

# Redo surgery risk in patients with cardiac prosthetic valve dysfunction

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## Abstract

**Introduction:** The aim of the study was to analyse the risk factors of early and late mortality in patients undergoing the first reoperation for prosthetic valve dysfunction.

**Material and methods:** A retrospective observational study was performed in 194 consecutive patients (M = 75, F = 119; mean age 53.2 ±11 years) with a mechanical prosthetic valve (*n* = 103 cases; 53%) or bioprosthesis (91; 47%). Univariate and multivariate Cox statistical analysis was performed to determine risk factors of early and late mortality.

**Results:** The overall early mortality was 18.6%: 31.4% in patients with symptoms of NYHA functional class III-IV and 3.4% in pts in NYHA class I-II. Multivariate analysis identified symptoms of NYHA class III-IV and endocarditis as independent predictors of early mortality. The overall late mortality (> 30 days) was 8.2% (0.62% year/patient). Multivariate analysis identified age at the time of reoperation as a strong independent predictor of late mortality.

**Conclusions:** Reoperation in patients with prosthetic valves, performed urgently, especially in patients with symptoms of NYHA class III-IV or in the case of endocarditis, bears a high mortality rate. Risk of planned reoperation, mostly in patients with symptoms of NYHA class I-II, does not differ from the risk of the first operation.

**Key words:** prosthetic valve, reoperation, echocardiography.

## Introduction

Artificial mechanical valves and bioprostheses which are implanted nowadays are highly durable and with little thrombogenicity [1-4]. However, redo surgeries in patients with implanted artificial valves are still a serious problem; this is so mainly because of the higher early mortality rate. In studies which have been published so far and which are based on analyses of a large amount of data [5-9], the authors usually presented the results of redo surgery performed during a period of about 30 years. A significantly higher early surgical mortality rate has already been reported before [7, 9, 10]. During the period included in the analysis, trans-oesophageal echocardiography was the basic method used in recognizing dysfunctions

of artificial valves and in qualifying for redo surgery treatments [11, 12].

Therefore the aim of our study was to analyse the risk factors of early and late mortality in patients undergoing a redo operation for prosthetic valve dysfunction.

## Material and methods

### Patients' characteristics

The material includes 194 successive patients with implanted artificial mechanical valves or with bioprostheses who were qualified to undergo a reoperation because of a valve prosthesis dysfunction between 1995 and 2006 in our department. Intraoperative diagnosis confirming the recognition was necessary for the patient to be included in the studied group. According to the proposition of Clark *et al.* [13], redo surgery was understood as reimplantation of a valve prosthesis which was implanted earlier.

The group of 194 patients contained 75 men and 119 women aged between 18 and 74 years (mean age 53.2 ±11 years). The period between the implantation of an artificial valve and a redo procedure ranged from 6 days to 19 years. A hundred and twenty patients had an artificial mitral valve implanted (62 of them had a bioprosthesis) and 36 patients had an artificial aortic valve implanted (13 of them had a bioprosthesis). Thirty-five patients had both a mitral valve and an aortic valve implanted;

13 of them had two bioprostheses. Three patients had a biological valve and a mechanical valve implanted.

Twenty-two patients underwent redo surgery within 30 days from the implantation of an artificial valve. Forty-two redo procedures were performed as urgent indications. A hundred and five patients (54%) were recognised as NYHA class III/IV. Atrial fibrillation was diagnosed in 145 patients. Structural dysfunction was the cause of redo procedure in 6 patients with a mechanical valve and in 76 patients with a bioprosthesis. Infectious endocarditis was recognised in 58 patients. In 30 patients with a mechanical valve a thrombus was the cause of blockage of the disc. Seventeen patients had a paravalvular shunt which was not connected with the ongoing endocarditis. Seven patients with mechanical valves underwent redo surgery because of other reasons (Table I). This time was the shortest for the infectious endocarditis. Thrombotic complications which occurred during the period between the implantation of an artificial valve and redo surgery were recognised in 17 patients.

### Protocol of the study

When making a decision concerning redo surgery, the authors used the protocol adopted for recognising dysfunctions of artificial valves. If a dysfunction of an artificial valve was recognised on the basis of transthoracic examination, the decision concerning the resignation from transoesophageal examination was made after

**Table I.** Characteristics of the entire study group – 194 patients reoperated on for a prosthetic valve (PV) dysfunction

Age [years]	Mean (from-to)	53.2 ±11 (18-74)
Sex	Men (%) / Women	75 (39) / 119
Time from implantation of PV [months]	Mean (from-to)	83.4 ±65.6 (1-230)
Reoperation: ≤ 30 days	n (%)	22 (12.4)
31-180 days	n (%)	38 (19.6)
> 180 days	n (%)	132 (68.0)
Urgent reoperation	n (%)	42 (21.7)
Atrial fibrillation	n (%)	145 (74.7)
NYHA class III/IV	n (%)	105 (54.1)
PV mechanical/bioprosthesis	n (%)	103 (53.1) / 91
Embolic complications	n (%)	17 (8.7)
<b>The reason for reoperation</b>		
Structural dysfunction of mechanical PV	n (%)	6 (3.1)
Structural dysfunction of bioprosthesis	n (%)	76 (39.2)
Infectious endocarditis	n (%)	58 (29.9)
Disc blockage by thrombus	n (%)	30 (15.5)
Paravalvular shunt	n (%)	17 (8.8)
Other*	n (%)	7 (3.6)

\*Temporal prosthetic valve dysfunction of unknown aetiology – 3 patients, pannus – 2 patients, "small" prosthetic valve – 2 patients, NYHA – New York Heart Association, PV – prosthetic valve

consultation with a cardiac surgeon. In order to achieve the aims of this study, the authors analysed numerous preoperative clinical and echocardiographic parameters as well as surgical data.

### Cardiac surgical procedures

In 152 patients the redo procedure involved only replacement of an artificial valve. In 42 patients aorto-coronary bridging or tricuspid annuloplasty was performed. Heart muscle protection was not significantly different in the patients undergoing redo surgery at the same time.

### Statistical analysis

Continuous variables were expressed as the mean value  $\pm$  SD; Student's *t*-test was used to perform a comparative analysis [14, 15]. Categorical variables were expressed as percentages and the  $\chi^2$  test or Fisher test was used for comparison [14, 15]. Results were recognised as statistically significant when  $p < 0.05$ . A multifactorial analysis, the Cox proportional hazard models [16], was performed using the step method, separately for early mortality rate and late mortality rate. The Statistica software package was used for statistical analysis (StatSoft Poland).

### Results

Early mortality ( $\leq 30$  days) in the patients who underwent redo surgery because of the dysfunction

of an artificial valve (Table II) was 18.6%: 31.4% in patients with symptoms of NYHA functional class III-IV and 3.4% in pts in NYHA class I-II. It was found that the following parameters have a significant influence on the result of a redo procedure: urgent indications ( $p < 0.01$ ), NYHA class III/IV ( $p < 0.001$ ), infectious endocarditis (IE) ( $p < 0.001$ ), redo surgery of an artificial mechanical valve ( $p < 0.005$ ), kidney insufficiency ( $p < 0.05$ ), atrial fibrillation ( $p < 0.02$ ), liquid in the pericardium ( $p < 0.05$ ) and ejection fraction (EF)  $< 55\%$  ( $p < 0.01$ ). The multifactorial analysis showed that the following were independent and significant negative prognostic factors: NYHA III-IV (odds ratio [OR] = 3.89,  $p = 0.01$ ) and infectious endocarditis (OR = 3.99,  $p < 0.01$ ).

The analysis of factors deciding about the results of redo surgery performed because of infectious endocarditis revealed the significant influence of the following parameters on the result of redo surgery: urgent indications ( $p < 0.02$ ), NYHA III/IV ( $p < 0.001$ ), time from the implantation of an artificial valve ( $p < 0.02$ ), kidney insufficiency ( $p < 0.01$ ), liquid in the pericardium ( $p < 0.05$ ) and EF  $< 55\%$  ( $p < 0.01$ ). The multifactorial analysis showed that NYHA III-IV (OR = 4.02,  $p = 0.01$ ) and ejection fraction below 55% (OR = 3.1,  $p < 0.01$ ) are significant independent negative prognostic factors.

In the group of 136 patients who underwent a redo procedure because of an artificial valve dysfunction caused by reasons other than infectious endocarditis (Table III) the following four significant

**Table II.** Clinical and echocardiographic predictors of death in early postoperative period in 194 patients reoperated on for prosthetic valve dysfunction

		Death (n = 36)	Survival (n = 158)	Value of p	
Age [years]	Mean (from-to)	54.2 $\pm$ 10.3, 21-71	53.0 $\pm$ 11.3, 18-74	NS	
Sex	Men/Women	n	12/24	65/93	NS
Urgent indications	n	14	28	< 0.01	
NYHA class III-IV	n	33	72	< 0.001	
Time from PVI [months] mean, med., from-to		45.9 $\pm$ 63, 8, 1-224	92.1 $\pm$ 62, 96, 1-230	< 0.001	
	$\leq 30$ days, n	11	14		
	31-180 days, n	20	17		
	> 180 days, n	5	127		
One valve	n	30	129	NS	
Two valves	n	6	29	NS	
PV mechanical/bioprostheses	n	27/9	76/82	< 0.005	
Additional procedures	n	9	33	NS	
Infectious endocarditis	n	14	44	< 0.001	
Atrial fibrillation	n	33	112	< 0.02	
Kidney insufficiency	n	3	2	< 0.05	
Liquid in the pericardium	n	7	6	< 0.05	
Ejection fraction < 55%	n	22	54	< 0.01	

med. – median, PVI – prosthetic valve implantation

**Table III.** Clinical and echocardiographic predictors of perioperative death in patients referred for reoperation due to causes of prosthetic valve dysfunction other than endocarditis

		Death (n = 22)	Survival (n = 114)	Value of p	
Age [years]	Mean (from-to)	54.57 ±8.7 (38-69)	53.91 ±10.7 (18-73)	NS	
Sex	Men/Women	n	4/18	40/74	NS
Urgent indications		n	5	20	NS
NYHA class III-IV		n	20	48	< 0.001
Time from PVR [months] mean, med., from-to			105.9 ±60, 114, 0-230	< 0.02	
	≤ 30 days; n	7	8		
	31-180 days; n	12	7		
	> 180 days; n	3	99		
One valve		n	20	93	NS
Two valves		n	2	21	NS
PV mechanical/bioprostheses		n	15/7	45/69	< 0.02
Additional procedures		n	6	23	NS
Prosthetic valve dysfunction*		n	15	45	–
Disc blockage		n	7	23	NS
Paravalvular leak		n	5	12	NS
Structural degeneration		n	2	4	NS
Other		n	1	6	NS
Atrial fibrillation		n	21	84	< 0.01
Ejection fraction < 55%		n	11	40	NS

PVI – prosthetic valve implantation, \*refers to patients operated on for mechanical prosthetic valve dysfunction

negative prognostic factors were distinguished: NYHA III-IV ( $p < 0.001$ ), time from the implantation of an artificial valve ( $p < 0.02$ ), redo surgery of a mechanical valve ( $p < 0.02$ ) and atrial fibrillation ( $p < 0.01$ ). The multifactorial analysis showed that NYHA III-IV (OR = 1.58,  $p < 0.05$ ) is the only significant independent negative prognostic factor.

The comparative analysis of the patients who underwent redo surgery because of infectious endocarditis and because of other reasons is

presented in Table IV. It revealed that men significantly outnumbered women in the IE group ( $p < 0.01$ ) and that there is no significant difference between the ages of the patients undergoing redo surgery. Redo procedures due to reasons other than IE were performed significantly later (median 109 months, for IE 15 months,  $p < 0.001$ ). The analysis of the direct cause of redo surgery in patients with an implanted mechanical valve showed that valvular shunt occurred significantly more often

**Table IV.** Characteristics of patients reoperated on for prosthetic valve (PV) dysfunction due to infective endocarditis (IE +) and other reasons (IE –)

		IE + (n = 58)	IE – (n = 136)	Value of p	
Age [years]	Mean (from-to)	51.43 ±12.49 (21-74)	54.0 ±10.4 (18-73)	NS	
Sex	Men/Women	n	31/27	44/92	< 0.01
Time from PVI [months] mean, med., from-to		49.3 ±56, 15, 1-190	98.9 ±64, 109, 1-230	< 0.001	
Bioprostheses		n (%)	13 (22.4)	76 (55.9)	< 0.001
<b>Direct cause of mechanical PV reoperation</b>					
Disc blockage		n (%)	16 (35.6)	30 (50.0)	NS
Paravalvular leak		n (%)	24 (53.3)	17 (28.3)	< 0.02
DB + PL		n (%)	5 (11.1)	–	–
Other		n (%)	–	13 (21.7)	–

med. – median, IE – endocarditis, PVI – prosthetic valve implantation

in the patients with IE. Co-occurrence of valvular shunt and blockage of a heart valve disc was observed only in patients with IE. The patients with an implanted bioprosthesis constituted a significantly smaller subgroup among the patients who underwent redo surgery because of IE ( $p < 0.001$ ).

Late results ( $> 30$  days) in the patients who underwent redo surgery because of the dysfunction of an artificial valve amounted to 8.2%. The observation time ranged from 4 to 132 months, 63 months on average; the total observation time amounted to 749.5 years. Late mortality rate was 0.62% per patient-year. It was revealed that the following parameters had a significant influence on the late result of redo surgery: a patient's age at the moment of redo surgery ( $p < 0.01$ ), male sex ( $p < 0.01$ ), redo procedure of a mechanical valve ( $p < 0.05$ ) and atrial fibrillation ( $p < 0.05$ ). The multifactorial analysis showed that the age of a patient at the moment of redo surgery was an independent and significant negative prognostic parameter (OR = 2.29,  $p < 0.05$ ). Nineteen patients (12%) underwent another redo procedure, including 5 patients (26.3%) who died during the perisurgical period.

## Discussion

Structural dysfunction of a mechanical valve was a cause of redo surgery in 3% of the patients. A similar percentage of structural dysfunctions was observed by Bortolotti *et al.* in a group of 549 patients who underwent a redo procedure within a period of 26 years [11]. In the present study, the most frequent cause of a redo procedure was structural dysfunction of a bioprosthesis (76 patients – 39.2%). Other authors indicate degeneration of a bioprosthesis as the most frequent cause of redo surgery as well [7, 17]. Each patient whose survival time is long enough needs redo surgery and this is connected with the limited durability of a bioprosthesis [18]. Taking that into account, it is proposed that implantation of bioprostheses be limited to patients over the age of 65. Summing up the results of a 15-year randomized study which compared bioprostheses and mechanical valves, Hammermeister *et al.* [19] stated that redo procedures occurred significantly more frequently only in a group of patients below the age of 65. In the presented material, a direct indication for redo surgery in a majority of the patients was valve incompetence (77.6%) and only in 17 cases was it the stenosis of a bioprosthesis. Only 5 patients underwent redo surgery urgently; the other ones underwent a redo procedure according to the schedule. These patients were re-examined every 3-6 months within the last year before the redo surgery. The diagnostic procedure which was used and the percentage of patients who underwent

a redo procedure according to the schedule did not differ from other authors' reports [17].

In the present study, the early mortality rate was 18.6%. Other authors reported mortality rates from 6% to 41% [7, 9, 10, 20-22] depending on many factors connected with the clinical condition of a patient, advancement of valve pathology and the surgical procedure used.

This research confirmed the earlier observations [5, 14, 22, 23] concerning the negative prognostic influence of NYHA class III-IV and urgent redo surgery performance on the perisurgical mortality rate. In the present study, the mortality of patients who underwent redo surgery in NYHA class III/IV was 31.4% compared to 3.4% in NYHA class I/II. Similarly, for redo procedures performed urgently it was 33% and for scheduled treatments 14.5%. Urgent recommendations were not a negative factor in patients undergoing redo procedures because of valvular dysfunction resulting from reasons other than infectious endocarditis (Table III). However, redo surgery cannot be treated as an independent negative prognostic factor because a majority of patients treated urgently were in NYHA class IV. In the group presented by Husebye *et al.* [15] only one of 223 patients undergoing scheduled redo surgery and 64% of patients undergoing a redo procedure urgently were in NYHA class IV. These authors assessed the risk of redo surgery performed according to schedule as 1.3%. In the present study, 33% of patients undergoing scheduled redo surgery were in NYHA class III/IV. These differences might have resulted in a higher mortality rate in the perisurgical period. Like the redo procedure, the time which elapsed from the first surgery is related to the functional condition. Patients who underwent redo surgery up to 180 days after the implantation of a valve were usually in NYHA class III/IV and in those cases the results of redo surgery were worse (Tables II-IV).

Structural dysfunction of a bioprosthesis does not increase the perisurgical risk if the surgery is performed according to schedule [24]. In the present study, the mortality rate was lower by 10% (71 out of 76 patients underwent scheduled redo procedures). The opinions of other authors are similar [7, 25, 26].

Infectious endocarditis usually [27] significantly increases the risk of perisurgical death (from 24% to 62.5%). In the present study, the mortality rate was only 24%, although all patients were in NYHA class III/IV and 9 out of 14 treated patients underwent redo surgery urgently. The multifactorial analysis revealed that infectious endocarditis is an independent factor which is prognostically negative.

Additional redo procedures are burdened with an increasing perisurgical mortality rate. The risk of the second redo surgery is only slightly higher

[22] but the risk of the third redo surgery and of subsequent ones is significantly higher at 45% [27]. Similarly, in the present study, the mortality rate because of further redo surgery was only slightly higher at 26.3%.

In the present study, ejection fraction lower than 55% was a negative prognostic factor in perisurgical mortality only in the group of patients with infectious endocarditis (Tables II, IV). It seems that it is mainly connected with quickly increasing valvular shunt, which haemodynamically corresponds to acute mitral or aortic incompetence. Turina *et al.* [28] did not find that a decrease in ejection fraction < 50% had an influence on perisurgical mortality in patients with an artificial valve dysfunction which led to valvular stenosis. However, they observed a tendency (not statistically significant) towards worsening of redo surgery results in patients with a dysfunction which led to mitral or aortal incompetence. Other analysed echocardiographic factors were not prognostically influential or were closely connected with functional condition (atrial fibrillation, kidney insufficiency or liquid in the pericardium).

Late mortality occurred in 0.62% of patients per year. The only independent factor which was prognostically negative was the age of the patients at the moment of redo surgery. Other authors have pointed to the importance of population factors [21, 27] and the functional condition (NYHA class IV) [7, 8]. In the opinion of Edwards *et al.* [29], the factors which negatively influence the late results of redo procedures performed because of infections of an artificial valve were the age of the patient and the replacement of a biological valve with a mechanical one.

In conclusion, redo procedures of patients with implanted artificial valves performed urgently, particularly in patients in NYHA class III/IV, and caused by infectious endocarditis, are burdened with a very high risk. However, the risk of scheduled redo surgery, particularly in patients in NYHA class I/II, does not differ from the risk of the first surgery which is implantation of a valve. Urgent redo surgery, burdened with a high risk, is necessary only in patients in NYHA class III/IV with valvular thrombosis, which results in the blockage of a valve, and with contraindications to thrombolytic treatment, as well as in patients with structural dysfunction of a mechanical valve or infectious endocarditis. Redo procedures in those patients should be performed as early as possible in order to avoid complications, particularly systemic embolism and cardiogenic shock. Other patients' condition usually improves after medical treatment which, most frequently, makes it possible to change the redo surgery qualification from urgent to scheduled. It is also important to distinguish

patients with higher risk of redo surgery from patients with implanted artificial valves. This concerns particularly bioprostheses and some mechanical valves as well as patients with recognised "mild valvular shunt".

According to generally accepted standards [15, 30], there are no recommendations for routine echocardiographic examinations in patients with implanted artificial mechanical valves. However, it should be considered to provide patients with valves of "an old type", particularly bell and cage valves and some disc valves [20, 25, 28] as well as patients with high risk of thrombotic-embolic complications with such examinations. Patients with "mild valvular shunt" also need routine examinations because the degree of their illness may increase [26]. Unlike cases with mechanical valves, there is a common consensus of opinion [15, 30] that it is necessary to monitor patients with implanted bioprostheses using echocardiography, particularly if the first symptoms of valve degeneration appear.

The aim of echocardiographic examination in patients with valvular thrombosis which causes blockage of the valve is to single out those cases where the probability of medical treatment effectiveness is low and which require urgent reoperation. Echocardiographic examination is of particular significance in patients with dysfunction of an artificial valve caused by infectious endocarditis [31].

The present study has some limitations. The study group contained a small number of patients with old generation valves in which structural dysfunctions occurred more frequently. The majority of valves implanted nowadays are free from this complication. It is difficult to compare results presented by various authors because of differences concerning the analysed periods, material, methodology and lack of a common definition for redo procedure which would be accepted by all authors.

The research which was carried out and the analysis of the literature make it possible to propose an algorithm for treatment in patients qualified for reoperation because of valve dysfunction based mainly on echocardiographic assessment.

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