Original Article

Epicardial Cardiac Basal Annuloplasty: Preliminary Findings on Extra-cardiac Mitral Valve Repair

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Background: **Correction of functional mitral regurgitation in ischaemic heart disease, with a better risk:benefit ratio is an unmet need. A new methodology of external approach of correcting the annulus (BACE: basal annuloplasty of the cardia externally) to repair and stabilise the mitral valve without entering the heart was used in this prospective study. This study was conducted to assess the efficacy and safety of the concept BACE device in patients with moderate functional mitral valve regurgitation as a result of symptomatic coronary artery disease and heart failure.**

Methods: **The study involved a group of patients who had complex cardiac surgery between January 2000 and December 2001 at the University of Melbourne Campus Hospitals, Melbourne, Australia. Twelve patients with ischaemic heart disease, congestive heart failure, and moderate functional mitral regurgitation (MR) (minimum 2+) underwent the BACE procedure along with coronary artery bypass grafting and/or left ventricular reconstruction.**

Results: **No peri-operative complications or deaths related to surgical procedures occurred in the study group. There were no clinically significant problems related to the BACE implantation procedure. Mean MR grade was significantly improved in BACE Group from baseline to post BACE implant (2.8 pre- and 0.3 post-surgery; $P < 0.05$). Mean left ventricular ejection fraction (LVEF) was significantly improved ($P < 0.05$) and maintained at 6, 12, and 18 months post BACE implant compared to pre-operative baseline, with a mean improvement of 20% (24% at baseline to 44% at 18 months post-operatively) ($P < 0.05$). In addition to that the patients also had a significant improvement ($P < 0.05$) in mean New York Heart Association (NYHA) functional status from pre-operative baseline to 6 and 18 months post procedure with BACE.**

Conclusions: **External stabilisation of the cardiac base with BACE was associated with significant improvement in mitral valve function with no significant intra-operative or post-operative problems in patients with moderate functional MR. These findings support further study of BACE in functional MR.**

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Keywords. Mitral regurgitation; Repair; Extra-cardiac; Heart failure

Introduction

Mitral valve reconstructive surgery is an accepted therapeutic option for the management of severe mitral regurgitation (MR) in patients with heart failure, but its use for moderate MR is controversial [1–3]. The reluctance to undertake valve repair or replacement in patients with less-than-severe mitral regurgitation is attributed primarily to the risk profile of mitral valve procedures. Mitral valve repair or replacement requires access to the mitral valve through an intra-cavitary approach, which is associated with morbidity and mortality. These procedures carry a mortality risk of 2–6% in the presence of ischaemic heart disease [4]. A mitral valve procedure with coronary artery bypass graft surgery carries a higher risk of mortality and a definite risk of stroke [5].

MR can progressively worsen, especially in patients with ischaemic heart disease and cardiomyopathy [6]. Furthermore, while prognosis worsens with increasing severity of MR, even moderate MR is associated with excess morbidity and mortality [7–9]. These observations underline the unmet need for the novel approach of mitral valve repair in moderate functional MR associated with ischaemic heart disease with better risk:benefit profile. This extra-cardiac approach by BACE (basal annuloplasty of the cardia externally) device is investigated as a potential option for meeting this need. This approach with BACE is used to repair and stabilise the mitral valve without entering the heart. It is applied epicardially to the base of the heart

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to reduce the size or to prevent the further dilation of the heart. BACE may confer the ability to correct the functional MR regardless of the concurrent use of cardiopulmonary bypass. The prospective cohort study described herein was conducted to assess the efficacy and safety of BACE in patients with moderate functional MR in the presence of symptomatic coronary artery disease and heart failure.

Methods

Cohorts

The study involved one group of patients who had complex cardiac surgery at the University of Melbourne Campus Hospitals, Melbourne, Australia. This study group comprised 12 patients with moderate MR (minimum 2+) assessed and quantified by transthoracic echocardiography (TTE), and colour Doppler. These elective patients had symptomatic triple-vessel coronary artery disease and associated congestive heart failure as assessed by coronary angiography and radionuclide ventriculography and had not previously undergone surgical revascularisation for ischaemic left ventricular dysfunction. The decision to implant the BACE device in these patients was based on the confirmation of the MR by pre-operative transthoracic or transoesophageal echocardiography (TEE). All of these patients were reviewed by a multi-disciplinary team, which included a cardiologist and a cardiac surgeon for the management of symptomatic heart failure, and were scheduled to have primary surgery in an elective setting. Each of these patients was in NYHA functional class III or IV. The predominant manifesting symptoms were shortness of breath though 8 of the 12 patients had symptoms of angina as well. The significant limiting symptom was shortness of breath.

All 12 patients had BACE implantation along with coronary artery bypass grafting (CABG) and/or left ventricular reconstruction with out other mitral valve intervention between May 2000 and June 2001. The BACE surgical technique is described later in this section. Left ventricular reconstruction was performed in 10 patients in this group.

Informed consent was obtained from all participating patients upon clear explanation of the surgical procedures in the study and their associated risks.

Surgical Procedures

All procedures were performed through a midline sternotomy incision. Cardiac surgical procedures were performed with the aid of cardiopulmonary bypass on a heart arrested by blood cardioplegia.

BACE SURGICAL TECHNIQUE. The schematic diagram in Fig. 1 illustrates the concept.

The heart size was assessed early after chest opening. The circumference of the base of the heart was measured soon after the pericardium was opened and while the heart was beating with resting filling pressures. This was done with a piece of intravenous tubing that was slipped around the heart to encircle the heart at the atrio-ventricular groove, and then cross-referenced with a ruler. This gave a measurement of the circumference of the base of the

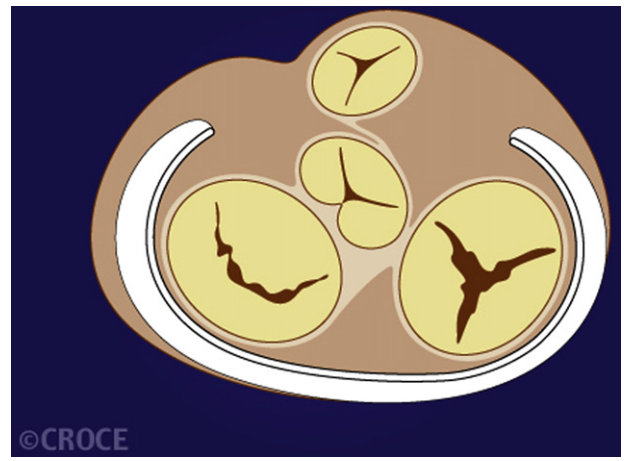

Figure 1. *Schematic showing the principle behind the BACE procedure.*

heart. The BACE device was then constructed with a strip of pliable polyester hernia mesh and tailored to the size measured on initial assessment of the base of the heart (~30 cm long, 4–5 cm wide). Once the cross clamp was applied and cardioplegia instilled, the heart was lifted. The BACE device was implanted along the atrio-ventricular groove on the posterior aspect of the heart. This is illustrated in Fig. 2 with the posterior sutures of the mesh to the a-v groove. It was then anchored on the atrial and ventricular sides of the atrio-ventricular groove with interrupted 4/0 prolene sutures, placed at 2–2.5 cm intervals. Once the BACE mesh was implanted, the distal anastomoses were constructed between the bypass grafts and coronary arteries. The coronary artery bypass grafts were then completed with the fashioning of the proximal anastomoses. Left ventricular reconstruction was performed in the presence of

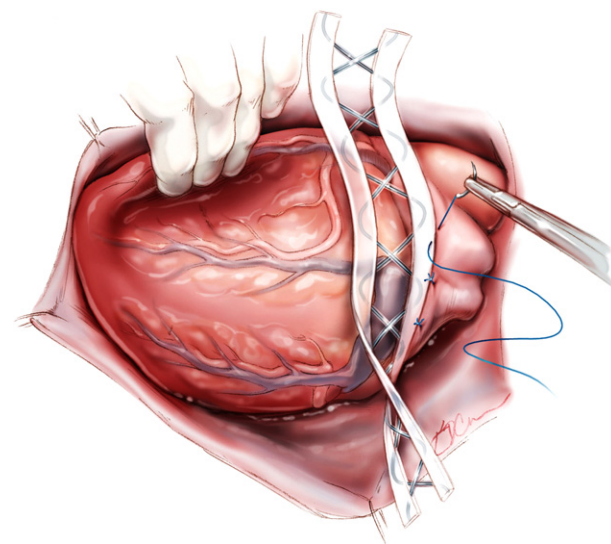

Figure 2. *Posterior implantation sutures of the mesh on atrial and ventricular side of the a-v groove. Note: the mesh here is stylised to show the underlying structures.*