PATTERN OF FINDINGS IN VENOUS DOPPLER ULTRASONOGRAPHY OF THE LOWER LIMB IN PATIENTS WITH SUSPECTED DVT

AT

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AND

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DECLARATION

CANDIDATE:

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

Signed:.....**Date:** 8.5.02

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

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DEDICATION

I would like to dedicate this thesis to the memory of my late father, Ruskin Gichana Sing'ombe, who inspired me to choose medicine as a career.

ABBREVIATIONS

ACR	AMERICAN COLLEGE OF RADIOLOGY
CCF	CONGESTIVE CARDIAC FAILURE
CFV	COMMON FEMORAL VEIN
CIV	COMMON ILIAC VEIN
CT	COMPUTERISED TOMOGRAPHY
CW	CONTINOUS WAVE
DFV	DEEP FEMORAL VEIN
DVT	DEEP VENOUS THROMBOSIS
IPG	IMPENDACE PLETHSMOGRAPHY
125-I	125-IODINE-LABELLED FIBRINOGEN
KNH	KENYATTA NATIONAL HOSPITAL
MAA	MACRO-AGGREGATES OF ALBUMIN
MRI	MAGNETIC RESONANCE IMAGING
PFV	PROFUNDI FEMORIS VEIN
PGs	PAGES
PTE	PULMONARY THROMBOEMBOLISM
SCD	SICKLE CELL DISEASE
SFV	SUPERFICIAL FEMORAL VEIN
S/S	SYMPTOMS AND SIGNS
US	ULTRASOUND
UON	UNIVERSITY OF NAIROBI

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SUMMARY

This is a retrospective study designed to obtain information on the demographic characteristics, risk factors, site of thrombosis in the lower limb, and the presence or absence of thrombi in patients who are referred for suspected deep venous thrombosis (DVT). The study was based at the KNH and UON radiology departments in the period between April 2000 and January 2001. Venous Doppler ultrasound was used as the mode of imaging. In most centres worldwide venous Doppler ultrasound has been adopted as the initial screening method for deep venous thrombosis (DVT) of the lower extremity. Because of the non-hazardous nature of US, this imaging modality allows repeated examinations to be done sometimes in one sitting and this has greatly increased its accuracy.

The deep venous examinations were done using a combination of grey- scale imaging, color flow imaging and spectral Doppler methods.

A total of 299 patients reports were analyzed: of these 70 were males (23.4%) and 229 were females (76.6%), with a female to male ratio of 3:1. 124 of the sampled patients were from the University of Nairobi, Department of Radiology and the rest from Kenyatta National Hospital. This is a much higher ratio compared to other centers that report a 2:1 ratio. The ages ranged between 13 years to 82 years (mean 41 ± 5) years. 121 of the patients were below 40 years (42.1%). This is a lower percentage compared to other studies. [8,12]

The main clinical features were of swelling alone 42.8%, pain alone 27.8%, swelling, pain and warmth 24.4%. Chest pain, numbness and suspected pulmonary thrombo-embolism made up a small percentage.

The left lower limb was involved in 65.9% of the patients, the right lower limb in 20.1% and involvement of both lower limbs occurred in 14% of the patients. There is yet no satisfactory explanation as to why it was more common in the left lower limb.

Positive radiological diagnosis of presence of thrombi was made in 42.1% while the rest 57.9% were negative. This indicates the low clinical suspicion of deep venous thrombosis as already noted in other studies.[5,8] .The location of the thrombi was also an important objective of this study: 38.9% of the thrombi were found in the popliteal veins; 29.4% in the common and superficial femoral veins combined; 22.2% in the external iliac vein; 7.1% in the three calf veins combined and 2.4 % of the patients showed extensive thrombosis involving external iliac vein the common iliac vein, superficial femoral vein and popliteal vein. In one case there was extension of thrombi into the short saphenous vein. In most of the females the thrombi was identified in the popliteal vein followed by the femoral veins then the calf veins. In the male patients, the distribution followed the same pattern.

Relevant clinical history was not indicated in the majority of cases (25.1%), while in the rest, there were predisposing factors as indicated in the result tables. Use of hormonal contraception played a major role in the clinical history followed by sudden onset of leg swelling. Presence of varicose veins was a major diagnostic enigma in the clinical history provided in the referral

notes. The risk factors in this study compare well with those done in other centers. [7-12,17-35]

The role of DVT in the causation of pulmonary thromboembolic disease was not well documented in most of the referral clinical notes. Only 2% of the patients had clinical suspicion of PTE. However, from literature review of studies done in other centers, DVT has been identified as a source of pulmonary emboli. [2,3,12]

The choice of venous Doppler ultrasound as the imaging modality was made on the basis of the very high sensitivity and specificity of results as documented in many other centres. [18-20]

1. INTRODUCTION

This study set out to evaluate the pattern of findings in venous Doppler ultrasound imaging of the lower limb in patients suspected to have D.V.T. from April 2000 to January 2001. The study was based at the Kenyatta National Hospital (K.N.H.) Radiology Department and the Department of Diagnostic Radiology, U O N.

KNH is both a referral as well as a teaching hospital with a bed capacity of 1503. It has outpatient clinics in all medical specialties. It also has one of the busiest emergency units. Private consultant clinics are also housed within the hospital premises. The Department of Diagnostic Radiology of the UON, which is located within the old wing of KNH, serves as a teaching unit as well as an imaging centre for KNH and patients referred from elsewhere.

The important features considered in the evaluation of D.V.T. are analysed and noted and documentation is made of the demographic characteristics, risk factors, site of thrombosis in the lower limb, and the presence or absence of thrombi in the patients that were referred. The diagnostic criteria used in the two centres was also analysed, since they are main teaching units in Kenya. The findings on venous Doppler ultrasonography were then computed and presented in the result section of this report and the results compared with similar work done elsewhere. This epidemiological study of DVT was confined to the outpatient population. As a result a true incidence in the general population has not been definitely determined.

2. LITERATURE REVIEW

The role of DVT in the causation of pulmonary thromboembolic disease has been shown by many studies done in various centers. This accounts for the various methods devised, both laboratory as well as radiological, to make the diagnosis.

Palevski and Fishman in their 1992 update on diagnosis and treatment of pulmonary thromboembolism showed that pulmonary thromboembolism (PTE) was a leading cause of morbidity and mortality and appeared in many clinical contexts. [1]

Epidemiological surveys have indicated that PTE is responsible for more than 50,000 deaths in the United States annually. This overall incidence is verified by autopsy statistics. [1,2]

Evidence of recent or old embolism was detected in 25 to 30 percent of routine autopsies with special techniques this figure exceeded 60 percent. [2]

In a local study done in the 80s, analysis of autopsy specimens with confirmed PTE as cause of death proved that 9% had origin of emboli from the lower limbs [12]

It has also been shown by Lundl and Cansau et al that the larger leg veins (popliteal and above) were by far the most common sources of those pulmonary emboli, which reached clinical attention. [1,2]

The incidence of embolism did not appear to be decreasing despite advances in diagnosis and prophylaxis. Advances in medical technology probably explain this apparent paradox, such as higher survival in trauma patients and other

medical and surgical procedures particularly among patients of the older age groups and the widespread use of indwelling catheters.

Thus, there is an expanding population at high risk of developing deep venous thrombosis. Data available indicates that more than 95 percent of pulmonary embolism arose from deep venous system of the lower extremities. [2]

Emboli occurring in the cardiac chambers or in other veins account for the remainder, but were uncommon unless some inciting factor was present, for example an indwelling catheter or intracavitary pacing wires. In situ pulmonary thrombosis was rare. Thus embolism should be viewed as a complication of DVT. [2]

Simon and Sheppard et al in their findings on deep venous thrombosis complicating myocardial infarction revealed that more than 90 percent of the deaths due to PTE occurred within an hour or two before a diagnostic-therapeutic plan could be implemented. [4] Given the above findings it is obvious that the following facts have important implications in the reduction of morbidity and mortality of PTE:

1. Prevention of DVT is the most effective approach to prevention of PTE and death due to embolism.
2. Prompt treatment of DVT may limit frequency of embolism.
3. Techniques which identify the patient at risk of DVT and allow prompt diagnosis are the key to reduction of embolic risk.

As has been mentioned, virtually all patients with pulmonary emboli have their origin from the veins of the pelvis and lower extremity.

Most venous return from the lower limb are channeled through the deep venous system.[2] It is for this reason that ultrasound - one of the investigative modalities, centers on the lower extremity veins.

In Kenya, no data is yet available to compare the sensitivity and specificity of venous Doppler ultrasound imaging in identifying DVT. This study was carried out to evaluate the pattern of findings for patients with lower limb swelling suspected to have DVT, using venous Doppler ultrasound as the imaging modality.

A previous study done in 1984 by Machi evaluated deep venous thrombosis at the major referral hospital (KNH) using venography as the investigative modality. [5] The results of this study were compared with those documented then and the values did not show a significant difference.

2.1 ANATOMY

The venous anatomy of the lower limb is divided into the deep and superficial systems.

Perforating and communicating channels connects these systems. The deep veins accompany the principal arteries and have the same names. The deep calf veins, the anterior tibial, posterior tibial and the peroneal vein are usually paired and lie on either side of the single posterior tibial, anterior tibial and peroneal arteries.[6] These paired deep calf veins drain proximally into the unpaired popliteal vein, which in turn drains into the superficial femoral vein. Below the inguinal ligament at the level of the groin, the deep femoral vein and long saphenous join the superficial femoral vein to form the common femoral vein. This in turn drains into the external iliac vein above the inguinal ligament.

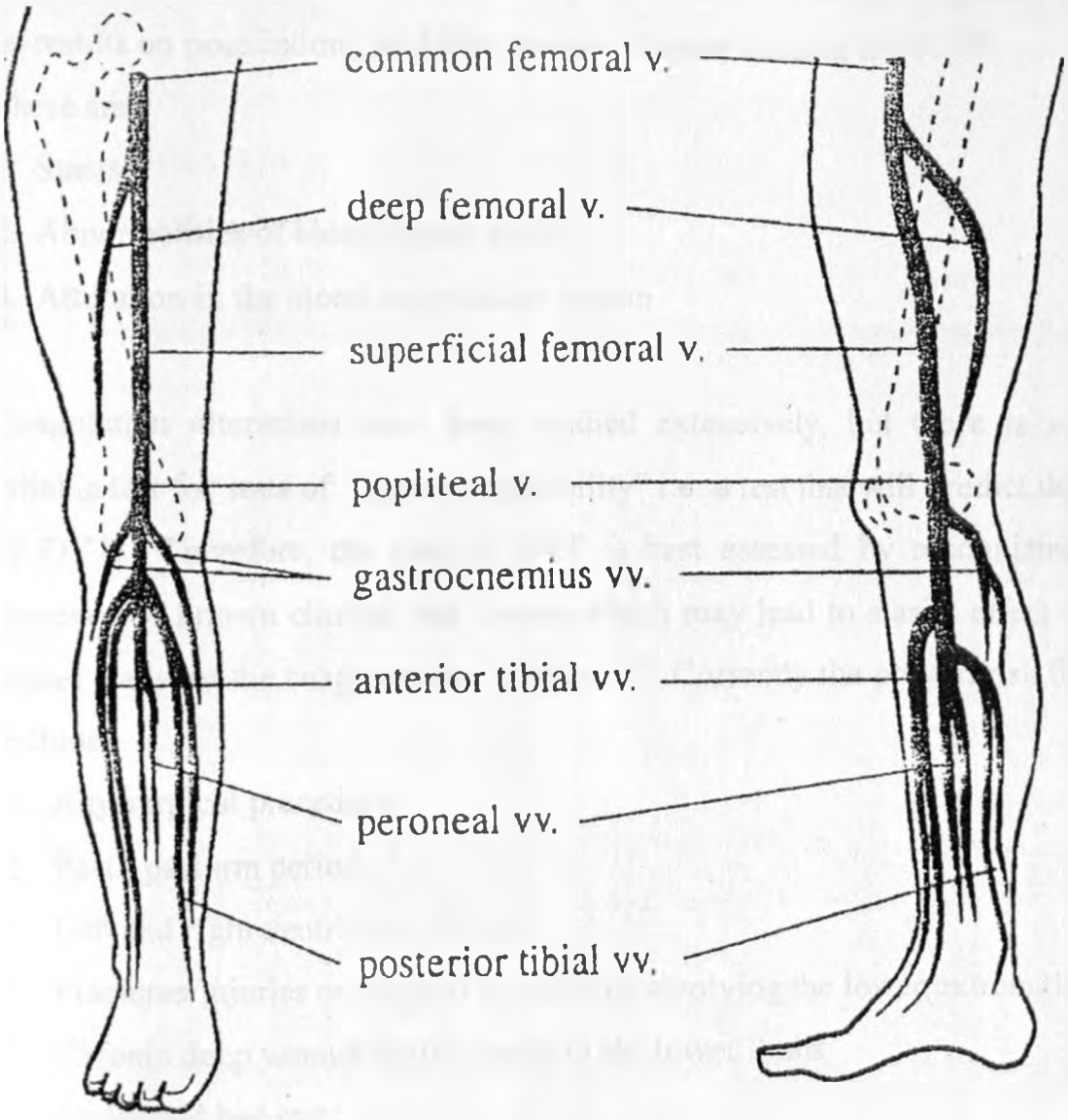
The long saphenous vein, the most prominent vein of the superficial system, begins at the medial malleolus and travels up the medial aspect of the calf and thigh. It is located close to the skin surface in most individuals and is not accompanied by an artery.[6]

The calf veins receive their flow from the venous plexuses of the foot and leg. They contain numerous valves which normally prevent retrograde flow. The veins at the level of the knee and those situated more proximally contain fewer valves than the veins in the calf. If the valves are incompetent then there is retrograde flow to the superficial veins and this may give rise to varicosities and venous stasis, which can give leg swelling.[7]

Venous thrombi commonly form at the base of these valve cusps, where venous flow is relatively stagnant.[6]

2.2 DEEP VENOUS SYSTEM OF THE LOWER EXTREMITY

(OVERLEAF)



Deep Venous System of Lower Extremity

2.3 *PATHOPHYSIOLOGY (7,8)*

Virchows defined the three factors that promote DVT in the 19th century based on results on postulations, and then proven factors causing DVT. [7,8]

These are:

1. Stasis
2. Abnormalities of blood vessel walls
3. Alteration in the blood coagulation system

Coagulation alterations have been studied extensively, but there is yet no reliable test for state of "hypercoagulability" i.e. a test that will predict the risk of DVT. Therefore, the risk of DVT is best assessed by recognizing the presence of known clinical risk factors which may lead to stasis, affect blood vessel walls, or the coagulopathy of blood. [9] Currently the proven risk factors include:

1. Any surgical procedure
2. Post - parturm period
3. Left and right ventricular failure
4. Fractures/injuries or surgical procedures involving the lower extremities
5. Chronic deep venous insufficiency of the lower limbs.
6. Prolonged bed rest
7. Carcinoma, mainly of the pelvic region
8. Obesity
9. Use of estrogens
10. Certain medications

Deep venous thrombosis usually begins at the valve cusps of the veins in the calf. Only 1% of the DVT in the calf produces PTE. [9] It is for this reason that

isolated calf thrombosis is not felt to be clinically significant as compared to that found in the SFV, CFV and the CIV. [8] The process begins by platelets aggregating forming a nidus (white thrombus), followed by development of a large fibrin (red thrombus). The process is usually a rapid one. Growth occurs by continued fibrin and platelet accretion. After formation, two processes may contribute to resolution, fibrinolysis and organization.

Fibrinolysis may result in complete resolution within hours to several days. Any remaining thrombus undergoes organization leaving behind a fibrin zone that becomes re-endotheliorised, and may affect the vessel wall. [8]

Valves are often rendered incompetent by this process and modest or extensive luminal narrowing may occur. Once thrombus growth has halted, available data indicate that fibrinolysis/organization reaches a stable state in 7 to 10 days. It is during the first few days after formation, therefore that emboli risk is greatest. Many investigators have classified the natural history of DVT into stages, [7,8] which include:

1. The Acute stage: red blood cells, platelets, white blood cells in a network of fibrin. At this stage the clot may expand the lumen. Clefts are present between the thrombi and the vein wall and thus embolisation potential is greatest. This lasts for approximately one week. Thrombus, which is not lysed by natural or therapeutic means, is invaded by fibroblasts and becomes organized as fibrous tissue, which persists indefinitely.

2. The Sub acute stage: Fragmentation and lysis of the clot occur with a decrease in size of the thrombus and resumption of venous flow.

3. The Chronic stage: Also referred to as "chronic thrombotic residua". This includes thickening of the intima with wall irregularities and abnormalities of valves with resultant reflux.

2.4 CLINICAL DIAGNOSTIC CRITERIA

In symptomatic cases, studies done for patients with DVT have demonstrated one or some of the following symptoms and signs: [8,9,10]

Sudden onset of unexplained:

a) Dyspnoea
b) Pleuritic chest pain
c) Haemoptysis
d) Syncope (a and b) when infarction has occurred
e) Occult presentations such as repetitive bouts of otherwise unexplained supraventricular tachyarrythmias
f) Sudden onset or worsening of CCF
g) Psychic hyperventilation (hysteria)
h) Lower limb swelling-before a thrombus is disengaged
   - localised tenderness
   - localised warmth
i) Fever usually 37.5-38.5^{O}c in PTE with infarction
j) Lower limb swelling
k) Lower limb pain (calf or thigh).

2.5 *IMAGING MODALITIES*

Various tests are available for the evaluation of the lower limb venous system. These include water- soluble contrast venography; venous US including doppler spectral analysis; impendence plethysmography (IPG); various radionuclide studies; magnetic resonance imaging (MRI) venography; computed tomography (CT); nonimaging continuous wave (CW) doppler analysis; and thermography. All these methods of evaluation were studied by the Cardiovascular Appropriateness Panel of the American

College of Radiology (ACR) and each was rated for appropriateness in 1995 (Table below). [16]

TABLE 1

American College of Radiology Appropriateness Criteria for Clinical Condition; Suspected Deep Venous Thrombosis (DVT).

Radiologic Exam Procedure	Appropriateness Rating
Duplex Doppler compression US	9
Leg venography	6
Pelvic venography	5
Impendance Plethsmograpy(IPG)	5
MRI venography	5
Color Doppler US without compression	4
Computed tomography CT pelvis with contrast	4
Radionuclide venography MAA	4
CW Doppler	2
Plain film radiography	1

Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = least appropriate 9 = most Appropriate.

The various modalities and their limitations are addressed in the following paragraphs.

2.5.1 VENOGRAPHY

89% sensitivity: 97% specificity [13]

False negative in 11%; false positive in 5% [13]

There have been a number of objective tests developed to diagnose DVT. Contrast venography is the most widely employed objective test for DVT, and the most familiar to radiologists and surgeons. [5,10,11]

When properly performed, it permits the study of the superficial and deep calf veins, the femoral and external iliac veins. Because of flow defects produced by merging vessels, study of the more proximal veins requires insertion of a catheter at the groin. Although it is universally accepted as the definitive test (gold standard) for DVT, there are problems associated with venography.[12]

Limitations

1. It is an invasive test involving injection of contrast material into the patient.

2. If both limbs are to be examined, both limbs must be punctured. This can be very painful especially if the limbs are swollen and multiple punctures are to be attempted.

3. Large amounts of contrast media are often used.

4. Sequential studies are seldom attempted or tolerated.
5. The study can elicit chemical phlebitis, which can lead to thrombosis.
6. The patient is at risk for contrast reaction.
7. Interpretation of the venogram can be difficult and vary among radiologists, even if its performance is standardized.
8. Nevertheless, contrast venography still remains the most widely accepted study for DVT and serves as the gold standard against which other tests are measured. [12]

ALTERNATIVE NON-INVASIVE TESTS

2.5.2 IMPEDANCE PLETHYSMOGRAPHY (I P G) [13,14]

87-95-100% sensitivity; 92-100% specificity for above knee DVT

17-33% sensitivity from below knee DVT [13]

False positives 6%

IPG quantitates the rate of venous emptying after relaxation of a compression tourniquet wrapped around the proximal thigh by measuring changes in electrical resistance at the calf. If a clot is present, the capacity of the venous system to accept additional flow is reduced from normal.

When the tourniquet is released, the outflow from the thrombosed venous system is less than that from the normal system.

Blood volume changes during testing are measured by recording alterations in electrical resistance detected between circumferential calf electrodes. [14]

Changes occurring in any individual are compared with normal values.

Limitations

1. The test is accurate in detecting a clot at the knee or above but not a clot that is limited to the calf itself.

2. The patient must lie quietly with the legs elevated and the calf and thigh muscles relaxed; this is very difficult for postoperative patients or very sick patients.

3. Unrecognized muscle contractions by the patient or too tight application of the cuffs by the examiner can result in false positive studies.

4. Patients with increased central venous pressure, ascites or with pelvic mass can also present with false positive studies. False negative results may occur with a non-occlusive thrombus or when a clot is confined to the calf. Sequential testing is easily carried out and is well tolerated.

False positives; (6%) [13] Severe cardiopulmonary disease
Pelvic mass
Reduced arterial flow

False negatives; [13] Calf vein thrombosis
Small thrombus

2.5.3 PHLEBOGRAPHY (PBG) [15,16]

This detects volume changes in the veins of the lower extremities.

It requires a high level of skill in examination and interpretation.

It is however, less accurate than IPG.

It cannot detect non-occlusive thrombus or clot limited to the calf.

2.5.4 125-LABELLED FIBRINOGEN [14,17]

90% sensitivity for calf vein thrombus

60-80% sensitivity for SFV

Insensitive for thrombus in upper thigh/pelvis

RISK: Results are not available for several days and there is a risk of transmission of viral infection.

This is the other only objective test that can reliably detect calf vein thrombosis other than venography.

Radiolabeled iodine fibrinogen is injected into the patient. If there is a thrombus, 125-I becomes incorporated into the thrombus and can be imaged using a gamma –camera. [17]

Limitations

1. 125-I is a relatively low energy emitter. Therefore, study of the deep vessels in the pelvis is not possible.

2. Radioisotope crosses the placenta; its use is contraindicated in pregnancy.

3. False positive studies occur from any area of local inflammation or fibrin deposit.

Therefore, 125-I fibrinogen has only limited utility.

False positives occur due to haematoma inflammation, wounds and old small thrombus isolated in common femoral/iliac veins. [17]

2.5.5 *B-MODE ULTRASONOGRAPHY* [18,19,20]

88-100% sensitivity; 92% specificity [13]

More than 90% Accuracy for DVT in thigh and popliteal veins. [13]

The first report for the use of high resolution B – Scan ultrasound for detecting DVT appeared in 1982. [18]

Duplex sonography and color flow imaging have been added to the diagnostic armamentum and this has improved the accuracy of the investigation. While a number of modifications to the sonographic technique have been added, the single most accurate means of identifying DVT is the lack of venous compression when pressure is applied over the vein at the groin, thigh popliteal region and at the calf with real time ultrasound transducer. [19,25]

All investigators reported very high levels of sensitivity and specificity for the technique. [19]

TABLE 11

	SULLIVAN ET AL CRONAN ET AL (25)	RAGHAVENDRA ET AL O" LEARY ET AL (19)	DAUZAT ET AL (9)	(8)	(17)
n	23	20	145	51	50
Sensitivity	100%	100%	94%	89%	88%
Specificity	92%	100%	100%	100%	96%

Reported results for the detection of lower limb DVT by ultrasound

Compression ultrasound technique has been found to be an adequate screening modality for calf vein thrombosis as well as in the larger leg veins, as shown by results from studies done by Raghavendra, Rosen and Horii et al. [21]

Other studies done by other investigators e.g. Margit Mantoni et al, Jacques Cornuz et al also support this ultrasound technique in demonstration of venous thrombosis. [22]

Advantages:

1. US machines are readily available in most hospitals. Therefore it has the potential for immediate and widespread use.
2. Only a short training period is required to master the technique
3. It requires less patient cooperation
4. It requires no patient preparation
5. It can be done at the bedside with no special room preparation as compared to Venography.
6. It is safe as it is non-ionizing especially in scanning pregnant women.

2.5.6 *THE PRINCIPLES OF VASCULAR ULTRSONOGRAPHY AND THE ULTRASOUND MACHINE*

Ultrasound is a wave of traveling acoustic variables described by frequency, propagation speed, amplitude, intensity and attenuation. Pulsed ultrasound is used in sonography. [28,30]

By sending short pulses of ultrasound into the body and using reflected and scattered sound received from tissues to produce images of internal structures, ultrasound is used as a medical diagnostic tool. [30]

Transducers convert electric energy to ultrasound energy and vise versa by piezoelectric property. Imaging systems consist of pulser, transducer, receiver, memory and display. [30]

Transducers can be linear, curvilinear or sector - shaped, and are of varying frequencies, depending on their actual use. Frequencies range from 2.5 to 11 MHz.

High-resolution ultrasound machines are often equipped with pulsed Doppler systems which can be useful in acquiring flow data, but the examination can be performed using systems lacking Doppler capabilities. [23]

The pulser delivers the energizing voltages to the transducers that respond by producing ultrasound pulses. Receivers amplify voltages representing returning echoes and compensate for attenuation. Digital memories store gray-scale image information and permit display on a television monitor.

The standard technique for evaluating the lower extremity for deep venous thrombosis consists of the use of real- time ultrasound equipment in which linear transducers varying from 3-7 MHz are used. [23] A 5MHZ ultrasound

probe can be used for most patients. Other studies indicate that a 7.5MHZ linear array probe offers adequate spatial resolution and sufficient penetration to be employed in the lower extremities. [29-34]

Lower frequency transducers, although capable of visualizing deeper structures, lack the resolution necessary for this kind of study.

As was mentioned above, neither duplex nor color flow Doppler systems are absolutely necessary, however, they make the examination easier to perform and do increase the accuracy in more subtle cases. The ultrasound machines that were used in this study were Philips 800 model and Image point Hx (Hp), both with Doppler capabilities.

DEFINITION OF TERMS

DOPPLER ULTRASOUND [22]

The principle underlying Doppler ultrasound is that the frequency of signals reflected from moving objects such as red blood cells shifts in proportion to the velocity of the target. The output from a continuous wave Doppler is usually presented as an audible signal, so a sound is heard whenever there is a movement of blood in the vessel being examined.

PULSED ULTRASONOGRAPHY [22,30]

Continuous wave ultrasonography provides little scope for restricting the area of tissue that is being examined because any sound waves that are intercepted by the receiving crystal will produce an output signal. The solution is to use pulsed ultrasonography. The investigator can focus on a specific tissue plane by transmitting a pulse of ultrasound and closing the receiver except when

signals from a predetermined depth are returning. This allows for example the centre of a vein and areas close to the vessel wall to be visualized in turn.

DUPLEX SCANNERS [27,30]

In a duplex scanner the availability of continuous-wave and pulsed –wave Doppler in the same system is useful. This is important, as it is possible to switch from pulsed –wave to the continuous-wave when necessary.

This has enabled the development of spectral analysis, which delineates the complete spectrum of frequencies (that is blood flow velocities) found in the normal waveform corresponding to the normal phasic pattern of venous flow. This is important as the other parameters that indicate occlusion like response to augmentation and response to the Valsalva maneuver can be demonstrated.

2.5.7 *DIAGNOSTIC CRITERIA USING VENOUS DOPPLER ULTRASOUND*

The diagnostic criteria for the identification of DVT has been classified into major and minor criteria. [24] The same criterion was adopted in identifying the thrombus in the two center's.

Major Criteria

1. Noncompressibilty of the veins
2. Visualization of the intraluminal clot
3. Abnormal or absent Doppler shift signal.

Minor Criteria

1. No alteration in size of the vein during the valsalva maneuver
2. Absence of normal venous pulsations.

3. Absence of visible venous blood flow especially in response to respiration.
4. Absence of normal valve motion especially in response to Augmentation.

Identification of any of the three major criteria is highly diagnostic of DVT[7]

Limitations

A few limitations have been sighted in the identification of the thrombus. These are:

1. The patient with recurrent venous thrombosis – There is usually irregularity and wall thickening of the vein that may be mistaken for an acute thrombus.
2. Difficulty in visualizing calf vein thrombus.

3. RATIONALE

Deep venous thrombosis is a much encountered disease entity in our clinical set up. Various investigative modalities have been adopted to try and categorize the findings as well as elucidate on their sensitivities and specificities. Although DVT is a common source of pulmonary emboli, clinical diagnosis of DVT is difficult and often unreliable. [5,8]

Approximately 50 to 60 % of patients with DVT are believed to be undiagnosed clinically. Of those presenting with the clinical manifestations of DVT only half are eventually shown to have thrombi. Failure to identify lower limb DVT leaves the patient at risk of pulmonary embolization, possibly with a fatal outcome as confirmed by the autopsy studies.

Conversely, a false positive diagnosis of DVT exposes the patient to medical and surgical interventions that carry their own significant hazards. In view of the limitation of the clinical diagnosis for DVT, it is recommended that all patients with suspected DVT be evaluated by objective investigation as a rational and cost effective approach to the identification of those who require treatment and those who do not.

From studies done in other center's, B-Scan ultrasound is one of the most useful tools available for this task, and the addition of Doppler technique extends the range and reliability of the technique. [27] It is therefore necessary in any set up to establish and document the basis, technique and valuable findings to confirm or exclude DVT.

A sonographic study of the lower extremities has several advantages as already alluded to in the analysis on sonography.

It can be done at the bedside, generally causes no complications, and does not involve the use of contrast material and it is non-ionizing. This study therefore will seek to:

1. To document locally available data on the findings in venous Doppler ultrasonography.

2. To develop a noninvasive, cheap baseline for investigations of DVT.

4. AIMS AND OBJECTIVES OF THE STUDY

AIM: To establish data baseline for the venous Doppler ultrasound diagnosis of DVT.

BROAD OBJECTIVES

I To describe the clinical presentation of patients referred for US with suspected DVT.

II To determine the role of Venous Doppler US in the investigation of patients suspected to have DVT.

SPECIFIC OBJECTIVES

1. To determine the most common symptoms and signs and relate this to Doppler ultrasound findings.

2. Determine the age, sex and other predisposing factors of patients referred for this investigation.

3. To determine the prevalence of DVT in patients referred for lower limb venous Doppler.

4. To determine the most common location of the thrombi.

5. ETHICAL CONSIDERATION

1. Consent to carry out the study was sought from the ethical committee of Kenyatta National Hospital and, University of Nairobi.
2. All information obtained from the study will be treated with utmost Confidentiality and used for the intended purpose.
3. Results obtained from the study shall not be availed to any machine Manufacturing company for commercial gains and will be purely for medical knowledge and for health improvement.
4. The proforma will bear no patients name. They will be identified by hospital or unit number.
5. The feedback will be availed to the study population under the recommendation of the principal supervisor.

LIMITATIONS OF THE STUDY

1. Ultrasonography and hence the findings depended on the evaluation of the sonologist- it is operator dependent
2. Being a retrospective study by different sonologists, the operator "error" may be higher than if it were done by one sonologist, and by the same machine.
3. Since the study will mainly deal with retrospective data, the patient information not included in the request form will be missed out.

6. METHOD AND MATERIALS

6.1 STUDY DESIGN

This was a retrospective descriptive analytical study done in Kenyatta National Hospital and the Department of Diagnostic Radiology. The study period was from April 2000 to January 2001.

6.2 STUDY METHODOLOGY

The study was conducted by the principal investigator under the guidance of the supervisor from the Department of Diagnostic Radiology, University of Nairobi.

Ultrasound machines with Doppler capability present in the two center's had been used to carry out the examinations.

All retrievable information on lower limb Doppler examinations that were carried out for suspected DVT, was included in the specified study period. The data was inserted into a structured proforma (see appendix I).

6.3 STUDY POPULATION

All data for patients who were referred with suspected DVT within the study period were included in this study. Data was collected from the two centres mentioned above. 124 of the patients' reports were from the University of Nairobi, Department of Diagnostic Radiology, and 175 from Kenyatta National Hospital.

6.4 *SAMPLE SIZE*

The sample size was based on the proportion of patients who presented to the above centres with suspected DVT.

To obtain a 95% confidence interval for this proportion using a precision of 5%, the required minimum sample "n" was calculated using the formula

$$N = \frac{Z^{2}_{1-a/2} P (1-P)}{D^{2}}$$

Where $Z_{1-a/2}$ was the standard normal deviation corresponding to 95% confidence level.

A = level of significance (5% = 0.05)

P was the estimated proportion of patients with lower limb swelling to those who have DVT

D = absolute precision (5%).

The calculated sample size was 269 patients.

ELIGIBILITY CRITERIA

INCLUSIONS

Venous ultrasounds of the lower limbs done for suspected DVT during the period April 2000 to January 2001.

EXCLUSIONS

Patients who underwent doppler examinations for other pathologies other than DVT such as, arterial disease, lymphatic obstruction, and suspected arterio-venous malformations.

6.5 *METHOD AND TECHNIQUE*

The method and technique that was adopted by the sonologists in the two centres is explained below. [28] The method and technique compared well with what is used in other centers.

Patient Preparation

There is no special preparation

Position

The patient is positioned in the supine/oblique position with the thigh externally rotated and the leg partially flexed at the knee.

In cases of venous insufficiency, the patient is told to stand or sit in order to distend the veins. Popiteal veins are examined in the prone or lateral decubitus position.

Technique

The examination is done using a 5-7MHZ linear probe. Scanning begins in the inguinal region where the femoral vessels are first identified as the landmark and progress is made distally to the adductor hiatus and popliteal vessels. This is done longitudinally and transversely, applying compression in the transverse plane approximately every inch as progress is made down the vessel. The following vessels are identified: CFV, SFV, DFV, Long Saphenous vein and the Popliteal vein. Not all centers image the calf vein, as thrombi from these veins are considered clinically insignificant.

Evaluation of the vein for thrombus or normal or abnormal Doppler interrogation is noted. The following guidelines are used to identify thrombi using the different modes available on US.

B-MODE IMAGING

In B-mode imaging the following are considered:

(a) Anatomy and course of the vein

(b) Vessel walls

(c) Vessel diameter (with and without valsalva)

(d) Presence of intraluminal clot

(e) Response to compressibility

(f) Per vascular soft tissues

COLOUR FLOW IMAGING

This usually gives direct visualization of various patterns within the vessels. Doppler helps differentiate arterial signals from venous ones. Color flow imaging allows for more rapid acquisition of flow information from a larger area. The presence and direction of flow in and around clots and perivascular soft tissues are the parameters analyzed in this mode of imaging.

SPECTRAL DOPPLER ANALYSIS

This analyses the wave format giving detailed quantitative information about flow presence, direction and velocity. Venous flow is then evaluated for spontaneity (visualization of flow), phasicity (alteration of flow with respiration), augmentation (increase in flow velocity with compression of the distal leg), and absence of color indicating thrombus. The response of the

venous system to the Valsalva maneuver is helpful especially in equivocal cases. The normal vein should increase in size indicating normal patency. This is quite useful in iliac veins, which might be difficult to visualize using conventional techniques.

REPORTS

In the write up the following information is noted:

(a) Flow pattern at rest and in response to dynamic tests e.g. compression
(b) Vessel walls
(c) Vessel compressibility
(d) Presence of intraluminal clots
(e) Abnormal anatomy
(f) Abnormal perivascular soft tissues

DIAGNOSIS OF DVT

The criteria for making a diagnosis of DVT in order of reliability are:

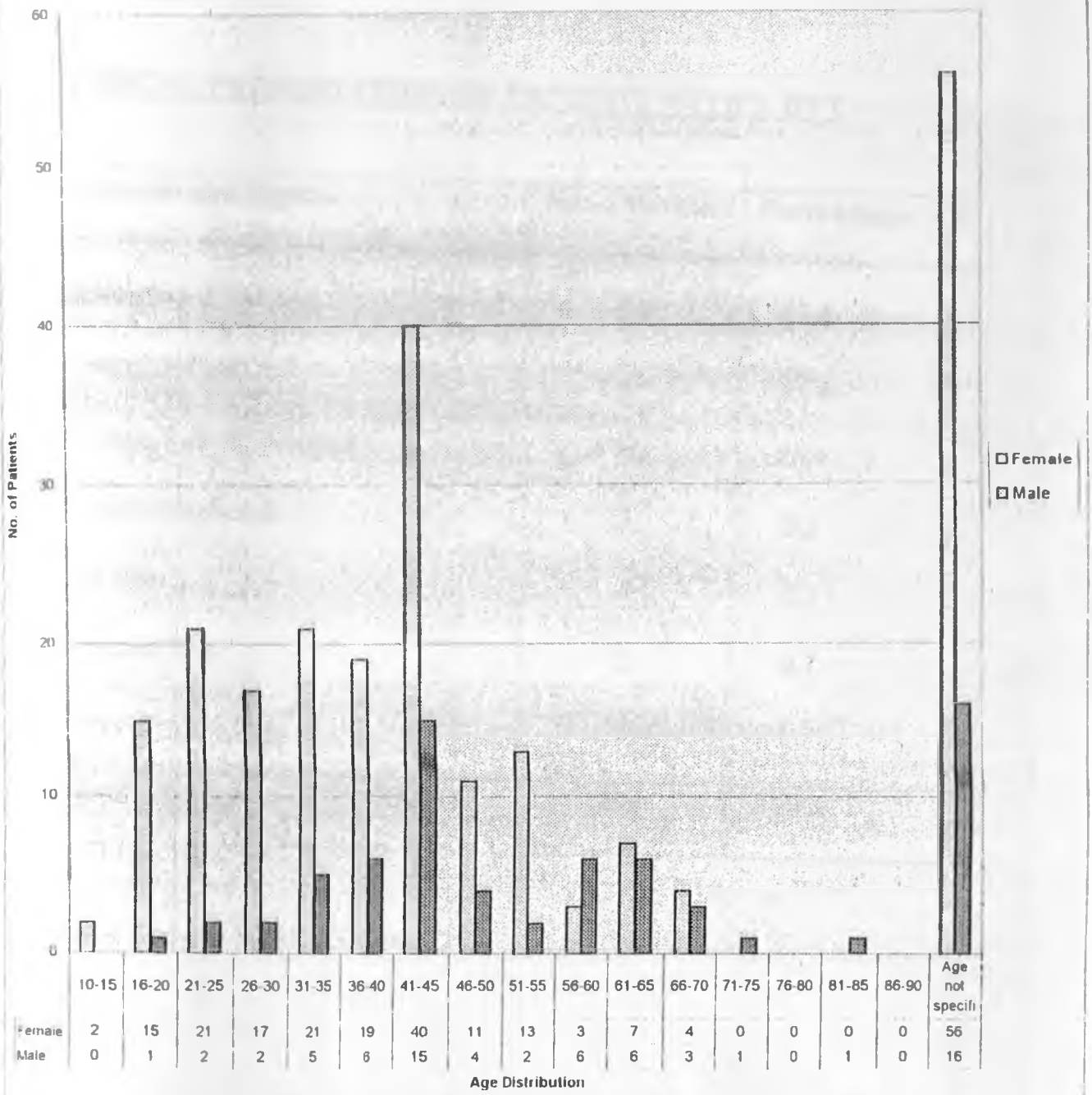
(a) Non-compressibility of veins
(b) Lack of normal Doppler signal
(c) Lack of augmentation
(d) Visualization of clot in the vein (acute clot is usually anechoic).

RESULTS

Clinical data was recorded on a preset protocol that contained information on demographic characteristics, symptoms and signs, location of thrombi, side of limb involved, and associated risk factors. The data was then analyzed using the SPSS computer package.

The results are presented in the form of Tables, Histograms, Graphs, and Figures. A list of tables and figures is included in the table of contents.

AGE DISTRIBUTION : NO OF PATIENTS



	10-15	16-20	21-25	26-30	31-35	36-40	41-45	46-50	51-55	56-60	61-65	66-70	71-75	76-80	81-85	86-90	Age not specifi
Female	2	15	21	17	21	19	40	11	13	3	7	4	0	0	0	0	56
Male	0	1	2	2	5	6	15	4	2	6	6	3	1	0	1	0	16

Age Distribution

TABLE 111

CLINICAL PRESENTATION OF PATIENTS WITH ? DVT

Symptoms and Signs	No. of Patients	Percentages - %
Swelling	128	42.8
Swelling & Pain	83	27.8
Swelling, Pain & Warmth	76	25.4
Pain and Numbness	1	0.3
Chest Pain	4	1.3
Suspected PTE	2	0.7
Pain	5	1.7
TOTAL	**299**	**100%**

TABLE 1V

POSITIVE ULTRASOUND DIAGNOSIS OF DVT: NO. OF PATIENTS (%)

Thrombi	No. of Patients	Percentage - %
YES	126	42.1
NO	173	57.9
TOTAL	**299**	**100%**

TABLE V

LOCATION OF THROMBI: NO. OF PATIENTS (%)

SITE	M	F	No of Patients	Percentage - %
Iliac	3	25	28	22.2
Femoral	12	25	37	29.4
Popliteal	10	39	49	38.9
Calf	3	6	9	7.1
Others	0	3	3	2.4
TOTAL	**28**	**98**	**126**	**100**

TABLE VI

CORRELATION OF S / S VERSUS PRESENCE OF THROMBI

	POSITIVE	%	NEGATIVE	%	TOTAL	%
Swelling Alone	36	12.0	92	30.8	128	42.8
Pain Alone	2	0.7	3	1.0	5	1.7
Swelling + Pain	35	11.7	45	15.1	80	26.8
Swelling + Pain + Warmth	52	17.4	27	9.0	79	26.4
Pain + Numbness	0	0.00	1	0.3	1	0.3
Chest Pain	0	0.0	4	1.4	4	1.4
? PTE	1	0.3	1	0.3	2	0.6
TOTALS	**126**	**42.1**	**173**	**57.9**	**299**	**100**

TABLE V11

SIDE OF LIMB INVOLVED: NO. OF PATIENTS (%)

Side of limb involved	No. of Patients	Percentage %
Left Lower Limb	197	**65.9**
Right Lower limb	60	**20.1**
Both Lower Limbs	42	**14.0**
TOTALS	**299**	**100%**

TABLE V111

SEX / GENDER BY RADIOLOGICAL DIAGNOSIS OF THROMBI: NO. OF PATIENTS (%)

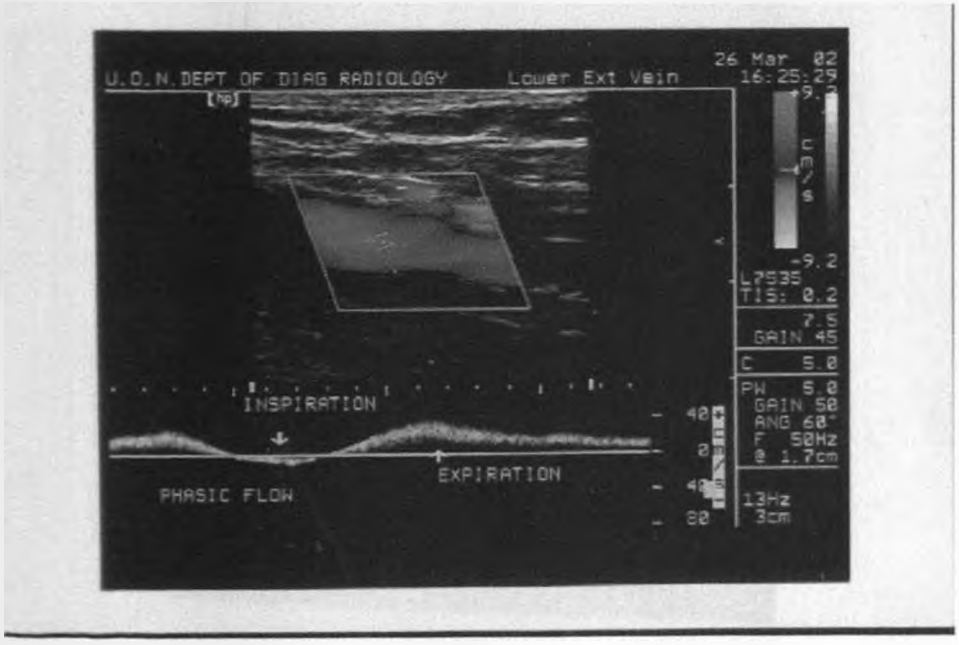
Vein	Male	%	Female	%	Total	%
Calf	3	2.4	6	4.7	9	7.1
Popliteal	10	7.9	39	31.1	49	38.9
Femoral	12	9	25	19.8	37	29.4
Iliac	3	2.4	25	19.8	28	22.2
Others	0	0.0	3	2.4	3	2.4
Total	**28**	**22.2%**	**98**	**77.8%**	**126**	**100 %**

ABLE 1X

ISK FACTORS VS PRESENCE OF THROMBI: NO. OF PATIENTS (%)

sk Factor	Presence of Thrombi			
	Present No.	Present %	Absent No.	Absent %
Not indicated	29	9.7	46	15.4
Lympho edema	5	1.7	16	5.4
Cellulitis	4	1.4	9	3
Use of hormonal Contraception/pregnancy	27	9	15	5.0
Trauma	9	3.0	6	2.0
Renal Disease	6	2.0	4	1.4
Cardiac Disease	7	2.3	4	1.4
Cancer	3	1.0	10	3.3
SCD	1	0.3	1	0.3
Post Surgery	5	1.7	4	1.4
History of Weight Gain	2	0.7	3	1.0
Chronic Leg Ulcer	0	0.0	3	1.0
History of Hospitalisation	6	2.0	13	4.2
Sudden onset	10	3.3	20	6.7
Varicose Veins	10	3.3	16	5.4
Nephrotic Syndrome	2	0.7	2	0.7
Sciatica	0	0.0	1	0.3
TOTALS	**126**	**42.1**	**173**	**57.9**

Figure 3

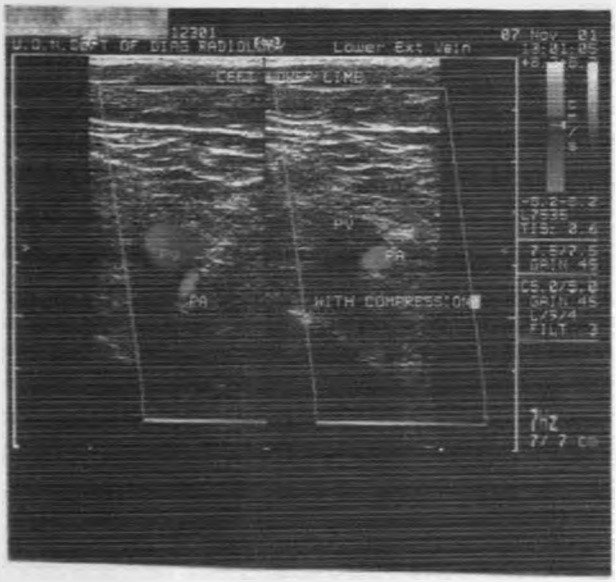


Color flow image of popliteal vein demonstrating normal physiologic changes

a) On inspiration, the flow is increased (augmented)

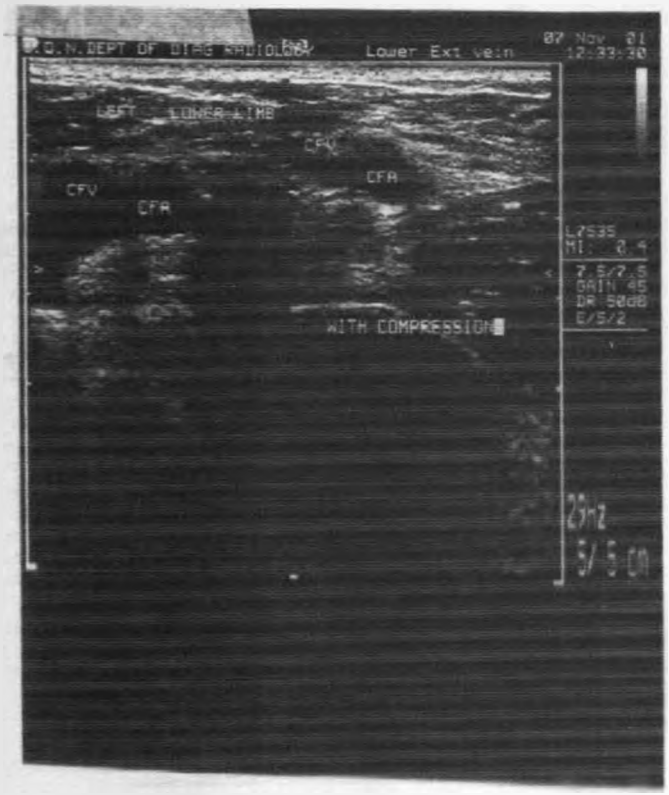
b) On deep expiration, flow appears to be absent or decreased

Figure 4



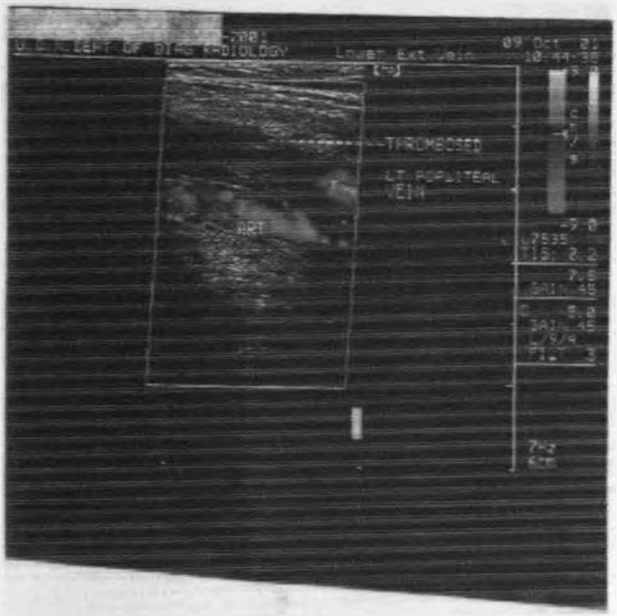
Transverse color doppler flow images showing normal popliteal vein with and without compression.

Figure 5



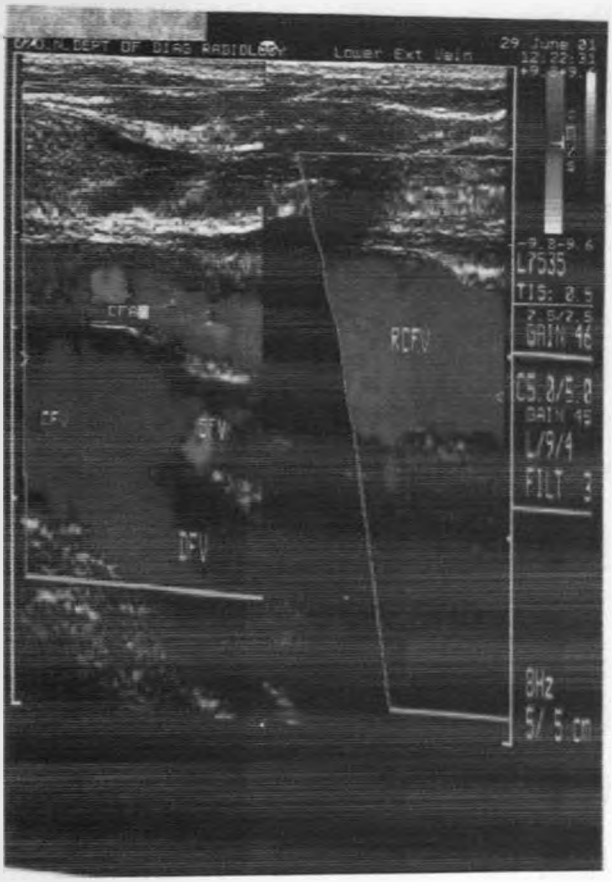
Grey scale images of the common femoral vessels with and without compression

Figure 6



Transverse compression shows the left popliteal vein, which is expanded hypo echoic, demonstrates no color, and does not compress.
These findings are typical of acute venous thrombosis.

Figure 7



SUPERFICIAL FEMORAL VEIN

Color flow imaging helps in identification of vessels

a) Blue color denotes flow towards the transducer

b) Red color denotes flow away from the transducer

8. DISCUSSION

8.1 Age Distribution

Lower limb venous Doppler ultrasonography examination reports of 299 patients suspected to have deep venous thrombosis of the lower limbs were analyzed. Of the 299 patients, the ages ranged between 13 years to 82 years with a peak age of 41 to 45 years (56%). No patient was below 10 years. In the study done by Machi, [5] the age distribution ranged from 13 years to 77 years with a peak age of 21-30 years much lower compared to this study. In a similar study done by E. Kent et al that concentrated on calf vein thrombosis [27] the age range was from 27-87 years with a mean age of 59.1 years. In a prospective evaluation of DVT by Timothy et al [28] the patients ranged between 8 to 98 years with a mean age of 63.2 years. From this study it is thus apparent that the age groups affected in the African set up tends to be much lower compared to the western figures. This is supported by studies done in Africa in the 70s and a more recent one done in 1998. [8-12]

8.2 Sex Distribution

Of the 299 patients evaluated 70 were male and 229 were female. The male to female ratio was 1:3. The Machi study showed the same ratio.[5] The males that were imaged were patients with chronic illness. In another prospective study by Timothy et al [28] on evaluation of deep venous thrombosis with compression US out of 48 patients, 27 were female, 19 were male. Of note in the two previous studies is the importance of the hormonal contraception used by the females being a major contributor. Male to female ratios reported in the western studies are much lower, 1:2. However, previous reports approximate a 1:1 male to

female ratio when female factors like pregnancy and contraception are not considered. [8,12]

8.3 Clinical Symptoms and Signs

Patients who present with the clinical symptoms of leg swelling with pain or edema are certainly at risk for acute deep venous thrombosis. Previous studies have however shown that, the clinical accuracy of diagnosis of this entity is known to be very poor. This is also reflected in the findings in this study as the values approximate to slightly less than half.
Similar studies in other center's also show similar findings.

Every clinical sign attributed to deep venous thrombosis has been statitistically analyzed and found to be of no value in reliably determining the presence or absence of deep vein thrombosis, J.J. et al. [26]
This is also supported in this study as the values for any single clinical symptom or sign does not average to 50% or more. Even that closely related to expected DVT-swelling, pain and warmth only showed 12% with positive diagnosis of thrombi.
In this analysis, the majority of the patients (42.8%) presented with leg swelling alone; swelling and pain 27.8%; swelling, pain and warmth 25.4%. Therefore, swelling was an important sign (96%). In the Machi [5] study using contrast venography as the imaging modality, 90.6% of the patient had swelling of the limb, a value close to this study. The distribution of symptoms and signs was equivalent to that of this study. This was also reflected by Cranley et al [29] who also found that limb swelling was the commonest clinical finding (90%) and McLachlin too. [30] The results of this study compare well with previous study

findings. Table X shows clinical findings of the study compared to clinical findings of Machlin [5] and Cranley. [29]

TABLE X

Author	Swelling No. of cases %	Swelling + pain No. of cases %	Swelling + pain + warmth No. of cases %
Cranley 1976 – 72	65/72 90.2%	65/72 90.2%	29/72 40.2%
Machlin 1983-54 cases	45/54 83.3%	45/54 83.3%	15/54 27.8%
Bonass 2001 – 299 cases	287/299 96%	83/299 53%	76/299 25.4%

With regard to pain or swelling, the location of signs and symptoms is generally known to be unrelated to the extent or location of clot within the veins. Symptoms localized to the calf may be produced by an abnormality in the femoral veins, and thigh pain may be related to occlusion of the calf veins as was revealed by observation made in this study. This is reflected in the study done by Edward Bluth.[36] The specificity for clinical diagnosis is low, since the symptoms associated with acute deep venous thrombosis can have, among other causes, a musculoskeletal or lymphatic basis. Furthermore, asymptomatic deep venous thrombosis has been known to occur, and the sequel can be severe enough to cause death by pulmonary embolism. This can only be confirmed by a study done in retrospect for patients with PTE.

8.4 *Side of Limb affected*

Most of the patients presented with the left lower limb were more affected than the right (65%: 9%). Bilateral involvement occurred in 12% of the patients. No explanation is yet available to explain why the left lower limb is more involved. Attempts have been made to relate this to the anatomy of the veins, but this is still not satisfactory.

8.5 *Site of Thrombosis (Distribution of Thrombi in the Various Veins)*

Most of the thrombi (38.9%) were found in the popliteal vein followed by common and superficial femoral veins combined (29.4%), 7.1% of the thrombi were found in the calf veins and 22.2% in the external /common iliac veins. The rest 2.4% were extensive thrombi found in the external iliac vein and the common/superficial femoral veins, sometimes extending up to the calf veins. This also includes the one case that was seen in the Short Saphenous vein. From this study it is important to note that pick up rate for calf vein thrombosis was not as low as has been shown in previous studies. E. Kent et al analysed below calf vein thrombosis using compression US. In his study the sensitivity was found to be 88% and a specificity of 96%[27]. If these results could be duplicated by other investigators in large series of patients, venous Doppler US (compression US) will be an adequate screening modality for calf vein thrombosis. In this study, compression US was used in evaluation of the calf vein. In another perspective study done by Frederick et al [31] it was found that there was no statistical difference in the frequency of an isolated thrombosis in any of the three veins (femoral vein, superficial femoral vein, popliteal vein). As a result, it appears that all these three major veins must still be carefully studied. The issue of what to do about studying the calf veins is also controversial. In the ACR standard, the study

of the calf veins is not emphasized. This is because of the generally accepted principle that it is safe to withhold anticoagulation treatment for an isolated calf vein thrombosis, since no important thrombi arise from these veins. However, although most calf vein thrombus resolve spontaneously, it has been reported by Pessulto et al that approximately 20% extend to the proximal venous system. [32] This suggests that a repeat study should be performed in any patient whose symptoms persist or worsen, even if an initial study was negative. Despite the few patients who had suspicious chest pain or suspected PTE, there were no thrombi found in their deep leg veins.

8.6 *Sex/ Gender by Radiological Diagnosis of Thrombi*

The distribution of thrombi in the males showed almost the same pattern as that seen in the females. The majority of the thrombi were located in the popliteal and femoral veins in equal proportions (7 %) and then the external iliac veins (3.5%).

8.7 *Risk Factors Vs Presence of Thrombi*

A presumptive conclusion of the risk factors associated with DVT is presented here as a clear picture could only be shown in a prospective study. Associated risk factors were not mentioned in 25.1% of the patients. In the mentioned predisposing factors, use of hormonal contraception was found to be the most common (14%) followed by presence of lympho-edema and cellulitis (7%). Presence of varicose veins was isolated as an important associated risk factor (8.7%). Sudden onset of limb swelling with no known predisposing risk factor was noted in (10%) of the 299 patients. The other risk factors are as indicated in table 1X.

A recent study done by Gebremedhin has shown similar risk factors as seen in this study.[8]

Use of hormonal contraception again appears as a major risk factor. History of hospitalisation however, was commoner in that population. Previous studies also reflect the same spectrum of risk factors.[12,22-36]

8.8 *Acute Venous Thrombosis and Routine Radiological Accuracy In Diagnosis of Thrombi*

When classic findings are present acute thrombosis appears to be hypoechoic. On color Doppler flow images, it can be shown as an intraluminal defect or color void.

Acute deep thrombosis expands the venous lumen; it is noncompressible and does not demonstrate augmentation, and as an indirect sign, the distal vein shows nonvariable venous signals or loss of phasicity. The latter finding is particularly important when the iliac veins are not well visualized and can only be secondarily evaluated by interrogating the common femoral veins.

Positive radiological diagnosis of thrombi was made in 42.1% of the patients and a negative result obtained in 57.9 % of the 299 patients scanned. In this set-up a combination of all or some of the major and minor criteria for identifying the thrombus were used. From previous studies done to evaluate the sensitivity and specificity of venous doppler ultrasound, loss of compressibility of the veins was the most important criteria and is the most universally accepted as being highly accurate. Cronan [26] pooled the results of several series with a total of 1,619 lower extremity and compared compression US imaging with ascending venography. The pooling of results showed a 95% sensitivity and 98%

specificity for compression US. Many studies have similarly shown the high accuracy of compression US imaging in the detection of acute deep venous thrombosis. Its sensitivities range from 88%-100%, and its specificities range from 92-100%. [33 – 47]

In several outcome studies, patients who had negative compression US images and were followed up but not treated with anticoagulation therapy did not have any evidence of developing pulmonary emboli. [48,49] This adds further credence to the accuracy of this technique.

9. RECOMMENDATIONS AND CONCLUSIONS

1. A large proportion of patients are delayed while awaiting radiological confirmation of acute DVT. This is because contrast venography is still considered the 'GOLD' Standard. From statistics quoted above venous Doppler US should now be the initial imaging modality. A sonographic study of the lower extremities can be done instantly. These examinations are bedside, generally cause no complications, and do not involve the use of contrast media or irradiation.

2. An ultrasound machine is readily available in most hospitals. Therefore, it has the potential of immediate and widespread use. Looking at the repercussions of a missed lower limb thrombi, this is worthwhile.

3. Only a short training period is required to master the technique. Therefore, the patients with suspected DVT need not be booked for examination as it is done in KNH. The examination should be done as a medical emergency.

4. A comprehensive clinical history was lacking in most of the request forms. It is important for the clinicians to liaise with the radiologists and this may improve the diagnostic acumen.

5. It is clear from the percentages of positive radiological diagnosis of DVT that US, a quick system of thrombus identification, is essential for the management of DVT.

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	Clinical Diagnosis				Radiological Diagnosis							Risk Factors
					Thrombi		Location					
Patient No.	Age	Sex	S/S	Limb	Yes	no	Iliac	femoral	Popliteal	calf	Others	

INDEX

RISK FACTORS

a	Not indicated
b	Lymphoedema
c	Cellulitis
d	Use of hormonal contraceptives/pregnancy
e	Trauma
f	Renal diseases
g	Cardiac diseases
h	Cancer
i	Sickle cell disease
j	Post surgery
k	History of weight gain
l	Chronic leg ulcer
m	History of Hospitalization
n	Sudden onset
p	Varicose veins
q	Nephrotic Syndrome
r	Sciatica