CLINICAL STUDY

Long-Term Prognosis of Patients Who Underwent Percutaneous Transvenous Mitral Commissurotomy for Mitral Stenosis

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Summary
The long-term prognosis for up to 20 years of patients who have undergone percutaneous transvenous mitral commissurotomy (PTMC) for mitral stenosis (MS) is unknown.
We examined 77 of 93 patients (83%) with MS and who underwent PTMC from 1989 to 2002 at our institute, as well as the occurrence of either one of the following clinical endpoints until September 1, 2018: all-cause death or repeat intervention for the mitral valve.
The mean follow-up duration was 20.5 ± 7.3 years. The mean age was 51 ± 11 years. Overall, the 20-year survival rate was 71% ± 5%; without any intervention, the 20-year survival rate was 40% ± 6%. In patients who achieved good immediate results (i.e., mitral valve area (MVA) of ≥ 1.5 cm² without mitral regurgitation (MR) of > 2/4 after PTMC), the 20-year survival rate was 80% ± 6%; without any intervention, the 20-year survival rate was 54% ± 7%.

In our 20-year observational study, patients who have undergone PTMC for MS had favorable prognosis, especially in those who achieved good immediate results. In those who had poor immediate results, careful follow-up is needed because they might have more clinical event and any intervention for the mitral valve.

Key words: Inoue balloon, Mitral valve area, Survival rate
Table I. Baseline Characteristics of the Entire Population

| Characteristic                          | All Patients (n = 77) |
|----------------------------------------|-----------------------|
| Age, years                             | 51 ± 11               |
| Female sex, n (%)                      | 61 (79)               |
| Height (cm)                            | 155 ± 8               |
| Weight (kg)                            | 52 ± 9                |
| NYHA functional class, n (%)           |                       |
| I                                      | 4 (5)                 |
| II                                     | 57 (74)               |
| III                                    | 16 (21)               |
| IV                                     | 0 (0)                 |
| Previous commissurotomy, n (%)         | 12 (16)               |
| Atrial fibrillation, n (%)             | 57 (74)               |
| Ejection fraction, %                   | 59 ± 10               |
| Left atrial diameter, mm               | 51 ± 10               |
| Preoperative mitral valve area, cm²    | 1.1 ± 0.3             |
| Preoperative mean mitral gradient, mmHg| 11 ± 5                |
| Final mitral valve area, cm²           | 1.8 ± 0.4             |
| Final mean mitral gradient, mmHg      | 5 ± 2                 |
| Balloon size, n (%)                    |                       |
| 22 mm                                  | 5 (6)                 |
| 24 mm                                  | 24 (31)               |
| 26 mm                                  | 39 (51)               |
| 28 mm                                  | 9 (12)                |

Table II. Outcomes of the Entire Population

| Outcome                          | All Patients (n = 77) |
|----------------------------------|-----------------------|
| Death, n (%)                     | 26 (34)               |
| Cardiovascular                   | 12 (16)               |
| Intervention, n (%)              | 32 (42)               |
| Repeat PTMC                      | 2 (3)                 |
| MVR                              | 30 (39)               |

PTMC indicates percutaneous transvenous mitral commissurotomy; and MVR, mitral valve replacement.

Results

Follow-up was completed for 77 patients (83%). We excluded 16 patients due to loss of contact or because there was no preserved medical record. The mean follow-up duration was 20.5 ± 7.3 years. Of the 77 patients, 55 had good immediate results and 22 had poor immediate results (Figure 1).

Entire population (analysis 1): The baseline characteristics of the entire population are detailed in Table I. The mean age at the time of intervention was 51 ± 11 years, and 79% were women; 12 patients underwent a previous mitral commissurotomy. The MVA increased from 1.1 ± 0.3 to 1.8 ± 0.4 cm² after PTMC. None of the patients had severe adverse events, including severe MR requiring emergency surgery in the acute phase. During the follow-up, 26 patients (34%) died, 12 of which were cardiovascular-related. Thirty-two patients (42%) under-
went repeat intervention for the mitral valve; MVR was performed on 30 patients (39%) and repeat PTMC on 2 (3%) (Table II). The Kaplan-Meier curve of the entire population is shown in Figure 2. The 10-year survival rate was 87% ± 4%, and the 20-year survival rate was 71% ± 5%. Without any mitral intervention, the 20-year survival rate was 40% ± 6%.

**Table III.** Baseline Characteristics of Both Groups

|                          | Good immediate results | Poor immediate results | Good versus poor |
|--------------------------|------------------------|------------------------|------------------|
| **Age, years**           | 50 ± 11                | 55 ± 9                 | *P* = 0.049      |
| **Female sex, n (%)**    | 41 (75)                | 20 (91)                | *P* = 0.13       |
| **Height, cm**           | 156 ± 8                | 152 ± 7                | *P* = 0.053      |
| **Weight, kg**           | 53 ± 9                 | 49 ± 8                 | *P* = 0.069      |
| **NYHA functional class, n (%)** |                      |                        | *P* < 0.001     |
| I                        | 4 (7)                  | 0 (0)                  |                  |
| II                       | 46 (84)                | 11 (50)                |                  |
| III                      | 5 (9)                  | 11 (50)                |                  |
| IV                       | 0 (0)                  | 0 (0)                  |                  |
| Previous commissurotomy, n (%) | 8 (15)                | 4 (18)                 | *P* = 0.73       |
| Atrial fibrillation, n (%) | 38 (69)                | 19 (86)                | *P* = 0.16       |
| Ejection fraction, %     | 60 ± 8                 | 56 ± 12                | *P* = 0.18       |
| Left atrial diameter, mm | 50 ± 10                | 53 ± 10                | *P* = 0.28       |
| Preoperative mitral valve area, cm² | 1.2 ± 0.3             | 0.9 ± 0.3              | *P* < 0.01       |
| Preoperative mean mitral gradient, mmHg | 11 ± 5                | 10 ± 4                 | *P* = 0.48       |
| Final mitral valve area, cm² | 2.0 ± 0.3             | 1.3 ± 0.2              | *P* < 0.01       |
| Final mean mitral gradient, mmHg | 5 ± 2                 | 6 ± 2                  | *P* = 0.06       |
| Final mitral regurgitation, n (%) |                      |                        | *P* < 0.01       |
| 0                        | 27 (49)                | 3 (14)                 |                  |
| 1                        | 19 (35)                | 12 (55)                |                  |
| 2                        | 9 (16)                 | 5 (23)                 |                  |
| 3                        | 0 (0)                  | 2 (9)                  |                  |
| 4                        | 0 (0)                  | 0 (0)                  |                  |
| Balloon size, n (%)      |                        |                        | *P* = 0.11       |
| 22 mm                    | 2 (4)                  | 3 (14)                 |                  |
| 24 mm                    | 17 (31)                | 7 (32)                 |                  |
| 26 mm                    | 27 (49)                | 12 (55)                |                  |
| 28 mm                    | 9 (16)                 | 0 (0)                  |                  |

Values are mean ± SD. NYHA indicates New York Heart Association.
Figure 3. Kaplan-Meier curves of both groups (analysis 2). A: In the group with good immediate results, the 10- and 20-year survival rates without all-cause death are 91% ± 4% and 80% ± 6%, respectively. B: The 20-year survival rate without intervention is 54% ± 7% in the group with good immediate results and only 5% ± 4% in the group with poor immediate results.

Table IV. Outcomes of Both Groups

|                      | Good immediate results | Poor immediate results |
|----------------------|------------------------|------------------------|
| n (n)                | 55 (26)                | 22 (55)                |
| Death, n (%)         | 14 (26)                | 12 (55)                |
| Cardiovascular       | 7 (13)                 | 5 (23)                 |
| Intervention, n (%)  | 20 (36)                | 12 (55)                |
| Repeat PTMC          | 2 (4)                  | 0 (0)                  |
| MVR                  | 18 (33)                | 12 (55)                |

PTMC indicates percutaneous transvenous mitral commissurotomy; and MVR, mitral valve replacement.

Discussion

This study revealed that the prognosis of patients with MS who underwent PTMC at Niigata University Medical Hospital was favorable. At 20 years after PTMC, 71% ± 5% of all patients and 40% ± 6% of those who did not receive any intervention for the mitral valve survived. In particular, in those with good immediate results, 80% ± 6% of all patients and 54% ± 7% of those who did not receive any intervention for the mitral valve survived after 20 years of the PTMC. We believe that this is the first study to report about the long-term prognosis (up to 20 years) of PTMC in Japanese population.

Reports on the long-term (>10 years) prognosis after PTMC are few, even in Japan. Bouleti et al.12 reported that of the 1,024 patients (mean age, 49 years) followed up for a median of 10.7 years after PTMC, the 20-year survival rates were 73% ± 2% overall and 34% ± 2% for those who did not receive intervention. Among patients who obtained good immediate results (n = 912), the 20-year survival rates were 75% ± 2% overall and 38% ± 2% without intervention. On the other hand, for surgical commissurotomy,3-5 the 20-year survival rate was reported to be 60%-70%, and the 20-year rate for freedom from reoperation was 50%-80%. Considering these previously reported results of PTMC and surgical commissurotomy, the long-term prognosis of our patients was relatively satisfac-
The reported predictors of poor long-term outcome after PTMC were Wilkins score of >8, increasing age, prior surgical commissurotomy, higher NYHA functional class, higher final mean gradient, MR of > 2, and smaller final MVA.\(^{(13)}\) These data suggested that the achievement of good immediate results may be difficult in patients with poor mitral valve characteristics secondary to old age or prior surgical commissurotomy.

In this study, the long-term prognosis depended on the achievement of good immediate results in the acute phase of PTMC. Mitral restenosis is a major cause of repeat intervention. It has been reported that the MVA decrease by 0.2 cm\(^2\) and that restenosis occur every 5 years.\(^{(13,15,16)}\) Therefore, if patients could not obtain an MVA of ≥1.5 cm\(^2\) in the acute phase, restenosis can occur earlier, requiring early repeat intervention. Similar to previous reports, our study suggested that the achievement of good immediate results may be difficult in patients who are relatively old and have high NYHA functional class and small MVA before and after PTMC and severe MR after PTMC. In this study, half of the patients who had good immediate results survived for 20 years without any mitral intervention.

**Study limitations:** This study was a single-center study on a small number of patients. Most of the patients were followed up outside our hospital; therefore, we could not ascertain the occurrence of heart failure or embolism after PTMC, as well as examine valve function.

**Conclusions**

In our 20-year observational study, patients who have undergone PTMC for MS had favorable prognosis, especially in those with good immediate results. In those with poor immediate results, careful follow-up is need because they might have more clinical event and any intervention for the mitral valve.

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**Disclosure**

**Conflicts of interest:** All authors have no conflicts of interest to declare.

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