CARDIOVASCULAR SURGERY

Embolic and bleeding events after modified Bentall procedure in selected patients

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Aim: As valve-sparing procedures gain increasing popularity, the long-term results of the total aortic root replacement (TARR) were evaluated using mechanical valve grafts in selected patients.

Methods and results: From January 1993 to December 2003, 100 patients (87 men), aged >65 years (mean 51 (SD 10.4 years), presenting with isolated aortic root dilatation with or without aortic valve insufficiency, undergoing elective root replacement using a mechanical valve graft were reviewed. The aetiology of aortic root disease was degenerative in 69 patients and related to the bicuspid aortic valve in 31 patients. In 11 patients, concomitant coronary artery bypass graft was performed. Hospital mortality was 4%. Overall survival was 93.9% (2.4%), 89.1% (3.5%) and 83.2% (5.2%) at 1, 5 and 7 years, respectively. 14 patients experienced 45 embolic events (3.21 (2.64) events/patient; range: 1–10 events). Thus, the linearised rate of embolic events was 10.3 per 100 patient-years (95% confidence interval (CI) 7.29 to 13.31). The actuarial embolism-free survival was 96.6% (1.9%), 77.1% (6%) and 74.3% (6.4%) at 1, 5 and 7 years, respectively. The linearised rate of bleeding events was 2.2 per 100 patient-years (95% CI 0.87 to 3.71). Actuarial bleeding free survival was 95.6% (2.1%), 93.2% (2.6%) and 87.7% (5.8%) at 1, 5 and 7 years, respectively. None of the patients required reoperation and no cases of structural or non-structural valve dysfunction were observed.

Conclusions: TARR using mechanical valve grafts yields excellent survival results in selected patients. However, a high rate of minor thromboembolic events was recorded. Aspirin in combination with oral anticoagulants might be of potential interest in these patients.

Since its first description by Bentall and De Bono in 1968,¹ the technique for composite aortic valve and root replacement has evolved to become the gold standard in the treatment of combined aortic valve and root diseases.^{2–4} All currently available heart valve substitutes, in addition to imperfect haemodynamic performance, have a considerable incidence of valve-related complications such as thromboembolism and bleeding.⁵ Therefore, the alternative of valve-sparing operations is becoming increasingly popular in the hope that these newer approaches will produce improved event-free survival.^{6–7} But the encouraging results of the valve-sparing interventions have to be compared in the long term to those of the traditional approach. Numerous series have reported the long-term results of the modified Bentall technique, but they include patients who might not be adequate candidates for valve-sparing procedures.^{3–8–9} For this reason, the present retrospective study reviews a single institution series of consecutive patients who underwent a modified Bentall procedure for aortic valve and root diseases, with the objective of providing an element for comparison with the results of valve-sparing procedures. Therefore, we analysed all patients <65 years of age, presenting with aortic root dilatation with or without aortic valve insufficiency, undergoing elective operation with a composite graft, with a special emphasis on late patient outcome.

METHODS

Patient selection

From January 1993 to December 2003, 240 consecutive patients underwent total aortic root replacement (TARR) using the modified Bentall technique at the Henri Mondor University Hospital, Créteil, France. Among these, we selected patients whom we considered to be putative candidates for a valve-sparing procedure. Thus, we retained patients <65 years of age,

presenting with isolated aortic root dilatation with or without aortic valve insufficiency and undergoing elective TARR using a composite graft. Associated coronary lesions were not considered to be an exclusion criterion. However, patients with other aetiologies of aortic root disease such as poststenotic aortic dilatation and aortic dissection were excluded to maintain the homogeneity of the group. Furthermore, three patients receiving a biological stentless valve were also excluded, as they could not be considered to be exposed to the same postoperative risks as patients with mechanical valves. Thus, 100 patients were retained for analysis. Most of the patients were men (87%); mean (standard deviation (SD)) age was 51 (10) years.

Degenerative aortic root disease associated with a tricuspid aortic valve was present in 69 patients, whereas aortic root dilatation related to a bicuspid aortic valve was noted in 31 patients. Features of the Marfan syndrome were present in 4 patients. Table 1 shows additional patient characteristics and the risk profile.

Surgical technique

TARR, using the modified button technique for coronary reimplantation, was performed in all patients. A cardiopulmonary bypass was conducted under moderate hypothermia (mean 29.3°C (SD 3.5°C)). The arterial cannulation site was either the femoral or distal ascending aorta or aortic arch, depending on the extent of the aneurysmal dilatation on the ascending aorta. Myocardial protection was achieved using an antegrade cold crystalloid cardioplegia associated with topical cold saline application. In most of the patients, the distal anastomosis was performed under aortic cross clamping. Deep hypothermic (15–16°C) circulatory arrest with selective antegrade cerebral perfusion was used in three patients for

Abbreviation: TARR, total aortic root replacement

Table 1 Patient characteristics and risk profile (n = 100)

Variable	n (%)
Mean (SD) age (years)	51 (10.4)
Range (years)	17–64
Male	87
Risk factors	
Hypertension	44
History of smoking	42
Diabetes	9
COPD	4
Peripheral vascular disease	4
Cerebral vascular disease	3
Previous neurological history	3
Associated coronary artery disease	10
EuroSCORE (mean (1 SD))	5.5 (0.7)
(range)	5–8
Aortic root disease	
Degeneration	69
Congenital	31

COPD, chronic obstructive pulmonary disease; EuroSCORE, European system for cardiac operative risk evaluation.

associated arch replacement (n = 2) or for performing an open distal anastomosis (n = 1). In 11 patients concomitant coronary artery bypass grafting was performed owing to pre-existing coronary artery disease (except in one patient in whom a saphenous vein graft to the right coronary artery was performed because of failure at re-implantation of a calcified coronary button). Table 2 outlines the additional operative characteristics.

Postoperative antithrombotic treatment

All patients received intravenous heparin until the ablation of epicardial electrodes, followed by oral anticoagulation using fluindione (a warfarin-like antivitamin K drug, with a half life of 31 h). International normalised ratio was targeted between 2 and 3, as recommended for St Jude bileaflet (St Jude Medical, Inc, St Paul, Minnesota, USA), Carbomedics bileaflet (Carbomedics, Inc, Austin, Texas, USA) and Medtronic Hall tilting-disk (Medtronic, Inc, Minneapolis, Minnesota, USA) mechanical valves.¹⁰

The administration of aspirin in combination with oral anticoagulants was left to the discretion of the cardiologist.

Data collection

Hospital records were reviewed retrospectively for patient demographic characteristics, preoperative status, preoperative comorbidity, intraoperative course and postoperative course. Preoperative risk factor assessment was carried out according to

Table 2 Intraoperative data (n = 100)

Variable	n (%)
Type of operation	
Bentall	87
Bentall+CABG	11
Bentall+aortic arch procedure	2
Valve type	
Tilting disc valve	81
Bjork Shiley	1
Medtronic-Hall	80
Bileaflet valve	19
St Jude	10
CarboMedics	9
CPB time (min)	151 (68)
Aortic cross-clamp time (min)	117 (49)

Results are mean (SD).

CABG, coronary artery bypass grafting; CPB, cardiopulmonary bypass.

the definitions of the European system for cardiac operative risk evaluation.¹¹

Follow-up information was obtained by telephone interview of the patient, the patient's relatives or the referring physician. Questions were targeted to precisely finding the cause and date of death. Late death was defined as death occurring after hospital dismissal. Definitions of complications followed the "Guidelines for reporting morbidity and mortality after cardiac valvular operations".¹² In addition, embolic events were classified as major (including stroke, reversible neurological deficit and peripheral embolism) or minor (transient ischaemic attack).

Follow-up was complete for 96 patients, with a mean (SD) of 4.36 (3) years (range 0.03–11.14 years) for a total of 436.7 patients-years.

Statistical analysis

Statistical analysis was carried out using SPSS Base V.12.0 statistical software. Continuous variables were expressed as mean (SD). Categorical variables were expressed as percentages. Linearised rates, calculated as the number of events divided by total follow-up years and then multiplied by 100 to convert to the percentage per patient-year, were used to describe late valve-related complications. Confidence limits of the linearised rates were calculated on the basis of the asymptotic variance of the point estimation. Survival data were analysed with standard Kaplan–Meier actuarial techniques for estimation of survival probabilities and expressed with corresponding standard error of the mean (SEM).

RESULTS

Mortality

Early mortality

Hospital mortality reached 4% (n = 4). Causes of early death (table 3) were heart failure (n = 1), ventricular arrhythmia (n = 1), fatal stroke (n = 1) and gastrointestinal bleeding (n = 1).

Late mortality

Twelve patients died during follow-up. Overall actuarial survival (SEM) was 93.9% (2.4%), 89.1% (3.5%) and 83.2% (5.2%) at 1, 5 and 7 years, respectively (fig 1). Table 3 lists the causes of late death. Two patients died from cerebromeningeal bleeding at 1.35 months and 132 months after the operation. Three patients died from an infectious condition other than endocarditis: one patient with severe preoperative aortic insufficiency required cardiac transplantation 30 months after

Figure 1 Actuarial survival of selected patients (n = 100) undergoing total aortic root replacement (TARR) using mechanical valved grafts (16 deaths). Error bars represent mean $\pm$ standard error of the mean (SEM).

Table 3 Causes of death during follow-up (n = 100)

Variable	Early (hospital) mortality, n (%)	Late mortality, n (%)
Heart failure	1	—
Stroke	1	—
Bleeding	1	2
Infectious (other than endocarditis)	—	3
Arrhythmia	1	—
Surgery for non-cardiac diseases*	—	5 (5)
Unknown	—	2 (2)
Total	4	12 (12)

*Lung cancer, after peripheral vascular, renal, visceral and ophthalmic surgery.

operation and died of pneumopathy; the other two died of peritonitis and pneumopathy. Five other patients died from complications after surgery for non-cardiac-related diseases. In two patients the cause of death was unknown.

Morbidity

Early morbidity

None of the patients were reoperated for bleeding, but one patient required reoperation for bacterial mediastinitis. One patient developed sepsis, with visualisation of vegetations on the mitral valve at echocardiography. The episode was controlled successfully with adequate antibiotic treatment without involvement of the composite graft. Two patients experienced a permanent stroke (one of these was fatal, as previously mentioned) and one patient had a reversible neurological deficit but recovered fully before discharge from hospital. These neurological events were not considered valve related as patients did not awake, or awoke after the operation with the neurological deficit. Table 4 gives the other postoperative complications.

LATE MORBIDITY

Embolic events

Fourteen patients experienced 45 embolic events (mean (SD) 3.21 (2.64) events/patient; range: from 1 to 10 events). Eight patients experienced more than one embolic event. Thus, the overall linearised rate of embolic events was 10.30 per 100 patient-years (95% confidence interval (CI) 7.29 to 13.31). The linearised rate of a first embolic event (major or minor) was

3.57 (95% CI 1.70 to 5.44) per 100 patient-years, and actuarial freedom of a first embolic embolic event (major or minor) was 96.6% (1.9%), 77.1% (6%) and 74.3% (6.4%) at 1, 5 and 7 years, respectively (fig 2). In patients in whom a first embolic event had occurred, the linearised rate of a subsequent event was 70.43 (95% CI 45.63 to 95.23) per 100 patient-years.

Table 5 lists the embolic events, classified as major and minor.

Major events

Central (cerebral) embolism occurred as a stroke in three patients (at 0.4, 10.7 and 52.9 months after operation) and as reversible neurological deficit in one patient (at 57.7 months after operation). Coronary ischaemia suspected to be of embolic origin occurred at 33.6 months postoperatively in one patient with previous history of *Amaurosis fugax* who reported a sudden onset of angina. At transoesophageal echocardiography, small clots were visualised on the prosthetic valve, without interference with valve function, and they completely resolved after thrombolysis.

Minor events

Nine additional patients experienced only transient ischaemic attacks, presenting as multiple episodes of isolated *Amaurosis fugax* in eight patients and as *A fugax* associated with one episode of upper limb paralysis that lasted for a couple of hours in one patient.

Bleeding events

Ten patients experienced one bleeding episode with a linearised rate of 2.29 per 100 patient-years (95% CI 0.87 to 3.71) and actuarial freedom of bleeding events was 95.6% (2.1%), 93.2% (2.6%) and 87.7% (5.8%) at 1, 5 and 7 years, respectively (fig 3). The level of anticoagulation at or very close to the moment of the event could not be determined retrospectively.

Table 5 details the bleeding events. Fatal gastrointestinal bleeding occurred in one patient at 1.2 months postoperatively and fatal cerebromeningeal bleeding occurred in two patients at 1.32 and 132 months after operation (previously mentioned). Seven other patients experienced less severe episodes of bleeding that required transfusion or hospitalisation. Thus, we encountered gastrointestinal bleeding (n = 1), gynaecological bleeding (n = 1), epistaxis and oral bleeding (n = 5).

Other valve-related morbidity

No structural valvular deterioration or non-structural valve dysfunction occurred during follow-up. No case of valve thrombosis requiring reoperation was encountered. No case of operated valvular endocarditis was encountered and no patient required reoperation of the aortic root during follow-up. One patient underwent cardiac transplantation, one patient underwent mitral valve replacement with tricuspid valve repair and one patient was reoperated on for coronary artery bypass graft, without involvement of the previously implanted valve conduit.

DISCUSSION

In our selected group of patients, the modified Bentall procedure yielded satisfactory results in terms of early and late survival, reoperation rate or occurrence of prosthetic valve endocarditis. These results compare favourably with those reported in the literature.^{3 8 9} However, the cohort in our study included only relatively young patients undergoing elective operation, which probably accounts for this favourable outcome. In a similarly selected group of patients (<65 years of age, undergoing first-time elective Bentall operation), Hagl *et al*¹³ had similar results in terms of survival and major postoperative events.

Table 4 Postoperative complications (n = 100)

Variable	n (%)
Cardiac	
Need for inotropic support	26
Supraventricular arrhythmia	22
Third-degree AV block (requiring pacemaker)	7
Pericardial effusion	6
Ventricular fibrillation	2
Neurological	
Stroke	2
Reversible neurological deficit	1
Infection	
Mediastinitis	1
Mitral-valve endocarditis	1
Bronchopulmonary infection	5
Urinary tract infection	3
Antibiotic treatment	22
Renal insufficiency (haemodialysis)	1
Respiratory complications (prolonged ventilation)	6
Lower limb ischaemia	1

AV, atrioventricular.

Figure 2 Actuarial freedom of major (stroke, reversible neurological deficit and peripheral embolism) and minor (transient ischaemic attacks) events in selected patients ($n=100$) undergoing total aortic root replacement (TARR) using mechanical valved grafts (14 events). Error bars represent $\pm$ standard error of the mean (SEM).

Major embolic events occurred in five patients in the form of stroke, reversible neurological deficit and peripheral embolic event, which accounts for a low linearised rate of 1.1 per 100 patient-years. Hagl *et al*¹³ found similar results, reporting only two strokes (1.4%) and one peripheral embolic event (0.7%) in a cohort of 142 patients with a mean follow-up of 3.5 years. However, these rates are underestimated by the retrospective nature of data collection and do not take into account minor embolic events. When these are considered, we obtain a much higher rate of 10.3 per 100 patient-years and this risk appears to be particularly high in patients who have already undergone one embolic event. These minor events are probably underestimated, patients reporting only an approximate number of events or completely forgetting these transient but repetitive incidents. Furthermore, Acar *et al*¹⁴ have shown that up to 46% of neurological events occurring in the first year after prosthetic heart valve replacement are asymptomatic and can only be detected on a computed tomography brain scan. Considering the significant correlation between silent brain infarction and

cognitive dysfunction,^{15 16} these transient but repetitive incidents might have a major repercussion on the late results and quality of life after the Bentall procedure.

Thus, TARR using composite valve graft seems to be a high-risk setting for thromboembolism. Because of the retrospective design of the study, precise international normalised ratio values at the time of events were not available. Thus, inadequate anticoagulation cannot be excluded, at least in some patients. On the other hand, TARR using the modified Bentall technique profoundly alters the normal aortic root dynamics¹⁷ and provides particular conditions for platelet activation.¹⁸ Firstly, the mechanical valve induces non-physiological flow patterns, causing platelet activation.¹⁹ It also produces short-duration high shear stress that may cause adenosine diphosphate release from red blood cells.²⁰ Some groups have reported significantly lower thromboembolism rates in patients with tilting disc valves when compared with bileaflet valves.²¹ Indeed, patients with tilting disc valves have

Table 5 Embolic and bleeding events during follow-up

Variable	n	Months after operation	
		Mean	Range
Embolic events			
Central			
Stroke	3	21.33	0.4–52.9
RND	1	57.7	—
TIA	9	36	7.9–63.4
Peripheral	1	57.14	—
Bleeding events			
Fatal			
Gastrointestinal	1	1.2	—
Cerebrovascular	2	66.6	1.35–132
Non-fatal			
Gastrointestinal	1	117.1	—
Gynaecological	1	8.7	—
Epistaxis and oral	5	46.4	11.1–91.5

RND, reversible neurological deficit; TIA, transient ischaemic attack.

Figure 3 Actuarial freedom of bleeding events in selected patients ($n=100$) undergoing total aortic root replacement (TARR) using mechanical valved grafts (10 events). Error bars represent $\pm$ standard error of the mean (SEM).

significantly lower occurrence of high-intensity transient signals as detected by transcranial Doppler after aortic valve replacement than patients with bileaflet valves,^{22–24} although there is still controversy with regard to the clinical significance of high-intensity transient signals. Our data do not allow any significant comparison between the two valve substitutes owing to the small number of patients with bileaflet valves in our group. Secondly, the blood-contacting surface of the vascular graft is rapidly coated with albumin, immunoglobulins and fibrinogen from plasma.²⁰ The vascular prosthesis thus provides a fibrinogen-coated foreign surface and creates conditions of low shear stress, mediating efficiently platelet aggregation in the presence of adenosine diphosphate.²⁵ The adhesion of platelets to fibrinogen on these surfaces is not as irreversible as to the von Willebrand factor-coated collagen of a damaged blood vessel,²⁰ and may account for an increased risk of embolisation of platelet–fibrin aggregates in Bentall repairs. In addition, the introduction of an inelastic graft in the highly distensible natural aorta results in increased pulse pressure and different propagation rates of pressure waves, dependent on wall elasticity, causing wave reflections and eddy currents.²⁶ These in turn have been shown to promote thrombi formation.²⁷ The coronary ostial anastomoses have also proved to be a possible source of micro-emboli in our experience: on reoperation of a patient with a previous Bentall repair, we found that one of the ostial buttons, a little generously tailored, had dilated to form a small pouch housing a thrombus.

Thus, the Bentall procedure seems to be a high-risk situation for platelet activation. Further research will have to determine whether platelet activation is effectively higher than after isolated aortic valve replacement. Additional antiplatelet therapy has been recommended after aortic valve replacement in high-risk situations such as atrial fibrillation, myocardial infarction, left atrial enlargement or thrombus, low ejection fraction or previous systemic embolisation.¹⁰ However, no specific recommendations have been made for patients with composite-valve grafts. In these patients, firm recommendations will have to await prospective trials designed to evaluate the effectiveness of aspirin combined with oral anticoagulants and to determine its optimal dose.

The risks of bleeding and thromboembolic events related with TARR using mechanical valve grafts have motivated a growing interest in different valve-sparing operations. The aortic root remodelling technique according to Yacoub *et al*⁶ or the aortic valve reimplantation technique described by David *et al*⁷ have produced very encouraging midterm results. Recently, increasing evidence suggests that these techniques can also be applied with good functional results in patients with Marfan syndrome^{28–29} or bicuspid aortic valve.³⁰ However, although these valve-sparing operations obviously avoid prosthetic heart valve-related complications, they nevertheless expose patients to the problems related to graft replacement of the ascending aorta and coronary reimplantation, as discussed above. Kallenbach *et al*³¹ have reported a marked reduction of thromboembolic and anticoagulation-related complications 1 year postoperatively in patients undergoing valve-sparing aortic root reconstruction as compared with matched controls with composite graft TARR. However, minor thromboembolic events were not mentioned in their study.³¹ More specific investigations will have to clarify this point and determine whether these advantages persist in the long term.

CONCLUSION

TARR using mechanical valve grafts yields excellent survival results in selected patients. However, we recorded a high rate of minor thromboembolic events. We hypothesise that the systematic addition of antiplatelet therapy to the anticoagulation regimen

in these patients might be of potential interest and should be evaluated in future trials.

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IMAGES IN CARDIOLOGY

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Non-coronary sinus of Valsalva aneurysm rupture

A 36-year-old woman presented with chest pain, dyspnoea and fatigue. There was a grade 2/6 systolic murmur and long decrescendo grade 3/4 diastolic murmur at the right sternal border. Transthoracic echocardiography showed a defect connecting the aorta (non-coronary sinus of Valsalva) and right heart at the level of the tricuspid valve (upper panels). Right heart catheterisation demonstrated a step up in oxygen saturation from 74% in the superior vena cava to 80% in the right atrium and 84% in the right ventricle, indicative of a left to right shunt. Qp:Qs was 1.8:1. Right atrial pressure was 8 mm Hg and mean pulmonary capillary wedge pressure was 13 mm Hg. Supravalvular aortography in the left anterior oblique projection showed a high velocity jet from the aorta to the right side of the heart. Careful examination of the cinematographic images indicated that the shunt flow entered the right atrium and hit the closed tricuspid valve leaflets in systole (lower panel), but passed unimpeded into the right ventricle through the open valve in diastole. Surgical repair of the non-coronary sinus of Valsalva to right atrium fistula was performed. A membranous “windsock” (1.5 cm in length, 0.6 cm in diameter and 0.1 cm in thickness), which

Transthoracic echocardiography in the parasternal short axis view at the level of the aortic valve. A colour flow jet from the aorta enters the right heart at the level of the tricuspid valve.

entered the right atrium adjacent to the anteroseptal commissure of the tricuspid valve, was resected and the defect repaired with bovine pericardium. The postoperative course was uneventful.

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Aortogram in the left anterior oblique projection. This image shows the contrast jet from the aortic root hitting the closed tricuspid valve in systole and filling the right atrium.