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# Clinical outcomes of percutaneous balloon valvuloplasty in patients with critical mitral stenosis

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## Abstract

**Background**: Clinical outcomes after percutaneous balloon valvuloplasty in patients with critical mitral stenosis is challenging and widely discussed.

**Aim** of the study was to analyze the results of balloon mitral valvuloplasty (BMV) using the Inoue technique in patients with critical mitral valve stenosis.

**Material and Methods:** From January 2020 to 2022, balloon mitral valvuloplasty was performed in 31 patients with critical mitral valve stenosis using the Inoue technique. There were 14 men (45.2%), women - 17 (54.8%). The patients were aged from 19 to 59 years, on average 42.4±6.1 years. All patients data were analyzed to evaluate the possible outcomes.

**Results**: In 30 (96.4%) patients, a successful BMV was performed. In 1 (3.2%) patients, PMV failed, including puncture was unsuccessful, and it was not possible to pass a balloon catheter from the LA to the LV through the critically narrowed mitral valve opening. These failures took place at the initial stages of mastering the technique. A lethal outcome was noted in 0 (0.0%) case. In all 30 (96.8%) patients after BMV, positive results were obtained: the area of the mitral orifice increased by an average of 2.5 times, from  $0.85\pm0.17$  to  $2.16\pm0.76$  cm2 (p< 0.001), the maximum gradient at the level of the mitral valve decreased by 60.5%, on average from  $26.9\pm2.95$  to  $8.9\pm0.6$  mm Hg. (p<0.0001). The maximum pressure in the LA statistically significantly decreased from  $40.29\pm6.01$  mm Hg. Art. up to  $21.43\pm3.83$  mm Hg (p<0.05), in LA - from  $49.7\pm10.9$  to  $29.7\pm8.2$  mm Hg. (p<0.05). According to EchoCG data, regurgitation on the mitral valve after BMV appeared in 6 (24.1%) patients up to I degree, in 1 (3.2%) - up to II, and in 1 (3.2%) - up to III. In 16 (61.5%) of 26 patients with initial mitral insufficiency after BMV, the degree of regurgitation remained at the same level, in 8 (30.7%) the latter increased to II, in 2 (7.7%) - to III degree.

**Conclusion**: BMV using the INOUE technique is a highly effective minimally invasive treatment method, accompanied by a low morbidity and mortality rate.

Keywords: Balloon valvuloplasty; Mitral stenosis; Mitral valve; Outcome

### 1. Introduction

Critical (severe) mitral valve stenosis (MVS) occurs in approximately 3.8% of people over 75 years of age [1]. MVS has a long latency period. However, from the moment the first symptoms appear (syncope, dyspnea, angina attacks, etc.), the average life expectancy is short. With the appearance of left ventricular (LV) dysfunction and chronic heart failure (CHF), it does not exceed 2 years [2].

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Several types of operations are used for surgical correction of mitral valve (MV) defect: MV replacement with mechanical and biological prostheses. Ross operation, endovascular interventions [3]. Over the past 40 years, operative mortality in MV replacement has ranged from 0.6 to 4.5% in the world's leading clinics [4,5]. According to the voluntary a registry, in-hospital mortality is 2.9–3.6% per year, and the risk of postoperative stroke is 1.5–1.8% [6]. In-hospital mortality in the United States is 8.8% [26]. In the case of surgical treatment in neglected patients, mortality can exceed more than 30% [7].

Currently, Euroscore risk assessment is an important factor in the decision to undergo surgery [8]. According to Euroscore, 1/3 of patients with MV malformation were denied surgery due to severe comorbidities, advanced age, atrial fibrillation, and heart failure (LV dysfunction).

Today, great hope is placed on endovascular methods, as they can improve outcomes in patients who have contraindications for open surgery, given that uncorrected mitral malformation has an extremely unfavorable prognosis. Thus, the PARTNER study provides data that in inoperable mitral stenosis, the 5-year survival rate is 4-5%. At the same time, the 5-year survival rate in operated patients was 85% [9].

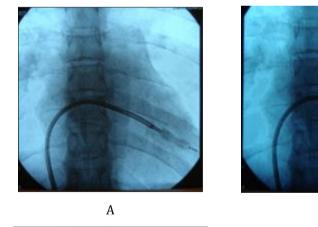
Percutaneous valve replacement (PVR) has been developed for patients with calcified MV stenosis who are considered inoperable [10,11]. To date, balloon valvuloplasty of the PVR in adult patients can be used as a "bridge" to MV repair in severe patients at high risk (class 2B, level of evidence C) [12].

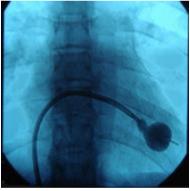
# Purpose

The purpose of this study is to analyze the results of BMV using the Inoue technique in patients with critical MVS.

# 2. Material and methods

From January 2020 to 2022, BMV was performed in 31 patients with critical MVS using the Inoue technique (Fig. 1.). There were 14 men (45.2%), women - 17 (54.8%). The patients were aged from 19 to 59 years, on average 42.4±6.1 years.





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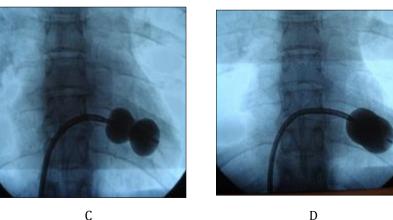


Figure 1 Inoue technique for the MVS

In 24 (77.4%) patients, mitral stenosis was primary, in 5 (16.1%) - restenosis, in 2 (6.4%) – restenosis. In 3 (9.6%) patients, the defect was complicated by a permanent form of atrial fibrillation. Of the patients with restenosis, 1 (3.2%) had a history of acute cerebrovascular insufficiency with left-sided hemiplegia. Of the concomitant diseases, 1 (3.2%) patient had bronchial asthma. All patients with MVS had a rheumatic etiology.

In patients with restenosis of the mitral orifice, BMV was performed from 2 to 18 years (on average, 12.81±5.24 years) after the previous commissurotomy.

All patients had a pronounced clinic of defect. In 29 (93.5%) patients with critical MVS, marked dyspnea at rest was noted, in 4 (13.8%) of them - a clinic of pulmonary edema. Two (6.4%) patients complained of shortness of breath and palpitations, cough with hemoptysis. In the rest of the patients, complaints were mainly of increased fatigue, arising from slight physical exertion.

In 19 (61.3%) patients, the appearance characteristic of MVS was noted: cyanosis of the lips and bright ruddy cheeks, indirectly indicating hypoxemia, low cardiac output and severe pulmonary hypertension.

Heart failure FC II according to NYHA was in 24 (77.4%) patients, FC III - in 5 (16.2%), FC IY - in 2 (6.4%) /

During auscultation, in all patients, an enhanced ("clapping") tone I was heard, as well as a "click" (tone) of the opening of the mitral valve, a diastolic murmur with presystolic amplification at the apex. In 17 cases, an accent of the II tone over the pulmonary artery was heard, indicating pulmonary hypertension.

On the ECG, 17 (54.83%) patients had sinus rhythm, 13 (42.0%) had atrial fibrillation. All showed signs of hypertrophy and dilatation of the left atrium, as well as signs of pancreatic hypertrophy.

According to EchoCG data, in 26 (84.4%) patients, the area of the mitral orifice (MVS) ranged from 0.8 to 1.47 cm2 (average  $1.1\pm0.23$  cm2), in 42 (13.5%) - from 0.4 to 0.79 cm2 (average  $0.67\pm0.18$  cm2). At the same time, the mobility of the mitral valve leaflets was limited. All patients had fibrosis of the valve leaflets of varying severity. In 2 (6.4%) patients, valve calcification of the I degree was found, in 1 (3.2%) - II degree and in 1 (3.2%) - III degree. In 3 (9.6%) patients, mitral valve regurgitation up to grade I was initially noted. 2 (6.4%) patients also had moderate aortic valve stenosis (GDM between the LV and the aorta up to 21 mm Hg), and 1 (3.2%) patients had aortic valve insufficiency up to grade I. Transmitral gradient according to Doppler echocardiography was from 18 to 34 mm Hg. (average  $26.9\pm2.95$ ). Systolic pressure in the pulmonary artery increased on average to  $55.68\pm14.07$  mm Hg, in 2 (6.4%) patients it exceeded 80 mm Hg (Fig 2, 3).



Figure 2 Photo of echocardiography before and after BMW MVS. The area of the mitral orifice before BMV was 0.9 cm2, after that it was 2.3 cm2

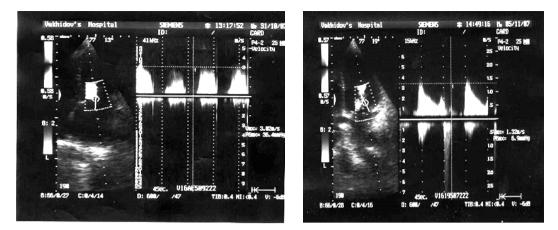


Figure 3 Doppler photo - echocardiography before and after BMW. Transmitral gradient before BMW - 36.4 mm Hg, after - 6.9 mm Hg

All patients with atrial fibrillation underwent transesophageal echocardiography to exclude thrombi in the LA. The presence of LA thrombosis was a contraindication to BMV. In 6 (19.2%) patients with severe MVS, spontaneous echocontrast of the LA was found. These patients, taking into account the potential for thrombus formation, were prescribed heparin 5,000 units 4 times a day s.c. before surgery, which was canceled 6 hours before the intervention.

Indications for BMV MVS were: clinical manifestations of the disease, mitral orifice area equal to 1.5 cm2 or less, transmitral gradient more than 10 mm Hg, mitral valve regurgitation not more than I degree. Mitral valve calcification located intramurally was not a contraindication for BMV, regardless of its distribution.

A contraindication to performing BMV was considered to be an area of the mitral hole of more than 1.5 cm2, the presence of regurgitation on the mitral valve of more than II degree, thrombosis of the left atrium, massive calcification, the absence of adhesions between the commissures, and severe aortic malformation.

The criteria for the success of the BMV SMO were: an increase in the area of the mitral orifice by more than 1.5 cm<sup>2</sup>, opening of at least one of the intercommissural adhesions, a decrease in the transmitral gradient below 10 mm Hg, the absence or appearance of regurgitation on the mitral valve of not more than I degree, clinical improvement in the condition.

# 3. Results and discussion

In 30 (96.4%) patients, a successful BMV was performed. In 1 (3.2%) patients, PMV failed, including puncture was unsuccessful, and it was not possible to pass a balloon catheter from the LA to the LV through the critically narrowed mitral valve opening. These failures took place at the initial stages of mastering the technique. A lethal outcome was noted in 0 (0.0%) case.

Intraoperative echocardiography plays an important role in evaluating the immediate results of the BMV MVS, with the help of which it is possible to accurately determine the area of the mitral orifice after each stage of mitral orifice expansion, the degree of opening of intercommissural adhesions, the dynamics of the transmitral gradient, the state of regurgitation on the mitral valve, which are important for early diagnosis of possible complications [13,14].

In all 30 (96.8%) patients after BMV, positive results were obtained: the area of the mitral orifice increased by an average of 2.5 times, from  $0.85\pm0.17$  to  $2.16\pm0.76$  cm2 (p< 0.001), the maximum gradient at the level of the mitral valve decreased by 60.5%, on average from  $26.9\pm2.95$  to  $8.9\pm0.6$  mm Hg. (p<0.0001) (Fig. 2). The maximum pressure in the LA statistically significantly decreased from  $40.29\pm6.01$  mm Hg. Art. up to  $21.43\pm3.83$  mm Hg (p<0.05), in LA - from  $49.7\pm10.9$  to  $29.7\pm8.2$  mm Hg. (p<0.05) (Figures 3). According to EchoCG data, regurgitation on the mitral valve after BMV appeared in 6 (24.1%) patients up to I degree, in 1 (3.2%) - up to II, and in 1 (3.2%) - up to III. In 16 (61.5%) of 26 patients with initial mitral insufficiency after BMV, the degree of regurgitation remained at the same level, in 8 (30.7%) the latter increased to II, in 2 (7.7%) - to III degree.

During the BMW and after it, no serious hemodynamic disturbances and complications were observed. In 10 (32.3%) patients with atrial fibrillation on the next day after surgery, electrical cardioversion was performed, in 9 (90.7%) of them it was possible to restore sinus rhythm.

In 2 (6.4%) patients with mitral stenosis, BMV was performed at 23 to 29 weeks of gestation. At the same time, their MVS varied from 0.9 to 1.36 cm2 (1.18  $\pm$  0.36 cm2 on average), the gradient on the MC ranged from 18 to 28 mm Hg. (average 22.1 $\pm$ 4.6 mm Hg). In all patients, BMV was adequately performed without any complications. It should be noted that interventions in these patients were performed in the mode of maximum protection from ionizing radiation. In addition to the standard protection, the abdominal area was obligatorily covered from all sides with a protective apron. Also, at all stages, the time of fluoroscopy was minimized and it was used to control only the most important stages of the intervention (MPP puncture, balloon insertion and expansion). The fluoroscopy itself was performed at a low (LOW) level and pulse mode. All this made it possible to significantly reduce the level of irradiation of the mother and fetus. On the 2-3rd day, all of them were discharged in a satisfactory condition from the hospital. In the future, all patients spontaneously gave birth to healthy children without any complications.

On the first day after the operation, all patients showed a significant positive dynamics of the clinical and functional state. All patients noted a significant improvement in their general condition. None of the patients complained at rest, cyanosis of the skin and other manifestations of MVS disappeared.

All patients were discharged in a satisfactory condition for 1-2 days from the hospital, with the recommendation of observation by a rheumatologist. Three patients with severe mitral regurgitation of III degree were recommended surgical correction of the defect.

# 4. Conclusion

Balloon mitral valvuloplasty using the INOUE technique is a highly effective minimally invasive treatment method, accompanied by a low morbidity and mortality rate. Successfully performed balloon mitral valvuloplasty leads to a significant improvement in the clinical and hemodynamic parameters of patients with mitral stenosis. Balloon mitral valvuloplasty may be an alternative to surgical correction of the defect. Furthermore, BV MVR can significantly reduce the risk of death during the subsequent replacement of MV in adult patients with high surgical risk.

# **Compliance with ethical standards**

### Acknowledgments

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### Disclosure of conflict of interest

The authors have nothing to declare in relation to this presentation.

### Statement of ethical approval

The study was approved at the ethical committee of the Republican Specialized Scientific Center of Emergency Medical Care.

### Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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