

Setting Up a MitraClip and TriClip Program

Essential considerations when expanding your practice.

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Surgical repair or replacement of the mitral valve has been the mainstream therapy for severe mitral regurgitation (MR) to improve quality of life and prognosis. However, surgical mitral valve repair tends to be underutilized in the high-risk elderly population who would otherwise benefit from this treatment modality. The Alfieri stitch surgical repair technique has successfully been translated as transcatheter valve repair using the MitraClip (Abbott Vascular),¹ resulting in a durable reduction in MR, a decrease in left ventricular end-diastolic volumes, and fewer hospitalizations with improved functional status with this percutaneous method.² Over time, MitraClip has become a highly effective procedure with reduced length of hospital stay and good patient experience with quick recovery. More than 60,000 patients have undergone MitraClip therapy since its initial CE Mark approval in 2008. This article highlights the steps necessary to set up a MitraClip program, which also serves as the basis to expand to a TriClip program in the future.

FUNDAMENTALS FOR STARTING A MITRACLIP PROGRAM

Medicare Requirements

In order to accept and treat Medicare patients, which constitutes a majority of patients, the Centers for Medicare & Medicaid Services mandates a requirement of 25 total mitral valve surgical procedures per year, and at least 10 should be mitral valve repair. The institution should be doing at least 1,000 cardiac catheterizations and 400 percutaneous coronary interventions per year.³ Other federal or national requirements may vary from country to country.

Buy-in From Hospital Leadership

It is imperative to understand your institution's geographic needs, focus, budget, and infrastructure. Apart from clinical needs, the economic impact of having a MitraClip program may need to be presented at an execu-

tive business meeting for the hospital administration to understand and get their buy-in and valuable support. This is paramount to have a sustainable program. The upfront costs for additional hardware, such as three-dimensional transesophageal echocardiography (TEE) probes, a hybrid cardiac catheterization laboratory, and the hiring of additional staff members and maintaining a registry should be highlighted. Most institutions keen on having a MitraClip program may already have an active transcatheter aortic valve replacement program with a heart team in place for care and coordination. The willingness of and full support from the administration stakeholders is the first step to get the process rolling.

Building the Team

The heart team concept embodies collaboration and dedication across various specialties to offer optimal patient-centered care. The team leveraging the multidisciplinary conference should be composed of a dedicated structural interventionalist, a dedicated imaging cardiologist, a heart failure specialist, a dedicated cardiothoracic surgeon, a dedicated anesthesiologist, and, importantly, a valve coordinator.

The extended heart team comprises cath lab/operating room, intensive/coronary care units, perfusion, and other staff, such as cardiac electrophysiology, neurology, physical therapy, cardiac rehabilitation, nursing, and a data abstractor for various registries.

Minimizing patient visits is extremely important. A tag-team approach in which the patient is evaluated by the entire team in one visit is very efficacious. Patients should be encouraged to include their family in the education process about the risks and benefits of the procedure, as well as their chosen power of attorney.

Workup

It is essential to perform a detailed patient evaluation with transthoracic echocardiography to assess the

severity of MR, followed by TEE to identify the nature of mitral valve pathology, preprocedural mitral valve gradient, mitral valve area, and other leaflet variables to determine the suitability of MitraClip. Chest CT might also be required to evaluate for mitral annular and leaflet calcification. Right and left heart catheterization is also a part of the preprocedural evaluation to assess pulmonary hemodynamics and coronary artery disease.

After a full workup, the next step is to present the case at a weekly valve conference consisting of surgeons, structural interventionalists, heart failure specialists, imaging specialists, cardiac anesthesiologists, nurse practitioners, and other medical specialists (nephrologists, pulmonologists, geriatricians, hepatologists, oncologists) involved in the care of the patient. The discussion should be collaborative and at a granular level, keeping the patient and family wishes in mind to determine the best approach on whether to proceed with MitraClip versus surgery or continue optimal medical management. A discussion regarding the flow and utilization of rehabilitation services either before (prehab) or after the procedure is important to reduce length of stay. Making an institutional flow chart of conditions indicating high-risk patients for which a longer length of stay is anticipated versus conditions indicating low-risk patients who could be fast tracked and possibly discharged on the next day is crucial.

Setting Up the Hybrid or Cardiac Catheterization Laboratory

There should be a dedicated fluoroscopy screen, apart from the regular setup, to allow the imaging cardiologist to determine the real-time steps and location of hardware (in orientation with the relevant TEE images) and get the area of interest under focus for the structural interventionalist.

LEVEL OF EXPERTISE AND TRAINING REQUIREMENTS

Due to widespread interest and the increasing procedural complexity of structural heart disease, at least 1 year of structural heart disease fellowship training is now considered a standard requirement for understanding the workup, planning, and procedural steps necessary for managing potential complications. This requirement is also becoming a norm in a majority of the medical executive committees for credentialing and privileging.

From a procedural standpoint, it is extremely important to have a dedicated team with one structural interventionalist, one cardiothoracic surgeon, and one imaging cardiologist so that the team becomes more proficient over time and establishes a rhythm with the procedural steps.

BUILDING THE FIRST 10 CASES

The valve clinic coordinator should compile the first 10 cases to ensure all the workup is done and presented at the multidisciplinary team conference. Imaging studies with TEE should be reviewed by the imaging cardiologist, structural interventionalist, and the surgeon to have a clear understanding of the suitability of the mitral valve for clip implantation, assess interatrial septum thickness, and educate and standardize used terminology during the procedure to have a smooth flow. It is imperative for the imaging cardiologist to understand the steps and help the team at every step by bringing the region of interest into focus. The different phases, steps, and maneuvers of the procedure primarily include transseptal puncture; watching the septum while crossing with the guide; making sure the entire atrium is visualized during straddling and aligning the system toward the mitral valve; and ensuring biplane views to view the mitral valve and the crossing, grasping, closure, and stability of clip; as well as monitoring gradients with respect to blood pressure.

Abbott Vascular offers a 2-day course for new sites in which the team can present their cases with TEE images to the clinical specialist and proctors who help screen for patient candidacy.

Preprocedural Planning

An extreme level of planning and alternative procedural strategies in case of obstacles or complications should be discussed constructively. It is invaluable to have the entire team visit an established center, pair up with their respective counterparts, and implement standard techniques. It is important to simulate the flow of a live case; one going well and another with potential complications to understand the readiness of everyone involved.

Detailed preprocedural instructions need to be given to the patients to reduce anxiety. Medication changes, such as the time to stop anticoagulants before the procedure, need to be conveyed in a written format.

PROGRAM MARKETING AND AUDIT

Marketing and outreach are important for the initial growth of a practice and to maintain and sustain the program. It is important to track referral patterns, communicate with referring physicians, and continue expanding the program. Prompt communication is the key to success.

Representing the practice as a truly multidisciplinary effort with unified ways of communication should be helpful. Some centers successfully installed a dedicated structural division led by cardiology, cardiac surgery, imaging, and anesthesiology to support this effort. Eventually, dedicated, high-quality patient management will be rewarded.

Patient selection, outcomes as compared to national average, procedure time, recovery time, total hospital stay, and patient satisfaction should be monitored on a continuous basis with process improvement protocols in place.

WOULD A MITRACLIP PROGRAM AFFECT SURGICAL MITRAL VALVE VOLUME?

There may be an inherent fear among cardiothoracic surgeons that this technology would reduce their volume of traditional open chest mitral valve surgeries. In fact, the opposite is true. With a MitraClip program in place, the message that goes out in the community and the referring physicians is very loud and clear; the structural and surgical teams are working as a team and patients are collectively offered the entire spectrum of the available options and not just one. There has been a very positive impact and growth of surgical volumes related to MitraClip programs.⁴

HOW TO MOVE ON TO TRICUSPID VALVE INTERVENTION

The field of transcatheter interventions for tricuspid regurgitation is a very new, fast-evolving, and promising field of interventional cardiology.^{5,6} Worldwide, among several different devices and techniques, MitraClip implantation in the tricuspid position currently represents the most frequently performed procedure on the tricuspid valve. Given that imaging is complex, patient selection is crucial at this stage because it is not fully understood and steering of the device is only possible with some modifications to the technique. Thus, MitraClip implantation into the tricuspid valve should be reserved for highly experienced centers in mitral valve interventions. Furthermore, given that this procedure is off-label, interventions should be mainly restricted to clinical trials at this time.

SUMMARY

This is a short and concise guide to starting a MitraClip program. It may be possible that some institution- and country-specific steps may have been missed. The fundamental elements for success include a dedicated team with a well-trained structural interventionalist, cardiothoracic surgeon, imager, anesthesiologist, and valve coordinator. Prompt communication with the referring physician is the key to building trust and expanding the practice. ■

1. Alfieri O, Maisano F, De Bonis M, et al. The double-orifice technique in mitral valve repair: a simple solution for complex problems. *J Thorac Cardiovasc Surg*. 2001;122:674-681.
2. Lurz P, Serpytis R, Blazek S, et al. Assessment of acute changes in ventricular volumes, function, and strain after interventional edge-to-edge repair of mitral regurgitation using cardiac magnetic resonance imaging. *Eur Heart J Cardiovasc Imag*. 2015;16:1399-1404.
3. Taramasso M, Maisano F, Latib A, et al. Clinical outcomes of MitraClip for the treatment of functional mitral regurgitation. *EuroIntervention*. 2014;10:746-752.
4. Downs E, Lim S, Ragosta M, et al. The influence of a percutaneous mitral repair program on surgical mitral valve volume. *J Thorac Cardiovasc Surg*. 2015;150:1093-1097.
5. Taramasso M, Maisano F. Novel technologies for percutaneous treatment of tricuspid valve regurgitation. *Eur Heart J*. 2017;38:2707-2710.
6. Besler C, Orban M, Rommel KP, et al. Predictors of procedural and clinical outcomes in patients with symptomatic tricuspid regurgitation undergoing transcatheter edge-to-edge repair. *JACC Cardiovasc Interv*. 2018;11:1119-1128.

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