Neurohormonal and Echocardiographic Results After CorCap and Mitral Annuloplasty for Dilated Cardiomyopathy

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Background. **Restrictive mitral annuloplasty (RMA) can be an effective treatment for functional mitral regurgitation in congestive heart failure (CHF). Passive cardiac restraint is another surgical approach, but the midterm results are not well characterized.**

Methods. **Thirty patients with functional mitral regurgitation were prospectively randomized to RMA alone or cardiac restraint with the CorCap Cardiac Support Device (Acorn Cardiovascular Inc, St. Paul, MN) and RMA. Clinical, echocardiographic, New York Heart Association (NYHA) functional class, Short Form 36-Item Health Survey (SF-36) quality of life scores, and N-terminal pro-B-type natriuretic peptide (NT-proBNP) results were analyzed.**

Results. **No hospital deaths or device-related complications occurred. The two groups had comparable morbidity ($p = 0.34$). Echocardiography showed a trend towards a slightly better functional improvement during follow-up in CorCap plus RMA patients (between groups, $p = 0.001$). Both groups showed improved results for SF-36, NYHA, and NT-pro.BNP; however, CorCap plus RMA patients had significantly better SF-36 at discharge ($p = 0.003$), postoperative NYHA ($p = 0.05$), and NT-pro.BNP ($p = 0.001$). Survival ($p = 0.46$), freedom from CHF ($p = 0.23$), and rehospitalization ($p = 0.28$) were comparable. Patients in whom CHF developed after postoperative day 1 had higher NT-pro.BNP values ($p = 0.001$ at all time-points).**

Conclusions. **Adjunctive application of CorCap with RMA correlated with better NT-pro.BNP at short-term follow-up together with slightly improved echocardiographic and functional results. This deserves further evaluation at midterm and long-term follow-up. Reduction of NT-pro.BNP at follow-up may be suggested as a prognostic index.**

(Ann Thorac Surg 2009;88:719–26)
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Congestive heart failure (CHF) with left ventricular (LV) dilation affects more than 20 million people worldwide. Surgical management of CHF represents the fastest-growing area of cardiovascular surgery [1]. Functional mitral regurgitation (FMR), defined by normal leaflets with annular dilation and restricted leaflet motion, is often involved in end-stage disease [2, 3]. Traditionally, valve operations have been considered controversial, being limited to the treatment of a structural consequence of CHF, but not addressing the underlying cause of LV dysfunction [2–6]. Therefore, several surgical procedures have been investigated to improve outcomes [4–6].

Cardiac restraint devices, such as the CorCap Cardiac Support Device (Acorn Cardiovascular Inc, St Paul, MN), have been regarded as means to limit or to prevent chronic cardiac dilation and the ensuing progression of CHF [7]. In particular, experimental models showed that CorCap could address the maladaptive mechanisms associated with increased wall stress [8, 9]. Such promising results drew attention to CorCap as a novel strategy to improve cardiac function [8, 9].

Accordingly clinical trials validated the feasibility of the technique, showing improvement of clinical symptoms, as well as hemodynamics and echocardiographic results [10–17]. However, the potential benefit of combining passive cardiac restraint devices with mitral valve (MV) procedures is still questionable [18]. Therefore, the aim of this study was to discern the early differences in neurohormonal release and echocardiographic findings in a subset of patients with CHF secondary to dilated cardiomyopathy and FMR, randomized to receive either CorCap plus restrictive mitral annuloplasty (RMA) or RMA alone.

Material and Methods

This study was approved by our institution's Ethical Committee/Institutional Review Board. Each patient who participated provided informed consent.

Accepted for publication May 18, 2009.

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0003-4975/09/$36.00
doi:10.1016/j.athoracsur.2009.05.050

Table 1. Baseline Characteristics

Variable	CorCap + RMA	RMA	*p* Value
No. (%) or mean ± SD			
Male	9 (60)	10 (66.7)	0.5
Age, y	62.1 ± 7.2	57.8 ± 6.9	0.103
Diabetes	5 (33.3)	4 (26.7)	0.5
Renal failure	2 (13.3)	3 (20)	0.5
Dialysis	2 (13.3)	0 (0)	0.241
Hypertension	2 (13.3)	4 (26.7)	0.326
EuroSCORE	12.7 ± 1.3	13.1 ± 2.1	0.405

EuroSCORE = European System for Cardiac Operative Risk Evaluation; RMA = restrictive mitral annuloplasty.

Patients and Inclusion Criteria

Between April 2007 and April 2008, 30 consecutive patients with FMR, eligible for RMA, were prospectively randomized by lottery to CorCap plus RMA (CorCap group) or RMA alone (RMA group). Inclusion criteria were New York Heart Association (NYHA) functional class III and IV, age between 18 and 80 years, FMR grade 3+ or 4+ due to severe annular dilation and dilated cardiomyopathy (Carpentier type I) at preoperative echocardiography (semiquantitatively from color-flow Doppler), left ventricular ejection fraction (LVEF) of 0.35 or less, and LV dilation, which was defined as LV end-diastolic diameter (LVEDD) of 6.5 cm or more despite optimal medical management including diuretics, angiotensin-converting enzyme inhibitors, and β-blockers. Tricuspid regurgitation 2+ or more at transthoracic echocardiography indicated the need for tricuspid annuloplasty. Mean arterial pressure and heart rate were monitored preoperatively (at hospital admission), at discharge, and at the end of follow-up. Follow-up was closed on October 31, 2008, and was 100% completed.

Patients requiring a concomitant operation, other than tricuspid annuloplasty, were excluded from the study.

Echocardiography

All echocardiograms were performed by either of 2 cardiologists, using a VIVID 7 Pro ultrasound machine (GE Technologies, Milwaukee, WI). All patients had transthoracic echocardiographic assessment preoperatively, at hospital discharge, and at midterm follow-up, consisting of standard examination, including grading of FMR and transmitral mean gradient semiquantitatively from color-flow Doppler, LVEDD, LV end-systolic diameter (LVESD), LVEF, and sphericity index (calculated as the long/short axis ratio). Recurrence of CIMR was defined as 3+/4+ or higher grade MR at any time postoperatively at semiquantitative color-flow Doppler analysis.

Intraoperative transesophageal echocardiograms (TEE) before the establishment of cardiopulmonary bypass (CPB) and after weaning from CPB ensured adequate CorCap fitting, defined as LVEDD reduction of about 10% of preoperative values. LVEF and valve function were also assessed intraoperatively. MV repair was considered successful at intraoperative TEE if there was no residual FMR after CPB discontinuation with an achieved adequate preload (central venous pressure between 10 and 15 mm Hg).

Biochemical Assays

Blood samples for assessment of N-terminal prohormone brain natriuretic peptide (NT-pro.BNP) levels were obtained preoperatively (before anesthetic induction), on postoperative day 1, at discharge, and at the end of follow-up. Samples were analyzed by an electrochemiluminescence immunoassay (Elecsys proBNP) using an Elecsys 2010 analyzer (Roche Diagnostics, Mannheim, Germany).

CHF Evaluation

NYHA and quality of life according to the Short Form 36-Item (SF-36) Health Survey were determined preoperatively, at discharge, and at the end of follow-up in the outpatient clinic. As a surrogate outcome of heart failure, the need and dose of furosemide were assessed preoperatively, on postoperative day 1, at discharge, and at the end of follow-up in the outpatient clinic.

Surgical Procedure

The RMA operation was performed using standard operative techniques, including CPB and undersized mitral annuloplasty. The patients were placed under general anesthesia, and the same surgeon (A. R.) performed all operations through a median sternotomy. The MV was exposed through a longitudinal atriotomy along the Waterston groove in all patients.

Ring size (Carpentier-Edwards Physio ring; Edwards Lifesciences, Irvine, CA) was determined after careful measurements of the height of the anterior leaflet and the intertrigonal distance, and then downsizing by two sizes (eg, size 26 when measuring 30). CPB was standardized: the ascending aorta was always cannulated and venous return always accomplished through a double caval cannulation. A Dideco (Mirandola-Modena, Italy) tubing set, which included a 40-μm filter, a Stockert roller pump (Stockert Instrumente, Munich, Germany), and a hollow-fiber membrane ox-

Table 2. Intraoperative and Postoperative Results

Variable	CorCap + RMA	RMA	*p* Value
Mean ± SD, or No. (%)			
CPB time, min	115 ± 18	120 ± 25	0.575
Aortic cross-clamp time, min	68 ± 16	61 ± 11	0.213
Tricuspid annuloplasty	5 (33.3)	4 (26.7)	0.5
Inotrope dose			
Low dose	6 (40)	7 (46.7)	0.562
Medium dose	6 (40)	7 (46.7)	0.549
High dose	3 (20)	1 (6.7)	0.435
Post-op complications	5 (33.3)	3 (20)	0.341

CPB = cardiopulmonary bypass; RMA = restrictive mitral annuloplasty.

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