Stability of Mitral Reconstructive Surgery at 10–12 Years for Predominantly Rheumatic Valvular Disease

Carlos G. Durán, MD, PhD, José M. Revuelta, MD, Luis Gaite, MD, Carlos Alonso, MD, and Manuel G. Fleitas, MD

All consecutive patients who underwent Duran flexible ring annuloplasty in 1975 and 1976 were reviewed until June 1987. Eighty-seven annuloplasties were performed in 85 patients. Aortic, tricuspid, or both surgeries were simultaneously performed in 44.8%. The hospital mortality was 2.3% (two of 85). Ten patients were lost to follow-up within 2 years after surgery, and there were three late deaths. Thromboembolic events were detected in 18 patients (seven peripheral and 11 central with one death); nine patients had partial recovery, and eight had full recovery. At the time of the thromboembolic event, eight patients were receiving anticoagulants; four, antiaggregants; one, both anticoagulants and antiaggregants; and five, none. Thirteen patients (13 of 73, 17.8%) required reoperation between 1 month and 11 years postoperatively. The valve was replaced in 11 patients, and two underwent a new flexible ring annuloplasty. The cause for reoperation was regurgitation in eight patients (10.9%), for whom the mean interval between operations was 20.6 months (range, 1 month–11 years). Stenosis was the cause for reoperation in five patients (6.8%), for whom the mean interval between operations was 87.8 months (range, 4–11 years). We conclude that reconstructive surgery after 10–12 years of follow-up for this group of predominantly rheumatic patients has an incidence of failure of approximately 18% attributable to incorrect surgery (11%) and restenosis (7%). (Circulation 1988;78[suppl I]:I-91–I-96)

Mitral reconstruction has almost as long a history as that of open heart surgery, although the former has been practiced only sporadically by a few surgeons.1–4 The advent of valvular prostheses, with their ease of implantation and guaranteed immediate competence, displaced the generally less successful repair techniques with the exception of open commissurotomy. However, progressive awareness of unacceptable long-term results with the earlier prostheses, especially when they were placed in the atrioventricular position, encouraged the development of standardized and, therefore, more reproducible reconstructive techniques, which subsequently encouraged wider application and acceptance.

The description by Carpentier and colleagues of the selective annular reduction technique with a prosthetic ring was instrumental in this development.5 Later, the experimental evidence6 and, more recently, the echocardiographic studies in humans7 showing the continuous changes in size and shape of the mitral annulus prompted us to develop a completely flexible ring that was capable of achieving a more physiological annuloplasty.8 Newer techniques to treat specific problems have been progressively developed, thereby increasing the scope of this type of surgery.9,10

Numerous reports have shown that these techniques can be applied to a variety of etiologies, and that these applications are associated with low mortality and morbidity.11,12 However, their long-term outcome is still largely unknown. The advantage of conserving the distorted natural tissue over its replacement is now generally accepted, although there remains some doubt about long-term results in terms of the influence of progressive underlying pathology on the stability of reconstruction. To study this particular aspect of mitral reconstruction, all patients who underwent Duran flexible ring annuloplasty (Medtronic Blood Systems, Anaheim, California) over 10 years ago were reviewed. The etiology was rheumatic in most cases.
Patients and Methods

Eighty-five patients underwent Duran flexible ring annuloplasty between January 1975 and December 1976. Seventeen patients were men and 68 were women. Ages ranged from 15 to 60 years, with a mean age of 39 years. The etiology was congenital in one case (1.2%), degenerative in two (2.4%), and rheumatic in 73 (85.9%). In nine cases (10.6%), the etiology could not be established. The preoperative diagnosis was predominant stenosis in 28 cases (32.9%), predominant regurgitation in 12 (14.1%), and mixed lesions in 45 (52.9%). Their functional class (New York Heart Association) was I in two cases (2.4%), II in 21 (24.7%), III in 57 (67.1%), and IV in 5 (5.9%). Thirty-three patients were in sinus rhythm (38.9%), and the remaining 52 were in atrial fibrillation (61.1%). All patients had complete (right and left) preoperative hemodynamic and angiographic studies.

We used the same surgical techniques for all patients. Bypass was established through a median sternotomy with a bubble oxygenator, and moderate body hypothermia was maintained at 32°C. The mitral surgery and, when necessary, the aortic surgery were performed during a single uninterrupted aortic cross-clamp period. Tricuspid surgery was performed under nonischemic conditions. Myocardial protection was achieved with topical hypothermia by a continuous pericardial cold saline perfusion, but cardioplegia was not used at that time. In 46 patients (54.1%), an isolated mitral valve repair was completed, and in 20, the aortic valve was also replaced (eight cases, 9.4%) or repaired (12 cases, 14.1%). In 28 patients (32.9%), the tricuspid valve was repaired with 11 commissurotomies and 25 flexible ring annuloplasties. Therefore, 30 cases (35.3%) involved double-valve surgery, and nine (10.6%) involved triple-valve surgery. In 77 cases (90.6%), no valve replacement was performed.

The 85 annuloplasties were performed with Duran flexible rings whose sizes ranged from 19 mm to 34 mm (mean size, 28.14 mm). Ring sizes corresponded to the measured intertrigonal distance and not the intercommissural distance as with the Carpentier rings. Intraoperative evaluation of the competence level achieved by this technique involved filling the left ventricular cavity with blood under pressure. Filling was achieved through the apical left vent, which was temporarily connected to the arterial line. The recommended anticoagulation therapy for those patients in sinus rhythm consisted of platelet antiaggregants only (dipyridamole and aspirin) for the first 3 postoperative months. Those patients in atrial fibrillation received anticoagulants for 3 months, and only those patients with giant left atria or massive thrombus were permanently maintained on anticoagulants. After the patient was discharged from the hospital, the anticoagulation regimen was assumed by the referring physician. All patients were assessed 3 and 6 months postoperatively and every 12 months thereafter until the follow-up period was terminated in June 1987. Patients who were not assessed at the center were contacted directly or through their referring physicians.

Results

For this group of patients, the mean total bypass time was 79.6 minutes (range, 38–187 minutes). The ischemic time varied between 28 and 95 minutes, with a mean time of 46.7 minutes. When isolated mitral repair was undertaken, the ischemic time ranged between 28 and 67 minutes with a mean time of 41.8 minutes. The hospital mortality was two cases (2.4%), attributable to hemorrhage in one and sepsis in the other. The hemorrhage occurred suddenly several hours after surgery through disruption of the apical left ventricular vent suture. Nine patients required reoperation because of hemorrhage (five), sternal dehiscence (two), and mediastinitis (two). One of the patients with mediastinitis died of sepsis from Serratia liquefaciens. Five patients required inotropic support during the postoperative period. There were two cerebrovascular accidents that may have been caused by air embolism; one patient recovered, but the other required tracheostomy and eventually died of sepsis. Three patients had severe arrhythmias that necessitated defibrillation.

Ten patients were lost to follow-up by failing to report after 2 years postoperatively. The cumulative follow-up period was 713 patient-years, and the mean follow-up period was 9.7 years, with a maximum of 12 years. There were three late deaths. One patient died 2 years postoperatively of a mesenteric embolism. Two other patients died at home of unknown causes at 9 and 10 years postoperatively.
Therefore, the linearized mortality rate is 0.42% per patient-year.

Eighteen patients had a thromboembolic accident, thereby yielding an incidence rate of 2.52% per patient-year and an actuarial thromboembolic-free rate of 72 ± 5.9% at 12 years (Figure 1). Eleven thromboembolic accidents were central and seven were peripheral; total recovery occurred in eight cases, partial recovery in nine, and death in one from mesenteric embolism. At the time of the accident, three patients were in sinus rhythm, 11 were in atrial fibrillation, and four had an unknown rhythm. Eight patients were receiving anticoagulants; four, antithrombicans; one, both treatments; and five, no antithrombotic therapy. No hemorrhagic accidents were recorded.

Thirteen patients required reoperation during the follow-up period; thus, the overall incidence for reoperation was 17.8% (13 of 73), and the linearized incidence rate was 1.8% per patient-year. The actuarial rate for freedom from reoperation at 12 years was 82 ± 3.1% (Figure 2). All patients requiring reoperation had a rheumatic etiology. Eleven of these 13 underwent mitral valve replacement, and a new flexible ring annuloplasty was performed in two. One patient also required an aortic bioprosthetic replacement. There were no operative or late deaths for reoperation. The predominant cause for reoperation was regurgitation in eight cases (11.0%). These eight patients required reoperation from 1 month to 7 years after their first surgery (mean time for reoperation was 20.6 months). However, six patients underwent reoperation within 2 years of the initial repair, and all had shown clinical signs of residual regurgitation before discharge from the hospital. The other two patients underwent reoperation at 3 years for chordal elongation and at 7 years for total valvular disruption. Five patients (6.8%) underwent reoperation for stenosis from 4 to 11 years postoperatively (mean interval, 87.8 months). All of these patients had undergone their initial surgeries with the preoperative diagnosis of stenosis or mixed lesions.

The postoperative functional class (New York Heart Association) was I in all surviving patients at 1 year after surgery; however, five required reoperation within the first postoperative year. After 10 years of follow-up, all patients with an implanted flexible ring (53), including those who sustained an embolic event with full recovery (nine), were assigned to functional classes I and II. The actuarial event-free incidence rate at 12 years was 56 ± 5.9% (Figure 3), and the overall survival was 92 ± 3.1% (Figure 4).

Discussion

Mitral valve reconstruction is currently considered an established and valid alternative to replacement. In fact, reconstruction has proved to be superior to replacement in terms of hospital mortality and postoperative quality of life. The important and related questions that must still be answered include the exact indications for this type of surgery and the long-term stability of each repair technique. With published evidence of the superiority of repair over replacement, it has been assumed that every effort must be directed toward mitral conservation regardless of the underlying pathology. We can reasonably expect, however, that some valves, in addition to those completely disorganized by calcification, will be beyond conservation. Answers to questions concerning indications for repair and long-term stability will emerge through detailed studies of the exact preoperative anatomic findings (now available with two-dimensional Doppler echocar-
diography) and of the long-term stability of the different techniques that have been applied to different pathologies.

We attempted to elucidate these problems by selecting a homogeneous sample of patients from the patient population who had undergone valvular repair. Although one of the authors of the present study (C.G.D.) had experience with annuloplasties performed with the Carpentier ring at another institution, we decided to include only those patients who underwent repair since January 1975 when we started using the Duran flexible ring. This decision allowed us to maintain accurate patient follow-up assessment and to avoid the inevitable initial "learning curve" period.

Despite these efforts, a complete follow-up was not possible, and 10 of 83 patients could not be traced. All 10 patients failed to report within the first 2 years after surgery and therefore, exclusion of data from these patients should not have a great impact on long-term results. Review of all 10 cases did not reveal any factors different from those of the other patients. The vast majority of patients in this study were rheumatic; only three of 85 were clearly nonrheumatic. Their age and sex distributions, together with the high incidence of stenotic component (85%), were in accordance with a rheumatic etiology. At initial surgery, 74 required a commissurotomy because some commissural fusion was present that required opening to improve cuspal mobility, even in rheumatic predominantly regurgitant lesions. An annuloplasty was performed in cases of predominant stenosis attributable to leaflet scarring; additionally, a significant regurgitant jet was detected intraoperatively after commissurotomy. Patients with predominant stenosis with leaflet scarring probably constitute the group for whom valvular repair is most difficult and in whom the indications for valvular repair are harder to define. Although intraoperative methods to detect residual regurgitation are satisfactory for these patients, there is no reliable method to predict the degree of postoperative residual stenosis that commonly occurs with this pathology. Intraoperative Doppler echocardiography should produce some definitive answers in this context.

The preoperative functional class distribution (24% of patients were assigned to class II) reflects our indications for surgery, which consider that class II patients should undergo mitral repair if a conservative procedure is elected. The predictive value of angiography was very high but was substantially lower than that of current two-dimensional Doppler echocardiography. The latter technique has become an essential step in this type of surgery because of the very detailed anatomic information it provides. Our recent experience, in fact, has shown that Doppler echocardiography has a remarkably high predictive value. The high incidence of valvular involvement (other than mitral valve involvement) is also characteristic of rheumatic etiology, and this incidence confirms that there are no contraindications to this surgery when other valves are involved. Furthermore, this conservative attitude is reflected in the fact that only eight of 133 valvular procedures performed on 85 patients involved valve replacement.

In this group of patients, very few mitral reconstructive maneuvers other than annuloplasty were performed, the exception being those procedures intended to increase leaflet mobility, like commissurotomy. Consequently, the ischemic times were kept to a minimum. The mean cross-clamping period for isolated mitral repair was 42 minutes, and this indicates that annuloplasty can be performed in 15–20 minutes and is, therefore, worth attempting even in doubtful cases in which valve replacement may be favored.

Although no cardioplegia was used and nearly 50% of cases required other valvular procedures, the hospital mortality was low (2.3%). The causes of death were clearly operative but were not related to the reconstructive procedure itself. However, it should also be noted that about 25% of patients were assigned to functional class II, and 39% were in sinus rhythm; these conditions reflect our preference for early surgery when reconstruction is anticipated. The thromboembolic rate, however, is high (2.5% per patient-year) compared with the thromboembolic rate after valve replacement. This high rate is particularly disturbing considering the large number of patients who were in sinus rhythm. In this series, 15 of the 18 patients who sustained an embolic accident were in atrial fibrillation, and only eight were receiving anticoagulants at the time. There is no apparent clustering of accidents in the early postoperative period; rather, the risk appears continuous throughout the follow-up period.

Other series of reconstructions have shown a lower incidence of thromboembolism than the pres-
ent study; however, the percentage of patients receiving anticoagulants was not reported, and the adequacy of anticoagulation was not determined. One possible way to reduce this problem is to recommend permanent anticoagulation therapy for patients in atrial fibrillation. In contrast to the high thromboembolic rate, no hemorrhagic accidents occurred in this series. A possible cause for this discrepancy may be that none of our patients had their atrial appendages surgically excluded, except in cases where the appendages were occupied by thrombi. It is also possible that the type of prosthetic ring may be responsible for the high thromboembolic rate. We can only state that, in all but two reoperated patients, the ring was completely covered by neointima as early as 1 month after surgery. In the remaining two patients, the ring was partially dehiscent, and a new annuloplasty was performed. Incidentally, the excised ring remained pliable in all reoperative cases up to 11 years after initial implantation.

In our opinion, the fundamental issue is the rate of reoperation in this series; as promising as the functional results are, they should be compared with the results from a similar group of patients with valve replacement. Several causes can be suggested to explain the need for reoperation: 1) The proper reconstructive technique was not indicated relative to the degree of valvular distortion. Consequently, poor functional results were obtained; 2) The reconstruction was not performed adequately; 3) The repair technique is unstable and deteriorates with time; and 4) The underlying pathology progresses. Analysis of this series may elucidate some of these issues because all patients requiring reoperation had a rheumatic etiology. About half of those needing reoperation (six of 13) clearly demonstrated unsatisfactory surgical results; these patients needed reoperation within 2 years of initial surgery and had clinical signs of residual regurgitation before hospital discharge. In these cases, either the repair should not have been attempted, or it was inadequately performed. These cases represent instances in which the benefits of mitral repair are doubtful, and in which intraoperative Doppler echocardiography may have indicated a valve replacement rather than valve repair. The second group is represented by the five patients who required surgery for stenosis, and who underwent reoperation at a much later date. All patients in this group had preoperative stenotic lesions and underwent valve replacement. In this second group, the cause for reoperation may be that either no satisfactory relief of their lesion had been achieved by the initial surgery, or that chronic rheumatic disease had progressed toward restenosis. In light of our previous experience in mitral reconstruction and the concomitant attenuated learning curve at the time of initial surgery, we suspect that operative causes are more likely a result of disease progression rather than a result of an overly conservative procedure in patients with very altered valves. Furthermore, the length of time between first and subsequent operations and the published evidence of restenosis after closed and open commissurotomy favor this last factor as causative.

We conclude that reconstructive surgery can be performed in rheumatic mitral disease and can result in low hospital and low late mortalities. The excellent functional results maintained during the long follow-up period confirm the stability of these techniques. However, the significant incidence of reoperation suggests the need for accurate preoperative and intraoperative anatomic evaluation of the valve. These results also suggest that a significant number of rheumatic patients will require reoperation attributable to the evolutive process of the underlying pathology.

Acknowledgments

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