CorHealth Ontario

Advancing cardiac, stroke and vascular care

Ontario Mitral Valve Clip Procedure: Patient Eligibility Criteria Guidelines & Facility Quality Criteria

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About CorHealth Ontario

As of June 22, 2017, we are CorHealth Ontario, an organization formed by the merger of the Cardiac Care Network of Ontario and the Ontario Stroke Network, with an expanded mandate spanning cardiac, stroke and vascular through the entire course of care including secondary prevention, rehabilitation and recovery. CorHealth Ontario proudly advises the Ministry of Health and Long - Term Care (MOHLTC), Local Health Integration Networks, hospitals, and care providers to improve the quality, efficiency, accessibility and equity of cardiac, stroke and vascular services for patients across Ontario. For more information, visit corhealthontario.ca.

Purpose

Percutaneous mitral valve repair using a Mitral Valve Clip system is a novel and promising therapy for the treatment of mitral regurgitation (MR). This therapy is a feasible option for select patients who are not suitable for surgery, such as those with advanced age, multiple comorbidities, and advanced heart failure.

Mitral Valve Clip (MitraClip®) was approved by Health Canada in 2014 and reviewed by the Ontario Health Technology Assessment Committee (OHTAC) in May 2015. OHTAC recommended "that the mitral valve clip procedure be funded in centres of excellence identified by CorHealth Ontario (Formerly: The Cardiac Care Network) and that all such centres enroll patients receiving the mitral valve clip procedure in a CCN supported registry".

In 2016, in the context of the rapidly evolving field of Mitral Valve Clip therapy, CorHealth Ontario called upon expert stakeholders in both the clinical and hospital administration community to form the Mitral Clip Advisory Committee (MCAC) for the purpose of making recommendations to the MOHLTC in a number of key areas, the first of which outlines patient selection criteria guidelines and the second, facility quality criteria.

To ensure all components of a quality Mitral Valve Clip program are in place, the Ontario Mitral Valve Clip Patient Eligibility Criteria Guidelines and Facility Quality Criteria have been developed and approved by CorHealth's Mitral Clip Advisory Committee.

Ontario Mitral Valve Clip Procedure – Patient Eligibility Criteria Guidelines

Mitral Valve Clip is a feasible option for the severely symptomatic mitral regurgitation patient who is at high surgical risk due to comorbidities. Determination of patient acceptance for the procedure will be made by the hospitals designated Multidisciplinary Heart Team whereby the following criteria and factors are considered.

INCLUSION CRITERIA:

1. Severe Mitral Regurgitation (MR)
   a. > 2+ MR
2. Severity of symptoms felt to be due to MR
   a. NYHA Class III or IV
   b. Occurrences of hospitalizations for a primary diagnosis of heart failure within the last year
3. High Surgical Risk (as detailed in Table 1)
4. Assessment by and agreement of the Multidisciplinary Heart Team

EXCLUSION CRITERIA:

1. Limited life expectancy (< 1 year)
2. Absolute anatomic unsuitability of the valve or inability to access the valve (i.e. mitral valve pathology does not meet anatomical echocardiographic criteria for optimal clip deployment as detailed in Table 1)

Table 1

FACTORS FOR CONSIDERATION

1. High Surgical Risk Factors

- 30-day Society of Thoracic Surgeons (STS) predictive operative mortality risk-score of ≥ 8%
- Porcelain Aorta or Extensively Calcified Ascending Aorta
- Frailty – Assessed utilizing Five Meter Walk Test
- Hostile Chest
  - › Sternotomy re-do
  - › Adhered graft
  - › Previous chest radiation
- Severe Liver Disease
  - › Cirrhosis
  - › MELD Score > 12
- Severe Pulmonary Hypertension (systolic pulmonary artery pressure > 2/3 systemic pressure)
- Other Unusual Extenuating Circumstances
  - › Chemotherapy for malignancy
  - › High aspiration risk

2. ECHO Anatomic Factors

- Primary regurgitant jet originates from A2 & P2 malcoaptation
- Coaptation length ≥ 2mm
- Coaptation depth ≤ 10mm
- Flail width <15mm
- Mitral valve orifice ≥ 4cm2
- LV end-systolic diameter < 55mm
- Absence of severe mitral annular calcification
- Assessment of severe TR
- LV Function Impairment Factors
  - › LV Function less than 20%

Note: Integration of measurements by both TEE and TTE shall be from a facility that meets the "Standards for Provision of Echocardiography in Ontario 2015"

3. Age/Life Expectancy Factors

- Advanced Age (>80 years)
- Life expectancy >1 year

4. Renal Function Factors

- Renal insufficiency (Cr > 130 µmol/L)
- GFR < 45 ml/min

5. Pre Procedure Log-N-Terminal-Pro-Brain-Natriuretic Peptide Factors

- log NTproBNP 8.3 ± 2
- NT BNP > 1,800 pg/ml (As per CCS Heart Failure Guidelines 2014)

6. Optimal Medical Therapy Factors

- Beta Blocker
- ACE/ARB
- Diuretics for functional MR
- ICD or CRT if indicated

7. Additional Factors

- Rheumatic mitral valve disease
- Endocarditis
- Intracardiac, inferior vena cava (IVC) or femoral venous mass or thrombus
- Prior mitral valve surgery
- Inability of patient to tolerate procedural anticoagulant or post procedural antiplatelet regimen
- Chemotherapy for malignancy

Ontario Mitral Valve Clip Facility Quality Criteria

VOLUME CRITERIA	
Criteria Description	**Method of Evaluation**
1. Procedure Volumes	
Institutional	Hospital Program shall perform: • 1000 Cardiac Catheterizations per year • 400 Percutaneous Coronary Interventions per year
Interventional Program	50 Structural heart procedures per year (including ASD/PFO, and experience with trans-septal punctures via Structural Heart Program or Electrophysiology Program)
Surgical Program	Hospital surgical programs shall perform a minimum of 25 mitral valve repairs per year.
Existing/New Programs	15 Mitral Valve Clip procedures per year

FACILITY CRITERIA	
Criteria Description	**Method of Evaluation**
2. Cath Lab/ hybrid operating suite with fixed x-ray imaging	
Programs performing Mitral Valve Clip procedures require an operating suite environment equipped with a fixed radiographic imaging system with flat-panel fluoroscopy offering catheterization laboratory-quality imaging and will support safe induction of anaesthesia. (Bashore, 2012)	Operating suite environment shall: • Meet OR specifications including maintaining controlled entry • Have infrastructure to manage anaesthesia gases and salvage • Facilitate safe management of sterile supplies and equipment within the operating suite environment • Have sufficient space to accommodate Echo, anaesthesia, CPB (Cardiopulmonary Bypass) equipment and multiple team members (i.e. minimum 800 sq. ft.) (Tomasso, 2014) • Ensure radiology services comply with Radiation Emitting Devices (RED) regulations and Healing Arts Radiation Protection (HARP) Act
3. Anaesthesia facilities	
Programs providing Mitral Valve Clip procedures shall ensure anesthesia equipment, drugs and supplies meet the same standards as those for conventional operating theatres. (Canadian Anesthesiologist Society)	Anaesthesia facilities shall: • Ensure standardized anaesthesiology equipment is available and maintained as per the organizations SOP
4. Access to Non-Invasive Imaging	
Programs providing Mitral Valve Clip procedures are required to have access to non-invasive imaging including: • Transthoracic Echo • Transesophageal Echo • Vascular Lab (Vascular Ultrasound, MRA, Peripheral Angiography) • CT Lab	Non-invasive imaging services shall: • Achieve Echo Quality Improvement Program - Standards for Provision of Echocardiography in Ontario (CCN, 2015) • Ensure access to 3D Echo • Include Echo Sonographers and Echocardiologist (Level 3 training) who have experience in valvular disease
5. Intensive Care Unit (CVICU/CICU) Facilities	
Programs providing Mitral Valve Clip procedures will have access to a Level 3 Intensive Care (CVICU/CICU) facility (Critical Care Services Ontario).	ICU facility shall: • Ensure nursing and allied health care team members are experienced in managing patients with conventional open heart valve procedures • Have defined standardized care processes for management of patients undergoing Mitral Clip procedures (i.e. pre-defined order sets, patient care pathways and standards of care algorithms)

CLINICAL SERVICES CRITERIA	
Criteria Description	**Method of Evaluation**
6. Multidisciplinary Heart Team	
Physicians on the Multidisciplinary Heart Team shall have extensive knowledge of valvular heart disease including the natural history of the disease, hemodynamics, appropriate diagnostics, optimal medical therapy, the application and outcome of invasive therapies, procedural, perioperative and postoperative care. Programs providing Mitral Valve Clip procedures will have a Multidisciplinary Heart Team. Core Heart Team is composed of: • Cardiac Surgeon • Interventional Cardiologist • Echocardiologist • Cardiac Anaesthesia • OR/Cath Lab Nurses Access to other multidisciplinary team members may include: • Cardiology/Heart Failure Specialist • Internal Medicine • Nephrology • Neurology • Perfusionists • Diagnostic Imaging/Medical Imaging • Imaging Techs • Vascular Lab Technicians • ICU/CVICU/CICU Nursing and Allied Health (PT, OT, Pharmacy, Social Work, Chaplin) • Nurse Practitioner • Other relevant members	Multidisciplinary Heart Team shall: • Ensure a cardiac surgeon and interventional cardiologist contribute to evaluating every case • Include Echocardiologist or Cardiac Anaesthesia experienced with TEE guided mitral valve surgical procedures • Utilize The Ontario Mitral Clip Procedure – Patient Eligibility Criteria Guidelines will be utilized for patient selection evaluation • Commit to principles of shared decision making which may include: › Ensuring patients and families are given comprehensive information of the various operative and non-operative treatment options › Patient and family educational materials reflect an appropriate health literacy level › Ensuring patients and families have direct access to representatives of each specialty • Remain current with new and evolving evidence as it relates to Mitral Clip therapy • Utilize appropriate evidence based guidelines (where applicable) to inform decision making • Ensure opportunity to train and work together regularly • Engage in strategies to continuously improve team functions • Ensure protocol-driven standardized approaches to discharge planning and follow-up which may include: › Assessment of patient readiness for discharge › Emphasizing specific issues that would warrant immediate contact with the Heart Team › Arrangement of follow-up appointments › Standardized printed patient education materials › Arrangement for rehabilitation when deemed appropriate › Standardized communications with referring physicians

CLINICAL SERVICES CRITERIA	
Criteria Description	**Method of Evaluation**
7. Hospital Administration	
Programs providing Mitral Valve Clip procedures will have a dedicated hospital administrator as part of the team.	Hospital Administrator shall: • Ensure all necessary infrastructure are in place to adequately support the Mitral Valve Clip Program (Shahian, 2016)
8. Training	
Programs providing Mitral Valve Clip procedures will ensure ongoing training for the Core Heart Team.	Programs shall: • Commit to ongoing relevant training for the Core Heart Team
9. CorHealth Ontario Registry Contribution	
Programs providing Mitral Valve Clip procedures will engage in ongoing outcome evaluation.	Programs shall: • Participate in CorHealth Ontario Registry • Participate in ongoing evaluation to ensure volume criteria are maintained
10. Quality Improvement	
Programs providing Mitral Valve Clip procedures will engage in quality improvement processes. (Tomasso, 2014, Shahanian,2016)	Programs shall: • Participate in ongoing outcome measurement (i.e. degree of MR post-procedure, morbidity, mortality)

Appendix 1 - Background

Mitral Regurgitation (MR) is the most common valve disease, affecting nearly 10% of those over age 75 years (Fam, 2016). MR is divided into two cohorts, primary (degenerative) where the abnormality is primarily associated with the valve itself, and secondary (functional), where the abnormality is caused by Left Ventricular (LV) dysfunction (usually secondary to heart failure).

Current guidelines by the American Heart Association (AHA)/American College of Cardiology (ACC) recommend surgery for patients with symptomatic, chronic severe MR due to primary valve disorders (Class I). While surgical repair and replacement of the mitral valve is considered the optimal treatment prior to the onset of heart failure or LV dysfunction, until recently there were limited options for patients considered high surgical risk due to heart failure or other comorbidities (Beigel, 2014).

The ACC/AHA has determined that Mitral Valve Clip therapy for chronic primary MR has a Class 2B recommendations with level of evidence B, in severely symptomatic patients (NYHA class III/IV), severe MR (Stage D) with prohibitive surgical risk due to severe comorbidities, and who have a reasonable life expectancy (Nishimura, 2014).The European Society of Cardiology has published guidelines for Mitral Valve Clip therapy providing recommendation class IIb, level of evidence C in patients with similar criteria.

There is limited data which shows improved outcomes with surgery, either in patient survival or quality of life for surgical repair or replacement of the mitral valve for patients with secondary MR (Beigel, 2014). Medical management of the non-surgical MR patient population has a poor prognosis, with those diagnosed with secondary MR faring worse than patients with primary MR. Data from Europe indicates that approximately one half of severely symptomatic patients are not offered surgery, primarily due to advanced age, poor LV function and other comorbidities (Beigel, 2014).

Percutaneous repair of MR with a Mitral Valve Clip procedure may offer an otherwise unserved and symptomatic population an alternate therapeutic option.

The establishment of the Mitral Valve Clip as a safe procedure demonstrated through randomized controlled studies (EVEREST and EVEREST II - Attizzani, 2015, Beigel, 2014) in low and moderate risk surgical candidates, has provided an option to patients who are considered too high risk to undergo the surgical procedure (Puls, 2016, Giannini, 2014). Furthermore, multiple large registries (TRAMI, ACCESS-EU, GRASP, REALITY, etc.) have shown that Mitral Valve Clip procedure is both safe and effective in the treatment of high risk patients with functional MR and advanced HF. Giannini found the patients undergoing Mitral Valve Clip procedure had a higher survival rate of 80.8% at 2 years versus 58.6% for those receiving optimal medical therapy. Data obtained from the German TRAMI registry of patients undergoing Mitral Valve Clip procedure repair, indicate the most common reason for denying surgery to MR patients was high surgical risk, (EuroSCORE ≥ 20% in 50% of cases), age, patient preference, frailty and limited prognosis from non-cardiac comorbidity (Puls, 2016).

As renal insufficiency was found to be the primary non-cardiac predictor of major adverse cardiac and cerebrovascular event (MACCE) by Zuern (2015) in the review of the TRAMI registry, this should be a consideration for patient selection. Puls et al., 2016 indicates that predictors of mortality at 1 year include NYHA class IV, anemia, previous aortic valve intervention, serum creatinine ≥ 1.5 umol/L, peripheral artery disease, LVEF < 30%, and severe tricuspid regurgitation should be considered by the Multidisciplinary Heart Team when contemplating Mitral Valve Clip procedure as an option for patients.

Appropriate patient selection is a key component of a successful Mitral Valve Clip program. As a surgical risk score cannot capture every nuance of patient's comorbidities the sole use of a surgical risk calculation for determination of patient appropriateness is not recommended. To that end patient selection for Mitral Valve Clip procedures in Ontario will be determined by the hospitals designated Multidisciplinary Heart Team utilizing The Ontario Mitral Valve Clip Procedure-Patient Eligibility Criteria Guidelines.

Appendix 2 - Summary of Supporting Literature

PATIENT SELECTION CRITERIA	KEY CONSIDERATIONS	REFERENCES
Etiology and severity of Mitral Regurgitation (MR): Severity Etiology of MR • Degenerative (1°) • Functional (2°) › Absence of severe tethering	MR ≥2+	EVEREST (Feldman et al., 2009) EVEREST II (Feldman et al., 2015)
	Lack of consistent data with improved outcomes in Functional (2°) MR in published literature. COAPT and RESHAPE HF trials underway.	EVEREST I (21% = 1°, 79% = 2°) EVEREST II (73 % =1°, 27% = 2°) TRAMI Registry (71 % =1° , 29% =2°) ACCESS-EU (69% = 1° , 31% 2°) Beigel (2014) Sorajja (2016)
Echocardiography results	Leaflet/scallop anatomy, involvement & motion: • Primary regurgitant jet originates from A2 & P2 malcoaptation; • Coaptation length ≥ 2mm; • Coaptation depth • ≤ 10mm; • Flail width <15mm; • Mitral valve orifice ≥ 4cm^2 : • Absence of mitral valve annular calcification;	EVEREST II Feldman (2015) Vahanian (2012) Beigel (2014) Gamperioli (2012)
+ LV Function (EF) >30% (**Note:** this was discussed by CCN Sub-WG and consensus was to reflect a LVEF of 20% in the Ontario criteria as a relative contraindication) LV end-systolic dimension <55mm	LVEF < 30% predictor of 1 yr. mortality EVEREST II - LVESD > 55mm pts were excluded LVESD < 45mm	Zuern (2015) Feldman (2015) Beigel (2014) Triantafyllis (2016)
+ High Surgical Risk (EuroSCORE or STS)	Elements for prohibitive surgical risk: STS score ≥8; porcelain aorta or extensively calcified ascending aorta; frailty; severe liver disease; severe PH; and other unusual extenuating circumstances.	STS 5 (EVEREST II, Feldman 2015) Log. EuroSCORE 20 &/or STS 6 (TRAMI) Puls, 2016). Beigel (2014) Sorajja (2016) Triantafyllis (2016) Schau (2016) Lim (2014)

PATIENT SELECTION CRITERIA	KEY CONSIDERATIONS	REFERENCES
+Hostile Chest	Sternotomy re-do or adhered graft Previous chest radiation	Sorajja (2016) Triantafyllis (2016)
+ NYHA functional class III/IV	NYHA class IV predictor of 30 day mortality	EVEREST (Feldman et al., 2009) EVEREST II (Feldman et al., 2015) Fam (2016) Sorajja (2016) Triantafyllis (2016)
+ Age	Advanced Age (> 80 years) is a predictor of 30 day mortality.	Beigel (2014) Fam (2016) Schau (2016) Sorajja (2016)
+ Renal Function • Cr • Cr clearance	Renal insufficiency (Cr > 130 µmol/L) is primary non-cardiac factor in predicting MACCE at 1 yr. GFR < 45 ml/min	Zuern (2015) Triantafyllis (2016)
High Pre procedure log-N-terminal- pro- brain-natriuretic peptide levels.	log NTproBNP 8.3 ± 2 associated with increased long term cardiac mortality. NT BNP > 10,000 pg/ml was predictor of 30-day mortality	Triantafyllis (2016) Schau (2016) Fam (2016)
Frailty	Assessment of frailty	Sorajja (2016) Surder (2016)
Pt receiving Optimal Medical Therapy	Defined as Beta Blocker ACE/ARB, diuretics for FMR patients. + ICD or CRT if indicated	
Life expectancy > 1 yr.		EVEREST (Feldman et al., 2009) EVEREST II (Feldman et al., 2015) Beigel (2014)
+ Heart Team Decision • Assessment by Cardiac Surgery specializing in MV Surgery • Assessment by Interventional Cardiologist • Assessment by Echocardiologist • Assessment by Cardiac Anaesthesia	Consensus that patient meets selection criteria	Feldman (2015) Triantafyllis (2016)

PATIENT SELECTION CRITERIA	KEY CONSIDERATIONS	REFERENCES
CONTRAINDICATIONS FOR MITRAL CLIP THERAPY		
Severe comorbidities that limit life expectancy below 6 months		Feldman (2015) Beigel (2014) Schau (2016)
Mitral valve pathology does not meet anatomical echocardiographic criteria for optimal clip deployment		Schau (2016), Triantafyllis (2016) EVEREST II Feldman (2015) Vahanian (2012) Beigel (2014) Gamperioli (2012)
Rheumatic mitral valve disease		Abbott Instructions For Use, (Surder 2016)
Prior mitral valve surgery Relative CI		Beigel (2014)
Endocarditis		Abbott Instructions For Use, (Surder 2016
Intracardiac, inferior vena cava (IVC) or femoral venous mass or thrombus		Abbott Instructions For Use, (Surder 2016) Beigel (2014) Triantafyllis (2016)
Inability of patient to tolerate procedural anticoagulant or post procedural antiplatelet regimen		Abbott Instructions For Use, (Surder 2016)

Appendix 3 - Additional Notes

The COAPT, RESHAPE-HF2 and Mitra Fr studies are underway to further define the role of Mitral Clip usefulness in functional /secondary MR and patients with NYHA Class II to IV, and reduced LV Function.

The Mitral Clip Advisory is dedicated to supporting the implementation of Mitral Valve Clip procedure as a MOHLTC funded procedure, with a focus on the standardization of:

- patient referral; wait times; urgency
- assessment processes;
- procedural details
- early and late clinical follow up with a focus on hard clinical outcomes including:
  - death
  - heart failure,
  - re-hospitalization,
  - quality of life,
  - durability of the Mitral Valve Clip implant and freedom from significant (≥2+) mitral regurgitation in early and long term follow up

Similar to other advanced adult cardiac procedures CorHealth Ontario will ensure that relevant Mitral Valve Clip procedure data is captured in the CorHealth Ontario Cardiac Registry.

Given that Mitral Valve Clip procedure is a newer technology, it is critical to collect clinical information on all patients referred for Mitral Valve Clip procedures, including patients who are accepted, as well as those who are referred for Mitral Valve Clip procedures and yet, do not receive the procedure. Patients may not receive Mitral Valve Clip procedure for different reasons, including:

1. Some patients, upon completion of their pre-procedure work-up, may not be suitable candidates for Mitral Valve Clip procedure;
2. Patients may decline to have the procedure performed; or
3. Patients may die before they receive their procedure.

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