

Office of Graduate and Advanced Degree Education in Medicine

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Project Title: TELESCOPE-CS: ThE Long tErm SuCcess Of Prolonged intEnsive care patients after Cardiac Surgery

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Summary (250 words max single spaced):

Background: Due to the aging demographic, increasing burden of heart disease and advances in medicine, cardiac surgery is being offered to older and more frail patients with multiple co morbidities. These patients often require a prolonged intensive care unit length of stay (prICULOS), yet little is know about their long-term health related quality of life (HRQoL) (i.e "survivorship").

Methods: A prospective, observational pilot study was undertaken utilizing linked data from the Manitoba Cardiac Surgery (MaCS) and WRHA ICU databases. Eligible cardiac surgery patients with a prICULOS (ICU length of stay of \ge 5 days) and matched controls with an ICU length of stay of < 5 days were recruited from May until December 2015. Enrolled patients underwent in-person clinical or telephone survey HRQoL assessments at 3-6 months and 1 year time points after their procedure.

Results: From January until August 2015, 682 cardiac surgeries were performed and 73 patients were identified as having a prICULOS (10.7%). 35 prICULOS patients and 35 non-prICULOS (control) patients were recruited. At the 3-6 month follow up the prICULOS patients were more frail with higher levels of weight loss, fear of falling, and driving deficits. At the 1 year follow up prICULOS patients had persistent functional deficits and required more assistance from family/home care. Additionally, they had more regret about having surgery.

Conclusion: This study confirms the need and demonstrates the feasibility of a "survivorship" clinic for the cardiac surgery patient with a prICULOS who was found to have a poorer mid and long-term HRQoL.

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List of Abbreviations:

5-GDS (Five Item Geriatric Depression Scale) ADLs (Activities of Daily Living) CES-D (Center for Epidemiologic Studies Depression scale) CFS (Clinical Frailty Scale) EQ-VAS (EuroQoL-Visual Analogue Scale) FES (Falls Efficacy Scale) HADS (Hospital Anxiety and Depression Scale) HRQoL (Health Related Quality of Life) IADLs (Independent Activities of Daily Living) ICCS (Intensive Care Cardiac Surgery) MaCS (Manitoba Cardiac Surgery database) MoCA (Montreal Cognitive Assessment) NYHA (New York Heart Association) PASE (Physical Activity Scale for the Elderly) PCL-C (PTSD CheckList-Civilian version) PICS (Post Intensive Care Syndrome) prICULOS (prolonged Intensive Care Unit Length of Stay) PTSD (Post Traumatic Stress Disorder) SPPB (Short Physical Performance Battery) TUG (Timed get-Up and Go) WRHA (Winnipeg Regional Health Authority)

Introduction & Background

Over the last 20 years, the increasing burden of heart disease within an aging population has resulted in cardiac surgery being offered to older patients with higher levels of frailty and multiple co-morbidities.¹ Advances in surgical, anesthesia and cardiac critical care medicine have allowed for improved perioperative care of these patients however, many experience a more complicated postoperative course resulting in a prolonged intensive care unit length of stay (prICULOS). Examination of "survivorship" in prICULOS patients with other non-cardiac critical illnesses has shown long term depression, anxiety, and post-traumatic stress disorder (PTSD) symptoms as well as impaired functional disability often referred to as Post Intensive Care Syndrome (PICS).^{2,3,4,5,6} Less is known about the effect of prICULOS and the occurrence of PICS in the postoperative cardiac surgery patient.

Intuitively, a potential key difference with the cardiac prICULOS patient is that there has been an attempt to restore function prior to their initial postoperative ICU stay. For example, the patient may have had a coronary bypass graft for coronary artery stenosis or a heart valve replacement for a stenotic valve. A patient with a prICULOS following a severe respiratory illness, in contrast, generally has a loss of pulmonary function that may or may not fully recover in addition to the deconditioning that occurs whilst in the ICU. As such it may be anticipated that a cardiac patient may recover differently than a non-cardiac patient. On the contrary, recent data has suggested that the cardiac surgery patient with a prICULOS experiences similar difficulties following hospital discharge.

A recent large retrospective analysis performed in Manitoba⁷ found that rates of prICULOS patients are increasing rapidly due to the changing demographic of the cardiac surgery patient. During the period of 2000 to 2009, 7.6% of cardiac surgery patients required a prICULOS. The percentage has increased to 11.3% between 2010 and 2013, a 57% increase. Functional survival (alive and not institutionalized) decreased between 1 and 5 years in the prICULOS patient, however a lack of more granular information on the health related quality of life (HRQoL) aspect of functional survival remains.

At present, consequently, there is a gap in knowledge regarding the presence and extent of PICS and associated decrements in HRQoL in the postoperative cardiac surgery patient with a prICULOS. Specifically, there is insufficient detailed post-discharge information regarding these patients' ability to function physically and mentally at home and in the community thereby providing the rationale behind our study.

We hypothesize that patients with a prICULOS following cardiac surgery will experience worse HRQoL than the non prICULOS patients at both mid-term (3-6 months) and long term (1 year) time points following their cardiac surgery. From this pilot study we hope to obtain information that will allow us to understand the feasibility of a "survivorship" clinic for the post-operative cardiac surgery patient, identify risk factors in patients who experience prICULOS who fail to thrive in the community, and to gain insight regarding how we may ensure successful recovery following hospital discharge (i.e. provide insight into potential impediments for a prICULOS patient to return to an adequate quality of life).

<u>Methods</u>

Study Population

A new post-operative clinic was established to conduct a prospective, observational cohort analysis for prICULOS patients undergoing cardiac surgery at a tertiary care center, with a patient catchment of approximately 1.1 million people. The study was approved by the University of Manitoba Research Ethics Board (REB) and the St Boniface Hospital Research Review Committee (RRC).

Inclusion/exclusion criteria: Cardiac surgery patients typically stay in the postoperative ICU (Intensive Care Cardiac Surgery; ICCS) for a median of 2 days following surgery. Therefore prICULOS was defined as an ICU stay of greater than or equal to 5 days or 2.5 to 5 times the normal ICU stay⁷. Consecutively consenting patients > 18 years of age who experienced a prICULOS in the ICCS unit following any cardiac surgery procedure (inclusive of any procedure type or urgency status) were eligible for inclusion. Patients were identified at time of cardiac surgery ward discharge or via the Manitoba Cardiac Surgery (MaCS) and Winnipeg Regional Health Authority (WRHA) ICU database. Due to the complexity of the assessments, patients who could not be reliably assessed were excluded (e.g. due to severe developmental delay, severe hearing disabilities, and inability to understand English with no access to a translator). Potential "control" subjects were identified using the MaCS database. In order to be considered a "control" the patients had to have an ICU length of stay < 5 days. Controls were matched to prICULOS patients based on gender, age, procedure date, procedure type, and urgency, respectively. The same exclusion criteria applied to control patients.

Patient Recruitment and Data Collection

Our patient recruitment occurred from June until December 2015. Patients were contacted by phone at 3 to 6 months following their cardiac surgery to consent for participation in the study. Patients were given the option to participate in either a 45 minute to 1 hour clinical assessment at the Clinic at St. Boniface Hospital or in a 20 to 25 minute phone survey. A list of 2-3 non-prICULOS "control" subjects per prICULOS patient was also generated. The control subjects were subsequently contacted by telephone; the most closely matched were called first. Subsequent controls were not contacted provided the previous control agreed to participate in the same assessment (clinic or phone) as their prICULOS patient. If all suitable controls declined a clinical assessment they were given the phone survey as an alternative.

Enrolled study participants underwent detailed assessments in order to determine their HRQoL at mid-term (3-6 months) and long-term (1 year) time points. HRQoL is a multi-dimensional concept that includes domains related to physical, mental, emotional and social functioning.⁸ Many of the assessments and questionnaires assessed multiple realms related to HRQoL and PICS. We arranged them into 5 areas: functional status, mental health, decision regret, frailty, and patient perceived overall HRQoL. We chose to include decision regret and frailty in our assessments as both regret and frailty can contribute negatively to HRQoL^{9,10}. An area related to "End of Life" care and the shared decision making between ICU staff and patient was included as a potential future area of study.

All study participants were assessed using standardized questionnaires for both in-person clinic and telephone interview (Table 1 & 2).

Patient Assessments:

1. Functional Status

The "Activities" questionnaire was utilized to determine the level of assistance a patient required with various activities. In the "Activities" questionnaire patients were asked if they could complete an activity "without help", "with some help", "unable", or "not applicable." Patients were deemed as having a deficit if they required some help or were unable to complete the activity and were given a score of 2 or 3, respectively. The more activities a patient was deemed independent with was associated with a better functional status.

Patients were asked how much assistance they required with their ADLs (Activities of Daily Living) and IADLs (Independent Activities of Daily Living). They could be "independent", "assisted", or "dependent" with the activity. They received a score of 2 if they required assistance and 3 if they were dependent therefore a higher score was associated with a poorer functional status.

Fear of falling with various activities was assessed with the Falls Efficacy Scale (FES)^{11,12}. The scale ranges from 1 to 10 with 1 being "not concerned at all" and 10 being "very concerned" that they may have a fall while performing ten different activities. A higher total score is associated with an increased fear of falling and therefore a lower self-efficacy or confidence that may contribute to decreased function.¹¹

The New York Heart Association (NYHA) classification is known to be a valid measure of functional status. ^{13,14} It determines the degree to which the patients' shortness of breath and or chest pain interferes with their ability to complete their daily activities. A patient can fall into one of four graded classes with the higher classes having patients with worse shortness of breath or chest pain that limits their daily activities. Patients who had a higher NYHA classification where determined to have a poorer functional status.

Patients were also asked about their current living arrangements and how they managed their daily activities. In particular, they were asked if they lived in their own home or a retirement residence and if they were completely independent or required assistance from family or home care to manage their daily activities. Patients who lived in their own home, condo or apartment and were completely independent were assumed to be functioning well. Post hospital discharge medical complications (eg. stroke, repeat cardiac surgery, dialysis, repeat hospital admissions) and overall satisfaction with their surgical outcome was determined with direct "yes" or "no" questions. Patients who answered "yes" to more questions and or had more readmissions to the hospital were assumed to lower functioning.

The Physical Activity Scale for the Elderly (PASE) has been found to be a valid and reliable measure of physical activity^{15,16}. Patients would recount the amount of physical activity completed in the last week and then a total score was calculated. The higher the score the more active the patient was deemed.

Patients who came in for a clinical assessment had their balance and mobility assessed with the Timed Get-up and Go (TUG). Patients were deemed "freely mobile", "mostly independent", "variable mobility", or "impaired mobility" depending on the average time it took them to complete the test on two consecutive turns. Time taken to complete the test is strongly correlated to level of functional mobility and has been found to be a sensitive and specific measure to identify individuals in the community who are at risk for falls.^{17,18}

2. Mental Health

The Hospital Anxiety and Depression Scale (HADS)¹⁹ was used to screen for depression and or anxiety. Patients could score in the "normal" (0-7), "borderline" (8-10), or "depressed" and/or "anxious" (11-21) range. The HADS has been found to be both a sensitive and specific screening tool with a cut off point of 8²⁰ therefore if a patient scored above 8 they were considered to be at risk for having depression and/or anxiety.

PTSD was assessed using the PTSD CheckList-Civilian Version (PCL-C)²¹. Patients were asked if they had any of the 17 key symptoms of PTSD. If they did not have a particular symptom they would receive 1 point. If they had experienced the symptom they were then asked to rate the severity. The higher the severity the higher the points received and therefore a higher total severity score and risk for having PTSD.

3. Decision Regret

A Decision Regret Scale was administered in order to see if the patient had distress or remorse about the decision to undergo cardiac surgery²². The patients were scored on their response to 5 statements and their level of agreement or disagreement with each statement. Patients could also answer neutrally by stating they did not agree or disagree. A total score was given ranging from 5 (no regret) to 25 (high regret).

4. Frailty

In order to assess frailty the following three assessments were used: the Modified Fried Criteria,²³the Short Physical Performance Battery (SPPB),²⁴ and the Clinical Frailty Scale (CFS).²⁵ Under the Modified Fried definition, patients were deemed "frail" if they met \geq 3 of the following 7 criteria: slowness (as determined by the 5-m gait speed measurement), weakness (handgrip strength measurement), weight loss (self-reported weight loss), exhaustion (the modified 2-item CES-D Scale), depression (the 5-GDS), low physical activity (the Paffenbarger Physical Activity Index) and cognitive impairment (the MoCA). The 5-GDS, self reported weight loss, modified 2-item CES-D, and Paffenbarger Physical Activity Index questionnaires were also included in the phone survey. Patients were deemed "frail" under the SPPB definition if their composite score was \leq 9 after the following 3 assessments were scored (each scored from 0-4): the 5-m gait speed measurement, the balance tests, and the repeated chair stand test. Finally, under the Clinical Frailty Scale definition, patients were deemed "frail" if their given score, based upon a clinical judgment regarding their level of activity, comorbidities, and disabilities, was \geq 4.

5. HRQoL

In order to get a sense of the patients perceived HRQoL the EuroQoL-Visual Analogue Scale was utilized. The EQ-VAS is a part of the EQ-5D questionnaire, which has been found to be an effective tool to measure HRQoL.^{26,27} The EQ-VAS scale ranges from 0 (worst imaginable health state) to 100 (best imaginable health state). Patients record their self-rated health. An EQ-VAS \leq 60 was associated with a poor HRQoL²⁸²⁹ Patients were also asked the 5D aspect of the questionnaire in order to determine if they perceived any problems with mobility, self-care and performing their usual activities as well as if they had any pain or discomfort and anxiety or depression.

6. Shared Decision Making and End of Life Care

A three item measure called CollaboRATE³⁰ was used to assess the shared decision making process in the cardiac ICU. Patients were asked 3 questions about how much effort the staff made to include them in their health care decisions. It was rated from 1 to 5 with 1 being no effort and 5 being lots of effort. Three additional questions with a "yes" or "no" response were asked in regards to being given the option of receiving comfort care³¹, if they had a living will, etc.,³¹ and if they had enough supports upon discharge³².

Statistical Analysis

All categorical variables were compared using a Chi-Square or Fisher's Exact Test; continuous variables were compared using a Mann-Whitney Test where appropriate. Given this was a prospective pilot study, a post-hoc power analysis was also performed to inform the design of future studies evaluating outcomes in prICULOS patients. All analyses were performed using SAS version 9.3.

Student's Role

Timelines of work:

March until May 2015: Proposal refinement and Ethics Submission June until December 2015: Patient recruitment, scheduling and performance of 3-6 month follow up in-person clinic (Jun – Aug) and telephone (Jun- Dec) assessments. January until July 2016: Follow-up scheduling and 1 year follow up telephone (Jan-July) and inperson clinic (May-July only) assessments, data analysis and interpretation, generation of thesis.

<u>Results</u>

Patient Cohort

During the period of January 2015 until August 2015, a total of 682 cardiac surgeries were performed at St. Boniface Hospital and 73 patients were identified as having a prICULOS (10.7%). The 73 patients were reviewed using the MaCS database and EPR (Electronic Patient Record) and 9 patients were found to have died in hospital for a 12% in-hospital mortality rate. Of the remaining surviving eligible patients, 17 patients declined, 5 could not be contacted, and 3 were excluded (Figure 1). Of the 3 that were excluded, one had an inability to participate secondary to limited English with no access to a translator and severe hearing disability, the second had developmental delay (Trisomy 10), and the third was still in hospital after 6 months due to other medical complications. The remaining 39 patients were matched to controls and 4 patients were excluded due to an incomplete match. A total of 35 prICULOS and 35 nonprICULOS patients agreed to participate in the study. At the 3-6 month follow up one prICULOS patient did not participate as she was already at her 1 year follow up when she was recruited. A higher proportion of phone surveys were completed in the non-prICULOS group, 4 patients could not come in for clinical assessments therefore phone surveys were done instead. At the 1 year follow up 6 prICULOS patients did not participate, 5 declined and 1 was out of the country with no means of making contact. Two patients who did a clinical assessment at the 3-6 month follow up could not make it in at the 1 year follow up to complete a clinical assessment but did agree to a phone survey. At the 1 year follow up in the non-prICULOS group, 8 did not participate, 7 declined and 1 could not be contacted. The control that only completed the 1 year follow up did a phone survey instead of a clinical assessment, contrary to her prICULOS match.

Enrolled patients' demographic and preoperative characteristics are shown in Table 3. The prICULOS patients had somewhat similar comorbidities as compared to their matched non-prICULOS patients. The intraoperative and postoperative characteristics are shown in Table 4. The prICULOS patients had more surgical and post-operative complications and remained in hospital longer than non-prICULOS patients.

Patient Assessments

At the 3-6 month follow-up prICULOS patients had greater self-reported weight loss, a higher Falls Efficacy Score, and more deficits with the ability to drive (Table 5). Additionally, a greater percentage of prICULOS patients were deemed to be frail using the Modified Fried Score, 44% in the non- prICULOS group and 62% in the prICULOS group. At the 1 year follow up prICULOS patients were found to have deficits with their ability to complete ADLs and IADLs and walking distance. In addition they required more assistance from their family or home care (Table 6). Reported weight loss tended to decrease in both groups at 1 year and was no longer statistically significant between groups (Figure 2). Initially, both groups have no statistical difference between deficits with ADLs and IADLs but then tended to diverge at the1 year follow up (Figure 3 & 4). Finally, we found prICULOS patients had more regret at both the 3-6 month follow up and 1 year follow up with no change between time points (Figure 5).

Although not statistically significant between groups we found that the average EQ-VAS score in the prICULOS group at the long-term follow up was 60, the cut off point for a low HRQoL. The non-prICULOS group had an average score of 70 that remained stable from the short term until the long term time points whereas the prICULOS group had an average score of 70 that dropped to 60. According to the literature^{33,34}, a 10 point change in the EQ-VAS suggests a clinical meaningful difference.

Discussion

The goal of "ThE Long tErm SuCcess Of Prolonged intEnsive care patients after Cardiac Surgery" (TELESCOPE-CS) was to determine if prICULOS patients experienced lower levels of HRQoL. Our pilot study examining mid and long-term functional outcomes in patients with a prICULOS following cardiac surgery has demonstrated that a "survivorship" clinic is feasible and there are risk factors unique to prICULOS patients that predispose them for failure to thrive in the community. Additionally, after reviewing the literature, we found that our study is one of the first studies to comprehensively examine granular HRQoL in the prICULOS cardiac surgery patient.

Of the 35 prICULOS patients, 29 patients completed the study to its entirety, a completion rate of 83%. This demonstrates that while the amount of testing is comprehensive, the questionnaires and assessments, in general, were well tolerated by the patients, and were easy to administer. Furthermore, through this analysis and interactions with patients redundant assessments can be identified and removed in order to reduce completion time.

We have discovered, not only do prICULOS patients have more intraoperative and postoperative complications that put them at risk for death, but they also have long term functional deficits placing them at risk for poor functional survival and increased reliance on family for assistance. In order for patients and families to make informed decisions and possibly minimize regret⁹ they need to know about both the mortality associated with cardiac surgery and risk of a deterioration in their HRQoL.⁷ This would not necessarily change their decision to undergo surgery but provide them with expectations to allow preparation for what is to come.

This potentially could assist in preventing functional complications and physical and mental hardship in the months to years following their surgery.

Previous studies^{35,36,37} have examined the prICULOS cardiac surgery population with a focus on outcomes related to mortality as opposed to HRQoL. We were able to find three studies^{38,39,40} that included an analysis of HRQoL. All three studies were larger in size, however they did not include several of the assessments included in this analysis nor did they include an in-person clinical component or a control group. One of the two more recent studies done was in Germany³⁸ with a study group of 119 patients with a mean age of 72 and ICU length of stay of 19 days. The Barthel Index to assess mobility and the SF-12 questionnaire to assess mental and physical health was completed over the phone at a 1 year follow up. They concluded that prICULOS patients had a higher in hospital and follow-up mortality but their psychological and physical recovery was similar to the general population. The other more recent study was done in Sweden³⁹ with a study group of 141 patients with a mean age of 68 years old and a mean ICU length of stay of 16 days. Patients were followed up at 1,3 and 5 years post cardiac surgery. The Karnofsky performance score was used to assess functional status and was completed by phone interview and the SF-36 was used to assess various aspects of HRQoL and was completed by mail. They found that two thirds of patients had close to normal functional capacity and a lower physical and mental health when compared to the general population. It is difficult to compare these studies to our study as they used different questionnaires, had much longer ICU length of stays, and a much larger population size. The lack of literature and various results further validates the need for further research in this area.

Limitations

The intention of this study was primarily to understand the feasibility of an ICU survivorship clinic for cardiac surgery patients in Manitoba. While the sample size was too small to demonstrate significant statistical differences between groups, we feel that the study still provides valuable pilot data for a future study. In addition, as with most studies of this nature, we had selection bias due to those who were willing to attend. We attempted to counter this selection bias with telephone surveys, however many still refused to participate. Our efforts of trying to understand patient issues using the CollaboRATE tool and "End of Life" questions provided limited information. Patients did not remember and may have been focusing on how the staff treated them rather than the information sharing aspect. As such in the future, we plan to examine this in more detail with a patient focus group and a focus group involving their community based primary care practitioner. Finally, we had a lack of baseline functional and mental health data as this is difficult to obtain for patients requiring emergent procedures. In the future this could possibly be countered by asking the patient to retrospectively comment on their mental health and general function prior to their surgery as done previously,³⁸ or part of a more comprehensive, prospective study design could formally assess this pre-operatively. A post-hoc power analysis was done to determine the sample size needed for a future study. In order to detect similar effect differences in the EQ-VAS as observed in this data between the prICULOS and non-prICULOS cohort, a future study would require a sample size of 123 individuals in each group with a two-tailed alpha of 5% and a power of 80%.

Conclusion and future aims

In a recent keynote address by Paul Wischmeyer (<u>@Paul Wischmeyer</u>) at the American Delirium Society (Nashville, June 2, 2016), it is important of the critical care community to consider "are we creating survivors or victims following critical illness?" This, by extension, should be equally important to healthcare practitioners and caregivers involved in the care of the older adult

undergoing cardiac surgery. Patients who experienced a prICULOS following their cardiac surgery procedure suffered from worse functional long-term deficits than non-prICULOS patients and importantly had more regret about their decision to undergo cardiac surgery all of which can contribute negatively to their HRQoL. In the future, we will involve patients, their caregivers and community based practitioners in a process to develop a larger study to examine methodologies to improve transition of care following hospital discharge to ensure that patients not just survive but thrive following hospital discharge.

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Table 1: Patient Questionnaires for Phone and Clinic

Questionnaires	Outcome Measure
Activities	Functional status
ADLs & IADLs	Functional Status
Falls Efficacy Scale	Fear of Falling
Post-discharge living situation (NYHA Classification, Current Living Arrangements and medical problems experienced post discharge as well as satisfaction with heart surgery outcome) (only assessed at 1 year follow up)	Functional status and level of assistance required
PASE Score	Level of Physical Activity
Hospital Anxiety and Depression Score (HADS)	Anxiety and Depression Screen
PTSD Check List (PCL-C)	Post-Traumatic Stress Disorder Screen
Decision Regret Scale	Degree of regret about having cardiac surgery
Self-reported Weight Loss and Nutrition	Part of the Modified Fried definition in order to assess frailty and to detect weight loss of greater than 4.5 kg in the last 12 months.
The Modified 2-item Center for	Part of the Modified Fried definition in order to
Epidemiologic Studies Depression (CES-D) Scale	assess frailty and to detect exhaustion.
Five Item Geriatric Depression Scale (5- GDS)	Part of the Modified Fried definition in order to assess frailty and to screen for depression.
Paffenbarger Physical Activity Index	Part of the Modified Fried definition in order to assess frailty and detect low physical activity.
EQ-VAS (EQ-5D)	Overall HRQoL
CollaboRATE and End of Life care	Shared decision making in the ICU

Table 2: Patient Assessments for Clinic Only

Assessments	Outcome Measure
Timed Get-up and Go	Functional mobility and fall risk
5-m gait speed measurement	Part of the Modified Fried/ Short Physical
	Performance Battery (SPPB) definition in order
	to assess frailty
Handgrip strength measurement	Part of the Modified Fried definition in order to
	assess frailty
Montreal Cognitive Assessment (MoCA)	Part of the Modified Fried definition in order to
	assess frailty
Side-by-side, semi-tandem, and tandem	Part of the Short Physical Performance Battery
stand balance tests	(SPPB) definition in order to assess frailty
Repeated chair stand test	Part of the Short Physical Performance Battery
	(SPPB) definition in order to assess frailty
Clinical Frailty Scale	Measure of frailty

Figure 1: Patient Recruitment Diagram

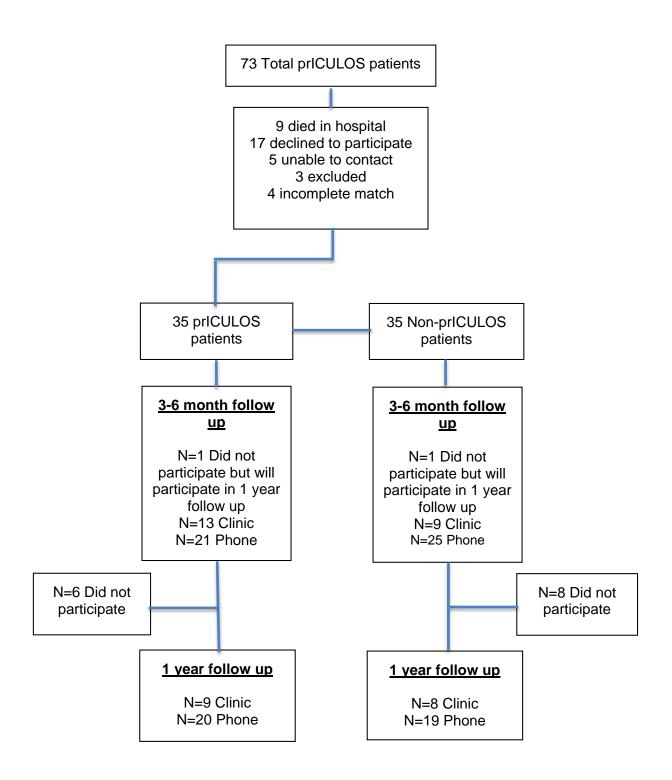


Table 3: Preoperative Characteristics of Non-PrICULOS & PrICULOS Patients

Variable	Non-PrICULOS Patients (N=35)	PrICULOS Patients (N=35)	P-Value
Demographics			
Age	67 (61 - 73)	66 (59 - 73)	0.76
Sex (Female)	13 (37%)	13 (37%)	1.00
BMI (kg/m2)	30.4 (25.6 - 33.7)	27.3 (26.2 - 30.9)	0.22
Comorbidities			
Diabetes	13 (37%)	11 (31%)	0.61
Hypertension	21 (60%)	28 (80%)	0.07
Dyslipidemia	20 (57%)	17 (49%)	0.47
Smoking History	15 (43%)	17 (49%)	0.63
Current Smoker	4 (11%)	6 (17%)	0.49
Previous MI	8 (23%)	16 (46%)	0.04
Congestive Heart Failure	4 (11%)	8 (23%)	0.20
Stroke	3 (9%)	3 (9%)	1.00
PVD	3 (9%)	3 (9%)	1.00
COPD	3 (9%)	0 (0%)	0.24
Preoperative Afib	2 (6%)	9 (26%)	0.02
Cardiogenic Shock	0 (0%)	4 (11%)	0.11
Preoperative Hemoglobin	130 (121 - 141)	130 (120 - 141)	0.70
Preoperative Creatinine	78 (69 - 95)	89 (70 - 115)	0.31
Preoperative Medications			
Aspirin	21 (60%)	12 (34%)	0.03
Ace Inhibitors	7 (20%)	10 (29%)	0.40
Beta Blockers	17 (49%)	13 (37%)	0.33
Ca Antagonist	12 (34%)	9 (26%)	0.43
Diuretics	4 (11%)	8 (23%)	0.20
Plavix	4 (11%)	6 (17%)	0.49
Operative Status			
Ejection Fraction (%)	60 (60 - 60)	50 (33 - 60)	<0.01
EuroSCORE II (%)	1.5 (1.0 - 2.3)	3.4 (2.2 - 5.3)	<0.01
Procedure Urgency			
Elective	18 (51%)	10 (29%)	
Urgent	12 (34%)	10 (29%)	0.02
Emergent	5 (14%)	15 (43%)	
Previous Procedures			
Previous CABG	0 (0%)	0 (0%)	1.00
Previous Valve	0 (0%)	3 (9%)	0.24
Previous PCI	2 (6%)	5 (14%)	0.43

*Continuous variables expressed as median (interquartile range) compared using Mann-Whitney Test; Categorical variables expressed as N(%) compared using Chi-Square or Fisher's Exact Test.

Table 4: Intraoperative and Postoperative Characteristics of Non-PrICULOS & PrICULOS Patients

Variable	Non-PrICULOS Patients	PrICULOS Patients (N=35)	P-Value	
Tunable	(N=35)	111002001 utients (11-55)	· · · ·	
Operative Characteristics				
Procedure				
Isolated CABG	19 (54%)	11 (210/)		
Isolated Valve		11 (31%)		
CABG + Valve	7 (20%)	4 (11%)	0.07	
Other	4 (11%)	8 (23%)		
Clamp Time (Minutes)	5 (14%)	12 (34%)	0.30	
	82 (65 - 107)	100 (64 - 131)	<0.01	
Pump Time (Minutes)	110 (89 - 141)	149 (115 - 190)	<0.01	
Blood Transfusions				
Red Blood Cells (Intraop)	12 (34%)	23 (66%)	< 0.01	
Fresh Frozen Plasma (Intraop)	4 (11%)	19 (54%)	< 0.01	
Platelets (Intraop)	5 (14%)	21 (60%)	<0.01	
Red Blood Cells (Postop)	15 (43%)	28 (80%)	<0.01	
Fresh Frozen Plasma (Postop)	2 (6%)	14 (40%)	< 0.01	
Platelets (Postop)	3 (9%)	11 (31%)	0.02	
	- (/	,		
Complications				
Ventilation Time (Hours)	4 (2 - 6)	31 (12 - 71)	< 0.01	
New Afib	10 (30%)	11 (42%)	0.34	
Cardiac Arrest	0 (0%)	2 (6%)	0.49	
Chest Tube Output in first 24h (ml)	663 (420 - 968)	935 (585 - 1407)	0.04	
Return to OR for Bleeding	1 (3%)	5 (14%)	0.20	
Return to OR - Any Reason	2 (6%)	9 (26%)	0.02	
Postop MI	0 (0%)	0 (0%)	1.00	
Any Infection	5 (14%)	22 (65%)	< 0.01	
Pneumonia	2 (6%)	6 (17%)	0.26	
Delirium (Any CAM+)	5 (14%)	20 (57%)	< 0.01	
Stroke	1 (3%)	2 (6%)	1.00	
Highest Postoperative Creatinine	85 (69 - 118)	151 (108 - 223)	<0.01	
Acute Kidney Injury (Rise in CR by 1.5x)	2 (6%)	14 (54%)	< 0.01	
New Dialysis	0 (0%)	4 (11%)	0.11	
ICU Length of Stay (Hours)	28 (22 - 51)	172 (140 - 264)	< 0.01	
Hospital Length of Stay (Days)	9 (6 - 15)	23 (16 - 47)	<0.01	
Discharge & Readmission				
Discharge Location				
Home	33 (94%)	28 (82%)		
Transferred to Hospital	2 (6%)	4 (12%)	0.22	
Rehab / Restorative Care	0 (0%)	2 (6%)		
Readmitted to Hospital in 30 Days	1 (3%)	3 (9%)	0.61	

 $\label{eq:continuous} \ensuremath{^{\ast}}\xspace{Continuous} \ensuremath{^{\ast}}\xspace$

Categorical variables expressed as N(%) compared using Chi-Square or Fisher's Exact Test.

Table 5: Statistically Significant 3-6 month Follow-up Results

Variable	Non-prICULOS	prICULOS	P-Value
Reported Weight Loss	29%	59%	0.01
Falls Efficacy Score	11	13	0.04
Driving deficit	12%	32%	0.04

Table 6: Statistically Significant 1 year Follow-up Results

Variable	Non-prICULOS	prICULOS	P-Value
Deficit with ability to walk 1.5 km	15%	41%	0.04
Any ADL deficit	4%	24%	0.05
Cooking deficit	4%	24%	0.05
Cleaning deficit	4%	28%	0.03
Shopping deficit	4%	31%	0.01
Driving deficit	7%	34%	0.02
Any IADL deficit	19%	45%	0.04
Living at home and independently	92%	65%	
Living at home with help from family	0%	25%	<0.01
Living at home with hired help	7%	11%	

