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Institutional report - Valves

Early clinical experience with the On-X prosthetic heart valve☆

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Abstract

The study aimed to assess the performance of the On-X valve (Medical Carbon Research Institute, Austin, TX). Between December 2000 and January 2003 On-X valves were implanted in 400 patients aged 19–85 years (mean: 55.6±16), 290 males and 210 females. There were 120 cases of aortic valve replacement (AVR), 258 mitral valve replacement (MVR) and 22 combined aortic and mitral valve replacement (DVR). Additional procedures were performed in 144 patients. Patients were followed up prospectively at 3- to 6-month intervals. Mean follow-up was 38.4±11.8 months (maximum 55.6 months). Overall hospital mortality was 3.5%. Freedom from adverse events at 4 years in the study were as follows: thromboembolism, 99.1% for AVR, 98.3% for MVR and 94.7% for DVR patients; thrombosis, 100% for AVR, 99.2% for MVR and 94.7% for DVR; bleeding events, 99.1% for AVR, 99.2% for MVR and 88.8% for DVR; prosthetic endocarditis, 98.2% for AVR, 99.2% for MVR and 94.7% for DVR. Overall survival at 4 years was 92±1%. At echocardiographical examination within 1 year of the AVR, the mean aortic valve gradient was 12.8±6, 10.3±3, 9.0±4, 8.3±3, and 6.2±3 mmHg for 19, 21, 23, 25, 27/29 mm valve sizes, respectively. MVR mean gradient was 4.9±2, 4.5±1.2 and 4.0±0.8 mmHg for 25, 27/29, 31/33 mm valve sizes, respectively. On-X valve is a highly effective mechanical valve substitute with low morbidity and mortality and good functional results.
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Keywords: Valve surgery; Bileaflet mechanical valve; On-X valve; Late results

1. Introduction

Despite recent advances regarding the treatment options for valvular heart disease, valve replacement with a prosthetic mechanical or a biological valve still remains the mainstay surgical therapeutic option for most patients with valvular heart disease. Currently available mechanical valve prostheses remain an acceptable choice for valve replacement in both aortic and mitral positions but still significant progress is required to reach the ideal valve substitute. The pyrolitic carbon material used in the currently available bileaflet mechanical valves has similar properties. However, there have been significant improvements recently by removing the silicon-alloying previously used in the production of pyrolytic carbon valves. The improved pyrolytic carbon technology has been shown to have better strength and deformability to allow hemodynamically superior orifice shapes [1]. This notion is based on studies that examined the homogenous microstructure of this new technology which provides lack of pores and discrete silicon carbide particles [1,2]. These advances may reflect as a reduction in thrombotic and thromboembolic complications in the clinical arena.

In 1996, Medical Carbon Research Institute (Austin, TX) introduced On-X Prosthetic Heart Valve, which has to date been implanted more than 30,000 times. Besides using pure, unalloyed pyrolytic carbon valve technology, On-X Prosthetic Heart Valve is the second generation bileaflet prosthesis with the unique characteristics of 90° opening leaflets, flared inlet, length-to-diameter ratio of 0.6, stasis-free hinges and reduced closing contact velocity. Furthermore for valves in the aortic position, the sewing ring is placed supra-annularly for sizes less than or equal to 25 mm.

Few data are available on the clinical outcome of patients undergoing valve replacement with the On-X valve. Therefore, the aim of this study was to evaluate the early and mid-term performance of this new generation bileaflet prosthesis. For this purpose, the collaborating investigative centers pooled the accumulated data in a computerized database at the University of Ankara and the following retrospective, observational survey was conducted. This study was planned to provide a rationale for a prospective,

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Table 1
Patient demographics

	AVR ($n=120$)	MVR ($n=258$)	DVR ($n=22$)
Age, y, mean±S.D. (range)	56.2±13 (21–85)	55.1±16 (19–75)	54.7±9 (30–69)
Sex, Male	78 (65%)	100 (39%)	12 (54.5%)
Female	42 (35%)	158 (61%)	10 (45.5%)
Diabetes	22 (18.3%)	49 (18.9%)	8 (36.4%)
Hypertension	54 (45%)	95 (36.8%)	11 (50%)
Ejection fraction <30%	6 (5%)	14 (5.4%)	3 (13.6%)
Cardiogenic shock	2 (1.6%)	11 (4.3%)	1 (4.5%)
Etiology			
Degenerative	54 (45%)	28 (10.8%)	2 (9.1%)
Rheumatic disease	49 (40.8%)	185 (71.7%)	14 (63.6%)
Ischemic	–	22 (8.5%)	–
Active endocarditis	6 (5%)	13 (5.1%)	–
Previous tissue valve	5 (4.2%)	5 (1.9%)	3 (13.6%)
Prosthetic dysfunction	3 (2.5%)	5 (1.9%)	2 (9.1%)
Congenital, %	2 (1.6%)	–	–
Para-prosthetic leak, %	1 (0.8%)	–	1 (4.5%)
Coronary artery disease	36 (30%)	29 (13.9%)	2 (9.1%)
Preoperative NYHA class			
I	3 (2.5%)	–	–
II	22 (18.3%)	32 (12.4%)	1 (4.5%)
III	53 (44%)	130 (50.3%)	13 (59.1%)
IV	42 (35%)	96 (37.2%)	8 (36.3%)
EuroSCORE mean±S.D.,	4.95±2.54	5.10±2.72	6.72±3.35
Median (min–max)	5 (0–13)	5 (0–17)	5.5 (3–16)

Values are numbers of patients, with percentage in parentheses. AVR, aortic valve replacement; MVR, mitral valve replacement; NYHA, New York Heart Association; S.D., standard deviation.

randomized trial between bileaflet prostheses at the University of Ankara.

2. Materials and methods

2.1. Patient cohort

Between December 2000 and January 2003, 400 consecutive patients received a total of 422 On-X mechanical valves in two centers by the same surgical team. Aortic valve replacement (AVR) was performed in 120 patients: 84 isolated, 36 AVR and coronary artery bypass grafting (CABG), mitral valve replacement (MVR) in 258 patients: 229 isolated, 29 MVR and CABG and double valve replacement (DVR) in 22 patients. Basic preoperative patient characteristics were as presented in Table 1 stratified by valve position. Concomitant cardiac surgery was performed in 36% (144) of the patients; CABG in 16.7% (67), left atrial procedures in 4.5% (18), tricuspid valve surgery in 10.7% (43), aortic surgery in 1.7% (7) and other procedures in 2.3% of the patients. Of the total population, 9% (36) had previous cardiac procedures, 3.7% were classified as emergent status and 1.3% as emergent-salvage status. Myocardial infarction had occurred within 21 days in 5.6% of the population. Renal failure was present in 6.5% of the patients. Over the study period, stented bioprosthesis, stentless biological valves and other mechanical valves were also implanted by the same surgical team. The prosthesis selection was at the discretion of the surgeon. Those who had implantations of On-X valve plus another valve type were excluded from the study.

Indication for AVR was aortic stenosis in 86 patients (60.5%), aortic regurgitation in 23 (16.2%) and mixed aortic valve disease in 33 (23.3%). Indication for MVR was mitral stenosis in 102 (36.4%), mitral regurgitation in 42 patients (15%), mixed mitral valve disease in 136 (48.6%). Degenerative aortic valve disease was the most common cause for mechanical AVR and rheumatic mitral valve disease was the most common cause for mechanical MVR (Table 1). The majority of patients were either in class II or in class III of the NYHA classification. Sinus rhythm was present in 75%, atrial fibrillation in 23% and complete heart block in 2% of patients undergoing AVR, however, 72% of patients who underwent MVR were in atrial fibrillation preoperatively. In mitral and double valve surgery, pulmonary artery systolic pressure exceeded 60 mmHg in 17.8% (46) of mitral patients and 45.4% (10) of DVR patients. In aortic stenosis the systolic gradient across the valve exceeded 120 mmHg in 7.5% (9) of the patients. Valve size distribution was 19–21 mm for AVR in 52% of the patients, 25–29 mm for MVR in 82% of the patients.

2.2. Surgical considerations

All patients were operated on via median sternotomy. Myocardial protection was provided with intermittent cold blood cardioplegia and moderate hypothermia (28–32 °C). In patients undergoing concomitant CABG, grafts were most commonly performed first, followed by valve replacement. A transverse aortotomy, 5 mm above the sinotubular junction was performed after aortic cross clamping for AVR. After valve excision and extensive decalcification of the annulus, the sizes of the annulus and the sinotubular junction were measured. In most cases, using horizontal mattress sutures of 2-0 polyester multifilament with supraannular pledgets were preferred. In most MVR cases,

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horizontal mattress sutures using pledgets on the atrial side were preferred. Interrupted pledgeted mattress sutures with the pledgets on the ventricular side were chosen when heavy calcification remained in some areas of the annulus. Chordal sparing procedures were performed whenever feasible for both anterior and posterior chordal attachments.

All patients received antibiotics at induction of anesthesia and post-operatively for 48 h; antibiotic treatment was prolonged in some patients where clinically indicated. All patients were started on a regimen of warfarin after the operations. Warfarin was titrated to a target international normalized ratio of 2–3 for AVR patients and 2.5–3.5 for MVR and DVR patients. Management of anticoagulation after hospital discharge was performed by the patient's own physician but generally followed these guidelines. Complete blood count, reticulocyte count, serum lactate dehydrogenase (LDH) and haptoglobin levels were measured at 6 months and annual follow-up. The criteria for intravascular hemolysis was previously described [3].

2.3. Follow-up and assessment of hemodynamics

Follow-up echocardiograms were obtained before discharge, at 6 months postoperatively and annually thereafter. Echocardiography was carried out using the Sonos-5500 device (Hewlett Packard, Andover, MA, USA) equipped with a second-harmonic 1.8- to 3.6-MHz transducer with facilities for continuous-wave and pulsed-wave Doppler. Parasternal long-axis views were obtained and the early-systolic diameter (D) of the left ventricular outflow tract (LVOT) was measured just below the prosthetic valve using an inner-edge-to-inner-edge method. For each patient, an average of three diameter measurements was used. Cross-sectional area (CSA) of the LVOT in cm^2 was calculated as: $CSA = \pi(D/2)^2$. Cardiac output (CO) in l/min was calculated as follows: $CO = VTI \times CSA \times HR$ where VTI was the velocity time integral in the LVOT, and HR in beats per min. Flow velocity across the valve was obtained by means of continuous-wave Doppler after interrogation from multiple windows. All Doppler measurements were averaged over three cycles in sinus rhythm or over five cycles in atrial fibrillation. The modified Bernouilli equation was used to calculate pressure drop (gradient) across the prosthesis in mmHg as follows: $\Delta P = 4(V_{CW}^2 - V_{PW}^2)$ where P was the pressure drop, and V_{CW} and V_{PW} were the velocities (peak or mean) across the valve (using continuous-wave Doppler) and in the LVOT (using pulsed-wave Doppler), respectively. The mean pressure drop was calculated by applying the modified Bernouilli equation at multiple instantaneous velocities throughout the velocity profile. The average of all such instantaneous pressure gradients represents the mean. Velocity ratio (VR), the ratio of mean subaortic to mean transaortic velocity, gave an approximate guide to orifice behavior independent of measurements of LVOT diameter. The aortic prosthetic valve effective orifice area (EOA) was calculated using the modified continuity equation in cm^2 as follows: $EOA_{aortic} = CSA \times VR$.

2.4. Statistical analysis

Valve related complications were reported according to the Guidelines of the Ad Hoc Liaison Committee of the Society of Thoracic Surgeons and the American Association of Thoracic Surgery [4]. However, operative mortality in this study was defined to include all deaths occurring during the hospitalization for the operation or within 30 days of the operation. Deaths within 30 days of reoperation on an operated valve were included as valve-related deaths and as valve complications. The recommended definitions of thromboembolic and hemorrhagic events proposed by Bodnar et al. [5] have been incorporated in the evaluation. Overall thromboembolic and hemorrhagic rates encompassed early events ($\leq$30 days) and late events ($>$30 days). Distribution for categorical variables was reported either as a percentage or as the mean and standard deviation. The significance of 41 variables on operative mortality and survival were tested with univariate and multivariate analysis (Appendix). Estimated survival and freedom from event rates were calculated by the Kaplan–Meier method (confidence limits 95%). Linearized complication rates were calculated as the number of events per 100 patient-years (%/patient-year). The statistical software SPSS PC (version 11.5, SPSS Inc., Chicago, IL) was used for final data analysis.

Clinical, operative, and follow-up data were recorded prospectively in a computerized database. Additional information was obtained by reviewing the medical records and by contacting the patients' general practitioners and/or families as required. The mean follow-up was 38.4 ± 11.8 months and ranged from 1 month to 55.6 months. Three patients were lost (1 AVR, 2 MVR) to follow-up; therefore follow-up was 99.2% complete overall.

3. Results

3.1. Early outcome

Overall operative mortality was 3.5% (14 patients). The operative deaths were 5 (4.2%) in the AVR cohort, 8 (3.1%) in the MVR cohort and 1 (4.5%) in the DVR cohort. Operative mortality was 3.6% for isolated AVR, 2.6% for isolated MVR, and 4.5% for DVR, 5.5% for AVR and CABG, 6.9% for MVR and CABG. Causes of death were cardiac failure (4), myocardial infarction (1), ventricular arrhythmias (3), endocarditis (1), stroke (1), sepsis (1), multiple organ failure (1), anticoagulant related hemorrhage (1), mesenteric ischaemia (1). Four of the 14 operative deaths occurred in patients who were in cardiogenic shock preoperatively. Early total valve-related adverse events were 1.66% for AVR, 1.93% for MVR and 9.09% for DVR. Early valve-related mortality were 0% for AVR and 0.38% for MVR. A total of 386 patients survived surgery and were discharged from hospital.

Significant univariate factors for operative mortality were NYHA Functional Class III and IV ($P=0.04$), non-elective surgery ($P=0.01$), poor LV function ($P=0.005$), redo AVR ($P=0.003$), ischemic mitral regurgitation ($P=0.003$), endocarditis ($P=0.0004$), cardiogenic shock ($P=0.0001$). On multiple logistic regression analysis, EF $<$30% ($P=0.02$), redo valve replacement ($P=0.01$), ischemic mitral regurgitation ($P=0.006$), endocarditis ($P=0.005$), cardiogenic shock ($P=0.001$) were predictors of operative death.

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One hundred and sixty-two patients (40.5%) required inotropic support, 86 (21.5%) were ventilated for more than 24 h postoperatively, 25 (6.3%) had renal replacement therapy, 18 (4.5%) needed intra-aortic balloon support, 12 (3%) were re-opened for bleeding, 7 (1.8%) required rewiring of sternum for mediastinitis and 22 (5.5%) had permanent pacemaker inserted prior to their discharge from the hospital. The mean length of stay in the intensive care unit was 2.2±4 days and mean hospital stay was 10.8±11 days.

Hospital survivors had improved NYHA functional class status six weeks after their operation. Compared with their preoperative status, NYHA functional class was improved in 352 patients (91.1%), remained the same in 31 (8.0%), and worsened in three patients (0.8%).

3.2. Doppler echocardiography assessment

Postoperative transthoracic echocardiography was performed at a mean of 348±40 days after valve replacement. At echocardiographical examination within one year of the operation, the mean aortic valve gradients were 12.8±6, 10.3±3, 9.0±4, 8.3±3, and 6.2±3 mmHg for 19, 21, 23, 25, 27/29 mm valve sizes, respectively. Mean pressure gradients and effective orifice areas for the more frequently implanted On-X valves were as shown in Table 2. MVR mean gradients were 4.9±2, 4.5±1.2 and 4.0±0.8 mmHg for 25, 27/29, 31/33 mm valve sizes, respectively.

3.3. Late outcome

There have been 15 late deaths at 4 years. The late deaths were 3 (2.6%) in the AVR cohort, 10 (4.0%) in the MVR cohort and 2 (9.5%) in the DVR cohort. A prosthesis-related death occurred in five patients as a result of endocarditis (3), thrombosis (1), intracranial hemorrhage (1). Four patients died from cardiac failure and/or ischemia; three of them had CABG at the time of valve replacement and one had non-graftable diseased coronary arteries. There were six non-valve-related deaths, from trauma, lung cancer, pneumonia, emphysema and a road traffic accident. Kaplan–Meier overall survival at 4 years was 92±1% (Fig. 1). At the most recent follow-up, 371 patients were alive with 367 having their original On-X valves.

Table 2
Mean pressure gradients of On-X mechanical valves in aortic and mitral position within one year of operation

Aortic valve size (mm)	Mean pressure gradient (mmHg)	EOA (cm^2)	No.
19	12.8±6	1.28±0.4	(18)
21	10.3±3	1.45±0.2	(53)
23	9.0±4	1.66±0.3	(39)
25	8.3±4	1.8±0.3	(15)
27/29	6.2±3	2.4±0.2	(11)
Mitral valve size (mm)			
25	4.9±2	2.0±1.1	(35)
27/29	4.5±1.4	2.2±0.7	(188)
31/33	4.0±0.8	2.6±1.2	(48)

EOA, effective orifice area.

3.4. Thromboembolism

There were six thromboembolic episodes, 1 AVR, 4 MVR and 1 DVR. Two were major with permanent deficit, described under 'operative mortality', and four were minor with good functional recovery. Early thromboembolic events (<30 days) occurred in 1 AVR (0.83%) and 1 MVR patients (0.38%). Kaplan–Meier 4 years freedom from thromboembolism was 99.1±1% for AVR patients, 98.3±1% for MVR and 94.7±5 for DVR.

In Fig. 2 overall freedom from thromboembolism at 4 years was 98.4±0.6%. The linearized rate for the occurrence of thromboembolism was 0.12%/patient-year after AVR and 0.3%/patient-year after MVR.

3.5. Thrombosis

Any thrombosis on prosthesis, obstructive or non-obstructive was included. There was no early thrombosed valve in this series. However, three late thrombotic episodes occurred 9, 17, 24 months postoperatively (2 MVR and 1 DVR) detected by Doppler echocardiography. Symptoms at presentation were heart failure in all patients. A reduced leaflet motion in two patients and an increased pressure

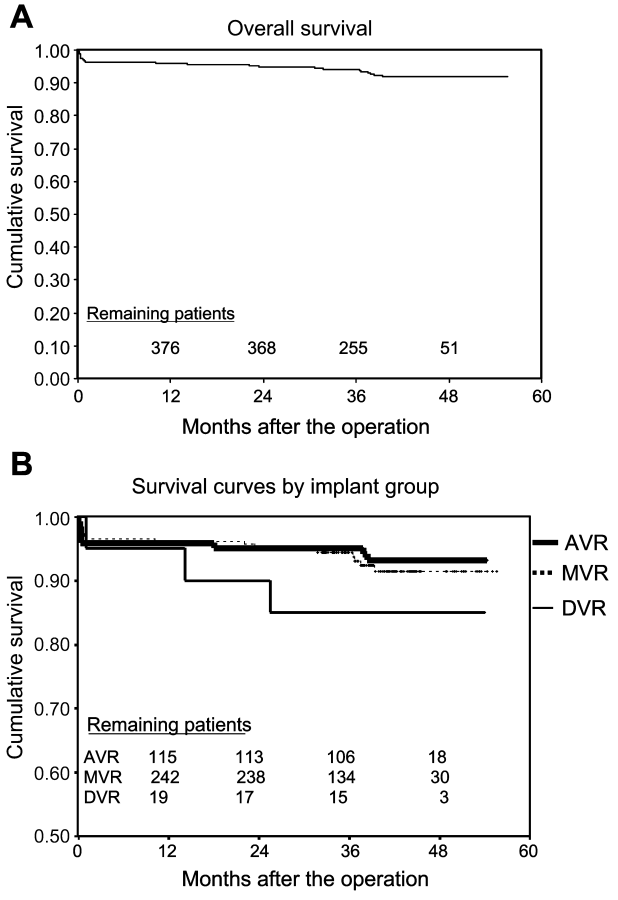


Fig. 1. Overall, Kaplan–Meier, survival at 4 years including early deaths was 91.8±1.4%. B, Kaplan–Meier survival curves including early deaths by implant group. Kaplan–Meier, survival at 4 years including early deaths was 93.2±2% for AVR patients (bold solid line), 91.5±2% for MVR (dotted line) and 85±7 for DVR (solid line).

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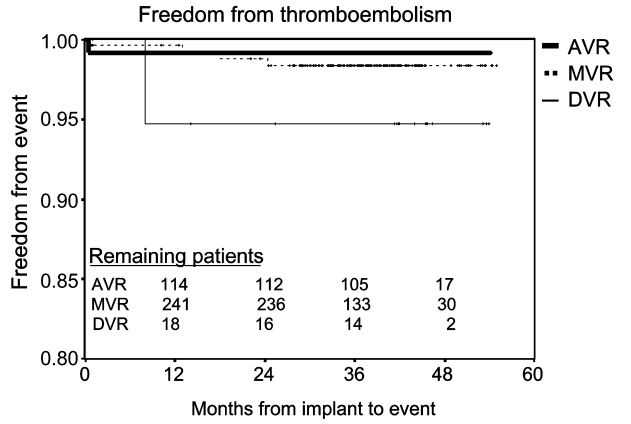


Fig. 2. Kaplan–Meier 4 years freedom from thromboembolism was 99.1±1% for AVR patients (bold solid line), 98.3±1% for MVR (dotted line) and 94.7±5 for DVR (solid line).

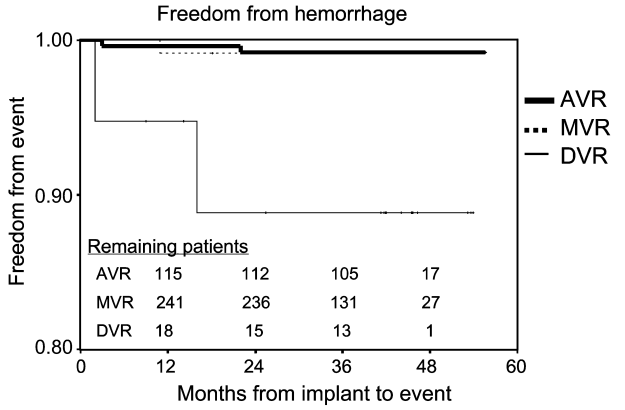


Fig. 4. Kaplan–Meier 4 years freedom from hemorrhage was 99.1±1% for AVR (bold solid line), 99.2±0.5% for MVR (dotted line) and 88.8±7% for DVR (solid line).

gradient in one patient were preoperative hallmarks of prosthetic thrombosis. INR levels were below 1.4 in all patients who presented with valve thrombosis. One patient was epileptic and was on Epdantoin; his INR levels were always below the target limits postoperatively. One patient was treated with thrombolysis and stabilized hemodnamically; the other two patients required urgent re-operation and are currently alive. Kaplan–Meier 4 years freedom from thrombosis was 100% for AVR, 99.2±1% for MVR and 94.7% for DVR (Fig. 3). Overall freedom from thrombosis at 4 years was 99.2±0.4%. The linearized rate of valve thrombosis was 0%/patient-year after AVR and 0.35%/patient-year after MVR.

3.6. Hemorrhage

Six episodes were reported: 1 AVR, 3 MVR, 2 DVR. Early bleeding events occurred in 2 MVR patients (0.77%) and one DVR patient (4.5%). Three patients developed late gastrointestinal bleeding and one of them was on non-steroid anti-inflammatory medication for rheumatic symptoms. Another patient developed an intracranial hemorrhage and died later from the event. Another patient developed hematuria and required a blood transfusion. All six patients involved were taking warfarin at the time of the bleeding event. Kaplan–Meier 4 years freedom from hemorrhage was 99.1±1% for AVR, 99.2±0.5% for MVR and 88.8±7% for DVR (Fig. 4). Overall freedom from bleeding events at 4 years was 98.6±0.5%; the linearized rate of anticoagulant-related hemorrhage was 0.2%/patient-year after AVR and 0.75%/patient-year after MVR.

3.7. Prosthetic valve endocarditis

All events, primary or recurring episodes related to preoperative valve infection were included. Six episodes of endocarditis occurred 6, 8, 12, 22, 29 and 35 months postoperatively on an On-X mechanical valve respectively (2 AVR, 3 MVR, 1 DVR). Five patients underwent reoperation for valve replacement; however, only two recovered. One patient recovered with antibiotic therapy and did not require reoperation. Kaplan–Meier, freedom from endocarditis was 98.2±1.2% for AVR, 99.2±0.5% for MVR and 94.7±5% for DVR at 4 years (Fig. 5). Overall freedom from prosthetic valve endocarditis at 4 years was 98.6±0.6%. The linearized rate of endocarditis in patients who had

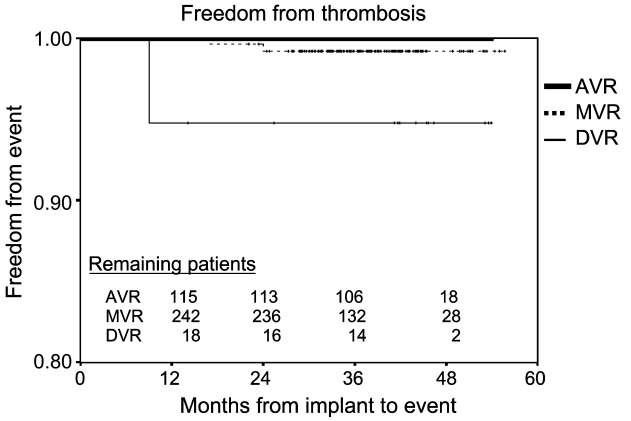


Fig. 3. Kaplan–Meier 4 years freedom from thrombosis was 100% for AVR (bold solid line), 99.2±1% for MVR (dotted line) and 94.7% for DVR (solid line).

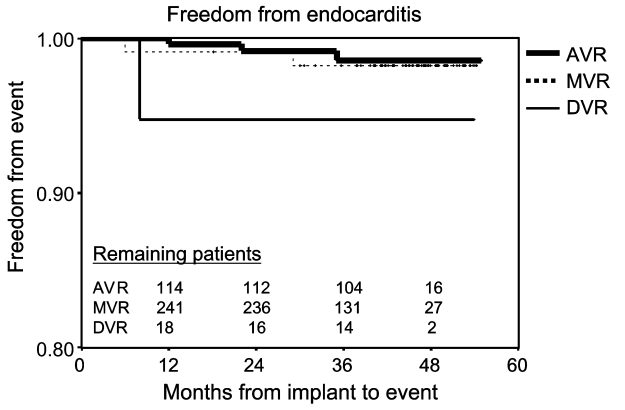


Fig. 5. Kaplan–Meier, freedom from endocarditis was 98.2±1.2% for AVR (bold solid line), 99.2±0.5% for MVR (dotted line) and 94.7±5% for DVR (solid line) at 4 years.

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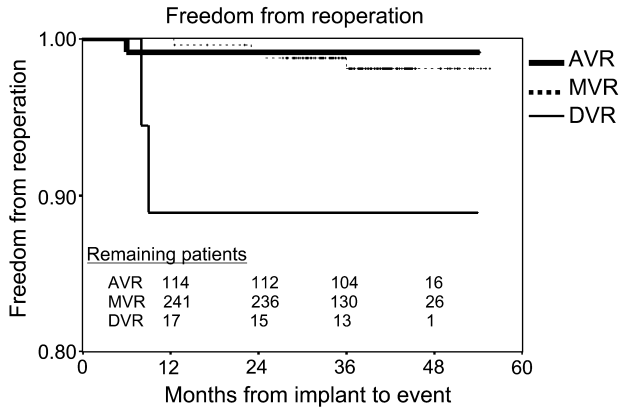


Fig. 6. Kaplan–Meier, freedom from reoperation was 99.1±0.8% for AVR (bold solid line), 98.7±0.7% for MVR (dotted line) and 88.9±7.4% for DVR (solid line) at 4 years.

undergone AVR and MVR was 0.35% and 0.25%/patient-year, respectively.

3.8. Structural valve failure

There were no cases of structural or mechanical valve failure in this series.

3.9. Non-structural valve deterioration and re-operation

Non-structural valve failure in the form of paravalvular leaks occurred early in 4 patients (1 AVR, 0.83%; 2 MVR, 0.77%; 1 DVR 4.5%) however, all detected paravalvular leaks were minor and not treated surgically. Mean serum levels of LDH (normal, 230–460 U/l) were 436±76 U/l after AVR, 495±105 U/l after MVR and 582±123 U/l after DVR at 6 months. Furthermore, haptoglobin levels were abnormally reduced in 56% of patients undergoing AVR, 74% of patients undergoing MVR, and 100% of patients undergoing DVR. However, hemoglobin levels and reticulocyte counts were approximately within normal range at 6 months and 1-year follow-up indicating that none of the patients experienced decompansated hemolytic anemia. Furthermore, there has been no tissue overgrowth in this series. Seven patients were reoperated: AVR 1, MVR 4, DVR two. Infective endocarditis (5), thrombosed valves (2) were the reasons for reoperation. Kaplan–Meier freedom from reoperation was 99.1±0.8% for AVR, 98.7±0.7% for MVR and 88.9±7.4% for DVR at 4 years (Fig. 6). Overall freedom from reoperation at 4 years was 98.4±0.6%.

4. Discussion

Since the introduction of the first mechanical prosthesis, Starr-Edwards caged-ball valve, several types of mechanical prostheses have been utilized for over 45 years as substitutes for diseased native valves. The major valve related complications of mechanical prostheses have been anticoagulant hemorrhage, thromboembolism, thrombosis, and structural failure. This study demonstrated the early clinical and hemodynamic performance of the On-X mechanical bileaflet prosthesis in the aortic and mitral positions to be satisfactory with an acceptable early mortality and morbidity. The 30-day mortality rate of 3.5% was independent of valve related complications apart from one patient. The mortality figures including subgroup analysis were comparable to other series of aortic and mitral valve replacement by any prosthesis in similar populations [6–10].

Hemodynamic results at 1 year in our study were in keeping with the findings of Chambers et al. [11] and Moidl et al. [12], and suggested that, even in the smaller size aortic roots, favorable mean pressure gradients and effective orifice areas can be accomplished using On-X prosthetic heart valve. In a review of the literature, Wang et al. [13] demonstrated EOAs of 0.9 to 1.0 cm^2 for 19 mm aortic bileaflet mechanical valves, in comparison to this result of 1.28 cm^2 at 1 year.

One of the major concerns of the mechanical valves is the life-long need for anticoagulation and thrombogenic complications. In this study, patients were maintained on permanent anticoagulant therapy. Overall freedom from thromboembolism, thrombosis and bleeding events at 4 years in this study were 98.4±0.6%, 99.2±0.4%, 98.6±0.5%, respectively. The prostheses thrombosis rates for our series was 0.35%/patient-year for mitral valve replacements. The thrombosis rate reported by Jamieson and coauthors [14] for Carbomedics and the St. Jude Medical bileaflet mechanical prostheses was 0.63%/patient-year for mitral replacements. Of the total three thrombosed mitral prostheses, one was managed successfully with thrombolysis and two with redo surgery. Furthermore, lack of thrombosed valve in the aortic position deserves attention for On-X valves. The lack of tissue overgrowth and hemolytic anemia in this series were also gratifying. Unique leaflet guards and the length of the valve orifice may provide a barrier to pannus overgrowth. Furthermore, normal or supra-normal values of serum LDH levels suggest that On-X valve design may substantially reduce turbulence. However, longer term follow-up is required to reach any conclusions.

4.1. Limitations

The major limitations of this study are lack of randomized comparison between the other bileaflet valves which limits conclusions about relative efficacy and freedom from complications. The authors also recognize the need for dobutamine or exercise echocardiography for hemodynamic evaluation of small aortic valve prostheses.

In summary, there are no clinically relevant differences among the most commonly used bileaflet aortic valves [15]. The data have given similar results with two recently published trials. However, with the unique features, the On-X valve performs satisfactorily in the first 4 years following AVR, MVR and DVR. Longer term follow-up studies are needed to determine prosthetic durability for On-X valve design.

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Appendix: Variables tested on univariate analysis

The following variables were examined in the univariate analysis:

Demography: Age (years), sex, body surface area (m^2), body mass index (kg/m^2). *Preoperative status:* New York Heart Association functional class, severity of angina, non-elective surgery, redo cardiac surgery, left ventricular function, pulmonary artery pressures (systolic PA pressure >60 mmHg), history of myocardial infarction, cardiogenic shock at the time of surgery, recent congestive cardiac failure, extent of coronary artery disease, presence of preoperative atrial fibrillation, presence of complete heart block.

Non-cardiac comorbidity: Smoking, hypercholesterolemia, diabetes mellitus, hypertension, peripheral vascular disease, previous stroke, chronic obstructive pulmonary disease, renal disease, peripheral vascular disease, requirement for renal replacement therapy, history of GI bleeding or duodenal ulcer, hepatic disease.

Operation-Related Variables: Type of operation (isolated AVR, aortic root surgery, modified Bentall's, preservation of subvalvular apparatus for MVR), prosthesis size (mm), indexed prosthesis size (mm/m^2), concomitant coronary artery surgery, concomitant surgery for atrial fibrillation, cross-clamp time, cardiopulmonary bypass time.

Late postoperative Variables: Postoperative LV function, postoperative NYHA functional class at 6 weeks, valve-related adverse events, postoperative mean transvalvular gradients, residual prosthetic regurgitation, continued smoking, inadequate anticoagulation.

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