

Long term outcomes of posterior leaflet folding valvuloplasty for mitral valve regurgitation

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Background: Posterior mitral valve leaflet prolapse due to degenerative mitral valve disease has been treated with tissue sparing repair techniques since 2002. The simplified foldoplasty technique effectively lowers the height of the redundant posterior leaflet and creates an optimal coaptation line for the anterior leaflet that results in excellent long term durability, freedom from reoperation, and return of functional status.

Methods: Patient demographics and in-hospital outcome data were extracted from electronic medical records of 229 patients, aged 60.6±13.7 years who underwent the procedure for mitral valve repair (MVR) involving the posterior leaflet from myxomatous disease between 2002 and 2014. Parametric analyses were performed on outcomes data, while long-term survival was assessed by Kaplan-Meier analyses.

Results: Concomitant coronary bypass surgery was performed on 32/229 (14%) patients, the mean perfusion time was 119±40 min, and the mean cross clamp time was 86±31 min. Post-operative mortality was 2/229 (0.9%), reoperation for bleeding occurred in 4 (1.7%) and postoperative stroke in 4 (1.7%) patients. Long term follow up rate was 100% and the mean study follow-up duration was 6.8±2.3 years. Overall late mortality rate was 24/229 (14.9%), and mitral valve re-intervention was performed on 7 patients (4.3%). NYHA class III/IV and clinically significant MR at follow up were significantly lower compared to preoperative values (both P<0.001).

Conclusions: Our results encourage further use of this simple and effective technique in patients with isolated posterior leaflet prolapse.

Keywords: Foldoplasty; ECHO; long-term; follow-up; mitral valve repair (MVR)



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Introduction

Posterior mitral valve leaflet prolapse due to degenerative mitral valve disease is the most common cause of mitral valve regurgitation (1). Over 90% of these patients undergo successful mitral valve repair (MVR) (2). The most common classic repair consists of triangular or quadrangular resection of prolapsed segment with sliding valvuloplasty of remaining posterior leaflet (3,4). Over the years, tissue sparing repair techniques of the posterior leaflet were introduced by Calafiore *et al.* and Mihaljevic *et al.* for patients whose anatomy of posterior leaflet prevented optimal result from being achieved with resection techniques (5,6). Popularization of the foldoplasty technique for posterior

leaflet prolapse was done by Tabata *et al.* who simplified the technique and expanded the indications (7). This technique effectively lowers the height of the redundant posterior leaflet and creates an optimal coaptation line for the anterior leaflet. Midterm results of this technique showed excellent durability and freedom from reoperation as well as excellent return of functional status (8).

We report mid to long term outcomes, including ECHO follow-up, of this simplified technique for posterior leaflet repair.

Technique

Patients were positioned and monitoring lines were

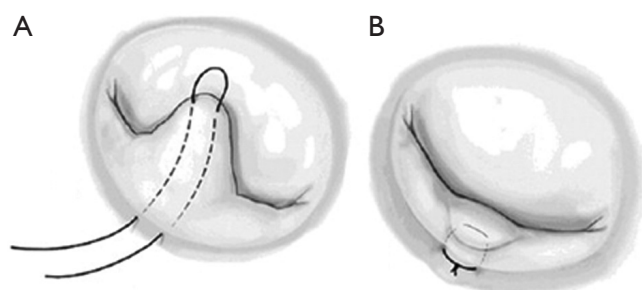


Figure 1 Foldoplasty technique with (A) 4-0 sutures to the posterior leaflet and subsequently (B) tied to the mitral annulus.

placed in a regular fashion. Procedures were performed through full sternotomy (FS) or minimally invasive lower hemisternotomy (LHS). Aorta was directly cannulated in both approaches while venous cannulation was direct bicaval for FS and percutaneous femoral for minimally invasive approach. Cardiopulmonary bypass (CPB) was initiated and myocardial protection was accomplished with intermittent cold blood cardioplegia given down the aortic root. Sondergaard's groove was opened and left atriotomy was performed exposing the mitral valve. The mitral valve was then inspected in detail and the prolapsed area was identified. Depending on the width of the prolapsed area, one to six double-armed 4-0 polypropylene sutures were placed from the leaflet edge to the annulus of the posterior leaflet (*Figure 1A*). These sutures were subsequently tied at the mitral annulus, thereby folding over the redundant leaflet to reduce the effective height of the leaflet by at least 50% (*Figure 1B*). We were able to adjust the leaflet height by changing the entry or exit points of the sutures. A flexible annuloplasty ring was subsequently inserted with 2-0 braided polyester mattress sutures in all patients. The size of the ring was based on the surface area of the anterior leaflet. An LV competency test was then done to confirm that the valve had been adequately repaired. Upon the completion of mitral repair, the left atrium was closed with 4-0 prolene suture. The patient's heart was deaired and the patient was weaned from CPB in the standard manner. Transesophageal echocardiography (TEE) confirmed adequate MVR.

Methods

With the approval of the Brigham and Women's Hospital Institutional Review Board, we conducted a retrospective review of all patients with myxomatous disease undergoing MVR of the posterior leaflet using the foldoplasty technique

between January 2002 and May 2014. Patients with less than moderate mitral regurgitation (MR) and those who had concomitant valvular resection were excluded; 229 patients met study criteria. Patient demographics and in-hospital outcome data were extracted from electronic medical records. Long-term follow-up of the 161 patients previously reported (8) was obtained from routine clinical follow-up and/or from the cardiologist of record. Survival data was obtained by additional query of the Social Security Death Index and from our State Department of Health. Primary outcomes of interest included repair durability, recurrence of clinically significant MR, and survival. See supplementary *Video 1* for footage of the procedure.

Statistical analysis

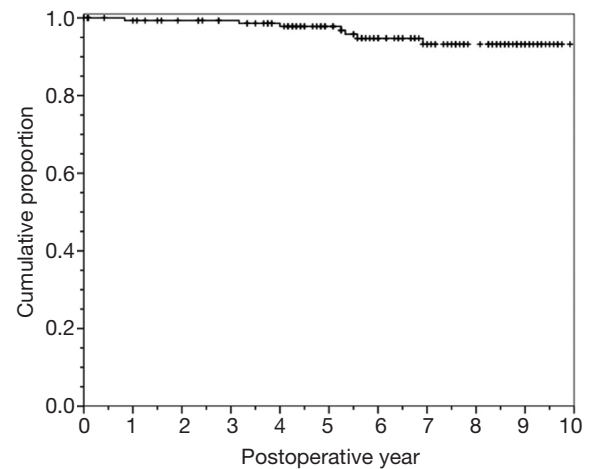
Binary variables are presented as percent and number (n); long-term follow up was compared to baseline using McNemar's test for repeated measures. Continuous variables are presented as mean $\pm$ standard deviation (SD); follow-up data was compared to baseline using repeated measures *t*-test. Kaplan-Meier analyses were used to evaluate long-term outcomes; follow-up time was calculated in months between the date of surgery and the date of the first of (I) follow-up echo showing clinically significant MR (defined as greater than moderate MR); (II) failure of the foldoplasty requiring reoperation; (III) death; (IV) date of last clinical follow-up documented. Study observation ended on July 31, 2014. All analyses were conducted using SPSS version 13.0 (SPSS Inc., Chicago, IL, USA) and $P \leq 0.05$ was the criterion for significance.

Results

Between January 2002 and May 2014, a total of 2,193 patients underwent MVR involving the posterior leaflet for myxomatous disease. Foldoplasty was performed on 229 (10.4%) of these patients, their mean age was 60.6 ± 13.7 years, and 105 (45.9%) were females. Clinical variables are presented in *Table 1*. Hypercholesterolemia was present in 147 (64.1%) foldoplasty patients, and 100 (43.7%) patients were hypertensive. Other comorbidities included diabetes (9/229; 3.9%), peripheral vascular disease (11/229; 4.8%), and previous cardiac surgery (3/229; 1.3%). Of the total cohort, 51 (22.3%) were in New York Heart Association (NYHA) class III/IV. Preoperative echocardiographic readings showed a mean PA pressure of 24 ± 10 mmHg and severe MR in 163 (71.2%) of the patients and moderate to severe

Table 1 Clinical variables

Variables	All Foldoplasty (N=229) (n, %)	Follow-up cohort (N=161) (n, %)
Preoperative characteristics		
Age, mean/SD (yrs)	13.7 (60.6)	14.0 (61.0)
Females	105 (45.9)	68 (42.2)
Diabetes	9 (3.9)	8 (5.0)
Preop creatinine, mean/ SD	0.2 (1.1)	0.2 (1.0)
Hypercholesterolemia	147 (64.1)	68 (42.2)
Hypertension	100 (43.7)	75 (46.6)
Peripheral vascular disease	11 (4.8)	9 (5.6)
Cerebrovascular accident	1 (0.4)	1 (0.6)
Cerebrovascular disease	5 (2.2)	4 (2.5)
Previous cardiac surgery	3 (1.3)	3 (1.9)
CABG	2 (0.9)	2 (1.2)
Valve	1 (0.4)	1 (0.6)
NYHA class III/IV	51 (22.3)	39 (24.2)
Ejection fraction, mean/SD [%]	8 [60]	8 [60]
Mean PA pressure, mean/SD [mmHg]	10 [24]	12 [24]
Degree of mitral regurgitation		
Moderate	34 (14.8)	28 (17.4)
Moderate-to-severe	32 (14.0)	15 (9.3)
Severe	163 (71.2)	118 (73.3)
Operative outcomes		
Concomitant CABG	32 (14.0)	25 (15.5)
Perfusion time, mean/SD [min]	40 [119]	40 [117]
Cross-clamp time, mean/SD [min]	31 [86]	29 [83]
Postoperative outcomes		
Operative mortality	2 (0.9)	1 (0.6)
Reoperations for bleed	4 (1.7)	4 (2.5)
Stroke	4 (1.7)	2 (1.2)
Total ICU stay, IQR/med. [hrs]	25-69 [46]	26-73 [46]
LOS, IQR/med. (days)	5-7.5 (6.0)	5-8 (6.0)
n, number of patients; SD, standard deviation; CABG, coronary artery bypass graft surgery; NYHA, New York Heart Association Classification; PA, pulmonary artery; ICU, intensity care unit; LOS, length of stay; med, median; IQR, interquartile range.		

**Figure 2** Freedom from reoperation.

in the remainder. Concomitant coronary artery bypass graft surgery (CABG) was performed on 32 (14%) patients and the mean perfusion time was 119 ± 40 min and the mean cross clamp time was 86 ± 31 min. Post-operative mortality was 2/229 (0.9%), reoperation for bleeding occurred in 4/229 (1.7%) and postoperative stroke in 4/229 (1.7%).

Long term follow-up was 100% and the study's mean observation time was 6.8 ± 2.3 years during which overall mortality was 24 (14.9%), and mitral valve reintervention was performed on seven patients (4.3%; *Figure 2, Table 2*). NYHA class III/IV and clinically significant MR at follow-up were significantly lower compared to preoperative values (both $P < 0.001$).

Discussion

MVR and its traditional techniques described by Carpentier (1) more than three decades ago, has become well established therapy for degenerative mitral valve disease with excellent durability (9,10). Multiple studies have demonstrated important benefits of MVR over replacement (11,12). In the centers of excellence, repair rates for the isolated posterior leaflet prolapse are over 95% (2,3,13,14). However the number of MVR procedures and repair rates in smaller centers is not as high. Reasons for this may be due to the complexity of the techniques and irreversibility of the attempted repairs that, in case of suboptimal result, end with mitral valve replacement and decreased long-term survival.

Foldoplasty introduced by Calafiore *et al.*, Mihaljevic *et al.*

Table 2 Follow up variables

Contents	Follow-up cohort (N=161)	P≤ vs. baseline
Follow up		
Total patient years	1,076	–
Study observation time, mean/SD (years)	2.3 (6.8)	–
Mortality during study (n, %)	24 (14.9)	–
Redo MVR or MVP (n, %)	7 (4.3)	–
Time to f/u echo, mean/SD (years)	2.7 (4.9)	
Ejection fraction, mean/SD (%)	8.0 (58.0)	0.029
MR at follow-up, mean/SD	0.9 (1.9)	0.001
Clinically significant MR (n, %)	12 (7.5)	0.001
NYHA class at follow-up, mean/SD	0.7 (1.6)	0.001
NYHA class III/IV (n, %)	10 (6.3)	0.001
SD, standard deviation; n, number of patients; MVR, mitral valve repair; MVP, mitral valve valvuloplasty; f/u, follow-up; MR, mitral regurgitation; NYHA, New York Heart Association.		

and Tabata *et al.*, has been part of our toolbox for MVRs since 2002 (5-7). Due to its appealing qualities, namely technical simplicity, broad applicability and reversibility, it has quickly become one of the favored procedures for posterior mitral leaflet prolapse. As described by Cevasco *et al.* (8) this technique yields excellent perioperative and mid-term results with 100% repair rate for isolated posterior leaflet prolapse and only two patients requiring reoperative procedure on mid-term follow up of 3 years.

We describe our results and long-term follow-up of 229 patients who underwent mitral valve foldoplasty. Follow-up in this series was 100% complete and consisted of 1,076 patient-years. In our cohort only 4.3% of the patients required reoperative surgery over a mean period of 6.8 years and 2% had moderate regurgitation on the follow-up echocardiography that was treated conservatively.

Gillinov *et al.* reported the Cleveland Clinic experience of 1,072 patients with 10 years freedom from reoperation of 93% (9). In their conclusion, repair durability was greatest in patients with quadrangular resections and annuloplasty. Braunberger *et al.*, in their paper from 2001, report on 162 patients with non-rheumatic MR with 74% freedom from cardiac events at 20 years (15) while Flameng *et al.* report 94% freedom from reoperation but only 71% freedom from

significant MR at seven years for degenerative mitral valve disease (16).

Similar results observed with the foldoplasty, as well as reproducibility and forgiveness due to tissue sparing repairs, encourage further use of this technique in patients with isolated posterior leaflet prolapse.

Limitations of this study include its retrospective observational nature and the lack of a control group. Further randomized studies that compare foldoplasty with other types of posterior mitral leaflet repair may be needed to further validate our results for this technique.

Acknowledgements

None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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