

# Influence of the patient's age on the probability of reoperation after aortic valve neocuspidalisation surgery (Ozaki technique)

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**The aim of this study** to determine the influence of age on the probability of postoperative regurgitation in patients of different age groups.

**Methods.** A single-centre retrospective study included 720 patients who underwent aortic valve neocuspidalisation surgery in Penza. Patients were divided into three groups according to age by WHO classification. Among them — 60 patients of young age group, 166 patients of middle age group and 494 elderly patients who underwent this procedure between 2015 and 2022.

**Results.** According to the data of our center, postoperative regurgitation occurred in 54 patients from different

age groups. Univariate regression analysis was performed to identify the significance of patient age as a predictor of postoperative regurgitation. The analysis revealed a statistically significant increase in the probability of regurgitation in younger patients. Increasing the age by 1 year decreases the probability of regurgitation by 3% (OD=0.970; p=0.03).

**Conclusion.** Neocuspidalisation surgery shows good long-term results. Younger age can be considered as a risk factor for postoperative regurgitation.

**Keywords:** Ozaki technique, neocuspidalisation, aortic valve stenosis.

**Conflict of interest:** none declared.

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## Introduction

Aortic valve (AV) stenosis is the most common indication for surgical intervention in valvular heart disease. In the Russian Federation, aortic stenosis (AS) occurs in 1–2% to 4% of patients over the age of 65. According to D.S. Bach, the prevalence of aortic valve disease is 1.4% in women, 2.7% in men, and 10.7% in people over 65. According to some studies, there is an association between the age of the patient and the prevalence of AS. Thus, in the group under 65 years of age, AS occurs in 0.2% of cases, in 65–74 years of age — 1.3% of cases, and in the group over 75 years of age — 2.8% of cases [1].

The indication for surgical treatment is a severe/critical AS. The issues of surgical tactics in this pathology are still under active discussion. To date, only AV replacement with biological or mechanical prostheses has found a place in clinical recommendations. The operation of neocuspidation of the AV leaflets from the autopericardium, proposed by S. Ozaki in 2011, is gaining popularity. This procedure has shown good results in elderly patients. However,

the prospects of this procedure in young (18–44 years according to WHO) and middle-aged (45–59 years according to WHO) patients remain controversial.

**The aim of this study** was to determine the influence of age on the probability of postoperative regurgitation in patients of different age groups.

## Methods

A single-centre retrospective study included 720 patients who underwent aortic valve neocuspidalisation surgery in Federal Centre of Cardiovascular Surgery of the Ministry of Health of Russia, Penza.

Patients were divided into three groups according to age by WHO classification. Among them — 60 patients of young age group, 166 patients of middle age group and 494 elderly patients.

The maximum follow-up period was 72 months.

Patients with coronary heart disease, multi-valve heart disease and other pathologies requiring surgical intervention were excluded from the study.

Table 1 shows the main clinical, demographic and echocardiographic data of the patients.

Table 1. Clinical, demographic and echocardiographic data of the patients before the surgery

Parameter, n	Young age, n=60	Middle age, n=166	Old age, n=494
<b>Clinical and demographic data</b>			
Age, years	35±7	54±4	66±4
Males, n	47 (74%)	104 (59%)	227 (46%)
BMI, kg/m <sup>2</sup>	26±5	29±5	30.2±5.02
Body surface area, m <sup>2</sup>	1.9±0.2	2±0.2	1.9±0.20
Diabetes, n	3(4%)	14(8%)	93 (19%)
Obesity, n	16(25%)	68(38%)	249 (50%)
EuroSCORE II	3.2±4.3	2.7±2.9	4.08±2.35
<b>Echocardiographic data</b>			
EF, %	53.13±15.16	58.5±12.49	59.81±12.25381
AVA, cm <sup>2</sup>	1.8±1.63	1.0 ±0.79	0.986598±0.804756
G mean, mmHg	30.3±20.38	42.7±21.99	47.71±21.59
G max, mmHg	54.0±34.79	73.4±34.73	82.36±35.76
Fibrous ring (FR), mm	24.3±4.11	23.11±3.46	22.39±3.103902

## Surgical technique

The procedure was performed through a median sternotomy. The autopericardium was then harvested and treated with glutaric acid solution, followed by exposure of the autopericardium to saline. Antegrade blood cardioplegia was performed in cases of preserved AV; in cases of insufficiency, cardioplegia was performed selectively in the coronary artery orifices. The intercommissural space was measured using classic Ozaki sizers after careful decalcification of the AV fibrous ring (FR). The excised leaflets were implanted in the desired position. The valve stability was assessed immediately after the implantation by hydroassay and by transesophageal echocardiogram control. The leaflets were stable in all patients.

## Statistical analysis

Statistical processing of the material was performed using SPSS version 21 software package (IBM Corp., Armonk, USA). The arithmetic mean ( $M = \sum / n$ ) and standard deviation from the general population ( $s$ ) were calculated to compare the results obtained between groups. Data are presented as mean ( $M$ ) and standard deviation ( $SD$ ) or as absolute values ( $n$ ) and percentages (%). Categorical data were compared using Pearson's criterion. The critical significance level was set at 0.05. Univariate regression analysis was performed to identify predictors of reoperation after AV neocuspidalisation.

## Results

The echocardiographic data of the patients after the surgery are shown in Table 2.

In the young age group, regurgitation was detected in 7 patients.

In the middle age group, regurgitation occurred in 19 patients.

In the elderly age group, regurgitation occurred in 28 patients.

Univariate regression analysis was performed to identify predictors of regurgitation after Ozaki operation. The results are presented in Table 3.

Based on the results of univariate regression analysis, age is a predictor of regurgitation. Increasing the age by 1 year reduces the probability of regurgitation in the remote postoperative period by 3% ( $OD=0.970$ ;  $p=0.01$ ).

## Discussion

Surgical treatment of AV defects (AVD) is becoming increasingly important as the population ages and the incidence of various AVD increases. It is particularly important to determine the surgical tactics in patients younger than 60 years of age. AV prosthesis with mechanical valve is the most commonly performed procedure for AVD.

However, this procedure has a significant impact on the patient's quality of life. The first is the need to take anticoagulants for the rest of the patient's life. This therapy is associated with a high risk of complications such as gastrointestinal bleeding, liver damage, etc. A special observation group is women of childbearing age, for whom pregnancy is contraindicated after AV prosthesis with mechanical valve, as well as patients with small AV FR, who often develop complications such as patient-prosthesis mismatch [4].

Table 2. The echocardiographic data of the patients after the surgery

Parameter, n	Young age, n=63	Middle age, n=175	Old age, n=494
LVEDV, ml	144±53,29	132,05±48,92	115,87±37,47
LVESV s, ml	61,05±43,10	56,66±36,68	47,52±26,42
Stroke volume (SV), ml	82,95±18,97	75,75±21,11	68,18±16,60
EF, %	60,27±8,97	59,63± 10,38	60,89±9,54
AVA, cm <sup>2</sup>	2,89±1,01	2,88±1,12	2,71±1,11
G mean, mmHg	6,79±3,87	6,75±4,37	6,44±4,45
G max, mmHg	13,82±8,15	14,20±9,10	13,57±8,24
FR, mm	23,15±3,03	22,05±2,88	20,98±2,69

Table 3. Results of the univariate regression analysis of reoperation

Predictors	OD	95% CI	p
Age	0,970	0,951-0,99	0,03

In 2011, S. Ozaki proposed an operation for AV leaflet neocuspidalisation (AVNeo) using autopericardium, pretreated with glutaric acid. This procedure showed good results in the older age group, with low mortality and reoperation rates [5].

According to the latest 2017 American Heart Association guidelines, patients with AVD between the ages of 50 and 70 can choose between a bioprosthesis and a mechanical prosthesis [6]. Implantation of a biological prosthesis frees the patient from taking anticoagulants, however, its durability is inferior to that of a mechanical one.

For patients with small FR of AV, guidelines favour transcatheter aortic valve implantation (TAVI), which has shown good results only in patients over 75 years old, and is still under the research in patients under 75 years [7].

The AVNeo procedure does not require anticoagulants, which makes future pregnancies possible, improves the quality of life, and increases the effective AV orifice due to the absence of a cuff to attach to the FR. Thus, this procedure may be an optimal solution for patients at high risk of bleeding, patients planning pregnancy, and patients with narrow FR [4, 8].

Amabile et al. point out in their study that the occurrence of aortic regurgitation is one of the most common causes of reoperation in patients (4.2%) [10].

Iida Y. et al. in their study of this technique in patients younger than 65 years old report a high survival rate (88.9% at 72 months of follow-up) and high reoperation-free rate (87.3% at 72 months of follow-up) of patients undergoing the Ozaki procedure [11].

According to some data, the occurrence of regurgitation in the postoperative period may be as high as 7% [12].

The Ozaki technique uses the patient's own pericardium, which, unlike other types of prostheses, is an inert tissue for the body. However, the pericardium undergoes various biodegradation processes. After implantation of neo-leaflet prostheses, hyperproliferation and hyperplasia of connective tissue are activated through various mechanisms. Also, immune-mediated factors leading to migration of immune cells (macrophages, neutrophils, T-lymphocytes, etc.) should be considered. All the above processes lead over time to irreversible changes of the neo-valve and its dysfunction. In the young age group, the biodegradation mechanisms are more prominent than in the older age group and lead to valve dysfunction faster [13, 14].

Our study included patients of different ages who underwent AVNeo surgery. It was found that younger patients had a higher risk of regurgitation than older patients. This will be the subject of further research.

## Conclusion

Neocuspidisation surgery shows good long-term results. It is now comparable to procedures such as TAVI and biological prosthesis implantation. This procedure is recommended for older patients because of the better long-term results in this group. Younger age can be considered a risk factor for regurgitation in the distant postoperative period.

**Conflict of interest:** none declared.

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