

Composite valve graft implantation for the treatment of aortic valve and root disease: Results in 1045 patients



Luca Di Marco, MD, PhD, Davide Pacini, MD, PhD, Antonio Pantaleo, MD, Alessandro Leone, MD, Giuseppe Barberio, MD, Giuseppe Marinelli, MD, and Roberto Di Bartolomeo, MD

ABSTRACT

Objectives: Aortic root replacement using a composite graft is the treatment of choice for a large variety of aortic root conditions with a diseased aortic valve. The objective of the current study was to evaluate the long-term results of this procedure.

Methods: Between 1978 and 2010, 1045 patients aged 58.7 ± 13.6 years underwent aortic root composite graft replacement using the following techniques: 95 Bentall operation; 926 the “button technique;” 24 the Cabrol technique. A mechanical composite valve graft was implanted in 69.6% of the patients. Six-hundred and thirty-five patients (62.3%) had annuloaortic ectasia and 162 (15.5%) had aortic dissection.

Results: Early mortality was 5.3% (55/1045). Independent risk factors for early mortality at logistic regression analysis were age ≥ 70 years ($P = .051$; odds ratio [OR], 2.97), New York Heart Association III-IV ($P = .052$; OR, 1.88), reoperation ($P = .021$; OR, 2.36), urgency/emergency ($P = .003$; OR, 3.09), mitral valve replacement ($P = .001$; OR, 6.01), or coronary artery bypass grafting (CABG) ($P < .001$; OR, 4.39); while bicuspid aortic valve (BAV) ($P = .013$; OR, 0.21), and time of operation 2001-2011 ($P = .025$; OR, 0.60) were protective predictors for early mortality. Overall survival at 5, 10, and 20 years was $84.1\% \pm 1.3\%$, $65.5\% \pm 2.6\%$, and $40.7\% \pm 4.6\%$, respectively. Multivariate analysis revealed chronic renal insufficiency ($P = .001$; hazard ratio [HR], 3.48), chronic obstructive pulmonary disease ($P = .027$; HR, 1.94), aortic dissection ($P = .001$; HR, 2.63), Cabrol technique ($P = .009$; HR, 15.34), and CABG ($P = .016$; HR, 2.02) to be significant predictors of late death, and BAV ($P = .010$; HR, 0.43) to be a significant protective predictor. Freedom from thromboembolism, bleeding complications, and endocarditis was $93.7\% \pm 2.6\%$, $90.3\% \pm 3.1\%$, and $98.4\% \pm 1\%$ at 20 years, respectively. Freedom from aortic reoperation was $91.8\% \pm 2.1\%$ at 20 years and was significantly lower in patients with aortic dissection.

Conclusions: Within the limitations of this retrospective study, we can conclude that aortic root replacement for aortic root aneurysms can be performed with low morbidity and mortality and with satisfactory long-term results. Few late serious complications were related to the need for long-term anticoagulation or a prosthetic valve. Reoperation on the proximal or in the distal aorta was most commonly performed in patients with aortic dissection. (J Thorac Cardiovasc Surg 2016;152:1041-8)

Aortic root replacement using a composite valve graft (CVG) is the treatment of choice for a diseased aortic valve and root dilatation. First described by Hugh Bentall and

Cardiac Surgery Department, S. Orsola-Malpighi Hospital, University of Bologna, Bologna, Italy.

L.D.M. and D.P. contributed equally to the paper.

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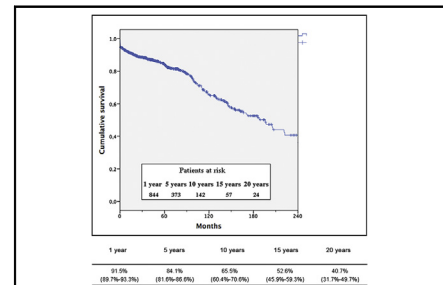
Anthony De Bono in 1968,¹ it is a widely used procedure for combined aortic valve and ascending aorta disease, including lesions associated with type A acute aortic

Address for reprints: Luca Di Marco, MD, PhD, Cardiac Surgery Department, S. Orsola-Malpighi Hospital, University of Bologna, via Massarenti 9, 40138 Bologna, Italy (E-mail: ludima08@libero.it).

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Survival rates (including hospital mortality) of the 1045 patients.

Central Message

Aortic root replacement with a composite valve graft provides good early and long-term results.

Perspective

This study reports the experience of 33 years of treatment of aortic root disease using a composite valve graft. The high number of patients included and the long period of follow-up make it the largest series to be published. Composite valve graft implantation can be performed with low morbidity and mortality, and with satisfactory long-term results.

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Abbreviations and Acronyms

AMI	= acute myocardial infarction
BAV	= bicuspid aortic valve
B-CVG	= biological composite valve graft
DHCA	= deep hypothermia with circulatory arrest
M-CVG	= mechanical composite valve graft
NYHA	= New York Heart Association
RF	= radiofrequency

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dissection and Marfan syndrome. However, despite its proven outcome and the good results obtained by experienced surgeons,¹⁻³ aortic root replacement using a composite graft also exposes patients to the problems associated with prosthetic valves, such as life-long anticoagulation for the mechanical prosthesis, structural valve deterioration for the biological prosthesis, and the increased risk of thromboembolism and endocarditis for both. In the present retrospective study we have evaluated the results of our 33-year's experience with 1045 patients with aortic root replacement using a CVG.

METHODS**Patients**

Between 1978 and December 2010, 1045 patients aged 58.7 ± 13.6 years underwent aortic root replacement using a CVG. Eight hundred and thirty-four patients (79.8%) were men and 211 were women (20.2%). Patient characteristics are shown in Table 1. In most patients, the indication for the CVG procedure was annuloaortic ectasia (635 patients [62.3%]) and aortic dissection (162 patients [15.5%]). One hundred and twenty-seven (12.2%) were redo operations, whereas 14 patients (1.3%) had previously undergone more than one aortic surgery. Nine hundred and thirty patients (89%) were operated on electively. Detailed surgical indications are shown in Table 2.

The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institute's human research committee and was approved by the Ethics Committee of Bologna Medical University.

All patient data were entered into a patient dataset; approval to conduct this retrospective study without individual patient consent was provided by our institutional review board.

Operative Technique

The operative technique has previously been described in detail.³

Briefly, a standard median sternotomy was performed and cardiopulmonary bypass was instituted by cannulation of the ascending aorta, aortic arch, femoral or axillary artery, or brachiocephalic trunk, depending on the extension of the aneurysm and the presence of dissection, and the right atrium or the superior and inferior vena cavae. Myocardial protection was

achieved with cold crystalloid cardioplegia and topical cooling with 4°C saline solution. The first 95 patients (9.1%) underwent the classic Bentall operation,¹ with the inclusion and wrapping technique. In 1994 we abandoned the classic Bentall operation and started using the button technique,^{4,5} a modification of the original technique.^{1,6} Since 1994, 926 patients (88.6%) have undergone aortic root and valve replacement with CVG according to the modified Bentall procedure, 24 (2.3%) underwent the Cabrol technique⁷ in the case of difficult coronary mobilization, such as extreme aortic dilatation or reoperation. Since 2000 we have been using biological CVG (B-CVG); initially homemade by combining a biological valve prosthesis with the tube graft and then using a composite graft prosthesis. A biological valve was chosen over a mechanical valve on the basis of patient age; patients older than 65 years and those with contraindications to anticoagulation were usually advised to opt for a biological valve. Patients younger than 60 years of age usually received a mechanical valve unless they were adversely affected by anticoagulation therapy. Some younger patients preferred a biological valve despite understanding that this would lead eventually to a second operation. Patients with a biological valve were advised to take warfarin daily only for the first 3 months and then to continue with aspirin. All patients with mechanical valves were treated with warfarin, with a target international normalized ratio of 2.0 to 3.0.

Three hundred and eighteen patients (30.4%) received a B-CVG, and 727 patients (69.6%) had a mechanical valve conduit inserted. Concomitant procedures included coronary artery bypass grafting (CABG) in 119 patients (11.4%), mitral valve replacement in 37 (3.5%), and mitral valve repair in 8 (0.8%). We performed atrial fibrillation radiofrequency (RF) ablation in 39 individuals (3.7%). In the event of concomitant arch surgery, cerebral protection was obtained with deep hypothermia with circulatory arrest (DHCA) in 15 patients, DHCA and retrograde cerebral perfusion in 1, and antegrade selective cerebral perfusion with moderate systemic hypothermia in 158.⁸ In 3.7% of the patients, we performed atrial fibrillation bipolar RF ablation using 2 different systems over 2 different periods. In the first period, we used the Cobra Bipolar system (Boston Scientific, San José, Calif) but in recent years we have used the Cardioablate BP (Medtronic, Minneapolis, Minn). Operative data and procedures are shown in Table 3.

Follow-up

Of all hospital survivors (990 patients), 966 (97.6%) were available and 24 were lost to follow-up. The mean follow-up time was 62.1 ± 58.6 months (ranging from 3 months to 380.4 months). Follow-up information was obtained by direct telephone interview with the patient or with a close relative, by contact with the referring physician, or by a visit to our outpatient clinic.

Statistical Analysis

Statistical analysis was carried out with SPSS 20.0 statistical software (SPSS, Chicago, Ill). Continuous variables were expressed as the mean \pm SD and were compared with the unpaired two-tailed *t* test. Categorical variables were analyzed with a χ^2 test or Fisher exact test where appropriate. All variables that achieved a *P* value less than .2 in the univariate analysis were included in a multivariate analysis and examined by stepwise logistic regression for early mortality, and Cox multivariate analysis for late mortality. Survival and event-free data were analyzed with Kaplan-Meier actuarial techniques for estimation of survival probabilities and compared with log rank tests.

Statistical significance was considered at *P* < .05.

RESULTS**Early Mortality**

Early mortality or in-hospital mortality was defined as death within 30 days or during initial hospitalization. In

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