



Report on Transcatheter Aortic Valve Implantation (TAVI) in Ontario November 2013 to March 2016

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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, in collaboration with ICES. The results and conclusions presented in this report are those of CorHealth Ontario and should not be attributed to the funding agencies.

Toronto, Ontario

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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.

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Parts of this material are based on data and/or information compiled and provided by the Canadian Institute of Health Information (CIHI). However, the analyses, conclusions, opinions and statements expressed in the material are those of CorHealth Ontario, and not necessarily those of CIHI.

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Executive Summary

In collaboration with the ICES, CorHealth Ontario has been monitoring and reporting on trends in the case-mix and outcomes of patients receiving select cardiac services since 1994. In 2015, CorHealth Ontario began reporting on trends and quality of care for patients undergoing Transcatheter Aortic Valve Implantation (TAVI) in Ontario and released its first “Report on Transcatheter Aortic Valve Implantation (TAVI) in Ontario: January 2007 – November 2013”.

For this report, CorHealth Ontario worked with ICES to monitor trends in the case-mix and outcomes of patients receiving TAVI procedures in Ontario from 2013-2016. In this study, the outcomes of patients undergoing TAVI procedures at each TAVI program in Ontario were examined for the period of November 2013 to March 2016 and compared to the provincial average for the same time period. 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 11 programs in Ontario providing TAVI services, 10 of which were active over the time period of this study.
2. Over the time period of this study, 1,570 TAVIs were performed in Ontario of which 83.2% were done via transfemoral access site. Rates of transfemoral access site usage varied across the programs in Ontario.
3. The overall crude all-cause mortality rates were determined to be:
 - a. Overall 30-Day: 5.7%
 - b. Transfemoral 30-Day: 4.6%
 - c. Overall 1-Year: 15.9%
 - d. Transfemoral 1-Year: 14.5%
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 TAVI in this study compared favorably with mortality rates reported by other jurisdictions.

Background

Transcatheter Aortic Valve Implantation (TAVI) is a procedure designed to treat aortic stenosis and was developed as a potential alternative to open heart surgery. TAVI has been performed in Ontario since 2007. There are currently 11 TAVI programs in the province, although only 10 were operational over the time period of this study. All TAVI programs are provincially funded to provide TAVI services to inoperable patients and high risk patients with severe aortic stenosis although over the time period of this study inoperable patients were the only approved funding indication for TAVI. All TAVI programs contribute data to the CorHealth Ontario Cardiac Registry.

In collaboration with the ICES, CorHealth Ontario has been monitoring and reporting on trends in the case-mix and outcomes of patients receiving select cardiac services since 1994. In 2015, CorHealth Ontario began monitoring and reporting on trends and quality of care for patients undergoing TAVI in Ontario and released its first “Report on Transcatheter Aortic Valve Implantation (TAVI) in Ontario: January 2007 – November 2013”.¹ This current report provides an opportunity to refresh the analysis presented in the initial TAVI outcomes report with more current data (2013-2016), while at the same time revising the analysis to align with the national TAVI quality indicators endorsed by the Canadian Cardiovascular Society (CCS).²

For this report, CorHealth Ontario worked with ICES to monitor trends in the case-mix and outcomes of patients receiving TAVI in Ontario. This report is based on data that includes all TAVI procedures performed in Ontario from November 2013 (the end of the previous TAVI outcomes analysis published by CorHealth Ontario) to March 2016. By linking TAVI data from the CorHealth Ontario Cardiac Registry to hospital discharge data from the Canadian Institute for Health Information (CIHI) discharge abstract database (DAD) and to the Ontario Registered Persons Database (RPDB), outcomes were analyzed at the provincial and program level.

The primary outcomes included unadjusted rates for the following:

- 30-day and 1-year all-cause mortality

¹ Cardiac Care Network of Ontario, Report on Transcatheter Aortic Valve Implantation (TAVI) in Ontario January 2007 – November 2013. August 2015.

² Canadian Cardiovascular Society, “Quality Indicators E-Catalogue, Transcatheter Aortic Valve Implantation”, 2013.

- 30-day and 1-year all-cause hospital readmission rates

Additional metrics presented in this report include:

- In-hospital stroke rates
- In-hospital permanent pacemaker implantation rates
- Wait times
- Length of stay (LOS)
- TAVI records with a documented STS score
- TAVI records with a documented heart team recommendation

Ontario TAVI Programs

The following 10 TAVI programs were active during the study period (2013 - 2016):

Program	Abbreviation	City
University Health Network	UHN	Toronto
University of Ottawa Heart Institute	UOHI	Ottawa
Hamilton Health Sciences	HHS	Hamilton
St. Michael's Hospital	SMH	Toronto
London Health Sciences Centre	LHSC	London
Sunnybrook Health Sciences Centre	SHSC	Toronto
Southlake Regional Health Centre	SRHC	Newmarket
Trillium Health Partners	THP	Mississauga
Kingston General Hospital	KGH	Kingston
Health Sciences North	HSN	Sudbury

Note: Health Sciences North started reporting TAVI cases in February 2014. All other sites reported TAVI cases for the entire reporting period.

Methods

Time Frame 2013 – 2016

To evaluate program performance for the 2013 – 2016 time period, this report includes all patients who had TAVI between November 2013 and March 2016. Data is reported as an aggregate across the entire time period.

General Comments

This report detailed the unadjusted primary outcomes of all-cause mortality (30-day and 1-year) and all-cause readmission (30-day and 1-year) following TAVI in Ontario. Other information also presented, includes:

- TAVI patient baseline characteristics
- Access site
- Documentation of a heart team recommendation
- Documentation of evaluation of procedural risk (i.e. Documented STS Score)
- Wait times
- In-hospital stroke rates
- In-hospital permanent pacemaker implantation rates
- LOS

Mortality rates were presented for all TAVIs performed and also stratified by transfemoral TAVI procedures. Access site was identified using data from the CorHealth Ontario Cardiac Registry. P-values for continuous variables were calculated using a one-way ANOVA, and for categorical variables using a Chi-square test.

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).

Data Linkage

The data linkage processes were similar to those used in previous report cards. Figure 1 outlines the data linkage steps and the processes used to generate the final data sets. Only those records identified as a TAVI procedure using CorHealth Ontario data, between November 1, 2013 and March 31, 2016, were retained for data linkage. In the case where a patient had more than one procedure over the study period, only the record for the first procedure was retained. If a patient had two TAVI procedures on the same day, one classified as transfemoral and one classified as non-transfemoral, the case was categorized as transfemoral.

Many of the comorbidities presented in this report were created as a composite data point by combining CorHealth Ontario and CIHI data sets. In addition, a number of demographic/comorbidity fields were obtained solely from CIHI data sets as the information was not in the CorHealth Ontario Cardiac Registry. These fields include:

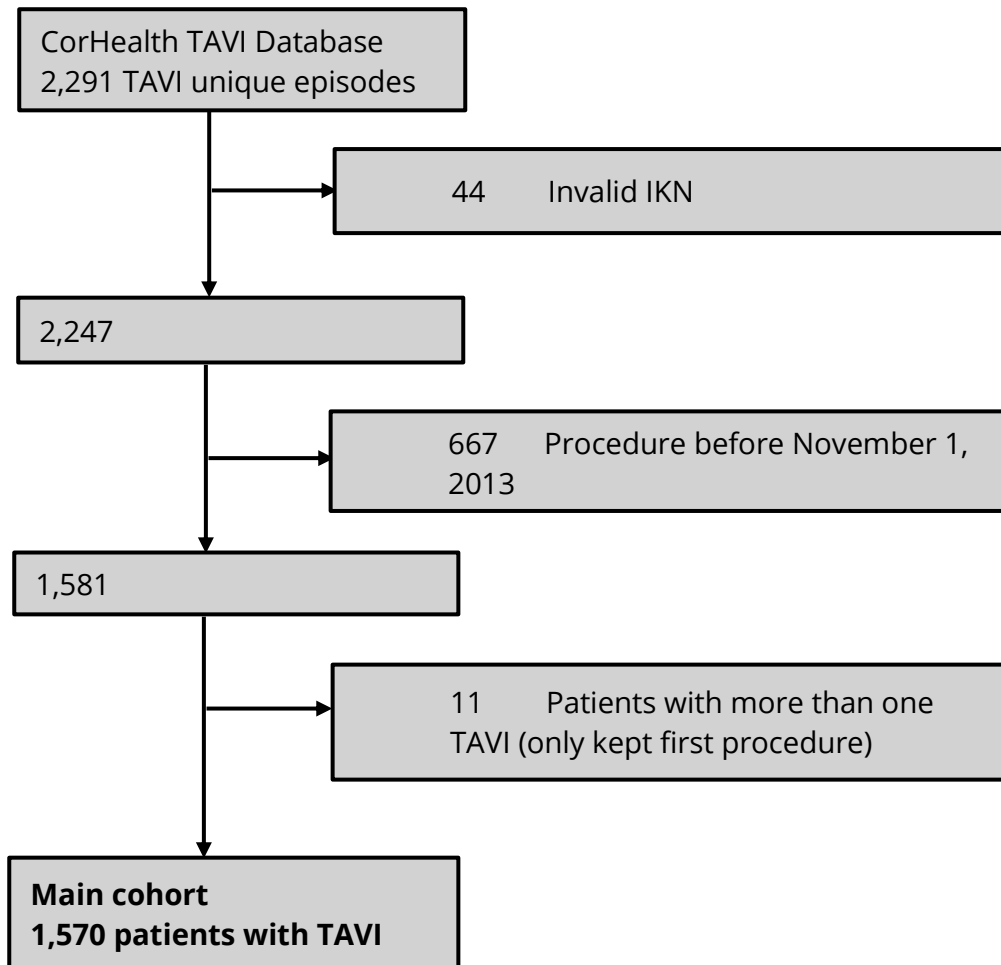
- Neighborhood income quintile
- Rural/urban
- Cognitive impairment/dementia
- Frailty
- Charleson score

Data linkage between CorHealth Ontario records and CIHI discharge abstracts was performed on health card number, institution and procedure date. Provincial health card numbers were converted to a unique ICES encrypted Health Card Number (IKN) and used for data linkage. Variables used for probabilistic linkage were first name, last name, date of birth, sex, and postal code. To create the final analysis data set, records unable to be linked by provincial health card number or probabilistic linkage were excluded. Only records for which a patient actually received a TAVI, as identified in the CorHealth Ontario Cardiac Registry were analyzed.

To capture 30-day and 1-year mortality, the records were linked by encrypted health card number/IKN to the Ontario Registered Persons Database (RPDB) to obtain out-of-hospital dates of death. Therefore 30-day and 1-year mortality analysis was restricted to records that had a valid health card number and could be linked to the RPDB.

Accordingly, non-Ontario residents who received TAVI in Ontario were not included in the 30-day and 1-year mortality analysis.

Figure 1. Cohort Flowchart



Results

Table 1 illustrates the volume of TAVIs performed in Ontario during the study period (November 1, 2013 to March 31, 2016) by program.

Table 1. Total volume of TAVIs performed in Ontario from November 2013 to March 2016.

Program	Acronym	Volume
Hamilton Health Sciences	HHS	192
Health Sciences North	HSN	51
Kingston General Hospital	KGH	53
London Health Sciences Center	LHSC	188
Southlake Regional Health Centre	SRHC	93
St. Michael's Hospital	SMH	185
Sunnybrook Health Sciences Centre	SHSC	276
Trillium Health Partners	THP	114
University Health Network	UHN	223
University of Ottawa Heart Institute	UOHI	195
Total	ON	1,570

Table 2 illustrates the demographics and characteristics of patients undergoing TAVI in Ontario. Patient characteristics at the program level can be found in Table B1 in Appendix B. Some of the key highlights at the provincial level are:

- Mean age of a TAVI patient was 82.1 ± 7.6 years old
- 80% of TAVIs were Elective and 20% Urgent
- 10% of TAVIs were Valve-in-Valve Procedures
- The breakdown of TAVI device use across the province was:
 - 43% Edwards Valves
 - 33% Medtronic Valves
 - 9% Other Valves
 - 15% of Valve type data was missing

Table 2. Summary of baseline characteristics for TAVIs performed in Ontario, November 2013 - March 2016

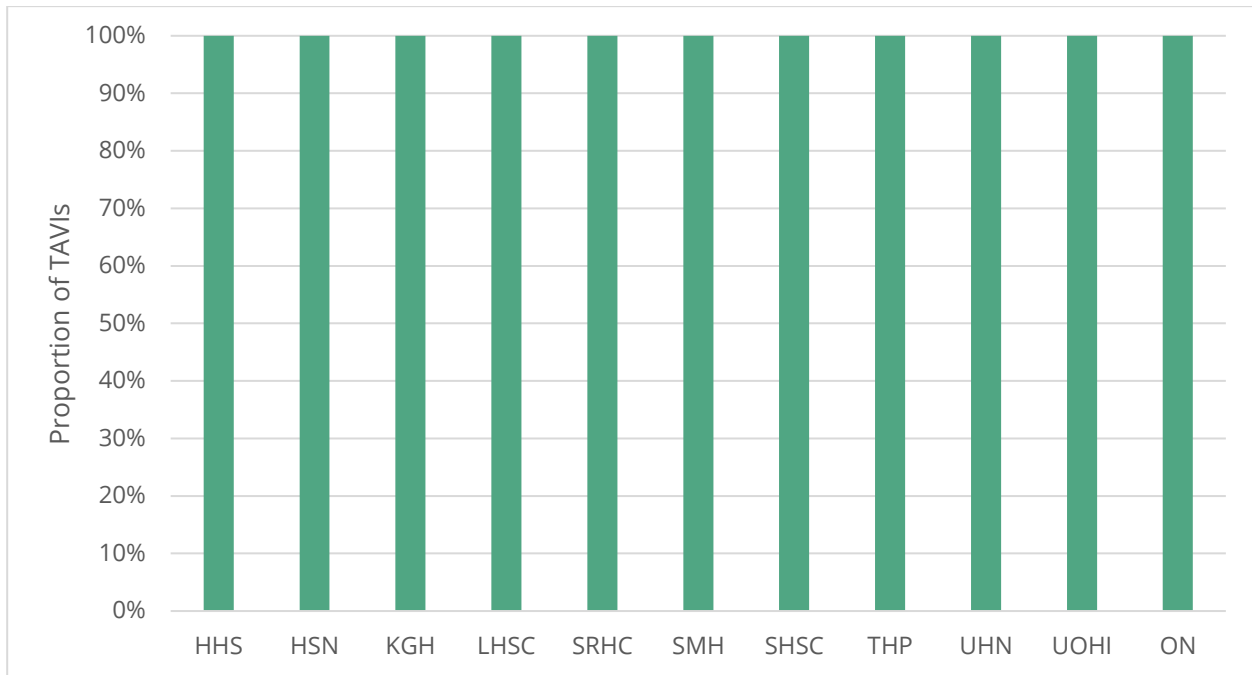
Characteristic	Total	p-Value
	N=1,570	
Age		
Mean ± SD	82.1 ± 7.58	<.001
Median (IQR)	83 (78-87)	<.001
Sex		
Female	720 (45.9%)	0.11
Male	850 (54.1%)	
Neighbourhood Income Quintile		
1	248 (15.8%)	0.442
2	320 (20.4%)	
3	327 (20.8%)	
4	337 (21.5%)	
5	331 (21.1%)	
Missing	7 (0.4%)	
Rural		
No	1,370 (87.3%)	<.001
Yes	200 (12.7%)	
Comorbidities and risk factors		
Diabetes	714 (45.5%)	0.211
Hypertension	1,492 (95.0%)	<.001
CHF	1,176 (74.9%)	<.001
Recent Heart Failure Hospitalization (<90 days)	360 (22.9%)	0.266
CAD/Ischemic Heart Disease	1,133 (72.2%)	<.001
Cardiac Arrhythmia/Atrial Arrhythmia	415 (26.4%)	0.414
Cerebrovascular disease	88 (5.6%)	0.083
PVD	85 (5.4%)	<.001
Dyslipidemia	1,074 (68.4%)	<.001
COPD	564 (35.9%)	0.113
Interstitial Lung Disease (incl. Pulmonary Fibrosis)	24 (1.5%)	0.771
Cognitive Impairment/Dementia	118 (7.5%)	0.004
Cancer	105 (6.7%)	0.301
Liver Disease	26 (1.7%)	0.246
Renal Disease	178 (11.3%)	0.003
Dialysis	60 (3.8%)	0.631

Frailty	338 (21.5%)	<.001
Charlson score		
Mean \pm SD	1.93 \pm 1.88	<.001
Median (IQR)	2 (0-3)	<.001
Previous PCI	563 (35.9%)	<.001
Previous CABG	363 (23.1%)	<.001
Previous Valve Surgery	213 (13.6%)	0.001
Vascular Access		
Transfemoral	1,307 (83.2%)	
Non-transfemoral	263 (16.8%)	<.001
TAVI Procedure Status		
Elective	1,261 (80.3%)	<.001
Urgent/Emergent	309 (19.7%)	
Aortic Valve-in-Valve Procedure	156 (9.9%)	<.001
Device Type		
Edwards	682 (43.4%)	<.001
Medtronic	523 (33.3%)	
Other	131 (8.3%)	
Missing	234 (14.9%)	

Baseline characteristics are presented at the program level in Table B1 in Appendix B.

Figure 2 illustrates the percentage of TAVIs performed in Ontario with a documented heart team recommendation. All TAVIs performed across the province during the time period of this study had a documented heart team recommendation.

Figure 2. TAVI Heart Team Recommendation by Program in Ontario, November 2013 - March 2016



Heart team recommendation data are from the CorHealth Ontario Cardiac Registry.

Figure 3 illustrates the breakdown of access site use for TAVI procedures across Ontario. Transfemoral access site is the most used approach with 83% of all TAVIs in Ontario performed using this approach, however there was variation in this rate observed across the TAVI programs in the province.

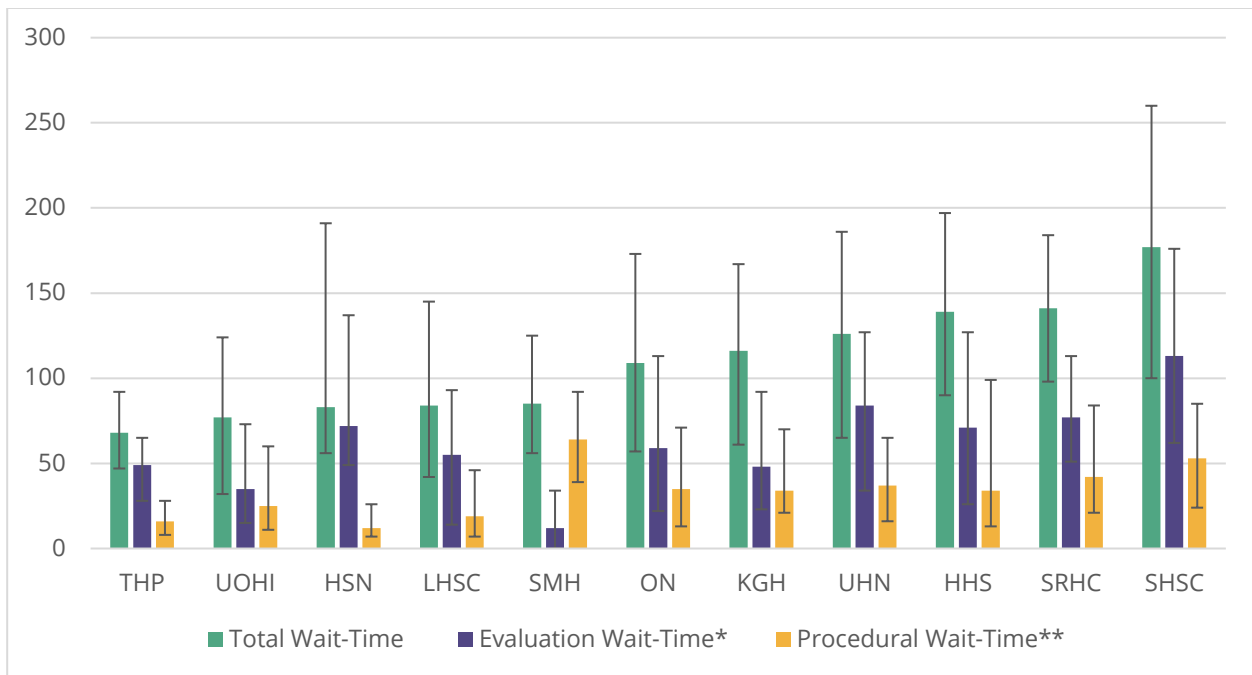
Figure 3. TAVI Access Site Use by Program in Ontario, November 2013 - March 2016



Access site data are from CorHealth Ontario Cardiac Registry data; Values for non-transfemoral TAVIs at HSN and KGH were suppressed as the counts were ≤ 5 , the true rate lies somewhere within the hatched section.

Figure 4 illustrates wait times for TAVI at the individual TAVI programs in Ontario. The total TAVI wait time is presented (from Referral for a TAVI to Procedure Date). Wait time data are also divided into the Evaluation Wait Time (alternatively known as Wait 1 - the Time of Referral for the TAVI to Time of Acceptance for the TAVI/Heart Team Decision) and the Procedural Wait Time (alternatively known as Wait 2 - the Time from Acceptance for the TAVI/Heart Team Decision to the Procedure Date). The median total wait time for TAVI in Ontario is 109 days with an almost 3-fold variation observed across individual TAVI programs. A more detailed table containing actual wait time values are included in Table B2 in Appendix B.

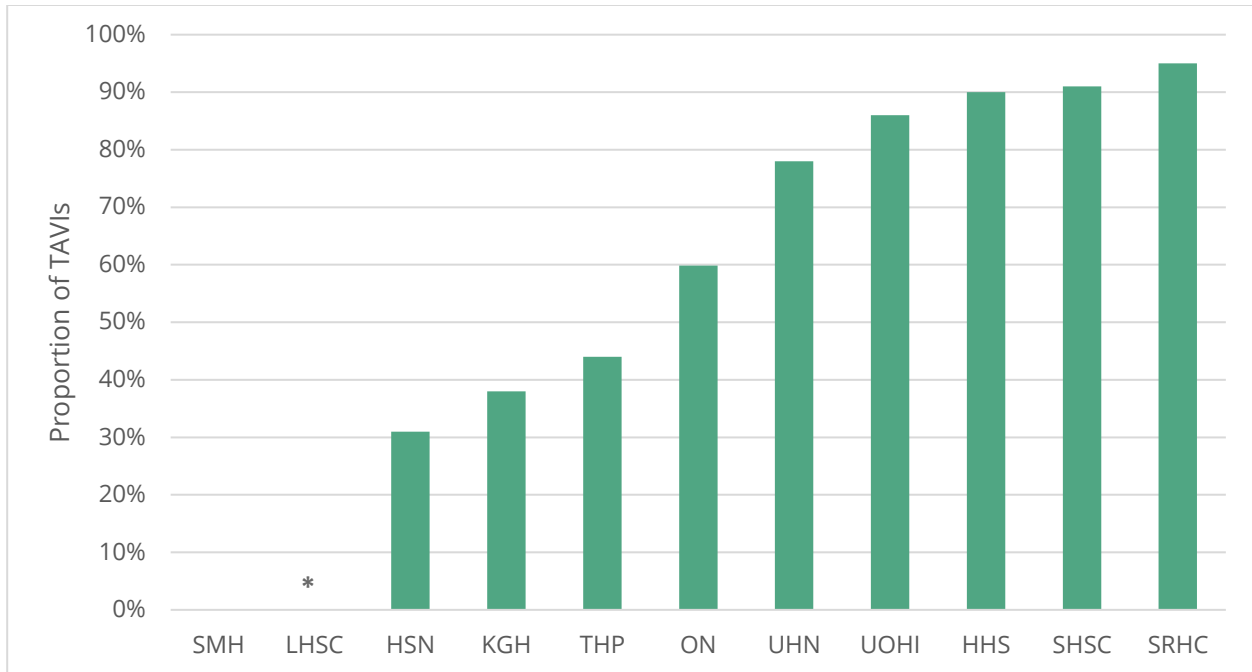
Figure 4: TAVI Wait Times by Program in Ontario, November 2013 - March 2016



Wait time data are from the CorHealth Ontario Cardiac Registry; Bars represent median wait time and error bars represent the Interquartile Range; *Evaluation Wait Time is the Time of Referral for the TAVI to Time of Acceptance for the TAVI/Heart Team Decision; **Procedural Wait-Time is the Time from Acceptance for the TAVI/Heart Team Decision to the Procedure Date.

Figure 5 illustrates the proportion of TAVIs that had an evaluation of procedural risk done prior to the procedure. Evaluation of procedural risk was defined as a documented STS Score (Society of Thoracic Surgeons) at the time of the procedure. There was considerable variation in the documentation of STS scores between the cardiac programs in Ontario. To note, the time period of this study extended to March 2016. In April 2016, CorHealth Ontario and the MOHLTC made a push for TAVI programs to provide CorHealth Ontario with documented STS scores for all TAVIs completed. Figure 11 in the Discussion section illustrates more recent data for this indicator for the 2017 calendar year which demonstrates that over 90% of TAVIs in Ontario now have a documented STS score.

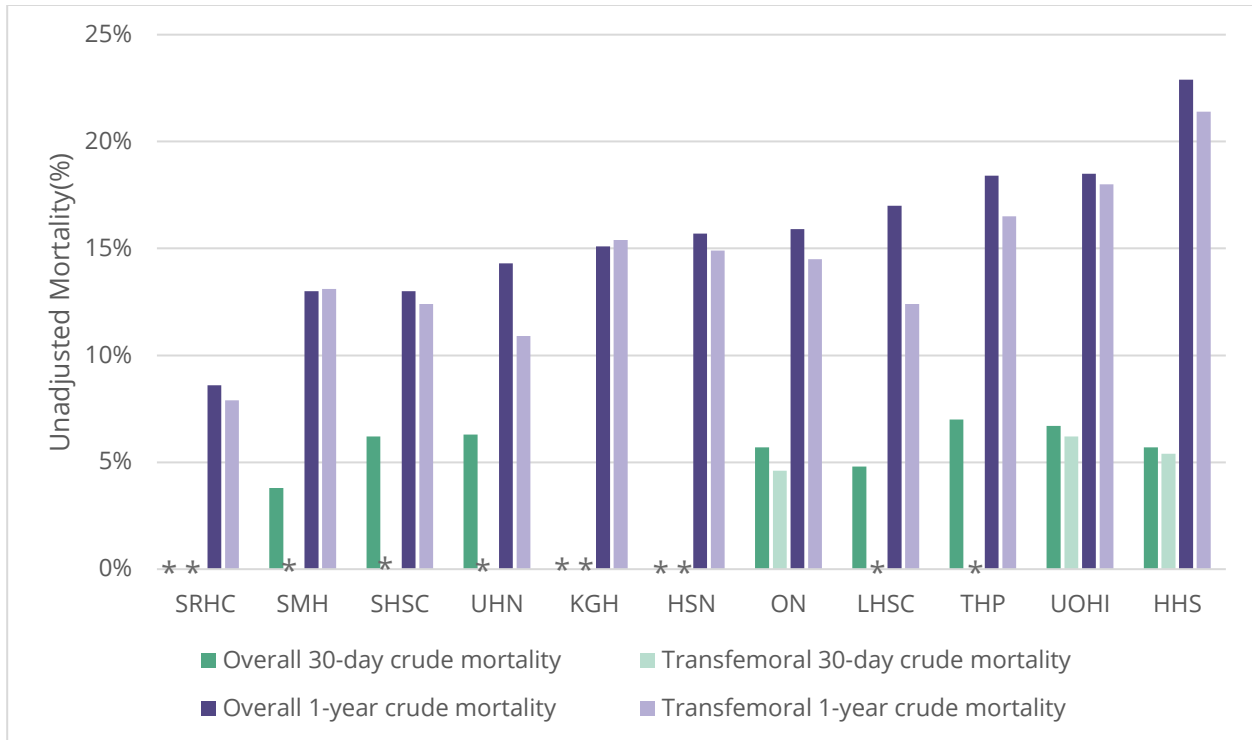
Figure 5. Evaluation of TAVI Procedural Risk (i.e. Documented STS Score) by Program in Ontario, November 2013 - March 2016



Data are from the CorHealth Ontario Cardiac Registry; * Cell counts ≤ 5 are suppressed to comply with privacy legislation.

Figure 6 illustrates the unadjusted all-cause TAVI mortality rates across the province of Ontario. Mortality rates are presented at 30-days and 1-year and are further categorized as total TAVIs and transfemoral TAVIs. Generally, transfemoral TAVI procedures had a lower mortality rate than the total TAVI mortality rate when non-transfemoral procedures were included. 30-day mortality rates were relatively consistent across the individual TAVI facilities while there was almost a two-fold variation in 1-year mortality rates (for actual values see Figure B3, Appendix B).

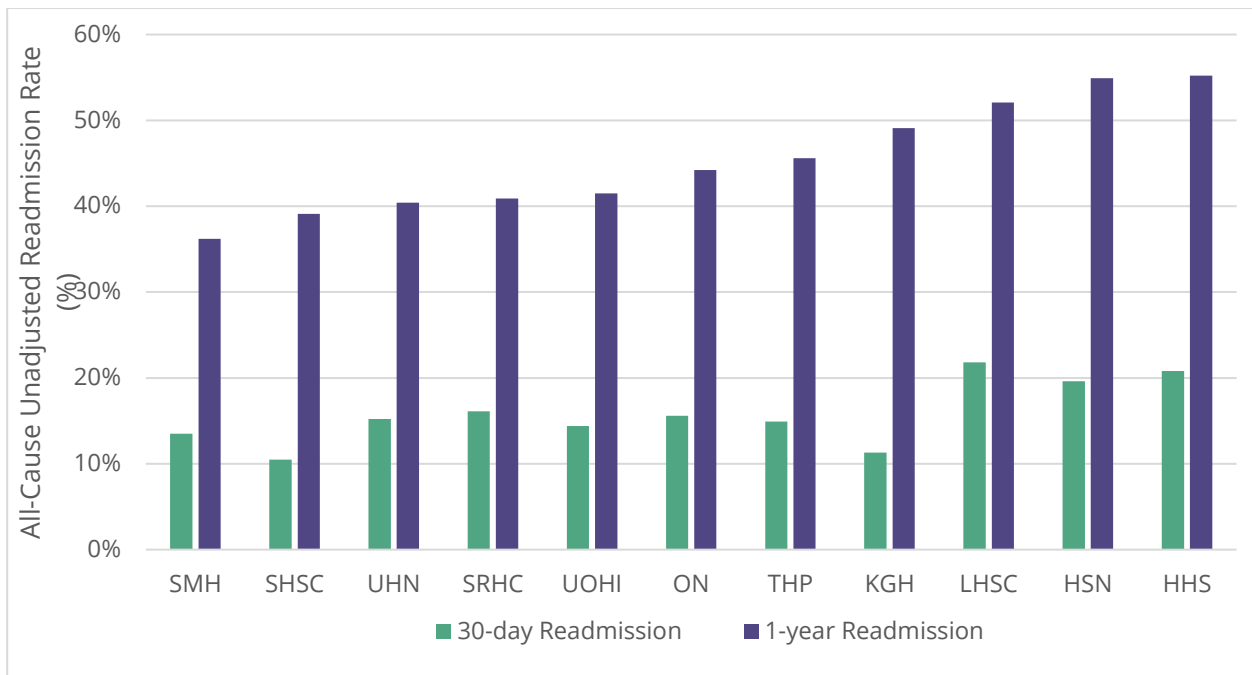
Figure 6. Unadjusted All-Cause TAVI Mortality Rates by Program in Ontario, November 2013 - March 2016



Procedure data are from the CorHealth Ontario Cardiac Registry; Death data are from the RPDB; *Cell counts ≤ 5 are suppressed to comply with privacy legislation; See Figure B3, Appendix B for more detailed information.

Figure 7 illustrates the variation in all-cause hospital readmission rates at 30-days and 1-year post-discharge across the TAVI programs in Ontario. There was an approximately 2-fold variation observed in 30-day readmission rates between the TAVI programs in Ontario and approximately 1.5-fold variation in the 1-year readmission rates.

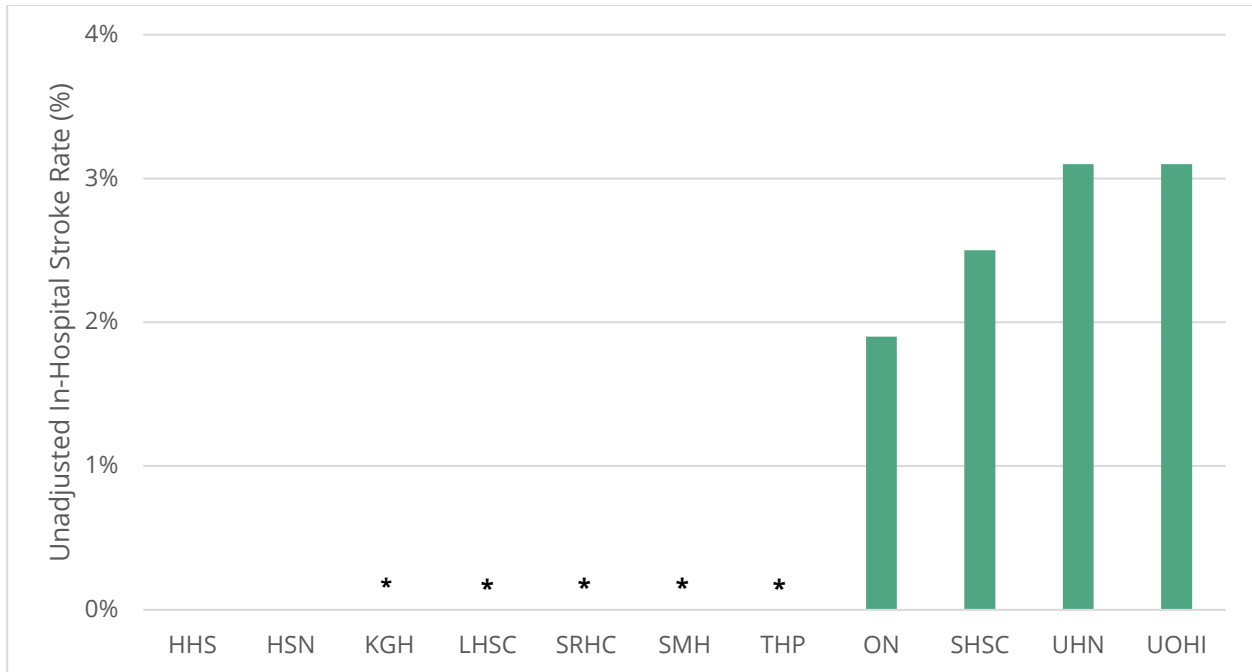
Figure 7. All-Cause Hospital Readmission Rates for TAVI by Program in Ontario, November 2013 - March 2016



Procedure data are from the CorHealth Ontario Cardiac Registry; Readmission data are from CIHI-DAD.

Figure 8 illustrates the post-TAVI in-hospital stroke rate across the province. In-hospital stroke was a relatively rare event with most programs either having no events or too few events to report on (≤ 5).

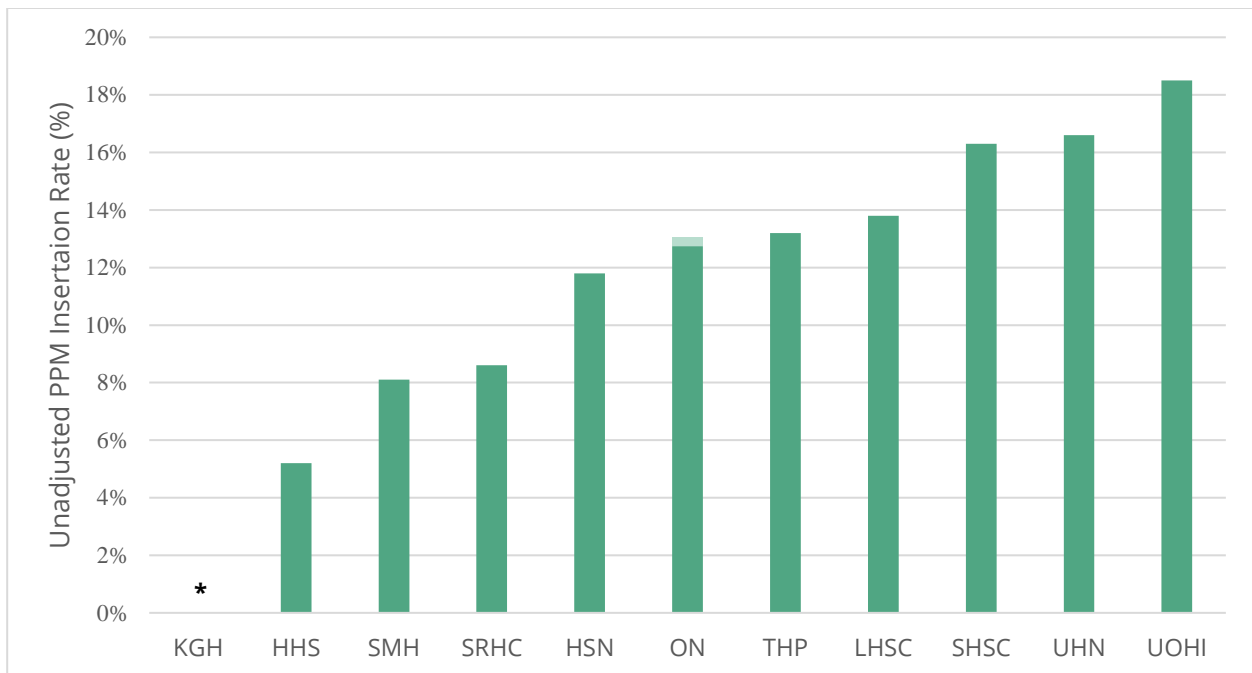
Figure 8. In-Hospital Stroke post-TAVI by Program in Ontario, November 2013 - March 2016



Data are from the CorHealth Ontario Cardiac Registry; *Cell counts ≤ 5 were suppressed to comply with privacy legislation.

Figure 9 illustrates the post-TAVI in-hospital permanent pacemaker implantation rate across the province. There was considerable variation observed in this rate between the TAVI facilities in Ontario, with rates ranging from approximately 5% to 18%.

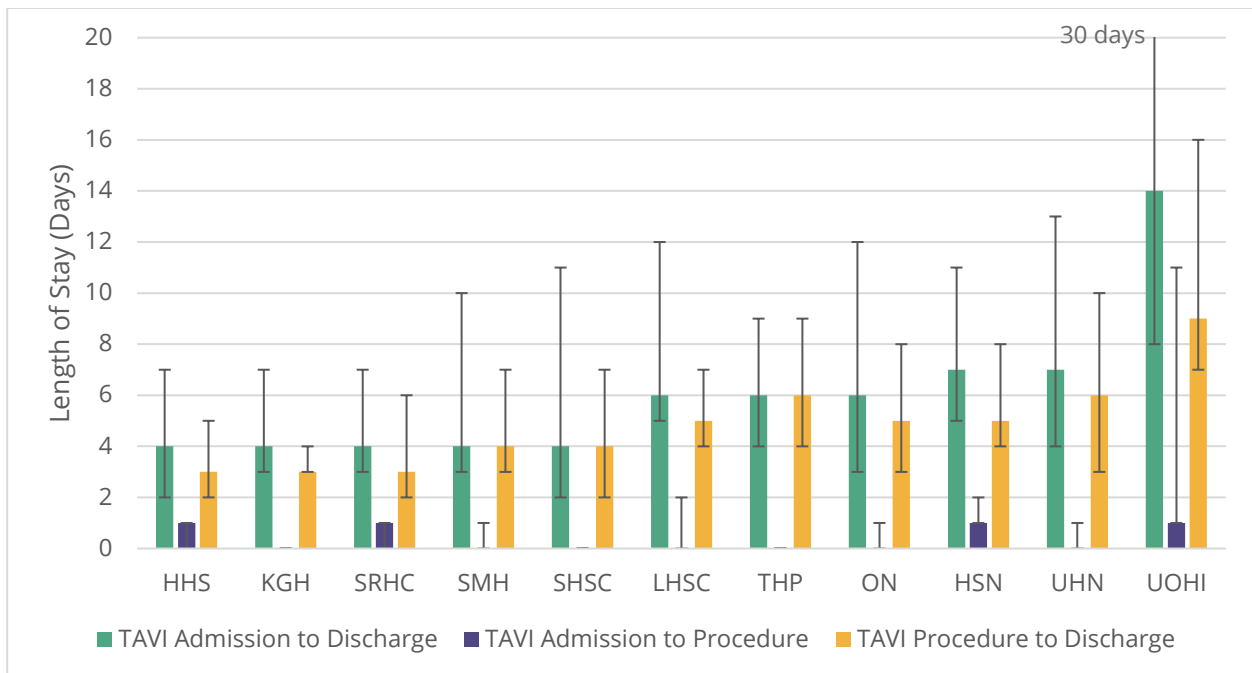
Figure 9. In-Hospital Permanent Pacemaker Implantation Rate by Program in Ontario, November 2013 - March 2016



*Procedure data are from the CorHealth Ontario Cardiac Registry; Pacemaker implantation data are from CIHI; *Cell counts ≤ 5 are suppressed to comply with privacy legislation and the ON rate was presented as a range to prevent recalculation of small cell, the true ON rate lies somewhere within the hatched area.*

Figure 10 illustrates the LOS for TAVI patients across the TAVI programs in Ontario. The total LOS was presented as Total LOS (Admission to Discharge) and further subdivided into Admission to Procedure and Procedure to Discharge. The median LOS in Ontario was approximately 6 days with most of that occurring from procedure to discharge. The median pre-TAVI LOS in Ontario (Admission to Procedure) was 0 days indicating most TAVIs were occurring on the day of admission. A more detailed table containing actual LOS values are included in Table B5 in Appendix B.

**Figure 10. TAVI Length of Stay (LOS) by Program in Ontario, November 2013
- March 2016**



Procedure data are from the CorHealth Ontario Cardiac Registry; LOS data are from CIHI; Bars represent median LOS; Error bars represent interquartile range; UOHI's 75th percentile LOS was 30 days but was cut off the graph to maintain scale; for more detailed data see Table B5 in Appendix B.

Discussion

Results in Context

CorHealth Ontario released its first TAVI outcomes report in August 2015.³ This initial report contained information on the case-mix and outcomes of patients receiving TAVI procedures in Ontario from 2007 to 2013. Over the time period of this initial study TAVI was approved in Ontario for use only in patients with severe aortic stenosis who were not candidates for open heart surgery.⁴ In this current report, we've looked at outcomes for TAVI procedures done in Ontario using more current data, 2013 to 2016. Over this time frame the approved indication for TAVI remained unchanged; it was restricted solely to patients who were not candidates for open heart surgery.

Comparing data presented in this report to the previous TAVI outcomes report released by CorHealth Ontario, with the exception of rates of permanent pacemaker implantations, many of the outcomes reported on have improved over the past 5 years (Table 3).

³ Cardiac Care Network of Ontario, Report on Transcatheter Aortic Valve Implantation (TAVI) in Ontario January 2007 – November 2013. August 2015.

⁴ Ontario Health Technology Advisory Committee (OHTAC), "OHTAC Recommendation Transcatheter Aortic Valve Implantation for Treatment of Aortic Valve Stenosis", 2012.

Table 3. Comparison of TAVI Outcomes in Ontario from 2007-2013 to 2013-2016

Outcome	2007 to 2013	2013 to 2016
All- Cause Mortality		
30-day (Total)	6.1%	5.7%
30-day (Transfemoral)	3.9%	4.6%
1-year (Total)	19.4%	15.9%
1-year (Transfemoral)	17.9%	14.5%
All-Cause Readmission		
30-day	17.5%	15.6%
1-year	49.3%	44.2%
Length of Hospitalization		
Mean ± SD	12.4 ±16.0	11.9 ± 25.24
Median (IQR)	8 (5-14)	6 (3-12)
In-Hospital Permanent Pacemaker Implantation	13%	12.9%

Over a similar time frame of this study the Society of Thoracic Surgeons (STS) released their 2016 annual report which covered all TAVI procedures captured in their Transcatheter Valve Therapy (TVT) Registry from 2012 to 2015.⁵ Table 4 illustrates a comparison between the unadjusted outcomes that were reported both in this study and in the TVT Annual Report. This comparison illustrates that outcomes for TAVIs in Ontario are comparable to those reported from other jurisdictions.

⁵ 2016 Annual Report of The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry. *J Am Coll Cardiol* 2017;69:1215-1230.

Table 4. Comparison of TAVI Outcomes in Ontario from 2013-2016 to the TVT Registry 2012-2015

Outcome	Ontario 2013 to 2016	TVT Registry 2012 to 2015
All- Cause Mortality		
30-day (Total)	5.7%	5.7%
1-year (Total)	15.9%	22.6%
Post-procedural Stroke Rate*	1.9%	2.1%
In-Hospital Permanent Pacemaker Implantation	12.9%	11.8%

*CorHealth Ontario measured in-hospital stroke rate while TVT registry measured 30-day stroke rate.

Observations

There was considerable variation observed between the in-hospital permanent pacemaker rates across the TAVI programs in Ontario (Figure 9). The requirement for a permanent pacemaker following TAVI is a significant clinical complication and also a significant driver of procedural cost. The extreme variation observed in this rate makes it an ideal target for quality improvement initiatives and should be investigated further. There are some limitations to the indicator that should be taken into consideration when interpreting these results. The rate of permanent pacemaker implantations may be affected by the subjectivity of the physician responsible for the decision to implant the device. This indicator was also reported as an in-hospital complication. If an institution were to discharge their patient and bring them back at a later time for a pacemaker insertion, that complication wouldn't be captured in this indicator. Finally, while it is known that permanent pacemaker implantations are more often associated with the use of self-expanding valves, this analysis doesn't address the appropriateness of valve section. There may be instances when a self-expanding valve is the more appropriate choice and an increased risk of complications requiring a permanent pacemaker implant is acceptable compared to the alternative.

Hospital readmission rates following TAVI were also high and variable across the TAVI programs in Ontario. 30-day readmission rates ranged almost two fold across the programs in Ontario, from 10.5% to 20.8% and 1-year readmission rates ranged from 36.2% to 55.2%. Provincially over 44% of TAVI patients are readmitted within 1-year following the TAVI procedure. While a high rate of readmission may be expected in this

patient cohort as TAVI patients are typically elderly, frail and have multiple comorbid conditions, there still may be opportunity for quality improvement initiatives to address the variability across the programs and decrease readmission provincially.

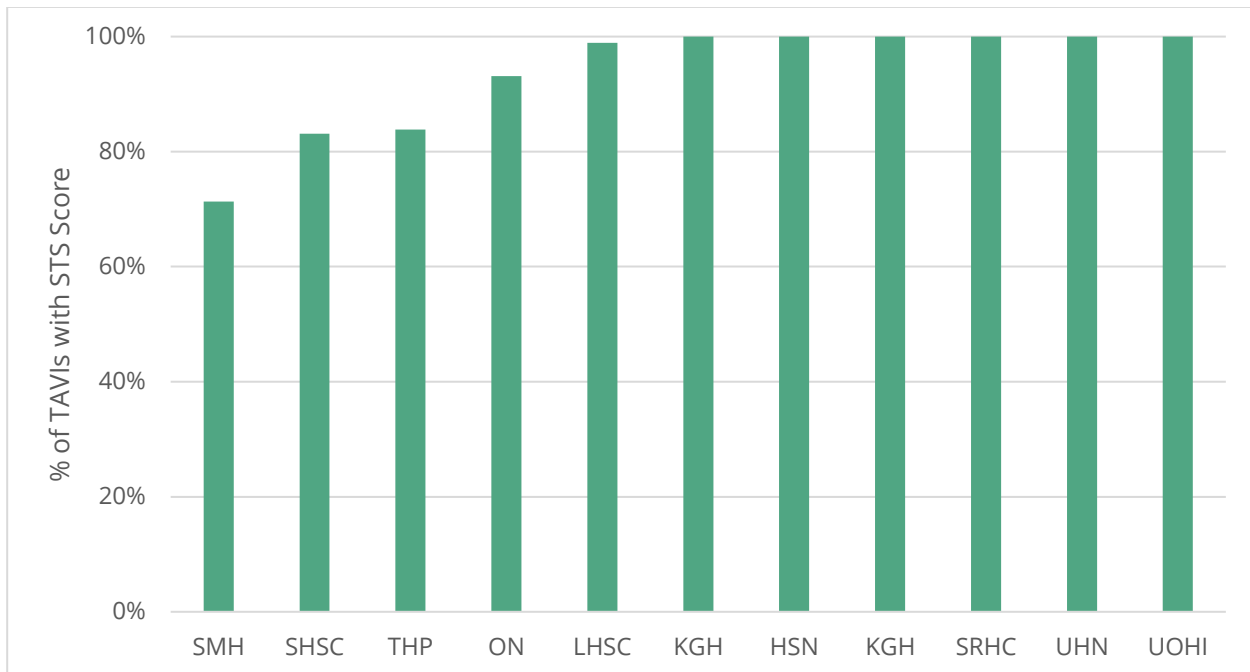
There was considerable variation observed in the total Length of Stay for TAVI procedures, ranging from a median of 4 days to 14 days across the TAVI programs in Ontario. The majority of the length of stay for TAVI patients occurred following the TAVI procedure with very short pre-TAVI hospitalizations for most cases. A consideration when interpreting this variation in length of stay is that this analysis did not aim to correlate length of stay with other outcomes. It is unclear if length of stay affects hospital readmission rates or any of the other outcomes.

Wait times for TAVI procedures were observed to be quite long over this study. At a provincial level the total median wait time for a TAVI procedure (from referral to procedure) was 109 days with an interquartile range of 57-173 days. While established wait time targets for TAVI don't currently exist, the Canadian Wait Time Alliance has developed national recommended benchmarks based on expert consensus for surgical aortic valve replacement.⁶ They recommend a target of 42 days for elective patients receiving conventional aortic valve replacement surgery. Wait time data from this study show that very few TAVI patients are meeting these targets in Ontario.

Figure 5 illustrates the variability in documented surgical risk (STS score) across the TAVI programs in Ontario. It was observed for some programs that many cases did not have a documented STS score. It should be noted that this analysis represents a snapshot in time of TAVI data across Ontario. Shortly after the conclusion of the data capture for this study, the Ontario MOHLTC made it mandatory for all TAVI programs in Ontario to provide CorHealth Ontario with a documented STS score for all TAVI cases performed. Figure 11 below illustrates data for this indicator captured just shortly after this analysis was completed (2017 calendar year). The rate of documented surgical risk has improved significantly from the time of analysis for this report.

⁶ www.waittimealliance.ca

Figure 11. Evaluation of TAVI Procedural Risk (i.e. Documented STS Score) by Program in Ontario, January 2017 – December 2017.



**Data are from CorHealth Ontario Cardiac Registry; Data represent TAVIs performed between January 1, 2017 and December 31, 2017.*

In addition to variation observed in the outcomes presented there was also fairly large variation observed in some of the procedural details across programs. Access site use varied with transfemoral access site use ranging from 52-96% across the TAVI programs in Ontario (Figure 3) and the proportion of Urgent/Emergent TAVIs ranged from 12-42% across the TAVI programs in Ontario (Appendix B, Table B1).

Limitations

The indicators chosen to present in this TAVI analysis were selected to align with the National TAVI Quality Indicators endorsed by the Canadian Cardiovascular Society (CCS)⁷. One indicator endorsed nationally that was excluded from this analysis was Evaluation of Quality of Life. The CCS recommends that a comprehensive assessment of health related quality of life, incorporating a heart failure-specific measure (Kansas City Cardiomyopathy Questionnaire) and a generic measure (EuroQoL 5D) should be assessed prior to the procedure and at 12 months post-procedure. Currently, none of the TAVI programs in Ontario submit Quality of Life data to CorHealth Ontario's

⁷ Canadian Cardiovascular Society, "Quality Indicators E-Catalogue, Transcatheter Aortic Valve Implantation", 2013.

provincial registry. Individual programs may be capturing Quality of Life data in their own local systems but CorHealth Ontario does not have access to Quality of Life data to support a provincial evaluation of TAVI patient reported outcomes.

The outcomes presented in this report are all presented as unadjusted rates without risk adjustment to allow for comparison between programs. Risk adjustment models for TAVI outcomes had not been developed at the time of this analysis and as TAVI volumes across the individual programs in Ontario are relatively low, special methodologies are required to develop risk adjustment models. Since this analysis was completed, CorHealth Ontario has worked with Dr. Harindra Wijeyesundera from the Sunnybrook Research Institute (SRI) to develop risk adjustment models for 30-day and 1-year all-cause mortality and readmission for TAVI, which are specifically developed to address small sample sizes. CorHealth Ontario will continue to monitor and report on TAVI outcomes in Ontario and will incorporate these risk adjustment models into future reports.

Conclusions

The outcomes data presented in this report demonstrate that TAVI is a relatively safe and effective procedure to treat aortic stenosis 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. The analysis in this report also highlighted areas of variability where targeted quality improvement initiatives could provide value including hospital readmission rates, procedural wait times and in-hospital permanent pacemaker rates. CorHealth Ontario will continue to refine and update this TAVI analysis and will continue to monitor these outcomes following TAVI procedures in Ontario as indications for the procedure continue to expand to include lower risk patients.

Appendix A

Abbreviations

CABG	coronary artery bypass graft
CAD	coronary artery disease
CHF	congestive heart failure
COPD	chronic obstructive pulmonary disease
IQR	interquartile range
PCI	percutaneous coronary intervention
PVD	peripheral vascular disease
SD	standard deviation

Appendix B

Table B1. Summary of baseline characteristics for TAVIs performed in Ontario, November 2013 – March 2016

Characteristic	TOTAL	HHS	HSN	KGH	LHSC	SRHC	SMH	SHSC	THSC	UHN	UOHI	p-Value
	N=1,570	N=192	N=51	N=53	N=188	N=93	N=185	N=276	N=114	N=223	N=195	
Age												
Mean ± SD	82.1 ± 7.58	82.6 ± 8.62	81.6 ± 6.71	80.9 ± 8.21	81.6 ± 6.91	81.4 ± 6.97	82.1 ± 6.50	82.2 ± 7.02	84.0 ± 6.51	80.4 ± 9.22	83.6 ± 7.24	<.001
Median (IQR)	83 (78-87)	84 (79-89)	84 (78-86)	82 (74-87)	82 (78-87)	82 (77-86)	84 (78-87)	83 (78-87)	86 (80-89)	82 (76-87)	85 (80-89)	<.001
Sex												
Female	720 (45.9%)	81 (42.2%)	14 (27.5%)	24 (45.3%)	92 (48.9%)	43 (46.2%)	92 (49.7%)	132 (47.8%)	56 (49.1%)	90 (40.4%)	96 (49.2%)	0.11
Male	850 (54.1%)	111 (57.8%)	37 (72.5%)	29 (54.7%)	96 (51.1%)	50 (53.8%)	93 (50.3%)	144 (52.2%)	58 (50.9%)	133 (59.6%)	99 (50.8%)	
Neighbourhood Income Quintile												
1	248 (15.8%)	29-33	13 (25.5%)	8-12	31 (16.5%)	13 (14.0%)	30 (16.2%)	43-47	13 (11.4%)	36 (16.1%)	19-23	0.442
2	320 (20.4%)	43 (22.4%)	8 (15.7%)	10 (18.9%)	34 (18.1%)	13 (14.0%)	40 (21.6%)	61 (22.1%)	22 (19.3%)	47 (21.1%)	42 (21.5%)	
3	327 (20.8%)	40 (20.8%)	12 (23.5%)	12 (22.6%)	42 (22.3%)	22 (23.7%)	39 (21.1%)	46 (16.7%)	26 (22.8%)	50 (22.4%)	38 (19.5%)	
4	337 (21.5%)	44 (22.9%)	10 (19.6%)	8 (15.1%)	41 (21.8%)	27 (29.0%)	32 (17.3%)	59 (21.4%)	27 (23.7%)	37 (16.6%)	52 (26.7%)	

5	331 (21.1%)	31 (16.1%)	8 (15.7%)	10 (18.9%)	40 (21.3%)	18 (19.4%)	44 (23.8%)	62 (22.5%)	26 (22.8%)	53 (23.8%)	39 (20.0%)	
Missing	7 (0.4%)	<=5	0 (0.0%)	<=5	0 (0.0%)	0 (0.0%)	0 (0.0%)	<=5	0 (0.0%)	0 (0.0%)	<=5	
Rural												
No	1,370 (87.3%)	177 (92.2%)	34 (66.7%)	42 (79.2%)	147 (78.2%)	65 (69.9%)	171 (92.4%)	271-275	109-113	199 (89.2%)	152 (77.9%)	<.001
Yes	200 (12.7%)	15 (7.8%)	17 (33.3%)	11 (20.8%)	41 (21.8%)	28 (30.1%)	14 (7.6%)	<=5	<=5	24 (10.8%)	43 (22.1%)	
Comorbidities and risk factors												
Diabetes	714 (45.5%)	73 (38.0%)	19 (37.3%)	22 (41.5%)	88 (46.8%)	49 (52.7%)	85 (45.9%)	119 (43.1%)	51 (44.7%)	113 (50.7%)	95 (48.7%)	0.211
Hypertension	1,492 (95.0%)	186-191	45-50	42 (79.2%)	179 (95.2%)	88-92	179-184	265 (96.0%)	107 (93.9%)	207 (92.8%)	185 (94.9%)	<.001
CHF	1,176 (74.9%)	143 (74.5%)	44 (86.3%)	29 (54.7%)	109 (58.0%)	58 (62.4%)	126 (68.1%)	270-275	77 (67.5%)	153 (68.6%)	162 (83.1%)	<.001
Recent Heart Failure Hospitalization (<90 days)	360 (22.9%)	45 (23.4%)	16 (31.4%)	9 (17.0%)	46 (24.5%)	11 (11.8%)	43 (23.2%)	60 (21.7%)	26 (22.8%)	54 (24.2%)	50 (25.6%)	0.266
CAD/Ischemic Heart Disease	1,133 (72.2%)	166 (86.5%)	43 (84.3%)	37 (69.8%)	132 (70.2%)	80 (86.0%)	130 (70.3%)	211 (76.4%)	68 (59.6%)	148 (66.4%)	118 (60.5%)	<.001
Cardiac Arrhythmia/Atrial Arrhythmia	415 (26.4%)	53 (27.6%)	13 (25.5%)	17 (32.1%)	49 (26.1%)	18 (19.4%)	57 (30.8%)	78 (28.3%)	27 (23.7%)	48 (21.5%)	55 (28.2%)	0.414
Cerebrovascular disease	88 (5.6%)	15 (7.8%)	<=5	<=5	8 (4.3%)	9 (9.7%)	<=5	21 (7.6%)	<=5	8 (3.6%)	8 (4.1%)	0.083
PVD	85 (5.4%)	36 (18.8%)	<=5	0 (0.0%)	10 (5.3%)	6 (6.5%)	7 (3.8%)	12 (4.3%)	<=5	<=5	<=5	<.001

Dyslipidemia	1,074 (68.4%)	146 (76.0%)	26 (51.0%)	18 (34.0%)	113 (60.1%)	49 (52.7%)	117 (63.2%)	225 (81.5%)	79 (69.3%)	154 (69.1%)	147 (75.4%)	<.001
COPD	564 (35.9%)	64 (33.3%)	26 (51.0%)	20 (37.7%)	65 (34.6%)	35 (37.6%)	61 (33.0%)	104 (37.7%)	31 (27.2%)	76 (34.1%)	82 (42.1%)	0.113
Interstitial Lung Disease (incl. Pulmonary Fibrosis)	24 (1.5%)	<=5	0 (0.0%)	0 (0.0%)	<=5	<=5	<=5	<=5	0 (0.0%)	<=5	<=5	0.771
Cognitive Impairment/Dementia	118 (7.5%)	15 (7.8%)	<=5	<=5	<=5	8 (8.6%)	12 (6.5%)	23 (8.3%)	<=5	18 (8.1%)	27 (13.8%)	0.004
Cancer	105 (6.7%)	14 (7.3%)	<=5	<=5	12 (6.4%)	10 (10.8%)	8 (4.3%)	22 (8.0%)	10 (8.8%)	17 (7.6%)	10 (5.1%)	0.301
Liver Disease	26 (1.7%)	6 (3.1%)	0 (0.0%)	<=5	0 (0.0%)	<=5	<=5	8 (2.9%)	<=5	<=5	<=5	0.246
Renal Disease	178 (11.3%)	27 (14.1%)	14 (27.5%)	<=5	17 (9.0%)	<=5	16 (8.6%)	34 (12.3%)	10 (8.8%)	23 (10.3%)	28 (14.4%)	0.003
Dialysis	60 (3.8%)	9 (4.7%)	<=5	<=5	<=5	<=5	7 (3.8%)	8 (2.9%)	6 (5.3%)	12 (5.4%)	8 (4.1%)	0.631
Frailty	338 (21.5%)	48 (25.0%)	16 (31.4%)	8 (15.1%)	27 (14.4%)	23 (24.7%)	38 (20.5%)	68 (24.6%)	15 (13.2%)	37 (16.6%)	58 (29.7%)	<.001
Charlson score												
Mean ± SD	1.93 ± 1.88	2.57 ± 2.16	2.35 ± 2.00	1.47 ± 1.72	1.85 ± 1.87	2.12 ± 1.95	1.59 ± 1.64	1.95 ± 1.84	1.52 ± 1.68	1.87 ± 1.83	1.90 ± 1.85	<.001
Median (IQR)	2 (0-3)	2 (1-4)	2 (1-4)	1 (0-2)	2 (0-3)	2 (1-3)	1 (0-3)	2 (0-3)	1 (0-2)	2 (0-3)	2 (0-3)	<.001
Previous PCI	563 (35.9%)	55 (28.6%)	28 (54.9%)	24 (45.3%)	30 (16.0%)	34 (36.6%)	57 (30.8%)	154 (55.8%)	26 (22.8%)	85 (38.1%)	70 (35.9%)	<.001
Previous CABG	363 (23.1%)	63 (32.8%)	10 (19.6%)	11 (20.8%)	64 (34.0%)	27 (29.0%)	25 (13.5%)	50 (18.1%)	24 (21.1%)	58 (26.0%)	31 (15.9%)	<.001

Previous Valve Surgery	213 (13.6%)	25 (13.0%)	9 (17.6%)	<=5	38 (20.2%)	9 (9.7%)	20 (10.8%)	50 (18.1%)	8 (7.0%)	33 (14.8%)	20 (10.3%)	0.001
Vascular Access												
Transfemoral	1,307 (83.2%)	168 (87.5%)	45-50	47-52	97 (51.6%)	76 (81.7%)	145 (78.4%)	266 (96.4%)	103 (90.4%)	175 (78.5%)	178 (91.3%)	<.001
Non-transfemoral	263 (16.8%)	24 (12.5%)	<=5	<=5	91 (48.4%)	17 (18.3%)	40 (21.6%)	10 (3.6%)	11 (9.6%)	48 (21.5%)	17 (8.7%)	
TAVI Procedure Status												
Elective	1,261 (80.3%)	163 (84.9%)	40 (78.4%)	44 (83.0%)	153 (81.4%)	80 (86.0%)	151 (81.6%)	233 (84.4%)	100 (87.7%)	184 (82.5%)	113 (57.9%)	<.001
Urgent/Emergent	309 (19.7%)	29 (15.1%)	11 (21.6%)	9 (17.0%)	35 (18.6%)	13 (14.0%)	34 (18.4%)	43 (15.6%)	14 (12.3%)	39 (17.5%)	82 (42.1%)	
Aortic Valve-in-Valve Procedure	156 (9.9%)	15 (7.8%)	<=5	<=5	27 (14.4%)	6 (6.5%)	18 (9.7%)	41 (14.9%)	<=5	32 (14.3%)	6 (3.1%)	<.001
Device Type												
Edwards	682 (43.4%)	188 (97.9%)	2-6	0 (0.0%)	9-13	85 (91.4%)	126 (68.1%)	33 (12.0%)	86 (75.4%)	132 (59.2%)	17 (8.7%)	<.001
Medtronic	523 (33.3%)	0 (0.0%)	44 (86.3%)	19 (35.8%)	86 (45.7%)	2-6	2-6	217 (78.6%)	23-27	86 (38.6%)	35 (17.9%)	
Other	131 (8.3%)	<=5	<=5	0 (0.0%)	90 (47.9%)	0 (0.0%)	9-13	20 (7.2%)	0 (0.0%)	<=5	6 (3.1%)	
Missing	234 (14.9%)	<=5	0 (0.0%)	34 (64.2%)	<=5	<=5	44 (23.8%)	6 (2.2%)	<=5	<=5	137 (70.3%)	

Table B2. TAVI procedure wait time, November 2013 – March 2016

	TOTAL	HHS	HSN	KGH	LHSC	SRHC	SMH	SHSC	THSC	UHN	UOHI	p-Value
	N=1,570	N=192	N=51	N=53	N=188	N=93	N=185	N=276	N=114	N=223	N=195	
Total Wait-Time (Days)												
Mean ± SD	128.60 ± 103.42	149.20 ± 91.94	120.06 ± 79.97	125.38 ± 84.79	99.35 ± 76.57	150.33 ± 94.54	90.36 ± 51.13	198.33 ± 146.58	73.80 ± 40.55	140.77 ± 108.88	84.97 ± 59.93	<.001
Median (IQR)	109 (57- 173)	139 (90- 197)	83 (56- 191)	116 (61- 167)	84 (42- 145)	141 (98- 184)	85 (56- 125)	177 (100- 260)	68 (47- 92)	126 (65- 186)	77 (32- 124)	<.001
Evaluation Wait-Time (Days)*												
Mean ± SD	79.69 ± 83.37	89.81 ± 86.01	91.51 ± 60.89	77.04 ± 84.89	66.81 ± 62.32	95.41 ± 80.84	22.97 ± 30.01	132.54 ± 108.66	52.64 ± 35.56	94.73 ± 92.73	49.95 ± 44.60	<.001
Median (IQR)	59 (22- 113)	71 (26- 127)	72 (49- 137)	48 (23- 92)	55 (14- 93)	77 (51- 113)	12 (0-34)	113 (62- 176)	49 (28- 65)	84 (34- 127)	35 (15- 73)	<.001
Procedural Wait-Time (Days)**												
Mean ± SD	48.91 ± 49.96	59.39 ± 59.46	28.55 ± 42.28	48.34 ± 35.63	32.54 ± 39.44	54.92 ± 41.34	67.39 ± 39.59	65.80 ± 66.45	21.16 ± 16.34	46.04 ± 48.79	35.03 ± 32.96	<.001
Median (IQR)	34 (13- 71)	34 (13- 99)	12 (7- 26)	34 (21- 70)	19 (7- 46)	42 (21- 84)	64 (39- 92)	53 (24- 85)	16 (8- 28)	37 (16- 65)	25 (11- 60)	<.001

*TAVI Evaluation time is defined as the time from referral to TAVI team to Heart Team decision; **TAVI Procedural Wait time, defined as time from "Date of Heart Team decision" (i.e., consensus treatment recommendation for TAVI, and patient is ready, willing and able) to "Date of procedure." IQR = interquartile range.

Table B3. Unadjusted All-Cause Mortality Rates for TAVI by Program in Ontario, November 2013 – March 2016

Program	Volume	Overall		Transfemoral	
		30-day mortality	1-year mortality	30-day mortality	1-year mortality
Hamilton Health Sciences	192	11 (5.7%)	44 (22.9%)	9 (5.4%)	36 (21.4%)
Health Sciences North	51	<=5	8 (15.7%)	<=5	7 (14.9%)
Kingston General Hospital	53	<=5	8 (15.1%)	<=5	8 (15.4%)
London Health Sciences Center	188	9 (4.8%)	32 (17.0%)	<=5	12 (12.4%)
Southlake Regional Health Centre	93	<=5	8 (8.6%)	<=5	6 (7.9%)
St. Michael's Hospital	185	7 (3.8%)	24 (13.0%)	<=5	19 (13.1%)
Sunnybrook Health Sciences Centre	276	17 (6.2%)	36 (13.0%)	<=5	33 (12.4%)
Trillium Health Partners	114	8 (7.0%)	21 (18.4%)	<=5	17 (16.5%)
University Health Network	223	14 (6.3%)	32 (14.3%)	<=5	19 (10.9%)
University of Ottawa Heart Institute	195	13 (6.7%)	36 (18.5%)	11 (6.2%)	32 (18.0%)
Ontario	1,570	89 (5.7%)	249 (15.9%)	60(4.6%)	189 (14.5%)
p-value		0.91	0.072	0.819	0.099

Mortality rates are presented as (n, %).

Table B4. Unadjusted All-Cause Hospital Readmission Rates for TAVI by Program in Ontario, November 2013 – March 2016

Program	Volume	30-day Readmission (N, %)	1-year Readmission (N, %)
Hamilton Health Sciences	192	40 (20.8%)	106 (55.2%)
Health Sciences North	51	10 (19.6%)	28 (54.9%)
Kingston General Hospital	53	6 (11.3%)	26 (49.1%)
London Health Sciences Center	188	41 (21.8%)	98 (52.1%)
Southlake Regional Health Centre	93	15 (16.1%)	38 (40.9%)
St. Michael's Hospital	185	25 (13.5%)	67 (36.2%)
Sunnybrook Health Sciences Centre	276	29 (10.5%)	108 (39.1%)
Trillium Health Partners	114	17 (14.9%)	52 (45.6%)
University Health Network	223	34 (15.2%)	90 (40.4%)
University of Ottawa Heart Institute	195	28 (14.4%)	81 (41.5%)
Ontario	1,570	245 (15.6%)	694 (44.2%)
p-value		0.046	0.001

Readmission rates are presented as (n, %).

Table B5. TAVI Length of Stay, November 2013 – March 2016

	TOTAL	HHS	HSN	KGH	LHSC	SRHC	SMH	SHSC	THSC	UHN	UOHI	p-Value
	N=1,570	N=192	N=51	N=53	N=188	N=93	N=185	N=276	N=114	N=223	N=195	
TAVI Admission to Discharge (Days)												
Mean ± SD	11.86 ± 25.24	7.56 ± 10.59	9.96 ± 9.57	12.85 ± 41.48	9.67 ± 9.36	7.91 ± 17.22	11.41 ± 33.08	10.59 ± 26.85	9.11 ± 10.00	13.72 ± 37.38	22.05 ± 21.64	<.001
Median (IQR)	6 (3-12)	4 (2-7)	7 (5-11)	4 (3-7)	6 (5-12)	4 (3-7)	4 (3-10)	4 (2-11)	6 (4-9)	7 (4-13)	14 (8-30)	<.001
TAVI Admission to Procedure (Days)												
Mean ± SD	2.89 ± 8.95	1.66 ± 3.70	3.12 ± 5.50	6.72 ± 34.78	2.13 ± 4.36	1.19 ± 2.21	2.59 ± 6.17	1.79 ± 5.15	1.63 ± 6.56	3.18 ± 7.90	6.77 ± 9.29	<.001
Median (IQR)	0 (0-1)	1 (0-1)	1 (1-2)	0 (0-0)	0 (0-2)	1 (0-1)	0 (0-1)	0 (0-0)	0 (0-0)	0 (0-1)	1 (1-11)	<.001
TAVI Procedure to Discharge (Days)												
Mean ± SD	8.98 ± 22.69	5.90 ± 9.42	6.84 ± 7.27	6.13 ± 13.37	7.54 ± 7.98	6.72 ± 17.08	8.82 ± 32.46	8.80 ± 24.71	7.47 ± 6.90	10.54 ± 36.52	15.27 ± 18.24	0.006
Median (IQR)	5 (3-8)	3 (2-5)	5 (4-8)	3 (3-4)	5 (4-7)	3 (2-6)	4 (3-7)	4 (2-7)	6 (4-9)	6 (3-10)	9 (7-16)	<.001