Role of the learning curve in very high–risk patients treated with MitraClip device for functional mitral regurgitation: a single-centre experience

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INTRODUCTION
The MitraClip device allows a minimally invasive repair of mitral regurgitation (MR). The available data confirm the safety and efficacy of the procedure despite its complexity [1–9]. The aim of our study was to assess the role of the learning curve in the MitraClip procedure in patients with functional MR.

METHODS
The study summarises a single-centre experience on all MitraClip procedures performed from 2012 to 2017. In this research, a retrospective analysis of clinical data was performed. The technical aspects of the MitraClip device implantation performed under transoesophageal echocardiography (TEE) guidance were described previously [1]. There were three interventional cardiologists (A.W., Z.C., and J.P.) including one (J.P.) who attended all the procedures guided by the same echocardiographer (P.S.). Except for the first two procedures, we used the same TEE device (General Electric Healthcare, Chicago, IL, USA) with the three-dimensional option. The clips were finally implanted and released if a significant reduction of MR was achieved without creating significant stenosis defined as a mean mitral gradient (MMG) ≥ 5 mmHg. The total device time was defined as the period between transseptal puncture and removal of a steerable guiding catheter from the femoral vein. Prior to discharge, all patients underwent control transthoracic echocardiography (TTE) with a focus on the stability of the clip position, MR grade, and MMG. An uncomplicated MitraClip implantation and MR reduction to grade ≤ 2+ assessed on the pre-discharge TTE was defined as a procedural success. All patients were scheduled for 30-day clinical follow-up. The procedure-related variables as well as immediate and 30-day results were compared between two groups of patients treated in two consecutive time periods. Continuous data were presented as mean ± standard deviation. We used either the independent-samples t test or the Mann-Whitney test to compare continuous variables. Categorical variables were presented as numbers and percentages and were compared using the χ² test.

RESULTS AND DISCUSSION
Between May 2012 and December 2017, we performed 53 MitraClip procedures (43 men; mean age, 67.8 ± 7.2 years). All subjects who underwent the procedure were diagnosed with heart failure and significant functional MR. Most (87%) patients were in functional New York Heart Association (NYHA) class III or IV. The mean left ventricular ejection fraction (LVEF) was 28% ± 9%. The majority of patients had pulmonary hypertension with a mean pulmonary artery systolic pressure of 52 ± 14 mmHg.

In the first four years (2012–2016) of the MitraClip programme, we performed 26 implantations (4–6 procedures per year; group 1). In 2017 the number of procedures significantly increased, and 27 patients were treated (group 2). The baseline demographic and clinical characteristics of patients were similar in both groups, except lower LVEF in group 2 (25% ± 10% vs. 31% ± 7%; p = 0.03).

Within 30 days of the procedure, three (5.6%) patients died (one patient from group 1 and two patients from group 2;
Learning curve during MitraClip procedure

The major finding from the current study is that the MitraClip procedure for functional MR requires a significant learning curve. As the team’s experience increased, the procedural time shortened and the acute results improved. However, we did not identify any impact of the learning curve on the incidence of procedural complications, MMG, or functional NYHA classification.

Interestingly, even though intuitively the MitraClip procedure requires a learning curve for its complexity, data on the relation between the operators’ experience and the procedure outcomes are conflicting [7–9]. Ledwoch et al. [7] did not report any impact of the learning curve on procedural safety, time, and acute MR reduction. The authors suggested that a strict proctoring system allows optimal results even during initial experience with the device. On the other hand, Schillinger et al. [8] and Eleid et al. [9], similarly to our data, reported a significant effect of the learning curve on the procedural time. However, neither Schillinger et al. [8] nor Eleid et al. [9] noted a significant influence of case experience on the extent of MR reduction. Interestingly, in both those studies, increasing experience with the device translated into a lower rate of complications, while in our experience the complication rate was constant. The possible explanation of the differences between our study and previous reports could be different MR aetiology (functional in our group vs. functional or primary in previous papers).

In our group MMG measured within a few days of the procedure exceeded 5 mmHg in about 20% of patients even though it was lower immediately after the procedure. This finding is in line with the report by Boerlage-van Dijk et al. [10], who also noticed a significantly higher gradient in daily life after the procedure than during MitraClip implantation. Importantly, several authors found that higher post-procedural mitral gradients are linked to worse clinical outcome [11, 12]. The difference between our study and previous reports could be different MR aetiology (functional in our group vs. functional or primary in previous papers).

In conclusion, the learning curve significantly influences procedural time and acute results in very high-risk patients with functional MR treated with MitraClip.

Conflict of interest: none declared

References


