









Complications following transcatheter edge-to-edge mitral valve repair: Personal experience and review of the literature

Dominik Maj^{1*}, Karolina Jasińska-Gniadzik^{1*}, Tomasz Kopiec¹,
Małgorzata Wieteska², Aleksandra Gąsecka¹, Adam Rdzanek¹, Adriaan O. Kraaijeveld³,
Krzysztof Pujdak⁴, Marcin Grabowski¹, Arkadiusz Pietrasik¹

¹1st Chair and Department of Cardiology, Medical University of Warsaw, Poland

²Chair and Department of Epidemiology and Clinical Research Methodology, Medical University of Lublin, Poland

³Department of Cardiology, University Medical Center Utrecht, The Netherlands

⁴Herford Klinikum, Herford, Germany

Abstract

Mitral valve dysfunction affects around 2% of the population and its incidence is still increasing, making it the second most common valvular heart disease, after aortic stenosis. Depending on the etiology of the disease, it can be classified into primary or secondary mitral regurgitation. The first line of treatment is optimal medical therapy. If ineffective, mitral valve intervention can be considered. For patients disqualified from surgical treatment, transcatheter edge-to-edge repair with the use of MitraClip may be considered. Over 100,000 MitraClip procedures have been performed which makes this the most established transcatheter technique for the treatment of severe mitral regurgitation. The aim of this review is to discuss the technical details of the MitraClip procedure, clinical evidence regarding the efficacy of MitraClip, complications related to the clip implantation alongside with acute complications based on the currently available evidence and clinical experience. (Cardiol J)

Key words: mitral valve dysfunction, mitral regurgitation, MitraClip, transcatheter edge-to-edge repair (TEER)

Introduction

Mitral valve dysfunction is one of the most common valvular heart diseases, affecting more than 4 million individuals only in the United States and around 2% of the general population [1]. It is present in more than 10% of patients over 75 years of age and its incidence is still increasing [2, 3]. In Europe, mitral regurgitation (MR) constitutes 32% of valvular disorders, which makes it the second most common valve disease, after aortic stenosis

(43%) [4]. MR can be classified into primary and secondary, with the latter being the most common form. Primary MR (PMR), also known as degenerative, can be caused by mitral valve prolapse, rheumatic heart disease, radiation or annular calcification. Secondary MR (SMR), also known as functional, mostly develops in patients with heart failure (HF) or ischemic heart disease [5]. According to the European Society of Cardiology (ESC) guidelines for the management of valvular heart disease, the recommended therapy in acute

Address for correspondence: Arkadiusz Pietrasik, MD, PhD, 1st Chair and Department of Cardiology, Medical University of Warsaw, ul. Banacha 1A, 02-097 Warszawa, Poland, tel: +48 22 599 19 51, e-mail: arkadiusz.pietrasik@wum.edu.pl

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*Dominik Maj and Karolina Jasińska-Gniadzik equally contributed to the manuscript and share the first authorship.

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PMR includes diuretics and nitrates to decrease the preload, as well as sodium nitroprusside to reduce the afterload [6]. Severity of PMR and SMR can be defined via echocardiography. In the first one effective regurgitant orifice area (EROA) is $\geq 40 \text{ mm}^3$ and regurgitant volume is $\geq 60 \text{ mL/beat}$, while in the second EROA is $\geq 20 \text{ mm}^3$ and regurgitant volume is $\geq 30 \text{ mL/beat}$. In severe chronic PMR angiotensin converting enzyme inhibitors should be considered, when a patient is not suitable for surgery, when symptoms remain after surgery or HF has developed. Regarding SMR, effective medical therapy should focus on HF treatment including cardiac resynchronization therapy in suitable patients [7]. If the symptoms of SMR preserve after the recommended line of therapy, indications for mitral valve intervention should be discussed. The ESC provides guidelines for an invasive treatment in patients suffering from severe PMR and severe SMR (ref to guideline). First class indications for surgical intervention, in case of severe PMR, include: symptomatic patients with left ventricular ejection fraction (LVEF) $> 30\%$ and asymptomatic patients with left ventricular dysfunction (left ventricular end-systolic diameter [LVESD] $\geq 45 \text{ mm}$ and/or LVEF $\leq 60\%$) and in case of chronic SMR: patients with severe SMR undergoing coronary artery bypass grafting and LVEF $> 30\%$.

In patients who are disqualified from surgical treatment (are at high surgical risk and accomplish the echocardiographic criteria, defined as appropriate valve morphology) transcatheter edge-to-edge repair (TEER) may be considered [6], for example with the use of MitraClip. Over 100,000 procedures have been performed thus far and as such it is the most established transcatheter technique for the treatment of severe MR [8]. Transcatheter method is associated with clinical status and outcome improvement in patients who fulfil the echocardiographic criteria and present an appropriate valve morphology [6, 9–11]. Although MitraClip is becoming increasingly common method used in patients with MR, it is not devoid of complications.

The aim of the review is to summarize the complications following mitral valve repair with transcatheter edge-to-edge method (TEER) based on the currently available evidence and own clinical experience. The main complications are related to clip implantation, such as: single leaflet device attachment, partial clip detachment, isolated leaflet damage, clip embolization, conversion to open heart surgery and no procedural success. Acute complications include in-hospital death, major bleeding incidents, major vascular complications,

renal failure, pericardial tamponade, ischemic events and infective endocarditis.

In individual paragraphs we will discuss technical details of the MitraClip procedure, clinical evidence regarding the efficacy of MitraClip, complications related to the clip implantation alongside with acute complications. Above all, patients characterized by advanced age, female sex and poor health status are more prone to develop any difficulties in the course of TEER [9, 12, 13].

Technical details of the MitraClip procedure

The MitraClip device is designed to bind two cusps of mitral valve during a non-invasive repair. It constitutes an alternative for surgical MR treatment in selected patients. The potential advantages of MitraClip include shorter hospitalization time, faster recovery and lower morbidity compared to open heart surgery.

Intervention is performed in an appropriately adapted hemodynamic laboratory with the use of fluoroscopy in combination with transesophageal echocardiography (TEE) guidance. The TEE also allows an estimation of the efficacy of MR reduction during TEER. The MitraClip system consists of an implant, steerable guide catheter and implant insertion system, which allows it to be placed over the cusps of the mitral valve. During the procedure, a catheter is guided through the femoral vein to the left atrium under TEE and fluoroscopic guidance. The interatrial septum is then punctured (Fig. 1). It is necessary to ensure that the tip of the steerable guide remains across the interatrial septum and to avoid an injury of the left atrial wall. Later on, the clip delivery system is introduced and two cusps of the valve are grasped.

The effectiveness of the grasp and the reduction of MR is assessed in specific projections in echocardiography using the Doppler method. In case of insufficient clinical effect with one MitraClip device, a second or third can be used to achieve an optimal correction of MR [11, 14–16].

Clinical evidence regarding the efficacy of MitraClip

Until now, the safety and efficiency of MitraClip has been evaluated in several different studies. For the purposes of this systematic review, we focused on the results of MITRA-FR trial, EVEREST Phase I, EVEREST Cohort, ACCESS-EU,

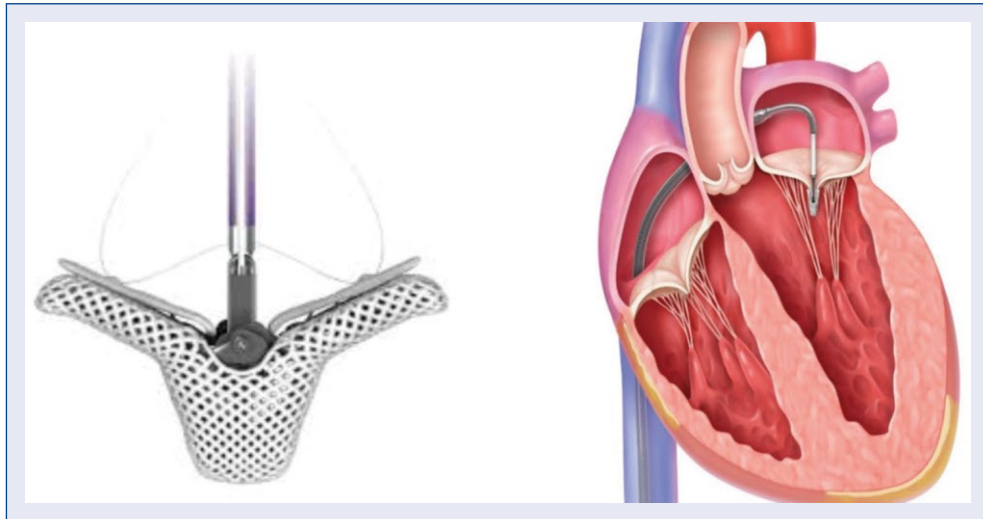


Figure 1. Introduction and placement of MitraClip in the heart (adapted from Abbott's original site: www.mitraclip.com).

GRASP, TRAMI, COAPT, STS/ACC TVT and MVR with Extended Clip Arms.

MITRA-FR trial was meant to compare TEER and medical therapy alone in preventing side effects. The randomized study included 304 patients with severe SMR and symptomatic systolic HF [17]. Primary efficacy endpoints were: death from any cause or hospitalization for HF at 1 year. No difference was found between intervention and control group in terms of rate of mortality or unplanned HF hospitalizations.

EVEREST Phase I was a study which enrolled 27 patients [18]. They met the criteria of moderate-to-severe or severe MR with symptoms, or, if asymptomatic, with impaired left ventricular function (LVEF < 60% or LVESD > 45 mm). In this study, the primary endpoints were defined as 30-day survival, cardiac tamponade, myocardial infarction (MI), stroke, septicemia, clip detachment and cardiac surgery for failed clip. Secondary endpoints included in-hospital vascular complications as well as endocarditis, major bleeding, clip thrombosis, hemolysis, mitral valve injury and cardiac surgery for failed clip in the 6-month follow-up.

EVEREST Cohort was a prospective, multicenter, single-arm study. It consisted of 107 patients with moderate-to-severe or severe MR with symptoms, or, if asymptomatic, with impaired left ventricular function (LVEF < 60% or LVESD > 45 mm) [19]. For this study, complex primary safety endpoints were: absence of major adverse cardiovascular events (MACE) at 30 days — death, MI, transfusion of > 2 units of blood, nonelective

cardiac surgery, reoperation for failed surgery, renal failure, stroke, gastrointestinal complications requiring surgery, necessity of ventilation for > 48 hours, deep wound infection, septicemia and new onset of permanent atrial fibrillation in the 12-month follow-up.

EVEREST II was a prospective, multi-center, randomized study, which aimed to evaluate the safety and effectiveness of an endovascular approach to the treatment of mitral valve regurgitation [9]. Enrolled patients (n = 279) had moderate-to-severe or severe MR, were symptomatic with > 25% LVEF and LVESD ≤ 55 mm or with one or more of the following: LVEF 25% to 60%, LVESD ≥ 40 mm, new onset of atrial fibrillation and/or pulmonary hypertension defined as pulmonary artery systolic pressure > 50 mmHg at rest or > 60 mmHg with exercise. The primary efficacy endpoint was defined as absence of surgery for valve dysfunction, death, and moderate to severe (3+) or severe (4+) MR at 12 months follow-up. Primary safety endpoints were MACE at hospital discharge or within 30 days, defined as death, MI, re-operation for failed surgical repair, non-elective cardiovascular surgery for adverse events, stroke, renal failure, deep wound infection, ventilation for greater than 48 hours, gastrointestinal complication requiring surgery, new onset of permanent atrial fibrillation, septicemia and transfusion of ≥ 2 units of blood.

ACCESS-EU was a non-randomized, prospective, multicenter study that included 567 symptomatic MR or asymptomatic moderate-to-severe or severe MR patients who underwent the MitraClip

procedure [20]. The primary outcome measure in this study was MR severity before the intervention and 12 months post intervention. Secondary outcome measures included procedure time, contrast volume, fluoroscopy duration, number of devices implanted, intensive care unit and hospital stay (from the day of procedure throughout 12 months of study period), discharge status, facility and MR severity, no all-cause mortality (at the day 0 and 30 as well as at 6 and 12 months), 1-day post procedure safety outcomes, need for mitral valve surgery, New York Heart Association (NYHA) functional class before the procedure and after 12 months, 6 minute walk test distance before the procedure and after 12 months and change in Minnesota Living With Heart Failure Quality of Life Score from baseline to 12 months.

GRASP was a prospective registry which enrolled a total of 117 patients with moderate-to-severe or severe MR who were at high surgical risk [21]. Primary safety endpoints were defined as survival, MI, stroke, renal failure, deep wound infection, reoperation for failed mitral valve surgery, non-elective cardiovascular surgery for adverse events, mechanical ventilation for > 48 hours, gastrointestinal complication requiring surgery, new-onset permanent atrial fibrillation, septicemia and transfusion of > 2 units of blood.

A German, multicenter, prospective registry — TRAMI — enrolled a cohort of 722 patients from 20 German centers who underwent MitraClip implantation. Primary outcome was defined as all-cause mortality [22]. Moreover, death or re-intervention and death or cardiac rehospitalization were also analyzed.

COAPT was a multicenter, randomized, controlled, parallel-group trial which enrolled 614 patients [23]. Included patients had moderate-to-severe or severe MR, cardiomyopathy with LVEF 20–50%, LVESD \leq 70 mm and NYHA functional class II–IVa. As a primary effectiveness endpoint, HF hospitalization at 24 months for MitraClip with guideline directed medical therapy (GDMT) vs. GDMT alone was compared.

STS/ACC TVT was an observational study that collected data from 2,952 patients who underwent TEER in the United States from 2013 to 2015 [24]. Primary outcomes included in-hospital, 30-day and 1-year mortality and rehospitalization for HF.

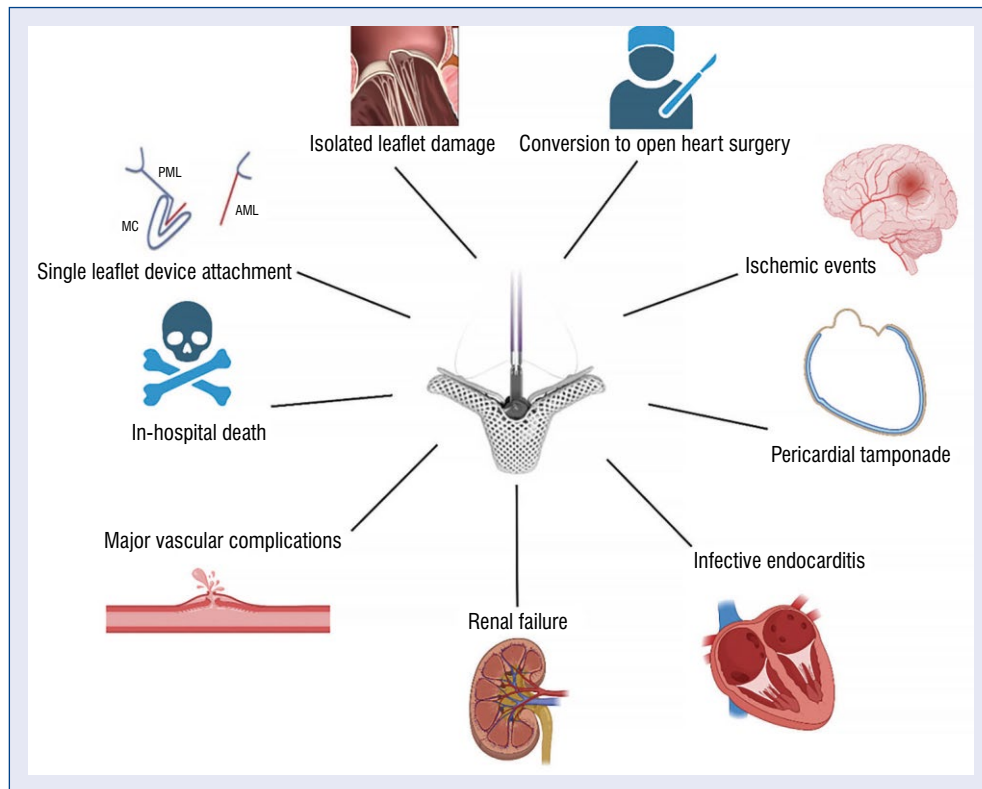
MVR with Extended Clip Arms was an observational, multicenter study that included 107 patients who underwent implantation of new generation of MitraClip — MitraClip XTR [25]. Patients

enrolled in this study were at high surgical risk and had symptomatic MR nonresponsive to medical treatment. The primary endpoints were technical success (defined as survival), emergency surgery or reintervention related to the device itself or access, successful access, successful delivery and retrieval of the device, deployed and positioned device at the end of the procedure and severity of MR at discharge. Main secondary endpoints were good procedure outcome at 30 days, defined as successful device implantation, lack of MR > 2 degree and relevant mitral stenosis, procedural mortality, stroke, additional surgical procedures and device failure. Additional secondary endpoints were cardiovascular mortality, MI, cerebrovascular events, bleeding complications acute renal injury, hospitalization for HF, reintervention for MR, change in 6-minute walk distance and in NYHA class.

The first, major study that covered the topic of MitraClip procedure and its safety — EVEREST Phase I — revealed that the MitraClip is a safe procedure [18]. In this study, primary efficacy endpoints were defined as survival and cardiac surgery at 12 months. It was achieved in 66% of patients. Acute procedural success was defined as placing clips which resulted in a reduction of MR to \leq 2+. 79 out of 107 (73.8%) patients met the criteria of acute procedural success. In this cohort, survival rate was at 95.9%, 94.0% and 90.1% at 1-, 2- and 3-year follow-up and absence of re-operation was at 88.5%, 83.2% and 76.3% at 1-, 2- and 3-year follow-up, respectively [19].

EVEREST II compared TEER with conventional surgery in a 12-month-follow-up and revealed that it was superior to the surgery when safety is considered. Despite being less efficient at reducing MR, the improvement of clinical outcome after TEER was comparable to classic surgery [9, 26]. It proved that TEER with the MitraClip is an effective and relatively safe procedure in comparison to the surgical mitral valve repair or optimal medical treatment [20, 27]. The MitraClip procedure can be done successfully in patients with a high risk of surgical mortality, suffering from severe MR. In EVEREST II it contributed to improving the NYHA functional class from III/IV to class I/II in 74% of treated patients, which also led to the improvement of their clinical status [10, 11].

Despite unfavourable factors such as increased comorbidities and older age, patients after TEER are characterized by a lower mortality rate and less frequent complications during hospitalization than those treated surgically [28].



Central illustration. Possible complications after MitraClip implantation; AML — anterior mitral leaflet; PML — posterior mitral leaflet; MC — MitraClip.

Complications related to the clip implantation

In the most recent study performed by Chhatrwalla et al. [13] the complication rate was 8.5%. The study aimed to examine the relationship between operator experience and procedural results of TEER in the United States. The cohort group consisted of 14,923 patients and 1,266 developed complications related to the procedure.

There are a number of complications that arise due to the clip implantation itself, including: (i) single leaflet device attachment, (ii) partial clip detachment, (iii) isolated leaflet damage, (iv) clip embolization, (v) conversion to open heart surgery, (vi) lack of procedural success. It might seem somewhat counterintuitive that these types of complications do not differ much between older and newer studies, but one must be aware of the fact that surgeons not only gain experience while performing clip implantation, but also operate on patients who are admitted to the clinic with a more complex mitral valve anatomy. Summary of possible complications of the procedure is shown in the Central illustration. The complication rate follow-

ing MitraClip implantation in hitherto conducted large-scale clinical trials is presented in Table 1.

Partial clip detachment

Early partial detachment of one of the leaflets is a similar complication to the previous one. Surprisingly, it was the most common unwanted outcome in early studies that covered the topic of TEER, where it turned out that it affected up to 11% of the cohort group [18]. Recent studies indicate that nowadays it is rather a rare complication, as in ACCESS-EU [20] and TRAMI [22] it was the case of 0.2% and 2% of interventions, respectively, and in the newest one, MVR with Extended Clip Arms [25], no cases of partial detachment of leaflet were reported. This might be caused by the fact that with the development of technology, more precise devices are being implanted.

Isolated leaflet damage

Most studies do not cover the topic of leaflet damage. Only two described the frequency of this complication and in one — EVEREST Phase 1 [18] no cases of damaging the leaflet were reported. The second study which explored this issue was

Table 1. Complication rates following MitraClip implantation in large-scale clinical trials.

Complications	EVEREST Phase I [18]	EVEREST Cohort [19]	ACCESS-EU [20]	GRASP [21]	TRAMI [22]	STS/ACC TVT [24]	COAPT [23]	MVR with Extended Clip Arms [25]
Number of patients	27	107	567	117	828	2952	302	107
Year of publication	2005	2009	2013	2013	2015	2017	2018	2019
Device generation	1 st	1 st	1 st	1 st	1 st	1 st	1 st and 2 nd	3 rd
Acute complications								
Acute renal failure	0%	0%	4.8%	0%	0.7%	No data	No data	1%
Cardiac tamponade	0%	2.8%	1.1%	0%	1.9%	1%	No data	0%
Endocarditis	0%	0%	No data	No data	0%	No data	No data	No data
In-hospital death	0%	0.9%	3.4%	0.9%	2.2%	2.7%	No data	0.9%
Major bleeding	3%	3.7%	No data	No data	7.4%	3.9%	No data	1%
Major vascular complications	0%	No data	No data	No data	1.4%	1.1%	No data	No data
Myocardial infarction	0%	0%	0.7%	0%	0%	0.1%	0%	0%
Need for resuscitation	0%	No data	1.8%	No data	0.8%	No data	No data	No data
Pulmonary embolism	0%	0%	0.2%	0%	0%	No data	0%	No data
Stroke	3.7%	0.9%	0.7%	0.9%	0.9%	0.4%	0.7%	0%
Related to clip implantation								
Cardiac surgery in first 30-days	3%	0.9%	No data	0%	0.9%	No data	No data	No data
Clip embolization	0%	0%	0%	No data	0%	0.1%	No data	0%
Conversion to open heart surgery	0%	1.8%	0%	0%	0%	0.7%	No data	4%
Partial clip detachment	11%	9%	0.2%	No data	1.9%	No data	No data	0%
Isolated leaflet damage	0%	No data	No data	No data	No data	No data	No data	2%
Relevant mitral stenosis	0%	No data	No data	No data	0.5%	No data	No data	No data
Thrombus on the clip	0%	No data	No data	No data	0.1%	0%	No data	0%
No procedural success	3%	26%	9%	0%	3.4%	8.2%	2%	7%

the newest one — MVR with Extended Clip Arms [25], where 2% of patients were affected. This might again prove that the more difficult anatomy of mitral valve, the higher the rate of complications regarding structure of the prosthesis itself. The MR location is another likely cause of this complication — higher in commissural compared to A2-P2 lesions.

Clip embolization

Another problem that might occur during implantation is clip embolization. This complication requires urgent conversion to a surgical operation. Thankfully, it is an extremely rare complication, reported in only one of the analyzed studies — in STS/ACC TVT, where it constituted 0.1% of the whole cohort [24].

Conversion to open heart surgery

Clip embolization is not the only cause of converting to open heart surgery. In most works there was no necessity to convert to surgery. In studies where this type of complication was found, it did not account for more than 4% [25], mostly due to inadvertent leaflet laceration.

No procedural success

Finally, no procedural success should also be considered as a complication during the procedure. As the definition differs from study to study, it is very difficult to measure the success rate. According to gathered/collected statistics, no procedural success was prevalent from 3% to 26% of times, with the highest percentage occurring in the EVEREST study [19]. Interestingly, in one of the most recent ones, COAPT [23], unsuccessful interventions constituted only 2% of cases.

Acute complications

In-hospital death

When considering in-hospital mortality rate, it slightly differs between performed studies. The lowest rate was observed in EVEREST Phase I [18] with no deaths reported. In the rest of the studies, the number of deaths was not higher than 3.4% [20]. It clearly shows that transcatheter implantation is a safe method. The need for resuscitation was required in 0% to 1.9% of patients, although this data is provided only in a few studies [18, 20, 22].

Major bleeding incidents

Major bleeding incidents defined as any overt bleeding resulting in hemodynamic instability or requiring transfusion contributed to 3% of compli-

cations in the EVEREST phase I [18]. However, it was over twice as common in the TRAMI study (7.4%) [22].

Major vascular complications

Vascular complications are less common than major bleedings. Although mitral valve interventions require catheters of a large size (the guiding catheter diameter of 24 French proximally) and most forces affect the incision place where bleeding takes place more easily, the reported rate of vascular complications ranges from 0.0% to 1.4% [18, 22].

Renal failure

The MitraClip procedure does not require administration of the iodinated contrast, which might be the reason why the acute renal failure incidents remain rare [2]. In the EVEREST Phase I Clinical Trial no cases of a renal failure were described [18, 21]. One study — ACCESS-EU reported a total of 27 cases of renal failure, accounting for 4.8% of patients. It is noteworthy that initially up to 42% of the treated patients were diagnosed with renal disease [20].

Pericardial tamponade

One major complication that might concern surgeons performing intravascular intervention is a possibility of breaking into the pericardium and, as a result, inducing tamponade. In most studies it affected from 0% to 1% of patients [18, 21, 24, 25], in contrast to the EVEREST study where it involved 2.8% of the cohort [19]. This might apply to the fact that the EVEREST study was one of the first ones and, as such, surgeons who performed operations were still at the beginning of their learning curve. As subsequent studies provided new data, there was a reduction in pericardial tamponades as a complication of that procedure — 1.9%, 1.0% and 0.0% in TRAMI, STS/ACC TVT and MVR with Extended Clip Arms, respectively [22, 24, 25].

Ischemic events

The MitraClip procedure is associated with the usage of potentially thrombogenic materials, transseptal puncture and maneuvering with the catheter in the beating heart, which might result in ischemic incidents [2]. Thankfully, as recent studies reveal, transcatheter treatment is related to low potential risk of complications such as MI, pulmonary embolism or stroke. The frequency of both MI and pulmonary embolism oscillates around 0–0.2%, whilst stroke occurs a little more frequently — in 0–1.4% of all cases [2, 12]. Moreover, the tendency is observed

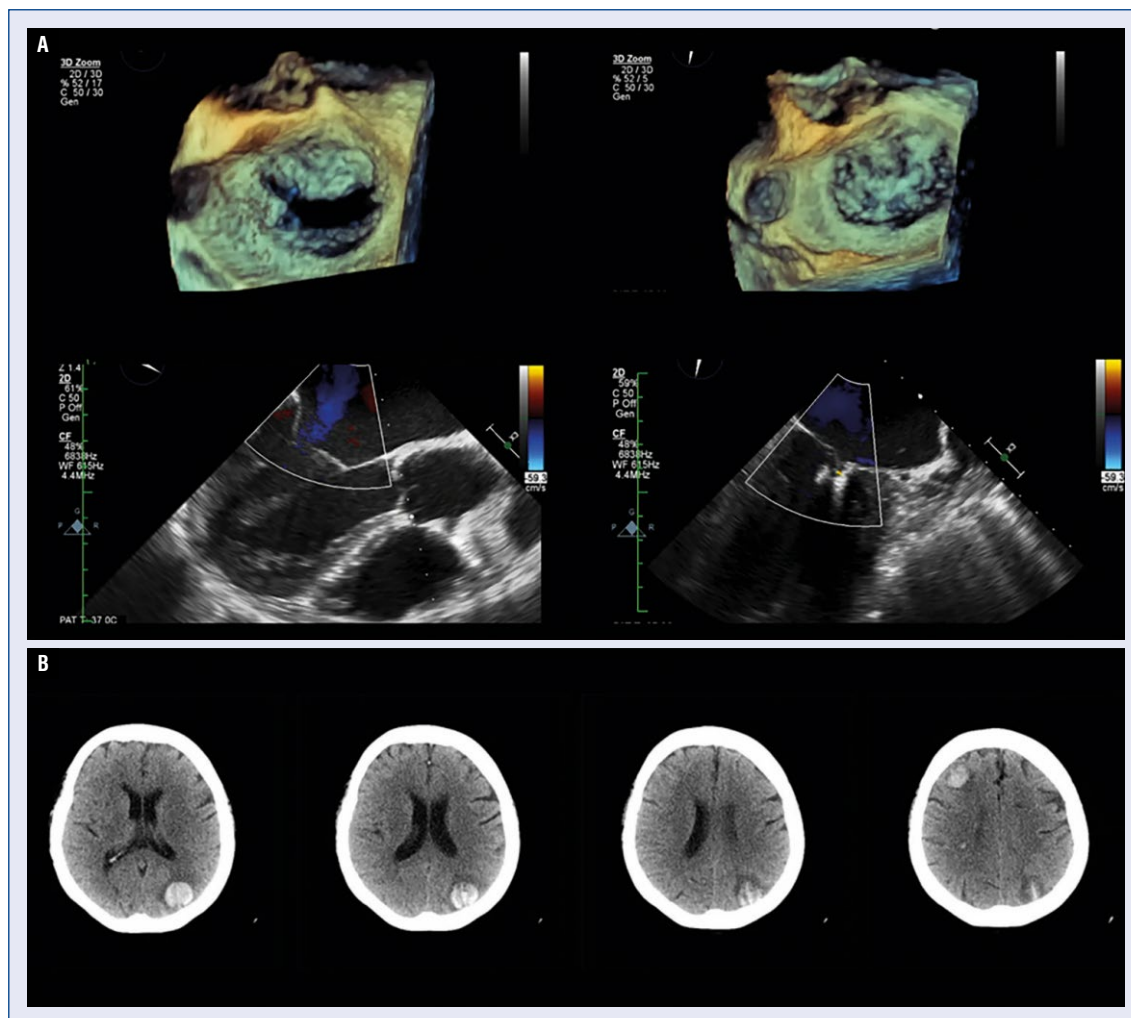


Figure 2. A. Transthoracic echocardiography before (left) and after (right) the MitraClip procedure; B. Brain computed tomography scan 5 days after the MitraClip procedure showing hyperdense focal hemorrhagic infarcts in the left occipital right frontal and right parietal lobe.

to reduce the post-procedure stroke rate in TEER in comparison with surgical mitral valve repair [27].

The appearance of ischemic events secondary to thromboembolism is not very frequent (< 1%). The presence of thrombogenic material, chamber dilatation, low cardiac output and atrial fibrillation are factors that predispose patients to the thrombus formation in the course of medical procedure [29].

In one of the latest studies, conducted by Braemswig et al. [30], a pre- and post-procedural magnetic resonance imaging (MRI) on a group of 24 patients was performed. The implantation was fully successful in all patients, however, 3 days after the procedure the MRI examination revealed new ischemic lesions in 21 out of 24 cases (87.5%) and the median number of new diffusion-weighted imaging lesions was 7. Moreover, during TEER,

a continuous transcranial Doppler examination was performed. During implantation of MitraClip, microembolic signals (MES) were noticed in all 54 patients. The number of ischaemic incidents differed during various procedural steps. Most commonly MES were detected while the device was interacting with the mitral valve (median number 66 MES). Nevertheless, non-disabling, minor stroke (< 3 points in the National Institute of Health, Stroke Scale) was observed in 9 out of 54 patients (17%).

Infective endocarditis

The Canadian research [31] reported 12 cases of prosthetic infective endocarditis following TEER, described in 10 different publications. Despite being a rare complication, its mortality rate

Table 2. Number of complications among 114 patients with mitral valve regurgitation who underwent transcatheter edge-to-edge repair using MitraClip device in 1st Chair and Department of Cardiology, Medical University of Warsaw between August 2014 and November 2022.

Type of in-hospital complication	Patients
In-hospital death	6 (5.2%)
Major bleeding	3 (2.6%)
Hemorrhagic stroke	1 (0.9%)
Minor bleeding	1 (0.9%)
Major vascular complications	2 (1.8%)
Exacerbation of heart failure	13 (11.4%)
Exacerbation of chronic kidney disease	2 (1.8%)
Acute kidney injury	0 (0%)
Pericardial tamponade	1 (0.9%)
Ischemic events	1 (0.9%)
Infective endocarditis	1 (0.9%)

Bleeding and major vascular complications were defined according to the BARC scale. One clasp detachment was observed from the posterior leaflet of the valve, which required reoperation about a year later. None of the cases required mitral valve surgery or led to nonelective cardiovascular surgery [Wells GA et al. Bleeding Classification System Definitions; Canadian Agency for Drugs and Technologies in Health, 2019; Mar. (CADTH Optimal Use Report, No. 9.2b.) Appendix 10, Bleeding Classification System Definitions. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK542934/>].

ranges up to 42%. An example of brain embolism caused by infective endocarditis following TEER is shown in Figure 2 (own material). In this case, a 62-year-old female patient with multivessel coronary artery disease (CCS class 1), HF with decreased ejection fraction (EF 22%), hypertension, diabetes mellitus type 2, chronic kidney disease and status post anterior hemicolectomy due to colorectal cancer, with subsequent radiotherapy, was admitted to the hospital for the interventional treatment of secondary MR. Given the high perioperative mortality risk (EuroScore II 30.16%), the patient was disqualified from cardiac surgery and qualified for MitraClip treatment by the Heart Team. The course of the MitraClip intervention was uneventful and allowed the achievement of good early results. The control echocardiography showed two clips with central, typical placement on the level of A2/P2, with the max/medium gradient values of 9/3 mmHg (Fig. 2A). Five days after the procedure, the patient experienced a syncope. The brain computed tomography showed three hyperdense focal infarcts in the left occipital, right frontal and right parietal lobe (Fig. 2B). Repeated echocardiography showed balloting vegetation (22 × 9 mm) under the left MitraClip. Infective endo-

carditis was diagnosed. Blood culture showed the presence of methicillin-resistant *Staphylococcus aureus*. Targeted therapy with antibiotics was started and continued for 4 weeks, allowing successful treatment of the patient. At hospital discharge, blood cultures were sterile and no vegetations were visible on echocardiography.

Based on the discussed clinical problems and our own experience, Table 2 summarizes other complications that occurred among 114 patients who underwent the MitraClip procedure in 1st Chair and Department of Cardiology, Medical University of Warsaw between August 2014 and November 2022.

Future directions and conclusions

Taken all the discussed issues into account, TEER using MitraClip poses a promising and a relatively safe method for MR treatment in patients with high surgical risk. In the latest prospective and multicentre EXPAND study, which included 1,041 patients, the third-generation MitraClip NTR/XTR was used. The enrolling centres noted leaflet adverse events in only 3.4% of treated patients. TEER with the third generation MitraClip is safe and supplies more sizing options than the older generations. Furthermore, in comparison to previous generations, lower rate of adverse events using newer MitraClip system was observed [32]. Compared to other transcatheter therapies such as transcatheter aortic valve implantation (TAVI), periprocedural complication rates seem to be relatively low. In the retrospective analysis by Würschinger et al. [33] the mortality after TAVI was 6%, whereas after MitraClip around 3%. The rate of vascular complications was around 4% for both transcatheter therapies, but when cerebrovascular events were considered, the rate was higher in TAVI than in MitraClip (2% vs. 0–1%). Acute kidney injury occurrence, on the other hand, was more common after MitraClip (18%), compared to TAVI (10%) [12, 33]. Altogether, the complication rate after TEER is relatively low and compared to other transcatheter therapies, but still not negligible.

As speculated before, with the development of technology, the number of postprocedural complications decreases and the clinical outcomes are satisfactory [2, 18, 19, 26, 34]. It was proven that edge-to-edge intervention is related with persistent reduction of the severity of MR at 1-year follow-up [32] and a high, immediate improvement of patients' quality of life [11, 34]. Despite

the low complication rate, dealing with severe side effects, such as brain embolism, bleeding or thrombus formation must be taken into account in patients referred for the developing transcatheter techniques.

Significant differences in the results of COAPT and MITRA-FR studies only emphasize that further research is needed to indisputably confirm the effectiveness of the procedure and to identify the subgroup of patients that will benefit most from MitraClip intervention. Long-term outcomes and durability of the treatment should also be observed. The ongoing clinical trials regarding MitraClip interventions aim to provide further evidence for its use in chronic HF patients [35] and to compare it to the reconstructive MR surgery [36]. The next step in the future could also be a combination of transcatheter procedures, such as combining MitraClip with percutaneous annuloplasty [37].

Ethics approval statement and patient consent statement

The presented patient provided a written informed consent. The study was conducted in accordance with ethics standards of institutional research committee and the Declaration of Helsinki.

Conflict of interest: None declared

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