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Regional Systems of Care to Optimize Outcomes in Patients Undergoing Transcatheter Aortic Valve Replacement

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ABSTRACT

OBJECTIVES This study sought to describe the development of a multicenter, transcatheter aortic valve replacement program and regional systems of care intended to optimize coordinated, efficient, and appropriate delivery of this new therapy.

BACKGROUND Transcatheter aortic valve replacement (TAVR) has become an accepted treatment option for patients with severe aortic stenosis who are at high surgical risk. Regional systems of care have led to improvements in outcomes for patients undergoing intervention for myocardial infarction, cardiac arrest, and stroke. We implemented a regional system of care for patients undergoing TAVR in British Columbia, Canada.

METHODS We describe a prospective observational cohort of 583 patients who underwent TAVR in British Columbia between 2012 and 2014. Regionalization of TAVR care in British Columbia refers to a centrally coordinated, funded, and evaluated program led by a medical director and a multidisciplinary advisory group that oversees planning, access to care, and quality of outcomes at the 4 provincial sites. Risk-stratified case selection for transfemoral TAVR is performed by heart teams at each site on the basis of consensus provincial indications. Referrals for lower volume and more complicated TAVR, including nontransfemoral access and valve-in-valve procedures, are concentrated at a single site. In-hospital and 30-day outcomes are reported.

RESULTS The median age was 83 years (interquartile range [IQR]: 78 to 87 years) and median STS score was 6% (IQR: 4% to 8%). Transfemoral access was performed in 499 (85.6%) cases and nontransfemoral in 84 (14.4%). Transcatheter valve-in-valve procedures in for failed bioprosthetic valves were performed in 43 patients (7.4%). A balloon-expandable valve was inserted in 386 (66.2%) and a self-expanding valve in 189 (32.4%). All-cause 30-day mortality was 3.5%. All-cause in-hospital mortality and disabling stroke occurred in 3.1% and 1.9%, respectively. Median length of stay was 3 days (IQR: 3 to 6 days), with 92.8% of patients discharged directly home.

CONCLUSIONS This experience demonstrates the potential benefits of a regional system of care for TAVR. Excellent outcomes were demonstrated: most patients had short in-hospital stays and were discharged directly home. (J Am Coll Cardiol Intv 2015;8:1944–51) © 2015 by the American College of Cardiology Foundation.

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Transcatheter aortic valve replacement (TAVR) is a transformative therapy for patients with severe symptomatic aortic stenosis who are at high surgical risk (1,2). The procedure has evolved from a novel technology to a mainstream treatment modality over the past decade. TAVR requires significant expertise and a multidisciplinary heart team to optimize patient screening, comprehensive evaluation, and case selection to individualize procedural planning and risk-stratified patient pathways (1). There are varying degrees of complexity of TAVR patients regarding vascular access approaches, implantation anatomy, valve selection, and individual risk profile that may necessitate infrequently practiced and specialized skills such as nontransfemoral-based procedures. The best results may be achieved through the regional coordination of these complex patients (3). Regional systems of care have been shown to improve outcomes in other cardiovascular conditions such as myocardial infarction (4), stroke, and cardiac arrest (5). There is limited reported evidence on the role of a regional approach to patients requiring TAVR. Ensuring optimized patient outcomes with minimal complications and streamlined post-procedure care to reduce hospital length of stay in TAVR patients will become increasingly important as the procedure is performed more widely in lower-risk populations. This report aims to describe the short-term clinical outcomes, including hospital length of stay and discharge location, as key performance indicators as a part of a TAVR regional system of care.

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ABBREVIATIONS AND ACRONYMS

IQR = interquartile range

TAVR = transcatheter aortic valve replacement

TF = transfemoral

METHODS

IMPLEMENTATION OF A REGIONAL SYSTEM OF CARE. The British Columbia Transcatheter Heart Valve (THV) program was established in 2011 by Cardiac Services BC, an agency of the publicly funded British Columbia Provincial Health Services Authority responsible for the planning, coordinating, monitoring, evaluating, and funding of cardiac services across the province, in collaboration with senior administrators and physicians. The Provincial Advisory Panel on Cardiac Health, whose membership includes cardiologists, cardiac surgeons, referring physicians, an ethicist, and other clinical and administrative stakeholders, recommended the planning of a single provincial program at multiple sites. The intent was to leverage the pioneering work and the expertise gained at St. Paul's Hospital, Vancouver (6,7), to accelerate the implementation of new sites while maintaining excellent outcomes and improving patient access. The objectives of establishing a regional system of care were to guide and monitor indications in a rapidly changing innovation landscape, provide case selection and procedural and program development mentorship, optimize available health resources, and support excellent outcomes from the inception of the new sites. The template of multidisciplinary collaboration and multimodality assessment established at St. Paul's Hospital since the earliest procedures performed in 2005 was used to develop a site readiness plan and mentorship program at 3 additional cardiac centers, which began in July 2011, March 2012, and July 2012.

The British Columbia TAVR program is led by a medical director in collaboration with an advisory group that meets biannually and is comprised of cardiologists, surgeons, and administrative representatives from all centers and referring physicians from non-TAVR centers. The centers are committed to program self-regulation and quality improvement. To this end, the British Columbia TAVR program mandates the reporting of all procedures, including data related to eligibility assessment and 30-day and 12-month clinical, echocardiographic, and quality-of-life follow-up. Data is collected in the BC TAVR Registry. The Valve Academic Research Consortium (VARC-2) guidelines are used for endpoint adjudication. Registry data is further linked to British Columbia Vital Statistics to report mortality, and hospital readmissions are verified with linkage to the Canadian Institute of Health information Discharge Abstract Database. A quality report with provincial and site-specific structure, process, and outcome quality indicators is shared yearly with clinical and administration stakeholders and regional safety committees for quality assurance purposes. An annual provincial heart team evaluation meeting inclusive of implanting physicians, cardiac imaging, anesthesiology, critical care, referring cardiologists, nurse coordinators, and administrators is held to

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discuss peer review of quality, case-based learning and opportunities for quality improvement. Program funding is contingent on participation in the provincial program; the funding model is on the basis of the costs of patient care and the device and is reviewed at regular intervals. Budget allocation reflects the evolving referral patterns, wait list volume, and site capacity.

Multimodality assessment and eligibility decisions are conducted in each center by a multidisciplinary team. In addition to standard diagnostic and medical consultations required for TAVR, the regional program mandates the assessment of functional status, frailty, and quality of life to help determine patients' likelihood to derive significant benefit for at least 2 years and to measure patient-reported outcomes. The multidisciplinary team's recommendation is documented. For the first 6 months following the opening of the 3 new centers, the medical director provided input on case selection and was available to support the implanting team's learning curve. Similarly, a nurse leader supported the implementation of the readiness plan and the development of a clinical pathway.

A transfemoral (TF) approach is the default strategy for all patients; all centers perform TF TAVR and select their preferred device system. As a starting point, the British Columbia TAVR program mandated that patients not suited for TF access are referred to a central THV site with significant accumulated expertise with alternate access procedures (7). Other more low-volume and complex THV procedures, such as transcatheter valve-in-valve implantation for failed surgical bioprosthetic valve (8), or transcatheter mitral, pulmonary, or tricuspid procedures also result in referral to a single specialized site. Patient access is facilitated by nurse program coordinators; the role is funded by the British Columbia TAVR program with deliverables focused on standardized referral management and assessment, wait list management and triage coordination, follow-up, and data collection. Medical leaders at each site further facilitate provincial collaboration to promote equitable patient access.

The aim of the present report is to describe the short-term clinical and procedural characteristics and outcomes of patients treated with TAVR in BC, using a range of TAVR device types and access routes, as part of a comprehensive regional collaborative system implemented to optimize access to care and support excellent outcomes in rapidly evolving and innovative treatment options.

DEFINITIONS AND ENDPOINTS. The primary study endpoint was all-cause 30-day mortality. Secondary outcome measures were in-hospital major adverse cardiac events including all-cause mortality, cerebrovascular events, myocardial infarction, bleeding complications, vascular or access-related complications, and acute kidney injury. Hospital length of stay and discharge location were also recorded for patients discharged alive. Serious adverse events were site-reported and checked for accuracy. All events were coded according to the standardized endpoint definitions proposed by the VARC-2 guidelines (9).

STATISTICS. Descriptive summaries are reported for all TAVR cases, as well as separately by access site. No statistical comparisons were carried out between TF and non-TF groups, as the choice of access was determined by patient indications. Baseline characteristics, procedural details, and clinical outcomes are reported as counts and percentages for categorical variables and median and interquartile range (IQR) for continuous variables. Outcomes for TF cases were compared by valve types (balloon expandable [Sapien XT and Sapien 3, Edwards Lifesciences, Irvine, California] and self-expanding [CoreValve, Medtronic, Minneapolis, Minnesota]); the chi-square test was used to compare the proportion of new permanent pacemakers, and Wilcoxon rank sum test to compare the hospital length of stay. All analyses were carried out using SAS software version 9.4 (SAS Institute, Cary, North Carolina).

RESULTS

A total of 583 patients underwent consecutive TAVR in BC at 4 sites between 2012 and 2014 for native aortic valve stenosis (92.6%) and failed aortic bioprostheses (7.4%). Baseline characteristics are described in **Table 1**. The median age was 83 years (IQR: 78 to 87 years) and 41% of patients were female. Patients were highly symptomatic, with 82.3% in New York Heart Association functional class III or IV. Patients had severe aortic stenosis with a median aortic valve area of 0.7 cm^2 (IQR: 0.6 to 0.8 cm^2) and a transvalvular gradient of 41 mm Hg (IQR: 31 to 52 mm Hg). Only 7% of patients underwent aortic valvuloplasty before TAVR.

Procedural details are highlighted in **Table 2**. TF access was performed in 499 (85.6%) cases and non-TF in 84 (14.4%). Transcatheter valve-in-valve procedures in patients with failed bioprosthetic valves were performed in 43 (7.4%). A hybrid operating theater was utilized in 472 (81.0%) cases, with 102 (17.5%) cases performed under local anesthetic and/or conscious sedation. A balloon-expandable valve was

inserted in 386 (67.1%) and a self-expanding valve in 189 (32.9%). The Sapien XT was implanted in 58.4%, CoreValve in 28.3%, Sapien 3 in 8.7%, Portico (St. Jude Medical, St. Paul, Minnesota) in 3.0%, Jenavalve (Jenavalve, Irvine, California) in 1.4%, and Lotus valve (Boston Scientific, Marlborough, Massachusetts) in 0.2%. More than 1 transcatheter valve was required in 2.1% of patients. Eight (1.4%) patients did not receive any TAVR valve, and 7 (1.2%) had conversion to open surgical valve replacement during the index procedure.

The 30-day all-cause mortality was 3.5%. In-hospital patient outcomes are presented in Table 3. All-cause in-hospital mortality occurred in 3.1%. Disabling stroke occurred in 1.9% and myocardial infarction in 0.9%. Major vascular complications were reported in 2.2% of patients, with 8.1% experiencing a major bleeding complication. Analysis of patients according to access site revealed lower mortality in TF cases (2.6%) compared with non-TF cases (6.0%). Similarly disabling stroke (1.6% vs. 3.6%) and major bleeding (6.8% vs. 15.5%) were lower in TF implants.

Moderate paravalvular regurgitation was seen in 4.9% of patients and severe paravalvular regurgitation in 0.2% at the time of 30-day echocardiography. Permanent pacemaker implantation was required in 9.1% of patients. Median length of stay for all patients was 3 days (IQR: 3 to 6 days), with 92.8% of patients discharged directly home (Tables 4 and 5).

Clinical outcomes were excellent for patients treated with the Sapien and CoreValve platforms. Fewer new pacemakers were required (6.2% vs. 18.2%; $p < 0.001$) and length of stay was shorter (median 3 days [IQR: 2 to 4 days] vs. 5 days [IQR: 3 to 7.6 days]; $p < 0.001$) following balloon-expandable compared with CoreValve TF procedures.

DISCUSSION

The centrally coordinated program infrastructure and health service planning, mentorship and local leadership, and evaluation framework are unique features of a regional approach. This study is the first multicenter evaluation of the effect of a regional system of care on patients undergoing TAVR, encompassing eligibility assessment, TAVR risk stratification, and utilization of all available TAVR devices. The main findings include excellent short-term outcomes combined with very short hospital stays and over 90% of patients discharged directly home.

Differences in patient characteristics and rapidly changing TAVR technologies make comparing outcomes between TAVR registries difficult (Figure 1). The overall 30-day mortality of 3.5% in high-risk British Columbia patients undergoing TAVR as part of a regional system of care, however, compares favorably with recent international registry outcomes (Tables 4 and 5). The U.S. Transcatheter Valve Therapy National Registry of patients undergoing TAVR

TABLE 1 Baseline Characteristics

	All (n = 583)	Transfemoral (n = 499)	Nontransfemoral (n = 84)
Age, yrs	83 (78-87)	84 (79-88)	81 (74-84)
Female	237 (40.7)	188 (37.7)	49 (59.0)
STS PROM, %	6 (4-8)	6 (4-8)	7 (4-10)
Valve area, cm^2	0.7 (0.6-0.8)	0.7 (0.6-0.8)	0.7 (0.6-0.8)
Mean gradient, mm Hg	41 (31-52)	41 (31-52)	38 (31-52)
Pacemaker	73 (16.3)	60 (16.0)	13 (17.8)
Prior angioplasty	156 (26.8)	132 (26.5)	24 (28.6)
Prior coronary bypass	138 (23.7)	114 (22.8)	24 (28.6)
Prior AVR	43 (7.4)	34 (6.8)	9 (10.7)
Bridging valvuloplasty	43 (7.4)	32 (6.4)	11 (13.1)
Severe COPD	72 (12.3)	61 (12.2)	11 (13.1)
Dialysis	21 (3.6)	18 (3.6)	3 (3.6)
Severe CKD	62 (10.7)	51 (10.3)	11 (13.1)
Porcelain aorta	47 (8.1)	28 (5.6)	19 (22.6)
NYHA functional class III/IV	480 (82.3)	404 (81.0)	76 (90.5)
LVEF ≤30%	26 (4.5)	24 (4.9)	2 (2.4)

Values are median (interquartile range) or n (%).

AVR = aortic valve replacement; CKD = chronic kidney disease; COPD = chronic obstruction pulmonary disease; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; STS PROM = Society of Thoracic Surgeons predicted risk of mortality.

TABLE 2 Procedural Details

	All (n = 583)	Transfemoral (n = 499)	Nontransfemoral (n = 84)
Time from treatment decision to procedure, days	37 (16-70)	35 (16-65)	57 (29-99)
Procedure location			
Catheterization laboratory	111 (19.0)	111 (22.2)	0
Hybrid operating room	472 (81.0)	388 (77.8)	84 (100)
Awake/conscious sedation	102 (17.5)	102 (20.4)	0
Access site			
Direct aortic	6 (1.0)	NA	6 (7.1)
Transapical	78 (13.4)	NA	78 (92.9)
Transfemoral	499 (85.6)	499 (100)	NA
Conversion to open heart surgery	7 (1.2)	3 (0.6)	4 (4.8)
Procedure aborted	8 (1.4)	6 (1.2)	2 (2.4)
Valve implanted	575 (98.6)	493 (98.8)	82 (97.6)
CoreValve	163 (28.3)	161 (32.7)	2 (2.4)
Jenavalve	8 (1.4)	0	8 (9.8)
Lotus	1 (0.2)	1 (0.2)	0
Portico	17 (3.0)	8 (1.6)	9 (11.0)
Sapien 3	50 (8.7)	43 (8.7)	7 (8.5)
Sapien XT	336 (58.4)	280 (56.8)	56 (68.3)
Contrast volume, ml	135 (95-171)	140 (101-175)	94 (55-126)
Fluoroscopy time, min	14 (9-20)	15 (10-21)	6 (5-10)

Values are median (interquartile range) or n (%).

TABLE 3 Clinical Outcomes: In-Hospital

	All (n = 583)	Transfemoral (n = 499)	Nontransfemoral (n = 84)
All-cause mortality	18 (3.1)	13 (2.6)	5 (6.0)
Death and/or disabling stroke	27 (4.6)	19 (3.8)	8 (9.5)
Any stroke	17 (2.9)	13 (2.6)	4 (4.8)
Disabling stroke	11 (1.9)	8 (1.6)	3 (3.6)
Myocardial infarction	5 (0.9)	5 (1.0)	0
New atrial fibrillation	10 (1.7)	3 (0.6)	7 (8.3)
Acute kidney injury			
No	566 (97.1)	486 (97.4)	80 (95.2)
Stage 1	9 (1.5)	6 (1.2)	3 (3.6)
Stage 2	3 (0.5)	3 (0.6)	0
Stage 3	1 (0.2)	1 (0.2)	0
New dialysis	4 (0.7)	3 (0.6)	1 (1.2)
Blood transfusion needed	74 (12.7)	56 (11.3)	18 (21.4)
Blood transfusion, U	2 (1–3)	2 (1–3)	2 (1–4)
Major vascular complication	13 (2.2)	11 (2.2)	2 (2.4)
Minor vascular complication	15 (2.6)	15 (3.0)	0
Life threatening/major bleed	47 (8.1)	34 (6.8)	13 (15.5)
Cardiac arrest	11 (1.9)	6 (1.2)	5 (6.0)
Multiple valves required	12 (2.1)	11 (2.2)	1 (1.2)
New permanent pacemaker	53 (9.1)	51 (10.2)	2 (2.4)
Aortic regurgitation*			
None	289 (55.1)	243 (53.9)	46 (62.2)
Mild	211 (40.2)	183 (40.6)	28 (37.8)
Moderate	25 (4.8)	25 (5.5)	0 (0)
Severe	0 (0)	0 (0)	0 (0)
Discharged home*	538 (92.8)	469 (94.2)	69 (84.1)
Hospital stay, days*	3 (3–6)	3 (3–5)	7 (5–11)

Values are n (%) or median (interquartile range). *For cases discharged alive.

with the Edwards Sapien device between 2011 and 2013 indicated a mortality rate of 7.6% (10). The FRANCE 2 Registry, which like the British Columbia registry included implantation of balloon-expandable and self-expanding valves, reported outcomes of 3,195 patients treated in 34 French centers between 2010 and 2011. The 30-day mortality rate was 9.7% (11). The SOURCE XT (Sapien Aortic Bioprosthesis European Outcome) Registry, an industry-sponsored post-approval European study, reported a 30-day mortality of 6.3% (12). The Swiss TAVI (Transcatheter Aortic Valve Implantation) registry of 697 patients undergoing TAVR between 2011 and 2013 indicated a 30-day mortality of 4.8% (13). The GARY (German Aortic Valve Registry) reported results in 3,866 patients undergoing TAVR in 2011 (14). Two-thirds underwent the procedure by a TF approach, with an in-hospital mortality of 5.1% and a very low rate of vascular complications, suggesting appropriate case selection and highlighting the potential advantages of a fully percutaneous technique for TF TAVR. The remaining one-third of procedures were performed by a transapical approach, with a mortality of 7.7%.

Our study also indicated higher mortality associated with the non-TF approach compared with the TF approach, which is consistent with a higher-risk cohort with higher rates of peripheral and coronary arterial disease. Other international reports have also highlighted increased mortality in patients utilizing the non-TF approach. The FRANCE 2 registry (TF 8.5% vs. transapical 13.9%; $p < 0.001$) (11), the U.K. TAVI registry (TF 5.5% vs. other routes 10.7%; $p = 0.006$) (15), and the recently reported multicenter trial of the Edwards Sapien 3 valve (TF 2.1% vs. non-TF 11.1%) (16). The British Columbia registry 30-day mortality of 6.3% in non-TF access is lower than other international reports of non-TF-access TAVR (**Table 5**). As part of the regional system of TAVR in British Columbia, all patients requiring non-TF access are referred to 1 large-volume center with significant expertise in dealing with this high-risk cohort of TAVR patients (7). Although it is difficult to compare results across studies, the increasing use of lower-profile TAVR devices will continue to drive a decrease in the rate of non-TF access. This trend will further bolster the potential benefits of a regional system of care to TAVR by concentrating higher-risk and lower-volume TAVR procedures at select centers. Alternatively, the demonstrated improvement in

TABLE 4 British Columbia Transfemoral TAVR Outcomes Compared With Other Registries

	BC THV Registry	TVT High Risk (10)	TVT Inoperable (10)	FRANCE2 (11)	GARY (14)	UK TAVI (15)	Swiss TAVI (13)
N	499	1,687	1,139	2,361	2,695	599	559
Hospital stay, days	3 (3–5)	5 (4–9)	5 (4–9)	10.5 ± 8.0	NA	8 (6–13)*	10.7 ± 6.0
Discharge home	94%	67%	70%	NA	NA	NA	29%
30-day mortality	3.0%	4.6%	6.7%	8.5%	5.1%†	5.5%	3.6%
30-day disabling stroke	1.4%‡	3.2%	1.6%	3.7%	1.7%†	4.0%	2.2%

Values are N, median (range), mean ± SD, or %. *Length of stay not stratified according to access. †In-hospital mortality and stroke. ‡In-hospital stroke.
BC = British Columbia; GARY = German Aortic Valve Registry; TAVI = transcatheter aortic valve implantation; THV = transcatheter heart valve.

TABLE 5 BC Nontransfemoral TAVR Outcomes Compared With Other Registries

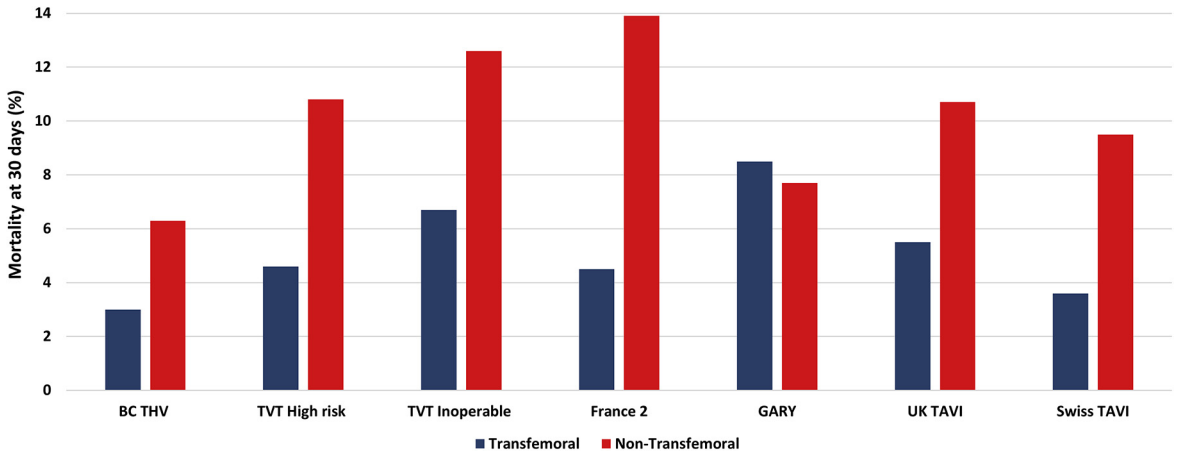
	BC THV Registry	TVT High Risk (10)	TVT Inoperable (10)	FRANCE 2 (11)	GARY (13)	UK TAVI (15)	Swiss TAVI (13)
N	84	1,147	1,139	567	1,181	599	138
Hospital stay, days	7 (5–11)	8 (6–12)	8 (6–11)	13.3 ± 8.0	NA	8 (6–13)*	10.7 ± 6.0
Discharge home	84%	55%	57%	NA	NA	NA	29%
30-day mortality	6.3%	10.8%	12.6%	13.9%	7.7%†	10.7%	9.5%
30-day disabling stroke	3.6%‡	2.2%	5.9%	2.1%	2.3%†	4.1%	3.7%

Values are N, median (range), mean ± SD, or %. *Length of stay not stratified according to access. †In-hospital mortality and stroke. ‡In-hospital stroke.
Abbreviations as in Table 4.

outcomes over time and increasing standardization of previously unproven therapies argues for continual reassessment of which therapies require centralized expertise, and which do not.

Aortic stenosis is the most common severe valvular heart disease in developed countries, and its effect on public health and health care resources is expected to increase due to aging Western populations (17). There is a growing focus on regionalized medical care as a strategy to promote equitable patient access, coordinate triage management, and optimize outcomes, while managing cost and limited resources (18). Regional systems of care have been recommended to maximize patient access to expert-level care in common cardiovascular conditions such as acute myocardial infarction (19) and cardiac arrest (20). The relationship between hospital volume and outcomes is complex and multifactorial but may also be associated with improved outcomes in TAVR (21). Although systems of care for cardiac arrest, acute myocardial infarction, and trauma are designed to foster timely access to time-sensitive conditions, much may be gained from a similar approach to coordination of care for TAVR. A regional system of care for TAVR patients can provide ongoing standardized and coordinated education for patients, providers, and the community; facilitate dissemination of new technology and procedures; and maximize the expertise of specialized services like cardiac imaging and nursing. A TAVR system of care may serve as a foundation for cost-effective care through self-regulation and cardiovascular accountable care organizations. As evidence emerges that indications for TAVR may expand and as new transcatheter therapies become available, a regional system of care can facilitate the development of consensus recommendations to support health service planning. Regional systems of care for TAVR should be designed to standardize and streamline the referral process, patient assessment and pre-procedural planning,

FIGURE 1 30-Day Mortality in International High-Risk Transcatheter Aortic Valve Replacement Registries



BC = British Columbia; GARY = German Aortic Valve Registry; TAVI = transcatheter aortic valve implantation; THV = transcatheter heart valve.

consensus treatment decisions, appropriate access route and device selection, and post-procedural care. Our reported short hospital stays with over 90% of patients being discharged home is indicative of the health service benefits of a regional approach to TAVR care. Although these metrics are infrequently reported in international registries, these measures will become increasingly important in real word practice as TAVR expands into lower-risk populations, where quality of life, program efficiencies, and costs will be important determinants of expanding programs.

STUDY LIMITATIONS. Data completeness in this province-wide registry was good. The data, including patients, procedural characteristics, and in-hospital outcomes, are reported by each site. Core laboratory analysis was not performed. Although internal consistency and range checks were conducted, and sites were contacted to clarify missing and unexpected values, the data were not subject to independent external validation. Patient wait times are an important performance indicator to the effectiveness of systems of care delivery. The British Columbia registry reports on waiting list times, but does not include time from referral to initial cardiac consultation, which, although not considered part of the "surgical waiting list period," can be considered part of the delay from recognition of symptomatic aortic stenosis until procedure. Additionally, given the significant change in TAVR devices and procedures over time, we felt that it was less relevant to perform a before and after analysis of the 1 original site expanding to 4 sites as part of the British Columbia regional system of care.

The development of a regional system of TAVR care in BC is also fundamentally linked to the universal health care system throughout Canada. Whether similar "spoke and hub" systems can be implemented in other countries, with different health systems, remains to be seen. Furthermore, although the British Columbia TAVR data highlights favorable short-term outcomes, important differences in patient baseline characteristics and the increasing use of later-generation devices throughout British Columbia makes comparison of our results to other registries difficult and was not the aim of this report. In this initial report of the British Columbia TAVR registry, we have also avoided risk-adjusted outcomes due to sample size, which will clearly become an important component of future data analyses.

CONCLUSIONS

The excellent short-term clinical outcomes, in conjunction with most patients having short in-hospital stays and being discharged directly home, demonstrates the potential benefits of a regional system of care for TAVR.

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PERSPECTIVES

WHAT IS KNOWN? TAVR is increasingly performed for elderly patients with symptomatic aortic stenosis. Implementation of regional systems of care has provided improved outcomes for a number of complex cardiac conditions. Whether such systems will also improve TAVR outcomes is less clear.

WHAT IS NEW? A regional system of TAVR care was developed and implemented in British Columbia, Canada, at 4 sites in the province. Non-TF access and more complicated TAVR procedures were referred to a single site. All-cause 30-day mortality was 3.5%, with a short median in-hospital stay of 3 days.

WHAT IS NEXT? Development of coordinated regional systems of care for TAVR patients may further improve outcomes.

REFERENCES

1. Webb J, Rodes-Cabau J, Fremes S, et al. Transcatheter aortic valve implantation: a Canadian Cardiovascular Society position statement. Canadian J Cardiol 2012;28:520–8.

2. Kodali SK, Williams MR, Smith CR, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med 2012;366:1686–95.

3. Hawkey MC, Lauck SB, Perpetua EM, et al. Transcatheter aortic valve replacement program development: recommendations for best practice. Catheter Cardiovasc Interv 2014;84:859–67.

4. Jacobs AK. Regional systems of care for patients with ST-elevation myocardial infarction: being at the right place at the right time. Circulation 2007;116:689–92.

5. Nichol G, Soar J. Regional cardiac resuscitation systems of care. Curr Opin Crit Care 2010;16:223–30.

6. Webb JG, Chandavimol M, Thompson CR, et al. Percutaneous aortic valve implantation retrograde from the femoral artery. Circulation 2006;113:842–50.

7. Lichtenstein SV, Cheung A, Ye J, et al. Transapical transcatheter aortic valve implantation in humans: initial clinical experience. Circulation 2006;114:591–6.

8. Gurvitch R, Cheung A, Ye J, et al. Transcatheter Valve-in-Valve Implantation for Failed Surgical Bioprosthetic Valves. J Am Coll Cardiol 2011;58:2196–209.

9. Kappetein AP, Head SJ, Genereux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. J Am Coll Cardiol 2012;60:1438–54.

10. Mack MJ, Brennan JM, Brindis R, et al. Outcomes following transcatheter aortic valve replacement in the United States. JAMA 2013;310:2069–77.

11. Gilard M, Eltchaninoff H, Iung B, et al. Registry of transcatheter aortic-valve implantation in high-risk patients. N Engl J Med 2012;366:1705–15.

12. Schymik G, Lefèvre T, Bartorelli AL, et al. European experience with the second-generation Edwards SAPIEN XT transcatheter heart valve in patients with severe aortic stenosis: 1-year outcomes from the SOURCE XT Registry. J Am Coll Cardiol Intv 2015;8:657–69.

13. Wenaweser P, Stortecky S, Heg D, et al. Short-term clinical outcomes among patients undergoing transcatheter aortic valve implantation in Switzerland: the Swiss TAVI registry. EuroIntervention 2014;10:982–9.

14. Hamm CW, Mollmann H, Holzhey D, et al. The German Aortic Valve Registry (GARY): in-hospital outcome. Eur Heart J 2014;35:1588–98.

15. Moat NE, Ludman P, de Belder MA, et al. Long-term outcomes after transcatheter aortic valve implantation in high-risk patients with severe aortic stenosis: the U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry. J Am Coll Cardiol 2011;58:2130–8.

16. Webb J, Gerosa G, Lefevre T, et al. Multicenter evaluation of a next-generation balloon-expandable transcatheter aortic valve. J Am Coll Cardiol 2014;64:2235–43.

17. Osnabrugge RL, Mylotte D, Head SJ, et al. Aortic stenosis in the elderly: disease prevalence and number of candidates for transcatheter aortic valve replacement: a meta-analysis and modeling study. J Am Coll Cardiol 2013;62:1002–12.

18. Graham KJ, Strauss CE, Boland LL, et al. Has the time come for a national cardiovascular emergency care system? Circulation 2012;125:2035–44.

19. Henry TD, Sharkey SW, Burke MN, et al. A regional system to provide timely access to percutaneous coronary intervention for ST-elevation myocardial infarction. Circulation 2007;116:721–8.

20. Nichol G, Aufderheide TP, Eigel B, et al. Regional systems of care for out-of-hospital cardiac arrest: a policy statement from the American Heart Association. Circulation 2010;121:709–29.

21. Badheka AO, Patel NJ, Panaich SS, et al. Effect of hospital volume on outcomes of transcatheter aortic valve implantation. Am J Cardiol 2015;116:587–94.

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