THE PREVALENCE AND SEVERITY OF PERIPHERAL ARTERIAL DISEASE AT DOPPLER ULTRASOUND AMONG DIABETIC PATIENTS AT MULAGO HOSPITAL

A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN RADIOLOGY OF MAKERERE UNIVERSITY

BY
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MBChB (MAK), Higher Diploma in Medical Ultrasound (ECUREI)

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DECLARATION

I, Dr Ameda Faith, do hereby declare that this is an original work done by me.

Contributions of other people in preparing and carrying out this study have been acknowledged and appreciated. The views expressed herein are mine unless otherwise stated, and where such has been the case acknowledgment or reference has been quoted. This dissertation in full or otherwise has not been submitted for an academic award in this or any other University or Institution of Higher learning.

Witness my hand this 18th Day of February 2010

Signed

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DEDICATION

To my husband Timothy
and our two fine sons David and Joseph

Barukh attah Adonai eloheinu melekh ha-olam
ACKNOWLEDGEMENT

The accomplishment of this study has been made possible by the support and encouragement of many people. 

My family: The Maari and Ameda clans.....you know the details. I certainly would not have stayed this long or come this far without your love and encouragement.

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Special thanks to Dr Muyinda Z, Dr Okello Omara R, Dr Bugeza S and Dr Kisembo H.

I am very grateful to Sr Agwang Betty who helped me to recruit the patients and Mr Lyazi Ivan who assisted me with the statistical analysis.

I would like to acknowledge the members of the department of Radiology who eased my burden along the way.

My fellow post graduate students who knew exactly where the shoe pinched because we wore the very same shoe. Aluta continua

I am very grateful to my dear patients who were patient and agreeable to the long examination. It truly would not have been possible without them.
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCDS</td>
<td>Colour coded duplex sonography interchangeably used with Doppler ultrasound</td>
</tr>
<tr>
<td>DM</td>
<td>Diabetes Mellitus</td>
</tr>
<tr>
<td>HT</td>
<td>Hypertension</td>
</tr>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>PAD</td>
<td>Peripheral arterial disease</td>
</tr>
<tr>
<td>P.I</td>
<td>Principal investigator</td>
</tr>
<tr>
<td>PSV</td>
<td>Peak systolic velocity</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical Package for Social Scientists</td>
</tr>
</tbody>
</table>
Definition of Terms

**Body mass index (BMI):** body weight (kgs)/height (m²)

BMI interpretation


**Diabetics:** Patients diagnosed with diabetes mellitus

**Clinical predictors:** In the history include age, the duration of diabetes mellitus, presence of hypertension, smoking, intermittent claudication, history of PAD.

In the physical examination include: body mass index (BMI), foot examination.

**Doppler ultrasound:** In this study will refer to colour coded duplex scan of the lower limb arteries.

**Peripheral arterial disease (PAD):** In this study will refer to lower limb vaso occlusive arterial disease.

**Plaques:** Focal thickening of the vessel wall with protrusion into the lumen by calcific and non calcific material.

**Stenosis:** Focal narrowing of vessel lumen.
Abstract

Introduction
 Peripheral arterial disease is a manifestation of macro vascular damage seen in diabetes mellitus, among other conditions, characterised by occlusion of the lower limb arteries. It is also a marker for coronary artery and cerebrovascular disease hence the importance of making an early diagnosis.

Objective
 The aim of this study was to establish, using Doppler ultrasound, the prevalence of peripheral arterial disease (PAD), clinical associations and sonographic findings in diabetic patients at Mulago hospital.

Methodology
 This was a cross sectional descriptive study carried out at Mulago national referral hospital, recruiting patients from the diabetic clinic. The sample size was 94 patients. All adult diabetic patients were eligible for the study except those with valvular heart lesions. The SA 9900 SONOACE by Medison was used. The principal investigator and supervisors scanned the patients. The linear probe (7-10 MHz) was used in lean patients and the curvilinear (3-5MHz) for the larger patients. The socio-demographic features, presence and duration of hypertension, duration of diabetes mellitus (DM), treatment for DM, BMI, the presence of calcifications, plaques and their length and peak systolic velocity (PSV) were recorded. Categorical data was summarized as frequency tables and charts, continuous data as mean, median and standard deviation. The chi square test was used to test for associations the significant p-value being <0.05.
Findings

The prevalence of peripheral arterial disease at Doppler ultrasound among DM patients was 26.6%. All the stenoses fell within the mild grade (0-49%). The majority of calcifications and plaques were found in the mid superficial femoral artery followed by the tibial arteries. Age and duration of diabetes mellitus were positively correlated with PAD in specific vessels only but not generally.

Conclusion

The prevalence of PAD at Doppler sonography among DM patients at Mulago Hospital is 26.6% and of a mild degree (0-49%).
CHAPTER ONE
INTRODUCTION

1.1 Background

Diabetes mellitus is a metabolic disorder of protein, fat, carbohydrate and minerals characterised by chronic hyperglycaemia due to defective insulin secretion, defective insulin action or both (1, 2, 3).

Over 150 million people are affected globally and the number is expected to increase (4, 5, 6, 7). In the sub-Saharan region the prevalence is reported to be up to 40%. Among Ugandans in the community the prevalence is 8.1% (8). The number of patients in the diabetic clinic has also increased to 20,000 registered patients (9). The metabolic derangement means that diabetics have several complications one of which is peripheral arterial disease (10). Diabetic peripheral arterial disease is due to endothelial dysfunction and thrombogenic changes due to altered flow patterns and platelet abnormalities.

The risk factors for peripheral arterial disease among diabetics are smoking, hypertension, hypercholesterolemia and albuminuria (11).

PAD is a marker for atherosclerosis and is closely associated with coronary and cerebrovascular disease (1, 2, 3). The severity of peripheral arterial disease has been correlated with an increased risk of myocardial infarction, stroke, and cardiovascular death. Intermittent claudication is the most frequent symptom of peripheral arterial disease (PAD) (3, 4, 5).

The diagnosis and treatment of peripheral arterial disease will reduce the mortality and morbidity of cardiovascular disease. It is reported that 25% of patients with ischaemia will develop critical limb ischaemia requiring amputation with its accompanying risks of mortality.

The availability of state of the art ultrasound machines at Mulago Hospital and clinics in Uganda
has revolutionized vascular imaging in the country. Doppler ultrasound displays vascular
anatomy and flow characteristics which enables diagnosis of vascular disease.
Colour coded duplex sonography (CCDS) is accurate, safe and cost effective for demonstrating
the site, type and size of stenoses. It is useful in diagnosing, planning treatment and follow up of
peripheral arterial disease. Classification criteria of disease severity and quantification of
stenoses by spectral Doppler remains the most accurate non invasive method.

1.2 Statement of the Problem

There is a global increase in the number of patients with diabetes mellitus. The number of
patients at the Mulago diabetic clinic has increased from 60-100 to as high as 300 patients per
day. Moreover many of the newly diagnosed patients come with the accompanying
complications of diabetes: peripheral arterial disease, renal failure and stroke. Fifty percent of the
admissions on the diabetic ward are due to PAD i.e. ulcers and gangrene of the lower limb.
Twenty seven percent of PAD patients get a major cardiovascular event within five years of the
PAD and 28% of these eventually die. Among patients with critical limb ischemia, up to 70% die
within five years. Four years ago Mwebaze carried out a study to determine the prevalence of
PAD among diabetic patients using ankle brachial index . Unfortunately, ankle brachial index
is not routinely done to screen patients for PAD in the diabetic clinic, and even if it were, it is
better at detecting more severe disease. There has been an increase in the number of diabetic
patients and there is expected a concomitant increase in the number of PAD patients as well.
This is compounded by the fact that half of the patients are asymptomatic or have atypical
symptoms until it’s late. There is therefore a need to find out the current prevalence.
1.3 Justification and Significance of the Study

Intermittent claudication leads to reduced mobility and eventual disability due to limb loss. Twenty seven percent of these patients go on to have a cardiovascular event and eventually die. Doppler sonography is an affordable, available, accurate and non invasive investigative modality for peripheral arterial disease. This study will give data on the current prevalence of PAD and establish the clinical predictors in our setting so that earlier diagnosis and management of PAD is done. For patients diagnosed with PAD, there are two goals of treatment: first, reducing the excessive cardiovascular risk and slowing the progression of disease, and second, addressing symptoms such as claudication and leg ischemia and preventing amputation. This means that patients will have aggressive blood pressure and lipid management and anti-platelet therapy. It is hoped that this will reduce the number of patients who come in with gangrene and ulceration due to diabetes mellitus and thus reduce the morbidity and mortality associated with limb loss.

1.4 Research Questions

Primary research question.

What is the prevalence of PAD at Doppler sonography among diabetes mellitus patients at Mulago hospital?

Secondary research questions

1. What are the grades of stenosis among diabetes mellitus patients at Mulago hospital?

2. What are the sonographic findings among the diabetic patients with PAD at Mulago hospital?

3. What are the clinical factors associated with diabetes mellitus patients at Mulago hospital?
1.5 Objectives

1.5.1 General objectives

To establish the prevalence and sonographic pattern of PAD at Doppler sonography among diabetes mellitus patients at Mulago Hospital.

1.5.2 Specific objectives

1. To establish the prevalence of PAD at Doppler sonography among diabetes mellitus patients at Mulago hospital.

2. To establish the severity of arterial stenoses among the diabetic patients with PAD.

3. To find out the sonographic pattern of PAD among the diabetic patients at Mulago hospital.

4. To determine the history and physical findings that are associated with the presence of PAD.
CHAPTER TWO
LITERATURE REVIEW

2.1 Diabetes Mellitus

Diabetes mellitus is a metabolic disorder of protein, fat, carbohydrate and minerals characterised by chronic hyperglycaemia due to defective insulin secretion, defective insulin action or both (1, 2, 3). Over 150 million people are affected globally. In the sub-Saharan region the prevalence is reported to be up to 40% and the number is expected to increase (4, 5, 6, 7). Among Ugandans in the community the prevalence is 8.1% (7). The metabolic derangement means that diabetics have several complications one of which is peripheral arterial disease (10).

2.2 Peripheral arterial disease in diabetic patients

Peripheral arterial disease is a manifestation of atherosclerotic change characterised by occlusion of the lower limb arteries. It is a marker for atherosclerosis and cardiovascular events such as myocardial infarction and stroke (15, 16, 17, 18). It is a pandemic in the U.S.A with close to 12 million people affected by it (15, 16, 17). The Fremantle study revealed a prevalence of 10% among diabetics whereas the Framingham study revealed that 20% of patients with peripheral arterial disease had diabetes (15, 16). At Mulago hospital the prevalence among diabetics is 39% using the ankle brachial index (22). Among patients with gangrene, 34% had a vascular cause in Uganda, whereas in neighbouring Kenya, 55% of the amputations were due to a vascular cause (23, 24). The metabolic derangement among diabetics results in endothelial dysfunction including apoptosis and oxidative stress which results in foam cell production a precursor of atheroma formation. These changes are mediated by C reactive protein and impaired nitrous oxide
bioavailability. Abnormalities of the smooth cells of the vessel walls results in plaque
destabilization and thrombosis. Hyperglycaemia causes platelets to take up more glucose and
subsequently aggregate further increasing the likelihood of thrombosis.
It is a chronic rather than an acute disease presenting with intermittent claudication that
progresses if not dealt with early enough. (20, 21, 22)

2.3 Severity of peripheral arterial disease
Intermittent claudication, rest pain and chronic ulcers are some of the symptoms that are
associated with peripheral arterial disease. Clinically the following symptoms have been related
to the severity of the stenoses: (19, 33) exertional pain is estimated to occur at 70% diameter
reduction, nocturnal pain at 70-90 % diameter reduction and ischaemic rest pain at 90 %
diameter reduction. In tight stenoses of acute onset the (thrombo-embolic) there may be no
progression of symptoms as noted above. At Doppler, the tighter the stenosis, the higher the
peak systolic velocity, as demonstrated in table1.

2.4 Risk factors
Among diabetic patients smoking, hypertension, hyperlipidaemia, poor glycaemic control and
proteinuria are risk factors for PAD (33, 13, 14, 15). The age of the patient, presence of peripheral
neuropathy and duration of diabetes mellitus also increase the risk for PAD.

2.5 Clinical features
The commonest symptom of PAD is intermittent claudication defined as cramping or aching
pain in the calves, thighs or buttocks on exercise e.g. walking and relieved by rest (26, 27, 28).
The most reliable clinical findings include:

1. Absent dorsalis pedis and posterior tibial pulse. This has sensitivity of 63% and
specificity of 99%.
2. Femoral arterial bruit. This has a specificity of 95% and sensitivity of 29%.

3. Atypical colour: pale, red, blue cool limb. This has a specificity of 87% and sensitivity of 98%.

Other findings are dry, scaly, atrophic, hairless skin, brittle toe nails and non-healing ulcers or gangrene.

2.6 Diagnosis of PAD

The diagnosis of PAD begins with the medical history and physical examination to identify the patients who have risk factors, symptoms of claudication and functional impairment.

Intermittent claudication, rest pain and chronic ulcers are some of the symptoms. (33)

Exertional pain is estimated to occur at 70% diameter reduction.

Nocturnal pain is estimated to occur at 70-90 % diameter reduction.

Ischaemic rest pain is estimated to occur at 90 % diameter reduction.

The physical examination involves visual inspection of the foot and palpation of the peripheral pulses. Dependent rubor, absence of hair, fissuring of the skin, dystrophic toenails, pallour on elevation and cool, dry skin are signs of vascular insufficiency (26, 28).

The femoral, popliteal, dorsalis pedis and posterior tibial pulses should be palpated.

Non invasive assessment of disease

The available non-invasive methods of PAD assessment are ankle brachial index and Doppler sonography. The ankle brachial index is defined as the ratio of the systolic blood pressure in the ankle (dorsalis pedis and posterior tibial artery) to the systolic blood pressure in the arm (brachial artery) (29, 30). It has the distinct disadvantage of not being able to distinguish between long segment occlusions and short focal stenoses. Doppler sonography on the other hand has the advantage of high sensitivity and specificity in detection of stenotic lesions and can therefore be
used to screen and triage patients (30, 31, 32). Indeed; colour flow imaging has been found to reduce the need for arteriography in 22-62 % of cases (34). The main diagnostic criteria are direct measurement, peak systolic velocity ratios and waveform changes (33, 34).

Direct measurement

This may be done in the lower external iliac, common femoral, profunda femoris and upper superficial femoral arteries. Measurement of the diameter reduction is done after assessing the plaque distribution in both the longitudinal and transverse planes so that the most appropriate diameter is selected. The length of the affected segment is also measured.

Peak velocity ratio

Stenoses cause changes in the peak velocity ratios. Normal velocities in the lower limbs arteries at rest are: iliac segments 120 cm/s, 90cm/s in the superficial femoral segments and 70cm/s in the popliteal segment.

The stenosis is identified using colour after which the sample volume is appropriately placed.

Velocity at the stenosis and 1-2 cm upstream is measured and the velocity ratio calculated.

Table 1: Velocity criteria for the assessment of lower limb artery stenoses (33, 34)

<table>
<thead>
<tr>
<th>% stenosis (Diameter reduction)</th>
<th>Peak systolic velocity cm/s</th>
<th>Velocity ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;150</td>
<td>&lt;1:5:1</td>
</tr>
<tr>
<td>0-49</td>
<td>150-200</td>
<td>15:2:1</td>
</tr>
<tr>
<td>50-75</td>
<td>200-400</td>
<td>2:4:1</td>
</tr>
<tr>
<td>&gt;75</td>
<td>&gt;400</td>
<td>&gt;4:1</td>
</tr>
<tr>
<td>occlusion</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Waveform changes

There are three components in the normal waveform of the main arteries of the resting lower limb. In young healthy individuals up to five components may be seen. The first represents the rise in pressure and acceleration of blood flow at the onset of systole. The second is a short period of reversal of flow as the pressure wave is reflected from the constricted distal arterioles. The third component represents the forward flow produced by the elastic compliance of the main arteries in diastole. In disease the two main features which may be altered are the overall wave shape and the degree of spectral broadening. “Tardus” refers to the delay in reaching the peak systolic velocity. “Parvus” refers to reduction in the downstream peak systolic velocity (35).

Exercise modifies this waveform. Therefore patients are scanned when they have not had significant exercise fifteen minutes prior to the examination.

Exercise may be used in patients who do not seem to have significant stenosis to stress the circulation so that any stenosis can be visualized. If the stenotic portion cannot be visualized but significant waveform changes are seen above and below it, they signify disease. The waveform changes include the following:

- Loss of third and second phases of the waveforms (fig 3)
- Increased acceleration time
- Damping of the wave form(fig 2)
- Spectral broadening(fig 3)
- Absent flow in occlusion
CHAPTER THREE
METHODOLOGY

3.1 Study setting
The study was done in Mulago National Referral Hospital, a 1,500 bed tertiary care facility and a
teaching hospital for Makenere medical school. It serves the suburbs around Kampala and
referrals from all over the country as well as the Great lakes region and Southern Sudan.
The study was conducted in the department of Radiology recruiting patients from the diabetic
clinic. The diabetic clinic runs from Monday to Friday from 8am to 2pm. An average of fifty
patients both new and old are seen daily (male: female 1:2)

3.2 Study design

It was a cross-sectional descriptive study with an analytic component carried out in the period of

3.3 Study population
3.3.1 Reference population
Adult diabetes mellitus patients in Uganda i.e. above 18 years.

3.3.2 Accessible population
Patients with diabetes mellitus who presented at Mulago Hospital during the study period.

3.3.3 Study unit
Diabetes mellitus patients aged 18 years and above.
3.4 Selection Criteria

3.4.1 Inclusion criteria

All adult diabetes mellitus patients.

3.4.2 Exclusion criteria

Patients with valvular disease such as:

- aortic stenosis,
- mitral stenosis
- mitral regurgitation since these would interfere with the spectral waveform.

3.5 Sampling method

Two patients were randomly selected from the queue by the diabetic nurse daily.

3.6 Sample size estimation

The sample size was estimated using the formula by Kish, 1965, for cross sectional studies as follows: Sample \( N = \frac{z^2 \cdot p \cdot q}{d^2} \)

where  \( z = 1.96 \)

\( p \) = estimated prevalence of peripheral arterial disease (39\%) \(^{(22)}\)

\( q = 100\% - p \) (61\%)

\( d \) = acceptable error (10\%)

Therefore the estimated minimum required sample size is 91 patients.

3.7 Study instrument
A pre-tested and standardised questionnaire was used as the study instrument. The investigator administered the questionnaire.

3.8 Measurements
The variables measured were from the clinical history, clinical examination and Doppler findings. The research instrument was used to record the measurements.

Study variables include:

1. Socio-demographic characteristics: age, sex, tribe, educational level, smoking, alcohol intake, occupation, religion, previous history of PAD, history of amputation, physical address.
2. Clinical characteristics: duration of diabetes mellitus, hypertension, duration of hypertension, current therapy for diabetes and hypertension, intermittent claudication.
3. Physical findings: BP, weight, height, waist and hip measurements, waist/hip ratio, lower limb pulses, temperature of the feet, capillary refilling, reduced hair, atrophy, hyper pigmentation, ulcers/gangrene
4. Doppler findings: limb(s) involved, site(s), vessel wall calcification or thickening, presence or absence of flow, number, length and grade of stenoses.

3.9 Procedure
Consent was got from the diabetic patients to participate in the study. Socio demographic data was obtained and fed into the standard pre-coded questionnaire. The history pertaining to peripheral arterial disease was obtained. This included whether the patient had been amputated due to non healing wound, been told they had PAD or whether they had cramping or pain in the lower limb that was relieved by resting (claudication questionnaire appendix 2). On clinical
examination the weight, height, waist and hip circumference, peripheral pulses, blood pressure, skin changes were documented. Doppler ultrasound was then done using the SA9900 SONOACE by Medison Company (elaborated in appendix 3)
Stenoses were classified by the velocity criteria proposed by Cossman et al (below) (33).

3.10 Quality control
The questionnaire was pre tested and translated into the local language. The Doppler studies were carried out by the P.I under the supervision of a radiologist. The same machine was used through out the study period to avoid inter equipment variability. The hard copies of the Doppler tracings were reviewed by a second radiologist. The data sheets were cross checked for completeness daily. Data was then double entered into the data software (EPI-DATA) to minimize errors.

3.11 Data analysis
SPS11 (Statistical Package for Social Scientists) was used to analyse the data. Categorical data was summarised using frequency tables, bar charts and histograms whereas continuous variables were summarised using standard deviation, means and medians. Associations were determined using the chi square test for categorical data.

3.12 Ethical considerations
3.12.1 Institutional approval
Approval was obtained from the department of Radiology, The Makerere University Research and Ethics committee, Mulago hospital Research and Ethics committee and the Uganda National Council for Science and Technology.

3.12.2 Informed Consent
A thorough explanation of the nature of the study, risks and benefits to each of the patients was done and written consent obtained as a signature or thumbprint. This was a low risk study. The patient’s right not to participate or withdraw consent or withdraw from the study at any time without penalties was respected.
3.13 Study Limitations

The length of examination for each patient (one hour) was cumbersome. Some patients declined the examination most likely due to the waiting time prior to the examination.
CHAPTER FOUR
RESULTS

Ninety four adult diabetic patients from the outpatient clinic were scanned. Both lower limbs were scanned beginning at the common femoral artery. There were no amputees.

4.1 Socio demographic characteristics

Age

The age range was 19 - 83 years with the mean age being 51.9 years (standard deviation 12.6 years) and the median age 52 years (tab2).

Gender

The females were more than the males (n=94) in the ratio 1.8:1.

Marital status

Among the study participants 66 (70.2%) were married, 14 (14.9%) were widows or widowers, 6 (6.4%) were divorced and14 (8.5%) had never been married.

Education

Thirty nine of the participants had attained primary education (42.6%), 30(31.9%) ordinary level, 11 (11.7%) had no formal education, 6 (6.4%) advanced level and 7(7.5 %) had been to university or attained a diploma from a tertiary institution.

More males had attained a higher education level than the females and there were more females with minimal education compared to males (fig 3).
<table>
<thead>
<tr>
<th>Gender</th>
<th>Frequency (n=94)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>61</td>
<td>64.9</td>
</tr>
<tr>
<td>Male</td>
<td>33</td>
<td>35.1</td>
</tr>
<tr>
<td><strong>Education level</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No formal Education</td>
<td>11</td>
<td>11.7</td>
</tr>
<tr>
<td>Primary</td>
<td>40</td>
<td>42.6</td>
</tr>
<tr>
<td>O-Level</td>
<td>30</td>
<td>31.9</td>
</tr>
<tr>
<td>Advanced</td>
<td>6</td>
<td>6.4</td>
</tr>
<tr>
<td>University</td>
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<td>6.4</td>
</tr>
<tr>
<td>Other Tertiary Institution</td>
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<td>1.1</td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td>23</td>
<td>24.5</td>
</tr>
<tr>
<td>Full time worker</td>
<td>14</td>
<td>14.9</td>
</tr>
<tr>
<td>Self employed</td>
<td>56</td>
<td>59.6</td>
</tr>
<tr>
<td>Student</td>
<td>1</td>
<td>1.1</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never been married</td>
<td>8</td>
<td>8.5</td>
</tr>
<tr>
<td>Divorced</td>
<td>6</td>
<td>6.4</td>
</tr>
<tr>
<td>Married</td>
<td>66</td>
<td>70.2</td>
</tr>
<tr>
<td>Widow/widower</td>
<td>14</td>
<td>14.9</td>
</tr>
<tr>
<td><strong>Religion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Christian</td>
<td>72</td>
<td>76.6</td>
</tr>
<tr>
<td>Muslim</td>
<td>22</td>
<td>23.4</td>
</tr>
</tbody>
</table>
The outer doughnut represents the males and the inner one the females. More males had been through O and A level as well as university.

**Occupation**

Sixty percent (56) of the participants had their own businesses whereas twenty four percent (23) of them were retired and fourteen percent in full time formal employment (tab2). Only one participant was a student. There were slightly more retired females than males (13 cf 10). More females were self employed than men (41 out of 56). More males were in full time formal employment than females with a ratio of 8:6.

**Religion**

There were 72 (76.6%) Christian and 22 (23.4%) Muslim participants.
4.2 Prevalence and severity of Peripheral arterial disease among DM patients at Mulago hospital

Out of the ninety four patients, there were sixteen patients with plaques and calcifications, fifteen with calcifications only and nine with plaques only. Therefore twenty five patients out of ninety four, equivalent to 26.6% had Peripheral Arterial Disease.

All of the patients with plaques had a mild degree of stenosis (0-49%) graded according to Cossman et al (34). There were no patients with moderate (50-75%) or severe stenosis (>75%).

4.3 Clinical factors

*BMI*

Sixty eight of the ninety four participants had an abnormal BMI (72.3%); 41 (60.3%) were overweight, 20 (29.4%) obese and 7(10.3%) were morbidly obese. Only 26 (27.7%) of the patients had a normal body mass index. Forty nine women compared to nineteen men had an abnormal BMI.

There was no statistical association between the BMI and the presence of PAD (p=0.692).

Table 3: Duration of diabetes mellitus among the different age groups.

<table>
<thead>
<tr>
<th>Duration of diabetes mellitus</th>
<th>&lt;50 years</th>
<th>&gt;50 years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10 years</td>
<td>80.6%(29)</td>
<td>56.9%(33)</td>
<td>66%(62)</td>
</tr>
<tr>
<td>10-20 years</td>
<td>16.7%(6)</td>
<td>37.9%(22)</td>
<td>29.8%(28)</td>
</tr>
<tr>
<td>&gt;20 years</td>
<td>2.8%(1)</td>
<td>5.2%(3)</td>
<td>4.3%(4)</td>
</tr>
</tbody>
</table>
The inner doughnut represents the females, the outer one the males. There was no male in the morbidly obese category. More males had a normal BMI than females.

The majority of the patients were in the overweight category.
Figure 7: PAD according to the duration of diabetes mellitus

The outer doughnut represents the male patients and the inner doughnut the female patients. Three quarters of the male patients and half of the female patients had been diabetic for less than ten years.

Figure 8: Distribution of PAD vs treatment option

The inner doughnut represents those who had PAD. OHGA = oral hypoglycaemic agents. Most of the PAD patients were on OHGA.
Duration of diabetes mellitus

More patients had diabetes for less than ten years i.e. 62 pts (73%). Twenty eight patients (22.4%) had diabetes for 11-20 years 4.6% had had diabetes for more than twenty one years (fig7).

Treatment options

Sixty six (70.1%) of the patients were treated on oral hypoglycaemic agents only, twenty two (23.4 %) were on insulin only and five (5.4 %) were taking insulin and oral hypoglycaemics. Only one patient was on exercise and diet alone (1.1%).

Sixty seven percent (67.5%) of the patients with PAD were on oral hypoglycaemic agents (fig8). Forty five (68.2%) of the sixty six patients on oral hypoglycaemics were above 50 years compared with 21 patients (38.2%) below the age of 50.

The majority,22 (63.6%) of the patients taking only insulin were below 50 years.

Hypertension

More than half of the patients were hypertensive 51 (56.4%).Thirty seven (69.8%) of the patients had been hypertensive for 10 years or less. Thirty percent (30.2%) had been hypertensive for 12-24 years (table 4). Seventy nine percent (53) of the hypertensive patients were above 50 years twenty one percent (41) were below 50 years. There were more females than males who were hypertensive (36 cf 17 i.e. 67.9 % cf 32.1 %).
Table 4: Duration of hypertension vs age

<table>
<thead>
<tr>
<th>Duration of HT</th>
<th>&lt;50 years</th>
<th>&gt;50 years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-5 years</td>
<td>8(72.7%)</td>
<td>17(40.5%)</td>
<td>25(47.2%)</td>
</tr>
<tr>
<td>6-10 years</td>
<td>1(9%)</td>
<td>11(26.2%)</td>
<td>12(22.6%)</td>
</tr>
<tr>
<td>11-15 years</td>
<td>2(18.2%)</td>
<td>9(21.4%)</td>
<td>11(20.8%)</td>
</tr>
<tr>
<td>16+ years</td>
<td>0</td>
<td>5(11.9%)</td>
<td>5(9.4%)</td>
</tr>
<tr>
<td>Total</td>
<td>11(100%)</td>
<td>42(100%)</td>
<td>53(100%)</td>
</tr>
</tbody>
</table>

4.4 Sonographic findings

There were three types of sonographic findings:

1. Calcified plaques only

This was calcific material that was heterogeneous and protruding into the vessel lumen.

2. Calcifications and calcified plaques

This included both echogenic material in the vessel wall and calcific material protruding into the vessel lumen.

3. Calcifications only

These were echogenic foci along the vessel wall but no areas of protrusion into the vessel lumen.

There were no soft plaques. Of the 188 lower limbs scanned, 9 had plaques only, 16 had both plaques and calcifications and 15 had calcifications only.
Figure 9 Calcifications of the vessel walls

Calcification of the walls of the mid superficial femoral and posterior tibial arteries (a and b).
The calcifications appear as echogenic "dashes" along the vessel wall. Normal vessel walls are noted in figure 10c.

The majority of the patients had multiple plaques, all of which were heterogeneous. The total number of plaques was 35, distributed as shown below (fig 13).

There were more plaques in the right lower limb (65.7%) than in the left limb (34.3%). The majority of the plaques were in the mid superficial femoral artery. The average plaque length was 0.41 mm with a range of 0.2-1.4 mm.

Calcified plaques ("plaques only")

There were nine patients that had calcified plaques only. Six (66.7%) of the patients were below the age of 50 (tab 5).

The age of the patient was not significantly related to the presence of plaques p=0.066.

Females were the only patients with plaques only. There were no male patients with plaques only (table 6). There was a significant association between the female gender and the presence of plaques only (p=0.02).
All the nine patients with “plaques only” had been diabetic for less than twenty years (p=0.662). Seventyeight percent (7) of the nine patients with “plaques only” had been diabetic for less than ten years (tab7).

Seventy eight percent of the patients with “plaques only” were being treated with oral hypoglycaemic agents (p=0.692).

Table 5: “Plaque only” distribution according to patient age

<table>
<thead>
<tr>
<th></th>
<th>Age Below 50</th>
<th>Age 50 and above</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLACtE ONLY</td>
<td>Absent</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>6</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>83.3%</td>
<td>16.7%</td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td>55</td>
<td>3</td>
<td>58</td>
</tr>
<tr>
<td></td>
<td>94.8%</td>
<td>5.2%</td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td>85</td>
<td>9</td>
<td>94</td>
</tr>
<tr>
<td></td>
<td>90.4%</td>
<td>9.6%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Most of the plaques were in the patients below 50 years of age.

Table 6: “Plaques Only” in the different gender

<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th>Male</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLACtE ONLY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>52</td>
<td>33</td>
<td>85</td>
</tr>
<tr>
<td></td>
<td>85.2%</td>
<td>100.0%</td>
<td>90.4%</td>
</tr>
<tr>
<td>Present</td>
<td>9</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>14.8%</td>
<td></td>
<td>9.6%</td>
</tr>
<tr>
<td>Total</td>
<td>61</td>
<td>33</td>
<td>94</td>
</tr>
<tr>
<td></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

No males had plaques only
Table 7: Duration of DM among the patients with “plaques only”

<table>
<thead>
<tr>
<th>Duration of DM</th>
<th>Less 10 years</th>
<th>10 - 20 years</th>
<th>More than 20 years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLAQUE ONLY</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>55</td>
<td>26</td>
<td>4</td>
<td>85</td>
</tr>
<tr>
<td></td>
<td>88.7%</td>
<td>92.9%</td>
<td>100.0%</td>
<td>90.4%</td>
</tr>
<tr>
<td>Yes</td>
<td>7</td>
<td>2</td>
<td></td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>11.3%</td>
<td>7.1%</td>
<td></td>
<td>9.6%</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>28</td>
<td>4</td>
<td>94</td>
</tr>
<tr>
<td></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Seven of the nine patients with plaques had been diabetic for less than ten years.

Table 8: BMI vs. “Plaques only”

<table>
<thead>
<tr>
<th>18.5 - 24.9</th>
<th>25.0 - 29.9</th>
<th>30.0 - 39.9</th>
<th>More than 40</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Over wt</td>
<td>Obese</td>
<td>Morbidly obese</td>
<td></td>
</tr>
<tr>
<td>PLAQUE ONLY</td>
<td>No</td>
<td>Yes</td>
<td>Total</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>25</td>
<td>1</td>
<td>7</td>
<td>85</td>
</tr>
<tr>
<td></td>
<td>96.2%</td>
<td>3.8%</td>
<td>100.0%</td>
<td>90.4%</td>
</tr>
<tr>
<td>Yes</td>
<td>36</td>
<td>5</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>87.8%</td>
<td>12.2%</td>
<td>100.0%</td>
<td>9.6%</td>
</tr>
<tr>
<td>Total</td>
<td>26</td>
<td>41</td>
<td>20</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

There were no underweight patients. None of the morbidly obese patients had “plaques only.”
**Figure 10:** Calcified plaques in the left anterior tibial artery

*Note the irregular protrusion into the vessel lumen as well as the heterogeneously echogenic appearance.*

**Figure 11:** Calcified plaques in the mid superficial femoral arteries

*Irregular calcific protrusion into the mid SFA lumen. There is a flow void along the lumen when colour is applied. Aliasing is seen just proximal to the plaque (different patients).*
Spectral broadening and loss of the second wave form as well as markedly elevated PSV in the left posterior tibial artery.

Figure 13: Distribution of the plaques in the lower limb arteries.

The superficial femoral artery had the largest number of plaques followed by the common femoral and the tibial arteries.
The inner doughnut represents the patients who had PAD, the outer, those who didn't. More older patients had PAD.

**Calcified plaques and calcifications**

These were the majority of the findings among those who had pathology. Sixteen of the patients had calcified plaques and calcifications.

Thirteen of the patients were fifty years and above; three were below fifty years (fig 10).

There was no significant relationship between the age of the patient and the presence of both plaques and calcifications (p=0.077).

Ten of the sixteen patients who had plaques and calcifications were male. There was a significant relationship between the male gender and the presence of calcifications and plaques (p=0.012).

Seven of the sixteen patients had had diabetes mellitus for the duration 10-20 years. There was no significant relationship between the duration of diabetes and the presence of PAD.
Twelve of the sixteen patients with plaques and calcifications were hypertensive. There was no significant relationship between the presence of hypertension and the presence of both calcifications and plaques (p=0.99).

Twenty percent of the patients had been hypertensive for 1-5 years and this was the largest group. There was no significant relationship between the duration of hypertension and the presence of calcifications and plaques.

There was a significant relationship between the treatment option (p=0.039 for the patients on oral hypoglycaemic agents) and the presence of calcifications and plaques. Eight out of sixteen patients who were on oral hypoglycaemic agents had both calcifications and plaques.

**Calcifications only**

There were seven calcifications in the common femoral artery, fifty four in the superficial femoral artery, ten in the popliteal artery, twenty two in the posterior tibial artery and twenty four in the anterior tibial artery.

Thirteen of the fifteen patients with calcifications only were above fifty years (tab9). The presence of calcifications only was positively associated with age (p=0.03).

More females than males had calcifications only but there was no statistical association (p=0.665) see tab10.

Fifty three percent (7 out of 15) of the patients who had calcifications had a normal BMI (tab11). There was no significant association between the BMI and the presence of calcifications p=0.366.
Table 9: Calcifications only vs. age

<table>
<thead>
<tr>
<th></th>
<th>Below 50</th>
<th>50 and above</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CALCIFICATION ONLY</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>34</td>
<td>45</td>
<td>79</td>
</tr>
<tr>
<td></td>
<td>94.4%</td>
<td>77.6%</td>
<td>84.0%</td>
</tr>
<tr>
<td>Present</td>
<td>2</td>
<td>13</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>5.6%</td>
<td>22.4%</td>
<td>16.0%</td>
</tr>
<tr>
<td>Total</td>
<td>36</td>
<td>58</td>
<td>94</td>
</tr>
<tr>
<td></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

*Over eighty percent of the patients with calcifications only were fifty years and above.*

Table 10: Calcifications only vs gender

<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th>Male</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CALCIFICATION ONLY</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>52</td>
<td>27</td>
<td>79</td>
</tr>
<tr>
<td></td>
<td>85.2%</td>
<td>81.8%</td>
<td>34.0%</td>
</tr>
<tr>
<td>Present</td>
<td>9</td>
<td>6</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>14.8%</td>
<td>18.2%</td>
<td>16.0%</td>
</tr>
<tr>
<td>Total</td>
<td>61</td>
<td>33</td>
<td>94</td>
</tr>
<tr>
<td></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

*Sixty percent of the patients with calcifications only were female*
Table 11 Calcifications only vs. BMI

<table>
<thead>
<tr>
<th></th>
<th>18.5 - 24.9</th>
<th>25.0 - 29.9</th>
<th>30.0 - 39.9</th>
<th>More than 40</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CALCIFICATION</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ONLY Absent</td>
<td>19</td>
<td>35</td>
<td>18</td>
<td>7</td>
<td>79</td>
</tr>
<tr>
<td></td>
<td>73.1%</td>
<td>85.4%</td>
<td>90%</td>
<td>100.0%</td>
<td>84.0%</td>
</tr>
<tr>
<td>Present</td>
<td>7</td>
<td>6</td>
<td>2</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>26.9%</td>
<td>14.6%</td>
<td>10%</td>
<td>16.0%</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>26</td>
<td>41</td>
<td>20</td>
<td>7</td>
<td>94</td>
</tr>
<tr>
<td></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

None of the morbidly obese patients had calcifications only. Over eighty percent of the patients with calcifications only were in the normal and overweight categories.

Table 12 Calcifications only vs. Duration of DM

<table>
<thead>
<tr>
<th></th>
<th>Duration of DM</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Less 10 years</td>
<td>10 - 20 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>79</td>
<td>84.0%</td>
</tr>
<tr>
<td>CALCCIFICATION</td>
<td>Absent</td>
<td></td>
</tr>
<tr>
<td>ONLY</td>
<td>53</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>85.5%</td>
<td>78.6%</td>
</tr>
<tr>
<td>Present</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>14.5%</td>
<td>21.4%</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

All the patients with calcifications only had been diabetic for less than twenty years.

None of the patients with calcifications only had been diabetic for more than twenty years.
CHAPTER FIVE
DISCUSSION

5.1 Baseline characteristics

Ninety four patients were scanned equivalent to one hundred eighty eight lower limbs. The common femoral, superficial femoral, popliteal and both tibial arteries were scanned.

Gender

The females are more than the males with a ratio of 2:1. This is the expected ratio seen globally as well as in the clinic \(^{(9)}\). This may be due to the fact that females have better health seeking behaviour than males as well as the normal population distribution of males: females in the community.

Age

The mean age of the patients was 51.9 years with a standard deviation of 12.6 years which was the expected mean age. The majority of the patients have type II diabetes and this is in the older age group i.e. above 45 years \(^{(9)}\).

Smoking

There was only one patient still smoking. This may be explained by the fact that as part of their health education, patients are discouraged from smoking and encouraged to take a healthy diet. Smoking is a known risk factor for peripheral arterial disease as well as coronary artery disease and stroke.

Education

Females had a lower level of education compared to men. This is a global trend and in some studies has been found to have a bearing on the self care and hence diabetic control. \(^{(36)}\)
5.2 The prevalence and severity of Peripheral arterial disease

Of the 94 patients scanned 9 had plaques only, 15 had calcifications only and 16 had plaques and calcifications. The prevalence of peripheral arterial disease among DM patients at Mulago hospital is, therefore, 26.6%. This is a lower prevalence than that found by Mwebaze but within the range of the prevalence in sub-Saharan Africa and the United States of America (15, 22).

The lower prevalence maybe because of the separation of plaques from calcifications in this study. Some argue that the calcifications are a continuum of plaques, in which case the prevalence would be 40.1% which is closer to Mwebaze’s.

There was no severe or moderate grade of stenosis. The only grade of stenosis was mild (0-49%). The shorter duration of Diabetes Mellitus and the younger age of our population may explain this finding.

5.3 Clinical factors

BMI

Obesity is known to be a risk factor for DM. It is therefore not surprising that 73% of the study participants were obese in varying degrees (41). Moreover obesity in the community is not uncommon (8). Females were more obese than males. Similar findings were reported by Mwebaze as well as Lasky D, Otim M et al. (8,22) There was no association between the presence of PAD and the BMI p=0.469. This is surprising since obesity is closely associated with metabolic syndrome which is one of the causes of PAD among DM patients (45). The distribution of the patients with the abnormal BMI, with more patients being over weight as opposed to morbidly obese, is likely to be the reason for the lack of relationship in this study.
Duration of diabetes mellitus

The majority of our patients were below fifty years of age. Since most of them had adult onset DM, the number of patients with a short duration were the majority (73% were diabetic for less than ten years). The duration of DM as opposed to the glycaemic control has been found to be associated with PAD in other studies. The relative youth of the Ugandan population compared to the population in the West would explain the shorter duration of DM as well. Since not much can be done about the passage of time, other factors that contribute to the risk of PAD and its complications such as dyslipidaemia and endothelial abnormality can be addressed. The use of cholesterol lowering drugs, irrespective of the cholesterol levels, and anti thrombotic agents has been recommended in other studies.

Hypertension and Duration of hypertension

There was no statistical association between the presence or duration of hypertension and the presence of peripheral arterial disease (p=0.17). This may be explained by the fact that the majority of patients (37= 69.8%) had been hypertensive for less than ten years since a longer duration of hypertension is a risk factor for peripheral arterial disease. Hypertension increases the risk for PAD in patients with DM because it causes physical stress to an already abnormal endothelium. This means that there must be good control of the hypertension to delay its deleterious effects.

Treatment options

Most of the patients were on oral hypoglycaemic agents since they had type II diabetes. There was no significant association between the presence of PAD and the treatment option p=0.469. The correlation of the use of oral hypoglycaemic agents with the presence of PAD is not discussed in any other literature.
5.4 Sonographic findings

5.4.1 Distribution of plaques and calcifications

The majority of plaques were in the mid superficial femoral artery followed by the tibial arteries. Van Freen et al found, at angiography, that the majority of plaques were in the popliteal–tibial segments as opposed to the femoral–popliteal segment. These findings may support the school of thought that says calcifications and plaques are a continuum of the same disease process or they may be due to a difference found in our population possibly related to the younger age group. It is, therefore, not sufficient to interrogate only below the knee in our DM patients since more pathology is proximal.

Calcified Plaques “plaques only”

The lack of relationship between the presence of plaques and age may be due to the relatively younger age of the Ugandan patients in this study since increasing age has been found to be a risk factor for PAD in other studies. As our population begin to age, it will be prudent to screen them, routinely, for PAD.

The female gender was significantly related with the presence of “plaques only” vs. plaques and calcifications. Other authors have found no difference in the prevalence of PAD between males and females. More females had the traditional risk factors for PAD including abnormal BMI and hypertension which may be explain this finding. A screening program would do well to prioritize females.

In spite of the majority of patients having abnormal BMI there was no significant relationship between the presence of plaques and the BMI. A similar finding was reported in a study in Taiwan. The distribution of the abnormal BMI towards the lower scale i.e. overweight and obese vs. morbidly obese may explain this. The possibility of minimal or no dyslipidaemia is
also likely since this is the underlying cause of PAD in obesity\(^{(45)}\). Our patients should be encouraged to keep their weight within the expected BMI.

*Calcifications and calcified plaques*

The lack of correlation between the presence of plaques and calcifications with age may be due to the relatively younger age group in the Ugandan population. Rabin K and Khoo EM in Malaysia reported no significant relationship found between the age, gender smoking, hypertension, and duration of diabetes mellitus or dyslipaediaemia\(^{(38)}\). In addition, a study in Taiwan found age, duration of diabetes mellitus and albuminuria were confounders\(^{(39)}\).

Other studies have shown increasing age to be a risk factor\(^{(18,19,20,27)}\).

The male gender was significantly related to the presence of plaques and calcifications (\(p=0.012\)). Health seeking behaviour and compliance differences between men and women may explain this since there is no difference in the lipid profile of diabetic men and women\(^{(36,37,42)}\). Women have been shown to be more sensitive to illness and more compliant to medication than men\(^{(42)}\).

The younger age of the Ugandan population as well as the shorter duration of DM (73\% of the sample size had been diabetic for less than eleven years) may explain the lack of relationship between the presence of calcifications and plaques. In studies where the relationship between the presence of calcifications and plaques and the duration of DM was significant the duration of significance were fifteen-twenty years\(^{(40,41)}\). A screening program to diagnose PAD needs to be put in place as our population ages.

There was no statistical association between the presence or duration of hypertension and the presence of calcifications and plaques unlike most other studies (\(p=0.17\)).
This may be explained by the fact that the majority of patients had been hypertensive for less than ten years (69.8%) since a longer duration of hypertension is a risk factor for calcifications and plaques\(^{13,14,15}\).

**Calcifications**

The majority of the calcifications were in the superficial femoral artery followed by the anterior and posterior tibial arteries. Calcifications may not be innocent bystanders. Guzman et al found that tibial artery calcifications could predict amputation in patients with PAD\(^{48}\). This suggests that our patients with calcifications should be treated the same as those with plaques to reduce the risk of stroke and coronary events as well as limb loss.

There was a significant relationship between the age of the patient and the presence of calcifications \(p=0.03\). Medial sclerosis has been postulated as the cause of calcification in the older patients. This may not be the case in our patients who had a mean age of 51.9 years.

Intimal calcifications are found in PAD\(^{49}\). They are characterised by focal areas of echogenicity as opposed to long segments of calcifications. It would be interesting to look at the layers involved at ultrasound and possibly differentiate between intimal and medial calcifications.

The duration of diabetes mellitus was not associated with the presence of peripheral calcifications (\(p\)-value = 0.477). These findings are in agreement with the study carried out by Rabin K and Khoo EM in Malaysia where no significant relationship was found between the age, gender, smoking, hypertension, duration of diabetes mellitus or dyslipidaemia\(^{38}\). In addition, a study in Taiwan found age, duration of diabetes mellitus and albuminuria were confounders\(^{39}\).

Thirteen of the fifteen patients with calcifications only had normal BMI (7) and six were overweight. Coustacou et al had similar findings\(^{50}\).
CHAPTER SIX
CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

The prevalence of peripheral arterial disease at Doppler ultrasound among DM patients at
Mulago hospital is 26.6%.

The grade of stenosis was mild (0-49%) in all the patients examined.

The presence of both plaques and calcifications was the most common pathology.

All the plaques were calcified.

The majority of calcifications and plaques were in the superficial femoral and tibial arteries.

Among the out patients one third had calcifications.

The female gender is significantly associated with the presence of plaques.

The male gender is significantly associated with the presence of both calcifications and plaques.

6.2 Recommendations

Based on the study findings, the following are recommended:

- Have a screening and interventional program in place since our population is ageing and
  therefore likely to have a larger number of patients with PAD in the next ten-fifteen
  years.

- Follow up the patients with both calcifications and plaques.

- A larger study be done to further assess the clinical predictors of PAD among diabetic
  patients.

- A study be done to further elucidate on the location of calcifications in the vessel wall to
  determine whether in our setting the implication of a calcification is similar to a plaque.
REFERENCES
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APPENDICES

Appendix 1a: English Consent form

Title of the study

The prevalence and severity of peripheral arterial disease at Doppler ultrasound among diabetic patients at Mulago hospital.

Investigator

My name is Dr Ameda from the department of Radiology, Mulago hospital. I am carrying out a study on “The prevalence and severity of peripheral arterial disease at Doppler ultrasound among diabetic patients at Mulago hospital”.

Purpose and background of the study

Peripheral arterial disease is a progressive disease of the blood vessels which leads to gangrene (drying up or rotting of the legs) if not treated early. It is common among diabetic patients. This study will help the doctors know how big this problem is. It will also help them to know, from some of the questions you will answer and the examinations carried out, which patients are likely to have this disease and so start them on treatment before it worsens.

Procedure

If you agree to take part in this study you will answer some questions on your social and medical history. There after you will be requested to have a physical examination which will include measurement of your height, hip and waist width as well as your weight and your blood pressure. After this your feet will be examined Finally you will have your lower limb blood vessels examined by an ultrasound machine (ka TV) at the department of Radiology.

You will be asked to lie on a couch and expose the lower limb upto the groin. Your privacy will be protected. Ultrasound gel will be spread on each of the lower limbs and a scan done. Pictures will be taken of the blood vessels on the ultrasound machine. (Not of yourself). There
will be minimal discomfort when compression may have to be done to improve the image
quality. The examination takes thirty to forty five minutes.

Risk and discomfort

There may be some discomfort from some of the questions and when compression may have to
done on your leg. The examination may be long. All the information obtained from you will be
treated with the utmost confidentiality and only used for research and your treatment where
necessary.

Benefits

You will be able to find out if your leg arteries are sick and so get treated early. Many other
patients will be able to get earlier treatment because of the results from this study and so avoid
losing their limbs. You will not be required to pay for any of the procedures.

Withdrawal from the study will not affect your usual treatment in any way. You participate
voluntarily and withdraw voluntarily. If you have any problem with this study please feel free to
call me on 0772565863 or Dr Ibingira Charles on 0414530020

Confidentiality

Your name will not be included anywhere in the data sheets. All the information obtained
will be carefully stored.
Statement of Consent

I have received an explanation of the study that is being carried out. I understand that I will be asked some questions, be examined, and undergo ultrasound examination of my lower limb vessels. I have understood the risks involved and I agree to participate in this study.

Patient’s name................................................Signature or thumbprint.................................

Date..........................................................

Investigator...............................................signature.........................................................

Date..........................................................

Witness’s name..........................................Signature.........................................................
Appendix 1b: Luganda Consent Form

FOOMU Y'OUKKKIRIZA KW'ANNEETABA MU KUNOONYEREZA KU
BULWADDE BWE MISUWA MUBALWADDE BA SUKALI MU DWALIiro LYE
MULAGO NGA TUKOZESA KA SCAN(KA TIVI)
Nze dokita Ameda Faith omunoonyereza omukulu mu kunoonyereza bulwadde bwe misuwa mubalwadde ba sukaali mu dwaliro lye Mulago nga tukoza ka san (aka TV). Ndi musomi mu department eya radiology (ebyebibanaanyi)

Ensibuko nebigendelelwa byo kunoonyereza kuno
Obulwadde bwe misuwa gya magulu butandikiriza mpola naye buviramu ekitundu kyokugulu ukuvuunda nokukala oba okutemwako singa buba tebulabiridwa bulungi mukusooka. Obulwadde buno busangibwa nyo mubalwadde basukaali. Okunonyereza kuno kujja kuyamba okumanya obukulu bwobulwadde buno mubalwadde ba sukaali era kijja kuyamba okusobola okutandika obujjanjabi amangu nokuziyiza ebigere okufa

Ebinkolebwa
Bwokiriza okwettaba mumusomo guno, ojja kubaako byobuzibwa kubikukwatta kumbeerayo nobulwadde. Ojja kukeberebwa omusaawo omuli nokukoizesa ekyuma ekyomulemba eky a scan(ka TV). Ojja kutekebwa ku kitanda okeberebwe okugulu okuiira ddala ku bisambi okutuuka ku bigere. Ebifananyi bye misuwa gyamagulu ebinava mu scan bijja kуwebwa omusawo asobole okujjanjaba ne bilala bitwalibwe Dr. Ameda okuyamba mu kunonyereza kuno

Ebirungi ebiri mukunonyereza kuno:
Ebinazuulibwa biggya kweyongera okuyamba n’okutaangazza enzijjanjaba yobulwadde bwemisuwa mubalwadde ba Sukaali. Essiringi emitwalo etaano zewalisasulidde sikaani eno toja zisasula.

Obuzibu mukunonyereza kuno:
Sikaani eyinza okutwaala edakiika nga asaatu okolebwa naye terina ngeri yonna gyekosa bulamu bwo.

Ebikwata ku ddembe lyo ngomulwadde
Nnyinyonyoddwa era nkakasiddwa ntì sijjakufuna obukosefu oba obulabe oluvanyuuma lwokukolwebwako scan eno(aka TV) era nga kufuna obujjanjabi bwe bumu nga obwabo
abatectabye mu kunoonyereza kuno naye nga balina obulwadde bwe bumu.
Ntegezeddwa nti ndi wa ddembbe okuva mu kunoonyereza kuno esaawa y'onna bwemba njagadde ewataali okunyigirizzibwa eri obujjanjjabibwange.
Ebirala byonna bye nnetaaga okumanya biweebwa Dr.Faith Ameda,(0772565863)
omunoonyereza omukulu oba bakalabalaba bo'okunoonyereza kuno bano wamanga;
Prof Kawooya M.G. essimu: 0772505189 (Dept of Radiology –Mulago Hospital)
Dr. Byanyima R.K essimu: 0772500680 (Dept of Radiology-Mulago Hospital)
Dr. Ibingira C essimu 0414530020 (Sentebe w'akakiko akakulira okunoonyereza mu Ttendekero ly'abasawo mu Makerere University)

Okukkiriiza
Ntegedde nti byonna ebikwatako /ebikwaata ku mulwadde wange bijjakukuumibwa nga bya kyama.
Ntegedde nti mukuteckaako omukono ku kiwaandiko kino mpaddeyo okukkiriiza kwange nti ebinazuulibwa kunze/ ku mulwadde wange bijja kukozezibwa mu kunoonyereza kuno.
Nsobola okufuna ko foamu eyange bwembanga njisabye.

Omukono/ekinkumu ky’omulwadde /omujanjjabi.................Ennaku
z’omwezi................
Omukono gw’omunoonyereza gwekikwatako.............. Ennaku z’omwezi....................
Appendix 2: Questionnaire

The prevalence and severity of peripheral arterial disease at Doppler ultrasound among diabetic patients at Mulago Hospital

Date: ___________________ Study number_____

Demographic data

Age (complete yrs)

Sex: 1. Female 2. Male [ ]

Address: Mob Phone Fixed line

Village Sub county District

Tribe:

Educational level: 1. No formal education 2. Primary level 3. Ordinary level

4. Advanced level 5. University 6. Other (specify) [ ]

Occupation: 1. Retired 2. Full time employment (specify)

3. Self employed (specify) 4. Student [ ]

Marital status: 1. Never been married 2. Divorced

3. Married 4. Widow(er)

Religion: 1. Christian 2. Moslem 3. Other (specify) [ ]

Clinical data

History

Smoker 1. Yes 2. No [ ]

If yes specify:
Duration ________ number of sticks/packs per day ________ Type ____________

Duration of DM ____________ Medication ____________/diet & exercise

Hypertensive 1. Yes 2. No [ ]

If yes, specify: Duration ____________ Medication

Ever been diagnosed with a disease of the arteries of the legs? 1. YES 2. NO [ ]

If yes: duration ____________

Edinburgh Intermittent Claudication Questionnaire

1. Do you get pain or discomfort in your legs when you walk?
   1. YES 2. NO [ ]
   (If no, ask no further)

2. Does this pain begin when you are standing or sitting still?
   1. YES 2. NO [ ]

3. Do you get it if you walk uphill or in hurry?
   1. YES 2. NO [ ]

5. Do you get it if you walk at an ordinary pace on level ground?
   1. YES 2. NO [ ]

6. What happens if you stand still?
   1. Usually continues for more than ten minutes
   2. Usually disappears in ten minutes or less [ ]

7. Where do you get this pain or discomfort?

Interpretation of positive claudication answers:
   a. Yes to (1), No to (2), Yes to (3)
   b. Grade 1: No to (4)
c. Grade 2: Yes to (4)  

Critical limb ischaemia

Rest pain 1. Yes  
2. No

If yes, what is the duration you have experienced it?

What relieves it?

1. Hanging the leg over the side of the bed/chair  
2. Painkiller  
3. Nothing

Physical examination

Body habitus

Height (cm)  

Weight (kgs)  

BMI

Waist circumference (cm)

Hip circumference (cm)

Waist: Hip ratio

BP (mmHg) sitting

Peripheral arterial pulses

<table>
<thead>
<tr>
<th>Quality</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral</td>
<td>Normal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diminished</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not palpable</td>
<td></td>
</tr>
<tr>
<td>Popliteal</td>
<td>Normal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diminished</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not palpable</td>
<td></td>
</tr>
<tr>
<td>Dorsalis pedis</td>
<td>Normal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diminished</td>
<td></td>
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</table>
Not palpable

Posterior tibial    Normal

Diminished

Not palpable

Summary of physical findings in PAD

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<th>Symptoms/sign</th>
<th>present</th>
<th>absent</th>
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<tr>
<td>Intermittent claudication</td>
<td></td>
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<tr>
<td>Cold feet</td>
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</tr>
<tr>
<td>Nocturnal pain</td>
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<td>Rest pain</td>
<td></td>
<td></td>
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<tr>
<td>Absent/Diminished pulses</td>
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<td></td>
</tr>
<tr>
<td>Atrophy of subcutaneous tissues</td>
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<td></td>
</tr>
<tr>
<td>Shiny appearance of skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss of hair on foot and toes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thickened nails</td>
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</tr>
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<td>Gangrene</td>
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<td></td>
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<td>Ulcers</td>
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### Sonographic Doppler findings

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<th>Left Lower Limb</th>
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<td>Plaque +/-</td>
<td>Plaque +/-</td>
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<tr>
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<td>Calcification +/-</td>
<td>Calcification +/-</td>
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<tr>
<td></td>
<td>Site</td>
<td>Site</td>
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<td></td>
<td>Fixed/mobile</td>
<td>Fixed/mobile</td>
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<td>Homogeneous/heterogenous</td>
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<td>Length</td>
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<tr>
<td></td>
<td>Flow +/-</td>
<td>Flow +/-</td>
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<td>PSV (cm/s)</td>
<td>PSV (cm/s)</td>
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<td></td>
<td>EDV (cm/s)</td>
<td>EDV (cm/s)</td>
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<td></td>
<td>VR</td>
<td>VR</td>
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<td>% STENOSIS</td>
<td>% STENOSIS</td>
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<td>Plaque +/-</td>
<td>Plaque +/-</td>
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<td>Flow +/-</td>
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<td>%STENOSIS</td>
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<td>Plaque +/-</td>
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<tr>
<td></td>
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<td>Calcification</td>
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<td></td>
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</table>
| Anterior tibial artery | Plaque +/-  
|                       | Calcification +/-  
|                       | Site  
|                       | Fixed/mobile  
|                       | Homogenous/heterogenous  
|                       | Length  
|                       | Flow +/-  
|                       | PSV(cm/s)  
|                       | EDV(cm/s)  
|                       | VR  
|                       | % STENOSIS  
| Peroneal artery       | Plaque +/-  
|                       | Calcification +/-  
|                       | Site  
|                       | Fixed/mobile  
|                       | Homogenous/heterogenous  
|                       | Length  
|                       | Flow +/-  
|                       | PSV(cm/s)  
|                       | EDV(cm/s)  
|                       | VR  
|                       | % STENOSIS  

55
Appendix 3: Waist – hip ratio

Waist circumference was measured by placing a flexible tape on the horizontal plane at the level of the torso as seen from the anterior view.

The hip circumference was measured in the horizontal plane at the level of the maximum circumference including the maximum extension of the buttocks posteriorly.

Men with a waist circumference >102 cm or waist-hip ratio >0.95 and women with a waist circumference of >88 cm or a waist – hip ratio of 0.85 or more were considered to be at risk of cardiovascular disease.

Body mass index (BMI)

The BMI evaluates the degree of excess weight. It was calculated from the weight and square of height as follows:

\[ \text{BMI} = \frac{\text{body weight (in kg)}}{\text{Stature (Height, in meters)}^2} \]

- **Underweight** \( \leq 18.4 \)
- **Normal** \( 18.5 - 24.9 \)
- **Overweight** \( 25.0 - 29.9 \)
- **Obesity I** \( 30.0 - 34.9 \)
- **Obesity II** \( 35.0 - 39.9 \)
- **Extreme obesity** \( \geq 40.0 \)

**Doppler ultrasound procedure**

Doppler ultrasound was then done using the SA9900 SONOACE by Medison Company.

Stenoses were classified by the velocity criteria proposed by Cossman et al. \(^{35}\)

A linear array transducer 5-12 MHz or 3-7 MHz curvilinear transducer was used depending on the build of the patient. The patient exposed the lower limbs up to the groin. Each limb was examined, sequentially with the patient initially in the supine position for the common femoral artery to the superficial femoral arteries then in the decubitus or prone positions for the popliteal...
arteries, posterior tibial and peroneal arteries. The patient then returned to the supine position and the anterior tibial arteries were scanned. Longitudinal and transverse views were done. B mode was, initially, used to locate the common femoral artery lateral to the common femoral vein after which colour and spectral Doppler were used to obtain recordings of the velocities. An angle of 45 was used, the Doppler gate being placed in the middle of the lumen. The bifurcation was then studied and the proximal 3-5 cm of the profunda femoris examined after which the superficial femoral artery was examined and recordings made for the proximal mid and distal segments. In the lateral decubitus the superficial femoral artery was followed as far as possible along the medial aspect of the thigh and then the popliteal artery was located in the posterior fossa and followed superiorly to the distal segment of the superficial femoral artery. The popliteal artery was followed down to the division of the tibioperoneal trunk and anterior tibial artery. The posterior tibial artery was then scanned. It was located by placing the transducer over the medial aspect of the mid calf area behind the tibial and applying colour Doppler to show the course of the vessel. The anterior tibial artery was examined from the antero lateral aspect through the extensor muscles lying between the tibia and fibula. The dorsalis pedis artery was scanned at the ankle just before it passes into the metatarsals.

Stenoses were graded according to Cossman et al (table 1)