

The MitraClip System: A Systematic Review of Indications, Procedural Requirements, and Guidelines

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Abstract

Background Transcatheter interventions (TIs) are new treatment options for patients with severe mitral valve regurgitation (MR) who cannot undergo open mitral valve surgery (oMVS). Despite the lack of scientific evidence demonstrating the benefit of these procedures, there has been a steady increase in their use. The aim of this study was to evaluate whether there are any indication criteria, process, and structural requirements, or scientific society and institutional guidelines for the use of the MitraClip System (Abbott Vascular-Structural Heart, Menlo Park, California, United States).

Method A systematic literature search was conducted using the common medical and scientific databases. Of a total of 1,395 publications, 42 publications met the inclusion criteria and were included for the evaluation.

Results Despite a general lack of high-quality evidence and of consensus recommendations from scientific societies or institutions, an assessment of indication criteria and process and structural requirements for the use of the MitraClip System, including noncontrolled studies, was possible. The majority of studies agree that an interdisciplinary heart team including a cardiothoracic surgeon, an interventional cardiologist, and an echocardiographic specialist should actively participate in clinical decision making, and in the procedure itself. Participation in a scientific-based registry is strongly recommended.

Conclusions The MitraClip System is a promising procedure, but evidence-based indication criteria, structural, and process requirements for its use are lacking. Further results from prospective, randomized controlled trials are needed to determine patients, potential adverse events, device durability, and long-term follow-up. MitraClip should be used in only a small number of centers with procedure-specific, high-quality surgical and interventional experience, and training.

Keywords

- ▶ MitraClip
- ▶ mitral regurgitation
- ▶ mitral valve repair
- ▶ transcatheter interventions

Introduction

Mitral valve regurgitation (MR) is the second most common valve disease in Europe.¹ The classification and recommendations for intervention in MR are defined in the Clinical Practice

Guidelines of the European Society of Cardiology (ESC) and the American College of Cardiology and American Heart Association (ACC/AHA) Task Force.^{2,3} Surgical mitral valve repair (MVR) is generally considered the “gold standard” treatment for MR; however, randomized studies documenting the

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outcomes and long-term follow-up of patients are still lacking.^{3–6} As a significant number of patients (49%)⁷ with severe MR are not treated because of age, reduced left ventricular function, comorbidities, or other contraindications to open mitral valve surgery (oMVS),⁷ less invasive percutaneous MVR procedures have been developed.

The MitraClip System (Abbott Vascular-Structural Heart, Menlo Park, California, United States) is the only approved system in Europe for beating-heart endovascular transcatheter MVR. In this technique, both mitral valve leaflets are attached with one or more clips, resulting in a so-called “double-orifice mitral valve”. Despite the lack of scientific evidence of proven benefit of the MitraClip procedure, a steady increase in its use has been seen in Germany and Europe. According to Federal Statistical Office registered data (provided on request), 51 endovascular MVR procedures were performed in 2008, whereas in 2010, 809 procedures were performed, corresponding to an increase of 1,500%. The age distribution (<75 years) seems to suggest that the procedure was not restricted to only elderly and high-risk patients.

Aims of the Study

The aims of this study were to perform a systematic literature review to evaluate (1) whether there are any indication criteria, process and structural requirements, or scientific society and institutional guidelines for the use of the MitraClip System, and (2) to establish whether there is an evidence base demonstrating clinical benefit of the MitraClip System.

Method

A systematic literature search was performed and analyzed with evidence criteria in the following databases: PubMed/Medline, Cochrane Library, and Health Technology Assessment of the German Institute of Medical Documentation and Information. In addition, a general topic-based search was performed using the Google search engine, and a manual search for publications was performed. The search was limited by the following criteria: meta-analyses, controlled clinical trial, humans, randomized controlled trial (RCT), comparative study, review, systematic review, practice guidelines, guidelines, and 10-year period.

Results

A total of 1,395 search results were obtained, and after checking for duplicates and relevance a total of 223 publications remained for evaluation. Of the 1,395 publications, 42 were included to answer the questions. In March 2013, the German Cardiac Society (DGK) together with the German Society of Thoracic and Cardiac- and Vascular Surgery (DGTHG) published a consensus statement and requirements for the treatment of mitral regurgitation and transcatheter treatment with the MitraClip System.^{8,9} No further consensus statements or requirements/guidelines from relevant European and international scientific societies or health-care

institutions were found. Because of the lack of evidence and controlled studies, the presented results with respect to indications, for the procedure, and structural and process requirements, are also based on data extracted from noncontrolled (NC) studies. The publications included in the review and analysis are presented in ►Table 1.

Scientific Evidence Base for the Use of the MitraClip System

In the only RCT, the EVEREST II study (Endovascular Valve Edge-to-Edge Repair Study), the MitraClip (MitraClip group) was compared with conventional oMVS (oMVS group) for the first time in 279 patients.¹⁰ The EVEREST II study, funded by Abbott Vascular, is a multicenter, prospective, single-arm study to evaluate the feasibility, safety, and effectiveness of the MitraClip System with a 30-day, 6-month, 12-month, and 5-year clinical follow-up (Clinicaltrials.gov number NCT00209339). The primary end point for effectiveness at 12 months was absence of death, reoperation due to mitral valve dysfunction, or MR >+2. Procedural success was between 80 and 100%, and reduction of MR to <+2 at 30 days was 77% in the MitraClip group versus 100% in the oMVS group. This was consistent with the success rates seen in the NC studies, which showed a reduction in MR in 60 to 100% of the patients. The need for a second oMVS procedure in EVEREST II was 5.7% in the MitraClip group versus 0% in the oMVS-group at 30 days, and 20 versus 4% at 12 months. The NC studies also showed reoperation rates between 6 and 22.7%. After 2 years, the reoperation rates were 22 and 4% for the MitraClip group and oMVS group, respectively. New York Heart Association (NYHA) class and quality of life were improved within the first 30 days, but there was no difference after 12 months between the two groups in the RCT. The NC studies showed an improvement in NYHA class in 60 to 100% of the patients after 12 months. The major adverse event (MAE) rate was significantly lower at 30 days in the MitraClip group compared with oMVS group. NC studies showed MAE rates between 3 and 26% in patients treated with MitraClip, and therefore, the superiority of the clipping procedure with respect to MAE remains to be proven. With respect to mortality at 30 days (1%) and at 12-month and 24-month follow-up (7%), there was no difference between the two groups in the RCT. NC studies showed mortality rates between 0 and 15% at 30 days and between 7 and 24% at 12 months after the MitraClip procedure. The MitraClip procedure is less invasive than oMVS. To date, no data about cost effectiveness are available, although it has been suggested that costs might be reduced using transcatheter interventions (TIs) such as MitraClip because of shorter hospital stays and a reduction in hospital admissions.¹¹

Measures for Quality Assurance

Despite the lack of evidence, poor quality of the majority of the publications, and lack of international guidelines, indication criteria, and structural and procedural standards could be extracted from the current literature. The extracted requirements are shown in ►Tables 2–4.

Table 1 Studies included in the analysis

1	Alegria-Barrero E, Chan PH, Paulo M, et al. Edge-to-edge percutaneous repair of severe mitral regurgitation—state-of-the-art for Mitraclip [®] implantation. <i>Circ J</i> 2012;76:801–808 ¹⁸
2	Application 1192. Final Decision Analytic Protocol (DAP) to guide the assessment of reduction of mitral regurgitation through tissue approximation using transvenous/transseptal techniques. Available at: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1192 . Accessed May 2012 ¹⁹
3	Auricchio A, Schillinger W, Meyer S, et al. Correction of mitral regurgitation in nonresponders to cardiac resynchronization therapy by MitraClip improves symptoms and promotes reverse remodeling. <i>J Am Coll Cardiol</i> 2011;58:2183–2189 ¹³
4	Baldus S, Schillinger W, Franzen O, et al. MitraClip therapy in daily clinical practice: initial results from the German transcatheter mitral valve interventions (TRAMI) registry. <i>Eur J Heart Fail</i> 2012;14(9):1050–1055 ¹⁴
5	Boekstegers P, Hausleiter J, Baldus S, et al. Interventionelle Behandlung der Mitralklappeninsuffizienz mit dem MitraClip-Verfahren. <i>Kardiologe</i> 2013;7:91–104 ⁸
6	Bohnenblust, H., Hitz, P., Stettbacher, D., et al. Perkutane, Katheter-basierte Behandlung der schweren Mitralklappen-insuffizienz (Percutaneous Mitral Valve Repair). Gesundheitskonferenz GDK. Medical Board. 2010. ¹⁵
7	Conradi L, Treede H, Franzen O, et al. Impact of MitraClip therapy on secondary mitral valve surgery in patients at high surgical risk. <i>Eur J Cardiothorac Surg</i> 2011;40:1521–1526 ²⁰
8	Conradi L, Treede H, Baldus S, Seiffert M, Blankenberg S, Reichenspurner H. [Treating mitral regurgitation: a surgical and interventional update]. <i>Herz</i> 2011;36:677–685 ⁵³
9	Divchev D, Kische S, Paranskaya L, et al. In-hospital outcome of patients with severe mitral valve regurgitation classified as inoperable and treated with the MitraClip [®] device. <i>J Interv Cardiol</i> 2012;25:180–189. ²¹
10	Feldman T, Glower D. Patient selection for percutaneous mitral valve repair: insight from early clinical trial applications. <i>Nat Clin Pract Cardiovasc Med</i> 2008;5:84–90 ⁵⁰
11	Feldman T, Cilingiroglu M. Percutaneous leaflet repair and annuloplasty for mitral Regurgitation <i>J Am Coll Cardiol</i> 2011;57:529–537 ²²
12	Feldman T, Foster E, Glower DD, et al. Percutaneous repair or surgery for mitral regurgitation. <i>N Engl J Med</i> 2011;364:1395–1406 ¹⁰
13	Franzen O, Seiffert M, Baldus S, et al. Percutaneous mitral valve repair as a bail-out strategy for patients with severe mitral regurgitation after cardiac surgery. <i>J Thorac Cardiovasc Surg</i> 2011;142:227–230 ²³
16	Franzen O, van der HJ, Baldus S, et al. MitraClip [®] therapy in patients with end-stage systolic heart failure. <i>Eur J Heart Fail</i> 2011;13:569–576 ²⁴
17	Glower D, Ailawadi G, Argenziano M, et al. EVEREST II randomized clinical trial: predictors of mitral valve replacement in de novo surgery or after the MitraClip procedure. <i>J Thorac Cardiovasc Surg</i> 2012;143: S60–S63 ²⁵
18	Holmes DR, Jr., Mack MJ. ACCF/AATS/SCAI/STS expert consensus document on transcatheter aortic valve replacement: developed in collaboration with the American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Failure Society of America, Mended Hearts, Society of Cardiovascular Anesthesiologists, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance <i>Thorac Cardiovasc Surg</i> 2012;144(3): e29–e84 ²⁶
19	Jilaihawi H, Hussaini A, Kar S. MitraClip: a novel percutaneous approach to mitral valve repair. <i>J Zhejiang Univ Sci B</i> 2011;12:633–637 ²⁷
20	Maisano F, Alfieri O, La CG. Percutaneous mitral repair with the MitraClip. <i>Ann Fr Anesth Reanim</i> 2011;30 Suppl 1:S33–S37 ²⁸
21	Maisano F, Godino C, Giacomini A, et al. Patient selection for MitraClip therapy impaired left ventricular systolic function. <i>Minerva Cardioangiol</i> 2011;59:455–471 ¹²
22	Neuss M, Schau T, Schoepf M, et al. Patient selection criteria and midterm clinical outcome for MitraClip therapy in patients with severe mitral regurgitation and severe congestive heart failure. <i>Eur J Heart Fail</i> 2013;15(7):786–795 ²⁹
23	NHC. Transcatheter mitral valve repair for severe mitral valve regurgitation. National Health Committee, New Zealand; 2011:1–8 ¹¹
24	NICE. National Institute for Health and Clinical Excellence: Percutaneous mitral valve leaflet repair for mitral regurgitation. Available at: http://guidance.nice.org.uk/ipg309 . ³⁰

25	Nickenig G, Mohr FW, Kelm M et al. Konsensus der Deutschen Gesellschaft für Kardiologie – Herz- und Kreislaufforschung und der Deutschen Gesellschaft für Thorax-, Herz- und Gefäßchirurgie zur Behandlung der Mitralinsuffizienz. <i>Kardiologie</i> 2013;7:76–90. ⁹
26	Obadia JF. MitraClip: Actual data and perspectives. Congrès EBR 2012, Marseille, France, May 3–4th 2012. ³¹
27	Rosenhek R, Iung B, Tornos P, et al. ESC Working Group on Valvular Heart Disease Position Paper: assessing the risk of interventions in patients with valvular heart disease. <i>Eur Heart J</i> . 2012; 33:822–828, 828a, 828b ¹⁷
28	Siegel RJ, Luo H, Biner S. Transcatheter valve repair/implantation. <i>Int J Cardiovasc Imaging</i> 2011;27: 1165–1177 ³²
29	Siegel RJ, Luo H. Echocardiography in transcatheter aortic valve implantation and mitral valve clip. <i>Korean J Intern Med</i> 2012;27:245–261 ³³
30	Smith T, McGinty P, Bommer W, et al. Prevalence and echocardiographic features of iatrogenic atrial septal defect after catheter-based mitral valve repair with the mitralclip system. <i>Catheter Cardiovasc Interv</i> 2012;80(4):678–685 ³⁴
31	Sürder D, Pedrazzini G, Gaemperli O, et al. Predictors for efficacy of percutaneous mitral valve repair using the MitraClip system: the results of the MitraSwiss registry. <i>Heart</i> 2013;99(14):1034–1040 ³⁵
32	Sven TP, Krumdorf U, Schulz-Schönhausen M, Chorianopoulos E, Katus HA, Bekerredjian R. Endovascular MitraClip repair of severe mitral valve regurgitation in patients with endstage heart failure. <i>EuroIntervention</i> 2011;7 ³⁶
33	Swaans MJ, Van den Branden BJ, Van der Heyden JA, et al. Three-dimensional transoesophageal echocardiography in a patient undergoing percutaneous mitral valve repair using the edge-to-edge clip technique. <i>Eur J Echocardiogr</i> 2009;10:982–983 ³⁷
34	Tamburino C, Imme S, Barbanti M, et al. Reduction of mitral valve regurgitation with Mitraclip® percutaneous system. <i>Minerva Cardioangiol</i> 2010;58:589–598 ³⁸
35	Taramasso M, Denti P, Buzzatti N, et al. Mitraclip therapy and surgical mitral repair in patients with moderate to severe left ventricular failure causing functional mitral regurgitation: a single-center experience. <i>Eur J Cardiothorac Surg</i> 2012;42:920–926 ³⁹
36	Treede H, Schirmer J, Rudolph V, et al. A heart team's perspective on interventional mitral valve repair: percutaneous clip implantation as an important adjunct to a surgical mitral valve program for treatment of high-risk patients. <i>J Thorac Cardiovasc Surg</i> 2012;143:78–84 ⁴⁰
37	Turi ZG, Rosenbloom M. An option for the high-comorbidity patient with mitral regurgitation. <i>J Am Coll Cardiol</i> 2012;59:140–142. ⁴¹
38	Van den Branden BJ, Swaans MJ, Post MC et al. Percutaneous edge-to-edge mitral valve repair in high-surgical-risk patients: do we hit the target? <i>JACC Cardiovasc Interv</i> 2012;5:105–111 ⁴²
39	Whitlow PL, Feldman T, Pedersen WR, et al. Acute and 12-month results with catheter-based mitral valve leaflet repair: the EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study. <i>J Am Coll Cardiol</i> 2012;59:130–139 ⁴³
40	Yuksel UC, Kapadia SR, Tuzcu EM. Percutaneous mitral repair: patient selection, results, and future directions. <i>Curr Cardiol Rep</i> 2011;13:100–106 ⁴⁴
41	Zamorano JL, Badano LP, Bruce C, et al. EAE/ASE Recommendations for the Use of Echocardiography in New Transcatheter Interventions for Valvular Heart Disease. <i>J Am Soc Echocardiogr</i> 2011;24:937–965 ⁴⁵
42	Vahanian A, Iung B. 'Edge to edge' percutaneous mitral valve repair in mitral regurgitation: it can be done but should it be done? <i>Eur Heart J</i> 2010;31:1301–1304 ⁴⁶

Discussion

Benefit Assessment

Until now, there have been no systematic studies evaluating the evidence regarding the safety, efficacy, and cost-effectiveness of the MitraClip System compared with oMVS. In the only published RCT no superiority of MitraClip is demonstrated. Although quality of life and NYHA class were significantly improved in the first 12 months postprocedure, there was no difference to oMVS. There were also no significant differences with respect to MAE and mortality rate. The high reoperation

rate after the MitraClip procedure of 20% at 12 months, missing data on long-term follow-up and outcomes, and inadequate reporting of the number and nature of MAEs also cannot be ignored.

Recommendations Concerning Indication Criteria

There are no clear, scientifically based, indication criteria for the use of the MitraClip System. The literature suggests that there may be a benefit for “inoperable” or “high-risk” patients with severe MR (3+ or 4+) with clear indication for oMVS (similar to the definition of inoperability and high risk in

Table 2 Indication criteria and contraindications for the use of the MitraClip system

Certain indications (patients benefit from treatment)	References
Symptomatic/asymptomatic MR 3+ to 4+ with reduced LVEF Functional MR	8–12,19,29,31,35,36,39,40,47,48
Multimorbidity, high-risk patient, contraindication for oMVS: log EuroScore > 20% and/or STS-Score >10%	11,13,14,19,21,24,26,31,35,42,43,48,49
AHA/ASC/ESC criteria for oMVS fulfilled	10–12,20,21,38,40,43,45,47,50
Previous cardiac surgery	13,14,20,26,40,45
Echocardiographic criteria for treatment with MitraClip system fulfilled	8,9,19,32,33
Chest radiation/porcelain aorta	8,9,16,26,45,51
Possible indications	
Symptomatic or asymptomatic MR 3+ to 4+ with normal LVEF and above described risk factors Degenerative MVR (DMI)	11,13,14,19,21,24,31,35,42,43,48,49 8,9
Ultima ratio after failed oMVS	8,9,23
Younger patients (< 75 y) as a bridge to cardiac surgery or for whom life-long anticoagulant medications would be unacceptable (women before childbearing or pregnant)	8,9,19
Contraindications	
Mitral valve area < 4.0 cm ² Severe annular and leaflet calcification Active endocarditis Transient ischemic attack or stroke 6 mo previously Myocardial infarction < 3 mo previously Intracardiac thrombus mass Degenerated from rheumatic disease Clip placement not possible due to anatomical characteristics Flail leaflet LVESD von > 60 mm LVEF < 20% MI 2+ coronary artery disease with the need of revascularization	8,9,12,18,21,44,48,50

Abbreviations: AHA, American Heart Association; ESC, European Society of Cardiology; LVEF, left ventricular ejection fraction; left ventricular enddiastolic diameter; MI, myocardial infarction; MR, mitral regurgitation; oMVS, open mitral valve surgery.

transcatheter aortic valve implantation [TAVI] procedures). There is, however, agreement within the literature that indications for the use of the MitraClip System should be adapted to the guidelines of the ESC and ACC/AHA for the treatment of MR.^{2,3} There are ongoing discussions about suitable etiologies of MR indicating the use of MitraClip for treatment. Functional MR (FMR) is currently the main indication for the MitraClip System; in FMR, there are no structural alterations of the mitral leaflets so optimal clip placement is anatomically possible. The decision for treatment should be taken according to similar guidelines established for the TAVI procedure, namely, in a multidisciplinary heart team which includes an interventional cardiologist, a cardiac surgeon, and an echocardiography specialist (►Table 3).

Recommendations for Structural, Procedural, and Documentation Standards

This literature does not provide the scientific evidence base for the structural, procedural, or documentation standards that should be adopted for MitraClip use. Before MitraClip treatment,¹² medications need to be optimized and, if applicable, cardiac resynchronization therapy should be performed.¹³ The

presence of a catheter laboratory and/or a hybrid operation room, and transesophageal echocardiography (TEE), are minimal requirements (►Table 3). Many authors recommend three-dimensional TEE, a specialized echocardiography laboratory, and an echocardiographic specialist with specialist expertise in the MitraClip System and/or expertise in MVR (►Tables 3 and 4). The MitraClip procedure should be performed only in an interdisciplinary heart team in hospitals with departments of cardiac surgery and cardio-anesthesia that possess technical equipment for treatment of intraprocedural complications using extracorporeal circulation (ECC). A special focus is placed on the demand for an interventional cardiologist with specialist expertise in transseptal puncture. A further recommendation is the inclusion of the patients treated with the MitraClip System in a scientific registry and controlled clinical studies, the German aortic valve registry could serve as a model for this (►Table 4).^{14–16}

Further Areas of Research

Before any further expansion of the use of the MitraClip procedure further data about indications and long-term results are needed to enable valid comparison with “gold-standard” oMVS. In the early postoperative course, the MAE

Table 3 Structural requirements

Structural requirements	References
Technical resources	
TEE and TTE Echocardiography laboratory (ideally 3D TEE)	8,9,11,12,19,22,27 32,37,43,45,49,51
Hybrid operation room (Cardiac catheter laboratory/fluoroscopy) (mobile X-ray with C-arm not sufficient)	8,9,12,19,22,27,43,49
Cardiac surgery on-site (to handle potential intraprocedural complications)	49,52
Intensive care unit (24 h monitoring)	3,19,22,27,45,49
Anesthesiologist with cardiac expertise	3,19,22,27,45,49
Personnel resources	
Interventional cardiologist (expertise in transseptal puncture)	8,9,13,19,45,47,49,52
Special echocardiography training (Mitral valve repair, transseptal puncture)	3,8,9,19,45,49,52
Heart team—multidisciplinary (cardiac surgeon and cardiologist)	3,8,9,11,19,49,52

Abbreviations: TEE, transesophageal echocardiography; TTE, transthoracic echocardiography; 3D, three-dimensional.

rate is an essential criterion, in particular bleeding, although neurological and renal complications should also be evaluated. Furthermore, critical points for evaluation are reoperation and reintervention rates in the early postoperative period, and during long-term follow-up. A clear definition of high-risk patients is missing, although the TAVI definitions might provide a framework for future guidelines.¹⁷ So far, no superiority in cost effectiveness has been shown for the MitraClip System.

Perspectives

Currently, there do appear to be hazards associated with MitraClip therapy. However, the MitraClip procedure has the potential to be a valid treatment option for selected patients with severe MR. In particular, based on current evidence, high-risk symptomatic, or otherwise inoperable patients with severe MR seem to be the best candidates for the MitraClip System, whenever echocardiographic criteria of eligibility are met. From the current results, no conclusions can be drawn on what the routine indications are for the MitraClip System. It is also of concern that there is no obligate or statutory regulation on necessity for multidisciplinary care, with involvement of a cardiac surgeon and cardiac anesthesiologist. The MitraClip device should be used only in a small number of centers, with specialized surgical and interventional experience and training. It is believed that other innovative interventional procedures are already in

Table 4 Process requirements

Process requirements	References
Indication by interdisciplinary team: primary cardiologist, interventional cardiologist, cardiac surgeon, cardiac anesthesiologist, imaging specialist	3,8,9,11,12,19,41,45,49,52
Before first implantation specific training of all participants and technical support of the manufacture	45,49,52
Performed by interdisciplinary heart team (cardiologist, interventional cardiologist (with expertise in trans-septal puncture), cardiac surgeon, anesthesiologist with cardiac expertise)	11,19,45,49,53
Echocardiologist with special expertise and training in MVR and cardiac interventional procedures, special training for MitraClip intervention, special expertise in TEE and 3D TEE	8,9,11,19,25,32,34,45,49,52
Participation in registry or clinical trial	11,14,15,52

Abbreviations: TEE, transesophageal echocardiography; 3D, three-dimensional.

use for treatment of MR, rules and recommendations need to be applicable and available at an early stage of implementation.

Conclusions

Analogous to the widely used TAVI procedures, treatment with the MitraClip System should be restricted to patients in which oMVS is contraindicated, or where there is very high perioperative risk (such as Society of Thoracic Surgeons score > 10 or EuroScore > 20, age > 75 years) in selected cases. Specific risk scores and models should be developed for the implementation of novel products for transcatheter interventions.

The majority of studies are in agreement that a “heart team” approach, in which a cardiac surgeon, an interventional cardiologist and an echocardiographic specialist actively participate in the procedure. Participation in a national scientific-based registry is strongly recommended. Further results from prospective, RCTs are needed to determine device durability and the ideal candidates for the procedure.

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