

## Effect of systematic downsizing rigid ring annuloplasty in patients with moderate ischemic mitral regurgitation

Denis Bouchard, MD,<sup>a</sup> Henrik Jensen, MD,<sup>a</sup> Michel Carrier, MD,<sup>a</sup> Philippe Demers, MD,<sup>a</sup> Michel Pellerin, MD,<sup>a</sup> Louis P. Perrault, MD, PhD,<sup>a</sup> and Jean Lambert, PhD<sup>b</sup>

**Objective:** Functional ischemic mitral regurgitation (FIMR) increases mortality independently of the baseline characteristics and ventricular function. The effect of treating FIMR with annuloplasty is unclear when mitral regurgitation is moderate. Myocardial revascularization alone has been shown to improve mitral valve function.

**Methods:** We randomized 31 patients with moderate (grade 2-4) FIMR to receive either coronary artery bypass grafting (CABG) alone or CABG plus downsizing mitral ring annuloplasty. The patients were followed up for clinical outcomes and echocardiographic assessment of mitral valve function and left ventricular dimensions at 3 and 12 months. Clinical improvement was assessed using the Minnesota quality-of-life questionnaire, 6-minute walk test, and brain natriuretic peptide levels.

**Results:** The clinical course was similar in the 2 groups of patients during the study period. FIMR was perfectly corrected intraoperatively in the ring group. Echocardiographic follow-up at 3 months showed no difference in the FIMR grade between the 2 groups (66% less than grade 2 in the CABG alone and 86% in the CABG plus ring group;  $P = .316$ ). The improvement in the CABG alone group was even more marked at 12 months (85% less than grade 2 in the CABG group and 85% in the CABG plus ring group). The left ventricular ejection fraction was significantly better at 3 months in the CABG alone group, although at 12 months, the left ventricular ejection fraction in the 2 groups had improved similarly.

**Conclusions:** Although initially effective at reducing moderate FIMR, the addition of a ring did not change the clinical course after CABG surgery. At 12 months, no echocardiographic difference was found in terms of residual mitral regurgitation, left ventricular dimensions and function, or clinical outcomes. (*J Thorac Cardiovasc Surg* 2014;147:1471-7)



Earn CME credits at  
<http://jtcvs.com/cme/home>

Functional ischemic mitral regurgitation (FIMR) increases mortality independently of the baseline characteristics and ventricular function and is directly related to the degree of FIMR.<sup>1</sup> Many surgeons address FIMR at surgical revascularization, because some clinical studies have not supported coronary artery bypass grafting (CABG) as an effective treatment of FIMR.<sup>2</sup> Downsizing ring annuloplasty (ring) as an adjunct procedure to CABG has been used to correct Carpentier type I and type IIIB dysfunction in patients with FIMR, with a high freedom rate from intraoperative mitral regurgitation, although it can recur with time. Some

investigators have reported excellent long-term results,<sup>3,4</sup> although others have reported an exponentially increasing rate of recurrent FIMR up to approximately 70% at 5 years.<sup>4-6</sup> The effect of adding downsizing ring annuloplasty to CABG in patients with ischemic mitral regurgitation has been thoroughly addressed in published studies. A recent meta-analysis of a nonrandomized series<sup>7</sup> and 2 randomized studies<sup>8,9</sup> comparing CABG and CABG combined with downsizing ring annuloplasty showed that the addition of a ring resulted in a lower mitral regurgitation grade and New York Heart Association (NYHA) class compared with CABG alone but did not improve the survival rate. The present study reports the results of a randomized trial focusing on the clinical and echocardiographic outcomes throughout 1 year after surgery.

### METHODS

#### Study Population

From 2002 to 2008, 67 patients with coronary artery disease and FIMR were referred for cardiac surgery at the Montreal Heart Institute and were screened for randomization. The inclusion criteria were grade 2+ FIMR with a concomitant need for CABG. The exclusion criteria were papillary muscle rupture, a concomitant need for aortic valve surgery, life expectancy less than 12 months from noncardiac causes, creatinine >200  $\mu\text{mol/L}$ , and more than grade 2 FIMR. A total of 31 patients were included in the study and randomized to CABG alone ( $n = 16$ ) or CABG combined with ring annuloplasty ( $n = 15$ ). All the patients provided written informed

From the Department of Cardiac Surgery,<sup>a</sup> Montreal Heart Institute and Université de Montréal; and the Department of Social and Preventive Medicine,<sup>b</sup> Université de Montréal, Montreal, Quebec, Canada.

This study was supported by a Montreal Heart Institute clinical research grant.

Disclosures: Authors have nothing to disclose with regard to commercial support. Received for publication Dec 13, 2012; revisions received Jan 29, 2013; accepted for publication May 23, 2013; available ahead of print July 15, 2013.

Address for reprints: Denis Bouchard, MD, Department of Cardiac Surgery, Montreal Heart Institute, 5000 Belanger St, Montreal, QC H1T 1C8, Canada (E-mail: Denis.Bouchard@icm-mhi.org).

0022-5223/\$36.00

Copyright © 2014 by The American Association for Thoracic Surgery

<http://dx.doi.org/10.1016/j.jtcvs.2013.05.024>

**Abbreviations and Acronyms**

BNP	= brain natriuretic peptide
CABG	= coronary artery bypass grafting
ERO	= effective regurgitation orifice
FIMR	= functional ischemic mitral regurgitation
QOL	= quality of life
LA	= left atrial
LV	= left ventricular
LVEF	= LV ejection fraction
MR	= mitral regurgitation
NYHA	= New York Heart Association
OR	= operating room

consent, and the local ethics committee approved the study. All authors had full access to, and take full responsibility for, the integrity of the data.

**Operative Technique**

All surgical procedures were performed through a midline sternotomy. Mild hypothermic cardiopulmonary bypass and cold blood cardioplegia were used. The left internal mammary artery was grafted to the left anterior descending coronary artery in all patients. The remaining revascularization was done using saphenous vein grafts. In the CABG group, 2 patients underwent surgery with an off-pump beating heart technique. In the CABG plus ring group, rigid ring annuloplasty was performed (size 26–28), downsized by 2 sizes according to the anterior leaflet height and intercommissural distance. Three patients received a Carpentier Edwards ETlogix ring (Edwards Lifesciences, Irvine, Calif), and 12 patients received a Carbomedics Annuloflo ring (Sorin, Milano, Italy).

**Echocardiography**

Serial transthoracic echocardiographic studies were performed pre-, intra-, and postoperatively at 3 and 12 months. The left ventricular (LV) M-mode spectrum was obtained in the parasternal long-axis view; the LV dimensions at both end cardiac diastole (LVDD) and systole (LVDS) were measured. LV fractional shortening was calculated as  $(LVDD - LVDS)/LVDD \times 100\%$ . Apical 4-chamber and 2-chamber views were recorded. The Simpson method was used to calculate the end-systolic and end-diastolic LV volumes (LVVd, LVVs). The LV ejection fraction (LVEF) was calculated as  $(LVVd - LVVs)/LVVd \times 100\%$ . Mitral regurgitation (MR) was quantified by measurements of the MR jet area and left atrial (LA) area using color mapping of the apical 4-chamber view during cardiac systole. MR was semiquantitatively graded using the jet area/LA area  $\times 100\%$ , with grade I representing  $<20\%$ ; grade II, 20–40%; and grade III–IV,  $\geq 40\%$ . The effective regurgitation orifice (ERO) area, MR volume, and regurgitation fraction were calculated using the proximal isovelocity surface area or Doppler method, as previously described.<sup>10,11</sup> MR was further quantitatively graded as I, II, III, IV, with an ERO of  $<20$ , 20–29, 30–39, and  $\geq 40$  mm<sup>2</sup>, regurgitant volume of  $<30$ , 30–44, 45–59, and  $\geq 60$  mL, and regurgitation fraction of  $<30$ , 30–39, 40–49, and  $\geq 50\%$ , respectively.

**Clinical Follow-up**

The patients completed the Minnesota quality of life (QOL) questionnaire<sup>12</sup> at 3 months. The French version of this questionnaire was tested for validity and reliability.<sup>13</sup> Cronbach's alpha ranged from 0.73 to 0.93, except for its incapacity dimension (0.40). The intraclass correlation coefficients were all greater than 0.70 in the 4 dimensions of the questionnaire. These results were similar to those obtained with the original questionnaire.<sup>12</sup> The patients also performed a 6-minute walk test and underwent brain natriuretic peptide (BNP) measurements. BNP measurements were

taken and the QOL questionnaire was completed preoperatively and at the 3- and 12-month follow-up examinations conducted by physicians at the Montreal Heart Institute Valve Clinic.

**Study Endpoints**

The primary endpoint was the LV dimension changes at 1 year. The secondary endpoints were difference in the BNP levels, QOL score, and 6-minute walk test results at 3 months, and the NYHA class and MR grade at 3 months and 1 year.

The randomization took place in the operating room (OR), after the skin incision. The patients were unaware of the mitral correction status for the first year after their surgery. The surgeons and cardiology teams treating the patient and the echocardiographers analyzing the images were aware of the correction status.

**Statistical Analysis**

Continuous data are presented as the mean  $\pm$  standard deviation, and the categorical data are presented as numbers (percentages).

Between the groups, comparisons were performed using Student *t* tests and Pearson's chi-square tests for continuous and categorical variables, respectively. For continuous variables with preoperative measures, the postoperative values were compared between groups using analyses of covariance to reduce the error mean squares.

Within group comparisons were performed using paired *t* tests and the McNemar-Bowker chi-square test for continuous and categorical variables, respectively.

Usual assumptions such as normality and homoscedasticity of the variance were verified. Transformations and/or more robust procedures such as nonparametric tests were used when necessary. Parallelism of the regression lines (or interaction) was verified when using analyses of covariance, but no interaction was detected. The level of significance was set at .05 for all procedures. Because of the small sample sizes, adjustments for multiplicity of testing were not used. All analyses were performed using the Statistical Package for Social Sciences, version 20 (SPSS, Inc, Chicago, Ill).

**RESULTS****Patient Population and Perioperative Outcomes**

Table 1 lists the baseline characteristics of the 2 groups, and the operative procedure details are listed in Table 2. No significant difference was found in the preoperative patient characteristics between the 2 groups. As expected, the group randomized to CABG plus ring had longer crossclamp and cardiopulmonary bypass times.

**Clinical Follow-up**

**Postoperative versus preoperative.** The clinical follow-up data are listed in Table 3. In both groups, the NYHA class had improved at 3 and at 12 months compared with preoperatively. The percentage of patients in NYHA class III and IV decreased from 50% at the preoperative evaluation to 17% and 0% at 3 and 12 months, respectively, for the CABG group and from 40% preoperatively to 0% and 8% for the CABG plus ring group. However, owing to small samples, these important decreases were not statistically analyzable using the McNemar-Bowker chi-square test.

No statistically significant improvement in QOL was observed at 3 months of follow-up in either group (CABG,  $P = .276$ ; CABG plus ring,  $P = .131$ ). A trend was seen toward a reduction in BNP at 3 months in the

Download English Version:

<https://daneshyari.com/en/article/2980655>

Download Persian Version:

<https://daneshyari.com/article/2980655>

[Daneshyari.com](https://daneshyari.com)