CorHealth Ontario

Advancing cardiac, stroke and vascular care

Ontario Percutaneous Left Atrial Appendage Closure Patient Eligibility Criteria Guidelines & Facility Quality Criteria

January 2019

Table of Contents

Ontario Percutaneous Left Atrial Appendage Closure

Patient Eligibility Criteria Guidelines

Percutaneous left atrial appendage (LAA) closure is a relatively new procedure which may be able to prevent stroke in people with nonvalvular atrial fibrillation (AF), as an alternative to treatment with oral anticoagulant medication[1]. According to 2017 Ontario Health Technology Advisory Committee (OHTAC) recommendations, percutaneous LAA closure should be considered as a viable treatment option in patients with nonvalvular AF in whom all oral anticoagulants are contraindicated[2]. Determination of patient acceptance for the procedure will be made by the hospital's designated Interdisciplinary Heart Team, whereby the criteria and factors outlined in the following sections are considered. Patients should be evaluated by a provider with expertise in medical therapy for stroke prevention and an LAA closure procedural specialist, as well as appropriate subspecialties as determined by the Interdisciplinary Heart Team[3].

[1] LAAC Device with Delivery System: A Health Technology Assessment (OHTAC, 2017)
[2] LAAC Device With Delivery System: OHTAC Recommendation (OHTAC, 2017)
[3] ACC/HRS/SCAI Left Atrial Appendage Occlusion Device Societal Overview (2015)

Considerations for identifying patients who are eligible for percutaneous LAA closure in Ontario:

1. Nonvalvular atrial fibrillation (AF)[2]
    - AF in the absence of rheumatic mitral stenosis[4]
    - Paroxysmal, persistent, or permanent
    - Electrocardiographic documentation is recommended to establish the diagnosis of AF[2]

2. Risk of stroke
    - CHA_2DS_2 - VASc ≥ 2 or $CHADS_2$ ≥ 1[5]

3. Absolute or relative contraindication to all oral anticoagulants[2], including the following:
    - History of overt bleeding related or unrelated to oral anticoagulants[6]
    - Increased risk of bleeding or bleeding tendencies[6]
    - Contraindications to warfarin and/or direct OAC[6], example:
        i. Severe renal failure
        ii. Allergy to the above agents
    - Other contraindications including:
        i. Intracranial mass[7]
        ii. End-stage liver disease[7]
        iii. Age > 85 years[7]
        iv. Anemia[7]
        v. Dementia[7]
        vi. Hematological malignancy[7]
        vii. Lifestyle or occupational bleeding risk (i.e. risk of trauma)[6]
        viii. Other medical or psychosocial reasons that make OACs unsuitable (e.g. elderly patient with lack of social support)[6]

[2] LAAC Device With Delivery System: OHTAC Recommendation (OHTAC, 2017)
[4] ACC/AHA/HRS Guideline for the Management of Patients with Atrial Fibrillation (2014)
[5] EHRA/EAPCI Expert Consensus Statement on Catheter-based LAA Occlusion (2014)
[6] The Assessment of the Watchman Device in Patients Unsuitable for Oral Anticoagulation (ASAP-TOO) trial (Holmes et al, 2017)
[7] Contraindications to Anticoagulation Therapy and Eligibility for Novel Anticoagulants in Older Patients with Atrial Fibrillation (Steinberg et al, 2015)

Note: See Appendix A for detailed list of absolute and relative contraindications. The following factors related to patient preference are specifically excluded from absolute and relative contraindications:

a) *Patients declining the option to take OACs*
b) *Patient preference for alternative to OACs*

4. Ability to receive antiplatelet drug therapy[5]
5. Anatomic suitability for the LAA closure device[5]
6. Assessment by and agreement of the Interdisciplinary Heart Team in consultation with patient

Imaging Assessment

Imaging is critical for pre-procedural, periprocedural, and post-procedural assessment of the left atrial appendage[5].

- Transesophageal echocardiogram (TEE) prior to procedure to determine anatomic suitability and appropriate size for implanted device. MRI and CT may also be used in conjunction with TEE for this assessment[5]
- TEE or intracardiac echocardiogram (ICE) immediately prior to procedure to rule out LAA thrombus[5]
- Real-time visualization of the LAA during the procedure for device positioning and deployment. This may be done with TEE, fluoroscopy, ICE, or a combination of these techniques[5,8]
- TEE or CT post-procedure to assess device position and peridevice residual flow[5]

Note: Integration of measurements by TEE shall be from a facility that meets CorHealth Ontario's Standards for Provision of Echocardiography in Ontario.

[5] EHRA/EAPCI Expert Consensus Statement on Catheter-based LAA Occlusion (2014)
[8] SCAI/ACC/HRS Institutional and Operator Requirements for LAA Occlusion (2016)

Ontario Percutaneous Left Atrial Appendage Closure Facility Quality Criteria

Procedure Volumes Criteria

The hospital program must maintain the following:

- Minimum volume of 20 percutaneous LAA closure procedures per year. In order to maintain currency of the team's LAA closure skillset, procedures should be scheduled at minimum once every 3 months
- 50 structural heart disease or left-sided catheter ablations per year, at least 25 of which involve transseptal puncture through an intact septum[8]

    - Qualifying procedures include: LAA occlusion involving a transseptal catheterization that is primary or adjunctive to a percutaneous pericardial approach, percutaneous left ventricular assist device placement in which transseptal approach is used, endovascular catheter ablation within the left side of the heart, pulmonary vein stenting, balloon mitral valvuloplasty, percutaneous closure of prosthetic mitral paravalvular leaks using transseptal approach, antegrade balloon aortic valvuloplasty, mitral valve repair involving transseptal puncture, atrial septal defect closure, patent foramen ovale closure, and diagnostic transseptal catheterization

[8] SCAI/ACC/HRS Institutional and Operator Requirements for LAA Occlusion (2016)

FACILITY CRITERIA	
Criteria Description	**Method of Evaluation**
1. Cardiac catheterization lab, electrophysiology suite, or hybrid suite	
Programs performing percutaneous LAA closure procedures require a cardiac catheterization lab, electrophysiology suite or hybrid suite.	Cath lab/ electrophysiology suite/ hybrid suite environment shall have[8]: • Fixed radiographic imaging system with flat-panel fluoroscopy, offering quality imaging • Sufficient space (approx. 800 sq ft), in a sterile environment, to accommodate necessary personnel, anaesthesia equipment, and echocardiography machines • Hemodynamic system to allow for continuous pressure monitoring • Equipment for safe procedures and handling of complications such as device stabilization, retrieval, and managing pericardial effusions. Equipment should include: selection of endovascular sheaths, diagnostic catheters, transseptal kits, wires, snares, bioptomes, vascular occluders, and pericardiocentesis equipment
2. Anesthesia facilities	
Programs performing percutaneous LAA closure 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 anaesthesia equipment is available and maintained as per the organization's standard operating procedures
3. Access to imaging	
Programs providing percutaneous LAA closure procedures will have access to[8]: • Transesophageal Echocardiography (TEE) or Intracardiac Echocardiography (ICE) • Transthoracic Echocardiography (TTE) • Fluoroscopy	Imaging services shall: • Achieve CorHealth Ontario's certification in Standards for Provision of Echocardiography in Ontario • Include Cardiac Sonographers and Echocardiologist (Level 3 training) who have experience in guiding structural heart interventions
4. Post-procedure care	
Programs providing percutaneous LAA closure procedures will have access to a post-anaesthesia care environment and Level 3 Intensive Care Unit with personnel experienced in managing patients who have undergone complex cardiac procedures[8].	ICU facility shall: • Ensure healthcare team members are experienced in managing patients who have undergone complex cardiac procedures[8]
5. Other facilities/services	
• Active cardiothoracic surgery program with cardiac surgeons and perfusionists on site[8] • Ready availability of cell-saver technology in case of pericardial effusion and tamponade[8] • Access to blood bank products[8] • Physical clinic space/setup to accommodate assessment of LAA closure patients • Vascular surgery • Peripheral vascular interventional expertise	

[8] SCAI/ACC/HRS Institutional and Operator Requirements for LAA Occlusion (2016)

CLINICAL SERVICES CRITERIA	
Criteria Description	**Method of Evaluation**
6. Multidisciplinary Heart Team	

In order to allow for comprehensive patient care, a percutaneous LAA closure program should be imbedded in a comprehensive atrial fibrillation and structural heart program[8]. A percutaneous LAA closure program must have a functioning Interdisciplinary Heart Team (IHT) in order to optimize patient outcomes. The IHT is defined as *all members of the program* required from initial pre-procedural work-up, eligibility determination, procedural care, post-procedural in-hospital care, and subsequent outpatient follow-up. The roles of each team member may vary by individual site, however sites will have specific documentation of each role and a documented process for determining patient eligibility.
 	
Core IHT shall be composed of the following members:
 	
• Percutaneous LAA Closure Procedural Specialists
  • Electrophysiologist and/or Interventional Cardiologist
  • Echocardiologist/Imaging Specialist
• Cardiac Anesthesiologist (if required)
• Procedure Room Nurses and/or Technicians
 	
Core IHT shall have access to the following adjunct members as needed:
 	
• Neurology
• Heart Failure Specialist
• Hematology
• Gastroenterology
• Urology
• Allied Health (Physiotherapy, Occupational Therapy, Pharmacy, Social Work, Chaplin)
	Interdisciplinary Heart Team Responsibilities:
	• Patients should be evaluated by a provider with expertise in medical therapy for stroke prevention and a percutaneous LAA closure procedural specialist, as well as appropriate subspecialties as determined by the IHT[3]. A documented process must be in place to ensure this co-evaluation is operationalized
	• Utilize the Ontario Percutaneous LAA Closure Patient Eligibility Criteria Guidelines to inform patient selection
	• When a patient is accepted for an LAA closure procedure, the reason for the IHT's decision to treat the patient with this intervention as opposed to oral anticoagulants must be documented
	• Commit to principles of shared decision making which may include:
	  • Ensuring patients and families are given comprehensive information on the various 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 LAA closure
	• 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 patient care, discharge planning, and follow-up which may include:
	  • Standardized care pathways that include optimization of Length of Stay (LOS)
	  • Assessment of patient readiness for discharge
	  • Emphasizing specific issues that would warrant immediate contact with the IHT
	  • Arrangement of follow-up appointments
	  • Standardized printed patient education materials
	  • Standardized communications with referring physicians

[8] SCAI/ACC/HRS Institutional and Operator Requirements for LAA Occlusion (2016)
[3] ACC/HRS/SCAI LAA Occlusion Device Societal Overview (2015)

CLINICAL SERVICES CRITERIA	
Criteria Description	**Method of Evaluation**
7. Hospital Administration	
Programs providing percutaneous LAA closure procedures will have a dedicated hospital administrator as part of the team. The administrator shall ensure all necessary infrastructure are in place to adequately support the LAA closure program.	Hospital Administrator shall: • Ensure all necessary infrastructure are in place to adequately support the TAVI program
8. Training	
Programs providing percutaneous LAA closure procedures will ensure ongoing relevant training for the IHT.	Programs shall: • Ensure ongoing relevant training for the IHT • Ensure IHT remains up to date with new and evolving evidence as it relates to LAA closure
9. CorHealth Ontario Registry Participation	
Programs providing percutaneous LAA closure procedures will engage in ongoing outcome evaluation.	Programs shall: • Participate in CorHealth Ontario Registry • Including all data elements required for quality monitoring as determined by CorHealth Ontario • Participate in ongoing evaluation to ensure volume criteria are maintained
10. Quality Improvement	
Programs providing percutaneous LAA closure procedures will engage in quality improvement processes.	Programs shall: • Engage in quality improvement processes including ongoing outcome measurement

[8] SCAI/ACC/HRS Institutional and Operator Requirements for LAA Occlusion (2016)
[3] ACC/HRS/SCAI LAA Occlusion Device Societal Overview (2015)

Appendix A: References Considered in Definition of Absolute and Relative Contraindications

Note: he following table summarizes the two main references considered in defining absolute and relative contraindications to oral anticoagulants (OACs) for the purpose of this document (see pages 3-4).	
Contraindications to Anticoagulation Therapy and Eligibility for Novel Anticoagulants in Older Patients with Atrial Fibrillation (Steinberg et al, 2015)	The Assessment of the Watchman Device in Patients Unsuitable for Oral Anticoagulation (ASAP-TOO) trial (Holmes et al, 2017)
Absolute Contraindications: Diagnosis of: • intracranial hemorrhage • intracranial mass • end-stage liver disease **Relative Contraindications:** • Age > 85 years • Anemia • Prior gastrointestinal bleed • Dementia • Thrombocytopenia • Hematological malignancy • Traumatic intracranial hemorrhage	**Acceptable reasons for unsuitability for OACs (i.e. absolute and relative contraindications):** **1. History of overt bleeding related or unrelated to oral anticoagulants:** • Prior history of intracranial or subdural hemorrhage • Other clinically relevant organ bleeding as defined by requiring hospitalization, transfusion or medical intervention, including the following: gastrointestinal; genitourinary; ocular; spinal; pulmonary; retroperitoneal; pericardial; or ear, nose, and throat. Last event must be within the past 6 months. • Epistaxis requiring emergency department visit, hospitalization, or physician intervention. Last event must be within the past 6 months. **2. Increased risk of bleeding or bleeding tendencies:** • Gastrointestinal lesions resulting in clinically relevant bleeding as defined by requiring hospitalization, transfusion, or medical intervention (e.g., esophageal varices, diverticular disease with a history of bleeding in which the site was not identified and presumed to be diverticular). Last event must be within the 6 m prior to randomization. • Active inflammatory bowel disease • Peptic ulcer disease with gastrointestinal bleeding in which it is deemed that anticoagulation cannot be safely initiated or restarted following healing of the peptic ulcer • Uncontrolled seizures • History of traumatic falls with the likelihood of recurrence • Cerebral amyloid angiopathy • Significant thrombocytopenia (defined as platelet count <50 × 109/L) • Need for lifelong dual antiplatelet therapy **3. Contraindications to warfarin and/or direct OAC** • Severe renal failure (glomerular filtration rate <30 mL/[min/1.73 m3]) • Allergy to the above agents **4. Other contraindications including:** • Lifestyle or occupational bleeding risk (i.e., anyone who is at risk of trauma as a result of their occupation or their lifestyle. For example, high-voltage electrical line workers, airline pilots, manual laborers, extreme sports enthusiasts) • Poor control on warfarin (time in therapeutic range < 50%) and intolerance to the direct OACs • Other medical or social reasons that make OACs unsuitable (e.g., an elderly patient with poor social support and a high risk of bleeding resulting in the use of aspirin alone despite a high stroke risk)

Appendix B: Acronyms and Abbreviations

ACC = American College of Cardiology

AHA = American Heart Association

AF = Atrial Fibrillation

EHRA = European Heart Rhythm Association

EAPCI = European Association of Percutaneous Cardiovascular interventions

HRS = Heart Rhythm Society

ASAP-TOO = Assessment of the Watchman Device in Patients Unsuitable for Oral Anticoagulation Trial

CT = Computed Tomography

LAA = Left Atrial Appendage

MRI = Magnetic Resonance Imaging

OAC = Oral Anticoagulant

OHTAC = Ontario Health Technology Advisory Committee

SCAI =Society for Cardiovascular Angiography and Interventions

TEE = Transesophageal Echocardiography

References

1. Health Quality Ontario. Left atrial appendage closure device with delivery system: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2017 Jul;17(9):1-106. Accessed February 2018 from: http://www.hqontario.ca/evidence-to-improve-care/journal-ontario-health-technology-assessment-series
2. Health Quality Ontario. Left atrial appendage closure device with delivery system: OHTAC recommendation [Internet]. Toronto (ON): Queen's Printer for Ontario; 2017 July. 4 p. Accessed February 2018 from: http://www.hqontario.ca/evidence-to-improve-care/recommendations-and-reports/OHTAC/appendage-closure-device
3. Masoudi FA, Calkins H, Kavinsky CJ, Drozda JP Jr., Gainsley P, Slotwiner DJ, Turi ZG. 2015 ACC/HRS/SCAI left atrial appendage occlusion device societal overview: a professional society overview from the American College of Cardiology, Heart Rhythm Society, and Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol 2015;66:1497–513.
4. January CT, Wann LS, Alpert JS, Calkins H, Cigarroa JE, Cleveland JC Jr, Conti JB, Ellinor PT, Ezekowitz MD, Field ME, Murray KT, Sacco RL, Stevenson WG, Tchou PJ, Tracy CM, Yancy CW. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol 2014;64:2246–80.
5. Meier, B., Blaauw, Y., Khattab, A., Lewalter, T., Sievert, H., et al. EHRA/EAPCI expert consensus statement on catheter-based left atrial appendage occlusion. Europace. 2014, 16, 1397-1416.
6. Holmes, D., Reddy, V., Buchbinder, M., Stein, K., Elletson, M., et al. The Assessment of the Watchman Device in Patients Unsuitable for Oral Anticoagulation (ASAP-TOO) trial. American Heart Journal. 2017; 189:68-74.
7. Steinberg, B., Greiner, M., Hammill, B., Curtis, L., Benjamin, E. et al. Contraindications to Anticoagulation Therapy and Eligibility for Novel Anticoagulants in Older Patients with Atrial Fibrillation. Cardiovascular Therapeutics. 2015. 33, 177-183.
8. Kavinsky, C., Kusumoto, F., Bavry, A., Bailey, S., Ellenbogen, K., et al. SCAI/ACC/HRS Institutional and Operator Requirements for Left Atrial Appendage Occlusion. Journal of the American College of Cardiology. 2016, 67(19).