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Root replacement with stentless Freestyle bioprostheses for active endocarditis: a single centre experience[†]

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Abstract

OBJECTIVES: Few studies have examined the use of stentless Freestyle bioprostheses in patients with active valve endocarditis (VE). The aim of this study was to evaluate outcomes of stentless Freestyle bioprostheses in patients undergoing full-root replacement.

METHODS: From February 2000 to June 2010, 180 patients with VE underwent cardiac surgery at our institution, of which 71 (39.5%) had prosthetic VE. Eighteen patients underwent full-root replacement with Freestyle bioprostheses: 3 patients (16%) had native aortic VE, 14 (78%) had aortic prosthetic VE and 1 (6%) had mitral and aortic prosthetic VE. Mean age was 66.7 ± 10.1, M/F: 6/12, mean logistic EuroSCORE 36.4 ± 21.6. Eight patients (42%) underwent concomitant procedures (two mitral valve replacements, three ascending aorta replacements, one coronary artery bypass grafting (CABG), one ventricular septal disease (VSD) repair, one CABG + ascending aorta + VSD repair).

RESULTS: Two patients (11%) died in-hospital. At the median follow-up of 24 months (range 1–113 months), no death occurred and freedom from reoperation was 87.5% (2 patients for aortic root pseudo-aneurysm at 1 and 23 months). All patients are in NYHA functional class I and have satisfactory echocardiographic data (EF 54.3 ± 8%, peak and mean trans-prosthetic gradients 12 ± 6.7 mmHg and 7.5 ± 3.6 mmHg) with 100% freedom recurrence of VE.

CONCLUSIONS: Our experience shows that root replacement with Freestyle stentless bioprostheses in patient with VE, is associated with low rates of early and mid-term mortality, good haemodynamic performance and low rates of valve-related morbidity as well as low recurrence of infection.

Keywords: Aortic root • Aortic valve • Valve replacement

INTRODUCTION

Infective valve endocarditis (VE) is a serious illness associated with significant morbidity and mortality after cardiac surgery [1–3]. The epidemiological features of VE are changing as a result of increasing longevity, new predisposing factors and increase in nosocomial cases. The incidence of community-acquired native VE ranges from 1.7 to 7 episodes per 100 000 person-years in Western countries, and men are more often affected than women (mean male-to-female ratio, 1.7 : 1) [4, 5]. In the setting of prosthetic aortic VE, the incidence of infective endocarditis varies from 0.2 to 1.4 episodes per 100 patient-years, depending on the type of prosthetic valves implanted [6–9].

The best treatment option for patients with infective prosthetic VE is surgery associated with antibiotics [2, 3]. However, surgical intervention for active prosthetic aortic VE still remains a challenge with a high in-hospital mortality rate of 20–40%. [9]. Although many authors [2, 10–14] consider the aortic homograft the gold standard for the treatment of infective prosthetic VE, the new recent ESC guidelines recommend, in addition to homograft, the xenograft root replacement for the treatment of prosthetic VE, especially in presence of extensive aortic root destruction with aorto-ventricular discontinuity [3].

The Medtronic Freestyle bioprosthesis (Medtronic Inc., Minneapolis, MN, USA) is an intact porcine aortic root, which has shown excellent haemodynamic results as well as good long-term durability and low rate of valve-related morbidity [15, 16]. The Freestyle aortic root bioprosthesis can be implanted by several surgical techniques: complete or modified subcoronary valve replacement, root inclusion and full-root replacement [17]. Few studies have examined the use of stentless Freestyle porcine bioprostheses as an alternative to aortic homograft in patients with active VE [18–20]. Therefore, the aim of this study was to evaluate postoperative outcomes of stentless Freestyle bioprostheses in patients undergoing full-root replacement for active prosthetic or native VE.

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MATERIAL AND METHODS

Patient data

From February 2000 to June 2010, 18 patients underwent full-root replacement with Freestyle bioprostheses. The study was approved by the local Ethical committee and individual consent was waived. The data collection form was entered in a local database and includes three sections that are filled consecutively by cardiac surgeons, anaesthetists and perfusionists involved in the care of the patients.

The diagnosis of infective endocarditis was based on the combination of blood cultures, clinical signs and symptoms according to modified Duke criteria [3]. As suggested by the current guidelines, the diagnosis of infective endocarditis in a patient with a pathological murmur or a valvular prosthesis and unexplained fever lasting >72 h included an assessment for vascular and immunological phenomena, three to five sets of blood cultures and a trans thoracic echocardiogram [2, 3]. In those cases with a technically inadequate or non-diagnostic trans-thoracic echocardiogram, a transoesophageal echocardiogram was obtained. Finally, all patients undergoing surgery received an intraoperative transoesophageal echocardiogram.

In-hospital mortality was defined as any death occurring during the same hospital admission for surgery. According to the ESC guidelines, relapse was defined as a repeated episode of VE caused by the same micro-organism as the previous episode and reinfection was defined as a new infection due to a different micro-organism [3]. Two patients (11%) were not traced, so follow-up was 89% complete. Follow-up was obtained by a telephonic interview and an echocardiographic control. Last echocardiographic data were obtained from the patients' family cardiologists.

Surgical technique

All the patients underwent median sternotomy and cardiopulmonary bypass was established at 34°C; for those undergoing reoperation, the chest was re-entered through a repeated sternotomy. The left ventricle was vented through the right superior pulmonary vein. The heart was arrested with warm cardioplegia solution administered both antegradely and retrogradely during aortic clamping. The root replacement technique was required due to the presence of extensive aortic root destruction. After radical debridement of the abscess cavity and all friable tissue with removal of the native or prosthetic valve, a Freestyle stentless valve was implanted with full-root replacement technique with coronary reimplantation. The abscess cavity in each patient was closed with a pericardial patch. The proximal anastomosis was accomplished with simple interrupted sutures of 3-0 braided polyester and reinforced with a running suture using 4-0 polypropylene. The distal end of the bioprosthesis was sewn end-to-end to the aorta or to the interposition artificial graft with continuous 4-0 polypropylene suture. The coronary arteries were implanted as buttons to the side to the corresponding sinus of the bioprosthesis with a continuous 5-0 polypropylene suture. Valve sizes used were 21 mm ($n = 5$), 23 mm ($n = 3$), 25 mm ($n = 4$), 27 mm ($n = 4$) and 29 mm ($n = 2$).

Microbiology

In 2 patients, blood and valve cultures were positive for *Staphylococcus aureus*, one of them was resistant to methicillin. Other micro-organisms isolated were *Staphylococcus epidermidis* ($n = 3$), *Staphylococcus capitis* ($n = 1$), *Staphylococus hominis* ($n = 1$), *Streptococcus viridans* ($n = 2$) and *Enterococcus faecalis* ($n = 3$). In 6 patients, bacterial cultures were negative because they were given empirical antibiotic therapy at the onset of fever before blood cultures had been obtained.

Statistical analysis

Data are presented as mean ± standard deviation for continuous variables and as percentage for categorical variables.

RESULTS

Preoperative data are shown in Table 1. There were 6 men (33%) and 12 women (67%), with a mean age of 66.7 ± 10.1 (range, 34–76 years). The mean (+SD) weight was 73.2 (±17.5) kg and mean height was 164 (±9.8) cm, with a mean BSA of 1.8 ± 0.25 m^2. Mean logistic EuroSCORE was 36.4 ± 21.6 (cardiovascular risk factors are shown in Table 2). The valvular lesion was native aortic VE in 3 patients (16%), aortic prosthetic VE in 14 (78%), 1 patient (6%) had mitral and aortic prosthetic VE (Table 3). Preoperative trans thoracic echocardiographic control at rest was performed in all patients by experienced cardiologists and preoperative echocardiographic data are shown in Table 4.

Eight patients (42%) underwent concomitant surgical procedures: two mitral valve replacements (MVR), three ascending aorta replacements, one coronary artery bypass grafting (CABG), one ventricular septal defect repair, one CABG, ascending aorta replacement and ventricular septal defect. Surgical procedures are shown in Tables 5.

Postoperatively (Table 6), 2 patients (11%) died in-hospital because of septic shock; 1 (5.6%) patient underwent surgical reintervention for bleeding; 1 (5.6%) patient experienced acute renal failure requiring continuous veno-venous haemofiltration;

Table 1: Clinical data

Variables	$n = 18$
Age, years (mean ± SD)	66.9 ± 10.1
Male/female	6/12
Weight, kg (mean ± SD)	73.2 ± 17.5
Height, cm (mean ± SD)	166 ± 9.8
Body surface area, m^2 (mean ± SD)	1.8 ± 0.24
Log-EuroSCORE (mean ± SD)	36.4 ± 21.6

Table 2: Cardiovascular risk factors

Variables	n	(%)
Hypertension	9/18	50
Diabetes mellitus	3/18	16.7
Familiarity	3/18	16.7
Chronic renal failure	1/18	5.6
Dyslipidemia	9/18	50
Pulmonary disease	3/18	16.7
Smoke	3/18	16.7
Peripheral arterial disease	4/18	22.2

Table 3: Diagnosis

Variable	*n*	(%)
Native aortic valve endocarditis	3/18	16.7
Aortic prosthetic valve endocarditis	14/18	77.7
Mitral and aortic prosthetic valve endocarditis	1/18	5.6

Table 4: Preoperative echo

Variable	*n* = 18
Ejection fraction (%)	59 ± 13.3
V_{max} (m/s)	3.5 ± 1.5
Peak gradient (mmHg)	56.7 ± 42.7
Mean gradient (mmHg)	56.2 ± 42.6
Aortic root diameter (mm)	35.3 ± 5.6
Ascending aorta diameter (mm)	37.7 ± 7.8
LVEDD (mm)	55 ± 12.1
LVESD (mm)	33.1 ± 11.8
LVEDV (ml)	120.5 ± 48.7
LVESV (ml)	48.7 ± 38.1

LVEDD: left ventricular end diastolic dimension; LVESD: left ventricular end systolic dimension; LVEDV: left ventricular end diastolic volume; LVESV: left ventricular end systolic volume

3 (16.7%) patients had low cardiac output syndrome treated with pharmacological inotropic support and 2 (11%) patients had acute respiratory failure requiring re-intubation.

At the median follow-up of 24 months (range 1 to 113), no death occurred and freedom from reoperation was 87.5%. Two patients underwent reoperation because of aortic root pseudo-aneurysm respectively at 1 and 23 months. One patient underwent a new root replacement with homograft and, in the other patient, the pseudo-aneurysm was treated with a patch repair. In both cases, blood cultures and the cultures of the material excised were negative. All patients are in NYHA functional class I and have satisfactory echocardiographic data as shown in Table 7. No significant aortic regurgitation was found at postoperative echo as well as at the follow-up. The freedom from relapse or reinfection was 100%.

DISCUSSION

Our results show that the implantation of the Freestyle stentless bioprosthesis in patients undergoing AVR for either native or prosthetic endocarditis is a safe procedure, associated with excellent haemodynamic performance, low recurrence of infective endocarditis and reoperation for valve dysfunction. Moreover, no death occurred at follow-up and no valve related morbidity was reported by their general practitioner.

The Medtronic Freestyle bioprosthesis is a complete porcine aortic root with ligated coronary arteries and a thin skirt over the porcine septal muscle bar. The prosthesis is fixed with low pressure applied to the aortic wall, but with a net zero pressure across the leaflets. It was then treated with alpha-amino-oleic acid for anticalcification treatment with the aim of improving both haemodynamic and bioprosthesis durability [15, 16]. Ennker

Table 5: Surgical procedures

Variables	*n*	(%)
ARR	10/18	55.6
ARR + mitral valve replacement	2/18	11.1
ARR + ascending aorta replacement	3/18	16.7
ARR + CABG	1/18	5.6
ARR + ventricular septal defect repair	1/18	5.6
ARR + CABG + Asc. Ao replacement + VSD repair	1/18	5.6

ARR: aortic root replacement; CABG: coronary artery bypass grafting; VSD: ventricular septal disease.

Table 6: Postoperative complications

Variables	*n*	(%)
Bleeding	1/18	5.6
Low cardiac output	3/18	16.7
Acute renal failure	1/18	5.6
In-hospital death	2/18	11.1
Acute respiratory failure	2/18	11.1

Table 7: Postoperative echo

Variables	*n* = 18
Ejection fraction (%)	54.3 ± 8
V_{max} (m/s)	1.7 ± 0.4
Peak gradient (mmHg)	12 ± 6.7
Mean gradient (mmHg)	7.5 ± 3.6

et al. analysed 1014 patients undergoing AVR with Freestyle stentless bioprostheses and showed low operative mortality with encouraging mid-term durability and low rates of valve-related morbidity. In particular, freedom from valve prosthesis endocarditis, reoperation and valve degeneration after 9 years were 97 ± 6%, 92 ± 9% and 97 ± 5%, respectively [15].

Many authors consider the aortic homograft an excellent solution for the treatment of prosthetic aortic VE or when there is extensive aortic root destruction with aorto-ventricular discontinuity [11–14]. In these cases, the use of an aortic homograft has shown a low risk of reinfection, ranging from 3.8 to 6.8%. Specifically, Yankah *et al.* reported a reinfection rate of 6.8 and 91% freedom from reinfection at 10 years, whereas Grinda *et al.* showed 5.7% reinfection rate and a freedom from reinfection at 10 years of 93% [12, 13]. Finally, Sabik *et al.*, in a series of 103 consecutive patients with prosthetic VE treated with homografts, reported a reinfection rate of 3.8% and a freedom from reinfection at 10 years of 95% [11]. However, the aortic homograft is not always easily available, and the use of a stentless prosthesis has been shown to be a valid alternative for the treatment of prosthetic VE [3]. Siniawski *et al.* compared patients undergoing aortic homograft vs stentless prostheses and

demonstrated an equal reinfection rate of 4% as well as a lower mortality for the patients treated with stentless valves (12 vs 16%) [21]. Musci *et al*. published a series of 255 patients with aortic VE undergoing surgery with Shelhigh stentless bioprostheses (Shelhigh Inc., Union, NJ, USA), reporting an overall reinfection rate of 8.6% with freedom from reinfection at 5 years of 83% and a 5-year survival of 46% [22]. In a smaller series, Santini *et al*. reported outcomes of 9 patients treated with Biocor stentless valves (St Jude Medical Inc., St Paul, MN, USA) and showed 100% freedom from recurrent endocarditis, concluding that the use of stentless valves may be an additional tool when active aortic valve infection is complicated by extensive destruction of contiguous tissue and a homograft is not available [23]. Finally, Müller *et al*. in a series of 10 patients undergoing aortic root replacement with Freestyle stentless bioprostheses for either native or prosthetic VE, showed 100% freedom from recurrence of VE at follow-up [18]. Similarly, in our series, we found excellent postoperative outcomes with a freedom from recurrence of infective endocarditis of 100%. In our opinion, these results might be related to radical debridement of the abscess cavities and to the intrinsic proprieties of the Freestyle such as the fixation process and anticalcification treatment. However, 2 patients underwent reoperation for aortic root pseudo-aneurysm respectively at 1 and 23 months and freedom from reoperation was 89%. In both cases, blood cultures and the cultures of the material excised were negative. We believe that in the former, the pseudo-aneurysm was due to the presence of native tissue degeneration, whereas in the latter it was due to the excessive use of gelatine resorcinol formaldehyde glue. It has been shown that formaldehyde component of the gelatine resorcinol formaldehyde glue may be toxic to the aortic media and cause tissue necrosis, leading to late re-dissection and pseudo-aneurysm formation [24].

CONCLUSIONS

Our experience shows that root replacement with Freestyle stentless bioprostheses in patient with acute VE is associated with low rates of early and mid-term mortality, good haemodynamic performance and low rates of valve-related morbidity as well as low recurrence infection, especially in case of prosthetic VE.

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