

PREDICTING THE LENGTH OF STAY IN OLDER ADULTS UNDERGOING
TRANSAPICAL TRANSCATHETER AORTIC VALVE IMPLANTATION

by

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Abstract

Background. Aortic stenosis (AS) is a valvular heart disease that predominantly affects older adults. Valve replacement is the treatment of choice for severe symptomatic AS. However, some older adults cannot undergo open surgical aortic valve replacement (SAVR) due to their higher risk for complications. Over the past decade, transcatheter aortic valve implantation (TAVI) has emerged as the recommended therapy for selected high surgical risk patients. One of the main approaches of TAVI, the transapical (TA) TAVI, is often reserved for older adults who are not candidates for other surgical procedures because of their increased risk for complications. However, the length of hospital stay (LOS) after TA TAVI tends to be longer than other surgical procedures. *Objective.* The objective of this study was to identify the individual characteristics, procedural details, and post-procedure factors predictive of LOS after TA TAVI. *Method.* 62 predictor variables were identified based on literature review, available clinical data, consultation with experts. A retrospective review of 128 consecutive medical charts was then conducted to collect relevant data. Univariate descriptive statistics, bivariate ordinal logistic regression, and multivariate ordinal logistic regression analyses were performed to describe the sample and examine predictors of LOS. All relevant Research Ethics Board (REB) approvals were obtained prior to the commencement of this study. *Results.* The average age of the sample in this study was 78.8 years. 57.4% were female older adults. The mean and median LOS after TA TAVI was 11.1 days and 7.0 days, respectively. Based on the trimmed multivariate model, increased age of patients and duration of stay in the critical care unit were associated with prolonged LOS. Having chronic lung disease and requiring a temporary pacemaker upon the completion of TA TAVI also increased the odds of having longer LOS postoperatively. Additionally, shorter LOS after TA TAVI was associated with higher hemoglobin levels. In addition, predicted risk of

mortality based on the Society of Thoracic Surgeons risk score (STS) was associated with longer LOS after TA TAVI, though the sample involving this variable was much smaller due to missing data (N= 57). *Conclusion.* This study identified several important individual characteristics, procedural details, and post-procedure factors that are associated with increased LOS following TA TAVI. Its findings may alert nurses to heed the implications of these predictors in TA TAVI patients and initiate nursing interventions to reduce the risk of prolonged LOS related complications. Future studies are recommended to confirm these findings and the effects of STS score and other potential predictors.

Keywords: aortic stenosis, transapical transcatheter aortic valve implantation, length of stay, hospital stay

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List of Abbreviations

<i>ADL</i>	Activities of Daily Living
<i>AS</i>	Aortic stenosis
<i>BAV</i>	Balloon Aortic Valvuloplasty
<i>BMI</i>	Body Mass Index
<i>CABG</i>	Coronary Artery Bypass Surgery
<i>COPD</i>	Chronic Obstructive Pulmonary Disease
<i>CSHA CFS</i>	Canadian Study of Health and Aging Clinical Frailty Scale
<i>eGFR</i>	estimated Glomerular Filtration Rate
<i>Hgb</i>	Hemoglobin
<i>IADL</i>	Instrumental Activities of Daily Living
<i>ICD</i>	Implantable Cardioverter Defibrillator
<i>LOS</i>	Length of stay
<i>LOSICU</i>	Length of stay in the critical care unit
<i>LVEF</i>	Left Ventricular Ejection Fraction
<i>MI</i>	Myocardial infarction
<i>MMSE</i>	Mini Mental State Examination
<i>NYHA</i>	New York Heart Association classification
<i>PCI</i>	Percutaneous Coronary Intervention
<i>PPM</i>	Permanent pacemaker
<i>SAVR</i>	Surgical aortic valve replacement/repair
<i>STS</i>	The Society of Thoracic Surgeons risk score
<i>TA TAVI</i>	Transapical Transcatheter Aortic Valve Implantation
<i>TAVI</i>	Transcatheter Aortic Valve Implantation
<i>TF TAVI</i>	Transfemoral Transcatheter Aortic Valve Implantation

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Dedication

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For my dear family. Without you all, I could not have reached many finish lines in my life, including this one. I love you all.

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Chapter One: Introduction

Unprecedentedly, the world population is rapidly ageing. In Canada, the 2011 Canadian Census confirmed that the population of adults aged 65 and over was nearly five millions, and this number was projected to double to more than ten million by 2036, reflecting a significant demographic shift toward an ageing society (Federation of Canadian Municipalities, 2013).

With advanced age, many age-related health challenges may occur. Aortic stenosis (AS), the most common valvular heart disease, is predominant in older adults in their seventh to eighth decade of life. In their study, Nkomo and colleagues (2006) confirmed that, in 2000, the prevalence of AS in the United States population was 0.7% in patients between 18 to 44 years older, and 13.3% in those who were 75 years and older. Hence, much effort has been invested in pursuing innovative, safe yet cost-effective treatments for AS. Nearly a decade ago, a minimally invasive procedure called transcatheter aortic valve implantation (TAVI) emerged and has quickly become a viable therapy for AS in addition to the conventional surgical aortic valve replacement (SAVR) (Webb et al., 2012). At present, there are different accesses used in TAVI procedure. Transcatheter access (TA TAVI) is recommended for patients who are older, sicker, and have more peripheral artery disease. Despite the fact that the overall knowledge of TAVI has significantly increased since its inception, particularly in the areas related to its clinical application, efficacy, and safety, little has been explored in relation to the length of stay (LOS) after TA TAVI.

1.1 Aortic Stenosis: Etiology and Treatments

In AS, the aortic valve progressively narrows with age, thus restricting the output of blood to the systemic circulation. Calcific AS of the trileaflet valve is the most common type in older adults and results from an active inflammatory process and progressive calcification. Other

major causes of AS include congenital defects of the bicuspid aortic valve structure and rheumatic heart disease. Clinically, the classic presenting symptoms of severe AS include angina, syncope and heart failure. If left untreated, severe AS can lead to heart failure, impaired left ventricular function, decreased quality of life, and even death (Sawaya, Liff, Stewart, Lerakis, & Babaliaros, 2012).

Treatments such as medical management and balloon aortic valvuloplasty alone do not provide adequate clinical benefits for patients with severe AS (Lichtenstein et al., 2006; Sawaya et al., 2012). Conventionally, SAVR has been well established as the gold standard treatment for symptomatic AS. Due to advanced age and co-morbidities, however, up to 30% of older adults with severe symptomatic AS are believed to be at high risk¹ for SAVR (Sawaya et al., 2012; Webb et al., 2012). For these people, one of the possible options is TAVI. Because of different approaches of TAVI, the Canadian Cardiovascular Society position statement on TAVI recommends that patients who are considered at high risk for SAVR should be evaluated for multidisciplinary assessment of their suitability for specific TAVI procedures, including TA TAVI (Webb et al., 2012).

The clinical safety and efficacy of TAVI have been established in the literature. The Placement of AoRtic TraNscathetER Valves (PARTNER) trial randomized non-operable patients to either standard medical therapy group or transfemoral TAVI (TF TAVI) group, and found that patients in the treatment arm (TF TAVI group) had significant survival benefits including reduced mortality rate and improved cardiac symptoms (Leon et al., 2010). In their study, Smith et al. (2011) found that TAVI was non-inferior to SAVR. Other clinical trials and national registry studies have also served to established TAVI as a safe and viable treatment

¹ Webb et al. (2012) considered that patients would be at high risk for surgery if they had a mortality risk of 8% or greater, or major morbidity that was greater than 50% within thirty days of surgery, as predicted by experienced cardiac surgeons.

option for higher risk patients (Mack et al., 2013; Hamm et al., 2014; Adams et al., 2014; Pighi et al., 2014). In the current clinical practice, the procedure of interest in this study, TA TAVI, is often reserved for the patients who are deemed not suitable for other treatments, due to their higher surgical risk.

1.2 TA TAVI

In the TA TAVI procedure, a small incision is first made at the apex of the heart. A vascular access sheath is subsequently inserted through which a prosthetic heart valve is deployed in place by using a balloon-expandable delivery system (Cheung & Lichtenstein, 2012).

1.2.1 Indications. Indications for TA TAVI largely depend on the assessment of patients' surgical risk and the expert team's consensus. Currently, TA TAVI is often chosen for patients who are older, have a higher mean risk score, and have more concomitant health issues, thus characterizing a sicker and frailer patient population than those who typically undergo the TF TAVI or SAVR (Thielmann et al., 2008; Strauch et al., 2010; Higgins et al., 2011; Walther et al., 2012; Lardizabal et al., 2013).

As compared to other approaches, the TA TAVI procedural approach has certain advantages. For example, several studies indicated that TA TAVI was the preferred treatment for high risk older adults, especially those with concomitant renal dysfunction, as TA TAVI required significantly less use of contrast media (Bleiziffer et al., 2009; Ewe et al., 2011; Madershahian et al., 2012). This feature of TA TAVI is clinically favorable for older adults because many of them are susceptible to contrast induced kidney injuries by virtue of advanced age and multiple co-morbidities.

1.2.2 Implications. Despite the potentially advantageous features of TA TAVI, there are risks associated with this procedure. Pasic et al. (2010) described TA TAVI as "a procedure

of 1001 details, a series of small sequences that [needed] to be performed precisely, in perfect order, and with perfect timing and excellent coordination between the members of the team" (p. 1467), indicating that TA TAVI is a complicated procedure, which likely entails heightened surgical risk, especially when it is associated with the steep learning curve of performance.

In addition to the technical challenges of performing this procedure, there are a variety of complications and challenges that may arise during the pre-, peri-, and post-procedural periods of TA TAVI. Pasic et al. (2010) identified several preoperative, intraoperative, and postoperative problems and difficulties associated with TA TAVI. Preoperatively, one of the main challenges that they encountered was the uncertainty associated with the selection criteria for TA TAVI patients. Intraoperatively, Pasic et al. (2010) stated that procedure-related complications, including hemodynamic instability of patients who had severe pulmonary hypertension and poor left ventricular function, were the major challenges associated with TA TAVI procedure. Neurologic complications were among the major postoperative complications (Pasic et al., 2010).

At present, within the range of transcatheter options available for treating patients with high risk, TA TAVI is often indicated for those with the highest risk, who are not eligible for other surgical procedures, including SAVR or TF TAVI, and are characterized by unique vulnerabilities and additionally complex care requirements.

1.3 Statement of Problem

By the end of 2014, the study center chosen for this study had performed over 1,000 TAVI procedures and over 200 of these were TA TAVI cases. The majority of patients who underwent TA TAVI procedure were older adults. While there are various connotations and nuances associated with the term of old age, the population of older adults is often defined chronologically as pertaining to people who are 65 years old and over.

Clinical data showed that TA TAVI patients had longer LOS. For instance, the median reported LOS after TA TAVI was 8.0 days (mean = 12.1 days) in 2011 and 7.0 days (mean = 10.5 days) in 2013 whereas that of TF TAVI was 4.0 days (mean = 6.2 days) in 2011 and 3.0 days (mean = 4.6 days) in 2013 (S Lauck, personal communication, March 2014). Because prolonged LOS is hazardous to older patients, we were interested in understanding the factors associated with the LOS after TA TAVI.

1.4 Significance of Problem

The significance of this study's focus is twofold. First, prolonged LOS has important implications for institutions, health economics and clinical practice (Khairudin, 2012). In general, there is a consensus that reducing LOS is beneficial for patients, especially older adults who are at higher risk for prolonged hospitalization-related complications such as functional decline and disabilities, de-conditioning, and nosocomial complications (Kleinpell, Fletcher, & Jennings, 2008; Khairudin, 2012). With an increasingly ageing population, it is anticipated that more older adults suffering from symptomatic AS will likely require TAVI procedures. Because the TA TAVI procedure is predominantly reserved for older adults who are not eligible for other interventions due to their more advanced peripheral arterial diseases, this patient population is at higher risk, more frail and has less overall reserve capacity than those undergoing other treatments. It is anticipated that they are more susceptible to potential consequences of prolonged hospitalization. Hence, identifying the factors of TA TAVI associated with longer LOS will likely aid in the pre-procedure planning and may decrease overall LOS by contributing knowledge that addresses these predictors of LOS, thus enhancing overall patient care.

Second, more studies have supported TAVI as an effective, viable alternative when other treatments (e.g., conventional SAVR) are not indicated. With this ever-growing body of

knowledge and evidence, it is postulated that the care of TAVI patients could be streamlined and standardized by the development of clinical pathways. The importance of having a clinical pathway has been well illustrated in the literature. Specifically, clinical pathways, as evidence-based structured multidisciplinary care plans, aim to standardize care for specific clinical problems by defining the time and sequence by which care should be delivered. The utilization of clinical pathways contributes to reduce variations in the multi-faceted health care system, thus minimizing the probability of medical errors and ultimately improving patient outcomes (Kleinpell et al., 2008). In the literature, there is currently little information on what factors from patients' individual characteristics, preoperative status and postoperative complications are related to LOS after TA TAVI procedure. Therefore, conducting an analysis of such potential factors would further the understanding of the TA TAVI patient population and their care needs, which may in turn inform future studies on the pre-procedure planning, practice policy making, and clinical pathway development.

Furthermore, as a major indicator of patient outcome, hospital performance and resource consumption, LOS reflects the joint effort of the entire interdisciplinary team, among which nursing plays a pivotal role. Studies have established the association between nurse staffing and patient outcomes, including LOS (Kane, Shamliyan, Mueller, Duval, & Wilt, 2007). Needleman and Hassmiller (2009) asserted that "shorter stays reflect not just reductions in complications that extend stays, but the ability of nurses to do their work and coordinate the work of others in a timely and effective manner" (p.627). Given the nature of nursing work in the hospital which entails carrying out critical tasks including assessing patients, initiating interventions, coordinating care, and educating patients and families, it is important for nurses to understand what predicts the LOS following TA TAVI for older adults.

1.5 Research Question

This study was designed to use existing clinical data to explore the possible predictors of LOS after TA TAVI from the perspective of clinical nursing practice. By systematically analyzing relevant data collected through a retrospective chart review, the study addressed the following research question: To what extent do individual characteristics, procedural details, and postoperative factors influence the LOS in older adults who have undergone the TA TAVI procedure?

1.6 Chapter Summary

With an ageing population worldwide, it is anticipated that AS will be increasingly prevalent in the older population. TA TAVI, as an emerging minimally invasive intervention, has become a viable option for this patient population, especially those who are inoperable for other procedures due to their higher surgical risk. Relevant clinical data showed that, as compared to TF TAVI, TA TAVI resulted in longer LOS. As few studies have explored the LOS after TA TAVI, this study aimed to identify what might predict the LOS after TA TAVI and to what extent these predictors might be associated with it.

Chapter Two presents the findings of two literature reviews. The first literature review had a focus on the LOS that was relevant to TA TAVI patient population while the second literature review explored the LOS related to general older patient population. The purpose of the literature reviews was to provide the conceptual foundations of this study. The design of this study is described in Chapter Three, illustrating the selection of candidate predictor variables and the steps of analytical method. Relevant ethical considerations are also discussed. Chapter Four presents the results of the statistical analyses of the clinical data collected through a retrospective chart review. The study's sample and candidate variables are described and the results of

bivariate and multivariate ordinal logistic regression models with different variable datasets are discussed. Last, Chapter Five compares the key findings of this study with that of literature reviews, evaluates the appropriateness of using the study models specifically designed for this study, discusses the implications that this study may have in nursing education and practice, and appraises this study's strengths and limitations.

Chapter Two: Literature Review

The outcome of interest of this study is defined as the total LOS, which refers to the period from the commencement of the TA TAVI procedure to the discharge date, excluding death. In this chapter, the findings of two literature reviews are discussed. The first literature review had a focus on the LOS related to TA TAVI whereas the second literature review was focused on the LOS in older adults in general. The purpose of conducting the two literature reviews was to appraise the literature findings in relation to the LOS in older adults who underwent TA TAVI, identify the variables that potentially influenced the LOS, and provide conceptual foundations to this study.

2.1 LOS in TA TAVI Related Literature

To gain an understanding of what was currently present in TAVI literature with regard to LOS, a literature review was conducted in electronic databases including CINAHL, MEDLINE, PubMed, BioMed, and SAGE on December 22, 2013. The keywords used for searching included the combination of 1) “transapical AVI” OR “Transcatheter aortic valve implantation transapical” OR “TAVI transapical” OR “TAVI transapical approach” OR “TA TAVI” OR “Transapical aortic valve implantation” OR “TAVR²,” 2) “Elder*” OR “older adult” OR “geriatric” OR “gerontology” OR “aged” OR “senior;” and 3) “Hospitalization stay?” OR “hospital stay” OR “length of hospitalization” OR “length of stay.” Only articles written in English were included. In addition, the relevant cited references were reviewed and retrieved. As a result, a total of 21 articles were included for this review.

The majority of the identified studies focused on appraising the performing experience of TA TAVI procedure or comparing it against other procedures, including SAVR and TF TAVI.

² TAVR is the commonly used term for transcatheter aortic valve replacement in the United States while TAVI is the term used in Europe and Canada.

Several studies explored TAVI related hospital cost. Among the studies involving LOS-related discussion, the LOS after TA TAVI was mostly described numerically and was compared with that of other procedures. The findings involving LOS seemed to vary, depending on many co-variables such as the performed procedures, the pre-, intra-, or post- procedural variables, study perspectives, geographic factors, and health care providers' clinical preferences. In the following section, the LOS-related findings from the literature review are discussed and presented according to the differences among TA TAVI and other procedures, TAVI procedure-related variables and hospital cost.

2.1.1 LOS after TA TAVI and other procedures. Several studies have compared the LOS after TA TAVI with that of several other procedures, including TF TAVI, SAVR, and the transaortic approach for TAVI (TAo) (Table 1).

Table 1
Studies Comparing LOS in TA TAVI and Other Procedures

Study	Procedure Sample Size Compared		Procedure Mean LOS (days) Compared		<i>p</i>
Thielmann et al. (2009)	TA	TF	TA	TF	0.580
	24	15	12	11	
Zierer et al. (2009)	TA	SAVR	TA	SAVR	<0.001
	21	30	5	12	
Ewe et al. (2011)	TA	TF	TA	TF	0.210
	59	45	6	6	
Smith et al. (2011)	TAVI	SAVR	TAVI	SAVR	<0.001
	348	351	8	12	
Higgins et al. (2011)	TA	SAVR	TA	SAVR	0.205
	46	46	9	8	
Dahle et al. (2012)	TA	TF	TA	TF	N/A
	25	25	8	7	

Conradi et al. (2012)	TAVI 82	SAVR 82	TAVI 14	SAVR 11	0.110
Di Mario et al. (2013)	TA 749	TF 3390	TA 43.8% had LOS >10 days	TF 22.0% had LOS >10 days	<0.010
Lardizabal et al. (2013)	TA 76	TAo 44	TA 10	TAo 8	0.140
Chevreur et al. (2013)	TA 78	Arterial 209	TA Average LOS: 15 days. No significant differences in LOS between two groups.	Arterial	N/A

Note. The values of LOS were uniformly rounded and reported as the mean LOS in days. *Abbreviations.* TAVI, Transcatheter aortic valve implantation; TA TAVI, Transapical transcatheter aortic valve implantation; TF TAVI, Transfemoral transcatheter aortic valve implantation; SAVR, SAVR; TAo, Transaortic TAVI; LOS, Length of stay. N/A, Not available.

As shown in Table 1, Thielmann et al. (2009) found longer LOS after TA TAVI ($p = 0.580$). In their study, Di Mario and colleagues (2012) found that the relative frequency of patients who had LOS greater than ten days was significantly higher among the patients undergoing TA TAVI in comparison to those undergoing TF TAVI. Likewise, Dahle et al. (2012) found a longer mean LOS in TA TAVI patients. By contrast, Ewe and colleagues (2011) found that LOS for both TA TAVI and TF TAVI did not show much difference.

When compared with conventional SAVR, Zierer and colleagues (2009) found that patients undergoing TA TAVI had significantly shorter operation time, ventilation time, intensive care unit stay and overall hospital LOS. Moreover, the randomized control trial report by Smith et al. (2011) on behalf of the PARTNER investigators found that patients in the TAVI group had significantly shorter overall LOS. By contrast, Higgins et al. (2011) used propensity scoring to match up the patients of TA TAVI group with those of SAVR group. They concluded that there were no significant differences in LOS between the two matched-up groups. Similarly,

the propensity scoring analysis of Conradi and colleagues (2012) confirmed that TAVI, including transapical and transfemoral approaches, resulted in shorter time with regard to operative time, ventilation time, and stay in the intensive care unit.

Lardizabal et al. (2013) found that there was no significant difference in LOS between TA TAVI group and transaortic approach for TAVI group, which used transaortic access to perform TAVI. Moreover, a multicenter national registry data analysis by Chevreul et al. (2013) on 287 patients undergoing TAVI procedures (TA TAVI and TAVI using arterial access) showed that mean LOS did not significantly differ between groups.

Overall, studies report varying results of LOS in patients undergoing TA TAVI. Despite one study showing significantly shorter LOS following TA TAVI procedure, other studies have consistently revealed a longer LOS in patients undergoing TA TAVI regardless of the comparing procedures.

2.1.2 TA TAVI-related variables. In the literature, clinical variables related to TA TAVI, including procedural complications and patient's individual characteristics seemed to play a role in influencing LOS. One of the common post-TAVI complications, acute kidney injury due to the use of contrast media, has been examined in several studies. Based on a sample of 261 patients who had TA TAVI, Van Linden et al. (2011) reported that acute kidney injury did not significantly prolong LOS. This finding is consistent with that of Strauch et al. (2010). Madershahian et al. (2012) reported that in TA TAVI the doses of contrast media used intra-procedurally did not result in significant difference in LOS. However, Van Linden et al. (2011) found that, when older adults had acute kidney injury, those who required the renal replacement therapy had significantly longer LOS than those who did not require renal replacement therapy.

Other procedural factors including blood transfusion and general anaesthesia were also found to be associated with prolonged LOS (Di Mario et al., 2012; Mwipatayi et al., 2013)

Practice experience of surgeons seemed to influence LOS in TA TAVI patients as well. In their initial TA TAVI experience of 12 patients, Spargias et al. (2008) reported that average LOS was eight days. The authors argued that those patients were kept in the hospital for longer observations because the surgeons were new to this procedure. Conradi and colleagues (2012) stated that one of the reasons underlying the unreduced overall LOS in their study was the extended period of continuous telemetry monitoring postoperatively for observing conduction disorders in TA TAVI patients. Interestingly, based on a sample of 287 people, Chevreul et al. (2013) found that LOS decreased from a median of thirteen days in the first third of the sample to eleven days in the last third of the sample, indicating the possible existence of learning curve associated with the innovative TA TAVI procedure. Nonetheless, because only a few studies explored surgeons' experience, especially in the early stage of clinical application of TA TAVI, caution is needed in inferring that variations in surgeons' experiences of performing TA TAVI are associated with LOS.

In addition, Dahle et al. (2012) argued that prolonged LOS might be associated with logistical challenges and geographic differences. For example, some of their patients had to be kept longer in hospital due to their complicated transportation arrangements.

In conclusion, research has examined several variables related to the LOS after TA TAVI. Factors, including use of general anaesthesia, blood transfusion, and acute kidney injury-induced renal replacement therapy, tended to prolong LOS while acute kidney injury itself seemed not to affect the LOS. Other possible factors associated with prolonged LOS included surgeons' practice and experiences related to this procedure and patients' transitional care arrangements

due to their geographic locations. Nevertheless, with regard to the LOS, the impact of many other factors such as procedure-related complications (e.g., postoperative bleeding) and older adults' co-morbidities or functional status has not been examined in current TA TAVI literature, indicating the needs for further research in this area.

2.2 LOS in Older Adults: General

There is a paucity of research taking into consideration the associations between the characteristics of TA TAVI patients, especially co-morbidities and health conditions (i.e., functional ability and frailty), in relation to LOS. Moreover, because TA TAVI patients are typically older, it is useful to appraise in general what the common issues related to LOS are in older adults. The underlying rationale for conducting this literature review was therefore twofold. First, understanding how prolonged LOS would affect older adults in acute care settings in general might help to appreciate what may impact older adults undergoing TA TAVI. In other words, if literature generally agreed that prolonged LOS could significantly impact older people, then exploration of TA TAVI related LOS might have meaningful clinical implications. Second, as TA TAVI is primarily indicated for older older adults, exploring LOS in older adults from a more general point of view might help with identifying the relevant variables relevant to LOS after TA TAVI as well as developing the theoretical thinkings for conducting this study.

The second literature review of LOS in older adults in general was conducted in both CINAHL and MEDLINE on December 22, 2013. The keywords included “older adult” OR “senior” OR “aged 65+,” and “length of hospitalization” OR “length of stay,” and “review” OR “literature review” OR “systematic review.” Only reviews published in peer reviewed journals in English between 2008 and 2013 were included. Cited references were also reviewed and searched if relevant. Initially, there were a total of twenty articles retrieved, of which eleven

studies were finally selected for the review. The findings are presented below from the perspective of how LOS was related to patient's individual characteristics including advanced age and co-morbidities, iatrogenic complications, functional status, and frailty.

2.2.1 Advanced age and co-morbidities. Advanced age is an important factor in influencing the LOS in older adults in general. Studies have shown that age was an independent predictor for prolonged LOS in the older patients (Kaysar et al., 2008; Kofteridis et al., 2009; Morse, Boland, Blackhurst, & Roettger, 2010). Kaysar et al. (2008) studied age in relation to community-acquired pneumonia and found that, compared to younger counterparts, older adults were more likely to have severe pneumonia and longer LOS. Similarly, Kofteridis et al. (2009) reported that age played a role in older adults with diabetes mellitus and made them more susceptible to nosocomial infections such as urinary tract infection. More importantly, in their study, Morse et al. (2010) found that, compared to younger patients, those aged 80 and older had a statistically higher incidence of catheter-related urinary tract infection, vascular catheter infection, longer hospital LOS, and greater median hospital cost.

Another prominent factor in influencing LOS is the co-morbidities status of older adults. Kofteridis et al. (2009) confirmed that diabetes mellitus was independently predictive of bacteremia and urinary tract infection in the hospitalized older adults, leading to longer hospitalization and higher mortality. Moreover, co-morbidities often resulted in polypharmacy in older adults, which was in turn associated with increased risk of prescription errors, and temporary harm, and required more interventions, thus further complicating older adults' care during hospitalization (Yong, Lau, Li, Hakendorf, & Thompson, 2012).

In addition, the complex nature of older care was evident in several studies on the effectiveness of specialty care for hospitalized older adults. In their evaluation of the

effectiveness of an unique pharmacist-led program, Mortimer, Emmerton, and Lum (2011) found that LOS of older adults involved in this program was longer than that of those who were not involved. Although confounding was likely, Mortimer et al. argued that the reasons for prolonged LOS likely lay in the fact that those patients involved in the program received more attention from the pharmacist who demonstrated greater vigilance while assessing and monitoring patients' polypharmacy issues, indicating the need for more specialized, individualized care in older populations. Considering LOS as one of the efficiency measurements, Sorbero, Saul, Liu, and Resnick (2012) compared the outcome between geriatrician-led care and non-geriatrician-led care for hospitalized older adults. They found that older adults benefited from more specialty care, which led to more diagnoses, shorter LOS, and lower cost per admission.

In summary, the literature review showed that advanced age and co-morbidities with the possibility of concurrent polypharmacy were consistently associated with prolonged LOS in hospitalized older adults. Specialized geriatric care models and programs seemed to have inconclusive impact on LOS in older adults.

2.2.2 Iatrogenic complications. In the literature, there was a consensus that, once iatrogenic complications occurred during hospitalization, older adults were at greater risk for mortality, delayed recovery, and prolonged LOS (Kaye et al., 2009; Bjorkelund, Hommel, Thorngren, Lundberg, & Larsson, 2011). Specifically, Kaye et al. (2009) identified the positive correlation between surgical site infection and mortality risk and prolonged LOS in older adults. Moreover, in older adults having hip fractures, Bjorkelund et al. (2011) found that postoperative complications, including anemia-induced blood transfusion, were associated with prolonged LOS.

Furthermore, lower Braden Scale³ scores, computed by the well-established Braden Scale, usually indicated greater risk for developing pressure sores (Bergstrom, Braden, Laguzza, & Holman, 1987). By analyzing 102 older adults undergoing abdominal surgeries, Cohen et al. (2012) concluded that lower Braden Scale scores were predictive of thirty-day postoperative complications, longer LOS, and discharge to institution or nursing home rather than to the patient's home.

2.2.3 Functional and frailty status. Several studies have documented the course of functional decline in hospitalized older adults (Callen, Mahoney, Wells, Enloe, & Hughes, 2004; Kleinpell et al., 2008; Lafont, Gerard, Voisin, Pahor, & Vellas, 2011). However, the literature, that examined LOS in relation to functional decline in hospitalized older adults, lacks consistency because there is no consensus on measurements for assessing functional status. Regardless, it is generally agreed that preventing or mitigating functional decline for older adults while hospitalized likely reduces LOS. One clinical intervention recommended in the literature is early implementation of physical exercise programs (i.e., early physical rehabilitation programs) for hospitalized older adults. The study of Kosse and colleagues (2013) showed that early physical rehabilitation programs improved hospitalized older adults' physical functional performance, thus reducing overall LOS and increasing the likelihood of being discharged home rather than to facilities with nursing care.

Though conceptually distinct, functional status is closely interrelated with frailty status. This has been exemplified by the use of the Braden Scale with hospitalized older adults. A number of studies showed that the Braden Scale scores were indicative of both functional status

³ The Braden Scale is a clinical assessment tool used for predicting the development of pressure ulcers. It sums a total score from six to 23 by assessing risk in six areas (sensory perception, skin moisture, activity, mobility, nutrition and friction/shear). The lower the score is, the higher the risk for developing a pressure ulcer. Its psychometric properties have been established (Bergstrom, Braden, Laguzza, & Holman, 1987; Kring, 2007).

and frailty of older adults. And lower Braden Scale scores were associated with greater functional decline in hospitalized older adults (Kleinpell et al., 2008; Lafont et al., 2011). Comparing the Braden Scale with several proposed frailty models in the literature, Cohen et al. (2012) confirmed that the six domains of the Braden Scale corresponded well with the widely accepted phenotypic features of Frailty Syndrome, including poor cognition, weakness, sense of exhaustion, and weight loss (Fried et al., 2001). In addition, they found that lower Braden Scale scores are associated with functional decline. Moreover, Cohen et al. (2012) stated that functional decline in older adults while hospitalized was indicative of a frailer status, and was associated with more postoperative complications, longer LOS and higher incidence of altered level of care (i.e., discharging to a nursing home instead of their own home).

2.3 Conceptual Foundations of Study

In this section, we summarize the findings of literature review that help with variable identification and provide conceptual thinking relevant to this study.

Overall, the LOS after TA TAVI is understudied. Despite being inconclusive, the majority of literature has observed a longer LOS in TA TAVI patients, especially while compared to other TAVI procedures. The factors of LOS that have been explored in the literature include individual characteristics of patients (i.e., transitional care arrangements); TA TAVI's peri-procedural factors (i.e., the use of general anaesthesia); post-procedural complications (i.e., acute kidney injury, vascular access complications and the need for blood transfusion); and finally, the surgeons' experiences and familiarity with this procedure.

The literature review suggests that many other factors that could possibly influence LOS in patients undergoing TA TAVI. For instance, the characteristics of older adults, including advanced age and co-morbidities and frailty status, were intrinsically associated with the

susceptibility for prolonged LOS. A longer LOS, in turn, could contribute to undesirable outcomes, including functional decline, disabilities and even death (Kleinpell et al., 2008; Lafont et al., 2011). Specific to TA TAVI, Thielmann et al. (2009) suggested that “factors like social integration, mobility, frailty, and individual overall health status” be taken into account to carefully evaluate TAVI patients preoperatively (p. 1473), indicating the existence of multiple variables related to the LOS after TA TAVI, and the need for more studies.

Overall, the various LOS-related variables reported in the literature correspond with the following categories, which are further described below: patient’s individual characteristics and procedure-related features and complications.

2.3.1 Individual characteristics. To understand the impact of patient’s individual characteristics, it is helpful to first define what individual characteristics might be included. In the literature, individual characteristics have been defined, including demographic, developmental, psychological and biological factors. All of these could potentially affect biological function, which, in turn, could impact functional ability and quality of life (Ferrans et al., 2005). Other important components of individual characteristics include environmental factors, which could be divided into two categories: social and physical (Ferrans et al., 2005). Studies have shown that interpersonal relationships of older adults with their families, friends, and health care providers have a strong influence on their overall health. In addition, it is widely accepted that hospital environments are not conducive to optimal recovery, especially for older adults who lack appropriate social support (Ferrans et al., 2005; Cohen et al., 2012).

In addition, functional and frailty status are considered important individual characteristics. In the literature, there is a consensus that prolonged hospitalization is a significant event for older adults because it is closely associated with functional loss, de-

conditioning and serious multi-system complications (i.e., muscle mass loss and malnutrition) (Kleinpell et al., 2008; Lafont et al., 2011; Khairudin, 2012). Related to LOS, several studies affirmed that Frailty Syndrome is prevalent in older adults and is associated with more hospitalization-related functional disabilities and complications, and prolonged LOS (Ahmed, Mandel, & Fain, 2007; Dasgupta, Rolfson, Stolee, Borrie, & Speechley, 2009; Noimark, 2009; Puts et al., 2010; Lafont et al., 2011; Cohen et al., 2012).

Surprisingly, few characteristics of TA TAVI patients, other than geographic location, have been explored with regard to their impact on LOS. Given that TA TAVI is mainly indicated for older adults with higher risk, whose frail status is typically characterized by declined physiological and functional reserve and complex co-morbidities status, it is anticipated that these individual characteristics could impact the LOS after TA TAVI patients.

2.3.2 Procedure-related characteristics. TA TAVI is an innovative but complex, sophisticated procedure. Literature about the Peri-procedure phase shows that a variety of factors might influence the procedure's outcome, including LOS. Examples of these factors include the use of general anaesthesia, the need for blood transfusion, and the experience of the surgeons' performing the procedure. This area, however, remains underexplored. Given consideration to the high-risk nature of the TA TAVI procedure and its target patient population's frail status, it is postulated that procedure-related factors (i.e., the use of invasive equipment or chest tube) could impact the LOS after TA TAVI.

Several common post-TA TAVI complications have also been identified in the literature. These include stroke, postoperative atrioventricular block, postoperative bleeding, acute kidney injury, wound infection, vascular complications, postoperative atrial fibrillation, postoperative myocardial infarction, delirium, and heart failure. Other less common complications include

prosthesis related issues, para-valvular leak, tamponade, and pleural effusion (Kappetein et al., 2012). Among these complications, acute kidney injury has been studied in several studies with regard to its impact on the LOS after TA TAVI (Strauch et al., 2010; Van Linden et al., 2011; Madershahian et al., 2012). Other studies have found that vascular complications are common in TA TAVI patients and associated with higher incidence of blood transfusion and thus prolonged LOS (Webb et al., 2009; Smith et al., 2011; Mwipatayi et al., 2013). Nonetheless, many post-procedural complications remain underexplored, thus giving rise to this study.

2.4 Study Models

Because no LOS-related conceptual frameworks were found in the literature that were applicable to this study, and based on the findings of the literature reviews and the consultation with the clinical data and experts, we developed the Predicting LOS after TA TAVI: TA TAVI Surgical Process Model (Figure 1) to be used as the underlying conceptual thinking for this study.

As shown in Figure 1, the timeline of a TA TAVI patient's surgical process was divided into three phases prior to discharge. To help with defining the three phases, five key points of time were defined as follows: 1) "Date of Referral" was defined as the date when the TA TAVI patient was referred to the Transcatheter Heart Valve (THV) program at the study center of this study; 2) "Date of Acceptance" was defined as the date on which the TA TAVI patient was accepted into the THV program; 3) "Procedure Start Time" was defined as the start time of the TA TAVI procedure; 4) "72-hour Post-op" was defined as the time of occurring 72 hours after the start time of the TA TAVI procedure, excluding the time point of 72 hours; and 5) "Date of Discharge" was defined as the date on which the patient was discharged alive in this study.

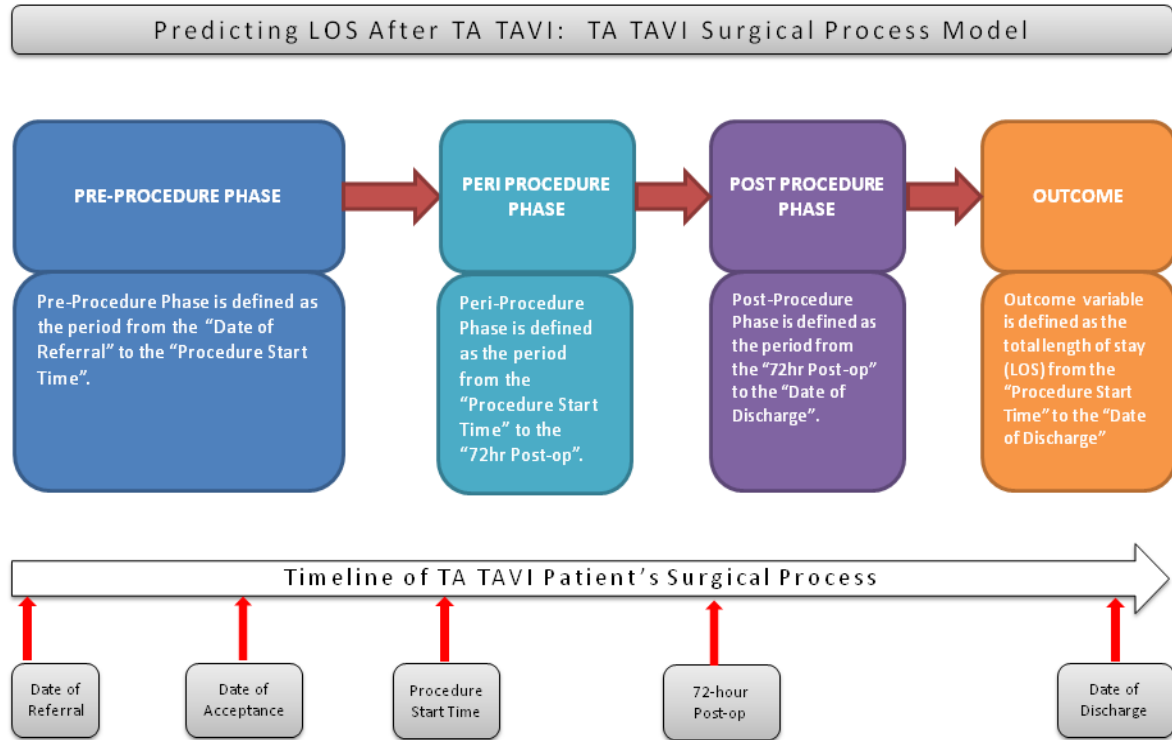


Figure 1. Predicting LOS after TA TAVI: TA TAVI Surgical Process Model. This figure illustrates the three consecutive phases of TA TAVI procedure surgical process defined in this study.

Building on the TA TAVI Surgical Process Model (Figure 1), we postulated that the three phases might be interrelated, and could exhibit a cumulative effect on LOS. Meanwhile, each of the three phases might individually impact LOS to varying degrees. To describe and categorize these relevant variables, we then developed the Predicting LOS after TA TAVI: Conceptual Model (Figure 2). This model includes the categories of variables that have been previously explored in the literature. Considering the exploratory nature of the predictors of LOS in this population, other potentially relevant variables were added to each category. We therefore

present the following possible candidate variables by using the conceptual modal above and propose that these variables could be associated with the LOS after TA TAVI.

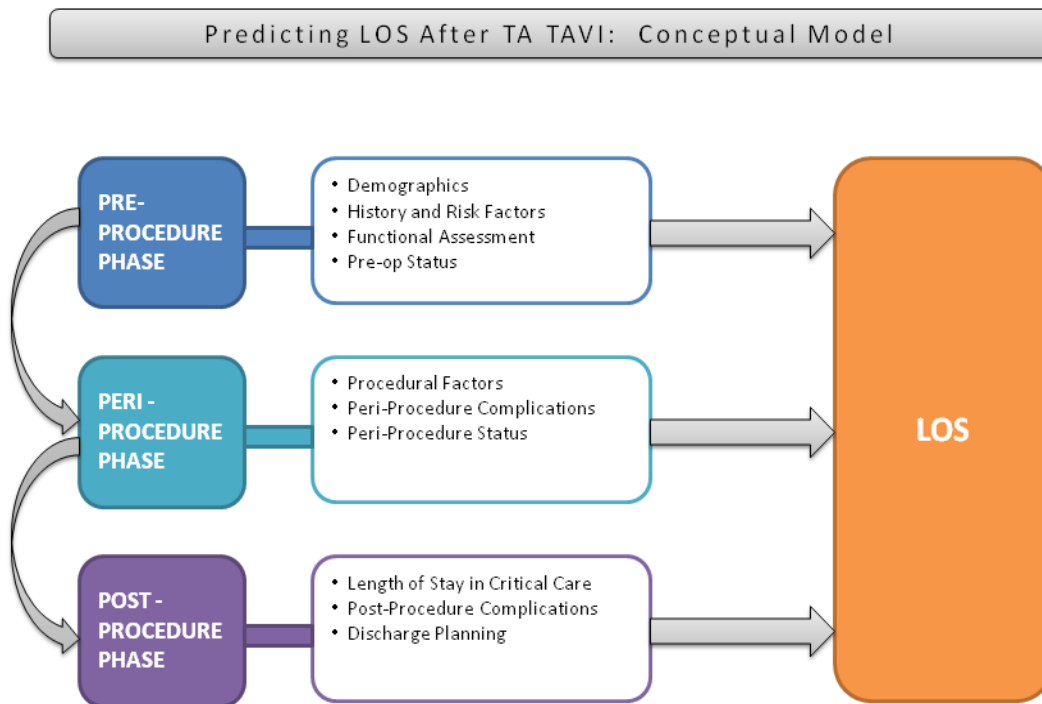


Figure 2. Predicting LOS after TA TAVI: Conceptual Model. This figure illustrates this study's conceptual model.

2.4.1 Pre-procedure phase. The Pre-procedure phase was defined as the period from the “Date of Referral” to the “Procedure Start Time” (Figure 1). Variables during this phase were further categorized under four subgroups: Demographics, History and Risk Factors, Functional Assessment, and Pre-op Status.

First, the Demographics subgroup included variables pertaining to patients' socio-demographic characteristics and TA TAVI procedure preparation information prior to the "Procedure Start Time" (Figure 1). Thus, examples of such variables included age and gender, geographic location, preoperative health status, and TA TAVI procedure specific variables such as wait time related variables.

Second, the History and Risk category described patients' previous medical history and co-morbidities prior to the "Date of Acceptance" as shown in Figure 1. Examples included previous cardiac surgeries, chronic lung diseases, prior stroke history and the like.

The third category pertained to patients' functional assessments. In fact, functional status is a complex phenomenon that can be measured by a plethora of functional assessment instruments and approaches. Leidy (1994) defined functional status as "a multidimensional concept characterizing one's ability to provide for the necessities of life" (p. 197). In this study, the category of Functional Assessment specifically refers to TA TAVI patients' preoperative functional and frailty status prior to the "Date of Acceptance," as well as living environment and home support services received prior to the TA TAVI procedure. Examples of the Functional Assessment variable included the Activities of Daily Living (Katz, Down, Cash, & Grotz, 1970).

Last, the Pre-op Status variables pertained to TA TAVI patient's preoperative health conditions. Variables included surgical risk factors and preoperative laboratory results completed within two weeks before the "Procedure Start Time". Examples of such variables included the Left Ventricle Ejection Fraction (LVEF) and the New York Heart Association classification (NYHA) (American Heart Association, 2015). Preoperative laboratory values (i.e., preoperative serum hemoglobin and creatinine levels) were also included.

2.4.2 Peri-procedure phase. The Peri-procedure phase was defined as the period from the “Procedure Start Time” to the point of “72-hour Post-op.” This phase included variables describing the procedural factors of TA TAVI, major postoperative complications, characteristics of patients’ immediate postoperative status, and relevant required critical care. The selection of the time frame for reporting peri-procedure events reflected the standard set by the Society of Thoracic Surgeons/ American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry (version 1) established to monitor outcomes (Mack et al., 2013). Examples included TA TAVI procedure operation time, types of heart valve operated, use of chest tube upon the completion of the procedure and the like. Major complications, including annular dissection and tamponade, new conduction or native pacemaker disturbances, bleeding and blood transfusion, were included as well (Figure 1 & Figure 2).

2.4.3 Post-procedure phase. The Post-procedure phase was defined as the period from the point of “72-hour Post-op” to the “Date of Discharge.” Similar to those defined in the Peri-procedure phase, variables in this phase described major postoperative complications and relevant patient-care factors from the time of 72 hours after the TA TAVI procedure until discharge. Examples included complications such as stroke, cardiac arrest, bleeding, incidence of atrial fibrillation, and the like (Figure 1 & Figure 2).

2.5 Research Objective

Based on the proposed Predicting LOS after TA TAVI: TA TAVI Surgical Process Model (Figure 1) and Predicting LOS after TA TAVI: Conceptual Model (Figure 2) above, the objectives of this study were as follows: 1) to identify the factors predictive of the LOS after TA TAVI; and 2) to evaluate the relative importance of these factors in predicting LOS.

2.6 Chapter Summary

In this chapter, we present the results of two literature reviews that were conducted in this study. The first literature review specifically focused on the LOS after TA TAVI while the second one had a broader focus on LOS-related literature in the general older population.

Overall, the LOS after TA TAVI is understudied. Several studies reported that TA TAVI seemed to result in longer LOS. A number of factors have been explored in association with longer LOS after TA TAVI. These include types of anaesthesia, blood transfusion, acute kidney injury related treatments, and healthcare providers' experience. In general, there is consensus that patients' individual characteristics, including advanced age and functional status, influence the LOS. In addition, literature has indicated that, as an innovative but complex procedure, the characteristics of TA TAVI might impact the LOS. To conceptually organize various factors potentially relevant to TA TAVI in this study, we developed two models, the Predicting LOS after TA TAVI: TA TAVI Surgical Process Model (Figure 1) and the Predicting LOS after TA TAVI: Conceptual Model (Figure 2), by which the process of TA TAVI surgical process was divided into three consecutive phases, namely, the Pre-procedure phase, the Peri-procedure phase, and the Post-procedure phase. Accordingly, examples of potential variables under the three phases were discussed. In the following chapter, we proceed to discuss this study's method.

Chapter Three: Method

3.1 General Description of Research Design

This study analyzed the data retrieved through a retrospective chart review. The appropriateness of using this design in this study is discussed as follows.

In the literature, the terms of medical record review and chart review are often interchangeable. Worster and Haines (2004) defined “medical record review” as studies that “use pre-recorded, patient-focused data as the primary source of information to answer a research question” (p.1). This methodology had its inherent strengths as well as weaknesses (Worster & Haines, 2004; Gearing, Mian, Barber, & Ickowicz, 2006). The main strengths included 1) the availability of a wealth of clinical data that had been already collected; and 2) the appropriateness of addressing research questions that could not be answered via randomized prospective trials due to potential harm and/or benefits. The main concern with the method of medical chart review lay in the reproducibility and validity of the data collected (Worster & Haines, 2004; Gearing et al., 2006). It is recognized that subjective interpretations of medical records may vary. In addition, conflicting or missing data are common and pose potential threats to data quality. Several research strategies have been proposed to mitigate such threats and ensure the reliability of data. The use of explicit and objective criteria was one of the strategies that minimized the risk of varying subjective interpretations (Worster & Haines, 2004). In addition, Gregory and Radovinsky (2012) argued that the use of rigorous data collection methods, including the precise data collection tool and coding manual, correlated to the reliability of data and studies.

Since the objectives of this study did not involve evaluating the outcomes of an intervention, a randomized controlled trial was not appropriate. In addition, much of the

information were already recorded in the medical records. Therefore, using the chart review was considered more feasible and efficient to conduct an analysis of the data for answering this study's research question. Furthermore, as the majority of variables involved in this study were objectively defined and explicitly measured, a retrospective chart review was appropriate in this regard. To ensure the consistency in data extraction and enhance the quality of data extracted, the Data Collection Form (Appendix A) and the Code Manual (Appendix B) were also developed.

3.2 Study Sample and Eligibility Criteria

This study's sample included the 128 consecutive medical records of patients who had TA TAVI at the study center from 2010 to 2014. A power analysis revealed that, when using multivariate logistic regression, a sample of 120 was required for analyzing 12 covariates (Peduzzi, Concato, Kemper, Holford, & Feinstein, 1996).

This study's eligibility criteria were as follows: patients who were 65 years old and over, had symptomatic AS, were accepted by the THV program, underwent TA TAVI procedure at the study center from 2010 to 2014, and were discharged alive.

3.3 List of Variables

As discussed in Section 2.4, in consideration of the literature review and the consultations with clinical experts, as well as the data available in the medical records, a collection of 62 candidate independent variables (Table 2) were selected and classified according to the Predicting LOS after TA TAVI: TA TAVI Surgical Process Model (Figure 1) and the Predicting LOS after TA TAVI: Conceptual Model (Figure 2).

Table 2
List of 62 Independent Variables

Pre-procedure Phase Variables	
<i>Demographic Variables</i>	<i>Functional Assessment Variables</i>
Age	Home Support
Sex	Living Situation
Status of Referral	CSHA CFS
Location of Residence	ADL
WaitTime1	IADL
WaitTime2	MMSE
WaitTime3	Mean 5-m Walk
<i>History and Risk Factors Variables</i>	<i>Pre-op Status Variables</i>
Prior PPM	NYHA
Prior ICD	LVEF
Chronic Lung Disease	STS
Diabetes	BMI
Prior Stroke	Hgb
Prior MI	Creatinine
Prior Atrial Fibrillation	eGFR
Prior Other Cardiac Surgery	
Prior CABG	
Prior PCI	
Prior SAVR	
Prior BAV	
Peri-procedure Phase Variables	
<i>Procedural Factors Variables</i>	<i>Peri-Procedure Complications Variables</i>
Procedure Total Time	≤72hr Pacemaker
Valve Type	≤72hr Atrial Fibrillation
Procedure Type	≤72hr Stroke
<i>Peri-Procedure Status Variables</i>	≤72hr Annular Dissection
Airway Status	≤72hr Cardiac Arrest
Pulmonary Artery Catheter	≤72hr Perforation
Chest Drain	≤72hr Bleed
Temporary Pacemaker	≤72hr Blood Transfusion
	≤72hr Blood Transfusion Units
Post-procedure Phase Variables	
<i>LOS in Critical Care Variable</i>	<i>Post-Procedure Complications Variables</i>
LOSICU	>72hr Pacemaker
<i>Discharge Planning Variables</i>	>72hr Atrial Fibrillation

Lowest Hgb	>72hr Stroke
Discharge Hgb	>72hr Cardiac Arrest
Highest Creatinine	>72hr Perforation
Discharge Creatinine	>72hr Bleed
	>72hr Blood Transfusion
	>72hr Blood Transfusion Units

Abbreviations. PPM, permanent pacemaker; ICD, implantable cardioverter defibrillator; MI, myocardial infarction; CABG, coronary artery bypass surgery; PCI, percutaneous coronary intervention; SAVR, SAVR; BAV, balloon aortic valvuloplasty; CSHA CFS, Canadian Study of Health and Aging Clinical Frailty Scale; ADL, Activities of Daily Living; IADL, Instrumental Activities of Daily Living; MMSE, Mini Mental State Examination; Mean 5-m Walk, mean 5-m Gait Speed test score; NYHA, New York Heart Association functional classification; LVEF, Left Ventricular Ejection Fraction; STS, the Society of Thoracic Surgeons risk score; BMI, Body Mass Index; Hgb, hemoglobin; eGFR, estimated Glomerular Filtration Rate; $\leq 72hr$, less than or equal to the first 72 hours after TA TAVI ; $>72hr$, more than 72 hours after TA TAVI procedure.

3.4 Level of Measurement of Variables

As the levels of measurement of the majority of the 62 variables are self-explanatory, for example, the Demographic and History and Risk Factors variables describe the TA TAVI patients' age, sex and medical histories, which are mostly categorical variables. In the following sections, we discuss the levels of measurement of a number of variables that are either modified for or specific to this study: 1) three modified ordinal-level variables, namely, *LOS ordinal*, *$\leq 72hr$ Blood Transfusion Units* and *$>72hr$ Blood Transfusion Units*); and 2) the variables specifically used in the THV program at the study center, which include the following: a) Wait Time variables, including *WaitTime1*, *WaitTime2*, and *WaitTime3*; b) the Functional Assessment variables, including the Gait Speed test (*Mean 5-m Walk*) (Wilson, Kostsucu, & Boura, 2013); the Activities of Daily Living (*ADL*) (Katz et al., 1970); the Instrumental Activities of Daily Living (*IADL*) (Lawton & Brody, 1969); the Mini-Mental State Examination (*MMSE*) (Folstein, Folstein, & McHugh, 1975); and the Canadian Study of Health and Aging Clinical Frailty Scale (*CSHA CFS*) (Dalhousie University Faculty of Medicine, 2012); and c) the Pre-op Status

variables, including New York Heart Association Classification (*NYHA*) (American Heart Association, 2015); and the Society of Thoracic Surgeons risk score (*STS*) (The Society of Thoracic Surgeons, 2014).

3.4.1 LOS ordinal. The dependent variable of this study was *LOS*, which was defined as the total days of one's hospital stay from the date of the TA TAVI procedure to the date of discharge. It was originally a continuous-level variable, which was highly skewed. To mitigate for these distributional challenges and to facilitate interpretation of the results, the original variable was converted into an ordinal-level variable, *LOS ordinal*, consisting of four approximately equal quartiles (Table 3).

Table 3
LOS Ordinal

LOS Ordinal	Level
LOS is between 1 - 5 days	1
LOS is between 6 - 7 days	2
LOS is between 8 - 12 days	3
LOS is 13 days and more	4

Abbreviation. *LOS*, length of stay.

3.4.2 Blood transfusion units variables. Similar to the dependent variable, *LOS ordinal*, the two blood transfusion units related variables were converted from continuous level to ordinal level. The variable of $\leq 72hr$ *Blood Transfusion Units* was defined as the total units of blood product that TA TAVI patient received within the first 72 hours postoperatively while the variable of $> 72hr$ *Blood Transfusion Units* was defined as the total units of blood products that TA TAVI patient received 72 hours after the completion of the procedure. As shown from the original data, when blood transfusion was indicated after the TA TAVI procedure, the total units

of given blood products varied within a small range of one to five units. Therefore, it was more pragmatic to convert them to ordinal type for the purpose of statistic analysis (Table 4).

Table 4
Blood Transfusion Units Variables: Ordinal Level

Variables	Level
≤ 72 hr Blood Transfusion Units	
More than 1 unit	1
1 unit	2
None	3
> 72 hr Blood Transfusion Units	
More than 1 unit	1
1 unit	2
None	3

Abbreviations. ≤ 72 hr, less than or equal to the first 72 hours after TA TAVI procedure; > 72 hr, more than 72 hours after TA TAVI procedure.

3.4.3 Wait time variables. In the THV program at the study center, there was a screening and referral process by which TA TAVI candidates were evaluated. Generally, patients were first referred to the program and evaluated for acceptance. On the acceptance day, the multidisciplinary Heart TA TAVI candidates completed the preoperative assessments at the center, and were given the date of the TA TAVI procedure. Hence, in this study, Wait Time variables consisted of three variables, namely, *WaitTime1*, *WaitTime2*, and *WaitTime3*. The variable of *WaitTime1* was defined as the duration from the Date of Referral to the THV program until the Date of Acceptance. The variable of *WaitTime2* was defined as the time period from the Date of Acceptance to the date of TA TAVI. And the variable of *WaitTime3* was defined as the total sum of *WaitTime2* and *WaitTime3*. All three variables were continuous and were measured and recorded in days.

3.4.4 Functional assessment variables. As discussed previously, TA TAVI patients are usually more frail and vulnerable due to a constellation of risk factors. Despite the fact that there are controversies around measurements used for frailty assessment in the literature, frailty is generally defined as a multi-factorial geriatric syndrome that develops over time as a result of an accumulation of stressors and that results in a reduced ability to maintain or regain homeostasis at advent of a destabilizing event (i.e., undergoing surgery or hospitalization). One of the commonly accepted measurements for frailty assessment involved the use of the following five criteria: unintentional weight loss (ten pounds in past year), self-reported exhaustion, weakness (grip strength), slow walking speed, and low physical activity. To determine whether one is frail, at least three of these five criteria must be met (Fried et al., 2001; Ferrucci et al., 2004). Moreover, according to Leidy (1994), functional status consisted of four dimensions: functional capacity, functional performance, functional capacity utilization, and functional reserve. One's functional capacity indicated his/her ability of performing activities in the physical, social, psychological or cognitive domains, which likely influenced the outcome of treatments and interventions. Hence, the inclusion of functional assessments preoperatively has gained more popularity in TAVI related literature (Green et al., 2012; Schoenenberger et al., 2012).

In the THV program, four functional assessment instruments were routinely utilized, including the Gait Speed (Wilson et al., 2013); ADL (Katz et al., 1970); IADL (Lawton & Brody, 1969); MMSE (Folstein et al., 1975); and CSHA CFS (Dalhousie University Faculty of Medicine, 2012). In the following section, the psychometric properties of the five instruments are briefly discussed.

3.4.4.1 Gait Speed. Gait Speed is used as a frailty clinical marker and is commonly measured by the 5-m Walk test. Recorded in seconds, the 5-m Walk test assesses functional

capacity and performance by averaging the time that one takes to walk, with or without walking aids, a distance of five meters for three times. Studies have demonstrated that the Gait Speed test was a valid and reliable predictor of mortality and morbidity (Afilalo et al., 2010; Green et al., 2012; Wilson et al., 2013). In their study, Afilalo and colleagues (2010) found that the Gait Speed test was “a simple and effective test that [might] identify a subset of vulnerable older adults at incrementally higher risk of mortality and major morbidity after cardiac surgery” (p. 1668).

3.4.4.2 Activities of Daily Living. The ADL test (Katz et al., 1970) is one of the most commonly used instruments to assess one’s ability of independent daily living. It addresses six functions, including bathing, dressing, toileting, transferring, continence, and feeding. On a scale of zero to six, a maximum score of six indicates full function. Lower test scores are indicative of greater functional impairment. The ADL test had internal consistency with α of 0.94 but poor test-retest reliability (Hamrin & Lindmark, 1988; Law & Letts, 1989; Shelkey & Wallance, 1998). Other studies found that there was evidence of construct validity and predictive validity (Katz et al., 1970; Brorsson & Asberg, 1983; Wallace & Shelkey, 2008).

3.4.4.3 Instrumental Activities of Daily Living. The IADL test (Lawton & Brody, 1969) assesses independent living abilities and interactions with the physical and social environment. Eight domains are assessed to obtain a score that ranges from zero to eight with higher values indicating higher level of function and independence. Studies have reported that the IADL had the reliability of internal consistency, test-retest, and inter-rater, and construct and concurrent validity (Kim, Won, & Cho, 2005; Graf, 2009).

3.4.4.4 Mini Mental State Examination. The MMSE (Folstein et al., 1975) is widely used for testing one’s cognitive function change. By asking eleven questions addressing

different aspects of one's mental abilities, the MMSE gives scores ranging from zero to 30, with lower scores indicating more severe cognitive impairment. Tombaugh and McIntyre (1992) compared the validity of the MMSE against a variety of gold standards, including Diagnostic and Statistical Manual of Mental Disorders. Other studies found that the MMSE showed high levels of sensitivity for moderate-to-severe cognitive impairment and lower levels for mild degrees of impairment, and the overall validity and reliability were considered satisfactory (Vertesi et al., 2001).

3.4.4.5 Canadian Study of Health and Aging Clinical Frailty Scale. In the THV program at the study center, the CSHA CFS (Dalhousie University Faculty of Medicine, 2012) was adopted to assess one's frailty status preoperatively. CSHA CFS scores range from one to nine. Higher scores indicate greater degree of frailty status. A five-year prospective cohort study of testing this scale in 2305 older adults revealed that it was highly correlated ($r = 0.80$) with the Frailty Index. Furthermore, statistical analyses showed that, as compared against other measures of cognition, function or comorbidity, the CSHA CFS performed better in predicting mortality (Dalhousie University Faculty of Medicine, 2012).

Appendix C lists the functional assessment instruments used in the study center's THV program.

3.4.5 Pre-op status variables.

3.4.5.1 New York Heart Association Classification. The NYHA (American Heart Association, 2015) is commonly used in the clinical practice to assess and measure patient's heart functional capacity within the past two weeks. It is defined as a four-class and ordinal-level variable, ranging from Class I (with cardiac disease but resulting in no limitation of physical activity) to Class IV (with cardiac disease resulting in inability to carry on any physical

activity without discomfort). The higher class indicates worse heart functional capacity (American Heart Association, 2015). Studies report that the NYHA is a reliable and valid tool for assessing functional status. It has been widely used as one of the important outcome comparing variables in the evaluation of TAVI procedures' efficacy (Leon et al., 2010; Smith et al., 2011). Bennett, Riegel, Bittner, and Nichols (2002) reported that the NYHA had high inter-rater reliability and convergent validity.

3.4.5.2 The Society of Thoracic Surgeons risk score. According to the Society of Thoracic Surgeons (STS) (2014), the STS risk models “[predicted] the risk of operative mortality and morbidity after adult cardiac surgery on the basis of patient demographic and clinical variables, [and were] primarily used to adjust for case mix when comparing outcomes across institutions with different patient populations” (p. 1). Higher scores indicate higher operative risk. In comparison to other risk profile systems such as the European system for cardiac operative risk evaluation score, the STS risk score seemed to be superior and more suitable in assessing perioperative mortality (Wendt et al., 2009). In the absence of a TAVI-specific risk score, it is important to note that the STS risk score should be used in conjunction with the expert team's clinical judgments to guide clinical decision making (Piazza et al., 2010).

3.5 Analytical Method

To address the objectives of this study, we applied the following structured stepwise approach to the analysis.

Step 1. A retrospective chart review was first conducted to extract data from 128 consecutive medical charts of older adults, who underwent TA TAVI procedure at the study center from 2010 to 2014. A Data Collection Form (Appendix A) was developed based on literature reviews, previous experience and consultations of experts, and was applied by the same

data abstractor throughout the data collection process. A corresponding Coding Manual (Appendix B) was developed and was used as a guide for ensuring consistency in data extraction (Gregory & Radovinsky, 2012). The data of the 128 consecutive medical records were entered into an Excel file and then imported into an IBM SPSS Statistics file for statistical analyses.

Step 2. In SPSS, univariate descriptive statistical analyses were first performed to describe the distributions of the 62 independent variables as well as the dependent variable, *LOS ordinal*. Frequencies and percentage were obtained to indicate the distributions of either categorical or ordinal variables whereas means, medians and standard deviations were computed for continuous variables.

Step 3. Bivariate ordinal logistic regression analyses were then performed to evaluate the associations of the 62 independent variables with the dependent variable, *LOS ordinal*, defined as an odds ratio. The odds ratio is the measure that describes the strength of association between a predictor and the response of interest. The Wald (χ^2) statistics and corresponding p values were also calculated. One of the purposes of obtaining the Wald (χ^2) statistics and corresponding p values was to identify the variables that were thought-to-be-more-significant for inclusion in the multivariate ordinal logistic regression analyses. To select variables for multivariate logistic regression analysis, Hosmer and Lemeshow (2000) suggested that a p value of 0.250 be used as a conventional cutoff. In this study, a more stringent p value of 0.100 was adopted to avoid exceeding the maximum number of variables that could be included to achieve adequate statistical power given sample size restrictions. Hence, for the purpose of variable selection, we chose the independent variables that had the Wald χ^2 statistics with p value equal or less than 0.100 and considered them more significant than those which had the Wald (χ^2)

statistics of p value greater than 0.100 in terms of their impact on the length of stay after the TA TAVI procedure.

Step 4. The independent variables that met the criteria in **Step 3** were included in a multivariate ordinal logistic regression analysis to evaluate their overall impact on the dependent variable, *LOS ordinal*.

Step 5. Multivariate trimming was performed to determine the independently significant predictors of the LOS after TA TAVI. The details of the trimming process were as follows:

1. The Wald χ^2 and corresponding p values of all the variables that had p equal or less than 0.100 were collectively calculated by running the multivariate ordinal logistic regression in SPSS. Likelihood Ratio χ^2 was obtained.
2. The variable with the smallest Wald χ^2 and largest p value was first removed from the initial variable set. The remaining variables were then entered in the multivariate ordinal logistic regression for computing Wald χ^2 , corresponding p values, and Likelihood Ratio χ^2 .
3. The iterative process was repeated. The difference between two subsequent values of Likelihood Ratio χ^2 was calculated every time when a variable was removed.
4. At each step, the difference of Likelihood Ratio χ^2 was compared against the critical value of χ^2 distribution with one degree of freedom (95% CI), which is 3.841 (NIST Sematech, 2013). Should the absolute value of the difference was greater than 3.841, the corresponding variable was then considered to have independently significant impact on the LOS after TA TAVI, and was therefore retained in the multivariate ordinal logistical regression model. Variables that did not meet this criteria were excluded.

Step 6. After the multivariate trimming process, a new set of variables that were deemed independently significant in terms of their impact on the LOS after TA TAVI remained, and were included again in the full multivariate ordinal logistic regression analysis to estimate their combined associations with the dependent variable, LOS ordinal.

3.6 Ethical Considerations

The following ethical guidelines were adhered to: 1) Special measures were taken to protect patients' personal identities. In this study, the variables pertinent to patients' personal identities were sex and discharge date. Sex was one of the independent variables of interest in this study while discharge date was used for calculating the LOS; 2) Computerized data collection forms were kept by authorized study personnel in a secure location, and the collected data were saved on the encrypted and password protected computers of the researchers. Furthermore, the data would be kept for additional five years at the end of the study, and be destroyed afterwards. There was no plan for future use of the data; 3) Prior to the commencement of the study, the Research Ethics Board (REB) approvals from Trinity Western University REB (TWU REB) and the University of British Columbia Providence Health Care REB (UBC PHC REB) were granted; and 4) the Providence Health Care Institutional Approval was obtained.

3.7 Chapter Summary

This chapter discussed the design and statistical methods of this study. This study analyzed the data obtained from 128 consecutive TA TAVI medical records through a retrospective chart review. Based on this study's Predicting LOS after TA TAVI: TA TAVI Surgical Process Model (Figure 1) and Predicting LOS after TA TAVI: Conceptual Model (Figure 2), 62 independent variables were initially selected. For the purpose of statistical analysis, three originally continuous variables, *LOS*, *≤72hr Blood Transfusion Units* and *>72hr*

Blood Transfusion Units, were descritized to ordinal variables. In addition, Wait Time variables and the instrument-type variables, including the Functional Assessment variables and risk factor variables unique to this study, were described. Furthermore, the details of the statistical analyses used in this study were provided. This study was approved by all relevant REBs. In the following chapter, we present the results of this study.

Chapter Four: Results

In this chapter, a sample description is first provided. The results of univariate descriptive statistical analyses of the 63 variables are then discussed, followed by the results of the bivariate ordinal logistic regression and multivariate ordinal logistic regression analyses. The selections of variables for several multivariate ordinal logistic regression analyses are illustrated through the multivariate trimming. Finally, the results of multivariate ordinal logistic regression analyses with the variable, *STS*, are presented.

4.1 Sample Description

This study's sample consisted of 115 medical records ($N=115$) of patients who underwent TA TAVI procedure at the study center from 2010 to 2014, excluding eight deaths, three TAO⁴, and two aborted TA TAVI from the initial sample of 128 cases.

Table 5
Sample Description

Variables (Missing)	Mean (SD)	Frequency (Percent)
Age (0)	78.8 (8.7)	-
Sex (0.9%)		
<i>Female</i>	-	66(57.4%)
<i>Male</i>	-	48(41.7%)
Status of Referral (7.8%)		
<i>Elective</i>	-	91(85.8%)
<i>In-patient</i>	-	15(14.2%)
Location of Residence (0)		
<i>VCH</i>	-	36(31.3%)
<i>FHA</i>	-	28(24.3%)
<i>IHA</i>	-	23(20.0%)
<i>VIHA</i>	-	17(14.8%)
<i>NHA</i>	-	7(6.1%)
<i>Other</i>	-	4(3.5%)

⁴ Transaortic (TAO) is an alternative surgical access used in TAVI. The TA and TAO approaches differ in peri- and post-procedure requirements. We excluded the TAO cases from this study.

Home Support (35.7%)		
<i>None</i>	-	51(68.9%)
<i>Part time</i>	-	22(29.7%)
<i>Full time</i>	-	1(1.4%)
Living Situation (24.3%)		
<i>Lives alone/ Independent</i>	-	81(93.1%)
<i>Nursing home</i>	-	3(3.4%)
<i>Lives with family</i>	-	3(3.4%)

Note. $N = 115$. *Abbreviations.* *FHA*, Fraser Health Authority; *IHA*, Interior Health Authority; *NHA*, Northern Health Authority; *VIHA*, Vancouver Island Health Authority; *VCH*, Vancouver Coastal Health Authority.

As shown in Table 5, the mean age of this sample was 78.8 years ($SD = 8.7$), with a relatively normally distribution (Skewness = - 0.77; Kurtosis = - 0.04, $SD = 0.4$). Geographically, more than half of the sample came from the areas in relatively close proximity of the study center (the Vancouver Coastal Health Authority (VCH) (31.3%) and Fraser Health Authority (FHA) (24.3%)). Prior to the TA TAVI procedure, 68.9% of the candidates did not require any home support services (missing 35.7%), and 93.1% lived alone or independently (missing 24.3%). When referred to the THV program, the majority were elective patient status (missing 7.8%). On average, TA TAVI patients had to wait 79.8 days ($SD = 85.7$) from the Date of Referral to the Date of Acceptance, and 107.3 days ($SD = 95.1$) from the Date of Acceptance to the date of the TA TAVI procedure. The median total wait time was 148.0 days ($SD = 141.9$) (Figure 3).

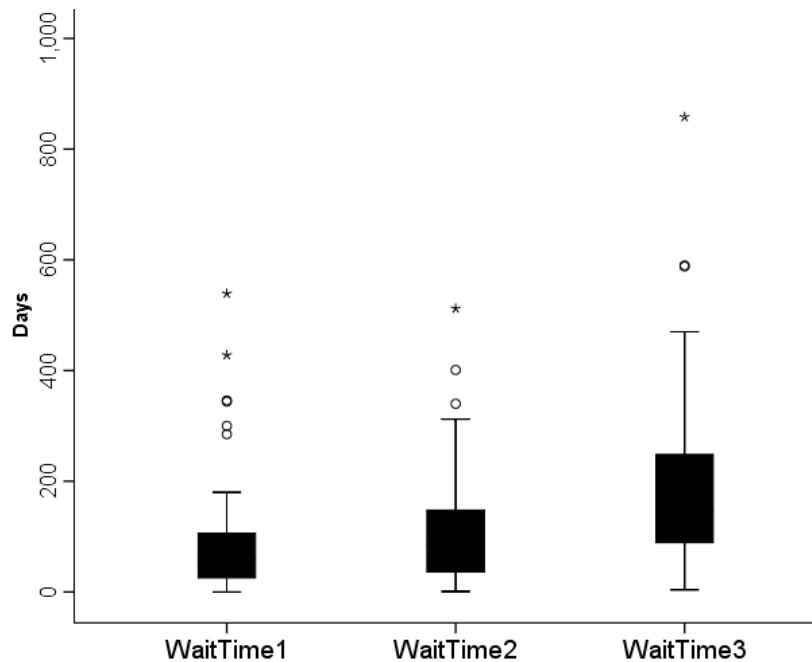


Figure 3. Distributions of Wait Time Variables⁵. This figure illustrates the distributions of three Wait Time variables in this study. $N = 115$.

4.2 Variable Descriptions

Univariate analyses were first conducted to provide the descriptions of the remaining independent variables as well as the dependent variable.

4.2.1 Dependent variable. As described in Section 3.4.1, the original continuous-level dependent variable, *LOS*, was converted to an ordinal-level variable, *LOS ordinal*. Figure 4 shows the comparison of the distributions of the two different levels of measurement of *LOS*. As illustrated, the distribution of the continuous-level variable, *LOS*, was skewed to right (Skewness= 3.2; Kurtosis= 11.6, SD= 0.4), while the ordinal-level variable, *LOS ordinal* demonstrated a relatively uniform distribution. The mean and median of *LOS* was 11.1 days and 7.0 days, respectively. Most of the TA TAVI patients had a *LOS* less than eight days.

⁵ Wait Time variables: WaitTime 1: The time period from the Date of Referral to the Date of Acceptance; WaitTime 2: The time period from the Date of Acceptance to the date of TA TAVI procedure; WaitTime 3: The time period from the Date of Referral to the date of TA TAVI procedure, all recorded in days.

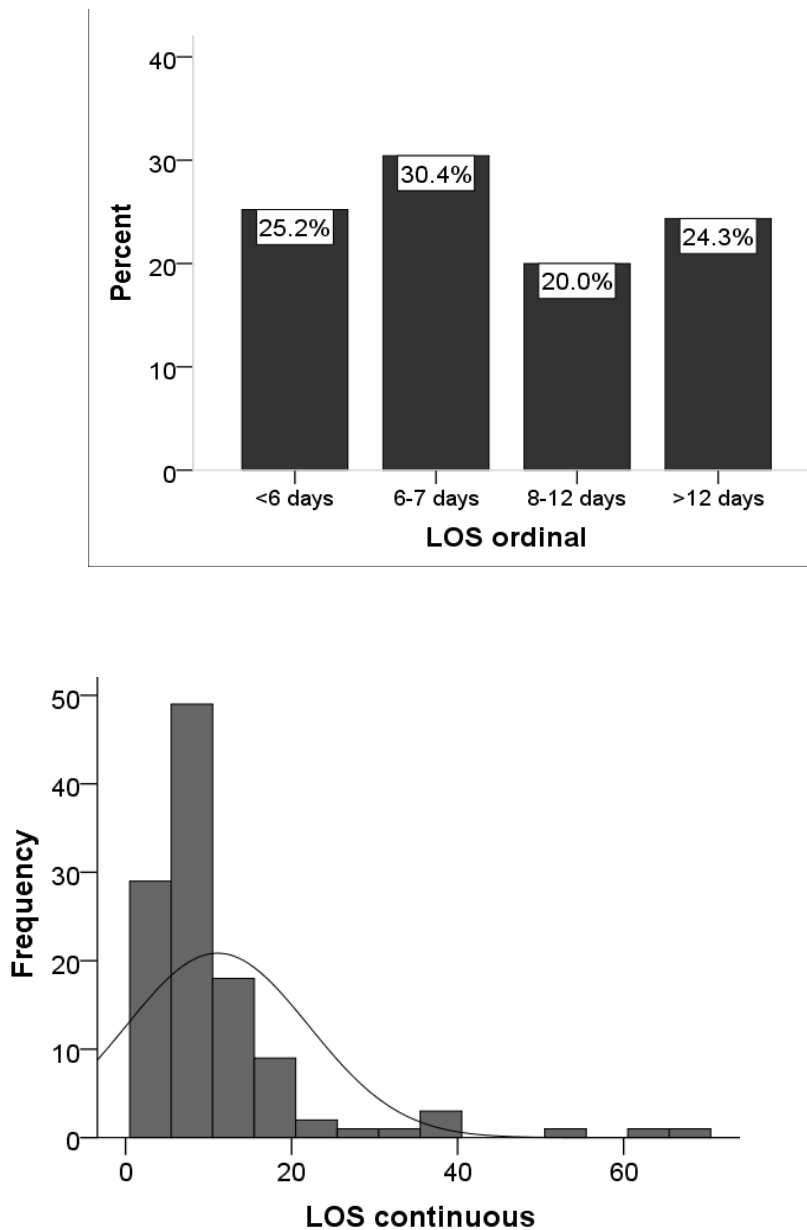


Figure 4. Comparison of the Distributions of *LOS Continuous* vs. *LOS Ordinal*. The figure compares the distributions of the dependent variable, *LOS*, before and after discretization.

4.2.2 Pre-procedure phase variables.

4.2.2.1 History and risk variables. Among the 12 medical history factors selected in this study, the most prevalent History and Risk factor was *Prior Atrial Fibrillation* (45.9%), followed

by *Prior SAVR* (42.6%) and *Prior Other Cardiac Surgery* (41.6%). The *Prior ICD* was the least prevalent History and Risk factor, that is, 96.4% of the sample did not have an implantable cardioverter defibrillator prior to the TA TAVI (Figure 5).

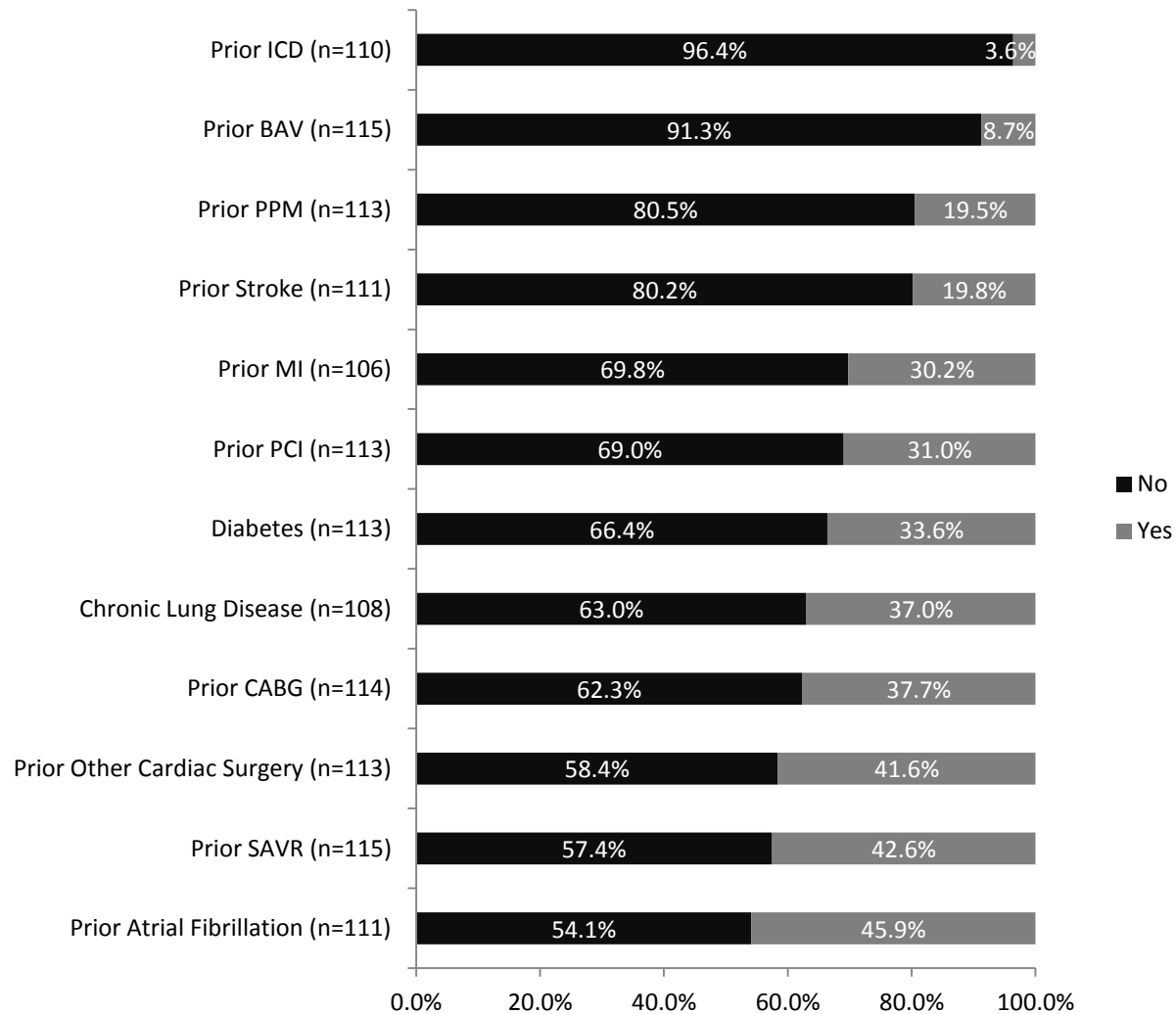


Figure 5. Distributions of History and Risk Variables. This figure illustrates the distributions of the 12 History and Risk variables of Pre-procedure phase. $N = 115$.

4.2.2.2 Functional assessment variables. The functional assessment variables consisted of five instruments, namely, the 5-m Gait Speed test (*Mean 5-m Walk*), Mini Mental State Examination (*MMSE*), Canadian Study of Health and Aging Clinical Frailty Scale (*CSHA CFS*),

Instrumental Activities of Daily Living test (*IADL*), and Activities of Daily Living test (*ADL*), this study's sample demonstrated relatively high functional capacities (Table 6). The mean *MMSE* was 27.2/30 (SD= 2.4), indicating that overall the sample's average cognitive function was within the normal range. In addition, the results of *CSHA CFS* (Mean= 4.3/9; SD= 0.6), *ADL* (Mean= 5.9/6; SD= 0.5), and *IADL* (Mean= 6.5/8; SD= 2.0) show that this sample was generally vulnerable and mildly frail with moderate-to-high functioning independence. However, the missing response rates of all of the seven variables were high.

Table 6
Distributions of Functional Assessment Variables

Variables (Missing)	Mean (SD)	95% CI for Mean	Min	Max
Mean 5-m Walk (59.1%)	7.2 (2.8)	[6.38, 8.00]	3.8	15.6
MMSE (51.3%)	27.2 (2.4)	[26.56, 27.84]	19.0	30.0
CSHA CFS (44.3%)	4.3 (0.6)	[4.18, 4.48]	3.0	6.0
IADL (38.3%)	6.5 (1.9)	[6.05, 6.97]	2.0	8.0
ADL (37.4%)	5.9 (0.5)	[5.75, 5.97]	4.0	6.0

Note. *N* = 115. *Abbreviations.* *CSHA CFS*, Canadian Study of Health and Aging Clinical Frailty Scale; *ADL*, Activities of Daily Living; *IADL*, Instrumental Activities of Daily Living; *MMSE*, Mini Mental State Examination; *Mean 5-m Walk*, mean 5-m Gait Speed test score.

4.2.2.3 Pre-op status variables. The Pre-op Status variables consisted of seven variables, including six continuous-level variables, *LVEF*, *STS*, *BMI*, *Hgb*, *Creatinine*, and *eGFR*, and an ordinal variable, *NYHA*. As shown in Figure 6, *NYHA* Class III was 71.3%, followed by *NYHA* Class IV (22.6%), indicating that this study's sample population was predominantly *NYHA* Class III or IV, and had marked limitations and inability of physical functions due to cardiac disease (AHA, 2015). Additionally, the mean *LVEF* was 54.0% with a range from 20.0% to 70.0% (missing 5.2%). Overall, this study's sample population had a mean *BMI* of 25.5 kg/m²

(SD= 5.9), an elevated serum creatinine level (mean= 120.3 $\mu\text{mol/L}$, SD= 81.6) and a low-to-normal hemoglobin level (mean= 121.5 g/L, SD= 16.8) preoperatively. On average, the STS score was 8.7% (SD= 7.7), with a high missing response rate of 45.2%.

Table 7
Distributions of Pre-op Status Continuous Variables

Variables (Missing)	Mean (SD)	95% CI for Mean	Min	Max
LVEF (5.2%)	54% (0.1)	[0.51, 0.56]	20%	70%
STS (45.2%)	8.7% (7.7)	[6.78, 10.63]	1.0%	42.0%
BMI (0)	25.5 (5.9)	[24.43, 26.62]	15.2	43.7
Hgb (0)	121.5 (16.8)	[118.36, 124.56]	83.0	175.0
Creatinine (0)	120.3 (81.6)	[105.18, 135.33]	53.0	496.0
eGFR (2.6%)	55.5 (23.6)	[51.13, 59.96]	6.0	120.0

Note. $N = 115$. *Abbreviations.* *LVEF*, Left Ventricular Ejection Fraction; *STS*, the Society of Thoracic Surgeons risk score; *BMI*, Body Mass Index; *Hgb*, hemoglobin; *eGFR*, estimated Glomerular Filtration Rate.

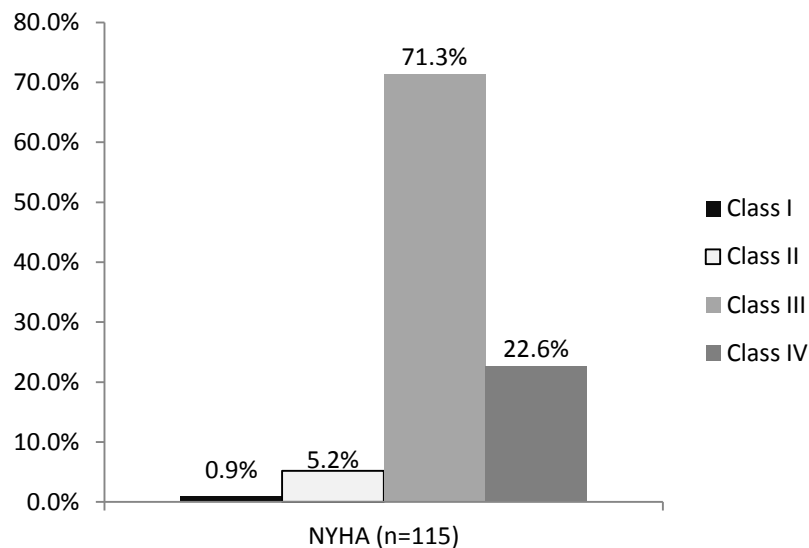


Figure 6. Distributions of NYHA. $N = 115$.

4.2.3 Peri-procedure phase variables. The Peri-procedure phase variables consisted of three sub-group variables: 1) three Procedural Factors variables (*Procedure Total Time*, *Valve Type*, and *Procedure Type*); 2) four Peri-procedure Status variables describing the TA TAVI patients' status immediately after the completion of the procedure (*Airway Status*, *Pulmonary Artery Catheter*, *Chest Drain*, and *Temporary Pacemaker*); and 3) nine Peri-procedure Complications variables pertaining to the critical care that patients received within the period of less than or equal to the first 72 hours of the TA TAVI.

4.2.3.1 Procedural factors variables. As illustrated in Figure 7, the mean total operating time of the TA TAVI was 103.1 minutes (SD= 3.7), with a median of 92.5 minutes and a range of 41.0 to 242.0 minutes (missing 0.9%). In TAVI, as compared to native-valve procedure procedures, which refers to TAVI procedures pertaining to the transcatheter replacement of the native aortic valve, a transcatheter heart valve implantation within a failed bioprosthesis is called a valve-in-valve procedure. In this study, 72.2% were native-valve procedures while 27.8% were valve-in-valve procedures. In addition, the majority of TA TAVI patients had their aortic valves replaced (78.3%). Only 2.6% of the TA TAVI cases involved both aortic- and mitral-valve replacement (Figure 8).

4.2.3.2 Peri-procedure status variables. As shown in Figure 9, prior to admission to the critical care unit, 26.3% of the TA TAVI patients had pulmonary artery catheter, and 17.7% had used temporary pacemakers. The number of patients who were intubated was approximately 1.5 times of those who were extubated. Over 90.0% had chest drain inserted.

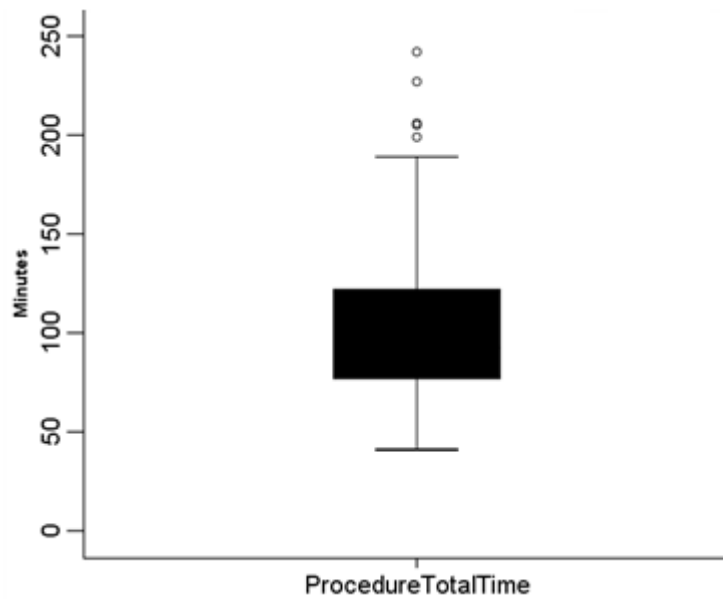


Figure 7. Distribution of Procedure Total Time. $N = 114$, missing 0.9%.

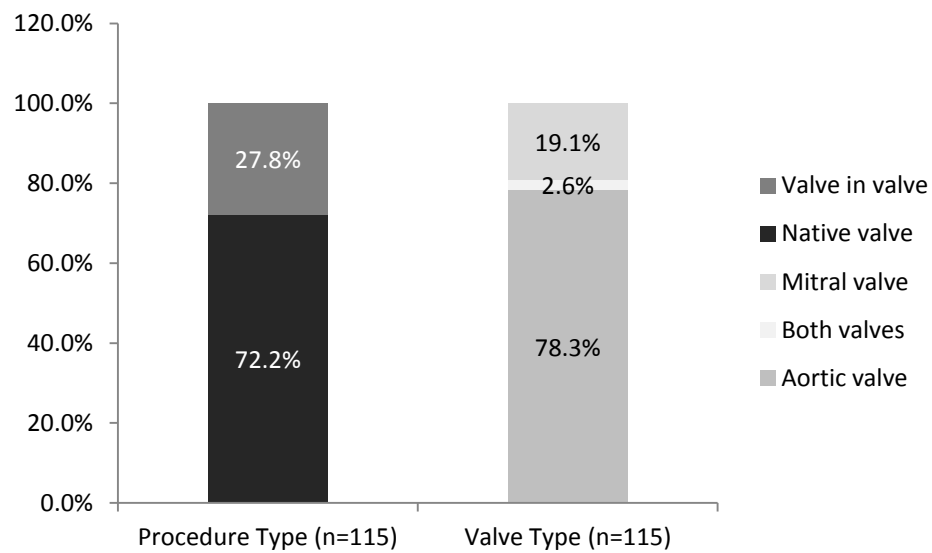


Figure 8. Distributions of Procedure Type and Valve Type. This figure compares the two procedural variables of TA TAVI. $N = 115$.

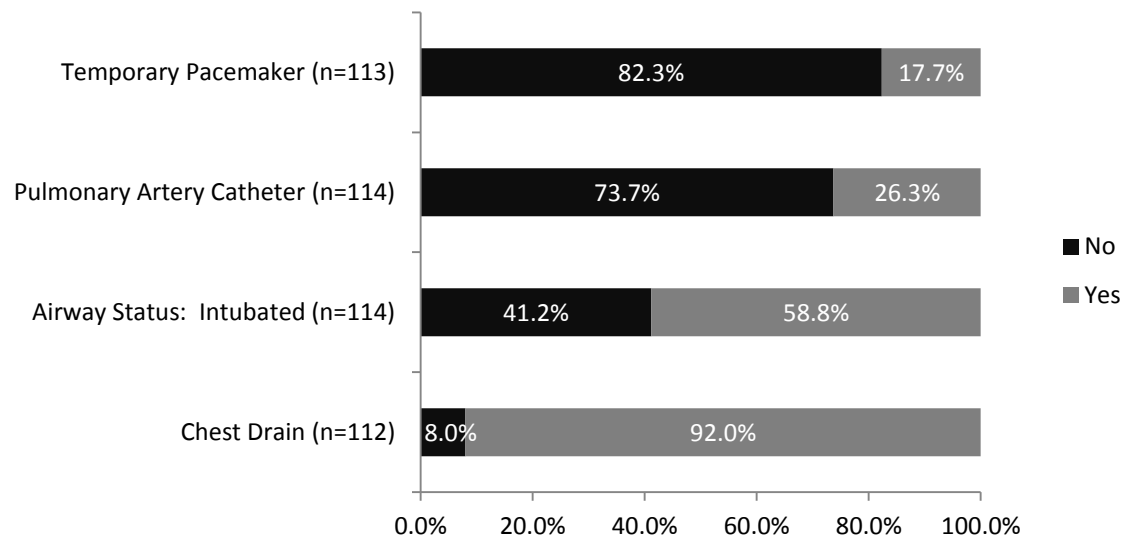


Figure 9. Distributions of Peri-procedure Status Variables. This figure illustrates the distributions of the four variables pertaining to TA TAVI patients' postoperative status within the period of less than or equal to the first 72 hours of TA TAVI ($\leq 72\text{hr}$). $N = 115$.

4.2.3.3 Peri-procedure complications variables. In this study, three common postoperative complications of the TA TAVI were included: 1) the variables pertaining to permanent pacemaker implantation due to postoperative aberrant cardiac conduction (pacemaker-related variables); 2) the variables pertaining to new-onset postoperative atrial fibrillation (atrial fibrillation-related variables), and 3) the variables pertaining to the occurrence of postoperative bleeding, within and after the first 72 hours time periods (bleeding and blood transfusion-related variables).

As illustrated in Figure 10, within the first 72 hours since the start time of the TA TAVI, there was no single case of perforation and annular dissection, three cases of cardiac arrest, and two cases of stroke. Among the sample, 5.2% required permanent pacemaker implantation and 11.3% developed new-onset atrial fibrillation shortly after the TA TAVI. In addition, the occurrences of postoperative bleeding and blood transfusion were 20.0% and 22.6%, respectively,

indicating that these two were the most prevalent postoperative complications of the TA TAVI. Furthermore, 13.0% of TA TAVI patients received one-unit blood transfusion while 9.6% of patients received more than one unit of blood products (Figure 11). Of the patients who received more than one unit of blood products through blood transfusion, seven had two units; one had four units; two had five units; and one had seven units.

4.2.4 Post-procedure phase variables. The variables of the Post-procedure phase consisted of three sub-group variables: 1) one variable pertaining to the length of critical care (*LOSICU*); 2) four discharge planning related variables (*Lowest Hgb*, *Discharge Hgb*, *Highest Creatinine*, and *Discharge Creatinine*); and 3) eight Post-procedure Complications variables pertaining to postoperative complications after the first 72 hours of the TA TAVI (Table 2).

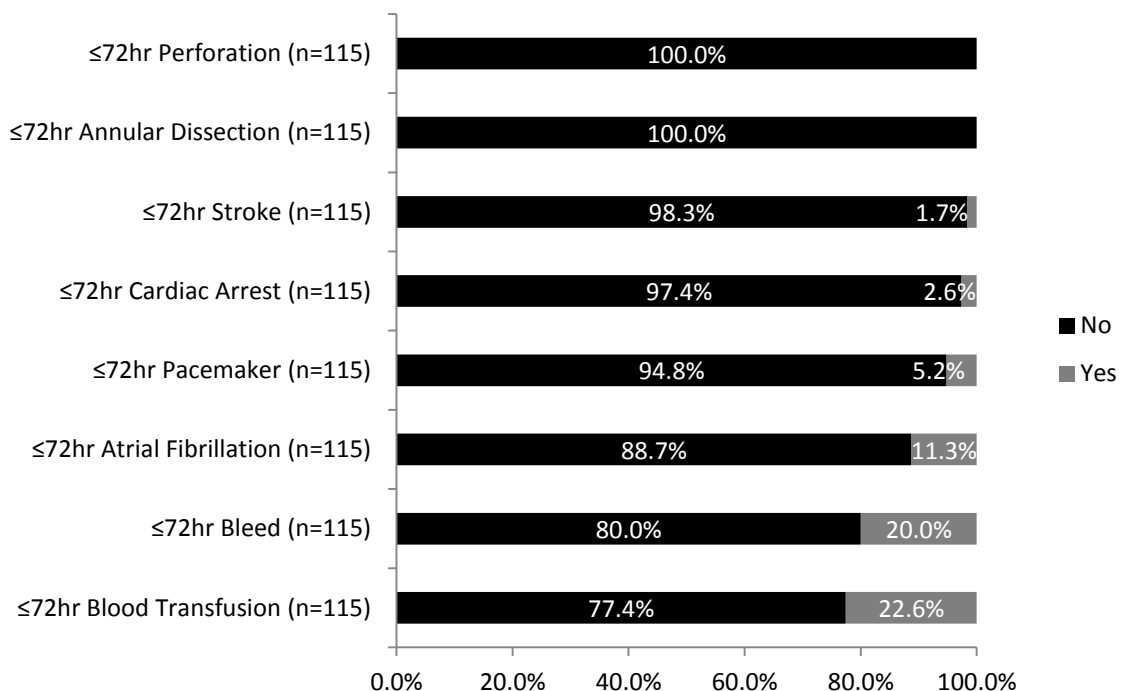


Figure 10. Distributions of Peri-procedure Complications Variables. This figure illustrates the distributions of eight Peri-procedure Complications variables within the period of less than or equal to the first 72 hours of TA TAVI (≤ 72 hours). $N = 115$.

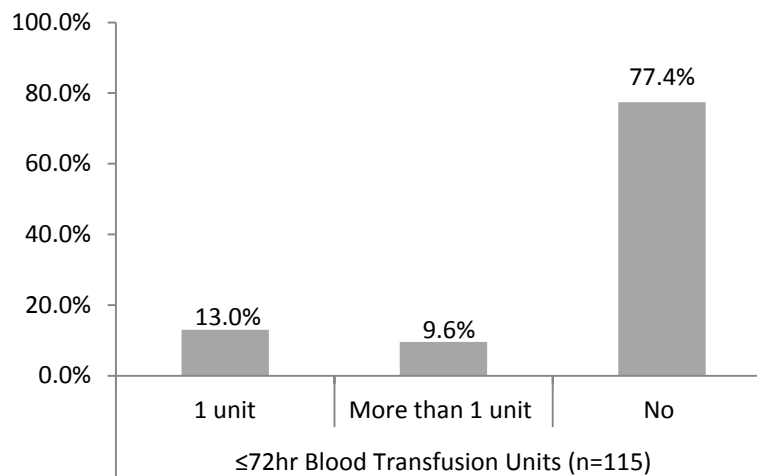


Figure 11. Distributions of ≤72hr Blood Transfusion Units. This figure illustrates the distribution of blood transfusion units within the first 72 hours of TA TAVI (≤72 hours). $N = 115$.

4.2.4.1 LOS in critical care variable. The mean and median of the length of stay in the intensive care unit (*LOSICU*) was 42.0 hours and 41.5 hours, respectively ($SD = 96.8$), with a range of 18.0 to 961.0 hours ($Kurtosis = 67.0$, $SD = 0.5$) (Figure 12).

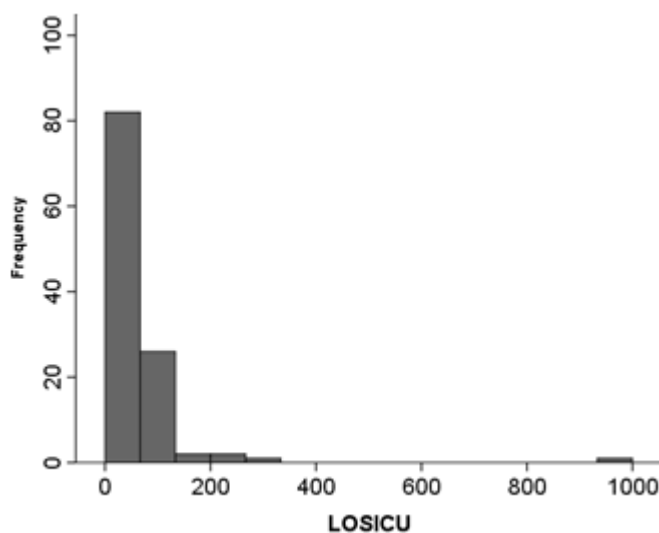


Figure 12. Histogram of *LOSICU* (hours). This figure illustrates the distribution of the length of stay in the critical care. $N = 114$, missing 0.9%.

4.2.4.2 Discharge planning variables. On average, the lowest value of hemoglobin of TA TAVI patients during their hospitalization was 95.8 g/L (SD= 15.1; median= 95.5 g/L), as compared to their mean hemoglobin level of 106.3 g/L at the time of discharge (SD= 14.5; median= 105.5 g/L), indicating an overall improvement in hemoglobin level. Similarly, the mean highest creatinine level of TA TAVI patients during hospitalization was 147.7 $\mu\text{mol/L}$ (SD= 107.3; median= 119.0) while the average creatinine level at the time of discharge was 121.2 $\mu\text{mol/L}$ (SD= 80.2; median= 99.5), showing an overall downward trending of creatinine level in the sample through the course of the TA TAVI (Figure 13).

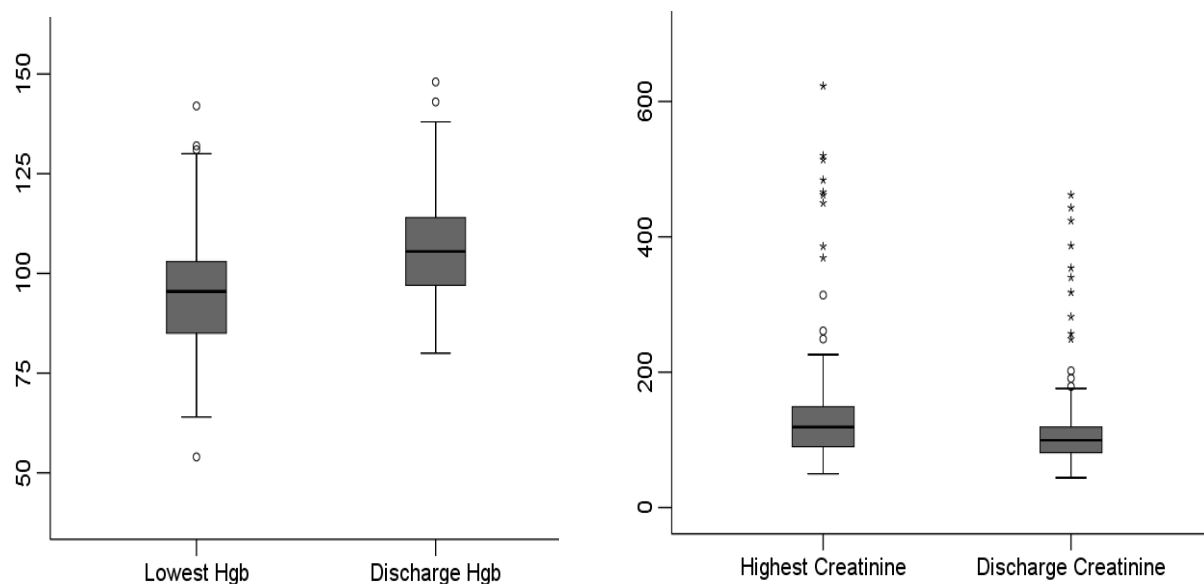


Figure 13. Distributions of Discharge Planning Variables⁶. This figure compares the distributions of the four Discharge Planning variables, including the values of hemoglobin (d/L) and creatinine ($\mu\text{mol/L}$) during the hospitalization and upon discharge. $N=114$, missing 0.9%.

⁶ Discharge Planning variables: In this study, Discharge Planning variables refers to the variables used in the discharge planning for TA TAVI patients. Four variables were included, namely, *Lowest Hgb*, *Discharge Hgb*, *Highest Creatinine*, and *Discharge Creatinine*.

4.2.4.3 Post-procedure complications variables. As compared to the Peri-procedure Complications variables, the eight Post-procedure Complications variables described the same perimeters of the TA TAVI patients' care and status but in a different time period, that is, after the first 72 hours postoperatively until discharge. Figure 15 illustrates the comparison between the two groups of variables. As shown, during this time period, there was no single case of cardiac arrest or perforation, and two cases of postoperative stroke. From the Peri-procedure phase to the Post-procedure phase, it is evident that there was a decreasing trend of the general incidence of major postoperative complications, especially the new-onset atrial fibrillation episodes and bleeding and blood transfusion events. Nonetheless, when blood transfusion was required, most TA TAVI patients received more than one unit of blood product (4.4%), indicating that blood transfusion events after the first 72 hours postoperatively might be more significant than those within the first 72 hours time period (Figure 14). Among the five TA TAVI patients who received more than one blood products, three received two units while the other two received five units.

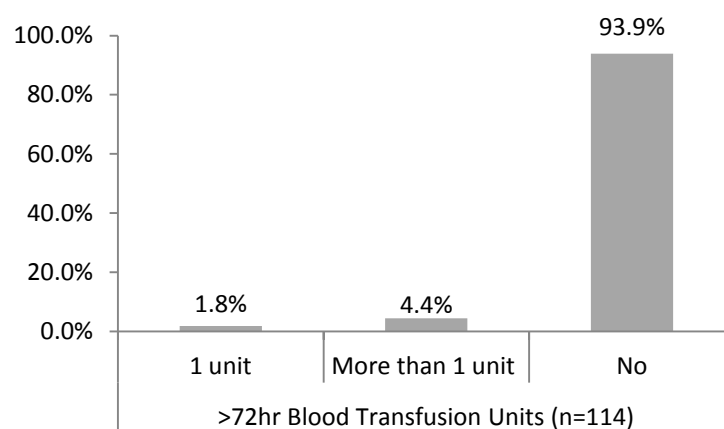


Figure 14. Distribution of >72hr Blood Transfusion Units. This figure illustrates the distribution of the units of blood transfusion that TA TAVI patients received during the period from 72 hours after the procedure to the discharge (>72 hours). $N = 115$.

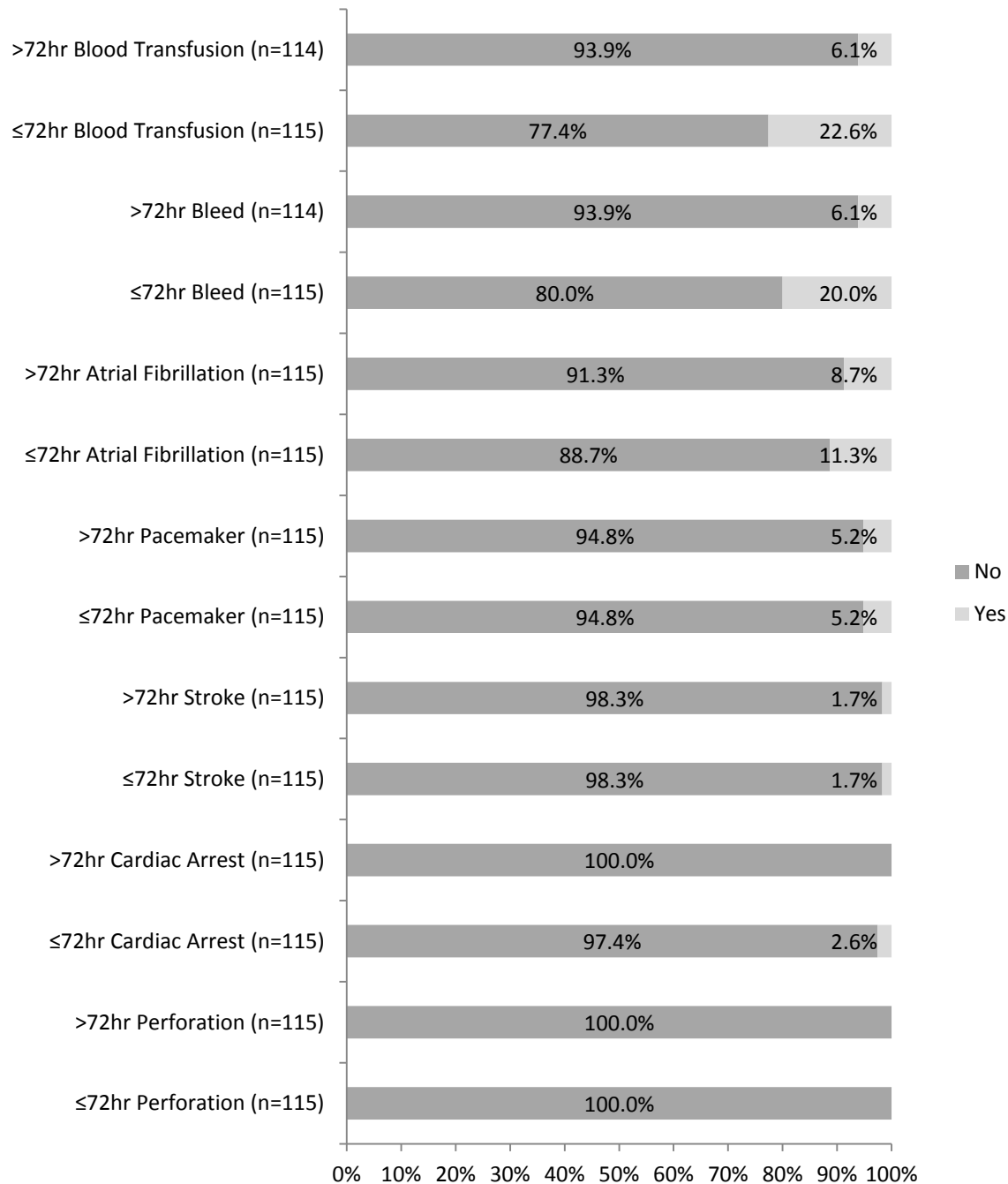


Figure 1516. Comparison of Distributions of Post-procedure Complications variables and Peri-procedure Complications variables. Six TA TAVI procedure related postoperative complications in two time periods (>72 hours vs. ≤72 hours) were compared. $N = 115$.

4.3 Bivariate Ordinal Logistic Regression Model

4.3.1 Results: pre-procedure phase demographic variables. As shown in Table 8, for every additional year in age, the odds of having longer LOS after the TA TAVI increased by 1.07 times, Wald $\chi^2(1) = 10.01$, $p = 0.002$. All the other Demographic variables had p values greater than 0.100, indicating that they were not statistically significant predictors of the LOS and thus were excluded in the subsequent multivariate regression full model.

Table 8

Bivariate Ordinal Logistic Regression Report: Pre-procedure Phase Demographic Variables

Variable (Missing)	Percent/ Mean (SD)	OR [95% CI]	Wald χ^2 (df)	p
Sex (0.9%)			0.35(2)	0.839
<i>Female</i>	57.4%	1.00		
Male	41.7%	0.83 [0.43, 1.62]		
Status of Referral (7.8%)			0.23(1)	0.633
<i>Elective</i>	85.8%	1.00		
In-patient	14.2%	1.27 [0.48, 3.38]		
Location of Residence (0)			3.30(5)	0.653
<i>VCH</i>	31.3%	1.00		
FHA	24.3%	0.71 [0.29, 1.72]		
IHA	20.0%	0.66 [0.26, 1.68]		
VIHA	14.8%	0.72 [0.26, 2.03]		
NHA	6.1%	0.94 [0.22, 4.01]		
Out of Province	3.5%	0.18 [0.02, 1.34]		
Age (0)	78.8(8.7)	1.07 [1.03, 1.11]	10.01(1)	0.002*
WaitTime1 (0)	79.8(85.7)	1.00 [0.99, 1.00]	0.81(1)	0.369
WaitTime2 (0)	107.3(95.2)	1.00 [1.00, 1.00]	0.51(1)	0.476
WaitTime3 (0)	187.1(141.9)	1.00 [1.00, 1.00]	0.98(1)	0.322

Note.

1. $N = 115$.
2. The italicized group for each variable is the reference group for the comparison.
3. The odds ratio indicates to what extent the variable influences LOS relative to its reference group. A ratio greater than 1.00 indicates an increase in LOS, while a ratio less than 1.00 indicates a decrease in LOS.

4. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald χ^2 (df) and p value. A bolded p value with asterisk indicates p equals 0.100 or less.

5. *Abbreviations.* *VCH*, Vancouver Coastal Health Authority; *VIHA*, Vancouver Island Health Authority; *FHA*, Fraser Health Authority; *IHA*, Interior Health Authority; *NHA*, Northern Health Authority.

4.3.2 Result: pre-procedure phase history and risk variables. The odds ratios of the 12 History and Risk variables are presented in Table 9. Among the 12 variables, TA TAVI patients who had chronic lung diseases were 2.25 times more likely to have a longer LOS than those who did not have such medical condition preoperatively, Wald $\chi^2(1) = 4.93, p = 0.026$. None of the other variables had p values less than or equal to 0.100.

Table 9

Bivariate Ordinal Logistic Regression Report: Pre-procedure Phase History and Risk Variables

Variables (Missing)	Percent/ Mean (SD)	OR [95% CI]	Wald χ^2 (df)	p
Prior PPM (1.7%)			0.07 (1)	0.788
<i>No</i>	80.5%	1.00		
Yes	19.5%	1.12 [0.49, 2.59]		
Prior ICD (4.3%)			0.50 (1)	0.478
<i>No</i>	96.4 %	1.00		
Yes	3.6%	1.92 [0.32, 11.67]		
Chronic Lung Disease (6.1%)			4.93 (1)	0.026*
<i>No</i>	63.0%	1.00		
Yes	37.0%	2.25 [1.10, 4.60]		
Diabetes (1.7%)			0.51 (1)	0.474
<i>No</i>	66.4%	1.00		
Yes	33.6%	0.77 [0.38, 1.56]		
Prior Stroke (3.5%)			0.69 (1)	0.405
<i>No</i>	80.2%	1.00		
Yes	19.8%	1.43 [0.62, 3.31]		
Prior MI (7.8%)			0.00 (1)	0.982
<i>No</i>	69.8%	1.00		
Yes	30.2%	1.01 [0.48, 2.12]		

Prior Atrial Fibrillation (3.5%)			2.09 (1)	0.149
<i>No</i>	<i>54.1%</i>	<i>1.00</i>		
Yes	45.9%	1.64 [0.84, 3.23]		
Prior Other Cardiac Surgery (1.7%)			0.76 (1)	0.383
<i>No</i>	<i>58.4%</i>	<i>1.00</i>		
Yes	41.6%	0.74 [0.38, 1.45]		
Prior CABG (0.9%)			0.49 (1)	0.486
<i>No</i>	<i>62.3%</i>	<i>1.00</i>		
Yes	37.7%	0.79 [0.40, 1.55]		
Prior PCI (1.7%)			0.22 (1)	0.643
<i>No</i>	<i>69.0%</i>	<i>1.00</i>		
Yes	31.0%	1.19 [0.58, 2.42]		
Prior SAVR (0)			1.61 (1)	0.204
<i>No</i>	<i>57.4%</i>	<i>1.00</i>		
Yes	42.6%	0.65 [0.33, 1.26]		
Prior BAV (0)			0.05 (1)	0.832
<i>No</i>	<i>91.3%</i>	<i>1.00</i>		
Yes	8.7%	1.13 [0.36, 3.63]		

Note.

1. $N = 115$.
2. The italicized group for each variable is the reference group for the comparison.
3. The odds ratio indicates to what extent the variable influences LOS relative to its reference group. A ratio greater than 1.00 indicates an increase in LOS, while a ratio less than 1.00 indicates a decrease in LOS.
4. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald χ^2 (df) and p value. A bolded p value with asterisk indicates p equals 0.100 or less.
5. Abbreviations. PPM, permanent pacemaker; ICD, implantable cardioverter defibrillator; MI, myocardial infarction; CABG, coronary artery bypass surgery; PCI, percutaneous coronary intervention; SAVR, SAVR; BAV, balloon aortic valvuloplasty.

4.3.3 Results: pre-procedure phase functional assessment variables. Table 10

presents the results of these variables. The two social and environmental variables were *Home Support* and *Living Situation*, neither of which was statistically significantly associated with the LOS. Likewise, none of the functional assessment variables had p values less than 0.05, indicating that these variables were not statistically significant predictors of LOS after TA TAVI. For instance, the odds ratios of *CSHA CFS* and *ADL* were 1.59 and 1.54, with $p = 0.230$ and

0.364, respectively. It should be noted, however, that all of the seven functional assessment variables had relatively high missing response rates, which might have influenced the significance of their associations with the LOS. Nonetheless, none of the variables from this category was selected into the subsequent multivariate regression full model due to their p values, which were all greater than 0.100.

Table 10

Bivariate Ordinal Logistic Regression Report: Pre-procedure Phase Functional Assessment Variables

Variables (Missing)	Percent/ Mean (SD)	OR [95% CI]	Wald χ^2 (df)	p
Home Support (35.7%)			1.24 (2)	0.539
<i>None</i>	68.9%	1.00		
Full Time	1.4%	2.68 [0.07, 97.12]		
Part Time	29.7%	1.59 [0.65, 3.93]		
Living Situation (24.3%)			2.95 (2)	0.229
<i>Lives alone/ Independent</i>	93.1%	1.00		
Nursing home	3.4%	2.49 [0.31, 20.39]		
Lives with Family	3.4%	5.99 [0.60, 59.86]		
CSHA CFS (44.3%)	4.3 (0.6)	1.59 [0.75, 3.39]	1.44 (1)	0.230
ADL (37.4%)	5.9 (0.5)	1.54 [0.60, 3.95]	0.82 (1)	0.364
IADL (38.3%)	6.5 (1.9)	0.93 [0.75, 1.16]	0.38 (1)	0.537
MMSE (51.3%)	27.2 (2.4)	1.01 [0.82, 1.23]	0.00 (1)	0.964
Mean 5-m Walk (59.1%)	7.2 (2.8)	1.02 [0.85, 1.23]	0.05 (1)	0.830

Note.

1. $N = 115$.
2. The italicized group for each variable is the reference group for the comparison.
3. The odds ratio indicates to what extent the variable influences LOS relative to its reference group. A ratio greater than 1.00 indicates an increase in LOS, while a ratio less than 1.00 indicates a decrease in LOS.
4. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald χ^2 (df) and p value. A bolded p value with asterisk indicates p equals 0.100 or less.
5. *Abbreviations.* CSHA CFS, Canadian Study of Health and Aging Clinical Frailty Scale; ADL, Activities of Daily Living; IADL, Instrumental Activities of Daily Living; MMSE, Mini Mental State Examination; Mean 5-m Walk, mean 5-m Gait Speed test.

4.3.4 Results: pre-procedure phase pre-op status variables. As illustrated in Table 11, under this category, the variables that met the study's selection criteria for the multivariate regression full model ($p \leq 0.100$) included *STS*, *BMI*, and *Hgb*. Despite the high missing response rate, the variable of *STS* had an odds ratio of 1.08, indicating that a relative increase in *STS* was associated with increased odds of having longer LOS, Wald $\chi^2 (1) = 4.57, p = 0.033$. The mean BMI was 25.5 (SD= 5.9). The odds ratio of BMI (OR= 0.95) indicated that for every unit of increase in BMI value, the odds ratio of having longer LOS decreased 0.95 times, Wald $\chi^2 (1) = 3.58 (1), p = 0.058$. Similarly, the preoperative baseline hemoglobin level of TA TAVI patients seemed to play a relatively significant role in influencing the LOS (OR = 0.98, Wald $\chi^2 (1) = 4.47, p = 0.034$).

The TA TAVI population was predominantly NYHA Class III and IV (93.9%). As shown in Table 11, the NYHA classification was not statistically significantly associated with the LOS (Wald $\chi^2 (3) = 0.49, p = 0.921$). Similarly, neither the preoperative baseline creatinine level nor eGFR level was statistically significantly associated with having longer LOS (OR = 1.00 and 0.99, $p = 0.781$ and 0.202 , respectively).

Table 11

Bivariate Ordinal Logistic Regression Report: Pre-procedure Phase Pre-op Status Variables

Variables (Missing)	Percent/ Mean (SD)	OR [95% CI]	Wald χ^2 (df)	<i>p</i>
NYHA (0)			0.49 (3)	0.921
Class III	71.3%	1.00		
Class I	0.9 %	2.09 [0.06, 74.67]		
Class II	5.2%	0.90 [0.20, 3.97]		
Class IV	22.6%	1.25 [0.57, 2.75]		
STS (45.2%)	8.7% (7.7)	1.08 [1.01, 1.16]	4.57 (1)	0.033*
LVEF (5.2%)	54% (0.1)	0.51 [0.05, 5.57]	0.30 (1)	0.583
BMI (0)	25.5 (5.9)	0.95 [0.89, 1.00]	3.58 (1)	0.058*

Hgb (0)	121.5 (16.8)	0.98 [0.96, 1.00]	4.47 (1)	0.034*
Creatinine (0)	120.3 (81.6)	1.00 [1.00, 1.00]	0.08 (1)	0.781
eGFR (2.6%)	55.5 (23.6)	0.99 [0.98, 1.01]	1.63 (1)	0.202

Note.

1. $N = 115$.
2. The italicized group for each variable is the reference group for the comparison.
3. The odds ratio indicates to what extent the variable influences LOS relative to its reference group. A ratio greater than 1.00 indicates an increase in LOS, while a ratio less than 1.00 indicates a decrease in LOS.
4. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald χ^2 (df) and p value. A bolded p value with asterisk indicates p equals 0.100 or less.
5. *Abbreviations.* NYHA, New York Heart Association Functional Classification; LVEF, Left Ventricular Ejection Fraction; STS, the Society of Thoracic Surgeons Risk score; BMI, Body Mass Index; Hgb, hemoglobin; eGFR, estimated Glomerular Filtration Rate.

4.3.5 Results: peri-procedure phase variables. Table 12 presents the odds ratios of the 16 Peri-procedure phase variables. Within the first 72 hours of the TA TAVI surgical process, seven variables, namely, *Procedure Total Time*, *Procedure Type*, *Chest Drain*, *Temporary Pacemaker*, $\leq 72\text{hr Bleed}$, $\leq 72\text{hr Blood Transfusion}$, and $\leq 72\text{hr Blood Transfusion Units}$, were statistically significantly associated with the LOS. The odds ratio of *Procedure Total Time* is 1.01, meaning that longer total operating time of the TA TAVI was associated with increased odds of 1.01 times in having longer LOS postoperatively (Wald χ^2 (1) = 4.74, $p = 0.029$). Similarly, patients who had the valve-in-valve TA TAVI had decreased odds of having longer LOS by 0.46 times (Wald χ^2 (1) = 4.11, $p = 0.043$), as compared to those who had native-valve TA TAVI. In addition, the use of chest drain and temporary pacemaker at the completion of the TA TAVI were associated with increased odds of having longer LOS, though the latter was not statistically significant (OR = 5.15 and 2.37, $p = 0.018$ and 0.055, respectively). Moreover, the three bleeding and blood transfusion related variables were significantly associated with LOS after TA TAVI.

Table 12

Bivariate Ordinal Logistic Regression Report: Peri-procedure Phase Variables

Variables	Percent/ Mean (SD)	OR [95% CI]	Wald χ^2 (df)	<i>p</i>
Valve Type (0)			2.17 (2)	0.339
<i>Aortic Valve</i>	78.3%	1.00		
Both	2.6%	1.29 [0.16, 10.16]		
Mitral Valve	19.1%	0.54 [0.23, 1.26]		
Procedure Type (0)			4.11 (1)	0.043*
<i>Native Valve</i>	72.2%	1.00		
Valve-in-valve	27.8%	0.46 [0.22, 0.98]		
Airway Status: Intubated (0.9%)			0.96 (1)	0.326
<i>No</i>	41.2%	1.00		
Yes	58.8%	1.40 [0.72, 2.74]		
Pulmonary Artery Catheter (0.9%)			0.00 (1)	0.984
<i>No</i>	73.7%	1.00		
Yes	26.3%	1.01 [0.48, 2.13]		
Chest Drain (2.6%)			5.55 (1)	0.018*
<i>No</i>	8.0%	1.00		
Yes	92.0%	5.15 [1.32, 20.12]		
Temporary Pacemaker (1.7%)			3.67 (1)	0.055*
<i>No</i>	82.3%	1.00		
Yes	17.7%	2.37 [0.98, 5.74]		
≤72hr Pacemaker (0)			0.02 (1)	0.880
<i>No</i>	94.8%	1.00		
Yes	5.2%	1.12 [0.26, 4.89]		
≤72hr Atrial Fibrillation (0)			0.04 (1)	0.846
<i>No</i>	88.7%	1.00		
Yes	11.3%	0.90 [0.32, 2.54]		
≤72hr Stroke (0)			1.29 (1)	0.257
<i>No</i>	98.3%	1.00		
Yes	1.7%	4.95 [0.31, 78.37]		
≤72hr Perforation (0)			-	-
<i>No</i>	100.0%			
Yes	0			

≤72hr Annular Dissection (0)			-	-
<i>No</i>	<i>100.0%</i>			
Yes	0			
≤72hr Cardiac Arrest (0)			0.62 (1)	0.430
<i>No</i>	<i>97.4%</i>	<i>1.00</i>		
Yes	2.6%	2.33 [0.29, 18.91]		
≤72hr Bleed (0)			11.36 (1)	0.001*
<i>No</i>	<i>80.0%</i>	<i>1.00</i>		
Yes	20.0%	4.51 [1.88, 10.82]		
≤72hr Blood Transfusion (0)			10.23(1)	0.001*
<i>No</i>	<i>77.4%</i>	<i>1.00</i>		
Yes	22.6%	3.85 [1.69, 8.80]		
≤72hr Blood Transfusion Units (0)			10.50 (2)	0.005*
<i>No</i>	<i>77.4%</i>	<i>1.00</i>		
1 unit	13.0%	4.68 [1.65, 13.33]		
More than 1 unit	9.6%	2.98 [0.95, 9.42]		
Procedure Total Time (0.9%)	103.1 (39.7)	1.01 [1.00, 1.02]	4.74 (1)	0.029*

Note.

1. $N = 115$.
2. The italicized group for each variable is the reference group for the comparison.
3. The odds ratio indicates to what extent the variable influences LOS relative to its reference group. A ratio greater than 1.00 indicates an increase in LOS, while a ratio less than 1.00 indicates a decrease in LOS.
4. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald χ^2 (df) and p value. A bolded p value with asterisk indicates p equals 0.100 or less.
5. *Abbreviation.* ≤72hr, less than or equal to the first 72 hours after TA TAVI procedure.

4.3.6 Results: post-procedure phase variables. The 13 variables included in the Post-procedure phase are focused on the length of stay in the critical care, patients' postoperative complications after the first 72 hours until the time of discharge, and discharge planning. Table 13 presents the 13 variables' odds ratios and their corresponding p values.

As shown in Table 13, during this time period, seven variables, including *LOSICU*, *Lowest Hgb*, *Discharge Hgb*, *Highest Creatinine*, *>72hr Bleed*, *>72hr Blood Transfusion*,

and *>72hr Blood Transfusion Units*, seemed to be statistically significantly associated with the LOS. Specifically, *LOSICU* had an odds ratio of 1.03, indicating that every hour of increase in the total stay of the critical care was associated with an increase of 1.03 time in having longer LOS postoperatively (Wald χ^2 (1) = 17.27, p = 0.000). Likewise, for every unit of increase in the baseline hemoglobin level during hospitalization and hemoglobin level upon discharge, the likelihood of having longer LOS decreased by 0.96 and 0.98 times, respectively, though the latter was not statistically significant (Wald χ^2 (1) = 12.13 and 3.49, p = 0.000 and 0.062). Despite an odds ratio of 1.00, *Highest Creatinine* was also significantly associated with LOS (p = 0.042)

Furthermore, similar to the other three corresponding bleeding and blood transfusion related variables within the first 72 hours of the TA TAVI surgical process, the bleeding and blood transfusion occurrences in this time period were associated with the LOS, with p values all less than 0.100.

Table 13
Bivariate Ordinal Logistic Regression Report: Post-procedure Phase Variables

Variables (Missing)	Percent/ Mean (SD)	OR [95% CI]	Wald χ^2 (df)	p
>72hr Pacemaker (0)			1.99 (1)	0.158
<i>No</i>	94.8%	1.00		
<i>Yes</i>	5.2%	3.00 [0.65, 13.80]		
>72hr Atrial Fibrillation (0)			1.84 (1)	0.175
<i>No</i>	91.3%	1.00		
<i>Yes</i>	8.7%	2.27 [0.70, 7.41]		
>72hr Stroke (0)			0.00 (1)	0.999
<i>No</i>	98.3%	1.00		
<i>Yes</i>	1.7%	-		
>72hr Perforation (0)			-	-
<i>No</i>	100.0%	-		
<i>Yes</i>	0	-		

>72hr Cardiac Arrest (0)			-	-
<i>No</i>	100.0%	-		
Yes	0	-		
>72hr Bleed (0.9%)			7.74 (1)	0.005*
<i>No</i>	93.9%	<i>1.00</i>		
Yes	6.1%	11.81 [2.07, 67.22]		
>72hr Blood Transfusion (0.9%)			5.16 (1)	0.023*
<i>No</i>	93.9%	<i>1.00</i>		
Yes	6.1%	5.84 [1.27, 26.76]		
>72hr Blood Transfusion Units (0.9%)			5.16 (2)	0.076*
<i>No</i>	93.9%	<i>1.00</i>		
1 unit	1.8%	5.66 [0.36, 89.52]		
More than 1 unit	4.4%	5.92 [0.99, 35.39]		
LOSICU (0.9%)	62.0 (96.8)	1.03 [1.01, 1.04]	17.27 (1)	0.000*
Lowest Hgb (0.9%)	95.8 (15.1)	0.96 [0.94, 0.98]	12.13 (1)	0.000*
Discharge Hgb (0.9%)	106.3(14.5)	0.98 [0.96, 1.00]	3.49 (1)	0.062*
Highest Creatinine (0.9%)	147.7 (107.3)	1.00 [1.00, 1.01]	4.13 (1)	0.042*
Discharge Creatinine (0.9%)	121.2 (80.2)	1.00 [1.00, 1.01]	1.30 (1)	0.255

Note.

1. $N = 115$.
2. The italicized group for each variable is the reference group for the comparison.
3. The odds ratio indicates to what extent the variable influences LOS relative to its reference group. A ratio greater than 1.00 indicates an increase in LOS, while a ratio less than 1.00 indicates a decrease in LOS.
4. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald χ^2 (df) and p value. A bolded p value with asterisk indicates p equals 0.100 or less.
5. *Abbreviations.* *Hgb*, hemoglobin; *eGFR*, estimated Glomerular Filtration Rate; *>72hr*, more than 72 hours after TA TAVI.

4.4 Independent Variables with $p \leq 0.100$

As discussed in Chapter 3, in this study, variables that had p value equal or less than 0.100 from the bivariate ordinal logistic regression analyses were considered potentially significant and would therefore be included in the multivariate ordinal logistic regression model (Hosmer & Lemeshow, 2000). According to the findings above, 19 out of 62 independent

variables had met this requirement. Although the variable of *STS* also met this criterion, it was excluded because of its high percentage of missing responses (45.2%). As a result, 18 independent variables (Table 14) were selected into the multivariate ordinal logistic regression analysis that follows.

Table 14
18 Independent Variables with $p \leq 0.10$ by Procedure Phases

Pre-Procedure Phase	Peri-Procedure Phase	Post-Procedure Phase
Age	Procedure Total Time	LOSICU
Chronic Lung Disease	Procedure Type	>72hr Bleed
BMI	Chest Drain	>72hr Blood Transfusion
Hgb	Temporary Pacemaker	>72hr Blood Transfusion Units
	≤ 72 hr Bleed	Lowest Hgb
	≤ 72 hr Blood Transfusion	Discharge Hgb
	≤ 72 hr Blood Transfusion Units	Highest Creatinine

Note. Dependent Variable: LOS ordinal. *Abbreviations.* *LOSICU*, length of stay in critical care; *BMI*, Body Mass Index; *Hgb*, hemoglobin; ≤ 72 hr, less than or equal to the first 72 hours after TA TAVI ; > 72 hr, more than 72 hours after TA TAVI.

4.5 Multivariate Ordinal Logistic Regression Model: Full Model

4.5.1 Full model: assumptions. Statistics were first conducted to test the 18-variable model's multicollinearity and goodness of fit. In Table 15, multicollinearity statistics show that, when eighteen variables were included, the variables pertaining to blood transfusion and blood transfusion units had Variance Inflation Factor (VIF) values of ten or greater. It is not surprising that these variables were highly correlated considering that they all pertained to the occurrence of a blood transfusion. A decision was then made to retain only one of the blood transfusion variables. After removing the three variables that had VIF greater than ten, namely, ≤ 72 hr Blood Transfusion, > 72 hr Blood Transfusion, and > 72 hr Blood Transfusion Units, the remaining

fifteen variables had the VIF values that were less than ten (Table 15). Table 16 presents the 15 independent variables with p value equal or less than 0.100 that were finally selected in the multivariate ordinal logistic regression model.

Table 15

Full Model Multi-collinearity Test: 18 Variables vs. 15 Variables

Independent Variables	Collinearity Statistics 18 Variables	Collinearity Statistics 14 Variables
	VIF	VIF
>72hr Blood Transfusion	23.38	—
>72hr Blood Transfusion Units	16.90	—
≤72hr Blood Transfusion	13.33	—
≤72hr Blood Transfusion Units	9.12	2.75
>72hr Bleed	8.28	1.55
Lowest Hgb	4.70	4.40
≤72hr Bleed	4.60	2.92
Discharge Hgb	4.22	3.83
Hgb	2.40	2.26
LOSICU	1.77	1.55
BMI	1.35	1.33
Age	1.34	1.33
Procedure Total Time	1.23	1.15
Chronic Lung Disease	1.21	1.16
Temporary Pacemaker	1.18	1.13
Highest Creatinine	1.15	1.15
Procedure Type	1.14	1.14
Chest Drain	1.13	1.12

Note. Dependent Variable: LOS ordinal. *Abbreviations.* *LOSICU*, length of stay in intensive care unit; *BMI*, Body Mass Index; *Hgb*, hemoglobin; *≤72hr*, less than or equal to the first 72 hours after TA TAVI; *>72hr*, more than 72 hours after TA TAVI.

Table 16
List of 15 Independent Variables of Full Model

Pre-procedure Phase	Peri-procedure Phase	Post-procedure Phase
Age	Procedure Total Time	LOSICU
Chronic Lung Disease	Procedure Type	>72hr Bleed
BMI	Chest Drain	Lowest Hgb
Hgb	Temporary Pacemaker	Discharge Hgb
	≤72hr Bleed	Highest Creatinine
	≤72hr Blood Transfusion Units	

Note. Dependent Variable: LOS ordinal. *Abbreviation.* *LOSICU*, length of stay in critical care; *BMI*, Body Mass Index; *Hgb*, hemoglobin; *≤72hr*, less than or equal to the first 72 hours after TA TAVI ; *>72hr*, greater than 72 hours after TA TAVI.

In addition, as assessed by a full likelihood ratio test comparing the residual of the fitted location model to a model with varying location parameters, $\chi^2(32) = 129.7, p = 0.000$, the assumption of proportional odds was not met. To further investigate the assumption of proportional odds, separate binomial logistic regression analyses were run by recoding the dependent variable, *LOS ordinal*, into three dichotomised cumulative categories, named as *LOS Ordinal Category 1* (LOS more than 12 days), *LOS Ordinal Category 2* (LOS more than 7 days), and *LOS Ordinal Category 3* (LOS more than 5 days). These three dichotomous dependent variables represented the cumulative splits of the four categories of the ordinal dependent variable, *LOS ordinal*, and were necessary for establishing the viability of the assumption of proportional odds.

Table 17 shows the results of the separate binomial logistic regression statistics. As shown, the proportional odds assumption might be met, depending on the variables. For instance, the odds ratios of the variable of pre-operative baseline hemoglobin level were similar (OR= 0.99, 1.00, and 0.98, respectively), indicating that, for this variable, the assumption of

proportional odds appeared tenable. On the other hand, several variables had different odds ratios to varying degrees. For example, considering the variable of ≤ 72 *Blood Transfusion Units More than 1 unit*, the odds ratios for *LOS Ordinal Category 2* and *3* were similar, but different from the odds ratio for *LOS ordinal Category 1*, indicating that, for this variable, the assumption of similar odds might not be tenable and thus required caution in the interpretation of the final ordinal regression model.

4.5.2 Full model: goodness of fit. The Deviance goodness-of-fit test indicates that the model was a good fit to the 15-variable dataset ($\chi^2(287) = 222.2, p = 0.998$). In addition, the Pearson goodness-of-fit test supports that the model was a good fit ($\chi^2(287) = 298.4, p = 0.309$). However, when interpreting these two measures, caution should be given to the fact that there were 306 (75%) cells with zero frequencies. Nonetheless, the final model statistically significantly predicts the dependent variable, *LOS ordinal*, over and above the intercept-only model ($\chi^2(16) = 56.1, p = 0.000$), indicating that the goodness of fit was met in this model. Moreover, the pseudo R-square tests reports a Cox and Snell of 0.42 and Nagelkerke of 0.45, both supporting the goodness of fit requirement.

Table 17
Full Model Proportional Odds: Variables in the Equation

Independent Variable	B (parameter estimates)			Exp(B) (Odds Ratio)		
	LOS Ordinal Category 1	LOS Ordinal Category 2	LOS Ordinal Category 3	LOS Ordinal Category 1	LOS Ordinal Category 2	LOS Ordinal Category 3
Age	0.13	0.08	0.01	1.14	1.08	1.01
BMI	0.05	-0.03	-0.05	1.05	0.97	0.95
Hgb	-0.01	0.00	-0.02	0.99	1.00	0.98
Procedure Total Time	-0.01	0.00	0.02	0.99	1.00	1.03
LOSICU	0.02	0.03	0.05	1.02	1.03	1.05

Lowest Hgb	-0.02	-0.03	-0.04	0.98	0.97	0.96
Discharge Hgb	-0.05	0.00	0.03	0.96	1.00	1.03
Highest Creatinine	0.00	0.00	0.00	1.00	1.00	1.00
≤72hr Blood TransfusionUnits (>1 unit)	1.29	-0.50	-0.78	3.63	0.60	0.46
≤72hr Blood TransfusionUnits (1 unit)	-0.24	0.57	-0.22	0.79	1.76	0.80
Chronic Lung Disease	2.52	1.19	0.52	12.40	3.29	1.69
Procedure Type	-2.02	-1.25	0.71	0.13	0.29	2.03
Chest Drain	-2.65	-0.68	2.52	0.07	0.51	12.44
Temporary Pacemaker	2.02	2.60	1.13	7.50	13.49	3.11
≤72hr Bleed	1.01	0.32	0.53	2.74	1.38	1.71
>72hr Bleed	0.67	18.88	17.13	1.96	1.58*10 ⁸	2.74*10 ⁷
Constant	-4.59	-5.31	-3.51	0.01	0.00	0.03

4.5.3 Full model: results. Fifteen independent variables were included in the multivariate ordinal logistic regression full model to compute their odds ratios in association with, and estimate their effect on, the dependent variable, *LOS ordinal*. A *p* value equal or less than 0.050 was considered significant.

As illustrated in Table 18, the sample size was 102, and the overall missing response rate was 11.3 %. Over 50 % of the sample had a LOS of less than eight days. Among the 15 independent variables, three variables, *Chronic Lung Disease*, *Temporary Pacemaker*, and *LOSICU*, had statistically significant overall effect on the LOS ($p = 0.013$, 0.022 , and 0.002 , respectively). Specifically, the incidences of chronic lung disease and temporary pacemaker use

at the completion of the TA TAVI procedure were associated with increased odds in having longer LOS by 2.96 and 3.67 times, respectively, both with statistically significant overall effects (Wald $\chi^2(1) = 6.16$ and 5.25 , $p = 0.013$ and 0.022 , respectively). In addition, every additional hour that TA TAVI patient spent in the critical care increased the likelihood of having longer LOS by 1.02 times (Wald $\chi^2(1) = 9.62$, $p = 0.002$).

In conclusion, 18 independent variables were first identified to have p equal or less than 0.100, which were computed from the bivariate ordinal logistic regression. After the tests for the assumptions, only 15 of them remained and were selected in the multivariate ordinal logistic regression full model. With the 15-variable dataset, the full model had no multi-collinearity issue and showed goodness of fit to this study's dataset. The assumption of proportional odds appeared to be tenable. Finally, according to the results of the full model, among the 15 variables, three variables, including *Chronic Lung Disease*, *Temporary Pacemaker*, and *LOSICU*, demonstrated a statistically significant effect on the LOS after TA TAVI.

Table 18

Report of Multivariate Ordinal Logistic Regression Full Model: 15-variable Dataset

	Percent/ Mean (SD)	OR [95% CI]	Wald χ^2 (df)	p
<u>Dependent Variable</u>				
LOS ordinal				
Less than 6 days	24.5%			
6 - 7 days	32.4%			
8 - 12 days	17.6%			
More than 12 days	25.5%			
<u>Independent Variables</u>				
Chronic Lung Disease			6.16 (1)	0.013*
No	62.7%	1		
Yes	37.3%	2.96 [1.26, 6.98]		
Procedure Type			0.69 (1)	0.408
Native Valve	71.6%	1		
Valve in valve	28.4%	0.68 [0.27, 1.70]		

Chest Drain			1.21 (1)	0.272
<i>No</i>	5.9%	<i>1</i>		
Yes	94.1%	2.64 [0.47, 14.95]		
Temporary Pacemaker			5.25 (1)	0.022*
<i>No</i>	83.3%	<i>1</i>		
Yes	16.7%	3.67 [1.21, 11.18]		
≤72hr Bleed			0.06 (1)	0.800
<i>No</i>	81.4%	<i>1</i>		
Yes	18.6%	0.77 [0.10, 5.87]		
≤72hr Blood Transfusion Units			1.00 (2)	0.606
<i>No</i>	78.4%	<i>1</i>		
More than 1 unit	7.8%	1.33 [0.17, 10.30]		
1 unit	13.7%	2.71 [0.34, 21.45]		
>72hr Bleed			0.52 (1)	0.471
<i>No</i>	93.1%	<i>1</i>		
Yes	6.9%	2.28 [0.24, 21.29]		
Age	78.7 (8.5)	1.04 [0.99, 1.10]	2.14 (1)	0.144
BMI	25.5 (6.1)	0.99 [0.92, 1.06]	0.09 (1)	0.765
Hgb	121.0 (17.0)	1.00 [0.96, 1.03]	0.09 (1)	0.761
Procedure Total Time	103.5 (39.9)	1.01 [1.00, 1.02]	1.17 (1)	0.280
LOSICU	61.7 (101.4)	1.02 [1.01, 1.04]	9.66 (1)	0.002*
Lowest Hgb	95.8 (15.1)	0.98 [0.93, 1.03]	0.67 (1)	0.414
Discharge Hgb	106.9 (14.7)	1.00 [0.95, 1.05]	0.01 (1)	0.935
Highest Creatinine	150.0 (112.0)	1.00 [1.00, 1.01]	1.20 (1)	0.274

Note.

1. $N = 102$. Missing 11.3%.
2. The italicized group for each variable is the reference group for the comparison.
3. The odds ratio indicates to what extent the variable influences LOS relative to its reference group. A ratio greater than 1.00 indicates an increase in LOS, while a ratio less than 1.00 indicates a decrease in LOS.
4. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald χ^2 (df), p value. A bolded p value with asterisk indicates p equals 0.050 or less.
5. *Abbreviations.* *LOSICU*, length of stay in critical care; *BMI*, Body Mass Index; *Hgb*, hemoglobin; *≤72hr*, less than or equal to the first 72 hours after TA TAVI ; *>72hr*, more than 72 hours after TA TAVI.

4.6 Full Model Multivariate Trimming

To identify the subset of the variables that were independently significant predictors of the LOS after TA TAVI from the 15-variable dataset, we performed the multivariate trimming. In the following sections, the results of multivariate trimming process are discussed and presented.

4.6.1 Results. Table 19 shows the initial values of Wald χ^2 of the 15-variable dataset in the order of smallest to largest as well as their corresponding p values, which were obtained from the statistics of Tests of Model Effects in the full model. The computation suggested that the variable of *Discharge Hgb* had the smallest Wald χ^2 and the largest p values among this dataset (Wald $\chi^2(1) = 0.01$, $p = 0.935$). Hence, the variable of *Discharge Hgb* was first removed. The Likelihood Ratio χ^2 was then obtained for the remaining fourteen-variable dataset and compared with that of the initial 15-variable dataset, and difference was calculated. While comparing to the critical value of χ^2 with one degree of freedom (3.841), the first difference of 0.000 from removing *Discharge Hgb* indicated that the change in χ^2 from the 15-variable dataset to the fourteen-variable dataset was insignificant, suggesting that the variable of *Discharge Hgb* be excluded.

Table 20 further illustrates this iterative process. After the variable of *Discharge Hgb* was removed, the Wald χ^2 and p values of the remaining fourteen-variable dataset were recalculated. As shown, the variable of ≤ 72 *Bleed* became the next one to be trimmed in the model because of its largest p value and smallest Wald χ^2 (Wald $\chi^2(1) = 0.06$, $p = 0.801$) in this computation.

Table 19

Report of Test of Model Effects on 15-variable Full Model

	Wald χ^2	df	<i>p</i>
Discharge Hgb	0.01	1	0.935
≤ 72 hr Bleed	0.06	1	0.800
BMI	0.09	1	0.765
Hgb	0.09	1	0.761
> 72 hr Bleed	0.52	1	0.471
Lowest Hgb	0.67	1	0.414
Procedure Type	0.69	1	0.408
≤ 72 hr Blood Transfusion Units	1.00	1	0.606
Procedure Total Time	1.17	1	0.280
Highest Creatinine	1.20	1	0.274
Chest Drain	1.21	1	0.272
Age	2.14	1	0.144
Temporary Pacemaker	5.25	1	0.022*
Chronic Lung Disease	6.16	1	0.013*
LOSICU	9.66	1	0.002*

*Note.*1. $N = 102$. Missing 11.3%.2. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald χ^2 (df), *p* value. A bolded *p* value with asterisk indicates *p* equals 0.050 or less.3. *Abbreviations.* *LOSICU*, length of stay in critical care; *BMI*, Body Mass Index; *Hgb*, hemoglobin; ≤ 72 hr, less than or equal to the first 72 hours after TA TAVI ; > 72 hr, more than 72 hours after TA TAVI.

Table 20

*Report of Test of Model Effects on 14-variable Dataset of Full Model:**Removing Discharge Hgb*

	Wald χ^2	df	<i>p</i>
≤ 72 hr Bleed	0.06	1	0.801
BMI	0.09	1	0.767
Hgb	0.09	1	0.761

>72hr Bleed	0.53	1	0.469
Procedure Type	0.69	1	0.408
≤ 72 hr Blood Transfusion Units	1.00	2	0.606
Lowest Hgb	1.15	1	0.284
Procedure Total Time	1.17	1	0.280
Highest Creatinine	1.20	1	0.273
Chest Drain	1.21	1	0.272
Age	2.21	1	0.137
Temporary Pacemaker	5.25	1	0.022*
Chronic Lung Disease	6.16	1	0.013*
LOSICU	9.76	1	0.002*

Note.

1. $N = 102$. Missing 11.3%.

2. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald χ^2 (df), p value. A bolded p value with asterisk indicates p equals 0.050 or less.

3. Abbreviations. *LOSICU*, length of stay in critical care; *BMI*, Body Mass Index; *Hgb*, hemoglobin; ≤ 72 hr, less than or equal to the first 72 hours after TA TAVI; > 72 hr, more than 72 hours after TA TAVI.

Following this approach, the 15 variables were being trimmed one after another. To reiterate, the trimming process started with removing the variable of *Discharge Hgb*. The difference between the two Likelihood Ratio χ^2 values was 0.00, which was computed from subtracting 56.09 of the 15-variable dataset from 56.09 of the fourteen-variable dataset without the variable of *Discharge Hgb*. Subsequently, nine variables, ≤ 72 hr *Bleed*, *Hgb*, *BMI*, > 72 hr *Bleed*, *Highest Creatinine*, *Chest Drain*, *Procedure Type*, ≤ 72 hr *Blood Transfusion Units*, and *Procedure Total Time*, were removed in the similar manner in the full model, as the differences between Likelihood Ratio χ^2 values were all less than 3.841.

When removing the variable of *Age*, however, the change over the Likelihood Ratio χ^2 values was 5.99, indicating that this change was significant for χ^2 distributions with one degree

of freedom. Hence, the variable of *Age* was retained because of its independently significance in the dataset of the model. Similarly, the significance of four other variables, *Lowest Hgb*, *Temporary Pacemaker*, *Chronic Lung Disease*, and *LOSICU*, were confirmed by this trimming process. Their corresponding χ^2 changes over the Likelihood Ratio χ^2 values were 8.03, 9.33, 6.19, and 15.90, respectively. As a result, the five variables were considered significant and were thus kept in the following trimmed model to further evaluate their impact on the LOS after TA TAVI collectively. Table 21 presents the results of this trimming process.

Table 21
Report of Full Model Multivariate Trimming: 15-variable Dataset

Variables Information				Regression Model			
Variable Trimmed in Order	Wald χ^2	df	<i>p</i>	Likelihood Ratio χ^2	df	<i>p</i>	Difference
<i>No trimming</i>	—	—	—	56.09	16	0.000	—
Discharge Hgb	0.01	1	0.935	56.09	15	0.000	0.00
≤72hr Bleed	0.06	1	0.801	56.03	14	0.000	0.06
Hgb	0.05	1	0.817	55.97	13	0.000	0.06
BMI	0.14	1	0.706	55.83	12	0.000	0.14
>72hr Bleed	0.51	1	0.476	55.98	11	0.000	0.15
Highest Creatinine	0.94	1	0.333	55.17	10	0.000	0.81
Chest Drain	0.94	1	0.333	55.51	9	0.000	0.34
Procedure Type	1.20	1	0.273	54.25	8	0.000	1.26
≤72hr Blood Transfusion Units	1.47	2	0.481	52.85	6	0.000	1.40
Procedure Total Time	1.66	1	0.198	53.62	5	0.000	0.77
Age	4.05	1	0.044	49.52	4	0.000	5.99*
Lowest Hgb	6.33	1	0.012	46.22	4	0.000	8.03*
Temporary Pacemaker	6.68	1	0.010	43.52	4	0.000	9.33*

Chronic Lung Disease	8.25	1	0.004	47.43	4	0.000	6.19*
LOSICU	13.53	1	0.000	33.62	4	0.000	15.90*

Note.

1. $N = 102$. Missing 11.3%. Dependent variable: *LOS ordinal*
2. The italicized group is the 15-variable dataset full model where no variable was trimmed.
2. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald $\chi^2(df)$, p value. A bolded p value with asterisk indicates p equals 0.050 or less.
3. Difference was calculated by subtracting the Likelihood Ratio χ^2 from the previous one, while the previous variable was removed from this model. A bolded difference with asterisk indicates a value greater than 3.841.
4. *Abbreviations.* *LOSICU*, length of stay in critical care; *BMI*, Body Mass Index; *Hgb*, hemoglobin; $\leq 72hr$, less than or equal to the first 72 hours after TA TAVI ; $>72hr$, more than 72 hours after TA TAVI.

4.7 Multivariate Ordinal Logistic Regression Model: 5-variable Trimmed Model

Through the trimming process discussed above, five independent variables, including *Age* and *Chronic Lung Disease* from the Pre-procedure phase, *Temporary Pacemaker* from the Peri-procedure phase, and *LOSICU* and *Lower Hgb* from the Post-procedure phase, were selected in the final trimmed multivariate ordinal logistic regression model to compute their overall effects on the dependent variable, *LOS ordinal* (Table 22).

Table 22

List of 5 Independent Variables of Trimmed Model

Pre-procedure Phase	Peri-procedure Phase	Post-procedure Phase
Age	Temporary Pacemaker	LOSICU
Chronic Lung Disease		Lowest Hgb

Note. Dependent variable: *LOS ordinal*. *Abbreviations.* *LOSICU*, length of stay in critical care; *Hgb*, hemoglobin.

4.7.1 5-variable trimmed model: assumptions. As tested in the full model, this 5-variable dataset trimmed model had no multicollinearity problem. When assessed by a full likelihood ratio test comparing the residual of the fitted location model to a model with varying

location parameters, however, the assumption of proportional odds was not met ($\chi^2(10) = 25.3$, $p = 0.005$). Therefore, separate binomial logistic regressions were conducted to further investigate the assumption of proportional odds. Table 23 presents the results of separate binomial logistic regressions of this 5-variable dataset on the three dichotomous *LOS ordinal* categories, namely, *LOS ordinal Category 1*, *LOS ordinal Category 2*, and *LOS ordinal Category 3*. As shown, the assumption of proportional odds might appear tenable for variables of *Age*, *LOSICU*, and *Lowest Hgb*, as the odds ratios for the three different binomial logistic regressions were similar. However, the odds ratios for variables of *Chronic Lung Disease* and *Temporary Pacemaker* were not similar, indicating that the assumption of parallel odds for these two variables might not be tenable.

Table 23
5-variable Trimmed Model Proportional Odds: Variables in the Equation

Independent Variable	B (parameter estimates)			Exp(B) (Odds Ratio)		
	LOS ordinal Category 1	LOS ordinal Category 2	LOS ordinal Category 3	LOS ordinal Category 1	LOS ordinal Category 2	LOS ordinal Category 3
Age	0.07	0.08	0.04	1.07	1.08	1.04
Chronic Lung Disease	2.16	1.39	0.49	8.63	4.02	1.63
Temporary Pacemaker	1.03	2.72	1.57	2.79	15.18	4.82
LOSICU	0.02	0.03	0.04	1.02	1.03	1.04
Lowest Hgb	-0.06	-0.04	-0.02	0.94	0.96	0.98
Constant	-2.99	-5.21	-1.59	0.05	0.01	0.20

4.7.2 5-variable trimmed model: goodness of fit. Despite the large percent of cells with zero frequencies (75%), overall the model was a good fit. The Deviance test indicates that

the trimmed model was a good fit to this dataset with $\chi^2(307) = 233.5, p = 0.999$. Likewise, the Pearson test reports similar results ($\chi^2(307) = 276.2, p = 0.896$). Furthermore, the Pseudo R-square reports Cox and Snell of 0.40 and Nagelkerke of 0.43, and the final model statistically significantly predicts the dependent variable, *LOS ordinal*, over and above the intercept-only model, $\chi^2(5) = 53.6, p = 0.000$, in this model, all indicating that this 5-variable trimmed model met the goodness of fit requirement.

4.7.3 5-variable trimmed model: results. Table 24 reports the five independent variables' odds ratios and Wald χ^2 values in association with the dependent variable, *LOS ordinal*, in this trimmed model. A p value equal or less than 0.050 was considered significant. As shown, the sample size was 105 with a missing response of 8.7%. Over 55% of the TA TAVI patients had a LOS that was less than eight days.

Overall, all of the five independent variables had p values less than 0.050, indicating their statistically significant associations with the LOS after TA TAVI. *LOSICU* had the largest Wald χ^2 of 12.89 ($p = 0.000$), followed by *Chronic Lung Disease* (Wald $\chi^2 = 9.78, p = 0.002$), *Temporary Pacemaker* (Wald $\chi^2 = 9.35, p = 0.002$), *Lowest Hgb* (Wald $\chi^2 = 6.11, p = 0.013$), and *Age* (Wald $\chi^2 = 4.05, p = 0.044$). The odds ratios of the five variables indicated that four variables, *Temporary Pacemaker*, *Chronic Lung Disease*, *Age* and *LOSICU*, were associated with increased odds in having longer LOS. For instance, having chronic lung diseases increased the odds of having longer LOS by 3.60 times while the use of temporary pacemaker at the completion of the TA TAVI procedure increased the same odds by 4.95 times. In addition, every unit of increase in the age and the length of stay in the critical care increased the chances of having longer LOS by 1.05 and 1.03 times, respectively. By contrast, a higher baseline

hemoglobin level during hospitalization was associated with a lower likelihood of having longer LOS by 0.97 times.

Table 24

Report of Multivariate Ordinal Logistic Regression 5-variable Trimmed Model: 5-variable Dataset

	Percent/ Mean (SD)	OR [95% CI]	Wald χ^2 (df)	<i>p</i>
<u>Dependent Variable</u>				
LOS ordinal				
Less than 6 days	23.8%			
6 - 7 days	31.4%			
8 - 12 days	18.1%			
More than 12 days	26.7%			
<u>Independent Variables</u>				
Chronic Lung Disease				
<i>No</i>	<i>61.9%</i>	<i>1</i>	9.78 (1)	0.002*
Yes	38.1%	3.60 [1.61, 8.02]		
Temporary Pacemaker				
<i>No</i>	<i>81.9%</i>	<i>1</i>	9.35 (1)	0.002*
Yes	18.1%	4.95 [1.78, 13.81]		
Age	78.7 (8.5)	1.05 [1.00, 1.10]	4.05 (1)	0.044*
Lowest Hgb	95.6 (15.1)	0.97 [0.94, 0.99]	6.11 (1)	0.013*
LOSICU	62.4 (100.6)	1.03 [1.01, 1.04]	12.89 (1)	0.000*

Note.

1. *N* = 105. Missing 8.7%.
2. The italicized group for each variable is the reference group for the comparison.
3. The odds ratio indicates to what extent the variable influences LOS relative to its reference group. A ratio greater than 1.00 indicates an increase in LOS, while a ratio less than 1.00 indicates a decrease in LOS.
4. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald χ^2 (df), *p* value. A bolded *p* value with asterisk indicates *p* equals 0.050 or less.
5. *Abbreviations.* LOS, length of stay; LOSICU, length of stay in critical care; Hgb, hemoglobin.

4.8 Multivariate Ordinal Logistic Regression: 6-variable Trimmed Model with STS

Clinically, the STS risk score is used as a surrogate score to primarily support case selection in TAVI procedures. Due to its high missing rate in this study, however, the variable of *STS* was first excluded from the full model (Table 22). In a post-hoc analysis to examine its potential relevance, *STS* was re-entered in the multivariate ordinal logistic regression with the other five independently significant predictors of the LOS after TA TAVI. In the following section, the results of this 6-variable dataset regression trimmed model are presented and discussed. Table 25 lists the six variables included in this model.

Table 25
List of 6 Independent Variables of 6-variable Trimmed Model with STS

Pre-procedure Phase	Peri-procedure Phase	Post-procedure Phase
Age	Temporary Pacemaker	LOSICU
Chronic Lung Disease		Lowest Hgb
STS		

Note. Dependent variable: LOS ordinal. *Abbreviations.* *LOSICU*, length of stay in critical care; *STS*, the Society of Thoracic Surgeons risk score; *Hgb*, hemoglobin.

4.8.1 6-variable trimmed model with STS: assumptions. As tested in the full model, there was no collinearity problem within this 6-variable dataset model. To test the assumption of proportional odds, a full likelihood ratio test was conducted to compare the residual of the fitted location model to model with varying location parameters ($\chi^2 = 12.4$, $p = 0.403$), indicating that this assumption was met in this model.

4.8.2 6-variable trimmed model with STS: goodness of fit. Overall, the statistic tests showed that this model was a good fit. The Deviance test reports the goodness of fit of this model with $\chi^2(307) = 119.9$, $p = 0.986$. Correspondingly, the Pearson test shows that the model was a good fit with $\chi^2(307) = 148.3$, $p = 0.657$. The final model statistically significantly

predicts that the dependent variable, *LOS ordinal*, over and above the intercept-only model, $\chi^2 (6) = 32.0, p = 0.000$, indicating the goodness of fit of the model. In addition, the findings of the Pseudo R-square tests and the Likelihood-ratio test are supportive (Cox and Snell $R^2 = 0.44$; Nagelkerke $R^2 = 0.44$; and McFadden $R^2 = 0.21$).

4.8.3 6-variable trimmed model with STS: results. Table 26 reports the results of this 6-variable trimmed model with the variable of *STS*. As shown, the sample size was 55 with a missing rate of 52.2%. The variable of *STS* had an odds ratio of 1.05 that was not statistically significant (Wald $\chi^2 (1) = 3.76, p = 0.053$).

Overall, compared to the results of the 5-variable trimmed model without *STS* discussed above, this 6-variable regression model showed that the six variables demonstrated similar predicting effects on the LOS after TA TAVI, but with varying statistical significances. For instance, both models found that the incidence of chronic lung disease in TA TAVI patients had statistically significant effect on increasing the odds of having longer LOS (OR = 3.60, Wald $\chi^2 (1) = 9.78$ and 10.02, $p = 0.002$ and 0.002, respectively). Likewise, the variable of *LOSICU* was shown to be another statistically significant predictor of the LOS after TA TAVI in both models (OR = 1.03; Wald $\chi^2 = 12.89$ and 5.34, $p = 0.000$ and 0.021, respectively).

Table 26
*Report of Multivariate Ordinal Logistic Regression 6-variable Trimmed Model with STS:
6-variable Dataset*

	Percent/ Mean (SD)	OR [95% CI]	Wald χ^2 (df)	<i>p</i>
<u>Dependent Variable</u>				
LOS ordinal				
Less than 6 days	25.5%			
6 - 7 days	23.6%			
8 - 12 days	21.8%			
More than 12 days	29.1%			

Independent Variables

Chronic Lung Disease			10.02 (1)	0.002*
<i>No</i>	65.5%	<i>I</i>		
Yes	34.5%	3.60 [1.61, 8.02]		
Temporary Pacemaker			2.11 (1)	0.147
<i>No</i>	74.5%	<i>I</i>		
Yes	25.5%	4.95 [1.78, 13.81]		
Age	77.6 (8.4)	1.05 [1.00, 1.10]	1.63 (1)	0.202
STS	8.5% (6.6)	1.05 [1.00, 1.10]	3.76 (1)	0.053
Lowest Hgb	97.5 (14.4)	0.97 [0.94, 0.99]	3.64 (1)	0.056
LOSICU	66.0 (129.4)	1.03 [1.01, 1.04]	5.34 (1)	0.021*

Note.

1. $N = 55$. Missing 52.2%.
2. The italicized group for each variable is the reference group for the comparison.
3. The odds ratio indicates to what extent the variable influences LOS relative to its reference group. A ratio greater than 1.00 indicates an increase in LOS, while a ratio less than 1.00 indicates a decrease in LOS.
4. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald χ^2 (df), p value. A bolded p value with asterisk indicates p equals 0.050 or less.
5. Abbreviations. *LOS*, length of stay; *LOSICU*, length of stay in critical care; *STS*, the Society of Thoracic Surgeons risk score; *Hgb*, hemoglobin.

4.9 6-variable Trimmed Model with STS Multivariate Trimming

Despite its high missing data rate in this study, the potential impact of STS on the LOS after TA TAVI was worth further investigation given its clinical relevance in TAVI procedures. Hence, multivariate trimming on the 6-variable trimmed model with *STS* was conducted to evaluate the potential independent significance of *STS* on the LOS after TA TAVI in relation to other five predictors.

4.9.1 Results. Table 27 presents the results of this trimming process. Compared to other variables' Wald χ^2 values, the variable of *Age* had the smallest Wald χ^2 (1.63) in this initial 6-variable dataset, thus became the first one to be removed. The difference between the two values

of Likelihood Ratio χ^2 were then computed and compared with the critical value of χ^2 with one degree of freedom (3.841). Following this iterative process, the variables of *Age*, *Temporary Pacemaker*, and *Lowest Hgb* were removed subsequently. By contrast, the independent significance of *STS*, *Chronic Lung Disease*, and *LOSICU* could not be neglected. Thus, the three variable were collectively kept in the following multivariate ordinal logistic regression 3-variable dataset trimmed model to evaluate their predicting significance on the LOS after TA TAVI.

Table 27

Report of 6-variable Trimmed Model with STS Multivariate Trimming: 6-variable Dataset

Variables Information				Regression Model			
Variable Trimmed in Order	Wald χ^2	df	<i>p</i>	Likelihood Ratio χ^2	df	<i>p</i>	Difference
<i>No trimming</i>	—	—	—	32.00	6	0.000	—
Age	1.63	1	0.202	30.30	5	0.000	1.70
Temporary Pacemaker	2.14	1	0.143	28.62	4	0.000	1.68
Lowest Hgb	2.87	1	0.090	26.55	3	0.000	2.07
STS	5.71	1	0.017	34.04	2	0.000	7.49*
Chronic Lung Disease	7.24	1	0.007	13.55	2	0.001	20.49*
LOSICU	5.99	1	0.014	18.15	2	0.000	4.60*

Note.

1. $N = 55$. Missing 52.2%. Dependent variable: LOS ordinal.
2. The italicized group is the 6-variable trimmed model with STS where no variable was trimmed.
2. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald χ^2 (df), *p* value. A bolded *p* value with asterisk indicates *p* equals 0.050 or less.
3. Difference was calculated by subtracting the Likelihood Ratio χ^2 from the previous one, while the previous variable was removed from this model. A bolded difference with asterisk indicates a value greater than 3.841.
4. *Abbreviations.* *LOSICU*, length of stay in intensive care unit; *Hgb*, hemoglobin; *STS*, the Society of Thoracic Surgeons risk score.

4.10 Multivariate Ordinal Logistic Regression: 3-variable Trimmed Model with STS

4.10.1 3-variable trimmed model with STS: assumptions. In this 3-variable trimmed model with *STS*, there were three variables, *STS*, *Chronic Lung Disease*, and *LOSICU*, identified from the multivariate trimming process discussed above. The assumptions and goodness of fit of this model were first tested.

As tested in the full regression model, there was no multicollinearity issue in this model. Moreover, a full likelihood ratio test showed that the assumption of proportional odds was not met for this model ($\chi^2 = 24.2, p = 0.000$). To further explore this assumption, therefore, separate binomial logistic regression analyses were conducted on the three dichotomized cumulative categories of *LOS ordinal*, namely, *LOS Ordinal Category 1* (LOS more than 12 days), *LOS Ordinal Category 2* (LOS more than 7 days), and *LOS Ordinal Category 3* (LOS more than 5 days). Table 28 presents the results of the separate binomial logistic regression, which showed that the assumption of the proportional odds might be tenable for the variables of *STS* and *LOSICU* because of their similar odds ratios. The odds ratios of the variable of *Chronic Lung Disease*, however, varied among the three categories of *LOS ordinal*, indicating that this assumption might not be tenable for the variable of *Chronic Lung Disease* in this model.

Table 28
3-variable Trimmed Model with STS Proportional Odds: Variables in the Equation

Independent Variable	B (parameter estimates)			Exp(B) (Odds Ratio)		
	LOS ordinal Category 1	LOS ordinal Category 2	LOS ordinal Category 3	LOS ordinal Category 1	LOS ordinal Category 2	LOS ordinal Category 3
Chronic Lung Disease	2.68	2.12	0.25	14.59	8.35	1.29
STS	0.15	0.38	0.16	1.16	1.46	1.17
LOSICU	0.01	0.05	0.03	1.01	1.05	1.03
Constant	-4.17	-5.78	-1.56	0.02	0.00	0.21

4.10.2 3-variable trimmed model with STS: goodness of fit. Overall, this trimmed model was a good fit for this 3-variable dataset. The results of statistic tests for goodness of fit are reported in the Table 29.

Table 29
3-variable Trimmed Model with STS: Goodness of Fit Test

Pseudo R-Square Tests				
	R^2			
Cox and Snell	0.37			
Nagelkerke	0.40			
McFadden	0.17			
Likelihood-Ratio Test				
	-2 Log Likelihood	χ^2	df	p
Intercept-only	157.7			
Final	131.2	26.5	3	0.000
Overall Goodness-of-Fit Tests				
		χ^2	df	p
Pearson		159.7	165	0.602
Deviance		131.2	165	0.976

4.10.3 3-variable trimmed model with STS: results. Table 30 presents the results of this 3-variable trimmed model with *STS*. As shown, the sample size was 57 with a missing response rate of 50.4 %. All of the three variables appeared to be statistically significant predictors of the LOS after TA TAVI ($p < 0.050$). The variables of *Chronic Lung Disease* and *LOSICU* remained statistically significant in predicting the LOS after TA TAVI. As shown in Table 30, the variable of *STS* had an odds ratio of 1.16, with Wald $\chi^2 (1) = 5.71, p = 0.017$.

Table 30

*Report of Multivariate Ordinal Logistic Regression 3-variable Trimmed Model with STS:
3-variable Dataset*

	Percent/ Mean (SD)	OR [95% CI]	Wald χ^2 (df)	<i>p</i>
<u>Dependent Variable</u>				
LOS ordinal				
<i>Less than 6 days</i>	24.6%			
6 - 7 days	24.6%			
8 - 12 days	22.8%			
More than 12 days	28.1%			
<u>Independent Variables</u>				
Chronic Lung Disease			9.39 (1)	0.002*
<i>No</i>	66.7%	<i>1</i>		
Yes	33.3%	5.98 [1.91, 18.78]		
STS	8.4% (6.6)	1.16 [1.03, 1.30]	5.71 (1)	0.017*
LOSICU	67.1 (127.3)	1.02 [1.00, 1.04]	6.20 (1)	0.013*

Note.

1. *N* = 57. Missing 50.4%.
2. The italicized group for each variable is the reference group for the comparison.
3. The odds ratio indicates to what extent the variable influences LOS relative to its reference group. A ratio greater than 1.00 indicates an increase in LOS, while a ratio less than 1.00 indicates a decrease in LOS.
4. A variable's overall test of significance indicates its overall influence on LOS, expressed in Wald χ^2 (df), *p* value. A bolded *p* value with asterisk indicates *p* equals 0.050 or less.
5. *Abbreviations.* *LOSICU*, length of stay in intensive care unit; *STS*, the Society of Thoracic Surgeons risk score.

4.11 Chapter Summary

In this chapter, we discussed the results of the statistic analyses of the 62 candidate variables in association to the LOS after TA TAVI. Univariate statistics were first performed to provide the descriptive information of the 62 independent variables as well as the dependent variable, *LOS ordinal*. From the bivariate ordinal logistic regression analyses, eighteen variables were initially identified for the multivariate ordinal logistic regression analysis. Due to multicollinearity issue, however, only fifteen of them were finally selected in the full model.

The results of the 15-variable dataset multivariate ordinal logistic regression full model indicated that, among the fifteen independent variables, three variables, including *Chronic Lung Disease*, *Temporary Pacemaker*, and *LOSICU*, appeared to have statistically significant effect on the LOS after TA TAVI, thus leading to the multivariate trimming for further investigating the interrelationships of the fifteen variables in terms of their impact on the LOS after TA TAVI. As a result, five variables, including *Chronic Lung Disease*, *Temporary Pacemaker*, *Age*, *Lowest Hgb*, and *LOSICU*, emerged to be independently significant predictors of the LOS after TA TAVI.

Despite its clinical relevance in TAVI procedures, the variable of *STS* was initially excluded from the 15-variable dataset full model, due to its high missing response rate in this study, but was included in a full regression model with the other five significant predictors to estimate its influence on the LOS after TA TAVI. The statistic regression models reported similar findings. For instance, with the addition of the variable of *STS*, two of the five predictor variables, namely, *Chronic Lung Disease* and *LOSICU*, remained as statistically significant predictors of the LOS after TA TAVI, while the effects of the other three predictor variables, including *Age*, *Temporary Pacemaker*, and *Lowest Hgb*, changed and became statistically insignificant.

Although not statistically significant in the multivariate regression full model ($p = 0.056$), the variable of *STS* was significantly associated with LOS in the bivariate analysis. To further distinguish the impact of this variable in relation to the other five predictors, multivariate trimming was performed again in the 6-variable dataset model. As a result, two variables, including *Chronic Lung Disease* and *LOSICU*, remained statistically significant predictors of the LOS after TA TAVI. Moreover, the potential impact of *STS* appeared to be too significant to be

neglected. Therefore, the three variables were collectively included in a separate regression model to evaluate their combined associations with the LOS. The results revealed that all three variables were statistically significant predictors of the LOS after TA TAVI. Nonetheless, considering the small sample size in this model, the influence of STS warrants further investigation as a potentially relevant predictor of the LOS after TA TAVI.

Chapter Five: Discussion

The purpose of this study was to identify the individual characteristics, procedural factors and complications, and patient care factors were predictive of LOS after TA TAVI, and to what extent they predicted it. In the following sections, we will compare this study's key findings with previous findings, appraise their implications, and discuss the methodological strengths as well as limitations.

5.1 Key Findings Compared with Literature Review

First, compared to the findings of the literature reviews, this study's key findings are consistent with that of some studies. For example, we found that the mean age of our sample was 78.8 years old (SD = 8.7). Every additional year of increase in age was associated with increased odds of having longer LOS after TA TAVI (OR = 1.05), a relatively large overall effect of Wald χ^2 of 4.05, $p = 0.044$. Other studies have also reported that, in general, advanced age was an independently important predictor of LOS in older adults (Kaysar et al., 2008; Kofteridis et al., 2009; Morse et al., 2010). Similarly, the level of creatinine is used in clinical practice to measure renal function. In our study, the variable of *Highest Creatinine*, which described TA TAVI patients' highest creatinine level during hospitalization, was initially estimated to be a potentially significant predictor based on its bivariate odds ratios, but was excluded through the trimming process due to its statistically insignificant overall effect. This finding is consistent with that of the studies of Van Linden et al. (2011), who reported that acute kidney injury, resulting from the use of contrast media was not significantly associated with prolonged LOS in post-TAVI patients.

Second, this study's findings have addressed certain gaps in the literature. For example, despite the general consensus that factors, including co-morbidities and iatrogenic complications,

were associated with prolonged LOS in the hospitalized older adults in general, little has been reported in relation to TA TAVI (Kaye et al., 2009; Bjorkelund et al., 2011). Our analysis begins to address this gap. In this study, chronic lung disease, as one example of co-morbidities, was shown to be significantly predictive of the LOS after TA TAVI. Similarly, another significant predictor is the need for a temporary pacemaker at the completion of TA TAVI, indicating that procedural complications, including dysrhythmia derived from aberrant conduction, did significantly influence the LOS after TA TAVI.

Third, this study's findings provide additional details that complement that of other studies. With regard to blood transfusion related variables, previous studies reported that blood transfusion and general anesthesia were associated with prolonged LOS (Di Mario et al., 2012; Mwipatayi et al., 2013). In the bivariate analyses of this study, we found that postoperative bleeding events and the use of blood products increased the odds of having longer LOS. However, the results of the multivariate trimming showed that, in the context of other variables, including *Age*, *Chronic Lung Disease*, *Temporary Pacemaker*, *LOSICU*, and *Lowest Hgb*, the bleeding and blood transfusion related variables were not independent predictors of the LOS after TA TAVI. Nonetheless, we did find that the lowest value of the hemoglobin level of TA TAVI patients during hospitalization played a significant role in predicting LOS. Clinically, hemoglobin is an important indicator of anemia. Anemia is prevalent in older population, and can be aggravated by postoperative bleeding. Literature reported that anemia-induced blood transfusion more likely prolonged the LOS of older adults (Collins, Daley, Henderson, & Khuri, 1999). In this regard, this study is consistent in reporting that, when comparing the lowest values of the hemoglobin level among the TA TAVI patients during hospitalization, the lower the hemoglobin level was, the more likely the patient would have longer LOS.

Last, despite lack of relevant findings in previous studies, the significant impact of the LOS in critical care on overall LOS was evidently self explanatory and statistically supported in this study. However, as LOS in critical care is a multifaceted phenomenon attributed to various factors, future studies may be needed to further explore the context of this surrogate measure in order to gain better understanding of its impact on the LOS after TA TAVI patients.

5.2 Findings Related to Study Models

No previously developed conceptual frameworks readily applicable to this study were found in the literature review. To address this study's questions, we developed a map-like approach, which consists of two models, namely, the Predicting LOS after TA TAVI: TA TAVI Surgical Process Model (Figure 1) and the Predicting LOS after TA TAVI: Conceptual Model (Figure 2).

In developing the two models, we carefully consulted the findings of literature review and the presentation of clinical data relevant to possible structure and constructs. For instance, several studies reported that factors, including patients' individual characteristics (i.e., co-morbidities) and procedural complications (i.e., acute kidney injury), influenced LOS (Kofteridis et al., 2009; Mwiripatayi et al., 2013). To some extent, such findings have given the empirical evidence in supporting our assumptions that TA TAVI-related LOS might be attributed to individual characteristics (i.e., demographic characteristics) in the context of TA TAVI (i.e., postoperative TA TAVI complications). In addition, we examined the patterns of the available clinical dataset, and postulated that the trajectory of undergoing TA TAVI could be divided into phases (i.e., the Pre-procedure phase, the Peri-procedure phase, and the Post-procedure phase) to provide an clinically intuitive yet systematically logical approach in identifying potential candidate variables and examining the inter-relationships.

Both the findings from this study and the literature review have supported the feasibility and appropriateness of the two models in this study. First, by using the two models, we demonstrated that there were independent predictors of LOS from different phases throughout the TA TAVI process. For example, identifying the demographic variable of *Age* from the Pre-procedure phase, the variable of *Temporary Pacemaker* from the Peri-procedure phase, and the variable of *Lowest Hgb* from the Post-procedure phase, supported the feasibility of defining the TA TAVI procedure phases. Second, we confirmed that by using the two models, this study's findings were not only supportive of the assumptions underlying the research question, but they also correlated with that of other studies. One such example is the finding of the variable of *Chronic Lung Disease*. Due to the intrinsically complex nature of interactions between pulmonary diseases and cardiovascular functions, chronic obstructive pulmonary disease (COPD) was initially considered and selected as one of the 62 candidate variables. Moreover, the literature review showed that, as one of the common respiratory disorders in older adults, COPD was one of the predictors of prolonged LOS (Chang, Calligaro, Lombardi, & Dougherty, 2003), further supporting the selection of this variable for analysis. Finally, in this study, the variable of *Chronic Lung Disease* was demonstrated as statistically predictive of LOS TA TAVI. Therefore, the usefulness of the two models in this study is supported.

In summary, we consider that the two models, the Predicting LOS after TA TAVI: Model of Surgical Process (Figure 1) and Conceptual Model (Figure 2), and have provided a relevant and suitable organizing framework for this study. As this study is exploratory, however, we acknowledge the developmental and experimental nature of the two models. Thus, further refining through more studies are recommended.

5.3 Implications

In general, older adults are more frail and susceptible to adverse outcomes such as delayed recovery and prolonged LOS postoperatively (Kaye et al., 2009; Bjorkelund et al., 2011). Due to their higher surgery risk or other prohibitive conditions including peripheral artery disease or atherosclerotic disease, more older adults with severe symptomatic AS are not candidates for conventional SAVR or TF TAVI. Therefore, TA TAVI is an appropriate alternative therapy for a selected patient population. However, as discussed previously, in the literature, little has been explored about the LOS after TA TAVI patients. This study found that median LOS was seven days, which was longer than the median hospital stay of six days reported by the Society of Thoracic Surgeons/ American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry (Mack et al., 2013). The findings of this study may have implications relevant to nursing education and practice and policy making in the context of the LOS after TA TAVI patients.

At the nursing education level, identifying the predictors of the LOS after TA TAVI may increase nurses' knowledge with regard to TA TAVI-specific patient care. Generally speaking, lengthy LOS is an undesirable and detrimental outcome, especially for older adults. Although prolonged LOS is inevitable under certain circumstances, studies ascertained that quality of nursing care played an important role in improving the quality of patient care, thus reducing the likelihood of prolonged LOS (Thungjaroenkul, Cummings, & Embleton, 2007; Stauber, 2013). One way nurses can improve the quality of care is to increase relevant knowledge while individualizing patient care. Specifically, in this study, chronic lung disease was demonstrated to have a statistically significant positive correlation with the LOS after TA TAVI, thus highly likely to increase TA TAVI patients' risk of having adverse sequelae derived from lengthy LOS

(i.e., de-conditioning or delayed recovery). As stated previously, COPD was already found to be the predictor of prolonged LOS in other surgeries (Chang et al., 2003). Fried, Fragoso, and Rabow (2012) stated that COPD was “characterized by high symptom burden, healthcare utilization, mortality and unmet needs of patients and caregivers” (p.1254). Hence, the adversarial impact of COPD on older adults should not be taken lightly. Knowledge of the existence of this predictor could alert nurses and motivate them to become more familiar with COPD-related care management for TA TAVI patients with such health challenges. Another indicator which could increase nursing knowledge is the predictor of temporary pacemaker use at the completion of TA TAVI. This may call nurses’ attention to increase relevant telemetry monitoring and become more attuned to nursing skills including electrocardiogram interpretation, especially during the Peri-procedure phase.

At the nursing practice level, it is acknowledged that the key findings of this study are mostly related to factors that are essentially non-modifiable, for example, patient age and medical history. Nonetheless, the findings of this study may still have practice implications on how to care for this patient population, especially from the perspective of de-conditioning prevention. Gillis and MacDonald (2005) described that de-conditioning was a “complex process of physiological change following a period of inactivity, bedrest or sedentary lifestyle”, and in hospitalized older, may occur acutely within “as little as two days of bedrest” (p. 17). Moreover, predictable effects of de-conditioning were often seen through the functional losses, which were often aggravated by lengthy LOS, and in turn increased a patient’s frailty. In this study, we found that the mean and median LOS after TA TAVI patients was 11.1 days and 7.0 days, respectively, longer than that of other types of interventions. In addition, despite its high missing data rate, in the bivariate analyses on the Functional Assessment variables, we noted that

the variable of *CSHA CFS* (Table 9) had the odds ratio of 1.59 ($p = 0.230$), meaning that, while analyzing this frailty measurement variable in relation to LOS, high *CSHA CFS* scores might positively increase the odds of having longer LOS after TA TAVI. Therefore, to purposefully prevent de-conditioning in TA TAVI patients, recommendations to nursing practice include continuing education on de-conditioning management, and early implementation of functioning-improving strategies during hospitalization (Gillis & MacDonald, 2005; Kleinpell et al., 2008; Kosse et al., 2013). On the other hand, because of the high missing response rates of the Functional Assessment variables included in this study, it is recommended that future studies explore in depth the inter-relationships they may have with the LOS after TA TAVI. Moreover, it is recognized that this study included only five functional assessment measures. The five selected measures might not inclusively capture appropriate predictors of the LOS after TA TAVI. Therefore, future studies could focus on other types of functional assessment to evaluate their predictive effects.

At the nursing policy level, LOS is often an important outcome measure of quality of care and resource consumption. As TA TAVI procedure is not only indicated for saving lives, but more importantly for enhancing quality of life in older adults with severe AS, it seems desirable if the TA TAVI patient can be discharged as expected. Fried et al. (2012) stated that nursing practice might incorporate streamlined care guidelines (i.e., pathways) that were specifically developed to supplement independent clinical decision making based on individualized patient needs. In this regard, the findings of this study may have implications. For instance, this study found that TA TAVI led to relatively longer LOS, and several factors (i.e., respiratory challenges or hemoglobin level) appeared to prolong it. Although nurses can do little to alter the pathophysiological nature of TA TAVI patients' medical conditions, by identifying common

characteristics in this population, nurses may be able to make positive changes in nursing practice that cater to their unique care needs. Moreover, in consideration of the impact of long LOS on potential de-conditioning in TA TAVI patients during hospitalization, clinical pathways for preventing de-conditioning in this patient population may be specifically developed based on the best practice evidence available. Nonetheless, it is recognized that, although this study provides a preliminary identification of the predictors of the LOS after TA TAVI, it did not explore evidence in nursing practice relevant to clinical pathway development for de-conditioning management. Future research and analysis of best practice guidelines in this direction are required to provide substantive empirical evidence.

Based on the discussion above, we are cautious in making recommendations on changing established nursing practice in the context of TA TAVI-related LOS. Hence, in consideration of the findings of this study, we recommend that 1) in practice, health care practitioners including nurses may increase their awareness of the existence of these identified predictors; and 2) in research, future studies may focus on validating the findings of this study, exploring other possible predictors, and appraising the best evidence in nursing practice.

5.4 Methodological Strengths

Methodologically, this study has several strengths, including developing a structured approach in identifying and organizing variables, adopting a stepwise process in data analyses, and applying statistical techniques of multivariate trimming.

The first and foremost challenge that this study had to deal with was how the multiple candidate variables could be reasonably identified and feasibly handled. To address this challenge, we designed a systematically structured approach. Specifically, we first conducted comprehensive literature reviews and consulted experts to identify the 62 candidate variables.

Theoretically, we then developed the Predicting LOS after TA TAVI: TA TAVI Surgical Process Model (Figure 1) and the Predicting LOS after TA TAVI: Conceptual Model (Figure 2) as the underlying framework to classify and organize the candidate variables. Furthermore, to ensure the accuracy in the process of data collection, we developed the Predicting LOS after TA TAVI: Data Collection Form (Appendix A) and Code Manual (Appendix B), and consistently applied them in the retrospective chart review. As the primary threat to data reliability and validity while using a chart review method is the subjective interpretation in data collection, we mitigated this impact by selecting the variables that were either objectively measured or explicitly described, thus maximizing the reproducibility and quality of the data collected (Worster & Haines, 2004; Gregory & Radovinsky, 2012).

During data analysis, the major challenge we faced was how the 62 independent variable's impact on LOS could be statistically evaluated. For this challenge, we used an iterative statistical process by which we first used bivariate ordinal logistic regression to explore the 62 independent variables' individual impact on LOS, and then included the selected significant variables in the multivariate ordinal logistic regression full model. This stepwise process is systematic and replicable if needed in future studies with different sample sizes.

Finally, to pinpoint the variables that were independently significant predictors of the LOS after TA TAVI, we applied the multivariate trimming technique. In consideration of sample size and covariance effect, the application of this robust process was crucial in reinforcing the findings of this study. Furthermore, the power analysis reviewed that, in multivariate logistic regression, a sample size of ten was required for each variable in the model (Peduzzi et al., 1996). After the multivariate trimming, the number of independent variables decreased to five, which made the total sample size of 102 sufficient for this study.

5.5 Limitations

One of the methodological shortcomings is the study's sample. This study included subjects who were carefully screened and selected for the TA TAVI procedure. Moreover, because this study used a single study center's clinical data, the sample only represented this center's individual experience of TA TAVI. Therefore, the generalization of this study's findings is unknown. In addition, to enhance the rigor of a study using retrospective chart review, ideally, a team of at least two data abstractors was recommended for data collection, and kept blind to the purpose of the study (Gregory & Radovinsky, 2012). This, however, was not feasible for this study given constraints in resources. Nonetheless, the strategies that this study employed to mitigate the impact of such limitations included the development of the Data Collection Form (Appendix A) and the Code Manual (Appendix B) and consistent application of the two forms in the process of data collection. Recommendations for future research are using multi-center databases and applying more rigorous data collection techniques.

Other limitations are related to the variable selection and missing data rates. Although the 62 variables included were systematically and comprehensively selected, the list is unlikely exhaustive, thus recommending future research to explore other relevant variables. For example, clinical feedback suggested that pain related to the TA TAVI procedure postoperatively might have potential impact on LOS. Due to lack of data, however, pain was not included in this study's variable selection. In addition, several variables had high missing data rates. Among the 115 samples of this study, it is noted that only 63 had the STS risk scores (missing 45.2%), and the majority of the 63 STS risk scores (95%) were recorded after 2012. Nonetheless, statistic analyses in this study did show that, despite its high missing response rate, the STS risk score appeared to have significant impact on the LOS after TA TAVI patients. Therefore, in

consideration of its clinical relevance, it is recommended that future studies may explore in depth the impact of STS risk score on the LOS after TA TAVI with larger sample size. Likewise, in this study, the five Functional Assessment variables were excluded in the early analytic stage. Their high missing response rates may have contributed to their early exclusion, thus making the estimates of their impact on LOS underexplored in this study. Furthermore, the limited sample size may also have caused some variables not to be statistically significant predictors. In this regard, it is recommended that future research explore the inter-relationships between functional assessment variables and the LOS after TA TAVI with sufficient sample size.

5.6 Conclusion

With an ageing population, the prevalence of AS is expected to be increasingly common. Over the years, TA TAVI has been proven to be a feasible procedure with safety and efficacy for the non-operative older adults who are at higher risk for SAVR and other TAVI interventions.

In this study, with the purpose of identifying the predictors of the LOS after TA TAVI, we conducted a retrospective chart review on the 128 medical charts of TA TAVI patients, collected data of the 62 potential predictors selected from the literature review and consultations with experts, and analyzed them by using bivariate and multivariate ordinal logistical regression models. As a result, the mean and median LOS after TA TAVI was eleven and seven days, respectively. Among the 62 candidate variables, we have found that five appeared to significantly predict the LOS after TA TAVI. These five predictors include the patient's age, the lowest hemoglobin level during hospitalization, the medical history of chronic lung diseases, the need for using temporary pacemaker upon the completion of the procedure, and the length of stay in critical care. Based on this study's findings, we conclude that if a TA TAVI patient has chronic lung disease or needs a temporary pacemaker when the TA TAVI is completed, the odds

of having longer LOS will likely increase. Likewise, the older the patient is, the longer the LOS after TA TAVI will likely be. Moreover, postoperative stay in the critical care increasingly affects one's chance of having longer LOS after TA TAVI. Conversely, when comparing two TA TAVI patients' lowest level of hemoglobin, the one with the lower value is likely to have increased odds of having longer LOS after TA TAVI. Furthermore, as TA TAVI appeared to have longer LOS than other interventions, it is highly recommended that nursing practice be more proactive in managing potential de-conditioning that may result from longer LOS after TA TAVI.

Moreover, this study's findings are consistent with and complementary to those of other studies, and have addressed several knowledge gaps in the TA TAVI literature. This may have implications on nursing education and practice relevant to caring for TA TAVI patients. In addition, as LOS is often an indicator of outcome measurement on quality of care and resource consumption, this study may provide insights into TA TAVI-related practice and policy making. Methodologically, this study has merits as well as limitations. Furthermore, several variables, including the Functional Assessment variables and the STS risk score, were underexplored due to their high missing data rates in this study. Nonetheless, it is acknowledged that this study is exploratory and preliminary in nature. Hence, future studies are strongly recommended to further validate the findings and explore the underexplored variables in terms of their impact on the LOS after TA TAVI patients.

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Appendix A: Predicting LOS After TA TAVI: Data Collection Form

Chart Number:			Procedure:
PRE-PROCEDURE PHASE VARIABLES			
DEMOGRAPHICS VARIABLES			
Age: yrs	Sex: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Other		
Date of Referral:	/ / <input type="checkbox"/> Missing	Wait Time 1	d
Date of Acceptance:	/ / <input type="checkbox"/> Missing	Wait Time 2	d
Date of Procedure:	/ / <input type="checkbox"/> Missing	Wait Time 3	d
Status of Referral: <input type="checkbox"/> Elective <input type="checkbox"/> In Patient <input type="checkbox"/> Missing			
Location of Residence: <input type="checkbox"/> FHA <input type="checkbox"/> IHA <input type="checkbox"/> VIHA <input type="checkbox"/> NHA <input type="checkbox"/> VCH <input type="checkbox"/> Other <input type="checkbox"/> Missing			
HISTORY & RISK VARIABLES			
Prior PPM : <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing	Prior Cardiac Interventions: Prior CABG: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing Prior other Cardiac Surgery: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing Prior PCI: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing Prior SAVR: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing Prior BAV: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing		
Prior ICD: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing			
Prior Stroke: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing			
Chronic Lung Disease: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing			
Diabetes: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing			
Prior MI: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing			
Prior Atrial Fibrillation: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing			
FUNCTIONAL ASSESSMENT VARIABLES			
CSHA CFS: / 9 <input type="checkbox"/> Missing	Home Support <input type="checkbox"/> None <input type="checkbox"/> Full-time <input type="checkbox"/> Part-time <input type="checkbox"/> Missing	Living Situation <input type="checkbox"/> Lives alone/ Independently <input type="checkbox"/> Lives with family <input type="checkbox"/> Nursing home <input type="checkbox"/> Missing	
ADL: / 6 <input type="checkbox"/> Missing			
IADL: / 8 <input type="checkbox"/> Missing			
MMSE: / 30 <input type="checkbox"/> Missing			
5-m Walk: Time 1: sec Time 2: sec Time 3: sec Mean: sec <input type="checkbox"/> Missing			
PRE-OP STATUS VARIABLES			
NYHA: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Missing	LVEF: % <input type="checkbox"/> Missing	STS: % <input type="checkbox"/> Missing	
Ht: cm <input type="checkbox"/> Missing	Wt: kg <input type="checkbox"/> Missing	BMI: kg/m ²	
Hgb: g/L <input type="checkbox"/> Missing	Creatinine: μmol/L <input type="checkbox"/> Missing	eGFR: ml/min <input type="checkbox"/> Missing	

PERI-PROCEDURE PHASE VARIABLES									
PROCEDURAL FACTORS VARIABLES									
Procedure Start Time: <input type="checkbox"/> Missing			Procedure End Time: <input type="checkbox"/> Missing			Procedure Total Time: min			
Valve Type: <input type="checkbox"/> Aortic <input type="checkbox"/> Mitral <input type="checkbox"/> Both <input type="checkbox"/> Missing				Procedure Type: <input type="checkbox"/> Native Valve <input type="checkbox"/> Valve-in-valve <input type="checkbox"/> Missing					
PERI-PROCEDURE STATUS VARIABLES									
<u>While leaving procedure room</u>									
Airway Status			<input type="checkbox"/> Extubated		<input type="checkbox"/> Intubated		<input type="checkbox"/> Missing		
Pulmonary artery catheter:			<input type="checkbox"/> Yes		<input type="checkbox"/> No		<input type="checkbox"/> Missing		
Chest Drain:			<input type="checkbox"/> Yes		<input type="checkbox"/> No		<input type="checkbox"/> Missing		
Temporary Pacemaker:			<input type="checkbox"/> Yes		<input type="checkbox"/> No		<input type="checkbox"/> Missing		
PERI-PROCEDURE COMPLICATIONS VARIABLES									
≤72 Pacemaker: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing					≤72 Annular Dissection: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing				
≤72 Atrial Fibrillation: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing					≤72 Cardiac Arrest: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing				
≤72 Stroke: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing					≤72 Perforation: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing				
≤72 Bleed: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing									
≤72 Blood Transfusion: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing									
≤72 Blood Transfusion Units: <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5+ <input type="checkbox"/> Missing									
POST-PROCEDURE PHASE VARIABLES									
LOS IN CRITICAL CARE VARIABLE									
LOS ICU = hr <input type="checkbox"/> Missing									
POST-PROCEDURE COMPLICATIONS VARIABLES									
GT72 Pacemaker: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing					>72 Perforation: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing				
GT72 Atrial Fibrillation: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing					>72 Stroke: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing				
>72 Cardiac Arrest: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing									
>72 Bleed: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing									
>72 Blood Transfusion: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing									
>72 Blood Transfusion Units: <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5+ <input type="checkbox"/> Missing <input type="checkbox"/> N/A									
DISCHARGE PLANNING VARIABLES									
Discharge Status: <input type="checkbox"/> Alive <input type="checkbox"/> Deceased									
Discharge Location: If Alive, <input type="checkbox"/> Home <input type="checkbox"/> Nursing Home <input type="checkbox"/> Extended Care/ Rehab <input type="checkbox"/> Hospice <input type="checkbox"/> Other Hospitals <input type="checkbox"/> Other									
Lowest Hgb: g/L <input type="checkbox"/> Missing					Discharge Hgb: g/L <input type="checkbox"/> Missing				
Highest Creatinine: μmol/L <input type="checkbox"/> Missing					Discharge Creatinine: μmol/L <input type="checkbox"/> Missing				
Date of Discharge: / / <input type="checkbox"/> Missing									
OUTCOME OF INTEREST									
LOS = D									

Appendix B: Predicting LOS After TA TAVI: Code Manual⁷

Predicting LOS after TA TAVI: Code Manual			
Study Sample & Eligibility Criteria: 128 medical charts of patients who had symptomatic aortic stenosis, were accepted by the Transcatheter Heart Valve (THV) program, underwent TA TAVI procedure at the study center from 2010 to 2014, and were discharged alive.			
#	Variable Name	Variable Definition	Notes
Chart Information			
1	Chart Number	Study sample number assigned to each medical chart	000-999
2	Procedure	Types of TAVI procedure	TA TAVI
Pre-procedure Phase Variables			
<i>Pre-procedure Phase variables pertains to TA TAVI patients' individual characteristics and preoperative status information at the time of acceptance for TA TAVI at the study center. Variables are categorized into four subcategories: Demographics, History and Risk Factors, Functional Assessment, and Pre-op Status.</i>			
Demographics Variables			
Demographics variables include TA TAVI patient's socio-demographic characteristics and procedure information from the Date of Referral to the start time of TA TAVI procedure.			
3	DOB	TA TAVI patient's date of birth.	mm/dd/yyyy
4	Age	TA TAVI patient's age on arrival for the procedure.	Years
5	Sex	TA TAVI patient's sex at the time of TA TAVI.	M/F
6	Date of Referral	The date when the TA TAVI patient was referred to the Transcatheter Heart Valve (THV) program.	mm/dd/yyyy

⁷ Source: Cardiac Services BC (2008)

7	Date of Acceptance	The date when the TA TAVI patient was accepted by the Transcatheter Heart Valve (THV) program.	mm/dd/yyyy
8	Date of Procedure	The date when the TA TAVI patient had the TA TAVI procedure.	mm/dd/yyyy
9	Wait Time 1	The time period from the Date of Referral to the Date of Acceptance.	Days
10	Wait Time 2	The time period from the Date of Acceptance to the Date of Procedure.	Days
11	Wait Time 3	The time period from the Date of Referral to the Date of Procedure.	Days
12	Status of Referral	TA TAVI patient's status at the Date of Referral: Elective vs. In-patient	Elective/ in-patient
13	Location of Residence	The health authority to which TA TAVI patients' primary residences originally belong. Five health authorities are in BC, Canada: Fraser Health Authority (FHA); Interior Health Authority (IHA); Vancouver Island Health Authority (VIHA); Northern Health Authority (NHA); Vancouver Coastal Health Authority (VCH).	FHA/IHA/ VIHA/NHA/ VCH/ Other
History & Risk Variables			
History and Risk Factors variables include TA TAVI patients' previous cardiac history, co-morbidities and risk factors prior to the Date of Acceptance.			
14	Prior PPM	History of permanent pacemaker implantation (PPM) prior to the Date of Acceptance. This includes patients who had a PPM previously, but the device was no longer in place prior to the procedure.	Y/N
15	Prior ICD	History of implantable cardioverter defibrillator (ICD) implantation prior to the Date of Acceptance. This includes patients who had an ICD previously, but the device was no longer in place prior to the procedure.	Y/N
16	Chronic Lung Disease	History of a chronic lung disease prior to the Date of Acceptance. It included patients with chronic obstructive pulmonary disease, chronic bronchitis, or emphysema. It also included a patient who was currently being chronically treated with inhaled or oral pharmacological therapy (e.g., beta-adrenergic agonist, anti-inflammatory agent, leukotriene receptor antagonist, or steroid). Patients with asthma or seasonal allergies were not considered to have chronic lung diseases in this study.	Y/N
17	Diabetes	History of diabetes prior to the Date of Acceptance.	Y/N

18	Prior Stroke	History of stroke prior to the Date of Acceptance.	Y/N
19	Prior MI	History of myocardial infarction (MI) prior to the Date of Acceptance.	Y/N
20	Prior Atrial Fibrillation	History of atrial fibrillation (A Fib) prior to the Date of Acceptance.	Y/N
21	Prior Other Cardiac Surgery	History of other cardiac surgeries other than SAVR/repair prior to the Date of Acceptance.	Y/N
22	Prior CABG	History of coronary artery bypass graft (CABG) surgery prior to the Date of Acceptance.	Y/N
23	Prior PCI	History of percutaneous coronary intervention (PCI) prior to the Date of Acceptance.	Y/N
24	Prior SAVR	History of SAVR (SAVR) prior to the Date of Acceptance.	Y/N
25	Prior BAV	History of balloon aortic valvuloplasty prior to the Date of Acceptance.	Y/N
Functional Assessment Variables			
Function Assessment variables include the patient's functional and frailty status and home environment characteristics prior to the Date of Acceptance.			
26	Home Support	Defined as the home support services that TA TAVI patients received prior to the Date of Acceptance. Three types of Home Support were included in this study: #1: None – independent, no need for home support #2: Full time – require full-time home support #3: Part time- require part-time home support	None/ Full-time/ Part-time
27	Living Situation	Defined as the living conditions in which TA TAVI patients lived prior to the Date of Acceptance. Three types of Living Situation were included in this study: #1: Lives alone / independently #2: Lives with family #3: Nursing home, including other facilities (i.e., Assisted Living)	Lives along/ Independently/ Lives with family/ Nursing home

28	CSHA CFS	Refers to the Canadian Study of Health and Aging Clinical Frailty Scale (CSHA CFS) score. CSHA CFS was used to assess TA TAVI patients preoperative frailty status. Scores range from 1 to 9. Higher scores indicate greater degree of frailty status. Details of scoring are as follows: ≤ 3: Well and Fit 4-6: Vulnerable to Moderately Frail 7-9: Severely Frail to Terminally Ill	1-9
29	ADL	Refers to the Katz Index of Independence in Activities of Daily Living scale score (ADL). ADL was used to assess TA TAVI patients' ability to perform activities of daily living preoperatively. It assesses six functions of bathing, dressing, toileting, transferring, continence, and feeding. Scores range from 0 - 6. Higher score indicates higher level of independence. A full score of 6 indicates full function while a score of 2 or less indicates severe functional impairment. Details of scoring are as follows: 5-6: High function 3-4: Moderate impaired function 0-2: Severe impaired function	0-6
30	IADL	Refers to the Lawton Instrumental Activities of Daily Living scale score (IADL). IADL was used to assess TA TAVI patients' functional status preoperatively. It assesses eight domains: Using telephone, shopping, preparing food, housekeeping, doing laundry, using transportation, handling medication, and handling finances. Scores range from 0 (low function, dependent) to 8 (high function, independent). Details of scoring are as follows: 6-8: High function 3-5: Moderately impaired function 0-2: Severely impaired function	0-8
31	MMSE	Defined as the Mini-Mental State Examination (MMSE) scale for assessing patient's cognitive impairment. Scores range from 0 to 30. Higher scores indicate less cognitive impairment. Details of scoring are as follows: 26-30: No or little cognitive impairment 20-25: Mild cognitive impairment: 10-19: Moderate cognitive impairment 0-9: Severe cognitive impairment	0-30

32	5-m Walk	<p>Refers to the 5-m Gait Speed test (5-m Walk test) score. The 5-m Walk test was used to assess TA TAVI patients' mobility capacity and performance. During the 5-m Walk test in this study, TA TAVI patient was asked to walk, with or without walking aids, a distance of five meters for three times (Time 1, Time 2, and Time 3), and then the average of the times was calculated. The last value in this study was taken between 30 days prior to the procedure and the procedure .</p> <p>Time 1: the time in seconds it took the TA TAVI patient to walk 5 meters for the first of three tests.</p> <p>Time 2: the time in seconds it took the TA TAVI patient to walk 5 meters for the second of three tests.</p> <p>Time 3: the time in seconds it took the TA TAVI patient to walk 5 meters for the third of three tests.</p>	Seconds
Pre-op Status Variables			
Pre-op Status variables include the TA TAVI patient's surgical risk assessment and preoperative laboratory results completed within two weeks prior to the start time of the TA TAVI procedure.			
33	NYHA	<p>The New York Heart Association (NYHA) classification:</p> <p>Class I: Patient has cardiac disease but without resulting limitations of ordinary physical activity.</p> <p>Class II: Patient has cardiac disease resulting in slight limitation of ordinary physical activity, and is comfortable at rest.</p> <p>Class III: Patient has cardiac disease resulting in marked limitation of physical activity. Patient is comfortable at rest.</p> <p>Class IV: Patient has cardiac disease resulting in inability to perform any physical activity without discomfort. Patient has dyspnea at rest that increases with any physical activity.</p>	Class I/ Class II/ Class III/ Class IV
34	LVEF	The left ventricle ejection fraction (LVEF), indicating the percentage of the blood emptied from the left ventricle at the end of the contraction. Enter a percentage in the range of 1 - 99. If a percentage range is reported, report a whole number using the "mean" (i.e., 50-55%, is reported as 53%).	%
35	STS	The Society of Thoracic Surgeons Predicted Risk of Mortality (STS) score, which is one of the commonly used risk profile systems for assessing operative risks and identifying high-risk patients for TAVI procedures. The STS score is comprised of over 40 clinical parameters and has been demonstrated to be reliable in assessing operative risk in TAVI patients. Higher scores indicate higher operative risk.	
36	Ht	Height of the TA TAVI patient.	cm
37	Wt	Weight of the TA TAVI patient.	kg
38	BMI	The Body mass index (BMI) for measuring body fat based on height and weight prior to the date of the TA TAVI procedure. $BMI = \text{Weight (kg)} / \text{Height}^2(\text{m}^2)$	kg/m ²

39	Hgb	TA TAVI patient's preoperative hemoglobin level prior to the Date of Procedure.	g/L
40	Creatinine	TA TAVI patient's preoperative creatinine level prior to the Date of Procedure.	μmol/L
41	eGFR	TA TAVI patient's preprocedure estimated glomerular filtration rate (eGFR) level prior to the Date of Procedure.	ml/min
Peri-procedure Phase Variables			
<i>Peri-procedure Phase variables include TA TAVI procedural information, TA TAVI-related complications, TA TAVI patients' postoperative status during the period from the start time of TA TAVI procedure up to 72 hours after the procedure.</i>			
Procedural Factors Variables			
Procedural Factors Variables include the information of TA TAVI procedure.			
42	Procedure Start Time	The time when the TA TAVI procedure started.	Hr:min
43	Procedure End Time	The time when the TA TAVI procedure ended.	Hr:min
44	Procedure Total Time	The time period from the Procedure Start Time to the Procedure End Time.	Minute
45	Valve Type	The types of valve(s) that TA TAVI procedure was involved: Aortic or mitral.	Aortic/ Mitral/ Both
46	Procedure Type	The types of TA TAVI. TAVI involving the replacement of the native aortic valve is called native-valve procedure whereas TAVI involving valve implantation within a failed bioprosthesis is called valve-in-valve procedure.	Native/ VIV
Peri-procedure Status Variables			
Peri-procedure Status Variables describe TA TAVI patients' postoperative status within this time period.			
47	Airway Status	Indicates whether TA TAVI patient was extubated or intubated prior to admission to the critical care unit.	Extubated/ Intubated
48	Pulmonary Artery Catheter	Indicates whether TA TAVI patient had pulmonary artery catheter inserted prior to admission to the critical care unit. Y indicates Yes. N indicates No.	Y/N

49	Chest Drain	Indicates whether TA TAVI patient had chest drain inserted prior to admission to the critical care unit. Y indicates Yes. N indicates No.	Y/N
50	Temporary Pacemaker	Indicates whether TA TAVI patient had temporary pacemaker attached prior to admission to the critical care unit. Y indicates Yes. N indicates No.	Y/N
Peri-procedure Complications Variables			
Peri-procedure Complications Variables pertain to the procedure-related complications within this time period.			
51	≤72 Pacemaker	Indicates if TA TAVI patient developed conduction/ native pacer disturbance that required new pacemaker during the period from the start time of TA TAVI procedure up to 72 hours after the procedure. Y indicates Yes. N indicates No.	Y/N
52	≤72 Atrial Fibrillation	Indicates if TA TAVI patient developed new-onset atrial fibrillation during the period from the start time of TA TAVI procedure up to 72 hours after the procedure. Y indicates Yes. N indicates No.	Y/N
53	≤72 Stroke	Indicates if TA TAVI patient had stroke during the period from the start time of TA TAVI procedure up to 72 hours after the procedure. Y indicates Yes. N indicates No.	Y/N
54	≤72 Annular Dissection	Indicates if TA TAVI patient had annular dissection during the period from the start time of TA TAVI procedure up to 72 hours after the procedure. Y indicates Yes. N indicates No.	Y/N
55	≤72 Cardiac Arrest	Indicates if TA TAVI patient had cardiac arrest during the period from the start time of TA TAVI procedure up to 72 hours after the procedure. Y indicates Yes. N indicates No.	Y/N
56	≤72 Perforation	Indicates if TA TAVI patient had perforation during the period from the start time of TA TAVI procedure up to 72 hours after the procedure. Y indicates Yes. N indicates No.	Y/N
57	≤72 Bleed	Indicates if TA TAVI patient had bleeding episodes during the period from the start time of TA TAVI procedure up to 72 hours after the procedure. Y indicates Yes. N indicates No.	Y/N
58	≤72 Blood Transfusion	Indicates if TA TAVI patient required blood transfusion during the period from the start time of TA TAVI procedure up to 72 hours after the procedure. Y indicates Yes. N indicates No.	Y/N
59	≤72 Blood Transfusion Units	Indicates how many units of blood products that TA TAVI patient received from blood transfusion during the period from the start time of TA TAVI procedure up to 72 hours after the procedure. Y indicates Yes. N indicates No.	Units

Post-procedure Phase Variables			
<i>Post-Procedure Phase variables include TA TAVI-related complications and patient-care related complications that occurred from the time of 72 hours post-TA TAVI procedure to the discharge.</i>			
LOS in Critical Care Variable			
LOS in Critical Care Variable refers to the length of stay in the intensive care unit.			
60	LOSICU	Defined as the length of stay of TA TAVI patient in the critical care after TA TAVI. Recorded in hours.	Hours
Discharge Planning Variables			
Discharge Planning Variables pertain to TA TAVI patients' information and laboratory values for discharge planning.			
61	Discharge Status	Indicates if TA TAVI patient was alive or deceased at the time of discharge.	Alive/Death
62	Discharge Location	Indicates the locations to which TA TAVI patient was discharged, including 1) Home; 2) Nursing Home; 3) Extended Care/Rehab 4) Hospice; 5) Other Hospitals; and 6) Other.	Vary
63	Lowest Hgb	Defined as the lowest value of hemoglobin that TA TAVI patients had during hospitalization.	g/L
64	Discharge Hgb	Defined as the value of TA TAVI TA TAVI patient's hemoglobin upon discharge.	g/L
65	Highest Creatinine	Defined as the highest value of creatinine that TA TAVI patients had during hospitalization.	μmol/L
66	Discharge Creatinine	Defined as the value of TA TAVI patient's creatinine upon discharge.	μmol/L
67	Date of Discharge	Defined as the date when TA TAVI patient was discharged alive from the hospital.	mm/dd/yyyy

Post-procedure Complications Variables			
Post-procedure Complications Variables pertain to the procedure-related complications within this time period.			
68	>72 Pacemaker	Indicates if TA TAVI patient developed conduction/ native pacer disturbance that required new pacemaker during the period from the time of 72 hours post-TA TAVI procedure to the discharge. Y indicates Yes. N indicates No.	Y/N
69	>72 Atrial Fibrillation	Indicates if TA TAVI patient developed new-onset atrial fibrillation during the period from the time of 72 hours post-TA TAVI procedure to the discharge. Y indicates Yes. N indicates No.	Y/N
70	>72 Stroke	Indicates if TA TAVI patient had stroke during the period from the time of 72 hours post-TA TAVI procedure to the discharge. Y indicates Yes. N indicates No.	Y/N
71	>72 Cardiac Arrest	Indicates if TA TAVI patient had cardiac arrest during the period from the time of 72 hours post-TA TAVI procedure to the discharge. Y indicates Yes. N indicates No.	Y/N
72	>72 Perforation	Indicates if TA TAVI patient had perforation during the period from the time of 72 hours post-TA TAVI procedure to the discharge. Y indicates Yes. N indicates No.	Y/N
73	>72 Bleed	Indicates if TA TAVI patient had bleeding episodes during the period from the time of 72 hours post-TA TAVI procedure to the discharge. Y indicates Yes. N indicates No.	Y/N
74	>72 Blood Transfusion	Indicates if TA TAVI patient required blood transfusion during the period from the time of 72 hours post-TA TAVI procedure to the discharge. Y indicates Yes. N indicates No.	Y/N
75	>72 Blood Transfusion Units	Indicates how many units of blood products that TA TAVI patient received from blood transfusion during the period from the time of 72 hours post-TA TAVI procedure to the discharge. Y indicates Yes. N indicates No.	Units
Outcome of Interest			
76	LOS	Defined as TA TAVI patient's hospital stay from the date of the TA TAVI procedure to the date of discharge, excluding death. Recorded in days.	Days

Appendix C: Transcatheter Heart Valve (THV) Program Functional Assessments


**TRANSCATHETER HEART VALVE REFERRAL
FUNCTIONAL ASSESSMENT**

Date: _____

Assessment conducted by: _____

Printed name: _____ RN Signature: _____

<input type="checkbox"/> Eligibility assessment <input type="checkbox"/> 1-Month follow-up <input type="checkbox"/> 12-Month follow-up <input type="checkbox"/> Other:	
Clinical Frailty: _____/9 as per CSHA Frailty Scale	
Instrumental Activities of Daily Living: Independent: <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 Total score: _____/8 as per Lawton-Brody Scale	Activities of Daily Living: Independent: <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 Total score: _____/6 as per Katz Index
Home Environment Independent: <input type="checkbox"/> Apartment <input type="checkbox"/> House <input type="checkbox"/> Stairs: # _____ Facility: <input type="checkbox"/> Assisted Living <input type="checkbox"/> Residential Care	Living Situation <input type="checkbox"/> Lives alone <input type="checkbox"/> Lives with spouse <input type="checkbox"/> Lives with adult child or other relative
Home Supports <input type="checkbox"/> No caregiver/home supports required <input type="checkbox"/> Part time caregiver/home supports (Either at home or care facility) <input type="checkbox"/> Full time caregiver/home supports (Either at home or care facility) <input type="checkbox"/> Patient is a caregiver to family member	Mobility Aids: <input type="checkbox"/> None <input type="checkbox"/> Cane or Walker <input type="checkbox"/> Wheelchair
Falls: Fall within the last 6 months: <input type="checkbox"/> No <input type="checkbox"/> Yes:	
5 metre walk test: Trial 1: _____ sec Trial 2: _____ sec Trial 3: _____ sec <input type="checkbox"/> Unable to complete	Hand Grip Strength Right hand: _____ kg <input type="checkbox"/> Dominant hand Left hand: _____ kg <input type="checkbox"/> Dominant hand <input type="checkbox"/> Unable to complete
Cognition – Clock test (drawing space provided on page 2) <input type="checkbox"/> Complete: Shape, numbers, hands, time <input type="checkbox"/> Unable to complete: Any of the above missing	Cognition – MMSE (assess using form PHC-EL010) _____/30 assessment diagrams on reverse

Comments: Please include Nurse Coordinator's opinion about suitability and likelihood to benefit, symptom burden, patient's motivation, and other information likely to support eligibility decision

Discharge planning needs:

Family contact:



**TRANSCATHETER HEART VALVE REFERRAL
FUNCTIONAL ASSESSMENT**

CLOCK TEST:

A large, empty rectangular box with a thin black border, intended for the patient to draw a clock face.

“Draw a clock. Put all the numbers in and set the time to 10 minutes after 11 o’clock.”

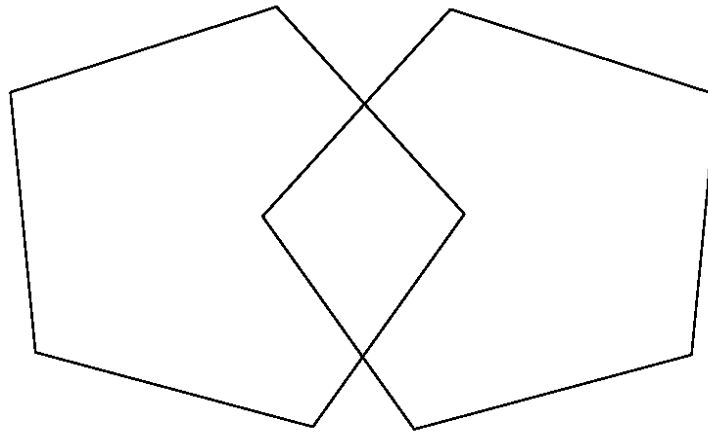
A large, empty rectangular box with a thin black border, intended for the patient to write a sentence.

WRITE A SENTENCE (Question 10 from MMSE):



**TRANSCATHETER HEART VALVE REFERRAL
FUNCTIONAL ASSESSMENT**

COPY THE DESIGN SHOWN (Question 11 from MMSE):

A large, empty rectangular box with a thin black border, intended for the patient to copy the design shown below.



**TRANSCATHETER HEART VALVE REFERRAL
FUNCTIONAL ASSESSMENT**

Edmonton Symptom Assessment System (ESAS)

© 2005 University of Alberta

Please circle the number that best describes:

No pain	0	1	2	3	4	5	6	7	8	9	10	Worst possible pain
Not tired	0	1	2	3	4	5	6	7	8	9	10	Worst possible tiredness
Not nauseated	0	1	2	3	4	5	6	7	8	9	10	Worst possible nausea
Not depressed	0	1	2	3	4	5	6	7	8	9	10	Worst possible depression
Not anxious	0	1	2	3	4	5	6	7	8	9	10	Worst possible anxiety
Not drowsy	0	1	2	3	4	5	6	7	8	9	10	Worst possible drowsiness
Best appetite	0	1	2	3	4	5	6	7	8	9	10	Worst possible appetite
Best feeling of wellbeing	0	1	2	3	4	5	6	7	8	9	10	Worst possible feeling of wellbeing
No shortness of breath	0	1	2	3	4	5	6	7	8	9	10	Worst possible shortness of breath
Other problem	0	1	2	3	4	5	6	7	8	9	10	

Patient's Name _____

Date _____ Time _____

Complete by (check one)

- ☐ Patient
☐ Caregiver
☐ Caregiver assisted

Clinical Frailty Scale*



1 Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.



2 Well – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally.



3 Managing Well – People whose **medical problems are well controlled**, but are **not regularly active** beyond routine walking.



4 Vulnerable – While **not dependent** on others for daily help, often **symptoms limit activities**. A common complaint is being "slowed up", and/or being tired during the day.



5 Mildly Frail – These people often have **more evident slowing**, and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.



6 Moderately Frail – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.



7 Severely Frail – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).



8 Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.



9. Terminally Ill - Approaching the end of life. This category applies to people with a **life expectancy <6 months**, who are **not otherwise evidently frail**.

Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common symptoms in mild dementia include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In moderate dementia, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In severe dementia, they cannot do personal care without help.

* 1. Canadian Study on Health & Aging, Revised 2008.

2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005; 173:489-495.

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