The role of learning curve in very high risk patients treated with the MitraClip device for functional mitral regurgitation. The single center experience

Authors: Adrian Kłapyta, Jerzy Pregowski, Zbigniew Chmielak, Piotr Szymański, Jarosław Skowroński, Patrycjusz Stokłowa, Krzysztof Kukuła, Mariusz Kłopotowski, Paweł Tyczynski, Paweł Jelski, Łukasz Kalińczuk, Kacper Milczanowski, Adam Witkowski

DOI: 10.5603/KP.a2018.0192

Article type: Short communications

Submitted: 2018-05-23

Accepted: 2018-08-01

Published online: 2018-09-11

This article has been peer reviewed and published immediately upon acceptance. It is an open access article, which means that it can be downloaded, printed, and distributed freely, provided the work is properly cited.
Articles in "Polish Heart Journal" are listed in PubMed.
The role of learning curve in very high risk patients treated with the MitraClip device for functional mitral regurgitation. The single center experience

Brief title: Learning curve during MitraClip procedure

Adrian Kłapyta1*, Jerzy Pręgowski2*, Zbigniew Chmielak2, Piotr Szymański2, Jarosław Skowroński2, Patrycjusz Stokłosa2, Krzysztof Kukula2, Mariusz Kłopotowski2, Paweł Tyczyński2, Paweł Jelski2, Łukasz Kalińczuk2, Kacper Milczanowski2, Adam Witkowski2

1Freelance
2Institute of Cardiology, Warsaw, Poland
*Both authors equally contributed to the study.

Address for correspondence:

Dr. Jerzy Pręgowski, Institute of Cardiology, ul. Alpejska 42, 04–628 Warszawa, Poland, e-mail: jerzypregowski74@gmail.com

INTRODUCTION

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

METHODS

The study summarises the single centre experience on all MitraClip procedures performed from 2012 till 2017. In this research, retrospective analysis of clinical data was performed. The technical aspects of the MitraClip device implantation performed under transesophageal echocardiography guidance (TEE) 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 (General Electric Healthcare) with three-dimensional option. The clips were finally implanted and released if significant reduction of MR was achieved without creating significant stenosis defined as mean mitral gradient (MMG) $\leq 5$ mmHg. The total device time was defined as period between trans-septal puncture, continued with insertion and removal of steerable guiding catheter from the femoral vein. Prior to the discharge, all patients underwent control transthoracic echocardiography (TTE) with focus on the stability of the clip position, MR grade, as well as MMG. An uncomplicated MitraClip implantation and MR reduction to grade $\leq 2+$ assessed in the pre-discharge TTE, were defined as a procedural success. All patients were scheduled for 30 day clinical follow-up. The procedure related variables and immediate and 30 day results were compared in the two groups (group 1, n = 26 patients and group 2, n = 27 patients) in two consecutive treatment periods. Continuous data are presented as means $\pm$ standard deviation. We used either independent-samples t test or Mann-Whitney test to compare continuous variables. Categorical variables are presented as numbers and percentages and compared using the chi-square test.

Results and Discussion

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

Over 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 the procedures significantly increased and 27 patients were treated (group 2). The baseline demographic and clinical patients’ characteristics were similar in both groups, with the exception of the lower LVEF in group 2 (25% $\pm$ 10% vs. 31% $\pm$ 7%; p = 0.03).

Within 30 days from the procedure, three (5.6%) patients died (one patient from group 1 and two patients from group 2; p = 0.6). One death (group 1) was directly related to the MitraClip procedural complication (leaflet rupture). In group 2 two deaths occurred: one in
the course of deteriorating heart failure and one sudden cardiac death. Two patients from group 1 required mitral valve surgery including one urgent in a patient with acute leaflet rupture. Partial clip detachment occurred in two patients from group 1 and in two patients from group 2 ($p = 0.5$).

In the whole study group of patients who survived 30 days there were 16 subjects in NYHA class III or IV as compared to 46 patients with severe symptoms prior to the intervention ($p < 0.001$). However, at 30 days the number of patients in functional NYHA class > 2 was similar in group 1 and group 2 (10 vs. 6; $p = 0.6$).

The total device time and fluoroscopy time were significantly shorter in group 2 (166 ± 62.5 vs. 106.3 ± 44.9; $p = 0.0002$ and 61.5 ± 25.1 min vs. 41.0 ± 18.9 min; $p = 0.0014$, respectively) while the number of clips implanted was similar in both groups (1.8 ± 0.6 vs. 1.9 ± 0.5; $p = 0.8$). The residual MR after the procedure was smaller in group 2 (Fig. 1). The procedure success defined as MR grade ≤ 2+ was achieved in 77% of patients in group 1 and in 96% from group 2 ($p = 0.039$). In the TEE performed at the end of the procedure there were no subjects with MMG ≥ 5, but in the postprocedural TTE the moderate iatrogenic mitral stenosis was found with the similar prevalence in both study groups (4 [15%] vs. 6 [22%]; $p = 0.5$).

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

Interestingly, even though intuitively the MitraClip procedure requires learning curve for its complexity, the data on relation between operators’ experience and the procedure outcomes are conflicting [7–9]. Ledwoch et al. [7] did not find any impact of learning curve on procedural safety, time, and acute MR reduction. The authors suggested that strict proctoring system allows optimal results even during initial experience with the device.

Nonetheless, Schillinger et al. [8] and Eidel et al. [9] similarly to our data, reported significant impact of learning curve on the procedural time. However, neither Schillinger et al. [8] nor Eidel et al. [9] noticed significant influence of case experience on the magnitude of MR reduction. Interestingly, in both studies mentioned above the increasing experience with the device translated into lower rate of complications while in our experience the complication rate was constant.
The speculative 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 after the procedure exceeded 5 mmHg in around 20% of patients even though it was lower immediately after procedure. This finding is in line with the report by van-Dijk et al. [10] who also noticed significantly higher gradient in daily life post procedure than during MitraClip implantation. Importantly, several authors found that higher post-procedural mitral gradients are linked to worse clinical outcome [11, 12]. According to our data the mitral valve gradient was not affected by the learning curve. This is a new information as so far there was no data on the impact of case experience on the risk of iatrogenic mitral stenosis. It is possible that avoidance of increased MMG is the part of the procedure that will remain the “most resistant” to the learning curve as there will always be a need for compromise between optimal MR reduction and risk of significant iatrogenic stenosis.

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

Conflict of interest: none declared

References


Figure 1. Residual mitral regurgitation (MR) after MitraClip procedure in both study groups
Figure 1. Residual MR after MitraClip implantation

p=0.0531 (chi2)*