Management of severe ischemic cardiomyopathy: Left ventricular assist device as destination therapy versus conventional bypass and mitral valve surgery

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Objectives: Patients with severe ischemic cardiomyopathy (left ventricular ejection fraction <25%) and severe ischemic mitral regurgitation have a poor survival with medical therapy alone. Left ventricular assist device as destination therapy is reserved for patients who are too high risk for conventional surgery. We evaluated our outcomes with conventional surgery within this population and the comparative effectiveness of these 2 therapies.

Methods: We identified patients who underwent conventional surgery or left ventricular assist device as destination therapy for severe ischemic cardiomyopathy (left ventricular ejection fraction <25%) and severe mitral regurgitation. The era for conventional surgery spanned from 1993 to 2009 and from 2007 to 2011 for left ventricular assist device as destination therapy. We compared baseline patient characteristics and outcomes in terms of end-organ function and survival.

Results: A total of 88 patients were identified; 55 patients underwent conventional surgery (63%), and 33 patients (37%) received a left ventricular assist device as destination therapy. Patients who received left ventricular assist device as destination therapy had the increased prevalence of renal failure, inotrope dependency, and intra-aortic balloon support. Patients undergoing conventional surgery required longer ventilatory support, and patients receiving a left ventricular assist device required more reoperation for bleeding. Mortality rates were similar between the 2 groups at 30 days (7% in the conventional surgery group vs 3% in the left ventricular assist device as destination therapy group, $P = .65$) and at 1 year (22% in the conventional surgery group vs 15% in the left ventricular assist device as destination therapy group, $P = .58$). There was a trend toward improved survival in patients receiving a left ventricular assist device compared with the propensity-matched groups at 1 year (94% vs 71%, $P = .171$).

Conclusions: The operative mortality and early survival after conventional surgery seem to be acceptable. For inoperable or prohibitive-risk patients, left ventricular assist device as destination therapy can be offered with similar outcomes. (J Thorac Cardiovasc Surg 2014;147:1246-50)

ACD

The presence of mitral regurgitation (MR) in the setting of left ventricular (LV) dysfunction is associated with increased mortality.[1,2] With improvements in surgical techniques, mitral valve (MV) surgery for severe MR in the setting of advanced LV dysfunction has become an accepted option.[3,4] However, in patients with severe ischemic cardiomyopathy, the surgical treatment of severe MR is still associated with increased operative risks and perioperative morbidity.[5] Although studies have suggested a potential survival advantage of MV repair over replacement, ongoing debates remain regarding the effectiveness of mitral surgery in patients with end-stage ischemic cardiomyopathy[6] and factors that really influence survival.[7] Nonetheless, the management of patients with severe ischemic mitral regurgitation (IMR) and severe ischemic cardiomyopathy remains challenging and is still associated with poor outcomes.[8]

Left ventricular assist devices (LVADs) have become the standard of care for patients with life-threatening heart failure refractory to optimal medical therapy.[9] The HeartMate II LVAD (Thoratec, Pleasanton, Calif) has been approved for use as destination (permanent) therapy (DT) for patients with end-stage congestive heart failure who are ineligible for heart transplantation because of age, additional health problems, or other complications.[10] Thus, the use of mechanical support devices in adult patients has recently become commonplace in many centers, and excellent reported outcomes have allowed the widespread use of the

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Abbreviations and Acronyms

CABG = coronary artery bypass grafting
CS = conventional surgery
DT = destination therapy
IABP = intra-aortic balloon pump
IMR = ischemic mitral regurgitation
LV = left ventricular
LVAD = left ventricular assist device
LVEF = left ventricular ejection fraction
MR = mitral regurgitation
MV = mitral valve

HeartMate II device in high-risk patients with end-stage cardiomyopathy.[10]

We conducted this study to understand the surgical results in patients with severe ischemic cardiomyopathy and severe IMR. The primary objective of this study was to evaluate surgical results in patients with severe ischemic LV dysfunction (left ventricular ejection fraction [LVEF] $\leq$25%) and severe IMR. The secondary objective was to compare the effectiveness of conventional surgery (CS) (coronary artery bypass grafting [CABG] + MV surgery) versus LVAD as DT in this high-risk population.

PATIENTS AND METHODS

Study Design

This is a retrospective analysis of prospectively gathered data over more than a 10-year period (median, 3.6 years; range, 0-15 years). The Mayo Foundation Institutional Review Board approved this study, and individual consent was obtained for all patients included in this study. For patients in the conventional CABG + MV surgery group, the cardiac surgery database (1993 to 2009) at Mayo Clinic (Rochester, Minn) was used to identify a homogeneous study cohort of patients who underwent cardiac surgery for ischemic heart disease with severe IMR. We identified patients who underwent a combined CABG and MV repair or MV replacement first. Then, we excluded those who have had any one of the following conditions: LVEF greater than 25%, concomitant mitral prolapse, infective endocarditis, congenital valvular heart disease, rheumatic valvular disease, or any degree of mitral stenosis. We used the same cardiac surgery database (2007-2011) to identify patients with end-stage ischemic cardiomyopathy with severe IMR who underwent implantation of a HeartMate II LVAD as DT during this period. Since the inception of our multidisciplinary LVAD program in 2007, LVAD DT was offered only to those who were deemed inappropriate for CS on the basis of having very poor to no coronary target vessels to improve myocardial ischemia. The frequency of CS per year was examined over time (pre- and post-LVAD DT). This study included only patients with the HeartMate II continuous-flow device (Thoratec, Pleasanton, Calif). All other device types were excluded from this study. All patients considered for LVAD DT were considered initially for conventional therapy. Myocardial viability in relation to suitable coronary targets and probability of mitral surgery were generally assessed first, and the decision was left to the surgeon's discretion to refer for advanced heart failure therapies.

Definitions

The cause of MR was ischemic; all operative and echocardiographic findings were reviewed in detail for all patients included in this study. All patients were deemed to have severe IMR on the basis of leaflet tethering and prior myocardial infarction. Our institutional policy has been to preserve the posterior leaflet whenever possible with an increasing recent tendency toward preserving the anterior leaflet and by transposing it to the posterior annulus at the time of MV replacement. The operative mortality was defined as death from any cause within 30 days of surgery or during the same hospitalization. All patients in the MV repair group had the implantation of an undersized ring/band when applicable. In patients with mitral repairs, the ring was chosen according to the undersized intercommissural distance. In patients with posterior bands, the band was cut and undersized to the appropriate length. Prolonged intubation was defined as the need for mechanical ventilation greater than 48 hours. Of note, extubation protocol was not standardized among groups and left to physician preferences. Reported postoperative infections include superficial sternal, urinary tract, and pulmonary infections. Preoperative renal failure was defined as an uncorrected creatinine clearance less than 60 mL/min.

Follow-up

Patients were followed systematically using mailed questionnaires, telephone interview, or examination at the Mayo Clinic. Clinical follow-up was 100% complete. Mean follow-up among survivors was 4.2 years (range, 0-15.7 years).

Statistical Analysis

Mann–Whitney Wilcoxon rank-sum test was used to compare variables between patients with CS and patients with an LVAD. Categoric variables between 2 groups were compared using the Fisher exact test. The Kaplan–Meier method was used to construct survival curves, and survival was analyzed for both unmatched and matched populations. Differences in survival between 2 groups were obtained using the log-rank test. Statistical analysis was performed using R: A language and environment for statistical computing (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Patient Characteristics

In this study, 88 patients were identified and had concomitant severe ischemic cardiomyopathy and severe IMR. From 1993 to 2009, 55 patients were labeled to have CS, because they had a combined CABG and MV (replacement or repair) procedure. From 2007 to 2011, 33 patients had an LVAD implanted as DT. The baseline characteristics of all patients and 2 subgroups according to the type of procedure (CS vs LVAD DT) are shown in Table 1. The Society of Thoracic Surgeons predicted mortality for patients in the CS group was 10.4%. As shown in Table 1, age, preoperative LVEF, incidence of diabetes, and rate of redo surgeries were comparable between groups ($P > .05$). However, as expected, there were significant observed differences between groups. Compared with patients with CS, patients in the LVAD DT group had a higher incidence of preoperative renal failure (70% vs 15%, $P < .001$), a higher rate of preoperative intra-aortic balloon pump (IABP) (79% vs 13%, $P < .001$), and a higher rate of preoperative inotrope dependency (58% vs 15%, $P < .001$). Preoperative IABP is frequently used to optimize hemodynamic, right ventricular function, or kidney function before definitive LVAD therapy. We believe a short bridging ($\leq$48 hours) strategy with IABP helps optimize the preoperative condition before