A STUDY FOR DEFINING THE TYPES AND DETERMINING THE RISK FACTORS FOR READMISSIONS FOLLOWING REVASCULARIZATION FOR CRITICAL LIMB ISCHEMIA (CLI)

By

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Dissertation submitted to the National Board of Examinations, New Delhi.

In partial fulfilment of the requirements for the degree of

DNB Super-specialty

In

PERIPHERAL VASCULAR SURGERY

Under the guidance of

DR. SUMANTH RAJ K B

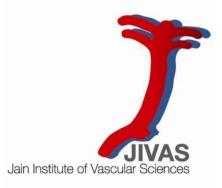
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December 2021

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DECLARATION CUM UNDERATKING FOR FRESH THESIS

I Dr. Surya Kiran I hereby declare that this thesis entitled **"A STUDY FOR DEFINING THE TYPES AND DETERMINING THE RISK FACTORS FOR READMISSIONS FOLLOWING REVASCULARIZATION FOR CRITICAL LIMB ISCHEMIA** (CLI)" is 'bonafide' in nature and was carried out by me under the guidance and supervision of my guide Dr Sumanth Raj K B. The interpretations put forth are based on my reading and understanding of the original texts and they are not published anywhere in the form of books, monographs or articles. The other books, articles and websites, which I have made use of are acknowledged at the respective place in the text. For the present thesis, which I am submitting to the National Board of Examinations, New Delhi, no degree or diploma or distinction has been conferred on me before elsewhere.

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I hereby declare that this dissertation titled "A STUDY FOR DEFINING THE TYPES AND DETERMINING THE RISK FOR FACTORS READMISSIONS **FOLLOWING** REVASCULARIZATION FOR **CRITICAL LIMB ISCHEMIA** (CLI)" is a bonafide and genuine research work carried out by me under the guidance and supervision of Dr. Sumanth Raj K B, Vascular surgeon, Jain Institute of Vascular Sciences (JIVAS), Bhagwan Mahaveer Jain Hospital, Bengaluru, in partial fulfilment of the requirement of National Board of Examinations regulation for the award of the Degree of DNB in Peripheral Vascular Surgery.

This has not formed the basis for the award of any degree or diploma me before and I have not submitted this to any other university or board previously.

Date: 30-12-2021

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Place: Bengaluru

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> Dr. (Wg Cdr) M.D. MARKER Medical Director, Bhagwan Mahaveer Jain Hospital

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During this journey of the compilation of my thesis, I have been helped, supported and encouraged by many, and I am feeling short of words to express my gratitude towards them.

I consider myself lucky to have **Dr. Sumanth Raj K B,** Consultant Vascular Surgeon, Jain Institute of Vascular Sciences (JIVAS), as my supervisor and mentor. He has been a great teacher and a splendid personality. His clinical acumen, surgical skill and wisdom are well known and unparalleled. I will always cherish the time I spent under his guidance. He is, and will always remain as a source of inspiration for me.

I am extremely thankful to my co-supervisors **Dr. K,R, Suresh,** Director, JIVAS and **Dr. M.D. Marker**, Medical Director, Bhagwan Mahaveer Jain Hospital for their helping attitude and invaluable guidance that has helped me bring this work to its logical conclusion.

I express my sincere thanks to Dr. Vivekanand, Dr. Vishnu Motukuru, Dr. Indushekar, Dr. Mamatha S H, and Dr. Girija, Consultants, JIVAS for their valuable help and the encouragement and support they provided me, during my work.

I am very grateful to my family for their encouragement, constant love and affection towards me. I express my gratitude for the generous help and cooperation provided to me by my seniors Dr. Vishal., Dr. Siva Krishna, Dr Nishan and my colleagues Dr. Ahsan, Dr. Pavan and Dr. Pranjal in completing my work. I will like to express my gratitude to Dr. Sridhar for important contribution in writing materials and statistics during my work. I would like to express my gratitude to all our department staff Mrs. Deepa, Mr Ashok, Mrs. Hema, Mrs. Sophia, Mrs. Prema, Mrs. Sumati , Mr. Sunil, Mr. Uday and Mr. Albert for their help in maintaining patient records and for data collection.

I am thankful to all my dear friends for the constant, unconditional support and inspiration which I received from them. All my friends were very co-operative and always helpful to me.

I sincerely thank all the patients who were part of the study for their cooperation

Place: Bengaluru

December 2021

LIST OF ABBREVIATIONS

ALI	ACUTE LIMB ISCHEMIA
AKI	ACUTE KIDNEY INJURY
BMI	BODY MASS INDEX
CLI	CRITICAL LIMB ISCHEMIA
CKD	CHRONIC KIDNEY DISEASE
CVS	CARDIOVASCULAR SYSTEM
CNS	CENTRAL NERVOUS SYSTEM
CVA	CEREBROVASCULAR ACCIDENTS
CHS	CONGESTIVE HEART FAILURE
COPD	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
ER	EMERGENCY ROOM
FND	FOCAL NEUROLOGICAL DEFECITS
MALE	MAJOR ADVERSE LIMB EVENTS
MACE	MAJOR ADVERSE CARDIAC EVENTS
OPD	OUT PATIENT DEPARTMENT
OR	ODDS RATIO
PAD	PHERIPHERAL ARTERIAL DISEASE
LOS	LENGTH OF STAY
SSI	SURGICAL SITE INFECTION

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ABSTRACT

Background- Majority of patients with Critical limb ischemia (CLI) have multiple comorbidities, which makes them prone to post-operative complications and delayed recovery period. This in turn results in increased hospital visits and readmissions. The relative contributions of patient comorbidities, operative factors and postoperative complications are unknown and it is not clear which factors are the main drivers of readmissions. Our aim was to analyze the reasons for readmissions in patients with CLI following successful revascularization procedure and to report potential areas for focused efforts aimed at readmission reduction.

Aims and Objectives-The purpose of the study was to study multiple potential drivers of readmission in patients undergoing revascularization for CLI. Primary objective was overall readmission to our hospital within 6 months of index procedure. The secondary objectives were major adverse limb events (MALE), major adverse cardiac events (MACE) and mortality.

Materials and Methods- This is a Non-randomised, prospective, single centre, observational study conducted at Jain Institute of Vascular Science, Bangalore. From November 2019 to December 2020, all patients who underwent successful revascularization for CLI and were discharged from the vascular surgery service and subsequently readmitted as an inpatient within 6 months of index procedure were included. We divided readmissions into groups based on their relation to the index surgery and whether or not they are planned. Readmitted patients were followed up at 6 months; MALE, MACE and mortality were noted. Data analysis included calculation of the percentages -total overall readmitted patients stratified by characteristics of the patients' demographics, index hospitalization details, and readmission specifics. A multivariate analysis of readmission LOS was conducted based on patient demographics, pre-existing comorbidities, index LOS, index procedure type, and reason for readmission. A multivariate analysis comparing the reasons for early (0-30 days) readmission as compared to late (30- 180days) readmission was also conducted for all readmissions.

Results- During the study period i.e., from November 2019 to December 2020; Out of 1272 admissions to our vascular department, total readmissions were 260 (20.4%), of these 108(41.5%) were revascularized CLI readmissions; Common comorbidities were diabetes (88.1%), hypertension (59.4%) and cardiac (34.7%); The mean age of those readmitted was 65.6 years; majority belonged to CLI category 4 (58.4%) and were overweight (31.7%); Index vascular operations included endovascular lower extremity procedures (69.3%), open lower extremity procedures (8.9%) and hybrid procedures (21.8%); Mean index length of stay (LOS) was 5.9 days (±2.5 days); Patients got readmitted to our institution, on average, within 58.9 days (±50.9 days); Reasons for readmissions were for surgical causes (55.4%), medical causes (17.8%), and planned procedures (26.7%). Reasons for medical readmissions most commonly included anemia (28%). Common surgical causes for readmission were for wound care (69%), graft failure (19.6%) and surgical site infection (7.1%); Of the planned readmissions, most were for skin grafting (48.1%) and wound care (29.6%); Readmissions mean LOS was 5.2 days (±3.6 days). Majority of the readmission procedures were for wound care (83.2%). We had mortality rate of 7.9% among readmissions and MALE and MACE was seen among 7.9% and 9.9% of the patients respectively.

Conclusion- Critical limb ischemia is a challenging disease associated with high readmission during the first year after revascularization. Expected patient risk factors, such as diabetes, obesity, renal insufficiency, and cigarette smoking, were less important in predicting readmission. Our findings suggest that most of the readmissions are unplanned and index procedure related. The most common reason for unplanned surgical readmissions was surgical, for wound care. So, careful operative planning and expeditious operations with aggressive wound management may be the most effective approaches to reducing readmissions. Better understanding of readmissions following vascular surgery procedures could help lower readmission rates and adjust policy benchmarks for targeted readmission rates.

Key words – critical limb ischemia (CLI), readmissions, planned and unplanned readmissions

INTRODUCTION

Peripheral arterial disease (PAD) represents a significant form of systemic atherosclerotic disease and patients with PAD usually have multiple, serious medical conditions that may be responsible for perioperative complications.¹ PAD is one of the most common conditions treated by vascular surgeons. The anatomic level for PAD can be divided into two groups: aortoiliac occlusive disease and infrainguinal occlusive disease. Aortoiliac occlusive disease is different from infrainguinal disease in multiple aspects: it represents an aggressive form of atherosclerosis; patients often present with severe, disabling claudication or critical limb ischemia.^{2,3} Critical limb ischemia (CLI) is the most severe manifestation of peripheral artery disease affecting the lower extremities leading to major amputation in the absence of revascularization. The optimal modality for revascularization in the treatment of CLI remains controversial and is the focus of on-going randomized controlled trials.^{4,5}

Symptomatic lower extremity PAD arises from inadequate blood flow, causing oxygen supply and demand mismatch. Critical limb ischemia (CLI) is the most severe form of lower extremity PAD. It is defined as lower extremity pain that occurs at rest or in the presence of ulcers or gangrene, secondary to severe compromise of blood flow. Critical limb ischemia generally refers to Rutherford categories 4, 5, and 6 (ischemic rest pain, minor tissue loss, and major tissue loss, respectively).⁶ The National Health and Nutrition Examination Survey estimated the prevalence of PAD in adults aged 40 years or older at 4.3%; this represents approximately 5 million individuals in the United States. PAD was defined as an ankle–brachial index (ABI) of <0.90 in either leg. ⁷

Historically, the incidence of CLI was reported to be much lower: only 2% of patients with symptomatic PAD would progress to CLI. This would account for about 500 to 1000 incident cases per million populations each year in the United States. Two recent data, however, suggest that CLI may be more common than previously realized. The Reduction of Atherothrombosis for Continued Health (REACH) registry showed that among patients with symptomatic PAD, 15% will eventually have a lower limb amputation.⁸

Patients with PAD are at increased risk of myocardial infarction (MI), stroke, and cardiovascular death. Among elderly populations with PAD, the incidence of coronary artery disease and stroke may be as high as 68% and 42%, respectively.⁹ In addition; the relative risk (RR) of cardiovascular death in patients with PAD is increased almost 6-fold. ¹⁰ The prognosis of patients with CLI, however, is even graver. After the onset of symptoms, 25% of patients with CLI will be dead and 25% will have a major amputation in one year follow up.⁷

Readmission is a common occurrence that results in increased costs both to the patients and to the healthcare system as a whole. Under the assumption that at least a fraction of these readmissions are related to breakdown in care and poor transition from the inpatient to the outpatient setting, readmissions have become a marker of quality of care, and reducing readmissions has become a focus of healthcare reform.⁷

Up to 21.3% of patients undergoing lower extremity revascularization (LER) for CLI suffer from an unplanned readmission and 8.5% undergo repeat revascularization within a month.¹¹ However, the modality of LER, open or endovascular, did not seem to impact the readmission rate.¹²

Furthermore, vascular readmissions reportedly cost more than any other readmission studied, including coronary artery bypass graft surgery.¹³ A recent review summarizing the existing data on risk factors for readmission in vascular surgery patients identified a number of categories that could be addressed to reduce preventable readmissions, including preoperative, operative, postoperative, postdischarge, and transitional care factors.¹⁴ The relative importance of the many variables that have been found to be risk factors for readmission in vascular patients is unclear. Preoperative elements such as patient comorbidities and socioeconomic factors, intraoperative variables such as operation type and length, and postoperative factors such as discharge destination and occurrence of complication may all play a role in postoperative readmissions.¹⁵ However; approaches to reducing readmissions after vascular surgery are not well studied, making it difficult to devise reasonable interventions targeted toward readmission reduction.¹⁶

Hospital readmission rates have been increasingly used as a quality-of-care metric, and reduction in readmissions represents a target for decreasing hospital costs.¹⁷ Expected expansion of legislation to include vascular surgical readmission makes it highly relevant to better understand which patients are at high risk for readmission and allow for the reduction in readmission rates by developing preventative techniques, specific patient care strategies, and more accurate metrics to improve quality and reduce costs.¹⁸

Vascular surgery patients are well known as a group of patients with multiple comorbidities. This not only puts them at higher risk for postoperative complications but also results in more frequent visits to healthcare professionals, both of which would result in increased readmission rates.¹⁹ As such, when analysing readmission statistics, it is important to clearly differentiate both between planned and unplanned readmissions as well as readmissions that were directly related to the principal procedure versus those unrelated.²⁰

REVIEW OF LITERATURE

Postoperative readmissions are frequent in vascular surgery patients, but the reasons are still uncertain. Lower extremity revascularization for critical limb ischemia (CLI) remains a subject of clinical equipoise. Readmissions and repeat lower extremity revascularization increase the cost of care and decrease the value of initial treatment. Optimization of select chronic conditions, closer follow-up of patients in poor health and those who required return to the operating room and early detection of surgical site infections may improve readmission rates.²¹

In a study conducted by Caitlin W Hicks et al in Baltimore to study the predictors of postdischarge infections and unplanned readmissions especially operative variables in vascular surgery, it was reported that thirty-day readmission occurred in 10%, of which 91% were unplanned. Of the unplanned readmissions, 61% were related to the index vascular surgery procedure. Infectious complications were the most common reason for a surgery-related readmission (39%), with surgical site infection being the most common type of infection related to unplanned readmission. Multivariable analysis showed the top five preoperative risk factors for postdischarge infections were the presence of a preoperative open wound, inpatient operation, obesity, work relative value unit, and insulin-dependent diabetes. When operative and postoperative factors were included in the model, total operative time was the strongest predictor of postdischarge infectious complications (OR, 2), obesity (OR, 1.8), and discharge to rehabilitation facility (OR, 1.7; P < .001 for all). Insulin-dependent diabetes, cigarette smoking, dialysis dependence, and female gender were also predictive, albeit with smaller effects.¹⁶

Natalia Glebova et al studied about drivers of readmissions in vascular surgery patients; it was found that the unplanned readmission rate was 9.3%. The preoperative model based on patient demographics and comorbidities predicted readmission risk with a low C index of 0.67; the top five predictors of readmission were American Society of Anaesthesiologists class, preoperative open wound, inpatient operation, dialysis dependence, and diabetes mellitus. The postoperative model using operative factors and postoperative complications predicted readmission risk better (C index, 0.78); postoperative complications were the most significant predictor of readmission, overpowering patient comorbidities. Importantly, postoperative complications identified before discharge from the hospital were not a strong predictor of readmission as the model using pre-discharge postoperative complications had a similar C index to our preoperative model (0.68). The top five predictors of readmission were post-discharge deep space infection, superficial surgical site infection, pneumonia, myocardial infection and sepsis.²²

A study was conducted by Georges Tahhan et al in 2016; they identified 649 vascular surgery discharges with 135 (21%) readmissions. Common comorbidities were diabetes (56%), coronary artery disease (40%), congestive heart failure (24%), and chronic obstructive pulmonary disease (19%). Index vascular operations included open lower extremity procedures (39%), diagnostic angiograms (35%), endovascular lower extremity procedures (16%), dialysis access procedures (7%), carotid/cerebrovascular procedures (7%), amputations (6%), and abdominal aortic procedures (5%). Average index length of stay (LOS) was 7.48 days (+6.73 days). Reasons for readmissions were for medical causes (43%), surgical complications (35.5%), and planned procedures (21.5%). Reasons for medical readmissions most commonly included malaise or failure to thrive (28%), unrelated infection (24%), and hypoxia/CHF complications (21%). Common surgical causes for readmission were surgical site infections (69%), graft failure (19%), and bleeding complications (8%). Of the planned readmissions, procedures were at the same site (79%), a different site (14%), and planned podiatry procedures (7%). Readmission LOS was on average 7.43 days (+7.22 days).¹⁸

Pardis Pooshpas et al conducted a study in 2018 to study the factors associated with increased risk of unplanned hospital readmission after endovascular aortoiliac interventions, it was found that out of 823 patients, 86 were readmitted. Readmission was related to the principal procedure in 48 (73.9%) patients. A total of 61 (7%) patients underwent an unplanned operation within 30 days after the index procedure. A multivariable logistic regression model identified the following variables to be significantly associated with 30-day risk of readmission: the use of pre-procedural beta blocker, external/internal iliac intervention, critical limb ischemia, and unplanned return to the operating room. The predicted probability of readmission was as follows: 5.5% for critical limb ischemia, 5.9% for external iliac artery angioplasty/stenting, 6.2% for preoperative beta blockers, 17.7% for patients with cardiac arrest, 27% for unplanned return to the operating room and 94.7% for patients with all of these risk factors.¹

Rami Tadros et al studied about defining types and determining risk factors for vascular surgery readmissions in New York. The overall 30-day readmission rate was 21.9% (n=213). The related, unplanned readmission cohort (n=83) had the highest readmission rate at 8.5%. The related, planned readmission rate was 5.9% (n=58), while the unrelated, unplanned readmission rate was 5.6% (n=55). In contrast, the overall 1-year readmissions at 19.7% (n=191). The related, unplanned readmission rate was 8.7% n=85) while the related, planned readmission rate was 5.7% (n=55). Compared to other types of readmissions, unplanned, related readmissions tended to affect patients who were younger, had poor glycaemic control and had higher BMIs.²⁰

Work by Jencks et al. provides much of the basis of our current understanding of the issue of 30-day readmissions. While the average estimated readmission rate for Medicare patients for all-comers is as high as 18% of patients, readmission rates vary by geographic area and by specialty, with an average 11.1% of surgical patients readmitted within 30 days of discharge.²³

Within surgical specialties, readmission rates also vary. In a recent study within the VA population, 16% of vascular patients were readmitted within 30 days of discharge compared to only 9.6% of orthopaedic patients. Indeed, unplanned readmission rates for vascular surgery patients are high, and range from 9.3% to 24%⁻ Surgery for peripheral vascular disease had the third highest rate of 30-day readmission behind only congestive HF and psychosis.²³

Ninety-day readmission rates climb significantly higher, to an average 17.9% for vascular patients tracked in the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP).²⁴

Orr et al. found that readmissions potentially requiring repeat intervention, including endoleaks and graft occlusion, were associated with significantly higher median costs than complications that could potentially be managed non-operatively including surgical site infections.²⁵

In a single institution trial, among 605 open procedures and 421 endovascular procedures there was no significant difference between the two groups in terms of index hospitalization institutional cost (\$27,653 vs. \$23,999), unplanned readmission rates (16.9% vs. 17.8%), or cost of readmission (\$19,117 vs. \$17,887).²⁶

Brooke et al. reported a framework to address the issue of readmissions in vascular surgery across various phases of care from patient selection to post procedure follow-up, and point out the various opportunities for complications in patient care as well as research at each phase.²⁷

In one study by Joynt KE et al. the most frequent reasons for readmission included new soft tissue infections, either related to intravenous drug use (16.8%) or de novo (13.3%), or to disposition support issues (14.5%)²⁸ Furthermore, according to van Walraven et al. the degree to which readmissions are preventable, even those that are related to the index hospitalization or hospital level factors has also been raised as a concern. Some estimates report that less than one-third of all readmissions are actually preventable.²⁹

There has been concern that a move toward enhanced recovery pathways and earlier discharge may drive increases in readmission rates. However, in both cases, this has not been seen.³⁰ In fact; it appears that standardizing care likely leads to better coordination and fewer deviations from care pathways and that stronger adherence to pathways are associated with better outcomes and decreased readmissions.³¹

In a recent report by Lachat et al. describing the safety and feasibility of outpatient endovascular aneurysm repair, postoperative morbidity was minimal, and readmission occurred in only 4% of patients. The authors also noted that use of an outpatient model minimized delirium, which is common in elderly patients recovering from inpatient vascular surgery, and cost significantly less than a standard inpatient model approach.³²

AIMS AND OBJECTIVES

AIMS

Aim of this study was to study multiple potential drivers of readmission in patients undergoing revascularization for CLI.

OBJECTIVES

<u>Primary</u>: Overall readmission to our hospital within 6 months of index procedure <u>Secondary</u>:

- 1. Overall 6 months morbidity (MALE and MACE)
- 2. Overall 6 months mortality

MATERIALS AND METHODS

<u>Study Setting</u>: The study was conducted at single centre in Jain Institute of Vascular Sciences (JIVAS) Bhagwan Mahaveer Jain Hospital, Vasanth Nagar, Bengaluru.

Study Duration: Recruitment period: November 2019- October 2020 (1 year)

Follow up period: November 2020- April 2021 (6 months)

Study Design: Non-randomised, prospective, single centre, observational study.

<u>Study sample</u>: All patients presenting to the Jain Institute of Vascular Sciences (JIVAS) with Critical Limb Ischemia undergoing revascularization.

Sample size: Minimum of 100 patients who have underwent successful revascularization

Inclusion criteria:

All patients who underwent successful revascularization for Critical Limb Ischemia and are discharged from the vascular surgery service and subsequently readmitted as an inpatient within 6 months of index procedure

Exclusion criteria

- Patients with unsuccessful index procedure.
- Planned major amputation during index admission.
- Open and endovascular infra renal aortic aneurysm repairs.

Methodology:

- We divided readmissions into groups based on their relation to the index surgery and whether or not they are planned.
- Data analysis included calculation of the percentages -total overall readmitted patients stratified by characteristics of the patients' demographics, index hospitalization details, and readmission specifics.
- The percentages were also calculated as a factor of unplanned medical, unplanned surgical and planned readmissions for each characteristic.

- A multivariate analysis of readmission LOS was conducted based on patient demographics, pre-existing comorbidities, index LOS, index procedure type, and reason for readmission.
- A multivariate analysis comparing the reasons for early (0-30 days) readmission as compared to late (30- 180days) readmission was also conducted for all readmissions.

Index admission characteristics

- > Information regarding the patient's index hospitalization investigated was
 - Demographic information including age, gender.
 - o Diagnosis- CLI Category (Rutherford classification)
 - Length of stay (LOS)
 - Planned length of follow-up
- Comorbidities
 - o Diabetes
 - o Hypertension
 - o Dyslipidaemia
 - Congestive heart failure/ Coronary artery disease (CVS)
 - Stroke/transient ischemic attack (CNS)
 - Chronic obstructive pulmonary disease (Pulmonary)
 - o Renal dysfunction
 - Obesity (BMI >30)
 - Underweight (BMI<18.5)
 - o Smoking
 - o Alcohol
- Index procedures were categorized as
 - Open lower extremity revascularization

- o Endovascular lower extremity revascularization and
- Hybrid procedures (Open + Endovascular)
- > Index Admission vascular intervention characteristics studied were
- Vascular procedure
 - Bypass
 - Angioplasty
 - Stenting
- Procedure's technical success
- Concurrent wound care procedure
- MACE (Major Adverse Cardiac Events)
- MALE (Major Adverse Limb Events)
- Major bleeding requiring blood transfusion
- Renal dysfunction
- Cerebrovascular accidents (CVA)

Readmission characteristics

- Readmission
 - o Planned readmission / Unplanned readmission
 - Related to index surgery / Not related to index surgery
- Admission from –Emergency room(ER) / Out patient department(OPD)
- > Days after discharge got readmitted
- Readmission diagnosis /Causes
 - o Medical-
 - Anaemia
 - Diabetes related

- Pulmonary
- MACE
- CVA
- Renal dysfunction
- o Surgical-
 - Graft failure
 - Surgical site infection (SSI)
 - Pseudo aneurysm
 - Bleeding
 - Wound care
- ➢ Treatment at readmission
 - o Medical
 - \circ Surgical -- Major re-intervention of treated arterial segment
 - Open
 - Endovascular
 - -- Wound care procedures
- Length of hospital stay

Follow up:

At the end of 6 months, the following are noted

- MALE
- MACE
- Death due to any cause

Ethical Consideration

Ethical clearance was taken from Ethical Committee before conducting the study.

STATISTICAL METHODS:

Following statistical methods were applied in the study:

- Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance.
- Student 't' test
- Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.
- One Way Anova

Significant figures

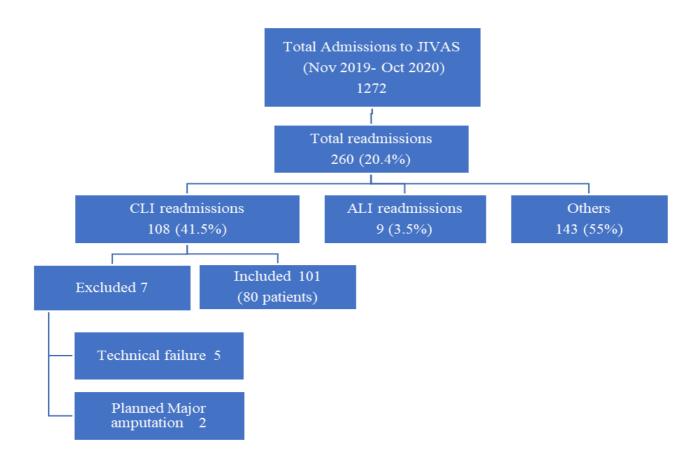
- + Suggestive significance (P value: 0.05<P<0.10)
- * Moderately significant (P value:0.01<P<0.05)
- ****** Strongly significant (P value: P<0.01)

Statistical software: The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc

RESULTS

During the study period i.e., from November 2019 to December 2020, there were total 1272 admissions to vascular department, of these revascularized CLI patients' admissions were 621. During this period total readmissions were 260. Among the readmissions 108 were revascularized CLI patients' readmissions, 9 were revascularized ALI patients' readmissions and 143 were readmissions due to other causes. We excluded 7 patients of CLI revascularization based on exclusion criteria (technical failure-5, planned major amputation-2). We included 80 revascularized CLI patients in the current study. Of these 80 patients, 3 patients were admitted thrice and 15 patients were admitted twice within 6 months of index procedure, accounting for 22.5% (13/80) of patients. So, in total 101 readmissions were studied in this analysis.

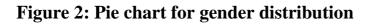
Figure 1: Flow chart of study design



Of the 101 admissions who were readmitted within 6 months after discharge from the vascular surgery service at our institution during the study period, the baseline characteristics of readmitted patients is represented in Table 1. The mean age of those readmitted was 65.6 years with SD of 9.9 years, and most patients were males (77.2%). The majority of readmitted patients were either overweight (31.7%) or obese (31.7%). The most commonly observed comorbidity of those readmitted was diabetes (88.1%), followed by hypertension (59.4%) and cardiac comorbidities (34.7%). 38.6% had history of smoking.

Table1: Baseline characteristics of patients readmitted

Variables		Frequency	Percentage
Gender	Male	78	77.2%
	Female	23	22.8%
Age	<60 years	30	29.7%
	>60 years	71	70.3%
BMI	Underweight (<18.5kg/m ²)	4	4%
	Normal (18.5 to 24.9kg/m ²⁾	33	32.7%
	Overweight (25 to 29.9kg/m ²⁾	32	31.7%
	Obese (>30kg/m ²)	32	31.7%
Со-	Anaemia	34	33.7%
morbidities	Diabetes	89	88.1%
	Hypertension	60	59.4%
	Dyslipidaemia	9	8.9%
	Renal	19	18.8%
	Pulmonary	6	5.9%
	Cardiac	35	34.7%
	CNS	5	5%
Habits	Smoking	39	38.6%
	Alcohol consumption	5	5%



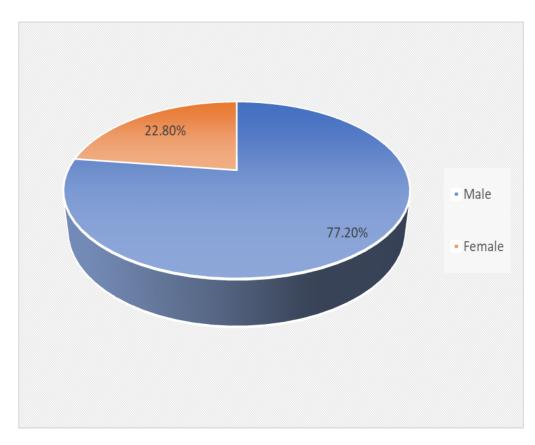


Figure 3: Bar graph for age distribution

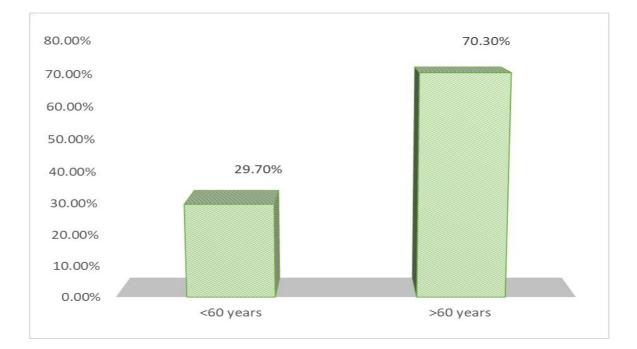
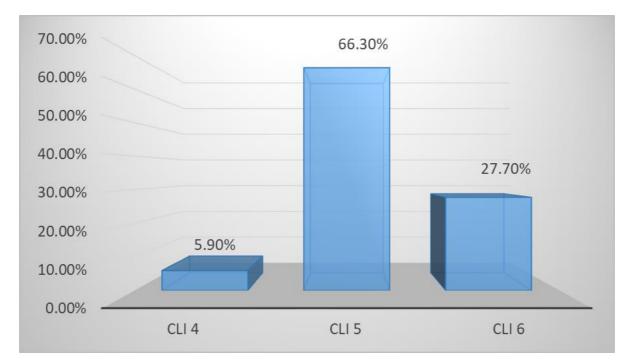


Table 2 shows the index admission characteristics of the patients. Majority of the cases were left limb revascularization (51.5%) and presented without any past history of revascularization (75.2%) and belonged to CLI category 5 (66.3%)

Table 2: Index admission characteristics of the patients

	Frequency	Percentage
Right	49	48.5%
Left	52	51.5%
Yes	25	24.8%
No	76	75.2%
4	6	5.9%
5	67	66.3%
6	28	27.7%
	Left Yes No 4 5	Right 49 Left 52 Yes 25 No 76 4 6 5 67

Figure 4: Bar graph for CLI Category



For all readmitted patients, the mean index hospital LOS was 5.9 (± 2.5 days). Hospitalized inpatients in this sample underwent open procedures (8.9%) like femoro-popliteal bypass (5.6%) axillo bifemoral bypass (1%), fem-fem crossover bypass (1%), and iliac to popliteal bypass (1%). Endovascular procedures were done in 69.3% of patients, while Hybrid procedures (Open+Endovascular) were done in 21.8% of patients. The most common endovascular procedure was infrapopliteal angioplasty (32.7%) followed by femoropopliteal + infrapopliteal angioplasty (15.8%) and SFA stenting (8.9%). In 62.3% of patients a concomitant wound care procedure was done. Most of the index admissions were elective (93.1%). All cases achieved technical success (100%) and about 21.8% patients had blood transfusion post revascularisation, 7.9% had MALE, 4% had MACE and 5.9% had SSI (Table 3).

Variables		Frequency	Percentage
Index	Open procedure	9	8.9%
Procedure	Endovascular procedure	70	69.3%
	Hybrid procedure	22	21.8%
	CO ₂	17	16.8%
	Bypass with graft	15	14.9%
	Wound care procedure	64	63.3%
Index	Emergency	7	6.9%
admission	Elective	94	93.1%
Post-	Technical success*	101*	100%
procedure	Major Adverse Limb Events (MALE)	8	7.9%
outcome	Major Adverse Cardiac Events (MACE)	4	4%
	Surgical Site Infection (SSI)	6	5.9%
	Blood transfusion	22	21.8%
	Renal dysfunction	3	3%

Table 3: Index procedure characteristics of patients

*Patients with technical success only were included in the study

Readmissions were classified into three separate groups: Readmissions that occurred between 0-30 days (n=44), 31-60 days (n=21) and >60 days (n=36). Patients got readmitted to our institution, on average, within 58.9 days with SD 50.9 days. A total of 43.6% of patients were deemed early readmissions within 30 days, of which 13 admissions were within 10 days of index discharge and 56.4% were late readmissions (>30 days). The unplanned readmissions had the highest readmission rate at 73.2%, while the planned readmission rate was 26.8%. About 82.2% of readmissions were index procedure related, while 17.8% were unrelated to the index procedure. Many (40.7%) of the planned readmissions were early. There was no statistical difference in the multivariate analysis between reasons for readmission as no parameters were significant when chi-square test was applied (p>0.05) (Table 4)

V	⁷ ariables	Readmission Days		p-value	
		Early	La	ate	
		0 to 30days	31- 60days	>60 days	
Gender	Male	10 (22.7%)	4 (19%)	9 (25%)	0.91
	Female	34 (77.3%)	17 (81%)	27 (75%)	
Age	<60 years	12(27.3%)	8 (38.1%)	10 (27.8%)	0.637
	>60 years	32 (72.7%)	13 (61.9%)	26 (72.2%)	
BMI	Underweight (<18.5kg/m ²)	3 (6.8%)	0	1 (2.8)	0.738
	Normal (18.5 to 24.9kg/m ²⁾	14 (31.8%)	7 (33.3%)	12 (33.3%)	
	Overweight (25 to 29.9kg/m ²)	14 (31.8%)	9 (42.9%)	9 (25%)	
	Obese (>30kg/m ²)	13 (29.5%)	5 (23.8%)	14 (38.9%)	

 Table 4: Comparison of Reasons for Early and Late Readmission

Co-	Anaemia	16 (36.4%)	6 (28.6%)	12 (33.3%)	0.795
morbiditi		10 (30.4%)	0 (28.070)	12 (33.3%)	0.795
	Diabetes	36 (81.8%)	19 (90.5%)	34 (94.4%)	0.247
	Hypertension	23 (52.3%)	15 (71.4%)	22 (61.1%)	0.328
	Dyslipidaemia	5 (11.4%)	0	4 (11.1%)	0.316
	Renal Dysfunction	8 (18.2%)	3 (14.3%)	8 (22.2%)	0.847
	Pulmonary	2 (4.5%)	1 (4.8%)	3 (8.3%)	0.862
	Cardiac	12 (27.3)	9 (42.9%)	13 (36.1%)	0.799
	CNS	3 (6.8%)	0	2 (5.6%)	0.716
Habits	Smoking	17 (38.6%)	8 (38.1%)	14 (38.9%)	1
	Alcohol consumption	2 (4.5%)	1 (4.8%)	2 (5.6%)	1
Index pro	cedure related	41 (93.2%)	19 (90.5%)	23 (63.9%)	0.001
Planned		11 (25%)	4 (19%)	12 (33.3%)	0.516
Unplanne	d	33 (75%)	17 (81%)	24 (66.7%)	
Same side	Yes	44 (100%)	20 (95.2%)	35 (97.2%)	0.39
	No	0	1 (4.8%)	1 (2.8%)	
Medical cause	Diabetes complication	2 (4.5%)	0	0	0.686
	Anaemia/blood transfusion	4 (9.1%)	3 (14.3%)	2 (5.6%)	0.537
	Septic shock	0	0	2 (5.6%)	0.166
	Renal Dysfunction	0	1 (4.8%)	3 (8.3%)	0.144
	Pulmonary	2 (4.5%)	0	3 (8.3%)	0.52
	Cardiac	1 (2.3%)	0	1(2.8%)	1
Surgical cause	SSI	2 (4.5%)	0	2 (5.6%)	0.825
caube	Graft failure	3 (6.8%)	1(4.8%)	7 (19.4%)	0.186
	Pseudo aneurysm	1 (2.3%	0	0	0.813
	Wound care (Amputation/Debridement)	24 (77.3%)	13 (85.7%)	27 (72.2%)	0.16

Table 5. shows the reasons for readmissions following discharge. Majority of the readmissions were due to surgical cause (55.4%) especially for Wound care procedure (Amputation/Debridement) (71.5%).

Table 5. Reasons for	Readmission	Following	Discharge
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Readmission			Frequency (%)
Planned	readmissions	Split skin grafting (SSG)	13 (48.1%)
(n=27)		Wound care procedure	8 (29.6%)
Medical	readmissions	Diabetes complication	2 (11.1%)
(n=18)		Anaemia/blood transfusion	9 (50%)
		Septic shock	2 (11.1%)
		Renal dysfunction	4 (22.2%)
		Pulmonary	5 (27.8%)
		Cardiac	2 (11.1%)
		CVA/FND	0
Surgical	readmissions	SSI	4 (7.1%)
(n=56)		Graft failure	11 (19.6%)
		Bleeding	0
		Pseudo aneurysm	1 (1.8%)
		Wound care	40 (71.5%)
		(Amputation/Debridement)	

Majority of the patients who were readmitted back to the vascular surgery service were readmitted with surgical cause (55.4%). The readmitted LOS for these patients was differed significantly between three groups viz., planned readmission, medical cause readmission and surgical cause readmission (P<0.05) when one-way ANOVA was done.

Majority of the planned and surgical readmissions were males and medical readmissions were females and this was statistically significant when chi-square test was applied (p<0.05).

Majority of the medical readmissions were having anaemia and majority of the surgical readmissions were smokers and this difference was statistically significant when chi-square test was applied (p<0.05) (Table 6).

Variables		Planned	Surgical	Medical	p-value
		Readmission	Readmission	Readmission	
		(n=27)	(n=56)	(n=18)	
Mean Lengtl	h of stay	4.96 (4.4)	4.61 (1.7)	7.4 (5.5)	0.013
Gender	Male	24 (88.9%)	46 (82.1%)	8 (44.4%)	0.002
	Female	3 (11.1%)	10 (17.9%)	10 (55.6%)	
Age	<60 years	9 (33.3%)	15 (26.8%)	6 (33.3%)	0.797
	>60 years	18 (66.7%)	41 (73.2%)	12 (66.7%)	
BMI	Underweight	2 (7.4%)	2 (3.6%)	0	0.268
	Normal	9 (33.3%)	19 (33.9%)	5 (27.8%)	
	Overweight	7 (25.9%)	18 (32.1%)	7 (38.9%)	
	Obese	9 (33.3%)	17 (30.4%)	6 (33.3%)	
Со-	Anaemia	9 (33.3%)	11 (19.6%)	14 (77.8%)	<0.001
morbidities	Diabetes	25 (92.6%)	48 (85.7%)	16 (88.9%)	0.775
	Hypertension	14 (51.9%)	37 (66.1%)	9 (50%)	0.292
	Dyslipidaemia	3 (11.1%)	3 (5.4%)	3 (16.7%)	0.212
	Renal	4 (14.8%)	10 (17.9%)	5 (27.8%)	0.543
	Pulmonary	1 (3.7%)	3 (5.4%)	2 (11.1%)	0.619
	Cardiac	8 (29.6%)	19 (33.9%)	7 (38.9%)	0.766
	CNS	1 (3.7%)	3 (5.4%)	1 (5.6%)	1
Habits	Smoking	11 (40.7%)	26 (46.4%)	2 (11.1%)	0.019
	Alcohol consumption	1 (3.7%)	4 (7.1%)	0	0.830

Table 6: Characteristics of Readmission Hospitalization.

Table 7 shows the treatment and outcomes of readmissions. The mean length of stay of readmissions was 5.2 days with SD 3.6 days. Majority of the readmission procedures were for wound care (83.2%). We had mortality rate of 7.9% among readmissions and MALE and MACE was seen among 8 and 10 patients respectively during the 6 months follow up.

Variables		Frequency	Percentage
Readmission Procedure	Medical Treatment	6	5.9%
	Surgical procedure- Open	7	6.9%
	Surgical procedure- Endovascular procedure	6	5.9%
	Surgical procedure- Wound care	84	83.2%
Post- procedure	Mortality	8	7.9%
outcome	Major Adverse Limb Events (MALE)	8	7.9%
	Major Adverse Cardiac Events (MACE)	10	9.9%
	Major Adverse Cardiac Events (MACE)	10	9.9

Table 8 shows the mean day for readmission after index discharge. There were no variables which has significant effect on mean days to readmission after index discharge when t-test/ANOVA was applied (p>0.05)

Table 8: Mean days to readmission after index discharge

Variables		Mean (SD)	p-value
CLI category	4	59.33 (51.8)	0.243
	5	53.3(49.1)	
	6	72.3 (51.3)	
Gender	Male	59.6 (51.4)	0.814
	Female	56.7 (50.2)	
Age	<60 years	59.4 (48.7)	0.949
	>60 years	58.7 (52.1)	
BMI	Underweight (<18.5kg/m ²)	50.75 (67.8)	0.76
	Normal (18.5 to 24.9kg/m ²)	63.1 (55.7)	
	Overweight (25 to 29.9kg/m ²)	51.6 (44.4)	
	Obese (>30kg/m ²)	62.9 (51.3)	

DISCUSSION

Studies suggest that patients undergoing vascular surgery operations are at a higher risk for readmission as compared to other specialties due to a high prevalence of planned operations and pre-existing comorbidities. Also in some cases, the reasons for these readmissions are not well characterized. To an extent, it also reflects on the quality of patient care. Therefore, it is important to identify patients at high risk for readmission and to characterize the risk factors for readmission^{14, 33}

The present study describes the significance of understanding the nature of readmission of patients to the vascular department. The most common causes of vascular surgery readmissions and the factors that are associated with these readmissions were analysed in the study.

Lower extremity revascularization is associated with the greatest risk of readmission, at 15.2% in a study by Iannuzzi et al.³⁴ Previously reported ranges vary widely from <10% to >20% after lower extremity bypass. Vogel et al evaluated readmissions among patients undergoing procedures for peripheral arterial disease within the Health Facts database and found a 14.5% 30-day readmission rate. The additional risk factors that they identified included length of stay, aspartate aminotransferase, and >30 medications ordered. The Vogel study was able to identify the cause of readmission, and found that 22.1% of readmissions were secondary to surgical infection.³⁵

The overall Vascular readmissions in a year, seen in our study were 20.2% (260/1272), while the post revascularization, CLI readmissions were 41.5% (108/260) and 22.5% (13/80) of patients got readmitted more than once. Most patients that get readmitted once are likely to be subject to a second readmission and approximately a quarter of patients treated with revascularization for CLI will undergo a second procedure regardless of the initial modality of treatment, open or endovascular. In fact, Turley et al., when examining readmissions among Medicare beneficiaries treated with peripheral endovascular interventions performed in the inpatient setting, showed an incidence of repeat revascularization of 25.1 at 1 year.³⁶

Approximately 1 in 5 patients were readmitted to Boston Medical Centre within 30 days following discharge from the vascular surgery service, and this includes both unplanned and planned readmissions. It is common practice on vascular surgery services to stage procedures (eg, to evaluate patients with an angiogram during index procedure and then plan a follow-up readmission for a surgical intervention). These planned readmissions inflate vascular readmission rates, causing them to appear higher than most other surgical specialties.¹⁸ As

demonstrated in our study, planned readmissions accounted for 21% of all readmissions. Once adjusted for planned readmissions, the readmission rate dropped to 16.33%, which nears the national surgical readmission rate of 15.6% for all specialties. Also surgical patients readmitted following a major vascular surgery procedure were more likely to be readmitted for medical causes than for surgical complications. Vascular surgery patients have been shown to be prone to readmission for pre-existing comorbidities.³⁷

In order to understand the reasons for readmission and the risk factor, studying the characteristics of index admission is of utmost importance. Our study noted that majority of such patients had undergone endovascular procedure during the index admission period and the most common procedure was infra-popliteal angioplasty. Further, to understand the time period between the index admission and readmission, we categorized the patients into three categories, as early (0-30 days) and late (31-60 days and >60 days). However, there was no significant difference seen between the groups from the results of multivariate analysis. Wound care was noted to be one of the major reasons for readmission. Planned and surgical readmissions were common among men when compared to women who got readmitted mainly for medical causes. Anaemia and history of smoking were significantly noted among readmissions.

Characteristics of readmitted patients:

Older age group patients were likely to get readmitted for endovascular studies as noted in a study by Ochoa Chaar C et al. where in the patients undergoing endovascular revascularization were more likely to have diabetes and end stage renal disease. The study also reported that patients undergoing open revascularization were more likely to be smokers^{.21} As compared to patients in other surgical specialties, vascular surgery patients are more likely to smoke and to have a history of dyspnoea, functional dependence, severe COPD, CHF, hypertension, acute renal failure, an open wound, and/or bleeding disorders. Furthermore, these patients are more frequently dialysis dependent and more often use long-term steroids for a chronic condition.²² According to our study diabetes, hypertension and cardiac comorbidities were the common comorbidities observed in the readmission group. Mostly because of the smaller sample size compared to much larger samples in similar database studies, it did not carry enough statistical power for some variables.

Index admission characteristics of patients:

The average age of those readmitted was 66 years according to a study by Tahhan G et al. which was consistent with our study. And the majority of readmitted patients were either overweight (35%) or obese (30%) and were admitted to the hospital with at least 1 comorbidity. Similar findings were noted in our study.¹⁸

Our findings indicated that majority of the patients were smokers and had a history of diabetes. This was consistent with a study done by Gupta PK et al.³⁷ A study by Tadros G et al. showed similar findings where majority of the patients were smokers and had history of diabetes. However, strong association demonstrated by this study with BMI was not consistent with our present study.²⁰

Reasons for early and late readmissions:

Wound care (amputation/debridement), anaemia requiring blood transfusion, diabetes complication were the most common reasons for readmission noted in our study. Ochoa Chaar C et al. reported similar findings with atherosclerosis of the extremities with gangrene, ulceration and septicaemia being the most common diagnosis for readmissions.²¹

In a study conducted by Caitlin W. Hicks et al. it was noted that among the readmissions 91% were unplanned, of which 61% were related to the index vascular surgery procedure, while in our study 73.2% were unplanned readmissions and 83.2% were related to the index procedure.¹⁶ Gupta PK et al. noted that surgical patients readmitted following a major vascular surgery procedure were more likely to be readmitted for medical causes than for surgical complications. This was in contrast to our present study.³⁷

Dialysis dependence and diabetes mellitus were reported to be the top five predictors of readmission by Glebova et al. Post discharge deep space infection, superficial surgical site infection, pneumonia, myocardial infection, and sepsis were also found to be the predictors of readmission in the final model.²² Similar findings were also reported by Pardis et al.¹ However, our study did not show statistically significant difference among these categories

Surgical site infection was the most common reason for unplanned readmission, with superficial surgical site infections accounting for 30% of readmissions and deep surgical site infections accounting for 19%. The most common vascular operations associated with readmission for infection were lower extremity bypass and amputation.¹⁶ Recent studies also reported that wound complications are the most common cause for readmission after some vascular operations. These data suggest that postoperative infections, particularly those associated with surgical wounds, are frequent and morbid complications of vascular surgery. This is in contrast with our study where the finding was not statistically significant.^{19, 25}

In the study by Tahhan et al, planned readmissions were most frequently seen after diagnostic

angiogram (62%) or endovascular lower extremity interventions (24%). Patients readmitted for surgical complications were commonly readmitted after open lower extremity procedures (60%) or diagnostic angiograms (27%) and typically had longer index hospital stays (8.47 days) than those with either planned (4.72 days) or medical readmissions (8.03 days). Concurrent wound care procedures were transmetatarsal amputation (TMA) (29%), isolated toe or metatarsal resections (43%), and debridement's (29%).¹⁸

In a recent study, one of the major contributing factors for the sharp increase in planned readmissions was found to be higher proportions of amputations and peripheral revascularizations. Readmission rates for amputations and peripheral revascularization have been consistently higher than other vascular procedures as reported by Gupta PK et al.³⁷ and Iannuzzi et al.³⁴

Mean days of readmisision and Length of stay:

Ochoa Chaar C et al. reported that more than a third of patients undergoing revascularization for CLI get admitted at least once during the subsequent year. In our study, majority of patients got readmitted within 3 months of discharge following index admission. The study also reported that inpatient mortality was 1.6 with no difference between the open and revascularization groups. We had mortality rate of 7.9% among readmissions in our study.²¹

Average index length of stay was noted to be 7.48 days (+6.73 days) by a study done by Tahhan et al. which was consistent with our study. However, the association was not statistically significant.¹⁸ Reasons for readmissions were for medical causes (43%), surgical complications (35.5%), and planned procedures (21.5%). Based on their definition of preventable readmission, a study by Dawes et al. determined that 21% of their readmissions were preventable, 49% with closer follow-up after discharge, 42% with outpatient management, and 9% by avoiding premature discharge.³⁸ A study regarding the duration of hospital stay and incidence of readmission suggested that by reducing patients' in-hospital length of stay, exposure to unnecessary risks such as nosocomial infections could be reduced, which rises steadily as the hospital length of stay increases. This in turn could reduce the overall risk of postoperative infection and ultimately postoperative readmissions, especially among high-risk patients.³⁹

As described in the McPhee study, despite increased awareness, readmission rates did not decrease over time, which may suggest that the inclusion of the complex but smaller vascular patient population in an incentive based readmission program may not have as large of an economic impact as other larger-volume, higher-cost diagnoses.⁴⁰

Readmission rates can be reduced through faster patient recognition and early identification of a potential infection or other complication. Additionally, because postdischarge complications are often difficult to predict, preoperative optimization of comorbidities such as diabetes and CAD, where possible, may also help to reduce readmissions.⁴¹

CONCLUSIONS

- Critical limb ischemia is a challenging disease associated with high readmission during the first year after revascularization.
- Expected patient risk factors, such as diabetes, obesity, renal insufficiency, and cigarette smoking, were less important in predicting readmission days.
- Our findings suggest that most of the readmissions are unplanned and index procedure related, with surgical causes being the common reason for readmission.
- Reasons for unplanned medical readmissions included anaemia and blood transfusion. The most common reason for unplanned surgical readmissions was for wound care.
- So, careful operative planning and expeditious operations may be the most effective approaches to reducing readmissions in vascular surgery patients.
- Better understanding of readmissions following vascular surgery procedures could help lower readmission rates and adjust policy benchmarks for targeted readmission rates.

LIMITATIONS

The limitations of this study were

- The number of subjects included was small
- The duration of follow up was short
- Patients readmitted to a hospital other than our centre could not be included in the study

SUMMARY

This is a Non-randomised, prospective, single centre, observational study conducted at Jain Institute of Vascular Science, Bangalore. From November 2019 to December 2020, all patients who underwent successful revascularization for CLI and were discharged from the vascular surgery service and subsequently readmitted as an inpatient within 6 months of index procedure were included.

The readmissions were divided into groups based on their relation to the index surgery and whether or not they are planned. Total overall readmitted patients were stratified by characteristics of the patients' demographics, index hospitalization details and readmission specifics. Readmitted patients were followed up at 6 months; MALE, MACE and mortality were noted.

During the study period, out of 1272 admissions to our vascular department, total readmissions were 260 (20.4%) and of these the revascularized CLI readmissions were 108 (41.5%). 3 patients were admitted thrice and 15 patients were admitted twice within 6 months of index procedure. So, in total 101 readmissions (80 patients) were studied.

The mean age of those readmitted was 65.6 years. Majority belonged to CLI category 4 and were overweight. Common comorbidities were diabetes, hypertension and cardiac. Most of them are active smokers.

Most common index vascular operations were endovascular lower extremity procedures and most common endovascular procedure was infrapopliteal angioplasty; others were open and hybrid lower extremity procedures. In majority of the patients a concomitant wound care procedure was also done. Mean index length of stay was 5.9 days.

Patients got readmitted on average within 58.9 days of the index procedure. Many of readmissions were deemed early readmissions within 30 days. There were no variables which has significant effect on mean readmission days after index discharge.

Reasons for readmissions were mostly for surgical causes, rest being medical causes and planned procedures. Reasons for medical readmissions most commonly included anemia and diabetic complications; while common surgical causes for readmission were for wound care,

graft failure and surgical site infection. Of the planned readmissions, most were for skin grafting and wound care.

Majority of the readmission procedures were for wound care. There was no statistical difference in the multivariate analysis between reasons for readmission. Majority of the medical readmissions had anaemia and most of the surgical readmissions were smokers which was statistically significant.

The highest readmission rate was for unplanned readmissions and most of them are related to the index procedure. Majority of the planned and surgical readmissions were males and medical readmissions were females and this was statistically significant.

Readmissions mean LOS was 5.2 days. The readmitted LOS for the patients differed significantly between three groups viz, planned readmission, medical cause readmission and surgical cause readmission.

Critical limb ischemia is a challenging disease associated with high readmission during the first year after revascularization. Expected patient risk factors, such as diabetes, obesity, renal insufficiency, and cigarette smoking, were less important in predicting readmission.

The study findings suggest that most common reason for revascularised CLI readmissions are unplanned surgical readmissions and for wound care. So, careful operative planning and expeditious operations with aggressive wound management may be the most effective approach to reduce readmissions. This would help lower readmission rates among vascular patients and help to adjust policy benchmarks for targeted readmission rates.

BIBLIOGRAPHY

- 1. Pooshpas P, Lehman E, Aziz F. Factors associated with increased risk of unplanned hospital readmission after endovascular aortoiliac interventions. Cureus 2018; 10(11):3558-74.
- 2. Davis FM, Sutzko DC, Grey SF, et al.: Predictors of surgical site infection after open lower extremity revascularization. J Vasc Surg. 2017, 65:1769-1778.e3. 10.1016/j.jvs.2016.11.053
- Nguyen BN, Neville RF, Abugideiri M, Amdur R, Sidawy AN: The effect of graft configuration on 30-day failure of infrapopliteal bypasses. J Vasc Surg. 2014, 59:1003-1008. 10.1016/j.jvs.2013.10.091.
- Menard MT, Farber A. The BEST-CLI trial: a multidisciplinary effort to assess whether surgical or endovascular therapy is better for patients with critical limb ischemia. Semin Vasc Surg 2014; 27:82e4.
- Popplewell MA, Davies H, Jarrett H, et al. Bypass versus angioplasty in severe ischemia of the leg - 2 (BASIL-2) trial: study protocol for a randomised controlled trial. Trials 2016; 17:11.
- 6. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). J Vasc Surg. 2007; 45(suppl s):S5-S67.
- Selvin E, Erlinger TP. Prevalence of and risk factors for peripheral arterial disease in the United States: results from the national health nutrition examination survey, 1999-2000. Circulation. 2004; 110(6):738-74.
- Cacoub PP, Abola MT, Baumgartner I, et al. Cardiovascular risk factor control and outcomes in peripheral artery disease patients in the reduction of atherothrombosis for continued health (REACH) registry. Atherosclerosis. 2009; 204:e86-e92.
- Bonaca MP, Scirica BM, Creager MA, et al. Vorapaxar in patients with peripheral artery disease: results from TRA2 P-TIMI 50. Circulation. 2013; 127(14):1522-1529, 1529e1521-1526.

- Criqui MH, Langer RD, Fronek A, et al. Mortality over a period of 10 years in patients with peripheral arterial disease. N Engl J Med. 1992; 326(6):381-386.
- Secemsky EA, Schermerhorn M, Carroll BJ, et al. Readmissions after revascularization procedures for peripheral arterial disease: a nationwide cohort study. Ann Intern Med 2017; 168:93e9.
- Kolte D, Kennedy KF, Shishehbor MH, et al. Thirty-day readmissions after endovascular or surgical therapy for critical limb ischemia: analysis of the 2013 to 2014 nationwide readmissions databases. Circulation 2017; 136: 167e76.
- Hackbarth GM, MME. Report to the Congress: promoting greater efficiency in Medicare. Washington, DC: MedPAC; 2007. Available at: <u>https://permanent.access.gpo.gov/LPS106668/LPS106668/www.medpac.gov/documents/Jun</u> <u>07_</u>EntireReport.pdf. Accessed March 30, 2014.
- 14. Eun JC, Nehler MR, Black JH, Glebova NO. Measures to reduce unplanned readmissions after vascular surgery. Semin Vasc Surg 2015; 28:103-1.
- Wiseman JT, Guzman AM, Fernandes-Taylor S, Engelbert TL, Saunders RS, Kent KC. General and vascular surgery readmissions: a systematic review. J Am Coll Surg 2014; 219: 552-69.e2.
- 16. Hicks CW, Bronsert M, Hammermeister KE, Henderson WG, Gibula DR, Black JH et al. Operative variables are better predictors of postdischarge infections and unplanned readmissions in vascular surgery patients than patient characteristics. J Vascular surgery 2016; 1(1):1-20.
- 17. Benbassat J, Taragin M. Hospital readmissions as a measure of quality of health care: advantages and limitations. Arch Intern Med. 2000; 160(8):10740-10.
- Tahhan G, Farber A, Shah NK, Krafcik BM, Sachs TE, Kalish JA et al. Characterization of planned and unplanned 30-day readmissions following vascular surgical procedures. J Vascular Endovascular Surgery 2017; 51(1):17-22.

- Engelbert TL, Fernandes-Taylor S, Gupta PK, Kent KC, Matsumura J Clinical characteristics associated with readmission among patients undergoing vascular surgery. Journal of vascular surgery 2014:59:1349-1355.
- Tadros RO, Png CYM, Lau IH, Vouyouka AG, Qian L, Marin ML, Faries PL, Defining Types and Determining Risk Factors for Vascular Surgery Readmissions, Annals of Vascular Surgery (2018). doi: <u>https://doi.org/10.1016/j.avsg.2018.07.039</u>.
- 21. Cassius Ochoa Chaar, Navid Gholitabar, Philip Goodney, Alan Dardik, Marwan S. Abougergi, One-Year Readmission after Open and Endovascular Revascularization for Critical Limb Ischemia, Annals of Vascular Surgery, Volume 61,2019, Pages 25-32.e2
- 22. Glebova NO, Bronsert M, Hammermeister KE, et al. Drivers of readmissions in vascular surgery patients. J Vasc Surg. 2016; 64(1):185–194.
- Jencks SF, Williams MV, Coleman EA. Rehospitalisation among patients in the Medicare fee-for-service program. N Engl J Med. 2009; 360(14):1418–1428.
- 24. Xenos ES, Lyden JA, Korosec RL, Davenport DL. Ninety-day readmission risks, rates, and costs after common vascular surgeries. Am J Manag Care. 2014; 20(10):e432–e438.
- 25. Orr NT, El-Maraghi S, Korosec RL, Davenport DL, Xenos ES. Cost analysis of vascular readmissions after common vascular procedures. J Vasc Surg. 2015; 62(5):1281–1287.
- Gracon ASA, Liang TW, Easterday TS, et al. Institutional cost of unplanned 30-day readmission following open and endovascular surgery. Vasc Endovascular Surg.2016; 50(6):398–404.
- Brooke BS, De Martino RR, Girotti M, Dimick JB, Goodne PP. Developing strategies for predicting and preventing readmissions in vascular surgery. J Vasc Surg.2012; 56(2):556– 562.
- 28. Van Walraven C, Bennett C, Jennings A, Austin PC, Forster AJ. Proportion of hospital readmissions deemed avoidable: a systematic review. CMAJ. 2011; 183(7):E391–E402.
- 29. Joynt KE, Jha AK. Thirty-day readmissions-truth and consequences. N Engl J Med. 2012; 366(15):1366–1369.

- Ljungqvist O, Scott M, Fearon K. Enhanced recovery after surgery a review. JAMA Surg. 2016; E1–E7.
- Hoyer EH, Odonkor CA, Bhatia SN, Leung C, Deutschendorf A, Brotman DJ. Association between days to complete inpatient discharge summaries with all-payer hospital readmissions in Maryland. J Hosp Med. 2016; 11(6):393–400.
- 32. Lachat ML, Pecoraro F, Mayer D, Guillet C, Glenck M, Rancic Z, et al. Outpatient endovascular aortic aneurysm repair: experience in 100 consecutive patients. Ann Surg 2013;258: 754-8; discussion: 758-9
- 33. Gani F, Lucas DJ, Kim Y, Schneider EB, Pawlik TM. Under- standing variation in 30-day surgical Readmission in the era of accountable care: effect of the patient, surgeon, and surgical sub- specialties. JAMA Surg. 2015; 150(11):1042-1049.
- 34. Iannuzzi JC, Chandra A, Kelly KN, Rickles AS, Monson JR, et al. Risk score for 22 unplanned vascular readmissions. Journal of vascular surgery 2014:59:1340-134723 e1341.
- 35. Vogel TR, Kruse RL. Risk factors for readmission after lower extremity procedures for peripheral artery disease. J Vasc Surg 2013; 58: 90-7.
- 36. Turley RS, Mi X, Qualls LG, et al. The effect of clinical care location on clinical outcomes after peripheral vascular intervention in Medicare beneficiaries. JACC Cardiovasc Interv 2017;10:1161e71
- 37. Gupta PK, Fernandes-Taylor S, Ramanan B, Engelbert TL, Kent KC. Unplanned readmissions after vascular surgery. J Vasc Surg. 2014; 59(2):473-482.
- 38. Dawes AJ, Sacks GD, Russell MM, Lin AY, Maggard-Gibbons M, Winograd D, et al. Preventable readmissions to surgical services: lessons learned and targets for improvement. J Am Coll Surg 2014; 219: 382-9.
- 39. Delgado-Rodríguez M, Bueno-Cavanillas A, López-Gigosos R, de Dios Luna-Castillo J, Guillén-Solvas J, et al. Hospital stay length as an effect modifier of other risk factors for nosocomial infection. Eur J Epidemiol 1990; 6:34-9.

- 40. McPhee JT, Barshes NR, Ho KJ, Madenci A, Ozaki CK, Nguyen LL, et al. Predictive factors of 30-day unplanned readmission after lower extremity bypass. J Vasc Surg 2013; 57: 955-62.
- 41. Morris MS, Graham LA, Richman JS, et al. Postoperative 30-day readmission: time to focus on what happens outside the hospital [published October 26, 2016]. Ann Surg. 264(4):621-631.

ANNEXURE -1

STUDY PROFORMA

Demographic Data	
NAME	:
ADDRESS	:
AGE/SEX	:
HOSPITAL No.	:
TELEPHONE NO	:
DATE OF ADMISSION	:

Comorbidities :

Diabetes -			Duration			
Yes No			Treatment	-	OHA	Insulin
Hypertension		Yes		No	Duration On	medication
Renal		Yes		No		
Bleeding Tendencie	s 🗆	Yes		No		
Dyslipidaemias		Yes		No		
Cardiac		Yes		No		
Social History:						
Tobacco:	No		Yes 🖂 I	Duration	n 🖂 Ex-sm	oker
Alcohol	No 🗆		Yes 🗆 I	Duratio	n	

Index admission Data

CLI Category(4/5/6)	
Procedure (Open/Endovascular/Hybrid)	
CO ₂ use (Yes/No)	
Conduit for bypass (Vein/ Dacron/ PTFE)	
Wound care	
Emergency/Elective	
Technical Success	
MALE	
MACE	
SSI	
Blood Transfusion	
AKI	

Readmission Data

Days after index admission	
Index procedure related (Yes/No)	
Planned / Unplanned	
Reason for Readmission (Medical / Surgical)	
If Surgical (Open/ Endovascular/ Hybrid/ Wound-care)	
Length of Stay (in days)	

Follow up after at 6months

MALE	
MACE	
Mortality	

ANNEXURE -2

PATIENT CONSENT FORM

Study title: A study for defining the types and determining the risk factors for readmission following revascularization for critical limb ischemia (CLI).

Study site: Jain Institute of Vascular Sciences, Bhagwan Mahaveer Jain Hospital, Bangalore.

I have been explained about the nature of the study. I have been explained that the study identifies risk factors for readmission after revascularization for Critical Limb Ischemia and provides a simple predictive risk score that accurately identifies patients at high risk for readmission.

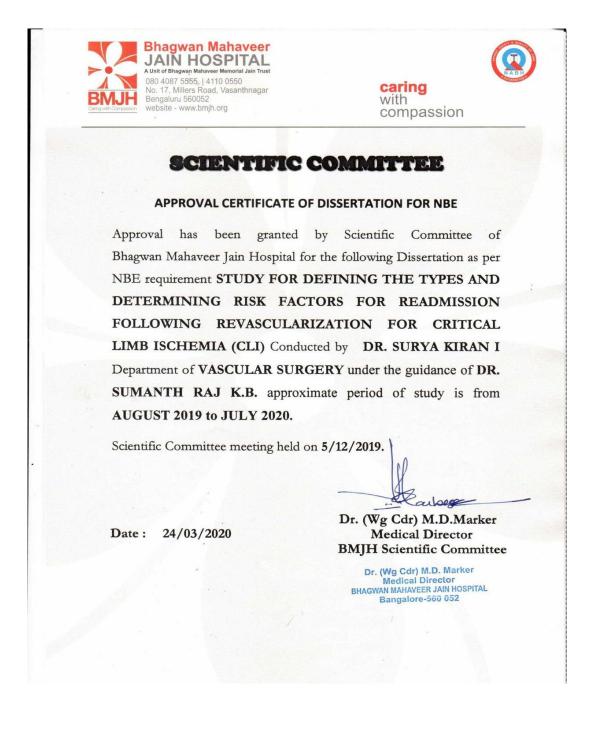
I have been read to about and understand the purpose of the study, type of study, risk and benefits associated with my involvement. I have been given the opportunity to ask questions regarding various aspects of the study. I understand that confidentiality is maintained in patient details. The information collected is only for research. I also understand that I am free to withdraw from the study at any point of time and standard of care provided to me does not change if I am quitting/not willing to take part in the study.

I the undersigned agree to voluntarily participate in this study and authorize the collection and disclosure of my personal information for the purpose of research.

Date:
Date:
Date:
D

ANNEXURE – 3

SCIENTIFIC COMMITTEE APPROVAL



ANNEXURE – 4

ETHICS COMMITTEE CERTIFICATE



ANNEXURE – 5

MASTERCHART