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Prikaz pacijenta

# Percutaneous repair of mitral regurgitation with the Mitraclip system: clinical indications and first Slovenian experience

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**Abstract** The MitraClip is the first percutaneous therapy for mitral regurgitation. It can be used in both etiologies: primary (degenerative) and secondary (functional) mitral regurgitation. The technique mimics surgical suture-based approach by implanting a clip that grasps free edges of both leaflets and creates dual mitral valve orifice. After Conformité Européenne (CE) mark in 2008, the MitraClip system is increasingly used in Europe for both types of mitral regurgitation. The Food and Drug Administration (FDA) so far has approved the Mitraclip only for patients with severe primary mitral regurgitation who are at high surgical risk. The decision for the MitraClip therapy should be accepted within the heart team. Transesophageal echocardiography plays a key role in selection of the patients, procedural guidance and follow-up and is essential to the Mitraclip success. First Mitraclip implantation performed in Slovenia is presented.

**Key words:** mitral regurgitation, MitraClip, first experience

## Introduction

Percutaneous transcatheter mitral valve repair using the MitraClip system (MClip, Abbott Vascular, Abbott Park, Illinois, USA) is a relatively novel method for treatment of mitral regurgitation. The technique is based on the creation of a double mitral orifice, similar to surgical Alfieri's stitch, by connecting ideally the middle scallops of the anterior and the posterior leaflet of a regurgitant mitral valve[1]. The MClip is currently the only percutaneous procedure available in clinical practice. According to the latest European and American guidelines it is considered as an alternative treatment for selected high-risk inoperable patients with primary mitral regurgitation[2,3]. The European guidelines have included MClip as a potential option also for patients with secondary mitral regurgitation due to ischemic or non-ischemic dilated cardiomyopathy who remain symptomatic despite optimal medical therapy and cardiac resynchronization when indicated[2] (Table 1). Namely, surgical correction of secondary MR is controversial, because the primary pathology is left ventricular dysfunction and not the diseased mitral valve, the results of surgery are not favorable and operative mortality is much higher compared to primary mitral disease[4,5]. The initial data of the EVEREST trials (Endovascular Valve Edge-to-Edge Repair Study), including predominately patients with degenerative mitral regurgitation demonstrated feasibility and safety of the MClip procedure. Compared to surgery percutaneous repair was less effective at reducing mitral regurgitation[6,7]. Subsequent studies and registries have confirmed MClip feasibility and low procedural risk and shown promising results in terms of reducing mitral regurgitation grade, improvement of functional status and quality of life[8-11]. In real-life practice there has been a shift in the indications for MClip toward secondary mitral regurgitation, which presents currently about 80% of MClip implantations in Europe.

Patient selection for the MClip therapy depends on clinical factors as well as specific anatomical criteria that need to be fulfilled. Echocardiography has an essential role in patient selection and evaluation of the final results after clip implantation. Moreover, it is the central imaging modality for guiding the procedure[12]. The first step in the patients selection is to assess the severity of mitral regurgitation, then to determine the morphology of the mitral valve and abnormalities in left ventricular function. According to the EVEREST studies mitral regurgitation needs to be moderate to severe or severe (grade 3+ or 4+, respectively, when classifying regurgitation into four grades). The mitral valve morphology and the etiology of mitral regurgitation should be assessed in detail by transoesophageal echocardiography (TEE), as suitable morphology is essential to a successful Mitraclip procedure. For patients with secondary mitral regurgitation, the co-

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**Table 1.** Indications for percutaneous mitral valve repair using the Mitraclip system according to the latest European and American guidelines.

| | ESC | AHA/ACC |
|---|---|---|
| | **Class of recommendation/ level of evidence** | **Class of recommendation/ level of evidence** |
| Percutaneous mitral valve repair may be considered in patients with symptomatic severe **primary** MR who fulfill the echo criteria of eligibility, are judged inoperable or at high surgical risk by a heart team and have life expectancy greater than 1 year | **IIb C** | **IIb B** |
| Percutaneous mitral valve repair may be considered in patients with symptomatic severe **secondary** MR despite optimal medical therapy (including CRT if indicated) who fulfill the echo criteria of eligibility, are judged inoperable or at high surgical risk by a heart team and have life expectancy greater than 1 year | **IIb C** | |

ESC=European Society of Cardiology guidelines on the management of valvular heart
Disease, AHA/ACC=American Heart Association/American College of Cardiology guidelines on the management of valvular heart disease, MR=mitral regurgitation, CRT=cardiac resynchronization therapy.

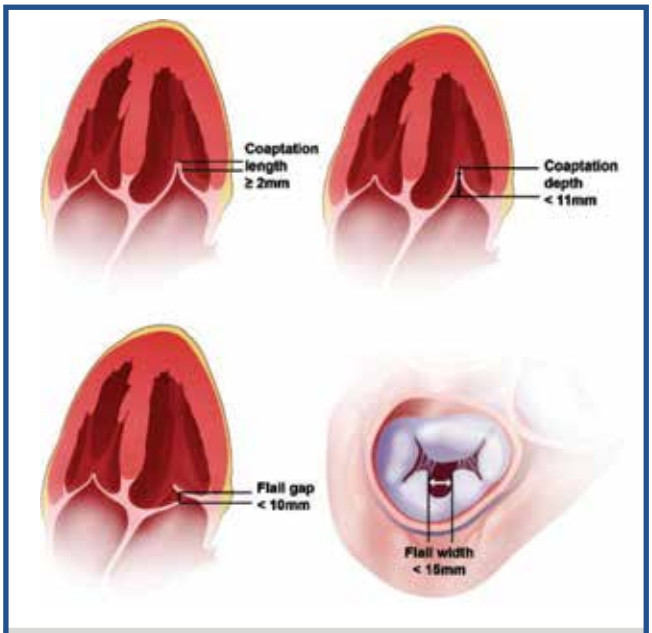


**Figure 1.** Anatomic eligibility criteria for MitraClip (EVEREST trial). In secondary MR the coaptation length must be at least 2 mm and coaptation depth <11 mm, so that there is some tissue for grasping with the clip. In primary MR with prolapse and/or flail, flail depth must be <10 mm and flail width <15 mm. EVEREST=Endovascular valve edge-to-edge repair study, MR=mitral regurgitation.

aptation length must be at least 2 mm, and the coaptation depth < 11 mm. For patients with primary mitral regurgitation due to prolapse or flail leaflet, the gap of the prolapsed or flailed segment must be <10 mm and its width <15 mm (Figure 1). MClip is not applicable to patients not fulfilling above echocardiographic criteria, those with rheumatic mitral disease or with calcifications of the grasping area. The mitral valve area should not be less than 4 cm² in order to avoid creating mitral stenosis after the procedure[6,7].

We present the first Slovenian MClip procedure in a patient with secondary mitral regurgitation due to ischemic cardiomyopathy.

## Case report

A 75-year old man with a long history of diabetes type 2 on insulin, arterial hypertension, hypercholesterolemia and chronic renal disease (creatinine of 150 µmol/L) had been admitted to our department for heart failure. He had a history of surgical coronary revascularization 2 years ago (LIMA to LAD and vein grafts to RCA and OM1). In 2014 he was admitted to our hospital with heart failure and angina. Coronary angiogram had shown occlusion of all grafts and percutaneous coronary recanalization of LAD, LCX and RCA was undertaken. 6 months later he was admitted again due to heart failure. He was in sinus rhythm, with narrow QRS complex. Transthoracic echocardiography demonstrated mild enlargement of the left ventricle with moderately reduced ejection fraction (45%), akinesia of the apical segments and hypokinesia of inferior and inferolateral wall. Significant functional mitral regurgitation was present that was graded as severe regarding the ischemic etiology (effective regurgitant orifice area of 0.26 cm², regurgitant volume of 30 ml). Right ventricle function was preserved and estimated systolic pulmonary pressure was 55 mmHg. According to nuclear imaging the antero-apical myocardial wall was non-viable. TEE confirmed normal morphology of the mitral valve and reviled the mechanism of regurgitation: left ventricular remodeling with symmetric tenting and malcoaptation of the mitral valve leaflets. Echocardiographic anatomical criteria were suitable for Mitraclip implantation (Figure 2). The patient's coronary situation was the same as 6 months before; there were no additional revascularization options. He was already on optimal medical therapy and not a candidate for cardiac resynchronization. His therapeutic options were discussed at our hospital heart team which agreed that he was suitable for a Mitraclip procedure.

The procedure was done under general anaesthesia, with a venous femoral access. The interatrial septum was punctured in postero-superior aspect under TEE guidance, using short axis, bicaval and four chamber views (Figure 3). The 24F Mitraclip catheter was introduced into the left atrium. According to the wide mitral

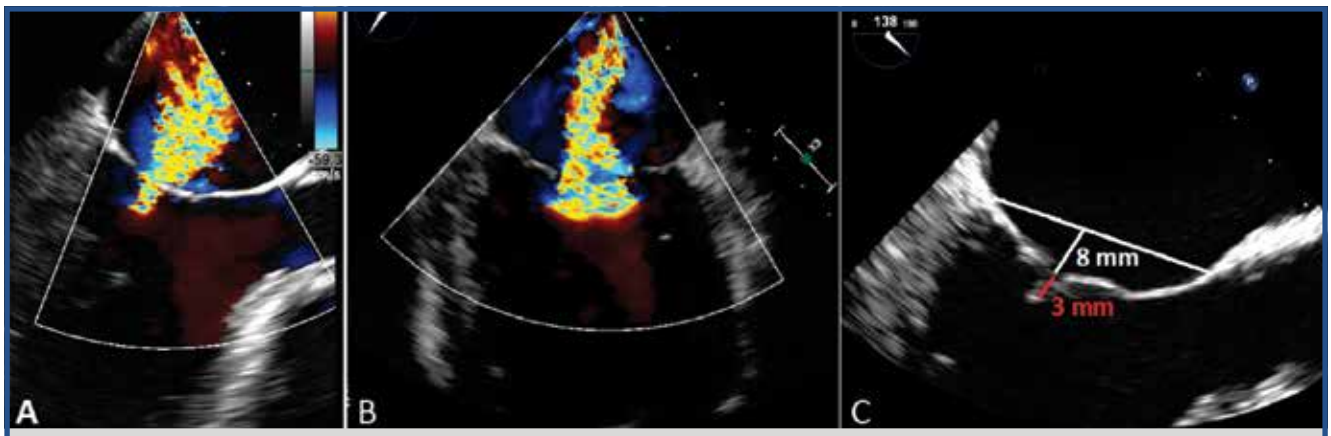


**Figure 2.** 2-dimensional TEE at mid-esophageal long axis (A) and inter-commissural view (B) showing the regurgitant mitral jet which is smaller in the long axis, but much wider in inter-commissural view, pointing ellipsoid shape of the regurgitant area, typical for secondary mitral regurgitation. C illustrates tenting of the mitral valve leaflets. Remaining degree of coaptation is enough for grasping (3 mm) and the coaptation length is not too long (8 mm).

regurgitation jet we assumed two clips would be needed. The first clip was positioned more to the medial part of the regurgitant jet with the aid of 2- and 3-dimensional TEE (Figure 4). The clip was then introduced into the left ventricle where the two leaflets were grasped and clipped. Mean gradient across the mitral valve was 4 mmHg (what is acceptable) and residual mitral regurgitation at the lateral aspect of the valve. According to the initial decision the second clip was introduced and aligned laterally to the first clip under TEE guidance. After grasping and clipping the leaflets with the second clip the mean gradient and residual regurgitation was assessed. The result was satisfactory with considerable reduction in regurgitation and without significant mitral obstruction (Figure 4). After the system was pulled out through the interatrial septum we noticed small and hemodynamically non significant iatrogenic atrium septum defect. There were no complications after the procedure. The patient was discharged on a 5$^{th}$ day with dual antiplatelet therapy for 3 months.

## Conclusion

We presented first Slovenian experience with the MClip procedure. The MClip represents an exciting advancement in the field of percutaneous structural heart interventions. As for aortic valve disease with great expansion of transcatheter aortic valve implantations, the MClip system has been developed to enable mitral valve repair in patients with severe mitral regurgitation. To date more than 15.000 MClip procedures were performed worldwide. It should be offered to carefully selected patients who fulfill echocardiographic anatomical criteria and are discussed within a heart team comprising of cardiac surgeon, interventional cardiologist, referring cardiologist, imaging specialist and cardiac anesthesiologist. There is growing tendency for MClip therapy in heart failure patients with secondary mitral regurgitation, as an adjunctive treatment when optimal medical therapy fails to provide clinical improvement. There are currently ongoing prospective, randomized, comparative studies (MITRA-FR, COAPT), which will assess the MClip device efficacy in this population of patients, already on optimal medical therapy [13].


**Figure 3.** Puncture of the interatrial septum. Determination of the puncture site is shown in a bicaval view (A) and short axis view at the base (B). The tenting of the needle is demonstrated (white arrows). In four chamber view the measurement of the height above the mitral valve annulus is done (C).
LA=left atrium, RA=right atrium, LV=left ventricle.

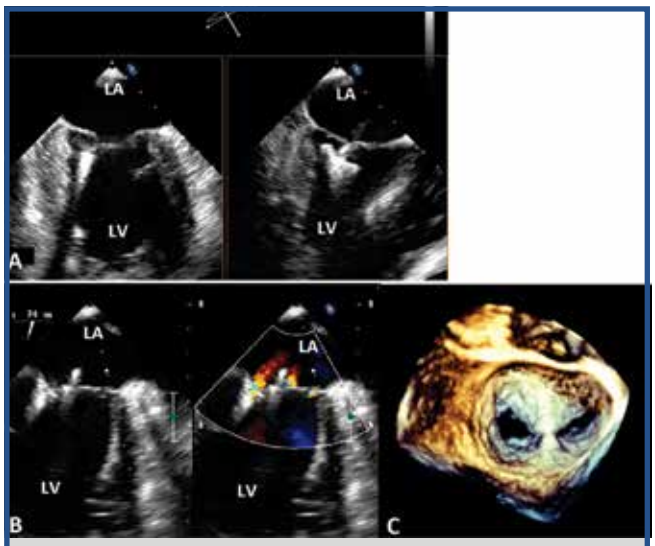


**Figure 4.** A: simultaneous biplane imaging at intercommissural and long axis view demonstrates positioning of the Mitraclip. Once the proper position is set, the opened Mitraclip is advanced into the left ventricle. B: mild residual regurgitant jets after the second clip deployment. C: 3-dimensional TEE imaging using enface surgical view from the left atrium showing the final result-newly created double mitral valve orifice.
LA=left atrium, LV=left ventricle.

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