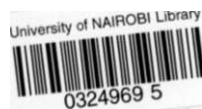


**OUTCOME OF MANAGEMENT OF PERIPHERAL  
ARTERIAL OCCLUSIVE DISEASE AT KNH. A 10 YEAR  
RETROSPECTIVE STUDY (1993 - 2002)**

**BY**

**DR. PAUL MUCHAI (MBUGUA  
MB. ChB (NAIROBI)**

**A DISSERTATION SUBMITTED IN PART  
FULFILLMENT FOR THE DEGREE OF MASTER OF  
MEDICINE IN SURGERY OF THE UNIVERSITY OF  
NAIROBI**



**2002**

## DECLARATION

### CANDIDATE

This dissertation is my original work and has not been presented for a degree in any other university.

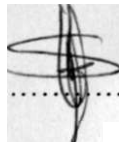
Signed:  Date

DR. PAUL MUCHAI MBUGUA  
MB. ChB. (NAIROBI)

### SUPERVISOR

This dissertation has been submitted for examination with my approval as a University Supervisor

Signed:



Date

PROF. S.W.O. OGENDO  
ASSOCIATE PROFESSOR AND CONSULTANT  
CARDIOTHORACIC SURGEON, DEPARTMENT OF SURGERY,  
UNIVERSITY OF NAIROBI.

## ACKNOWLEDGEMENT

I would like to acknowledge the contributions of the following persons in the preparations of this dissertation:

1. My Supervisor, Prof S.W.O. Ogendo, Consultant Cardiothoracic Surgeon, Department of Surgery, University of Nairobi, for his keen and clear supervision during the preparation of this document.
2. My sister Teresiah Wanjiru, for her accurate and prompt secretarial input which enabled the completion of the document on time.
3. Kenyatta National Hospital Ethical and Research Committee for approving the study.
4. **Ministry of Health for sponsoring me for the M.Med Surgery course.**
5. My wife Margaret, and daughter Sylvia for their great support during the course of this work.

<b>TABLE OF CONTENTS</b>	<b><u>PAGE</u></b>
<b>Declaration</b>	<b>(i)</b>
<b>Acknowledgment</b>	<b>(ii)</b>
<b>Table of Contents</b>	<b>(iii)</b>
<b>List of Tables</b>	<b>(iv)</b>
<b>List of Figures</b>	<b>(v)</b>
<b>List of Abbreviations</b>	<b>(vi)</b>
<b>Summary</b>	<b>1.</b>
<b>Introduction</b>	<b>3.</b>
<b>Literature Review</b>	<b>4.</b>
<b>Justification of the study</b>	<b>21</b>
<b>Study objectives</b>	<b>22.</b>
<b>Materials and methods</b>	<b>22.</b>
<b>Results</b>	<b>26.</b>
<b>Discussion</b>	<b>40</b>
<b>Conclusions</b>	<b>44</b>
<b>Recommendations</b>	<b>45</b>
<b>References</b>	<b>46</b>
<b>Appendix - Data collection form</b>	<b>56</b>
<b>KNH - ERC approval</b>	

<b>LIST OF TABLES</b>		<b>Page</b>
<b>Table 1</b>	<b>: Distribution by gender</b>	<b>26</b>
<b>Table 2</b>	<b>: Distribution by age and gender</b>	<b>27</b>
<b>Table 3</b>	<b>: Incidence for the years of study</b>	<b>27</b>
<b>Table 4</b>	<b>: Distribution by level of education</b>	<b>28</b>
<b>Table 5</b>	<b>: Distribution by geographical regions of birth</b>	<b>29</b>
<b>Table 6</b>	<b>: Distribution of signs and symptoms</b>	<b>30</b>
<b>Table 7</b>	<b>: Duration of symptoms in months</b>	<b>30</b>
<b>Table 8</b>	<b>: Diagnostic modalities used</b>	<b>30</b>
<b>Table 9</b>	<b>: Side involved and type of management</b>	<b>31</b>
<b>Table 10</b>	<b>: Sites of occlusion</b>	<b>31</b>
<b>Table 11</b>	<b>: Cause of occlusion</b>	<b>32</b>
<b>Table 12</b>	<b>: Frequency of primary mode of management</b>	<b>32</b>
<b>Table 13</b>	<b>: Frequency of secondary modes of management</b>	<b>34</b>
<b>Table 14</b>	<b>: Frequency of secondary procedures for the primary modes of management</b>	<b>34</b>
<b>Table 15</b>	<b>: Complications of management</b>	<b>35</b>
<b>Table 16</b>	<b>: Frequency of infection by primary mode of management</b>	<b>35</b>
<b>Table 17</b>	<b>: Mean duration of hospital stay by primary mode of management</b>	<b>35</b>
<b>Table 18</b>	<b>: Distribution of risk factors</b>	<b>36</b>
<b>Table 19</b>	<b>: Primary mode of management of risk factors</b>	<b>37</b>
<b>Table 20</b>	<b>: Frequency of deaths by primary management</b>	<b>38</b>
<b>Table 21</b>	<b>: Frequency of deaths by risk factors</b>	<b>38</b>
<b>Table 22</b>	<b>: Frequency of co-morbidities</b>	<b>39</b>
<b>Table 23</b>	<b>: Frequency of deaths by co-morbidity</b>	<b>39</b>

<b>LIST OF FIGURES</b>	<b>Page</b>
<b>Figure 1 : Distribution by gender</b>	<b>26</b>
<b>Figure 2 : Incidence for the years under study</b>	<b>28</b>
<b>Figure 3 : Distribution by level of education</b>	<b>28</b>
<b>Figure 4 : Distribution by geographical regions of birth</b>	<b>29</b>
<b>Figure 5 : Diagnostic modalities used</b>	<b>31</b>
<b>Figure 6 : Frequency of primary mode of management</b>	<b>33</b>
<b>Figure 7 : Distribution by risk factors</b>	<b>36</b>

## **LIST OF ABBREVIATIONS**

<b>PAOD</b>	<b>PERIPHERAL ARTERIAL OCCLUSIVE DISEASE</b>
<b>KNH</b>	<b>KENYATTA NATIONAL HOSPITAL</b>
<b>ABPI</b>	<b>ANKLE - BRACHIAL SYSTOLIC PRESSURE INDEX</b>
<b>TSPI</b>	<b>TOE SYSTOLIC PRESSURE INDEX</b>
<b>DM</b>	<b>DIABETES MELLITUS</b>

## SUMMARY

This is a retrospective study of the outcome of management of PAOD at ICNH. It covered a 10 year period between January 1993 and November 2002. It was carried out by a review of medical records.

A total of 80 patients with 100 involved limbs were studied. Twenty four patients were excluded from the study as their files could not be traced or lacked sufficient data for analysis. Ninety three lower limbs and seven upper limbs were involved. Twenty five patients had bilateral lower limb disease and one had bilateral upper limb disease.

There were 61 (76.3%) males and 19 (23.8%) females giving a male:female ration of 3.2:1.

The mean age of the patients seen was 52.6 years with a range of 16 to 100 years. The disease was uniformly spread between the ages of 30 to 79 years in both males and females.

The majority of patients (72.6%) had primary level of education and below. Central province had the highest number of patients by birth (56.3%).

Fifty percent of the patients were smokers while 15% were diabetics and 15% hypertensives.

Gangrene and rest pain were the most frequent presenting features occurring in 63% and 59% of the cases respectively.

Arteriography as a diagnostic modality was used in 80.6% of the cases.

Amputation was the most common primary mode of management reflecting the late presentation of the disease at presentation. It was done in 26 (32.5%) cases as the sole procedure and in 6 (7.5%) cases in combination with other primary procedures. Conservative management formed the next common mode of management in 16 (20.0%) cases. Amputation also formed the commonest secondary mode of management following failure of a primary revascularization procedure or after failure of conservative management.



There was a statistically significant higher rate of secondary procedures after graft surgery than after amputation.

The rate of sepsis following primary amputation (46.2%) was statistically higher than following graft surgery (8.3%).

## **INTRODUCTION**

Atherosclerosis is the most common cause of chronic arterial occlusive disease of the lower extremities.

The arterial narrowing or obstruction that occurs as a result of the atherosclerotic process reduces blood flow to the lower limb during exercise or at rest. Intermittent claudication denotes pain distal to the arterial narrowing or obstruction, that develops in the affected limb exercise and is relieved with rest.

The symptoms of chronic arterial insufficiency of progress rather slowly over time but despite this relatively benign prognosis for the affected limb, symptoms of intermittent claudication should be viewed as a sign of systemic atherosclerosis.

Epidemiological studies indicate that upto 5% of men and 2.5% of women 50 years of age or older have symptoms of intermittent claudication. <sup>(1)</sup> The prevalence is at least threefold higher when sensitive non-invasive tests are used to make the diagnosis of arterial insufficiency in asymptomatic and symptomatic individuals.<sup>(2)</sup>

## **LITERATURE REVIEW**

### **HISTORICAL BACKGROUND**

Of necessity, the evolution of vascular surgery awaited the development of arteriography, anaesthesia, anticoagulation, blood transfusion, and synthetic graft materials<sup>(3)</sup>

Hallowell of England reported the first successful arterial operation in 1759 when he performed a lateral arterial repair of a traumatic wound.

Eck is credited with the first formal blood vessel anastomosis when he sutured the portal vein to the inferior vena cava of a dog in 1877.

Murphy performed the first end-to-end arterial anastomosis in a human being two decades later when he successfully rejoined the femoral artery by invagination of the proximal into the distal end after excision of an arteriovenous fistula of the thigh.

Alexis Carrel and Charles Guthrie pioneered the use of Dorfler's technique of through-and-through sutures of all layers of the vascular wall.

Rapid advances in vascular surgery began after World War II, beginning with the treatment of the arterial lesions with endarterectomy by Dos Santos in 1947 and with bypass using autogenous vein by Kuhl in 1951.

Dubost first replaced an abdominal aortic aneurysm with an aortic homograft in 1951, and Voorhees and Blakemore used a graft made of synthetic fabric the following year.

### **NORMAL ARTERIAL PHYSIOLOGY**

The flow of blood through the arterial system is governed by a set of haemodynamic principles that describe relationships among parameters such as fluid energy, pressure, velocity, and resistance<sup>(4)</sup>. These principles, together with the mechanical characteristics of the arterial wall, arterial geometry, and certain properties of the blood, influence arterial flow patterns. While some energy loss occurs as blood

flows through normal arteries, the arterial system is a remarkably efficient conduit for blood, and pressure gradients are minimal.

However, arterial occlusive disease can produce marked flow disturbances that reduce distal pressure and flow.

## **ARTERIAL FLOW PATTERNS**

### **Laminar Flow**

When the motion of blood is parallel to the walls of the vessel and the blood is arranged in concentric layers or laminae, a laminar flow pattern is present. The velocity within each lamina remains constant, with the lowest velocity adjacent to the vessel wall and the highest in the centre of the lumen, resulting in a parabolic flow profile.

### **Turbulent Flow**

Turbulence is a flow pattern in which velocity varies at random with respect to both space and time. This disorderly flow state can result in considerable energy loss. The transition between laminar and turbulent flow depends primarily on vessel diameter and the mean flow velocity.

### **Pulsatile Flow and Velocity Waveforms**

When flow is pulsatile as in the arteries, pressure and velocity vary continuously with time.

The velocity pattern in the peripheral arteries is normally triphasic. There is the initial large forward velocity phase resulting from cardiac systole, followed by a brief phase of reversed flow in early diastole and a smaller phase of forward flow in late diastole. The reversed flow phase is particularly sensitive to changes in peripheral resistance. It is diminished by vasodilatation and is more prominent with vasoconstriction.

## **PATHOPHYSIOLOGY OF ARTERIAL OBSTRUCTION**

### **ENERGY LOSSES DUE TO STENOSIS**

As blood travels through a stenosis, the velocity of flow must increase to maintain the same flow volume in the narrowed segment as in the vessel just proximal to it. This increased velocity produces greater kinetic energy in the stenosis. The increase in kinetic energy corresponds exactly to a decrease in potential energy (i.e., pressure). As long as flow remains ordered and laminar at the entrance and exit to the stenosis, energy is efficiently converted between pressure (potential energy) and velocity (kinetic energy) resulting in reduced flow and pressure.

### **CRITICAL STENOSIS**

The extent of the energy loss and of the resulting reduction in pressure and flow due to stenosis is exquisitely sensitive to stenosis diameter. Arterial lesions are considered critical if they cause reduction in blood flow.

Pressure loss across a stenosis increases with increased blood flow. Flow is augmented when peripheral resistance is lowered either by exercise, reactive hyperaemia, or administration of vasodilators.<sup>(5)</sup>

### **COLLATERAL CIRCULATION**

The collateral circulation provides a parallel pathway for blood flow when major branches become occluded or significantly narrowed.

This network develops as a result of enlargement of **pre-existing** arteries, rather than development in new vessels. The stimulus for these arteries to increase their diameter is an increase in blood flow and velocity due to reduced peripheral resistance.<sup>(6)</sup>

Dilatation of collateral vessels occurs gradually over a period of weeks to months; therefore, slowly progressive chronic occlusions are much better tolerated than are acute occlusions of previously normal vessels.

No matter how well developed the collateral network, collateral resistance is always greater than that of the normal unobstructed artery. Peripheral resistance vessels beyond major occlusions are usually maximally dilated, even under resting conditions. Therefore, flow through collateral channels cannot be increased significantly with exercise, resulting in claudication.

Furthermore, while collateral channels can generally compensate adequately for single level occlusions, they cannot compensate for multiple level occlusions.

## **EPIDEMIOLOGY OF PAQD**

Atherosclerotic vascular disease affecting the lower extremities is the most common form of peripheral vascular disease.

Depending on its severity, Lower extremity arterial disease can present in several ways, including: -

1. asymptomatic arterial insufficiency
2. symptomatic disease presenting as intermittent claudication with positive non-invasive tests, and
3. critical leg ischaemia, which defines a sub-group of patients in whom the ischaemic process endangers part or all of the lower limb.<sup>(7)</sup>

Many population-based studies have shown that the prevalence of intermittent claudication is highly dependent on age, sex and geographic location of the subjects.<sup>(8,9)</sup> In the Edinburgh Artery Study, a cross-sectional survey was conducted on an age-stratified sample of men and women aged 55 to 74 years selected from age-sex register in ten general practices in the city. Results suggested a slight preponderance of asymptomatic disease in males and were consistent with an increasing prevalence with age and lower social class. Mean ABPI was lower in the left leg than the right suggesting an unilateral predisposition to the disease.

Reunanen A, et al examined the prevalence of symptoms of intermittent claudication in a population from 4 geographic areas of Finland. Claudication was most prevalent in East Finland and among persons with agricultural occupations.

## **RISK FACTORS**

### **Age**

The incidence of lower extremity arterial disease increases with age. For a man younger than 50, the prevalence of intermittent claudication is about 1% to 2%, whereas for those older than 50, prevalence increases to about 5%.<sup>(1,0)</sup> A similar trend is seen in women.

### **Male Gender**

The prevalence of intermittent claudication in women over 50 is approximately 2.5% (cf male 5%). After the age of 70, however, prevalence rates for men and women are almost identical.

### **Diabetes Mellitus**

Numerous studies have demonstrated an association between diabetes mellitus and the development of lower extremity arterial disease.<sup>(n,12)</sup>

### **Smoking**

All epidemiological studies on lower extremity arterial disease have confirmed cigarette smoking as a strong risk factor for development of lower extremity arterial disease with relative risk ratios ranging from 1.7 to 7.5.<sup>(3,4)</sup>

### **Hypertension**

The Framingham Study provides the most convincing epidemiological evidence linking hypertension with lower extremity arterial disease in a hypertensive population, with females experiencing a relative risk ratio near 4 and males a relative risk of about 2.

## **Hyperlipidaemia**

Almost 50% of patients with lower extremity arterial disease have hyperlipidaemia. Treatment of hyperlipidaemia reduces both progression of atherosclerosis in the peripheral arteries and incidence of intermittent claudication.<sup>(5)</sup>

## **RISK OF CARDIOVASCULAR MORBIDITY AND MORTALITY**

Because patients with either asymptomatic or symptomatic lower extremity arterial disease have widespread arterial disease, they have significantly increased risk of stroke, myocardial infarction, and cardiovascular death. At least 10% of patients with lower extremity arterial disease have cerebrovascular disease, and 28% have coronary heart disease.<sup>(10)</sup>

The mortality rate in patients with intermittent claudication is two or three times higher than that in age- and sex-matched controls<sup>(6)</sup>

More than 50% of the mortality following arterial reconstruction of any type is attributable to cardiac events. These observations mandates careful assessment and treatment of underlying cardiovascular disease.<sup>(3)</sup>

# **EVALUATION OF LOWER EXTREMITY ARTERIAL DISEASE**

## **NONINVASIVE TESTS**

### **PRESSURE MEASUREMENTS:**

#### **ANKLE - BRACHIAL SYSTOLIC PRESSURE INDEX**

With increasing degrees of arterial narrowing, there is a progressive fall in systolic blood pressure distal to the sites of involvement.<sup>(17)</sup>

Normally there is amplification of the systolic pressure further down the limb, i.e., systolic pressure at the ankle level should be at least equal or higher than that recorded from the upper arms.<sup>(18)</sup> Thus the normal ABPI should be 1.0. To account for variability in the measurement, it



is generally agreed that a value of 0.95 is normal. Differences between measurements can be minimized by performing repeated measurements or by using more experienced observers<sup>(19)</sup>

The absolute pressure should also be recorded and in general, a pressure >50mmHg is consistent with good collateral circulation, whereas lower levels often indicate marginal perfusion of the foot.

### **Exercise Testing**

Measurements of the ankle blood pressure can be made both before and after exercise to assess the dynamics of the intermittent claudication.

At modest workloads a healthy subject can maintain ankle systolic pressures at normal levels. If the exercise is strenuous, there may be a transient fall in systolic pressure that rapidly returns to baseline levels. If a patient with intermittent claudication walks to the point of claudication, ankle systolic pressure falls precipitously, often to unrecordable levels, and will not return to baseline levels for several minutes.<sup>(20,21)</sup>

In general, if ankle pressure falls by more than 20% of the baseline value and requires more than 3 minutes for recovery, the test is considered abnormal.

### **Toe Systolic Pressure Index**

Calcification of the media is common in diabetics with arterial disease. However, as medial calcification does not extend into the digital arteries, it is possible to assess perfusion pressure by measuring toe systolic pressure using either a strain gauge sensor or a photoplethysmograph.

Toe systolic pressure can then be expressed as a ratio of pressure recorded from the arm to obtain the toe systolic pressure index (TSPI).

Normally, the TSPI should be >0.60

### **Segmental Pressures And Pulse Volume Recordings**

The level of the arterial disease can be estimated by measuring pressures at multiple levels, i.e., ankle, calf, above the knee, and upper thigh.<sup>(18)</sup>

The pulse volume recorder uses the recorded contour of the transmitted pulse as the index of normalcy, since the pulse of normal volume has a sharp systolic peak and a dicrotic wave on the downslope.<sup>(23)</sup>

### **FLOW VELOCITY DETERMINATION**

Normally, the arterial velocity patterns in the lower limb at rest have a triphasic pattern, i.e. a large forward flow, a reverse flow, and later a small forward flow.<sup>(24)</sup> With pressure- and flow-reducing lesions, the following may be noted:

1. an increase in peak systolic velocity at the site of narrowing,
2. turbulence distal to the lesion,
3. loss of the reverse flow component, and
4. a reduction in the peak systolic velocity distal to the site of involvement.

### **CONTINUOUS WAVE (CW) DOPPLER**

With experience, all the above changes can be assessed with a CW Doppler simply by using the audio output of the system.

One disadvantage of the CW System is that it does not provide precise information on the artery being studied. This problem is eliminated by using ultrasonic duplex scanning.

### **ULTRASONIC DUPLEX SCANNING**

This combination of real time B-mode scanning and Doppler spectral analysis, is an accurate non-invasive method of detecting and following vascular lesions.<sup>(25)</sup>

It should, however, only be used when the patient is scheduled for some form of intervention such as balloon angioplasty or direct arterial surgery, to localize the stenotic segments.

## **INVASIVE TESTS**

### **ARTERIOGRAPHY**

Arteriography is the main invasive test done for diagnosis and follow-up of patients with arterial occlusive disease. A contrast media is introduced into the vessel usually via a percutaneously introduced angiographic catheter. The vascular section to be studied should be demonstrated as selectively as possible, so that the required amount of contrast is kept to a minimum. This also achieves valuable X-ray exposures with optimum contrast due to the slight dilution of the medium by the blood. Injection of contrast is done with a special apparatus (rather than by hand) because a sharp contrast is achieved only with rapid injection under the related high pressures.

### **BIOPSY AND HISTOLOGY**

Skin and muscle biopsy is necessary when there is suspicion of polyarteritis nodosa and other inflammatory conditions of the arteries.

Histological examination of the material obtained during embolectomy, thrombectomy and endarterectomy is a valuable adjunct to clinical diagnosis. Nevertheless, it is often not possible to differentiate histologically between an embolus and a thrombus developed in situ.

## **OTHERS**

### **Spiral Computed Tomography (CT) Scan**

Spiral Computed Tomography is a noninvasive modality that provides computer-reformatted images of contrast-enhanced arterial lumen. Rapid imaging produces a CT image similar to that obtained from conventional arteriography. Three-dimensional reconstructions of the data permit images that may be rotated and viewed from a variety of angles.

### **Magnetic Resonance Angiography**

Magnetic Resonance Angiography (MRA) has been used as a less invasive, contrast-free alternative to conventional angiography and offers the added advantage of improved visualization of patent distal

vessels when flow is minimal. The cost of the test is considerable and Duplex ultrasonography still provides sufficient information at considerable savings.

## **MANAGEMENT OF PAOD**

### ***GOALS OF THERAPY***

The goals of therapy in patients with chronic arterial insufficiency of the lower extremities are twofold. First, with respect to the affected limb, the goal is to eliminate ischaemic symptoms and prevent progression to vascular occlusion. The second goal of therapy is to prevent cardiovascular complications (stroke, myocardial infarction, and death), which may result from widespread atherosclerosis <sup>(26)</sup>

### ***NATURAL HISTORY***

A knowledge of the natural history of lower extremity arterial disease is necessary when planning management strategies. When patients with intermittent claudication are followed for 5 years, about 50% either have no change in symptoms or may show improvement in functional status presumably due to development of collateral flow. Symptoms progress in about 16% of these patients, and a full 25% will require surgery or experience tissue loss. Less than 4% of patients require a major amputation. <sup>(27)</sup>

In the Framingham study only about 30% of patients with intermittent claudication had persistent symptoms for a minimum of 4 years. <sup>(28)</sup>

In one population-based study of patients with lower extremity arterial disease undergoing initial revascularization surgery, about 20% of patients eventually required an ipsilateral amputation, and 26% required at least one repeat ipsilateral revascularization procedure. <sup>(29)</sup>

## **MEDICAL TREATMENT**

### **Exercise Therapy**

Regular exercise therapy coupled with risk factor modification, especially smoking cessation, is the mainstay of conservative therapy for intermittent claudication. Critical review of the available literature suggests that exercise therapy is the most consistently effective medical treatment for this condition.<sup>(30,31)</sup> Regularity rather than intensity should be stressed. Exercise rehabilitation also results in favourable alterations in cardiovascular risk factor profile, which is an important element in the management of PAOD.<sup>(32)</sup>

### **Smoking Cessation**

Cigarette smoking is the most significant independent risk factor for the development of chronic PAOD and is associated with progression of established disease and a higher likelihood of disabling claudication, limb-threatening ischemia, amputation, and the need for intervention.<sup>(33,34,35)</sup>

In addition, many observational studies report poorer patency of lower extremity vascular reconstruction among smokers.<sup>(36,37)</sup>

### **Drug Therapy**

In contrast to the uniform improvement with exercise therapy, improvement after drug treatment of intermittent claudication is much more variable.

(i) Vasodilators

Vasodilators are ineffective because large vessels dimensions are fixed by the atherosclerotic process and collaterals are maximally dilated in patients with intermittent claudication.

(ii) Rheologic Agents

Pentoxifylline, a methylxanthine derivative, has been reported to improve abnormal erythrocyte deformability, reduce blood viscosity, and decrease platelet reactivity and

plasma hypercoagulability. The actual improvement in walking distance attributable to pentoxifylline is often unpredictable. <sup>(38,39)</sup>

#### Antithrombotic Therapy

Aspirin therapy may modify the natural history of chronic lower extremity arterial insufficiency. Used alone or combined with dipyridamole, it will delay progression of established arterial occlusive disease <sup>(40)</sup> and decrease the need for arterial reconstruction when used for primary prevention in males.

In general, clinical trials show that antiplatelet therapy with aspirin prevents thrombotic occlusion of grafts.

The antiplatelet agent ticlopidine has also been evaluated, and reports suggest beneficial effects in relieving symptoms, increasing walking distances and improving ankle pressure indices. <sup>(41)</sup>

#### Thrombolytic therapy

Thrombolysis has increasingly gained favour both as a primary treatment modality and as an adjunct to surgical treatment such as thromboembolectomy and bypass. Traditionally streptokinase and urokinase have been used.

Other thrombolytic agents that have been found effective in recent studies include the recombinant tissue plasminogen activators, Alteplase and Reteplase, and a glycoprotein (GP) IIb/IIIa platelet receptor antagonist Abciximab <sup>(42,43,44)</sup>

The less invasive approach of regional thrombolysis is preferred (see below).

#### Lipid-lowering Agents

e.g. Simvastatin, Pravastatin

There is evidence that 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitors significantly reduce coronary events in patients with hypercholesterolemia. <sup>(45,46)</sup> but there is no evidence that these agent will alter

the course of the peripheral arterial disease,

- (vi) Immune modulation therapy is a safe and apparently effective treatment for patients with short distance claudication.<sup>(47)</sup>

## **RADIOLOGICAL INTERVENTIONAL PROCEDURES**

### **Percutaneous Transluminal Angioplasty (PTA)**

PTA is an appropriate choice only when the arterial disease is localized to a vessel segment <10 cm in length and there is availability of a skilled vascular interventionalist.<sup>(48)</sup>

Only a very small cytokine response is caused by PTA reflecting the small surgical trauma.<sup>(49)</sup>

### **Intravascular Stents**

At present the role of stents in the treatment of lower extremity arterial disease is unclear. The Hamobahn endoprosthesis is a self-expanding polytetrafluoroethylene - covered nitinol stent graft currently under trial. The long term outcomes of patients treated with angioplasty and hemobahn stent grafting will determine the role of stent grafting in the management of occlusive arterial lesions below the aortic bifurcation.<sup>(50)</sup>

It appears that stents are useful for management of PTA-induced dissections.<sup>(51,52)</sup>

### **Catheter-directed Intraarterial Thrombolysis**

Traditionally, balloon embolectomy has been the treatment of choice for patients with acute arterial embolism. However, because thrombectomy is less successful in patients with acute or chronic arterial thrombosis, intra-arterial thrombolysis is an attractive alternative.

Use of systemic infusion of streptokinase to recanalize occluded peripheral arteries produced disappointing results, with only 30% successful thrombolysis.<sup>(53)</sup> More encouraging results were obtained when streptokinase was given intra-arterially in lower doses.<sup>(54)</sup>

In a number of studies, thrombolytic therapy was associated with limb salvage rates varying from 60% to 70%.<sup>(55,56)</sup>

### **Percutaneous Mechanical thrombectomy**

A number of percutaneous mechanical thrombectomy devices are currently being used or undergoing chemical evaluation for the treatment of acute and chronic limb-threatening ischemia<sup>(57)</sup>

## **C) SURGICAL TREATMENT**

### **INDICATIONS FOR SURGERY**

The primary indications for an interventional procedure in patients with lower extremity arterial disease include: -

1. Incapacitating claudication interfering with life or lifestyle;
2. Limb salvage in patients with limb threatening ischemia as manifested by pain at rest, nonhealing ulcers and/or infection or gangrene; and
3. vasculogenic impotence

Intermittent claudication is considered only a relative indication for surgical treatment and then only after an adequate trial of nonsurgical therapy. Presently there is no consensus regarding disease severity, whether assessed by the symptoms or haemodynamic parameters, for which operative treatment of claudication is appropriate.

### **Graft Replacement**

This can be done using an autologous vein graft or a prosthetic graft.

### **Bypass Graft**

This is the procedure of choice in more than 90 per cent of patients with symptomatic disease of the aortoiliac segment.



**Endarterectomy**

This physically removes plaque by cutting, pulverizing, or shaving it in atherosclerotic arteries. There remains some role for endarterectomy in the treatment of localized aortoiliac occlusive disease. The extent of the iliac plaque should stop 1 to 2 cm short of the iliac bifurcation, as external iliac endarterectomy has a high incidence of early thrombosis and late failure secondary to recurrent stenosis.

**RESULTS OF SURGERY**

The results of treatment of lower extremity ischemia are typically evaluated by multiple parameters that have been summarized in the recommended reporting standard of the joint vascular societies.

These include operative morbidity and mortality associated with the treatment, the patency of the surgical repair, limb salvage and long-term patient survival.

**Patency**

Patency is best defined in haemodynamic terms as a 15% sustained improvement in ABPI as well as by other objective means such as post operative angiography or duplex scanning. Patency is classified as primary or secondary

Primary patency means uninterrupted patency of the original treatment without any revisions.

Secondary patency refers to patency of the repair as maintained by other measures.

It is widely accepted that primary patency describes the success of the procedure itself whereas secondary patency describes the success of the procedure and its post operative follow-up as well as the detection and treatment of complications.

**Limb Salvage**

Surgical procedures on the lower extremity to relieve symptoms of the limb-threatening ischaemia are evaluated by calculation of limb salvage. This is defined as retention of the limb without need for amputation above the metatarsal level (i.e., without the need for a prosthesis to permit ambulation).

**Long-Term Patient Survival**

This is also used in evaluation of surgical procedures.

**Other Parameters**

Relief of pain, healing of ischaemic lesions, return to unimpeded ambulation, maintenance of independent living (freedom from nursing home), and general level of patient satisfaction or quality of life are all valid parameters for assessment of lower extremity revascularization, especially, from the patients point of view.

The factors that influence the outcome of surgical procedures include indication for operation (claudication or limb-threatening ischaemia), surgical site (aortoiliac, infrainguinal, or multilevel), and whether the operation was for primary revascularization or reoperation. For infrainguinal bypass operations, the bypass conduit material (greater saphenous vein, alternate veins or prosthetic) and the site of distal anastomosis (popliteal, tibial, or pedal) are also important.

**SURGERY COMPARED WITH OTHER TREATMENTS**

Surgical treatment of intermittent claudication was compared with exercise therapy by Lundgren and coauthors in 1979.<sup>(59)</sup> The authors randomly assigned 75 patients with intermittent claudication verified by vascular laboratory testing to either surgery alone, surgery combined with exercise training, or exercise training alone. The magnitude of improvement was significantly greater in the operation plus the exercise group than those who underwent surgery alone, and the group that underwent surgery had greater improvement than the exercise - alone group. There were more complications in the surgical groups.

Several series have documented the ability of surgical revascularization to provide durable salvage of unselected limbs threatened by ischaemia in 85% to 90% of cases.<sup>(60)</sup>

Aggressive reoperation for recurrent lesions and/or recurrent symptoms is necessary in 10% to 15% of patients during follow-up. Surgical mortality is <5%. Five year survival in the group of patients with limb-threatening ischaemia is approximately 50%, emphasizing the advanced age and severe coronary and cerebral atherosclerosis present in these patients.<sup>(61)</sup>

Although there has never been a randomized study comparing revascularization with amputation for limb-threatening ischaemia, this issue has been addressed in part by the study of Ouriel and colleagues.

<sup><62)</sup> These investigators compared mortality and morbidity results of non-randomized, but concurrently performed, amputation and revascularization procedures from the same hospital in which patients in each group were stratified for operative risk. Operative mortality, hospital stay, and long-term survival were all superior in the revascularization group.

In the past some surgeons have recommended primary amputation in patients presenting with far advanced ischaemia, including extensive gangrenous lesions of the foot. However, recent studies have demonstrated healing of even extensive ischaemic foot lesions using a combination of revascularization, minor foot amputations and reconstructive surgical techniques. <sup>(63,64)</sup>

For aortoiliac disease the results of aortofemoral bypass and aortoiliac endarterectomy are equivalent with respect to patency. Most surgeons prefer bypass because endarterectomy operations are longer, more technically demanding and associated with greater blood loss. For elderly patients and those with increased operative risk, satisfactory results have been reported with extra-anatomic bypass grafting procedures (axillofemoral, femorofemoral) that avoid the physiological stress of aortic clamping and abdominal cavity surgery.

For infrainguinal bypass, the superiority of saphenous vein over prosthetic conduit is well established by large randomized trials.<sup>(65)</sup> This is clearly true when the distal anastomosis is below the knee.

## **JUSTIFICATION OF THE STUDY**

The management options for arterial occlusive disease are mainly a conservative approach, amputation, arterial graft bypass surgery and embolectomy.

The outcomes of these modes of management at KNH have never been evaluated.

The evaluation of arterial graft bypass surgery is especially important as it is the major limb saving procedure carried out here.

This study aims to evaluate the outcomes of these methods in the management of the disease under **study**.

Recommendations will be made on ways to improve the management of PAOD at KNH.

## **JUSTIFICATION OF THE STUDY**

The **management options for arterial occlusive disease are mainly a conservative approach, amputation, arterial graft bypass surgery and embolectomy.**

The **outcomes of these modes of management at KNH have never been evaluated.**

The **evaluation of arterial graft bypass surgery is especially important as it is the major limb saving procedure carried out here.**

**This study aims to evaluate the outcomes of these methods in the management of the disease under study.**

**Recommendations will be made on ways to improve the management of PAOD at KNH.**

## **STUDY OBJECTIVES**

The study objectives were as follows: -

### **BROAD OBJECTIVE**

To determine the outcome of management of all patients presenting with PAOD, to KNH over a 10 year period (1993-2002).

### **SPECIFIC OBJECTIVES**

1. To determine the demographic characteristics of PAOD as seen at KNH.
2. To determine the patterns of presentation of patients with PAOD.
3. To determine the outcomes of amputation, arterial graft bypass surgery, embolectomy and conservative management in the management of PAOD.
4. To give recommendations on the future management of PAOD at KNH.

## **MATERIALS AND METHODS**

### **Study Design**

This was a retrospective study. It was carried out by a review of medical records of patients presenting to KNH with PAOD between January 1993 and November 2002.

### **Study Area**

The study was conducted at Kenyatta National Referral and Teaching Hospital. Patients' files were retrieved from the records department.

### **Study Population**

The study was done on patients with PAOD who presented to KNH for treatment during the study period, if they satisfied the inclusion criteria below.

## **Sample Size**

All the patients who satisfied the inclusion criteria were included in the study.

## **Criteria for inclusion or exclusion**

### ***Inclusion***

All patients seen and managed for PAOD during the study period.

Patients managed in the cardiothoracic unit, the medical wards, or in the other surgical units were all studied.

### ***Exclusion***

1. Patients whose medical records could not be retrieved, despite clear evidence that they had and were treated for PAOD at KNH, were excluded from the study.

Failure of retrieval of records could have resulted from: -

- (i) The case not yet being coded at the time of the study.
  - (ii) The case having been coded erroneously.
  - (iii) The records having been misplaced or lost.
2. Patients whose medical records contained such insufficient data that no conclusion could be derived from its analysis.
  3. Patients with other arterial diseases other than occlusive.

## **DATA MANAGEMENT AND ANALYSIS**

Data was collected using a pretested data collection form (appendix I).

Data was entered into a micro computer using SPSS/PC + for windows version 10.05 data entry programme. Data validation was done before analysis. Analysis was done using SPSS/PC+ programme and involved descriptive statistics like means and standard deviations, medians, proportions and frequency distributions. For comparisons where the data was categorical, chi square statistic was used

and for 2 by 2 tables where conditions for use of chi square were not met, Fisher's exact probability test was used.

### **ETHICAL CONSIDERATIONS**

The research proposal was first submitted to the Kenyatta National Hospital Ethical and Research Committee and following their approval, the study was commenced.

The data and information obtained during the study was used in strict confidentiality and only for the sole purpose of meeting the objectives of the study.

### **STUDY LIMITATIONS**

Where a patient's record could not be traced by the records department, the patient was excluded from the study. This led to loss of vital statistics.

There lacked uniformity in recording some important information in patients' files. For example, not all files had the information on whether the patient smoked cigarettes, how many sticks/packets per day, total duration that the patient had smoked, and for how long the patient had stopped smoking. This caused difficulties in standardizing results and introduced inaccuracies. Some patients had to be entered as "unknown" for those particular statistics.

The lack of uniform recording of the clinical outcomes of management e.g. relief of pain, return to independent ambulation etc, made it impossible to analyse this data.

### **DEFINITION OF TERMS**

- |                        |   |  |
|------------------------|---|--|
| Smoking                | - | All the patients studied had smoked more than one packet of cigarette per day for more than 10 years.  |
| Hypertension           | - | All the hypertensive patients studied were "known hypertensives" at the time of presentation with PAOD.  |
| Diabetes Mellitus (DM) | - | Most patients were "known diabetics" at presentation with PAOD. For the patients not previously diagnosed, a random blood sugar >11.1 mmol/L was diagnostic of DM. |



Hypcriipidaemia

Hyperlipidaemia was taken as serum cholesterol level >5.2

mmol/L and a fasting triglyceride level > 2 mmol/L.

<> A i>w of .104 p&dmh warn wnh PAOf> qv|r the period of s^yl Hi

i fc< i vft ntetf W t h e su^fcati w d ? (c&rdsioihottwsic fl gsmmi Kp\$ftf:^ M jMKBMw^\_

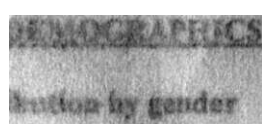
% mim^-itM nr the medical ward\* icr m© tu»e oi a\*\*:^\*\*; jMift^^ wfc0

^Ml^^wily pequtied ad i o i M i rj/r W

tiUyer two wis done CP i p lmm\*

• ^ tfishu&ti fVoikHS

i i p i w l i i i -j



Ik® , V • i l P ^ H W i i

	PercevitaiRe^	
	76.3-	Hpiflwi; Z'^wmWl
		iiiiii

- ••" a Mg E i i i ' \_\_\_\_\_ S ^ ^ S j tnafet I \$\*«) limafe\* g^vvn^ ^ mak: w S k 0 k > f \$ t | f&SI

IVit

X 4 ' V; v • ^ BP.ii

## RESULTS

Hospital records indicate that a total of 104 patients were seen with PAOD over the period of study.

All the patients studied had been admitted to either the surgical wards (cardiothoracic unit, general surgical wards, orthopaedic wards) or to the medical wards at one time or another. The patients who were managed conservatively usually required admission to the ward a day before a planned arteriogram and were discharged a day or two after it was done.

Twenty four patients were excluded from the study leaving 80 patients who were studied.

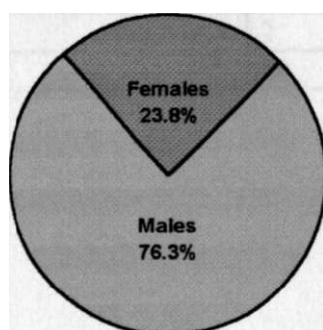
### I. PATIENT DEMOGRAPHICS

Table 1. Distribution by gender

Gender	Frequency	Percentage
Males	61	76.3
Females	19	23.8
Total	80	100.0

There were 61 (76.3%) males and 19 (23.8%) females giving a male : female ratio 3.2:1

Figure 1: Distribution by gender



**Table 2. Distribution by age and gender**

Age range	Frequency		
	Males (%)	Females (%)	Total (%)
<30	3 (4.9)	4(21.1)	7(8.8)
[30-39	12(19.7)	3 (15.8)	15(18.8)
"40"-49	11 (18.0)	2(10.5)	13(16.3)
50-59	10(16.4)	2(10.5)	12(15.0)
60-69	12(19.7)	4(21.1)	16(20.0)
70-79	9(14.8)	4(21.1)	13(16.3)
>80	4 (6.6)	0(0)	4 (5.0)
Total	61 (76.3)	19(23.8)	80(100.0)

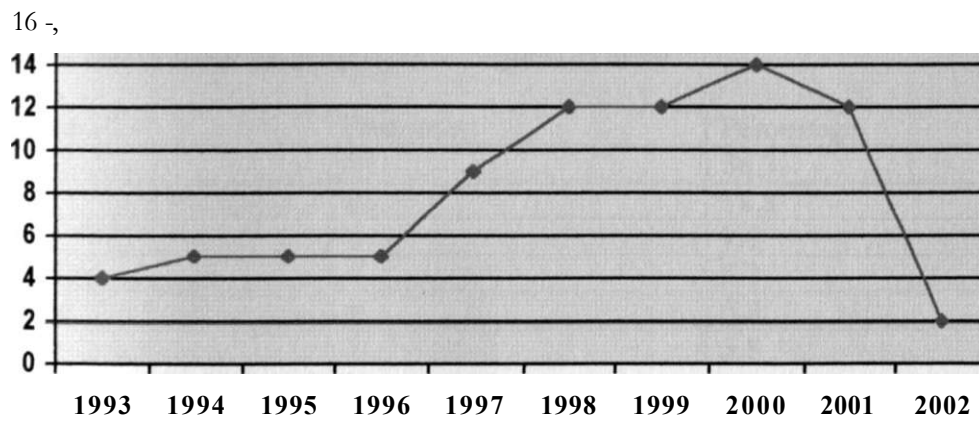
The proportion of females affected increased above the age of 60 years so that 42.2% were in the age group 60 - 80 years compared to 36.8% between the ages 30 - 59 years.

The distribution in males was more uniform.

**Table 3. Incidence for the years under study**

YEAR	Frequency
1993	4
1994	5
1995	5
1996	5
1997	9
1998	12
1999	12
2000	14
2001	12
2002	2
Total	80

Figure 2: Incidence for the years under study

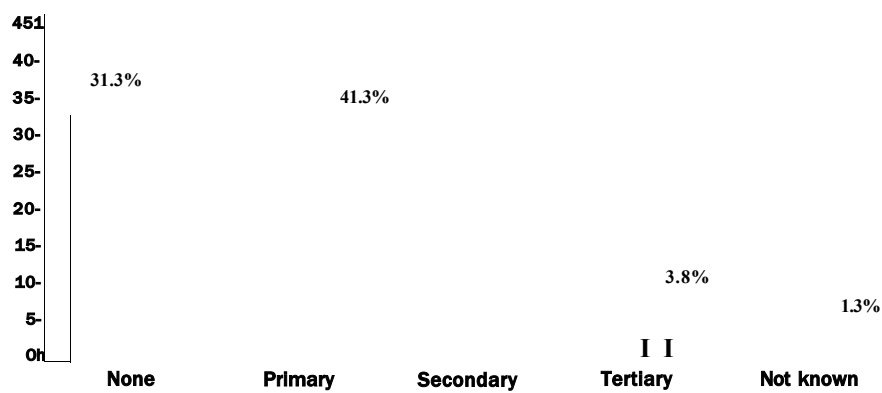


There was an increase in the number of patients managed for PAOD at KNH from 4 cases in 1993 to 14 cases in 2000. Files for patients seen in the year 2002 may have been missed because they were not yet coded for the diagnosis.

Table 4. Distribution by level of education

Level of education	Frequency	Percentage
None	25	31.3
Primary	33	41.3
Secondary	18	22.5
Tertiary	3	3.8
Not known	1	1.3
<b>Total</b>	<b>80</b>	<b>100.0</b>

Figure 3: Distribution by level of education



The majority of patients (41.3%) had primary level of education.

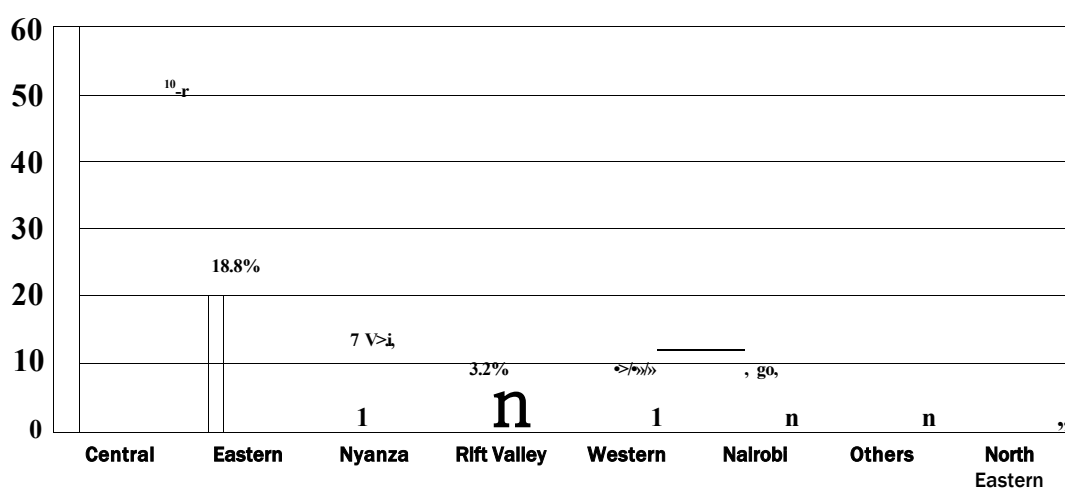
Seventy two point six percent of the patients had primary level education and below.

**Table 5. Distribution by geographical regions of birth**

Province	Frequency	Percentage
Central	45	56.3
Eastern	15	18.8
Nyanza	6	7.5
Rift Valley	4	5.2
Western	4	5.2
Nairobi	3	3.8
North Eastern	1	1.3
Others	2	2.5
<b>Total</b>	<b>80</b>	<b>100.0</b>

**Figure 4: Distribution by geographical regions of birth n = 80**

Distribution by provinces



Forty five (56.3%) patients came from Central Province by birth while 15 (18.8%) came from Eastern Province. Therefore 75.1% of the patients came from the two provinces.

## II. PATTERNS OF PRESENTATION

**Table 6: Distribution of signs and symptoms n = 100 (total no. of limbs involved)**

Signs/symptoms	Frequency	Percentage
Gangrene	63	63.0
Rest pain	59	59.0
Intermittent claudication	28	28.0
Ischaemic ulcers	20	20.0
Pregangrenous state	14	14.0
<b>Others:</b> Swelling	9	9.0
Darkening	8	8.0
Numbness	7	7.0
Paraesthesia	4	4.0

It can be seen that most people presented for treatment when the disease was advanced. Sixty three percent of patients had established gangrene at presentation. Intermittent claudication was a complaint in about a third of the patients at presentation

**Table 7. Duration of symptoms in months**

Mean = 6.4

Median = 2.0

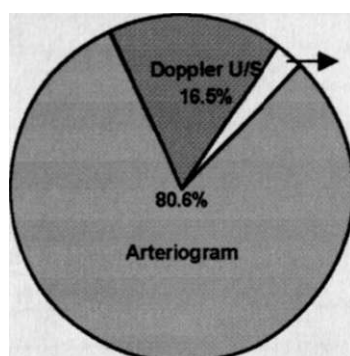
Mode = 3.0

The patients with the longest durations of symptoms had the symptoms for 13,5,4, and 3 years.

The others had symptoms for less than 1 year.

**Table 8. Diagnostic modalities used**

Investigation	Frequency	Percentage
Arteriogram	83	80.6
Doppler u/s	17	16.5
Histology	3	2.9
<b>Total</b>	<b>103</b>	<b>100.0</b>

**Figure 5: Diagnostic modalities used**

Arteriography was the most frequently used investigation modality. It was performed in 80.6% of the investigations. Biopsy for histopathological examination was taken during the revascularization procedure i.e. biopsy was not used for pre-operative diagnosis.

**Table 9. Side involved and type of management**

	Operative management	Conservative management	Total
LOWER LIMB			
Right	39	9	48
Left	34	11	45
UPPER LIMB			
Right	2	0	2
Left	3	2	5
<b>Total</b>	<b>78</b>	<b>22</b>	<b>100</b>

Ninety three cases involved the lower limb while 7 cases involved the upper limbs.

**Table 10: Sites of occlusion**

Site	Frequency	Percentage
Aortoiliac	19	19.0
Femoropopliteal	45	45.0
Infrapopliteal	4	4.0
Multilevel	10	10.0
Subclavian artery	2	2.0
Brachial artery	2	2.0
Small vessel disease	6	6.0
Unknown	12	12.0
<b>Total</b>	<b>100</b>	<b>100.0</b>

The disease involved the aortoiliac and femoropopliteal segments in 54 (54%) cases.

**Table 11. Cause of occlusion**

Cause	Frequency	Percentage
Atherosclerosis	47	58.8
Thrombus	14	17.5
Emboli	6	7.5
Vasculitis	4	5.0
Hypercoagulable state	1	1.3
Buerger's disease	1	1.3
Atherosclerosis + thrombus	6	7.5
Atherosclerosis + emboli	1	1.3
Total	<b>80</b>	<b>100.0</b>

As expected, atherosclerosis was the commonest cause of occlusion 47 (58.8%) cases. Its diagnosis was mostly suggested from the features on arteriograms and also on histology on the few cases in which this was done. Thrombus as a cause was suggested from operation notes and from histology where this was appropriate.

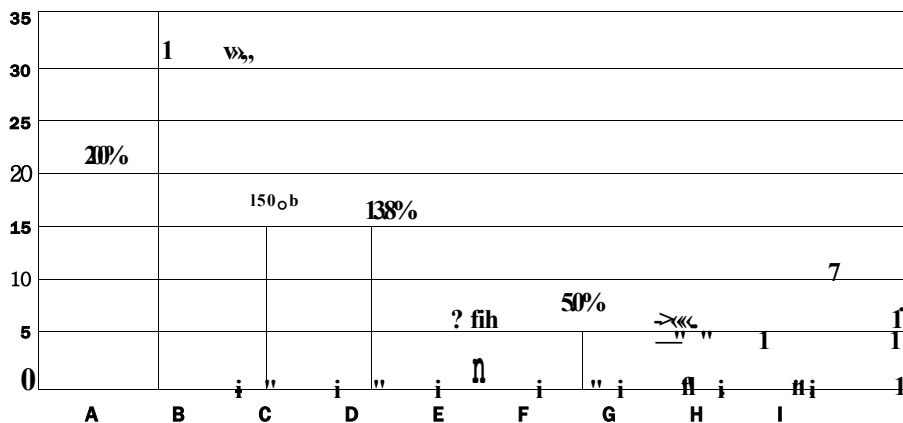
### **III. MANAGEMENTS AND THEIR OUTCOMES**

**Table 12. Frequency of primary mode of management**

Primary mode of management	Frequency	Percentage
Conservative	16	20.0
Amputation	26	32.5
Bypass Graft Surgery	12	15.0
Embolectomy/Thrombectomy	11	13.8
Amputation and grafting	2	2.5
Amputation and embolectomy	4	5.0
Grafting and embolectomy	2	2.5
Grafting and endarterectomy	1	1.3
Not applicable	6	7.5
Total	<b>80</b>	<b>100.0</b>



Figure 6: Frequency of primary modes of management



KEY

- A            Conservative
- B            Amputation
- C            Bypass Graft Surgery
- D            Embolectomy/Thrombectomy
- E            Amputation and grafting
- F -          Amputation and embolectomy
- G -          Grafting and embolectomy
- H -          Grafting and endarterectomy
- I -          Not applicable

In total, 58 (72.5%) patients underwent primary surgical intervention and 16 (20.0%) were managed conservatively. Six (7.5%) patients did not fit in either group e.g. those who died or were transferred to other hospitals before management was instituted.

Amputation was the most common mode of primary management having been done alone in 26 (32.5%) of the patients. It was also performed in combination with other procedures in 6 cases (with grafting 2 cases, with embolectomy 4 cases), making a total of 32 (40.0%) amputations. Bypass graft surgery was done in 17 (21.3%) patients. It was done as the sole procedure in 12 (15.0%) patients while in 5 (6.3%) patients it was done in combination with other procedures. Embolectomy/Thrombectomy was also done in 17 (21.3%) patients [alone in 11 (13.8%) patients and

**Table 13: Frequency of secondary modes of management**

Secondary mode of management	Frequency	Percentage
Amputations (n = 26*)	11	42.3
Reamputations (n = 32**)	9	28.1
Grafting (n cannot be determined)	1	-
Unblocking of graft n = 17***)	1	5.9
Total	22	-

\*n =26 = revascularization procedures

\*\*n = 32 = total primary amputations

\*\*\*n = 17 = total primary bypass grafts

Twenty two (29.7%) of the 74 patients (excluding the "not applicable" group) had secondary procedures done.

Eleven patients out of the 26 who had a primary revascularization procedure were amputated secondarily (42.3%). Nine patients out of the 32 who had primary amputation were reamputated (28.1%). One patient out of the 17 who had primary grafting procedure had unblocking of the graft (5.9%). It is not possible to determine what was the primary procedure in the 1 patient in whom grafting was done as a secondary procedure.

**Table 14: Frequency of secondary procedures for the primary modes of management**

Primary Management	SECONDARY PROCEDURES	
	Frequency	Percentage
Conservative (n = 16)	1	6.3
Amputation (n = 26)	6	23.1
Graft surgery (n = 12)	7	58.3
Embolectomy/thombectomy (n = 11)	4	36.4
Amputation and embolectomy (n = 4)	2	50.0
Graft and embolectomy (n = 2)	1	50.0
Graft and endarterectomy (n = 1)	1	100.0
Total	22	-

Secondary procedures were done following graft surgery in 7 (58.3%) cases and following amputation in 6 (23.1%) cases. The higher rate of secondary procedures after graft surgery compared to amputation was statistically significant (Fisher's exact probability = 0.04).

There was no statistically significant difference between the rate of secondary procedures between graft surgery (58.3%) and embolectomy/thrombectomy (36.4%) ( $p = 0.29$ ).

**Table 15: Complications of primary management**

Complication	Frequency	Percentage
Infection (n = 80)	16	20.0
Intraoperative haemorrhage (n = 58)	1	1.7
Graft occlusion (n = 17)	3	17.6
Re-occlusion after embolectomy (n = 17)	1	5.9
Phantom pain/sensation (n = 32)	2	6.3

Infection was the commonest complication occurring in 16 (20.0%) patients.

As the estimated blood loss was seldom recorded in operative notes, the only case of intraoperative haemorrhage noted was one that required transfusion post-operatively.

**Table 16: Frequency of infection by primary mode of management**

Primary mode of management	INFECTIONS	
	Frequency	Percentage
Conservative (n = 16)	2	12.5
Amputation (n = 26)	12	46.2
Graft surgery (n = 12)	1	8.3
Grafting and embolectomy (n = 2)	1	50.0
<b>Total</b>	<b>16</b>	-

The rate of infection was higher after amputation (46.2%) compared to graft surgery, (8.3%). This was statistically significant (Fisher's exact probability = 0.02).

**Table 17: Mean duration of hospital stay by primary mode of management**

Primary mode of management	Mean duration (days)
Conservative	51.9
Amputation	63.2
Graft surgery	57.8
Embolectomy/Thrombectomy	29.8

Amputation had the longest mean duration of hospital stay (63.2 days).

The mean duration of stay for the entire population was 49.0 days

Amputation had the longest mean duration of hospital stay (63.2 days).

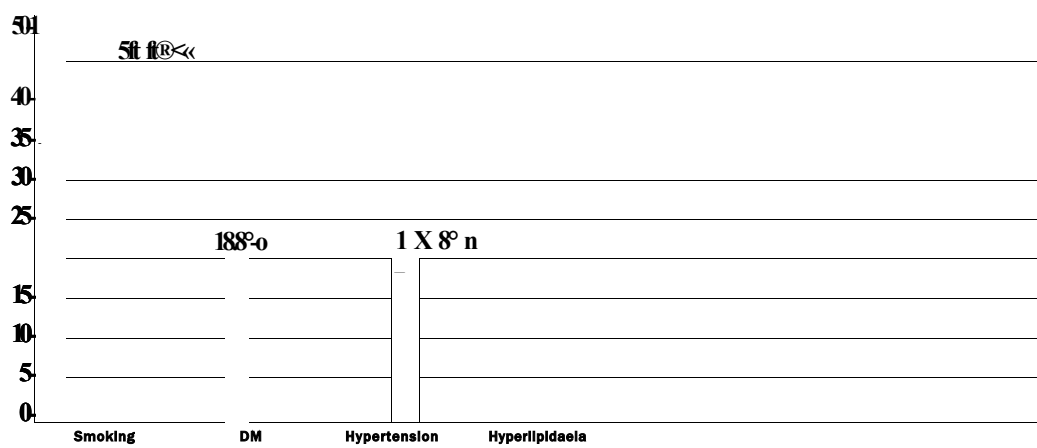
The mean duration of stay for the entire population was 49.0 days

**Table 18. Distribution of risk factors**

**n = 80**

Risk factor	Frequency	Percentage
Smoking	40	50.0
DM	15	18.8
Hypertension	15	18.8
Hyperlipidaemia	3	3.8
None	7	8.8

**Figure 7: Distribution of risk factors**



Forty (50.0%) patients were smokers while 15 (18.8%) were diabetics and 15 (18.8%) were hypertensives.

**Table 19: Primary mode of management by risk factors**

Risk factor	FREQUENCY AND PERCENTAGE OF PRIMARY MANAGEMENT							
	Conservative	Amputation	Graft Surgery	Embolectomy & Throsectomy	Amputation & Grafting	Amputation & Embolectomy	Grafting & Embolectomy	Grafting & Endarterectomy
Smoking n = 40 "	7 (17.5)	15 (37.5)	10 (25.0)	2 (5.0)	2 (5.0)	1 (2.5)	2 (5.0)	0 (0)
DM n=15	2 (13.3)	4 (26.7)	5 (33.3)	2 (13.3)	0 (0)	0 (0)	0 (0)	1 (6.7)
Hypertension n = 15	2 (13.3)	3 (20.0)	5 (33.3)	1 (6.7)	0 (0)	1 (6.7)	0 (0)	1 (6.7)

Smokers had 15 (37.5%) primary amputations while diabetics had 4 (26.7%). The difference was not statistically significant, ( $p = 0.45$ ). The amputation rates between smokers 15 (37.5%) and hypertensives 3 (20.0%), and between diabetics and hypertensives were also not statistically different (Fisher's exact probability = 0.18 and 0.8 respectively).

The higher rate of graft surgery in diabetics 5 (33.3%) compared to smokers 10 (25.0%) was not statistically significant (Fisher's exact probability = 0.38)

**Table 20: Frequency of deaths by primary management**

Primary mode of management	DEATHS	
	Frequency	Percentage
Amputation (n = 26)	1	3.8
Embolectomy/Thrombectomy (n = 11)	1	9.1
Amputation & embolectomy (n = 4)	2	50.0

There were 4 operative deaths giving an operative mortality of 6.9% [n = 58 (80 - 16 - 6), Table 12].

There were 8 deaths in total giving an overall mortality of 10% (n = 80).

The death rate (50.0%) after the 4 combined amputation and embolectomy procedures was statistically higher in comparison to amputation alone (3.8%) (Fisher's exact probability = 0.04).

The difference between the death rate after embolectomy/thrombectomy (9.1%) and that after amputation (3.8%) was not statistically significant (Fisher's exact probability = 0.51).

There were no deaths after bypass procedures.

**Table 21: Frequency of deaths by risk factors**

Risk factor	DEATHS	
	Frequency	Percentage
Smoking (n = 40)	3	7.5
DM (n = 15)	1	6.7
Hypertension (n = 15)	2	13.3

The higher death rate among smokers (7.5%) was not statistically significant compared to that in diabetics (6.7%) (Fisher's exact probability = 0.70), neither was that between smokers (7.5%) and hypertensives (13.3%) (Fisher's exact probability = 0.88).

**Table 22. Frequency of co-morbidities n = 80**

Co-morbidity	DEATHS	
	Frequency	Percentage
Cardiovascular disease	14	17.5
Cerebrovascular disease	2	2.5
Others: HIV +ve	6	7.5
Thyrotoxicosis	1	1.3
Prostate cancer	1	1.3

The commonest co-morbidities were cardiovascular diseases. However, these were not necessarily ischaemic in nature.

**Table 23. Frequency of deaths by co-morbidity**

Co-morbidity	DEATHS	
	Frequency	Percentage
Cardiovascular disease (n = 14)	3	21.4
Cerebrovascular disease (n = 2)	1	50.0
Others: HIV +ve (n = 6)	1	16.7
Thyrotoxicosis (n = 1)	1	100.0
Prostate cancer (n = 1)	1	100.0

The higher death rate in patients with cerebrovascular disease (50.0%) was not statistically significant compared to that in patients with cardiovascular diseases (21.4%) (Fisher's exact probability = 0.45)

## DISCUSSION

PAOD may present with a wide spectrum of symptomatology ranging from asymptomatic disease to the severe symptoms of critical ischaemia. It is a disease that causes more of morbidity rather than mortality. Mortality in PAOD is largely associated with the effects of the widespread arterial disease on the cardiovascular and cerebrovascular systems.<sup>(3)</sup>

There was an increase in the number of patients with PAOD seen every year over the period of study (Figure 2). This suggests an increase in the incidence of PAOD but it may also be that the total patient population seen at KNH has increased.

In this study there were 61 (76.3%) males and 19 (23.8%) females, giving a male : female ratio of 3.2:1 (Figure 1). The male gender is a known risk factor for the disease with a male:female ratio for the prevalence of intermittent claudication of 2:1 for those over 50 years of age.<sup>(6,0)</sup> In this study there was an increase in the proportion of females seen between the ages of 60 - 80 years (42.2%) compared to those seen between the ages of 30 - 59 years (36.8%) (Table 2).

The distribution in males was more uniform. The incidence of PAOD in females is known to increase after menopause so that the prevalence of the disease after the age of 70 is almost identical to that of males.<sup>(6,0)</sup>

The distribution of patients by their geographical origins of birth was studied as the prevalence of intermittent claudication and PAOD is also known to be dependent on the geographical location of the subjects.<sup>(8,9)</sup> It was found that the largest number of patients came from Central province 45 (56.3%) followed by Eastern province, 15 (18.8%) (Figure 4). Thus the two provinces contributed 75.1% of all the patients seen with PAOD at KNH. This presents an apparently higher incidence of the disease in these provinces but there are other possible explanations:

if the absolute populations are higher in these provinces, the number of patients with PAOD would also be expected to be higher than in other provinces when other factors are constant.



it maybe easier to access KNH from these provinces because of their proximity. Health workers may therefore find it easy to refer the patients to KNH.

- The migration patterns from the various regions of birth to Nairobi may be different with higher migration rates from these provinces.

Patients with symptomatic PAOD may either present with intermittent claudication with positive non-invasive tests or with signs and symptoms of critical leg ischaemia where the ischaemic process endangers part or all of the lower limb. <sup>(7)</sup> Most patients in this study presented as the latter group with 63% having established gangrene at presentation (Table 6). This is a sad state of affairs considering that PAOD is a slowly progressive disease. On a 5 year follow-up of patients with intermittent claudication, only about 16% of the patients show progression in symptoms while 50% show no change or actually show improvement in functional status. About 25% will require surgery or experience tissue loss and only less than 4% will require a major amputation. <sup>(27)</sup> The aim of management is to prevent tissue or limb loss either through conservative management or by revascularization procedures. This would call for early referral and/or presentation of those patients with progressive symptoms.

Arteriography is the main invasive test done for diagnosis and follow-up of patients with PAOD and in this study it comprised 80.6% of the investigations. The non-invasive clinical tests are usually done in doubtful cases presenting with intermittent claudication. Most patients presented with clinical features of PAOD that only required a decision on whether salvage surgery was appropriate or not (Table 6). Intermittent claudication was a presenting symptom in only 28% of the patients.

In the Edinburg Artery Study, <sup>(9)</sup> the mean ABPI was lower in the left leg than the right suggesting a unilateral predisposition to PAOD. In this study, however, the prevalence of PAOD was slightly higher in the right leg (Table 9).

Atherosclerotic vascular disease affecting the lower extremity is the most common form of peripheral vascular disease and in this study it was the cause of occlusion in 47 (58.0%) patients. It was diagnosed

from features on arteriograms or from the physical status of the vessels as seen intraoperatively. Only in 3 (2.9%) patients was it diagnosed after intra-operative arterial biopsy.

The majority of patients were managed surgically with 58 (72.5%) undergoing a primary surgical intervention procedure and 22 (29.7%) patients undergoing secondary procedures. Only 16 (20.0%) were managed conservatively primarily. A total of 32 (40.0%) amputations were done as part of primary procedures (see analysis Figure 6) making it the commonest primary procedure. The reamputation rate was also high at 28.1% (Table 13) and was necessitated mainly by the high post-operative infection rate (46.2%) (Table 16). Of the patients who had a primary revascularization procedure 42.3% had to be amputated later (Table 13). This high rate of amputations again emphasize the need for early referral and/or presentation to raise the success rate of revascularization procedures and avoid loss of limbs. As indicated earlier, less than 4% of patients with intermittent claudication in the population should require a major amputation.<sup>(27)</sup> This study, however, was done in a referral hospital and this statistics may not apply here. The post-operative infection rate was statistically higher after amputation (46.2%) than after graft surgery (8.3%) (Fisher's exact probability = 0.02). The mean duration of hospital stay was also longer for amputation (63.2 days) compared to graft surgery (57.8 days).

There was a statistically significant higher rate of performing secondary procedures following graft surgery (58.3%) than following amputation (23.1%) (Fisher's exact probability = 0.04) (Table 14). This could indicate an initial bias towards performing graft surgery in an attempt to avoid an amputation. Not all the secondary procedures were amputations. In one population-based study of patients with lower extremity arterial disease undergoing initial revascularization surgery, about 20% of patients eventually required an ipsilateral amputation.<sup>(29)</sup>

Cigarette smoking, DM, hypertension and hyperlipidaemia have well established association with the development of PAOD. In this study, 40 (50.0%) patients were smokers, 15 (18.8%) were diabetics, 15 (18.8%) were hypertensives and 3 (3.8%) had hyperlipidaemia. Hyperlipidaemia was not

searched for in most patients despite the knowledge that almost 50% of patients with PAOD have hyperlipidaemia and that its treatment reduces both the progression of atherosclerosis and the incidence of intermittent claudication.<sup>(5)</sup>

The primary amputation rates between smokers 15 (37.5%), diabetics 4 (26.7%) and hypertensives 3 (20.0%) were not statistically different (Table 19). Smokers were expected to have a higher amputation rate as cigarette smoking is known to be associated with a higher likelihood of amputation.<sup>03,34,35\*</sup>

The operative mortality was 6.9% while the overall mortality was (10%) (Table 20). Surgical mortality should be less than 5%.<sup>(61)</sup> There were 4 patients in whom amputation and embolectomy were done at the same sitting but on different limbs. Two of these patients died giving a mortality rate of 50.0% for these combined procedures. This mortality rate was statistically higher than that of amputation alone (3.8%) probably indicating the higher severity of the disease in the former especially its effects on the cardiovascular system. More than 50% of the mortality following arterial reconstruction of any type is attributable to cardiac events.<sup>(3)</sup>

There were no statistically significant differences between the death rates in smokers (7.5%), diabetics (6.7%) and hypertensives (13.3%) (Table 21). There were also no statistically significant differences between the death rates in patients with cardiovascular disease (21.4%) and those with cerebrovascular disease (50.0%) (Table 23). Patients with PAOD have significantly increased risk of stroke, myocardial infarction, and cardiovascular death.<sup>(10)</sup>

## CONCLUSIONS

The number of patients being managed for PAOD at KNH is on the rise. This is a worrying trend because apart from its morbidity, PAOD is associated with increased risk of stroke, myocardial infarction, and cardiovascular death.<sup>(10)</sup>

Males are more affected than females. This is a universal trend.<sup>(10)</sup>

The majority (75.1%) of the patients came from Central and Eastern provinces by birth. Geographical location is a known factor in determining the prevalence of PAOD<sup>(8,9)</sup> In the study by Reunanen A, et al claudication was most prevalent in East Finland and among persons with agricultural occupations.

Cigarette smoking is common in patients with PAOD in our setup. It is a strong risk factor for the development of PAOD.<sup>(3,4)</sup>

Most patients come to KNH when they already have rest pain and features of gangrene (critical limb ischaemia). This may explain the high number of limbs undergoing primary amputation (40.0%) and also the high rate of failure of primary revascularization procedures (42.3%) (Table 13).

Amputations have a high post-operative infection rate (46.2%) and the longest duration of hospital stay.

Ways to reduce the high post operative infection rate should be worked out. The main aim of treatment of PAOD should however be the avoidance of loss of the limb.

Bypass graft surgery had a high rate of secondary surgical interventions (58.3%) (Table 14). The reasons for this finding cannot be derived directly from this study and both surgeon and patient factors could play a role.

## **RECOMMENDATIONS**

1. A study needs to be done to find out whether the increasing number of patients seen with PAOD at KNH reflects a rising incidence of the disease in the country. This will assist in the planning of prevention programmes.
2. The high proportion of cigarette smokers in the patients with PAOD should be reduced.
3. Early presentation to hospital needs to be encouraged through public awareness in order to reduce the higher amputation rate and its attendant complications.
4. The high rate of secondary surgical interventions following graft surgery could be reduced probably by improving patient selection.

## REFERENCES

1. **Jelnes R, Gaardsting O, Hougaard Jensen K, et al.**  
Fate in intermittent claudication: outcome and risk factors.  
Br Med J (Clin Res Ed). 1986; 293:1 137-1140
2. **Criqui MH, Fronek A. Barrett-Conner E, et al.**  
The prevalence of peripheral arterial disease in a defined population  
Circulation. 1985;71:510-515.
3. **Kenneth Ouriel, Richard M. Green.**  
Arterial disease.  
Seymour I. Schwartz (Ed). Principles of Surgery, 7<sup>th</sup> Edition McGraw-Hill, 1999  
Vol 1:931-998.
4. **Eugene R.**  
Normal arterial physiology.  
D. Eugene, (Ed). Vascular diseases: Surgical and interventional therapy. Churchill Livingstone.  
1994:Vol 1:57-64
5. **Strandness DE JP, Bell JW.**  
Hemodynamic response of the claudicating extremity to exercise.  
Surg Gynecol Obstet 1964; 119:1237.
6. **LeGougnec HA.**  
Velocity measurements with a 2 MHz pulsed Doppler ultrasound probe in normal and stenosed  
models of the carotid bifurcation.  
MS thesis. Georgia Institute of Technology, Atlanta, 1991
7. Second European Concensus document on chronic critical leg ischaemia.  
Eur J. Vase Surg. 1992;6 (Suppl A): 1-32.

**8. Reunanen A, Takkunen H, Aromaa A.**

Prevalence of intermittent claudication and its effects on mortality.

Acta MedScand. 1982;211:249-256.

**9. Fowkes FGR, Housley E, Cawood EH, et al.**

Edinburgh Artery Study: prevalence of asymptomatic and symptomatic peripheral arterial disease in general population.

Int J Epidemiol. 1991;20:384-392.

**10. Vogt MT, Wolfson SK, Kuller LH.**

Lower extremity arterial disease and the aging process: a review.

J Clin Epidemiol. 1992;45:529-542.

**11. Stout RW.**

Diabetes, atherosclerosis and aging.

Diabetes Care. 1990; 13 (suppl 2):20-23.

**12. Gordon T, Kannel WB.**

Predisposition to atherosclerosis in the head, heart, and legs: the Framingham study.

JAMA. 1972;221:661-666.

**13. Hughson WG, Mann JI, Garrod A.**

Intermittent claudication: prevalence and risk factors.

Br Med J. 1978;1:1379-1381.

**14. Goffin R, Kark JD, Friedlander Y, et al.**

Peripheral vascular disease in a middle aged population sample: the Jerusalem Lipid Research Clinic Prevalence Study.

IsrJ. MedSci. 1987;23:157-167.

15 **Duffield RGM, Lewis B, Miller NE, et al.**

Treatment of hyperlipidaemia retards progression of symptomatic femoral atherosclerosis: a randomized controlled trial.

Lancet. 1983;2:639-642

16 **Kannel WB, McGee DL.**

Update on some epidemiological features of intermittent claudication: the Framingham Study.

**J Am Geriatr Soc. 1985;33:13-18**

17. **Sumner DS, Strandness DE Jr.**

The relationship between calf blood flow and ankle blood pressure in patients with intermittent claudication.

Surgery. 1969;65:763-771.

18 **Strandness DE Jr, Bell JW.**

Peripheral vascular disease: diagnosis and objective evaluation using a mercury strain gauge.

Ann Surg. 1965;161 (suppl): 1-35.

19 **V. Kaiser, A.D.M. Kester, H.E.J.H. Stoffers, et al**

The influence of Experience on the Reproducibility of the Ankle-brachial systolic pressure ratio in PAOD.

Eur J Vase Surg. 1999;18:25-29

20. **Strandness DE Jr.**

Exercise testing in the evaluation of patients undergoing direct arterial surgery.

J Cardiovasc Surg (Torino). 1970;11:192-200.

21. **Strandness DE Jr, Bell JW.**

Ankle pressure responses after reconstructive arterial surgery.

Surgery. 1966;59:514-516.



**22. Orchard TJ, Strandness DE Jr.**

Assessment of peripheral vascular disease in diabetes: report and recommendations of an international workshop sponsored by the American Diabetes Association and the American Heart Association, September 18-20, 1992, New Orleans, Louisiana.

Circulation. 1993;88:819-828.

**23. Raines JK.**

The pulse volume recorder in peripheral arterial disease.

In: Berstein EF, Ed. Vascular Diagnosis. 4<sup>th</sup> Ed. St Louis, Mo: CV Mosby Co;

1993:159-195.

**24. Strandness DE Jr.**

Hemodynamics of the normal arterial and venous system.

In: Strandness DE Jr, ed. Duplex Scanning in Vascular Disorders.

New York, NY: Raven Press; 1993:45-79.

**25. Jager KA, Phillips DJ, Martin RL et al.**

Noninvasive mapping of lower limb arterial lesions.

Ultrasound Med Biol. 1980; 11:515-521.

**26. Jeffrey I Weitz, John Bryne, Patrick Clagett, et al.**

Diagnosis and Treatment of Chronic Arterial Insufficiency of the Lower Extremities: A Critical Review of the Literature

Circulation. 1996;94:3026-3049.

**27. McDaniel MD, Cronenwett JL.**

Basic data related to the natural history of intermittent claudication.

Ann Vase Surg. 1989;3:273-277.

28. **Peabody CN, Kannel VVB, McNamara PM.**  
Intermittent claudication: surgical significance.  
Arch Surg. 1974;109:693-697.
29. **Farkouth ME, Rihal CS, Gersh BJ, et al.**  
Influence of coronary disease on morbidity and mortality after lower extremity revascularization surgery: a population-based study in Olmsted County, Minnesota (1970-1987).  
J Am Coll Cardiol. 1994;24:1290-1296
30. **Ernst E, Fialka V.**  
A review of the clinical effectiveness of exercise therapy for intermittent claudication.  
Arch Intern Med. 1993;153:2357-2360.
31. **Radack K, Wyderski RJ.**  
Conservative management of intermittent claudication.  
Ann Intern Med. 1990; 113:135.
32. **Anna M.I., Andrew W.G., Claudia C.P., et al**  
Effects of exercise rehabilitation on cardiovascular risk factors in older patients with PAOD.  
J Vase Surg 2000;31:670-677
33. **Hughson W G, Mann JI, Tibbs DJ, et al.**  
Intermittent claudication: factors determining outcome.  
Br Med J. 1978;1:1377-1379.
34. **Jonason T, Ringquist I.**  
Factors of prognostic importance for subsequent rest pain in patients with intermittent claudication.  
ActaMed Scand. 1985;218:27-33.

**35 Myers KA, King RB, Scott DF, et al.**

The effect of smoking on the late patency of arterial reconstruction in the legs.

Br J. Surg. 1978;65:267-271.

**36 Robicsek F, Daugerty HK, Mullen DC, et al**

The effect of continued cigarette smoking on the patency of synthetic vascular grafts in leriche syndrome.

J Thorac Cardiovasc Surg. 1975;70:107-113.

**37. Ameli FM, Stein M, Provan JL, et al.**

The effect of postoperative smoking on femoropopliteal bypass grafts.

Ann Vase Surg. 1989;3:20-25

**38 Porter JM, Cutler BS, Lee BY, et al.**

Pentoxifylline efficacy in the treatment of intermittent claudication: multicenter controlled double-blind trial with objective assessment of chronic occlusive arterial disease patients.

Am Heart J. 1982;104:66-72.

**39. Reilly DT, Quinton DN, Barrie WW, et al.**

A controlled trial of pentoxifylline (Trental 400) in intermittent claudication: clinical, haemostatic and theological effects.

N Z Med J. 1987;100:445-447.

**40. Hess H, Mietaschk A, Diechsel G.**

Drug induced inhibition of platelet delays progression of peripheral occlusive arterial disease: a prospective double-blind arteriographically controlled trial.

Lancet. 1985;1:415-419.

**41. Arcan JC, Panak E.**

Ticlopidine in the treatment of peripheral occlusive arterial disease.

Semin Thromb Hemost. 1989;15:167-170.

**42. Kenneth Ouriel, Barry K, Mark M, et al**

Retepase in the treatment of Peripheral Arterial and Venous Occlusions: A Pilot Study

J Vase Intervent Rad 2000; 11:849-854

**43. Charles P.S., Timothy P.M., Curtis W.B., et al**

Thrombolytic Therapy with use of Alteplase (rt-PA) in PAOD: Review of Clinical Literature.

J Vase Intervent Rad 2000; 11:149-161

**44. Peter Drescher, Martin R. Crain, William S. Rilling**

Initial Experience with the combination of Tereplase and Abciximab for Thrombolytic Therapy in PAOD: A Pilot Study.

J Vase Intervent Rad 2002; 13:37-43

**45. Randomized trial of cholesterol lowering in 4444 patients with coronary heart disease : the Scandivavian Simvastatin Survival Study (4s).**

Lancet. 1994;344:1383-1389.

**46. Shepherd J, Cobbe Sm, Fort I, et al.**

Prevention of coronary heart disease with pravastatin in men with hypercholesterolemia: West of Scotland coronary Prevention Study Group.

NEngJMed. 1995;333:1301-1307.

**47. C. McGrath, R. Robb, A.J. Lucas, et al**

A randomized, double blind, placebo-controlled study to determine the efficacy of immune modulation therapy in the treatment of patients suffering from PAOD with intermittent claudication.

Eur J Vase Endovasc Surg 2002; 23:318-387

**48. Johnson K W.**

Aortoiliac disease treatment: a surgical comment.

Circulation. 1991; 83(suppl I): 161-162

**49. P. Danielsson, P. Schatz, P. Swartbol, et al**

Response of inflammatory markers to balloon angioplasty in PAOD.

Eur J Vase Endovasc Surg 2000; 20:550-555

**50. Brian G. rubin, Gregorio A. Sicard**

The Hemobahn endoprosthesis: A self-expanding polytetrafluoroethylene-covered endoprosthesis for the treatment of PAOD after balloon angioplasty.

J Vase Surg 2001; 33:S 124-128

**51. Wolf GL, Wilson SE, Cross AP, et al.**

For the principle investigators and their associates of Veterans Administration Cooperative Study Number 199. Surgery or balloon angioplasty for peripheral vascular disease: a randomized clinical trial.

J. Vase Interv Radiol. 1993; 4: 639- 648

**52. Bonn J, Gardiner GA Jr, Palmaz J, et al.**

Improved angioplasty hemodynamics after Palmaz Vascular Stent placement.

Circulation. 1989; 80(suppl II):II-411.

**53. Amery A, Deloof W, Vermeylen J, et al.**

Outcome of recent thromboembolic occlusions of limb arteries treated with streptokinase.

BMJ. 1970;4:639-644

**54. Hess H, Ingrisch H, Mietaschk A, Rath H.**

Local low-dose thrombolytic therapy of peripheral arterial occlusions.

N Engl J Med. 1982;307:1627-1630.

**55. Results of a prospective randomized trial evaluating surgery versus thrombolysis for ischemia of the lower extremity: the STILE trial.**

Ann Surg. 1994;220:251-266

56. **Browse D, Torrie EP, Galland RB.**

Early results and 1-year follow-up after intra-arterial thrombolysis.

Br J Surg. 1993;80:194-197.

57. **Karthikeshwar Kashirajan, Ziv J. Haskal, Kenneth Ouriel, et al**

The use of Mechanical Thrombectomy Devices in the management of Acute PAOD.

J Vase Intervent Rad 2001; 12:405-411

58. The Ad Hoc Committee on Reporting Standards, Society for Vascular Surgery/North American Chapter, International Society for Cardiovascular Surgery. Suggested standards for reports dealing with lower extremity ischemia.

J Vase Surg. 1986;4:80-94.

59. **Jonason T, Jonzon B, Ringqvist I, et al.**

Effect of physical training on different categories of patients with intermittent claudication.

Acta Med Scand. 1979; 206: 253-258.

60. **Veith FJ, Gupta SK, Wengerter KR, et al.**

Changing arteriosclerotic disease patterns and management strategies in lower-limb-threatening ischaemia.

Ann Surg. 1990;212:402-414.

61. **Taylor LM Jr, Hamre D, Dalman RL, et al.**

Limb salvage vs amputation for critical ischemia: role of vascular surgery.

Arch Surg. 1991; 126: 1251-1258.

62. **Ouriel K, Fiore WM, Geary JE.**

Limb threatening ischaemia in the medically compromised patient: amputation or revascularization?

Surgery. 1988; 104: 667-672.

**63. Veith FJ, Gupta SK, Samson RH, et al.**

Progress in limb salvage by reconstructive arterial surgery combined with new or improved adjunctive procedures.

Ann Surg. 1981; 194: 386-401.

**64. Cronenwett JL, McDaniel MD, Zwolak RM, et al.**

Limb salvage despite extensive tissue loss: free tissue transfer combined with distal revascularization.

Arch Surg. 1989; 124: 609-615.

**65. Veith FJ, Gupta SK, Ascer E, et al.**

Six year prospective multicenter randomized comparison of autologous saphenous vein and expanded poly tetra-fluoroethylene grafts in infra-inguinal arterial reconstructions.

J Vase Surg. 1986; 3: 104-114.





- | 13. MAIN SYMPTOMS AND SIGNS                       | YES = 1 | NO = 2 | RIGHT | LEFT |
|---|---------|--------|-------|------|
| a) Intermittent claudication (distance =          |         |        |       | •    |
| b) Rest pain                                      |         |        |       | •    |
| c) Ischaemic ulcers                               |         |        |       | n    |
| <b>d)</b> Pregangrenous changes                   |         |        |       | •    |
| e) Gangrene                                       |         |        |       | n    |
| <b>0</b> Others (specify)                         |         |        |       | •    |
|   |         |        |       |      |
| 14. DIAGNOSTIC INVESTIGATIONS                     | YES = 1 | NO = 2 |       |      |
| (a) Doppler ultra sound                           |         |        | ●     |      |
| (b) Arteriogram                                   |         |        | ●     |      |
| (c) Others (specify)                              |         |        | ●     |      |
| (d) None  |         |        | ●     |      |
|   |         |        |       |      |
| 15. SITE(S) OF OCCLUSION                          | YES = 1 | NO = 2 |       |      |
| a) Aortoiliac                                     |         |        | ●     |      |
| b) Femoropopliteal                                |         |        | ●     |      |
| c) Infrapopliteal                                 |         |        | ●     |      |
| <b>d)</b> Multilevel                              |         |        | ●     |      |
| e) Generalized disease                            |         |        | ●     |      |
| <b>0</b> Others (specify)                         |         |        | ●     |      |
|   |         |        |       |      |
| 16. UNDERLYING CAUSE OF OCCLUSION                 | YES = 1 | NO = 2 |       |      |
| a) Atherosclerosis                                |         |        | ●     |      |
| b) Emboli   |         |        | ●     |      |
| c) Vasculitis                                     |         |        | ●     |      |
| d) Others (specify)                               |         |        | ●     |      |
| e) Unknown  |         |        | ●     |      |
|   |         |        |       |      |
| 11. PRIMARY MODE OF MANAGEMENT                    | YES = 1 | NO = 2 |       |      |
| a) Conservative                                   |         |        | ●     |      |
| b) Amputation (specify)                           |         |        | ●     |      |
| c) Graft Surgery (specify)                        |         |        | ●     |      |
| d) Embolectomy/Thrombectomy                       |         |        | ●     |      |
| e) Radiological intervention (specify)            |         |        | ●     |      |
| <b>f)</b> Others (specify)                        |         |        | ●     |      |
|   |         |        |       |      |
| 17. INDICATION FOR THE SURGICAL INTERVENTION      | YES = 1 | NO = 2 |       |      |
| a) Incapacitating Claudication                    |         |        | ●     |      |
| b) Limb threatening ischaemia/pregangrenous state |         |        | ●     |      |
| c) Gangrene                                       |         |        | ●     |      |
| d) Others (specify)                               |         |        | ●     |      |

19. CONSERVATIVE MANAGEMENT YES = 1 NO = 2

- a) Stopped smoking
- b) Exercised
- c) Drug therapy (specify)
- d) Others (specify)

20. OUTCOME OF PRIMARY MANAGEMENT YES = 1 NO = 2

- a) Relief of pain
- b) Healed ischemic ulcers
- c) Return to unimpeded ambulation
- d) Persistent symptoms
- e) Recurrence of symptoms
- f) Healed amputation stump
- g) Operative mortality (within 30 days of operation)
- h) Lost to follow-up (last contact \_\_\_\_\_)
- i) Others (specify)\_

21. COMPLICATIONS OF MANAGEMENT YES = 1 NO = 2

- (a) Intraoperative haemorrhage
- (b) Infection
- (c) Anastomotic leak
- (d) Graft Occlusion
- (e) Others (specify)

*medical*  
*Diversity* Lt b \* a » +  
JB NAIKUM

22. SECONDARY MODE OF MANAGEMENT YES = 1 NO = 2

- a) None
- b) Amputation
- c) Reamputation(s) specify no.
- d) Grafting
- e) Unblocking of graft
- f) Revision of graft
- g) Others (specify)

Tel.: 726300-19  
726450-9  
726550-9

Fax: 725272



**KENYATTA NATIONAL HOSPITAL**  
**P.O. Boi 20723, Nairobi**

Telegrams: "MEDSUP", Nairobi

Email: knh@heaJthnet.or.ke

Rcf KM-ERC/01/1490

Date AA ,?P.P.ember 2002

Dr. Paul Muchai Mbugua  
Dept. of Surgery  
Faculty of Medicine  
University of Nairobi

Dear Dr. Mbugua,

**RESEARCH PROPOSAL** "OUTCOME OF MANAGEMENT OF PERIPHERAL ARTERIAL  
OCCLUSIVE DISEASE AT KENYATTA NATIONAL HOSPITAL" (P38/4/2002)

This is to inform you that the Kenyatta National Hospital Ethical and Research Committee has reviewed and approved the revised version of your above cited research proposal.

On behalf of the Committee I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of data base that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Thank you.

Yours faithfully,

PRO N. GUANTAI  
**SECRETARY, KNH-ERC**

c.c. Prof. K.M. Bhatt,  
Chairman, KNH-ERC,  
Dept. of Medicine, UON.

Deputy Director (CS),  
Kenyatta N. Hospital.

Supervisor: Dr. S.W.O. Ogendo, Dept. of Surgery, UON

The Chairman, Dept. of Surgery, UON

The Dean, Faculty of Medicine, UON

CMRO