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# EFFICACY AND SAFETY OF MITRACLIP IN THE TREATMENT OF MITRAL REGURGITATION: COMPARISON WITH TRADITIONAL TECHNIQUES

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**Abstract : Introduction:** Secondary mitral regurgitation (MR) is a negative prognostic factor, affecting approximately 6.4% of the population aged 65 years or older. It results from dysfunction in mitral structures and can be classified as primary or secondary, guiding treatment options. MitraClip is a promising transcutaneous device approved for the treatment of MI, which reduces mitral regurgitation in patients at high surgical risk. **Objective:** To compare the clinical outcomes and morbidity associated with the use of MitraClip compared to other traditional treatment techniques for MI. **Method:** A descriptive-analytical review of the literature was performed using the PUBMED Central database, focusing on articles published in the last five years on clinical outcomes and morbidity associated with MitraClip. **Results: The** initial search identified 72 articles, of which 23 were preselected for full-text reading and 16 were included in the final analysis. **Discussion:** MitraClip has been shown to be effective in reducing mitral regurgitation and improving patient symptoms, with lower mortality and rehospitalization rates compared to drug therapy alone. Although less invasive, it presents risks, such as structural complications. **Conclusion:** MitraClip represents a safe and effective alternative for high-risk patients with MI, comparable to conventional surgery. However, further studies are needed to validate its long-term efficacy in low- and intermediate-risk patients.

**Keywords:** MitraClip. Mitral Valve Insufficiency. Treatment. Morbidity MitraClip. Mitral Valve Insufficiency. Treatment. Morbidity

## INTRODUCTION

ABC Cardiol points to secondary mitral regurgitation (MR) as a predictor of poor prognosis, regardless of other factors (BARROS-GOMES et al., 2021). This pathology is characterized by incomplete closure of the mitral valve, causing a regurgitant jet of blood that travels retrograde through the bloodstream to the left atrium, in the opposite direction to its anterograde and physiological flow toward the systemic circulation. It should be noted that the alteration may result not only from the valves that make up the mitral apparatus, but also from its other structures: leaflets, fibrous ring, chordae tendineae, and papillary muscles (TARASOUTCHI et al., 2011). Its prevalence in moderate and severe degrees is estimated to be 6.4% in the population aged 65 years or older. In addition, about 15-30% of patients with heart failure have this condition. (ROGERS & FRANZEN, 2011)

MI is divided into two groups: primary and secondary, and this classification will influence the choice of appropriate treatment. Primary MI occurs when there is direct damage to the valve, such as myxomatous degeneration. Secondary MI occurs due to cardiac damage that affects mitral valve function, with dilated cardiomyopathy being common (TARASOUTCHI et al., 2020). Given this, choosing an effective treatment is a challenge in these cases. For this purpose, transcutaneous intervention using the MitraClip device is a promising alternative for both etiologies (SHUVY et al., 2023).

MitraClip (Abbott) is a device used in symptomatic patients, first approved by the United States Food and Drug Administration (FDA) in 2013 for patients with primary MI who were at high risk for surgery, and later, in 2019, for the treatment of secondary MI (MAHABIR et al., 2020). The device works by bringing the anterior and posterior leaflets closer together, aiming to reduce the degree of mitral regurgitation through a less invasive procedure (performed by catheter) than conventional surgery (STONE et al., 2018).

Therefore, this study aims to compare the clinical outcomes and morbidity associated with the use of MitraClip compared to other traditional treatment techniques for MI.

## METHODS

A descriptive-analytical review of the literature was conducted to compare the clinical outcomes and morbidity associated with the use of MitraClip in relation to conventional treatment techniques for MI. To this end, a comprehensive search was conducted in the PUBMED Central (PMC) database, focusing on updating and consolidating knowledge on the subject within a limited time frame.

Electronic data collection was performed in October 2024, using the following descriptors, combined in Portuguese, English, and Spanish: "MitraClip" AND "mitral insufficiency" AND "treatment" AND "morbidity." Initially, the descriptors were cross-referenced, filtering articles published in the last five years, with full texts available.

The first selection phase involved analyzing the titles and abstracts of the articles found, applying specific inclusion criteria: (a) the article should focus primarily on clinical outcomes or morbidity related to

the use of MitraClip; (b) the study should have been collected and published in the last five years; (c) the full text should be available. Articles that did not meet the theme, incomplete articles, and duplicates were excluded.

In the second selection phase, 23 articles that met the criteria were read in full, resulting in a final sample of 16 studies after excluding duplicates. A detailed critical reading of each article was performed by all authors, followed by the organization and indexing of the extracted data, allowing for an analysis with bibliometric characteristics.

Based on the terms selected for the research, 72 articles were found. As inclusion criteria, articles in English, Portuguese, and Spanish, published in the last 5 years, and with texts available in full, were selected. Then, the titles and abstracts of the previously selected articles were read, and those that were not related to the theme were excluded. After applying these criteria, we obtained a sample of 23 articles. Finally, after reading the published works in full, 16 of them were selected to compose the present study. The search and exclusion process for the present study is represented in the flowchart below (Figure 1).

After selecting the 16 articles that fully met the previously established inclusion criteria, detailed analyses of each study were performed, which were organized according to the specificities of each publication. During the writing of the study, an additional search was conducted, and three other articles were selected using the same criteria and sources previously established. This allowed for the articulation of the concepts and knowledge produced in the various publications.

## RESULTS AND DISCUSSION

The MitraClip is a percutaneously implanted device that aims to transform the valve apparatus into a competent structure in order to reduce and even eliminate mitral regurgitation (ROGERS & FRANZEN, 2011). Its indication, according to the 2020 Brazilian Guideline on Valvular Heart Disease of the Brazilian Society of Cardiology (SBC), would be: patients at high surgical risk or who have contraindications to surgery and primary mitral regurgitation of non-rheumatic etiology with refractory symptoms (recommendation class [CR] IIa) or associated with secondary mitral regurgitation and ischemic/dilated cardiomyopathy with persistent refractory symptoms (CR IIa). (TARASOUTCHI et al., 2020)

On the other hand, conventional treatment through surgery can be used in two ways: mitral valve repair or valve replacement. The first technique is preferable to the second, provided there is favorable anatomy and a skilled surgical team. However, for patients with primary mitral regurgitation of rheumatic etiology, valve repair receives CR IIb, while valve replacement receives CR I. For non-rheumatic patients, both techniques have CR I. In turn, patients with secondary ischemic or dilated disease have CR IIa for both techniques, provided they are also candidates for myocardial revascularization. Otherwise, the CR changes to IIb. (TARASOUTCHI et al., 2020)

Studies indicate that transcatheter mitral valve repair (TMVR) associated with drug therapy (GDMT) improved symptoms 2.23 times more compared to clinical treatment alone. In addition, it increased patients' physical and social capacity, quality of life, and autonomy. It was found that

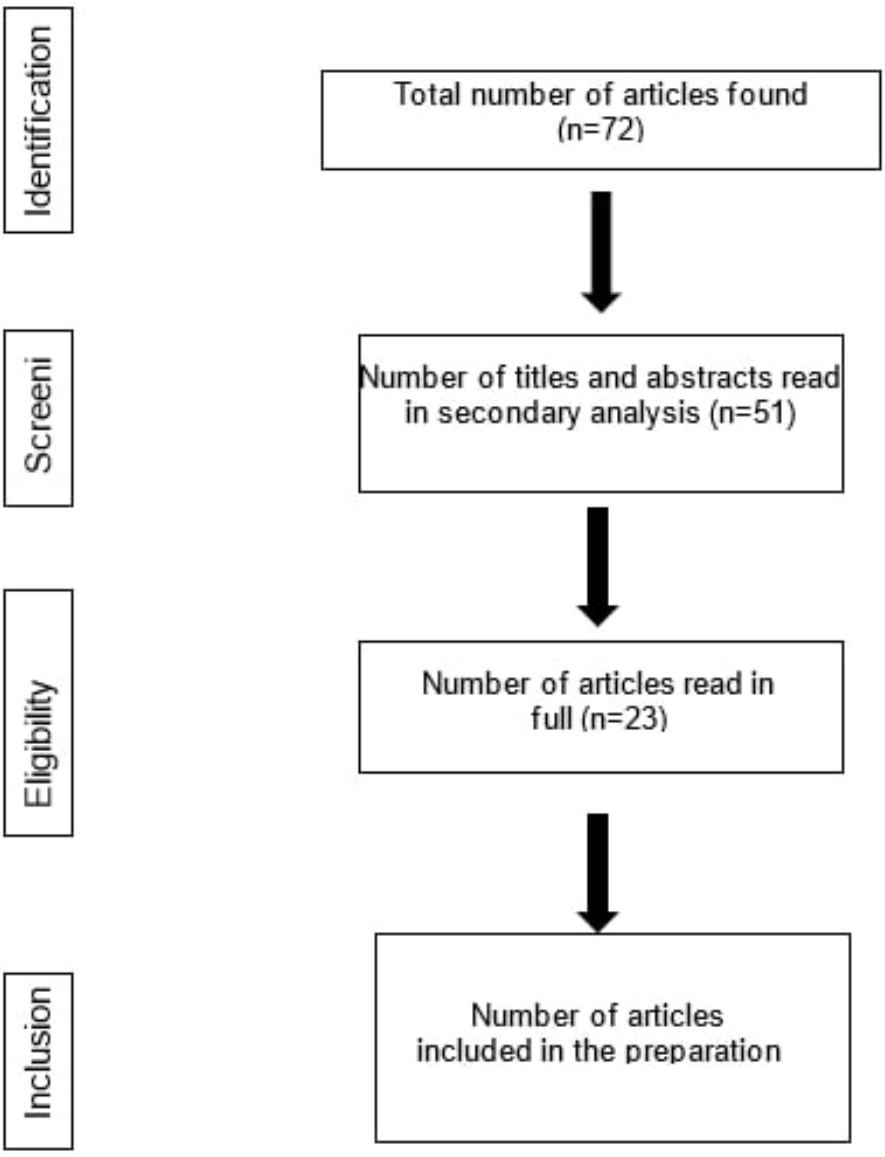


**Figure 1** – Flowchart of the search and retrieval of articles for this review.

TMR associated with GDMT reduced key outcomes such as mortality and hospitalization for heart failure by up to 14% within 2 years after the start of the intervention (ARNOLD, 2020).

At the same time, this combination showed good results on echocardiography, in contrast to GDMT alone. MitraClip was able to reduce the mitral regurgitation gradient by up to 2+ in 95% of patients who underwent the implant. Specifically, patients who had an effective regurgitant orifice area (EROA) >0.3 $cm^2$ and left ventricular end-diastolic volume (LVEDV) ≤96 mL/$m^2$[22] and left ventricular end-diastolic volume (LVEDV) ≤96 mL/$m^2$ had 287% more success when compared to treatment with GDMT alone over a 24-month period (LINDENFELD, 2021).

According to the results of a systematic review and meta-analysis of 14 observational studies, which evaluated the efficacy of percutaneous mitral valve repair with MitraClip in parallel with surgery and clinical therapy, there is no difference in the mortality rate at 12 and 24 months when compared to the surgical approach. Regarding the durability of the procedure, MitraClip was not inferior to surgery. However, when compared to clinical therapy, there was a considerable reduction in mortality (KADDOURA et al., 2023).

In this regard, a study conducted from 2000 to 2011 at two centers in Milan observed 143 patients with mitral regurgitation and severe ventricular dysfunction. It was observed that in conventional surgery, hospital mortality was higher when compared to MitraClip, being 6.6% and 0%, respectively, demonstrating that the surgical procedure could be linked to a higher chance of such a negative outcome. Regarding cardiovascular mortality, the values were 9.9% for surgery and 3.8% for MitraClip, corresponding to a follow-up of 45 months and 12 months for the respective procedures. In addition, a higher probability of infections and sepsis was associated with surgery (16.5%) compared to the transcatheter procedure (3.8%), which may be correlated with in-hospital death outcomes. There was no difference in 1-year survival, corresponding to 88.9% for surgery and 87.5% for MitraClip (TARAMASSOA et al., 2012).

Another meta-analysis evaluated the clinical outcomes associated with mitral repair using MitraClip for functional regurgitation. Seven studies were included, with a total of 2,189 patients, divided into 1,174 who underwent the percutaneous procedure and 1,015 who underwent drug therapy. It was observed that rehospitalization at 1 year was significantly lower in the MitraClip group compared to drug therapy, corresponding to 29.9% and 54.1%, respectively. In addition, 1-year mortality was also lower in the group of patients who underwent the procedure, with a rate of 18.4% compared to the use of medications, with a rate of 25.9%. Thus, the efficacy and safety of MitraClip are observed, being considered superior to the use of medications alone. (MARMAGKIOLIS et al., 2019)

From this perspective, a meta-analysis of 29 studies was published in 2006 with the objective of evaluating mortality, morbidity, and clinical outcomes associated with conventional mitral valve repair or replacement surgery. It was observed that there was no statistical difference between the two techniques when analyzing the time to reoperation, with a hazard ratio of 0.88 [95% CI = (0.48, 1.62)]. As a clinical outcome of postoperative thromboembolism, there is a

higher chance of such an event in valve replacement, with a hazard ratio of 1.86 [95% CI = (1.24, 2.81)]. Regarding early mortality, valve repair also has a significant advantage, with a significant reduction in death [OR = 2.24, 95% CI = (1.78, 2.80)]. When analyzing total survival after surgery, there are worse outcomes when using valve replacement, with a 58% increase in the chance of such a fatal outcome, corresponding to a hazard ratio of 1.58 [95% CI = (1.41, 1.78)]. (SHUHAIBER & ANDERSON, 2006)

Aiming to understand the presence of symptoms and the results obtained after the procedure, the EVEREST II study followed up 327 patients 12 months after mitraclip implantation. During this period, the NYHA (New York Heart Association) functional class improved in 82% of patients classified as class III and IV at the beginning of the study, progressing to class I or II after 12 months. The Kaplan-Meier survival assessment at the end of the study was 77.2%. In addition, mitral regurgitation was reduced to less than or equal to 2+ in 84% of patients after 1 year, showing a decrease in mortality and improvement in symptoms. (GLOWER et al., 2014)

From a similar perspective, the COAPT study was conducted to understand the relationship between functional class and outcomes related to heart failure and mitral regurgitation in patients undergoing mitraclip compared to the use of medications. It was observed that, of the 613 patients observed over 2 years, the mortality and hospitalization rates for heart failure were reduced with the device by: 39.7% and 63.7% (HR of 0.54; 95%, CI: 0.37-0.77), respectively for NYHA II; 46.6% and 65.5% (HR of 0.60; 95% CI: 0.45-0.82), respectively for NYHA III; 66.7% and 85.2% (HR of 0.55; 95% CI: 0.28-1.10), respectively for NYHA IV. This shows that the use of MitraClip is effective in several functional classes. (GIUSTINO et al., 2020)

Recent studies highlight the importance of treating mitral regurgitation (MR) to prevent ventricular remodeling and progression to intrinsic myocardial disease. In patients considered high risk or in cases where traditional surgical repair is not feasible, percutaneous intervention with the MitraClip device is a minimally invasive alternative. This approach aims to correct mitral regurgitation, promoting improved cardiac function and symptom relief, and is especially advantageous for patients with traditional surgical contraindications (KADDOURA et al., 2023).

Although clinical therapy for MI is effective in relieving symptoms, it does not halt the progression of the disease, making intervention with MitraClip or other surgical approaches essential for long-term control. In cases of significant mitral regurgitation, direct structural correction is crucial, as without it, the condition can progress to irreversible complications and functional deterioration. Thus, the use of MitraClip offers an alternative that goes beyond symptomatic control, being essential to prevent disease progression and preserve cardiac function (ZHOU et al., 2020).

Despite the advantages of MitraClip, the procedure is not without risks and possible complications, such as the need for reintervention in cases of implantation failure or device displacement. As a foreign body, MitraClip can cause damage to the valve apparatus and chordae tendineae, raising new structural concerns. There is also a risk, albeit rare, of vascular injury, mitral steno-

sis, and intraoperative complications, such as stroke and acute myocardial infarction, which must be considered when assessing the patient's risk profile. This scenario highlights the importance of rigorous selection and post-procedure follow-up to minimize risks and maximize the benefits of the intervention (MAHABIR, 2020).

## CONCLUSION

MitraClip has emerged as a viable and promising alternative for the treatment of mitral regurgitation in patients at high cardiovascular risk, offering the benefits of a less invasive approach and reduced hospital stays, with a safety profile comparable to that of conventional surgery. However, despite its benefits, there are still challenges related to possible complications, such as insertion failures or damage to adjacent cardiac structures. Studies show that, in the long term, mortality associated with MitraClip is similar to that of conventional surgery, which reinforces the importance of a personalized therapeutic choice based on the specific needs of each patient to optimize clinical outcomes. Although initial results are encouraging, expanding the use of MitraClip to low- to intermediate-risk patients requires further investigation to ensure its long-term durability and effectiveness, especially in this population, which has been less studied to date.

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