COMPARISION OF COLOUR DUPLEX ULTRASOUND, ANKLE BRACHIAL PRESSURE MEASUREMENT IN PERIPHERAL VASCULAR DISEASE IN TYPE 2 DIABETES PATIENTS WITH FOOT INFECTIONS

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CERTIFICATE

This is to certify that the dissertation titled **"COMPARISION OF COLOUR DUPLEX ULTRASOUND, ANKLE BRACHIAL PRESSURE MEASUREMENT IN PERIPHERAL VASCULAR DISEASE IN TYPE 2 DIABETES PATIENTS WITH FOOT INFECTIONS"** of **Dr.SHIVANSHU MISRA** in partial fulfillment of the requirements for **M.S. Branch – I (General Surgery)** Examination of the Tamilnadu Dr. M.G.R. Medical University to beheld in APRIL 2014. The period of study was from January 2013 to December 2013.

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DECLARATION

I, **Dr.SHIVANSHU MISRA** solemnly declare that dissertation titled, "**COMPARISION OF COLOUR DUPLEX ULTRASOUND, ANKLE BRACHIAL PRESSURE MEASUREMENT IN PERIPHERAL VASCULAR DISEASE IN TYPE 2 DIABETES PATIENTS WITH FOOT INFECTIONS"** is a bonafide work done by me at Govt. Stanley Medical College & Hospital during January 2013 - December 2013 under the guidance and supervision of my Unit Chief

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Place : Chennai.

Date :

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It is my proud privilege to express, my sincere thanks to **Prof. Dr.GEETHA LAKSHMI M.D., P.hd.,** Dean, Stanley Medical College, Chennai 1, for permitting me to conduct this study.

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Last, but not the least ,my heart goes to all the patients for their utmost co-operation, during whole of my study, which has made me come up to this stage of my work.

CONTENTS

ABSTRACT

This is the study done in our Hospital Government Stanley Hospital, Department of General Surgery. The following study is a prospective study, for which ethical clearance was obtained. No. of Patients studied were 50, and consent was taken from all the patients. The Patients studied were diabetic, which included all types of Type II DM patients on treatment and with foot infections. No individuals with rest pain, or signs suggestive of lower limb critical ischaemia and other causes of peripheral neuropathy or history of reconstructive vascular surgery were taken into consideration. The study period was from January 2013 to December 2013.

After doing thorough history taking and clinical examination, including proprio reception, capillary blood glucose, arterial colour duplex imaging (CDU) and ankle brachial pressure index (ABPI) were done in the all the patients.

The sensitivity and specificity of ABPI was compare with CDU. We concluded that ABPI has high specificity (85.71%) and Low sensitivity (72.72%) has compare to CDU. The overall agreement of ABPI with CDU was poor.

KEY WORDS

DM	-	Diabetes Mellitus
ABPI	-	Ankle Brachial Pressure Index
CDU	-	Colour Duplex Ultrasound

INTRODUCTION

The term diabetes is the short name for diabetes mellitus. Diabetes mellitus arise from "**diabainein**", that means siphon and the Latin word "**mellitus"** that means sugary. This name was given to this disease because in excess sugar is found in blood and urine of the patient is the classical finding of this disease. In earlier centaury, it was known as the **"pissing evil**".

In 1675, **Thomas Willis** added the word "'**mellitus**'" to the word diabetes. This was because of the sweet taste of the urine.

The term "**diabetes**" was designated by **Apollonius** of Memphis by around 250 BC.

History of the treatment of diabetes

Sushruta, Arataeus, and Thomas Willis were the, pioneers of the diabetes treatment. Therapy that applied in diabetes included wine, overfeeding to compensate for loss of weight, starvation, fluid, diet, etc.

Matthew Dobson(1776) confirmed that the sweet taste of urine of diabetics was more due to a kind of sugar in the urine and blood of people with diabetes.

In earlier times, diabetes,personified,sentence of death. Sushruta (6th century BC) coined the term,“**Madhumeha**”. By looking ants attracted to urine,ancient Indians,detected diabetes.

Avicenna (980–1037), in Persia, described, DM in “"**The Canon of Medicine”**. They observed, abnormal increased appetite and the decrease of sex desire or associated ejaculatory dysfuction with sugery urine. Diabetic gangrene was described by them only. Sir Avicenna also described diabetes insipidus very precisely. It was later on, that **Sir Johann Peter Frank** in the 19th century differentiated diabetes mellitus and diabetes insipidus.

Role of pancreas in diabetes was founded by **Sir Joseph Mering** and **Oskar Minkowski** (1889).

Banting, Best, and Collip (1921), purified the insulin hormone from the pancreas and got Noble prize for their work in physiology subsequently.

Amputations surgical principals was given by **Sir Ambrose Pare.**

AIMS AND OBJECTIVES

The purpose of this study is

To compare the sensitivity and specificity of Ankle Brachial Pressure index calculated by peripheral hand held Doppler with colour duplex ultrasound for the diagnosis of admitted patients in our hospital with Peripheral Arterial Disease with Type 2 Diabetes mellitus patients with foot infections on treatment.

This study is also being done to assess, whether ABPI, can be used as a screening test for the patients of diabetes mellitus with foot infections.

REVIEW OF LITERATURE

1-Premalatha G et al (2002) studied 100 cases of type 2 DM with lower limb infections underwent both colour doppler ultrasound and ankle-brachial pressure index measurements and they concluded ABPI is a good screening test but some patients with marked stenosis of vessel in limb could be missed, if alone ABPI measurement is utilized for the diagnosis of Periferal vascular disease. (J Assoc Physicians India 2002).

2- Sharmistha Dey et al (study from July 2008 to May 2009) studied 88 patients of type 2 Diabetes with foot infection with and without neuropathy, both ABPI and PI (by CDU) calculated and they concluded Pulsatility Index (PI) decreased and Ankle Brachial Index (ABI) increased in diabetic neuropathic group. There was significant difference of Pulsatility Index (PI) and Ankle Brachial Index (ABPI) found between diabetic patients with and without neuropathy.

3- Dachun Xu et al (Oct 2010) comprises 8 studies including 2043 cases concluded high specificity (85-99.2%) and accuracy (72.1-90%) was calculated for an ABI $\leq$ 0.90 in detecting $\geq$ 50% obstruction, but there were different sensitivity (15-80%). Sensitivity was less. The test of ABI $\leq$ 0.90 can be used for diagnosing PAD with

serious obstruction, and it may be a replacement for all other non-invasive tests in practice.

4- Williams DT et al (sep 2005) studied 130 limbs in 68 patients with no severe obstruction, duration of study 9 months. ABPI calculated and CDU waveform analysed. They concluded that Screening tools like ABPI and CDU that are effective in early diagnosis of lower-limb PAD in the nondiabetic patients are less efficacious in diabetic patients, specially with PN. waveform analysis appear to be much better screening methods than the ABPI and foot pulses specially in high-risk limbs with PN.

5- Williams, et al from *Wound Healing Research Unit, Surgery Deparment, University of Wales College of Medicine, studied* **Capacity of screening Methods Used for Lower-Limb Arterial Disease . They found out methods for detecting patients with arterial disease in DM .**

6-Allen J ,Hederson, C Oates (March 1996) studied 200 cases concluded ABI is good for detecting severe disease and is more correspond with CDU when the severely diseased limbs are compared. Agreement found to be poor (68%, Kappa 0.37)in mild diseased limb.

Compared with symptoms after trademill test, agreements with duplex and ankle brachial index were both 67% (Kappa 0.27). Better agreement with severely diseased (90%) .

7 - Mohan, Ravikumar R et al (2000) studied Vessel wall thickness of carotid in south Indian people. In study of population of chennai.

8 - Sastry NG, Shanthirani et al (1995) studied peripferal vascular disease in south Indian non insulin dependent diabetics patients.

9- Diabetic Foot Disorders:

CLINICAL PRACTICE GUIDELINE(2006 revised)

Robert Frykberg , DPM, MPH ,1 Thomas Zgonis, DPM,

David G.A Armstrong, DPM, PhD, 3Vickie Driver, DPM, MS4

John M. Giurini, DPM,Steven R. Kravitz, DPM, S.Adam Landsman, DPM, PhD, Lawrence, Lavery, DPM, MPH,J. Christopher Moorey, DPM, John M. Schuberthy, DPM, Dane K. Wukich, MD,11 Anderson, MD,12 and John V. Vanoore, D P M

S–2 JOURNAL OF FOOT & ANKLE SURGERY

10 - Diagnosis and Treatment of Diabetic Foot Infections

Benjamin A . Lipsky, Anthony . Berendt, H. Gunner Deery , John M A. Embil, Warren S. Joseph, Adolf . Karchmer, Jack S. Le Frock, Daniel P. Lew,

Jon T. Mader, Carl R. Norden, and James S. Tan.

DIABETES MELLITUS

Diabetes mellitus, is an array of metabolic diseases which may be due to , either when the pancreas , which does not produce enough insulin or it may also be due to the resistence of the organs from insulin, which in both cases, produces high blood sugar in a person . Symptoms produced by high blood sugar include the following : polydipsia (increase in thirst), polyuria (increased frequency of urination) and excessive eating day and night.

CLASSIFICATIONS

- **Type 1** : Here, failure of body's insulin production, and there is requirement by the person to inject insulin or have an insulin pump. This form was initially referred as "insulin dependent diabetes mellitus" or "juvenile diabetes".

- **Type 2** : due to, insulin resistance, in which cells have an improper usage of insulin , sometimes insulin completely absent . In the past it is called as "adult onset diabetes".

- The last type, **gestational diabetes**, diabetes of pregnant ladies who have high glucose level. 50% of them develop type 2 DM in future.

Other types of DM are congenital, due to **genetic** defects, **cystic fibrosis**, steroid induced due to high doses , and many other types of **monogenic diabetes.**

If diabetes is left untreated, it may leads to many complications. Acute complications are:

diabetic ketoacidosis (DKA) and

nonketotic hyperosmolar coma.

Long-term complications include:diabetic retinopathy , CVD , and chronic kidney failure.thats why proper timed diagnosis and proper treatment plus complication regular screening is must.

Since 1921, all types of diabetes have been treatable since insulin came into existence and type 2 diabetes can be curtailed by

various sort of ways. Severe hypoglycemia, may be caused by insulin and few oral medications. It may be fatal at times. Type1 and type 2, DM are, both, chronic conditions, in which there is no cure. Little success has been got with Pancreatic transplants, in type 1 diabetes mellitus patients. In patients with, morbid obesity, bypass gastric surgery has been tried with variable success. GDM mostly get cured after delivery.

Classification

Difference between type 1 and 2 diabetes mellitus

DM Type 1	**DM Type 2**
Sudden start	Gradual start
Seen in youngs	Seen in elder
Thin	Fatty
Common	Less common
Present	Absent
Low / absent	Normal/decreased /increased
60% seen in MZ twins	90% seen in MZ twins
~10% prevelant	~85% prevalent

Type 1 diabetes mellitus

Type 1 diabetes is characterized by loss of beta cells(which produce insulin) of islets of Langerhans in the pancreas, causing deficiency of insulin. This type can be further categorized into immune mediated or idiopathic. Majority of type 1 DM is mediated by immunity, in which there is loss of beta cells which is a T-cell mediated autoimmune reaction . No preventive measure against type 1 DM, are known, which causes approximately 10% of diabetes mellitus cases in different parts of the world. Most of the affected people are otherwise healthy when onset occurs. Responsiveness and senstivity to insulin are usually normal, in the initial stages. Type 1 DM, can affect both children and adults, but was termed "juvenile diabetes" as a majority of these diabetes cases were in seen in children.

"Brittle" diabetes, has fluctuations on and off swings in levels of glucose of blood , and it is insulin dependent. This term, however, should not be used,as it has no biological basis. There are innumerable causes for DM type 1, oftenly associated with fatal with painstaiking complication, probably due to, altered counterregulatory hypoglycaemic response, altered response to hidden infection, gastroparesis (leading to un precedented absorption of dietary carbohydrates), as well as

endocrinopathies (like Addison's disease). These phenomena occur in no more frequently than in 1% to 2% of individuals with type 1 diabetes.

Type 2 diabetes mellitus

Diabetes mellitus type 2 is the most common type.

Characteristic of Type 2 diabetes mellitus –

A-insulin resistant

B- sometimes addition with low insulin secretion

C- Due to receptor defect (unknown defects)

Diabetes mellitus of pregnancy

Gestational diabetes mellitus (GDM)

1- Is like type 2 diabetes
2- Incidence-3 to 8 percent of pregnant ladies.
3- Mostly become alright after child birth.
4- Remedy –approx 100 percent.
5- Needs strict surveillance all throughout pregnancy.
6- 50 percent develop type 2 DM in old age.

7- Mainly risky for foetus.

8- Adverse effects to foetus- increase in size of baby leads to difficult delivery, can cause various injury to mother and foetus.

9- Birth defects in foetus-CVS, CNS, Musculoskeletal system.

10- Difficulty in resuscitation, increase in billirubin .

11- May leads to SIDS and early neonatal death.

Various study show that chances of development of type 2 DM in future is high in babies born to GDM patients.

Other types

Prediabetes – condition where a patient glucose is high but it is less than to diagnose type 2 DM.

Many drugs inhibit insulin secretion and some toxins damage beta cells.

Signs and symptoms

Are following-

1- weight loss

2- polyuria,

3- polydipsia

4- polyphagia.

5- Eye changes-lens shape, vision changes, development of cataract, Blurred vision

6- Skin rashes

Diabetic emergencies

People (usually with type 1 diabetes) may present with **diabetic ketoacidosis**, a state of metabolic dysregulation characterized by the smell of **acetones**, a rapid, deep breathing known as **Kussmaul breathing**, nausea, vomiting and abdominal pain, and altered consciousness.

A rare but equally severe possibility of **hyperosmolar nonketotic state**, which is more common in type 2 diabetes and is mainly the result of dehydrated state.

Complications

All forms of diabetes basically increase the risk of long-term complications. These typically develop after many years (10–20yrs), but may be the first symptom specially in those who have not received a diagnosis before that time. The major long-term complications specially

related to damage to blood vessels. It doubles the risk of cardiovascular disease. The main **"macrovascular" diseases** are-

1- Diseases due to blood supply to the heart muscles (angina and Heart attack),
2- CVA and
3- Peripheral vascular disease.

Types of microvascular diseases-(due to capillary endothelial damage)

Diabetic retinopathy - affects neovascularisation, micro aneurysm formation which ultimately leads to decreased vision and complete blindness.

Diabetic nephropathy - associated with

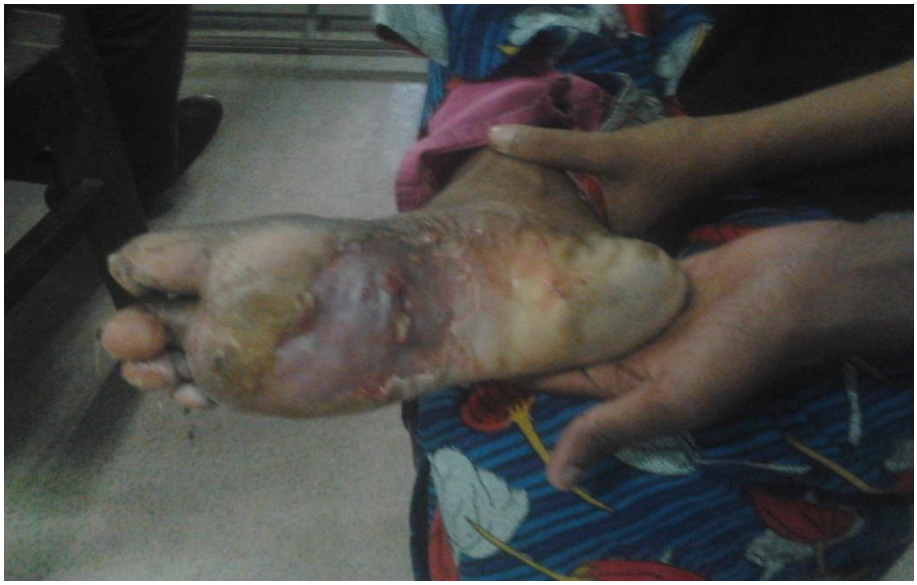
- micro albuminuria,
- glycosuria,
- basically associated with renal cortical damage
- ultimately leading to small scarred kidney
- finally landed up into chronic renal failure requiring dialysis life long.

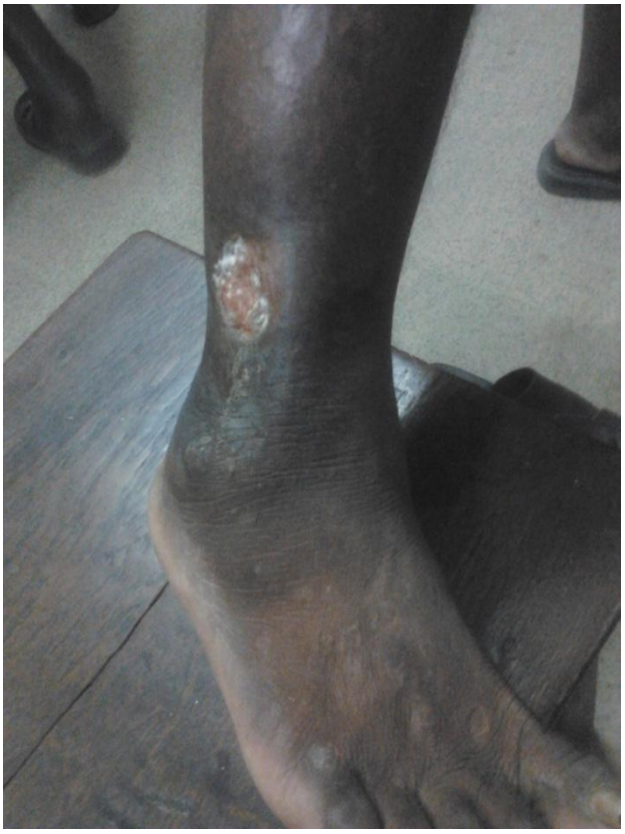
CNS and PNS symptoms

Diabetic neuropathy, causes impact on the peripheral nervous system causing –

- numbness,
- tingling,

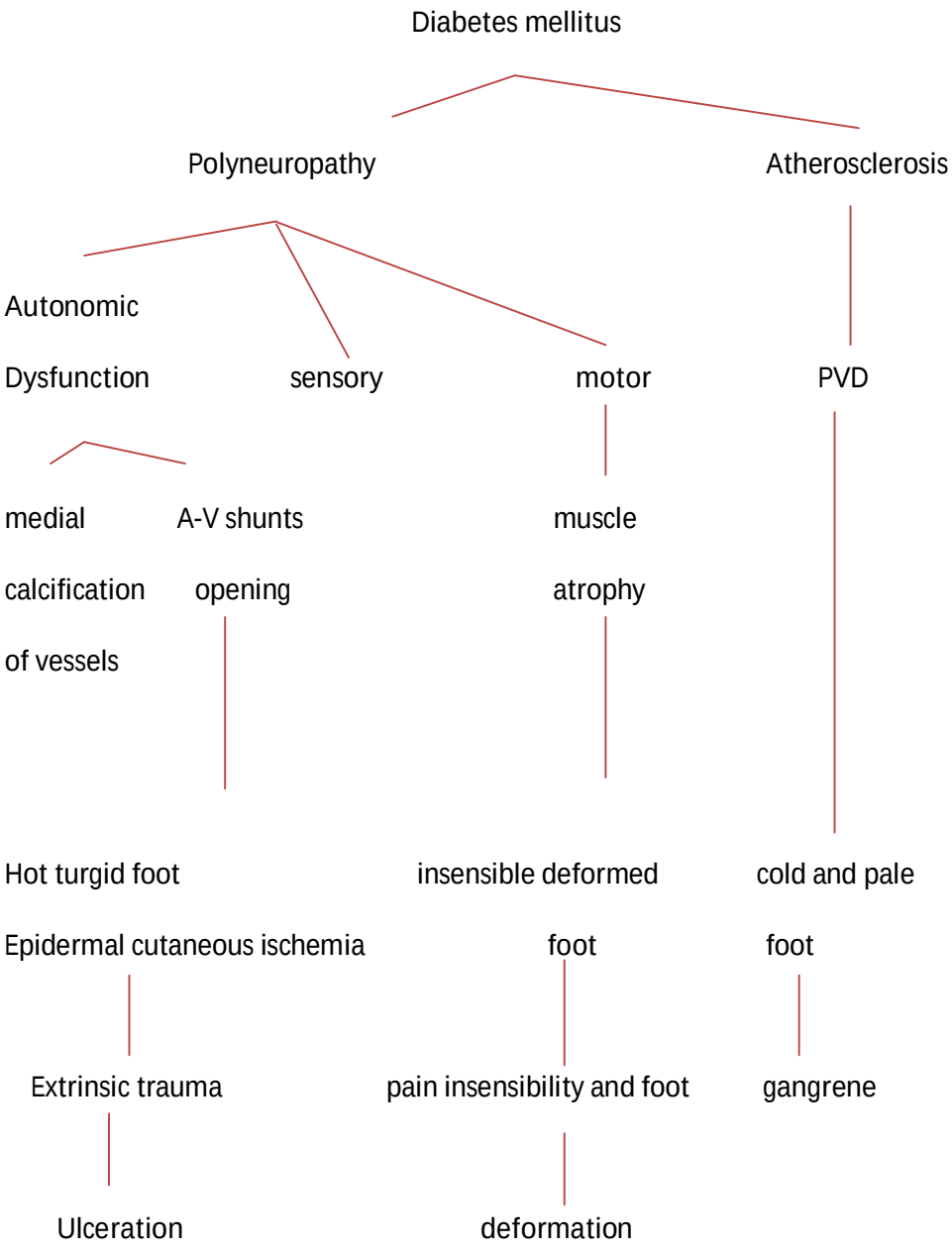
PHOTOGRAPHS SHOWING DIABETIC PATIENTS WITH FOOT INFECTIONS, TAKEN FOR OUR STUDY ADMITTED IN OUR WARD





- pain in the feet and
- proximal neuropathy causes weakness and painful muscle wasting.

Many studies have shown and suggested direct proportional relationship between diabetes and loss of cognitive functions.



Causes

The cause of diabetes depends on the type.

The following are the causes of diabetes:

- Genetic disorders of β-cell dysfunctions
  - MODY
  - Mitochondrial mutations
- Genetic defects in insulin production or insulin action
  - Defects in conversion
  - Mutations in gene producing insulin per-se.
  - Mutations in Insulin receptor
- Exocrine pancreatic defect

  1-Chronic pancreatitis

  2-Pancreatectomy
- Endocrinopathies
  - Growth hormone excess (acromegaly)
  - Cushing syndrome
  - Hyperthyroidism
  - Pheochromocytoma
  - Glucagonoma
- Infections
  - Cytomegalovirus infection
  - Coxsackievirus B
- Drugs
  - Glucocorticoids
  - Thyroid hormone
  - β-adrenergic agonists

3-Pancreatic neoplasia

- Statins

4-Cystic fibrosis

5-Hemochromatosis

6-Fibrocalculous pancreatopathy

Pathophysiology

The alteration(red) of blood sugar and the sugar decreasing hormone (blue)insulin in humans beings during the course of a day of 3 meals - one of the effects of a diet rich in sugar vs a diet rich instarch is emphesized.

Mechanism of release of insulin in normal pancreatic beta cells – production of insulin ,is more or less same, within the beta cells. Its release is started by food, mainly, diet containing ,absorbable glucose.

Insulin is the main hormone ,that controls uptake of glucose from the blood into most cells (mainly, muscle and adipose cells, but not, CNS cells). Therefore, lack of insulin or the insensitivity of its receptors plays a en-equivocal role in all types of diabetes mellitus.

Humans beings are capable of digesting few carbohydrates, mainly, those common in food; starch, and few disaccharides, such as sucrose,

are turned, within a few hours to simpler forms, mostly the monosaccharide glucose, the main carbohydrate source used by the body. The others are passed on for processing by microflora, mainly in the colon. Insulin is secreted, into the blood by beta cells , found in the islets of Langerhans of the pancreas, in response to increasing levels of blood glucose, mainly, after eating. Insulin is used by around two-thirds of the body's cells to assimilate, glucose from the blood for use as energy source, for conversion to other wanted molecules, or for storage, for other future purposes.

Insulin is also the main control signal for change of glucose to glycogen for storage in liver and muscle cells .Decreased glucose levels ,leads to, both in the reduced release of insulin from the beta cells and also ,in the reverse conversion of glycogen to glucose, when glucose levels decrease in the blood. glucagon act in a opposite manner compared to the insulin.

Glycogenolysis is a process by which there is conversion of stored glycogen in liver cells to free glucose level in the blood stream.

Muscle donot have this mechanism of converting glycogen to glucose.

It causes-

1. Growth of cells
2. Multiplication of cells
3. Protein building
4. Fat building

CONSEQUENCES OF LESS INSULIN IN THE BODY

1. Ketosis
2. Decrease in affects of glucose in body cells
3. Improper storage of glucose in muscle and liver cells
4. Metabolic derangements like acidosis
5. Improper absorption of glucose in kidney leading to increased glucose in urine.
6. Increased loss of fluid from the body due to excessive micturation leads to dehydration and increase want of water.

Diagnosis

Glycosylated haemoglobin and GTT

Criteria for Diagnosis Of Diabetes			
Condition	**2 hour glucose levels** mmol/l (mg per dl)	**Fasting glucose levels** mmol/l (mg per dl)	**HbA_{1c}** Percentage
Normal condition	<7.8 (<139)	<6.2 (<112)	<6.0
Impaired fasting glycaemic levels	<7.8 (<139)	≥ 6.2(≥112) and <7.0(<126)	6.0 to 6.3
IGT	≥7.8	<7.0	6.0–6.3
Diabetes mellitus	≥11.0 (≥200)	≥7.0 (≥126)	≥6.4

Diabetes is characterized by these -

- Fasting glucose level $\geq$ 126 mg/dl
- Post prandial Glucose greater than 200 mg/dL after OGT.
- Symptoms of raised blood sugar and RBS $\geq$ 200 mg/dl
- Glycosylated haemoglobin of $\geq$ 6.5%.

1. Results should always should be confirmed by a repetition of either of the above tests on some different day.
2. It is easy and feasible to do a FBS
3. Two consecutive fasting glucose measurements greater than 126 mg/dl (7.0 mmol/l) diagnosis of diabetes mellitus confirmed.
4. As we discussed earlier people with FBS levels from 110 – 126 mg/dl are called as to have impaired fasting glucose test.
5. People with plasma glucose above or at 140 mg/dL , but less than 200 mg/dL post prandial following OGT is a better test than any of the following.
6. Also doing HBA1c (Glycosylated hemoglobin) outbalances FBS , to find out future micro and

macrovascular complication of DM like Diabetic nepharopathy, retinopathy, CVS complications,CVA etc.

Treatment of DM

AIM of the treatment

1. To maintain euglycemia and
2. Early diagnosis and prevention of further complications of DM.
3. Awareness, understanding, and voluntury participation of person.

Treatment modalities of DM-

1. **DIET**
2. **LIFE STYLE MODIFICATION**
3. **PROPER EXCERCISE REGIMEN**
4. **ORAL HYPOGLYCEMIC AGENTS USAGE**
5. **INSULIN**
6. **COMBINATION OF EITHER OF THE ABOVE.**

MONITORING METHODS OF DM-

1) **HbA1c -Aim of treatment HbA1C to be less than 6.5%.**
2) Also we have to have an eye on –

Dyslipidemia ,

cigratte smoking,

uncontrolled BMI

Hypertension

Irregular life style.

Using proper and comfortable shoes.

Lifestyle

There are roles for patient awareness ,

diet support , and

proper exercise regimes,

with the aim of keeping both short term and long term glucose blood levels within acceptable limits.

In addition, knowing the associated

increased risks of cardiovascular disease,

lifestyle alterations are required timely,to control blood pressure.

Medications

Oral Hypoglycaemic Drug-

Metformin first line drug for type 2 diabetes melitus, good evidence,from the studies done in the past, that it reduces mortality.

Aspirin usage, though, has not been found to enhance outcomes in uncomplicated diabetes.

Type 1 diabetes is perfectly managed by

i) **a combinations of NPH and regular insulin preparations,** or

ii) **synthetic insulin substitutes**.

In type 2 diabetes start with long-acting preparations and gradually continue OHD...

Dose monitoring

Proper titration of insulin dose is always required which require an help of expert endocrinologist.

Proper rehabilitative measures play a pivotal role in the people undergoing amputations due to type 2 DM.

Epidemiology

Diabetes prevalence worldwide in 2000 (per 1,000 persons) - world average accounted for 2.9%

≤ 7.5	45.1–52.5
7.6–15	52.6–60
15.1–22.5	60.1–67.5
22.6–30	67.6–75
30.1–37.5	75.1–82.5
37.6–45	≥ 82.5

DALY index for type 2 diabetes mellitus inhabitants in 2011

<100	601–700
101–200	701–800
201–300	801–900
301–400	901–1,000
401–500	1,001–1,500
501–600	>1,500

Approximate rate of increase of diabetic patients globally-

The health burden of diabetes and its impact on the economy of the world is increasing in logorythmic manner .

By 2040 if such a rise is there we can expect the doubling of diabetic population .

PERIPHERAL ARTERIAL DISEASE

INTRODUCTION

a) **comes under atherosclerotic occlusive disease.**
b) **Apart from CVS and CNS diseases ,it is associated with amputation of limb.**

PREVALENCE OF PAD TOGETHER WITH DIABETES

Initiated by atherosclerosis

Mainly affects lower limbs

Decrease in arterial blood flow during various body movements

Total prevalence increases with age

(around 5% in youngs and 15% in elderly above 65 years)

SYMPTOMS OF PAD

i) Mostly asymptomatic

ii) If symptomatic then intermittent claudication (33% cases)

iii) Critical limb ischemia

iv) Gangrene

PAD often leads to amputation if overlooked.

PAD affects multi system organs like

- Heart vessels
- Vessels of kidney
- Vessels of brain

Eventually leading to fatal outcome.

RISK FACTORS FOR PAD

(i) SMOKING

(ii) DIABETES

(iii) AGE > 60YRS

(iv) DERANGED LIPID PROFILE

(v) INCREASE IN FIBRINOGEN LEVELS

(vi) INCREASE IN HOMOCYSTIEN LEVELS

(vii) DERRANGED LIPOPROTIENS

(viii) INCREASED VISCOSITY OF BLOOD

(ix) ETHINIC DIFFERENCES

BROAD DIFFERENCE BETWEEN DISEASE DUE TO PAD AND DISEASE DUE TO DIABETES

Disease due to PAD – affects below knee vessels.

Disease due to diabetes- affects above knee vessels

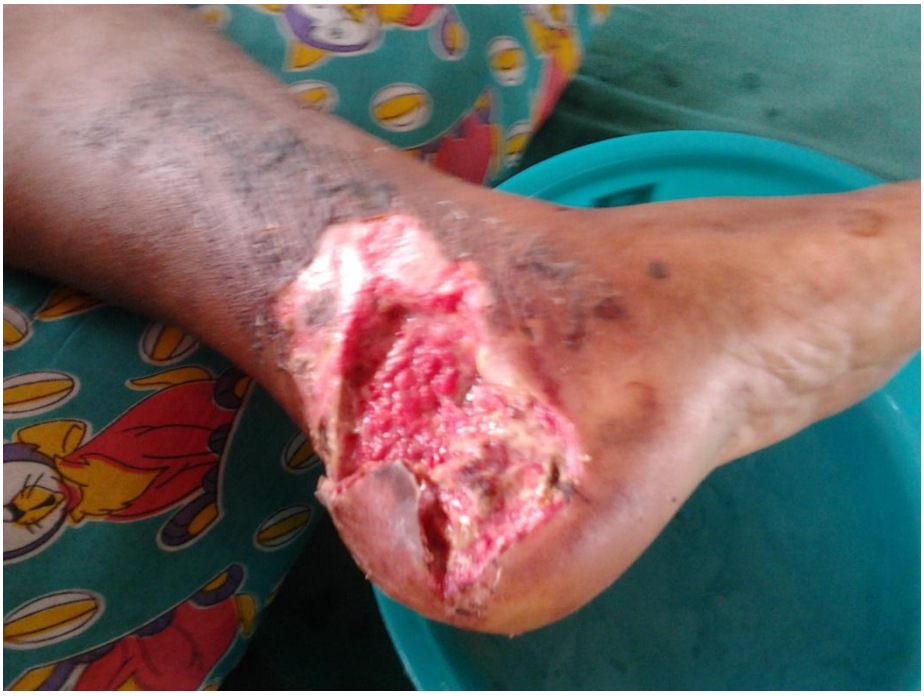
Clinical feature of PAD of diabetic foot patients

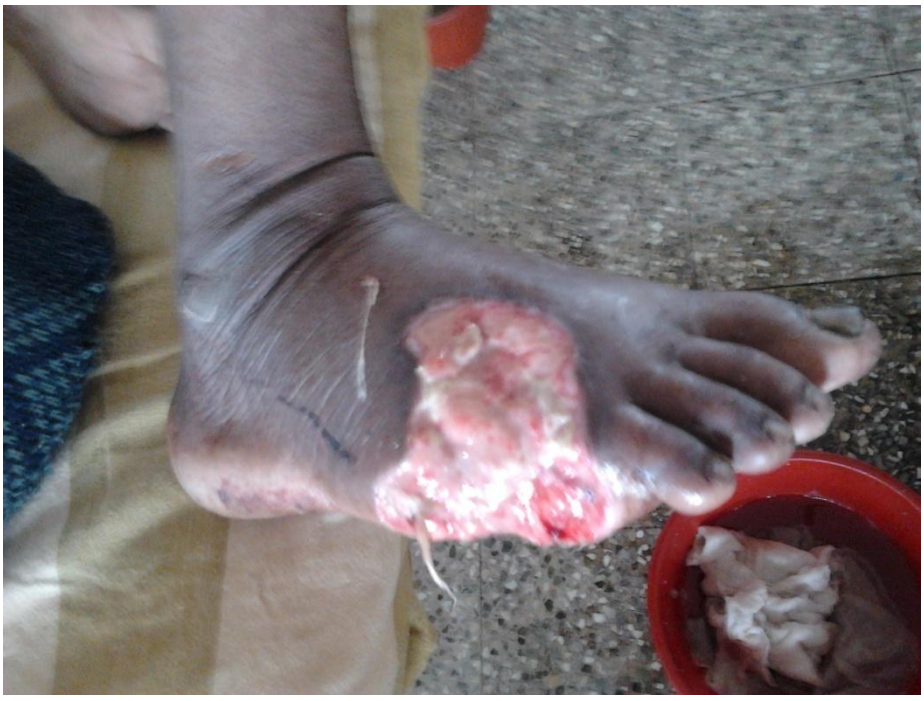
Due to lack of adequate propriorecption, whenever

There is constant source of irritation and foreign body sensation to the foot, a person usually does not able to feel the pain sensation because of peripheral neuropathy in this DM.

These are the symptoms of the patients with DM which leads to PAD as as follows -

PHOTOGRAPHS SHOWING DIABETIC PATIENTS WITH FOOT INFECTIONS, TAKEN FOR OUR STUDY ADMITTED IN OUR WARD





1. Pain and cramping sort of pain in the lower limb while doing moderate to severe activity, this is also known as intermittent claudication.

   It affects the following part of the lower limb,which are as follows-

a) Muscles of buttocks ,

b) Muscles of thighs ,

c) Muscles of legs.

   This sort of pain mentioned above becomes alright after taking rest.

2. Due to persistent lack of nutrients and oxygen in the lower limb , this may sometimes progress on to ischemia of limbs, which is very critical (CLI).

3. Due to devitalization of the tissues, the tissues become dead , and following can happen-

   a. Dry gangrene Usually there is no infection seen.

   b. Wet gangrene Usually associated with secondary infections, and it has crepitus and fowl smelling discharge accompanying it.

4 . **Ulcer** which are non healing and requires proper medical attention and care.

5 . If all these conditions are unnoticed and neglected, this may turn into **amputation**.

6 **. Sepsis** to the patient due to the extensive spread of the infection mayleads to multiple end organ failure and ultimately result in septic shock and death.

7 . DM also affects CVS, CNS, PNS, musculo skeletal system. This shows that DM is the disorder involving multiple system organs of our body.

PATHOGENESIS OF DIABETIC FOOT

Vascular system is mainly affected apart from peripheral nerves constituting the major etiopathogenesis.

In the Blood vessels following changes are seen –

A. Changes in the structure of blood vessels

B. Changes in basic functions of the vessels

FACTORS RELATED TO DM WHICH AFFECTS VASCULAR SYSTEM ARE THE FOLLOWING-

I. Atherosclerotic changes-

There is Endothelial dysfunction mainly.

II. Inflammatory reaction and associated changes

There is associated increase in

- C- reactive protein
- Low density lipo protein
- Increase in free fatty acid

III. Blood factors- There is increase in

- Chemotactins
- Leukocyte wall adhesions
- Decrease in nitric oxide
- Increase in the plasminogen activator inhibitor

IV. Increase in free oxygen radicals

- Decrease intake of protective factors like

  Vit A

  Vit C

  Vit E

  These protect Poly unsaturated fatty acids from peroxidation. Amount of lipid peroxide is directly proportional to the atherosclerosis occurring in the body.

V. Other blood related factors-

- Increase in factor 8
- Increase in factor 13
- Increase in plasminogen
- Increase in platelet fuctions

These all factors lead to increase in clotting of blood and a hypercoagulable state created which may cause thromboembolic phenomenon.

VI. Person with stressful life and type A personality have higher risk factors.

There is a whole series of events, of the above mentioned factors and, which lead to complication of diabetes foot patients and its related complications.

Due to persistent high level of glucose level, there is resistance to insulin.

These factors, increase with the ageing of the patient and there is deterioration of the function as the age increases.

Preventive factors related to prevention of PAD in diabetics

1. **Low fat containing diet**
2. **Proper daily exercise**
3. **Avoid smoking**
4. **Consumption of anti oxidant rich food**
5. **Doing meditation and pranayam to decrease stress.**
6. **Consumption of small amount of alcohol**

MOLECULAR LEVEL CHANGES LEADING TO PAD IN DIABETICS

Due to persistent increase in blood glucose level

↓

There is increased cellular glucose

↓

There is increase in Sorbitol levels

↓

Causes direct neurotoxicity to the neural cells

↓

Also increase **in** blood glucose levels

↓

Decrease in myoinositol

↓

Decrease in Na-K pump

↓

Causes impaired nerve conduction

MACROSCOPIC CHANGES IN DIABETIC FOOT

Due to increased blood glucose levels

It causes stretching of ligament and joint capsule of foot

↓

Leads to multiple foot deformities
like claw foot and prominent metatarsal

↓

The combination of subluxation of foot arches, inflammation and neuropathy leads to **CHARCOT ARTHROPATHY**

↓

High pressures in these areas causes

shearing stress forces in all the directions

↓

Repeated trauma to above mentioned stress

points traumatizes the underlying tissues forming a callus

↓

The space between the above skin, subcutaneous tissue, underlying fascia and bone get involved as the disease progresses

↓

There is subsequent infection of these spaces

causing progressive devitalization of the foot

↓

Non healing ulcers

TESTS TO DIAGNOSE PERIPHERAL ARTERIAL DISEASES IN DIABETIC PATIENTS

Due to lack of adequate proprioreception and inability to detect pain and touch sensation, a person is unable to feel pain in his foot because of peripheral neuropathy, as explained earlier. Therefore tests like

1. Sensation of peripheral pulsations
2. Relying upon mere symptoms related to Diabetes are insufficient and inadequate.

   Better and more yielding tests like Ankle brachial index, Toe brachial index, wave form analysis of the arteries of lower limbs, colour duplex etc. Help us to detect this disease easily.

   We should abide by the following protocol for diagnosing PAD in diabetes-

   - ✓ Daily foot examination (self / clinician)
   - ✓ General health of the patient and other associated medical factors-
     a. BMI
     b. Per day cigarette / Biddi intake
     c. Other co-morbid conditions

- ✓ Regular eye checkup-
  a. Refraction error checkup
  b. Examination of the fundus,look for diabetic retinopathy changes
- ✓ Frequent medical checkup –concept of “At risk” foot should be advocated.
- ✓ Skin condition and contour of the ulcer and the surrounding area.

  Following things have to be looked for in this category-

  - Skin pallor and color
  - Skin temperature
  - Cracks and fissures over the skin
  - Presence or absence of secondary infection
  - Detailed examination of the ulcer like margin, base, edge, presence or absence of slough , surrounding pigmentation of the skin.
- ✓ Clinical methods

  Following things have to be seen-

  - Muscle power and tone

- Reflexes of knee and ankle(can use nylon monofilaments)
- Foot pulsations

This test have variable result, variation is interobserver bias checking the pulse.

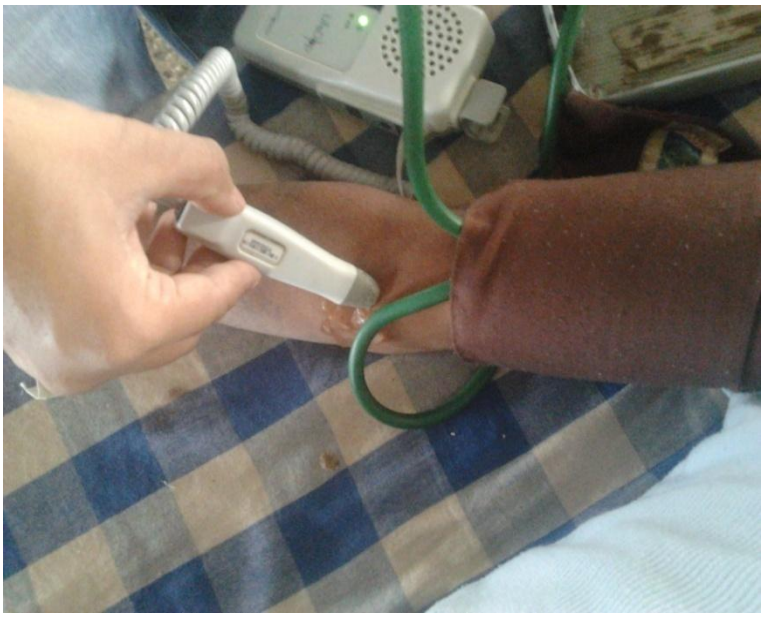
✓ **ANKLE BRACHIAL INDEX**

It is an Easy, quite accurate and non-invasive method to detect PAD. It can be performed simplely.

Method of measurement-

- It Measured by using manual BP cuff at ankle and arm level.
- Along with hand held continuous wave Doppler probe
- Position of the patient supine
- Systolic pressure is measured when Doppler signal comes backs to the probe
- Multiple cuffs can be applied to the different parts of the limb.

MEASURING ABI WITH HAND HELD DOPPLER IN ONE OF THE PATIENTS ADMITTED WITH FOOT INFECTIONS WITH DIABETES IN OUR WARD



CALCULATION OF ABI- Done by dividing higher of the two pressure measured in the ankle and higher of the two brachial pressure measured in the arm.

$$ABPI_{Leg} = \frac{P_{Leg}}{P_{Arm}}$$

CLINICAL CORRELATION OF ABI

Normal – 0.91 – 1.30

- Mild degree obstruction – 0.71 – 0.90
- Moderate degree obstruction – 0.41 – 0.69
- Severe degree obstruction - < 0.40
- Poorly compressible vessel - > 1.30

Clinically

1.1 $\rightarrow$ Normal status of the vessel.

0.6 – 1.1 $\rightarrow$ Features of intermittent claudication.

< 0.6 $\rightarrow$ Features of ischemic foot disease and impending gangrene

People with palpable distal pulses and normal resting ABI should undergo exercise test like trade mill test and there should be measurement of ABI post exercise as exercise causes **vasodilation.**

Value of ABPI	**Conclusion**	**Action to be taken**	**Nature of ulcers (if present)**
above 1.3	Abnormal Vessel hardening from PVD	Routinely refer.	Venous ulcer use of full and tight compression bandage.
1.0 to1.3	Normal.	Nil	
0.9 to1.0	Acceptable.		
0.8 to 0.9	Minimal arterial disease.	Manage the risk factors	
0.5 to0.8	Moderate arterial disease.	Routinely refer to higher centre.	Mixed ulcers put tight bandage
Less than 0.5	Severe arterial disease.	Immediate specialist referral centre.	Ulcers which are arterial no compression bandaging used.

In palpable foot pulses

i. ABI < 0.9 ⟶ likeliness of PAD is more

ii. ABI 0.9 – 1.1 ⟶ PAD is unlikely

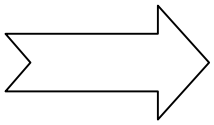
iii. ABI >1.1 ⟶ Calcification must be ruled out and also probability of PAD is there so we have to evaluate further.

Palpation of peripheral pulses

If pulses are not palpable

- ABI < 0.9 ⟶ chances of PAD are there so futher evaluation needed
- ABI 0.9 – 1.1 ⟶ chances of PAD are there so futher evaluation needed
- ABI > 1.1 ⟶ calcification present

Drawbacks of ABI

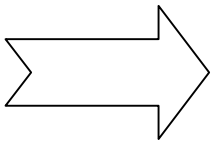


✓ Calcified vessels

ABI gives wrong reading in calcified vessels as they are less compressible as compare to the normal noncalcified vessels.

Value seen in such cases are ABI > 1.3

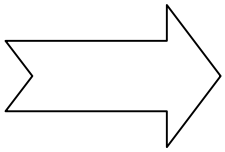
Mostly seen in Diabetic and end stage renal disease patients.



✓ Contraindicated in heart patients

Sometimes during treadmill test for symptomatic patients with palpable distal pulses with a normal ABI, may develop angina, MI or sudden death.

So always rule out coronary arterial disease before performing treadmill test in such patients.



✓ Inter observe variation in interpretation

COLOUR DOPPLER ULTRASOUND

Introduction

It is a non-invasive test for lower limb arterial disease, combined with the elaborative history and proper examination of the limbs it helps to formulate our plans of management and further treatment.

It gives information about regarding anatomy and physiology of the blood vessel concerned.

EQUIPMENTS USED IN COLOR DOPPLER

- ✓ Tranducers
  - **Low frequency tranducer** **2-**3MHz
    ⇩
    Good for deep vessels informations.
  - High frequency tranducer 5-7 MHz
    ⇩
    Good for superficial vessel informations.
- ✓ Standard color Doppler uses a combination of B-mode imaging and pulsed wave form interpretation.

  One should have a thorough of the following things while doing colour Doppler-
- ✓ Color gain

- ✓ Color velocity measurement
- ✓ Wall filter

USES OF COLOUR DOPPLER-

1. Anatomy of artery ⟶ can detect plques and calcification.
2. Complimented with wave form pattern
   ↘ Can detect severity of arterial disease
3. Can detect flow disturbances produce by the arterial disease.

GOALS OF COLOUR DOPPLER-

A. Identification of the anatomy and physiology of the diseased vessel.
B. To quantify the number, the characteristic, exact location and extent of the lesion.
C. To find out the disease progression by follow up
D. To decide the management protocol.
E. In case of injury to the arteries, it can find out the extent of injury.
F. To find out peripheral aneurysm.
G. Post operative follow up.
H. Can differentiate stenosis from total obstruction.

PRINCIPLE OF DOPPLER STUDIES-

IN THE CASE OF OBSTRUCTION IN THE ARTERY

IF THE VESSEL SIZE IS DECREASED BY HALF THE RESISTANCE INCREASES BY 16 TIMES, AND BLOOD FLOW DECREASED BY 16 TIMES.

Hence at the site of the obstruction following features can be appreciated-

- Increased resistance
- Increased velocity
- Decreased blood flow

PREPARATION OF THE PATIENT FOR COLOUR DOPPLER-

- Usually done early in the morning.
- The patient optimally should do night fasting.
- Supine comfortable position.
- Optimum room temperature (to avoid temperature induced vasoconstriction).

- Hip should be externally rotated.
- The most accurate velocity measurements are done at the angle of 60 degree.
- Time taken for doing CDU of lower limb 30 – 60 min.
- Avoid tobacco products few hours before the test.

Arteries visualized in colour Doppler of lower limbs

i. Upper abbominal Aorta
ii. Aortic bifurcation by placing transducer at umbilicus.
iii. Illiac artery by placing transducer at the level of iliac crest.
iv. Common femoral artery
v. Deep femoral artery
vi. Superficial femoral artery
vii. Popliteal artery (in prone position with flexed and externally rotated knee)
viii. Tibial and peroneal arteries
ix. Dorsal pedis artery

COMPARISION OF PEAK SYSTOLIC VELOCITIES & ARTERIAL DIAMETERS OF ARTERIES OF LOWER LIMB

Popliteal artery → approximate diameter of 0.5cm

PSV of around 70 cm /sec

Distal superficial femoral artery

Approximate diameter of 0.55cm

PSV of around 94 cm /sec

Proximal superficial femoral artery

Approximate diameter of 0.6cm

PSV of around 90cm /sec

Common femoral artery

Approximate diameter of 0.8cm

PSV of around 115 cm /sec

External iliac artery → approximate diameter of 0.8cm

PSV of around 120cm /sec.

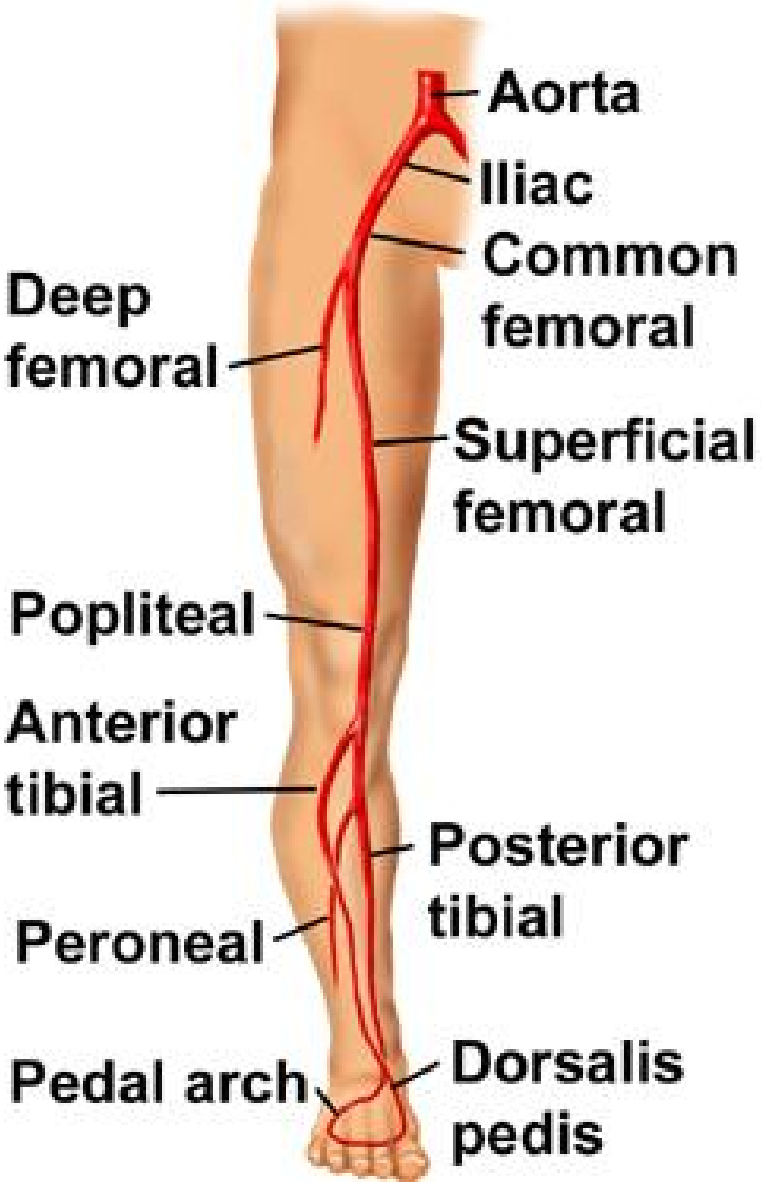


FIGURE SHOWING

ARTERIAL DEPICTION OF LOWER LIMB

INTERPRETATION OF COLOR DUPLEX

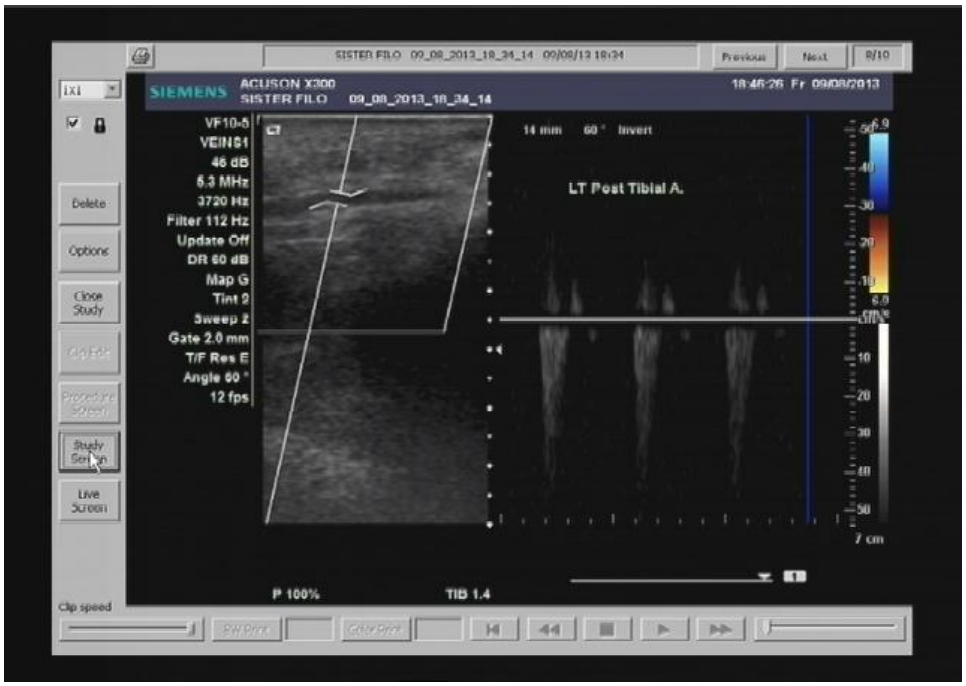
Depending upon the mean arterial diameter and peak systolic velocities and on the established normal as well as abnormal features of spectral wave form a set of criteria for categorizing diseased lower extremities artery segments was originally discovered at the University of Washington.

1. **Minimal disease** (1-19%) reduction of diameter and slight increment of spectral width. With <30%increase of Peak systolic velocity as compare to the adjacent proximal vessel segment.

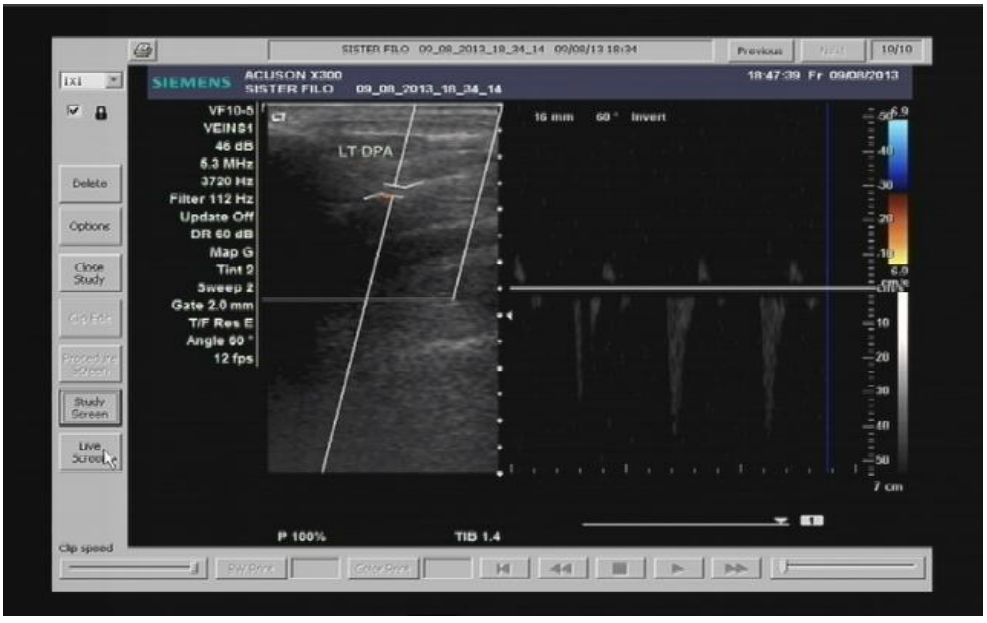
2. **Moderate disease (20-49%)** reduction of diameter and more prominant increment of spectral width, with increase of Peak systolic velocity up to 100% as compare to the adjacent proximal vessel segment.

3. **High Grade disease (50-99%)** reduction of diameter, causes most severe flow disturbance and extensive increment of spectral width, with increase of Peak systolic velocity >100% as compare to the adjacent proximal vessel segment, also characterized by loss of the reverse flow component.

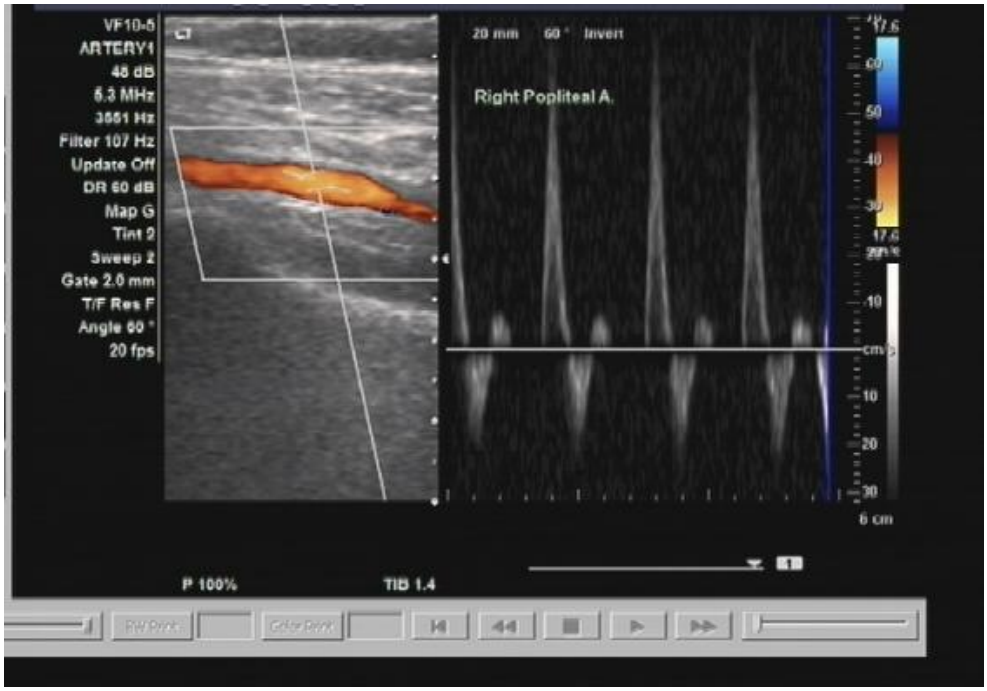
PHOTOGRAPHS SHOWING COLOUR DUPLEX OF LEFT POSTERIOR TIBIAL ARTERY OBSTRUCTION IN DIABETIC PATIENTS WITH FOOT INFECTIONS, TAKEN FOR OUR STUDY ADMITTED IN OUR WARD



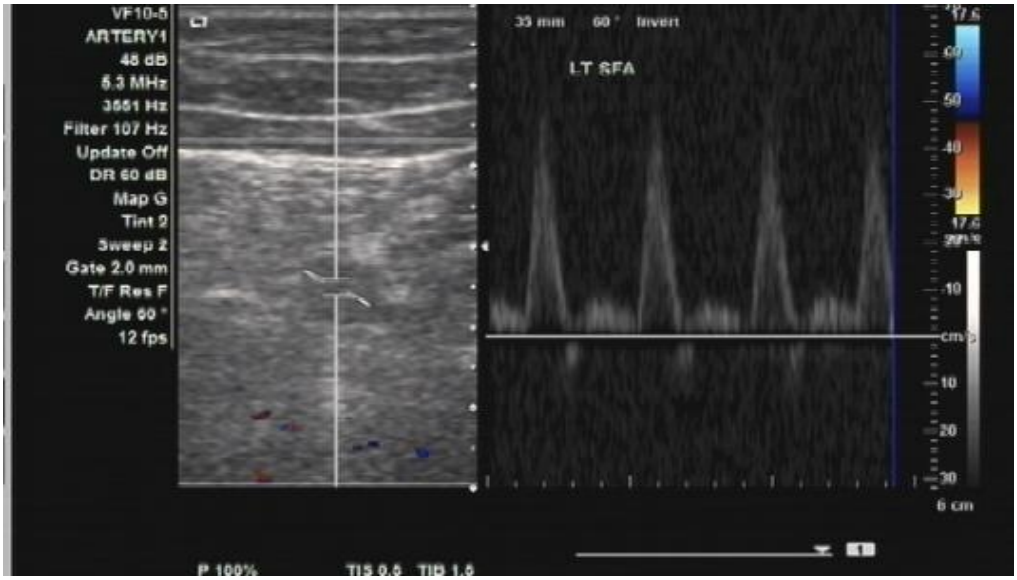
PHOTOGRAPHS SHOWING COLOUR DUPLEX OF LEFT DORSALTS PEDIS ARTERY OBSTRUCTION IN DIABETIC PATIENTS WITH FOOT INFECTIONS, TAKEN FOR OUR STUDY ADMITTED IN OUR WARD



PHOTOGRAPHS SHOWING COLOUR DUPLEX OF RIGHT POPLITEAL ARTERY OBSTRUCTION IN DIABETIC PATIENTS WITH FOOT INFECTIONS, TAKEN FOR OUR STUDY ADMITTED IN OUR WARD



PHOTOGRAPHS OF COLOUR DUPLEX WAVE FORM PATTERN IN LEFT SUPERFICIAL FEMORAL ARTERY IN DIABETIC PATIENTS WITH FOOT INFECTIONS, TAKEN FOR OUR STUDY ADMITTED IN OUR WARD



4. **Occlusion (100%)** reduction of diameter, no Doppler signals are detected in the lumen of the vessel. spectral wave form distal to the stenosis are monophasic and havind reduced systolic velocities.

Peak systolic velocity ratio is the ratio between maximum velocity within the stenosed vessel and the peak velocity measured in the normal arterial, proximal to the stenosis. It is independent of changes in BP,Cardiac output and the vascular compliance.

PSV ratio >2 is used by various vascular laboratories as an indication for a peripheral arterial stenosis of >50% diameter reduction.

Factors affecting Doppler results:

(a)Bones over lying the area being concerned.

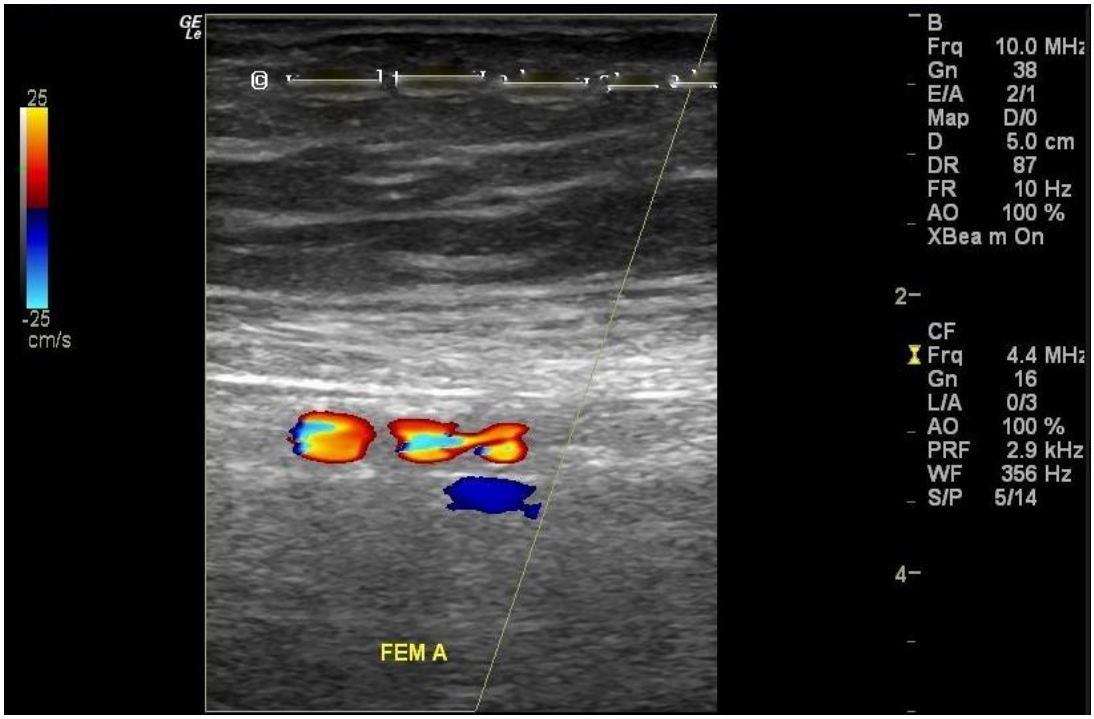
(b)Restless people

(c) Fatty people

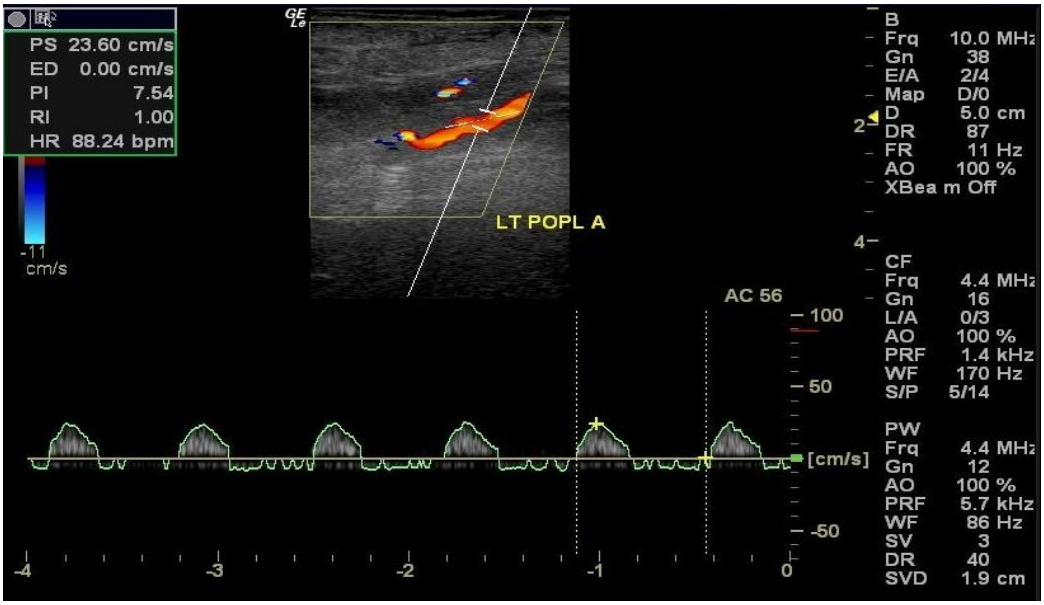
(d) Patients with conduction defect of heart and hemodynamically unstable.

(e) Cold arm or leg, which causes slowing of blood flow .

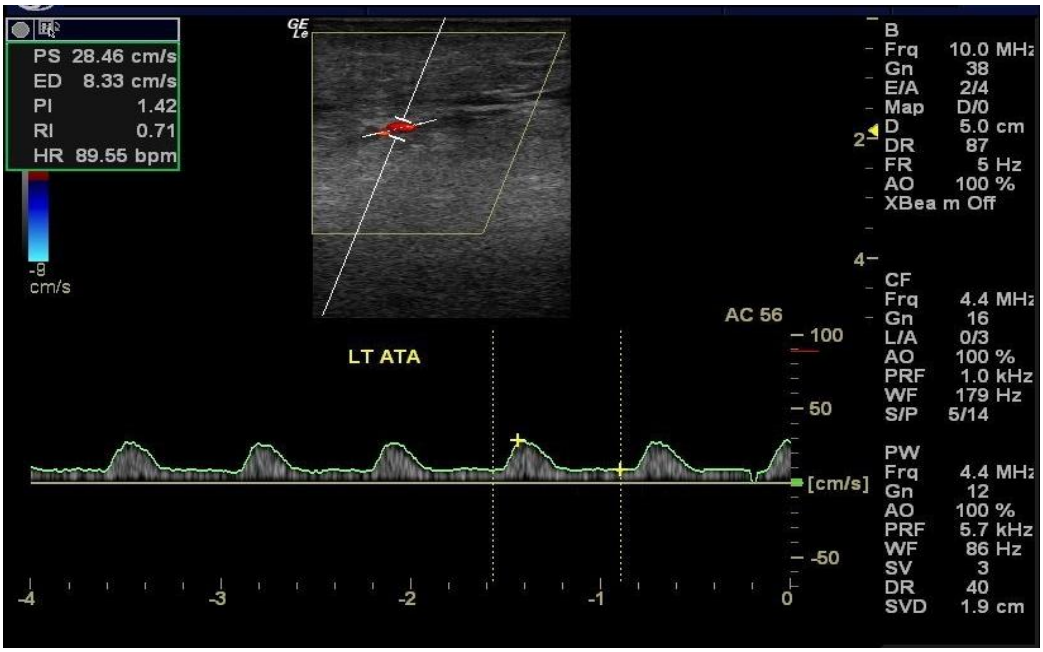
PHOTOGRAPHS SHOWING COLOUR DUPLEX OF FEMORAL ARTERY OBSTRUCTION IN DIABETIC PATIENTS WITH FOOT INFECTIONS, TAKEN FOR OUR STUDY ADMITTED IN OUR WARD



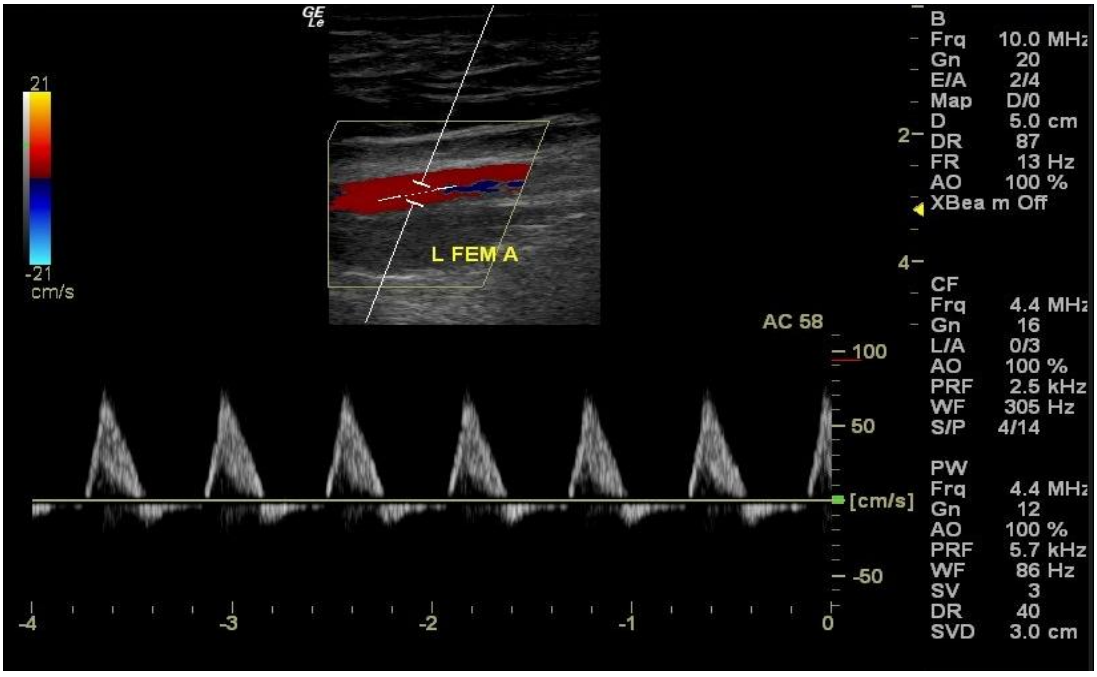
PHOTOGRAPHS SHOWING COLOUR DUPLEX OF LEFT POPLITEAL ARTERY OBSTRUCTION IN DIABETIC PATIENTS WITH FOOT INFECTIONS, TAKEN FOR OUR STUDY ADMITTED IN OUR WARD



PHOTOGRAPHS SHOWING COLOUR DUPLEX OF LEFT ANTERIOR TIBIAL ARTERY OBSTRUCTION IN DIABETIC PATIENTS WITH FOOT INFECTIONS, TAKEN FOR OUR STUDY ADMITTED IN OUR WARD



PHOTOGRAPHS SHOWING COLOUR DUPLEX OF LEFT FEMORAL ARTERY OBSTRUCTION IN DIABETIC PATIENTS WITH FOOT INFECTIONS, TAKEN FOR OUR STUDY ADMITTED IN OUR WARD



(f) Raw exposed area over the limb.

Other advanced modalities for PAD

CT Angiography-

Now a days 64 slice scanner is used to improve the quality of the image and also the precision quality of the image.

There has to be expert radiologist to clinically interpret these images.

Now a days 3D images have come into exisistance and it is very useful in better quality images.

Important things to be taken care of while doing CT-angiogram—

- Position of the patient
- Renal parameters of the patients
- Rate of injecting dye into the body
- Patient allergic susceptibility to the dye
- Other associated medical problems of the patients
- No. Of slices of CT angiogram.
- Pitch of the CTA

- Reconstruction methods of the CTA
- Availability of anaesthetist to take care of Emergency.
- Proper hydration of the patient
- Patient should be hemodynamically stable
- Collimation property of CTA
- Gating property of CTA
- Reformations of the image done by the CTA machine

ADVANTAGES OF Multidetecter CTA-

- Provides images from the pelvis to the foot with 3D enhancement.
- Easy and safe to use.
- Fast method and decreases time for scan
- Decrease artefact levels.
- Important information like vessel wall inflammation, hematoma, plaqueformation, impending rupture of plaques.
- Any aneurysms in the arterial wall can be seen.

BUT

CT over diagnoses obstruction .In these conditions MRI is beneficial.

ANGIOGRAPHY

Following are the important features of angiography

- It is an invasive procedure
- Has the maximum resolution
- We can club angiography with interventional methods like angioplasty.
- This is the only method which can measure the pressure difference between either sides of the stenosis.
- Contrast used is renotoxic.
- It cannot be done as an OP procedure
- We cannot found out the information regarding the surrounding structures.
- Other Complications reported are hematoma formation, thromboembolic phenomenon.
- Involves excessive radiation exposure to medical staff.
- Expertise and expensive so not available everywhere.

Management of diabetic foot

ulcer evaluation:

Assessment of the following--

- Skin changes around the ulcer.
- Ulcer characteristics- size site shape.
- Condition of ulcer- wound edges and bed.
- Presence of necrosis, pain, cellulitis and gangrene.

RISK CATEGORIZATION SYSTEM:

Category	**Risk**	**Evaluation**
0	Normal	yearly
1	Presence of peripheral Neuropathy	½ yearly
2	Presence of peripheral Neuropathy, PAD or Deformity	quarterly
3	Amputations Past h/o ulcer	monthly to quaterly

FOLLOWING DRESSINGS ARE USED IN DIABETIC FOOT:

1. **Hydrocolloid dressing**:
    - ✓ Having carboxy-methyl- cellulose and gelatin.
    - ✓ Usually combined with adhesives and elastomers.
    - ✓ Wound debridement functions by autolysis.
    - ✓ Less Frequent dressings once a week sufficient.

Disadvantages:

Hypergranulation on chronic use.

2. **Hydrogel dressing**:
    - ✓ Hydrate wounds and debridement due to autolysis.
    - ✓ useful in painful and burning wounds.
3. **Thick gels**:

    PURILON, INTRASITE
4. **Thin gels**:

    SOLUGEL, SULUSITE

    Can be kept in wound for 3 days.

5. **Alginate dressing(** Agar –agar)
    - ✓ Synthesised from sea weed.
    - ✓ Contains calcium ions – biodegradable.

- ✓ Needs active exudation from the wound for it to function.
- ✓ Not for dry wounds.

6. **Foam dressing**:
   - ✓ For exudative wound due to its absorbable property
   - ✓ Has thermal protection
   - ✓ contraindicated in the presence of infection
   - ✓ Can be impregnated with silver and thus acts as bactericidal dressing.
7. **Iodine preparations**:
   - ✓ Antiseptic.
   - ✓ Bactericidal action.
   - ✓ Used in infected wounds.
   - ✓ Usually combined with systemic antibiotics.
   - ✓ Prevents skin excoriation in exudating ulcers.
   - ✓ Especially used for cavitary wounds.

Wound bed preparation:

It has been proven by various studies that diabetic wound will not heal in the presence of debris, non viable tissues and bacterial colonisation. Wound debridement is become must for the management of diabetic foot.

Debridement is an integral part of management of diabetic foot.

- It Removes all necrotic tissues and callus.
- It Reduces pressure effect.
- It Helps in evaluating wound bed properly.
- Reduces infection burden.
- Facilitates drainage of pus from abscess.
- Adequate debridement must be done before applying topical healing agents and wound closure.

Types of debridement:

- ✓ Surgical
- ✓ Enzymatic
- ✓ Autolytic
- ✓ Mechanical
- ✓ Biological

Out of which only **surgical debridement** is the only proven and effective measure. It is done till the healthy tissue visualized and fresh bleeding points visible in the wound bed.

Aim of debridement

- To convert chronic non healing ulcer

acute healing ulcer

- For deep abscess I and D must be done.
- If osteomyelitis present

amputation indicated

- Necrotic tissues management

excised and debrided

Enzymatic debridement:

Use of synthetic proteolyic enzymes for wound debridement.

Eg.bacterial collagenase, papain, trypsin, fibrinolysin.

Autolytic debridement:

Occurs in moist healthy environment. When blood supply is maintained.

Mechanical debridement:

This includes both wet to dry dressing

Uses High pressure irrigation

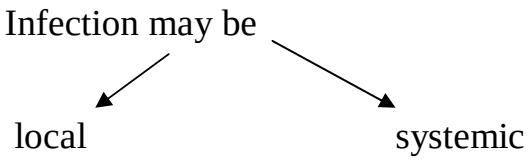
Based on Pulsed lavage and hydrotherapy.

Biological therapy:

Here proteolytic enzymes secreted by maggots is used that liquefies necrotic.

Infection and inflammation control:

Start proper antibiotic according to pus culture and sensitivity.



Signs of inflammation will be absent in immune compromised patients. In such case raised blood sugar value serves as marker for infection.

UPCOMING MODALITIES IN WOUND CARE:

Growth factor therapy

- Genetically engineered platelet derived growth factor (PDGF)
- Becaplermgel (REGRANE x tm)
- Works by stimulating chemotaxis.

AMPUTATION IN DIABETES:

The incidence of amputation is 20 to 40 times higher in diabetes when compared to non- diabetic patients.

It serves as the marker for disease severity.It is due to impairment of blood supply due to atherosclerosis .May also be an independent risk factor causing amputation and predisposes to gangrene.

Infection and persistently high glucose levels (hyperglycemia), has also been established, as risk factor leading to amputation.

Infection leads to sepsis, soft tissue destruction, abscess formation and osteomyelitis.

Chronic hyperglycemia causes microangiopathy, glycosylation of collagen and affects host phagocytosis mechanism. Both these factors, ultimately lead to amputation. Past history of amputation and ulcer in the lower extremity are major causative factors for subsequent amputations.

MATERIALS AND METHODS

A study period from January 2013– December 2013, a total of 50 patients who were admitted with diabetic foot infections in the Department Of General Surgery, Government Stanley Hospital Chennai - 1, were studied.

After admission

- Thorough history taking which must include age , sex , history of smoking , duration of disease and treatment taken by the patient for diabetes(oral hypoglycaemic drugs insulin , diet , or a combination of either of these)

- clinical examination including

  (a) General examination that includes blood pressure measurement,

  (b) Systemic examination

  (c) Local examination includes measurement of ABPI.

  ABPI was measured in both the limbs, by the bed side of the patient by using Hand held Doppler and measuring the

ratio between highest pressure measured in the ankle (signifying Tibial artery pressure)divided by highest pressure measured in the arm (signifying brachial artery pressure).

- Routine blood investigations

  Includes fasting blood sugar, HbA1c and other relevant blood investigations. Wound pus swab culture and sensivity, were done.

- Radiological investigation includes colour Doppler of both the lower limbs and the arteries included external iliac, femoral (proximal and distal), popliteal (anterior and posterior),tibial(anterior and posterior) and dorsalis pedis artery.

  Following components were look for

  Mean arterial diameter

  Peak systolic flow velocity

  Spectral wave form patterns

On the basis of above mentioned components % obstruction of the arteries, were calculated.

Blood sugar values, fasting blood levels were checked in all patients.

Both oral and intravenous antibiotics were given according to the pus culture and sensitivity report.

Regular, through surgical debridement was done.

Daily dressings were done.

Inclusion Criteria:

1- All Type-II DM patients, on treatment or diet control with foot infection.

2- Age group of 35yrs to 80yrs.

Exclusion Criteria:

1- Individuals with rest pain.

2- Individual with signs suggestive of lower limb critical ischemia.

3- Other causes of peripheral neuropathy.

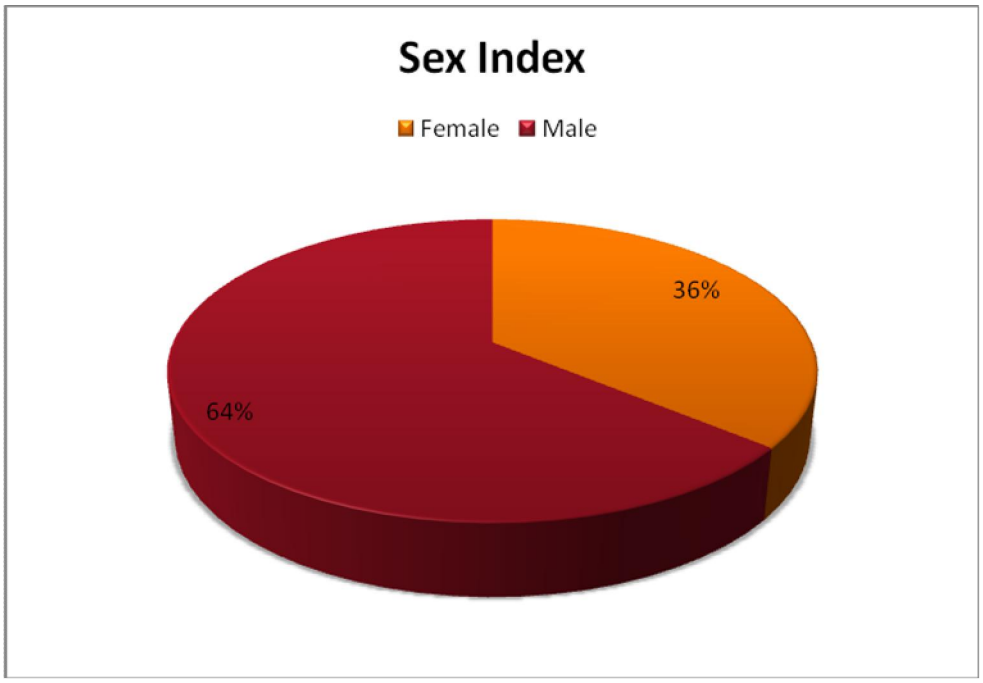
4- Any history of reconstructive vascular surgery.

OBSERVATIONS

AGE	Male	Female	Total	%
<50yr	10	3	13	26%
50-60	16	6	22	44%
>60yrs	6	10	16	32%

Patients distribution done on the basis of age, 13 were of age <50 yrs, 22 were of age between 50 to 60 yrs and 16 were of age >60 yrs. Age of Youngest patient is 35yrs and oldest patient 80yrs. The distributions are shown in the table above and pie chart below.

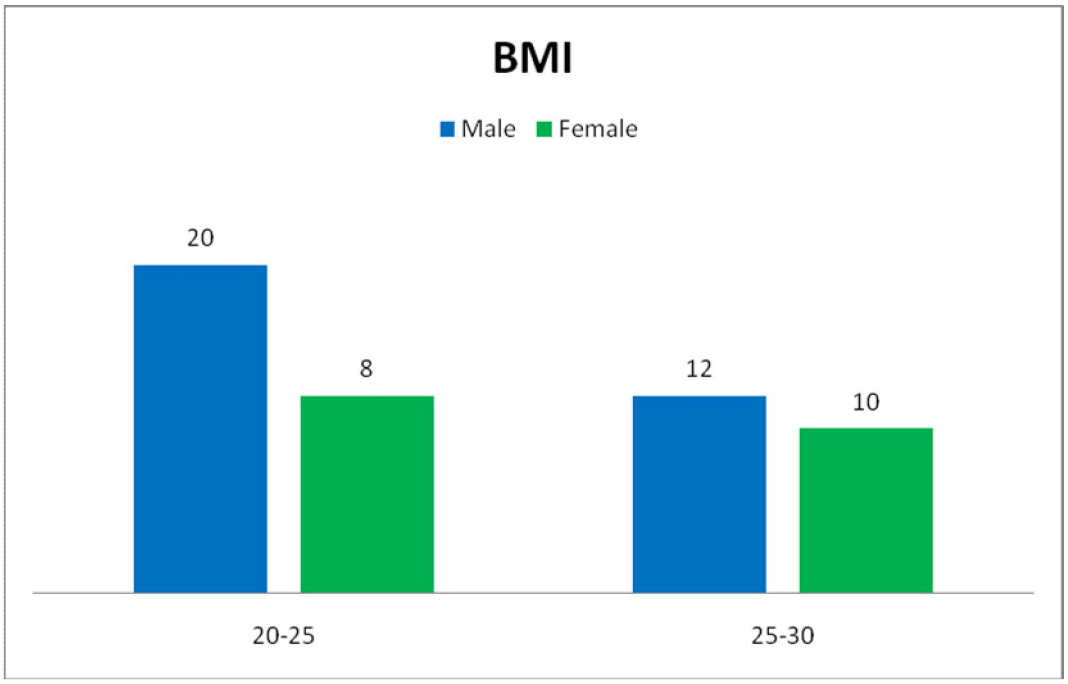
In this study 32 patients (64%) were males and 18 patients (36%) were females. Pie chart below shows the sex index. The Mean age was 59.5 ± 10.1 years.

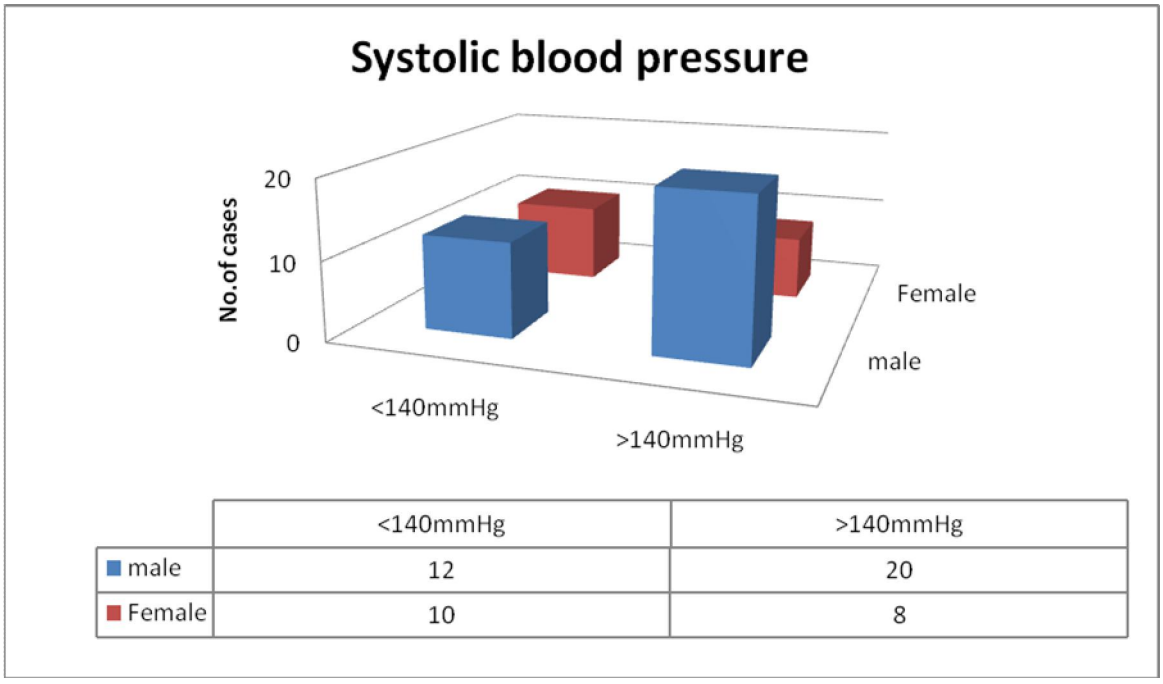


Out of 50 patients 28 were having BMI between 20 to 25 and 22 were having BMI between 25 to 30.

Mean Body mass index was 24.2 ± 3.5.

Chart below shows the BMI distribution.





	<140mmHg	>140mmHg
male	12	20
Female	10	8

Chart above shows distribution on the basis of systolic blood pressure. Mean systolic blood pressure is 136 ±19 mm Hg.

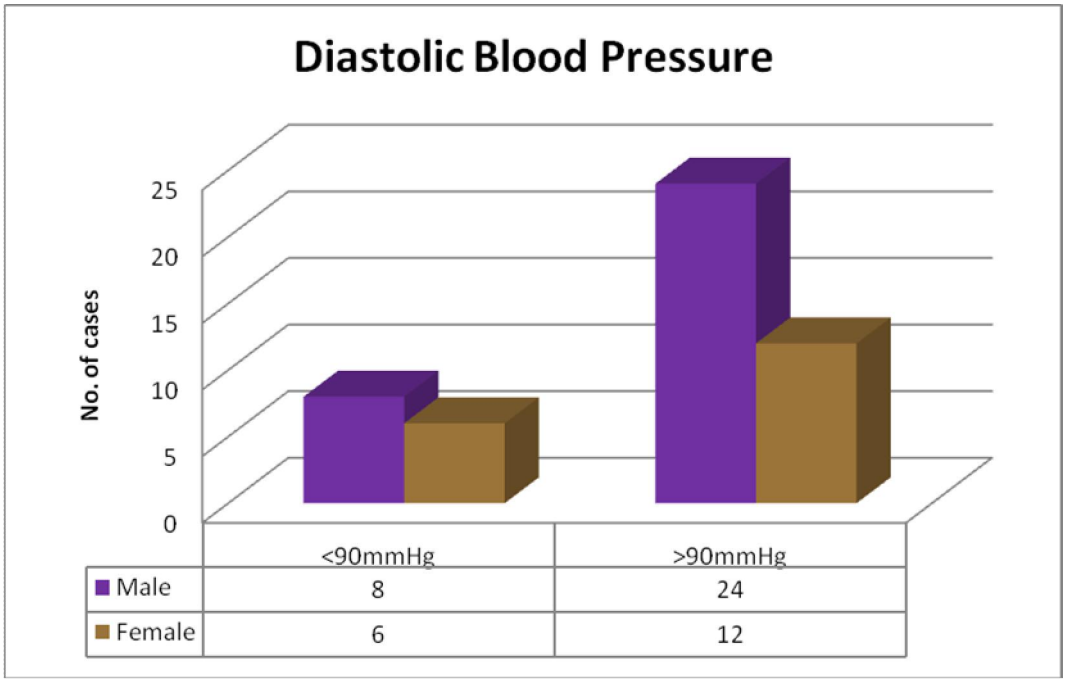


Chart above shows distribution on the basis of Diastolic blood pressure. Mean Diastolic blood pressure is 86±11 mm Hg.

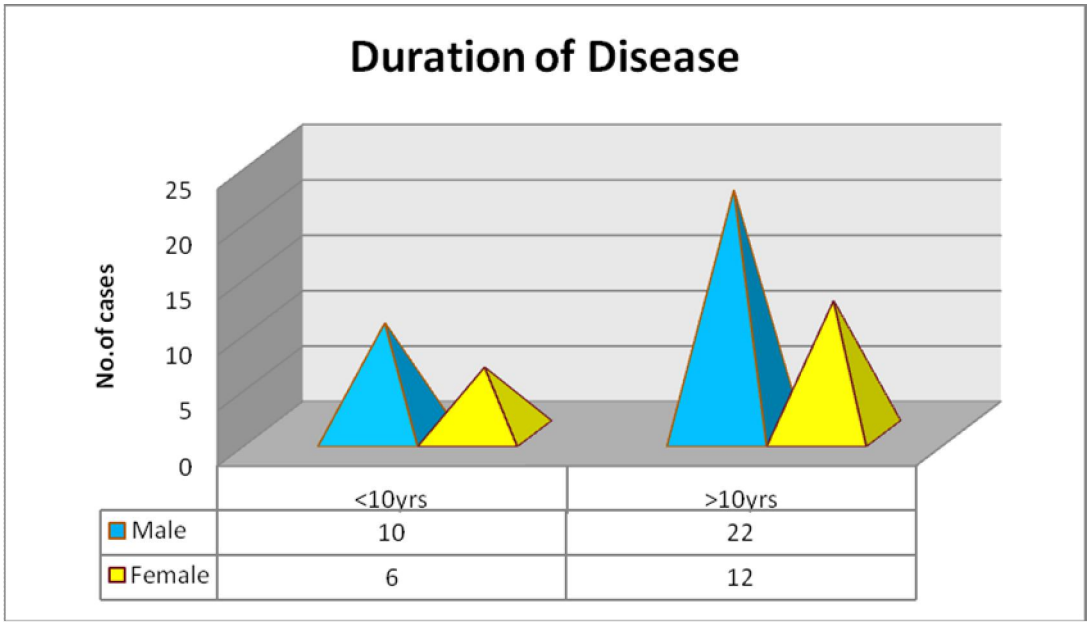
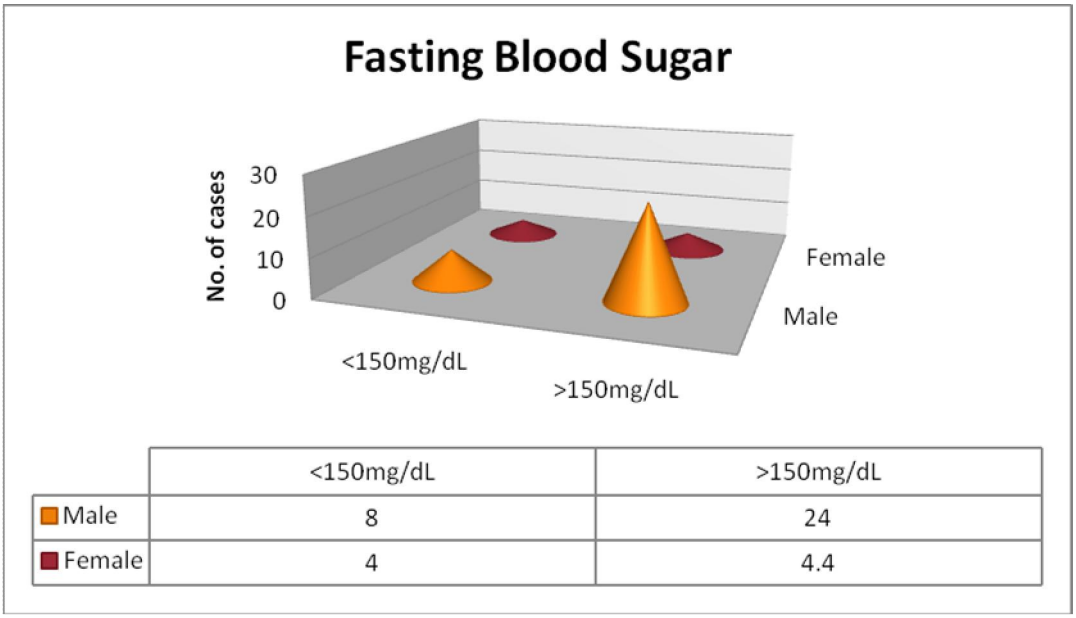
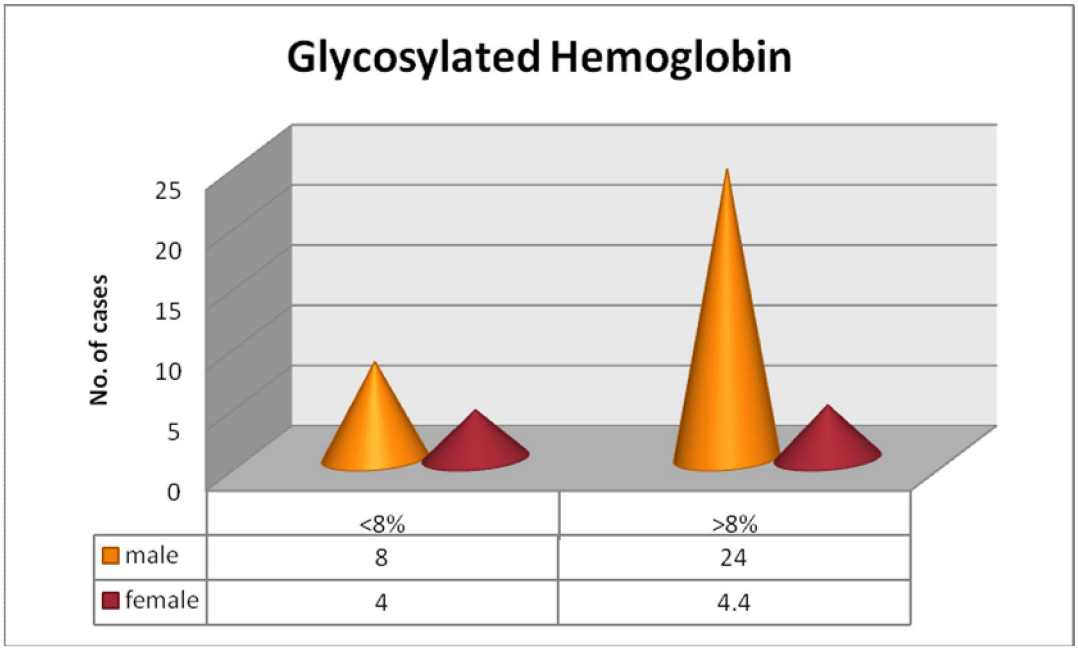


Chart above shows distribution of the patients on the basis of duration of disease (diabetes mellitus). Mean duration of diabetes in the study population 11.7±8.1 yrs.

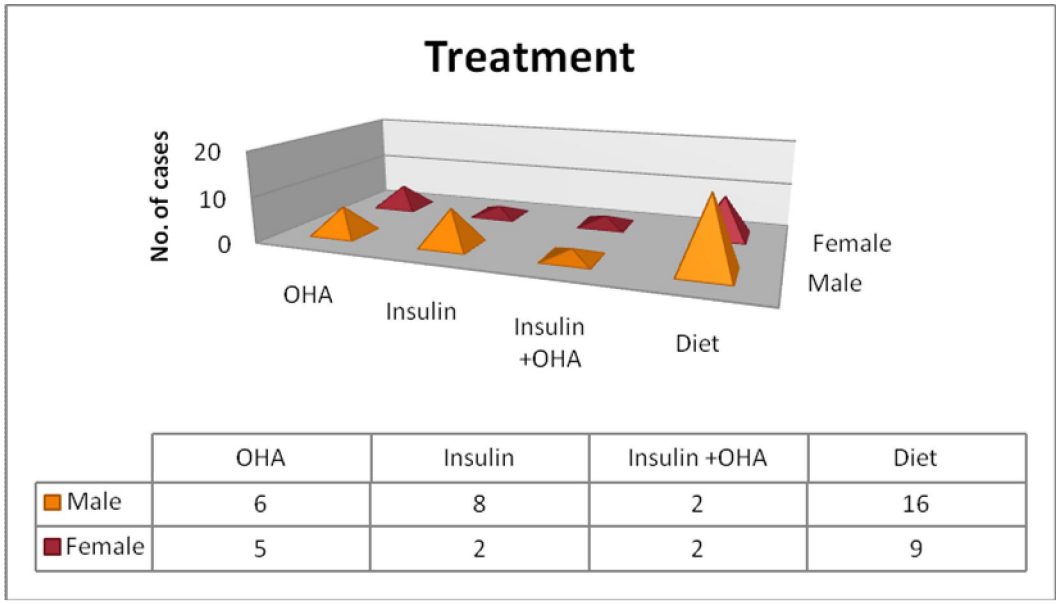


	<150mg/dL	>150mg/dL
Male	8	24
Female	4	4.4

The fasting blood sugar value ranges from 132 to 240mg% .minimum value is 132 mg/dL presentation and the maximum value 240 mg/dL. Mean fasting blood sugar of study population is 186±76 mg/dL.

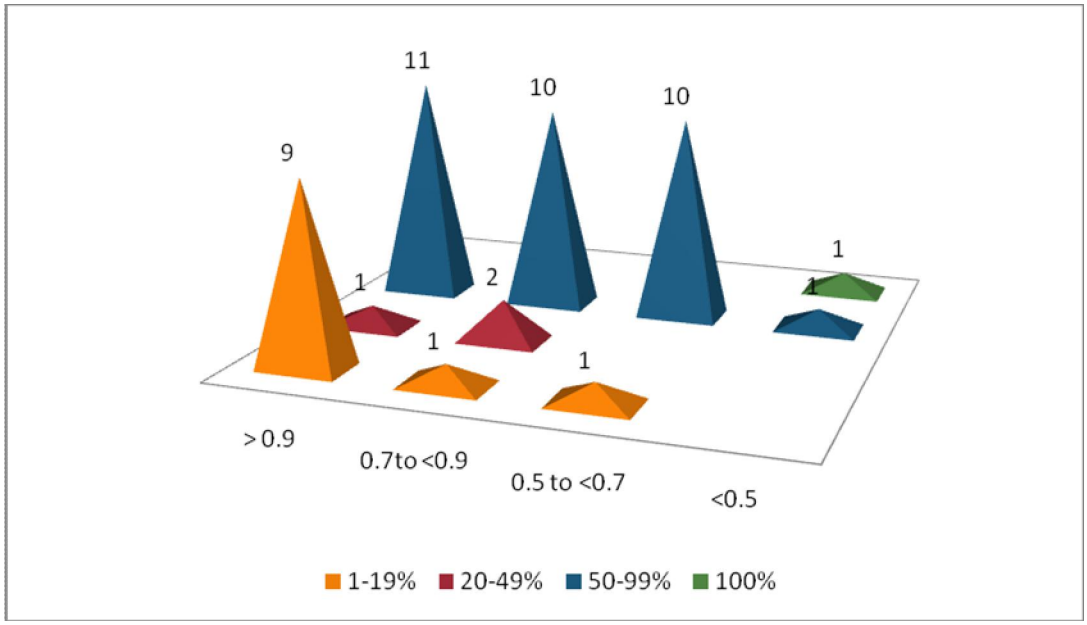


Above chart shows distribution of study population on the basis of HbA1C. Minimum HbA1C of the study is 7% and maximum is 11.2%. Mean HbA1c of the study population is 9.5±2%.



	OHA	Insulin	Insulin +OHA	Diet
Male	6	8	2	16
Female	5	2	2	9

Above chart shows distribution of patients on the basis of type of treatment was taken by the patients. 22% patients were on OHA, 20% patients were on insulin treatment,8% were on both combined insulin and OHA therapy and 50 % patients were only on diet control.



Above chart shows ABPI <0.5 showed a 100% agreement with CDU.

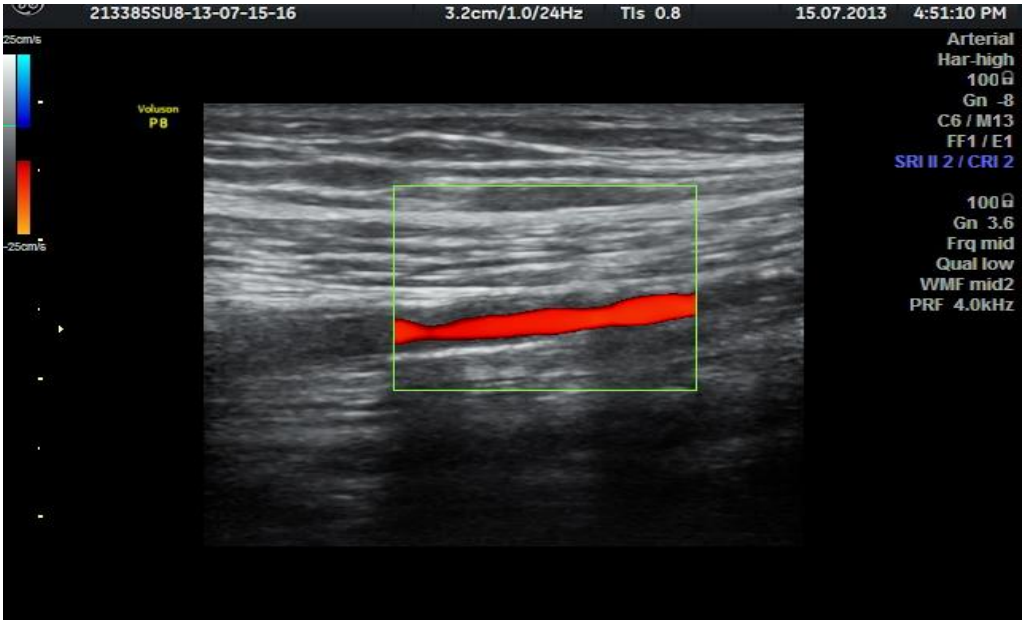
ABPI between 0.5 to 0.7 showed a 90.9% agreement with CDU.

ABPI between 0.7 to 0.9 showed a 76.92% agreement with CDU.

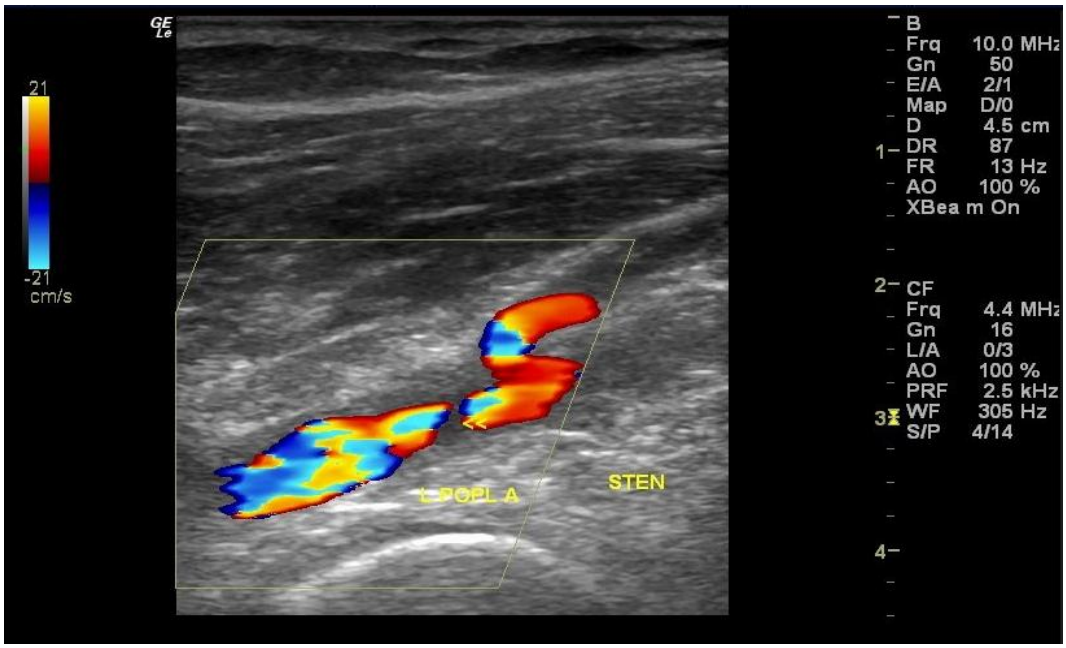
ABPI > 0.9 showed a 52.38% agreement with CDU.

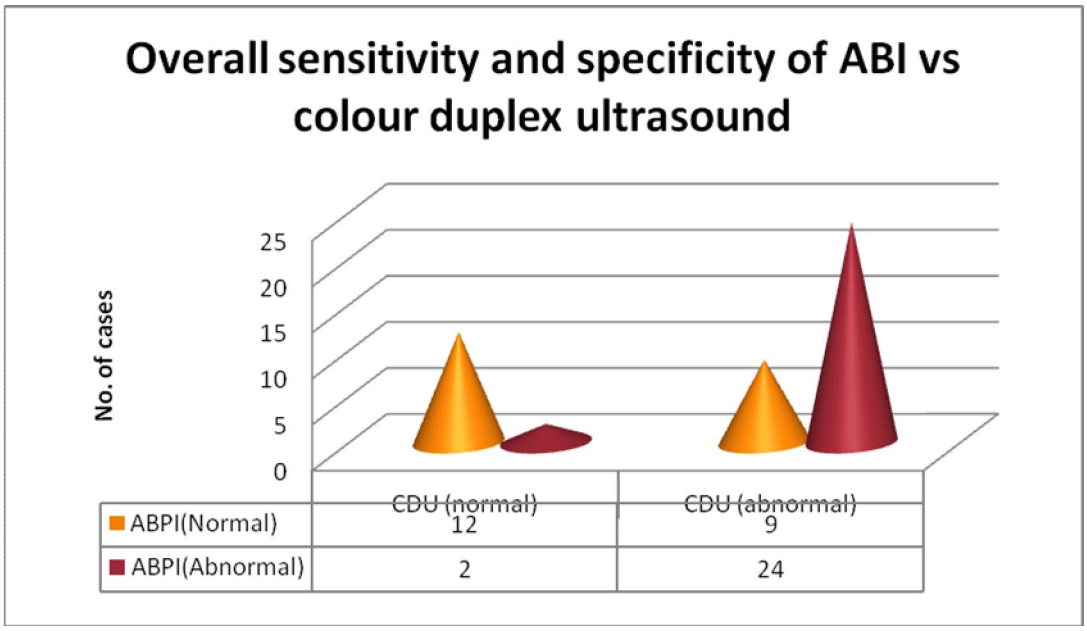
Overall agreement of ABPI with CDU was poor.(kappa value_0.2_)

PHOTOGRAPHS SHOWING COLOUR DUPLEX OF LEFT FEMORAL ARTERY COMPLETE STENOSIS IN DIABETIC PATIENTS WITH FOOT INFECTIONS, TAKEN FOR OUR STUDY ADMITTED IN OUR WARD



PHOTOGRAPHS SHOWING COLOUR DUPLEX OF LEFT POPLITEAL ARTERY STENOSIS IN DIABETIC PATIENTS WITH FOOT INFECTIONS, TAKEN FOR OUR STUDY ADMITTED IN OUR WARD





Of the total 50 subjects,3 patients had detected calcification of peripheral vessels on colour Doppler ultrasound and they were not included while calculating sensitivity and specificity of ABI.

ABI<0.9 was cut off used for the diagnosis of peripheral arterial disease.

In CDU >50% block considered as abnormal.

Out of 33 individual diagnosed to have PAD based on CDU, only 24 individual categorized as PAD by the ABI. Thus 9 individuals remain undiagnosed if ABI alone were used for diagnosis of PAD. Sensitivity of ABI 72.72%.

Conversely only 2 patients out of 26 subjects diagnosed as having PAD according to ABI were classified as normal by CDU. Specificity of ABI 85.71%.

Positive predictive value of ABI 92.30% and negative predictive value of ABI is 57.14%

DISCUSSION

By the recent projection from WHO identified that by 2025,>20% of diabetic population in the world will be contributed by India that is over 57 million diabetic patients. This will cause a tremendous health burden on our nation. Thats why accurate estimate of the mobidity caused by diabetes are therefore of great importance.

We had used ABI in our study to assess PAD, as it is difficult to do CDU in population based study. In order to get a good pick up of PAD, we taken to study a group of type 2 DM patients admitted to our hospital with severe foot infection.

Earlier studies suggested ABI as a reliable method for diagnosis of PAD and ABI value of <0.9 has 95% sensitivity compared to angiography.ABI in our population was a poor predictor of peripheral artery disease.

With recent development of scanning technique Colour Doppler scanning is used for diagnosis of PAD. It has many clinical applications like blood flow sensing, wave form analysis, localizing blood flow and two dimensional mapping of flow of blood.CDU is very effective in detecting and grading of atherosclerotic plaque in the arteries.

Comparative study of CDU and ABPI in the Rancho Bernando study revealed that Ankle brachial index <0.8 had optimum sensitivity and specificity. This study also revealed that peripheral Doppler is ideal for detecting majority of the subject with PAD.

In our study Age of Youngest patient is 35yrs and oldest patient 80yrs.In this study 32 patients (64%) were males and 18 patients (36%) were females. Mean duration of diabetes in the study population 11.7 $\pm$ 8.1 yrs.This indicates development of PAD in diabetic patient require time lapse. It is a long term complication of diabetes.

The fasting blood sugar value in our study ranges from 132 to 240mg%. Minimum value is 132 mg/dL and the maximum value 240 mg/dL. Mean fasting blood sugar of our study population is 186 $\pm$ 76 mg/dL. Mean HbA1c of the study population is 9.5 $\pm$ 2.This indicates glycemic control in diabetic patients is very important factor for development of PAD.

Mean systolic blood pressure is 136 $\pm$ 19 mm Hg and Mean Diastolic blood pressure of study population is 86 $\pm$ 11 mm Hg indicates our study inference are not affected by atherosclerotic changes caused by hypertension.

After analyzing the results of our study conducted from January 2013 to December 2013 we observed ABI has good specificity (85.71%) and low sensitivity (72.72%). Low sensitivity indicate it may miss some cases with PAD. As ideal screening test must have very few false negative means high sensitivity.

ABI <0.5 showed very good (100%) agreement with CDU. As ABI increases agreement with CDU decreases. Overall agreement between these two methods are very poor.

Around 42.85% of patients diagnosed to be normal by ABI who had significant (>50%) obstruction when examined by CDU. The reason for high ABI inspite of significant stenosis probably may be due to collateral circulation that maintains blood circulation beyond the point of obstruction in the limb. And higher ABI in stenosed vessel may be due to calcification of the vessel wall.

Support for our study comes from a study from the UK done by Allen J et al which assessed the agreement between both the tests in nondiabetic population result was that ABI technique detects only those patients who have significant or serious disease with increasing the value of ABI agreement become poor. Even by adding post exercise ABI value agreement for significant obstruction increases by 2%.

CONCLUSION

In our study we concluded that ABI has high specificity but low sensitivity compared to CDU. (ABI has good specificity (85.71%) and sensitivity (72.72%)). Low sensitivity indicates it may miss some cases with PAD. If ABI is used alone many patients with stenosis will be diagnosed as normal. But in view of the ease of performing and its low cost, ABI would be still a good screening test. If ABI is abnormal diagnosis is almost certain but if normal and patient is asymptomatic indicates no further evaluation but in case patient is symptomatic and ABI is normal means definitely go for CDU before concluding the patient normal.

Another problem with ABI measurement is calcified vessel which is very common in diabetic patients. In these patient ABI either measured falsely high or recording not possible due to fully calcified vessel wall in such patients CDU is the last resort for the accurate diagnosis. But limitation with CDU is that it needs expensive instrument, skilled person (radiologist), and not available widely specially in smaller centres.

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COMPARISION OF COLOUR DUPLEX ULTRASOUND, ANKLE BRACHIAL PRESSURE MEASUREMENT IN PERIPHERAL VASCULAR DISEASE IN TYPE 2 DIABETES PATIENTS WITH FOOT INFECTIONS

Investigator – Dr Shivanshu Misra PGY-3 M.S General Surgery
Guide – Prof Dr C Balamurugan Chief S7

INFORMED CONSENT

Name: Age/Sex: IP:

I herewith declare that I have been explained in a language fully understood by me regarding the purpose of this study, methodology, proposed intervention, plausible side-effects, if any and sequelae.

I have been given an opportunity to discuss my doubts and I have received the appropriate explanation.

I understand that my participation in this study is completely voluntary and that I am free to withdraw from this study at any time without any prior notice&/ or without having any medical or legal rights affected.

I permit the author and the research team full access to all my records at any point, even if I have withdrawn from the study. However, my identity will not be revealed to any third party or publication.

I hereby permit the author and the research team to use the results and conclusions arising from this study for any academic purpose, including, but not limited to dissertation/ thesis/ publication/ presentation at any level.

Therefore, in my full conscience, I give consent to be included in the study and to undergo any investigation or any intervention therein.

Patient's Sign

Investigator's Sign

(DR SHIVANSHU MISRA)

COMPARISION OF COLOUR DUPLEX ULTRASOUND, ANKLE BRACHIAL PRESSURE MEASUREMENT IN PERIPHERAL VASCULAR DISEASE IN TYPE 2 DIABETES PATIENTS WITH FOOT INFECTIONS

Investigator – Dr Shivanshu Misra PGY-3 M.S General Surgery
Guide – Prof Dr Balamurugan Chief S7

Patient Information Module

You are being invited to be a subject in this study.

Before you participate in this study, I am giving you the following details about this trial, which includes the aim, methodology, intervention, possible side-effects (if any) and outcomes.

All patients admitted in SMC-GS ward with type 2 diabetes and diabetic foot infections during January to December, 2013 are included in this study. Thorough history and clinical examination will be done. Limbs were grouped on the basis of presence or absence of diabetes, clinically detectable peripheral neuropathy, and PAOD identified on colour duplex imaging. Comparative analysis of the ABPI and the distal Colour Duplex analysis were performed.

The study will be done after the patient's sign the informed consent form.

The results arising from this study will be analysed and used for academic purposes. You will be given clear instructions at every step and you are free to ask/clarify any doubts. Your identity will remain confidential. You are free to withdraw from this trial at any point of time, without any prior notice &/or without any medical or legal implications.

I request you to volunteer for this study.

Thanking you.

Investigator's Sign

(DR SHIVANSHU MISRA)
Patient's Sign

COMPARISION OF COLOUR DUPLEX ULTRASOUND, ANKLE BRACHIAL PRESSURE MEASUREMENT IN PERIPHERAL VASCULAR DISEASE IN TYPE 2 DIABETES PATIENTS WITH FOOT INFECTIONS

Investigator – Dr Shivanshu Misra PGY-3 M.S General Surgery
Guide – Prof Dr Balamurugan Chief S7

Name: **Age/Sex:** **I.P.No:**
Address: **Contact No:**

D.O.A: **D.O.D:**
CHIEF COMPLAINTS AND RELEVANT HISTORY:

VITAL SIGNS:
SYSTEMIC EXAMINATION:
CVS/RS/CNS/ABDOMEN:

LOCAL EXAMINATION:
COLOUR DUPLEX **ANKLE BRACHIAL INDEX**

Investigations:

HEMATOLOGY			**LFT**	
HB			T.BIL	
PCV			D.BIL	
RBC			AST	
TC			ALT	
DC			ALP	
PLATELET			T.PROTEIN	
ESR			S.ALBUMIN	
B.UREA				
S.CREAT				
$S.Na^+$				
$S.K^+$				
$S.Cl^-$				
$S.HCO_3^-$				

X-RAY	
ECG/ECHO	
PUS CULTURE AND SENSITIVITY	
DATE	
CBG	
FOOT PULSES	
ABPI	
COLOUR DUPLEX	

PROJECT PROPOSAL

Name of study: **COMPARISION OF COLOUR DUPLEX ULTRASOUND, ANKLE BRACHIAL PRESSURE MEASUREMENT IN PERIPHERAL VASCULAR DISEASE IN TYPE 2 DIABETES PATIENTS WITH FOOT INFECTIONS**

Investigator – Dr Shivanshu Misra PGY-3 M.S General Surgery
Guide – Prof Dr Balamurugan Chief S7

Introduction: Foot related disease is the most common cause of hospital admission among diabetes population and is recognised as the most common cause of non-traumatic lower limb amputation. People with diabetes are greater than 20 times more likely to undergo an amputation than the rest of the population. The main risk factors for the development of diabetic foot disease are peripheral neuropathy and peripheral arterial occlusive disease (PAOD).

The detection of significant arterial disease is vital to the prevention and treatment of foot disease. The unreliable nature of the symptoms and signs of lower limb arterial insufficiency in diabetes means that non-invasive tests are essential to achieve effective screening. The European working group on critical leg ischemia recommends an additional, non-invasive vascular assessment for patients with diabetes and foot ulceration.

Screening techniques commonly used in assessing lower limb perfusion are the palpation of foot pulses and calculation of the ankle-brachial pressure index (ABPI) and/or Toe-brachial pressure index (TBPI). There is continued debate regarding the influence of peripheral neuropathy and arterial calcification on the reliability of vascular screening in diabetes. The international consensus on the diabetic foot (ICDF) guidelines suggested that an ABPI of 1.15 be the upper limit above which measurements are deemed unreliable. The TBPI is an alternative test, but the influence of arterial calcification and neuropathy on Toe pressures is uncertain.

Colour duplex imaging (CDI) incorporating, Doppler wave form analysis, has been demonstrated to accurately grade the severity of arterial stenotic disease. However, the accuracy of wave form analysis alone in assessing the severity of lower limb arterial disease is uncertain.

The aim to evaluate the efficacy of foot pulses, ABPI, TBPI, and doppler wave form analysis in screening for lower limb arterial disease in diabetes, by comparison with gold standard non-invasive assessment, CDI stringent inclusion and exclusion criteria, particularly for individuals with arterial disease, would reduce the number of subjects eligible for participation.

Objectives: The aim of the study was to compare the specificity and sensitivity of ankle-brachial pressure index (ABPI) measured by peripheral Doppler with the colour duplex ultrasound (CDU) for diagnosis of PVD.

Protocol:

1. Setting:	Department of General Surgery Government Stanley Hospital, Chennai
2. Study Design:	Prospective observational study
3. Ethical clearance:	Obtained
4. Study Period:	1 year
5. Number of patients:	50
6. Materials:	All patients with diabetes
7. Inclusion Criteria:	All Type-II DM patients on treatment and Diabetic foot
8. Exclusion Criteria:	No individual, rest pain or signs suggestive of lower limb critical ischemia, other causes of peripheral neuropathy or history of reconstructive vascular surgery.

9. Methodology: All patients admitted in SMC-GS with diabetes and diabetic foot during Jan-Dec, 2013 are included in this study. Thorough history and clinical examination will be done. Various examinations including proprioception, capillary blood glucose (CBG), arterial colour duplex imaging, foot pulses and ABPI was done and sensitivity and specificity of Ankle-Brachial pressure index was compared with colour duplex imaging. The study will be done after the patients sign the informed consent form.

10. Analysis: Using SPSS 16.0.2

INSTITUTIONAL ETHICAL COMMITTEE, STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : Comparison of colour duplex ultrasound ankle brachial Pressure measurement in peripheral vascular disease in type 2 diabetes patients with foot infections

Principal Investigator : Dr.Shivanshu Misra

Designation : PG in M S (General Surgery)

Department : Department of General Surgery
Government Stanley Medical College,
Chennai-1

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 08.04.2013 at the Council Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.

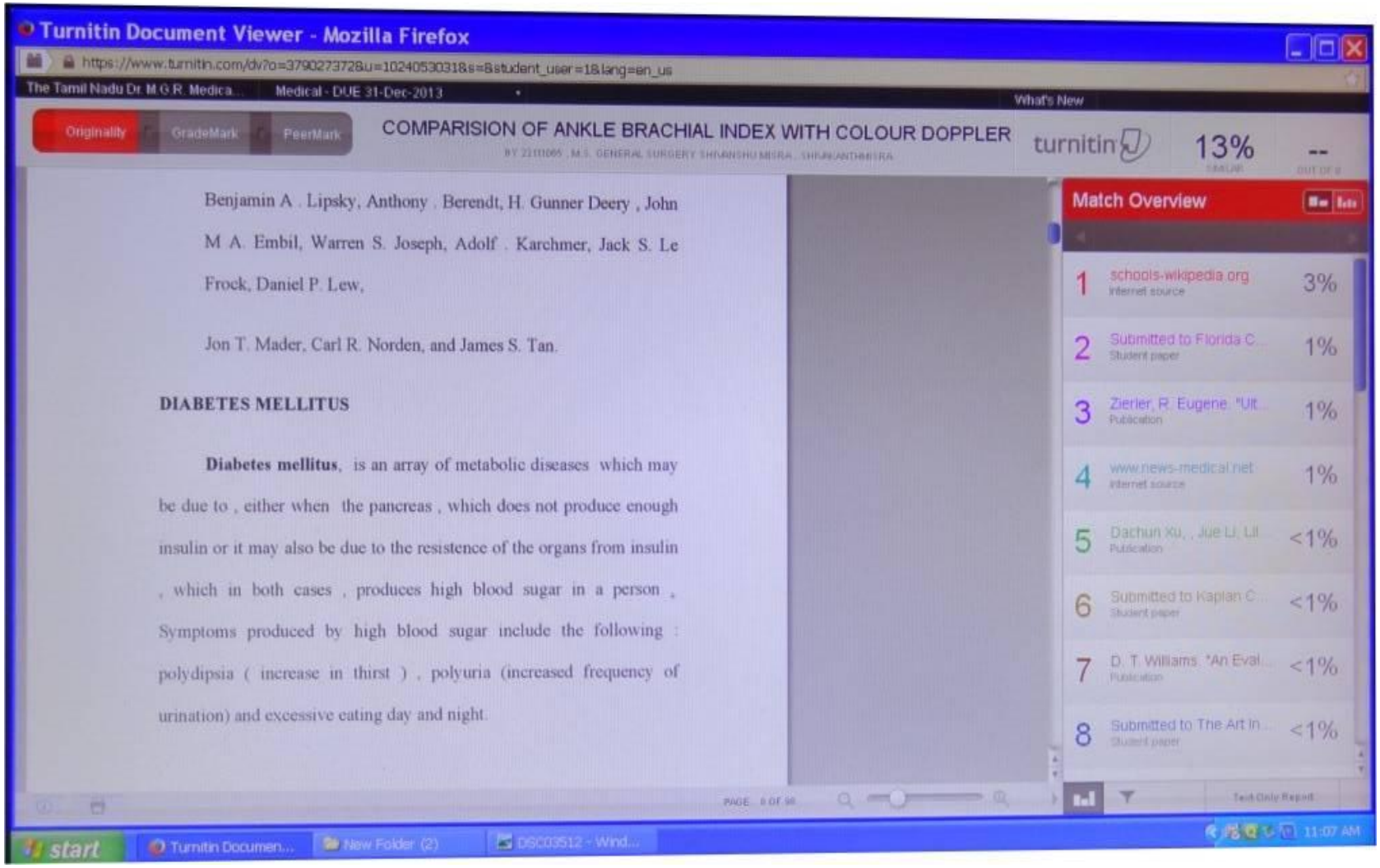
MEMBER SECRETARY, 26/10/13
IEC, SMC, CHENNAI

MASTER CHART

Sl.	IP NO.	Name	Age /Sex	DOA	Duration of disease (in year)	Socio Economic Status	BMI Kg/M^2	SBP (mmHg)	DBP (mmHg)	FBS (Mg/dl)	HBA1C %	Smoking Y/N	Treatment given OHA/Insulin /Diet/O+I	CDU% of obstruction	ABPI
1	6924	Narasimmala	35/M	25.01.2013	2	Low	21	136	88	144	7.8	N	O	30%(N)	.7(A)
2	20281	Jawarlal Nehru	54/M	05.02.2013	8	Low	22	138	84	156	9	Y	D	32%(N)	.8 (A)
3	24017	Munnusamy	54/M	17.02.2013	12	Low	23	132	96	148	7.7	Y	D	60%(A)	.7 (A)
4	25817	Bakar	46/M	09.03.2013	11	Low	21	142	82	144	7.6	Y	I	68%(A)	.5 (A)
5	27905	Ramu	43/M	19.02.2013	8	Low	22	144	80	160	9.6	Y	D	10%(N)	1 (N)
6	42336	Jothi	58/M	03.03.2013	13	Low	28	130	96	169	9.7	N	O	69%(A)	.7(A)
7	3734	Munnusamy	52/M	07.03.2013	11	Low	29	146	96	190	9.8	Y	I	70%(A)	.6(A)
8	5900	Ramdoss	50/M	26.03.2013	9	Low	28	130	100	194	11	Y	D	78%(A)	1.1(N)
9	6925	Amir basha	55/M	02.04.2013	13	Low	21	150	80	140	9.9	Y	O	72%(A)	.8(A)
10	13499	Palani	55/M	03.04.2013	12	Low	29	132	100	200	13	Y	D	(C)	-
11	14672	Mohideen Kasal	42/M	12.04.2013	11	Low	22	160	80	204	9.8	Y	I	8%(N)	1(N)
12	31736	Kuppusamy	57/M	24.07.2013	13	Low	27	130	96	202	9.9	N	D	70%(A)	.7 (A)
13	32474	Ganesan	52/M	29.07.2013	12	Low	23	150	92	220	11	Y	O	78%(A)	1 (N)
14	33410	Sadhu	45/M	05.08.2013	7	Low	21	132	82	148	9.9	N	D	32%(N)	1 (N)
15	34791	Subbaiya	68/M	13.08.2013	13	Low	28	140	90	240	10	Y	I	80%(A)	.5(A)
16	34753	Hussain	60/M	13.08.2013	12	Low	20	142	96	230	9.6	Y	O+I	(C)	-
17	36012	Munnusamy	71/M	22.08.2013	14	Low	29	130	94	240	10	N	D	60%(A)	1.1(N)
18	34557	Hamsamotdeen	45/M	26.08.2013	6	Low	23	142	92	132	7.4	Y	O	11%(N)	1(N)
19	37171	Velu	40/M	29.08.2013	10	Low	24	134	96	180	9.7	N	D	92%(A)	.8(A)
20	37695	Sridharan	57/M	02.09.2013	12	Low	22	140	80	186	10	Y	I	84%(A)	1.3(N)
21	37566	Murugesan	55/M	05.09.2013	13	Low	28	132	98	190	12	N	D	84%(A)	.6(A)
22	39749	Vinayaga Moorthy	46/M	10.09.2013	8	Low	23	142	100	140	9.8	Y	I	12%(N)	.1(N)
23	39749	Sekar	48/M	16.09.2013	7	Low	24	144	94	204	11	Y	O	13%(N)	.7(A)
24	42283	Dhayalan	55/M	01.10.2013	13	Low	29	146	100	196	11.1	Y	D	80%(A)	.5(A)
25	42278	Ambethkar	38/M	01.10.2013	3	Low	24	148	100	142	11.2	Y	I	14%(N)	.6(A)

26	42959	Pichamuthu	60/M	08.10.2013	13	Low	28	150	96	197	7	Y	D	68%(A)	1.1(N)
27	44591	Thiyagarajan	75/M	21.10.2013	16	Low	24	154	92	190	7.6	Y	D	100%(A)	.3(A)
28	45121	Pushparaj	60/M	24.10.2013	18	Low	28	144	96	210	8	Y	D	80%(A)	.5(A)
29	45596	Dhanraj	60/M	28.10.2013	20	Low	23	146	100	200	7.4	Y	D	91%(A)	.6(A)
30	45625	Mani	57/M	28.10.2013	6	Low	24	136	98	200	7.5	Y	D	10%(N)	1.2(N)
31	47355	Pattabi	70/M	09.11.2013	20	Low	24	148	92	198	7.3	Y	I	62%(A)	.1(N)
32	43928	Thangavel	70/M	09.11.2013	19	Low	28	138	100	196	9.7	N	o+I	60%(A)	.7(N)
33	18870	Chandra	45/F	06.05.2013	5	Low	29	136	100	144	7.6	N	I	68%(A)	.1(N)
34	26612	Lakshmi	68/F	23.06.2013	11	Low	24	138	96	190	9.6	N	O	60%(A)	.7(N)
35	27305	Durgadevi	67/F	26.06.2013	13	Low	29	132	100	200	9.8	N	D	70%(A)	1.2(N)
36	30407	Jeer	60/F	16.07.2013	16	Low	23	140	80	220	9.7	N	O	62%(A)	.5(A)
37	31922	Thangammal	50/F	25.07.2013	8	Low	28	136	98	188	11	N	D	12%(N)	.1(N)
38	30588	Fathima	44/F	25.07.2013	3	Low	23	142	82	142	7.2	N	I	10%(N)	.1(N)
39	32366	Kannamma	65/F	29.07.2013	7	Low	29	138	92	186	9.8	N	O	12%(N)	.1(N)
40	31818	Sarasvathi	68/F	31.05.2013	12	Low	22	146	86	200	10	N	D	82%(A)	.3(A)
41	33965	Janaki	50/F	08.08.2013	13	Low	28	138	96	190	10	N	D	80%(A)	1.3(N)
42	35815	Alsar John	65/F	21.08.2013	12	Low	24	150	100	140	7.8	N	O	78%(A)	.6(A)
43	36437	Loganaygi	82/F	24.08.2013	18	Low	29	136	100	180	9.7	N	D	82%(A)	.8(A)
44	36765	Radha	58/F	26.08.2013	9	Low	23	144	84	140	7.7	N	I+O	82%(A)	.1(N)
45	37008	Durgadevi	75/F	28.08.2013	18	Low	28	132	96	188	9.2	N	O	84%(A)	1.1(N)
46	37207	Gajavalli	80/F	29.08.2013	20	Low	28	142	98	186	9.6	N	D	74%(A)	.5(A)
47	39846	Ponnammal	40/F	03.09.2013	6	Low	24	130	88	198	9.8	N	O+I	10%(N)	.1(N)
48	38688	Lalitha	63/F	10.09.2013	15	Low	27	150	110	220	11	N	D	(C)	-
49	41413	Muneera	70/F	25.09.2013	16	Low	28	132	82	200	10.4	N	D	76%(A)	.7(A)
50	42155	Rajeshwari	65/F	01.10.2013	13	Low	24	140	98	198	9.9	N	D	78%(A)	.8(A)

DOA-	Date of Admission	Y-	Yes	CDU-	Colour Duplex Ultrasound	RI -	Resistance Index
BMI-	Body Mass Index	N-	No	ABPI-	Ankle Brachial Pressure Index	PSV-	Peak Systolic Velocity
SBP-	Systolic Blood pressure	D-	Diet	C-	Calcification	PI-	Pourcelot Index
DBP-	Diastolic Blood Pressure	O-	Oral Hypoglycaemic Drugs				
FBS-	Fasting Blood Sugar	I-	Insulin				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DIABETES MELLITUS
Diabetes mellitus, is an array of metabolic diseases which may be due to , either when the pancreas , which does not produce enough insulin or it may also be due to the resistence of the organs from insulin , which in both cases , produces high blood sugar in a person . Symptoms produced by high blood sugar include the following : polydipsia (increase in thirst) , polyuria (increased frequency of urination) and excessive eating day and night.
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