



Report on Mitral Valve Clip Implantation in Ontario April 2015 to March 2018

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About CorHealth Ontario

In 2016, the Cardiac Care Network of Ontario and the Ontario Stroke Network merged to form one organization, with a mandate spanning cardiac, stroke and vascular care in the province. On June 22, 2017, after a year of transition, the new entity became CorHealth Ontario. CorHealth Ontario proudly advises the Ministry of Health and Long-Term Care, 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.

This report was prepared by CorHealth Ontario. The results and conclusions presented in this report are those of CorHealth Ontario and should not be attributed to the funding agencies.

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Acknowledgements

CorHealth Ontario wishes to acknowledge its Participating Hospitals for their participation in the registry and their dedication to providing high quality cardiovascular care to Ontarians.

CorHealth Ontario serves as system support to the Ontario Ministry of Health and Long-Term Care (MOHLTC), Local Health Integration Networks (LHINs) and care providers and is dedicated to improving quality, efficiency, access and equity in the delivery of adult cardiac services in Ontario. CorHealth Ontario is funded by the MOHLTC.

Table of Contents

About CorHealth Ontario.....	1
Acknowledgements	2
Executive Summary	4
Key Observations	4
Background.....	5
Ontario Mitral Valve Clip Programs.....	6
Methods	7
Results	8
Discussion	15
Results in Context	15
Limitations	15
Conclusions.....	16
Appendix A.....	18

Executive Summary

Mitral Valve Clip is a percutaneous alternative to open heart surgery designed to treat severe chronic mitral regurgitation. Mitral Valve Clip is a relatively novel procedure having only been performed in Ontario since 2013. This report marks the first Mitral Valve Clip outcomes report released for Ontario.

In this study, the outcomes of patients undergoing Mitral Valve Clip procedures at each Mitral Valve Clip program in Ontario were examined for the period of April 1, 2015 to March 31, 2018 and compared to the provincial average for the same time period. Indicators included in this report were selected based on input from CorHealth Ontario's Mitral Valve Clip Advisory Committee (MCAC) and Minimally Invasive Structural Heart (MISH) Working Group and based on data availability. The intention of this report, when coupled with regular dialogue among providers, is to help stimulate quality improvement activities at the provincial level and within individual cardiac centers in the province of Ontario.

Key Observations

1. There are currently 7 programs in Ontario who are approved for funding to provide Mitral Valve Clip services, 5 of which were active over the time period of this study.
2. Over the time period of this study, 450 Mitral Valve Clips were performed in Ontario.
3. The overall crude all-cause mortality rates were determined to be:
 - a. 30-Day: 5.7%
 - b. 1-Year: 15.9%
4. The overall crude all-cause readmission rates were determined to be:
 - a. 30-Day: 15.6%
 - b. 1-Year: 44.2%
5. Mortality rates following Mitral Valve Clip in this study compared favorably with mortality rates reported by other jurisdictions.

Background

Mitral Valve Clip is a procedure designed to treat severe chronic mitral regurgitation and was developed as a potential alternative to open heart surgery. Mitral Valve Clip has been performed in Ontario since 2013 and is provincially funded for use in inoperable patients and high risk patients with severe mitral regurgitation. There are currently 7 programs in the province who receive provincial funding to provide Mitral Valve Clip services, although only 5 were operational for a long enough period of time to allow adequate follow up on their patients for this study. All Mitral Valve Clip programs contribute data to the CorHealth Ontario Cardiac Registry.

In May 2015 the Ontario Health Technology Advisory Committee (OHTAC) released their recommendation on Mitral Valve Clip for the Treatment of Mitral Regurgitation, recommending that “mitral valve clip procedures be funded in centers of excellence identified by the Cardiac Care Network (CCN), and that all such centers enroll all patients receiving the mitral valve clip procedure in a CCN-supported registry”¹. Following this recommendation, the MOHLTC announced that Mitral Valve Clip would be funded in Ontario for the 2016/17 fiscal year and in 2017, the MOHLTC in collaboration with CorHealth Ontario convened the Mitral Valve Clip Advisory Committee (MCAC). The MCAC was a committee consisting of mitral disease subject matter experts, hospital administrators, and policy makers with a mandate to make recommendations to the MOHLTC on the implementation, dissemination and evaluation of Mitral Valve Clip services in Ontario. The MCAC group evolved into the Minimally Invasive Structural Heart (MISH) working group with an expanded mandate to include all minimally invasive structural heart (i.e. Transcatheter Aortic Valve Implantation, Mitral Valve Clip, and Left Atrial Appendage Occlusion devices). The MISH WG continued the work of the MCAC with respect to Mitral Valve Clip services.

Among the deliverables of the MCAC/MISH WG was the release of the “Ontario Mitral Valve Clip Procedure: Patient Eligibility Criteria Guidelines & Facility Quality Criteria”² and

¹ Mitral Valve Clip for Treatment of Mitral Regurgitation: OHTAC Recommendation (2015) OHTAC; <https://www.hqontario.ca/Portals/0/Documents/evidence/reports/recommendation-mitral-valve-clip-1505-en.pdf>

² Ontario Mitral Valve Clip Procedure: Patient Eligibility Criteria Guidelines & Facility Quality Criteria (2017) CorHealth Ontario; <https://www.corhealthontario.ca/resources-for-healthcare-planners-&-providers/mish/Ontario-Mitral-Valve-Clip-Procedure-Patient-Eligibility-Criteria-Guideline.pdf>

a recommendation for a list of Quality Measures that should be measured and reported to support the evaluation of Mitral Valve Clip services in Ontario. The final list of quality measures in the recommendation included 21 quality measures; 4 structure measures, 5 process measures, and 12 outcomes measures (see Appendix A for a full list of Mitral Valve Clip quality measures).

Eight of those measures can be reported with data currently available in the CorHealth Ontario Cardiac Registry and are included in this report. Data was not available to CorHealth Ontario at the time of this study to report on the additional 13 quality measures. The measures that were included in this report include the following:

- Minimum volumes of interventional cardiology procedures as they align to the “Ontario Mitral Valve Clip Procedure: Patient Eligibility Criteria Guidelines & Facility Quality Criteria”
- Wait Time 1 and Wait Time 2
- 30-day and 1-year all-cause mortality
- 30-day and 1-year repeat mitral valve procedure rates

Ontario Mitral Valve Clip Programs

The following 7 Mitral Valve Clip programs are currently funded to provide Mitral Valve Clip services in Ontario. The 5 programs highlighted in grey were active during the period of this analysis and their outcomes are included in this report.

Program	Abbreviation	City
Hamilton Health Sciences	HHS	Hamilton
London Health Sciences Centre	LHSC	London
St. Michael’s Hospital	SMH	Toronto
Sunnybrook Health Sciences Centre	SHSC	Toronto
Trillium Health Partners	THP	Mississauga
University Health Network	UHN	Toronto
University of Ottawa Heart Institute	UOHI	Ottawa

Methods

All data were obtained from the CorHealth Ontario Cardiac Registry with the exception of mortality status which was obtained via linkage to the Ontario Registered Persons Database (RPDB). To evaluate program performance for the 2015 – 2018 time period, this report includes all patients who had Mitral Valve Clip procedure, at one of the 5 active Mitral Valve Clip programs, between April 1, 2015 and March 31, 2018. As some quality measures require 1-year follow-up and additionally there is a 6 month lag in CorHealth Ontario’s access to RPDB data, not all indicators were reported for the entire three year period. Additionally, minimum volume requirements are based on an annual requirement so only the most recent year of volumes were analyzed. Data for all other indicators are reported as an aggregate across the entire time period that data was available for. Table 1 below shows the data availability for each indicator.

Table 1. Time period reported on for each Mitral Valve Clip Quality Measure

Indicator	Time Frame	Total Aggregate Time
Minimum Volume Requirement Indicators	FY 2017/18	1 year
Wait Time Indicators	FY 2015/16, FY 2016/17 and FY 2017/18	3 years
30-Day Mortality	FY 2015/16, FY 2016/17, and Q1 & Q2 FY 2017/18	2.5 years
1-Year Mortality	FY 2015/16, and Q1 & Q2 FY 2016/17	1.5 years
30-Day Repeat Mitral Valve Procedure Rate	FY 2015/16, FY 2016/17, and FY 2017/18	3 years
1-Year Repeat Mitral Valve Procedure Rate	FY 2015/16, and FY 2016/17	2 years

When reporting data, with all descriptive and outcomes tables, if the sample size was less than or equal to 5, the values were suppressed and reported in the table as “≤5” according to standards in place to comply with privacy legislation. Additional measures were also taken at times to ensure small cells could not be calculated (i.e. suppression of other numbers). As small cell sizes were common in this analysis, hospital level data was presented without volumes and without hospital identifiers in order to be able to visualize variation across programs without having to suppress results.

Results

Table 2 illustrates the volume of Mitral Valve Clip procedures performed in Ontario during the study period (April 1, 2015 to March 31, 2018) by program. While THP and UHN performed Mitral Valve Clip procedures during this time period, they were excluded from the outcomes analysis as there wasn't sufficient time for follow up as these centres only started offering Mitral Valve Clip services recently.

Table 2. Total volume of Mitral Valve Clips performed in Ontario from April 2015 to March 2018.

Program	Acronym	Volume
Hamilton Health Sciences	HHS	68
London Health Sciences Center	LHSC	37
St. Michael's Hospital	SMH	108
Sunnybrook Health Sciences Centre	SHSC	137
Trillium Health Partners	THP	6
University Health Network	UHN	15
University of Ottawa Heart Institute	UOHI	79
Total	ON	450

Table 3 illustrates the demographics and characteristics of patients undergoing Mitral Valve Clip procedures in Ontario. Due to small samples sizes, patient characteristics were not analyzed at the individual program level as a significant proportion of the data would be required to be suppressed to comply with privacy policies (i.e. cell counts ≤5).

Table 3. Summary of baseline characteristics for Mitral Valve Clips performed in Ontario, November 2013 - March 2016

Characteristic	Total
	N=447
Age (Mean)	76.3
Female	39.6%
BMI	
<25	48.6%
25-30	35.3%
>30	16.1%
<i>Missing</i>	34.7%
Comorbidities	
MI ≤ 30 days	1.7%
<i>Missing</i>	8.5%
MI ≥ 30 days	26.0%
<i>Missing</i>	4.5%
Dialysis	1.9%
<i>Missing</i>	3.8%
Diabetes	20.5%
<i>Missing</i>	4.0%
Hypertension	65.0%
<i>Missing</i>	4.3%
Hyperlipidemia	61.9%
<i>Missing</i>	4.3%
CVD	9.1%
<i>Missing</i>	6.5%
PVD	5.7%
<i>Missing</i>	6.0%
COPD	12.6%
<i>Missing</i>	5.8%
CHF	68.9%
<i>Missing</i>	5.1%
Previous CABG	24.0%
<i>Missing</i>	5.8%
Previous PCI	26.4%
<i>Missing</i>	5.1%
CCS/ACS Class	
0	63.9%

Characteristic	Total
1	27.0%
2	4.5%
3	3.0%
4	0.2%
ACS Low	0.5%
ACS Intermediate	0%
ACS High	0.7%
ACS Emergent	0.2%
<i>Missing</i>	9.6%
NYHA Class	
1	5.6%
2	23.0%
3	57.4%
4	9.9%
N/A	4.1%
<i>Missing</i>	7.6%
LVEF	
≥50%	49.3%
35-49%	21.3%
20-34%	22.9%
<20%	6.5%
<i>Missing</i>	17.9%
Creatinine	
Mean	129.6 µmol/L
0-120 µmol/L	59.7%
120-180 µmol/L	26.9%
>180 µmol/L	13.4%
<i>Missing</i>	16.8%

Data are from the CorHealth Ontario Cardiac Registry. Data includes Ontario funded patients only.

Table 4 below demonstrates the minimum volumes of interventional cardiology procedures performed at each of the active Mitral Valve Clip programs for the 2017/18 FY as they align to the “Ontario Mitral Valve Clip Procedure: Patient Eligibility Criteria Guidelines & Facility Quality Criteria”. All of the active Mitral Valve Clip programs met the minimum volume requirements in the 2017/18 FY with the exception of LHSC who performed 9 Mitral Valve Clip procedures compared to the minimum requirement of 15.

Table 4. Minimum Volumes Performed in FY 2017/18 by program in Alignment with the Facility Quality Criteria

Indicator	HHS	LHSC	SHSC	SMH	UOHI
Number of CATH procedures performed by program (minimum 1,000 CATHs per year)	6,095	4,661	3,190	2,909	6,255
Number of PCI procedures performed by program (minimum 400 PCIs per year)	2,437	1,469	1,892	1,505	2,521
Number of Structural Heart procedures performed by program (minimum 50 Structural Heart procedures per year including ASD/PFO and trans-septal punctures)	155	143	158	160	214
Number of Mitral Valve Repair procedures performed by program (minimum 25 Mitral Valve Repair surgeries per year)	75	70	49	42	114
Number of Mitral Valve Clip procedures performed by program (minimum 15 procedures per year)	28	9	52	49	35

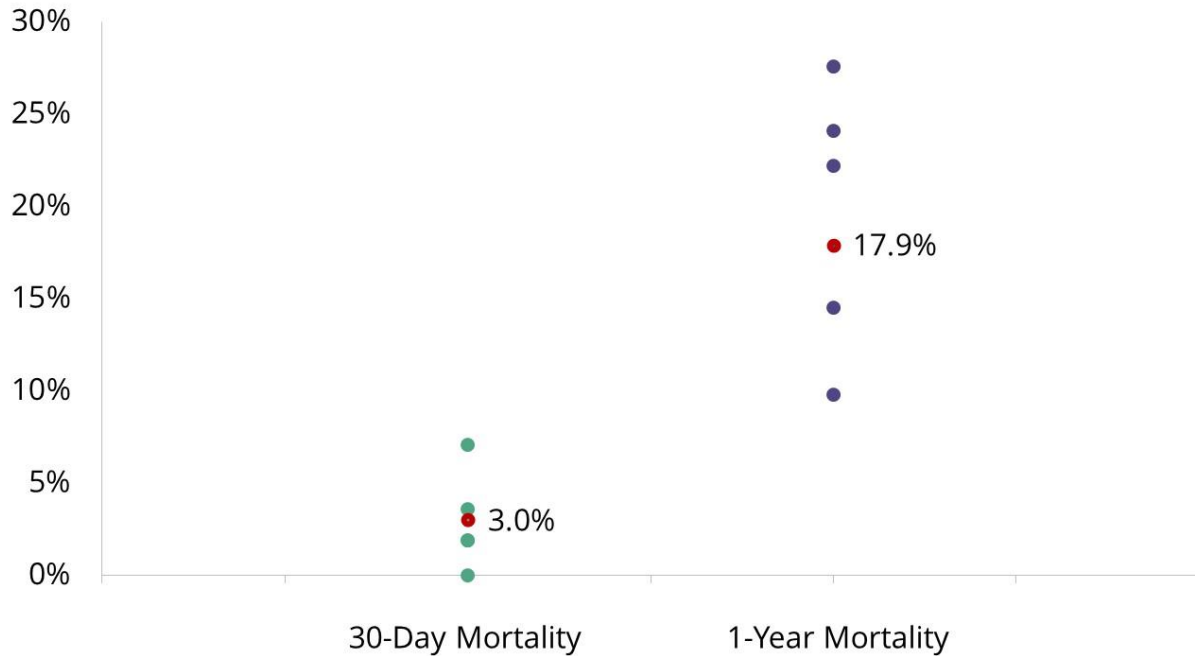
Table 5 illustrates the aggregate provincial wait times for Mitral Valve Clip procedures in Ontario. The wait times are presented as Wait Time 1, the time from referral for a procedure to the time of acceptance for a procedure, and Wait Time 2, the time from acceptance for a procedure to the actual procedure. Wait times weren’t presented at the individual program level as there was a large variation observed between programs which suggested issues with data quality at some of the programs. CorHealth is working to provide institutions with their own wait time data for review and is working on an education initiative to ensure wait time data definitions are captured in a standardized way across the province.

Table 5. Provincial Wait Times for Mitral Valve Clips in Ontario

Indicator		Wait Time (Days)
Provincial Mitral Valve Clip Volumes		450
Wait Time 1: Time from referral for a procedure to time of acceptance for a procedure	Median	0
	90 th Percentile	47
Wait Time 2: Time from acceptance of procedure to time of procedure	Median	10.5
	90 th Percentile	90.5

Figure 1 illustrates the 30-day and 1-year all-cause unadjusted mortality rates following Mitral Valve Clip procedures in Ontario. Each dot represents an individual program with the red dot representing the provincial average. The average 30-day mortality in Ontario was 3% which ranged from 0 to 7.1% between programs and the average 1-year mortality rate was 17.9% and ranged from 9.8 to 27.6 % between programs.

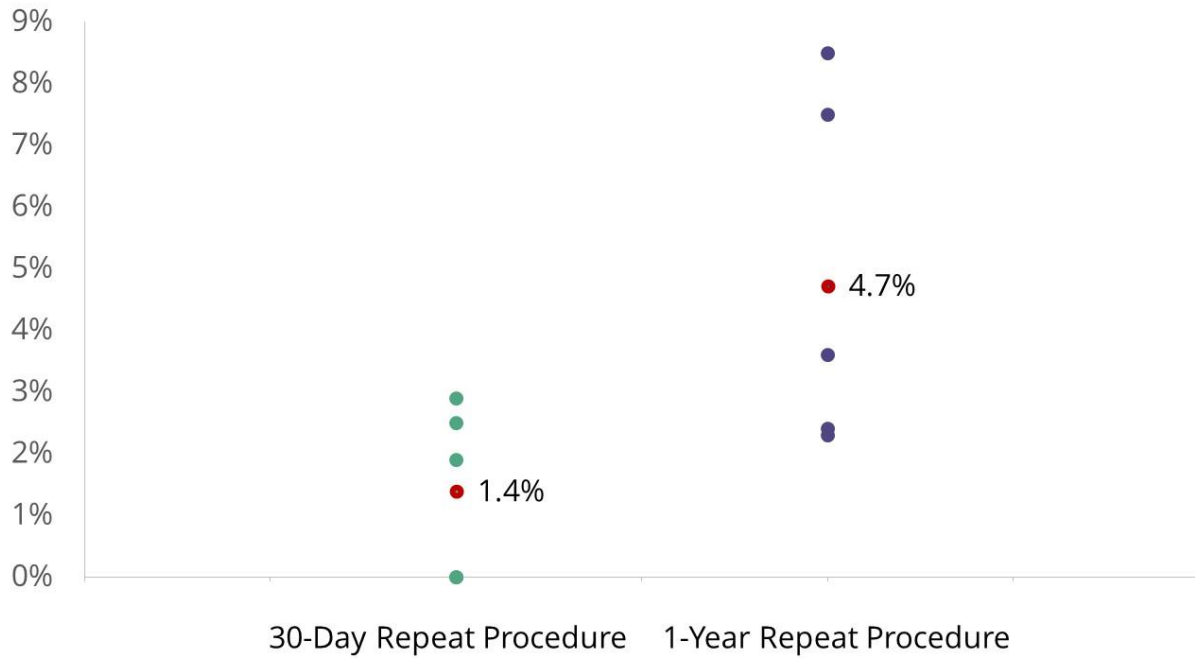
Figure 1. 30-Day and 1-Year All-Cause Mortality Rates Following Mitral Valve Clip Procedures in Ontario, April 2016 – March 2018



Data are from CorHealth Ontario Cardiac Registry; Death data are from RPDB; Each dot represents a Mitral Valve Clip Program; Red dots indicate the provincial average.

Figure 2 illustrates the repeat mitral valve procedure rate following Mitral Valve Clips in Ontario. Repeat Mitral Valve Clip procedures included both repeat Mitral Valves Clips as well as follow-up surgical Mitral Valve procedures. The 30-day repeat rate was relatively low at 1.4% across the province and ranged from 0 to 2.9%. The 1-year repeat rate was 4.7% and ranged from 2.3 to 8.5%.

Figure 2. 30-Day and 1-Year Mitral Valve Repeat Procedure Rates Following Mitral Valve Clip Procedures in Ontario, April 2016 – March 2018



Data are from CorHealth Ontario Cardiac Registry; Repeat procedures include a second Mitral Valve Clip as well as follow-up Mitral Valve Surgery; Each dot represents a Mitral Valve Clip Program; Red dots indicate the provincial average.

Discussion

Results in Context

The results in this report represent the first attempt at reporting on outcomes following Mitral Valve Clip procedures in Ontario. As such, it's important to compare these results to results from other jurisdictions to put into context how well Ontario is performing. Comparing data presented in this report to the results of published data from Mitral Valve Clip clinical trials illustrate that the mortality rates we observe in Ontario in this report compare favorably with those reported in the literature. The MITRA-FR trial was designed to assess Mitral Valve Clip, as compared to optimal standard of care therapy, in patients with severe secondary mitral regurgitation. This trial reported 1-year all-cause mortality rate of 24.3%³ compared to the 1-year all-cause mortality rate of 17.9% in this report. The COAPT trial was designed to assess the safety and efficacy of Mitral Valve Clip among symptomatic heart failure patients with secondary mitral regurgitation as compared to guideline-directed medical therapy. This trial looked at 2-year all-cause mortality and reported a rate of 29.1%⁴. Overall these results demonstrate that the mortality rates observed in Ontario compare favorably to those reported in the literature.

Limitations

There are a number of limitations in this report that should be addressed. The first is around the wait time data for Mitral Valve Clip procedures. Program specific wait times were not presented in this report as there was wide variation observed between programs and conversations with programs suggested the variation was due to data quality and differing interpretations of data element definitions rather than true variation. Many of the programs reported a median Wait Time 1 of 0 days indicating that patients were being referred, worked up, and accepted on the same day. Wait Time 2 wait times appeared to be more reasonable however there were still 2 programs observed with a median Wait Time 2 of 0 days meaning patients were being accepted and receiving a procedure on the same day. As such, the wait time data in this report is

³ Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation. Obadia JF et al., N Engl J Med. 2018 Dec 13;379(24):2297-2306.

⁴ Transcatheter Mitral-Valve Repair in Patients with Heart Failure. Stone GW, et al., N Engl J Med. 2018 Dec 13;379(24):2307-2318.

most likely under reporting the provincial aggregate length of time patients are waiting for Mitral Valve Clip procedures. However, it was felt it was important that this data be included in the report to highlight this issue to the programs.

CorHealth has met with representatives from the Mitral Valve Clip programs across the province and has begun an education initiative to ensure standardization of wait time definitions across all of the programs.

While outcomes were reported for individual programs (mortality rates and repeat Mitral Valve procedure rates) they were done so in an anonymized fashion. Each of the programs will receive their own results however for the provincial report it was decided not to name programs. This was done because this was the first provincial Mitral Valve Clip outcomes report and it was felt programs should have the opportunity to review their own outcomes before they were made available to the other programs.

This initial report marks an important first step in reporting on Mitral Valve Clip outcomes in Ontario, there are a number of important details that were not able to be included in this report due to data availability. CorHealth does not currently capture the type of mitral regurgitation each patient is being treated for (i.e degenerative vs functional mitral regurgitation), nor do we capture the degree of mitral regurgitation. Both of these are two very important elements that will help to put Mitral Valve Clip outcomes into context.

Finally, while we were able to report on crude mortality rates and repeat procedure rates, we were unable to include any of the functional type indicators in this report, such as improvement in mitral regurgitation post-procedure, change in NYHA class post-procedure or change in Quality of Life Post-Procedure. These are all outcomes that CorHealth Ontario's Minimally Invasive Structural Heart (MISH) Working Group have recommended CorHealth should be monitoring and reporting on. CorHealth will work towards expanding on this report in the future to include additional indicators that have been recommended by the MISH WG.

Conclusions

The outcomes data presented in this report demonstrate that Mitral Valve Clip is a relatively safe and effective procedure to treat severe mitral regurgitation in patients who are at extreme risk for conventional surgery in Ontario. Mortality rates following this procedure were found to be relatively consistent across the province and comparable to those reported by other jurisdictions. CorHealth Ontario will continue to refine and update this Mitral Valve Clip analysis. CorHealth has already engaged ICES to

supplement this analysis through linkages to administrative analysis for its next iteration. CorHealth will continue to monitor these outcomes following Mitral Valve Clip procedures as its use continues to expand across Ontario.

Appendix A

Table A1. List of Mitral Valve Clip Indicators as Recommended by the Mitral Valve Clip Advisory Committee (MCAC)

Structure Indicators
1. Number of procedures performed by program meet minimum Mitral Valve Clip volume requirements as outlined in the Ontario Mitral Valve Clip Facility Criteria (15 procedures per year)
2. Number of Mitral Valve procedures performed by program meet minimum requirements as outlined in the Ontario Mitral Valve Clip Facility Criteria (25 Mitral Valve repair surgeries per year)
3. Number of structural heart procedures performed by program meet minimum requirements as outlined in the Ontario Mitral Valve Clip Facility Criteria (50 Structural Heart procedures per year including ASD/PFO and trans-septal punctures)
4. Number of CATH/PCI procedures performed by program meet minimum requirements as outlined in the Ontario Mitral Valve Clip Facility Criteria (1,000 CATHs and 400 PCIs per year)
Process Indicators
1. Wait Time 1 - Time from referral for a procedure to time of acceptance for a procedure
2. Wait Time 2 - Time from acceptance of procedure to time of procedure
3. Evaluation of procedural risk performed and documented prior to procedure (i.e. STS score, EuroSCORE)
4. Documented consensus treatment recommendation made by a Heart Team
5. Documented comprehensive assessment of health related Quality of Life (QoL) incorporating a heart failure-specific measure. QoL should be assessed prior to the procedure and at 12 months post-intervention
Outcome Indicators
1. In-hospital, 30-day and 1-year mortality
2. 30-day and 1-year rate of repeat mitral valve procedures (Surgical/Percutaneous)
3. Post-procedural change in mitral regurgitation
4. 30-day and 1-year all-cause hospital readmission

6. 30-day and 1-year partial clip detachment
7. Change in NYHA class 1-Year post-procedure
7. In-hospital blood product use (red blood cell)
8. 30-day and 1-year clip embolization
9. Procedural access site and vascular complication rate
10. Changes in Quality of Life 1-Year post-procedure
11. 30-day and 1-year post-procedural renal failure
12. 30-day and 1-year post-procedural stroke