MIDTERM CLINICAL AND RADIOLOGICAL PATENCY OUTCOMES OF SUBINTIMAL ANGIOPLASTY WITH SELECTIVE STENTING IN TASC II C AND D FEMOROPOPLITEAL DISEASE

THESIS

SUBMITTED IN PARTIAL FULFILLMENT FOR DEGREE OF

DM CARDIOVASCULAR IMAGING AND VASCULAR INTERVENTIONAL RADIOLOGY

(2019-2021)

OF

THE SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM, INDIA

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CERTIFICATE

This is to certify that the work incorporated in this thesis titled **"Midterm clinical and radiological patency outcomes of subintimal angioplasty with selective stenting in TASC II C and D Femoro-popliteal disease"** *for the degree of* ***DM CARDIOVASCULAR IMAGING AND VASCULAR INTERVENTIONAL RADIOLOGY*** *has been carried out by* ***Dr. Ansan Joseph J*** *under our supervision and guidance. The work done in connection with this thesis has been carried out by the candidate himself and is genuine.*

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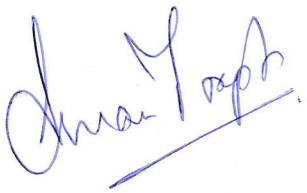
*I hereby declare that this thesis titled "***Midterm clinical and radiological patency outcomes of subintimal angioplasty with selective stenting in TASC II C and D Femoro-popliteal disease***" has been prepared by me under the supervision and guidance of Dr.Anoop Ayyappan (Assistant Professor), Dr Jineesh Valakkada (Assistant Professor), Dr Santhosh Kumar (Additional Professor), Department of Imaging Sciences and Interventional Radiology, Dr Shivanesan (Assistant Professor, Department of Vascular Surgery), Sree Chitra Institute for Medical Sciences and Technology, Trivandrum.*



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ACKNOWLEDGEMENT

- *I hereby express my sincere gratitude to all my teachers & guides especially Dr. Anoop Ayyappan (Assistant Professor), Dr Jineesh Valakkada (Assistant Professor), Dr Santhosh Kumar (Additional Professor), Department of Imaging Sciences and Interventional Radiology, for their constant unwavering support, insightful criticism, expert supervision and immense patience throughout this study.*

- *I would specially like to acknowledge my gratitude to my past and present colleagues and the technologists of the Department of IS and IR and the advanced radiology technology trainees of the department for their valuable assistance at all times during this study.*

- *I would also like to extend my heartfelt gratitude to my family for being immensely supportive all through my endeavours. I could not have achieved what I have without their prayers, love and support.*

- *Last but not least I am eternally grateful to all my patients & their relatives who have been very understanding and generous with their cooperation all through the study.*

CONTENTS

ABSTRACT

TITLE: Midterm clinical and radiological patency outcomes of subintimal angioplasty with selective stenting in TASC II C and D Femoro-popliteal disease.

Aim: There is no definitive consensus between endovascular treatment and surgery in the management of TASC C and D femoro-popliteal (FP) disease. In addition, the best option among the endovascular options (primary or selective stenting, DCB, DES) in long complex femoro-popliteal lesions has not been well described. This study aims to find out the mid-term patency and clinical outcomes of subintimal angioplasty with selective stenting in TASC C and D FP disease. The patient, technical and radiological factors that affect the clinical outcomes post-intervention are analysed.

Methods and Materials: A single centre retrospective study with a prospective arm was performed in 52 consecutive patients undergoing endovascular treatment for TASC C and D FP disease from 2017 to 2021. Primary endpoints were primary and secondary clinical and radiological patency rates. Secondary endpoints were amputation free survival rate, limb salvage rate and occurrence of major adverse cardiac events. Kaplan-Meier curves were used to compare patency rates. Multivariable Cox regression analysis was performed to identify the variables which may affect patency rates.

Results: A total of 52 patients were analyzed with a mean follow up of 15.8 months. 17 patients (30.9%) were stented (PTA-S group). Primary radiological patency rates at 6, 12, 18 and 24 months were 92.3%, 80.7%, 71% and 69.2% in the total study population. Primary radiological patency rate at 6, 12 and 18 months for PTA group was 91.4%, 80% and 68% and for PTS group it was 94.1%, 82.3% and 82.3%

respectively(P=0.145). Clinical patency rates were also comparable for the PTA and PTA-S group (91.4 vs 88.2%, P=0.849). Multivariate analysis showed that smoking, quadrant wise calcium score (270-360 degree) of artery and post angioplasty dissection grade severe (>30 percent luminal narrowing) as independent predictors of loss of vascular patency

Conclusion: Subintimal angioplasty with selective stenting has good midterm outcomes in TASC C and D femoropopliteal disease, comparable with surgical bypass.

MIDTERM CLINICAL AND PATENCY OUTCOMES OF SUBINTIMAL ANGIOPLASTY WITH SELECTIVE STENTING IN TASC II C AND D FEMORO-POPLITEAL DISEASE

INTRODUCTION

Peripheral artery disease (PAD) remains a problem of increasing prevalence causing increased health care costs and disability. Chronic limb-threatening ischemia (CLTI) which represents the final stage of the PAD causes significant morbidity resulting in amputation and reduced quality of life among the affected individuals. Though multidisciplinary management for PAD is available, lack of awareness and failure for early diagnosis remain as obstacles for effective management.

Open surgical bypass and endovascular treatment remain the two treatment options for PAD not responding to medical management. TransAtlantic Inter-Society Consensus II (TASC II) recommends open surgical bypass for the treatment of TASC C and D lesions of the femoral-popliteal arteries(1). The recent Society of Vascular Surgery (SVS) 2020 guidelines also suggest open surgical bypass for long (>20cm) femoro-popliteal (FP) disease in average-risk patients(2). However, due to advancements in endovascular techniques and devices, most physicians follow an "endovascular-first" approach for these lesions because of decreased procedural morbidity. Among the endovascular options, the European Society of Cardiology (ESC) guidelines 2017 suggest primary stenting in patients with <25cm femoropopliteal (FP) disease. No clear guidelines regarding the treatment of choice have been mentioned for >25cm FP disease. Considering the high initial costs and uncertainty regarding the medium and long term patency of stents in long segment TASC C and D FP disease, many physicians perform selective stenting only in cases if there is significant residual stenosis of >30% post angioplasty or when a flow-limiting dissection occurs. A systematic review comparing balloon angioplasty vs bare-metal stenting in SFA (superficial femoral artery) disease found a short-term benefit in primary patency for the stented group at 6 months, but this was lost at 12 months follow up(3). Even though few randomized controlled trials suggest long term patency for bare-metal stent, none of them focus solely on TASC C and D FP disease.

Most of them are sponsored by stent manufacturers and hence interpreted with a pinch of salt.

REVIEW OF LITERATURE

The term 'peripheral arterial diseases' comprises all arterial diseases caused by altered structure and function of the arterial wall other than those involving the coronary arteries and the aorta. Among the various pathological processes affecting arteries, atherosclerosis remains the most important cause(4). This should not be confused with the term 'peripheral artery disease(PAD), which is used mainly to describe lower extremity artery disease (LEAD).(5)The term "critical limb ischemia" (CLI) was replaced by the term Chronic Limb threatening Ischemia(CLTI) to include a broader spectrum and more diverse group of patients with varying degrees of ischemia that can delay wound healing and increased risk for amputation.

CLTI is a clinical syndrome defined by the presence of objectively documented PAD with any of the following clinical symptoms or signs:

- Ischemic rest pain confirmed by one or more abnormal hemodynamic tests.(Ankle-brachial index (ABPI) <0.4, highest measurable ankle pressure< 50mm Hg, absolute toe pressure <30mm Hg, transcutaneous partial pressure of oxygen (TcPO2)<30mm Hg
- Tissue loss or ulceration of lower limbs for at least 2 weeks

The term does not include patients with purely venous and neuropathic ulcers, trauma, acute limb ischemia (< 2 weeks of presentation)or those related to non-atherosclerotic conditions like vasculitis, Buerger's disease and radiation arteritis(2).

Epidemiology:

According to 2010 estimates, more than 200 million people worldwide were living with PAD In a meta-analysis, the prevalence of PAD in men ranged from 6.5% (aged 60-69 years) increasing to 11.6% (aged 70-79 years) and peaking at 29.4% (>80 years)(6). The prevalence is high among men in high-income countries, whereas in low- and middle-income countries women show higher prevalence(7). Asians and Hispanics have a lower prevalence of PAD than whites, suggesting environmental and geographic risk factors as causes for PAD rather than genetic factors alone(8). CLTI contributes to 11.08% of the total PAD patients of which 0.11%-1.59% correspond to

severe CLTI(9). Woman present with more symptomatic disease because of their higher life expectancy compared to men.

Risk factors:

Modifiable risk factors for PAD include smoking, diabetes, hypertension, hypercholesterolemia, and air pollution. Smoking is the most significant risk factor for development and progression of PAD, while those with diabetes have higher risk of amputation than other risk factors(10). There are studies suggesting lower rates of PAD in patients with a higher body mass index (BMI) called the "obesity paradox", which might be explained by the fact that smoking is associated with a lower BMI(11). Elevated total cholesterol and low-density lipoprotein cholesterol (LDL-C) and reduced high-density lipoprotein cholesterol(HDL-C) levels is associated with increased mortality in patients with PAD(12). Chronic kidney disease (CKD) patients with end stage renal disease have heavily calcified arteries and demonstrate a distal pattern of disease and act as a strong risk factor for PAD(11). Air pollution, high homocysteine, obesity and sedentary life style are also considered as risk factors (11).

Natural history

Untreated PAD and CLTI after a median follow-up period of 12 months has a mortality and amputation rate of 22%(13). A meta-analysis by Sigvant et al. showed a progression rate of 12-29% for untreated PAD to CLTI over a five years. However approximately 50% of CLTI patients do not have a history of PAD(Primary CLTI)(14). Marston et al, in his study of 574 patients with CLTI who did not undergo revascularization, showed a mortality rate of 31.6%, mainly due to cardiovascular disease(CVD), and 23% required major amputation(15).The rate of progression from PAD to CLTI appears to be higher in men, who have had a stroke, heart failure, and associated diabetics. So aggressive medical management can prevent progression of PAD to CLTI thus improving the overall prognosis(16).Although PAD is a multilevel disease there are a few anatomic patterns observed based on the risk factors present. Advanced age, diabetes and CKD produce a predominant infrapopliteal disease with involvement of pedal arteries. Male gender, hypercholesterolemia and smoking are associated with predominantly femoropopliteal disease(17).

Clinical classification systems

a. Rutherford classification:

Rutherford described a classification system in 1997 combining clinical symptoms with objective findings like Doppler, ankle brachial indices (ABI), and pulse volume recordings(18).

b,Fontaine classification:

Table 1: Comparing Fontaine and Rutherford classification systems for PAD

FONTAINE			RUTHERFORD		
STAGE	SYMPTOMS		GRADE	CATEGORY	SYMPTOMS
I	Asymptomatic		0	0	Asymptomatic
II	IIa	Non disabling intermittent claudication	I	1	Mild Claudication
	IIb	Disabling intermittent claudication	I	2	Moderate claudication
III		Ischemic rest pain	I	3	Severe claudication
IV		Ulceration or gangrene	II	4	Ischemic rest pain
			III	5	Minor tissue loss
			III	6	Major tissue loss

C. TASC classification 2007:

TASC II(Figure 1) classification which was updated in 2007, addresses many aspects of PAD, with main focus on the anatomy and assigning treatment recommendations (open vs endovascular) based on the lesion grading. Type C FP lesions include multiple stenoses or occlusions for a total length of 15 cm and recurrent lesions that need revascularization after two previous endovascular procedures. Type D FP lesions include chronic total occlusions of CFA or SFA (>20 cm, involving the popliteal artery), chronic total occlusion of popliteal artery and proximal trifurcation vessels of any length. Based on this recommendation, endovascular therapy is the treatment of choice for TASC A lesions. For TASC B lesions endovascular approach is the preferred approach.(19) For TASC C lesions surgical management provides better long-term results with endovascular techniques reserved for patients at high risk for surgery. They recommended open surgery for TASC D lesions. However, due to advancement of endovascular techniques, many studies suggest an endovascular first management of TASC II C and D lesions(20).

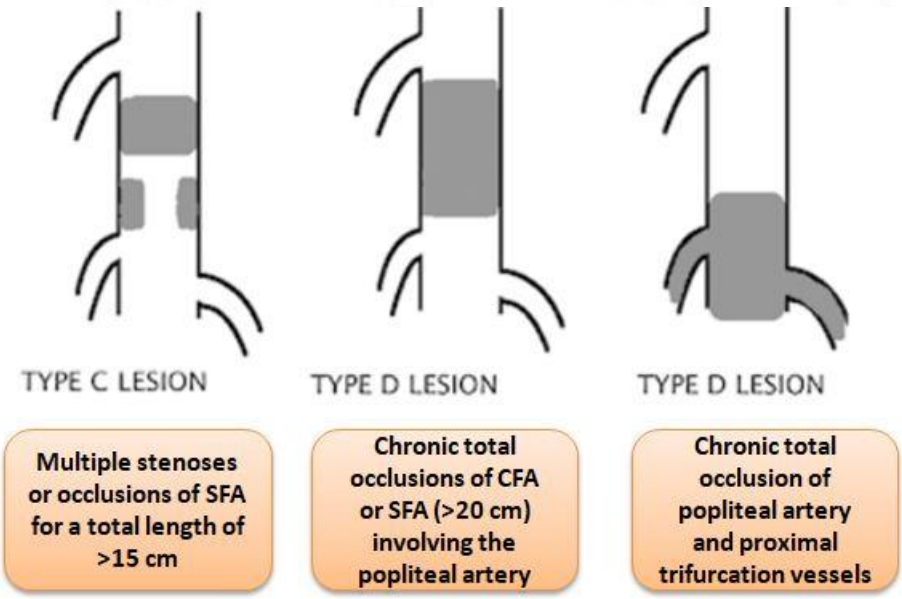


Figure 1: Demonstrating TASC II C and D classification of FP disease

d. WIFI classification 2019:

The Global vascular surgery guidelines 2019 recommends use of the WIFI classification to stage the limb in patients with CLTI. The WIfI system takes into

account three key factors: wound, ischemia, and foot infection. WIfI correlates with limb salvage rates, amputation free survival and wound healing and can stratify patients who are likely to benefit from revascularization(21).

e. GLASS scoring system-SVS 2019:

The previously used anatomic classification schemes for PAD are lesion or segment based and mainly focus on quantifying the overall burden of disease, rather than incorporating the lesion complexity. To solve this, GLASS (Global Limb Anatomic Staging System) was developed to aid in clinical decision-making. GLASS incorporates, the target arterial path (TAP) and estimated limb-based patency (LBP) concepts. TAP is defined as the optimal arterial pathway to restore in-line (pulsatile) flow to the ankle and foot based on least diseased path or angiosome preferred path as decided by the operating radiologist. LBP is the maintenance of in-line flow throughout the TAP(2).

f. SVS Runoff score:

The modified SVS runoff score(Table 2) was introduced to grade the severity of PAD by taking into account the individual angiographic run-off scores of the popliteal artery and infrapopliteal arteries. The popliteal artery, ATA, PTA and peroneal artery are given a score of 0-3 based on the degree of stenosis(22).

Table 2: Demonstrating Modified SVS runoff scoring system

Score	Degree of stenosis
0	<20% stenosis
1	21% to 49% stenosis
2	50% to 99% stenosis
2.5	Vessel occluded for less than half of its length
3	Vessel occluded for greater than half the vessel length

The individual score for the popliteal artery is multiplied by 3 and 1 is added to it, so that the possible popliteal artery scores range from 1 to 10. The individual scores of all popliteal, ATA, PTA and peroneal arteries are futher added together to give the Modified SVS runoff score which ranges from 0-19. We classified our patients into two groups, one with runoff score <10, the other with score >=10.

g. Post angioplasty dissection scoring systems in SFA:

According to Kobayashi et al(23), post angioplasty SFA dissections can be graded into

1) Grade A, no evidence of angiographic dissection;
2) Grade B, mild dissection, with diameter of the dissected lumen less than one-third of the normal diameter;
3) Grade C, severe dissection, with diameter of the dissected lumen more than one-third of the normal diameter

The National Heart Lung Brain Institute proposed a classification system(Table 3) for grading of post angioplasty dissections in coronary arteries(24). Some studies have applied the same to FP segment.

Table 3: NHLBI classficiation of post angioplasty dissection:

Type	Description
Type A	Radiolucency within the lumen with no persistence of contrast.
Type B	Parallel tracts or a double lumen separated by a radiolucent area with no stagnation of contrast.
Type C	Contrast seen outside the lumen
Type D	Spiral luminal filling defects with contrast stasis in false lumen.
TypeE	New, persistent filling defects inside the lumen.
Type F	Total occlusion of the lumen.

Imaging of vascular anatomy:

Vascular imaging must be done in all patients with suspected CLTI to identify the extent and severity of the disease and to plan revascularization. In patients who are candidates for revascularization complete anatomic staging of the disease should be performed. DUS imaging is considered as the first arterial imaging modality in patients with suspected CLTI. Other noninvasive vascular imaging modalities like CTA, MRA can be performed before invasive catheter angiography in patients with who are candidates for revascularization.

Compared to DSA, CTA was found to have high sensitivity and specificity in the Aorto-iliac disease (95% and 96%, respectively) and Femoro-popliteal disease (97% and 94%) but was found to be inferior in the infra-popliteal segment (95% and 91%) because of the blooming artifacts encountered in calcified arteries in the infra-popliteal segment(25). For assessing infrapopliteal disease, CE-MRA showed better specificity and sensitivity over CTA and DUS(26).

MANAGEMENT

Medical management:

In the absence of aggressive management of risk factors and associated co morbidities, CLTI has a mortality rate of 20% to 26% within 1 year. So the goal should be not only to salvage a functional limb but also to reduce cardiovascular morbidity and mortality through aggressive risk factor modification and by providing best medical therapy.

A single antiplatelet preferably clopidogrel is the agent of choice in patients with CLTI(27). Low-dose aspirin and rivaroxaban, 2.5 mg twice daily, can be used to reduce adverse cardiovascular events and ischemic events in patients with CLTI(28). Moderate- or high-intensity statin therapy with rosuvastatin (20-40 mg) and Atorvastatin (40-80 mg) is recommended to reduce all-cause and cardiovascular mortality in patients with CLTI(29). Anthony et al, demonstrated that PAD patients had a significantly higher incidence of MACE compared with those without PAD (16.3% vs 9.2%). Hypertension control with target levels of <140mm Hg systolic and <90mm Hg diastolic significantly reduces MACE in these patients(30). Angiotensin-

converting enzyme inhibitors (ACEIs), diuretics and calcium channel blockers have proven to reduce cardiovascular events to a similar extent(31).

Metformin should be used as the primary hypoglycemic agent of choice in patients with type 2 DM and CLTI, to achieve a HBA1c of <7%(32). Strict complete and permanent tobacco stopping interventions like pharmacotherapy and counseling should be considered along with adopting a healthy diet, weight control, and regular exercise for preventing MACE and disease progression(33). Paracetamol in combination with opioids can be used for pain control in patients with CLTI.

Exercise therapy:

In a systematic review including 30 RCTs, it was found that exercise therapy(ExT) is effective in improving symptoms and QOL and maximal walking distance in patients with intermittent claudication with a maximal walking distance improvement of 5 min(34). Exercise therapy should be done for minimum 3 months, with at least 3 hr/week, attaining the maximal or sub maximal distance every time. Supervised ExT provided better improvement in maximum walking distance than unsupervised ExT(35). In patients with femoropopliteal disease, where the profunda femoral artery is normal, the claudication will be relieved with ExT and intervention is mostly unnecessary. Only in patients whose daily life activities are restricted due too claudication, revascularization should be considered(36).

Endovascular vs surgery:

The challenge in endovascular therapy for long segment TASC C and D FP lesions is the long-term patency and durability of stents especially because FP segment is highly mobile. Currently, there are no RCTs comparing the endovascular vs surgery for TASC C and D lesions. With lack of long term durability of stents in long segment FP lesions, only ESC suggests primary stenting for <25cm(37).

For lesions >25 cm in length, there are no current recommendations for the choice of treatment whether endovascular or surgical bypass. There are no randomized controlled trials comparing endovascular therapy and surgery for long segment SFA lesions at present. 2017 ESVS guidelines suggest that for long segment lesions

surgical bypass using the great saphenous vein (GSV) graft is to be preferred because of its better long term patency rates than endovascular therapy. The 2 year primary patency rate of saphenous vein and PTFE bypass graft was 80 and 69%, respectively, and after 5 years it was 74 and 39% respectively (38). Endovascular treatment may be reserved for patients not deemed to be fit for surgery. Aihara et al, compared long term outcomes of endovascular vs bypass surgery in TASC C and D FP lesions and concluded that endovascular therapy is a good option because of its lower complication rate and good secondary patency rate in patients who are not fit for bypass(39). The challenge of endovascular therapy in long segment FP lesions is the long-term patency and durability of stents where the artery is very mobile, mainly in the adductor canal region.

For CLTI in average and low surgical risk patients the following protocol has to be followed based on the GLASS and WIFI scoring (SVS 2019 guidelines).(Figure 2). For high risk patients endovascular intervention is preferred irrespective of the GLASS scoring.

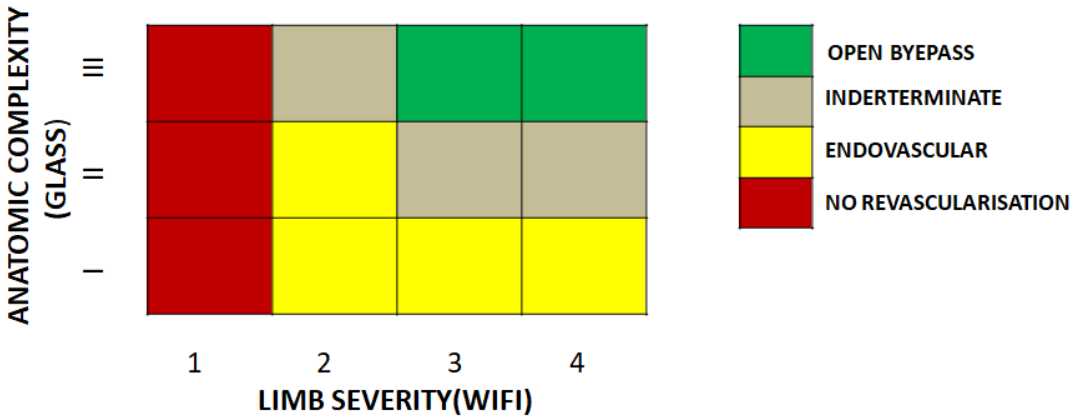


Figure 2: SVS 2019 protocol for CTLI based on GLASS scoring.

The Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial compared endovascular therapy to open surgery in CLTI patients in FP segment. They found no significant difference between endovascular therapy and surgery regarding amputation-free survival at 2 years followup. Bypass surgery was associated with improved survival (on average 7 months, P = 0.02) and amputation-free survival (6

months, P = 0.06) after 2 yearfollowup. However BASIlL trial included all grades of SFA disease and was not specific to long segment FP disease(40).

Patients with TASC D lesions commonly suffer from significant comorbid medical conditions and are therefore at increased risk for adverse events when treated with bypass surgery. Due to advanced techniques and devices, most physicians follow an "endovascular-first" approach for complicated long segment lesions because of decreased procedural morbidity. The increased biomechanical stress at the femoropopliteal artery challenges the durability of stent -based endovascular interventions performed at this segment, increasing the risk of stent fracture and associated re stenosis or re occlusion. Among the endovascular options, plain balloon angioplasty, drug-coated balloon (DCB), stent placement (bare-metal stent, drug-eluting stent [DES], or covered stent), and atherectomy are the available options in these complex long segment anatomies. However, there are only few comparative studies to decide the choice of a specific endovascular approach in complex CLTI.

Comparison of endovascular techniques in FP segment

The VIASTAR trial compared heparin bonded covered stents and bare metal stents for long femoropopliteal lesions and demonstrated significantly high clinical and patency benefits for heparin-bonded covered stents compared with BMS in lesions ≥20 cm(41). Schillinger et all compared plain balloon angioplasty with optional stenting vs primary nitinol stenting in FP lesions with mean (+/-SD) length of the lesion 132+/-71 mm in the stent group and 127+/-55 mm in the angioplasty group. They demonstrated higher patency rates in primary stenting group in the intermediate term, compared to balloon angioplasty with optional secondary stenting group(42).

The Zilver PTX trial, compared primary DES versus percutaneous transluminal angioplasty (PTA), and PTA with BMS and demonstrated that 5 year followup, patency (66.4% versus 43.4%, P<0.01), and freedom from reintervention (83.1% versus 67.6%, P<0.01) was higher for the DES group compared to the PBA and BMS group. However the median length of the lesions included in the study was 66.4+/-38.9mm(43).

The LEVANT II trial which showed superior patency and survival rates for paclitaxel DCB over PBA over 5 year. However the mean treated lesion length was 107.9mm(44). The THUNDER trial demonstrated that reduced TLR rate related to DCB in FP lesions was maintained over the 5-year duration. Mean treated lesion length was 7.4 ± 6.5 cm(45).

A post hoc analysis of IN.PACT global study which compared DCBs with PBA for mean lesion length of 12+/-10cm showed freedom from 12-month TLR of 91.6%(46). No studies as of now show superiority and safety of DCBs over PBA for lesions longer than 20cm.

The three year followup results from RESILIENT trial suggests that for femoropopliteal lesions up to 15 cm length primary stenting was found to have superior short-term patency and better long term TLR and freedom from adverse events compared to balloon angioplasty alone. The 3 year freedom from target lesion revascularization (TLR) was 75.5% for the stent group vs. 41.8% for the angioplasty group ($p<0.0001$). However at 3 years, no significant difference in survival rates and major adverse events were noted between the stent and angioplasty groups(47).

Armstrong et al compared the patency rates and balloon angioplasty vs. nitinol stent placement for patients with long femoropopliteal (FP) with mean length of 254±58 mm and concluded that stent placement in long FP lesions is associated with superior outcomes to balloon angioplasty at 1 year.

Elmahdy et al. demonstrated primary patency rates of 81.4±1.1%, 77.7±1.9% and 74.4±2.8% at 12, 24, and 36 months respectively for primary nitinol placement for SFA lesions with mean length of the lesions was 17.9±11.3mm(48).

A systematic review and metaanalysis comparing various endovascular interventions in long segment FP occlusions with lesion length >20 mm showed that heparin bonded ePTFE covered stents (69%) and DCBs (73%) showed higher 1-year primary patency rates than self-expanding nitinol stents (55%) or percutaneous transluminal angioplasty (PTA) with provisional stenting (54%) (49).

Rossen et al in their study compared long term clinical patency of PTA with optional stenting in SFA lesions and found that PTA with selective stenting showed comparable long term clinical patency rates compared to primary stenting(50). Further RCTs should be done comparing the various endovascular options for treating complex TASC C and D SFA disease with prime focus on long term clinical patency rates and cost effectiveness.

Lacunae in literature regarding intervention for long segment(TASC C and D disease

Although various endovascular options like plain balloon angioplasty, drug-coated balloon (DCB), stent placement (bare-metal stent, drug-eluting stent [DES], or covered stent), and atherectomy devices are the available for complex long segment FP lesions there are no adequate RCTs and long term followup studies comparing the efficacy of various methods. Most of the studies available are sponsored and so the results should be interpreted with caution. The available studies are based on duplex ultrasound derived patency rates rather than clinical patency rates, which has better correlation with the patient's symptoms.

The clinical risk factors, pre and post procedure radiological factors which adversely affect the patency of stenting in long segment FP lesions have not been analysed by large population clinical studies. Only very few studies have compared the outcomes between intraluminal vs subintimal techniques of angioplasty. No study has clearly demonstrated the superiority of one technique over other.

Though multiple studies have shown superiority of vasculomimetic stents over self expanding nitinol stents and plain balloon angioplasty in FP lesions limited literature evidence exists regarding their long term followup outcomes in TASC C and D lesions.

There is no standardized consensus in performing selective stenting vs primary stenting for TASC C and D lesions. Also if a protocol of selective stenting is followed especially in patients whose life expectancy is less or whose ambulation is restricted due to other comorbidies and in patients who have cost constraints, the pre and post procedure factors which favour stenting have not been clearly defined. Our study was

performed with an intention to cover all these lacunae in literature pertaining to the intervention for TASC C and D FP disease.

AIMS AND OBJECTIVES

- **Primary objective**

1. To analyze the midterm clinical and radiological patency outcomes of subintimal angioplasty with selective stenting for TASC II C and D Femoro-popliteal disease).
2. To compare the clinical and radiological patency outcomes of subintimal angioplasty vs stenting group

- **Secondary objectives**

1. To identify the clinical, radiological and procedural risk factors which affect patency of endovascular treatment in TASCII C and D FP disease.
2. To suggest if selective stenting in long segment FP lesions is justified over primary stenting.

MATERIALS AND METHODS

Study type:

This is a single center retrospective cohort study with a prospective arm, in patients undergoing endovascular intervention for femoro-popliteal (FP) disease between January 2017 and March 2021. All consecutive patients who underwent treatment for a first episode of symptomatic femoropopliteal disease were selected.

Inclusion criteria:

- TASC II C and D femoropopliteal disease with who underwent endovascular treatment
- Patients with documentation of age, sex, presence of DM, hypertension, CAD, stroke, Rutherford and Fontaine classification, ankle brachial index (ABI) and a preprocedural CT angiogram in hospital registry
- Rutherford 4-6 symptoms
- Rutherford 3 not responding to medical / exercise therapy

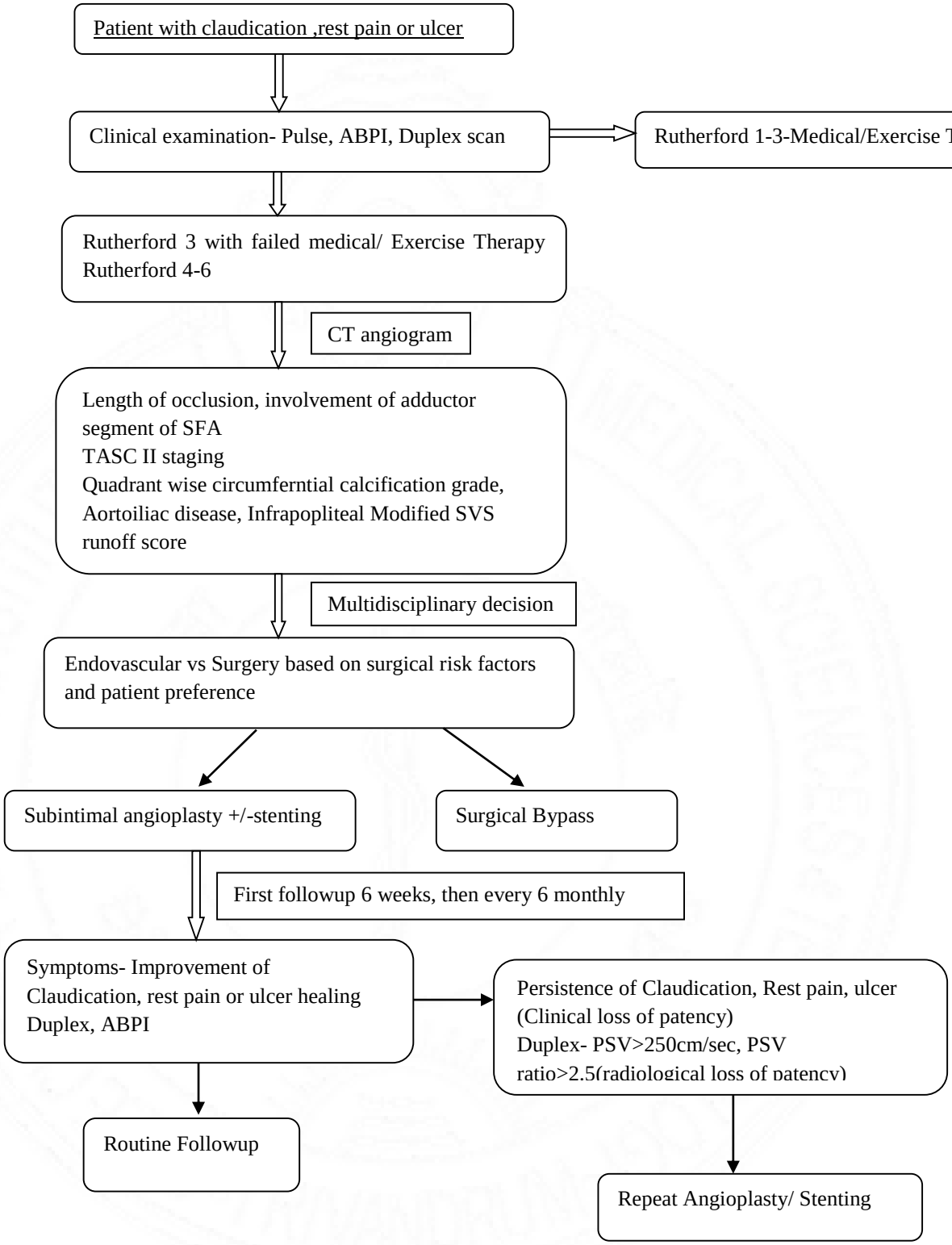
Exclusion criteria:

1) Patients with TASC II A and B FP disease

2) Concomitant Aortoiliac disease

3) Patients not willing for follow up

Study design:



The clinical details and demographics of the patients were obtained from all the patients (Table4) The pre procedure doppler and ABPI was obtained in all patients.

A pre-procedure CTangiogram was performed in all patients with Rutherford 3-6 symptoms. The CT scan was analyzed and classified on TASC score, the length of obstruction, the degree of vessel wall calcification presence of aortoiliac disease and infrapopliteal disease was quantified according to SVS score .

Table 4: Proforma for preprocedure evaluation

CLINICAL DETAILS	**PRE-PROCEDURE CTA**
Symptoms- Claudication, rest pain, ulcer/gangrene	Length of occlusion
Age, Sex, Smoking	TASC II Grading
Diabetes, Hypertension, CAD	Quadrant wise circumferential vessel wall calcification
Stroke, Hypercholesterolemia	Concomitant Aorto-iliac disease
	Involvement of adductor segment of SFA
IMAGING	
Duplex and ABPI	

The choice of treatment between endovascular and surgical management was based on a multidisciplinary evaluation and patient interest. The endovascular procedure was performed by a team of interventional radiologists with more than five years of experience in vascular interventions. Subintimal angioplasty was performed in all patients. Decision for stent placement was taken when there was a residual stenosis of more than 30% after subintimal angioplasty is seen or if a flow limiting dissection (Kobayashi grade 2/3) occurred. Stent placement was also based on the

decision of the treating radiologist based on his experience. Two patients with residual stenosis of more than 30% were not stented considering the cost constraints of the patient. Thus, based on these factors a selective stenting policy was followed for all lesions.

Endovascular procedure

. The ipsilateral antegrade approach was used when the ipsilateral CFA was of good calibre free of atheromatous plaque and at least 10cm length of normal segment CFA and proximal SFA was there to accommodate the sheath. Contralateral retrograde approach was used for cases where an antegrade route was risky due to extreme obesity, diseased ipsilateral CFA or flush SFA occlusions. A Balkin modification of flexor long sheath (COOK Medicals) was used to cross over the aortic bifurcation in cases of contralateral retrograde approach. A subintimal channel was created by making a 'Bolia loop' using a 0.035" inch J tip hydrophilic wire (Terumo, Tokyo, Japan) with the wire supported by a 5F RC catheter. In most cases a slight modification of the tip of the 5F RC catheter was used for re-entry into the true lumen. No dedicated re-entry catheters were used. In cases where re-entry was not possible, retrograde pedal approach was attempted and crossed using SAFARI technique. 5000 IU of heparin was administered after crossing the lesion and confirming the intraluminal location of the catheter followed by angioplasty from distal to proximal using a 5mm or 6 mm balloon depending on the diameter of normal, non-diseased SFA. Decision for stent placement was taken when there was a residual stenosis of more than 30% after subintimal angioplasty or if a flow limiting dissection occurred. Some patients with residual stenosis of more than 30% were not stented considering the non-affordability. Stenting was performed using self-expanding nitinol stents covering the entire subintimal channel including entry and re-entry points. Post stenting angioplasty was performed in all cases. The sheath was removed after ACT comes less than 175 seconds. Intravenous heparin was given for 48 hours and Dual antiplatelets continued for 6 weeks and changed to single anti-platelet after 6 weeks.

Follow up protocol:

Post procedure ABPI was measured and all patients were followed up with clinical examination, ABPI and duplex scan (Table 5) at 6 weeks post procedure then

at 6 monthly intervals for 36 months. All patients received proper instructions on how to report any symptoms in the treated leg. The follow up time of each patient was calculated from first day of treatment to the date of lost to follow-up, death, or the end of the follow up period (April 1, 2021).

Duration- First follow-up 6 weeks post procedure, then 6 monthly thereafter.

Table 5: Profroma for post procedure followup

CLINICAL	**IMAGING**
Clinical examination- Pulse	ABPI
Improvement in claudication, rest pain and ulcer healing	Duplex imaging

Endpoints:

The primary endpoint was the clinical and radiological primary patency rates of both the PTA (subintimal angioplasty only) and PTA-S (Angioplasty with stenting) groups. Primary clinical patency was defined as freedom from symptoms of claudication, rest pain, non-healing ulcer and freedom from revascularization of the lesion (any one of these parameters). Primary radiological patency was defined as freedom from stenosis of more than 50% or PSV ratio >2.5 or PSV of >250cm/sec in the previously treated FP lesion site.(PSV ratio is the ratio between PSV taken at the level of maximum stenosis and PSV taken at approximately of 2cm above the stenosis(in normal vessel)

Secondary clinical patency was defined as freedom from symptoms (claudication, rest pain, non-healing ulcer) and from revascularization after a re-intervention had taken place to restore patency. Secondary radiological patency was defined as freedom from stenosis of more than 50% or PSV ratio >2.5 or PSV of >250cm/sec after a re-intervention has taken place to restore patency. Secondary endpoints were the amputation free survival rates, limb salvage rates and overall survival rates between both the groups.

Reintervention

If there was return of patient symptoms (claudication/rest pain or ulcer) or restenosis of more than 50% in doppler or PSV ratio of >2.5, then reintervention (PTA/PTS) was done with the same technique and protocol used in the previous setting.

Data sources/ measurements:

Patient data and information on stent type and size, number of stents, size of balloon used, and reason for stent placement were collected from patient's hospital medical records. For data which were found missing, pair wise deletion was done. CTAs were reviewed to determine TASC II classification and GLASS classification of the lesions. DSA images were analyzed to identify the access site, techniques for crossing the lesion, complications, and grade of calcification and the post angioplasty dissection grades.

Statistical analysis:

The collected data were analysed with IBM SPSS Statistics for Windows, Version 23.0. (Armonk, NY: IBM Corp). Frequency and percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables. The Kaplan Meier curve was used to find the primary clinical and radiological patency rate and multivariate analysis was used to find variables possibly associated with loss of primary patency. The patients were divided into angioplasty only (PTA) group or PTA-S (Angioplasty plus stenting) groups and then analyzed. Continuous and non-continuous data between the groups were compared using the Student t test and the chi-square test, respectively. Mann–Whitney U test was used if the distribution was not of normal or Gaussian pattern. Kaplan–Meier analysis was used to analyze the event free period and Mantel Cox log rank test was used to compare the radiological patency, clinical patency, overall survival and amputation free survival between PTA and PTA-S groups. Adjustments were made for age, diabetes, hypertension, ankle brachial index, TASC and GLASS classification, Fontaine classification, CAD and stroke. A multivariate analysis was performed using a Cox proportional hazard regression model to identify factors which effect of patency,

survival and amputation rates during follow up. Statistical significance was defined as $p < .05$.

RESULTS

Between January 2017 and April 2021, 472 patients underwent invasive treatment for femoropopliteal disease. After excluding patients undergoing surgical bypass and those with TASC A and B lesions, a total of 53 patients were planned for endovascular interventions either PTA or PTS. Of the 53 patients technical success was achieved in 52 patients (98.11%) and one of the patient had to resort to surgical bypass due to diffuse thrombosis of SFA even after multiple attempts of thromboaspiration and CDT. 35 patients were treated by PTA and 17 patients were treated by PTA with stenting

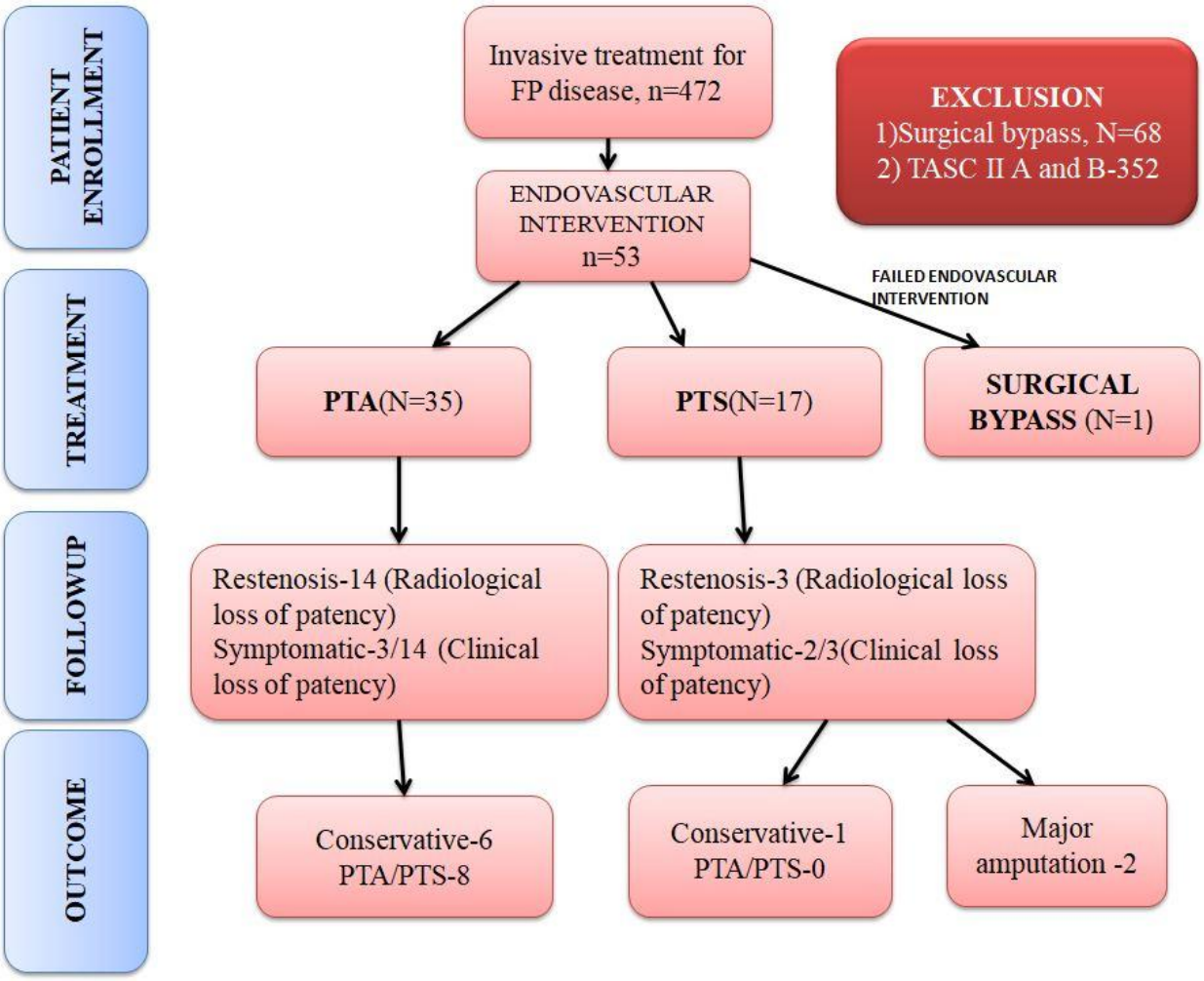


Figure 3: Flowchart of study results

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1.DEMOGRAPHICS

A.Gender Characteristics:

Among the study population 41were males(78.8%). Among the PTA group 28 (80%)were and in the PTS group 13(76%).

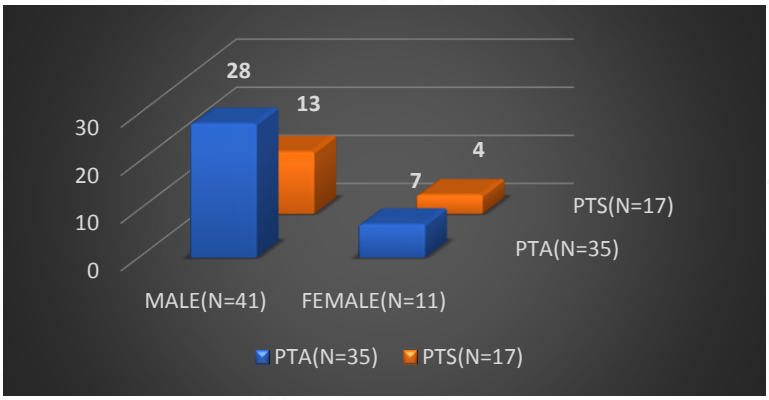


Figure 4: Gender characteristics of population

B. **Age characteristics:**

36.3% fell under the 60-69-year age group correlating with the major incidence of PAD in this age group globally. 3 patients were in age group less than 50 years

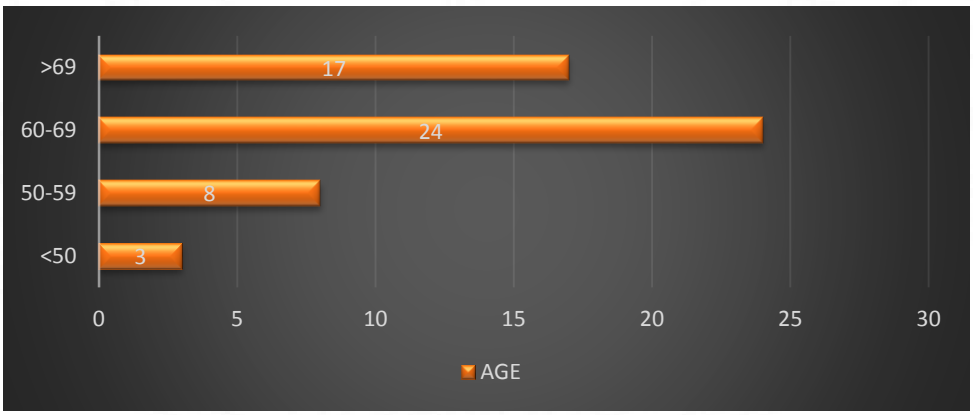


Figure 5: Age characteristics of population

C. **Risk factor**

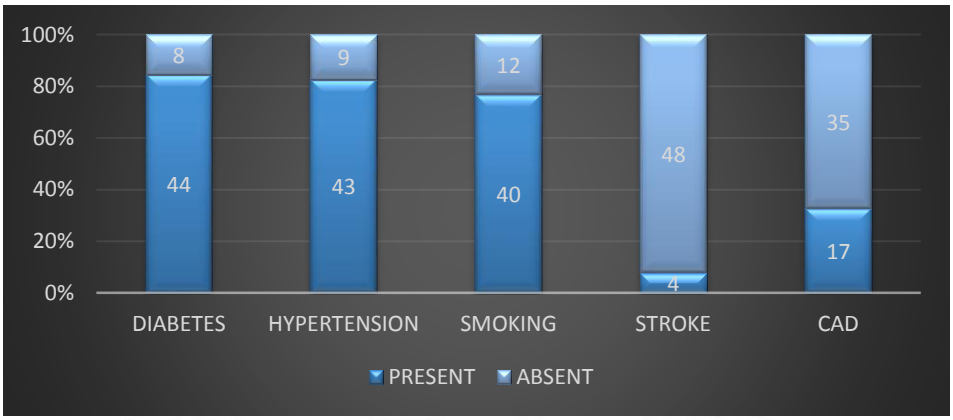


Figure 6: Risk factor distribution of population

Among various risk factors Diabetes (84.6%), smoking (76.9%) and hypertension (82.6%) were predominantly found in our study population. Around 1/ 3 of the patients had significant coronary artery disease.

D. Fontaine and Rutherford classification subgroups:

29 (56%) patients presented with ulcer or tissue loss. 11 patients (21%) presented with only rest pain without ulcer. 12 patients (23%) who presented with claudication after failure of supervised exercise therapy (SET) were treated endovascularly.

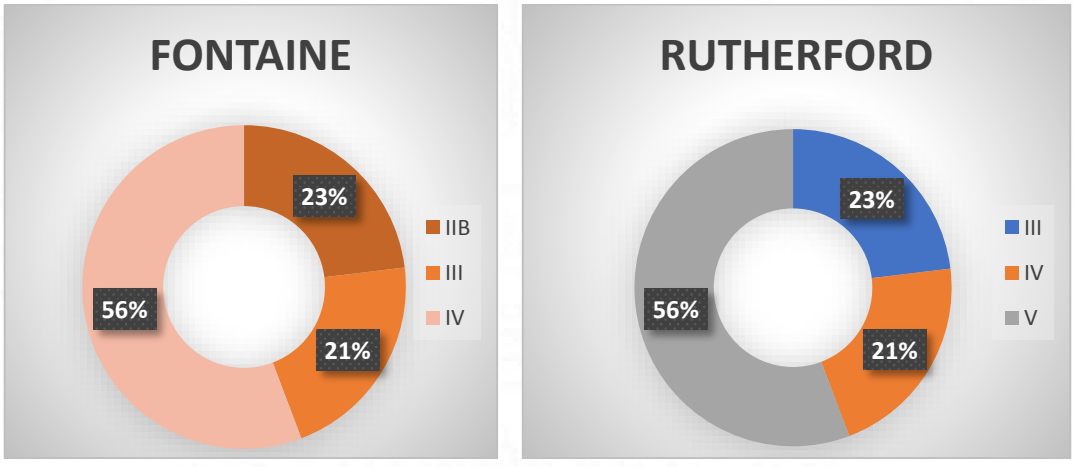


Figure 7: Rutherford and Fontaine classification among the study population

E. TASC II and GLASS classification subgroups:

Approximately 31(59.6%) patients had TASC II D FP disease and 24(46%) had GLASS IV disease based on the pre-procedure CTA images.

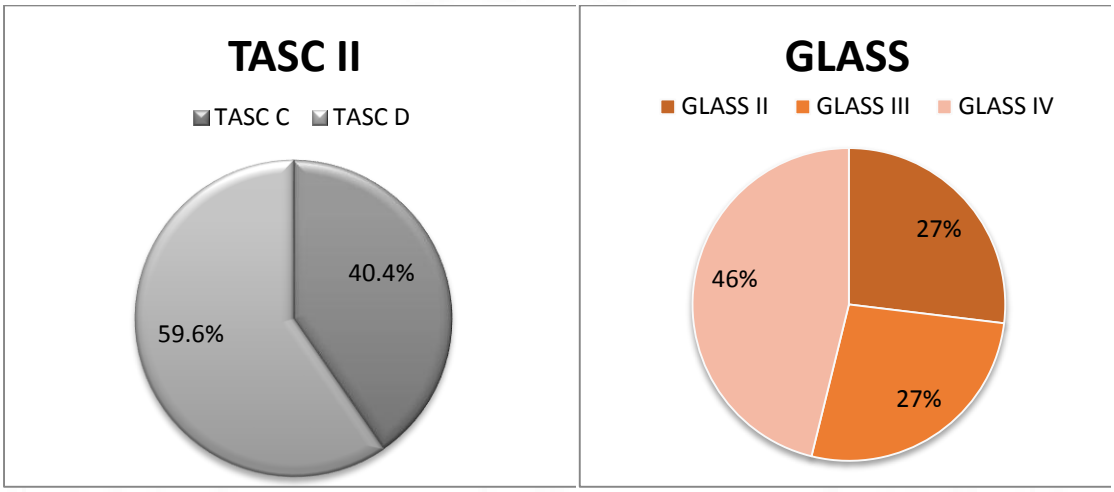


Figure 8: TASC II and GLASS staging among the study population

2.PATIENT CHARACTERISTICS BETWEEN PTA AND PTS GROUPS:

A. Among the 52 patients, plain balloon angioplasty was performed in 35 patients and 17 patients underwent PTA with stenting as per the decision of the operating interventional radiologist. There were no significant differences between pretreatment characteristic between both the groups based on the age, gender distribution, pre procedure ABPI, TASC II, GLASS, Rutherford and Fontaine classifications

Table 6- Patient characteristics between PTA and PTS groups

	Total	PTA n (%)	PTS n (%)	P value
Patient Numbers	52	35(67.3%)	17(0.32)	
Age, mean (SD)	63.11(6.02)	63.22(4.72)	63.47(8.3)	0.89
Gender, male (%)	42(80.7%)	28(53.8%)	13(25%)	0.77
ABPI, mean	0.60(0.04)	0.62(0.58-0.71)	0.64(0.56-0.70)	-
TASC II Classification	0.26			
TASC C	21(40.4%)	16(45.7%)	5(29.41%)	
TASC D	31(59.6%)	19(54.28)	12(70.58%)	
GLASS	0.48			
GLASS II	14(27%)	11(31.4%)	3(17.6%)	
GLASS III	14(27%)	8(22.9%)	6(35.3%)	
GLASS IV	24(46%)	16(45.7%)	8(47.1%)	
Fontaine classification	0.40			
Fontaine II	12(23%)	10(28.5%)	2(11.7%)	
Fontaine III	11(21%)	7(20%)	4(23.5%)	

	Total	PTA n (%)	PTS n (%)	P value
Fontaine IV	29(56%)	18(51.4%)	11(64.7%)	
Rutherford classification	0.40			
Rutherford III	12(23%)	10	2	
Rutherford III	11(21%)	7	4	
Rutherford IV	29(56%)	18	11	

B. There was no statistically significant difference between both the groups based in the distribution of risk factors and comorbidities like current smoking, diabetes, hypertension, CAD, Stroke and hypercholesterolemia (Table 7). Both the groups did not differ in their mean and median follow up period (mean, 16.68 vs 15.05 months, p=0.48). Median follow-up period was 12 months in both the groups.

Table 7- Risk factor distribution between PTA and PTS groups

RISK FACTORS	TOTAL(n=52)	PTA(n=35)	PTS(n=17)	P Value
Current smoking	17(32.7%)	12(34.3%)	5(29.4%)	0.72
Diabetes	44(84.6%)	31(88.6%)	13(78.5%)	0.41
Hypertension	43(82.7%)	31(88.6%)	12(70.6%)	0.13
CAD	17(32.7%)	11(31.4%)	6(35.3%)	0.78
Stroke	4(7.7%)	4(11.4%)	0	0.29
Hypercholesterolemia	7(13.4%)	5(14.2)	2(11.7%)	0.80
Follow-up (months)(SD)	15.86	16.68(9)	15.05(4)	0.48

C.LESION CHARACTERISTICS:

The median lesion length in our study population was 20cm (6-33cm range). Approximately 45(86.5%) of patients showed involvement of adductor portion of SFA. Out of 52 patients 9 (17.2%) patients had concomitant popliteal artery involvement.

Calcium scoring system in SFA:

We used CTA images in axial plane to grade the circumferential vessel wall calcium distribution. The vessel wall was divided in axial plane into four sectors and the calcium grading was done by assessing the distribution of calcium in one or more of the four 90° sectors: grade 1 (0–90°), grade 2 (0–180°), grade 3 (0–270°), and grade 4 (0–360°)(51)

Table 8- Lesion characteristics between PTA and PTS groups

	TOTAL(n=52)	**PTA(n=35)**	**PTS(n=17)**	**P value**
Length of occlusion in cm, median(range)	20(6-33cm)	19(6-33cm)	21(10-25cm)	-
Involving adductor canal SFA	45(86.5%)	31(88.5%)	14(82.3%)	0.5
SVS run-off score				0.11
<10	37(71.1%)	22(62.8%)	15(88.2%)	
>=10	15(28.8%)	13(37.2%)	2(11.8%)	
Quadrant wise circumferential calcium score				

	TOTAL(n=52)	PTA(n=35)	PTS(n=17)	P value
Grade 4(270-360 degree)	16(30.7%)	13(37.14%)	3(17.64%)	
Grade 1-3(0-270 degree)	36(69.23%)	22(62.8%)	14(82.35%)	
Post Angioplasty Dissection scoring				
Grade 3	19/35(54.28%)			
Grade 1-2	16/35(45.71%)			

3. TECHNIQUES

In 18(34.6%) patients, in whom, due to the long and chronic nature of the occlusion, where re-entry was no possible, SAFARI technique was performed by ATA or PTA puncture. 8 patients (15.38%) underwent revascularization with antegrade approach. In 2 patients, where the popliteal trifurcation was not visualized, the entire procedure was performed with only infrapopliteal (ATA) puncture. Of the 53 patients technical success was achieved in 52 patients (98.11%) and one of the patient had to resort to surgical bypass due to diffuse thrombosis of SFA even after multiple attempts of thromboaspiration and CDT. 35 patients were treated by PTA and 17 patients were treated by PTA with stenting.

Table 9- Analysis of technical approach in the study population

APPROACH	No of patients
Ipsilateral CFA(Antegrade)	8
Contralateral CFA(Retrograde)	42

SAFARI Technique	18/24
Retrograde pedal	2

Stent characteristics:

Vasculomimetic stent (SUPERA, ABBOTT) was used in all patients. Among the 17 patients who underwent stenting, 2 stents were deployed in 2 patients (11.76%) in view of very long segment lesion. In 10 patients (58.8%), the reason for stent placement was residual stenosis of more than >30%. In 2 patients due to the acute thrombus formation post angioplasty in the SFA, stent was deployed.

Table 10: Reasons for stent placement

Residual stenosis	10
Dissection	5
Acute thrombus within SFA	2

4. OUTCOME ANALYSIS:

Total 17(32.7%) patients were found to have restenosis/occlusion (radiological loss of patency) by duplex scan during follow-up till 24 months. Out of these 14(40%) patients belonged to PTA group and 3(17.6%) patients belonged to PTS group. However out of these only 5(9.6%) patients presented with symptoms (clinical loss of patency) during follow-up, 3(8.5%) in the PTA group and 2(11.7%) in the PTS group (p=0.73).

Table 11- Outcomes in the study population

EVENTS	Total	PTA	PTS	P Value
Clinical loss of patency (worsening claudication, rest pain, ulcer)	5(9.6%)	3(8.5%)	2(11.7%)	0.71
Radiological loss of patency	17(32.7%)	14(40%)	3(17.6%)	0.10
Reintervention (plasty+/-stenting)	8(15.3%)	8	0	-
Major Amputation	2(3.84%)	0	2(11.6%)	-
MACE	13(25%)	9(25.7%)	4(23.5%)	0.94

Total 8 patients (including 3 with symptoms) underwent reintervention by plasty or stenting. All of them belonged to PTA group. Other 6 patients in whom radiological loss of patency was found, were kept under conservative management because of lack of symptoms and unwillingness to undergo re-intervention. Both the symptomatic patients in the PTS group were unwilling to undergo repeat intervention. During follow-up no major amputation was done in the angioplasty only group. 2(11.6%) patients in the PTS group underwent major amputation, one below knee and another above knee amputation.

Major complications included thromboembolism in 6 patients of which 2 patients were treated by stenting and 3 patients were managed by suction thrombectomy and balloon angioplasty. One patient was managed with catheter directed thrombolysis. Wire induced perforation of the collaterals from SFA was noted in 3 patients, which was managed by gelfoam embolisation

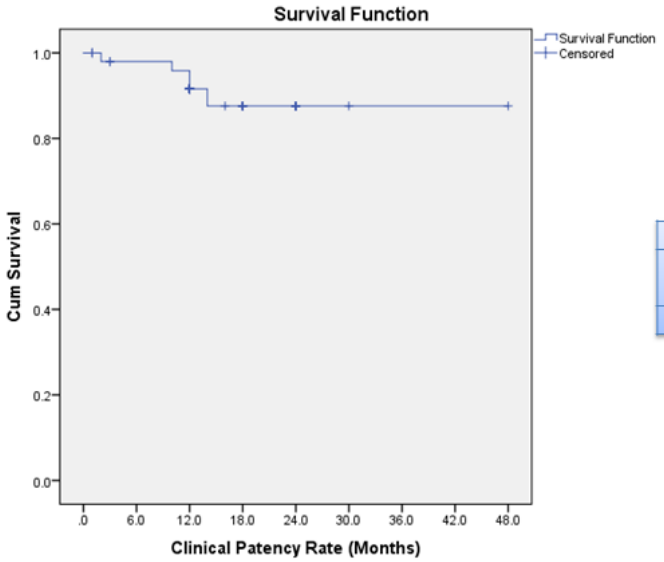
MACE was defined as new onset fatal/non-fatal myocardial infarction, stroke, hospitalization for unstable angina, coronary revascularization, or hospitalization for heart failure., Total of 13(25%) patients died due to MACE during the follow-up period, 4(23.5%) patients in PTS group and 9(25.7%) patients belonging to PTA group. No statistical significance was noted between the PTA and PTS groups in terms of occurrence of MACE, major amputation, radiological patency and clinical patency.

Patency rate

Kaplan–Meier analysis was used to assess the patency, limb salvage and survival rates.

A. CLINICAL PATENCY RATES:

Clinical patency rate was 90.4% at mean follow-up of 15.6 months, Total 5 patients, 3 in PTA group and 2 in PTS group presented with symptoms of restenosis (Rest pain and non-healing ulcer)

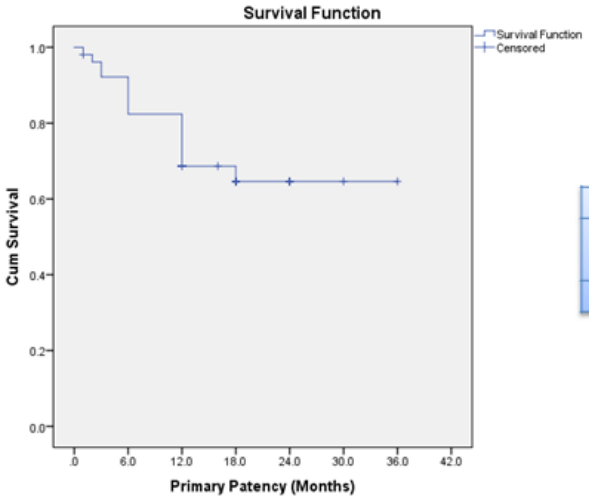


Case Processing Summary			
		Censored	
Total N	N of Events	N	Percent
52	5	47	90.4%

Figure 9: Survival analysis for primary clinical patency rates.

B. RADIOLOGICAL PATENCY RATES:

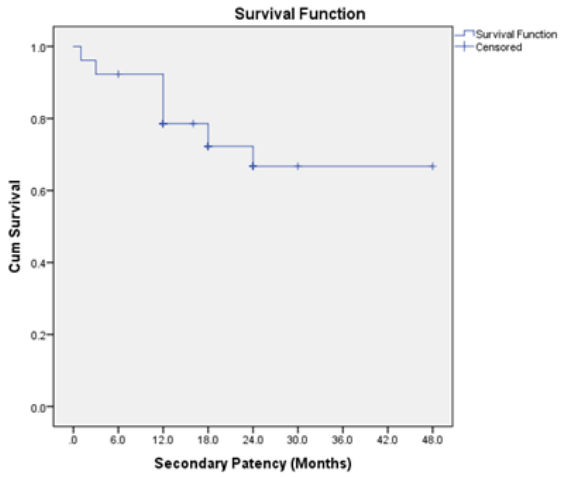
Primary patency rate of endovascular procedure at 6, 12, 18 and 24 months were 92.3%, 80.7%, 71% and 69.2% respectively in the total study population. The mean survival time is 26. 4 months.



Case Processing Summary			
		Censored	
Total N	No of Events	N	Percent
52	17	35	67.3%

Figure 10: Survival analysis for primary radiological patency rates.

Secondary patency rates at 6, 12, 18 and 24 months were 94.2%, 90.3%, 82.6%, 78.8% respectively in the total study population. The median survival time is 36.2 months.

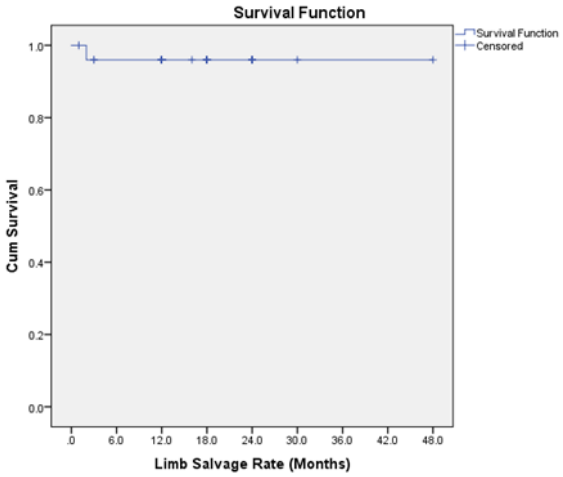


Case Processing Summary			
		Censored	
Total N	No of Events	N	Percent
52	14	38	73.1%

Figure 11: Survival analysis for secondary radiological patency rates.

C.LIMB SALVAGE RATE

Limb salvage rate was 96.2% at mean follow-up of 15.6 months. Total 2 patients among the entire study group underwent major amputation (one above knee, other below knee) within 2 months of procedure.

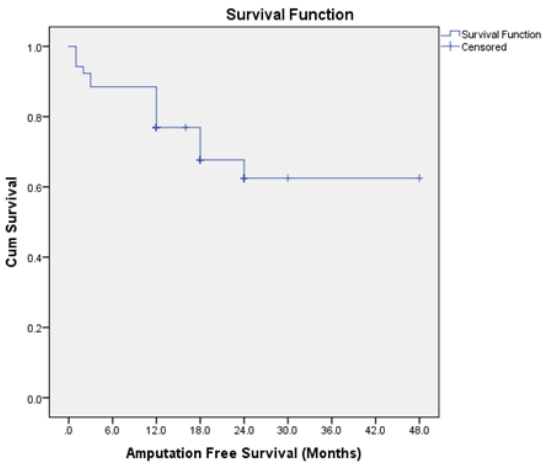


Case Processing Summary			
		Censored	
Total N	N of Events	N	Percent
52	2	50	96.2%

Figure 12: Survival analysis for limb salvage rates.

D.AMPUTATION FREE SURVIVAL RATE:

Mean Amputation free survival was 34.5 months.



Case Processing Summary			
		Censored	
Total N	N of Events	N	Percent
52	16	36	69.2%

Figure 13: Survival analysis for amputation free survival rates.

Variables associated with loss of primary radiological patency:

A multivariable analysis was done using a Cox proportional hazard regression model to identify predictors and factors associated with loss of primary patency during follow up. Factors like Diabetes, Hypertension, CAD, stroke, Age, current smoking, preprocedural ABPI and symptoms at presentation for procedure like rest pain only or ulcer were analyzed in multivariate analysis. Angiographic features like complete occlusion of the vessel vs stenosis, TASC C vs D, GLASS scoring, Length of the occlusion, Involvement of SFA at the adductor canal, calcium scoring on CT and size of angioplasty balloon used were subjected to multivariate analysis. Other post procedure angiographic features like Modified SVS run off scores and post angioplasty dissection grades by using Kobayashi classification and NHLBI classification were analyzed.

Table 12: Variables affecting primary patency

VARIABLES AFFECTING PRIMARY PATENCY	B	S.E.	Wald	df	P value	Exp(B)	95% C.I.for EXP(B)	
							Lower	Upper
HYPERTENSION	1.311	.787	2.772	1	.096	3.709	.793	17.351
CAD	-.730	.666	1.199	1	.274	.482	.131	1.780
STROKE	-1.242	1.106	1.261	1	.261	.289	.033	2.524
Age	-.069	.074	.871	1	.351	.933	.806	1.079
DIABETES	2.085	1.415	2.171	1	.141	8.041	.503	128.664
CURRENT SMOKING	-3.363	1.305	6.635	1	.010	.035	.003	.448
ABPI	6.318	10.320	.375	1	.540	554.519	.000	-
RESTPAIN	3.015	1.643	3.364	1	.067	20.380	.813	510.674
ULCER	.085	1.362	.004	1	.950	1.089	.075	15.717
GLASS GRADE (2 vs 3/4)	-.761	.771	.972	1	.324	.467	.103	2.120
TASC II (C vs D)	0.527	1.1	.025	1	0.53	1.5	0.200	13.988
SFA- ADDUCTOR CANAL	-2.226	1.850	1.447	1	.229	.108	.003	4.058
LENGTH OF OCCCLUSION (<20 vs >20cm)	.081	.099	.676	1	.411	1.085	.894	1.316

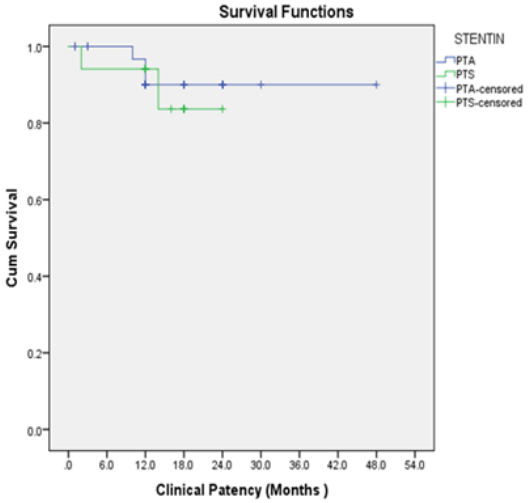
VARIABLES AFFECTING PRIMARY PATENCY	B	S.E.	Wald	df	P value	Exp(B)	95% C.I.for EXP(B)	
							Lower	Upper
MODIFIED SVS RUNOFF SCORE (<10 vs > 10)	-1.139	.800	2.028	1	.154	.320	.067	1.535
CALCIUM SCORE (4 vs 1-3)	-2.282	.779	8.587	1	.003	.102	.022	.470
BALLOON DIAMETER (5vs 6mm)	1.795	1.295	1.922	1	.166	6.017	.476	76.086
DISSECTION CLASSIFICATION-NHLBI- (GRADE C-F vs A-B)	1.679	1.169	2.064	1	.151	5.360	.542	52.973
DISSECTION CASSIFICATION-KOBAYASHI- (GRADE C vs A/B)	-4.072	1.228	10.988	1	.001	.017	.002	.189

Among the demographical and radiological factors analyzed, current smoking(>10 cigarettes/day), quadrant wise circumferential calcium scoring grade 4(>270 degree) and post angioplasty dissection grade C (severe) proposed by Kobayashi et al. were found as independent risk factors affecting primary patency in multivariate analysis. Modified SVS runoff score <10 showed a positive correlation with loss of primary patency but no statistical significance was noted. (P value =0.154). Similarly post angioplasty dissection grades C- F by NHLBI showed a positive correlation with loss of primary patency but no statistical significance was noted. (P value =0.151)

5.COMPARISON BETWEEN PTA AND PTS groups:

Primary patency, limb salvage rates, Amputation free survival rates and clinical patency rates were compared between PTA and PTS groups using mantel cox log rank test.

A. CLINICAL PATENCY RATES:



Case Processing Summary

STENTING	Total N	N of Events	Censored	
			N	Percent
PTA	35	3	32	91.4%
PTS	17	2	15	88.2%
Overall	52	5	47	90.4%

Overall Comparisons

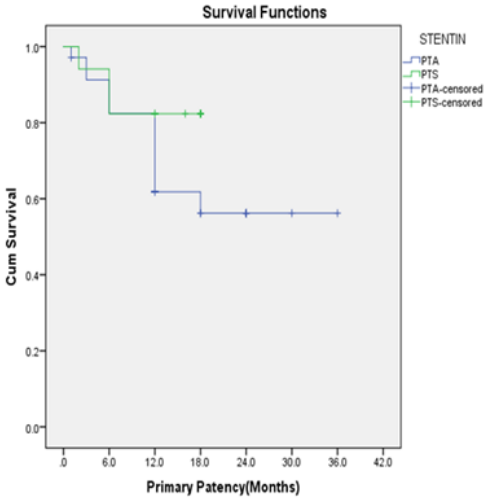
	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	.036	1	.849

Figure 14: Survival analysis comparison of clinical patency rates between PTA and PTS groups.

Mean Clinical patency was 44.33 months in PTA group and 21.66 months in PTS groups. No statistical significance was noted between both groups in terms of clinical patency.

B. PRIMARY RADIOLOGICAL PATENCY:

Primary patency rate at 6, 12 and 18 months for PTA group was 91.4%, 80% and 68% and for PTS group it was 94.1%, 82.3% and 82.3% respectively. No statistical significance was found in terms of primary patency survival curves between PTA and PTS groups(P=0.145)



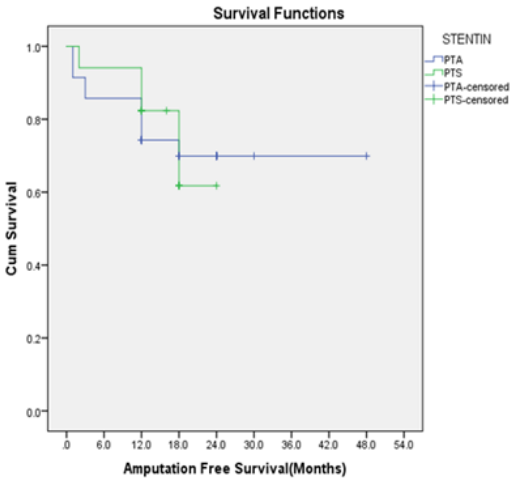
Case Processing Summary				
			Censored	
STENTING	Total N	N of Events	N	Percent
PTA	35	14	21	60.0%
PTS	17	3	14	82.4%

Overall Comparisons			
	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	2.122	1	.145

Figure 15: Survival analysis comparison of primary radiological patency rates between PTA and PTS groups.

C.AMPUTATION FREE SURVIVAL RATES:

No significant difference between both groups in terms of AFS rates was noted.



Case Processing Summary				
			Censored	
STENTING	Total N	N of Events	N	Percent
PTA	35	10	25	71.4%
PTS	17	5	12	70.6%
Overall	52	15	37	71.2%

Overall Comparisons			
	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	.001	1	.981

Figure 16: Survival analysis comparison of amputation free survival rates between PTA and PTS groups.

ILLUSTRATIVE CASES

Case 1: 69 year old male, chronic smoker, presented with claudicating pain right lower limb with claudication distance of 10m for past 5months.

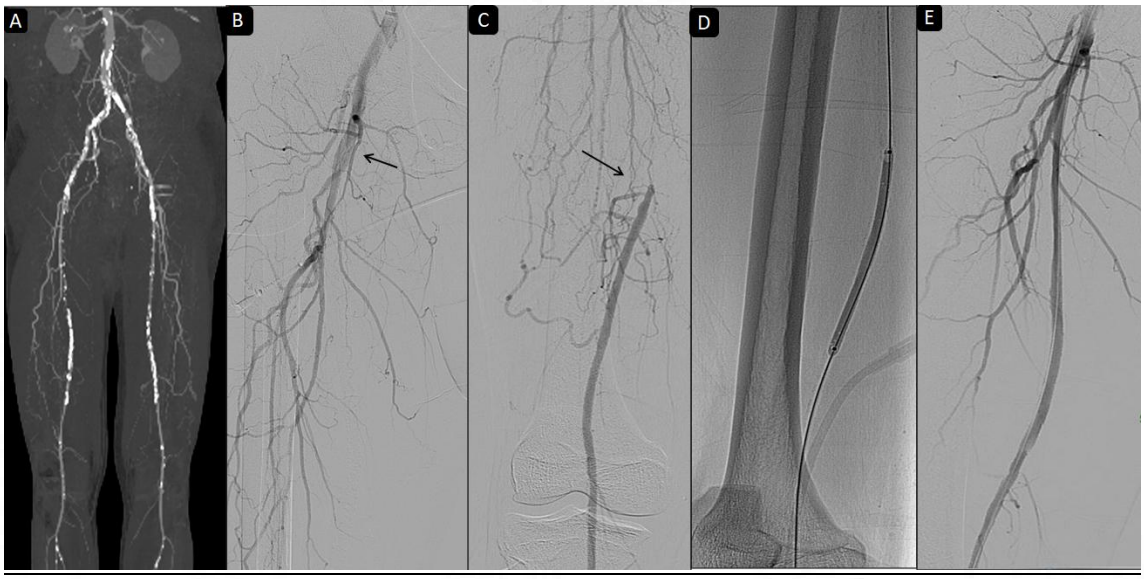


Figure: 17 A) CTA revealed TASC C femoropopliteal disease on right side. B)Left CFA retrograde approach with cross over sheath angiogram showed occlusion of proximal and mid SFA(arrow in B) with reformation at the adductor canal(arrow in B).C)Subintimal angioplasty performed using a 6mmx10cm balloon with good opening of the occluded segment and good distal flow(D).

Case 2: 62 yr old male with history of rest pain in right lower limb for 3 months.

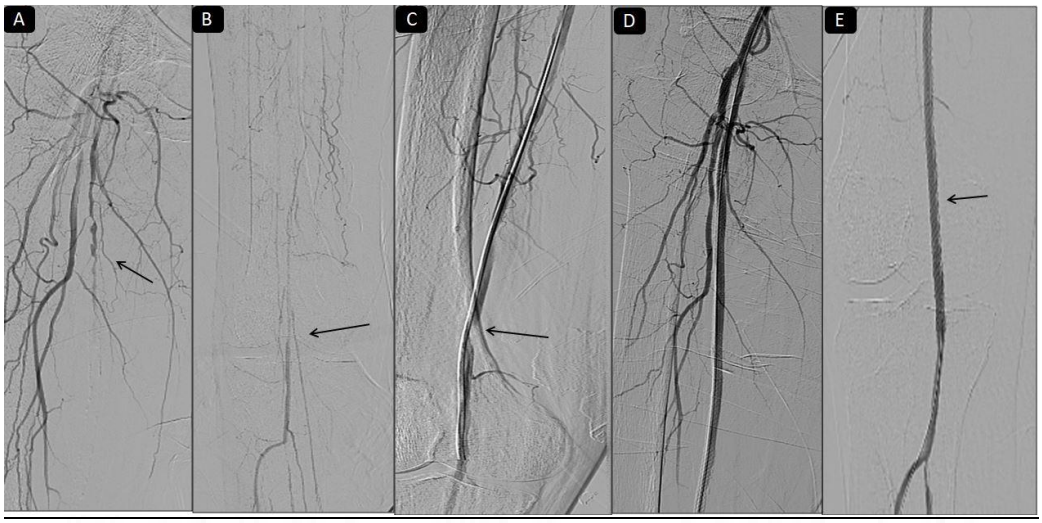


Figure :18 A)DSA with left CFA retrograde approach revealed TASC D disease of right proximal, mid and distal SFA(arrow in A) with reformation(arrow in B) at P1 popliteal artery(B). Angiogram post subintimal angioplasty using a 6mmx10cm balloon revealed more than 30 percent residual stenosis(arrow in C)at the reentry site(C). Supera stent(6mmx200cm) was deployed covering the entire occluded segment and the reentry site with good flow within(D and E).

Case 3: 71 year male, with diabetes and hypertension, presented with rest pain and nonhealing ulcer in left heel for past 4 months.

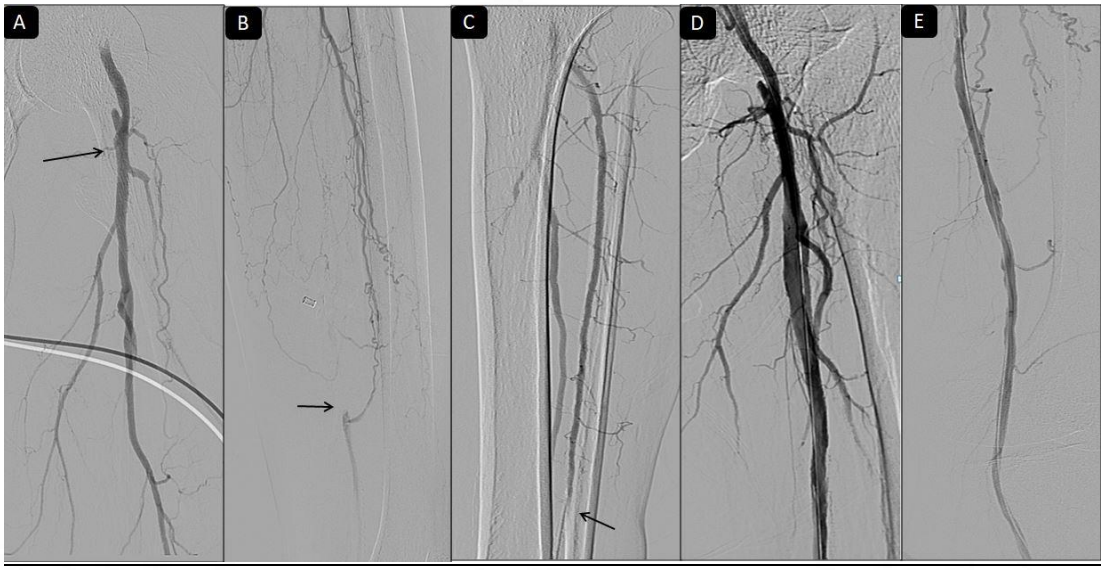


Figure:19 A and B) DSA showing flush occlusion of left SFA(arrow in A) with reformation at the adductor canal(arrow in B). Multiple attempts in crossing the lesion from right CFA retrograde approach failed in view of flush SFA occlusion. So subsequently left ATA was punctured(C) and the lesion was crossed subintimally in retrograde manner. Post angioplasty angiogram revealed complete opening of the occluded segments with no significant residual stenosis(D and E)

Case 4: 59 year old male with gangrene of right foot past 1 month.

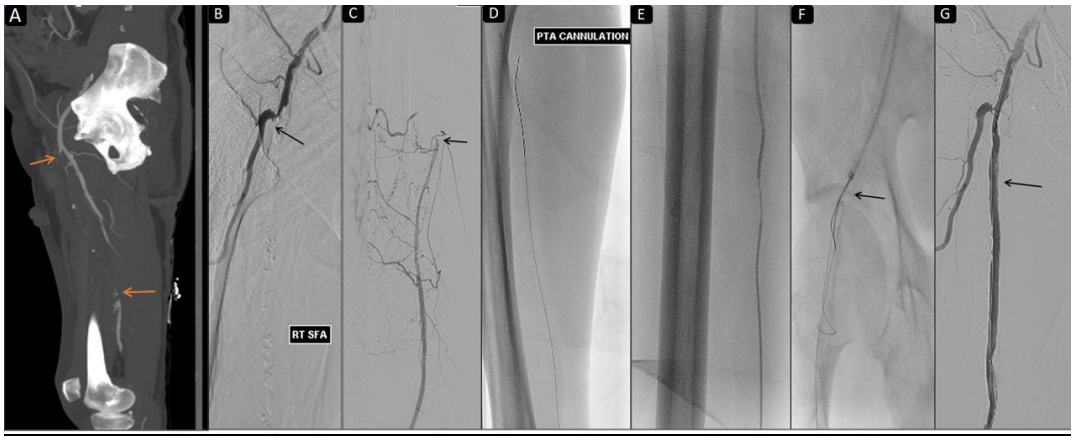


Figure: A)CTA showing flush occlusion of right SFA with a very small proximal stump(arrow). B and C)Angiogram from left CFA retrograde approach revealed calcified flush occlusion of right SFA(arrow in B), with reformation in adductor SFA(arrow in C). After failed attempt in crossing the lesion from retrograde approach, right PTA was cannulated and planned to proceed with SAFARI technoique(D). E and F) The terumo wire from PTA approach was captured and sneared(arrow in F) into the cross over sheath from left CFA and a through and through access was achieved. G) Followed by SUPERA stent deployment covering the reentry site with good flow across the stent

Case 5: 62 year female with CKD and non healing ulcer in right foot past 3 months.

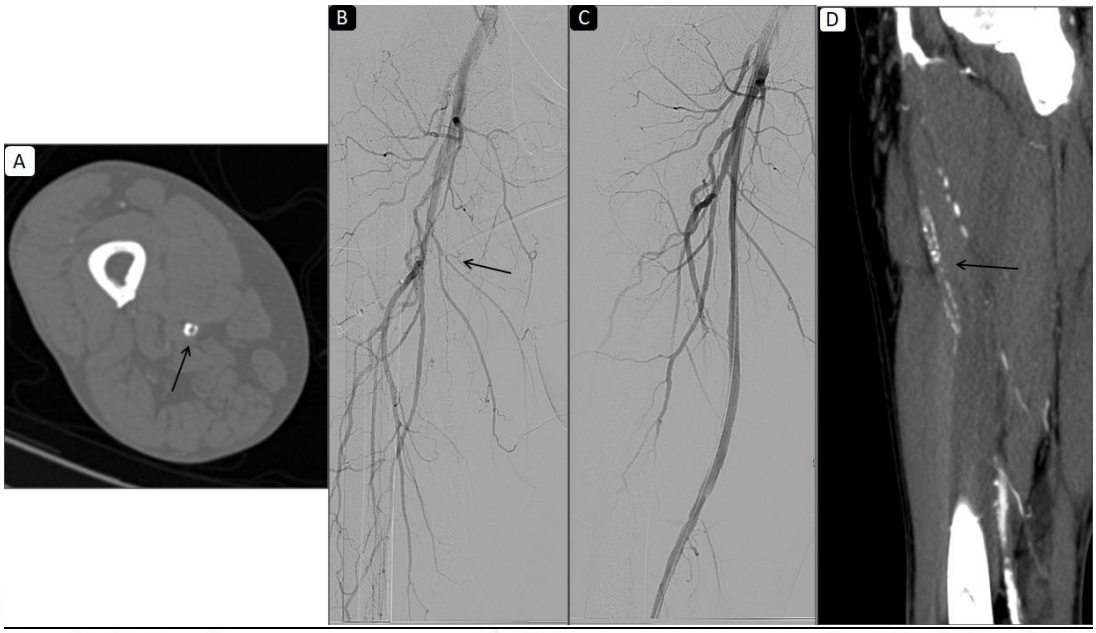


Figure:20 A) CTA in axial plane shows circumferential calcium deposition (arrow in A) in SFA(360%) suggestive of Grade IV calcium. B)DSA showing TASC C occlusion of proximal and mid SFA. C) Post angioplasty angiogram revealed good opening of occluded SFA with no residual stenosis.6 months post angioplasty, patient presented with non-healing ulcer. D) CTA shows reocclusion of the previously opened SFA probably due to the high pre-procedure calcium grading,

Case 6: 69 year old male with claudication pain in right calf past 5 months with claudication distance of 50m,

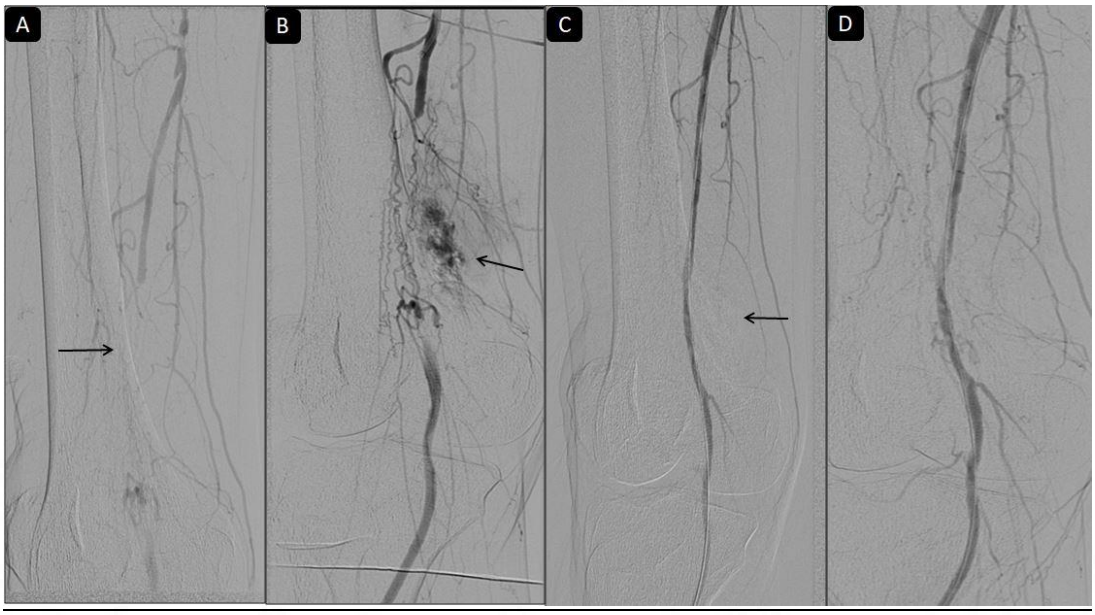


Figure 21: A)DSA with left CFA retrograde approach reveals TASC C stenosis of mid SFA with occlusion at adductor SFA(arrow). B) Subintimal angioplasty was attempted using a terumo wire. Patient developed severe pain in thigh region. Sheath angiograms revealed contrast extravasation in right adductor canal region due to wire induced perforation of a small collateral, which was subsequently embolised with gelfoam(arrow in C). Further angioplasty was proceeded and post procedure angiograms revealed good opening of the occluded SFA with no contrast extravasation(D)

Case 7: 67 year old male, chronic smoker with history of dry gangrene of right 4th and 5th toe past 4 months.

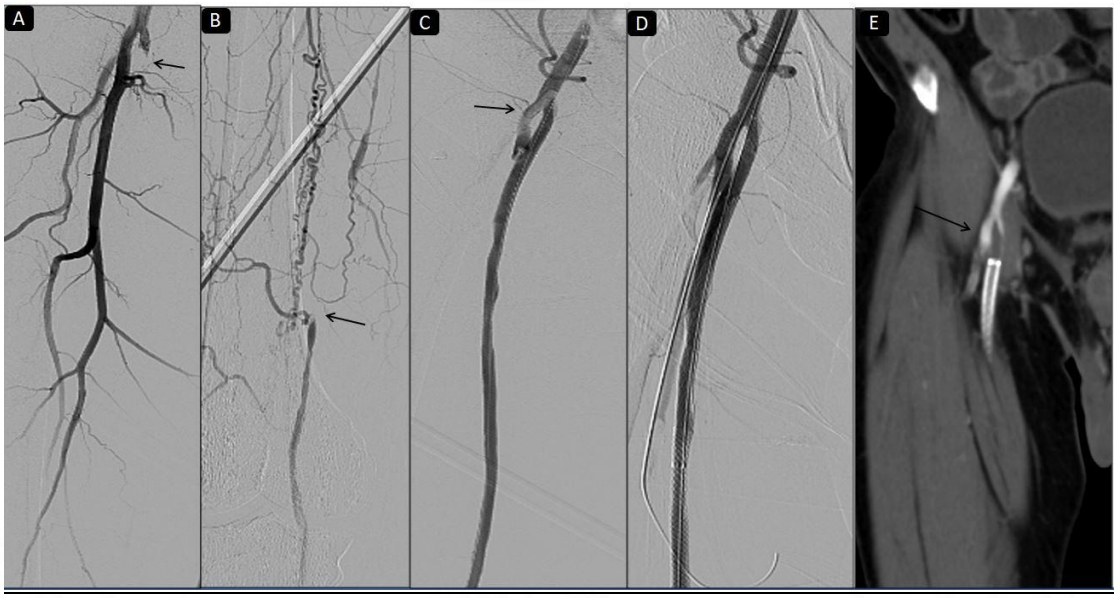


Figure:22 A and B) DSA shows TASC D occlusion of right proximal and mid SFA except for a small patent proximal stump (arrow in A) and distal reformation at adductor canal. Subintimal angioplasty followed by SUPERA stenting was done due to residual stenosis of >30% post angioplasty. C)Post stenting angiograms revealed acute thrombus at the proximal portion of the stent extending into profunda femoris(arrow). D)Thromboaspiration was performed using an Envoy guide catheter and angiogram revealed complete resolution of SFA thrombus and good flow across the stent. However filling defects in profunda femoris persisted. 6 months post procedure, patient presented with claudication pain in right lower limb. E) CTA revealed thrombus in proximal portion of stent, probably due to acute stent induced dissection at proximal portion. No flow was noted across the stent. Patient opted against further attempt of revascularization.

Case 8: 61 year old male presented with non healing ulcer with rest pain in right heel for 3 months.

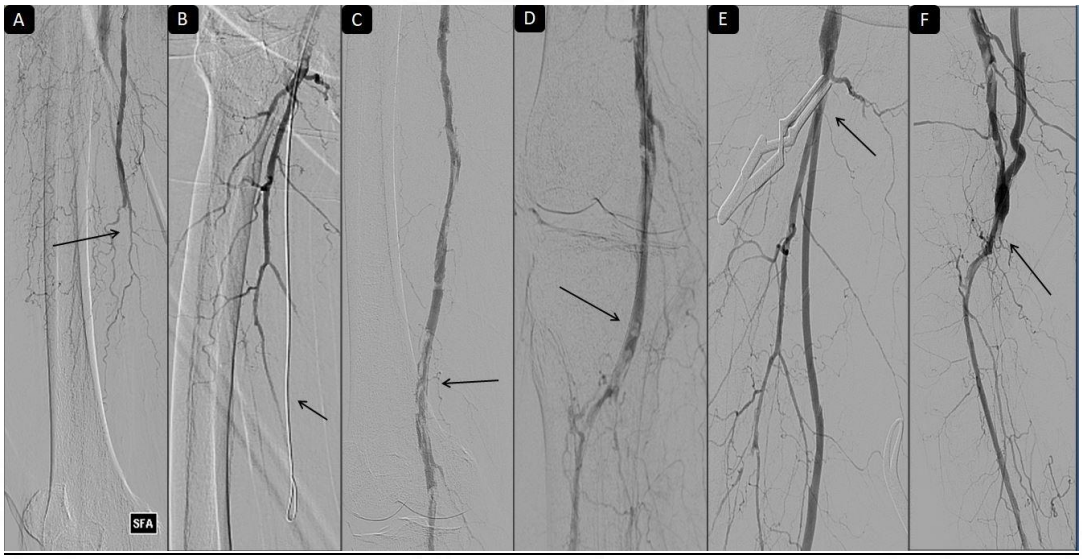


Figure: 23 A)DSA revealed TASC C occlusion of right mid and distal SFA(arrow) B)Subintimal angioplasty was performed using a terumo wire. Post angioplasty using a 6mmx10cm balloon angiograms revealed multiple filling defects in right SFA and popliteal artery suggestive of acute thrombosis(C and D). Multiple attempts of thromboaspiration, mechanical thrombectomy using stent retriever and overnight catheter directed thrombolysis was done. But there was no resolution of the thrombus in SFA and popliteal artery. So it was planned to perform on table surgical femoeopopliteal bypass by vascular surgeons. Post bypass angiograms(E and F) revealed the proximal and distal anastomotic sites of the graft(arrows in E and F respectively) with good flow into the popliteal artery.

DISCUSSION

1)Summary of Aim:

Our study intended to analyze the midterm clinical and radiological patency outcomes of subintimal angioplasty with selective stenting in TASC II C and D Femoro-popliteal disease. The clinical and radiological patency outcomes between subintimal angioplasty vs stenting group were also compared. Also the clinical, radiological and procedural risk factors which affect patency of endovascular treatment in TASC II C and D FP disease were also analysed.

2)Summary of results:

Our primary results showed that subintimal angioplasty with selective stent placement provides a good midterm radiological primary patency of 92.3%, 80.7%, 71% and 69.2% at 6, 12, 18 and 24 months respectively and a clinical primary patency of 90.4% at mean follow-up of 15.6 months. Clinical patency rates did not differ between the PTA group vs PTS group at the end of 18 months follow-up (91.4% vs 88.2%, p=0.849). Among the demographical and radiological factors analyzed, current smoking(>10 cigarettes/day), quadrant wise circumferential calcium scoring and post angioplasty dissection grade C (severe) proposed by Kobayashi et al. were found as independent risk factors affecting primary patency in multivariate analysis.

3)Resuts of Outcome analysis:

A) Clinical outcomes:

While anatomical patency is important, most important reason for performing any intervention is symptomatic relief, improved quality of life, and clinical improvement. Clinically-driven TLR was not different between the primary stenting and angioplasty groups, in most of the RCTs which suggests a gap between anatomical patency and the patient related clinical and symptomatic improvement in these long segment SFA lesions. In our study, clinical patency rates did not differ between the PTA group vs PTS group at the end of 18 months follow-up (91.4% vs 88.2%, p=0.849).

Vossen et al. in their study comparing clinical patency rates between PTA and PTS group found similar results. The primary clinical patency rates at 1, 3, and 5 years in their study were 82.8%, 71.0%, and 65.6% after PTA and 76.3%, 65.7%, and 58.1% after stent placement (PTA-S), respectively (p = .30)(50).

A post hoc analysis comparing balloon angioplasty with provisional stenting vs primary stenting in the RESILIENT trial showed that The clinical patency at 36 months was 63.2% for the primary stent group compared to 47.5% for the angioplasty plus provisional stent group (P- NS). And there was no difference in survival (90.0% vs. 91.7%, p=0.71) or major adverse events (75.2% vs. 75.2%, p=0.98) between the stent and angioplasty groups(47). This is concordant with the results of clinical patency rates in our study. Thus, angioplasty with optional stenting in SFA lesions is justified over primary stenting in terms of clinical patency.

B)Radiological outcomes:

Our study showed that Subintimal angioplasty with selective stent placement provides an good midterm radiological primary patency of 92.3%, 80.7%, 71% and 69.2% at 6, 12, 18 and 24 months respectively in complex TASC C and D femoropopliteal lesions. Primary patency rate at 6, 12 and 18 months for PTA group was 91.4%, 80% and 68% and for PTS group it was 94.1%, 82.3% and 82.3% respectively. Although PTS group had a higher primary radiological patency rate compared to PTA group, no statistical significance was found in terms of primary patency survival curves between PTA and PTS groups(P=0.145)

Our primary patency rates were high compared to previous established studies of primary stenting for long segment SFA lesions. Armstrong et al in their study showed a primary patency rate of 65% for primary nitinol stent placement in long femoropopliteal (FP) lesions with mean length of 254±58 mm after a followup of 1 year(52). Durabillity-200 study, which analyzed primary stenting with Protégé Ever Flex 200-mm-long self-expanding nitinol stent in TASC C and D lesions (average lesion length of 242 mm) demonstrated a primary patency rate of 64.8% at 1 year(53). STELLA trial which demonstrated primary nitinol self-expanding stent (Life Stent(®), for TASC C and D FP lesions demonstrated a primary patency rate of 68%

at 1 year with stent fracture rate of 17.7%(54). None of the stented patients in our study population developed fracture of stent during the followup period.

The higher patency rates in our study may be attributed to the increased usage of self-expanding interwoven technology based nitinol stents(SUPERA, Abbott systems) when compared to the Durabillity-200, STELLA and Armstrong et al studies which used laser cut nitinol stents. Also higher threshold for restenosis by using a PSV>250cm/sec and PSV ratio>2.5 might have led to the higher primary patency rates compared to other studies which used a PSV ratio of >200cm/sec or PSV ratio >2 for defining restenosis(53)(54)(52).

Elmahdy et al. demonstrated primary patency rates of 81.4±1.1% and 77.7±1.9% at 12 and 24 months respectively for primary nitinol stent placement for SFA lesions with mean length of the lesions was 17.9±11.3mm, similar to our study(48). Although vasculomimetic stents were not used in their study the lesser mean lesion length compared to DURABILITY-200, STELLA, and Armstrong et al., studies in which the mean length was 24.2, 22, and 25.4 cm, respectively might have led to the higher patency rates. The mean lesion length in our study was 20cm which also might have contributed to our higher patency rates.

The problem with other trials comparing the primary vs selective stenting is that the definition of target lesion revascularization which is the crucial endpoint for assessing treatment outcome is not standardized among various trials(55). TLR should be clinically driven based on patients' symptoms rather than based in radiological patency. In a meta-analysis by Acin et al, comparing primary nitinol stenting vs balloon angioplasty and optional stenting, TLR at 12 months favored the stent group (OR 2.47, 95% CI 0.72 to 8.49, p=0.065), but with no statistical significance(56).

C)Limb Salvage rates:

Limb salvage rate was 96.2% at mean follow-up of 15.6 months in the combined angioplasty and stenting population. Brouillet et al, in their study of primary stenting of TASC C and D lesions demonstrated an LSR of 95.5% like our study. Elmadhy et al, demonstrated no major amputation in their study following primary stenting of TASC C and D lesions after a mean follow-up of 36 months(57). Their

high limb salvage rate may be due to the smaller mean lesion length of 17cm in their study compared to our study (20cm).

D)Stenting versus angioplasty alone:

There is substantial evidence in literature to suggest stenting has better patency outcomes compared to angioplasty alone for FP disease(52). However in our study Primary radiological patency rate at 6, 12 and 18 months for PTA group was 91.4%, 80% and 68% and for PTS group it was 94.1%, 82.3% and 82.3% respectively. Although PTS group had a higher primary radiological patency rate compared to PTA group, no statistical significance was found in terms of primary patency survival curves between PTA and PTS groups(P=0.145). Our higher patency rates in the angioplasty alone group might be due to use of subintimal angioplasty in all cases and SAFARI technique in 18(34.6% of cases) which could have resulted in preservation of collateral circulation and thus might have resulted in higher patency outcomes in the balloon angioplasty group. Subintimal approach appears to achieve a higher technical success rate than intraluminal approach(used in most of the studies)especially in long segment CTO lesions (58). One more reason might be the smaller sample size in our study which might have resulted in lack of statistical significance in patency rates between both the groups.

4. Factors affecting patency

Among the demographical and radiological factors analyzed, current smoking(>10 cigarettes/day), quadrant wise circumferential calcium scoring and post angioplasty dissection grade C (severe) proposed by Kobayashi et al. were found as independent risk factors affecting primary patency in multivariate analysis. Other risk factors like diabetes, hypertension, old age, male gender, stroke and CAD were not associated with loss of patency in multivariate analysis.

Numerous studies demonstrate that the length of occlusion adversely affects the patency rates. Lazaris et al in their study, (only subintimal angioplasty was performed)in which the median lesion length was 30cm, patients with >30cm long lesion demonstrated significantly lower patency compared to <30cm group(59). However results from STAR registry suggest no difference in patency between 5-

10cm long lesion group and >10cm lesion group(60). In our study with median lesion length of 20cm, lesion length was not found to affect the primary patency in multivariate analysis. This might be due to the relatively high mean and median lesion length in our population compared to other study groups.

There was no significant difference between the patency outcomes between the TASC C and D groups in our study. However, Brouillet et al., in their study on primary stenting of TASC C and D lesions, showed higher rates of in-stent restenosis for TASC D lesions compared to TASC C lesions (35% vs. 10% respectively, P=0.005). Our protocol of selective stenting and the smaller stent group in our study might have contributed to our result(61). Studies in which only angioplasty was performed without stenting demonstrate reduced patency if the angioplasty segment involved the distal third of SFA/ adductor canal(62)(63).This is attributed to the mechanical stress on the artery in the adductor canal due to anchorage by the adductor magnus fascia(64). However in our study due to the use of vasculomimetic stents with higher kink resistance, lesions in adductor canal were not associated with loss of patency.

There has been substantial evidence to state that the vessel wall calcium is associated with post angioplasty dissections, acute vessel recoil and increased used of stents as well as high risk of stent fractures.. In our study using the quadrant wise circumferential calcium scoring of 270-360 degree was found to be an independent factor affecting the primary patency in multivariate analysis. Fanelli et al in their study also found a positive correlation of circumferential calcium deposition of 360% to reduced drug absorbance after DEB angioplasty and poor patency rates(51). currently there is no standardized approach and consensus on the quantification of calcium on CTA and DSA(65). There is a need to develop a standardized and dedicated calcium scoring system on CTA and DSA for FP lesions to predict the clinical outcome and guide appropriate management.

In our study, post angioplasty dissection grade C (severe) proposed by Kobayashi et al. was found to be affecting primary patency independently in multivariate analysis. Kobayashi et al in their study also had similar results and he proposed that especially in long length lesions, severe post angioplasty dissection with >30% of luminal narrowing resuled in poor patency outcomes. While the NHBLI

proposed dissection grading used in coronary was applied in the multivariate analysis, the statistical significance was lost. This might be because of the higher plaque burden, larger vessel diameter and the relatively longer occlusions in FP vessels compared to coronary arteries. This suggests the need for a dedicated grading system for post angioplasty dissection grading in FP arteries(23). Also, this supports the current practice of selective stenting when the post angioplasty dissection causes >30% narrowing of the lumen.

In our study, although Modified SVS runoff score >10 showed a positive correlation with loss of primary patency but no statistical significance was noted. (P value =0.154). Davies et al, in their study divided the patients into three runoff score groups, <5 (Good), 5-10 (Compromised), and >10 (Poor) and found that poor and compromised scores affected the primary patency rates adversely. However, in their study the proportion of TASC A lesions in the Good score group was significantly greater (P > .004) compared to the other groups. Lee et al in their study demonstrated that there was no difference in the primary patency after primary stenting between segments with good runoff and those with compromised runoff. Also the runoff score did not impact the limb salvage rate (P = .063)(66). With studies showing conflicting results, regarding the influence of runoff score on patency. a standardized run off score cutoff should be postulated by larger studies to aid in selecting the appropriate management based on the runoff scores.

Among the risk factors in our study population, age, sex, diabetes, hypertension, CAD and stroke were not associated with loss of primary patency. Lazaris et al in his study also suggested that none of the risk factors of atherosclerosis affected the primary patency post angioplasty for FP lesions(59). Even though multiple studies have shown that diabetes is associated with loss of patency, as most of our study population belong to the diabetic group, no the statistical significance was found(60). In our study current smoking (>10 cigarettes/day) was associated with loss of primary patency(P=0.01). Multiple studies have demonstrated smoking as a major risk factor associated with progression of PAD and also adversely affecting the patency of femoropopliteal bypass grafts(67). Elmahdy et al. demonstrated smoking

to be an independent risk factor for restenosis post angioplasty and stenting for Type C and D femoropopliteal disease(48).

5. Techincal success

Our very high technical success rate of 98% in these long segment FP lesions may be attributed to the use of preferential subintimal approach and the use of SAFARI technique (34.8% cases)whenever reentry was not possible. Ko et al demonstrated that Subintimal approach appears to achieve a higher technical success rate than intraluminal approach especially in long segment CTO lesions(58). Our technical success rate without usage of SFARI technique would be 66% comparable to the studies on long segment FP disease. Baker et al in their study also showed a technical success rate of 86% after using SAFARI technique, comparable to our study(68). Ipsilateral Antegrade CFA approach was performed in 8(15.3%) patients in our study. No difference in complication rates and patency outcomes were noted between the ipsilateral antegarade CFA approach and retrograde contralateral approach was noted in our study, This is in concordance with Cragg et al. study which showed that no difference in periprocedure complication rates were noted between ipsilateral antegrade and contralateral retrograde approaches(69).

6. Complications:

Major complications included thromboembolism in 6 patients(11%). No puncture related complications occurred in our study. Our complication rates were in comparison with other studies of SFA angioplasty which suggest an acceptable complication rate of around 10%. Sato et al in his study on 2145 patients demonstrated a complication rate of 10% which is similar to our study(70).

7. Incidence of MACE

13(25%) patients died due to MACE during the follow-up period, No statistical significance was noted between the PTA and PTS groups in terms of occurrence of MACE. Our MACE rates were very high compared to the published studies. Three year follow up from STELLA register demonstrate a MACE rate of

7%(71). This can be attributed to the difference in the risk factor prevalence like diabetes, smoking, hypertension, CAD and stroke between the population,

8. Endovascular versus surgery

Our primary radiological patency rates at end of 12 and 24 months followup were 80% and 69% respectively, which is higher compared to the patency rates of surgical bypass by Enzmann et al, 72% and 56% respectively. Enzmann et al in their RCT comparing nitinol stenting vs bypass surgery for TASC C and D lesions, and they demonstrated that primary and secondary patency at 24 months, for the stent group were 60% and 72%, compared with 56% and 73% in the bypass group, respectively($p=0.42$ and $p=0.09$ respectively), with no statistical significance. Limb salvage rate in Enzmann et al study also showed no significant difference between both the groups with 100% in the stent group versus 88% in the bypass group at 2 years(72). Our LSR was 96.2% similar to Enzmann et al study. Thus, an endovascular first protocol for TASC C and D FP lesions is justifiable. However long term follow-up and larger population studies are needed. The ongoing BEST-CLI trial is expected to provide further insights into the best treatment option for long segment FP lesions.

9. Subintimal vs Intraluminal angioplasty:

Studies show that subintimal approach appears to achieve a higher technical success rate than intraluminal approach especially in long segment CTO lesions(58). This might have contributed to our higher technical success rate (98%) compared to other studies. Antusevas et al, in their study demonstrated a technical success rate of 87.7% for subintimal angioplasty versus 81.3% for intrauminal angioplasty(73). No randomized controlled trial has compared subintimal angioplasty versus intraluminal angioplasty for femoropopliteal artery disease. Distal embolisation into popliteal trifurcation was observed in only one patient in our study. However acute thromboembolism of the SFA post angioplasty occurred in 6 patients(11%). Ko et al in his review suggested that though it has been previously postulated that due to the lack of plaques and thrombus in the subintimal channel distal embolization occurs less frequently in subintimal angioplasty than intraluminal angioplasty, the incidence is similar in both the subintimal vs intraluminal group ranging from 0% to 7.3%(58).

Also he demonstrated that other procure-related complications also do not differ between the 2 techniques which was similar to our study results.

10. Justification of selective stenting:

Our study shows that an endovascular first approach with selective stenting with a vasculomimetic stent is effective and safe with high primary and secondary midterm outcomes at a follow-up of 2 years in long segment complex TASC C and D FP lesions comparable to surgical bypass and primary stenting. Current smoking(>10 cigarettes/day), quadrant wise circumferential calcium scoring grade 4(>360 degree)and post angioplasty dissection grade C (severe) were found as independent risk factors affecting primary patency in multivariate analysis. Also considering the high MACE incidence in this group of patients, stenting can be performed only when any one of the above mentioned risk factors is present. Thus a protocol of selective stenting is justifiable in this group of patients,

STRENGTHS OF STUDY:

Standardized protocols were followed during pre-procedure evaluation, follow-up and during intervention. Relatively good sample size for analysis considering the complexity and technical difficulties in performing interventions in these TASC C and D lesions. Clinical patency rates were considered and included in analysis apart from duplex derived patency. Multiple factors including demographical, radiological, technical and clinical factors were analyzed simultaneously. Newer scoring systems for calcification grading and post angioplasty dissection grading were highlighted and included in analysis.

LIMITATIONS:

This is a single center retrospective cohort study with a prospective arm with a modest sample sizeof 52 patients with TASC C and D FP disease. Due to its retrospective arm, strict elimination of confounding factors was not possible. Our study did not include a control arm containing patients undergoing surgical bypass, which is the current gold standard treatment for long segment FP lesions. Patient selection for endovascular treatment vs surgical bypass and the choice of endovascular

treatment like angioplasty vs stenting was decided on basis of patient preference in some cases.

Our study did not follow an intention to treat analysis design. Stenting was not performed in 3 patients even with post angioplasty residual stenosis of >30% because of financial constraints. Reentry devices were not used. Advanced endovascular options like DEB, DES and atherectomy devices which have shown to provide better patency outcomes in long segment FP lesions were not performed in our study. Long term followup is still needed.

CONCLUSION:

Despite these limitations, our study shows that an endovascular first approach with selective stenting with a vasculomimetic stent is effective and safe with high primary and secondary midterm outcomes at a follow-up of 2 years in long segment complex TASC C and D FP lesions comparable to surgical bypass and primary stenting. Stenting has to be performed in patients with quadrant wise calcium scoring of grade 4(>270 degree) and post angioplasty dissection grade severe(compromising >30% of lumen). Subintimal approach has higher technical success and similar patency and complication rates comparable to intraluminal angioplasty. SAFARI technique significantly increases the technical success rates, especially in very long segment lesions. Current smoking(>10 cigarettes/day), quadrant wise circumferential calcium scoring grade 4(>270 degree)and post angioplasty dissection grade C (severe) were affect primary patency independently. There is a need for standardized grading system for calcium scoring and dissection scoring post angioplasty to improve outcomes.

Diabetes, Hypertension ,CAD, stroke, infrapopliteal run off scores, length of occlusion and TASC grading do not affect patency rates. Considering high incidence of MACE in this population close followup and cardiac risk factor management should be strictly followed. Strict abstinence of smoking should be advised. As the rate of reocclusion or restenosis especially in angioplasty alone group is high, close follow-up is needed. In future higher population and longer follow-up studies comparing various endovascular options like DEB, DES and atherectomy with surgical bypass and with a focus on cost effectiveness should be done to determine the ideal first choice option for these complex long segment FP lesions.

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ANNEXURES

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
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Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/1406/JULY-2019

07.08.2019

Dr. Ansan Joseph J
Senior Resident, Department of IS & IR
SCTIMST, Thiruvananthapuram

Dear Dr Ansan Joseph,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "MID AND LONG TERM RESULTS OF ENDOVASCULAR INTERVENTIONS IN TRANSATLANTIC INTERSOCIETY CONSENSUS (TASC) II C AND D AORTO-ILIAC AND FEMORO-POPLITEAL DISEASE (IEC/1406)" on 26th July, 2019.

The following documents were reviewed:

1. *Covering Letter addressed to the Chairperson, IEC, SCTIMST dated 27.06.2019 with checklist*
2. *TAC Approval Letter*
3. *IEC Application Form*
4. *Project Proposal*
5. *Proforma*
6. *Information Sheet and Consent Form in English and Malayalam*
7. *CV of Principal Investigator and Co-Principal Investigators*

The following members of the Ethics Committee were present at the meeting held on 26th July, 2019 at Noshir H Wadia Conference Hall, AMCHSS, SCTIMST

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. Harikrishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
2.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
3.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
4.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
5.	Dr. Mala Ramanathan	PhD	Female	Social Scientist (Member Secretary)	Yes

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:
The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Mala Ramanathan
Member Secretary, IEC

INFORMATION SHEET

TITLE: **MIDTERM CLINICAL AND RADIOLOGICAL PATENCY OUTCOMES OF SUBINTIMAL ANGIOPLASTY WITH SELECTIVE STENTING IN TASC II C AND D FEMOROPOPLITEAL DISEASE**

Study number:

Participant's name: Date of Birth/Age (in years): son/daughter of……..

Peripheral arterial disease is a age related process affecting the peripheral arteries causing blockage of the blood flow resulting in pain during walking, running and non-healing ulcers in lower limb.You have been informed that there is an occlusion in your lower limb arteries, for which, you have undergone or will be undergoing a digital subtraction angiography (DSA) followed by intervention (Angioplasty/stenting) as a part of treatment of your disease

You are being requested to participate in a study to evaluate the Mid and long term results of endovascular interventions in TASC II C and D Aorto-iliac and Femoro-popliteal disease**.** Participating in this study, in which only data from the investigations you have undergone for your treatment will be used, will in no way influence treatment decisions.

What is TASC II C and D femoropopliteal disease?

It is a severe form of arterial occlusive disease where most of the major blood vessels supplying the lower limbs are occluded. This can cause pain in bilateral lower limbs while walking and ulcers.

What is Endovascular intervention(Angioplasty/Stenting) and does it have any harmful effects?

Endovascular Angioplasty/Stenting is the process of treating arterial occlusion using small balloons or stents with in diseased vessel segment to reinstate normal blood flow. It will be done using a DSA, which is an advanced imaging technique using X Rays where the blood flow to your vessels will be evaluated by injecting a dye into

the arteries through a small tube which will be inserted through the artery in your groin.

You will not experience much pain as an injection will be given on your groin prior to the procedure to make it numb. You will not feel any pain during the rest of the procedure. In rare cases some people may have allergic reaction to the dye. There is also a very small risk of injury to the blood vessel and slight chance of bleeding at site of puncture. Even after failure of the procedure , the scope of surgery for treatment of the disease will still be available.

Does it involve only interventional procedure?

Medical treatment, clinical and imaging follow up should go hand in hand to check for the adequacy of treatment and detect progression of disease in other location

If you take part what will you have to do?

For this study, we'll be using some of the data like history and other clinical details, Imaging details (CT/Doppler), Angiograms (DSA), treatment technique, outcome of the procedure, delayed follow up clinical and radiological regarding your disease and treatment which you undergo in this hospital.

No additional cost will be incurred /no additional drugs will be used and there are no additional risks as a part of the research.Analysis of these data may or may not be useful for you later, but this is likely to give more understanding of this disease and treatment, for the benefit of future generation. You understand that strict confidentiality will be maintained.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related injury?

This study only analyzes the results of your investigation and treatment details and thus we do not expect any injury to happen to you but if you do develop any side effects or problems due to the study, these will be treated at this institute by the experienced team of medical professionals. We are unable to provide any monetary compensation, however.

Will you have to pay for the study?

The study will only analyze the results of the investigations and treatment which you will undergo in natural process of your treatment at this institute and no extra cost will be borne by you for this particular study.

What happens after the study is over?

You may or may not benefit from this study, after the study we will be able to assess the the Mid and long term results of endovascular interventions in TASC II C and D Femoro-popliteal disease ; it may thus benefit other patients with similar illness.

Will your personal details be kept confidential?

The results of this study may be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any further questions, please ask Dr. Ansan Joseph (tel: 8758836925) or email:

josephansan**@sctimst.ac.in or contact IEC member secretary Dr. Mala ramanathan(tel: 0471-2524263)**

CONSENT FORM ENGLISH:

TITLE: **MIDTERM CLINICAL AND RADIOLOGICAL PATENCY OUTCOMES OF UBINTIMAL ANGIOPLASTY WITH SELECTIVE STENTING IN TASC II C AND D FEMOROPOPLITEAL DISEASE**

Study number:

Participant's name: Date of Birth / Age (in years): I_____,
Son/daughter of _____(Please tick boxes)

• Declare that I have read the above information provide to me regarding the study: '**Midterm clinical and radiological patency outcomes of ubintimal angioplasty with selective stenting in tasc ii c and d femoropopliteal disease**' and have clarified any doubts that I had. [ ]

• I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights. [ ]

• I also understand that study investigators will be using some of the data like history and other clinical details, Imaging details (CT/Doppler/ CTA), Angiograms (DSA), Angioplasty technique, outcome of the procedure(Immediate angiographic and clinical) , delayed follow up clinical and radiological regarding the disease and treatment which I undergo in hospital. [ ]

• I also understand that no additional cost will be incurred /no additional drugs will be used and there are no additional risks as a part of the research. [ ]

• I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access. [ ]

• I understand that my identity will not be revealed in any information released to third parties or published. [ ]

• I voluntarily agree to take part in this study. [ ]

• I received a copy of this signed consent
form]

Name:

Signature: Date:

Name of witness:

Relation to participant

Date:

(Person Obtaining Consent) I attest that the requirements for informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____ _____

Name and Signature of Person Obtaining Consent

Principal Investigator.

സമ്മതപത്രം

പഠനശീർഷകം: റ്റിഎഎസ് സി II സിയും ഡിയും, അയോർട്ടോഇലിയാക് - ഫെമറോപൊപ്ലിറ്റിയൽ രോഗങ്ങളുടെ **എൻഡോവാസ്ക്കുലാർ നടപടികളുടെ മദ്ധ്യ-ദീർഘകാല ഫലങ്ങൾ**.

പഠനനമ്പർ:

പങ്കാളിയുടെ പേര്:

ജനനതീയതി/വയസ്സ് (വർഷത്തിൽ)

ഞാൻ.....പുത്രൻ/പുത്രി.....

(ദയവായി കോളങ്ങളിൽ ശരിയടയാളപ്പെടുത്തുക)

- മുകളിൽ റ്റിഎഎസ് സി II സിയും ഡിയും, അയോർട്ടോഇലിയാക് - ഫെർമോപൊപ്ലിറ്റിയൽ രോഗങ്ങളുടെ **എൻഡോവാസ്ക്കുലാർ നടപടികളുടെ മദ്ധ്യ-ദീർഘകാല ഫലങ്ങൾ** എന്ന പഠന സംബന്ധിയായി എനിക്കു നൽകിയ വിവരങ്ങൾ വായിച്ചു എന്നു പ്രസ്താവിക്കുന്നു. എന്റെ എല്ലാ സംശയങ്ങളും പരിഹരിച്ചു.[ ]
- എന്റെ ഈ പഠനത്തിലുള്ള പങ്കാളിത്തം പൂർണ്ണമായും സ്വമേധയാ ആണെന്നും അനുവാദം എനിക്ക് ഏതുസമയത്തും എന്റെ ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളെയോ ബാധിക്കാതെ പിൻവലിക്കാൻ അവകാശമുണ്ടെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. [ ]
- ചികിത്സാചരിത്രം, മറ്റ് ആശുപത്രി വിവരങ്ങൾ, ഇമേജിംഗ് വിവരങ്ങൾ (സിറ്റി/ഡോപ്ലർ), അൻജിയോഗ്രാം (ഡിഎസ്എ), ആൻജിയോപ്ലാലാസ്റ്റി സങ്കേതങ്ങൾ, നടപടിയുടെ (ആൻജിയോഗ്രഫിയുടെയും ചികിത്സാപരമായതുമായി ഉടനെയുള്ള) ഫലം, ശേഷമുള്ള തുടർചികിത്സയുടെ ആശുപത്രി സംബന്ധവും റേഡിയോളജിക്കലുമായി താങ്കൾ ഈ ആശുപത്രിയിൽ വിധേയമാകുന്നചികിത്സയുടെ വിവരങ്ങൾ എന്നിവയാണ് പഠന ഗവേഷകർ ഉപയോഗിക്കുന്നത് എന്നും ഞാൻ മനസ്സിലാക്കുന്നു. [ ]
- നിക്ക് അധികം ചിലവുണ്ടാകുകയോ/അധികം മരുന്ന് ഉപയോഗിക്കുകയോ ചെയ്യുന്നില്ല എന്നതിനാൽ ഗവേഷണത്തിന്റെ ഭാഗമായി അധികമായ അപായങ്ങളുണ്ടാകില്ല എന്നും മനസ്സിലാക്കുന്നു. ഞാൻ ഈ പഠനത്തിൽ നിന്നും പിൻമാറിയാലും പഠനം നടത്തുന്നവർക്കും സ്ഥാപനത്തിലെ നൈതിക കമ്മിറ്റി അംഗങ്ങൾക്കും എന്റെ ആരോഗ്യരേഖകൾ പരിശോധിക്കുന്നതിന് എന്റെ അനുവാദം ആവശ്യമില്ലെന്ന്ഞാൻ മനസ്സിലാക്കുന്നു. അതിനോട് ഞാൻ യോജിക്കുന്നു. [ ]
- എന്നെ തിരിച്ചറിയാനുതകുന്ന വിവരങ്ങൾ ഒന്നും മൂന്നാം കക്ഷികൾക്കു നൽകുകയോ പ്രസിദ്ധീകരിക്കുകയോ ചെയ്യില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. [ ]
- ഞാൻ സ്വമേധയാ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു. [ ]
- സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു കോപ്പി എനിക്കു കിട്ടി [ ]

പങ്കെടുക്കുന്നയാളുടെ പേര്

ഒപ്പ്

തീയതി

സാക്ഷിയുടെ പേര്

ഒപ്പ്

പങ്കെടുക്കുന്ന ആളുമായുള്ള ബന്ധം

തീയതി

(സമ്മതം വാങ്ങുന്നയാൾ)

മെഡിക്കൽ റിസർച്ച് പ്രോജക്ടിനാവശ്യമായ സമ്മതപത്രത്തിനു വേണ്ടുന്ന എല്ലാ ഘടകങ്ങളും തൃപ്തികരമായി നിർവഹിച്ചിരിക്കുന്നുവെന്ന് ഞാൻ ബോധ്യപ്പെടുത്തുന്നു. പഠനപങ്കാളിയുമായി ഗവേഷണപദ്ധതിയെപ്പറ്റി സാങ്കേതികേതര പദങ്ങളുപയോഗിച്ച് എല്ലാ വിവരങ്ങളെപ്പറ്റിയും ചർച്ച നടത്തുകയും പ്രതീക്ഷിക്കാവുന്ന അപകടസാധ്യതകളും പാർശ്വഫലങ്ങളും വിശദീകരിക്കുകയും ചെയ്തു. പങ്കാളിയെ ചോദ്യങ്ങൾ ചോദിക്കാൻ പ്രേരിപ്പിക്കുകയും എല്ലാ ചോദ്യങ്ങൾക്കും ഉത്തരം നൽകുകയും ചെയ്തു എന്നും ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു.

സമ്മതപത്രം വാങ്ങുന്ന ആളുടെ പേര്

ഒപ്പ്

പ്രധാന ഗവേഷകൻ

PROFORMA:

TITLE: **MIDTERM CLINICAL AND RADIOLOGICAL PATENCY OUTCOMES OF UBINTIMAL ANGIOPLASTY WITH SELECTIVE STENTING IN TASC II C AND D FEMOROPOPLITEAL DISEASE**

a) Reallocated Anonymized Image identification number: ……..
b) Study / Sequence evaluated: CT PERIPHERAL ANGIO/DSA……...
c) Investigator analyzing study:…… Date of Image analysis:……
d) Quality of image: four-point scale score*: ……

CLINICAL DETAILS	**PRE-PROCEDURE CTA**
Symptoms- claudication, rest pain, ulcer/gangrene	Length of occlusion
Age, Sex, Smoking	TASC II Grading
Diabetes, Hypertension, CAD	Quadrant wise circumferential vessel wall calcification
Stroke, Hypercholesterolemia	Concomitant Aorto-iliac disease
	Involvement of adductor segment of SFA
IMAGING	
Duplex and ABPI	

Followup: 6 week, 6 months, 12 months, 18 months, 24 months

CLINICAL	**IMAGING**
Clinical examination- Pulse	ABPI
Improvement in claudication, rest pain and ulcer healing	Duplex imaging

Curiginal

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Analyzed document	ANSAN THESIS FINAL.docx (D110850614)
Submitted	7/29/2021 5:16:00 PM
Submitted by	Jineesh
Submitter email	jineesh174@sctimst.ac.in
Similarity	10%
Analysis address	jineesh174.sctims@analysis.urkund.com

Sources included in the report

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W	URL: https://www.researchgate.net/publication/311977422_Endovascular_treatment_of_the_common_femoral_artery_in_the_Vascular_Quality_Initiative Fetched: 6/10/2021 11:20:59 PM	1
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SA	**TalhaButt_Kappa_orginal_rättad efter mediatryck_10maj.docx** Document TalhaButt_Kappa_orginal_rättad efter mediatryck_10maj.docx (D105060396)	9
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SA	**Claudicatio 24 mån_rev AG 171012 SB.docx** Document Claudicatio 24 mån_rev AG 171012 SB.docx (D31257811)	1
SA	**Hans L kappa till e-spik.pdf** Document Hans L kappa till e-spik.pdf (D19002105)	1
SA	**Tesis completa2.docx** Document Tesis completa2.docx (D53633107)	3
W	URL: https://www.jstage.jst.go.jp/article/circj/74/9/74_CJ-10-0106/_pdf Fetched: 7/29/2021 5:19:00 PM	2
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Curiginal

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ABBREVIATIONS

ABPI- Ankle-brachial pressure index

ACEI- Angiotensin-converting enzyme inhibitors

AFS-Amputation free survival

ATA- Anterior Tibial Artery

BASIL- Bypass versus Angioplasty in Severe Ischaemia of the Leg

BMI- Body mass index

BMS- Bare metal stent

CAD- Coronary artery disease

CE-MRA- Contrast-Enhanced Magnetic Resonance Angiography

CFA- Common femoral artery

CKD- Chronic kidney disease

CLI- Critical limb Ischemia

CLTI- Chronic Limb Threatening Ischemia

CTA- Computed Tomography Angiogram

CTO- Chronic thrombotic occlusion

CVD- cardiovascular diseaseDCB- Drug coated balloon

DES- Drug Eluting stent

DUS- Duplex ultrasound

ESC- European Society of Cardiology

ESVS- European Society of Vascular Surgery

ExT- Exercise Therapy

FP- Femoropopliteal disease

GLASS- Global Limb Anatomic Staging System

HDL-C- high-density lipoprotein cholesterol

LBP- limb-based patency

LDL-C- low-density lipoprotein cholesterol

LEAD- Lower extremity artery disease

LSR- Limb salvage rate

MACE- Major Adverse Cardiac Events

MRA- Magnetic Resonance Angiography

NHLBI- National Heart Lung Brain Institute

PAD- Peripheral artery disease

PBA- Plain Balloon Angioplasty

PSV- Peak Systolic velocity

PTA- Percutaneous transluminal angioplasty

PTA- Posterior Tibial artery

PTA-S - Percutaneous transluminal angioplasty with stenting

PTFE- Polytetraflouroethylene

QOL- Quality of Life

RC-Right Coronary

RCT-Randomised Controlled Trial

SAFARI-Subintimal Arterial Flossing with Antegrade – Retrograde Intervention

SET- supervised exercise therapy

SFA- Superficial femoral artery

SVS- Society of Vascular Surgery

TAP- target arterial path

TASC- Trans-Atlantic Inter-society Consensus

TcPO2- transcutaneous partial pressure of oxygen

TLR- Target lesion revascularisation

WIfI- wound, ischemia, and foot infection

DATA SHEET

Hop ID	Name	age	sex	RA	HTN	CAD	STROKE	N0SMOK	PASTSMO	ABPI	DLP	STATINS	RESTPAIN	ULCER	AMPUTA	RUNOFF ATA	RUNOFF PTA
338141	LATHIKA	60	F	N	Y	N	N	Y	N	0.6	N	Y	Y	Y	N	Y	N
488292	RAMLA BEEVI	70	F	N	Y	N	N	Y	N	0.5	N	Y	Y	Y	N	N	N
487962	RAJAN	68	M	N	N	N	N	N	N	0.6	Y	Y	Y	Y	Y	Y	Y
487122	SUDARSANAN	63	M	N	Y	Y	N	N	Y	0.6	N	Y	N	Y	Y	Y	N
478173	SATHI KUMARI	56	F	Y	N	N	N	Y	N	0.65	N	Y	Y	Y	N	Y	N
481048	SREEKANDAN NAIR	58	M	N	Y	Y	N	N	Y	0.6	N	Y	Y	N	N	Y	N
482850	STEPHANOSE	72	M	N	Y	N	N	N	N	0.65	N	Y	N	N	N	Y	N
360158	VIKRAMAN NAIR	62	M	N	Y	Y	N	N	Y	0.6	N	Y	Y	Y	Y	N	N
470797	LUCY JOSEPH	57	F	N	Y	N	N	Y	N	0.65	N	Y	Y	N	N	Y	U
453356	SCARIYA CHACKO	57	M	N	N	N	N	N	N	0.7	N	Y	Y	N	N	Y	Y
439001	ZACHARIAH	62	M	N	Y	Y	N	N	Y	0.7	Y	Y	N	N	N	Y	Y
444011	KANAKALOJANA	62	F		Y	N	N	Y	N	0.65	Y	Y	Y	Y	N	Y	Y
413726	THAMPI	62	M	N	Y	Y	N	N	Y	0.6	N	Y	N	N	N	Y	Y
266840	GOPALAKRISHNAN PILLAI	62	M	N	Y	Y	N	N	Y	0.65	N	N	Y	N	N	Y	Y
458371	JAYAN	62	M	N	Y	N	N	N	N	0.65	N	Y	N	N	N	Y	N
459274	SHAHIL HAMEED	62	M	N	Y	N	N	N	Y	0.58	N	Y	Y	Y	N	Y	N
463286	MURALEEDHARAN NAIR	62	M	N	Y	N	N	N	N	0.6	N	Y	Y	N	N	Y	Y
464945	OMANAKUTTAN	62	M	N	Y	N	N	N	Y	0.6	N	Y	Y	N	N	Y	Y
385953	DEVADAS	62	Y	N	N	N	N	N	Y	0.65	Y	Y	N	N	N	Y	Y
9509570	SHAHUL HAMEED	62	Y	N	Y	Y	N	N	Y	0.68	Y	Y	Y	Y	N	Y	Y
465884	BUSHRA	62	F	N	N	N	N	Y	N	0.65	N	Y	N	N	N	N	N
465720	SAMUELKUTTY	62	M	N	Y	Y	N	N	Y	0.6	N	Y	Y	Y	N	Y	Y
465490	RUGMINI AMMA	62	M	N	Y	N	Y	N	Y	0.5	N	Y	Y	Y	N	Y	Y
324567	RAMACHANDRAN PILLAI	62	M	N	Y	N	N	N	Y	0.6	N	Y	N	N	N	Y	Y
466445	VIJAYAN	62	M	N	N	Y	N	N	Y	0.6	N	Y	Y	Y	N	Y	Y
377153	SASIDHARAN	62	M	N	Y	Y	N	N	Y	0.6	N	Y	N	N	N	Y	Y
468243	BABU	62	M	N	Y	N	N	N	Y	0.62	N	Y	Y	Y	Y	Y	Y
469008	SREEKUMARI	62	F	N	N	N	N	Y	N	0.65	N	Y	N	N	N	Y	N
472346	VELUMBI	62	M	N	Y	N	Y	N	N	0.5	Y	Y	Y	Y	N	Y	N
449608	MADHAVAN PILLAI	62	M	N	Y	N	N	N	Y	0.6	N	Y	Y	Y	N	N	N
473271	SASI	62	M	N	Y	N	N	N	Y	0.6	N	Y	Y	Y	N	Y	N
474664	MARIYAMMA GEE VARGHESE	62	F	N	Y	N	N	N	N	0.6	N	Y	Y	N	N	Y	Y
474668	RAMACHANDRAN PILLAI	62	M	N	Y	N	Y	N	Y	0.6	N	Y	Y	Y	N	Y	Y
476352	RAMACHANDRAN NAIR	62	M	N	Y	N	Y	N	Y	0.55	N	Y	Y	Y	N	N	N
476227	JAYAKUMAR	62	M	N	Y	N	N	N	N	0.6	N	Y	Y	Y	N	Y	N

RUNOFF PER	RUTHERFORD		RUTHER	FONTAINE	FONTAINE		TASC	DM	POPLITEAL		OCCLUSION	STENOSIS	CURSMOK	ANGIOSOME ULCER	GLASS	SFA
Y		1	v	IV		1	D	Y		0	Y	N	Y	2ND TOE GANGRENE	3	N
N		1	V	IV		1	C	Y		0	Y	N	N	1-3 TOE GANGRENE	2	Y
Y		1	V	IV		1	C	N		0	Y	N	Y	3-4 TH TOE	2	Y
N		1	V	IV		1	D	Y		0	Y	N	N	1-2 TOE	4	N
N		1	V	IV		1	D	N		0	Y	N	N	1ST TOE	3	Y
Y		0	IV	III		0	D	Y		1	Y	N	N	N	3	Y
Y		0	III	IIB		0	C	Y		1	Y	N	N	N	3	Y
Y		1	V	IV		1	C	Y		0	Y	N	N	4TH 5TH TOE	2	Y
N		0	IV	III		0	C	Y		0	Y	N	N	N	3	N
N		0	IV	III		0	D	N		0	Y	N	Y	N	4	Y
Y		0	III	IIB		1	C	Y		0	Y	N	N	NIL	3	N
Y		1	V	IV		0	C	Y		0	Y	N	N	N	3	Y
Y		0	III	IIB		0	C	Y		0	Y	N	Y	N	3	Y
Y		0	IV	III		0	D	Y		0	Y	N	Y	N	4	Y
Y		0	III	IIB		0	D	Y		0	Y	N	Y	N	4	Y
Y		1	V	IV		1	D	Y		0	Y	N	N	GREAT TOE	4	Y
Y		0	IV	III		0	C	Y		0	Y	Y	N	N	2	Y
Y		0	IV	III		0	C	Y		0	N	Y	N	N	2	N
Y		0	III	IIB		0	D	N		0	Y	N	N	N	4	Y
Y		1	V	IV		1	D	Y		0	Y	N	Y	CALCANEUM	4	Y
N		0	III	IIB		0	D	N		1	Y	N	Y	N	4	Y
Y		1	V	IV		1	C	Y		0	Y	N	N	GREAT TOE	3	Y
Y		1	V	IV		1	C	Y		0	Y	N	N	FOOT	4	Y
Y		0	III	IIB		0	D	Y		1	Y	N	Y	N	4	Y
Y		1	V	IV		1	D	Y		0	Y	Y	N	GREAT TOE	3	Y
Y		0	III	IIB		0	C	Y		0	Y	Y	N	N	2	Y
Y		1	V	IV		1	D	Y		0	Y	N	Y	3RD 4TH TOE	4	Y
N		0	III	IIB		0	D	Y		0	Y	N	N	N	3	Y
N		1	V	IV		1	D	Y		1	Y	N	Y	3RD AND 4TH TOE	4	Y
Y		1	V	IV		1	D	Y		1	Y	N	Y	DORSUM OF FOOT	4	N
Y		0	IV	III		0	D	Y		0	Y	N	N	N	4	Y
Y		0	IV	III		0	C	Y		0	N	Y	N	N	2	Y
Y		1	V	IV		1	C	Y		0	Y	N	N	GREAT TOE	2	Y
N		1	V	IV		1	C	Y		0	Y	N	N	3RD 4TH TOE	2	Y
Y		1	V	IV		1	D	Y		1	Y	N	Y	1ST AND 2ND TOE	4	Y

STENTIN	LENGTH	CAL SCORE		LENGTH	SAFARI	PATENCY	ANTEGRADE	INFRA PUNCTURE	RETROGRADE	SAF	INFRAPOP	PEDAL	RUN OFF
Y		1	0	21CM	Y	O	N	Y	Y	1	N	N	0
Y		0	0	16CM	N	O	N	N	Y		ATA	N	0
Y		0	0	15CM	N	C	N	N	Y		N	N	0
Y		1	0	21CM	N	O	N	N	Y		PERONEAL ART	N	0
Y		0	1	22CM	N	C		N	Y		PERONEAL ART	N	1
Y		0	0	12CM	N	O	N	N	Y		N	N	0
Y		0	1	16CM	Y	O	Y	Y	N	1	Y	N	0
Y		0	0	16CM	N	O	Y	N	N		N	N	1
Y		0	0	18CM	N	O	N	N	Y		N	N	0
Y		1	0	28CM	N	O	N	N	Y		N	N	0
N		0	0	15CM	N	O	Y	N	N		N	N	0
N		0	0	17CM	N	C	N	N	Y		N	N	1
N		0	1	18CM	N	C	Y	N	N		N	N	1
N		1	1	24CM	N	C	N	N	Y		N	N	0
N		1	1	23CM	Y	C	N	Y	Y	3	N	N	1
N		1	1	22CM	Y	O	N	Y	Y	1	ATA	N	1
N		0	0	17CM	N	O	N	N	Y		N	N	0
N		0	0	16CM	N	O	N	N	Y		N	N	0
N		1	0	23CM	N	C	N	N	Y		N	N	0
N		0	1	25CM	N	C	N	N	Y		N	N	1
N		0	0	13CM	N	C	N	Y	N		ATA	N	1
N		0	1	18CM	N	O	N	N	Y		N	N	0
N		1	1	21CM	Y	C	N	Y	Y	2	N	N	1
N		1	1	31CM	Y	C	N	Y	Y	2	N	N	0
N		1	0	25CM	N	O	N	N	Y		N	N	0
N		0	0	16CM	N	C	Y	N	N		N	N	0
N		1	0	31CM	Y	O	N	Y	Y	2	N	Y	0
N		1	0	23CM	Y	O	N	Y	Y	2	N	N	0
N		0	1	13CM	N	C	Y	N	N		Y	Y	1
N		0	1	6CM	N	C	Y	N	N		Y	Y	1
N		1	0	23CM	N	O	N	N	Y		N	N	0
N		0	0	16CM	N	O	N	N	Y		Y	Y	0
N		0	1	19CM	Y	O	Y	Y	N	1	ATA	Y	1
N		0	0	17CM	N	O	Y	N	N		ATA	Y	0
Y		0	0	10CM	N	O	Y	N	N		Y	Y	0

RUN OFF	SCORE	PATENCY	CAL SCORE	BALOON	DISS GRADE I	PATTERN	DISS GRADE II	DISSEC	RESIDUAL	THROMBUS	RUPTUR	TECHSUC	POSTABPI	FOLLOWUP
1	5	O	2	1	-	-	-	N	N	N	N	Y	0.85	12 MONTHS
1	5	O	2	1	-	-		N	Y	N	N	Y	O.9	12 MONTHS
2	7	C	2	2	-	-		Y	N	N	N	Y	0.9	6MONTHS
1	4	O	0	2	-	-		N	Y	Y	N	Y	O.85	12 MONTHS
2	10	C	4	1	-	-		Y	N	N	Y	Y	0.9	18 MONTHS
1	4	O	0	2	-	-		N	Y	Y	Y	Y	0.85	12 MONTHS
2	6	O	4	2	-	-		N	Y	N	N	Y	0.9	16 MONTHS
1	9	O	0	2	-	-		N	Y	N	N	Y	0.85	18 MONTHS
2	9	O	1	2	-	-		Y	N	N	N	Y	O.88	18 MONTHS
2	9	O	2	2	-	-		N	Y	N	N	Y	0.85	18 MONTHS
1	4	O	2	1	2	D		0 N	N	N	N	Y	O.9	24 MONTHS
2	11	C	0	1	2	E		1 N	N	N	N	Y	O.88	18 MONTHS
2	10	C	4	2	2	E		1 N	N	N	N	Y	O.9	1 MONTH
1	4	C	4	1	1	E		1 N	N	N	N	Y	0.85	3 MONTHS
3	11	C	4	2	1	B		0 N	N	N	N	Y	O.85	24 MONTHS
2	9	O	3	1	2	D		0 N	N	N	N	Y	0.85	12 months
1	4	O	2	1	2	D		0 N	N	N	N	Y	0.88	30 MONTHS
2	6	O	3	2	2	E		0 Y	N	N	N	Y	0.85	24 MONTHS
1	2	C	0	2	1	A		0 N	N	N	N	Y	0.9	48 MONTHS
2	8	C	0	2	1	E		1 N	N	N	N	Y	0.9	12 MONTHS
3	11	C	0	1	1	E		1 N	N	Y	N	Y	0.9	24 MONTHS
1	2	O	3	2	2	E		1 N	N	N	N	Y	0.85	24 MONTHS
3	11	C	3	1	2	E		1 N	N	N	N	Y	0.88	12 MONTHS
2	6	C	4	2	2	E		1 N	N	N	N	Y	0.8	24 MONTHS
1	4	O	3	2	1	C		0 N	N	N	N	Y	0.9	12 MONTHS
1	5	C	0	2	2	D		0 N	N	N	N	Y	0.85	24 MONTHS
2	7	O	3	2	1	C		0 N	N	N	N	Y	0.88	24 MONTHS
2	8	O	2	1	2	D		0 N	N	N	N	Y	O.85	12 momths
3	11	C	4	2	2	E		1 N	N	N	N	Y	0.8	18 MONTHS
3	11	C	4	2	1	C		0 N	N	N	N	Y	0.85	3 MONTHS
2	9	O	1	2	1	B		0 N	N	N	N	Y	0.85	24 MONTHS
2	6	O	2	1	1	C		0 N	N	N	N	Y	0.9	24 MONTHS
2	9	O	3	2	2	E		0 N	N	N	N	Y	0.65	12 MONTHS
2	8	O	2	2	2	E		1 N	N	N	N	Y	0.85	18 MONTHS
2	8	O	3	1	-	-	-	N	Y	Y	N	Y	O.88	18 MONTHS

SECPATE	PRIMPATENCY	PRIM PATENCY 6 MONTHS	E OR C	SURVIVAL E OR C	E OR C	LSR MONTHS	LSR E OR C	MAJAMP	AFS MONTHS	AFS E OR C
12 MONTHS	12MONTHS	0	0	0	0	12 MONTHS	0	N	12 MONTHS	0
12 MONTHS	12 MONTHS	0	0	0	0	12 MONTHS	0	N	12 MONTHS	0
6 MONTHS	2 MONTHS	1	1	0	1	2 MONTHS	1	Y	2 MONTHS	1
12 MONTHS	12 MONTHS	0	0	0	0	12 MONTHS	0	N	12 MONTHS	0
18 MONTHS	6 MONTHS	1	1	1	2	18 MONTHS	0	N	18 MONTHS	1
12 MONTHS	12 MONTHS	0	0	0	2	12 MONTHS	0	N	12 MONTHS	0
16 MONTHS	16 MONTHS	0	0	0	2	16 MONTHS	0	N	16 MONTHS	0
18 MONTHS	18 MONTHS	0	0	0	2	18 MONTHS	0	N	18 MONTHS	0
18 MONTHS	18 MONTHS	0	0	0	2	18 MONTHS	0	N	18 MONTHS	0
18 MONTHS	18 MONTHS	0	0	0	2	18 MONTHS	0	N	18 MONTHS	0
24 MONTHS	24 MONTHS	0	0	0	2	24 MONTHS	0	N	24 MONTHS	0
18 MONTHS	12 MONTHS	0	1	0	1	18 MONTHS	0	N	18 MONTHS	0
1 MONTH	1MONTH	0	1	1	2	1 MONTH	0	Y	1 MONTH	1
3 MONTHS	3 MONTHS	1	1	1	1	3 MONTHS	0	N	3 MONTHS	1
24 MONTHS	12 MONTHS	0	1	0	2	24 MONTHS	0	N	24 MONTHS	0
12 MONTHS	12 MONTHS	0	0	1	2	12 MONTHS	0	N	12 MONTHS	1
30 MONTHS	30 MONTHS	0	0	0	2	30 MONTHS	0	N	30 MONTHS	0
24 MONTHS	24 MONTHS	0	0	0	2	24 MONTHS	0	N	24 MONTHS	0
48 MONTHS	36 MONTHS	0	1	0	2	48 MONTHS	0	N	48 MONTHS	0
12 MONTHS	6 MONTHS	1	1	0	2	12 MONTHS	0	N	12 MONTHS	0
24 MONTHS	12 MONTHS	0	1	0	2	24 MONTHS	0	N	24 MONTHS	0
24 MONTHS	24 MONTHS	0	0	0	2	24 MONTHS	0	N	24 MONTHS	0
12 MONTHS	12 MONTHS	0	1	1	1	12 MONTHS	0	Y	1 MONTHS	1
24 MONTHS	12 MONTHS	0	1	0	2	24 MONTHS	0	N	24 MONTHS	0
12 MONTHS	12 MONTHS	0	0	1	2	12 MONTHS	0	N	12 MONTHS	1
24 MONTHS	18 months	0	1	0	1	24 MONTHS	0	N	24 MONTHS	0
24 MONTHS	24 MONTHS	0	0	0	2	24 MONTHS	0	N	24 MONTHS	0
12 MONTHS	12 MONTHS	0	0	0	2	12 MONTHS	0	N	12 MONTHS	0
18 MONTHS	12 MONTHS	0	1	0	1	18 MONTHS	0	N	18 MONTHS	0
3 MONTHS	3 MONTHS	1	1	1	2	3 MONTHS	0	Y	3 MONTHS	1
24 MONTHS	24 MONTHS	0	0	0	2	24 MONTHS	0	N	24 MONTHS	0
24 MONTHS	24 MONTHS	0	0	0	2	24 MONTHS	0	N	24 MONTHS	0
12 MONTHS	12 MONTHS	0	0	0	2	12 MONTHS	0	N	12 MONTHS	0
18 MONTHS	18 MONTHS	0	0	1	2	18 MONTHS	0	N	18 MONTHS	1
18 MONTHS	18 MONTHS	0	0	0	2	2 MONTHS	1	N	18 MONTHS	1

PATENCY	ULCER HEALING	REST PAIN	CD IMPROVED	CLINIC PATENCY	CLINIC PATENCY	MACE
O	Y	N	Y	12 MONTHS	0	N
O	Y	N	Y	12 MONTHS	0	N
C	N	N	N	2 MONTHS	1	N
O	N	N	Y	12 MONTHS	0	N
C	Y	N	Y	18 MONTHS	0	Y
O	Y	N	Y	12 MONTHS	0	N
O	Y	N	Y	16 MONTHS	0	N
O	Y	N	Y	18 MONTHS	0	N
O	Y	N	Y	18 MONTHS	0	N
O	Y	N	Y	18 MONTHS	0	N
O	Y	N	Y	24 MONTHS	0	N
C	Y	N	Y	18 MONTHS	0	N
C	Y	N	Y	1 MONTH	0	Y
C	Y	N	Y	3 MONTHS	0	Y
C	Y	N	Y	24 MONTHS	0	N
O	Y	N	Y	12 MONTHS	0	Y
O	Y	N	Y	30 MONTHS	0	N
O	Y	N	Y	24 MONTHS	0	N
C	Y	N	Y	48 MONTHS	0	N
C	Y	N	Y	12 MONTHS	0	N
C	Y	N	Y	24 MONTHS	0	N
O	Y	N	Y	24 MONTHS	0	N
C	Y	N	-	1 MONTHS	0	Y-
C	Y	N	Y	24 MONTHS	0	N
O	Y	N	Y	12 MONTHS	0	Y
C	Y	N	Y	24 MONTHS	0	N
O	Y	N	Y	24 MONTHS	0	N
O	Y	N	Y	12 MONTHS	0	N
C	Y	N	Y	18 MONTHS	0	N
C	Y	N	Y	3 MONTHS	0	Y
O	Y	N	Y	24 MONTHS	0	N
O	N	N	Y	12 MONTHS	1	N
O	Y	N	Y	12 MONTHS	0	N
O	Y	N	Y	18 MONTHS	0	N
O	N	Y	N	14 MONTHS	1	N

473449	VIJAYAN	61	M	N	Y	Y	N	N	Y	0.6	N	Y	Y	N	N	Y	Y
475292	RAVEENDRAN BHASKAR	72	M	n	y	N	N	N	Y	0.65	Y	Y	Y	N	N	N	Y
259975	BABU	62	m	n	n	y	N	y	N	0.7	N	Y	N	N	N	Y	Y
479340	SANDEEP VIJAYAN	41	M	N	N	N	N	N	Y	0.6	N	Y	Y	Y	N	Y	N
313566	VIJAYAN NAIR	62	M	N	Y	Y	N	Y	N	0.5	N	Y	Y	Y	N	Y	Y
482991	LEELA	72	F	N	Y	N	N	Y	N	0.6	N	Y	Y	Y	N	Y	Y
482925	SASIDHARAN	52	F	N	Y	N	N	N	Y	0.6	N	Y	Y	Y	N	Y	N
460265	RADHAKRISHNAN UNNI	72	M	N	Y	Y	N	N	Y	0.5	N	Y	N	N	N	Y	Y
484522	SUBAIDA BEEVI	75	M	N	Y	N	N	Y	N	0.6	N	Y	Y	Y	N	N	Y
329638	RADHAKRISNAN NAIR	63	M	N	Y	N	N	N	Y	0.55	N	Y	Y	Y	N	Y	Y
485179	RAVEENDRAN NAIR	76	M	N	Y	N	N	N	Y	0.6	N	Y	Y	Y	N	Y	N
486224	SERABIN MARIYADAS	61	M	N	Y	N	N	N	Y	0.6	N	Y	Y	Y	N	Y	Y
486286	RAJENDRAN	72	M	N	Y	Y	N	N	Y	0.6	N	Y	N	Y	N	Y	Y
9607567	PRASANNA KUMAR	58	M	N	Y	Y	N	N	Y	0.6	N	Y	N	N	N	Y	Y
9409218	RADHAMANI	70	F	N	Y	Y	N	Y	N	0.6	N	Y	Y	Y	N	Y	N
491260	PEERU MUHAMMED	62	M	N	Y	N	N	N	Y	0.6	N	Y	Y	Y	N	Y	Y
492510	MERI	78	M	N	Y	N	N	N	Y	0.56	N	Y	Y	N	Y	Y	N

Y	0	IV	III	0	C	Y	0	Y	Y	N	N	2 Y
Y	0	IV	III	0	D	y	0	Y	N	N	N	4 Y
Y	0	III	IIB	0	D	y	0	Y	N	Y	N	4 Y
N	1	V	IV	1	D	N	1	Y	N	N	ANTEROLATERAL LEG	4 Y
Y	1	V	IV	1	D	Y	0	Y	N	N	FOURTH AND FIFTH TOE	4 Y
Y	1	V	IV	1	C	Y	0	Y	N	N	DORSUM	2 Y
N	1	V	IV	1	D	Y	0	Y	N	N	LITTLE TOE	4 N
Y	0	III	IIB	0	C	Y	0	Y	N	N	N	2 Y
Y	1	V	IV	1	D	Y	0	Y	N	N	GREAT TOE	3 Y
Y	1	V	IV	1	D	N	0	Y	N	N	DORSUM	4 Y
Y	1	V	IV	1	C	N	0	Y	N	N	GREAT TOE	2 Y
Y	1	V	IV	1	C	Y	0	Y	Y	Y	HEEL	2 Y
Y	1	V	IV	1	D	Y	0	Y	N	N	GREAT TOE	4 Y
Y	0	III	IIB	0	D	Y	0	Y	N	N	N	4 Y
Y	1	V	IV	1	D	Y	0	Y	N	Y	GREAT TOE	4 Y
N	1	V	IV	1	D	Y	0	Y	Y	N	3RD TOE	3 N
N	0	IV	III	0	D	Y	1	Y	Y	Y	AMPUTATED WOUND	3 Y

N	0	0	16CM	N	O	N	N	Y		N	Y	0
Y	1	0	35CM	Y	O	N	Y	Y	2	N	Y	0
Y	1	1	32CM	Y	C	N	Y	Y	2	N	Y	0
Y	0	0	15CM	Y	O	N	Y	Y	2	Y	Y	0
Y	1	0	31CM	Y	O	N	Y	Y	2	N	Y	0
N	0	0	16CM	N	O	N	N	Y		ATA	N	1
N	1	0	26CM	Y	O	N	Y	Y	1	ATA	Y	0
N	0	0	16CM	N	C	N	N	Y		N	Y	0
Y	1	0	21CM	Y	O	N	Y	Y	2	ATA	Y	0
N	1	0	39CM	N	O	N	Y	N		N	Y	0
N	0	0	19cm	N	O	N	N	Y		ATA	T	0
N	1	0	16CM	Y	O	N	Y	Y	1	N	Y	1
Y	1	0	32CM	Y	O	N	Y	Y	1	N	Y	0
N	1	0	26CM	Y	O	N	Y	Y	1	N	Y	0
N	1	1	23CM	N	C	N	N	Y		N	Y	0
N	1	0	22CM	N	O	N	N	Y		N	Y	0
N	1	1	31CM	N	C	N	N	Y		ATA	Y	1

2	8	O	0	2	1	B		0	N	N	N	N	Y		0.9	18	MONTHS		
1	3	O	3	2	-	-	-		N	Y	N	N	Y		0.9	12	MONTHS		
1	2	C	4	2	-	-	-		N	Y	Y	N	Y	O.88		24	MONTHS		
1	5	O	0	2	1	B		0	N	N		N	Y		0.9	18	MONTHS		
2	8	O	3	2	-	-	-		N	Y	N	N	Y		0.9	18	MONTHS		
3	11	O	2	1	1	B		0	N	N	N	N	Y		0.9	12	MONTHS		
1	4	O	0	2	1	B		0	N	N	N	N	Y		0.87	12	MONTHS		
2	7	C	0	2	1	E		1	N	N	N	N	Y		0.89	18	MONTHS		
2	6	O	0	2	2	D		0	N	N	N	N	Y		0.85	12	MONTHS		
1	4	O	2	2	2	D		0	N	N	N	N	Y		0.92	12	MONTHS		
2	8	O	2	2	2	D		0	N	N	N	N	Y		0.89	12	MONTHS		
2	10	O	0	2	2	E		0	N	N	Y	N	Y		0.85	1	MONTHS		
1	5	O	2	2	2	D		0	N	N	N	N	Y		0.8	12	MONTHS		
1	4	O	1	2	1	B		0	N	N	N	N	Y		0.8	12	MONTHS		
1	5	C	3	2	2	E		1	N	N	N	N	Y		0.85	12	MONTHS		
1	5	O	2	2	2	D		0	N	N	N	Y	Y		0.82	12	months		
3	11	C	4	1	2	E		1	N	N	N	N	Y		0.82	12	MONTHS		

18 MONTHS	18 months	0	0	0	2	18 MONTHS	0	N	18 MONTHS	0
12 MONTHS	12 MONTHS	0	0	0	2	12 MONTHS	0	N	12 MONTHS	0
24 MONTHS	6MONTHS	1	1	1	2	24 MONTHS	0	N	24 MONTHS	1
18 MONTHS	18 MONTHS	0	0	0	2	18 MONTHS	0	N	18 MONTHS	0
18 MONTHS	18 months	0	0	0	2	18 MONTHS	0	N	18 MONTHS	0
12 MONTHS	12 MONTHS	0	0	0	2	12 MONTHS	0	N	12 MONTHS	0
12 MONTHS	12 MONTHS	0	0	1	2	12 MONTHS	0	N	12 MONTHS	1
18 MONTHS	12 MONTHS	0	1	0	1	18 MONTHS	0	N	18 MONTHS	0
12 MONTHS	12 MONTHS	0	0	1	2	12 MONTHS	0	N	12 MONTHS	1
12 MONTHS	12 MONTHS	0	0	0	2	12 MONTHS	0	N	12 MONTHS	0
12 MONTHS	12 MONTHS	0	0	0	2	12 MONTHS	0	N	12 MONTHS	0
1 MONTH	1 MONTHS	0	0	1	2	1 MONTH	0	Y	1 MONTH	1
12 MONTHS	12 MONTHS	0	0	1	2	12 MONTHS	0	N	12 MONTHS	1
12 MONTHS	12 MONTHS	0	0	1	2	12 MONTHS	0	N	12 MONTHS	1
12 MONTHS	6 MONTHS	1	1	0	2	12 MONTHS	0	N	12 MONTHS	0
12 MONTHS	12MONTHS	0	0	0	2	12 MONTHS	0	N	12 MONTHS	0
12 MONTHS	6 MONTHS	1	1	0	1	12 MONTHS	0	N	12 MONTHS	0

O	Y	Y	Y	12 MONTHS	1	N
O	Y	N	Y	12 MONTHS	0	N
C	Y	N	N	24 MONTHS	0	Y
O	Y	N	Y	18 MONTHS	0	N
O	Y	N	N	18 MONTHS	0	N
O	Y	N	Y	12 MONTHS	0	N
O	Y	N	Y	12 MONTHS	0	Y
C	N	N	N	10 MONTHS	1	N
O	Y	N	Y	12 MONTHS	0	Y
O	Y	N	Y	12 MONTHS	0	N
O	Y	N	Y	12 MONTHS	0	N
O	Y	N	Y	1 MONTH	0	N
O	Y	N	Y	12 MONTHS	0	Y
O	Y	N	Y	12 MONTHS	0	Y
C	Y	N	Y	12 MONTHS	0	N
O	Y	N	Y	12 MONTHS	0	N
C	Y	N	Y	12 MONTHS	0	N