

**STUDY OF MODIFIED SOCIETY OF VASCULAR SURGERY
RUNOFF SCORE AS PREDICTOR OF CLINICAL
OUTCOMES AFTER ENDOVASCULAR INTERVENTIONS
FOR SUPERFICIAL FEMORAL ARTERY DISEASE IN
CHRONIC LIMB THREATENING ISCHEMIA.**

By

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

In partial fulfillment of the requirements for the degree of

DNB Super-specialty

In

PERIPHERAL VASCULAR AND ENDOVASCULAR SURGERY

Under the guidance of

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DECLARATION CUM UNDERATKING FOR FRESH THESIS

I Dr. Ishita Mukund Jethwa hereby declare that this thesis entitled

**“STUDYOF MODIFIED SOCIETY OF VASCULAR SURGERY
RUNOFF SCORE AS PREDICTOR OF CLINICAL
OUTCOMES AFTER ENDOVASCULAR INTERVENTIONS
FOR SUPERFICIAL FEMORAL ARTERY DISEASE IN
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is ‘bonafide’ in nature and was carried out by me for under the guidance and supervision of my guide Dr. Vivekanand . 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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is a bonafide and genuine research work carried out by me under the guidance and supervision of **Dr. Vivekanand**, 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 DrNB in Peripheral Vascular Surgery.

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

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TABLE OF ABBREVIATIONS AND ACRONYMS:

ABI - Ankle-brachial index
AI - Aortoiliac
AKA - Above-knee amputation
AP - Ankle pressure
AT - Anterior tibial
BKA - Below-knee amputation
BMI - Body mass index
CAD - Coronary artery disease
CE-MRA - Contrast-enhanced MRA
CFA - Common femoral artery
CKD - Chronic kidney disease
CLI - Critical limb ischemia
CLTI - Chronic limb-threatening ischemia
CT - Computed tomography
CTA - Computed tomography angiography
CTO - Chronic total occlusion
CVD - Cardiovascular disease
DAPT - Dual antiplatelet therapy
DCB - Drug-coated balloon
DES - Drug-eluting stent
DFU - Diabetic foot ulcer
DM - Diabetes mellitus
DP - Dorsalis pedis
DSA - Digital subtraction angiography
DUS - Duplex ultrasound
EBR - Evidence-based revascularization
ESVS - European Society for Vascular Surgery
FP - Femoropopliteal
GLASS - Global Limb Anatomic Staging System

GSV - Great saphenous vein
IC - Intermittent claudication
IP - Infrapopliteal
LBP - Limb-based patency
MACE - Major adverse cardiovascular event
MALE - Major adverse limb event
MRA - Magnetic resonance angiography
PAD - Peripheral artery disease
PBA - Plain balloon angioplasty
PFA - Profunda femoris artery
PSV - Peak systolic velocity
PT - Posterior tibial
PVR - Pulse volume recording
RCT - Randomized controlled trial
SFA - Superficial femoral artery
SVS - Society for Vascular Surgery
TBI - Toe-brachial index
TcPO₂ - Transcutaneous oximetry
TP - Toe pressure
WFVS - World Federation of Vascular Societies
WIFI - Wound, Ischemia, foot Infection

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ABSTRACT

TITLE: “ Study of Modified Society of Vascular surgery runoff score as predictor of clinical outcomes after Endovascular interventions for Superficial Femoral Artery disease in Chronic Limb Threatening Ischemia .”

AIMS and OBJECTIVES:

To analyze the role of modified SVS runoff score as predictor of outcome in patient with CLTI undergoing endovascular intervention for Superficial Femoral Artery.

PRIMARY OBJECTIVE : Amputation free survival

SECONDARY OBJECTIVE :

1. Restenosis
2. Major adverse limb event
3. Major adverse cardiac event

MATERIALS and METHODS: This is a single center, prospective, observational and longitudinal study carried out at Jain Institute of Vascular Sciences (JIVAS), Bhagwan Mahaveer Jain Hospital, Bangalore. Total of 140 patients with CLTI who underwent successful Endovascular for SFA with or without Iliac/ Tibial vessel angioplasty at JIVAS between August 2022 to July 2023 were included in the study and followed prospectively at 1, 3 and 6 months as per study protocol. The endovascular intervention was carried out on the patients in accordance with established recommendations and the surgeon's personal preference and his clinical acumen. At the end of the follow up period we assessed the outcomes, i.e., Clinical and Hemodynamic improvement, Restenosis rates, Amputation free survival ,MALE and MACE .

RESULTS: The study included 140 patients between the ages 32 to 96 with a mean age of 68.8 ± 11.4 years. 70% patients were males. Most common comorbidity noted was diabetes mellitus (85.7%) followed by hypertension (71.4%), CAD (35%), CKD (10.71%).

. 27% patients were smokers. According to Rutherford classification, we had 6.3% Category 4 patients, 73.5% category 5 patients and 26.4% category 6 patients. The number of patients with Wifl stage 1, 2, 3, and 4 was 0 (0%), 14 (10%), 35(11.4%) and 89 (21.4%) respectively. The number of patients with GLASS stage I, II, and III was 7(5%), 96 (68.6%), and 37 (26.4%), respectively.

According to Modified SVS runoff scoring system calculated based on DSA, 4 (2.9%) patients in Good category, 50 (35.7%) patients in compromise category, 86 (61.4%) patients in category. Out of 140 patients, 89 (63.5%) underwent SFA Plain Balloon Angioplasty, SFA stenting done for 51 (36.5%) patients, 90 (64.2%) patients concomitant Tibial angioplasty was done, 10 (7.14%) patients concomitant iliac angioplasty/ stenting was done.

At the end of 6 months, 10 (8.13%) died, 12(9.7%) had major amputations and 17(12.14%) were lost to follow-up. AFS was 100%, 84%, 79% in good, compromise and poor category which was statistically significant.

CONCLUSIONS:

- Poor Modified SVS run off score adversely affects the AFS and overall survival.
- The Good score had low Restenosis rate , improved amputation Free survival.
- While planning a revascularization procedure for a patient with CLTI it is crucial to consider patient's comorbidities, complete clinical profile, severity of wound status and vascular lesion in order to provide the best possible therapeutic option.

INTRODUCTION

Peripheral arterial disease (PAD) represents a spectrum from asymptomatic stenosis to limb-threatening ischemia. The last decade has seen a tremendous increase in the variety of endovascular devices and techniques used to treat occlusive disease.

In the United States, PAD is estimated to affect around 7% of the population, equating to approximately 8.5 million adults ¹. In India, the prevalence of PAD ranges from 5% to 25% ².

PAD can be classified into four clinical stages: Asymptomatic, Chronic Symptomatic (which includes Intermittent Claudication), Chronic Limb-Threatening Ischemia (CLTI), and Acute Limb Ischemia. Among these stages, Asymptomatic PAD is the most prevalent, while CLTI is the most severe.

Chronic Limb-Threatening Ischemia signifies an advanced stage of PAD, and its prevalence is on the rise globally. This increase contributes to higher morbidity and mortality rates, escalating healthcare costs, and a detrimental effect on quality of life (QoL) and functional status.

CLTI is characterized as a clinical syndrome that arises when PAD is accompanied by rest pain, gangrene, or lower limb ulceration lasting more than two weeks, while excluding conditions related to venous issues, trauma, embolism, or nonatherosclerotic factors ³.

It has been estimated that CLTI develops in $\approx 11\%$ of patients with PAD, with population estimates placing this number at $\approx 1.28\%$ of the adult population over the age of 40 years or ≈ 2 million individuals ⁴.

The management of patients with CLTI requires a multidisciplinary approach involving vascular surgeons, podiatrists, wound care specialists, and rehabilitation professionals. Treatment strategies include medical management to address underlying comorbidities, revascularization through endovascular or surgical methods, and comprehensive wound care. Patients with CLTI face an increased risk of cardiovascular events and mortality, highlighting the necessity for thorough management.

AIMS AND OBJECTIVE :

To analyze the role of modified SVS runoff score as predictor of outcome in patient with Chronic Limb Threatening Ischemia undergoing endovascular intervention for Superficial Femoral Artery.

PRIMARY OBJECTIVE :

Amputation free survival (AFS)

SECONDARY OBJECTIVE :

4. Restenosis
5. Major adverse limb event (MALE)
6. Major adverse cardiac event (MACE)

REVIEW OF LITERATURE

SUPERFICIAL FEMORAL ARTERY(SFA):

The SFA is defined as “ extending from the femoral triangle , starting at the common femoral artery bifurcation, inferiorly through the adductor canal (AC) where it truncates at the adductor hiatus (AH), the exit from AC and continue as Popliteal Artery .

Special characteristics of Superficial femoral artery ⁵:

- **Length** : longest artery in the body with fewer side branches.
- **Location** : it is fixed between the hip and the knee joint . Also the artery dives through the AC ,marked by the junction of aponeurosis of vastus medialis , the adductor longus and the sartorius muscle.
- **Geometric forces**: As a result of complex motion of knee and hip joints the SFA is subject to unique forces including flexion, elongation and torsion. The SFA is further exposed to longitudinal and lateral compressional forces and even extrinsic muscular compression as the artery dives through the AC , during contraction of muscles.
- The magnitude of mechanical stressors that it is exposed to, the SFA has a particularly prominent smooth muscle layer that allows it to withstand these forces.
- Low shear stress in SFA in adductor canal , predisposes frequent atherosclerotic lesion in this region.

These unique characteristics make SFA lesions challenging to treat.

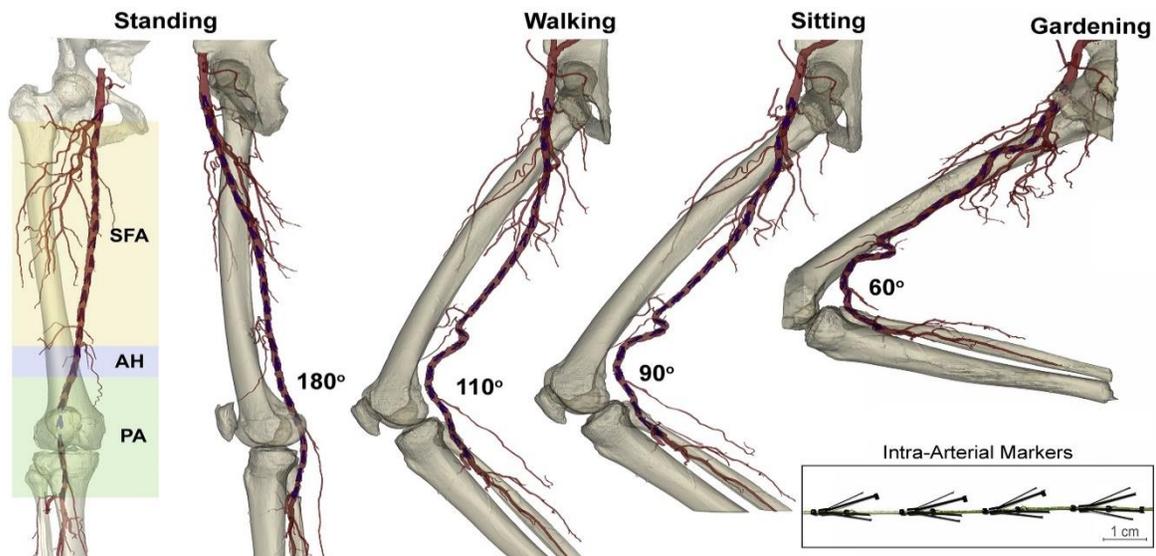


Figure 1 :Computed tomography (CT) of the limb flexion states demonstrating standing (180 degrees), walking (110 degrees), sitting (90 degrees), and gardening (60 degrees) postures. Bending angle is defined as the inner angle between the femur and tibia. Note severe deformations at the adductor hiatus (AH) and below the knee. Intra-arterial markers are blue. PA, Popliteal artery; SFA, superficial femoral artery ⁶.

ATHEROSCLEROSIS IN PERIPHERAL ARTERIES:

Morphological characteristics of atherosclerotic plaques in peripheral arteries differ from lesions in coronary and carotid arteries.

Plaques in SFA have more fibrotic component , less lipids and inflammatory cells, which make them more stable and less prone to rupture .

Factors that determine the different structure of plaque in SFA compared to coronaries include hemodynamic forces , vasa vasorum and calcification ⁸.

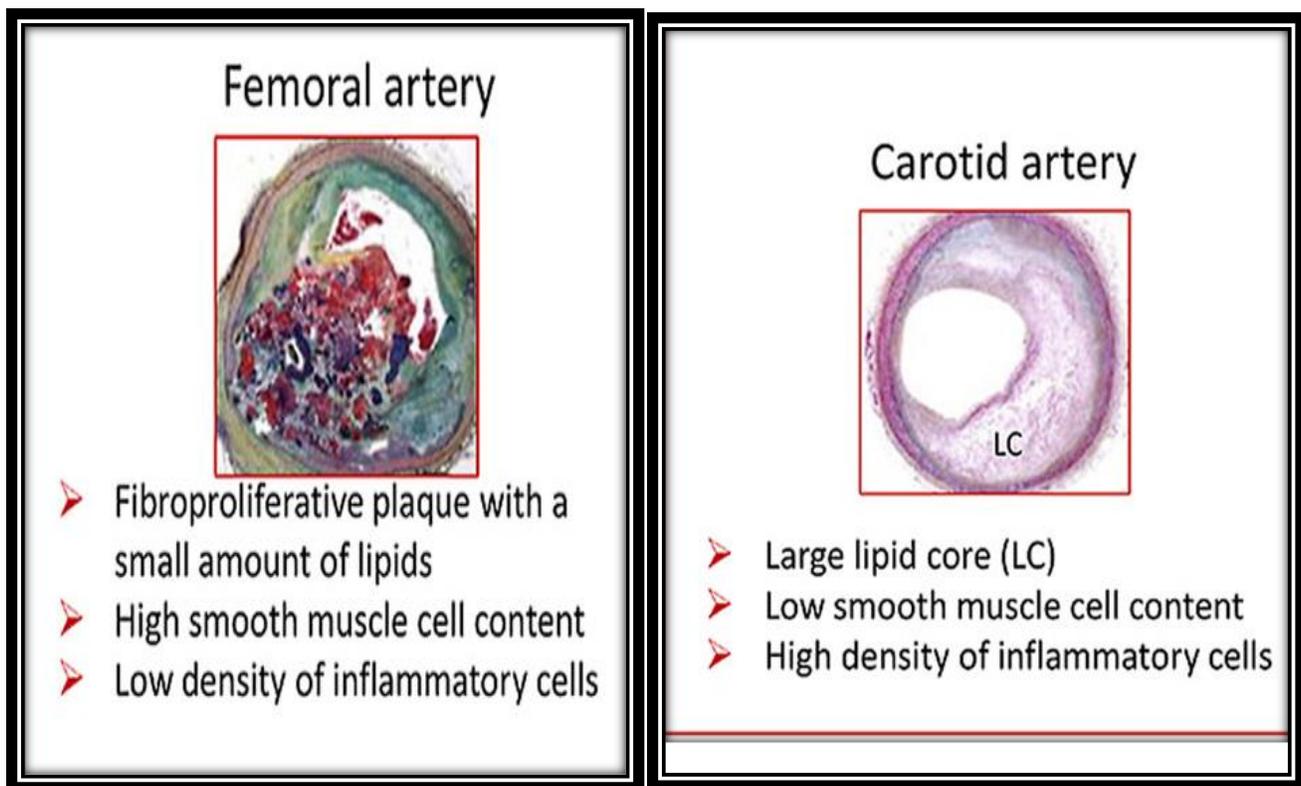


Figure 2 : Atherosclerotic plaque in femoral artery vs carotid artery ⁷.

The age adjusted prevalence of SFA atherosclerosis is 4%-15% and increases up to 30% with the age and in the presence of cardiovascular risk factors ⁷.

Results of endovascular repair vary according to the arterial bed , i.e result of stenting for carotid , coronary and peripheral arteries is different, these differences are related to distinguished plaque features in each of the vessel.

RISK FACTORS FOR SFA ATHEROSCLEROSIS :

PAD and Coronary Artery Disease (CAD) share most of the risk factors including smoking , diabetes, hyperlipidaemia , hypertension, and chronic renal insufficiency , but contribution of each factor to atherogenesis is different.

Smoking is a stronger risk factor for the development and progression of PAD than it is for CAD. Diabetes and smoking are the strongest risk factors and are associated with faster progression of PAD.

Clinical manifestations of atherosclerosis in other vascular beds (coronary and cerebral arteries) is the major determinant of prognosis in PAD. There is a 2-4 fold increase in coronary and cerebrovascular disease in patients with PAD. There is high Cardiovascular mortality in both asymptomatic and symptomatic PAD . Hence , all patients with CLTI should receive best medical therapy including Antithrombotic, lipid- lowering , Antihypertensive and Glycaemic control agents, as well as counselling on smoking cessation , diet , exercise and preventive foot care.

IMAGING MODALITIES

Digital subtraction angiography (DSA):

DSA is a fluoroscopic technique used for visualization of blood vessels. Radiopaque structures such as bones are digitally eliminated ("subtracted") from the image, thus allowing for an accurate depiction of the blood vessels. It is the gold standard for evaluation of the degree of stenosis and other features in PAD.

The Anatomic characteristics of the index lesion affect outcomes, and response to endovascular interventions.

Anatomic (angiographic) disease description in PAD patients needs a scoring system that is sensitive to differences in femoropopliteal and infrapopliteal artery disease.

Reporting standards as per Society of Vascular surgery SVS scoring systems used for anatomic characterization⁹ :

1. BOLLINGER SCORE:

The Bollinger scoring system consists of an additive score describing the severity of the lesions visualized on angiography within each study segment¹⁰.

The lesions are categorized in four groups:

Table 1: Bollinger Scoring matrix

Bollinger scoring matrix ^a				
Occlusion	Severity			Extent of disease
	Stenosis >50%	Stenosis 25%-49%	Plaques <25%	
13	4	2	1	Single lesion
	5	3	2	Multiple lesions affecting less than half the segment
15	6	4	3	Multiple lesions affecting more than half the segment

The score assigned is higher when the lesion is more severe.

The Bollinger score takes into account the most severe lesion and dictates that in the presence of occlusions, other lesions should not be considered; similarly, when both categories of stenoses (50%) are present, milder lesions, such as plaques, are not scored.

The Bollinger system appears well suited for detecting the difference between femoropopliteal and infrapopliteal disease.

A recent analysis of the Bypass vs Angioplasty in Severe Ischaemia of the Leg (BASIL) trial showed the below-knee Bollinger score appeared to discriminate better between individuals than the above-knee score¹¹.

2. MODIFIED SVS RUNOFF SCORE:

The modified SVS runoff score is calculated from angiographic images.

This score ranges from 0 to 19, with a higher score indicating more severe disease, and is calculated by assessing the patency and degree of stenosis/occlusion in the popliteal artery and the three tibial vessels.

A score of 0 is assigned to a vessel with <20% stenosis, a score of 1 for a 21% to 49% stenosis, 2 for 50% to 99% stenosis, 2.5 for a vessel occluded over an area less than half its length, and 3 for an occlusion greater than half the vessel length.

The score for the popliteal artery is multiplied by 3 and a value of 1 is added before adding all 4 vessel scores together, giving a range of possible popliteal artery scores from 1 to 10.

Three runoff score groups were identified: 5 (Good), 5-10 (Compromised), and >10 (Poor) and these groups were used for analysis in this study ¹⁰.

Table 2: Modified SVS Runoff score.

SCORE	LESION
0	<20% stenosis
1	21% to 49% stenosis
2	50% to 99% stenosis
2.5	vessel occluded over an area less than half its length
3	occlusion greater than half the vessel length.

- 3) **TASC II:** is a set of guidelines for managing PAD that was last updated in 2007.
 Lesion Stratification : lesions are divided in to 4 categories

The Trans Atlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) classification appears to have significant limitations in this patient group due to lack of reproducibility and definition of crural disease ¹².

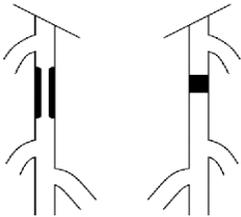
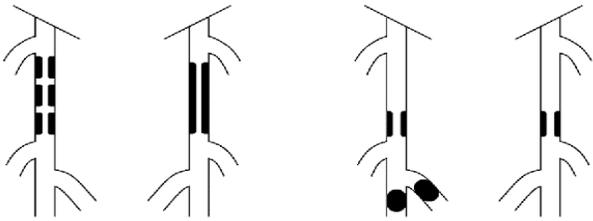
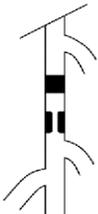
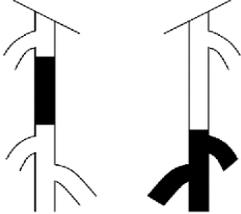
<p>TASC A lesions</p> <ul style="list-style-type: none"> • Single stenosis ≤ 10 cm in length • Single occlusion ≤ 5 cm in length 	
<p>TASC B lesions</p> <ul style="list-style-type: none"> • Multiple lesions (stenoses or occlusions), each ≤ 5 cm • Single stenosis or occlusion ≤ 15 cm not involving the infrageniculate popliteal artery • Heavily calcified occlusion ≤ 5 cm in length • Single popliteal stenosis 	
<p>TASC C lesions</p> <ul style="list-style-type: none"> • Multiple stenoses or occlusions totaling >15 cm with or without heavy calcification • Recurrent stenoses or occlusions after failing treatment 	
<p>TASC D lesions</p> <ul style="list-style-type: none"> • Chronic total occlusions of CFA or SFA (>20 cm, involving the popliteal artery) • Chronic total occlusion of popliteal artery and proximal trifurcation vessels 	

Figure 3 : Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC) classification of femoral popliteal lesions. CFA: common femoral artery; SFA: superficial femoral artery

Each category has a recommended initial treatment:

- Type A- Endovascular treatment
- Type B- Endovascular treatment with qualifications
- Type C-Open surgical (with qualifications)
- Type D- open surgical.

4.CALCIUM SCORE:

Lesion calcification has been recognized to have a potential effect on procedural technical success as well as midterm and long-term outcomes. It has been implicated in procedural embolic complications, stent fracture, and restenosis.

Noting the degree of calcification and its distribution is recommended. Scoring requires CT Angiogram or multiplanar DSA imaging of the vessel segment to accurately determine the extent of calcification. Although calcium scoring has not been validated for outcome after intervention, its effect on patency and procedural success has been recognized¹³.

If calcifications are present, they should be noted, the location should be specified, and the severity classified.

Calcification severity can be categorized as :

CALCIUM SCORE
NONE
<50% CIRCUMFERENCE – MILD
25%-50%- MODERATE
>50%- SEVERE

Table 3: Calcification severity

5.LESION LENGTH

Restenosis is the main drawback of endovascular peripheral interventions, particularly for long SFA lesions.

This is also reflected in the TASC II guide lines preferentially recommending the use of percutaneous transluminal angioplasty for short lesions.

Long calcified lesions have also been demonstrated to affect therapeutic options, because this has resulted in a rather high rate of secondary stenting owing to suboptimal results of balloon angioplasty alone.

Validation of lesion length as a determinate for infrageniculate interventional success has not been widely addressed in the literature, although it is an accepted factor¹⁴.

Lesions length should be categorized:

Table 4: Lesion length

< 6 cm	Short lesion
7 to 10 cm	Intermediate lesion
>10 cm	Long lesion

Chronic Limb Threatening Ischemia (CLTI) AND Critical Limb Ischemia (CLI):

The term “critical limb ischemia” (CLI) was first coined at the Working Party of the International Vascular Symposium held in 1981.

Critical Limb Ischemia (CLI) is defined as:

1. Ischemic rest pain with an ankle pressure (AP) <40mmHg or
2. Tissue necrosis with AP <60mmHg in patient without Diabetes Mellitus.
3. ABI <0.5

This definition specifically excluded patients with diabetes because of the confounding effects of neuropathy and susceptibility to infection. But these patients with PAD have increased prevalence of diabetes 50-70%, who present with neuroischemic foot ulcers. This definition failed to include a large group of patients who were at risk of amputation .

The term Chronic Limb Threatening Ischemia- CLTI was proposed to include a wider cohort of patients who are at a risk of limb amputation owing to delayed wound healing due to varying degrees of ischemia ¹⁵.

Chronic limb-threatening ischemia (CLTI) was defined as objectively documented atherosclerotic PAD in association with ischemic rest pain or tissue loss (ulceration or gangrene), present for >2 weeks and associated with one or more abnormal hemodynamic parameters such as:

1. Ankle-brachial index (ABI) <0.8
2. Absolute highest Ankle Pressure < 50mmHg, and
3. Absolute Toe Pressure <30mmHg,
4. Transcutaneous partial pressure of oxygen (TcPO₂) <30mmHg,
5. Flat or minimally pulsatile pulse volume recording (PVR) waveforms (equivalent to Wifi ischemia grade 3).

In patients with DM or End Stage Renal Disease , toe waveforms and systolic pressures are preferred. In this study we have taken the patients defined under CLTI.

CLTI SEVERITY AND RISK STRATIFICATION : THE WIfI CLASSIFICATION

The classification was developed in 2013 and proposed in SVS publication in 2014, it covers three most important parameters that put a limb at risk of amputation: Wound, Ischemia and foot infection.

WIfI classification has been proposed as the initial assessment of all patients with ischemic rest pain or wounds . The severity of limb threat is classified based on grading of Wounds, Ischemia, and foot Infection ¹⁶.

SVS grades for rest pain and wounds/tissue loss (ulcers and gangrene): 0 (ischemic rest pain; no ulcer) 1 (mild) 2 (moderate) 3 (severe)

Table 5: Wound Assessment

Grade	Ulcer	Gangrene
0	No ulcer	No gangrene
Clinical description: ischemic rest pain (requires typical symptoms + ischemia grade 3); no wound.		
1	Small, shallow ulcer(s) on distal leg or foot; no exposed bone, unless limited to distal phalanx	No gangrene
Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage		
2	Deeper ulcer with exposed bone, joint or tendon; generally not involving the heel; shallow heel ulcer, without calcaneal involvement	Gangrenous changes limited to digits
Clinical description: major tissue loss salvageable with multiple digital amputations or standard TMA.		

3	Extensive, deep ulcer involving forefoot and/or midfoot; deep, full thickness heel ulcer +/- calcaneal involvement	Extensive gangrene involving forefoot and /or midfoot; full thickness heel necrosis +/- calcaneal involvement
Clinical description: Extensive tissue loss salvageable only with a complex foot reconstruction or non-traditional TMA (Chopart or Lisfranc); flap coverage or complex wound management needed for large soft tissue defect.		

TMA-
Trans-

metatarsal amputation.

I: Ischemia:

Hemodynamics/perfusion: Measure TP or TcPO₂ if ABI noncompressible (>1.3)

SVS grades 0 (none), 1 (mild), 2 (moderate), and 3 (severe).

Table 6 : Ischemia Grades

Grade	ABI	Ankle Systolic Pressure	TP/TcPO ₂
0	≥ 0.80	> 100mmHg	> 60mmHg
1	0.6-0.79	70-100mmHg	40-59mmHg
2	0.4-0.59	50-70mmHg	30-39mmHg
3	≤ 0.39	< 50mmHg	< 30mmHg

ABI- Ankle-brachial index; PVR- pulse volume recording; TP- toe pressure; TcPO₂- transcutaneous oximetry.

Patients with Diabetes Mellitus should have TP measurements.

FI: foot Infection:

SVS grades 0 (none), 1 (mild), 2 (moderate), and 3 (severe: limb and/or life-threatening)

Table 7: Foot Infection Grades

Clinical manifestation of infection	Grade
No symptoms or signs of infection. Infection present, as defined by the presence of at least 2 of the following items: 1. Local swelling or induration. 2. Erythema > 0.5 to \leq 2 cm around the ulcer. 3. Local tenderness or pain. 4. Local warmth. 5. Purulent discharge	0
Local infection involving only the skin and the subcutaneous tissue	1
Local infection (as described above) with erythema >2 cm, or involving structures deeper than skin and subcutaneous tissues (e.g., abscess, osteomyelitis, septic arthritis, fasciitis).	2
Local infection (as described above) with the signs of systemic inflammatory response syndrome (SIRS)	3

Amputation risk according to Wifl category

In the Delphi Consensus, each member was asked to assign a limb threat clinical stage to each of the 64 theoretical patient combinations that would correlate with risk of amputation (stage 1 - very low; stage 2 - low; stage 3 - moderate; and stage 4 - high).

In general, risk of amputation was believed to increase as one proceeds down and to the right (increasing severity of each of the individual Wifl score components).

	Ischemia – 0				Ischemia – 1				Ischemia – 2				Ischemia – 3			
W-0	VL	VL	L	M	VL	L	M	H	L	L	M	H	L	M	M	H
W-1	VL	VL	L	M	VL	L	M	H	L	M	H	H	M	M	H	H
W-2	L	L	M	H	M	M	H	H	M	H	H	H	H	H	H	H
W-3	M	M	H	H	H	H	H	H	H	H	H	H	H	H	H	H
	fl-0	fl-1	fl-2	fl-3												

Four classes: for each box, group combination into one of these four classes



Fig 5. Amputation risk as per Wifl.

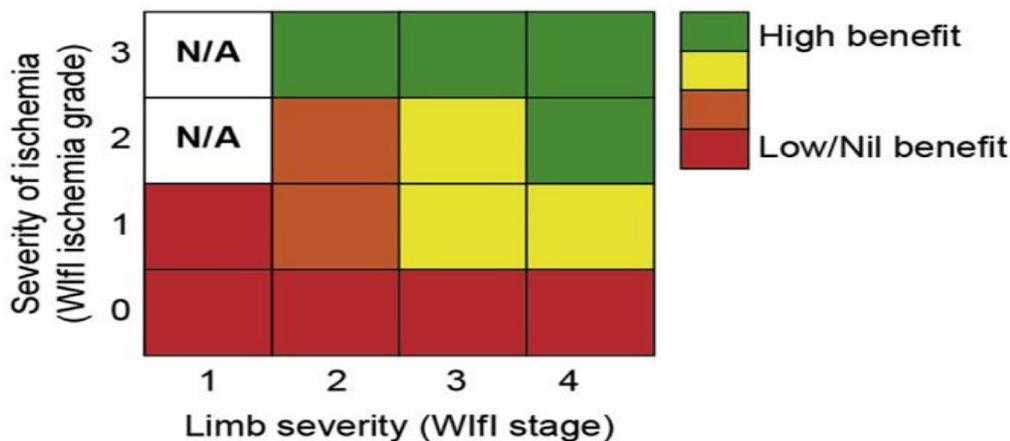


Fig 6. Benefit of revascularization as per Wifl

Patients with lesser degree of tissue loss i.e., Wifl stage 1 to 3 with mild to moderate ischemia, can be given a trial of infection control and wound and podiatry care. Revascularization may be considered in these patients if the wound fails to heal after 4-5weeks despite appropriate limb ca

TREATMENT OPTIONS FOR CLTI:

a) MEDICAL MANAGEMENT

The medical management includes

1. Antithrombotic agents,
2. Lipid-lowering agents,
3. Diet and exercise therapy,
4. Effective management of comorbidities like diabetes and hypertension,
5. Lifestyle modification,
6. Smoking cessation
7. Pain management.
8. Foot care and Modified preventive footwear .

b) REVASCULARISATION

Available options :

1. Endarterectomy
2. Open bypass surgery
3. Endovascular
 - Plain Balloon Angioplasty
 - Stenting
 - DEB
 - DES
 - Covered stent
 - Atherectomy
4. Hybrid procedures.

The choice between endovascular intervention and open bypass needs to be individualized for every patient depending on their risk profile, the condition of their wounds, and the type of vascular lesion while also taking into account the availability of a good-caliber Great Saphenous Vein either from the same or the contralateral limb.

The treatment for CLTI with Endovascular vs Open Surgery is an ongoing debate since ages, but no specific guidelines have been published which will help in the decision making, which considers all the factors .

The patient who are likely to life expectancy two years are better served by a bypass surgery-first preferably with vein. For patients who have life expectancy less than two years , or for whom vein is not available for bypass, a balloon angioplasty-first strategy is better .

The use of SFA angioplasty, with or without stenting, is becoming increasingly common, reflecting a more assertive approach to treating all TASC lesions. It is generally accepted that TASC A and TASC B lesions are appropriate for endoluminal treatment. In contrast, the use of endovascular therapy for TASC C and D lesions is still debated, with many specialists recommending surgical interventions for these cases.

However, due to improvements in endovascular techniques and devices, most interventionalists now favor an endovascular-first approach for these lesions, largely because of the reduced morbidity associated with such procedures.

Several factors affect the outcomes of endovascular interventions for SFA, including age, ethnicity, smoking status, diabetes, chronic kidney disease, lesion length and location, calcification, and distal runoff. Technical aspects such as subintimal and endoluminal angioplasty, dissection length, the use of drug-coated balloons (DCB), drug-eluting stents (DES), stent application, and the number of stents used are also crucial. While various studies have explored individual or multiple factors, there is currently no comprehensive research that addresses all these variables together.

c) **AMPUTATION.**

A significant proportion of CLTI patients present with severe disease, high grade infection or sepsis, or a non-constructible lesions, wherein the limb salvage is questionable, In these patients primary amputation is the treatment ¹⁸. Primary major amputation rates in patients unsuitable for revascularization are high (20-25%) ¹⁹.three conditions have been listed as the traditional grounds for amputation.

A)Dead limb i.e., advanced gangrene,

B)Deadly-limb i.e., wet gangrene

C) Dead-loss limb i.e., severe rest pain with non-reconstructible CLTI.

Review of World Literature.

Sadettin Karacagil et al in 1989 studied postoperative predictive value of Intraoperative angiographic assessment of runoff in femoropopliteal bypass grafting. 96 patients were investigated with intraop post-reconstruction angiography, which also took into account the foot vessel runoff.

Results of life-table analysis showed significantly higher patency rates in limbs with good runoff than in those with poor runoff. The difference in patency rates between vein (80%) and prosthetic graft (56%) was also significant. Among saphenous vein grafts, good runoff fared significantly better than those with poor runoff, with 12-month patency rates of 90% and 34%, respectively ($p < 0.001$). The use of prosthetic grafts resulted in a patency rate of 62% at 12 months in limbs with good runoff, compared with 38% in the group with poor runoff, but this difference was not statistically significant. A group of limbs at high risk of early occlusion after femoro-popliteal bypass can be predicted on the basis of new and simple intraoperative angiographic criteria for assessment of distal runoff¹⁹.

DeCarlo et al. in 2021 studied the association between the SVS femoral runoff score and limb-based patency outcomes in patients undergoing aortofemoral bypass surgery. They analysed 161 patients who underwent aortofemoral bypass (AFB), resulting in 316 revascularized limbs. Patients with a high runoff score (≥ 6) showed significantly different outcomes, including a higher incidence of postoperative myocardial infarction (11% vs. 1%) and respiratory failure (11% vs. 1%). They also had a higher 30-day mortality (8% vs. 0%). Overall, the study underscores the importance of the SVS femoral runoff score in predicting limb-based patency and guiding preoperative planning in aortofemoral bypass surgery²⁰.

The runoff score serves as an indicator of outflow resistance for bypass grafts. Greater disease in runoff vessels leads to higher resistance, slower flow velocities, and increased thrombosis rates. Poor runoff has been linked to graft and stent failures in various revascularization procedures, including iliac and femoropopliteal bypass.

In above both studies the SVS runoff score has been used as a predictor of outcome following bypass procedure. It has been proved that Poor runoff negatively affects the graft patency. The application of this score for endovascular interventions has not been studied much however, there are few studies where Modified SVS runoff score has been used as a predictor for outcome following SFA endovascular intervention.

Mark G Davies et al studied the impact of distal runoff on long-term outcomes of SFA endoluminal interventions for rest pain and tissue loss. They analyzed 306 limbs from 241 patients (57% male, average age 68) undergoing SFA interventions for critical ischemia (44% rest pain, 56% tissue loss). Patients were classified based on the quality of Modified SVS distal runoff into three groups: Good (< 5), Compromised (5-10) and Poor (> 10). The technical success rate was 96%, with most procedures involving angioplasty (61%) and primary stenting (37%). Long term outcomes showed: at 5 years, patency rates were significantly worse for patients with compromised (56%) and poor runoff (52%) compared to good runoff (82%). Freedom from recurrent symptoms and limb salvage rates also declined with worsening runoff: 65% for good, 39% for compromised, and 18% for poor runoff in terms of recurrent symptoms; and 65%, 41%, and 20% for limb salvage, respectively. The study concludes that compromised and poor distal runoff

significantly adversely affects the patency of SFA interventions in patients with rest pain and tissue loss. These findings align with existing literature on bypass grafts, indicating that runoff quality is critical for long-term success in endoluminal therapies for critical limb ischemia ²¹.

Hiramori et al. investigated the "runoff grade," a novel method for evaluating post-endovascular therapy (EVT) outcomes in patients with femoropopliteal lesions. Analyzing data from 859 patients (mean age 73) who underwent EVT, the researchers classified tibial runoff into three grades (0-2) based on angiographic findings and assessed its correlation with patency and adverse events over a mean follow-up of 31 months. Results showed Primary Patency Rate: Significantly lower in patients with runoff grade 0 compared to grades 1 and 2 at 1, 2, and 3 years. Secondary and Assisted Primary Patency Rates: Also lower in grade 0 patients, indicating worse outcomes. Freedom from Major Adverse Limb Events (MALE): Markedly reduced in the grade 0 group. The runoff grade emerged as an independent predictor of primary patency. The study concludes that a lower runoff grade is associated with poorer long-term outcomes following EVT, highlighting its importance in predicting therapy success ²².

Mohamed Elsharkawi et al. studied how runoff quality affects outcomes in endovascular interventions for superficial femoral artery (SFA) occlusive disease, particularly focusing on amputation-free survival and patency rates. A retrospective analysis was conducted on 220 patients who underwent SFA interventions for critical limb ischemia between 2011 and 2018. Patients were categorized by the Modified Society for Vascular Surgery (SVS) runoff score into three groups: Good: < 5, Compromised: 5-10, Poor: > 10. Outcomes measured included amputation-free survival, patency rates, and overall survival over five years. No significant differences in complication rates among the runoff categories, with an overall mortality of 3.5%. Patients with a good runoff score showed significant clinical improvement ($P < .001$). Five-year primary patency rates were 80% (good), 50% (compromised), and 22% (poor) ($P < .001$). Rates were 98% (good), 91% (compromised), and 78% (poor) at five years ($P < .001$). SFA stenting with tibial angioplasty improved patency in the poor runoff group. Poor runoff significantly correlates with lower amputation-free survival and patency rates after SFA interventions. Conversely, good runoff is associated with better clinical outcomes. This highlights the importance of assessing runoff quality in treatment planning for chronic limb ischemia ²³.

Noh B G et al evaluated the influence of the number and quality of infrapopliteal runoff vessels on the primary patency rates following superficial femoral artery (SFA) angioplasty with stenting in patients with claudication. A total of 153 limbs from 122 patients (88.2% male, mean age 69.1 years) were reviewed. The primary patency rates at 36 months were significantly different: 77.1% for TASC II A/B cases and 31.2% for C/D cases ($P < 0.001$). Using the modified SVS runoff scoring system, patency rates at 36 months were 64.6% for the good-to-compromised runoff group (≤ 9 points) and 49.8% for the poor runoff group (≥ 10 points) ($P = 0.011$). The modified SVS runoff scoring system effectively predicts primary patency after SFA angioplasty with stenting in patients with claudication, underscoring the importance of assessing infrapopliteal runoff vessels for better surgical outcomes. This study was done mainly for claudicants ²⁴.

LACUNAE IN LITERATURE

In India , the etiological aspects , diagnostic approaches , treatment modalities and other preventive measures for CLTI probably vary in different region. There are studies lacking wherein the CLTI population of India is studied , where there is more prevalence of Diabetes and severe wound status which adversely affect the limb salvage .

There are several studies in reported literature stressing on the role of SVS runoff score in predicting outcomes after bypass surgery. However, there are very few studies where the impact of modified runoff score on outcomes , in patients with CLTI undergoing SFA endovascular interventions is studied . Outcomes after endovascular interventions are based on multiple factors. Multiple studies have studied a particular risk factor , but there are no studies where in multiple risk factors affecting the Endovascular intervention outcomes are taken into consideration. Also they have studied the score for patients with CLI, but they have not studied for CLTI, where there is more severe PAD.

MATERIALS AND METHODS :

1) Study site :

This study was carried out at Jain Institute of Vascular Sciences (JIVAS), Bhagwan Mahaveer Jain Hospital , Bengaluru.

2) Study population:

Patients admitted with Chronic Limb Threatening Ischemia (CLTI) underwent successful Endovascular Intervention for SFA with or without concomitant Iliac/ Tibial vessel Angioplasty at JIVAS.

3) Study design:

A single centre , prospective , observational and longitudinal study.

4) Sample size:

calculated as per this formula

$$n = \frac{Z^2 * p * q}{d^2}$$

- p= Amputation free survival rate= 50%(Assumed)

$$q = 100 - P = 50\%$$

$$Z = Z \text{ score level of significance} = 1.96$$

$$d = \text{precision or allowable error} = 9\%$$

$$n = \frac{Z^2 * p * q}{d^2} = \frac{1.96^2 * 50\% * 50\%}{9^2} = \frac{9604}{81} = 118.56 \approx 119$$

the calculated sample size is 119, however 140 patients were enrolled in the study.

4) Time frame to address the study:

Recruitment Period: 1st August 2022 to 30th July 2023

Follow-up: 1, 3 and 6 months as per study protocol.

5) Inclusion criteria:

i) Age >18 years

ii) Patients with Chronic Limb threatening Ischemia (CLTI)who have undergone successful SFA revascularisation with or without Iliac / Infrapopliteal intervention.

CLTI is defined as a patient presenting with any of the following clinical signs or symptoms:

1. Ischemic rest pain
2. Gangrene involving any part of lower limb or foot
3. Non-healing ulcer on any part of the lower limb or foot

In addition to the following:

- a) With ABI \leq 0.8
- b) With decreased arterial flow documented by hemodynamic and imaging studies.

6) Exclusion Criteria:

- i) Previous vascular intervention either bypass or endovascular, in target limb
- ii) Acute limb ischemia
- iii) Embolic disease
- iv) Patients on immunosuppressants.
- v) Patient not willing to give consent.
- vi) Non- atherosclerotic chronic vascular conditions of the lower extremity (eg, vasculitis , Buerger disease , Radiation arteritis)
- vii) Allergy to iodinated contrast media

The Primary Endpoint : Amputation free survival

The Secondary Endpoint : MALE and MACE outcomes.

7) Methodology and Statistical method:

The study was conducted after obtaining clearance from The Institutional Ethics Committee and Institutional Scientific Committee. An informed consent was obtained from every patient included in the study. Cases were collected using piloted proformas meeting the objectives of the study. Patients were chosen as per the inclusion criteria mentioned above.

METHODOLOGY

Patient enrolment:

Demographic information of enrolled patients was collected through a comprehensive history and detailed physical examination conducted prior to surgery.

A) Preoperative:

- Demographics – Age, Sex
- Co morbidities – DM, HTN, IHD, CKD
- Tobacco use
- Routine baseline investigations (complete blood count, urea, creatinine and electrolytes, liver function test, PT – INR, aPTT, ECG ,2D Echo)

A thorough general physical and Local examination was performed on all patients.

- Meticulous documentation of the location of ulcers or gangrene , which could be on the toe , plantar surface , foot dorsum, heel or ankle.
- In case of multiple areas affected each area recorded separately. Patients were classified according to the level of Chronic ischemia using Rutherford-becker classification , risk stratification was conducted based on Wound, Ischemia and Foot Infection (WIFI) staging system.
- Documentation of vascular status of the both lower limb noted along with Non-invasive vascular lab measurement , which include ABI, TBI, PVR, AP , TP.
- Preop Imaging : Duplex ultrasound , CT Angiography, MR Angiography and MR Angiography with time-of-flight(TOF) sequences .
- Estimated Glomerular filtration rate was calculated for all patients

- Prior to procedure all patients were informed about the advantages and disadvantages of the intervention , and those who expressed willingness to proceed were included in the study.

B. Medical management:

- After admission Patients were started on IV hydration with 0.9% NaCl at 1 ml/kg/hr (0.5ml/kg/hr if ejection fraction was <40%) for 12 hours pre-procedure and for a minimum of 12 hours post-procedure based on the urine output.
- Empirical IV antibiotic as per wound burden / tissue loss and severity of infection. N-acetyl cysteine of 1200mg twice daily was started one day prior to procedure and continued for two days post procedure.
- All DM patients who were on oral hypoglycemic agents were switched over to regular insulin and strict glycemic control was ensured peri-operatively.
- All patients were started on aspirin 150mg once daily preoperatively and if the patient was already on double antiplatelets (aspirin + clopidogrel or aspirin + ticagrelol), they were continued. Post operatively all patients were put on dual antiplatelets (aspirin 150mg and clopidogrel 75mg or preoperative combination continued) once daily for a period of 1 months (3months in patients with inflow correction in the form of femoro-popliteal stenting).
- All patients received Statins (atorvastatin 20mg once daily or higher if dyslipidemic) or additional fibrates (based on fasting lipid profile) for 6 months.
- Non-steroidal anti-inflammatory drugs (NSAIDs) use was restricted for 2 days prior to the procedure. Medication for diabetes, hypertension, cardiac conditions and medical ailments were continued as per physician's advice. The analgesics were prescribed as per patient and procedure requirement.

C. Endovascular intervention:

- Non-ionic contrast media Iohexol 300mg per ml (Omnipaque®) or CO2 angiogram for indicated patients was used for imaging.
- Most of the procedures were carried out under local anaesthesia with monitored anaesthesia care (MAC) unless patient opted for general anaesthesia. Ultrasound guided femoropopliteal nerve blocks were used as the anaesthetic modality for CO2 angiograms. AngioSet CO2 gas delivery system was used for CO2 angiograms.

- All cases were done by 5 Consultant vascular surgeons with more than 10 years experience in open vascular and endovascular revascularisation.
- All patients underwent endovascular intervention using standard modified seldingers technique with either the contralateral femoral artery retrograde approach ,or the ipsilateral femoral artery antegrade approach or the brachial artery approach. If antegrade endovascular treatment failed in the process of antegrade recanalization of target lesions, retrograde puncture at the distal end of the lesion was considered for bidirectional recanalization.
- Systemic heparinisation was done at 50-80U/kg body weight and then 1000units IV for every passing hour. Initial digital subtraction angiogram was done for the femoral and the popliteal segment, followed by Infrapopliteal and foot vessels.
- After the guide wire passed through the lesion, the operator determined the treatment scheme according to the characteristics of the lesion with either plain balloon angioplasty alone, plain balloon angioplasty + stent implantation, drug-coated balloon angioplasty, drug-coated balloon angioplasty +stent implantation. Stents were utilized (at the discretion of the operator) primarily or as an adjunct for flow-limiting dissections, intimal flaps, or poor technical results (50% residual stenosis).
- Once inflow to the in segment was corrected (if any inflow lesion), standard wire and catheter techniques were used to cross the infrapopliteal lesions and the diseased segments were treated with plain balloon angioplasty, inflated to nominal pressure for a period of two minutes. Check angiogram was done to record the result of a plain balloon angioplasty and to rule out reocclusion, residual stenosis, spasm, dissection, recoil and thrombus.
- Check angiogram was done post angioplasty in all cases to record the final result and type of plantar arch. Activated clotting time (ACT) was used to keep track of the patient anticoagulation status for quick and efficient monitoring and was maintained at 250-300 seconds throughout the procedure. After the procedure, the sheath was removed when the ACT was dropped to less than 180 seconds. Manual compression was applied after sheath removal, for 10 minutes or till there was no bleeding with continuous hemodynamic monitoring in the recovery room.
- Post procedure pulse/doppler signals status was noted and the PVR, ABI/TBI within 48 hours post procedure.
- Perioperative- Any other significant perioperative events in form of morbidity (ACS etc) and mortality were also recorded, complications were identified by review of operative reports, discharge summaries, and physician progress notes

- Pre-Procedural initial angiograms were reviewed and Distal run off was calculated using Modified SVS runoff score.

MODIFIED SVS RUNOFF SCORE:

The modified SVS runoff score is calculated from angiographic images. This score ranges from 0 to 19, with a higher score indicating more severe disease, and is calculated by assessing the patency and degree of stenosis/occlusion in the popliteal artery and the three tibial vessels.

A score of 0 is assigned to a vessel with <20% stenosis, a score of 1 for a 21% to 49% stenosis, 2 for 50% to 99% stenosis, 2.5 for a vessel occluded over an area less than half its length, and 3 for an occlusion greater than half the vessel length. The score for the popliteal artery is multiplied by 3 and a value of 1 is added before adding all 4 vessel scores together, giving a range of possible popliteal artery scores from 1 to 10.

Three runoff score groups were identified: 5 (Good), 5-10

SCORE	LESION
0	<20% stenosis
1	21% to 49% stenosis
2	50% to 99% stenosis
2.5	vessel occluded over an area less than half its length
3	occlusion greater than half the vessel length.

(Compromised), and >10 (Poor) and these groups were used for subsequent analysis.



D. Secondary procedures

- Patients with infected ulcers or gangrene underwent wound debridement and toe amputation before or following angioplasty, based on the severity of infection .
- Depending upon the type of wound, they were either dressed with hydrocolloids, antiseptic spray or vacuum assisted device were used.
- In follow up period, unplanned toe amputations and debridement done as necessary for wound healing.
- All patients were counselled about life style modification, daily foot care and appropriate foot wear.

E. Follow up:

- 1st/3rd/6th month post procedure
- Clinical history
- Physical examination
- Ankle-Brachial Index (ABI)/Toe-Brachial Index (TBI)
- Pulse volume record (PVR)

- Duplex ultrasound examination/ CTA /MRA was performed if there was a worsening in their symptoms with an increase in one category in the Rutherford scale, decrease in ABI >0.15 /TBI >0.1 from the maximum post procedural level or clinical worsening of tissue loss.
- Duplex ultrasound examination was performed in an accredited vascular laboratory by experienced sonologist.
- Revascularisation was then planned if needed.
- Unplanned toe amputations and debridement was done as necessary for wound healing as per surgeons' clinical acumen.

OUTCOME DEFINITIONS:

1. **AMPUTATION FREE SURVIVAL:** Defined as time spent with the freedom from major limb amputation above the ankle level.
2. **RESTENOSIS:** Restenosis of the target area by more than 50%, Demonstrated by an accepted imaging technique of the specific arterial site treated, such as with DUS, CTA, MRA, or arteriography.
3. Hemodynamic improvement: ABI increase of at least 0.15, or toe-brachial index increase of 0.10.
4. **MALE** (Major adverse limb event) comprised of Major amputation above the ankle level.
5. **MACE** (Major adverse cardiac event): Myocardial infarction, Neurological event like stroke , or death .

6. Procedural success is defined as technical success and completion of the procedure without complications.
7. Technical success for LE-EV interventions is defined as successful use of a device or technique to re-establish vessel patency with a residual stenosis of <30%.
8. Death – All cause mortality.
9. Patency: Palpable pedal pulse post procedure compared with lack of palpable pulse preprocedural (subjective criteria.) or Improvement of ABI >0.15 or increase in PVR amplitude >50% compared with preprocedural values or Demonstrated by an accepted imaging technique of the specific arterial site treated, such as with DUS, CTA, MRA, or arteriography.

Statistical Analysis :

The data collected was entered in systemic manner in MS Excel.

The data on categorical variables is shown as n (% of cases) and the data on continuous variables is presented as mean and standard deviation (SD). The inter-group statistical comparison of distribution of categorical variables is tested using Chi-Square test or Fisher's exact probability test if more than 20% cells have expected frequency less than 5.

All results are shown in tabular as well as graphical format to visualize the statistically significant difference more clearly.

In the entire study, the p-values less than 0.05 are considered to be statistically significant.

The entire data is statistically analysed using Statistical Package for Social Sciences (SPSS ver 24.0, IBM Corporation, USA) for MS Windows.

RESULTS

The present study was carried out in 140 enrolled patients who underwent SFA endovascular intervention for chronic limb threatening ischemia (CLTI) in JIVAS.

Criteria for assessment of statistical significance was P-value < 0.05

Table.9. Gender distribution.

Gender	No. of Participants	Percentage
Female	42	30%
Male	98	70%
Total	140	100%

Of the total 140 patients , 98 (70%) were male and 42 (30%) were female.

Chart 1 : Distribution of cases as per their gender

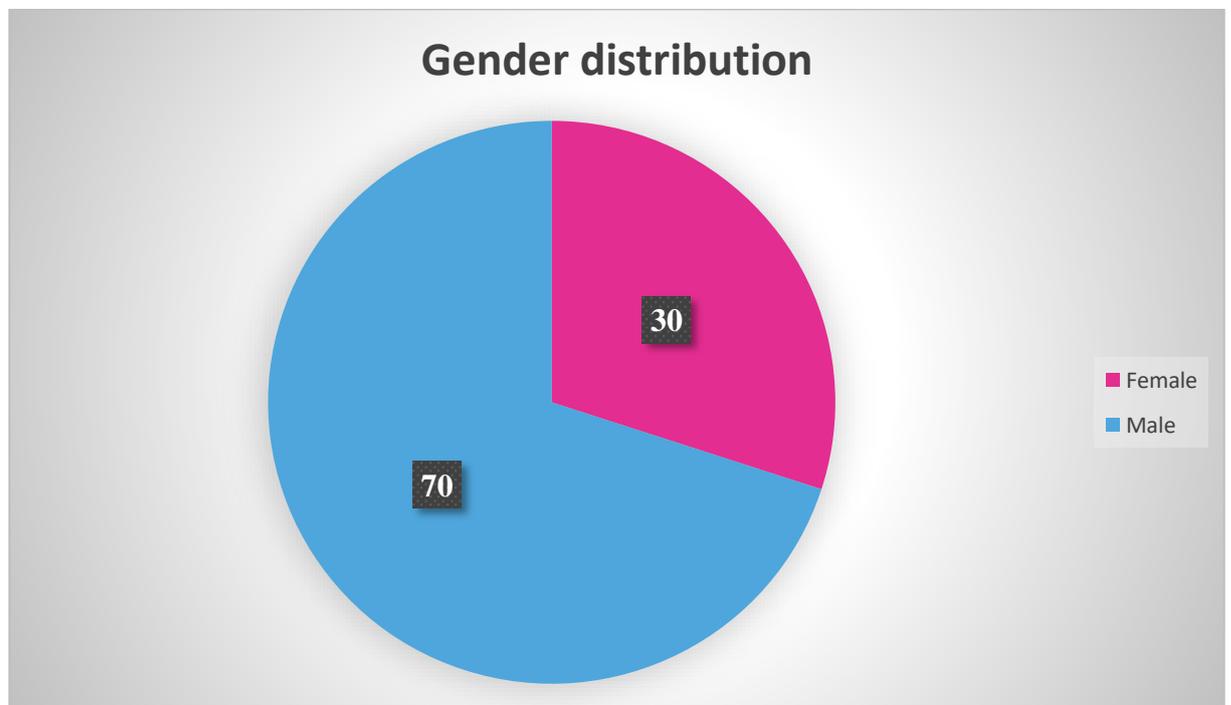


Table 10. Age distribution of the study population:

Age Groups	No. of Participants	Percentage
30-40	2	1.4%
40-50	6	4.3%
50-60	26	18.6%
60-70	43	30.7%
70-80	41	29.3%
80-90	16	11.4%
90-100	6	4.3%
Total	140	100.0%

Majority of the population 43 (30.7%) were in the age group of 60-70 years, followed closely by the 41 (29.3%) cases in 70-80 age group. Majority of cases falling within the 50-70 age range. The mean age of the study population was **68.8** years, and a standard deviation of 11.4. the age range was **32 to 96** years.

Chart 2: Age distribution of the study population .

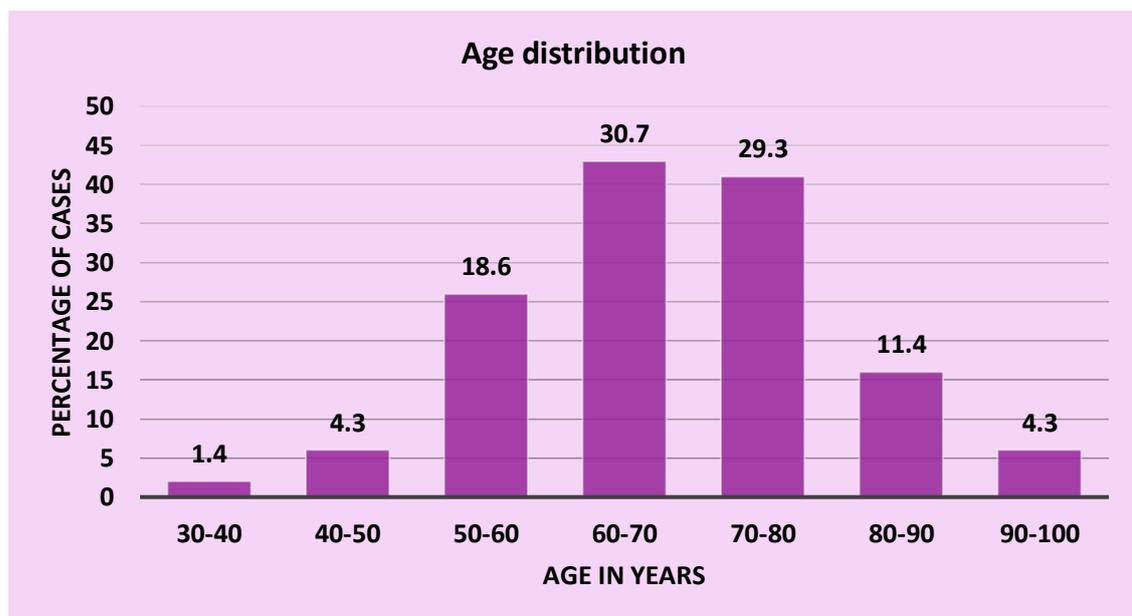


Table 11 : Distribution of Study Population based on to their comorbidities

S.N.	COMORBIDITY	NUMBER OF PATIENTS (Percentage)	
		Present (%)	Absent(%)
1	Diabetes Mellitus	120(85.7)	20(14.3)
2	Hypertension	100(71.43)	40(28.57)
3	Ischemic Heart Disease	49(35.0)	91(65.0)
4	CKD	15(10.71)	125(89.29)

The study participants had a high prevalence of diabetes mellitus (85.7%), as well as hypertension (71.43%). In contrast, ischemic heart disease (IHD) is less common, accounting only 35%. CKD was diagnosed in 10.71% of subjects.

Chart3 : Distribution of the study population based on their comorbidities

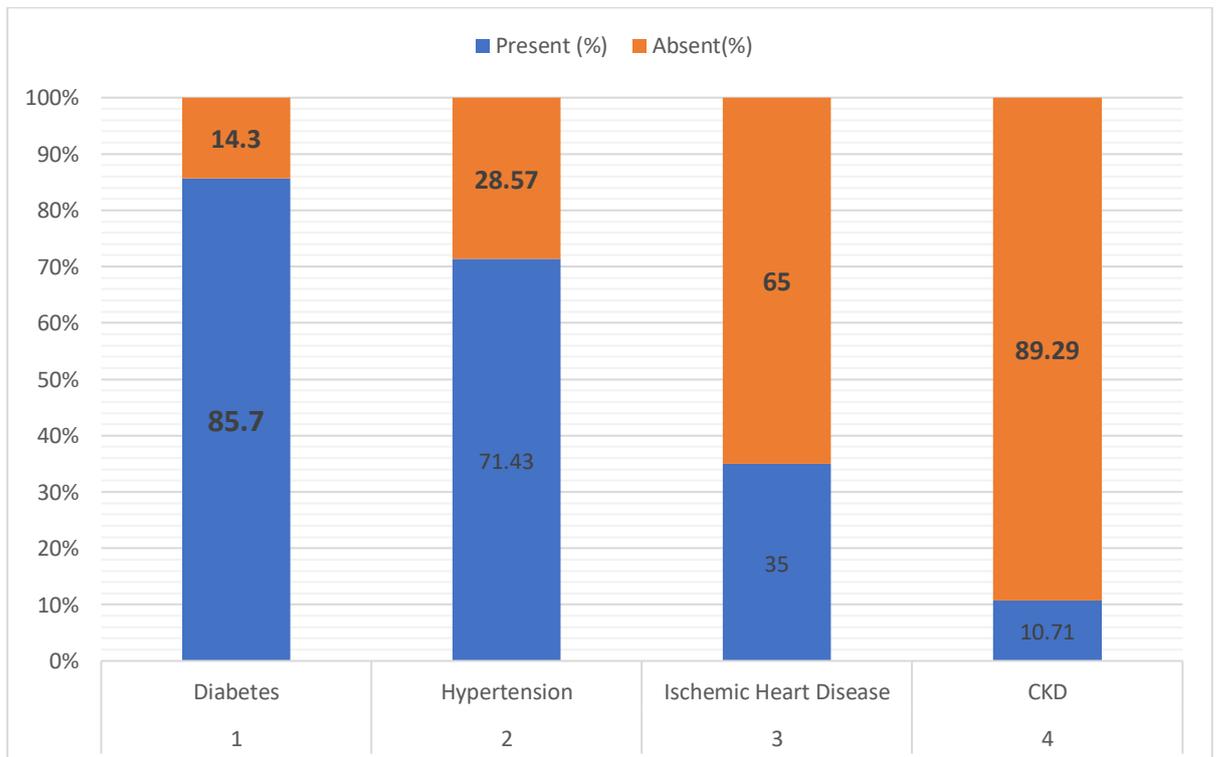


Table 12: Distribution of cases according to Modified SVS distal Run off score

MODIFIED SVS RUNOFF SCORE CATEGORY	No. of cases	Percent
GOOD (score < 5)	4	2.9%
COMPROMISE (score 5–10)	50	35.7%
POOR (score > 10)	86	61.4%
TOTAL	140	100.0%

The Evaluation of 140 patients based on their modified SVS run off score calculated based on Pre-procedural Angiogram shows that majority 86 patients (61.4%) were in "Poor" category, indicating scores greater than 10, while 50 patients (35.7%) were classified as "Compromise" with scores between 5 and 10. Only 4 patients (2.9%) were in "Good" category with a score of less than 5.

Chart 4: Distribution of cases according to Modified SVS Runoff score

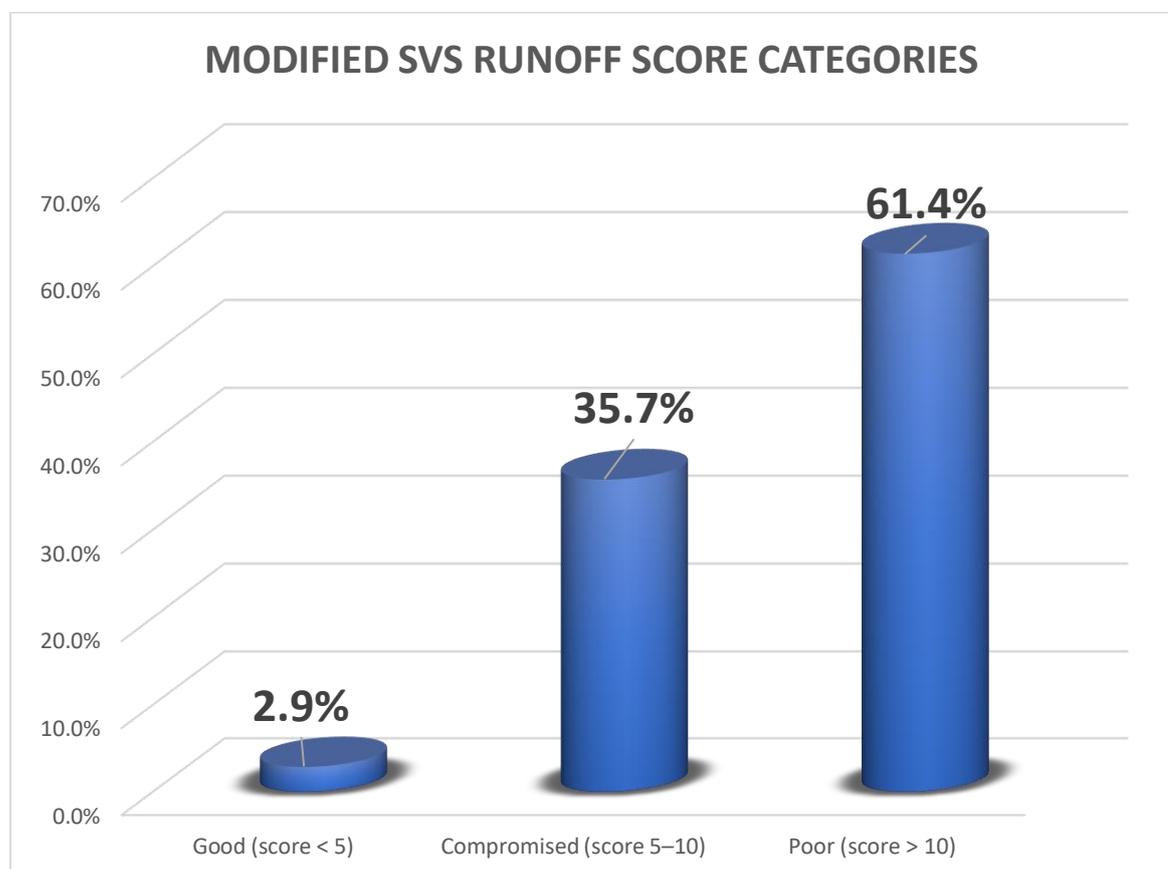


Table 13 : . **Distribution of cases according to their smoking status**

SMOKING	MODIFIED SVS RUNOFF SCORE CATEGORY			Total no. of cases	% of cases	Chi-square	P-value
	GOOD	COMPR OMISE	POOR				
Yes	1	13	23	38	27%	0.015	0.993
No	3	37	62	102	73%		
Total	4	50	86	140	100 %		

Chart 5. Distribution of cases according to their smoking status



Out of 140 case , 38 (27%) were current or ex -smokers and 102 (73%) were non-smokers as per clinical history. There is no association between smoking status and the grade of score.

Table No. 14: Distribution of cases according to Rutherford classification:

RUTHERFORD CATEGORY	MODIFIED SVS RUNOFF SCORE CATEGORY					Chi-square	P-value
	Good	Compromise	Poor	Total	Percent age %		
IV	2	3	6	11	7.8%	15.02	0.02
V	2	34	67	103	73.6%		
VI	0	13	13	26	18.6%		
Total	4	50	86	140	100%		

Out of 140 cases , majority 103(73.6%) cases were Rutherford class V, 26(18.6%) cases were Rutherford class VI and 11 (7.8%)cases were Rutherford class IV.

Chart 6: Distribution of cases according to Rutherford classification:

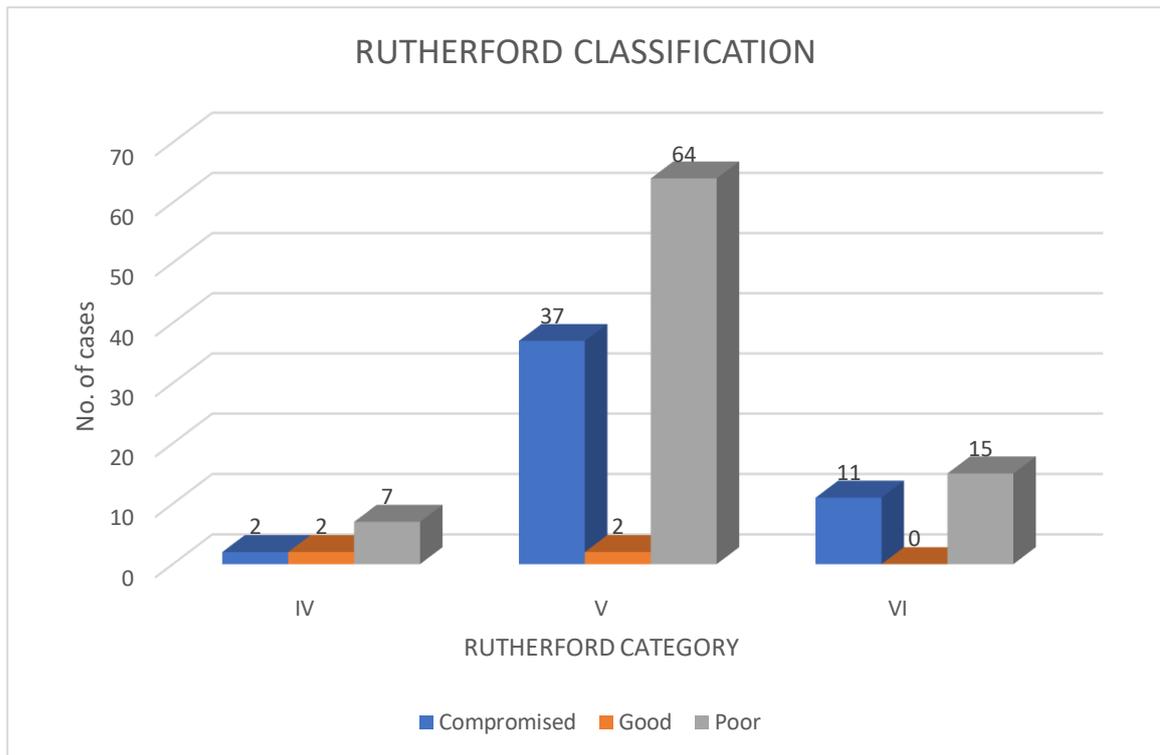


Table 15: Distribution according to Wifi classification

STAGE	MODIFIED SVS RUNOFF SCORE CATEGORY			TOTAL(%)	Chi square =0.8658 P=0.64
	Good	Compromis e	Poo r		
1	0	0	2	2(1.4%)	
2	0	6	8	14(10%)	
3	2	14	19	35(25%)	
4	2	30	57	89(63.5%)	
Total :140	4	50	86	140	

Distribution of cases based on Wifi stage, the majority 89(21.4%) cases were in Stage 4 ,Stage 3 follows with 35 cases (11.4%), while Stage 2 has 14 cases (10.0%). Stage 1 is the least common, with only 2 cases (1.4%). Patients distribution across Wifi score , maximum patients in Wifi - 4 category , which had 2 from good run off , 30 from compromised run off whereas maximum 57 from poor run off .

Chart 7: Distribution according to Wifi classification

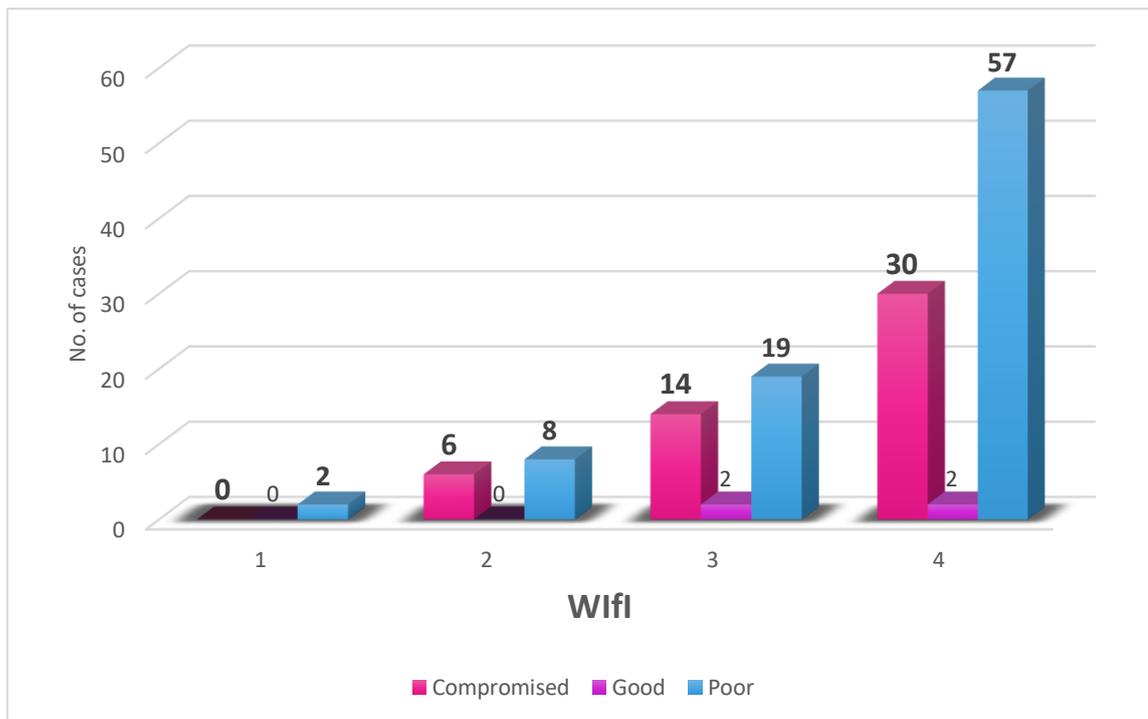


Table 16: Distribution of cases according to GLASS staging:

GLASS staging	MODIFIED SVS RUNOFF SCORE CATEGORY					Chi square is 17.55 P = 0.000028
	Good	Compromised	Poor	Total	Percent	
I	2	5	0	7	5.0%	
II	2	36	58	96	68.6%	
III	0	9	28	37	26.4%	
Total	4	50	86	140	100.0%	

The table provides a distribution of GLASS Stage (I, II, and III) based on their frequency and percentage of occurrence. There are 7 cases of stage I, which account for 5.0% of the total. Stage II is the most common, with 96 cases, making up 68.6% of the total. There are 37 cases of Stage III, comprising 26.4% of the total

Chart 8: Distribution of cases based on GLASS staging

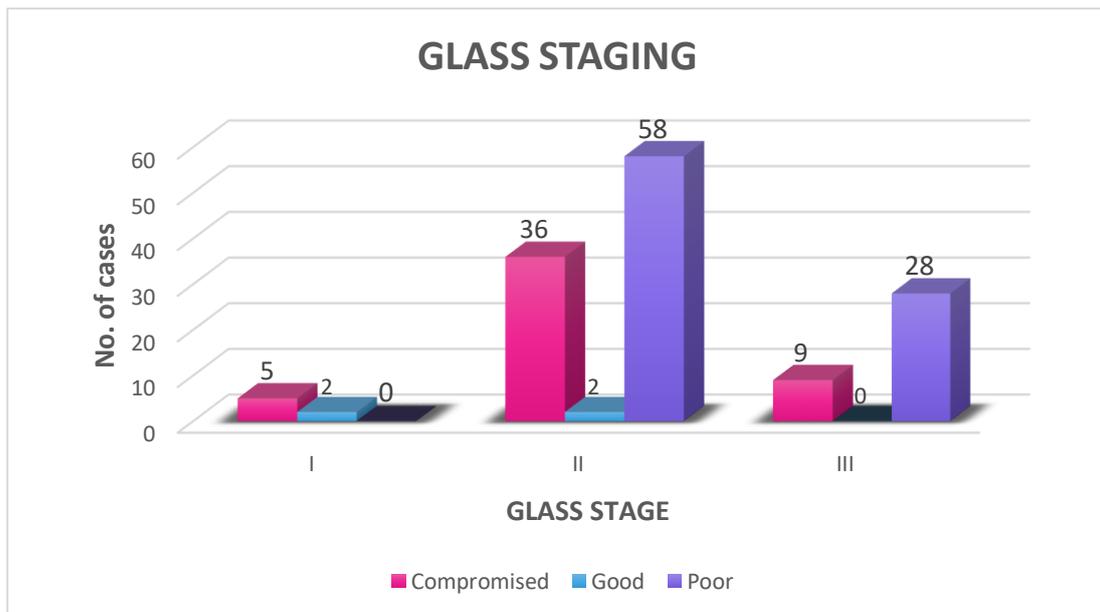


Table 17: Distribution of cases according to type of intervention

INTERVENTION DETAILS	MODIFIED SVS RUNOFF SCORE CATEGORY			TOTAL	PERCENTAGE
	GOOD	COMPROMISE	POOR		
SFA INTERVENTION	4	50	86	140	
1) Plain Balloon Angioplasty	1	31	57	89	63.5%
2) Stenting	3	19	29	51	36.5%
Concomitant Iliac Angioplasty / stenting	0	7	3	10	7.14%
Concomitant Tibial Angioplasty	0	27	63	90	64.2%

Total 140 patients underwent SFA Endovascular intervention, Plain Balloon Angioplasty done for 89 (63.5%) cases and Angioplasty + stenting done for 51 (36.5%) cases.

Out of 140 cases, in 90 (64.2%) concomitant Tibial angioplasty and 10 (7.14%) cases concomitant Iliac angioplasty/ stenting was done. Out of total 90 tibial Angioplasty, majority of 63(45%) cases were from Poor runoff category.

TYPE OF INTERVENTION

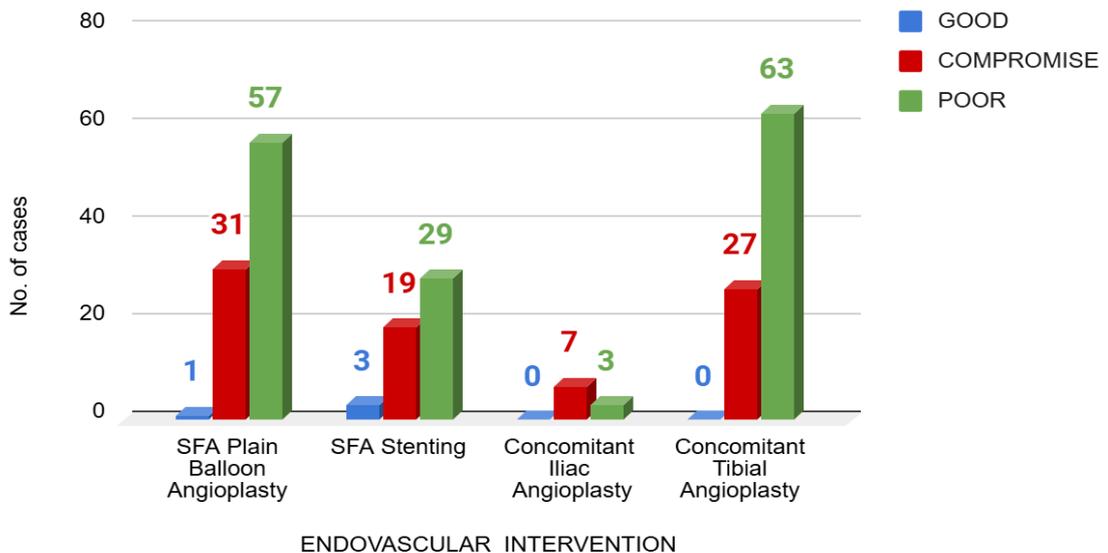


Chart 9: Distribution of cases based on the Type of Endovascular intervention

LOST TO FOLLOW UP :

Table 18 :Distribution of cases who were lost to follow-up

TIME	No. of cases	% of cases
1 MONTH	11	7.85%
3 RD MONTH	6	4.28%
6 TH MONTH	0	
TOTAL	17	12.1%

Out of 140 cases enrolled in the study , a total of 17 patients were lost to follow up by the end of 6 month post intervention. These patients will not be taken into consideration during the outcome evaluation.

LOST TO FOLLOW-UP

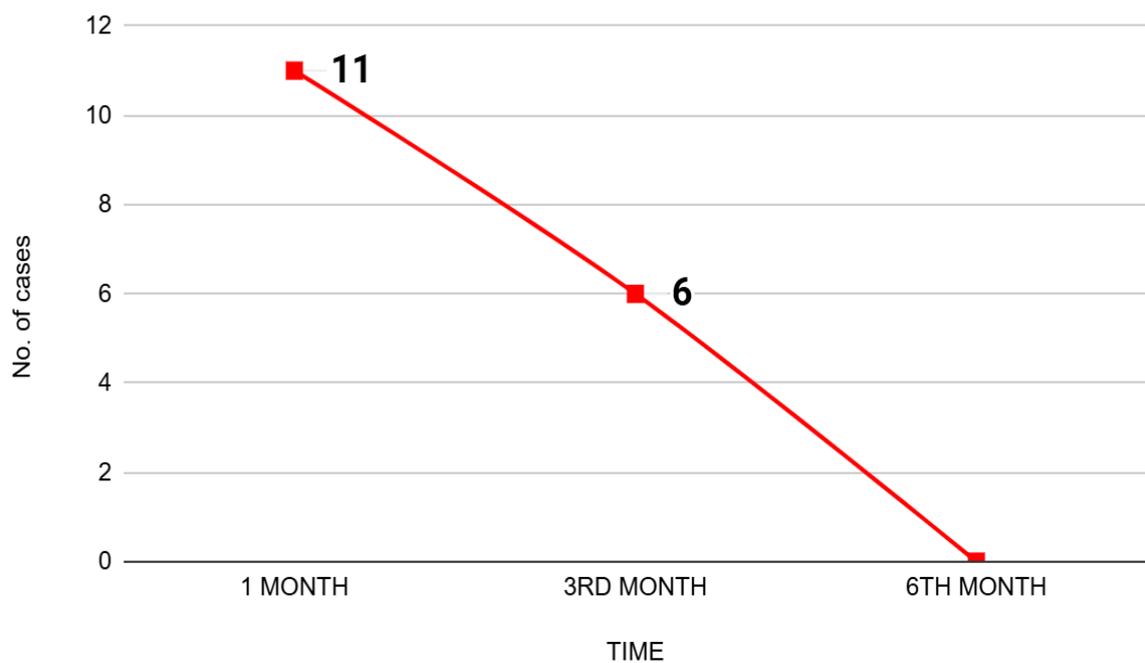


Chart 10: based on lost to follow up

WOUND PROCEDURE

All Patients with wounds were classified based on Wifi classification. They received wound care and procedure as required. The following table depicts the wound management procedure during admission pre / post angioplasty based on clinical judgement and severity of infection.

Out of 140 patients , 11 had no wound /had rest pain .14 had small wound / ischemic patch which did not require any for of debridement.48 patients (34.2 %) underwent wound debridement , it includes wound over foot plantar surface, dorsum of foot, heel and leg wounds.34 (24%)patients underwent single toe rays amputation ,where as 17 (12.6%) patients underwent 2 or more toe amputation. Whereas 16 (11.4) patients underwent Trans metatarsal amputation.

TABLE 19 : Distribution based on Wound management procedure done.

WOUND MANAGEMENT	TOTAL PATIENTS (N)	PERCENTAGE
REST PAIN (NO WOUND)	11	7.8
NO Debridement	14	10
Wound Debridement	48	34.2
Single Toe Amputation	34	24
Multiple Toe Amputation	17	12.6
TMA	16	11.4
TOTAL	140	100

WOUND HEALING STATUS :

Post procedure during follow up all patients were examined in Foot clinic , regular dressing advised with hydrocolloid material and foot wear modification , nail trimming and foot hygiene was counselled for. Secondary wound procedure were done as and when needed in minor OT like wound debridement and toe amputation.

Table 20.: Distribution of wound healing status among the entire study cohort

WOUND HEALING STATUS	Patients
Within 1 st Month	25
Between 1 st and 3 rd Month	50
Between 3 rd and 6 th Month	17
TOTAL	92

AMPUTATION FREE SURVIVAL:

Table 21:Amputation-Free Survival (AFS) rates for each score group using **Kaplan-Meier Estimation**

S.N.	Score Group	1-month AFS (%)	3-month AFS (%)	6-month AFS (%)	Median Survival time in months	
1	Good	100	100	100	>6	P<0.05 (P=0.025 Chi Square =7.41 dF=2)
2	Compromise	94.0 (83.5-98.5)	88.0 (76.4-94.5)	84.0 (71.4-91.6)	5.6 (3.8-7.4)	
3	Poor	93.0 (86.3-96.5)	84.3 (76.2-90.3)	79.1%(69.5-86.3)	4.8 (3.4-6.2)	

The results indicate significant differences in AFS rates among the score groups.

If we compare Good and Compromised P=0.133

If We compare Good and Poor P=0.011

If we compare Compromised and poor P=0.341

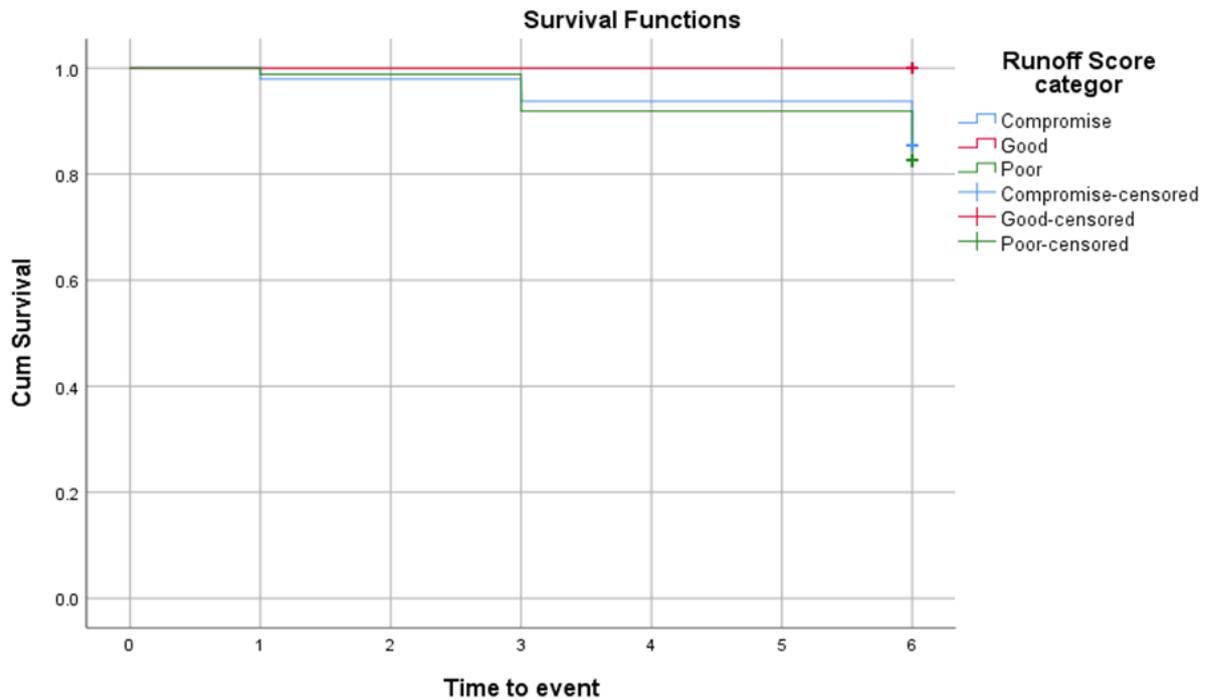


Chart 11: Amputation-Free Survival (AFS) rates for each score group using **Kaplan-Meier Estimation**

The Amputation Free Survival at end of 6 months was 100%, 84% and 79.1% in Good , Compromise and Poor category respectively which was statistically significant (p<0.02)

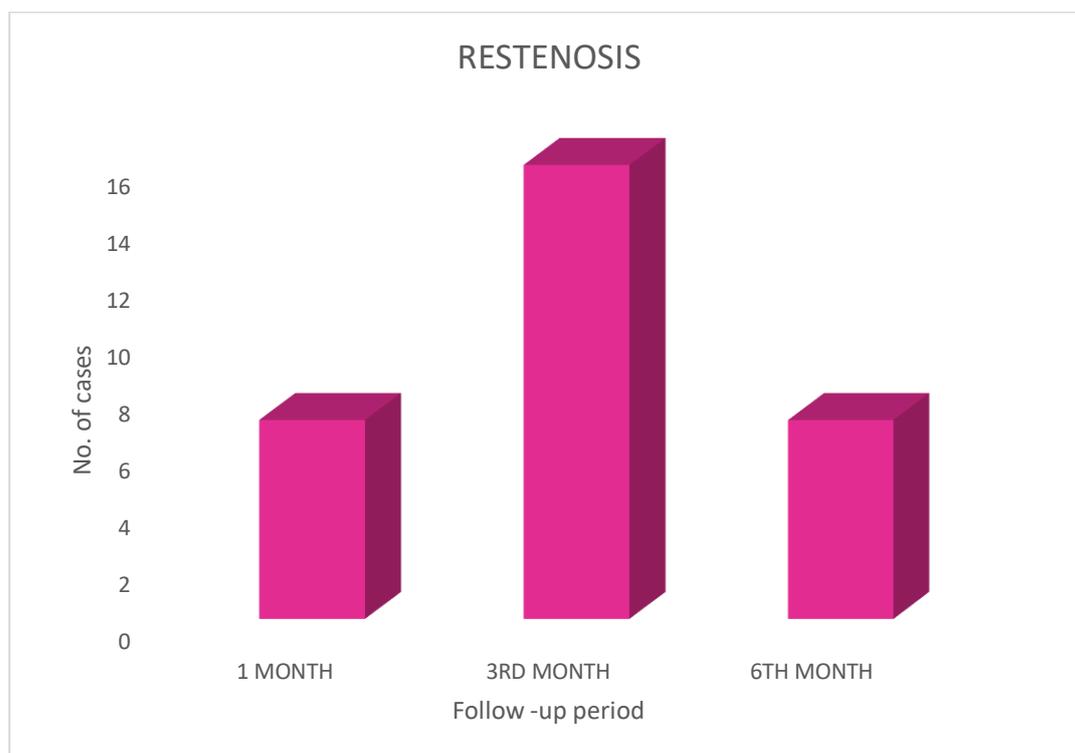
RESTENOSIS :

Table 22: Distribution of cases with Restenosis over 6 months.

RESTENOSIS OF TIME	MODIFIED SVS RUNOFF SCORE CATEGORY			No. of cases	% of cases
	GOOD	COMPROMISE	POOR		
1 MONTH	0	2	5	7	6.1%
3 RD MONTH	1	5	10	16	14.0%
6 TH MONTH	0	3	4	7	6.1%
TOTAL	1	10	19	30	26.3%

The total patient who had restenosis is 30 (26.3%) at the end of 6 month follow-up. Majority 16 (14.0%) cases had restenosis at 3 month follow-up .7 Case each at 1 and 6th month follow-up had restenosis. 19 case were from Poor, 10 from compromise and 1 from good category of Modified SVS Runoff score. The majority of the cases with Restenosis were from Poor category of Modified SVS runoff score, but was not statistically significant. (p=0.91)

Chart 12: Distribution of cases with Restenosis over 6 months



.Table 23: Distribution of outcome of cases with Restenosis

	1MONT H	3MONT H	6MONT H	TOTA L
MALE	3	3	2	8
AKA	2	2	1	6
BKA	1	1	1	2
MEDICAL MANAGEMENT	4	8	3	15
DEATH	0	1	0	1
REINTERVENTI ON	0	4	2	6
TOTAL	7	16	7	30

Out of 30 cases who had restenosis , 8 underwent Major amputation, 6 underwent Reintervention and 15 were managed with medical management. These 15 cases had no symptoms and had healed / healing wound. 1 patient with resetenosis died .

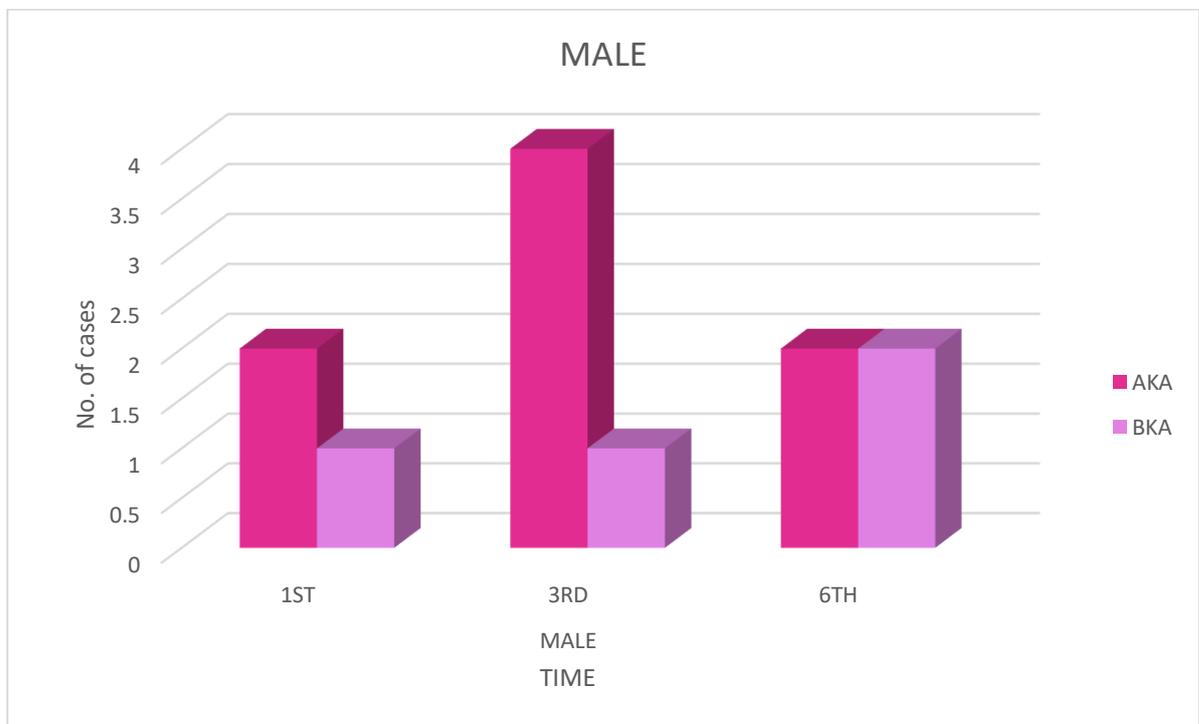
MAJOR ADVERSE LIMB EVENT:

Major Adverse Limb Events (MALE) is described as major amputation above the ankle level. 12 (9.7%) cases underwent Major amputation, out of which 8 (6.5%) were Above Knee Amputation and 4 (3.25%) were Below knee Amputation.

Table 24: Distribution of MALE

MAJOR AMPUTATION	MAJOR ADVERSE LIMB EVENT			TOTAL	Chi square = 0.9 P=0.637
	1ST	3RD	6TH		
AKA	2	4	2	8 (6.5%)	
BKA	1	1	2	4 (3.25%)	
TOTAL	3	5	4	12 (9.7%)	

Chart 12 : Distribution of MALE



MACE:

Table 25 : Distribution of MACE

MACE	FOLLOW UP			TOTAL
	1 ST MONTH	3 RD MONTH	6 TH MONTH	
MI	4	6	2	12 (9.7%)
STROKE	0	0	0	0
DEATH	4	5	1	10 (8.13%)
TOTAL	8	11	3	22 (17.8%)

Out of 123 patients , 10 (8.13%) patients died at the end of 6 month follow-up, whereas 12 (9.7%)patients had Myocardial Infarction.

Chart 13: Distribution of MACE

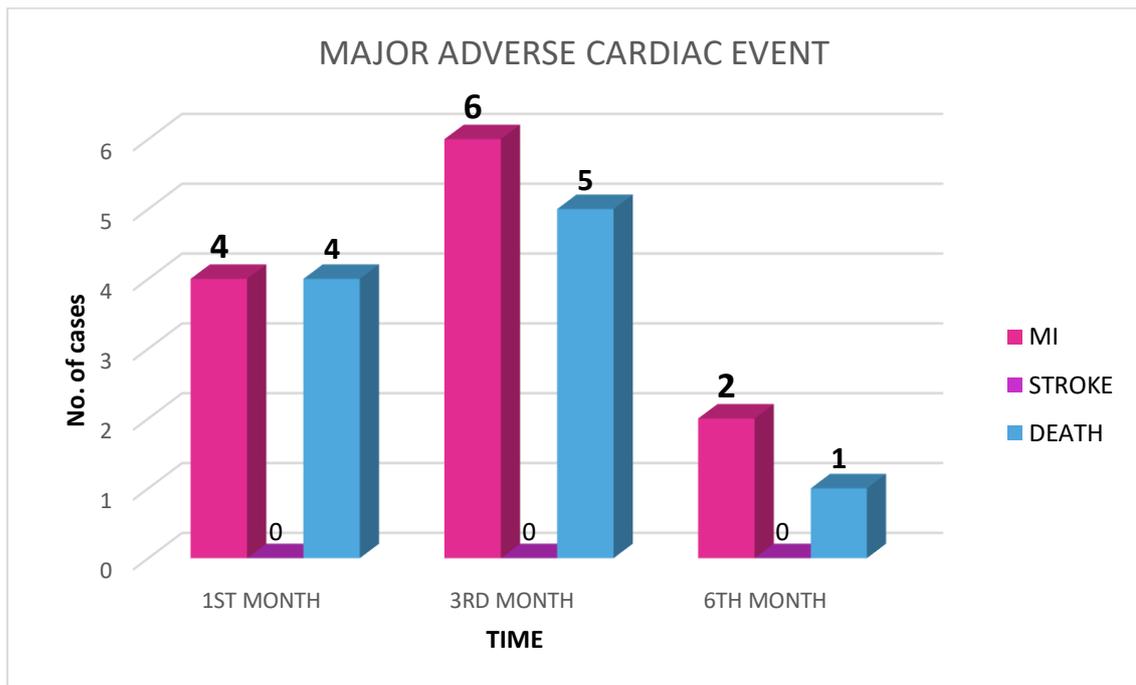


Table 26 : Distribution of patient demographics and procedure details.

MODIFIED SVS DISTAL RUNOFF SCORE	GOOD (n=4)	COMPROMISED (n=50)	POOR (n=86)	p VALUE
1) Age (years)	59.75±10.11	67.8±10.25	64.1±8.65	0.46
2) Males	4	40	54	<0.05
3) Comorbidities				
Diabetes Mellitus	3	43	74	0.08
Hypertension	2	33	65	0.7506
Ischemic Heart Disease	2	19	28	0.1293
CKD				
4) Tobacco Use	1	13	23	0.967
5) Rutherford Category				
Category IV	2	3	6	
Category V	2	36	64	
Category VI	0	11	16	
6) WIfI Stage				
Stage 1	0	0	0	
Stage 2	0	6	9	
Stage 3	2	14	19	
Stage 4	2	30	56	
7) GLASS Stage				
Stage I	2	1	0	
Stage II	2	36	58	
Stage III	0	9	28	
8) Type of Intervention				
Angioplasty	1	30	54	
Stenting	3	20	32	
9) Concomitant Procedure				
Iliac	0	7	3	
Tibial	0	27	63	

Multivariate analysis of comorbidities DM, HTN ,IHD, CKD was done the distribution across the 3 category of Modified SVS runoff score was not statistically significant.

Table 27 : Distribution of Procedure Outcomes

MODIFIED SVS DISTAL RUNOFF SCORE	GOOD (n=4)	COMPROMISED (n=50)	POOR (n=86)	P VALUE
1) RESTENOSIS	1	10	19	0.91
2) MALE AKA	0	7	5	0.06
BKA	0	4	3	
3) MACE	0	7	15	0.06
MI	0	5	7	
DEATH	0	2	8	0.02
4)REINTERVENTION	1	2	3	

As per statistical analysis, the distribution of Death across Good, Compromised and Poor score category was 0,2,8 respectively, which was found to be statistically significant.($p<0.02$) Poor score suggested severe the disease indicating higher mortality. However the MACE considered overall there are more no of events in poor group 15 , but the values are not statistically significant. ($p=0.06$).

The analysis of MALE, showed more no of events in compromised group as compared to poor group , but is not statistically significant ($p=0.06$).

The distribution of Restenosis, out of total 30 cases 19 were in Poor score group ,10 in compromise score and 1 in Good score group , overall number of event was more in poor score group , but it is not statistically significant.($p=0.91$).

DISCUSSION

Present study was a prospective observational study which was undertaken to study the role of Modified SVS runoff score as an outcome indicator for successful SFA Endovascular intervention for CLTI . The study was carried out in the department of Vascular Surgery, JIVAS, Bangalore during the period August 2022 to January 2023.

A total of 140 cases with CLTI that satisfied inclusion/exclusion criteria as per the study protocol were included in the study. The mean age of the participants was 68.8 ± 11.4 years, with the majority being in the 61-70 years age bracket. A notable majority of the patients with CLTI were male, comprising 70% of the cohort. Approximately 85.7% of the patients had a diagnosis of diabetes mellitus, which was the most common comorbidity, followed by hypertension at 71.43% and ischemic heart disease (IHD) at 35%. Furthermore, around 10% of the patients were diagnosed with chronic kidney disease. Smoking was reported in 27% of the patients, predominantly among males.

Rutherford category V representing the largest subgroup at 73.6%, whereas 7.8% were in category IV and 18.6% in category V. Assessment of wound status with severity of Infection and Ischemia done based on WIfI classification , showed 63.5% cases in stage 4 , followed by 25.5% in stage 3, 10% in stage 2 and 1% in stage 1.

During the endovascular procedures, preprocedural Angiography findings were utilized to calculate Modified SVS runoff score ,majority of cases 86(61.4%) were in Poor (score >10) category, followed by 35.7% in compromise (score 5-10) and 2.9% in Good (score <5) category. We also implement the global limb anatomic staging system (GLASS), which assessed by Preprocedural Angiogram findings of the femoropopliteal and infrapopliteal segments based on the severity of stenosis. The most frequently observed GLASS stage in this study cohort was stage II, accounting for 68.6%, followed by Stage III at 26.45 and stage I at 5%.

All patients who underwent successful endovascular intervention for SFA were included in the study. 63.5% were treated with Plain Balloon Angioplasty only, whereas in 36.55 % cases SFA stenting was done. 64.2% patients underwent concomitant Tibial Angioplasty, 45% of which were categorized under poor run off score category and 7.14% underwent concomitant Iliac angioplasty/ stenting.

All patients were followed up postop ,at 1st, 3rd and 6th month .Clinical evaluation ,

wound status examination and ABI/PVR/TBI noted . Any drop in ABI or worsening of wound status or new onset of symptoms ,imaging in the form of Duplex /CTA/ MRA was done. Restenosis if present, based on other parameters revascularization offered to patients

Following were the outcomes at the end of 6th month follow-up. 17 cases were Loss to follow-up. 12 (9.7%) patients had MALE, 4 (3.25%) were BKA and 8 (6.5%) were AKA.MACE was reported in 22 (17.8%) of the cases, 10 (8.13%) Death, 0 events of stroke noted, 12 (9.7%) had MI. 30(27.9%) patients had Restenosis , out of which 6 underwent AKA and 2 had BKA.15 patients were medically treated with close observation of wound status if present , 1 patient died ,6 had Reintervention. Out of 6 reintervention , 2 were Femoropopliteal bypass and 4 were Angioplasty and stenting. The Amputation Free Survival at end of 6 months was 100%, 84% and 79.1% in Good , Compromise and Poor modified SVS runoff score which was significant (p<0.02).

DEMOGRAPHICS and COMORBIDITIES COMPARISON ACROSS STUDIES:

	JIVAS STUDY N=140	Mark G Davies et al 2008 N=241	Seichi Hiramori et al 2014 N=792	Mohamed Elsharkawi et al 2021 N=254
country	India	USA	Japan	Ireland
Mean Age	68.8 years	68 years	73.4 years	69 years
Males	70%	57%	73.0%	54%
DM	85.7%	68%	56%	65%
HTN	71.43%	90%	83%	70%
CAD	35%	56%	60%	36%
CKD	10%	35%	-	-
SMOKING	27%	79%	20%	47%

Table 28: Comparison of Demographics and Comorbidities across studies.

The Comparison of Demographics and Comorbidities across similar studies , in whom Modified SVS runoff score/ or a modification of it was used as an outcome predictor after Endovascular SFA intervention.

The mean age of our study population was 68 ± 11.08 years, with 60% of the population was from the 60 to 80 years age group. Similar mean age was found in the study by Davies et al and M Elsharkawi et al. This finding suggests that with increasing age the prevalence of CLTI increases.

Gender distribution wise 70% were Males , which was seen in study by Seichi Hiramori.

Diabetes Mellitus emerged as the most prevalent comorbidity in our study, affecting 85.7% of participants. This prevalence is notably higher than that reported in other studies.

Diabetes is recognized as an independent risk factor for peripheral artery disease (PAD). Research by Andrew Bekken et al. demonstrated that PAD associated with diabetes tends to exhibit a more distal distribution of atherosclerotic disease, primarily affecting the infrageniculate arteries while leaving the foot arteries relatively unaffected. Conversely, the foot arteries are influenced by hyperglycaemia-induced microvascular angiopathy, which results in basement membrane thickening and functional impairment of the microvasculature. In patients presenting with critical limb ischemia (CLI), particularly those experiencing tissue loss, the rates of limb salvage are diminished in diabetic groups (both non-insulin-dependent diabetes mellitus and insulin-dependent diabetes mellitus), despite similar rates of patency and restenosis.

Hypertension was the second most common condition, observed in 71.4% of cases, aligning closely with findings from Mohamed Elsharkawi et al. However, higher prevalence rates were reported in studies by Davies et al. at 90% and Seichi Hiramori et al. at 83%.

Additionally, 27% of participants were smokers, a figure consistent with Seichi Hiramori et al.'s findings, while Davies et al. reported a significantly higher smoking prevalence of 79%.

The majority of patients presented with wounds and ischemia, with the severity of infection classified as WIfI stage 4 in 63% of cases, followed by stage 3 in 25%. According to the WIfI classification, stage 4 carries the highest risk of amputation and presents questionable benefits from revascularization. This observation is corroborated by our study, that the largest number of MALE cases were from the stage 4 WIfI category and poor category of Modified SVS runoff score, which suggest poor distal runoff increases the risk for amputation.

Notably, most studies utilizing the Modified SVS runoff score did not incorporate the WIfI scoring system, rendering our study distinctive in its classification and examination of wounds and ischemia. This is particularly relevant given the higher incidence of PAD with severe wounds in the Indian population. It is important to note that the worsening status of wounds, rather than the severity of ischemia alone, serves as a significant risk factor for major amputation.

The distribution of cases according to the Modified SVS runoff score revealed that 2.9% were classified as Good, 35.7% as Compromise, and 61.4% as Poor. This suggests that a significant majority of cases exhibited severe tibial lesions, which resulted in compromised blood flow to the foot. In comparison to other studies, our research demonstrated a higher proportion of cases

in the Poor category. A limitation of this study is that it does not account for the patency of foot vessels or the formation of the foot arch.

Out of 140 patients , 51(36.5%) underwent SFA stenting , majority 20% were from Poor runoff score category. Similar findings were seen in Mark G Davies et al study where 61% plain balloon angioplasty, 37% primary stenting and 2% SFA atherectomy.

Stenting improves initial results of SFA intervention via resistance of initial elastic recoil, prevention of flow limiting dissections, and minimizing residual stenoses.

Total of 90 cases (64%) underwent concomitant Tibial vessel angioplasty. Majority of which fall into the Poor runoff score category, this indicates that in the poor runoff score category measures were taken to improve the inline flow to foot. Noh et al showed that the number of infrapopliteal runoff vessels seems to be one of the factors influencing arterial patency in patients who had undergone SFA angioplasty with stenting ²⁵. Inflow correction with Iliac Angioplasty was required in 10 (7%)cases.

During the 6 months follow-up, the highest incidence of restenosis, at 14.1%, was observed at 3rd month . Kenagy et al. indicated that restenosis arises from a combination of thrombosis, negative remodelling, and intimal hyperplasia. Research conducted on experimental animals has shown that maximum intimal hyperplasia typically occurs 2 to 3 months following arterial injury.

The outcomes of major adverse cardiovascular events (MACE) across the Good, Compromise, and Poor categories were recorded as 0, 7, and 15, respectively, which did not reach statistical significance. However, when overall mortality was analysed across the three score grades, it was notably higher in the Poor category and was statistically significant.

AFS among the three categories of Modified SVS runoff score Good , Compromise and Poor was 100%, 84 %and 79 % respectively at the end of 6 months. This indicates with worsening runoff the AFS reduced. Mark G Davies et al study limb salvage (65 5%, 41 4%, and 20 6% for Good, Compromised, and Poor runoffs, respectively) reduced with worsening runoff. This study had lower limb salvage rates as , tibial lesions were not corrected. Overall mortality was 1% and 22% morbidity at 90 days.

LIMITATIONS OF THE STUDY :

Small sample size

Shorter duration of study, long term outcomes could not be dealt with.

Pedal vascular status is not taken into consideration which might adversely affect the limb patency and amputation free survival, poor healing of wound.

Distribution of population across Good , Compromise and Poor score is disproportional , good score as has less cases than poor score.

CONCLUSION

A prospective, observational, longitudinal study was conducted involving 140 patients from August 2022 to January 2023, who were diagnosed with chronic limb-threatening ischemia (CLTI) and underwent Endovascular intervention for SFA with or without Iliac/ tibial vessel angioplasty. The patients were categorized into three groups according to the Modified SVS runoff score into Good, compromise and poor score. The primary aim was to analyze the role of Modified SVS runoff score as an outcome indicator after Endovascular intervention for SFA. The primary objective was AFS and secondary outcomes being Restenosis, MACE and MACE.

Our study showed that Good score had higher AFS and poor score has lower AFS. Overall mortality in poor category is high as compared to nil in good score group. Modified SVS runoff score adversely affects the AFS and overall survival. We conclude that the quality of distal runoff vessels measured using the modified SVS runoff scoring system significantly predicts the outcomes after SFA stenting. The Good score has good patency, improved amputation-free survival. The poor score has poor outcome in terms of increase in overall mortality and reduced amputation-free survival. Modified SVS Runoff score can be used as an outcome indicator after Endovascular intervention along with other scoring systems.

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ANNEXURES

ANNEXURE – 1: STUDY PERFORMA

DIAGNOSTIC ANGIO				
INDEX ARTERIO	AORTA	CIA	BIA	IA
<input type="radio"/> CT	<input type="radio"/> Not seen	<input type="radio"/> Not seen	<input type="radio"/> Not seen	<input type="radio"/> Not seen
<input type="radio"/> MR	<input type="radio"/> <50% stenosis	<input type="radio"/> <50% stenosis	<input type="radio"/> <50% stenosis	<input type="radio"/> <50% stenosis
<input type="radio"/> DSA	<input type="radio"/> <50% stenosis	<input type="radio"/> <50% stenosis	<input type="radio"/> <50% stenosis	<input type="radio"/> <50% stenosis
SDE	<input type="radio"/> CTO	<input type="radio"/> CTO	<input type="radio"/> CTO	<input type="radio"/> CTO
<input type="radio"/> Left	<input type="radio"/> Diffuse disease, small caliber	<input type="radio"/> Diffuse disease, small caliber	<input type="radio"/> Diffuse disease, small caliber	<input type="radio"/> Diffuse disease, small caliber
<input type="radio"/> Right	<input type="radio"/> Concentric aneurysm	<input type="radio"/> Concentric aneurysm	<input type="radio"/> Concentric aneurysm	<input type="radio"/> Concentric aneurysm
	<input type="radio"/> Severe diffuse in distal revascularis	<input type="radio"/> Severe diffuse in distal revascularis	<input type="radio"/> Severe diffuse in distal revascularis	<input type="radio"/> Severe diffuse in distal revascularis
CFA	> 50% SPA DISEASE ?	SPA CTO	POP/ITRAJ	<50 % IF DISEASE?
<input type="radio"/> <50% disease	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> No CTO	<input type="radio"/> No significant disease	<input type="radio"/> Yes <input type="radio"/> No
<input type="radio"/> >50% stenosis	SPA DISEASE LENGTH	<input type="radio"/> ran-flush CTO <5cm	<input type="radio"/> Stenosis <2cm	TOP
<input type="radio"/> CTO	<input type="radio"/> None / insignificant	<input type="radio"/> ran-flush CTO 5-10cm (<1/3)	<input type="radio"/> Stenosis 2-5cm	<input type="radio"/> ATA
PSA	<input type="radio"/> < 1/3 (<30cm)	<input type="radio"/> ran-flush CTO 10-20cm (1/3-2/3)	<input type="radio"/> Stenosis > 5cm or extending into ilioacials any CTO	<input type="radio"/> PTA
<input type="radio"/> <50% disease	<input type="radio"/> 1/3-2/3 (10-30cm)	<input type="radio"/> flush CTO >20cm (>2/3)	SEV FEM POP CALCF?	<input type="radio"/> Peroneal
<input type="radio"/> >50% stenosis	<input type="radio"/> >2/3 (>30cm)	<input type="radio"/> Any CTO > 30cm (>2/3)	<input type="radio"/> Yes <input type="radio"/> No	ATA STENOSIS
<input type="radio"/> CTO				<input type="radio"/> No significant disease
ATA CTO	PERONEAL STENOSIS	PERONEAL CTO	PTA STENOSIS	<input type="radio"/> Focal stenosis < 3cm
<input type="radio"/> No CTO	<input type="radio"/> No significant disease	<input type="radio"/> No CTO	<input type="radio"/> No significant disease	<input type="radio"/> <=1/3 length
<input type="radio"/> Focal CTO (<1cm)	<input type="radio"/> Focal stenosis < 3cm	<input type="radio"/> Focal CTO (<1cm)	<input type="radio"/> Focal stenosis < 3cm	<input type="radio"/> 1/3 - 2/3 length
<input type="radio"/> Any CTO <=1/3 length	<input type="radio"/> <=1/3 length	<input type="radio"/> Any CTO <=1/3 length	<input type="radio"/> <=1/3 length	<input type="radio"/> >2/3 length
<input type="radio"/> CTO <=1/3 length involving origin	<input type="radio"/> 1/3 - 2/3 length	<input type="radio"/> CTO <=1/3 length involving origin	<input type="radio"/> 1/3 - 2/3 length	<input type="radio"/> Any CTO <=1/3 length involving origin
<input type="radio"/> Any CTO > 1/3 length	<input type="radio"/> >2/3 length	<input type="radio"/> Any CTO > 1/3 length	<input type="radio"/> >2/3 length	<input type="radio"/> Any CTO > 1/3 length
		<input type="radio"/> Any CTO of TP trunk		<input type="radio"/> Any CTO of TP trunk

CFA	PLANTAR	SPURR TIBIAL CALCF?	Aorta Iliac	ETIOLOGY
<input type="radio"/> <50% disease	<input type="radio"/> <50% disease	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> TASC A	<input type="radio"/> Atherosclerosis
<input type="radio"/> >50% stenosis	<input type="radio"/> >50% stenosis	PEDAL MODIFIER	<input type="radio"/> TASC B	<input type="radio"/> TAO
<input type="radio"/> CTO	<input type="radio"/> CTO	<input type="radio"/> P0 <input type="radio"/> P1 <input type="radio"/> P2	<input type="radio"/> TASC C	<input type="radio"/> Arteritis
			<input type="radio"/> TASC D	<input type="radio"/> Others

Diagnostic report:

Date: / / 20 Dr Name: Sign:

Date: / /20 Dr Name: Sign:

Intervention Details									
Previous Intervention								Date of present Intervention	
								<input type="radio"/> Left <input type="radio"/> Right	
Access1	Access2	Access3	USG guidance		Retrograde access	Sheath	contrast used	contrast volumes used	
<input type="radio"/> Retrograde CFA	<input type="radio"/> Retrograde CFA	<input type="radio"/> Retrograde CFA	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="radio"/> No	<input type="radio"/> 4Fr	<input type="radio"/> Iodix		
<input type="radio"/> Antegrade CFA	<input type="radio"/> Antegrade CFA	<input type="radio"/> Antegrade CFA	A1	<input type="checkbox"/>	<input type="radio"/> Popliteal	<input type="radio"/> 5Fr	<input type="radio"/> Non ionic		
<input type="radio"/> Brachial	<input type="radio"/> Brachial	<input type="radio"/> Brachial	A2	<input type="checkbox"/>	<input type="radio"/> ATA	<input type="radio"/> 4Fr	<input type="radio"/> Gadolinium		
<input type="radio"/> Radial	<input type="radio"/> Radial	<input type="radio"/> Radial	A3	<input type="checkbox"/>	<input type="radio"/> PTA	<input type="radio"/> 3Fr	<input type="radio"/> Co2		
<input type="radio"/> Retrograde pop	<input type="radio"/> Retrograde pop	<input type="radio"/> Retrograde pop			<input type="radio"/> Peroneal	<input type="radio"/> Crossover	<input type="radio"/> Combination		
<input type="radio"/> Retrograde tibial	<input type="radio"/> Retrograde tibial	<input type="radio"/> Retrograde tibial			<input type="radio"/> DPA				
ARTERY I									
LESION DETAILS			Wire for index intervention	Final Balloon Dia mm x len mm	STENT USED			OUTCOME	
Artery	Total lesion length	Heavy calcification			<input type="radio"/> Yes	Primary	Balloon	DETAILS	
		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> 0.035 <input type="radio"/> 0.018 <input type="radio"/> 0.014		<input type="radio"/> No			Diagonals	<input type="radio"/> Success <input type="radio"/> Failure
ARTERY II									
LESION DETAILS			Wire for index intervention	Final Balloon Dia mm x len mm	STENT USED			OUTCOME	
Artery	Total lesion length	Heavy calcification			<input type="radio"/> Yes	Primary	Balloon	DETAILS	
		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> 0.035 <input type="radio"/> 0.018 <input type="radio"/> 0.014		<input type="radio"/> No			Diagonals	<input type="radio"/> Success <input type="radio"/> Failure
ARTERY III									
LESION DETAILS			Wire for index intervention	Final Balloon Dia mm x len mm	STENT USED			OUTCOME	
Artery	Total lesion length	Heavy calcification			<input type="radio"/> Yes	Primary	Balloon	DETAILS	
		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> 0.035 <input type="radio"/> 0.018 <input type="radio"/> 0.014		<input type="radio"/> No			Diagonals	<input type="radio"/> Success <input type="radio"/> Failure
ARTERY IV									
LESION DETAILS			Wire for index intervention	Final Balloon Dia mm x len mm	STENT USED			OUTCOME	
Artery	Total lesion length	Heavy calcification			<input type="radio"/> Yes	Primary	Balloon	DETAILS	
		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> 0.035 <input type="radio"/> 0.018 <input type="radio"/> 0.014		<input type="radio"/> No			Diagonals	<input type="radio"/> Success <input type="radio"/> Failure
Endovascular Procedure Details:									
Date: / /20 Dr Name: Sign:									

RESULTS			
In-line flow to pedal arch	COMPLICATIONS	OUTCOME	Discharge ABI:
<input type="radio"/> Yes		<input type="radio"/> Improved	
<input type="radio"/> No		<input type="radio"/> Worse	
		<input type="radio"/> Status quo	

FOLLOW UP MONTH	WOUND STATUS	PVR/ ABI/ TBI
1 st Month		
3 rd Month		
6 th Month		
12 th Month		

- Any Additional Wound Procedure during Follow up Period:

- If fall in ABI/ TBI/ PVR noted, then month _____

- Any additional imaging performed (if wound ischemic/ fall in ABI/ TBI/ PVR noted): _____

- If restenosis noted in imaging, further management

Conservative (Medical Management)	Revascularization of the Restenosis Segment
-----------------------------------	---

- If revascularization performed post restenosis, then procedure

- Time taken for complete wound healing _____

- Any Major Amputation (month): _____

- Major Adverse Cardiac Events (MACE): _____

ANNEXURE 2
PATIENT INFORMATION SHEET

TITLE OF STUDY : STUDY OF MODIFIED SOCIETY OF VASCULAR SURGERY
RUNOFF SCORE AS PREDICTOR OF CLINICAL OUTCOMES AFTER
ENDOVASCULAR INTERVENTIONS FOR SUPERFICIAL FEMORAL ARTERY
DISEASE IN CHRONIC LIMB THREATENING ISCHEMIA.

AT A TERTIARY VASCULAR SURGERY CENTRE :
AN INSTITUTIONAL BASED PROSPECTIVE STUDY

The purpose of this form is to provide you with information so you can decide whether to participate in this study. Any questions you may have will be answered by the researcher or by the other contact persons provided below.

There are many ways of assessing the outcome post revascularization , modified society of vascular surgery runoff score is one such indicator.

This study aims to predict the clinical outcome of the patient with SFA(superficial femoral artery) disease undergoing endovascular intervention using mod SVS run off score .

Preoperatively all your details will be collected and modified run off score calculated using the MR/CT angiogram. No extra investigation will be done.

This will involve regular follow up of the participant (in this case you) from after surgery and discharge till 6 months post operatively. You will be assessed for your clinical improvement, wound status , patency , ABPI and doppler /duplex scan during this evaluation. This follow up will be the routine which is advised to patients post angioplasty.

You will also not be discriminated during your follow up visits for not consenting to participate. Patient's privacy will be always maintained during the study. No disclosure of any personal information will be resorted to.

The findings and interpretation of your progress will be entered and used in the dissertation, which may or may not be eventually published in a medical journal as well. The findings may be used to create a standardized protocol for patients with infrainguinal disease having SFA lesion.

You will not be charged any extra amount for participating in this study as compared to other patients in the form of extra tests or investigations. Similarly you will not receive any compensation (financial or otherwise) for participation either from the Principal Worker, Guide or the Department.

If you do not follow the instructions or advice of the Principal or Associate workers in a manner that either will hamper your progress or adversely affect the results of the Study, you will be withdrawn as a participant. Failure to regular follow up will also result in your removal from the Study. Patient's participation

in this study is voluntary and at any time if he /she wishes can withdraw from the study.

ANNEXURE – 3

INFORMED CONSENT FORM

Informed Consent Form:

I, _____ was explained in the language that i best understand the contents of the study. I was assured that my identity will not be revealed. I voluntarily agree to participate and give permission to use my medical data for this study.

signature/left thumb impression:

date:

place:

INFORMED CONSENT FORM

Subject identification number for this trial _____

Title of the Project: _____

Name of the Principal Investigator _____ Tel. No. _____

I have received the information sheet on the above study and have read and / or understood the written information.

I have been given the chance to discuss the study and ask questions.

I consent to take part in the study and I am aware that my participation is voluntary.

I understand that I may withdraw at any time without this affecting my future care.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible persons (ethics committee members / regulatory authorities). I give access to these individuals to have access to my records.

I understand I will receive a copy of the patient information sheet and the informed consent form.

Signature / Thumb Impression of subject Date of signature

Printed name of the subject in capitals

Signature / Thumb Impression of legally Date of signature

accepted representative. The legally acceptable representative signature should be added if the subject is a minor or is unable to sign for themselves. The relationship between the subject and the legally acceptable representative should be stated.

The impartial witness signature should be added if the subject / legally acceptable representative is unable to read or write and consent should be obtained in his presence.

Printed name of legally acceptable representative in capitals

Relationship of legally accepted representative to subject in capitals

Signature of the person conducting the Date of Signature
informed consent discussion

Printed name of the person conducting the Informed consent discussion in
capitals

Signature of impartial witness Date of signature

Printed name

SCIENTIFIC COMMITTEE APPROVAL CERTIFICATE



SCIENTIFIC COMMITTEE

APPROVAL CERTIFICATE OF DISSERTATION FOR NBE

Approval has been granted by Scientific Committee of Bhagwan Mahaveer Jain Hospital for the following Dissertation as per NBE requirement **STUDY OF MODIFIED SOCIETY OF VASCULAR SURGERY DISTAL RUN OFF SCORE AS PREDICTOR OF CLINICAL OUTCOMES AFTER ENDOVASCULAR INTERVENTIONS FOR SUPERFICIAL FEMORAL ARTERY DISEASE IN CHRONIC LIMB THREATENING ISCHEMIA** Conducted by **DR.ISHITA MUKUND JETHWA** Department of **VASCULAR SURGERY** under the guidance of **DR.VIVEKANAND** approximate period of study is from **01/08/2022 to 31/07/2023**.

Scientific Committee meeting held on 25/07/2022.

Date : 15/10/2024



Umesh
**MEDICAL DIRECTOR
BMJH Scientific Committee**

Dr. UMESH N
Medical Director
BHAGWAN MAHAVEER JAIN HOSPITAL
Bangalore-560 052



ETHICS COMMITTEE ON HUMAN RESEARCH
BHAGWAN MAHAVEER JAIN HOSPITAL
A UNIT OF BHAGWAN MAHAVEER MEMORIAL JAIN TRUST

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APPROVAL CERTIFICATE OF DISSERTATION FOR NBE

Approval has been granted by Ethics Committee of Bhagwan Mahaveer Jain Hospital for the following Dissertation as per NBE requirement
**STUDY OF MODIFIED SOCIETY OF VASCULAR SURGERY
DISTAL RUN OFF SCORE AS PREDICTOR OF CLINICAL
OUTCOMES AFTER ENDOVASCULAR INTERVENTIONS
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Ethics Committee meeting held on **25/07/2022**.

Date : 15/10/2024

MEMBER SECRETARY
BMJH Ethics Committee

Member Secretary in
Ethics Committee on Human Research
Bhagwan Mahaveer Jain Hospital
Miller's Road, Vasanthnagar
Bangalore-560 052

MASTER CHART