

**“EFFICACY OF TOE BRACHIAL INDEX COMPARED TO ANKLE
BRACHIAL PULSE INDEX AS A DIAGNOSTIC MODALITY IN
PERIPHERAL VASCULAR DISEASE IN DIABETICS”**

By

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In partial fulfillment for the degree of

MASTER OF SURGERY

IN

GENERAL SURGERY

Under the guidance of

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“To study the phenomenon of disease without books is to sail an uncharted sea, while to study books without patients is not to go to sea at all”

-Sir William Osler

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Dr. AHMED FARAAZ PATEL

LIST OF ABBREVIATIONS

| | | |
|--------------|---|-------------------------------------|
| ABI | – | Ankle Brachial Index |
| ABPI | – | Ankle Brachial Pulse Index |
| AHA | – | American Heart Association |
| BP | – | Blood Pressure |
| CAD | – | Coronary Artery Disease |
| CVD | – | Cerebrovascular Disease |
| CLI | – | Chronic Limb Ischaemia |
| DM | - | Diabetes Mellitus |
| DP | – | Dorsalis Pedis |
| DVT | – | Deep Vein Thrombosis |
| ECG | – | Electrocardiogram |
| ESRD | – | End Stage Renal Disease |
| FBS | – | Fasting Blood Sugar |
| GTT | – | Glucose Tolerance Test |
| HbA1c | – | Glycosylated Hemoglobin |
| HDL | – | High Density Lipoprotein |
| IC | – | Intermittent Claudication |
| IDDM | – | Insulin Dependent Diabetes Mellitus |
| LDL | – | Low Density Lipoprotein |
| LEAD | – | Lower Extremity Arterial Disease |
| PVD | – | Peripheral Vascular Disease |
| TBI | – | Toe Brachial Index |
| TG | – | Triglycerides |

ABSTRACT

Introduction:

Peripheral vascular disease (PVD) is a major cause of morbidity and mortality especially affecting the elderly population. The prevalence of PVD is multifold higher in patients with diabetes compared with age- and sex matched non-diabetic subjects, and this may be because of hyperglycemia, hypertension, hyperlipidemia, platelet factors, and other factors that are increased in diabetic subjects. Ankle Brachial Pulse Index (ABPI) has continued to be a well trusted diagnostic and prognostic modality in people suffering from PVD but its efficacy is reduced in diabetics with PVD due to the concomitant calcification in the crural vessels which gives a false high ankle systolic pressure. Toe Brachial Index (TBI) is another diagnostic modality that utilizes the great toe artery pressure instead of the anterior tibial and posterior tibial arteries. It is hypothesized that the great toe artery is not affected by medial sclerosis in diabetics and therefore could be utilized to get the correct value of the index between peripheral pressure and central pressure, thereby improving their prognosis by shortening the delay between diagnosis and treatment.

Objective of the Study:

To evaluate the efficacy of Toe Brachial index in comparison to Ankle brachial pulse index as a diagnostic modality in patients of diabetes for the diagnosis of Peripheral Vascular Disease.

Materials and Methods:

Data is collected from Diabetic disease cases admitted in B.L.D.E.U's Shri B. M. Patil Medical College, Hospital & Research Centre/attending surgical OPD from October 2014. Details of cases will be recorded including history, clinical

examination, measuring ABPI & TBI, Colour Doppler imaging & other routine investigations.

Procedure:

Patients diagnosed with diabetes based on their Fasting Blood Sugar (FBS) and Post Prandial Blood Sugar OR those who are already on drugs for the treatment of diabetes i.e. insulin or oral hypoglycemic agents are included in the study. The Ankle brachial pulse index (ABPI) and Toe brachial index (TBI) are then calculated using Hand held xioppler and the findings extrapolated using Arterial Colour Doppler as a confirmatory study.

Results:

Maximum numbers of cases were in the age group of 56 to 65 years with a mean of 53 years with a male: female ratio of 3:1. Majority of the patients (70%) were newly diagnosed diabetics. Poor control of diabetes was present in 85% of cases but none of the patients had any evidence of ESRD. TBI was able to diagnose PVD in 85% (68 patients) of patients of diabetes in the study group when compared to ABPI which could diagnose only 11.3% (9 patients) of patients in the study group.

Conclusion:

Toe Brachial Index is a more Sensitive & Accurate diagnostic modality than Ankle Brachial Pulse Index for the diagnosis of Peripheral Vascular Disease in diabetics.

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INTRODUCTION

The prevalence of Peripheral Vascular Disease is strikingly higher in a younger diabetic population, affecting one in three diabetics older than 50 years³. Hyperlipidemia, hypercholesterolemia, hypertension, diabetes mellitus, and exposure to infectious agents or toxins such as from cigarette smoking are all important and independent risk factors. Regardless of plans for intervention, it is recommended that asymptomatic patients at risk for PAD and those with symptoms undergo ABI testing⁴. The presence of DM involves a two- to fourfold increased risk of PVD by causing endothelial and smooth muscle cell dysfunction in peripheral arteries. Diabetics account for up to 70% of nontraumatic amputations performed, and a known diabetic who smokes has an approximately 30% risk of amputation within 5 years. PVD is common among patients with diabetes¹. Ischaemic change is twice as common among diabetic patients than among nondiabetic patients. An increase in HbA1C by 1% can result in more than a 25% risk of PAD. Major amputation rates are five to ten times higher in diabetics than nondiabetics²⁻⁵.

Insulin-dependent diabetic patients may have calcified walls of the medium and small arteries that can falsely elevate the segmental pressures of the leg. In this situation, digital pressures of the toes can be accurately measured and a pressure higher than 30 mm Hg is predictive of healing after local amputation and debridement. The presence of DM involves a two- to fourfold increased risk of PVD by causing endothelial and smooth muscle cell dysfunction in peripheral arteries^{8,13}.

A hand-held Doppler ultrasound probe is very useful in the assessment of occlusive arterial disease . A continuous-wave ultrasound signal is transmitted from the probe at an artery and the reflected beam is picked up by a receiver within the probe itself. The change in frequency in the reflected beam compared with that of the

transmitted beam is due to the Doppler shift, resulting from the reflection of the beam by moving blood cells. The frequency change may be converted into an audio signal that is typically pulsatile. Doppler ultrasound equipment can be used in conjunction with a sphygmomanometer to assess systolic pressure in small vessels.

This is possible even when the arterial pulse cannot be palpated. Ankle pressures <50 mmHg or toe pressures <30 mmHg are indicative of critical limb ischemia. The toe pressure is normally 30 mmHg less than the ankle pressure, and a toe-brachial index of <0.70 is abnormal. False-positive results with the toe-brachial index are unusual. The main limitation of this technique is that it may be impossible to measure pressures in the first and second toes due to preexisting ulceration^{17,19}.

OBJECTIVE

To evaluate the efficacy of Toe Brachial index in comparison to Ankle brachial pulse index as a diagnostic modality in patients of diabetes for the diagnosis of Peripheral Vascular Disease.

REVIEW OF LITERATURE

Harrison, Michelle L & et al: Preliminary assessment of an automatic screening device for peripheral arterial disease using ankle-brachial and toe-brachial indices - Assessed 80 limbs from 40 normotensive and hypertensive individuals (17 men and 23 women) with a mean age of 45 +/- 18 years.

RESULTS: There was a statistically significant correlation ($r=0.92$) between toe systolic blood pressures obtained manually with photoplethysmography compared with those obtained through the automated device. The same significant correlation was also seen between the two with ankle ($r=0.87$) and brachial ($r=0.88$) systolic blood pressures¹⁷.

Williams DT, Harding KG, Price P : An Evaluation of the efficacy of methods used in screening for lower-limb arterial disease in diabetes. They studied 130 limbs in 68 individuals with no critical ischemia over 8 months & concluded that screening tools that are effective in screening for lower limb PVD in the non-diabetic population are less efficacious in diabetes³¹.

Coni N, Tennison B, Troup M: Prevalence of lower-extremity arterial disease among elderly people in the community – studied 56 individuals aged more than 65 years with diabetes and peripheral vascular disease using hand held Doppler sonography and concluded that early diagnosis of PVD in the elderly improved the prognosis compared to those who were diagnosed later²³.

Maya S Huijberts (Univ Hosp Maastricht, Maastricht, The Netherlands); Jacqueline M Dekker (Vrije Univ Med Cntr, Amsterdam, The Netherlands); Coen D Stehouwer (Univ Of California) : Ankle Brachial Pressure Index is a better predictor of cardiovascular mortality than toe brachial index or abnormal Doppler flow curves in both diabetic and non-diabetic subjects : THE HOORN STUDY – followed 631

patients through 15 years of follow up after which 141 had died of cardiovascular causes. They concluded that only ABPI <0.9 was an independent predictor of Cardiovascular mortality in non-diabetics ($P=0.002$). In diabetic individuals this effect was as least strong ($P=0.007$)³²

Seong Chul Park (Soonchunhyang University College of Medicine, Gumi, Korea) & et al : Utility of Toe-brachial index for diagnosis of Peripheral artery disease³³ – measured ABI & TBI values in 51 patients with diabetic gangrene who were suspected of having lower extremity arterial insufficiency had ABI values of 0.9-1.3 despite presenting with diabetic gangrene or ulcers but had TBI values <0.6 ²⁸.

The Chennai Urban Population Study (CUPS) done to assess the Prevalence and Risk Factors of Peripheral Vascular Disease in a Selected South India Population was an epidemiological study involving 2 residential areas in Chennai in South India. Of the 1,399 eligible subjects (20 years of age), 1,262 (90.2%) participated in the study. All of the study subjects underwent an oral glucose tolerance test and were categorized as having normal glucose tolerance (NGT), impaired glucose tolerance (IGT), or diabetes. Peripheral Doppler studies were performed on 50% of the study subjects, and PVD was defined as an ankle-brachial index (ABI) <0.9 . The limitations included the use of Peripheral Doppler to measure ABPI because calcified non-compressible arteries occur with increased frequency in patients with diabetes³⁴.

Hospital based descriptive, cross-sectional, knowledge, attitude and practice (KAP) study on diabetes in Bijapur, Karnataka conducted by Diabetic clinic of SHRI B.M PATIL MEDICAL COLLEGE & RESEARCH HOSPITAL with a sample size of 726 was calculated with a prevalence rate of 12.1% were interviewed over one & half year period (2005-2006). The questionnaire for the assessment included risk

factors contributing to diabetes, self care, treatment, complications and their prevention. Overall in the study population, 15.35% had poor knowledge scores, 59.9% had average knowledge scores and 24.8% had good knowledge score. Chi square test showed association between duration of illness and level of knowledge to be significant. They concluded that diabetes and its complications can largely be prevented if appropriate measures are taken³³.

Peripheral artery occlusive disease, commonly referred to as peripheral arterial disease (PAD) or peripheral vascular disease (PVD), refers to the obstruction or deterioration of arteries other than those supplying the heart and within the brain. The common denominator among these processes is the impairment of circulation and resultant ischemia to the end organ involved.

Diabetes Mellitus is an important risk factor of lower extremity arterial disease (LEAD) in India. Smoking and insulin resistance are frequently present in patients with diabetes and contribute an additional risk for vascular disease. Peripheral Vascular Disease (PVD) in diabetes is complicated by peripheral neuropathy and susceptibility to infection, which leads to foot ulceration, gangrene and amputation of the affected extremity. Diabetes accounts for ~ 50% of all non traumatic amputations in India. Mortality is increased in diabetic patients with PVD. Three years survival after an amputation is < 50%.

In population based and epidemiology based studies,^{5,6} it is estimated that 20-30% of diabetic patients over 65 years of age have peripheral arterial disease. Approximately 30% of these diabetic patients with peripheral vascular disease require surgical or percutaneous revascularization. 10% require an amputation of the affected limb within 5-10 years of diagnosis. Progression from intermittent claudication to

critical limb ischemia occurs at the rate of 1.4% per year. Five year mortality of diabetic patients with PVD approaches 30%^{4,26}.

Vascular Wall Microanatomy

The arterial wall consists of three concentric layers:

1. The innermost layer is the intima. This is structurally a tube of endothelial cells in which the long axis of each cell is oriented longitudinally. The cells are aligned in a single layer and interface with the blood, providing metabolic reactivity and signaling via transport of mediators through their internal cellular architecture. The intima is separated from the media by the internal elastic membrane.
2. The media is the major structural support for the artery. It is composed predominantly of circumferentially arranged smooth muscle cells, collagen, elastin, and proteoglycans. Proteoglycans are formed of disaccharides bound to protein; they serve as binding or cement material in the interstitial spaces. The blood supply for the inner part of the media is by direct diffusion through the intima whereas the outer part is supplied by smaller penetrating arteries, known as *vasa vasorum*. The media is separated from the outermost layer, the adventitia, by the external elastic membrane.
3. The adventitia contains fibroblasts, collagen, and elastic tissue and is the strength layer of the artery.

The prevalence of PAD is strikingly higher in a younger diabetic population, affecting one in three diabetics older than 50 years. Hyperlipidemia, hypercholesterolemia, hypertension, diabetes mellitus, and exposure to infectious agents or toxins such as from cigarette smoking are all important and independent risk factors. Some abnormalities in the microcirculation in diabetics are not occlusive but

can alter the biology of the foot. There is evidence for thickening of capillary basement membrane,³ which is key in the exchange of nutrients and metabolic products between the capillary lumen and the interstitium. The chemical structure of the membrane is altered by glycosylation, causing crosslinking of proteins and a decreased in the number of highly charged sulphur groups.⁷ This may explain why molecules such as albumin leak through the capillary membrane in diabetics. There is no impairment in oxygen diffusion. In fact, diabetics with foot ulceration have higher levels of transcutaneous pO₂ than non diabetics.⁸

Further evaluation of microanatomy reveals more tortuous capillaries in diabetics, appearing as tufts instead of the typical hair pin loops. With ischemia there is less recruitment of new capillaries into the circulation, although per gram there is no difference in capillary concentration. Atherosclerotic occlusion in diabetes commonly involves tibial and peroneal arteries and spares superficial femoral artery and the arteries of the foot, especially the dorsalis pedis artery.⁹⁻¹³

Clinical Classification of Peripheral Arterial Disease: Fontaine and Rutherford Systems

| Fontaine Classification | | Rutherford Classification | |
|-------------------------|---------------------------------|---------------------------|-----------------------|
| STAGE | CLINICAL | GRADE | CLINICAL |
| I | Asymptomatic | 0 | Asymptomatic |
| IIa | Mild claudication | 1 | Mild claudication |
| IIb | Moderate to severe Claudication | 2 | Moderate claudication |
| III | Ischemic rest pain | 3 | Severe claudication |
| IV | Ulceration or gangrene | 4 | Ischemic rest pain |
| | | 5 | Minor tissue loss |
| | | 6 | Major tissue loss |

TASC II Classification of Femoral Popliteal Occlusive Lesions

Type A lesions

- Single stenosis 10 cm in length
- Single occlusion 5 cm in length

Type B lesions

- Multiple lesions (stenoses or occlusions), each 5 cm
- Single stenosis or occlusion 15 cm not involving the infra geniculate popliteal artery
- Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass
- Heavily calcified occlusion 5 cm in length
- Single popliteal stenosis

Type C lesions

- Multiple stenoses or occlusions totaling >15 cm with or without heavy calcification
- Recurrent stenoses or occlusions that need treatment after two endovascular interventions

Type D lesions

- Chronic total occlusions of CFA or SFA (>20 cm, involving the popliteal artery)
- Chronic total occlusion of popliteal artery and proximal trifurcation vessels

CFA = common femoral artery; SFA = superficial femoral artery; TASC II = Trans-Atlantic Inter-Society Consensus

The presence of DM involves a two- to fourfold increased risk of PVD by causing endothelial and smooth muscle cell dysfunction in peripheral arteries.

Diabetics account for up to 70% of nontraumatic amputations performed, and a known diabetic who smokes has an approximately 30% risk of amputation within 5 years. Diabetic Foot PVD is common among patients with diabetes (Fig. 63-12). IC is twice as common among diabetic patients than among nondiabetic patients. An increase in HgbA1C by 1% can result in more than a 25% risk of PAD. Major amputation rates are five to ten times higher in diabetics than nondiabetics¹².

Because of these causal relations, the American Diabetes Association recommends ABI screening every 5 years in patients with diabetes.⁸ The care of diabetic patients should start with preventive measures, and it is important to avoid infections in patients with insensate feet because of neuropathy. These patients need to wear properly fitted shoes at all times for protection. Orthotic inserts should be used to distribute weight evenly to avoid pressure on the metatarsal heads of the foot. Diabetic patients may be unaware of the presence of infections or ulcerative lesions because of peripheral neuropathy and a decreased ability to sense pain. In this population, infections can progress rapidly, with significant tissue damage from a combination of delayed presentation and compromised immune function⁸.

On presentation, a careful physical examination is important to plan for appropriate treatment. The overlying cellulitis is assessed, and any possible underlying abscess is examined by palpation for crepitus or detection of drainage of purulent fluid. Cellulitis should not be confused with dependent rubor caused by severe ischemia in patients with PAD. The presence of an abscess requires immediate drainage prior to revascularization. The status of arterial circulation is documented. The presence or absence of lower extremity pulses in the common femoral, popliteal, and pedal arteries is examined. The pulses may be difficult to palpate because of

swelling from foot infection; noninvasive arterial ultrasound can be useful in assessing the extent of arterial disease^{1,5,14}.

The physical examination begins with vital signs, which often reveals hypertension and tachycardia. Blood pressure in both arms should be documented. The presence or absence of carotid bruits, cardiac murmurs, abdominal, flank, or groin bruits should be noted. The abdomen should be palpated for the aortic pulsation. Incision scars should be noted. Bilateral carotid, radial, ulnar, femoral, popliteal, dorsalis pedis (DP), and posterior tibial (PT) pulses should be palpated and characterized. If pulses are not palpable, a continuous wave Doppler can be used to check for signals.

Common physical findings of PAD include hair loss and dry shiny skin with nail hypertrophy. In Chronic Limb Ischaemia (CLI), the classic findings of dependent rubor and pallor with elevation of the limb can be observed. In cases of severe rest pain, patients may have peripheral edema because they are unable to take their legs from the dependent position without pain. The feet should be meticulously inspected for wounds and signs of skin breakdown. A neurologic examination documenting equivalent strength and sensation in the limbs and cranial nerves should be performed.

Routine laboratory work should include a complete blood count, chemistry (to evaluate renal function and glucose), and a lipid panel. An albumin level can be helpful in delineating the adequacy of a patient's nutritional status, if this is in question. The hemoglobin A1c (HbA1c) level indicates the patient's level of glycemic control over the previous 120 days. A baseline electrocardiogram should be obtained. Any previous cardiac testing, including echocardiography, stress echocardiography, dobutamine-adenosine sestamibi scan, and coronary catheterization, should be reviewed and documented⁹.

Insulin-dependent diabetic patients may have calcified walls of the medium and small arteries that can falsely elevate the segmental pressures of the leg. In this situation, digital pressures of the toes can be accurately measured and a pressure higher than 30 mm Hg is predictive of healing after local amputation and debridement. The presence of DM involves a two- to fourfold increased risk of PVD by causing endothelial and smooth muscle cell dysfunction in peripheral arteries. Diabetics account for up to 70% of nontraumatic amputations performed, and a known diabetic who smokes has an approximately 30% risk of amputation within 5 years^{1,3,26}.

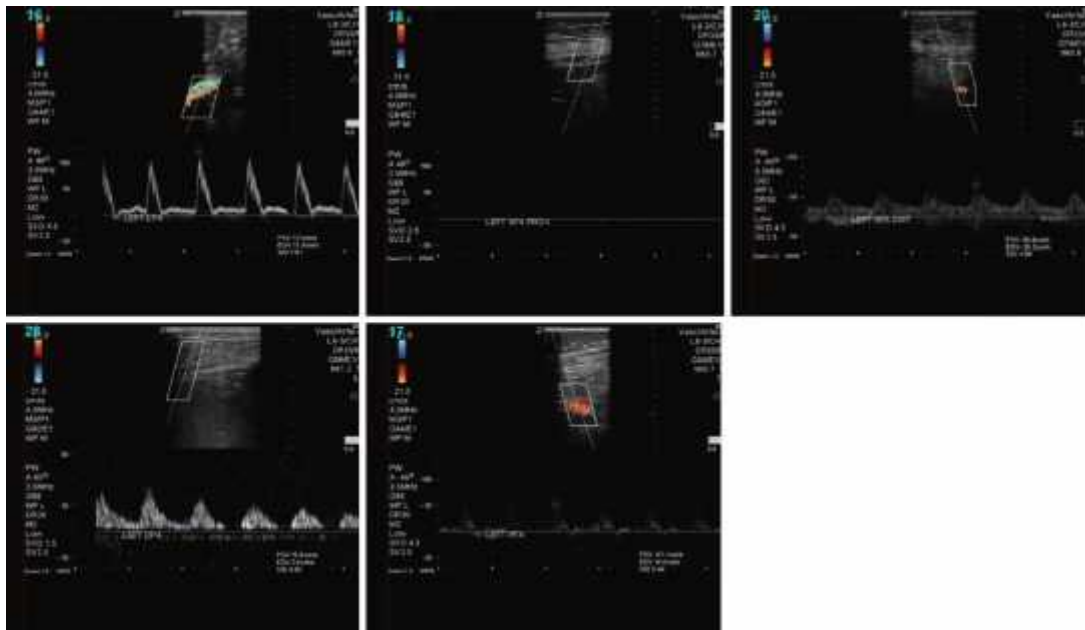
Regardless of plans for intervention, it is recommended that asymptomatic patients at risk for PAD and those with symptoms undergo ABI testing. This examination can be performed simply with a manual blood pressure cuff at the ankle and a continuous wave Doppler probe. With the patient in a supine position, after several minutes of rest to allow limb pressure to return to baseline, the cuff is inflated at the ankle, with the Doppler probe held at the location of the distal DP or PT signal. The systolic pressure is recorded as the pressure in the cuff when the Doppler signal returns. This process can be performed with multiple cuffs allowing for segmental pressure determination, which is helpful in localizing the level of the obstructing lesion. The ABI for a limb is calculated using the higher of the two ankle pressures divided by the higher of the two brachial pressures. Patients with an ABI of 0.90 or less have a three- to sixfold increased risk of cardiovascular mortality.

By placing serial BP cuffs down the LE (lower extremity) and then measuring the pressure with a Doppler probe as flow returns to the artery below the cuff, it is possible to determine segmental pressures down the leg. These data can then be used to infer the level of the occlusion. The systolic pressure at each level is expressed as a

ratio, with the highest systolic pressure in the upper extremities as the denominator. Normal segmental pressures commonly show high thigh pressures 20 mmHg or greater in comparison to the brachial artery pressures. The low thigh pressure should be equivalent to brachial pressures. Subsequent pressures should fall by no more than 10 mmHg at each level. A pressure gradient of 20 mmHg between two subsequent levels is usually indicative of occlusive disease at that level. The most frequently used index is the ratio of the ankle pressure to the brachial pressure, the ABI. Normally the ABI is >1.0 , and a value <0.9 indicates some degree of arterial obstruction and has been shown to be correlated with an increased risk of coronary heart disease.

Limitations of relying on segmental limb pressures include: (a) missing isolated moderate stenoses (usually iliac) that produce little or no pressure gradient at rest; (b) falsely elevated pressures in patients with diabetes and end-stage renal disease; and (c) the inability to differentiate between stenosis and occlusion.² Patients with diabetes and end-stage renal disease have calcified vessels that are difficult to compress, thus rendering this method inaccurate, due to recording of falsely elevated pressure readings. Noncompressible arteries yield ankle systolic pressures of 250 mmHg or greater and an ABI of >1.40 . In this situation, absolute toe and ankle pressures can be measured to gauge critical limb ischemia. Ankle pressures <50 mmHg or toe pressures <30 mmHg are indicative of critical limb ischemia. The toe pressure is normally 30 mmHg less than the ankle pressure, and a toe-brachial index of <0.70 is abnormal. False-positive results with the toe-brachial index are unusual. The main limitation of this technique is that it may be impossible to measure pressures in the first and second toes due to preexisting ulceration. The diagnosis of PAD is given to ABI <0.9 . ABI >1.3 is interpreted as abnormal because of

incompressible tibial arteries, frequently seen in diabetes and end stage renal disease^{18,27}.



Arterial duplex scanning, left critical limb ischemia. Although both ABIs are abnormal (A), the right limb waveforms are multiphasic and the left-sided waveforms are monophasic. Arterial duplex images show normal left CFA (B) and no flow in the proximal SFA (C); however, flow in the distal SFA (D) and dorsalis pedis arteries (E) is present because of collateral flow from the profunda femoris(F)

Doppler ultrasound blood flow detection:

A hand-held Doppler ultrasound probe is very useful in the assessment of occlusive arterial disease. A continuous-wave ultrasound signal is transmitted from the probe at an artery and the reflected beam is picked up by a receiver within the probe itself. The change in frequency in the reflected beam compared with that of the transmitted beam is due to the Doppler shift, resulting from the reflection of the beam by moving blood cells. The frequency change may be converted into an audio signal that is typically pulsatile.

Doppler ultrasound equipment can be used in conjunction with a sphygmomanometer to assess systolic pressure in small vessels. This is possible even when the arterial pulse cannot be palpated. Both the pressure and signal quality are important; a normal artery has a triphasic signal that can be detected by a trained observer. However, although the presence of a Doppler signal indicates moving blood, it does not necessarily indicate that the blood flow is sufficient to maintain limb viability and prevent limb loss¹⁶.

The ankle-brachial pressure index (ABPI) is the ratio of systolic pressure at the ankle to that in the arm. The highest pressure in the dorsalis pedis, posterior tibial or peroneal artery serves as the numerator, with the highest brachial systolic pressure being the denominator. Resting ABPI is normally about 1.0; values below 0.9 indicate some degree of arterial obstruction (claudication), less than 0.5 suggests rest pain and less than 0.3 indicates imminent necrosis^{6,7,13}. However, the values are merely a guide and normal values may be present with intermittent claudication. Retesting after exercise can be useful; a normal ABPI may subsequently fall in patients with ischaemia. Artificially high readings can be caused by calcified, incompressible arteries which are often found in diabetics.

A meta-analysis of 71 studies by Koelemay and associates confirmed that duplex scanning is accurate for assessing arterial occlusive disease in patients suffering from claudication or critical ischemia, with an accumulative sensitivity of 80% and specificity of over 95%.³³

Management Of Lower Limb Peripheral Vascular Disease

Management of Peripheral Vascular Disease can be divided into two categories :

- i. Medical Therapy
- ii. Lower limb revascularization

I. Medical Therapy

Exercise: Supervised exercise therapy has been shown to improve claudication in patients with PAD. In a metaanalysis of exercise programs, supervised exercise therapy increased the average distance walked to the onset of claudication by 179% and the maximal distance walked by 122%. The exercise schedule should be of at least 30 minutes duration at least twice a week. Supervised exercise therapy benefits by development of collateral vessels, expression of angiogenic factors, improvement in the endothelial functions and cardiovascular fitness. Control of risk factors (e.g. Diabetes Mellitus, Dyslipidemia, Hypertension and others) and total abstinence from smoking are corner stone of medical therapy^{9,12}.

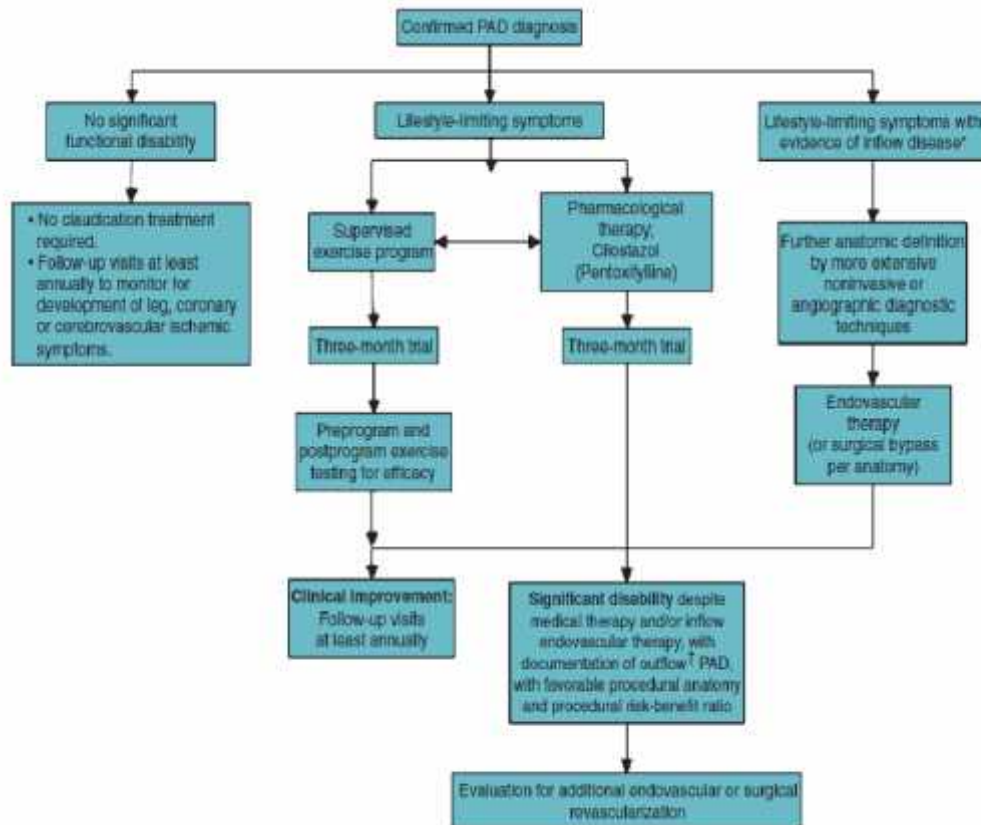
Aspirin therapy remains the most commonly prescribed therapy among patients with PAD. However, both **clopidogrel** and **cilostazol** have evolved in recent years as promising new therapies for patients with peripheral vascular disease. In the large multi-national CAPRIE Trial, 20 patients randomized to clopidogrel had a significant reduction in atherosclerotic events like vascular death, myocardial infarction and stroke compared with those randomized to aspirin²².

Cilostazol is a quinolinone and has many beneficial effects such as prevention of platelet aggregation; vasodilatation and inhibition of smooth muscle cell proliferation. When compared with pentoxifyline and placebo in patients with peripheral arterial disease, cilostazol results in a significant increase in the walking distance on the treadmill²².

Unfortunately, upto now, medical therapy has not provided a great deal of benefit in eliminating symptoms or progression of peripheral arterial disease. Currently, medical therapy is focused on reducing the morbidity and mortality from accompanying cerebrovascular and cardiovascular disease.

There are numerous novel pharmacologic therapies being actively investigated in patients with peripheral arterial disease. These include **arterial gene therapy** and metabolic agents such as **L-propionyl carnitine** and **glycoprotein IIb/IIIa receptor antagonist**. Each of these modalities will require further investigations²⁰.

Intermittent claudication treatment algorithm:



Guidelines for Risk Factor Modification (AHA):

1. Lipid Management

Goal: Primary—serum LDL <100 mg/dL; secondary—HDL >35 mg/dL, TG <200 mg/dL

Approach: Diet: <30% fat, <7% saturated fat, <200 mg/day cholesterol; specific drug therapy targeted to lipid profile

2. Weight Reduction

Goal: Ideal body weight

Approach: Physical activity, diet as outlined

3. Smoking

Goal: Complete cessation

Approach: Behavior modification, counseling, nicotine analogues

4. Blood Pressure

Goal: <140/90 mm Hg

Approach: Weight control, physical activity, sodium restriction, antihypertensive drugs

5. Physical Activity

Goal: At least 30 minutes of moderate exercise 3 to 4 times per week

Approach: Walking, cycling, jogging, lifestyle and work activities.

In contemporary surgical practice, lipid modification, antiplatelet and antihypertensive control, and smoking cessation strategies are all becoming standard management issues for the patient with vascular disease.

II. Revascularisation of Peripheral Vessels

Revascularization therapy could be achieved by either surgical operation or by percutaneous interventional procedures. Maintaining functional limb viability with the lowest procedural and long-term mortality should be the objective in the care of these patients. When chosen appropriately, both surgical bypass and endovascular techniques may benefit these patients. Whatever technique is used, the result should achieve a straight-line distal flow to the foot, preferably leading to distal pulsation. The patient should be followed closely for wound healing with vascular surveillance.

1. Percutaneous endovascular revascularisation

For the purpose of revascularisation, PVD is described in terms of inflow (Aorto-iliac), out flow (Infra-Inguinal) and Runoff (below knee) disease. Increasingly percutaneous endovascular treatment and/or Surgery is being used to optimise the patient outcome while minimising morbidity & limb loss. Intra arterial thrombolysis by urokinase is an important adjunct to the above treatment modalities. Peripheral angioplasty is better and more accepted technique than bypass surgery^{4,28}.

2. Aortic / iliac revascularization

The iliac arteries are technically the easiest vessels to approach percutaneously. The results of PTA are very good because of the large size and high flow rates. Although aortofemoral bypass has a patency of 93% at 42 months, it is still a major surgical procedure with potential of systemic complications in patients with preexisting significant comorbid conditions. With the advent of peripheral stents, the outcomes have improved, especially where the results of PTA are suboptimal. With this technique, large complex lesions and occlusions and aortic bifurcation disease can be treated with ease. In these cases the technical success is 96%, primary & secondary patency at 5 years is 63% & 86% respectively, approaching that of surgical bypass¹⁵.

3. Infrainguinal Revascularization

The role of infrainguinal angioplasty and stenting in the treatment of lower-extremity ischemia is more controversial than PTA and stenting for aortoiliac occlusive disease. Because of the small size of the infrainguinal vessels above and below the knee, dissections are more likely to be flow limiting, spasm is more common and relatively mild intimal hyperplasia or recoil of treated

lesions may lead to recurrence of clinical symptoms. In contrast, infrainguinal surgical bypass carries a lower rate of morbidity than iliac bypass and retains a high patency rate. Although percutaneous revascularization plays a less prominent role in the infrainguinal vasculature than in the aorto-iliac system, it remains attractive as a minimally invasive alternative to surgical bypass requiring shorter hospital stays and permitting faster recovery. Although dilatation of the common femoral and profunda femoral arteries is sometimes indicated, the most commonly treated femoropopliteal vessels are the superficial femoral artery (SFA) and popliteal artery. The technical success rate of femoropopliteal PTA is high at 93-95%¹³.

III. Amputation

Amputation should be considered when part of a limb is dead, deadly or a dead loss. A limb is dead when arterial occlusive disease is severe enough to cause infarction of macroscopic portions of tissue, i.e. gangrene. The occlusion may be in major vessels (atherosclerotic or embolic occlusions) or in small peripheral vessels (diabetes, Buerger's disease, Raynaud's disease, inadvertent intra-arterial injection). If the obstruction cannot be reversed and the symptoms are severe, amputation is required^{10,11}.

Indications for amputation

1. Dead limb – Gangrene
2. Deadly limb - Wet gangrene, Spreading cellulitis Other (e.g. malignancy)
3. 'Dead loss' limb - Severe rest pain with unreconstructable critical leg ischaemia.

The major choice is between an above- or below-knee operation. A below-knee amputation preserves the knee joint and gives the best chance of walking again

with a prosthesis. However, an above-knee amputation is more likely to heal and may be appropriate if the patient has no prospect of walking again. If the femoral pulse is absent, the amputation should be above the knee. Unfortunately, the presence of a femoral pulse does not guarantee healing of a below-knee amputation and sometimes a failed below-knee amputation may require revision to an above knee procedure^{2,16}.

METHODOLOGY

Source of data:

Diabetic disease cases admitted in B.L.D.E.U's Shri B. M. Patil Medical College, Hospital & Research Centre / attending surgical OPD.

Method of collection of data:

Diabetic disease cases admitted in B.L.D.E.U's Shri B. M. Patil Medical College, Hospital & Research Centre / attending surgical OPD during period of Oct 2014 to July 2016.

Details of cases will be recorded including history, clinical examination, measuring ABPI & TBI and Colour Doppler imaging & other routine investigations done. Detailed information regarding Peripheral Vascular Disease & Diabetes will be entered in the proforma. These patients with confirmed Peripheral Vascular Disease and Diabetes will undergo treatment as deemed necessary.

Inclusion Criteria

All cases of Diabetes admitted in B.L.D.E.U's Shri B. M. Patil Medical College, Hospital & Research Centre / attending surgical OPD will be included in the study.

Exclusion Criteria

1. Patients with peripheral vascular disease with no evidence of diabetes.
2. Patients with bilateral amputations of great toe or bilateral lower limb amputation.

Research Hypothesis

Toe Brachial Index (TBI) is better than Ankle Brachial Pressure Index (ABPI) as a diagnostic modality for the diagnosis of peripheral vascular disease in diabetics.

Procedure

Patients will be diagnosed with diabetes based on their Fasting Blood Sugar (FBS) more than 120mg/dl and Post Prandial Blood Sugar (PPBS) more than 180mg/dl OR those who are already on drugs for the treatment of diabetes i.e. insulin or oral hypoglycemic agents.

All patients included in the study will be subjected to hand-held Doppler examination of their bilateral peripheral vessels, notably brachial vessels, Anterior tibial artery, Posterior tibial artery, dorsalis pedis artery and artery of the great toe.

The Ankle Brachial Pressure Index (ABPI) is derived from the ratio of arm systolic pressure, taken as the best non invasive estimate of central systolic pressure, and the highest ankle systolic pressure, as measured in each of the above mentioned vessels at the ankle for each limb.

$$ABPI_L = P_L/P_A$$

where **ABPI_L**: Ankle Brachial Pressure Index for that leg

P_L: Highest pressure obtained from the ankle vessels for that leg

P_A: Highest brachial pressure of the two arms

ABPI normally >1.0

ABPI < 0.9 indicates arterial pathology

ABPI > 0.5 & <0.9 associated with claudication

ABPI < 0.5 indicates severe arterial disease and maybe associated with gangrene, ischemic ulceration or rest pain.

The Toe Brachial Pressure Index (TBPI) is derived from the ratio of arm systolic pressure, taken as the best non invasive estimate of central systolic pressure, and the highest Toe systolic pressure, as measured in artery of the great toe of each limb.

$$\text{TBPI}_L = P_T/P_A$$

where **TBPI_L** : **Toe Brachial Pressure Index for that toe**

P_T : **Highest Pressure obtained from the toe vessels for that leg**

P_A : **Highest Brachial pressure of the two arms**

TBPI normally >1.0

TBPI <0.75 indicates arterial pathology

All suspected cases will be advised Colour Doppler Imaging as a control test.

INVESTIGATIONS

Investigations or interventions required in this study are routine standardized procedures. There is no animal experiment involved in this study.

Complete blood count

Urine – microscopy, sugar, albumin

Fasting blood sugar (FBS)

Post Prandial blood sugar (PPBS)

HbA_{1C}

Blood Urea

Serum Creatinine

Ankle Brachial Pulse Index & Toe Brachial Index using Hand held Doppler

Colour Doppler Imaging



HAND HELD DOPPLER WITH BLOOD PRESSURE GAUGE AND TOE CUFF



HAND HELD DOPPLER MEASUREMENT OF POSTERIOR TIBIAL ARTERY
PRESSURE



HAND HELD DOPPLER MEASUREMENT OF ANTERIOR TIBIAL ARTERY
PRESSURE



HAND HELD DOPPLER MEASUREMENT OF ARTERY OF GREAT TOE
PRESSURE.

RESULTS

Table: Distribution of cases according to Age

| Age (Yrs) | N | % |
|-----------|----|------|
| 35 | 7 | 8.8 |
| 36-45 | 16 | 20.0 |
| 46-55 | 20 | 25.0 |
| 56-65 | 29 | 36.2 |
| 66-75 | 8 | 10.0 |
| Total | 80 | 100 |

| Parameters | Min | Max | Mean | SD |
|------------|-----|-----|------|------|
| Age | 24 | 75 | 53.0 | 11.6 |

Maximum number of cases were in the age group of 56 to 65 years with a mean of 53 years.

Figure: Distribution of cases according to Age

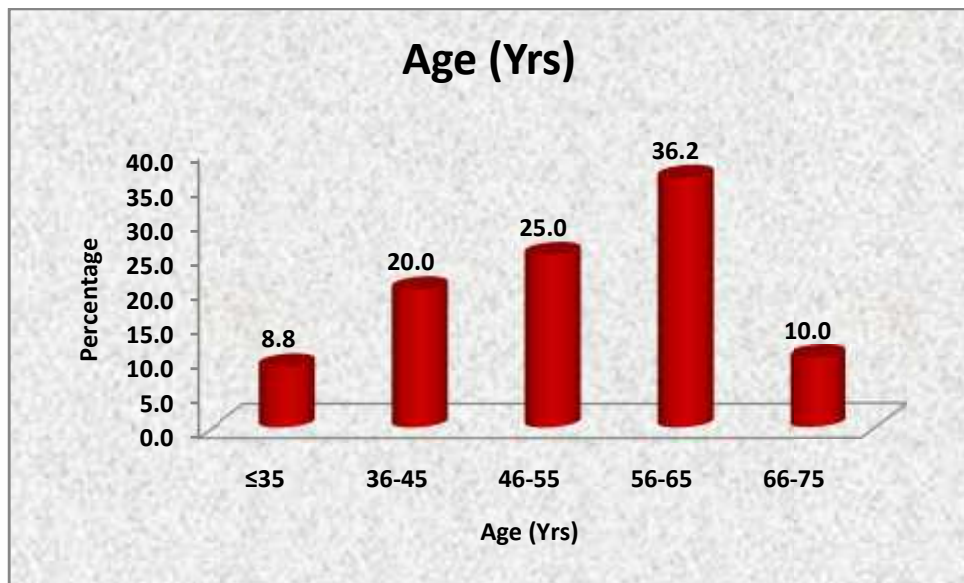
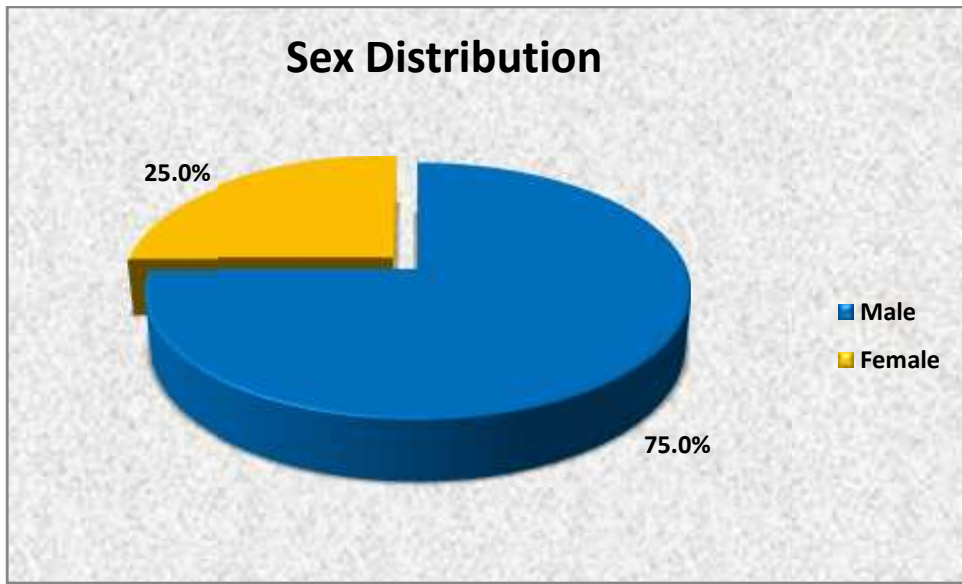


Table: Distribution of cases according to Sex

| Sex | N | % |
|--------|----|-----|
| Male | 60 | 75 |
| Female | 20 | 25 |
| Total | 80 | 100 |

Figure: Distribution of cases according to Sex



A male preponderance of 75% (60 patients) when compared to female patients (25%; 20 patients) is noted with the male : female ratio of 3:1.

Table: Distribution of cases according to Age and Sex

| Age (Yrs) | Male | | Female | | p value |
|----------------------|-------------|----------|---------------|----------|----------------|
| | N | % | N | % | |
| 35 | 7 | 11.7% | 0 | 0.0% | 0.575 |
| 36-45 | 12 | 20.0% | 4 | 20.0% | |
| 46-55 | 15 | 25.0% | 5 | 25.0% | |
| 56-65 | 20 | 33.3% | 9 | 45.0% | |
| 66-75 | 6 | 10.0% | 2 | 10.0% | |
| Total | 60 | 100.0% | 20 | 100.0% | |

Figure: Distribution of cases according to Age and Sex

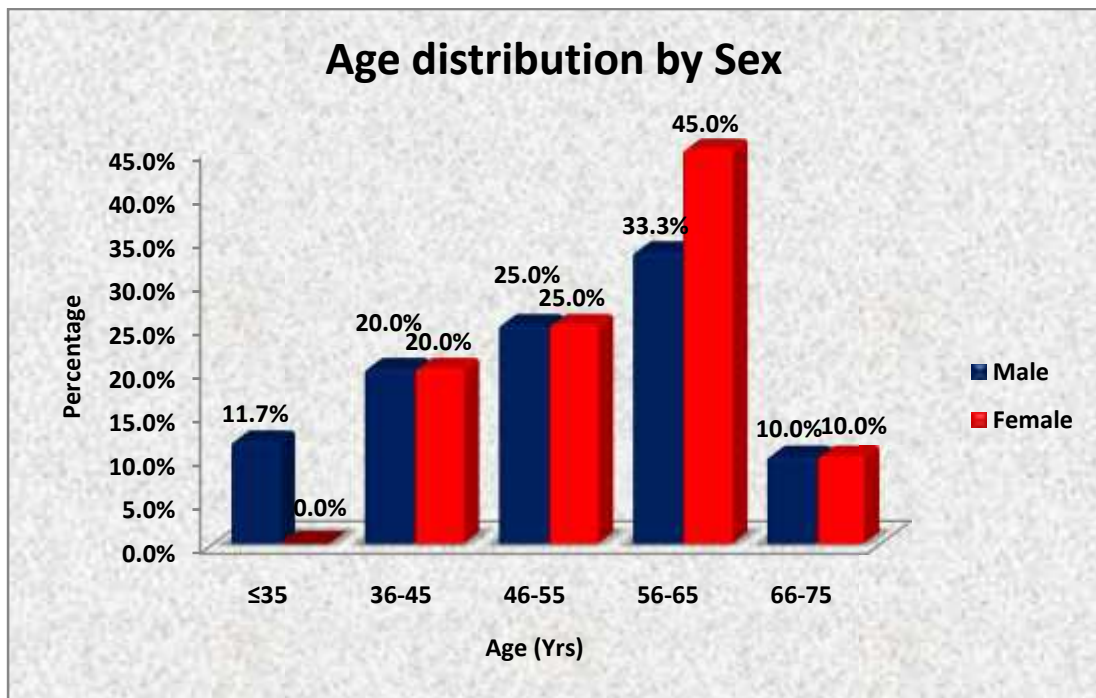


Table: Distribution of cases according to Diabetes

| Diabetes (New/Old) | N | % |
|-------------------------------|----------|----------|
| New | 56 | 70 |
| Old | 24 | 30 |
| Total | 80 | 100 |

Majority of the patients (70%) were newly diagnosed diabetics.

Figure: Distribution of cases according to Diabetes

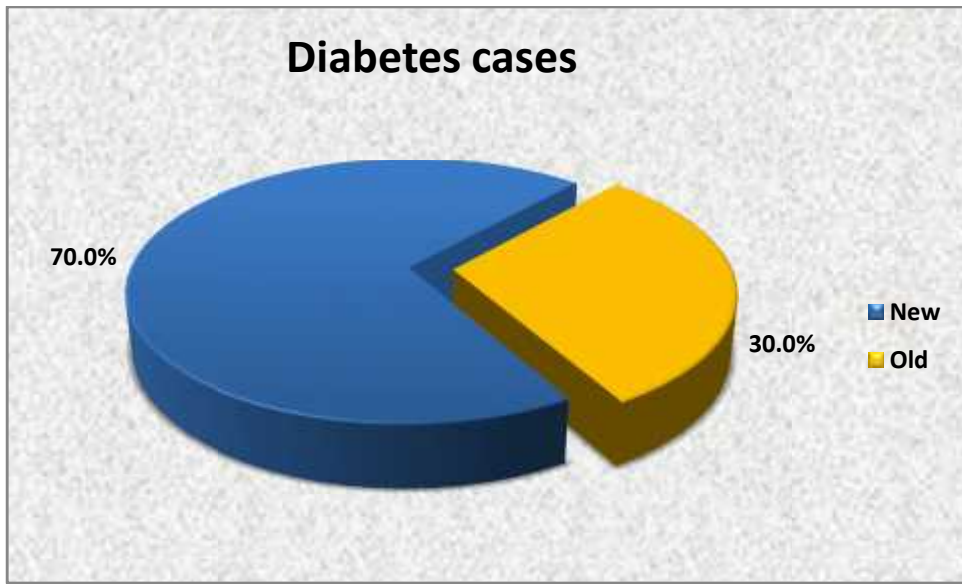


Table: Distribution of cases according to Procedure

| Procedure | N | % |
|-----------------------|----------|----------|
| Appendicectomy | 3 | 3.8 |
| Below knee amputation | 37 | 46.2 |
| conservative | 30 | 37.5 |
| Excision of mass | 1 | 1.2 |
| Fistulectomy | 1 | 1.2 |
| hemorrhoidectomy | 1 | 1.2 |
| Herniotomy | 1 | 1.2 |
| Jaboulay's Procedure | 2 | 2.5 |
| lipoma excision | 1 | 1.2 |
| Mesh Hernioplasty | 3 | 3.8 |
| Total | 80 | 100 |

Figure: Distribution of cases according to Procedure

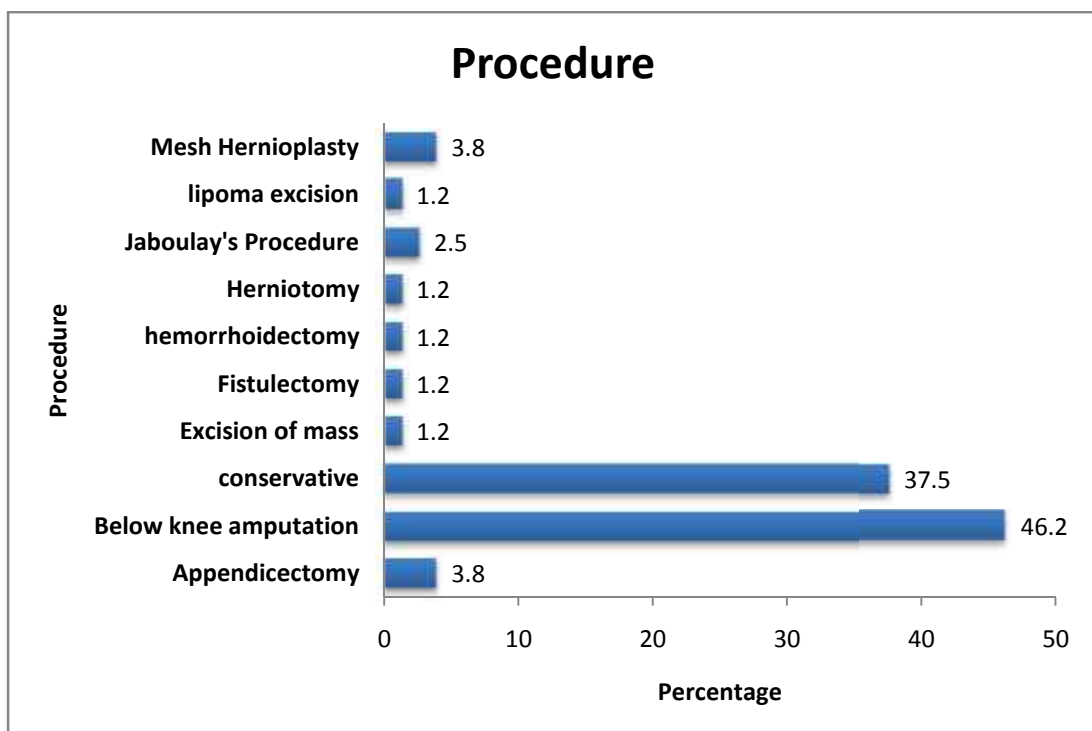


Table: Distribution of cases according to Outcome

| Outcome | N | % |
|-------------------------------|----------|----------|
| Recovered | 31 | 38.8 |
| Wound healed after amputation | 39 | 48.8 |
| Revision amputation | 10 | 12.5 |
| Total | 80 | 100 |

Figure: Distribution of cases according to Outcome

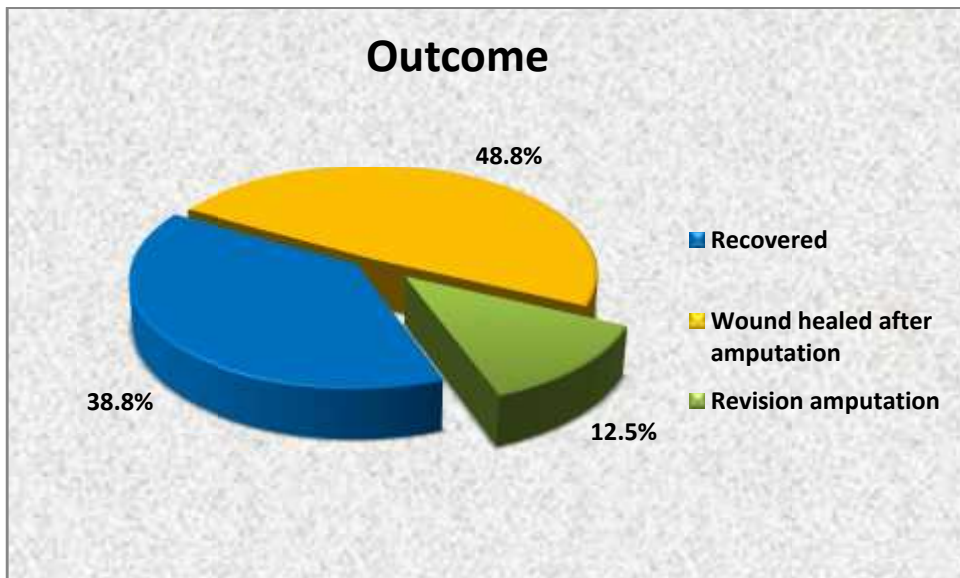


Table: Distribution of Parameters

| Parameters | Min | Max | Mean | SD |
|---------------------|-----|------|------|-----|
| HbA1c | 6.4 | 11 | 9.0 | 1.1 |
| B Urea (mg/dl) | 24 | 48 | 36.9 | 5.5 |
| S Creatnine (mg/dl) | 0.8 | 1.6 | 1.3 | 0.2 |
| ABPI | 0.8 | 1.62 | 1.2 | 0.2 |
| TBI | 0.5 | 0.7 | 0.6 | 0.1 |

Table: Distribution of cases according to HbA1c

| HbA1c | N | % |
|-------|----|-----|
| <8 | 12 | 15 |
| >8 | 68 | 85 |
| Total | 80 | 100 |

The mean HbA1c was 9, signifying a poor control of diabetes in 85% (68 patients) of cases with Peripheral Vascular Disease.

Figure: Distribution of cases according to HbA1c

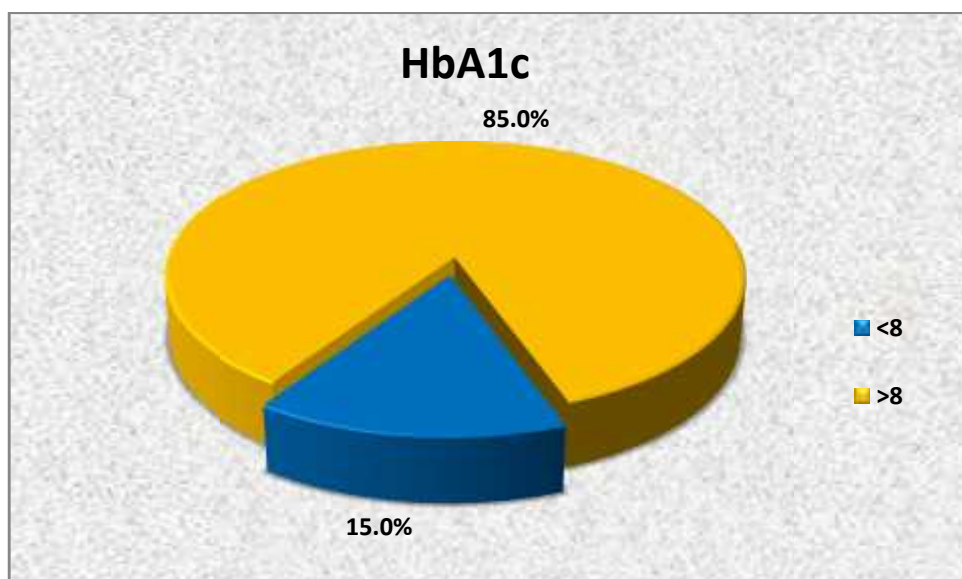


Table: Distribution of cases according to Blood Urea (mg/dl)

| Blood Urea (mg/dl) | N | % |
|---------------------------|----------|----------|
| <50 | 80 | 100 |
| >50 | 0 | 0 |
| Total | 80 | 100 |

Figure: Distribution of cases according to Blood Urea (mg/dl)

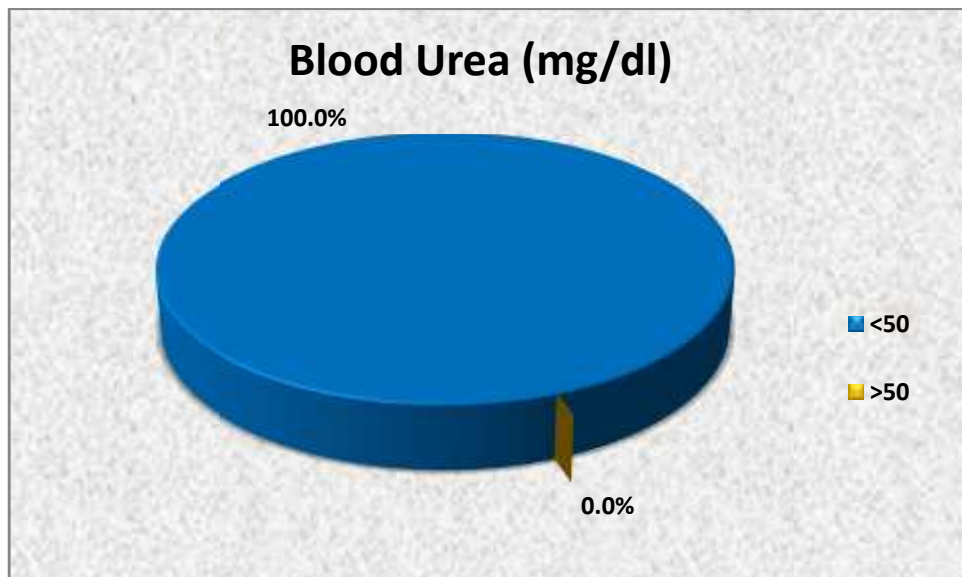
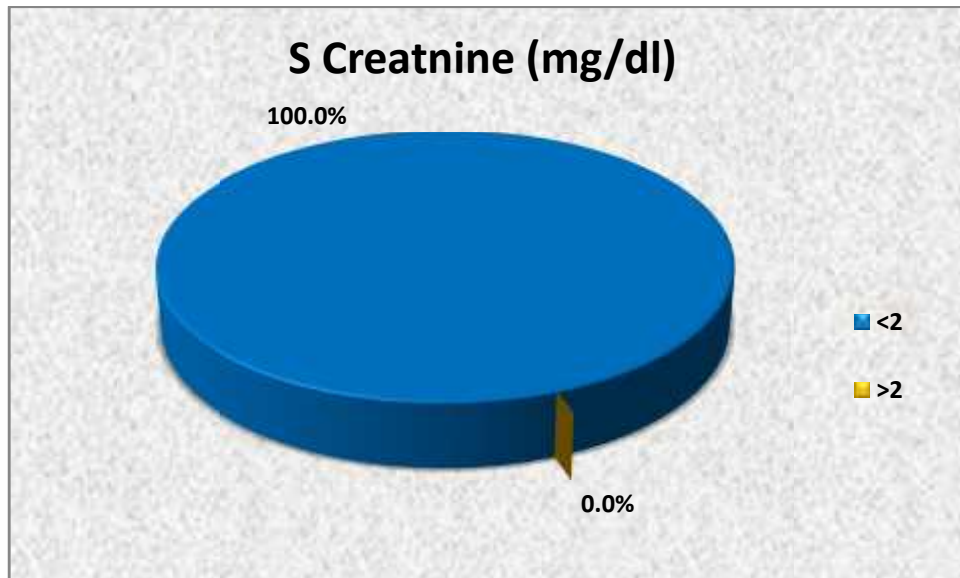


Table: Distribution of cases according to S Creatinine (mg/dl)

| S Creatinine (mg/dl) | N | % |
|----------------------|----|-----|
| <2 | 80 | 100 |
| >2 | 0 | 0 |
| Total | 80 | 100 |

Figure: Distribution of cases according to S Creatinine (mg/dl)



All the patients' Blood Urea & Serum Creatinine were within normal limits, signifying absence of End Stage Renal Disease (ESRD).

Table: Distribution of cases according to ABPI

| ABPI | N | % |
|-------------|----|------|
| +ve (<1.0) | 9 | 11.2 |
| -ve (≥ 1.0) | 71 | 88.8 |
| Total | 80 | 100 |

Amongst 80 cases, only 9 (11.2%) of diabetics were diagnosed with PVD accurately using ABPI.

Figure: Distribution of cases according to ABPI

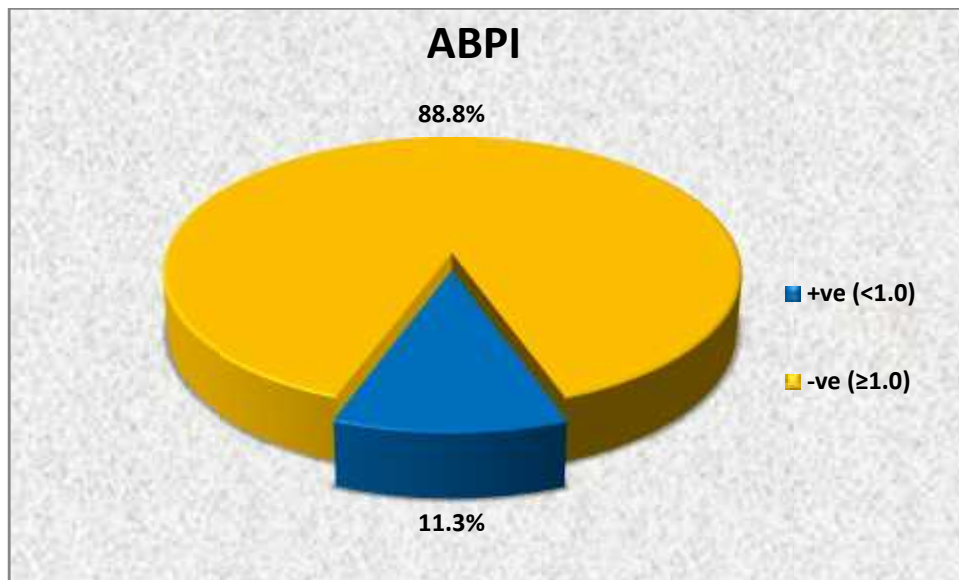


Table: Distribution of cases according to TBI

| TBI | N | % |
|--------------|-----------|------------|
| +ve (<0.7) | 68 | 85 |
| -ve (≥0.7) | 12 | 15 |
| Total | 80 | 100 |

TBI was able to diagnose PVD in 85% (68 patients) of patients of diabetes in the study group.

Figure: Distribution of cases according to TBI

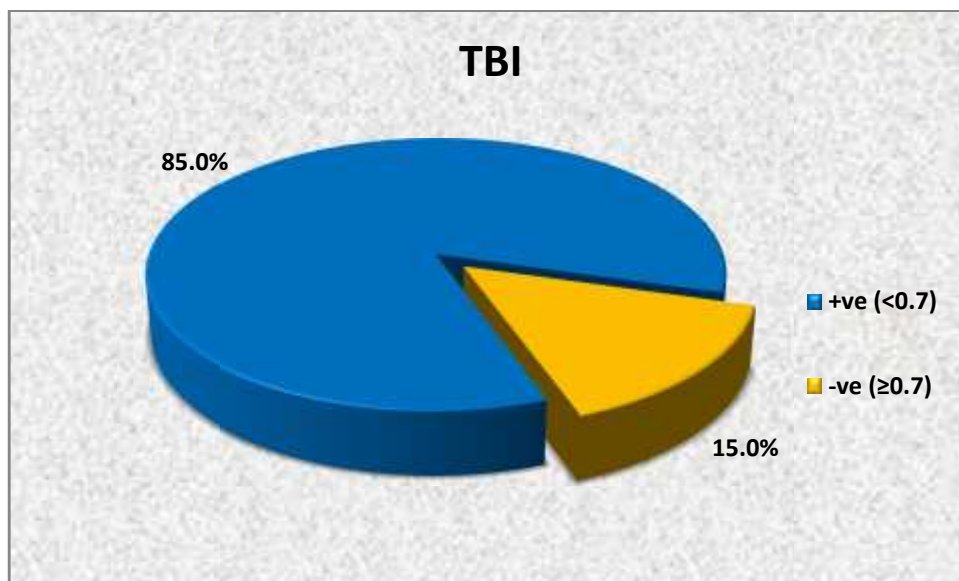


Table: Distribution of cases according to ABPI and TBI

| ABPI | TBI | | | | Total | p value |
|--|------------|--------|------------|-------|-------|---------|
| | +ve (<0.7) | | -ve (0.7) | | | |
| | N | % | N | % | N | |
| +ve (<1.0) | 9 | 100.0% | 0 | 0.0% | 9 | 0.181 |
| -ve (1.0) | 59 | 83.1% | 12 | 16.9% | 71 | |
| Total | 68 | 85.0% | 12 | 15.0% | 80 | |
| Agreement between TBI and ABPI= (9+12)/80 = 26.3% | | | | | | |

Agreement table between TBI & ABPI showing number of cases diagnosed by ABPI & TBI.

Table: Truth table for ABPI with Colour Doppler

| ABPI | Colour Doppler | | |
|--------------|-----------------------|----------------|--------------|
| | PVD +ve | PVD -ve | Total |
| +ve (<1.0) | 9 | 0 | 9 |
| -ve (1.0) | 71 | 0 | 71 |
| Total | 80 | 0 | 80 |

Truth Table comparing ABPI with colour doppler

Table: Truth table for TBI with Colour Doppler

| TBI | Colour Doppler | | |
|--------------|-----------------------|----------------|--------------|
| | PVD +ve | PVD -ve | Total |
| +ve (<0.7) | 68 | 0 | 68 |
| -ve (0.7) | 12 | 0 | 12 |
| Total | 80 | 0 | 80 |

Truth table comparing TBI with Colour Doppler.

Table: Sensitivity analysis of TBI vs ABPI

| | TBI | ABPI |
|--------------------|------------|-------------|
| Sensitivity | 85.0% | 11.3% |
| Specificity | NA | NA |
| PPV | 100.0% | 100.0% |
| NPV | 0.0% | 0.0% |
| Accuracy | 85.0% | 11.3% |

Sensitivity & Accuracy of TBI to diagnose PVD in diabetics is more than ABPI.

Statistical analysis

All characteristics were summarized descriptively. For continuous variables, the summary statistics of N, mean, standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries. Chi-square (χ^2)/Freeman-Halton Fisher exact test was employed to determine the significance of differences between groups for categorical data. Sensitivity- specificity analysis was done to check relative efficiency. If the p-value was < 0.05 , then the results will be considered to be significant. Data were analyzed using SPSS software v.23.0.

DISCUSSION

A key principle in the treatment of peripheral atherosclerosis is the hemodynamic assessment of circulatory impairment, which assumes paramount importance in comparison to the anatomic presence or distribution of lesions. The most common source of error in the ABI is false elevation resulting from extensive vascular calcification, as is common in diabetic patients. In these instances, other measures of distal perfusion (e.g., toe pressures, transmetatarsal pulse volume recording, transcutaneous oximetry) may be more reliable indicators of physiologic impairment.

In this study, Toe Brachial Index (TBI) was compared with Ankle Brachial Pulse Index (ABPI) to ascertain which one would be a better diagnostic test for the diagnosis of PVD in patients of Diabetes. The study was performed using Hand held Doppler and the results were confirmed using Colour Doppler. The hand held Doppler is a portable device, now widely used by general surgeons as well as vascular surgeons to assess the blood flow to a limb.

In this study, the mean age of presentation of patients was 53 years with maximum number of patients in the age group of 56 to 65 years. The number of newly diagnosed diabetics (70%) also greatly outnumbered the previously diagnosed or known diabetics (30%). This shows that late diagnosis of diabetes was due to late presentation of the patients to the hospital and that more number of complications were to be expected, including peripheral vascular disease.

The most common presentation of diabetics who were later diagnosed with peripheral vascular disease was Ulcer Over the Foot (26 patients; 32.5%) and 21 of those patients underwent below knee amputation. Revision amputation with above knee amputation was required in 6 of these patients, signifying a virulent form of the

disease. ABPI was normal in all these patients signifying the low sensitivity in patients with late presentation, most probably due to medial sclerosis that affects the peripheral arteries in long standing/ untreated diabetics. The mean HbA1c was 9, signifying a poor control of diabetes in 85% (68 patients) of cases with Peripheral Vascular Disease. Overall, 37 patients (46.2%) underwent below knee amputations signifying the high morbidity associated with late diagnosis of peripheral vascular disease in diabetes.

Amongst 80 cases, only 9 (11.2%) of diabetics were diagnosed with PVD accurately using ABPI when compared to TBI which was able to diagnose PVD in 68 patients (85%) of diabetes in the study group. This signifies the high sensitivity & accuracy of TBI (85%) when compared to ABPI (11.3%), thereby making it an ideal screening test for diabetes.

Early diagnosis of both Diabetes as well as PVD in those patients, coupled with regular treatment & follow-ups are key to the management of both Diabetes & PVD, and their complications. Prevention of morbidity should be aggressively pursued so as to provide a viable lifestyle to the patient. Cessation of smoking, exercise, low fat diet & weight control should be incorporated to the lifestyle modification that should be strenuously advised to the patients.

Hand held Doppler examination of the lower limb arteries provides a cheap & quick diagnosis of peripheral vascular disease in diabetics and therefore is a viable modality for prevention of morbidity in these patients.

SUMMARY

In this study, 80 patients admitted with diabetes were diagnosed with PVD using handheld Doppler & Colour Doppler. Male sex preponderance with a ratio of 3:1 and mean age of 53 years with maximum number of cases recorded in the age group of 56 to 65 years.

70% of patients were newly diagnosed diabetics with a mean HbA1c of 9 with poor control of diabetes in 85% of patients in the study. None of the patients had features of End Stage Renal Disease (ESRD).

TBI was found to be more sensitive & accurate when compared to ABPI in the diagnosis of PVD in diabetics, as seen in the Truth Table & sensitivity analysis of TBI vs ABPI, thereby proving the hypothesis of the study.

Medial sclerosis of the peripheral arteries can cause false high ABPI values thereby hindering the diagnosis of PVD in diabetics, resulting in higher rates of amputation & subsequent morbidity.

Early diagnosis & treatment of PVD is key to reduce morbidity in diabetics and thereby providing a healthier lifestyle & increased life expectancy.

CONCLUSION

Toe Brachial Index is a more Sensitive & Accurate diagnostic modality when compared to Ankle Brachial Pulse Index for the diagnosis of PVD in patients with diabetes and is therefore a better screening tool for the diagnosis of PVD in diabetics. With the widespread use of Handheld Doppler, TBI can be used to diagnose PVD earlier & more accurately in patients with diabetes, thereby reducing the lag time between diagnosis & treatment.

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- The Hoorn Study**
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ANNEXURE I

ETHICAL CLEARANCE CERTIFICATE

| | |
|---|---|
|  |  |
| <p>B.L.D.E. UNIVERSITY'S SHRI.B.M.PATIL MEDICAL COLLEGE, BIJAPUR-586 103 INSTITUTIONAL ETHICAL COMMITTEE</p> | |
| <p><i>INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE</i></p> | |
| <p>The Ethical Committee of this college met on <u>22-11-2014</u> at <u>3-30 pm</u> to scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected & revised version synopsis of the Thesis has been accorded Ethical Clearance.</p> | |
| <p>Title "<u>Efficacy of Toe Brachial Index as a Diagnostic modality in Peripheral Vascular Disease in Diabetics Compared to Ankle Brachial Pulse Index</u>"</p> | |
| <p>Name of P.G. student <u>Dr. Ahmed Fazaaz Patel</u> <u>Dept of General Surgery</u></p> | |
| <p>Name of Guide/Co-investigator <u>Dr. Basavaraj Narasimaji Asso. Professor</u> <u>Dept of General Surgery</u></p> | |
| <p><i>for</i>  DR. TEJASWINI VALLABHA CHAIRMAN INSTITUTIONAL ETHICAL COMMITTEE BLDEU'S, SHRI.B.M.PATIL MEDICAL COLLEGE, BIJAPUR.</p> | |
| <p>Following documents were placed before E.C. for Scrutinization</p> <ol style="list-style-type: none">1) Copy of Synopsis/Research project.2) Copy of informed consent form3) Any other relevant documents. | |

ANNEXURE II
INFORMED CONSENT FORM



B.L.D.E UNIVERSITY'S SRI B M PATIL MEDICAL COLLEGE

HOSPITAL VIJAYPUR

DEPARTMENT OF SURGERY

Informed Consent For Participation In Dissertation/Research

I, the undersigned.....s/o.d/o.w/o.....aged.....
Yrs ordinarily resident of do hereby state / declare that Dr.
Ahmed Faraaz Patel of B.L.D.E University's Sri B M Patil Medical College Hospital
has examined me thoroughly on..... at B.L.D.E University's Sri B M
Patil Medical College Hospital and has explained to me in my own language i.e.
..... that I am suffering from Diabetic Disease.

Further, Dr. Ahmed Faraaz Patel has informed me that he is conducting
Dissertation / Research titled : **“To study the Efficacy Of Toe Brachial Index As A
Diagnostic Modality In Peripheral Vascular Disease In Diabetics Compared To
Ankle Brachial Pulse Index”** under the guidance of Dr. Basavaraj Narasanagi,
requesting my participation in the study. Apart from the routine treatment , procedure
of doing Hand Held Doppler Examination, the pre-operative, operative, post operative
& follow-up observations will be utilized for the study as reference data.

Dr. Ahmed Faraaz Patel has also informed that during conduct of this
procedure, mild pain like adverse effects may be encountered. Among the above
complications, most of them are treatable but are not anticipated hence there is chance

of aggravation of my condition and in rare circumstances it may prove fatal in spite of anticipated diagnosis & best treatment made available. Further, Dr. Ahmed Faraaz Patel has informed me that my participation in this study will help in evaluation of results of the study which is useful reference for treatment or cure of the disease in near future, and also I may be benefitted in getting relieved of suffering or cure of the disease I am suffering.

The doctor has also informed me that information given by me, observations made/ photographs/ video graphs taken upon me by the investigator will be kept secret and not accessed by the person other than me or my legal hirer except for academic purposes.

The Dr. did inform me that though my participation is purely voluntary based on information given to me, I can ask any clarification during the course of the treatment / study related to the diagnosis, procedure of treatment, result of treatment or prognosis. At the same time, I have been informed that I can withdraw from my participation in this study at anytime I wanted or the investigator can terminate me from the study at any time but not the required procedure or treatment & follow up unless I request for a discharge.

After understanding the nature of dissertation or research, diagnosis made, mode of treatment I the undersigned Sri/Smt under my full conscious state of mind agree to participate in the said research or dissertation

Signature of Patient

Signature of Doctor

Witness 1

Witness 2

Date:

Place:

ANNEXURE III

SCHEME OF CASE TAKING

- 1) Name : CASE NO :
- 2) Age/sex : IP NO :
- 3) Religion : DOA :
- DOS :
- 4) Occupation : DOD :
- 5) Residence :

6) Chief Complaints :

7) Past History-

8) Treatment history – Any surgery

Systemic illnesses

9) Personal History –

Diet

Appetite

Bowel/Bladder

Sleep

Habits

10) Family History -

11) General Physical Examination -

Built

Nourishment

Pulse rate

Pallor:

| | |
|----------------|------------------|
| Blood pressure | Respiratory rate |
| Temperature | Jaundice |
| Clubbing | Cyanosis |
| Edema | Lymphadenopathy |

12) Examination of Peripheral pulses: RIGHT LEFT

Temporal artery:
 Radial artery:
 Ulnar artery:
 Femoral Artery:
 Popliteal artery:
 Brachial Artery:
 Tibialis Posterior Artery:
 Tibialis Anterior Artery:
 Dorsalis Pedis Artery:
 Great Toe artery

13) Hand held Doppler: RIGHT LEFT

Brachial Artery Pressure (in mm Hg):
 Tibialis Posterior Artery Pressure (in mm Hg):
 Tibialis Anterior Artery Pressure (in mm Hg):
 Dorsalis Pedis Artery Pressure (in mm Hg):
 Great Toe artery Pressure (in mm Hg):

14) ABPI & TBPI: RIGHT LEFT

ABPI
 TBI

15) Colour Doppler Report:

13) Other systemic examination

- Abdominal system
- Respiratory system.
- Cardiovascular system.
- Central nervous system.

14) INVESTIGATIONS UNDERGONE BY PATIENT:

Complete blood count

Urine- sugar, albumin, microscopy

Fasting blood sugar

Post Prandial blood sugar

HbA_{1C}

Blood urea

Serum creatinine

15) FINAL DIAGNOSIS

ANNEXURE VI - MASTER CHART

| Sl no. | Name | Age | Sex | IP No. | Diagnosis | FBS (mg/dl) | PPBS (mg/dl) | Diabetes(New/Old) | HbA1c | B Urea (mg/dl) | S Creatinine (mg/dl) | ABPI | TBI | Colour Doppler | Procedure | Outcome |
|--------|-----------------------|-----|-----|------------|-------------------------|-------------|--------------|-------------------|-------|----------------|----------------------|------|------|----------------|-----------------------|----------------------------------|
| 1 | Bhimraya Vittal | 60 | M | 2014/23408 | Ulcer over foot | 180 | 248 | New | 9.9 | 46 | 1.3 | 1.2 | 0.6 | PVD Present | Below knee amputation | wound healed |
| 2 | Iranna Balvantappa | 50 | M | 2014/23460 | fissure in ano | 160 | 200 | New | 7.6 | 44 | 1.1 | 1.3 | 0.62 | PVD Present | conservative | recovered |
| 3 | Ramesh Honnutgi | 35 | M | 2014/25886 | Ulcer over foot | 194 | 230 | New | 8.6 | 35 | 1.2 | 1.2 | 0.58 | PVD Present | Below knee amputation | wound healed |
| 4 | Veeresh Huggi | 54 | M | 2014/29378 | acute appendicitis | 148 | 180 | Old | 7.2 | 45 | 1 | 1.2 | 0.64 | PVD Present | Appendicectomy | wound healed |
| 5 | Subhashchandra | 59 | M | 2104/29751 | Inguinal Hernia | 140 | 190 | New | 7.4 | 32 | 1.3 | 1.2 | 0.68 | PVD Present | Mesh Hernioplasty | wound healed |
| 6 | Mahadev Ramchandra | 65 | M | 2014/30132 | Ulcer over foot | 240 | 290 | Old | 9.4 | 40 | 1.4 | 1.2 | 0.56 | PVD Present | Below knee amputation | wound healed |
| 7 | Suresh Hiremath | 45 | M | 2014/30332 | Gastritis | 150 | 200 | New | 8 | 38 | 1.2 | 1.3 | 0.64 | PVD Present | conservative | recovered |
| 8 | Vishwanath Biradar | 31 | M | 2014/31523 | fissure in ano | 140 | 190 | New | 8.2 | 30 | 0.9 | 1.2 | 0.7 | PVD Present | conservative | recovered |
| 9 | Anand Bhimrao | 48 | M | 2014/31739 | Cellulitis of left leg | 240 | 300 | Old | 9.3 | 28 | 1.3 | 0.9 | 0.6 | PVD Present | Below knee amputation | wound healed |
| 10 | Sadiq Malesab | 62 | M | 2014/31784 | Gastritis | 138 | 190 | New | 6.6 | 40 | 1.1 | 1.3 | 0.64 | PVD Present | conservative | recovered |
| 11 | Chikkaya Yallappa | 58 | M | 2014/31829 | Right Varicocoele | 120 | 180 | Old | 7.1 | 37 | 1.2 | 1.3 | 0.66 | PVD Present | Herniotomy | wound healed |
| 12 | Saddam Hussain | 48 | M | 2014/31890 | Ulcer over foot | 228 | 310 | New | 8.8 | 32 | 1.4 | 1.3 | 0.62 | PVD Present | Below knee amputation | wound healed |
| 13 | Shivamma Adagi | 54 | F | 2014/32103 | Ulcer over foot | 264 | 298 | New | 9 | 28 | 0.9 | 1.4 | 0.58 | PVD Present | Below knee amputation | wound healed |
| 14 | Adivappa Malagi | 64 | M | 2014/32334 | Cellulitis of right leg | 324 | 401 | New | 8.5 | 36 | 0.8 | 1.4 | 0.6 | PVD Present | Below knee amputation | wound healed |
| 15 | Madivalappa Gouda | 58 | M | 2014/32345 | Hemorrhoids | 146 | 194 | Old | 7.2 | 42 | 1 | 1.3 | 0.66 | PVD Present | conservative | recovered |
| 16 | Anand Adagal | 62 | M | 2014/32446 | Foot Abscess | 350 | 400 | New | 10.4 | 44 | 1.2 | 0.9 | 0.56 | PVD Present | Below knee amputation | revision amputation - Above knee |
| 17 | Basamma Aihole | 44 | F | 2014/32478 | Ulcer over foot | 286 | 340 | New | 9 | 37 | 1.4 | 1.2 | 0.58 | PVD Present | Below knee amputation | wound healed |
| 18 | Mallikarjun Hanchinal | 38 | M | 2014/32675 | Fistula In Ano | 194 | 260 | New | 9.4 | 28 | 0.9 | 1.4 | 0.68 | PVD Present | Fistulectomy | recovered |
| 19 | Allasab Bandiwal | 72 | M | 2014/33475 | Ulcer over foot | 258 | 320 | Old | 10.2 | 30 | 0.8 | 1.2 | 0.6 | PVD Present | Below knee amputation | wound healed |
| 20 | Prakash Devendrappa | 46 | M | 2015/116 | Pain in right leg | 384 | 463 | Old | 8.1 | 34 | 0.9 | 1.3 | 0.62 | PVD Present | conservative | recovered |
| 21 | Manjunath Balsaheb | 52 | M | 2015/386 | Pain in left leg | 282 | 340 | New | 9 | 42 | 1 | 1 | 0.58 | PVD Present | Below knee amputation | wound healed |
| 22 | Gouramma Satish | 62 | F | 2015/1054 | Right leg Cellulitis | 274 | 386 | New | 7.9 | 44 | 1 | 1.2 | 0.64 | PVD Present | conservative | recovered |
| 23 | Hanumanthappa Gouda | 38 | M | 2015/1456 | Healing ulcer over foot | 198 | 268 | Old | 7.1 | 30 | 1.1 | 1.2 | 0.68 | PVD Present | conservative | recovered |
| 24 | Amina Jagirdar | 45 | F | 2015/1674 | Road traffic accident | 194 | 205 | New | 7.5 | 46 | 1.4 | 1.2 | 0.64 | PVD Present | conservative | recovered |
| 25 | Ammanna Jadhav | 44 | M | 2015/1872 | Ulcer over foot | 208 | 280 | New | 9.8 | 28 | 1.3 | 0.8 | 0.56 | PVD Present | Below knee amputation | revision amputation - Above knee |
| 26 | Sameena akhtar | 57 | F | 2015/3046 | Gastritis | 132 | 240 | New | 6.4 | 32 | 1.1 | 1.2 | 0.7 | PVD Present | conservative | recovered |

| | | | | | | | | | | | | | | | | |
|----|--------------------------|----|---|------------|-------------------------|-----|-----|-----|------|----|-----|-----|------|-------------|-----------------------|----------------------------------|
| 27 | Gangamma Bagewadi | 75 | F | 2015/3585 | Ulcer over foot | 162 | 252 | Old | 9.1 | 38 | 1.2 | 1.2 | 0.7 | PVD Present | Below knee amputation | wound healed |
| 28 | Ishwar Gawali | 24 | M | 2015/6023 | Pain in B/L Feet | 280 | 360 | Old | 10.6 | 40 | 1.1 | 1.1 | 0.56 | PVD Present | Below knee amputation | revision amputation - Above knee |
| 29 | Mahadev Ganamote | 65 | M | 2015/6649 | Ulcer over foot | 300 | 390 | New | 9.8 | 36 | 1.4 | 1.4 | 0.6 | PVD Present | Below knee amputation | wound healed |
| 30 | Sidlingappagouda Biradar | 48 | M | 2015/8524 | acute appendicitis | 144 | 256 | Old | 9 | 32 | 1.2 | 1.5 | 0.66 | PVD Present | Appendicectomy | wound healed |
| 31 | Malappa Hagari | 60 | M | 2015/9147 | Ulcer over foot | 280 | 368 | New | 9.6 | 34 | 1.3 | 1.4 | 0.7 | PVD Present | Below knee amputation | wound healed |
| 32 | Basavaraj Talwar | 45 | M | 2015/9981 | Left Hydrocoele | 152 | 270 | New | 9.2 | 36 | 1 | 1.1 | 0.68 | PVD Present | Jaboulay's Procedure | wound healed |
| 33 | Harish Joshi | 30 | M | 2015/11030 | Ulcer over foot | 198 | 310 | New | 8.4 | 38 | 1.2 | 1.2 | 0.7 | PVD Present | Below knee amputation | wound healed |
| 34 | Devibai Chavan | 50 | F | 2015/12503 | Left Leg Cellulitis | 320 | 400 | New | 8.6 | 40 | 1.4 | 1.4 | 0.64 | PVD Present | conservative | recovered |
| 35 | Sahebgouda Kolli | 70 | M | 2015/14644 | Ulcer over foot | 286 | 368 | Old | 10.2 | 38 | 1.2 | 1.1 | 0.6 | PVD Present | Below knee amputation | wound healed |
| 36 | Neelkantrao Deshmukh | 65 | M | 2015/17933 | Road traffic accident | 168 | 250 | New | 9.1 | 32 | 1.3 | 1.4 | 0.7 | PVD Present | conservative | recovered |
| 37 | Gurappa Madar | 36 | M | 2015/20430 | acute appendicitis | 204 | 270 | New | 10 | 38 | 0.9 | 0.9 | 0.68 | PVD Present | Appendicectomy | wound healed |
| 38 | Kushi Gujari | 56 | F | 2015/20533 | Ulcer over foot | 328 | 390 | New | 9.6 | 36 | 1.5 | 1.2 | 0.66 | PVD Present | Below knee amputation | wound healed |
| 39 | Shivamma Kapse | 68 | F | 2015/20625 | Healing ulcer over foot | 220 | 310 | Old | 9.9 | 30 | 1.4 | 1.1 | 0.68 | PVD Present | conservative | wound healed |
| 40 | Basappa Talwar | 50 | M | 2015/20677 | Left Inguinal Hernia | 138 | 240 | New | 8.6 | 36 | 1 | 1.2 | 0.7 | PVD Present | Mesh Hernioplasty | wound healed |
| 41 | Tarabai Rathod | 65 | F | 2015/21265 | fissure in ano | 140 | 210 | Old | 8 | 28 | 1.2 | 1.4 | 0.64 | PVD Present | conservative | wound healed |
| 42 | Nagappa Hunshyal | 50 | M | 2015/21935 | Gastritis | 138 | 225 | New | 8.1 | 24 | 1.1 | 1 | 0.7 | PVD Present | conservative | wound healed |
| 43 | Kasturi Nanadi | 40 | F | 2015/22050 | Hemorrhoids | 148 | 230 | Old | 7.6 | 32 | 1.4 | 1.1 | 0.64 | PVD Present | conservative | wound healed |
| 44 | Mahadev Chandrashekhar | 65 | M | 2015/22574 | Ulcer over foot | 268 | 330 | Old | 9.4 | 34 | 1 | 0.9 | 0.6 | PVD Present | Below knee amputation | wound healed |
| 45 | Balappa Madar | 60 | M | 2015/23130 | Ulcer over foot | 240 | 300 | New | 10 | 30 | 0.9 | 1.3 | 0.68 | PVD Present | Below knee amputation | wound healed |
| 46 | Mohammed Punekar | 75 | M | 2015/28690 | Ulcer over foot | 320 | 389 | N | 8.8 | 46 | 1.6 | 1.2 | 0.62 | PVD Present | Below knee amputation | revision amputation - Above knee |
| 47 | Pavan Hosamani | 57 | M | 2015/29437 | Left Foot Abscess | 200 | 310 | N | 9.6 | 40 | 1.4 | 1 | 0.56 | PVD Present | Below knee amputation | wound healed |
| 48 | Nagaraj Santappa | 50 | M | 2015/21935 | Pain in right leg | 278 | 320 | N | 9 | 38 | 1.5 | 1.4 | 0.5 | PVD Present | Below knee amputation | revision amputation - Above knee |
| 49 | Kasappa Shival | 52 | M | 2015/22050 | Right Hydrocoele | 186 | 240 | N | 7.4 | 32 | 1.1 | 1.2 | 0.66 | PVD Present | Jaboulay's Procedure | wound healed |
| 50 | Pandit Myageri | 55 | M | 2015/22574 | Ulcer over foot | 350 | 460 | O | 10.8 | 46 | 1.4 | 0.9 | 0.5 | PVD Present | Below knee amputation | revision amputation - Above knee |
| 51 | Gurappa Nimbargi | 63 | M | 2015/23130 | Cellulitis of right leg | 412 | 490 | N | 11 | 48 | 1.6 | 1.2 | 0.64 | PVD Present | conservative | recovered |
| 52 | Sidamma sindhe | 58 | F | 2015/28690 | Fibroadenoma breast | 280 | 340 | N | 10.4 | 40 | 1.3 | 1.1 | 0.7 | PVD Present | Excision of mass | recovered |
| 53 | Mahantayya Hiremath | 45 | M | 2015/29437 | Abscess in Left foot | 300 | 368 | O | 9.9 | 36 | 1.6 | 1.2 | 0.6 | PVD Present | Below knee amputation | wound healed |
| 54 | Chanappa Bekanal | 55 | M | 2015/29451 | UTI | 264 | 320 | N | 8.4 | 32 | 1.5 | 1.1 | 0.58 | PVD Present | conservative | recovered |
| 55 | Bindiya Chavan | 50 | F | 2015/31513 | Cellulitis right leg | 260 | 368 | N | 9.2 | 36 | 1.4 | 1.2 | 0.66 | PVD Present | conservative | recovered |
| 56 | Amarinder Singh | 34 | M | 2015/31797 | Road traffic accident | 200 | 320 | N | 11 | 44 | 1.6 | 1.4 | 0.64 | PVD Present | conservative | recovered |
| 57 | Sharanappa Madar | 42 | M | 2015/35732 | B/L leg pain | 244 | 328 | N | 10.8 | 40 | 1.5 | 1.3 | 0.54 | PVD Present | Below knee amputation | revision amputation - Above knee |
| 58 | Yamanappa Kadabagavi | 65 | M | 2015/36207 | Cellulitis right leg | 340 | 410 | N | 9.8 | 38 | 1.3 | 1.1 | 0.6 | PVD Present | conservative | recovered |

| | | | | | | | | | | | | | | | | |
|----|-----------------------|----|---|------------|-------------------------|-----|-----|-----|------|----|------|-----|------|-------------|-----------------------|----------------------------------|
| 59 | Chandawwa Loni | 65 | F | 2015/36318 | Hemorrhoids | 264 | 330 | N | 8.8 | 36 | 1.2 | 1.2 | 0.68 | PVD Present | hemorrhoidectomy | recovered |
| 60 | Bhimanna Karjagi | 34 | M | 2015/36423 | Ulcer over foot | 346 | 400 | O | 9.2 | 44 | 1.6 | 1.3 | 0.54 | PVD Present | Below knee amputation | wound healed |
| 61 | Gangabai Patil | 60 | F | 2015/36578 | fissure in ano | 188 | 220 | O | 8.1 | 36 | 1.3 | 1.3 | 0.64 | PVD Present | conservative | recovered |
| 62 | Bheemangouda Biradar | 70 | M | 2015/37101 | Inguinal Hernia | 220 | 300 | N | 8 | 32 | 1.4 | 1.1 | 0.7 | PVD Present | Mesh Hernioplasty | recovered |
| 63 | Jumanna Chalawadi | 60 | M | 2015/37289 | Abscess in right foot | 340 | 440 | N | 10.4 | 40 | 1.6 | 1.4 | 0.56 | PVD Present | Below knee amputation | wound healed |
| 64 | Shailaja Bentoor | 46 | F | 2015/37590 | Lipoma Over the back | 286 | 350 | N | 9.1 | 38 | 1.4 | 1 | 0.64 | PVD Present | lipoma excision | recovered |
| 65 | Dharappa Parshe | 32 | M | 2015/38259 | fissure in ano | 184 | 240 | O | 8.1 | 30 | 0.9 | 1.2 | 0.7 | PVD Present | conservative | recovered |
| 66 | Sidappa Bajantri | 70 | M | 2015/38298 | Cellulitis right leg | 300 | 386 | N | 11 | 42 | 1.6 | 1.4 | 0.58 | PVD Present | conservative | recovered |
| 67 | Huvanna Balagnur | 65 | M | 2015/38314 | Upper GI Bleeding | 280 | 356 | N | 9.4 | 44 | 1.6 | 1.2 | 0.68 | PVD Present | conservative | recovered |
| 68 | Sahebgouda Bantanur | 60 | M | 2015/38327 | Ulcer over foot | 258 | 339 | N | 10.4 | 40 | 1.4 | 1.3 | 0.54 | PVD Present | Below knee amputation | wound healed |
| 69 | Kashibai Hiremath | 65 | F | 2015/38331 | Road traffic accident | 220 | 310 | N | 9.6 | 36 | 1.1 | 1.1 | 0.66 | PVD Present | conservative | recovered |
| 70 | Rukmini Subbanappagol | 60 | F | 2015/38338 | Cellulitis of left leg | 340 | 400 | N | 11 | 46 | 1.46 | 1.6 | 0.56 | PVD Present | Below knee amputation | wound healed |
| 71 | Satawva Kotyal | 55 | F | 2015/38369 | Ulcer over foot | 225 | 350 | N | 8.6 | 38 | 1.32 | 1.3 | 0.64 | PVD Present | Below knee amputation | wound healed |
| 72 | Sarojini Reddy | 44 | F | 2015/38370 | Gastroenteritis | 190 | 258 | N | 8.4 | 29 | 1.2 | 1.1 | 0.62 | PVD Present | conservative | recovered |
| 73 | Veeresh Havaladar | 46 | M | 2015/38413 | Ulcer over foot | 368 | 432 | O | 9.8 | 44 | 1.4 | 0.9 | 0.64 | PVD Present | Below knee amputation | revision amputation - Above knee |
| 74 | Rajesh Salunkhe | 45 | M | 2015/38429 | Ulcer over foot | 380 | 440 | N | 10.9 | 46 | 1.6 | 1.4 | 0.52 | PVD Present | Below knee amputation | revision amputation - Above knee |
| 75 | Sidappa Kerur | 66 | M | 2015/38431 | abscess over right foot | 348 | 428 | N | 9.8 | 40 | 1.4 | 1.3 | 0.56 | PVD Present | Below knee amputation | wound healed |
| 76 | Tavaru Rathod | 48 | M | 2015/41267 | Gastritis | 194 | 260 | N | 8.4 | 36 | 1.2 | 0.9 | 0.66 | PVD Present | conservative | recovered |
| 77 | Jagadev Talawar | 40 | M | 2015/41324 | fissure in ano | 175 | 224 | N | 8.1 | 32 | 0.9 | 1.2 | 0.7 | PVD Present | conservative | recovered |
| 78 | Hanumanthraya Biradar | 36 | M | 2015/41331 | Hemorrhoids | 158 | 240 | New | 8 | 34 | 1 | 1.1 | 0.62 | PVD Present | conservative | recovered |
| 79 | Abukalam Risaldar | 56 | M | 2015/41347 | Ulcer over foot | 288 | 350 | Old | 10.4 | 36 | 1.4 | 1.4 | 0.56 | PVD Present | Below knee amputation | revision amputation - Above knee |
| 80 | Abdulrehman Bannatti | 44 | M | 2015/41369 | Ulcer over foot | 340 | 410 | Old | 9.8 | 38 | 1.6 | 1.3 | 0.58 | PVD Present | Below knee amputation | wound healed |