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Early results of aortic valve replacement with Labcor biological prostheses

Andrzej Walczak[1], Anna Kośmider[1], Stanisław Ostrowski[1], Mirosław Bitner[1], Karol Bartczak[1], Sławomir Jander[1], Radosław Zwoliński[1], Marzanna Zielińska[2], Piotr Okoński[1], Ryszard Jaszewski[1]

Summary

Introduction: Aortic valve replacement (AVR) is indicated as a standard procedure in most cases of symptomatic artic valve disease. Two different types of prostheses are commonly used; mechanical and biological ones. Biological prostheses have weak thrombogenic properties and, in most of the patients, they do not require anticoagulation. Unfortunately, bioprostheses have relatively low durability which yields with a high rate of re-do operations. ***Material and methods:*** Between 2006 and 2008, in the Department of Cardiac Surgery, Medical University of Lodz, 268 patients were operated upon due to aortic valve disease. Thirty six of them had a porcine bioprosthesis Labcor TLPB-A Supra (Labcor Laboratorios Ltda., Brazil) implanted in aortic position. In this subset of patients were 15 women and 21 men, at the mean age of 72,2±3,7 years. The age of female patients ranged from 69 to 80 years (mean 73,8±3,65) and the male patients' age was between 65 and 76 years (mean 71±3,41). The mean Euro SCORE Risk Profile for this group was 7,07±4,37%. ***Results:*** Perioperative mortality was 8,3% (3 patients). The most frequently observed complication in the analyzed group, in early postoperative period was atrial fibrillation which occurred in 17 patients (47%). Low cardiac output syndrome and postoperative consciousness disorders were present in 11% of the patients. For small size bioprostheses of 19 and 21 mm, higher transvalvular gradients (mean and maximal) were observed. Values of indexed effective orifice area (EOAi) ranged from 0,76 cm^2/m^2 for 19 mm bioprosthesis to 1,0 cm^2/m^2 for 23 mm bioprosthesis. ***Conclusions:*** In spite of relatively high transvalvular gradients and low values of EOAi for 19 and 21 mm bioprostheses, early outcome of AVR procedure were good. The analyzed group requires further clinical and echocardiographic follow-up observation. ***(Clin Exp Med Lett 2008; 49(4): 223-227)***

Keywords: aortic valve replacement, biological prostheses

Introduction

Aortic valve replacement (AVR) is indicated as a standard procedure in most cases of symptomatic artic valve disease [1]. The AVR is the second most frequently performed cardiac surgery, after coronary artery by-pass grafting (CABG). Almost half of the century has passed since Harken implanted first aortic prosthesis in 1960 [2], but the ideal substitute of aortic valve combining good hemodynamic properties with long lasting durability and low risk of thromboembolism still does not exist. Two different types of prostheses are commonly used; mechanical and biological ones. Mechanical prostheses (nowadays bileaflet ones) have very good durability which yields with a low rate of re-do AVRs. Unfortunately, they are thrombogenic and require life-long anticoagulation which exposes the patients for a risk of hemorrhagic event. On the other hand, biological prostheses due to their weak thrombogenic properties do not require anticoagulation in most of the patients. However, their main disadvantage is poor durability connected with a fragility of tissues they are made of, which results in a high rate of re-do operations. Because of the limited durability, bioprostheses are recommended for the older patients, nowadays over 65, without risk factors for thromboembolism.

Material and methods

Between 2006 and 2008, in the Department of Cardiac Surgery, Medical University of Lodz, 268 patients were operated upon due to aortic valve disease. Ninety six of them had a bioprosthesis implanted in the aortic position. The rest underwent AVR procedure using a mechanical prosthesis. According to the current guidelines of American College of Cardiology and American Heart Association [1] and using the algorithm derived by Rahimtoola [3], bioprostheses were implanted in patients older than 65 years old with the sinus rhythm.

Among the patients that were given a bioprosthesis, there were 36 patients in whom a porcine bioprosthesis Labcor TLPB-A Supra (Labcor Laboratorios Ltda., Brazil) was implanted and these patients comprise the study group. In this group there were 15 women and 21 men, at the mean age of 72,2±3,7 years. The age of female patients ranged from 69 to 80 years (mean 73,8±3,65) and the male patients' age was between 65 and 76 years

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[1] Department of Cardiac Surgery, Medical University of Lodz, Poland
[2] Department of Cardiology, Medical University of Lodz, Poland
Correspondence address:
Andrzej Walczak
Department of Cardiac Surgery, Medical University of Lodz, Poland; 91-425 Łódź, ul. Sterlinga 1/3; Tel./Fax: (+48 42) 633 15 58;
E-mail: walczak@mm.com.pl

(mean 71±3,41). Due to the advanced age, every patient underwent a routine coronary angiography before the surgery. The angiography revealed significant lesions in coronaries in 10 (28%) of these patients (5 women and 5 men) requiring simultaneous surgical myocardial revascularization. In 2 patients AVR operation was an emergency, in cardiogenic shock after cardiac arrest. All patients had a logistic Euro SCORE Risk Profile calculated before the surgery. This profile predicted a perioperative death risk rate and was determined using the calculator available on the site: www.euroscore.org/calculators. The calculated mean Euro SCORE Risk Profile for this group was 7,07±4,37%. The preoperative data of the study group are shown in the Table 1.

Table 1. Preoperative data of the study group

Dane	Wartość
Age (years)	
range	65–80
mean ± SD	72,2±3,7
Gender	
female (n/%)	15/41,7%
male (n/%)	21/58,3%
Body mass (kg)	
range	42–117
mean ± SD	79,5±15,8
Height (cm)	
range	154–187
mean ± SD	168±7
Body surface area BSA (m^2)	
range	1,33–2,50
mean ± SD	1,95±0,24
Valve pathology (n/%)	
stenotic	27/75%
regurgitant	3/8,3%
mixed *	6/16,7%
HYHA class (n/%)	
I	0
II	8/22,2%
III	26/72,2%
IV	2/5,6%
Concomitant diaseases (n/%)	
coronary artery disease	10/27,8%
hypertension	29/80,6%
hyperlipidemia	17/47,2%
diabetes	4/11,1%
neurological dysfunction	3/8,3%
chronic pulmonary disease	5/13,9%
thoracic aorta aneurysm	1/2,8%
Logistic EuroSCORE	
range	2,54–16,94
mean ± SD	7,08±4,24
Emergency operations (n/%)	2/5,6%
LV ejection fraction EF(%)	
range	30–75
mean ± SD	58,36±11,25

*aortic regurgitation ≥2

All the patients were operated using the medial sternotomy approach, in normotermic cardio-pulmonary by-pass (CPB). The myocardial protection was obtained by the cold crystalloid cardioplegia according to St. Thomas Hospital formula, administrated directly to the both coronary ostia, in the dose of 10 ml per kg of body weight and supplemented each 30 minutes. The bioprostheses were implanted using interrupted mattress sutures with felt pledgets. The mean time of CPB was 96,9±33,2 minutes and the mean cross clamping time was 69,8±23,2 minutes. Among 36 implanted bioprostheses there were five ones of 19 mm size, eleven ones of 21 mm size, sixteen ones of 23 mm size and four ones of 25 mm size. According to the manufacturer's data these prostheses had effective orifice area (EOA) ranged from 1,3 to 2,1 cm^2 (Table 2). In 14 patients (39%) additional CABG and/ or other procedure was performed (Table 3). On the second postoperative day each patient was given orally anticoagulation (acenocoumarol). Until the target international normalized ratio (INR) was achieved, low-molecular heparin was administrated subcutaneously. The oral anticoagulation was initially set for three months and a decision of its discontinuation was taken during a control visit in the ambulatory.

Table 2. Number and size of implanted Labcor bioprosthese and their effective orifice area (EOA) according to the specification provided by the manufacturer

Type and prosthesis size	Ilość (n/%)	EOA (cm^2)
prosthesis TLPB-A 19A (19 mm)	5/13,9%	1,3
prosthesis TLPB-A 21A (21 mm)	11/30,6%	1,5
prosthesis TLPB-A 23A (23 mm)	16/44,4%	1,7
prosthesis TLPB-A 25A (25 mm)	4/11,1%	2,1

Table 3. Types of cardiac procedures performed in the study group

Operation	n
Aortic valvae replacement AVR (n/%)	22/61,1%
AVR + surgical revascularisation (n/%)	9/25%
AVR + mital anuloplasty (n/%)	1/2,8%
AVR + tricuspid anuloplasty + surgical revascularisation (n/%)	1/2,8%
AVR + mitral commissurotomy + tricuspid anuloplasty (n/%)	1/2,8%
AVR + ascending aorta repalcement (n/%)	1/2,8%
AVR + ablation (n/%)	1/2,8%

Early postoperative death was defined as a death within 30 days from the operation. The postoperative complications were defined according to the guidelines of American Association for Cardio-Thoracic Surgery, The Society of Thoracic Surgeons and the European Association for Cardio- Thoracic Surgery [4]. All patients had a transthoracic echocardiography performed in the early postoperative period (usually on the 10th postoperative day) using Acuson-Sequoia C256 device. The following parameters were assessed: mean and maximal transprosthetic gradient, maximal transprosthetic flow velocity, presence of regurgitation or perivalvular leak, heart chambers dimension and left ventricular ejection

fraction. Each patient had an indexed effective orifice area (EOAi) of the bioprosthesis calculated. The EOAi is expressed in cm^2/m^2 and is derived from EOA given by the manufacturer for each size of bioprosthesis and body surface area (BSA) of the patient.

The continuous variables were shown as mean values with standard deviations. The mortality and morbidity rates were shown in percents.

Results

In the study group, perioperative mortality rate was 8,3% (3 patients). One patient died on the operative day, the second one on the fourth postoperative day and the third one 13 days after the surgery. Two patients died due to the low cardiac output syndrome and one due to the multiorgan insufficiency. The most frequently observed complication in the early postoperative period was atrial fibrillation, which occurred in the study group in17 patients (47%). Low cardiac output syndrome and postoperative consciousness disorders were present in 11% of the patients. Data on postoperative morbidity are collected in the Table 4. The findings from postoperative transthoracic echocardiography are shown in the Table 5. For small size bioprostheses of 19 mm and 21 mm, higher transvalvular gradients (mean and maximal) were observed. Values of indexed effective orifice area (EOAi) ranged from 0,76 cm^2/m^2 for 19 mm bioprosthesis to 1,0 cm^2/m^2 for 23 mm bioprosthesis. The correlations between EOAi and BSA is presented in the Figure 1. and the correlation between EOAi and prosthesis size is shown in the Figure 2.

Table 4. Postoperative outcomes in the study group

Variable	N/%
Low cardiac output	4/11,1
IABP	3/8,3
Reoperation for bleeding	3/8,3
Sternum revision	1/2,8
Postoperative atrial fibrillation	17/47,2
consciousness disorders	4/11,1
Postoperative stroke	1/2,8
Postoperative ventricular arrhytmia	3/8,3
Respiratory failure	3/8,3
Postoperative renal failure	1/2,8
Pleural effusion (drainage)	2/5,6

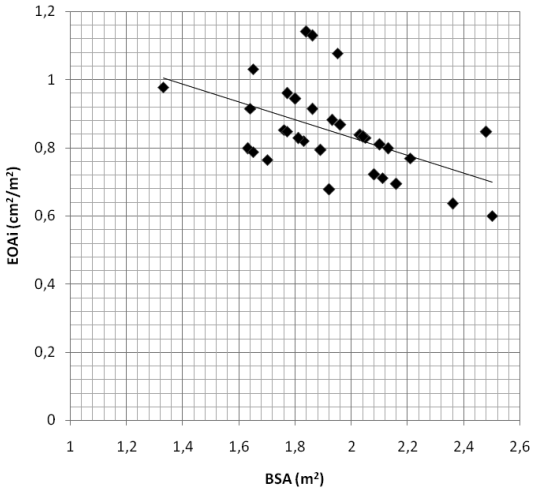

Figure 1. Correlation between indexed effective orifice area (EOAi) and body surface area (BSA)

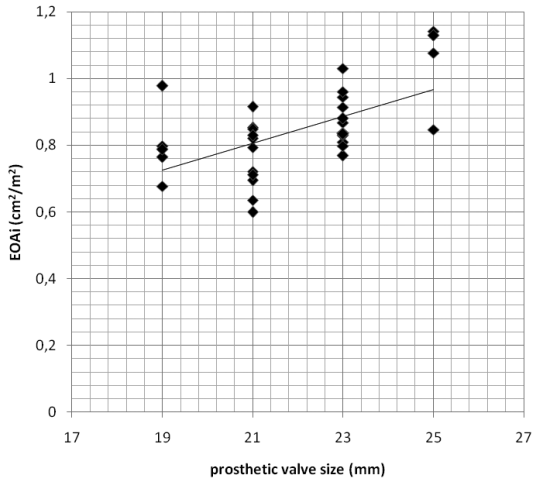

Figure 2. Correlation between indexed effective orifice area (EOAi) and prosthetic valve size

Discussion

The AVR is considered to be the most effective treatment method in aortic valve disease, especially critical aortic stenosis. This operation is the second most frequently performed cardiac surgery, after coronary artery by-pass grafting (CABG). Biological prostheses are commonly used in the elderly because of a high risk

Table 5. Selected postoperative echocardiographic parameters, body surface area (BSA) values and indexed effective orifice area (EOAi) values in relation to the size of implanted prosthesis

		Vmax (m/s)		Paek systolic gradient (mmHg)		Mean systolic gradient (mmHg)		BSA (m^2)		
Size (mm)	n	śr	sd	śr	sd	śr	sd	śr	sd	EOAi (cm^2/m^2)
19	5	3,58	0,15	51,25	4,15	29,75	0,83	1,70	0,11	0,76
21	11	2,81	1,01	42,88	11,83	24,77	6,19	1,99	0,25	0,75
23	15	2,71	0,33	30,95	5,80	16,33	4,36	1,97	0,14	0,86
25	5	2,40	0,37	24,00	8,04	12,66	3,68	2,09	0,27	1,00

of hemorrhagic complications and relatively short life expectancy (theoretically shorter than a valve durability) in this group of patients. For the patients older than 65 freedom from structural deterioration was 90% at 10 years [5]. The criteria for bioprosthesis implantation applied in the study group (age over 65, sinus rhythm) did not differ from commonly accepted standards [1,3]. Mistiaen et al. analyzed 1000 cases of AVR using pericardial bioprosthesis Carpentier-Edwards between 1986 and 2006 and found that during last 20 years the age of operated patients increased significantly, as well as their comorbidity [6]. Rahimtoola et al. [3] emphasized that the outcomes of AVR are strictly related to preoperative state of the patients, type of the procedure, type of the prosthesis and the quality of postoperative care. In the meta-analysis published in 2007, Tjang et al. list as the predictors of early death after AVR the following clinical circumstances: emergency operation, older age, aortic insufficiency, concomitant coronary artery disease, prolonged cardio-pulmonary bypass time, reduced left ventricular ejection fraction, infective endocarditis, pulmonary hypertension, implantation of mechanical prosthesis, preoperative pacing, dialysis-dependent renal failure and small prosthesis size [7]. The early mortality in our material (8,3%) concerns the patients of mean age over 72 years burdened with a number of concomitant diseases. Thirty nine per cent of these patients underwent simultaneously with AVR another surgery, usually CABG. Early mortality rates published by other authors assessing similar groups of patients do not differ significantly from our findings. Aksoyek et al., on the basis of material of 253 patients aged over 65 years, reported the early mortality after AVR with a mechanical prosthesis at the level of 11,1% [8]. In the material of Chiappini et al. the early mortality rate was 7% [9]. Pavie et al. analyzing 100 subsequent patients at the mean age of 80 who had a Labcor prosthesis implanted, observed the early mortality rate of as high as 15% [10]. The study material of He et al. comprised 371 patients after AVR (38,3% of them underwent additional CABG) at the mean age of 62 years and the early mortality rate in this group was 8,9% [11]. Alsoufi et al., analyzing a group of patients referred to the combined operation of AVR and CABG, noticed that operative mortality depended on the fact which disease was the primary indication for the surgery. If the primary indication was aortic valve disease, the mortality rate would be 4,8%. If the primary indication was ischemic heart disease, the mortality would be 9,1%. But in cases in whom both of the diseases were independent indications for the surgery, the mortality rate was as high as 11,5% [12]. Rao et al. in their paper analyzing nearly 3000 patients had a stented bioprosthesis implanted in aortic position at Toronto General Hospital and at Vancouver General Hospital, reported of the mean operative mortality of 5,3% [13]. The mortality, however, was significantly higher (9,3%) in the subset of patients who were given a bioprosthesis of 19 mm or 21 mm, in comparison with those patients who had a prosthesis of 23 mm or bigger implanted (4,2%). In our material, out of three patients who died two had had a 23 mm prosthesis implanted and one a 21 mm one.

The issue of small prosthesis in aortic ostium was noticed as early as in the seventies of the last century by Rahimtoola et al. who defined so called prosthesis-patient mismatch (PPM) in 1978 as the situation when "effective prosthetic valve area after insertion into the patient is less than that of normal human valve" [14]. In the other words PPM can be described as the situation when effective orifice area of the prosthesis is too small in relation to the patient's body size [15,16]. Rao et al. divided their patients into two group depending on EOAi with a cut-off value of 0,75cm^2/m^2 [13]. They observed that patients with EOAi below this border line had higher mortality rate (7,9% vs. 4,6%). According to Walther et al. [17] PPM does not occur when EOAi is higher than 0,85 cm^2/m^2, moderate PPM means EOAi between 0,65 cm^2/m^2 and 0,85 cm^2/m^2 and severe PPM is present when EOAi is below 0,65 cm^2/m^2. On the material of over four thousands patients, they found severe PPM in 2,4% and moderate PPM in 26,7%. The mortality rate was 6,9% for the patients with no PPM, 10,6% with moderate PPM and 5,2% with severe PPM. Blais et al., using the same criteria as Walther et al., observed severe PPM in 2% of their patients and moderate PPM in 36% [18]. Howell et al. [19] analyzing a group of 1480 patients after AVR did not find any correlation between PPM and in-hospital mortality, defining PPM as EOAi smaller than 0,6 cm^2/m^2. Also Hanayama et al. in their study involving 1129 subsequent patients undergoing AVR did not observed the influence of PPM defined as above, on the survival [20]. This brief review of papers concerning PPM shows that the criteria defining PPM are not determined. Rahimtoola also agreed with this thesis tending himself to describe the severe PPM as EOAi not bigger than 0,6 cm^2/m^2.

The EOA value for each size of Labcor prosthesis were taken from the manufacturer's brochure and are presented in the Table 2. Such a way of determining EOA was used also by Walther et al. [17], Blais et al. [18] and Howell et al. [19]. In our material, two patients (5,9%) had EOAi not bigger than 0,65 cm^2/m^2, 20 patients (58,8%) met the criteria of moderate PPM (0,66 cm^2/m^2-0,85 cm^2/m^2) and 12 patients (35,5%) had PPM bigger than 0,85 cm^2/m^2. However, using Rahitoola's criteria, only one patients from the study group had a severe PPM (EOAi not higher than 0,6 cm^2/m^2). The EOAi values of the patients who died were: 0,77 cm^2/m^2, 0,79 cm^2/m^2 and 0,88 cm^2/m^2. Analyzing EOAi in relation to the prosthesis size, we found that prostheses of 19 mm and 21 mm were EOAi values of 0,76 and 0,75 cm^2/m^2 and so they met the criteria of moderate PPM [18]. David et al. emphasize that due to a great number of measurable and immeasurable factors influencing operative mortality after AVR, it is very difficult to definitively assess the effect of prosthesis size on the postoperative outcomes [21].

The most frequently observed complication in the early postoperative period was atrial fibrillation (AF), which occurred in as many as 17 patients (47%) from the study group. Orłowska-Baranowska et al., analyzing prevalence of paroxysmal FA after AVR, on the material of 423 patients at mean age of 58 years, found its

occurrence in 28% and they also noticed a correlation between the episode of FA and the patients' age [22]. Collart et al., on the material of patients aged mean 83 years, observed paroxysmal FA in 31% [23]. The occurrence of other complications in their group was similar like in our material e.g. low cardiac output syndrome in 16,7% and surgical re-exploration in 6%. In Hellgren's et al. material of 1746 patients after AVR an episode of FA occurred in 40% of cases what is the value very close to that observed in our group. Also postoperative bleeding requiring re-thoracotomy took a place in a similar percentage of the patients (8,1%), whereas neurological complications, heart failure or necessity of intra-aortic balloon pump (IABP) use were more common in their material [24]. Almassi et al. analizing a huge cohort of over 3.000 patients after a cardiac surgery observed the prevalence of FA in 32,9% of patients who underwent isolated AVR and in 36,4% of patients who had AVR combined with CABG [25]. Ngaage et al. emphasize the influence of advanced age on the higher rate of neurological outcome after cardiac operations, what yield with longer hospitalization, increased costs and higher mortality [26].

Summarizing we can say that our early outcomes of AVR with Labcor biological prostheses do not differ significantly from the results published by other authors on the basis of similar clinical material.

Conclusions

In spite of relatively high transvalvular gradients and low values of EOAi for 19 and 21 mm bioprostheses, early outcome of AVR procedure were good.

The analyzed group requires further clinical and echocardiographic follow-up observation.

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