



Papillary Muscle Approximation Versus Restrictive Annuloplasty Alone for Severe Ischemic Mitral Regurgitation

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ABSTRACT

BACKGROUND Guidelines recommend surgery for patients with severe ischemic mitral regurgitation (MR). Nonrandomized studies suggest that subvalvular repair is associated with longer survival, but randomized studies are lacking.

OBJECTIVES This study sought to investigate the benefit of papillary muscle surgery on long-term clinical outcomes of patients with ischemic MR.

METHODS Ninety-six patients with severe ischemic MR were randomized to either undersizing restrictive mitral annuloplasty (RA) or papillary muscle approximation with undersizing restrictive mitral annuloplasty (PMA) associated with complete surgical myocardial revascularization. The primary endpoint was change in left ventricular end-diastolic diameter (LVEDD) after 5 years, measured as the absolute difference from baseline, which was evaluated by paired Student *t* tests. Secondary endpoints included changes in echocardiographic parameters, overall mortality, the composite cardiac endpoint (major adverse cardiac and cerebrovascular events [MACCE]), and quality of life (QOL) during the 5-year follow-up.

RESULTS At 5 years, mean LVEDD was 56.5 ± 5.7 mm with PMA versus 60.6 ± 4.6 mm with RA (mean change from baseline -5.8 ± 4.1 mm and -0.2 ± 2.3 mm, respectively; $p < 0.001$). Ejection fraction was $44.1 \pm 6\%$ in the PMA group versus $39.9 \pm 3.9\%$ in the RA group (mean change from baseline $8.8 \pm 5.9\%$ and $2.5 \pm 4.3\%$, respectively; $p < 0.001$). There was no statistically significant difference in mortality at 5 years, but freedom from MACCE favored PMA in the last year of follow-up. PMA significantly reduced tenting height, tenting area, and interpapillary distance soon after surgery and for the long-term, and significantly lowered moderate-to-severe MR recurrence. No differences were found in QOL measures.

CONCLUSIONS Compared with RA only, PMA exerted a long-term beneficial effect on left ventricular remodeling and more effectively restored the mitral valve geometric configuration in ischemic MR, which improved long-term cardiac outcomes, but did not produce differences in overall mortality and QOL. (J Am Coll Cardiol 2016;67:2334-46)
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The reported incidence of ischemic mitral regurgitation (MR) among persons who experience myocardial infarction is up to 39% (1,2). Ischemic MR is a consequence of a geometric disturbance of the mitral valve configuration due to papillary muscle injury and displacement (3-7).

Functional valve incompetence centers on the abnormal imbalance between closing and tethering forces with otherwise normal leaflets (8). Annular dilation, enlargement of the left ventricular (LV) chamber, and abnormal papillary muscle displacement with apical and lateral migration are



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consequences of the tethering forces. Reduction of LV contractility, global LV dyssynchrony, papillary muscle dyssynchrony, and altered mitral systolic annular contraction are expressions of the decreased closing forces (8) that lead to impaired leaflet coaptation and a variable degree of MR, which (often concurrently with the residual ischemia), in turn, can affect the state of ventricular filling, heart rhythm, and afterload (9,10). The 2014 American College of Cardiology Guidelines for patients with severe ischemic MR advocated consideration of mitral reparative surgery as an adjunct to treatment of the primary underlying pathology with coronary revascularization (3). However, published reports are not conclusive as to which of the currently proposed valve repair approaches is superior, and specifically, if standard annuloplasty requires an auxiliary subvalvular intervention to attenuate the incidence of MR recurrence (11). The latter point takes into account the accumulating evidence that suggests that preservation and restoration of papillary muscle function by relocation or approximation are associated with longer overall survival (12-14).

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A recent relevant randomized study claimed that a mitral replacement strategy was superior to repair in severe ischemic MR, in terms of recurrence of moderate-to-severe MR at 1 (1) and 2 years of follow-up (15). However, although this trial showed no significant between-group differences in LV reverse remodeling, MV repair with annuloplasty produced a significantly higher frequency of heart failure-related events; despite the increased recurrence of MR, no significant differences were found in major cardiac adverse event rates, overall mortality, or quality of life (QOL) (1,15). The results of this study constitute a significant landmark in decision making in ischemic MR, addressing the delicate tradeoff between mitral replacement, which provides a more durable correction of the MR at the cost of increased periprocedural mortality, and mitral repair, which guarantees a reduced perioperative risk burden but provides less satisfactory long-term results (16,17). However, as the investigators also pointed out, careful consideration of the mechanisms that underlie recurrence of MR after annuloplasty might elucidate explanations for the unsatisfactory outcomes. Factors, such as augmented leaflet tethering caused by the anterior displacement of the posterior leaflet (18), the role of adjunctive subvalvular procedures that may potentially influence recurrence of MR after annuloplasty (19), as well as the progressive adverse global and localized LV remodeling related to incomplete

revascularization (20) were not addressed. Thus, the effective benefit of the reparative approach may have been underestimated. In this context, recent innovations in cardiac imaging allow very accurate assessment of mitral valve geometry and have reopened the debate on surgical treatment of the subvalvar apparatus and ventricular wall as a potential key point in ischemic MR (21-24). The evidence suggests that an effective mitral repair approach needs to address the entire mitral complex, including not only the mitral annulus, but also the subvalvular apparatus. We pioneered the use of papillary muscle approximation (PMA) for ischemic MR in combination with restrictive undersizing annuloplasty (RA) with encouraging results, and other evidence on the use of this technique and on papillary muscle relocation produced survival benefit (12-14,21-24). However, the consensus about the role of papillary muscle surgery in ischemic MR is not unanimous, and there is not a univocal surgical attitude towards subvalvular repair in ischemic MR treatment (25,26), as demonstrated in a recent systematic analysis (11). Therefore, a randomized study was designed to compare standard RA alone with the combined annular and subvalvular approach, and to investigate the relative role of papillary muscle surgery in the context of ischemic MR. We also sought to elucidate the effective benefit of papillary muscle surgery in long-term follow-up of ischemic MR, with the aim of determining the optimal surgical strategy in these cases.

METHODS

STUDY DESIGN. This study was a prospective, randomized clinical trial that aimed to evaluate patients with severe chronic ischemic MR who underwent either isolated RA or PMA, associated with complete surgical myocardial revascularization. The trial was designed to enroll 96 patients and to evaluate them over a 5-year follow-up. The study was conducted in 1 referring center (Università Campus Bio-Medico di Roma, Rome, Italy) and recruited patients from 3 different regions in central Italy (Lazio, Campania, Abruzzo). Enrollment began in May 2007 and was completed in November 2010. Three different surgeons performed the surgical procedures. The aim of the study was to describe each patient in the cohort over a 5-year follow-up; the study concluded in November 2015. Endpoints were measured at 30 days, at 6 months, and every

ABBREVIATIONS AND ACRONYMS

CABG = coronary artery bypass graft

EROA = effective regurgitant orifice area

LV = left ventricle/ventricular

LVEDD = left ventricular end-diastolic diameter

MACCE = major adverse cardiac and cerebrovascular events, composite cardiac endpoint

MR = mitral regurgitation

NYHA = New York Heart Association

PMA = papillary muscle approximation associated with undersizing restrictive mitral annuloplasty

QOL = quality of life

RA = undersizing restrictive mitral annuloplasty

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