

**AN EXPLORATORY ANALYSIS OF FACTORS ASSOCIATED WITH LENGTH
OF STAY FOLLOWING TRANSCATHETER AORTIC VALVE
IMPLANTATION**

by

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Abstract

Background: Transcatheter aortic valve implantation (TAVI) is a minimally invasive treatment option for higher surgical risk patients with severe symptomatic aortic stenosis (AS) and significant co-existing conditions which may preclude them from surgical valve replacement. Patient characteristics and wait time have been shown to impact length of stay (LOS) in individuals with heart disease; however, these variables have not been extensively evaluated in the TAVI population.

Objective: The purpose of this study was to explore factors associated with post-TAVI recovery, as measured by hospital LOS.

Method: A retrospective chart review of consecutive patients who underwent TAVI in Vancouver, British Columbia between January 01, 2013 to December 31, 2014 was conducted. Study variables included patient characteristics and wait time. The outcome variable, LOS, was defined as time, in days, from procedure to hospital discharge. Univariate and bivariate analyses were used to select moderately correlated variables for multivariate regression analysis.

Results: The study sample consisted of 257 patients, with a mean age of 81.4 years. The median wait time from acceptance to procedure was 36 days, while the median LOS was 3.0 days. Bivariate analysis showed age, living situation, symptom severity, prior surgical aortic valve replacement (SAVR), and prior balloon aortic valvuloplasty (BAV) to be statistically significantly associated with post-TAVI stay in-hospital. The multivariate model revealed that relative to having a LOS of 1 to 2 days, patients who had previously undergone a BAV were 10.7 times more likely to stay 5 days or more (CI [1.16, 98.1]) compared with patients who had not undergone a BAV. No other baseline factors were found to be statistically predictive of prolonged LOS, although odds ratios suggest patients with lower symptom severity and patients

who underwent valve-in-valve TAVI were less likely to experience a longer LOS. The model also showed that patients 75 to 79 years of age, with NYHA class III or IV symptoms, and no prior history of an AVR were more likely to follow a standard course of recovery, staying 3 to 4 days, while patients who had a valve-in-valve procedure were more likely to stay 1 to 2 days.

Preface

Ethics approval was granted by the University of British Columbia Providence Health Care Research Ethics Boards (REB) with certificate number UBC-PHC H14-02516.

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List of Abbreviations

AS	aortic stenosis
ADL	activities of daily living
BAV	balloon aortic valvuloplasty
CABG	coronary artery bypass grafting
CCS	Canadian Cardiovascular Society
COPD	chronic obstructive pulmonary disease
Cr	creatinine
CSHA	Canadian Study of Health and Aging
EuroSCORE	European System for Cardiac Operative Risk Evaluation
FS	functional status
HRQOL	health related quality of life
ID	identifier
LOS	length of stay
LVAD	left ventricular assist device
LVEF	left ventricular ejection fraction
MVR	mitral valve repair
NYHA	New York Heart Association
PARTNER	Placement of Aortic Transcatheter Valves
PCI	percutaneous coronary intervention
PHCREB	Providence Health Care Research Ethics Board
QOL	quality of life
SAVR	surgical aortic valve replacement
SPH	St. Paul's Hospital
SPSS	Statistical Package for the Social Sciences
STS-PROMM	Society of Thoracic Surgeons Predicted Risk of Morbidity and Mortality
TA	transapical
TAVI	transcatheter aortic valve implantation
TF	transfemoral

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Dedication

To my husband David, for supporting me always.

Chapter 1: Introduction

Aortic stenosis (AS) is a heart valve abnormality, predominantly affecting older adults. Without treatment, the prognosis is poor with most individuals dying within three years of symptom onset (Carabello & Paulus, 2009; Otto, 2006). Although surgical aortic valve replacement (SAVR) remains the gold standard for the treatment of severe AS in most patients, transcatheter aortic valve implantation (TAVI) is an emerging intervention that offers a minimally invasive alternative for patients who are at high or excessive risk for surgery due to advanced age or multiple morbidities, and are likely to derive benefit (Leon et al., 2010). Early clinical experience demonstrates that TAVI is safe, feasible and can be performed with positive short and longer-term results (Mack et al., 2013; Toggweiler et al., 2012).

Patient selection is critical to TAVI success; however, clinicians lack some of the tools and evidence required for optimal decision-making. At present, risk indices do not accurately predict risk (the probability of suffering an adverse outcome as a result of undergoing surgery) in frail elderly individuals (Chikwe & Adams, 2010; Mack 2011; Walther & Kempfert, 2011). Moreover, there is limited data identifying factors associated with improved post-procedure outcomes. Although patient characteristics (e.g., age, comorbidities, functional status, etc.) and length of wait time have emerged in the literature as predictors of both surgical risk and postoperative recovery in older adults with heart disease (Afilalo et al., 2010; Atoui et al., 2008; Cowper et al., 2006; Lee, Buth, Martin, Yip, & Hirsch, 2010; Robinson et al., 2009; Sampalis, Boukas, Liberman, Reid, & Dupuis, 2001), there is a paucity of research evaluating the impact of patient characteristics and wait time on TAVI outcomes. The **purpose** of this study was to explore factors associated with post-TAVI recovery, as described by hospital length of stay

(LOS). LOS is an important measure as it relates to clinical outcomes in older adults and hospital resource consumption (Canadian Institute for Health Information [CIHI], 2008).

1.1 Aortic Stenosis

Aortic stenosis (AS) can present at any age but predominantly develops in the elderly, those aged 75 years and older. It is considered the most common valvular disease in older adults, affecting 2.8% of individuals over 75 years (Nkomo et al., 2006). With the number of elderly projected to double over the next two decades (Statistics Canada, 2010), the prevalence of AS is anticipated to rise substantially.

Individuals with severe AS experience devastating cardiac impairments associated with progressive symptoms, reduced functional status (FS), and decreased quality of life (QOL) (Carabello & Paulus, 2009). The condition typically manifests as a result of age-related calcification of the valve leaflets leading to limited valve opening and ultimately, reduced cardiac output. At the onset of classical symptoms – angina, dyspnea, syncope, and heart failure – clinical deterioration occurs rapidly (Ross & Braunwald, 1968). Without treatment, the disease is fatal with 75% of patients dying within 3 years (Otto, 2006). There is no medical therapy that can improve long-term prognosis as the blockage of valvular blood flow requires mechanical repair. Although surgical aortic valve replacement (SAVR) significantly improves symptoms and survival rates (Sharma et al., 2004), many elderly patients are unable to benefit from the invasive procedure. A prospective study on valvular heart disease found that one-third of individuals with severe AS are refused SAVR, in large part due to risks related to advanced age and multiple morbidities (Lung et al., 2003).

1.2 Transcatheter Aortic Valve Implantation

Transcatheter aortic valve implantation (TAVI) is a relatively new minimally invasive catheter-based treatment that is rapidly emerging as a safe and viable alternative to SAVR. In the procedure, a stent-mounted bioprosthetic valve is threaded through a catheter and implanted within the native diseased valve via a small incision made in the groin (transfemoral approach) or chest (transapical, direct aortic or subclavian approach). Without the need for sternotomy or cardiopulmonary bypass, the minimally invasive technique reduces the risk of intraprocedural mortality and postoperative complications in higher risk patients (Leon et al., 2010; Smith et al., 2011; Adams et al., 2014).

While early clinical experience has been promising, use of TAVI is in its early phase. The Canadian Cardiovascular Society (CCS) recently developed a consensus position statement providing evidence-based recommendations on appropriate TAVI use (Webb et al., 2012). The document advises that TAVI should be reserved for individuals with severe AS considered to be inoperable or at prohibitive risk for surgery, and likely to benefit from the procedure with respect to duration or QOL.

1.3 TAVI Patient Characteristics

Given the aforementioned criteria for candidacy, TAVI has been largely performed on elderly patients, with recent studies reporting a mean age of 81-83 years (Toggweiler et al., 2013). In this cardiac population of octogenarians, there is a high prevalence of multiple co-existing conditions including, but not limited to, chronic obstructive pulmonary disease (COPD), atrial fibrillation and renal dysfunction (Stortecky et al., 2012; Toggweiler et al., 2013). These comorbidities are highly correlated with decreased functional capacity and diminished QOL (Rich, 2005). In addition to the burden of advanced age and chronic disease, many individuals

who undergo TAVI are also frail (Rodes-Cabau & Mok, 2012). Frailty, an inconsistently defined concept in current literature, is a syndrome characterized by diminished physiologic reserves, with associated loss of functional abilities and increased vulnerability to stressors (Makary et al., 2010). The combination of old age, frailty and concomitant disease, place TAVI candidates at relatively high risk of post-procedural complications, general de-conditioning, and disability (Schoenenberger, 2012).

1.4 TAVI Wait Time

The complexities inherent to both the patient population and procedure (Gurvitch et al., 2011) have experts recommending that TAVI remain restricted to specialized tertiary care centres equipped with the modalities and multidisciplinary team members needed to evaluate patient eligibility and provide peri-procedural care (Webb et al., 2012). With growing demand, this limited capacity can lead to prolonged wait times which can further be exacerbated by availability and scheduling of pre-procedure imaging, the need for specialty consultations, and travel limitations related to repeated appointments (Lauck, Stub, & Webb, 2014). Of concern, individuals with severe AS can deteriorate quickly while waiting for treatment (Bainey et al., 2013).

For any emerging intervention, benchmarks – the maximum allowable time that clinical evidence suggests an individual should wait for care – are needed to promote patient safety and program planning (Canadian Wait Time Alliance, 2014). Unfortunately, no such standards exist in the context of TAVI. Researchers assert that the development of benchmarks will rely on a critical evaluation of the impact of treatment delays on patient recovery following the procedure (Lauck et al., 2014).

1.5 Length of Stay

One of the most common measures used to capture post-procedural recovery is length of stay (LOS) in hospital. Length of stay is an important marker not only for its impact on health care economics (Philbin, McCollough, William, & Disalvo, 2001) but also its association with clinical outcomes (Creditor, 1993). Research demonstrates that extended hospitalization is significantly correlated with higher risk of developing post-operative complications, particularly in geriatric patient populations (Mahesh et al., 2012). Although the average LOS after TAVI varies between countries and institutions, data shows that time spent in-hospital after the procedure follows a positively skewed distribution, indicating that a small number of TAVI patients experience prolonged hospital stays (Nuis, 2009; Kuwaki et al., 2012). Few researchers have investigated predictors of this phenomenon and to date, there are no published studies examining the association between LOS, patient characteristics and wait time.

1.6 Problem Statement

Although TAVI has emerged as a promising alternative to SAVR, more evidence is needed to improve current standards of care, which do not accurately account for the complex clinical profile of the frail, elderly patient population currently referred for the procedure. Given that patient characteristics and wait time are highly correlated with recovery following cardiac surgery, and hospitalization is known to have detrimental effects on the elderly, it is important to investigate how patient factors and wait time relate to LOS following TAVI.

1.7 Research Questions

Primary research question:

1. Is there a relationship between baseline factors (i.e., patient characteristics and wait time) and LOS following TAVI?

Secondary research questions:

2. What is the length of wait time from TAVI referral to acceptance (wait time 1), and from acceptance to procedure (wait time 2)?
3. Is there a relationship between patient characteristics and wait time for TAVI?

1.8 Significance of Proposed Study

Pre-TAVI decision-making focuses heavily on disease severity and procedural feasibility but does not fully, nor accurately, consider the impact of patient characteristics (e.g., comorbidities and functional status) and wait time on post-procedural success. This is in part due to the fact that little is known about the relationship between these factors and post-procedure outcomes, such as LOS, in individuals undergoing TAVI.

Length of stay is an important measure for its impact on both patient outcomes and health care costs. Prolonged LOS is known to have serious consequences on the elderly due to high risk of hospital-acquired complications, functional decline, and disability (Mahesh et al., 2012; Makary et al., 2010). Recognizing current economic and resource strains, there are also serious system demands to reduce LOS, particularly following interventional procedures where recovery trajectory is expected to follow a relatively predictable course (Pennone et al., 2011). By determining the extent to which patient characteristics and wait time are associated with post-TAVI LOS, the provision of quality risk stratification, patient selection and peri-procedural care may be guided. Although the scope of this research was restricted to TAVI, its findings may provide insight into the care practices of other cardiology procedures performed percutaneously on complex, elderly individuals.

1.9 Nursing Implications

This study has important implications for nurses involved in the care of TAVI patients. Information about the association between patient characteristics, wait time and TAVI recovery may potentially inform a number of nurse-led TAVI care practices including: evidence-informed selection of variables used to assess TAVI candidates, implementation of care strategies to optimize well-being during the wait period, and the development of patient education material focused on self-management. From a post-procedural perspective, findings from this study might also assist nurses to better understand the recovery and rehabilitation trajectory of patients following the procedure.

Chapter 2: Literature Review

This review of the published literature provides context to the proposed study by exploring patient characteristics, wait time, and length of stay (LOS) as they relate to transcatheter aortic valve implantation (TAVI). To begin, an introduction to TAVI is provided, including background on the procedure, clinical outcomes to date, and the process of patient selection. Following this, patient characteristics and wait time, and their association with one another, as well as cardiac surgical outcomes, are described. Length of stay, and its impact on the elderly, is then explored. Finally, the chapter ends with a summary of the reviewed literature, identifying gaps in knowledge that will be addressed by this study.

A number of sources were drawn upon for this literature review. The search included use of five electronic databases: Cumulative Index of Allied Health and Nursing Literature (CINAHL), MEDLINE, PsychInfo, EMBASE, and Google Scholar, with special attention to leading clinical journals in cardiology (i.e., European Heart Journal, Journal of the American College of Cardiology, and the Journal of Invasive Cardiology). Keywords included: transcatheter aortic valve implantation, cardiac surgery, elderly, patient characteristics, baseline characteristics, wait(ing) time, wait(ing) lists, length of stay, and prolonged hospitalization. These words were used in all possible combinations with mappings to subject headings (i.e., MeSH terms) wherever possible. Broad screening items for the selection of these articles included publication type, publication date and language of article written (Table 1).

Table 1

Selection Criteria for Literature Review

Characteristic	Criteria
Publication type	Peer-reviewed, full-text publications that report clinical outcomes and systematic reviews. Editorials, laboratory or animal studies excluded.
Publication date	2000-2015
Language	English
Intervention	Transcatheter aortic valve implantation (TAVI), cardiac surgery
Patient characteristics	Patients with severe AS, elderly (> 65 years)
Clinical outcome	Length of Stay

2.1 Transcatheter Aortic Valve Implantation

The following section provides the background needed to set the stage for the investigation of patient characteristics and wait time, as they relate to post-TAVI LOS.

2.1.1 History. Transcatheter aortic valve implantation has opened a new avenue for the treatment of high-risk patients with severe aortic stenosis (AS). Per the American College of Cardiology/American Heart Association Task Force (Nishimura et al., 2014), severe AS is defined as a mean aortic-valve area $<1.0 \text{ cm}^2$ and a mean aortic-valve gradient $>40 \text{ mm Hg}$ or a peak aortic-jet velocity 4.0 m/s . Patients considered eligible for TAVI undergo an intensive work-up that includes Doppler echocardiography, coronary angiography, and computed tomography. TAVI is an emerging and innovative technique that has gained substantial ground in the cardiovascular field over the past 15 years.

The history of TAVI began in 1989 when Dr. Henning-Rud Andersen implanted a balloon-expandable catheter-mounted valve in the aorta of pigs (Andersen, Knudsen, & Hasenkam, 1992). While other experimental concepts were tested thereafter (Moazami et al., 1996; Pavcnik, Wright, & Wallace, 1992), it was not until 2000 when Dr. Phillip Bonhoeffer implanted the first human valve in a right ventricle to pulmonary artery prosthetic conduit

(Bonhoeffer et al., 2000). On April 16th 2002, Dr. Alan Cribier performed the first-in-human TAVI on a 57-year-old patient with severe AS and cardiogenic shock (Cribier et al., 2002). The seminal case was successful, thus establishing procedural feasibility.

While transvenous access was initially utilized, the technical complexity and associated risks of an antegrade approach appeared to inhibit widespread uptake (Sakata, Syed, Salinger, & Feldman, 2005). In 2006, Webb and colleagues reported the first successful and reproducible retrograde transarterial implantation, simplifying the procedure, while enhancing delivery.

2.1.2 The Procedure. TAVI devices can be implanted percutaneously through an incision made in the groin (transfemoral) or chest (transapical, direct aortic or subclavian) under general (both approaches) or more commonly, local anesthesia (transfemoral approach). Eliminating the hazards involved with sternotomy and cardiopulmonary pass, TAVI presents a minimally invasive technique that theoretically, reduces the risk of intraprocedural mortality and post-operative complications in higher risk patients ((Leon et al., 2010; Smith et al., 2011; Adams et al., 2014).

2.1.3 Clinical Outcomes. Since the first procedure in 2002, TAVI has been performed in over 50,000 cases worldwide with favourable clinical outcomes (Gilard et al., 2012). Cohort studies demonstrate low intraprocedural mortality (1.2%) (Webb et al., 2009) and sustained hemodynamic improvement at 1- and 5- year follow-up (Toggweiler et al., 2013). In the seminal Placement of Transcatheter Aortic Valve Replacement (PARTNER) B clinical trial, 358 high-risk patients were randomized to either TAVI or medical therapy (Leon et al., 2010). TAVI was found to be significantly superior to medical therapy, with a 20% absolute reduction in 1-year mortality and a sustained improvement in functional capacity. The subsequent PARTNER A randomized clinical trial found no difference in 1-year mortality between TAVI and surgical

AVR (SAVR) (Smith et al., 2011); while the highly anticipated CoreValve Pivotal Trial demonstrated a higher 1-year survival rate in TAVI compared to SAVR (Adams et al., 2014).

2.1.4 Patient Selection. Although early TAVI research has focused largely on exploring the safety and efficacy of the procedure, investigators have started to take interest in TAVI patient selection due to the age and complexity of patients now presenting with severe AS (Chikwe & Adams, 2010; Mack 2011; Walther & Kempfert, 2011). In an expert position statement released by the Canadian Cardiovascular Society (CCS), it was recommended that patient selection carefully account for procedural feasibility, risk prediction, and likelihood of patient benefit (Webb et al., 2012).

Risk prediction is the estimated probability that an individual will suffer a negative outcome as a result of undergoing surgery (Nilsson, Algotsson, Høglund, Luhrs, & Brandt, 2006). Currently, the European System for Cardiac Operative Risk Evaluation (EuroSCORE) and the Society of Thoracic Surgeons Predicted Risk of Morbidity and Mortality (STS-PROMM) are the two most widely used risk stratification tools in cardiac surgery; however, their validity and reliability for use in lower risk catheter-based procedures, and patients with differing comorbid burden (e.g., frailty, porcelain aorta, severe respiratory disease, etc.) is questionable. With high-risk SAVR patients, the EuroSCORE overestimates mortality by 200-300% (Dewey et al., 2008; Ben-Dor et al., 2011), while the STS-PROMM underestimates mortality by up to 40% (Basraon et al., 2011). A new risk index is needed to account for the complex clinical profile of frail elderly patients currently referred for TAVI consideration (Chikwe & Adams, 2010; Mack 2011; Walther & Kempfert, 2011).

A second important goal of the selection process is to determine procedural benefit (Lauck et al., 2011; Webb et al., 2012). With frailty and concomitant diseases being common in

individuals with severe AS, estimating the benefits of TAVI is often challenging and subjective. Clinicians typically assert that individuals with end-stage disease, moderate to severe dementia, extreme frailty and end-stage malignancy will not benefit from undergoing the procedure (Ye, Soon, & Webb, 2012). Conversely, there are studies demonstrating that complex patients can achieve sizeable benefits (Krane et al., 2010; Ussia et al., 2009). Research investigating factors predictive of meaningful and sustained improvement post-TAVI is needed.

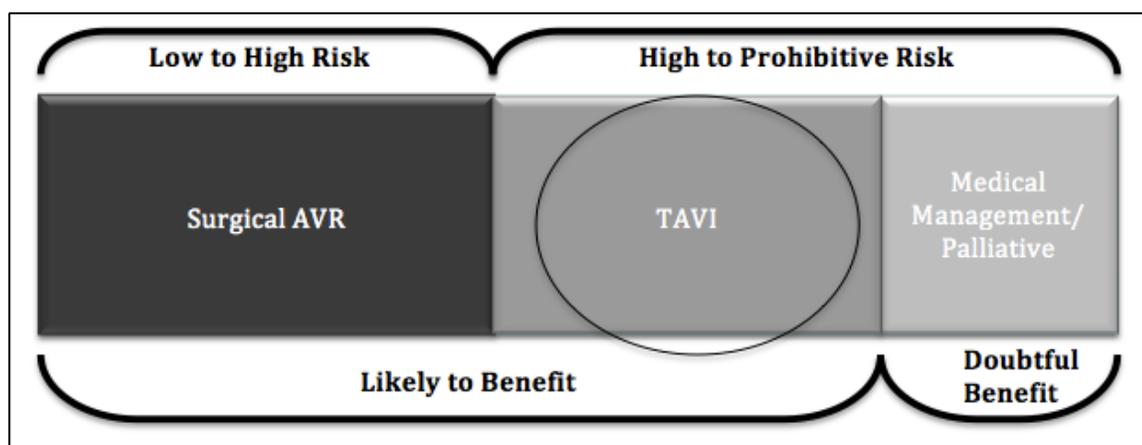


Figure 1. Patient Selection (Lauck, 2011).

2.2 Patient Characteristics

There is evidence to suggest that patient characteristics are important to consider in TAVI patient selection, as these factors can be strong predictors of both risk and benefit in elderly individuals undergoing cardiac surgery. However, as previously identified, there is a dearth of literature evaluating the role of such factors in the context of TAVI.

To conceptualize patient characteristics, this study drew on the Wilson and Cleary (1995) theoretical framework of health-related quality of life (QOL), as modified by Ferrans, Zerwic, Wilbur, and Larson (2005). While details of the above models will be further explored in Chapter 3, it is useful at this point, to define patient characteristics as a general construct. Sometimes described as individual or baseline attributes, patient characteristics consist of demographic, developmental, psychological and biological factors (Ferrans et al., 2005).

Together, these variables intersect with environmental characteristics (e.g., living location, housing situation and interpersonal relationships) to influence an individual's functional status (FS) and QOL (Ferrans et al., 2005; Wilson & Cleary, 1995). The proposed study defines patient characteristics in terms of: demographics, comorbidities, prior cardiac procedures, FS and surgical risk. In the absence of TAVI-specific studies, the next five subsections explore the association between patient characteristics and post-operative outcomes following major cardiac procedures, with a particular focus on LOS.

2.2.1 Advanced Age. As the population ages, cardiac surgeons are increasingly referred elderly individuals with heart disease. Research demonstrates that older individuals are more prone, compared to their younger counterparts, to prolonged hospitalization following cardiac surgery due to physical deconditioning, susceptibility to nosocomial infections and development of peri-operative complications (Ng, Ramli, and Awang, 2004).

In a study investigating morbidity and LOS following CABG, patients over 70 years were found to stay in hospital longer than those under 70, with an average post-operative LOS of 10.4 ± 0.9 days compared to 8.7 ± 0.2 days ($p < 0.049$) (Ng et al., 2004). While major complications were no different between groups, a higher incidence of wound infection occurred in the elderly. Similarly, an analysis of 67,674 patients at 22 hospital sites showed that older patients (octogenarians) were more likely to suffer from a post-CABG stroke and renal failure than their younger, under 80, peers (Alexander et al., 2000). Moreover, the older group experienced a longer median LOS post-surgery, staying seven days compared to six ($p < 0.001$). Findings identifying age as a risk factor for prolonged hospitalization have been well reported in the literature and are further summarized in Table 3.

2.2.2 Comorbidity. Amongst elderly patients, variability in cardiac surgical outcomes has led to increased interest in investigating the impact of comorbidities on post-operative recovery. Comorbidities, or concurrent conditions, are diseases unrelated in causality to the primary diagnosis (Valderas et al., 2009). In a prospective cohort study investigating the effect of comorbid illness on post-CABG mortality, Clough and colleagues (2002) found that after adjusting for age, sex, prior cardiac surgery, and disease severity, comorbid conditions were significantly associated with in-hospital death. Over the past two decades, similar results have been replicated in many cardiac studies (see Table 3).

While researchers have identified a number of comorbidities as being risk factors for adverse post-operative outcomes, renal dysfunction and severe COPD rank high on the list amongst elderly patients suffering from heart disease. In a study of post-operative outcomes following cardiac surgery (CABG or valve replacement), Mageed & El-Ghoniemy (2007) reported a mean LOS approximately twice that for individuals with renal dysfunction compared to those without ($p < 0.01$). In line with these findings, Eltheni and colleagues (2012) found that compared to their propensity match counterparts, patients with renal dysfunction (serum creatinine [Cr] higher than 1.4 mg/dL) were at significantly greater risk of staying more than two days in the intensive care unit. With respect to COPD, numerous studies have shown the detrimental impact of the disease on post-surgical recovery. Research evaluating the effect of COPD on patients undergoing CABG demonstrated that pre-operative COPD predicted longer hospital LOS (Angouras et al., 2010). In line with these findings, Cohen and colleagues (1995) found that compared to their matched controls, individuals with COPD experienced a longer hospital stay (8.1 ± 3.6 days versus 6.6 ± 1.7 days, $p = 0.02$), with more patients developing significant arrhythmias and requiring prolonged intubation.

2.2.3 Prior Cardiac Procedures. Given the progression and chronicity of heart disease, researchers have sought to better understand the effect of prior cardiac procedures on post-operative recovery. Consistently, findings demonstrate that compared to their propensity-matched peers, patients who have previously undergone cardiac intervention (e.g., CABG, mitral or aortic procedure, etc.) experience worse post-operative outcomes. In an analysis of 1,568 patients, Likosky and colleagues (2001) found that following CABG, patients who had a prior cardiac operation required more time for initial extubation and experienced a longer LOS. This same cohort also experienced a threefold increase in the odds of low post-operative cardiac output, as well as a nearly twofold increased hazard of death at up to 4-years of follow-up. In a study investigating predictors of LOS following left ventricular assist device (LVAD) implantation, researchers identified history of CABG and valve surgery to be significantly associated with prolonged hospitalization (Cotts et al., 2014).

Injury to cardiac structures during operation is often used to explain the above results. Researchers from the Mayo Clinic (Park et al., 2010) reported that 9% of patients with a prior history of cardiac surgery experienced injury upon undergoing CABG. Moreover, those who had experienced injury (predominantly to the saphenous vein and the internal mammary artery) were more likely to die in-hospital (6.5% versus 18.5%). Similarly, in a study investigating 1,847 patients who underwent cardiac surgery, injuries and adverse events occurred among 7% of the sample, with damage noted to prior grafts, great vessels, and the heart itself (Roselli et al., 2008).

2.2.4 Functional Status. Functional status (FS) is becoming increasingly recognized as an important indicator of surgical risk and post-operative prognosis in elderly cardiac patients (Afilalo et al., 2010; Lee, et al., 2010; Robinson et al., 2009). Although no consensus definition of the term exists, FS might be best described as an individual's ability to carry out activities to

support needs of daily living in physical, mental, social and spiritual domains of life (Wang, 2004). Functional status does not specifically speak to a patient's illness and comorbidities; instead, it captures subclinical markers of health status such as independence, cognitive ability, and physical function (Schoenenberger et al., 2012). It is these subtle indicators which are thought to account for the heterogeneity seen in older adults - explaining why two individuals of comparable age, comorbidity burden and disease severity can have hugely different recovery trajectories following cardiac surgery (Afilalo et al., 2009).

Researchers postulate that integrating measures of FS with current standards of pre-TAVI assessment could improve patient selection (Stortecky et al., 2012). Although numerous measures of FS exist, there is no agreement on the tool(s) most appropriate for use in TAVI candidates. Common measures include the Katz Activities of Daily Living (ADL) score and gait speed (Green et al., 2012).

The assessment of ADLs as a measure of FS has long been established, particularly for use in the elderly and individuals with chronic illness (Katz & Stroud, 1989). The term, as it is known in healthcare, refers to the self-care activities performed in the normal course of an individual's day, where ability or inability can be used as a practical measure of disability in many conditions (Bagur et al., 2011). The Katz Index of Activities for Daily Living is one of the most common FS tools used in current clinical practice, with foci on bathing, dressing, toileting, transferring, continence, and feeding (Katz, Ford, Moskowitz, Jackson, & Jaffe, 1963).

Psychometric studies demonstrate reasonable validity and reliability of the Katz Index. In a study of 1000 elderly patients, Brosson and Asberg (1984) reported satisfactory construct validity, with 0.74 coefficient of scalability (C of S). Supporting its external validity, the index has been found to be accurate in predicting functional outcomes in a number of populations

including: hospitalized patients (Borsson & Asberg, 1984), older adults in short-term care, and patients who have suffered a stroke (Hamrin & Lindmark, 1988). With respect to reliability, Hamrin and Lindmark (1988) have reported an α reliability coefficient of 0.94, while Borsson and Asberg (1984) have described low inter-observer variability and high usability (no statistics reported).

Gait speed, the time taken to walk a predefined distance, has also become a common measure of FS in TAVI pre-assessment (Chen, 2015). It is one of the most common physical performance tools used in the assessment of older adults given its low cost and high reliability (Guralnik et al., 2000). Supporting its use, there have been a number of published articles demonstrating its utility in risk prediction. In a study of 131 elderly cardiac surgical patients, Afialo and colleagues (2009) found that slow gait speed (taking more than 6 seconds to walk 5 metres) was a significant predictor of major adverse post-operative events (defined as a composite of all-cause death, need for re-operation, stroke, renal failure, prolonged intubation or deep sternal wound infection). In line with these findings, a retrospective analysis of 252 open-heart patients demonstrated a significant correlation between preoperative 5-metre gait speed and total hospital LOS (Wilson et al., 2015).

2.2.5 Surgical Risk. Cardiac surgical risk scores were developed to provide a standardized, reproducible evaluation of a patient's risk of experiencing a major adverse event as a result of undergoing surgery (Neugebauer & Lefering, 2002). Such systems create composite scores that draw on clinical characteristics identified in the literature as being significant surgical risk factors. Given that risk scores are objective and evidence-based, they are often used to facilitate clinical decision-making, patient selection, benchmarking, and allocation of resources (Chand, Armstrong, Britton, & Nash, 2007).

One of the most common risk-score systems used by cardiac surgeons today is the Society of Thoracic Surgeons Predicted Risk of Morbidity and Mortality (STS-PROMM) (Vahanian & Otto, 2010). The STS-PROMM risk score is a predicted probability (ranging from 0 to 1) derived from a multivariate regression model drawing on STS data within a specific time frame. Model coefficients (i.e., the weighting of risk factors) are recalibrated periodically to reflect evolving technology and changes in clinical outcomes as informed by the STS Adult Cardiac Database, a network with input from over 900 cardiac surgical programs in the United States (Shroyer, Plomondon, Grover, & Edwards, 1999). Patient characteristics used in the model include age, comorbidities, prior cardiac surgeries and symptom severity. While other predictive algorithms exist, including the Parsonnet score (Parsonnet, Dean & Berstein, 1989) and EuroSCORE (Nashef et al., 1999), the STS PROMM is thought to be the most rigorously recalibrated and suited for the assessment of perioperative outcomes in patients with severe AS (Dewey et al., 2008; Wendt et al., 2009).

Although researchers have criticized the STS PROMM for its inability to accurately capture risk in frail, elderly patients considered for TAVI (Basraon et al., 2011; Piazza et al., 2009), its scoring has been verified as valid and reliable in other cardiac settings. In analyzing the effectiveness of the STS PROMM in calculating risk of adverse events in patients undergoing CABG, standard performance measures, including the C index (measure of model discrimination) and Hosmer-Lemeshow test (measure of model calibration), indicate high predictive power (c-index = 0.789 and Hosmer-Lemeshow test = 0.99) (Shroyer et al., 1999). Quality of STS PROMM performance has remained consistent over time in patients undergoing CABG with a 2009 study reporting a c-index of 0.812 and an absolute difference of less than 1.5% between observed and expected rates of adverse rates (Shahian et al., 2009).

2.3 Wait Time

While patient characteristics are known to impact recovery following surgery, wait time is also thought to affect surgical outcomes. Research shows that time spent waiting for medically necessary procedures can lead to adverse events and poorer clinical results following treatment. In the coming sections, the concept of wait time is explored with respect to challenges associated with defining the term, its use in the Canadian health care system, and its relationship to cardiac surgical outcomes. The need for TAVI wait time benchmarks – and the evidence required to inform such markers – is also explored.

2.3.1 Defining Wait Time. Wait time is generally defined as the amount of time spent on a wait list before receiving an intended medical service or procedure (Sanmartin et al., 2000). While this construct may initially seem straightforward, the literature suggests that the term can represent different ideas to different stakeholders, depending on setting. Inconsistencies primarily lie in identifying precisely when the wait period begins and ends. Some surgical studies reference wait time as beginning when a patient is booked for a procedure and placed on a wait list (Coyte et al., 1994), while other studies define the term as the period between “decision-to-treat” (when a physician and patient deem treatment as necessary) and the date of treatment itself (Hanning, 1996). Still, others reference total wait, as marked by first medical contact (i.e., the date patient first sees a primary care provider) and delivery of treatment (Bloom & Fendrick, 1987).

Without a universally accepted definition, it is challenging to aggregate or compare wait time data. Experts in the field recommend developing standard definitions for similar waiting experiences within specialty groups, while policy makers assert the need to develop large-scale

system structures, such as national wait list tracking, with the capacity to work across a broad range of jurisdictions (Sanmartin et al., 2000).

2.3.2 Wait Times in Canada. Wait lists are a necessary, albeit challenging, part of operating a publicly funded health care system. Proponents often assert that wait lists exist to ensure the efficient use of limited resources and that without such lists, key parts of the system (e.g., capital, specialists, equipment, etc.) would sit idle, or at least, underutilized during periods of less demand (McCormick, 1988). Moreover, queuing should theoretically ensure timely access to care (Naylor, 1991). Excessive wait times, however, point to a larger systems-level problem in Canada. Across 12 major specialties and 10 provinces, wait time, between primary provider referral to treatment date, rose from 9.3 weeks in 1993 to 18.2 weeks in 2013 (Barua & Esmail, 2013). Current wait reduction strategies include increased funding, priority scoring (e.g., assigning a priority number based on condition severity), and coordination initiatives (e.g., developing systems that manage the waiting lists of multiple physicians) (Barua, Esmail, & Jackson, 2014). Canada has also made a strong push to develop and enhance information systems that will provide more timely information to referring physicians and their patients. Since 1993, the British Columbia Ministry of Health has maintained a database to track wait lists and wait times for a number of surgical procedures.

2.3.3 The Effect of Wait Time on Cardiac Surgical Outcomes. A review of the literature shows a strong association between wait times and cardiac surgical outcomes (Table 3). In one prospective cohort study of patients awaiting CABG, researchers found that longer waits were associated with a significant decrease in physical and social functioning both before and after surgery, in addition to increased incidence of postoperative adverse events (defined as a myocardial infarction, new unstable angina, hospital admission, or death) (Sampalis et al., 2001).

In an investigation of preoperative CABG mortality, Sobolev and colleagues (2008) reported wait time to be significantly correlated with increased risk of death, even in patients whose disease severity was considered “low risk” at pre-assessment.

Acknowledging the impact of treatment delays, the government has started to establish benchmarks for medically acceptable wait times in select clinical areas; however, these parameters can differ significantly from limits suggested by medical professional groups. In an attempt to evaluate the effect of such discrepancies, Sobolev et al. (2012) analyzed patient outcomes drawing on recommended wait times established by the Canadian Cardiac Society (CCS) (2 weeks for semi-urgent, 6 weeks non-urgent) versus the province of British Columbia (6 weeks for semi-urgent, 12 weeks non-urgent). The authors reported that patients who underwent surgery within CCS target times were 33% less likely to die post-operatively in-hospital compared to those who received treatment per provincial guidelines.

2.3.4 The Need for TAVI Wait Time Benchmarks. At present, TAVI is primarily restricted to highly specialized cardiac centres equipped with the expertise and services needed to perform TAVI care. Intensive coordination begins with a multidisciplinary assessment of procedural eligibility, with input from interventional cardiology, cardiac surgery, radiology, anesthesia, nursing, and other specialties as needed (Lauck et al., 2011). Additional work-up includes cardiac catheterization, echocardiography, computed tomography, and an assessment of FS (Lauck et al., 2011; Leipsic et al., 2011). Time delays can occur at any step of pre-TAVI evaluation given challenges inherent in the scheduling and availability of multiple services, resources, and clinicians.

With a limited number of sites capable of performing TAVI, potential pre-procedure bottlenecks and growing demand, the subject of TAVI wait time has started to garner attention.

Researchers and clinicians alike are interested in understanding the clinical consequences associated with leaving severe AS untreated while waiting for intervention. In patients who are surgical candidates, wait time may compromise the relative effectiveness of TAVI compared to SAVR; while, in inoperable patients, post-procedural benefit might decrease as a result of prolonged waiting (Winjensundra et al., 2014). Reinforcing these hypotheses, a recent prospective cohort study found that pre-procedural FS declined with longer wait times for TAVI, as evidenced by slower gait speed and higher frailty scores (Forman et al., 2014).

In an effort to understand how treatment delays might impact mortality, Wijensundra and colleagues (2014) employed mathematical simulation models to estimate the hypothetical effectiveness of TAVI based on 7 wait time scenarios. Drawing on data from the PARTNER trials, the group found TAVI effectiveness to be significantly compromised with increases in wait time. In the high-risk cohort, discrete event modeling yielded a 22.2% difference in wait-time mortality when individuals waited 180 days compared to 10 days. Using the same scenarios, a 27% difference in wait-time mortality was reported in the inoperable cohort. Lauck et al. (2014) highlight that although the above study is limited by several statistical assumptions and dated data (no longer reflective of current patient characteristics or clinical outcomes), the analysis raises important points related to the effect of waiting for TAVI and the need for wait-time benchmarks.

The Canadian Wait Time Alliance (2014) describes benchmarks as the maximum allowable time that a patient should wait for a treatment; after which, best evidence suggests adverse clinical effects are likely to occur. While TAVI wait-time benchmarks are needed to ensure patient safety, establishing targets will be challenging due to unpredictable, upcoming changes in procedural indications, risk stratification, urgency ratings, procedural techniques, and

peri-procedural care processes (Lauck et al., 2014). Having identified these confounders, Lauck and colleagues (2014) suggest that next steps involve the collection of accurate wait time data and an evaluation of patient outcomes related to treatment delays.

2.4 Length of Stay

In the context of a rapidly aging population, wait times, and restricted financial resources, Canadian policy makers and healthcare providers are being tasked to create strategies by which treatment interventions can be delivered not only effectively but also efficiently in older adults while optimizing quality of care and outcomes. Those working in the field of gerontology are now witnessing the introduction of frameworks that specifically demand the balancing of quality care and fiscal economy.

2.4.1 Dangers of Hospitalization in the Elderly. Prolonged LOS affects patient outcomes, particularly in the elderly. For many geriatric patients, a hospitalization can result in complications unrelated to the presenting problem on admission. Studies have shown that adverse events in-hospital are more common among those over 65 years than in their clinically comparable, younger counterparts (Covinsky et al., 2003; Thomas & Brennan, 2000). A number of factors associated with biological aging and hospitalization, individually and collectively, place the elderly at higher risk of complications. These factors include but are not limited to: diminished muscle strength, vasomotor instability, decreased pulmonary ventilation and altered appetite (Creditor, 1993; Hoenig & Rubenstein, 1991).

As described in the section on functional status, decline in muscle mass naturally occurs with biological aging, requiring muscle contractions of particular force and frequency to maintain normal function (Chevalier et al., 2003). In healthy older adults, 10 days of bed rest can result in significant loss of lower extremity strength as evidenced by reduced knee extensor

strength and decreased stair-climbing power (Kortebein et al., 2008). For older individuals with reduced physiologic reserves, the accelerated loss of muscle mass following prolonged inactivity in hospital can lead to dependency in ADLs (Corvinsky et al., 2003). Perhaps more concerning, diminished muscle strength has been linked to falls in the elderly (Oliver, Daly, Martin & McMurdo, 2004). Research shows that up to 30% of such falls can lead to major injury (e.g., fractures and soft tissues trauma), while nearly 60% are associated with either increased LOS or discharge to long-term institutional care (Rhymes & Jager, 1988).

With increasing age, syncope becomes a major concern as natural changes in autonomic function can cause baroreceptor insensitivity leading to reduced blood volume (Creditor, 1993). Bed rest in the supine position can exacerbate age-related hypovolemia resulting in total losses of 8%, 5%, and 0.9% in plasma, blood, and red cell volumes, respectively (Waters, Platts, Mitchell, Whitson, & Meck, 2005). The two most consistently reported effects of this phenomenon are postural hypotension and syncope (Kamiya et al., 2003; Kimmerly & Shoemaker, 2002). Both conditions place patients at considerable risk of injury when mobilizing (Ooi, Hossain, & Lipitz, 2000).

The aging process also compromises the mechanics of respiration. Age-related bone calcification, decreased respiratory muscle strength, and reduced elastic recoil of the lungs reduce ribcage expansion (Janssens, Pache, & Nicod, 1999). As a result, functional residual capacity increases, air becomes trapped, and individuals experience increased work of breathing (Zaugg & Lucchinetti, 2000). The supine position during bed rest further reduces ventilation by increasing the closing volume (Ward, Tolas, Benveniste, Hansen, & Donnica, 1966). This added reduction may be sufficient to cause confusion in older adults at the cusp of pulmonary

insufficiency (Creditor, 1993) or syncope in individuals experiencing vasomotor instability (Zaugg & Lucchinetti, 2000).

Malnutrition is yet another concern for the elderly as age-associated loss of taste and poor dentition are relatively common (Kagansky et al., 2005). Among hospitalized older adults, nutritional status is particularly impaired, with protein-energy malnutrition reported in up to 62% of inpatients over the age of 75 (Thomas et al., 2002). One retrospective pooled analysis of previously published datasets found that compared to community settings, rates of malnutrition were significantly higher in hospitals (5.8% compared to 38.7%, respectively) (Kaiser et al., 2010). Researchers assert that therapeutic diets (e.g., low sodium), difficulties eating in bed, and unfamiliar environment worsen dietary habits in-hospital (Creditor, 1993). Moreover, nutritional status is often overlooked in acute care due to the absence of appropriate dietary assessment standards and monitoring guidelines (Morley, 1991). Unfortunately, malnutrition has a detrimental impact on virtually every organ system. This ranges from decreased cardiac output to impaired gastrointestinal absorption, and in some cases depression and anxiety (Saunders, 2010).

Finally, hospitalized older adults appear to have an increased susceptibility to nosocomial infections with an incidence of 5.9 to 16.9 per 1000 hospital days (Riedinger, Robbins, Bergstrom, 1998). Data from the National Nosocomial Infections Surveillance (NNIS) showed that 54.0% of all hospital-acquired infections appear in patients 65 or older (Emori et al., 1991). Primary among such infections are hospital-acquired pneumonia (HAP) and urinary tract infections (UTIs). Current literature suggests that HAP is the second most common nosocomial infection (after UTIs) and the most common cause of death among hospital-acquired infections (Mandell, 2004). Research shows that the elderly are vulnerable to HAP due to decreased cough

reflex, lung capacity, and immunity (Rothschild, Bates, & Leape, 2000). Other risk factors include poor nutritional status, neuromuscular disease, and witnessed aspiration events (Hanson, Weber, Rutala, 1992).

Alarming, UTIs account for 40% of nosocomial infections and can range from symptomatic bacteriuria to bacteremic infection (Beveridge, Davey, Phillips, & McMurdo, 2011). Risk factors include use of urinary catheters and external urine collection equipment as both devices increase the frequency of bacteriuria (Beveridge et al., 2011). Additionally, general immune suppression and a number of common comorbidities in later life predispose the elderly. Neurological conditions such as Parkinson's disease, Alzheimer's disease, and cerebrovascular disease are associated with impaired bladder emptying (Nicolle, 2002), while diabetes mellitus has been linked to poor glycemic control and neurogenic bladder (Zhanel et al., 1995). Prostatic disease in men can also lead to urinary symptoms and urinary retention (Platt, Plock, Murdock, & Rosner, 1986). Complications of UTIs include: recurring infections, dehydration, kidney damage, and sepsis (Beveridge et al., 2011). In older adults, UTI with bacteremia is associated with a 28-day mortality of 5% (Tal et al., 2005).

2.4.2 Clinical Outcomes Associated with Prolonged LOS. The interaction between the pathophysiological processes of aging and hospitalization has the potential to produce a detrimental cascade of events leading to dysfunction and dependency in older adults. In the literature, there is a consensus that once complications occur and hospitalization becomes prolonged, there is an especially high risk of adverse long-term outcomes including major morbidity, mortality, readmission, and institutionalization (Cowper et al., 2006; Hein et al., 2006).

In a retrospective study examining recovery following coronary artery bypass grafting (CABG), prolonged LOS was associated with increased hospital morbidity and mortality, and higher rates of readmission (Cowper et al., 2006). Additionally, Cheng and colleagues (2003) found that with a one-day reduction in LOS, a higher post-surgical quality of life and improved survival rates could be obtained. It is important to note that LOS is not always inversely correlated with clinical outcomes. In one study of older adults undergoing surgery, researchers found that short LOS significantly increased the risk of early readmission (Heggestad, 2002).

2.4.3 Hospital Costs. Across medical specialties and interventions, LOS data has become a robust and useful indicator of resource utilization (Lee et al., 2003; Li, 1999; Wang et al., 2002). Research has proposed that longer inpatient hospitalizations are associated with greater cost of treatment (Lee et al., 2003; Philbin et al., 2001). As a result, reducing time spent in hospital is becoming a key focus for clinicians caring for patients and those involved in controlling health care expenses.

There is an abundance of data demonstrating the high financial burden associated with cardiac hospitalization. The annual cost of hospitalizing cardiac surgical patients in Canada is close to \$300 million, accounting for nearly 8% of acute care expenditures (Ariste et al., 2009). In patients who have undergone cardiac surgery, the estimated cost of each additional day in hospital is \$1,127 (Canadian Institute for Health Information [CIHI], 2008). This amount directly increases with respect to the presence of comorbid conditions. In some instances, the cost of treating patients with a comorbidity level of 4 (the highest tier of comorbidities) is five times higher than treating comparable patients with no comorbidities (CIHI, 2008).

At present, economic analyses support the use of TAVI as a cost-effective alternative to standard care (Reynolds et al., 2012) and SAVR (Eaton et al., 2014; Fairbairn et al., 2013) in

high-risk individuals. One cost-benefit study suggests that TAVI can be performed with an incremental cost per life year (the cost per year of life gained from undergoing an intervention) and quality adjusted life year (a measure of disease burden, the number of quality years added by an intervention) well within accepted values for cardiovascular technologies (Reynolds et al., 2012). Although transcatheter heart valve systems are currently more expensive than surgical valves (Webb et al., 2012), the overall cost of care may be less in TAVI, given faster recovery times and shortened intensive care and hospital LOS (Smith et al., 2011). TAVI costs and LOS as reported in the PARTNER trial are summarized in Table 3 (Reynolds et al., 2012).

Table 2

Resource Use and Costs of TAVI Hospitalization (n = 175) (Reynolds et al., 2012)

	Mean ± SD (Median)
LOS (days)	
ICU	4.0±7.0 (2)
Non-ICU	6.1±5.4 (5)
Total	10.1±10.1 (7)
Costs (\$)	
TAVI Procedure	42,806±15,206 (38,706)
Room and ancillary costs	30,757±27,484 (22,150)
Physician fees	4,979±1,697 (4,521)
Total for initial hospitalization	78,542±33,799 (67,551)

2.5 Summary

In this chapter, a review of the literature was undertaken to better understand TAVI patient characteristics and wait time. Additionally, the costs and clinical outcomes associated with LOS were explored.

Early TAVI research focused on establishing the safety and efficacy of the procedure; however, interest has since turned to the process of patient selection. At present, selection is suboptimal as clinicians are unable to accurately predict operative risk or procedural benefit in the elderly group being referred for consideration. Drawing on cardiac surgical outcome studies

(Table 3), data suggests that patient characteristics and wait time could be an important factor in projecting both risk and recovery in patients undergoing interventional procedures.

LOS is an important outcome measure for clinical and economic reasons given the hazards associated with hospitalization of older adults. From diminished muscle mass to decreased pulmonary ventilation, there are a number of age-related physiological processes that place elderly patients at high risk of adverse events in-hospital. Furthermore, the cost of hospitalizing cardiac patients is substantial and efforts should be made to reduce resource use where possible. The current cost of a transcatheter valve exceeds that of a surgical valve; however, fast recovery and shorter LOS may mean a lower overall price tag. In sum, this review of the literature demonstrates the need to examine the relationship between patient characteristics, wait time and post-TAVI recovery in-hospital, as measured by LOS.

Chapter 3: Methods

The following chapter provides a review of the study's research questions and presents the conceptual frameworks used to operationalize the study's primary variables of interest: patient characteristics, wait time, and length of stay (LOS). Following this, the research design is described in terms of site, sample, and data collection protocol. The approach to data analysis is then outlined, including a description of study variables, statistical methods, and software. To conclude, ethical considerations are discussed.

3.1 Research Questions

Primary Research Question:

1. Is there a relationship between baseline factors (i.e., patient characteristics and wait time) and LOS following TAVI?

Secondary Research Questions:

2. What is the length of wait time from referral to acceptance (wait time 1), and from acceptance to procedure (wait time 2)?
3. Is there a relationship between patient characteristics and wait time?

3.2 Conceptual Framework

3.2.1 Conceptualizing Patient Characteristics. This study's conceptualization of patient characteristics was largely guided by Ferrans and colleagues' (2005) revision of Wilson and Cleary's (1995) model of health-related quality of life (HRQOL). In the original framework, Wilson and Cleary propose a HRQOL construct that integrates both biological and psychological aspects of health outcomes using five major domains that are causally linked: (1) biological and physiological variables, manifesting as (2) symptoms, which constitute (3) functional status (FS) and ultimately, impact (4) general health perceptions and (5) overall QOL.

Ferrans et al. (2005) retain the same five domains, removing causality between the components (thought to restrict the characterization of their relationships), and further elaborate on the model by explicitly defining individual and environmental characteristics, and their multi-directional influence on all aspects of the patient (see Figure 2). Environmental characteristics include such elements as housing, relationships, and societal beliefs; while, individual characteristics encompass demographic, developmental, psychological, and biological factors. It is Ferrans' operationalization of individual characteristics that serve as the theoretical basis for the selection of patient variables used in this study (see Table 4).

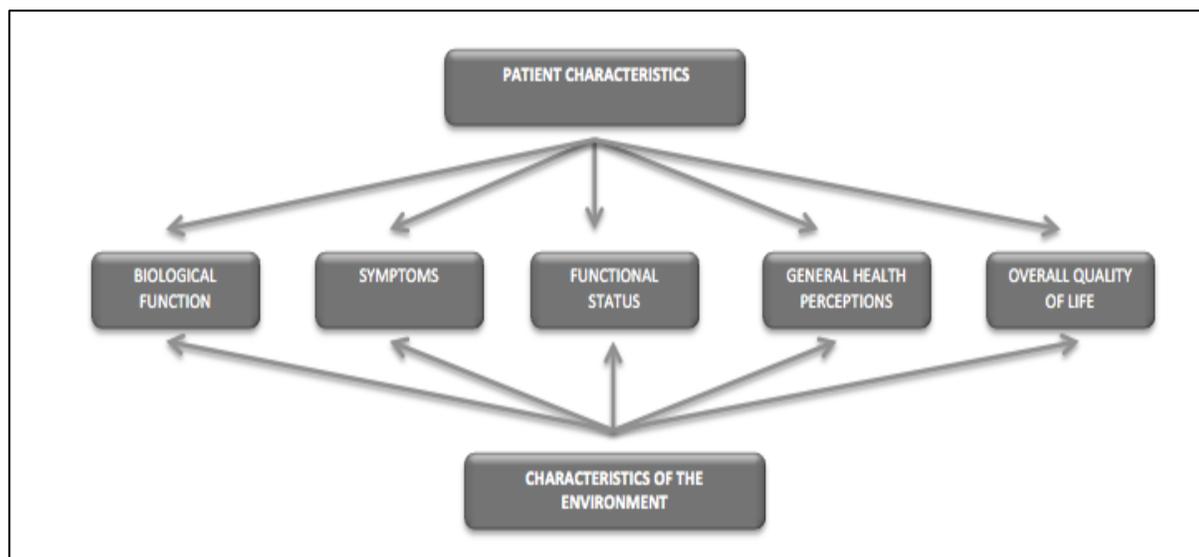


Figure 2. Revised Wilson and Cleary Model for Health-Related Quality of Life (Ferrans et al., 2005).

3.2.2 Conceptualizing Wait Time. As previously described in chapter 2, many definitions of wait time exist. Drawing on Lauck and colleagues' (2014) pathway from referral to procedure (Figure 3), this study operationalized total wait time in terms of two distinct time periods. Using the definitions below, 'wait time 1' refers to the time between referral and acceptance, while 'wait time 2' refers to the time between acceptance and procedure.

- Referral date: date in which referral for TAVI consideration is received by the Heart Team
- Acceptance date: date the patient is accepted (based on Heart Team decision consensus) and placed on the TAVI wait list
- Procedure date: date TAVI is performed

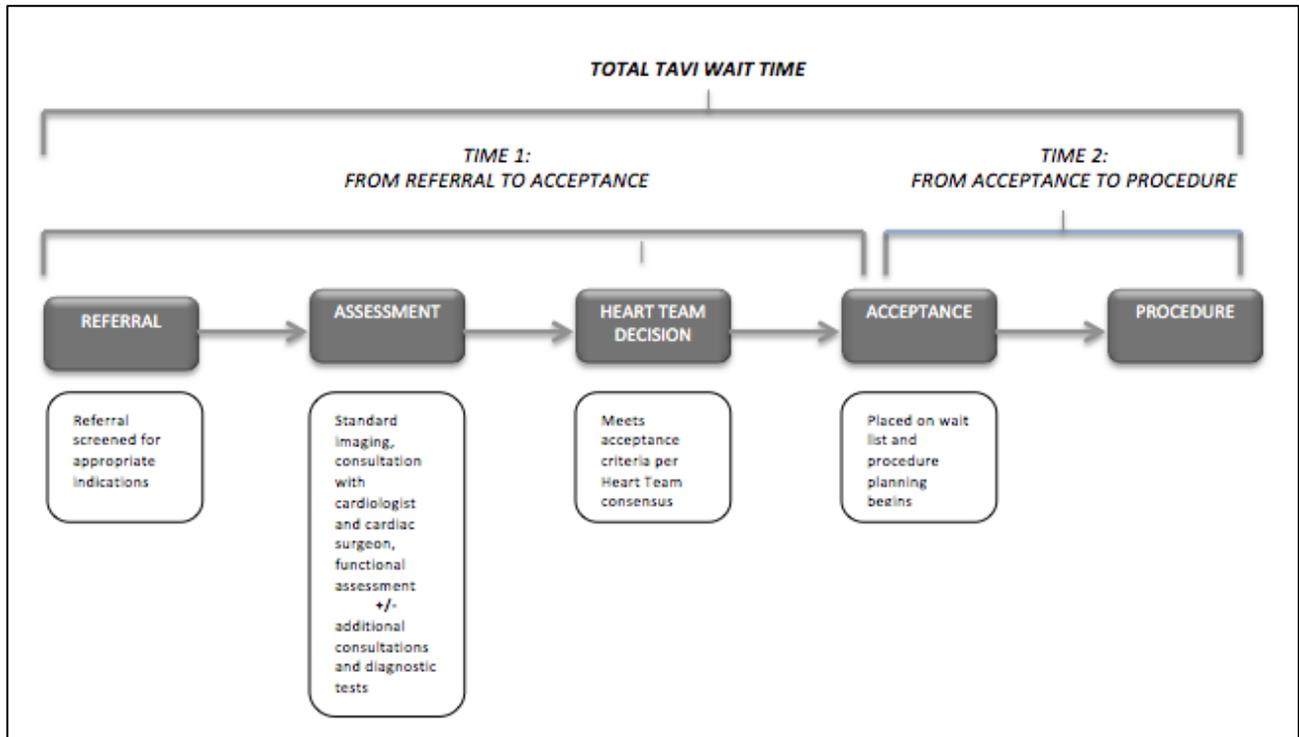


Figure 3. Total TAVI Wait Time (Lauck et al., 2014).

3.2.3 Conceptualizing Length of Stay. Findings from the literature (Table 3) suggest a LOS model based on two categories of risk factors associated with prolonged hospitalization: 1) patient characteristics and 2) wait time.

Table 3

Risk Factors for Prolonged LOS Following Cardiac Surgery

Study	Sample Size (N)	Procedure	Risk Factors	Categorization of Risk Factors
Cohen et al. (1995)	651	CABG	COPD	Patient characteristics: <ul style="list-style-type: none"> • Comorbidities
Alexander et	67,674	CABG +/- AVR or	Age, sex, diabetes, renal	Patient characteristics:

Study	Sample Size (N)	Procedure	Risk Factors	Categorization of Risk Factors
al. (2000)		MVR	insufficiency, dialysis, COPD, heart failure, vascular disease, prior CABG	<ul style="list-style-type: none"> • Demographics • Comorbidities • Prior cardiac surgery
Likosky et al. (2001)	20,703	CABG	Prior CABG	Patient characteristics: <ul style="list-style-type: none"> • Prior cardiac surgery
Sampalis et al. (2001)	266	CABG	Surgical wait time: date of acceptance to date of surgery	Wait time
Clough et al. (2002)	27,239	CABG	Diabetes, vascular disease, COPD, peptic ulcer, and dialysis-dependent renal failure	Patient characteristics: <ul style="list-style-type: none"> • Comorbidities
Ng et al. (2004)	1,594	CABG	Age	Patient characteristics: <ul style="list-style-type: none"> • Demographics
Cowper et al. (2006)	95,499	CABG	Age, sex, race, EF, prior open heart surgery, number of diseased vessels, calcified aorta, vascular disease, renal insufficiency, COPD, and diabetes.	Patient characteristics: <ul style="list-style-type: none"> • Demographics • Symptom severity • Comorbidities
Mageed & El-Ghoniemy (2007)	250	CABG or valve replacement	Renal failure	Patient characteristics: <ul style="list-style-type: none"> • Comorbidities
Sobolev et al. (2008)	7,316	CABG	Surgical wait time: registration on wait list to date of surgery	Wait time
Atoui et al. (2008)	426	CABG, valve replacement/repair or combined procedures	Sex (RR 1.93), age (RR 2.55), EF < 40% (RR 1.83), and history of renal failure (RR 5.39).	Patient characteristics: <ul style="list-style-type: none"> • Demographics • Symptom severity • Comorbidities
Afialo et al. (2010)	131	CABG +/- valve replacement or repair	5-metre gait speed	Patient characteristics: <ul style="list-style-type: none"> • Functional status
Angouras et al. (2010)	3,760	CABG	COPD	Patient characteristics: <ul style="list-style-type: none"> • Comorbidities
Lee et al. (2010)	3,826	Cardiac surgery (identified as isolated CABG and other)	Age, sex, COPD, renal failure, heart failure, frailty (as measured by Katz ADL score)	Patient characteristics: <ul style="list-style-type: none"> • Demographics • Comorbidities • Functional status
Makary et al. (2010)	594	Elective surgery (including cardiac surgery – details	Frailty (Fried frailty score)	Patient characteristics: <ul style="list-style-type: none"> • Functional status

Study	Sample Size (N)	Procedure	Risk Factors	Categorization of Risk Factors
		not specified)		
Eltheni et al. (2012)	150	CABG, valve replacement/repair or combined procedures	Renal dysfunction (OR 3.0), history of atrial fibrillation (OR 6.3), and high EuroSCORE risk value (OR 2.6)	Patient characteristics: <ul style="list-style-type: none"> • Comorbidities • Surgical risk
Robinson et al. (2013)	201	Colorectal and cardiac operations	Frailty as measured by: Katz score ≤ 5 , Timed Up-and-Go ≥ 15 seconds, Charlson Index ≥ 3 , anemia $< 35\%$, albumin < 3.4 gm/dL, and ≥ 1 fall within six-months.	Patient characteristics: <ul style="list-style-type: none"> • Functional status
Azarfarin et al. (2014)	280	CABG, valve replacement/repair or combined procedures	Age, EF, NYHA classification	Patient characteristics: <ul style="list-style-type: none"> • Demographics • Symptom severity
Cotts et al. (2014)	2200	LVAD	Age, race (non-white), prior CABG or valve surgery, ascites, and high right atrial pressure.	Patient characteristics: <ul style="list-style-type: none"> • Demographics • Comorbidities • Prior cardiac procedures
Holmes, Pritchard, & Halpin (2014)	661	Aortic valve or mitral valve surgery	STS surgical risk score	Patient characteristics: <ul style="list-style-type: none"> • Surgical risk
Wilson et al. (2015)	252	Open heart surgery (CABG, valve replacement or valve repair by median sternotomy)	5-metre walk test	Patient characteristics: <ul style="list-style-type: none"> • Functional status

Note. LOS = length of stay; CABG = coronary artery bypass grafting; ICU = intensive care unit; EF = ejection fraction; RR = relative risk; COPD = chronic obstructive pulmonary disease, OR = odds ratio; NYHA = New York Heart Association; LVAD = left ventricular assist device; and STS = Society of Thoracic Surgeons.

In the absence of a theoretical framework to guide the organization of all study variables, a conceptual framework (Figure 4) was developed using Ferrans et al.'s (2005) operationalization of patient characteristics, Lauck et al.'s (2014) definition of TAVI wait time, and findings from the literature (Table 3). This model depicts patient characteristics as a construct encompassing: demographics, symptom severity, prior cardiac procedures, comorbidities, FS, and surgical risk

(a variable estimating risk of dying following surgery based on demographic and clinical inputs).

Together, patient characteristics and wait-time influence post-TAVI recovery trajectory and adverse events in-hospital - the outcome of which is LOS, the time between procedure date and discharge.

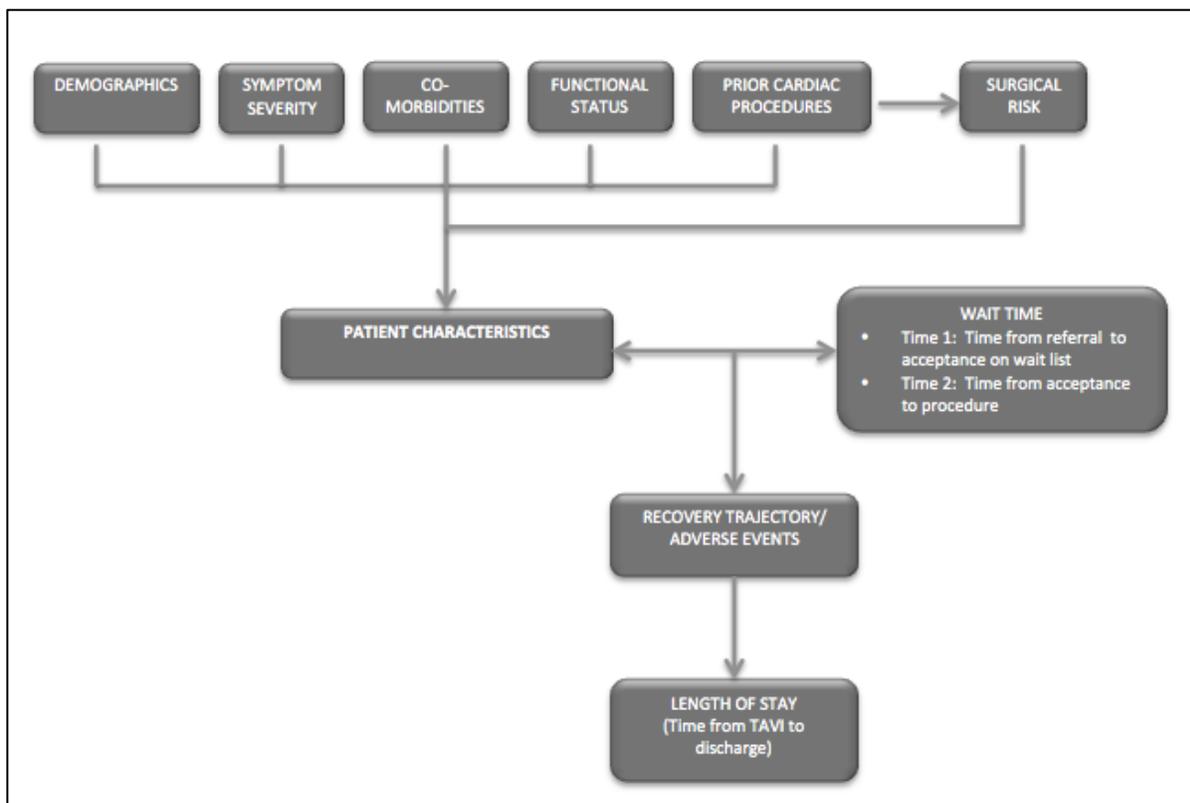


Figure 4. Proposed Conceptual Framework Depicting the Relationship Between Patient Characteristics, Wait Time, and LOS Following TAVI.

3.3 Research Design

A retrospective cohort design was employed. Using a chart review, data were collected on patient characteristics, wait time and LOS.

3.3.1 Site. The study was conducted at a high-volume TAVI centre in Canada.

3.3.2 Sample. To be considered for TAVI, patients must have severe AS and also be deemed unsuitable for conventional AVR due to high prohibitive surgical risk as assessed by a Heart Team that includes interventional cardiologists, cardiac surgeons, nurses and other

clinicians as required. Depending on valve size, severity of disease, and degree of calcification of iliofemoral arteries, patients are selected for either transapical (TA) or transfemoral (TF) approach. All cases are discussed and approved by a multidisciplinary team consisting of interventional cardiologists, cardiac surgeons, a TAVI nurse coordinator, a TAVI clinical nurse specialist and other consultants as needed. Once accepted on the wait list, patients are asked to provide written informed consent for the procedure.

The study consecutively sampled all patients who underwent a transfemoral TAVI between January 1, 2013 and December 31, 2014. The sample included all patients with severe AS, 60 years of age and older, and who have undergone a successful transfemoral (TF) TAVI. Exclusion criteria included: failed device implantation, intra-operative death and transapical TAVI. Using G*Power, an online statistical tool, a priori analyses of sample size was examined. Assuming medium sized effects, alpha = .05 (2-tailed) and statistical power of 80%, a sample size of 139 was required for a multivariate regression analysis of 15 predictor variables (see 'Study Variables' section for details).

3.3.3 Data Collection. Each chart was assessed for study eligibility. If the patient met the aforementioned inclusion criteria, a chart abstraction form (Appendix B) was used to collect all relevant information. The form draws on standard demographic and clinical data recorded in hospital charts and the TAVI Triage Functional Assessment Form (Appendix B) and patient's discharge summary. All data were collected by the investigator and stored in a locked office. A coding system (Appendix C) was prepared, with all personal identifiers removed (e.g., Personal Health Number). Data were subsequently entered on Statistical Package for the Social Sciences (SPSS) for Mac Version 21.0.

3.4 Study Variables

Table 4 outlines the study's predictor variables to be described in further detail in Section

3.4.1.

Table 4

Predictor Variables

Predictors	Study Variables
Patient demographics	<ul style="list-style-type: none">• Age• Sex• Living situation• Living location
Comorbidities	<ul style="list-style-type: none">• Severe COPD• Renal dysfunction
Symptom severity	<ul style="list-style-type: none">• LVEF
Prior cardiac procedures	<ul style="list-style-type: none">• PCI• CABG• SAVR• BAV
Functional status	<ul style="list-style-type: none">• ADL score• 5-metre gait speed
Surgical risk	<ul style="list-style-type: none">• STS score
Pre-procedure wait time	<ul style="list-style-type: none">• Wait time (date of referral acceptance to date of procedure)

3.4.1 Predictor Variables.

3.4.1.1 Demographics. The chart extraction tool recorded patient's age, sex, living situation and living location. Sex was recorded as male or female and analyzed as a categorical variable. Living situation was dichotomized into 'living independently' (i.e., living in the community, without the support of health care services or providers in the home) and living in a facility (i.e., living in assisted care environment where health care services are coordinated to support ADLs and health needs). Living location was categorized into ' ≤ 100 kilometres (km) from the procedure site' and '>100 km from the procedure site'. All demographic variables were drawn from the Vancouver Transcatheter Aortic Valve Replacement (TAVR) Patient Triage Report.

3.4.1.2 Biological Factors. As depicted in Table 4, patient clinical characteristics included: comorbidities, symptom severity, prior cardiac procedures, FS, and surgical risk. Drawing on findings from the literature review, comorbidities encompassed renal dysfunction and severe COPD, while FS was captured using the Katz Activity of Daily Living (ADL) score and 5-metre gait speed. Prior cardiac procedures included: percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG), surgical aortic valve replacement (SAVR), and balloon aortic valvuloplasty (BAV). Finally, surgical risk was measured using the Society of Thoracic Surgeons Predicted Risk of Morbidity and Mortality (STS PROMM). All baseline characteristics were taken from the Vancouver TAVR Patient Triage Report.

As a proxy of symptom severity, New York Heart Association (NYHA) class was measured. Common symptoms of severe AS include angina, dyspnea, syncope, and heart failure (Ross & Braunwald, 1968). The classification of symptoms – ranging from class I to IV – is made based on a physician’s assessment of a patient’s functional capacity over the past two weeks. Stratification is based on the extent to which an individual’s level of physical activity is limited by symptoms of heart failure. For analysis, NYHA was categorized into two groups: NYHA classes I and II (no impairment to mild impairment due to symptoms of heart failure), and NYHA classes III and IV (marked to severe limitations to physical activity due to symptoms of heart failure).

As previously discussed, FS was measured using the Katz ADL Score and 5-Metre Gait Speed. The Katz ADL score describes FS in terms of an individual’s ability to perform ADLs (i.e., bathing, dressing, toileting, transferring, feeding, and continence) (Katz, Ford, Moskowitz, Jackson, & Jaffe, 1963). Each item corresponds to a yes or no response, indicating independence or dependence, respectively. A maximum score of 6 indicates full function, a score of 4 indicates

moderate impairment, and 2 or less indicates severe impairment (Katz & Stroud, 1989). The Katz scale was published in 1963 and has since been cited more than 46,000 times (Gurland & Mayrer, 2012). For analysis, the Katz ADL score was stratified into score of 6 (full function) and score ≤ 5 (mild to severe functional impairment).

The 5-Metre Gait Speed was used to measure patient mobility. It is the time, in seconds, taken to walk 5 metres. During the assessment, the patient was asked to walk 5-metres at a comfortable pace. Each patient completed the walk three times (trial 1, trial 2, and trial 3). The average of the three trials was calculated. For statistical analysis, 5-metre gait speed was dichotomized into ≤ 7 seconds and > 7 seconds. 7-seconds is the cut-off score frequently cited in the literature to identify the slow and frail (Afialo et al., 2009).

Surgical risk was measured using the STS PROMM, a risk stratification tool widely used to estimate operative risks. The score was calculated using a formula inclusive of over 40 clinical and demographic inputs, such as age, sex, vascular health, and hemodynamics. Higher scores indicated higher risk of mortality following cardiac surgery.

3.4.1.3 Wait Time. In an effort to capture the full trajectory of care, total wait time was divided into two discrete periods. Wait time 1 referred to the time, in days, from referral to acceptance on wait list, while wait time 2 referred to the time, in days, from acceptance to procedure (see Figure 3). As there are no current wait time benchmarks for TAVI, a review of the literature was used to determine an appropriate cut-off score for statistical analyses. Drawing on a study conducted by Forman et al. (2014), a cut-off score of 42 days was used as findings showed that patients waiting longer than 42 days experienced a statistically significant decline in functional status, as evidenced by slower gait speed and higher frailty scores. This cut-off score is further validated by current practice where at some sites, TAVI teams follow the

recommended wait time of 42 days used for patients with severe AS waiting to undergo SAVR (S. Lauck, personal communication, July 6, 2015).

3.4.2 Outcome Variable: Length of Stay. Total LOS was defined as the time, in days, from TAVI procedure to hospital discharge. In patients who were transferred after TAVI to another institution, LOS was defined as the total time spent in treating and receiving hospital. This information was obtained from the patient's discharge summary. It was important to develop appropriate methods for statistical analysis as LOS generally follows a positively skewed distribution (Liu et al., 2001; Lee et al., 2003), with some patients staying in hospital for a long period of time. For the analysis of this proposed study, LOS will be categorized into three groups: 1 to 2 days, 3 to 4 days, and ≥ 5 days reflecting faster-than-standard, standard, and prolonged LOS, respectively (Barbanti et al., 2015; Durand et al., 2015).

3.5 Data Analysis

3.5.1 Data Screening. Data collection forms were reviewed for completeness and entered into an electronic file. Before conducting the primary analyses, descriptive statistics were generated to determine the extent of missing data and outliers and to assess the distributional properties of the variables. To avoid problems associated with missing data, efforts were made to accurately complete data sets by retrieving appropriate medical records.

3.5.2 Statistical Analysis. Descriptive analyses were used to describe the study sample and to answer the research question: *What is the wait time between referral and acceptance, and acceptance to procedure?* Descriptive statistics were primarily summarized as mean \pm standard deviation and frequency (%). Wait time and length stay were further described as percentiles, using the weighted average function in SPSS.

Inferential statistics were used to answer the questions: 1) *What is the relationship between patient characteristics and wait time?* and 2) *What is the relationship between baseline factors (i.e., patient characteristics and wait-time) and length of stay following transcatheter aortic valve implantation?* In investigating the association between baseline factors and LOS, bivariate analyses were conducted on all baseline factors (i.e., patient characteristics and wait time) expected to be predictors of LOS. Predictors were identified using the results of the descriptive statistics analysis (i.e., those variables whose prevalence in the sample are greater than 10%). Associations between categorical variables were assessed with Chi-square statistics for independence and Fischer's exact tests (when cell counts did not meet the minimum expectation of five cases). Group-specific means of continuous variables were analyzed using independent sample t-tests. Variables from the bivariate analyses that achieved a significance cutoff of $p < 0.05$ were selected for inclusion in the multivariate model, and then removed if not statistically significant in the model itself. The final polynomial regression model estimated LOS, regressed on select baseline factors.

The same multiple regression approach was applied to investigate the association between patient characteristics and wait time; however, bivariate analyses were conducted on patient characteristics only. SPSS Mac Version 21.0 software was employed for all data analyses.

3.5 Ethical Considerations

Approval to conduct this study was obtained from the Providence Health Care Research Ethics Board (PHCREB). As the proposed research involved a chart review and use of retrospective data (collected before the date of ethics approval), the study fulfilled the criteria for waiver of consent for the secondary use of information as outlined by Article 5.5 of the Tri-

Council Policy Statement. Protection of all patients was of high priority. Confidentiality was maintained by replacing all direct patient identifiers (IDs), such as first and last name, with unique and anonymous subject IDs on all study records. Electronic versions of study data will be password-protected. Hard copies were kept in a locked cabinet in a secure, private office. Data will be stored for five years and then destroyed in a manner consistent with REB policy.

Chapter 4: Results

This chapter begins with a description of participant screening and study enrollment. Descriptive statistics are then used to report patient characteristics (e.g., demographic data, prior cardiac history, and comorbidities), wait time, and length of stay (LOS). The remainder of the chapter focuses on inferential statistics applied to the research questions: 1) *What is the relationship between baseline factors (i.e., patient characteristics and wait-time) and LOS following transcatheter aortic valve implantation (TAVI)?* and 2) *What is the relationship between patient characteristics and wait time?* The results are based on multivariate regression analyses of baseline factors on LOS, and patient characteristics on wait time, respectively.

4.1 Study Sample

The study population included all patients who underwent a transfemoral TAVI at St. Paul's Hospital between January 1, 2013 to December 31, 2014 (see Figure 5). Within the study period, 264 TAVI procedures were performed, with a total of 257 (97.3%) patient charts meeting inclusion criteria. Two cases (0.76%) were excluded for failed device implantation, while 5 cases (1.9%) were excluded for intraoperative death. The failed implantations included one aborted procedure and one conversion to surgical aortic valve replacement (SAVR).

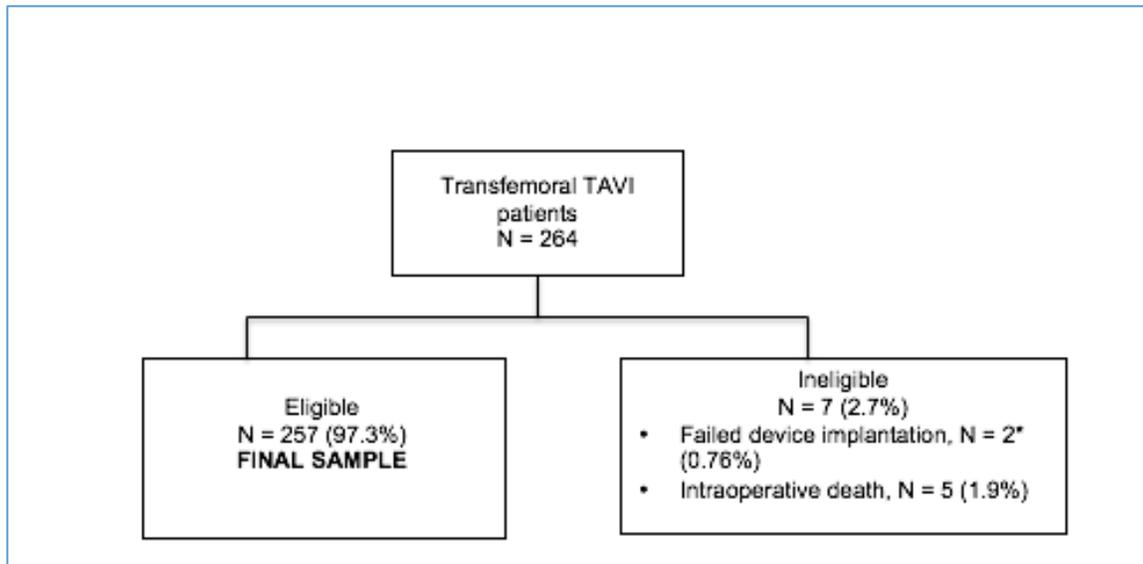


Figure 5. Flow Chart of Participant Screening and Enrollment.

*1 aborted procedure and 1 conversion to SAVR.

4.2 Baseline Characteristics

4.2.1 Patient Demographics. Table 5 provides a complete summary of the participants' demographics. The average age was 81.4 years ($SD = 7.6$, range: 56 to 96 years), with men comprising 59.5% of the sample. Prior to undergoing TAVI, 75.5% lived independently, while 3.9% lived in a facility (missing 20.6%). Geographically, the majority of patients (64.2%) lived within 100 kilometres (km) of the procedure site.

Table 5

Sample Demographics

Characteristic	Frequency (%) <i>N</i> = 257
Age in Years at Time of Referral (mean \pm <i>SD</i>)	81.4 \pm 7.6
Sex	
Male	153 (59.5)
Female	104 (40.5)
Living Situation	194 (75.5)
Lives independently	10 (3.9)
Lives in facility	

Characteristic	Frequency (%) <i>N</i> = 257
Living Location	
≤ 100 km from procedure site	165 (64.2)
> 100 km from procedure site	92 (35.8)

4.2.2 Patient Characteristics. As displayed in Table 6, the following 10 baseline patient characteristics were analyzed: estimated glomerular filtration rate (eGFR), chronic obstructive pulmonary disease (COPD), New York Heart Association (NYHA) class, history of prior cardiac procedures (including coronary artery bypass graft [CABG], SAVR, balloon aortic valvuloplasty [BAV], and percutaneous coronary intervention [PCI]), Society of Thoracic Surgeons (STS) surgical risk score, Katz Activity of Daily Living (ADL) score, and 5-metre gait speed. The mean eGFR was 58.6 ml/min, indicating overall mild to moderate renal dysfunction, while severe COPD was documented in 5.8% of the sample. With respect to symptom severity, over three quarters of patients fell into New York Heart Association (NYHA) class III ($n = 177$, 68.9%) or IV ($n = 25$, 9.7%), meaning individuals experienced fatigue, dyspnea, or shortness of breath with less than normal activity (American Heart Association [AHA], 2015). Despite marked symptom severity, the sample generally demonstrated moderate-to-high independent functioning, with a mean ADL score of 5.9 ($SD = 0.5$) and a mean 5-metre gait speed of 6.4 seconds ($SD = 2.3$).

An analysis of cardiac procedural history revealed nearly half of participants had previously undergone revascularization (CABG - 19.1% and PCI - 22.2%), while approximately one fifth had undergone aortic valve replacement or repair (SAVR -14.4% and BAV - 4.7%). The mean predicted 30-day risk of operative mortality and morbidity, as measured by the Society of Thoracic Surgeons (STS) risk score, was found to be 6.0% ($SD = 4.0$).

Table 6

Baseline Patient Characteristics

Patient Characteristic	(n = 257)
eGFR, ml/min ¹	
mean ± SD	58.6 ± 21.5
Severe COPD	
N (%)	15 (5.8)
NYHA class, n(%)	5(1.9)
I	50 (19.5)
II	177 (68.9)
III	25 (9.7)
IV	
Prior CABG	
% Yes	49 (19.1)
Prior SAVR	
% Yes	47 (14.4)
Prior BAV	
% Yes	12 (4.7)
Prior PCI	
% Yes	57 (22.2)
STS Risk Score (mean ± SD), % ²	6.0 ± 4.0
Katz ADL score (mean ± SD) ³	5.9 ± 0.5
5 metre gait speed (mean ± SD), seconds ⁴	6.4 ± 2.3

Abbreviations: COPD = chronic obstructive pulmonary disease; NYHA = New York Heart Association; CABG = coronary artery bypass grafting; BAV = balloon aortic valvuloplasty; PCI = percutaneous coronary intervention; SAVR = surgical aortic valve replacement; and ADL = activities of daily living; STS = Society of Thoracic Surgeons

Overall, this population was largely elderly, living independently, and represented nearly equally by men and women. The majority of participants (77.6%) had NYHA class III or IV

¹ eGFR ≥ 90 ml/min indicates normal renal function; eGFR 60-89 ml/min indicates mild renal dysfunction; eGFR 30-59 ml/min indicates moderate renal dysfunction.

² STS risk score of 6% indicates moderate surgical risk; STS risk score of 8% indicates high surgical risk

³ ADL score: a maximum score of 6 indicates full function with ADLs, a score of 4 indicates moderate impairment, and 2 or less indicates severe impairment.

⁴ 5 metre gait speed: > 7 seconds used as cut-off score to identify slow, frail individuals.

symptoms, though functioned reasonably well in terms of ADLs and gait speed. The predicted surgical risk was relatively low; however, as will be discussed in chapter 5, STS risk scores, a measure developed and used for cardiac surgical patients, can be hugely inaccurate in patients awaiting TAVI.

4.3 Wait Time

Wait time was assessed in three intervals: (a) wait time between the date of referral to the date of acceptance (i.e., wait time 1), (b) wait time between the date of acceptance to the date of procedure (i.e., wait time 2), and (c) total wait time between referral to procedure (i.e., the sum of “a” and “b”).

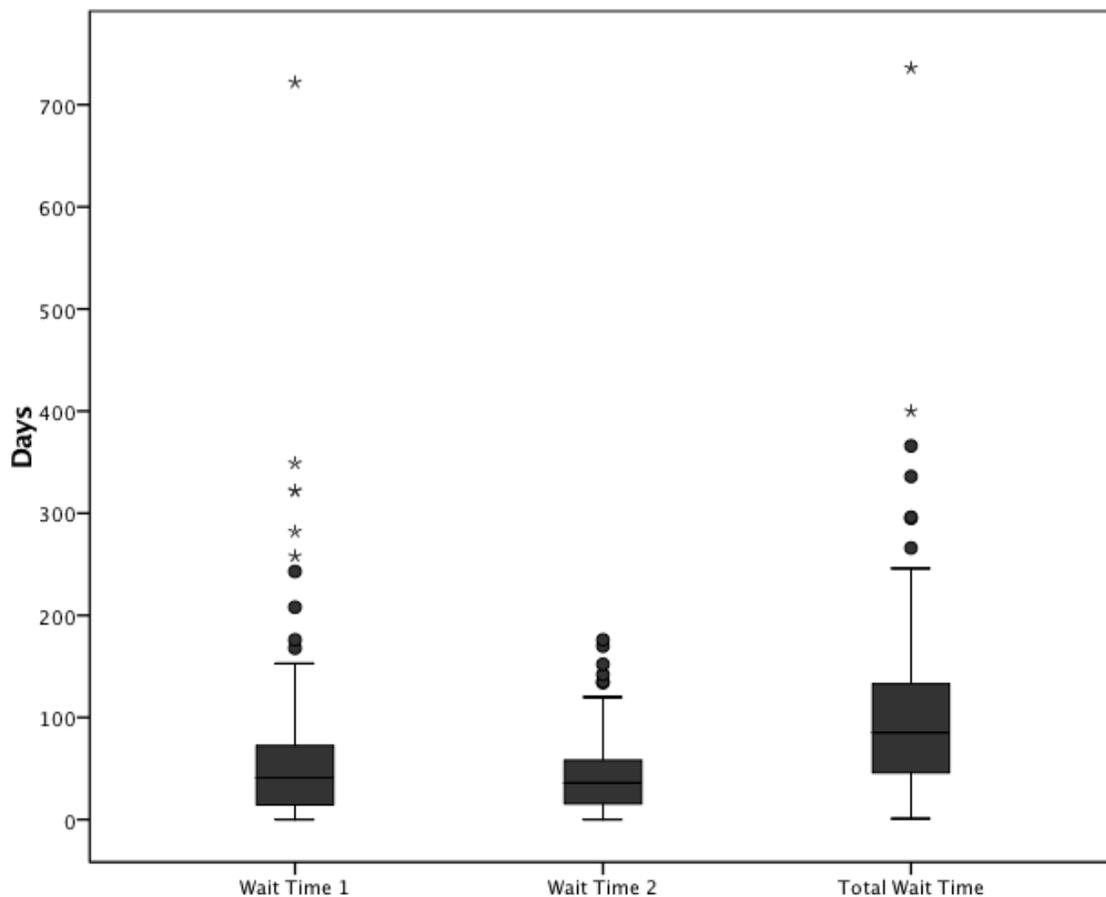


Figure 6. Distributions of Wait Time 1, Wait Time 2, and Total Wait Time.

The median total wait time was equal its mean (85 days), while the medians for wait times 1 and 2 were both less than their means at 41 days and 36 days, indicating a positive skew. Although the maximum total wait time was 735 days, 95% of patients waited less than 208 days from referral to procedure (see Table 7).

Table 7

Wait Time, in Percentiles

Outcome	Percentile ^a						
	5	10	25	50	75	90	95
Wait time 1, <i>days</i> (referral to acceptance)	2.0	6.0	14.3	41.0	72.8	121.9	148.3
Wait time 2, <i>days</i> (acceptance to procedure)	2.0	3.0	15.3	36.0	58.0	81.9	98.3
Total wait time, <i>days</i> (referral to procedure)	9.0	17.0	46.0	85.0	133.0	180.2	207.8

^aWeighted average method.

4.4 Length of Stay

As illustrated in figures 7 and 8, LOS was positively skewed. The mean LOS was 3.7 days, while the median was 3.0 days.

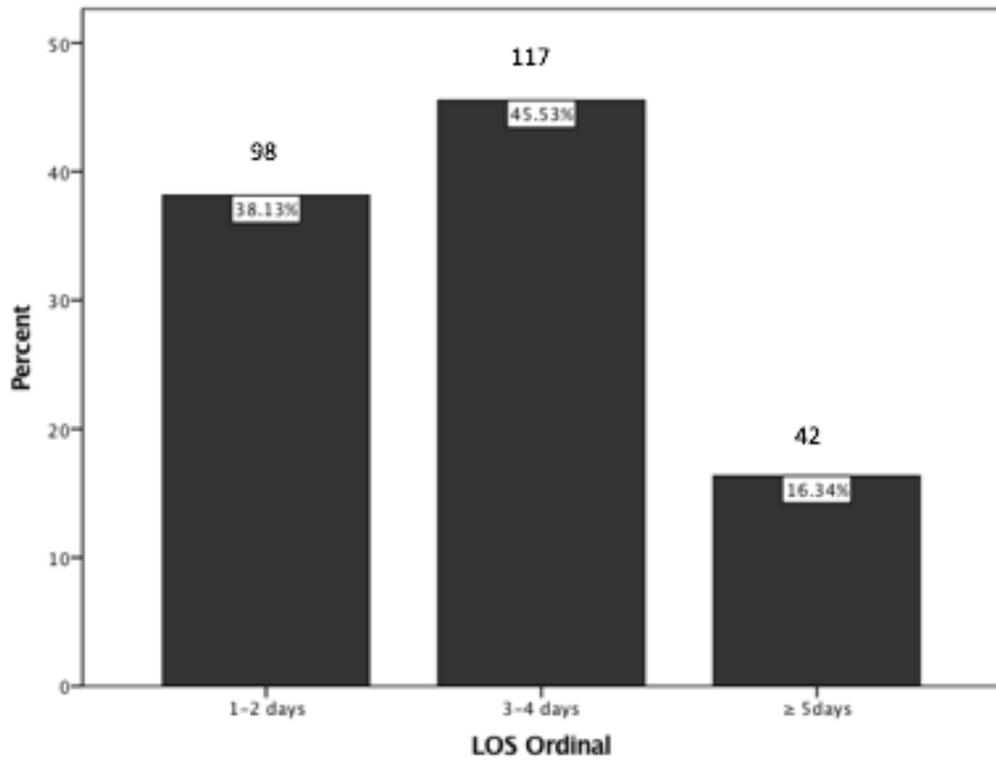


Figure 7. LOS Ordinal Distribution.

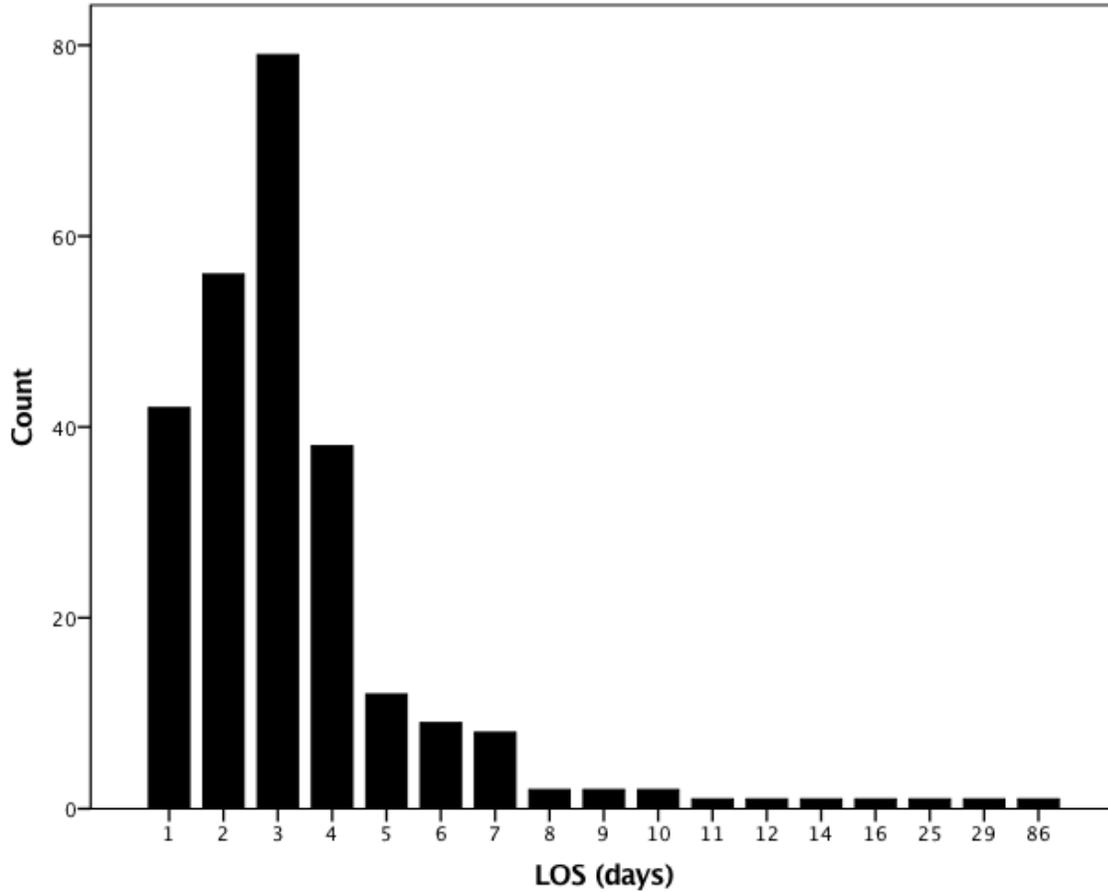


Figure 8. Frequency Count of Post-TAVI LOS.

Although the range for post-TAVI LOS was 1 to 86 days, most patients had a relatively short stay in-hospital. As shown in Table 9, 75% of patients stayed less than 5 days, while 95% of patients stayed less than 9 days.

Table 8

Post-TAVI LOS, in Percentiles

Outcome	Percentile ^a						
	5	10	25	50	75	90	95
Post-TAVI LOS (days)	1	1	2	3	4	6	8

^aWeighted average method.

4.4 The Association between Baseline Factors and Post-TAVI Length of Stay

4.4.1 Bivariate Analysis. In an effort to answer the primary research question “*what is the association between baseline factors and post-TAVI LOS?*” a bivariate analysis was undertaken to identify potential predictor variables to later be included in the final multivariate model. Post-procedural LOS was categorized into tertiles: 1 to 2 days, 3 to 4 days, and 5 or more days, representing early, standard, and delayed discharge, respectively (Barbanti et al., 2015; Durand et al., 2015). Chi-Square cross-tabulation showed age to be statistically significantly associated with post-TAVI LOS ($X^2 = 18.7, p = 0.005$), with younger patients tending to have a shorter recovery in-hospital. As shown in Table 9, the majority (52.8%) of patients less than 75 years stayed 1 to 2 days as compared to only 39.1% of those 88 years or older. With respect to delayed discharge, nearly a third (30.4%) of patients 88 years or older stayed 5 days or more; whereas, only 13.9% of those less than 75 years experienced the same.

A Fisher’s exact test was used to analyze living situation as 3 cell counts were less than 5. Results showed living situation to be statistically significantly associated with post-procedure LOS ($X^2 = 12.1, p = 0.001$); however, 20.6% of the charts reviewed contained missing data. From the information available, 60% of those previously living in a facility stayed 5 days or more, compared to 11.9% of individuals previously living independently. With consideration to the high percentage of missing data, living situation was not included in the multivariate analysis to follow. Neither gender nor living location were found to have significant relationships with LOS.

Table 9

LOS by Patient Demographics

Characteristic	N	LOS, <i>days</i>			Statistic	<i>p</i> -value
		1 to 2 N(%)	3 to 4 N(%)	≥ 5 N(%)		
Age					X² (6) = 18.7*	.005
< 75 years	36	19 (52.8)	12 (33.3)	5 (13.9)		
75 to 79 years	50	14 (28.0)	25 (50.0)	11 (22.0)		
80 to 87 years	125	47 (37.6)	66 (52.8)	12 (9.6)		
≥ 88 years	46	18 (39.1)	14 (30.4)	14 (30.4)		
Sex					X ² (2) = 0.93	.63
Male	153	55 (35.9)	71 (46.4)	27(17.6)		
Female	104	43 (41.3)	46 (44.2)	15(14.4)		
Living situation					X² (2) = 12.08*	.001
Lives independently	194	82 (42.3)	89 (45.9)	23 (11.9)		
Lives in facility	10	2 (20)	2 (20)	6 (60)		
Living location					X ² (2) = 3.03	.22
Lower mainland	165	69 (41.8)	69 (41.8)	27 (16.4)		
Out-of-town	92	29 (31.5)	48 (52.2)	15 (16.3)		

**p* < .05

In analyzing baseline patient characteristics, prior BAV, and prior AVR were found to be statistically significantly associated with hospital stay following TAVI. Specifically, with only 8.3% of prior BAV patients staying 1 to 2 days, compared to 39.6% in individuals with no such history, prior BAV was found to be statistically significantly associated with post-TAVI LOS ($X^2 = 7.18$, $p = 0.03$). Of note, a higher percentage of patients in the BAV group experienced a prolonged in-hospital recovery, with 41.7% staying 5 days or more, compared to 15.1% in the non-BAV group. A Fischer's exact test was used as 2 cells had counts less than 5.

Contrary findings were found in individuals who had previously undergone AVR. Although a Chi-Square cross tabulation showed a statistically significant association ($X^2 = 7.18$, $p = 0.03$), AVR patients tended to have a shorter LOS. That is, 56.8% of the AVR group stayed

1 to 2 days, compared to 35% in the non-AVR group. There were no significant differences between groups when LOS was greater or equal to 5 days.

Of interest, NYHA class closely approached statistical significance ($p = 0.048$). The analysis showed 64.8% of patients with NYHA class III or IV symptoms (i.e., marked symptom severity) had either a standard (49.5%) or prolonged recovery (15.3%); whereas, nearly half (49.1%) of those with NYHA class I or II symptoms were discharged early. Considering a p -value of 0.048 and taking into account evidence to support the association between NYHA class and post-procedural stay in-hospital (Azarfarin et al., 2014; Lee et al., 2010), NYHA class was included in the multi-variate analysis to follow.

Table 10

LOS by Baseline Patient Characteristics

Characteristic	N	LOS, days			Statistic	p -value
		1 to 2 N(%)	3 to 4 N(%)	≥ 5 N(%)		
Renal dysfunction ^a	17	3 (17.6)	12 (70.6)	2 (11.8)	$X^2 (2) = 4.75$.09
Severe COPD	15	4 (26.7)	9 (60.0)	2 (13.3)	$X^2 (2) = 1.37$.50
NYHA class III or IV	202	71 (35.1)	100 (49.5)	31 (15.3)	$X^2 (2) = 6.06$.048
Prior CABG	49	20 (40.8)	23 (46.9)	6 (12.2)	$X^2 (2) = 0.76$.68
Prior AVR	37	21 (56.8)	10 (27.0)	6 (16.2)	$X^2 (2) =$ 7.18*	.03
Prior BAV	12	1 (8.3)	6 (50.0)	5 (41.7)	$X^2 (2) =$ 7.49*	.02
Prior PCI	57	19 (33.3)	30 (52.6)	8 (14)	$X^2 (2) = 1.49$.47
ADL score < 6	22	6 (27.3)	10 (45.5)	6 (27.3)	$X^2 (2) = 3.67$.16
5m walk test ≥ 7 sec	61	16 (26.2)	35 (57.4)	10 (16.4)	$X^2 (2) = 5.30$.07
STS Risk Score > 8%	52	22(42.3)	20 (38.5)	10 (19.2)	$X^2 (2) = 1.00$.61

Note: COPD = chronic obstructive pulmonary disease; NYHA = New York Heart Association; CABG = coronary artery bypass grafting; BAV = balloon aortic valvuloplasty; PCI = percutaneous coronary

intervention; SAVR = surgical aortic valve replacement; and ADL = activities of daily living; STS = Society of Thoracic Surgeons

^aRenal dysfunction defined as eGFR < 30 ml/min.

* $p < .05$

Table 11 shows no statistically significant association between LOS and wait time ($X^2 = 2.41, p = 0.30$). That is, individuals who waited 42 days or less, from acceptance to procedure, were no more likely to be discharged early (34.8%) than those who waited more than 42 days (43.6%). Moreover, wait time did not appear to be statistically significantly associated with prolonged recovery.

Table 11

LOS by Wait Time 2 (From Acceptance to Procedure)

Characteristic	N	LOS, days			Statistic	p-value
		1 to 2 N(%)	3 to 4 N(%)	≥ 5 N(%)		
≤ 42 days	155	54 (34.8)	73 (47.1)	28 (18.1)	$X^2 (2) = 2.41$.30
> 42 days	101	44 (43.6)	44 (43.6)	13 (12.0)		

In summary, age, living situation, prior BAV, and prior AVR were found to be statistically significantly associated with post-TAVI LOS. Additionally, NYHA class closely approached statistical significance ($p = 0.048$). Early discharge, or a LOS of 1 to 2 days, was associated with being 75 years old or younger, living independently, and prior AVR; while delayed discharge, or LOS of 5 days or more, was associated with living in a facility and prior BAV.

4.4.2 Multivariate Analysis. In the multivariate analysis, variables that were not statistically significantly associated with LOS were excluded, with the exception of NYHA class given its p -value of 0.048 and evidence to support its inclusion (Azarfarin et al., 2014; Lee et al., 2010). Living situation, although associated with post-TAVI in-hospital recovery was not

included given the homogeneity seen in the sample (95% lived independently) and a relatively high percentage of missing data (20.6%).

Analyses were first conducted to test the model’s multi-collinearity and goodness of fit. In Table 12, multi-collinearity statistics show low correlation between independent variables, with Variance Inflation Factor (VIF) values close to 1, as desired. Moreover, the model was found to be statistically significantly predict the dependent variable, *LOS ordinal*, over and above the intercept only model ($X^2 = 39.2$, $df = 12$, $p < 0.001$), indicating goodness of fit. Finally, the Nagelkerke R^2 was 16.3%.

Table 12

Full Model Multi-Collinearity Test

Independent Variables	Collinearity Statistics
	VIF
Age	1.03
NYHA class III or IV	1.01
Prior BAV	1.04
Prior AVR	1.04

Note. Dependent variable: LOS ordinal. *Abbreviations.* NYHA, New York Heart Association, BAV, balloon aortic valvuloplasty, AVR, aortic valve replacement

Table 13 summarizes the findings of the final multivariate model. Four independent variables were used in the multivariate logistic regression to estimate the outcome variable, LOS (in quartiles) from the time of procedure to hospital discharge. As informed by the bivariate analyses, the following variables were used: age, NYHA class, prior AVR, and prior BAV. A p value equal or less than 0.05 was considered significant.

Relative to having a post-TAVI LOS of 1 to 2 days, patients who had previously undergone a BAV were 10.7 times more likely to stay 5 days or more (CI [1.16, 98.1]) compared with patients who had not undergone a BAV. No other baseline factors were found to be statistically predictive of prolonged LOS, although odds ratios suggest patients with lower

symptom severity (as measured by NYHA class) and prior AVR were less likely to experience a longer LOS.

Patients likely to experience a standard discharge were 75 to 79 years of age, with NYHA class III or IV symptoms, and no prior history of an AVR. Specifically, individuals 75 to 79 years old were 3.12 more likely to stay 3 to 4 days (CI [1.13, 8.62]) compared to patients 75 years or younger. The odds ratio for this LOS tertile decreased with increasing age. Calculating the inverse of the odds ratios reported in Table 9, the findings further demonstrate that relative to having a LOS of 1 to 2 days, patients with NYHA class III or IV symptoms were 2.27 (1/0.44 = 2.27) times more likely to stay 3 to 4 days compared to those with class I or II symptoms, while patients who had not previously undergone an AVR were 3.26 (1/0.31= 3.26) more likely to stay 3 to 4 days than those with an AVR history.

Table 13

Multivariate Logistic Regression Model of Post-TAVI LOS on Baseline Factors

Number of days	Predictors	OR (95% CI)	p-value
3 to 4 ^a	Age ^b		
	75-79 years	3.12 (1.13-8.62)	.03*
	80-87 years	2.20 (0.95-5.09)	.07
	≥ 88 years	1.07 (0.38-3.02)	.90
	NYHA Class I or II ^c	0.44 (0.22-0.89)	.02*
	Prior AVR ^d	0.31 (0.14-0.73)	<.01*
	Prior BAV ^e	3.75 (0.43-32.4)	.23
≥ 5 ^a	Age ^b		
	75-79 years	2.68 (0.73-9.79)	.14
	80-87 years	0.96 (0.29-3.15)	.95
	≥ 88 years	2.81 (1.13-8.62)	.10
	NYHA Class I or II ^c	0.87 (0.37-2.05)	.75

Number of days			
Predictors	OR (95% CI)	<i>p</i> -value	
Prior AVR ^d	0.82 (0.28-2.38)	.71	
Prior BAV ^e	10.7 (1.16 – 98.1)	.04*	

Note: OR = odds ratio; CI = confidence interval

^aReferent = 1 to 2 days

^bReferent = <75 years

^cReferent = NYHA Class III or IV

^dReferent = No prior AVR

^eReferent = No prior BAV

**p* < .05

4.5 The Association Between Patient Characteristics and Wait Time

4.5.1 Bivariate Analysis. A secondary aim of this study was to investigate the research question “*what is the association between patient characteristics and wait time?*” Sex was the only patient characteristic statistically significantly associated with wait time ($X^2 = 5.96, p = 0.02$), with males waiting fewer days. Table 14 shows that 66.7% of male patients waited 42 days or less, compared to 51.5% of females. A multivariate regression analysis was not undertaken given that only one variable was found to be statistically significant.

Table 14

Wait Time (from Acceptance to Procedure) by Patient Demographics

Characteristic	N	Wait Time, days		Statistic	<i>p</i> -value
		≤ 42 N(%)	> 42 N(%)		
Age				$X^2 (3) = 1.82$.61
< 75 years	36	24 (66.7)	12 (33.3)		
75 to 79 years	50	33 (66.0)	17 (34.0)		
80 to 87 years	124	72 (58.1)	52 (41.9)		
≥ 88 years	46	26 (56.5)	20 (19.8)		
Sex				$X^2 (1) = 5.96$.02*
Male	153	102 (66.7)	51 (33.3)		
Female	103	53 (51.5)	50 (48.5)		
Living situation				$X^2 (1) = 2.34$.13
Lives independently	193	107 (55.4)	86 (44.6)		
Lives in facility	10	8 (80.0)	2 (20.0)		

Characteristic	N	Wait Time, <i>days</i>		Statistic	<i>p</i> -value
		≤ 42 N(%)	> 42 N(%)		
Living location				X ² (1) = 2.49	.12
Lower mainland	165	94 (57.0)	71 (43.0)		
Out-of-town	91	61 (67.0)	30 (33.0)		

Table 15

Wait Time (from Acceptance to Procedure) by Patient Baseline Characteristics

Characteristic	N	Wait Time, <i>days</i>		Statistic	<i>p</i> -value
		≤ 42 N(%)	> 42 N(%)		
Renal dysfunction ^a	17	12 (70.6)	5 (29.4)	X ² (1) = 0.77	.38
Severe COPD	15	11 (73.3)	4 (26.7)	X ² (1) = 1.09	.30
NYHA class III or IV	201	126 (62.7)	75 (37.3)	X ² (1) = 1.79	.18
Prior CABG	49	33 (67.3)	16 (32.7)	X ² (1) = 1.17	.28
Prior AVR	36	26 (72.2)	10 (27.8)	X ² (1) = 2.39	.12
Prior BAV	12	7 (58.3)	5 (41.7)	X ² (1) = 0.03	.87
Prior PCI	56	36 (64.3)	20 (35.7)	X ² (1) = 0.42	.52
ADL score < 6	22	15 (68.2)	7 (31.8)	X ² (1) = 1.12	.29
5m walk test ≥ 7 sec	61	39 (63.9)	22 (36.1)	X ² (1) = 2.07	.15
STS Risk Score > 8%	52	31 (59.6)	21 (40.4)	X ² (1) = 0.03	.86

Note: COPD = chronic obstructive pulmonary disease; NYHA = New York Heart Association; CABG = coronary artery bypass grafting; BAV = balloon aortic valvuloplasty; PCI = percutaneous coronary intervention; SAVR = surgical aortic valve replacement; and ADL = activities of daily living; STS = Society of Thoracic Surgeons

^aRenal dysfunction defined as eGFR < 30 ml/min.

**p* < .05

4.6 Summary

This chapter presented descriptive statistics for baseline patient characteristics which included demographic data, comorbidities, prior cardiac history, and functional status. It also reported results of the inferential analyses used to answer both primary and secondary research questions.

The sample was made up of older adults (mean age = 81.4 years), both male (59.5%) and female (40.5%), largely living independently in the Vancouver Lower Mainland. Less than 10% of patients had documented severe COPD, while the mean eGFR was found to be 58.6 ml/min, indicating mild to moderate renal impairment. In examining prior cardiac procedural history, results showed 19.1% of patients had undergone CABG, 22.2% had undergone PCI, 14.4% had undergone SAVR, and 4.7% had undergone BAV. Although three-quarters of patients reported NYHA class III or IV symptoms, the group functioned reasonably well in terms of ADLs (mean = 5.9) and 5-metre gait speed (mean = 6.4 seconds). The overall predicted surgical risk prior to TAVI was low (mean STS risk score = 6.0%).

The mean and median wait time from acceptance to procedure (i.e., wait time 2) was 39.8 days and 36 days, respectively. The continuous LOS distribution was positively skewed (mean = 3.7 days, median = 3.0 days), with a range of 1 to 86 days. A weighted average analysis showed that 25% of patients stayed less than 3 days, while 95% stayed less than 9 days.

To evaluate the relationship between baseline factors and LOS, a bivariate analysis was conducted. Age, living situation, prior AVR, and prior BAV were all found to be statistically significantly associated with post-TAVI stay in-hospital. NYHA class came close to statistical significance ($p = 0.048$) and was later included in the multivariate analysis. Wait time was not associated with LOS. Due to homogeneity seen in the sample and a high percentage of missing data (20.6%), living situation was excluded from the final model.

The multivariate regression analysis showed that patients who had previously undergone a BAV were 10.7 times more likely to experience a prolonged post-procedure LOS (i.e., 5 days or more) than those with no such history. Although not statistically significant, odds ratios suggest patients with lower symptom severity (i.e., NYHA class I or II) and prior AVR were less

likely to experience a longer LOS. In examining standard discharges the analysis demonstrated that patients 75 to 79 years of age, with NYHA class III or IV symptoms, and no prior history of an AVR were most likely to stay 3 to 4 days. The final model met both multi-collinearity and goodness-of-fit requirements, and statistically significantly predicted LOS better than an intercept-only model ($X^2 = 39.2$, $df = 12$, $p < 0.001$).

Finally, an analysis of the association between patient characteristics and wait time showed only sex to be statistically significant. Specifically, males were more likely than females to wait less than 42 days between acceptance to procedure.

Chapter 5: Discussion

The purpose of this study was to explore factors associated with recovery following transfemoral transcatheter aortic valve implantation (TAVI), as measured by hospital length of stay (LOS). Using a retrospective chart review, the study aimed to describe the patient population, and distributions for both wait time and post-procedure LOS. Inferential analyses were also undertaken to investigate the relationships between patient characteristics and wait time, as well as baseline factors and LOS. In the sections to follow, key findings are summarized and compared with results reported in published literature. Methodological limitations are then appraised. The chapter concludes with implications for nursing practice, policy, and finally, future research.

5.1 Overview of Findings

This study showed that age, New York Heart Association (NYHA) functional classification, prior balloon aortic valvuloplasty (BAV), and prior surgical aortic valve replacement (SAVR) were statistically significantly associated with post-TAVI LOS. Early discharge, defined as a LOS of 1 to 2 days, was associated with age (75 years or younger) and prior SAVR; while, delayed discharge, a LOS of 5 days or more, was associated with prior BAV, and NYHA class III or IV symptoms.

In examining the relationship between patient characteristics and wait time, a bivariate analysis revealed sex as the only baseline characteristic associated with wait time, with more males (than females) waiting 42 days or less. Such findings suggest there may be other factors (e.g., scheduling and availability of pre-assessment diagnostics) – not investigated within the scope of this study – impacting wait time. In section 5.2.5, patient and operational variables potentially associated with TAVI wait time are further explored.

Overall, results point to two distinct patient populations of interest: 1) individuals with advanced heart disease (i.e., NYHA class III/IV and prior BAV) who are more likely to experience a prolonged recovery and 2) individuals who previously underwent SAVR before undergoing TAVI (i.e., valve-in-valve) who are more likely to experience a short recovery. In section 5.2.4, both patient groups are discussed in detail.

5.2 Findings in Relation to the Literature

5.2.1 Patient Demographics and Clinical Characteristics. The purpose of comparing samples is to provide context around the extent to which a particular study's findings can be generalized. Table 16 provides a comparison between the demographics and clinical characteristics of this study's sample and those reported by: i) the Society of Thoracic Surgeons (STS)/American College of Cardiology (ACC) Transcatheter Valve Therapy (TVT) Registry report (Holmes et al., 2015) and ii) a multi-centre Canadian study (Rodes-Cabau et al., 2010).

The STS/ACC registry was developed as an objective and scientifically-based resource to improve patient care, monitor device safety, and act as an analytic resource for research. Its database represents 348 American centres and 26,378 transfemoral (TF) and transapical (TA) TAVI patient records taken between January 2012 and December 2014. In contrast, Rodes-Cabau et al. (2010) provide a Canadian perspective. Although dated (reflecting use of older devices and indications), their data draws on 6 centres and 339 TF- and TA- TAVI patient records taken between January 2005 and January 2009.

Table 16

Sample Patient Demographics and Baseline Characteristics in Relation to the STS/ACC TVT Registry (Holmes et al., 2015) and a Multi-Centre Canadian Experience (Rodes-Cabau et al., 2010)

	Study Sample (<i>n</i> = 257)	STS/ACC TVT Registry (<i>n</i> = 26,378)	Multi- centre Canadian Experience (<i>n</i> = 339)
Demographics			
Age, years (mean)	81.4	82	81
Sex, male (%)	59.5	50.5	44.8
Clinical Characteristics			
COPD (%)	15	not reported	29.5
NYHA class III or IV (%)	78.6	not reported	90.9
Prior CABG (%)	19.1	31.4	34.2
Prior SAVR (%)	14.4	2.2	not reported
Prior BAV (%)	4.7	13.8	not reported
Prior PCI (%)	22.2	35.6	29.2
STS Risk Score (median)	6.0	6.1	9.8

Abbreviations: COPD = chronic obstructive pulmonary disease; NYHA = New York Heart Association; CABG = coronary artery bypass grafting; BAV = balloon aortic valvuloplasty; PCI = percutaneous coronary intervention; SAVR = surgical aortic valve replacement; STS = Society of Thoracic Surgeons.

Patient demographics were comparable across studies, with a mean age of approximately 81 years and nearly equal ratios of males to females. Of note, studies differed in clinical characteristics reported, possibly due to differences in study objectives, quality of pre-TAVI data, approaches to data collection, and unique practice and treatment preferences. For example, in the United States, TAVI patients must be deemed inoperable; whereas, in British Columbia, lower risk patients are accepted.

Of the clinical characteristics available, this sample had a higher percentage of prior SAVR cases and a slightly lower percentage of patients with COPD, NYHA class III or IV symptoms, prior CABG, prior BAV, and prior PCI. STS risk scores were comparable to scores documented in the STS/ACC TVT registry but were notably lower than scores reported by the multi-centre Canadian study. The Canadian scores may be partially attributable to the 5-year lag

between research dates, to the well documented failure of STS score to capture the risk for TAVI, and to data quality. In general, this study's sample was demographically comparable to past American and Canadian TAVI reports, with a slightly lower prevalence of prior cardiac procedures and comorbid illness.

5.2.2 Wait Time. A review of the literature revealed a paucity of publications on the topic of TAVI wait time despite the need for evidence-based benchmarks. As some clinicians have asserted, patient safety and effective program planning rely on the development of such wait time standards (Lauck et al., 2014). Particularly in cardiac surgical patients, prolonged wait times can result in a significant decrease in physical and social functioning, in addition to an increased risk of postoperative adverse events (Sampalis et al., 2001; Sobolov et al., 2008). To date, establishing TAVI wait time benchmarks has been challenging due to quickly evolving procedural indications, risk stratification, procedural techniques, and peri-procedural care processes (Lauck et al., 2014).

A search for publications yielded two studies that specifically explored time spent waiting for TAVI. In Wijenysundra and colleagues' discrete event simulation model (2014), the hypothetical effectiveness of TAVI was explored using 7 wait time scenarios. The model yielded a 27% difference in wait-time mortality when a wait of 180 days was compared to 10 days in inoperable patients and a 22.2% difference in wait-time mortality, using the same scenarios, in high-risk patients. While the projections point to the potentially detrimental effects of long wait times, overall findings are difficult to interpret. Looking to their methodology, the authors failed to capture the full trajectory of time spent waiting for TAVI (i.e., from referral to procedure date) and furthermore, used dated outcomes associated with first-generation devices and higher-risk patients.

In Forman et al.'s (2014) study, changes in functional status between the time of eligibility assessment and TAVI procedure date (i.e., wait time 2) were examined. Findings showed a statistically significant decline in functional status between the time of assessment and procedure and also found that patients who waited longer than 42 days for TAVI experienced a greater decline in gait speed. Of interest, patients waited 69 days from the time of their assessment until the time of TAVI ($SD = 62$, median = 55, range = 13 to 307), a total of 29.2 days longer than the average wait time 2 observed in this study (mean = 39.8 days, $SD = 32.2$, median = 36, range = 0 to 176). Wait time differences may have been due to varying wait times recorded in BC, discrepancies in sample size and data collection dates. With nearly two years between studies, it may be that with experience and advances in pre-TAVI care practices (e.g., risk stratification, urgency ratings, appointment scheduling, etc.), TAVI centres have been able to decrease time spent waiting for the procedure.

With limited research on the subject, this study contributes much needed data, capturing the complete course of TAVI wait time from referral to acceptance (i.e., wait time 1) and from acceptance to procedure (i.e., wait time 2). In the absence of benchmarks, the only point of comparison is the current cut-off of 42 days (between referral and acceptance), used by Cardiac Services BC for Priority II patients with severe AS awaiting SAVR (Personal communication – S. Lauck). With a median time 2 of 36 days, the study's sample waited below cut-off, suggesting that once accepted for TAVI, programs accomplished reasonably efficient procedure planning, risk stratification, and urgency evaluation.

With respect to the time between referral and acceptance (i.e., wait time 1), there were no TAVI standards or studies in which to compare results from this research (i.e., a median wait time 1 of 41 days). It is important to note that wait time 1 is a crucial measure as it encompasses

eligibility assessment, which can be highly variable within and between patients and cardiac centres. From scheduling specialty consultations to staging diagnostic tests and finally, landing on a multi-disciplinary consensus decision (Webb et al., 2012), time under assessment can significantly contribute to overall time spent waiting for the procedure (Lauck et al., 2014). Ultimately, more research is required to better understand the current state of TAVI wait time in its full trajectory. In Section 5.2.5, wait time outliers (as reported in chapter 4) are explored and potential factors associated with wait time are further discussed.

5.2.3 Length of Stay. Prolonged LOS, defined as 5 or more in-hospital (Lauck et al., 2014), can have serious implications for post-procedural outcomes, particularly in geriatric cardiac patients. Studies have shown that elderly individuals – those 80 years and older – are at significantly higher risk of experiencing adverse events in-hospital, compared to their clinically similar, younger counterparts (Covinsky et al., 2003; Thomas & Brennan, 2000). That is, older adults tend to experience more in-hospital complications due to age-associated accelerated muscle loss with inactivity (Oliver et al., 2004), decreased pulmonary ventilation (Creditor, 1993), malnutrition (Kagansky et al., 2005), and susceptibility to nosocomial infections (Rothschild et al., 2000). Furthermore, studies show that once complications occur and hospitalization is extended, geriatric patients are at particularly high risk for adverse long-term outcomes including major morbidity, mortality, readmission, and institutionalization (Hein et al., 2006).

At present, the STS/ACC TVT registry (Holmes et al., 2015) provides a reasonably recent and comprehensive report in which to compare TAVI LOS data. The authors document mean LOS in 2012, 2013, and 2014 as 6.3 days, 7.2 days, and 6.2 days, respectively. In comparison, this study found a mean LOS of 3.7 days (median = 3.0 days, range = 1 to 86 days,

skewness = 1.81), with 75% of patients staying less than 5 days and 95% of patients staying less than 9 days. A number of patient, procedural, and hospital-specific factors could account for the shorter LOS observed. Firstly, as described in Table 16, samples differed in pre-TAVI clinical status in terms of comorbidities, prior cardiac histories, symptom severity, and TAVI route (i.e., TF and TA). Secondly, patient groups may have experienced vastly different peri-procedural complications (e.g., stroke, atrial fibrillation, major bleed, etc.), as well as post-procedural outcomes (e.g., infection, time spent in critical care, need for permanent pacemaker implantation, etc.). Finally, care practices may have varied across programs and jurisdictions. Use of newer devices and smaller profile delivery catheters, clinical pathways, moderate procedural sedation, cardiac catheterization laboratory environments (versus operating rooms), and earlier post-procedure ambulation – although not captured within the scope of this research – may have also impacted time spent recovering in-hospital.

5.2.4 Factors Associated with Length of Stay.

5.2.4.1 Demographics. Of the demographic variables analyzed, age was found to be statistically significantly associated with LOS. That is, patients younger than 75 years were most likely to experience an early post-TAVI discharge (i.e., LOS of 1 to 2 days). The multivariate logistic regression also showed that individuals only slightly older – in the 75 to 79-year age bracket – were 3.12 times more likely to stay 3 to 4 days (CI [1.13, 8.62]).

The impact of age on LOS is well documented in cardiac surgical literature. In a study of 3,605 CABG patients, Rosen et al. (1999) found age to be a significant predictor of post-operative LOS, with patients 80 years old staying 1.35 days longer in hospital than their counterparts who were 70. In a study investigating determinants of hospital recovery after left ventricular assist device (LVAD) implantation, authors identified old age (i.e., 80 years or older)

as a significant predictor of post-surgical days spent in-hospital (Cotts et al., 2014). Many more studies have highlighted this relationship (Atoui et al., 2008; Azarfarin et al., 2014; Lee et al., 2010; Ng et al., 2004); however, from a clinical perspective, it may be worth noting that statistically significant mean differences between age groups often amount to an approximately 1-day discrepancy in LOS following cardiac surgery.

Researchers and clinicians are also beginning to draw attention to overall improvement in post-procedural outcomes in the elderly with advances in patient selection and risk stratification. In a large clinical study evaluating cardiac surgical outcomes in octogenarians, Alexander et al. (2000) found that while the relationship between age and post-CABG mortality appeared to be nearly linear, the gap between mortality in the young and old was significantly smaller than reported in earlier studies. Compared to post-CABG mortality estimates ranging from 11.5% to 24%, their sample of 67,764 patients (4,743 octogenarians) had a significantly lower mortality rate (8.1%). The authors attributed their findings to differences in pre-operative clinical status, with their sample having fewer comorbid illnesses. They concluded that in selected octogenarians without significant comorbidity, mortality approached that seen in younger patients. More recently, Lauck et al. (2014) explored the safety and feasibility of pre-procedural risk stratification for: 1) general anesthesia and transesophageal echocardiography (GA/TEE) versus awake TAVI and 2) post-procedural standard versus rapid discharge clinical pathways. The authors found a shorter median LOS (2 days) to be associated with awake TAVI and rapid pathway groups, while a longer LOS (median = 3 days) was associated with the GA/TEE and standard pathway groups. These findings support the notion that pre-TAVI risk stratification may significantly reduce in-hospital recovery in elderly, cardiac individuals.

5.2.4.2 Clinical Characteristics. Of the clinical characteristics analyzed, prior AVR, prior BAV, and NYHA class III/IV were found to be statistically significantly associated with post-TAVI in-hospital recovery; with prior AVR being associated with a LOS of 1 to 2 days, and prior BAV and NYHA class III/IV being associated with a LOS of 5 days or more. As previously described, these findings point to two distinct patient populations of interest: 1) valve-in-valve (VIV) patients (i.e., patients who underwent SAVR prior to TAVI) who are more likely to experience an early discharge, and 2) patients with advanced heart disease (i.e., BAV patients bridging to TAVI and patients with high symptom severity) who are more likely to experience a prolonged discharge.

The term ‘transcatheter aortic VIV implantation’ refers to an emerging therapeutic alternative to reoperation in patients with a failed surgical bioprosthetic aortic valve (Webb & Dvir, 2013). In general, bioprosthetic valves are favoured, and increasingly used, over mechanical valves in patients with severe AS because of a lower risk of thromboembolic events and the ability to avoid long-term anticoagulation (Jones et al., 2001; Maganti, Armstrong, Feindel, Scully, & David, 2008). However, bioprostheses have limited durability, with most projected to degenerate and eventually fail within 10 to 20 years (David, Ivanov, Armstrong, Feindel, & Cohen, 2001; Gao, Wu, Grunkemeier, Furnary, & Starr; 2004).

Transcatheter aortic VIV implantation is becoming a viable treatment option to replace bioprosthetic valves, particularly as repeat SAVR poses a high risk of significant morbidity and mortality in elderly patients with multiple comorbidities (Jones et al., 2001; Maganti et al., 2008). Over the last five years, numerous studies have demonstrated the safety and feasibility of the VIV approach (Bedogni et al., 2011; Linke et al., 2012; Webb et al., 2010), with results from the global VIV registry (n = 202, including 38 cardiac centres in Europe, North America, New

Zealand, and the Middle East) showing procedural success in 93.1% of cases and a 1-year survival rate of 83.2% (Dvir et al., 2012).

As the VIV approach is relatively novel, the findings from this study contribute to our understanding of short-term outcomes. Of the 37 patients who underwent VIV, 83.8% stayed 4 days or less. Moreover, compared to 35% of the non-AVR group, 56.8% of the VIV cohort were discharged early ($p = 0.03$). The multivariate regression analysis also showed that patients with no AVR history were 3.26 times more likely to stay 3 to 4 days than those who had undergone VIV ($p < 0.01$).

Compared to past reports, these findings represent a reduction in post-VIV LOS. In the global VIV registry (Dvir et al., 2012) and Webb et al.'s (2010) multi-centre study, patients stayed in-hospital for a median of 8 days post-procedure, with an interquartile range of 5 to 12 days and 4 to 12 days, respectively. The shortened LOS observed in this study may once again be attributable to differences in baseline characteristics (e.g., mechanism of surgical bioprosthetic valve failure, comorbidity burden, etc.), intra-procedural events, and post-procedural outcomes. It is also likely that clinical experience and advances in peri-procedural care may have reduced post-VIV complications (e.g., post-procedural stroke, need for pacemaker implantation, etc.) and improved short-term outcomes, giving way to a reduction in LOS. Further research into factors associated with LOS in VIV patients will help to validate current findings; though, these results suggest favourable short-term outcomes.

In addition to the VIV group, this study identified patients with advanced heart disease as a group of interest. That is, inferential analyses showed that patients with NYHA III or IV class symptoms and patients who had previously undergone BAV were more likely to experience

a prolonged post-TAVI stay in-hospital. Of note, patients with a prior BAV were 10.7 times more likely to stay 5 days or more, compared to individuals with no such history.

BAV has been utilized as a bridge to TAVI in patients who are not immediately suitable for the procedure due to illness severity or uncertainty of treatment utility (Nishimura et al., 2014). Specific indications include hemodynamic instability, poor left ventricular ejection fraction, severe mitral regurgitation, and malignancy (Nwaejike, Mills, Stables, & Field, 2015). Although studies have shown that BAV can result in immediate improvements in left ventricular systolic pressure, aortic valve area, mean gradient pressure, and NYHA class (Kefer et al., 2013), long-term outcomes of BAV alone (i.e., not followed by TAVI or SAVR) are poor. In a sample of 262 patients, Ben-Dor et al. (2010) found serious adverse events in 15.6% of patients and a 50% mortality rate at 181-day follow-up.

In studies comparing BAV alone to BAV followed by SAVR or TAVI, results consistently yield higher long-term survival rates in the latter group (Ben-Dor et al., 2013; Eltchaninoff et al., 2014; Saia et al., 2011). This evidence suggests that BAV is a temporizing intervention with poor long-term outcomes in the absence of subsequent treatment (Eltchaninoff et al., 2014). That is, BAV can be viewed as an acceptable bridge to TAVI in very high risk patients not immediately appropriate for definitive therapy (Ussia et al., 2010).

A review of the literature yielded one sub-study investigating differences between BAV and non-BAV patients who underwent TAVI. Using PARTNER trial data, Doshi et al. (2014) evaluated the patient characteristics and outcomes of both cohorts. Researchers found that prior BAV patients tended to be older, with higher STS risk scores, greater prevalence of pulmonary hypertension, and higher rates of NYHA III and IV symptoms (Doshi et al., 2014). Although there were no differences in all-cause mortality at 30-days post-procedure (6.5% with BAV

versus 6.1% without BAV, $p = 0.73$), there were significantly greater deaths in the prior BAV group at 1- year follow-up (21% versus 17%, $p = 0.03$). Although the authors did not investigate differences in LOS, their results generally support findings from this study. With BAV patients tending to be older and symptomatically more ill, with poorer long-term prognoses, it logically follows that compared to non-BAV patients, this cohort would be more likely to experience a longer recovery in-hospital. Ultimately, more research is required to better understand the short-term outcomes of BAV patients undergoing TAVI. It would be especially valuable to investigate the factors contributing to prolonged LOS, thereby informing risk stratification and peri-procedural care planning in this particular patient population.

5.2.5 Factors Associated with Wait time. With a positively skewed distribution, and a total wait time ranging from 1 to 735 days, many patients in this study waited longer than the median of 85 days. As shown in the weighted average analysis (see Table 7), it required 180.2 total wait time days to capture 75% of the entire sample. Interestingly, inferential analyses found sex to be the only baseline characteristic associated with time spent waiting for TAVI, with more men than women waiting less than 42 days from the time of acceptance to procedure ($p = 0.02$).

A few studies have investigated the relationship between sex and cardiac surgical wait times, and have largely demonstrated that, contrary to the above findings, sex differences do not exist. In an analysis of 2,102 patients awaiting CABG, AVR, or CABG plus AVR, sex was not associated with prolonged wait time but was predictive of urgent surgical status (Ray, Buth, Sullivan, Johnstone, & Hirsch, 2001). Similarly, Levy et al. (2007) found that after adjusting for priority ratings, male and female CABG wait times were statistically comparable. It is likely that while sex was found to be associated with TAVI wait times in this study, there may have been covariates – such as urgency and priority status – mediating this relationship.

The literature suggests there may indeed be other factors, not investigated within the scope of this research, impacting wait time. These factors can be broadly categorized as patient and operational characteristics. In terms of patient characteristics, access literature asserts that the size of a population, their distribution, and need for treatment can affect the level of services available. That is, population demand can shape access to services, which can ultimately impact time spent waiting for a procedure (Sobolev, Levy, Hayden, & Kuramoto, 2005). Furthermore, personal choices (e.g., willingness to travel to attend repeated appointments) and one's ability to navigate the hospital system can significantly delay time under procedural eligibility assessment (Lauck et al., 2014).

From an operational perspective, wait times can also be affected by physician and hospital factors. The number of available specialists, as well as their respective workload patterns (e.g., proportion of time in surgery versus time providing outpatient consultations) can significantly affect procedural capacity (i.e., the number of total procedures performed in a day) (Hwang & Karimuddin, 2013). Moreover, the number of beds, operating rooms, and staff (e.g., nurses, anesthesiologists, etc.), and the manner in which these resources are organized, can shape service distribution (Tyler, Pasquariello, & Chen, 2003). For example, increasing resources for cardiac surgery may mean reducing resources for renal care. Likewise, increasing emergency cases may result in reduced elective procedures. Specific to TAVI, hospital scheduling of diagnostic tests and specialist appointments can directly impact wait time, which can be further compounded by site-specific practice standards (e.g., routine use of transesophageal echocardiography) (Lauck et al. 2014). From a review of the literature, it is clear that further research is required to better understand the effect of patient and operational variables on time spent waiting for TAVI.

5.3 Limitations

This study faced a number of important limitations which included sampling, variable selection, study design, and analysis. As this research drew on one site, it was limited in its depth of sampling, possibility for subgroup analyses, and generation of generalizable results (Polit & Beck, 2011). A multi-site approach would have likely yielded a sample more diverse in demographic and clinical characteristics and furthermore, allowed for an analysis of the relationship between hospital-specific factors and study outcomes. Additionally, the explanatory variables selected (i.e., patient demographics and clinical characteristics) did not allow for an investigation of: 1) the relationship between peri-procedural events (e.g., need for temporary pacemaker, compromised airway status, etc.), post-procedural outcomes (e.g., major bleed, stroke, etc.), and LOS; or 2) the association between operational factors (e.g., physician availability, diagnostic scheduling, operating room utilization, etc.) and wait time.

While a retrospective chart review provided rich and accessible data, there were many shortcomings inherent to its design, including: unrecorded data, problematic verification of information, and variance in quality of information recorded (Polit & Beck, 2011). In an effort to address the listed concerns, several measures were taken to reduce issues with data quality. Study and outcome variables were selected based on information on current TAVI records and data collection forms were created to follow a logical order paralleling the flow of information in hospital documents.

Finally, as with all regression techniques, the interpretation of findings was limited to identifying the relationship between variables, without ascertaining an underlying causal mechanism. That is, while the results identified particular factors to be statistically significantly

associated with wait time and LOS, it could not be confirmed that specific variables caused an increase (or decrease) in outcome.

5.4 Implications

Per a review of the literature, it appears as though an investigation of factors associated with TAVI wait time and LOS has not been extensively undertaken. The findings from this study offer important insights into nursing practice, policy, and future research.

5.4.1 Nursing Practice. At present, peri-operative care standards for TAVI patients are lacking, due in part to the scarcity of reliable evidence informing the development of such standards. Specifically, few cardiac sites have established TAVI pathways or risk-stratified care management (RSCM) strategies. Given the need for clinical data, this study is timely and well-situated to provide recommendations.

Understanding that there are significant patient differences in post-TAVI short-term recovery, clinicians should consider RSCM, whereby patients are pre-assessed and assigned a risk status that is used to guide in-hospital care and ultimately, optimize LOS. Based on this study's findings, pre-procedure evaluation ought to include assessment of age, NYHA functional class, and prior history of BAV and SAVR. Higher-risk features include old age (i.e., greater or equal to 75 years), NYHA class III or IV symptoms, and a history of BAV; while, lower-risk features include younger age (i.e., less than 75 years), NYHA class I or II symptoms, and a history of SAVR. Logically, lower risk patients might be considered for an early discharge pathway (EDC), while higher risk patients might be considered for a standard discharge pathway (SDC).

Therapeutic approaches would likely be different for various arms of the pathway and would need to be informed by best evidence. Lauck et al. (2015) have demonstrated that peri-

procedure practices associated with EDC include local anesthesia, selection of a balloon expandable device, post-procedure removal of a temporary pacemaker, and avoidance of a urinary catheter; while SDC is associated with a new pacemaker and need for a blood transfusion. Moving forward, it is imperative to further refine pre-TAVI risk stratification and continue to explore safe care practices and LOS best-suited for patients of different risk statuses. Nurses should also look to provide patient education related to expected course of recovery in-hospital based on pre-procedure assessments and risk designations. With an estimate of LOS, nurses can also facilitate early discharge planning by ensuring functional needs are met, providing education to family members and care givers, reviewing home medications, and coordinating follow-up appointments (Fox et al., 2013).

5.4.2 Policy. This study also highlighted the need to establish evidence-based wait time benchmarks for TAVI, including standards around the time between referral and assessment (i.e., wait time 1, capturing diagnostic testing, eligibility assessment, etc.) and the time between acceptance and procedure (i.e., wait time 2, capturing procedure planning, urgency evaluation, etc.). Setting benchmarks will help gauge and support equitable and timely access to care, improve resource organization and distribution, and inform risk stratification, priority ratings, and urgency status (Lauck et al., 2014). On a program level, benchmarks can also be used to plan health services, evaluate and improve efficiencies related to scheduling and availability of pre-procedure diagnostic tests, specialist appointments, and multi-disciplinary team decision-making.

5.4.3 Future Research. There are substantial opportunities to build on findings from this study through further research. As previously described, expanding this analysis to include pre-procedure patient characteristics, peri-procedural events, and post-procedural outcomes would provide a more holistic view of the factors associated with TAVI LOS. Designing a multi-centre

study would also allow for a comparison between sites, making it possible to examine the impact of hospital characteristics (e.g., resource distribution, service availability, practice standards, etc.) on both outcome variables, LOS and wait time. Specifically investigating the impact of patients' geographical proximity to specialized centres would also contribute to our understanding of the impact of access on TAVI care (e.g., ability to attend pre-TAVI assessments and facilitating transfers home).

Future studies could also look at evaluating complications and outcomes associated with prolonged TAVI wait times and recovery in-hospital. Findings emerging from such research would help guide the development of wait time benchmarks, as well as inform approaches to risk stratification and individualized care planning. It would also be valuable to further investigate the course of recovery in patients who have previously undergone SAVR and BAV to validate – or perhaps, discredit – current findings and to better understand the unique care needs of these two emerging TAVI patient groups.

Another logical line of inquiry would be to study the association between hospital LOS and long-term TAVI patient outcomes including, but not limited to, quality of life, functional status, rates of readmission, major morbidity, and mortality. Understanding the extent to which hospital recovery, as measured by LOS, affects long-term outcomes could guide inpatient care and follow-up practices (e.g., specialist appointments and diagnostic testing) once patients are discharged.

5.5 Conclusion

The objective of this research was to explore factors associated with wait time and post-TAVI LOS. Using a retrospective chart review, this study found patients younger than 75 years and those who had previously undergone SAVR were more likely to experience a LOS of 1 to 2

days; whereas patients with NYHA class III/IV symptoms or had previously undergone BAV were more likely to experience a standard (3 to 4 days) or prolonged LOS (5 or more days).

While sex was found to be associated with wait time, this finding was inconsistent with current literature which suggests there may be confounding factors, such as priority rating and urgency status, mediating this relationship.

Although this study encountered limitations with respect to sampling, selection of study variables, study design, and analyses, its overall findings contribute to the limited evidence available on TAVI wait time and LOS. Recognizing there are significant patient differences in post-TAVI recovery, nursing practices aimed at risk-stratified care management ought to be adopted. Where it is possible to estimate risk and LOS, nurses might also educate patients around expected course of in-hospital recovery, as well as facilitate early discharge planning. These findings also highlight the need to establish evidence-based wait time benchmarks for the purposes of monitoring access and resource allocation. Finally, future research could focus on investigating pre-procedural patient characteristics, peri-procedural events, and post-procedural outcomes to develop a more complete understanding of the factors associated with TAVI LOS.

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Appendix A

 <p>TRANSCATHETER HEART VALVE REFERRAL TRIAGE FUNCTIONAL ASSESSMENT</p> <p>Date: _____</p>	
<p>Indication for physician referral:</p> <p>What do you hope to gain from having a special valve procedure?</p>	
<p>Clinical Frailty: _____/9 as per CSHA Frailty Scale</p>	
<p>Instrumental Activities of Daily Living:</p> <p>Independent:</p> <ul style="list-style-type: none"> • Ability to use telephone: <input type="checkbox"/> Yes <input type="checkbox"/> No • Shopping: <input type="checkbox"/> Yes <input type="checkbox"/> No • Food Preparation: <input type="checkbox"/> Yes <input type="checkbox"/> No • Housekeeping: <input type="checkbox"/> Yes <input type="checkbox"/> No • Laundry: <input type="checkbox"/> Yes <input type="checkbox"/> No • Transportation: <input type="checkbox"/> Yes <input type="checkbox"/> No • Medications: <input type="checkbox"/> Yes <input type="checkbox"/> No • Finances: <input type="checkbox"/> Yes <input type="checkbox"/> No <p>Total score: _____/8 as per Lawton-Brody Scale</p>	<p>Activities of Daily Living:</p> <p>Independent:</p> <ul style="list-style-type: none"> • Bathing: <input type="checkbox"/> Yes <input type="checkbox"/> No • Dressing: <input type="checkbox"/> Yes <input type="checkbox"/> No • Toileting: <input type="checkbox"/> Yes <input type="checkbox"/> No • Transferring: <input type="checkbox"/> Yes <input type="checkbox"/> No • Continence: <input type="checkbox"/> Yes <input type="checkbox"/> No • Feeding: <input type="checkbox"/> Yes <input type="checkbox"/> No <p>Total score: _____/6 as per Katz Index</p>
<p>Home Environment</p> <p>Independent: <input type="checkbox"/> Apartment <input type="checkbox"/> House</p> <p style="padding-left: 20px;"><input type="checkbox"/> Stairs: # _____</p> <p>Facility: <input type="checkbox"/> Assisted Living <input type="checkbox"/> Residential Care</p>	<p>Living Situation</p> <p><input type="checkbox"/> Lives alone</p> <p><input type="checkbox"/> Lives with spouse</p> <p><input type="checkbox"/> Lives with adult child or other relative</p>
<p>Home Supports</p> <p><input type="checkbox"/> No caregiver/home supports required</p> <p><input type="checkbox"/> Part time caregiver/home supports (Either at home or care facility)</p> <p><input type="checkbox"/> Full time caregiver/home supports (Either at home or care facility)</p> <p><input type="checkbox"/> Patient is a caregiver to family member</p>	<p>Mobility Aids:</p> <p><input type="checkbox"/> None</p> <p><input type="checkbox"/> Cane or Walker</p> <p><input type="checkbox"/> Wheelchair</p>
<p>Falls: Fall within the last 6 months: <input type="checkbox"/> No <input type="checkbox"/> Yes:</p>	
<p>5-Metre Gait Speed Test</p> <p>> Position the patient with his/her feet behind and just touching the 0-metre start line</p> <p>> Instruct to "Walk at your comfortable pace" until a few steps past the 5-metre mark (should not start to slow down before)</p> <p>> Begin each trial on the word "Go"</p> <p>> Start the timer with the (first foot/feet) after the 0-metre line</p> <p>> Stop the timer with the (first foot/feet) after the 5-metre line</p> <p style="text-align: right;">Trial 1: _____ sec</p> <p style="text-align: right;">Trial 2: _____ sec</p> <p style="text-align: right;">Trial 3: _____ sec</p> <p style="text-align: right;"><i>Repeat 3 times, allowing sufficient time for recuperation between trials (1 decimal point)</i></p>	
<p>Cognition – Clock test (drawing space provided on page 2)</p> <p><input type="checkbox"/> Complete: Shape, numbers, hands, time</p> <p><input type="checkbox"/> Unable to complete: Any of the above missing</p>	<p>Cognition – MMSE (assess using form PHC-EL010)</p> <p>_____ /30 assessment diagrams on reverse</p>
<p>Assessment conducted by:</p> <p>Printed name: _____ RN Signature: _____</p>	
 <p style="font-size: small;">Form No. HH103 (R. Jan 4-12) Page 1 of 3</p>	

Appendix B



STUDY TITLE:

An Exploratory Analysis of Factors Associated with Length of Stay
Following Transcatheter Aortic Valve Implantation

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TAVI Patient Characteristics, Wait Time, and Length of Stay

y	m	d
Study ID#:		
MRN:		

PART 1: PATIENT AND CLINICAL CHARACTERISTICS		
From TAVI Triage Assessment		
P. 1.	Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female
P. 2.	Age	___ years
P. 3.	Living Situation	<input type="checkbox"/> Lives alone <input type="checkbox"/> Lives with spouse <input type="checkbox"/> Lives with adult child or relative
P. 4.	Living Location	City: _____
C. 1.	Comorbidities	GFR: ___ml/min Severe COPD: <input type="checkbox"/> Yes <input type="checkbox"/> No
C. 2.	Symptom Severity	NYHA Class: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV
C.3.	Prior Cardiac Procedures	Prior cardiac interventions (check all that apply): <input type="checkbox"/> CABG <input type="checkbox"/> AVR <input type="checkbox"/> BAV <input type="checkbox"/> PCI
F. 1.	Functional Status	ADL score: ___/6 5 metre gait speed: ___ m/s
S.1.	Surgical Risk	STS PROMM score: ___

PART 2: WAIT TIME
From Sunrise Clinical Manager (SCM)

W. 1.	Wait time	Wait time 1 (referral to acceptance): ___ days Wait time 2 (acceptance to procedure): ___ days
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PART 4: LENGTH OF STAY

From Discharge Summary

L. 1.	Length of Stay	Total LOS: ___ days
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Appendix C

Code Manual

<p>Sample: Patients 60 years and older, with severe aortic stenosis, and who have successfully undergone a transfemoral TAVI procedure between April 2012 and April 2014.</p> <p>Setting: St. Paul's Hospital (Vancouver, BC).</p>			
#	Variable Name	Variable Definition	Code
CHART INFORMATION			
1	STUDY ID #	Number assigned to each patient chart, recorded as 000-999.	
DEMOGRAPHICS			
2	Gender	Patient's gender	1 = Male 2 = Female
3	Age	Patient's age on admission for TAVI	
4	Living Situation	Description of patient's current living conditions.	1 = Lives alone 2 = Lives with other adult
5	Living Location	Distance between place of primary residence and hospital.	1 = < 100 km (Vancouver lower mainland) 2 = ≥ 100 km (out-of-town)
CLINICAL CHARACTERISTICS			
Comorbidities, symptom severity, prior cardiac procedures, functional status, and surgical risk.			
6	Renal Dysfunction	Glomerular filtration rate (GFR), an indicator of renal function. Specifically, an estimate of the amount of blood passing through the glomeruli each minute, measured in ml/min.	1 = <30 ml/min 2 = ≥ 30 ml/min
7	Severe COPD	Prior history of severe chronic obstructive pulmonary disease (COPD).	1 = Yes 2 = No
8	NYHA Class	<p>Description of patient's activity limitations and severity of symptoms, per the New York Heart Association (NYHA) classification system.</p> <p>Class I (Normal): Patients with cardiac disease but resulting in no limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or angina pain.</p> <p>Class II (Mild): Patients with cardiac disease resulting in slight limitation of physical activity. Ordinary physical activity results in fatigue, palpitation, dyspnea or angina pain.</p> <p>Class III (Moderate): Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or</p>	1 = Class I or II 2 = Class III or IV

		<p>angina pain.</p> <p>Class IV (Severe): Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms may be present even while at rest.</p>	
9	Prior CABG	Prior history of coronary artery bypass graft (CABG) surgery.	1 = Yes 2 = No
10	Prior AVR	Prior history of aortic valve replacement (AVR) surgery.	1 = Yes 2 = No
11	Prior BAV	Prior history of balloon aortic valvuloplasty (BAV) surgery.	1 = Yes 2 = No
12	Prior PCI	Prior history of percutaneous coronary intervention (PCI).	1 = Yes 2 = No
13	ADL Score	Score on the Katz Index of Independence in Activities of Daily Living (ADL) scale, a tool used to assess a patient's ability to perform ADLs independently in six domains: bathing, dressing, toileting, transferring, continence, and feeding. Each item corresponds to a 'Yes' or 'No' response, indicating independence or dependence respectively. 'Yes' responses receive a score of 1. 'No' responses receive a score of 0. Total scores range from 0 (severe functional impairment) to 6 (full function).	1 = ADL score = 6 2 = ADL score \leq 5
14	5m Walk Test	<p>Time, in seconds, taken to walk 5-metres. During the assessment, the patient is asked to walk 5-metres at a comfortable pace. Each patient completes the walk three times (trial 1, trial 2, and trial 3). The average of the three trials is calculated for statistical analysis.</p> <p>Trial 1: Time (sec) taken to walk 5 metres for the first of three trials. Trial 2: Time (sec) taken to walk 5 metres for the second of three trials. Trial 3: Time (sec) taken to walk 5 metres for the third of three trials.</p>	<p>Average time taken to complete 5-metre walk test = ___ sec</p> <p>1 = < 7 sec 2 = \geq 7 sec</p>
WAIT TIME			
15	Wait time	<p>Time, in days, spent waiting for TAVI.</p> <p>Wait time 1: Time (days) from referral to acceptance on wait list. Wait time 2: Time (days) from acceptance to procedure.</p>	<p>Average wait time 1 = ___ days Average wait time 2 = ___ days</p>
LENGTH OF STAY			
16	LOS	Time (in days) from procedure to discharge date.	1 = 1-2 days 2 = 3-4 days 3 = \geq 5 days