgical interventions. There may be other important nonmeasured confounding factors which may account for patients deciding not proceed with further surgery or for going elsewhere for other procedures that we were not able to measure.

This study represents a group of patients who were operated on between 1992 and 2004. There is a multitude of confounding factors related to the temporal nature of this study. Changing medical therapy and surgical techniques, the broadening of eligibility criteria for the sickest of patients to be considered for MVR, and changes in perioperative protocols and procedures may all account for the improved surgical results and lower mortality rates for all patients over this time period. As noted previously, our use of tricuspid valve annuloplasty rings, atrial fibrillation procedures, and more aggressive indications for intervention based on 2+/4+ valve regurgitation all increased over the study period. In addition, the changing indications for MVR in geometric mitral disease, the earlier referral of symptomatic and asymptomatic patients and improved medical therapy of heart failure during this time have all played important roles in our evolving surgical practice. These factors also make it difficult to compare our study population to a matched group of medically treated heart failure patients or to other surgical series. One recent trial involving both flexible and nonflexible rings showed a greater tendency for recurrent MR in the flexible ring group.23 Also, the improved understanding of the pathophysiology of the left ventricle in heart failure suggests that even better results can be obtained with specific goals of ventricular modeling with newer 3-dimensional–shaped rings. There are other mitral valve repair techniques and other technologies aimed at altering left ventricular geometry and physiology that also need to be carefully investigated.

In addition, these results do not include routine follow-up echocardiograms of all patients over time to further delineate the temporal changes of the mitral valve and left ventricle. There was still a small group of patients in the non-flexible group who, despite the use of “best” surgical practice, developed recurrent MR. There is obviously a group of patients with MR and heart failure who will only derive a short-term benefit of MVR surgery and still progress to further heart failure requiring surgical intervention.

Summary

Together with previous short-term animal experiments and direct clinical observation, this retrospective study of a large cohort of patients with predicted high surgical risk shows that despite similar perioperative results, the choice of mitral valve annuloplasty ring does make a difference in terms of
long-term recurrence of MR and need for further operative interventions. Nonflexible rings provided the longest durability of repair and were associated with the least recurrence of MR requiring further surgical intervention. As our understanding of the complex relational changes in the geometry of the left ventricle increases and we are better able to understand the underlying pathophysiology of heart failure, we may be able to design new 3-dimensional-shaped rings to further optimize LV geometry and mechanics. Further studies are needed, including the development of new ring technology as well as prospective randomized trials to directly compare MR Annuloplasty treatment options. This retrospective study is hypothesis generating and begs a randomized controlled clinical trial.

Disclosures

S.F. Bolling is a consultant for St Jude Medical, Sorin–Carbomedics, Metronics, and Edwards Lifesciences.

References


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