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DIAGNOSTIC APPLICABILITY OF MODIFIED WELLS SCORE WITH COMPRESSION DUPLEX ULTRASOUND IN PREDICTING DEEP VEIN THROMBOSIS AMONG SUSPECTED CASES AT MUHIMBILI NATIONAL HOSPITAL

BY

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CERTIFICATION

This certifies that the signatory has examined and endorses the acceptance of the dissertation report titled, for consideration by Kairuki University: "DIAGNOSTIC APPLICABILITY OF MODIFIED WELLS SCORE WITH COMPRESSION DUPLEX ULTRASOUND IN PREDICTING DEEP VEIN THROMBOSIS AMONG SUSPECTED CASES AT MUHIMBILI NATIONAL HOSPITAL" in partial fulfillment of the requirements for the degree of Master of Medicine in Surgery.

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Date: _____

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As a resident researcher at Kairuki University, I recognize that plagiarism is a grave offense and affirm that all content in this research is solely of my authorship.

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Date: 28th November 2025

ACKNOWLEDGEMENTS AND DEDICATION

Primarily, I would like to thank God for granting me the strength and perseverance needed to complete this journey.

I would also like to express my deepest gratitude to my family, whose steadfast faith in me has continuously inspired and encouraged me. Your love and support have been my greatest strength.

This dissertation is sincerely dedicated to all patients affected by Deep Vein Thrombosis (DVT), and particularly to my father, Sure G.M. Mabusi, whose personal experience with DVT has profoundly influenced my dedication to this study. May this work provide understanding of the challenges they encounter and contribute to advancements in diagnosis and treatment.

Additionally, I dedicate this work to my treasured family: to my father, Sure G.M. Mabusi, whose resilience in the face of challenges has guided me throughout this journey; and to my mother, Neema G.W. Mabusi, whose unfailing love and selfless sacrifices have been the foundation of all I have become. This work is a tribute to your strength, and I am forever grateful for your unwavering support and inspiration.

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ABSTRACT

Background: Diagnosing DVT poses a challenge for clinicians due to its nonspecific symptoms and the limited sensitivity and specificity of physical examination findings. Various diagnostic methods have been employed, yet uncertainty regarding their accuracy challenges the establishment of cost-effective protocols. This is especially problematic in resource-limited settings, where excessive reliance on Compressed Duplex ultrasound can strain financial resources and delay care, while exclusive use of the Modified Wells Score may lead to under-diagnosis.

Objective: To assess the diagnostic applicability of the Modified Wells Score for deep vein thrombosis using compression duplex ultrasound as the reference standard

Methods: The study was conducted at Muhimbili National Hospital (MNH) from April to June 2025. Data regarding socio-demographic, clinical, type of diagnostic tool for DVT used, and operator factors were collected using a questionnaire. Data analysis was done using Statistical Package for Social Sciences (SPSS) version 23. The Receiver Operating Characteristic (ROC) curve was used to assess the validity of the Modified Wells Score and Compression Duplex Ultrasound in distinguishing between positive and negative DVT cases, along with calculating the area under the curve (AUC). The McNemar test was used to compare the two diagnostic modalities. A p-value of less than 0.05 will be considered statistically significant when appropriate.

Results: A total of 227 Patients were included, with 125 (55.1%) females and 207 (91.2%) having secondary education or higher.5 pt (2.2%) had a previous history of DVT (5, 2.2%). Hypertension was present in 139 (61.2%), Diabetes in 92 (40.5%), and Obesity in 33 (14.5%). According to the Modified Wells' score, 100 (44.1%) were classified as unlikely and 127 (55.9%) as likely to have DVT. Compression duplex ultrasound confirmed DVT in 80

(88.9%) of the likely group in MWS versus 10 (11.1%) in the unlikely group (p = 0.001). The Modified Wells Score showed fair accuracy (AUC = 0.775) at a cut-off >1, with sensitivity 88.9%, specificity 65.7%, overall accuracy 74.9%, NPV 90%, and PPV 63%, supporting its use as a screening tool rather than a confirmatory test.

Conclusion: The Modified Wells' score is a reliable screening and stratifying tool for deep vein thrombosis, especially effective in ruling out DVT in low-risk patients due to high sensitivity and negative predictive value. While its moderate specificity and lower positive predictive value require confirmatory imaging as an added diagnostic tool. Combining the score with D-dimer testing improves accuracy and cost-effectiveness, consistent with clinical guidelines. Given variability across populations and settings, local validation and cut-off adjustments are recommended to optimize its use. Overall, the Modified Wells' score supports efficient risk stratification and better resource allocation.

Recommendations: Clinicians may use the Modified Wells' score MWS to screen suspected DVT, especially to exclude low-risk cases and reduce unnecessary imaging. Positive scores require confirmatory imaging. Combining the Modified Wells' score with D-dimer testing improves accuracy and cost-effectiveness. Health-care institutions should validate and adjust cut-offs locally to optimize performance. Future research should assess diagnostic accuracy across diverse populations and settings.

TABLE OF CONTENTS

List of Tables

List of figures

ABBREVIATIONS AND ACRONYMS

DVT	Deep Vein Thrombosis
IREC	Institutional Research Ethics Committee
KU	Kairuki University
MNH	Muhimbili National Hospital
MoH	Ministry of Health
NPV	Negative Predictive Value
PE	Pulmonary Embolism
PPV	Positive Predictive Value
VTE	Venous Thromboembolism

DEFINITION OF TERMS

Applicability refers to the extent to which a concept, method, or finding is relevant, appropriate, and usable within a specific context, setting, or situation. It indicates how well the results or principles can be transferred, adapted, or implemented in the intended environment or population.

Accuracy is the degree to which a measurement or diagnostic test correctly identifies or excludes a condition.

Sensitivity: Probability that a test result will be positive when the disease is present (true positive rate) (1).

Specificity: Probability that a test result will be negative when the disease is not present (true negative rate)(1).

Negative Predictive Value (NPV): is the proportion of individuals with a negative test result who truly do not have the condition being tested for (1).

Positive Predictive Value: Probability that the disease is present when the test is positive (1).

Reliability: Refers to the consistency of the measurement. Reliability shows how trustworthy the score of the test is. (2).

Validity: Validity pertains to how accurately a measurement reflects what it is intended to assess. It indicates the extent to which a specific test is appropriate and applicable for a given situation. (2)

CHAPTER ONE

1.0 Introduction

Deep vein thrombosis (DVT) is a critical medical condition characterized by the formation of blood clots, primarily in the lower extremities, such as the legs or pelvis, though it can also occur in less common sites like the arms, mesenteric, and cerebral veins. (3,4). DVT is part of venous thromboembolism (VTE), which also includes pulmonary embolism (PE); together, these conditions represent the third leading cause of death from cardiovascular diseases after myocardial infarction and stroke (4–6). Pulmonary embolism, a potentially fatal complication of DVT, occurs when part of a thrombus detaches and migrates to the lungs, obstructing pulmonary circulation. (7,8). Despite its clinical importance, DVT is often underdiagnosed due to asymptomatic or nonspecific presentations. (7,8). Typical symptoms include unilateral leg pain, swelling, dilation of superficial veins, and skin discoloration, though many cases remain clinically silent (7). This nonspecific presentation complicates early detection, especially in settings lacking confirmatory diagnostics (9).

DVT risk is influenced by multiple factors, including advanced age, prolonged immobility, obesity, hormonal changes, surgery, trauma, cancer, and genetic predispositions (10). This broad risk profile increases the likelihood of underdiagnosis and highlights the need for structured, accessible diagnostic approaches that integrate both clinical and contextual factors. (11,12).

Globally, DVT poses a significant burden, with an estimated annual incidence of 80 cases per 100,000 people and a prevalence of approximately 1 per 1,000 population for lower limb DVT (8). Local research from Tanzania, although still relatively limited, shows that DVT/VTE is a significant concern, especially among patients recovering from surgery or those with immobilizing traumatic injuries. A study conducted at KCMC reported that approximately 10%

of lower-limb trauma patients had proximal DVT (13), while a larger longitudinal study at Bugando identified a VTE incidence of 11.8% in major surgical patients along with substantial VTE-related mortality (14). Both investigations also highlighted the inadequate use of thromboprophylaxis. Additionally, an audit from a hospital in Dar es Salaam found that 22% of admitted patients were categorized as at-risk for VTE, yet only about one-quarter of them received appropriate pharmacological prophylaxis (15). Beyond the acute risk of pulmonary embolism, long-term complications such as post-thrombotic syndrome (PTS) affect 30% to 50% of patients, causing persistent pain, swelling, skin changes, and, in severe cases, ulceration (16). Early interventions, including compression therapy, have been shown to reduce the risk of PTS, emphasizing the importance of timely diagnosis and management (17,18).

Diagnosing DVT is inherently challenging due to its nonspecific symptoms, making reliance on clinical judgment alone insufficient (19,20). The Modified Wells Score (MWS) offers a structured method to stratify patients based on clinical signs and history. (21). While valuable for guiding decision-making, MWS has limitations, including moderate sensitivity and specificity, particularly in populations with variable clinical presentations. (22).

Compression duplex ultrasound has become the preferred imaging modality for DVT. As a noninvasive first-line method, it provides high diagnostic accuracy and is widely used in practice, despite venography remaining the gold standard. (23–25). However, ultrasound requires specialized equipment and trained personnel, limiting its availability in resource-constrained settings where clinicians often rely on tools like the MWS. (24,25). Evaluating the applicability of MWS is therefore critical to ensure accurate patient stratification and efficient use of imaging resources.

Understanding the pathophysiological mechanisms of DVT, including venous stasis, endothelial injury, and hypercoagulability, further supports targeted diagnostic strategies and clarifies why specific risk factors are clinically significant (7,8,26). The interplay of clinical presentation, risk factors, pathophysiology, and diagnostic limitations underscores the need for an integrated approach to DVT assessment.

This study focuses on assessing the applicability of the Modified Wells Score in stratifying patients with suspected DVT at Muhimbili National Hospital.

1.1 Problem Statement

Deep Vein Thrombosis (DVT) is a significant global health concern due to its association with severe and potentially fatal complications, including Pulmonary Embolism (PE) (27). The incidence of DVT increases with age, affecting approximately 1.5 out of 1,000 adults annually in high-income countries, with rates rising significantly in individuals aged 85 and above. (28). Diagnosis of DVT is challenging due to nonspecific symptoms and their overlap with other conditions, leading to potential underdiagnoses or misdiagnoses. While Compression Duplex Ultrasound is considered the non-invasive first-line diagnostic modality, its reliance on specialized equipment and trained personnel may limit its availability in resource-constrained settings. (29).

The Modified Wells Score (MWS) offers a cost-effective, non-invasive initial screening tool for risk stratification in DVT diagnosis. (30). Studies have shown that a Wells score of less than 1 effectively rules out the possibility of DVT with high sensitivity and negative predictive value. (30). However, the predictive performance of the MWS may vary among different ethnic populations, and there is limited documentation regarding its utility in stratifying patients with suspected DVT in our setting in Tanzania. This lack of information hinders clinicians'

ability to decide on appropriate further evaluation or referral, potentially impacting patient outcomes.

Therefore, this study aimed to evaluate the diagnostic accuracy and applicability of the Modified Wells Score in stratifying patients with suspected DVT.

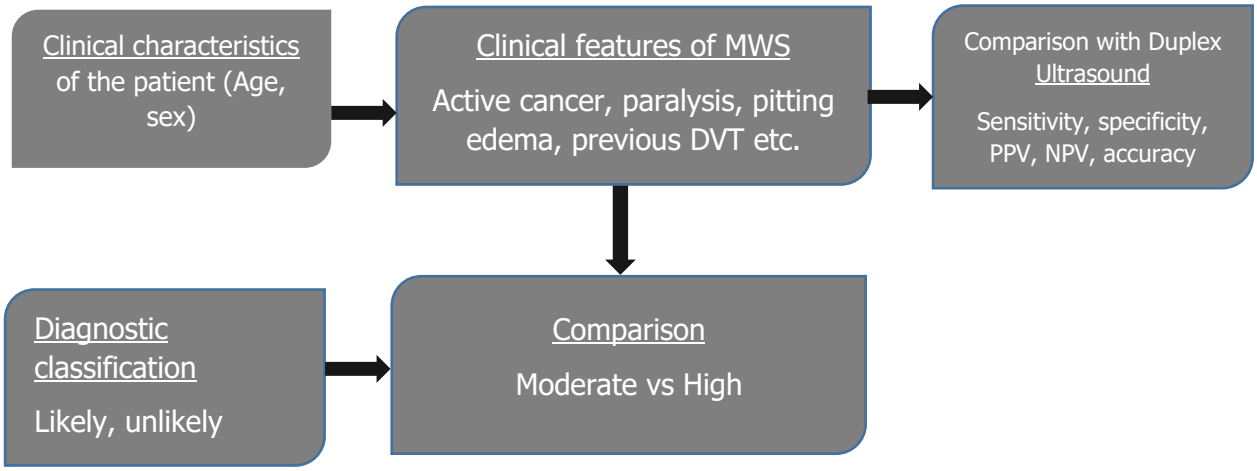
1.2 Rationale

The findings from this study will provide evidence of the Modified Wells Score in detecting DVT relative to compression duplex ultrasonography. Likewise, determining the diagnostic accuracy of the score will inform its utility in triaging patients for ultrasonographic evaluation. This may reduce unnecessary imaging, optimize resource utilization, and facilitate earlier diagnosis, particularly in settings where ultrasound equipment or trained personnel are limited.

1.3 Conceptual Framework

The diagnostic accuracy of DVT can vary depending on several interrelated factors. Patient-related characteristics, such as age, comorbid conditions, and symptom duration, influence clinical assessment outcomes. Operator factors, including clinical judgment and sonographic expertise, affect the interpretation of findings. Additionally, the type and quality of the diagnostic tool, particularly the compression duplex ultrasound equipment and technique used, contribute to variations in diagnostic performance, chart 1.

Chart 1: Conceptual Framework for Factors Affecting Diagnostic Accuracy



1.4 Research Question

What is the diagnostic accuracy of the Modified Wells Score in diagnosing deep vein thrombosis (DVT) among adult patients, using compression duplex ultrasound as the reference standard?

1.5 Objectives

1.5.1 Broad Objective

To assess the diagnostic applicability of the Modified Wells Score for deep vein thrombosis using compression duplex ultrasound as the reference standard

1.5.2 Specific Objectives

i. To describe the sociodemographic and clinical characteristics of patients with suspected deep vein thrombosis (DVT)
ii. To determine the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the Modified Wells Score in diagnosing DVT using compression duplex ultrasound as the reference standard
iii. To assess the diagnostic performance of the Modified Wells Score and compression duplex ultrasound using McNemar's test
iv. To determine the proportion of patients correctly classified by the Modified Wells Score

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Overview of DVT and Diagnostic Challenges

DVT is one of the leading preventable causes of illness and death globally (26). Although the exact number of people affected by DVT and PE is unclear, up to 900,000 individuals may be affected annually in the United States alone (31). In Africa, the prevalence of DVT ranges from 2.4% to 9.6% among postoperative patients and from 380 to 448 cases per 100,000 births annually in pregnant and postpartum women (32). In Tanzania, the incidence of venous thromboembolism (VTE) among patients undergoing major surgical procedures was reported to be 11.8% (14).

Conversely, the mortality rate for VTE is significant, with approximately 6% of patients with DVT and 13% of those with pulmonary embolism die within 30 days (33). Additionally, around 20% of individuals with a VTE event die within a year, and disabling complications are frequently observed among survivors (34). Studies have revealed that 10%-30% of persons who survive the first occurrence of VTE develop another VTE within 5 years (35). Thus, prompt and accurate diagnosis is critical to reducing the risk of PE and other adverse outcomes (27).

Diagnosing DVT is challenging due to non-specific vague symptoms, but recent advances have enabled rapid detection in high-risk individuals (7,8,26,36). Nonetheless, a strong level of clinical suspicion and a comprehensive approach that combines clinical evaluation, assessment of pre-test likelihood, and confirmatory diagnostic testing should be implemented (36). Diagnostic tests such as d-dimer are widely used in diagnosing DVT. D-dimer is a marker for coagulation and fibrinolysis, helping diagnose conditions like DVT and pulmonary embolism (PE). Elevated levels indicate active clot formation but are nonspecific, also rising

in conditions such as infection, inflammation, cancer, or pregnancy (37). It can also signal recurrent venous thromboembolism (VTE) (38). Although commonly used as an initial test in suspected VTE cases, its low specificity (40%-60%) leads to many false positives (38,39). D-dimer testing is most effective when combined with clinical prediction tools like the Modified Wells score to rule out DVT in low-risk patients (40). A normal result can exclude DVT in such patients, reducing the need for further imaging.

2.2 Modified Wells Score

The Original Wells Score, developed in 1997, was designed to estimate the clinical probability of DVT by integrating patient history, physical examination findings, and recognized risk factors. It comprises nine criteria with positive point assignments, stratifying patients into low, moderate, or high probability categories (41).

The Modified Wells Score was subsequently developed to enhance clinical utility and streamline decision-making. Key modifications include a simplified point system and dichotomization of risk into "DVT likely" (≥2 points) and "DVT unlikely" (<2 points) (21,42,43). In addition, the modified version explicitly accounts for the likelihood of alternative diagnoses, assigning negative points (-2) when another diagnosis is as likely as DVT, thereby improving predictive accuracy (44). This streamlined approach facilitates rapid bedside assessment and provides clearer guidance regarding the need for further investigations, such as compression duplex ultrasonography or D-dimer testing (42,44).

Studies have found sensitivities and specificities of the modified wells score in diagnosing DVT ranging from 80-100% and 6.5-74% respectively (30,45,46). Among patients with a low pretest probability, the Modified Wells score has a failure rate of 5.9% and an efficiency of 11.9% (47). As highlighted, the effectiveness of the Modified Wells score in diagnosing DVT is therefore contradicting; some studies directly approve its use for early prediction and

timely anticoagulant initiation (48), while others recommend its use (26,47,49–51). In another similar study, it was revealed that the Modified Wells score risk stratification alone cannot rule out DVT or guide management decisions, particularly in inpatient settings (47). Likewise, MWS is particularly affected by the subjective interpretation of clinical findings and is not useful in hospitalized patients and those with isolated distal DVT (52). Furthermore, the while the Modified Wells Score rule generally stratifies patients effectively by risk, its performance can vary in specific subgroups, such as patients with cancer or suspected recurrent events, which demographic factors may also influence (53).

While the Modified Wells score is widely used for DVT risk stratification, its variable sensitivity and specificity underscore the need for comparison with more definitive diagnostic tools like Doppler ultrasound. The present study employs the Modified Wells Score due to its simplified, dichotomized structure, which supports rapid clinical decision-making, reduces unnecessary imaging, and optimizes resource utilization, particularly in settings with limited access to compression duplex ultrasound. Its demonstrated predictive accuracy makes it an appropriate tool for guiding DVT diagnosis and improving patient outcomes (44).

2.3 Compression Duplex Ultrasound versus Venography

Venography is a radiographic imaging technique used to diagnose deep vein thrombosis (DVT). It involves injecting radiopaque iodine-based contrast dye into a vein, usually in the foot or ankle, to visualize the venous system through X-ray or fluoroscopic images (54). Due to its high accuracy and High-resolution anatomical mapping, in detecting thrombi in both proximal and distal veins, venography is considered the gold standard for diagnosing DVT. However, its use has declined due to its invasive nature, high cost, and associated risks such as allergic reactions or nephrotoxicity from contrast, Discomfort from needle puncture, radiation exposure, and Risk of contrast extravasation or thrombophlebitis (23,40).

As a result, compression duplex ultrasound has largely replaced venography as the reliable non-invasive first-line tool imaging modality for suspected DVT due to its safety, accessibility, and excellent diagnostic performance.

These compression duplex ultrasounds can either be elective, performed by radiologist, or conducted at the bedside by trained physicians, offering high accuracy (55). Globally, studies report a combined sensitivity of 95% and specificity of 98% (56). Despite its high accuracy, Doppler ultrasound faces challenges such as dependency on operator skill, equipment availability, and cost, particularly in resource-limited settings (24,25,57).

2.4 Factors Affecting Diagnostic Accuracy

Several factors affect the performance of these diagnostic methods, including a range of patient-specific characteristics. Factors such as advancing age, sex, and a personal or family history of thromboembolic events significantly elevate risk (58,59). Similarly, lifestyle factors such as prolonged immobility, obesity, and smoking promote venous stasis, comorbid conditions like cancer, heart failure, and autoimmune disorders exacerbate hyper-coagulability, hormonal influences, particularly during pregnancy, postpartum periods, and with estrogen-based therapies are notable risk enhancers in female patients, location of the thrombus and health-care system constraints (11,59,60).

The Modified Wells Score is also affected by the subjective interpretation of clinical findings and is not useful in hospitalized patients and those with isolated distal DVT (22,52). On the other hand, Compression duplex ultrasound’s accuracy depends on the operator's expertise and the timing of the evaluation (24,25). The diagnostic accuracy of compression duplex ultrasound for DVT also varies with the technique, demonstrating high sensitivity for proximal DVT, moderate sensitivity for distal DVT, and consistently high specificity (61). A meta-analysis reported that ultrasound has a pooled sensitivity of 94.2% for diagnosing proximal

DVT but only 63.5% for detecting distal DVT, underscoring its reduced accuracy for distal thrombi (26,61). The reduced accuracy of ultrasound in diagnosing distal DVT is largely attributable to anatomical and technical factors. Distal calf veins are smaller, paired, and often embedded within muscle compartments, making visualization and assessment of compressibility more difficult than in proximal veins (62,63). Additionally, distal thrombi are frequently asymptomatic or minimally symptomatic, reducing clinical suspicion and operator focus during scanning (62). From a technical standpoint, ultrasound resolution is less effective in smaller and deeper vessels, and compression testing is less reliable below the knee (62). Furthermore, distal DVTs often demonstrate dynamic behavior, including spontaneous resolution or later proximal extension, which complicates detection during a single examination

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 Study design

This is a facility-based prospective cross-sectional study.

3.2 Study setting

The study was conducted at Muhimbili National Hospital (MNH) in Dar es Salaam, which is both a National Referral and University Teaching Hospital in Tanzania. MNH has a 1,500-bed capacity and serves around 1,000 to 1,200 outpatients and admits a similar number of inpatients each week. Available data indicates that approximately 1,500 patients were diagnosed with DVT in 2024.

3.3 Study Population and Duration

All adult patients suspected of having lower-extremity DVT undergoing lower-extremity Compression duplex ultrasound studies between July to September 2025, were included.

3.4 Sample size estimation

A total of 227 patients were included in this study. The sample size was estimated using the Kish Leslie formula, applying a prevalence rate of 18% for DVT based on findings from a pilot study at MNH. Additionally, a 5% margin of error was considered in the calculation.

$$n = \frac{z^2 p(1-p)}{e^2}$$

Where, n = Sample size, z = at 95% confidence interval z value = 1.96, p = 18% based on findings from a pilot study at MNH, e=Margin of error at 5% (0.05),

$$n = \frac{1.96^2 \times 0.18\ (1-0.18)}{0.05^2} = 227 \text{ patients}$$

3.5 Sampling method

After obtaining informed consent, patients were recruited using a convenient sampling technique. All adult patients (aged 18 years and above) presenting to Muhimbili National Hospital in the wards (OPD and IPD), during the study period (July to September 2025) with clinical symptoms suggestive of DVT such as limb swelling, pain, or tenderness, were assessed for eligibility based on the inclusion and exclusion criteria. Eligible patients who were available and willing to participate at the time of data collection were consecutively consented and enrolled until the required sample size was attained. This approach was appropriate given the time constraints and the unpredictability of DVT presentations in the hospital setting.

3.6 Procedures for data collection

3.6.1 Data collection methods

This was a hospital-based prospective cross-sectional study conducted at Muhimbili National Hospital. The study was carried out in the Radiology and Imaging Department, where patients with clinical suspicion of deep vein thrombosis (DVT) were referred for diagnostic evaluation. Eligible adult patients (aged ≥18 years) who presented to the Emergency Department, Medical Wards, or Outpatient Clinics and were referred to the Radiology Department for DVT assessment were consecutively recruited during the study period. After obtaining informed consent, each participant was interviewed first and examined by the investigator followed by the radiological investigation.

Data were collected using a structured questionnaire developed by the authors to capture information relevant to the study objectives. The questionnaire included sections on sociodemographic characteristics (such as age, sex, and residence), clinical information (including risk factors and presenting symptoms), the type of diagnostic tool used, and

operator-related factors. Each participant underwent a clinical evaluation using the Modified Wells Score (MWS) to estimate the pretest probability of DVT. Based on the total score, participants were categorized as either "DVT likely" (≥2 points) or "DVT unlikely" (<2 points). All participants subsequently underwent a compression duplex ultrasound (CDUS) examination of the affected limb, performed by a radiologist. The ultrasound served as the reference standard to confirm or exclude the presence of thrombus. Findings were recorded immediately after the examination using a standardized reporting format.

3.6.2 The Modified Wells Score

Patients received 1 point for the presence of each clinical predictor (recently bedridden or major surgical procedure; entire leg swollen; localized tenderness along the distribution of deep venous system; active cancer; pitting edema; calf swelling; paralysis, paresis, or recent plaster immobilization of lower extremity; previously documented DVT; or collateral superficial veins), except for the presence of an alternative diagnosis, which subtracted 2 points. The sum of points was used to classify the patient's pretest probability of DVT as "DVT likely" (≥2 points) and "DVT unlikely" (<2 points).

Chart 2: Modified Wells Criteria: Clinical evaluation table for Predicting the Probability of DVT

Modified Wells Criteria: Clinical Evaluation Table for Predicting the Probability of a DVT	
Clinical Characteristic(s)	**Score**
Active cancer	+1
Paralysis, paresis, or recent plaster immobilization of the lower extremities	+1
Recently bedridden for three days or major surgery within the last 12 weeks	+1
Localized tenderness along the deep venous system	+1
Entire leg swollen	+1
Calf swelling ≥ 3 cm larger than asymptomatic side	+1
Pitting edema confined to symptomatic leg	+1
Collateral superficial veins	+1
Previously documented DVT	+1
Alternative diagnosis at least as likely as a DVT	-2
Clinical Probability of DVT	**Total Score**
Likely	< 2
Unlikely	≥ 2

3.6.3 Compression Duplex Ultrasound

Compression duplex ultrasound served as the reference standard for determining the true disease status (i.e., presence or absence of DVT). Patients with a clinical suspicion of DVT underwent a Compression duplex examination of both inferior limbs. Compression duplex ultrasound was performed by a radiologist. During the examination, the patient is positioned with the affected leg elevated or in a relaxed position. A transducer was then be placed along the veins, typically beginning at the common femoral vein and progressing downward. Blood flow was evaluated in real-time using color and spectral Doppler imaging. Each case was diagnosed as positive, negative, or inconclusive (64,65). The following criteria were used to interpret results as listed below:

Chart 3: Diagnosis of Deep Vein Thrombosis Using Compression Duplex Ultrasound

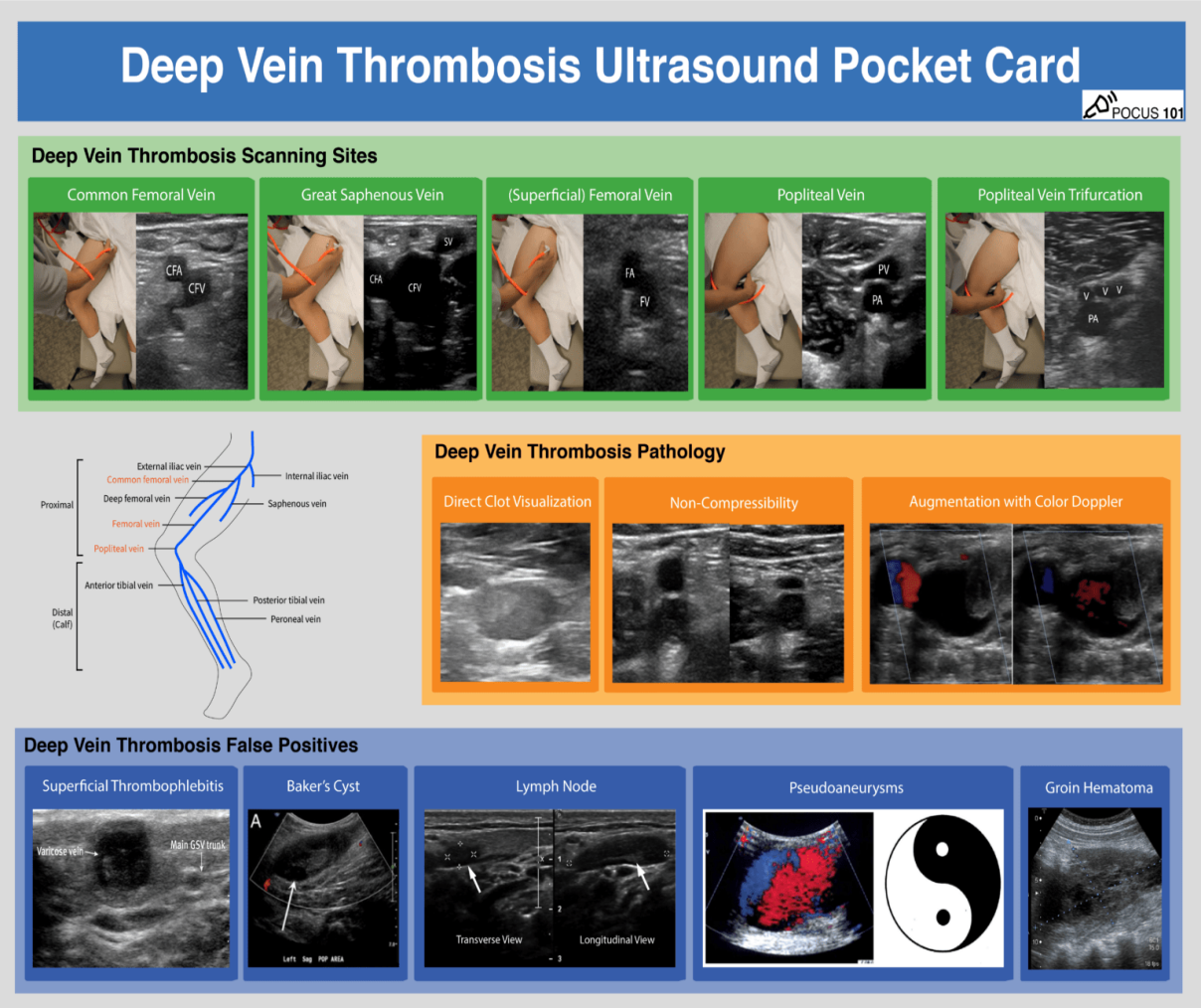


Chart 4: Interpretation of Compression Duplex Ultrasound results – Adapted from Karande et al (2016) - (65)**.**

No.	Criterion	Description
1.	Loss of vein compressibility	Vein fails to fully collapse when pressure is applied with the ultrasound probe, indicating a thrombus
2.	Visualization of thrombus	Echogenic or hypoechoic material visible within the vein lumen
3.	Absence of flow	Lack of colour flow or spectral Doppler signal in the affected vein due to obstruction
4.	Abnormal venous distention	Vein appears dilated or engorged, often associated with acute thrombi.
5.	Loss of respiratory phasicity	No change in venous flow with respiration; indicates proximal obstruction
6.	Loss of augmentation	No increase in venous flow when manual pressure is applied distal to the probe.
7.	Abnormal waveforms	Continuous spectral Doppler waveforms instead of normal pulsatile flow.

3.7 Eligibility criteria

3.7.1 Inclusion criteria

All consenting patients suspected of having DVT from both Inpatient and Outpatient settings within the Surgical, Medical, and Obstetrics and Gynecology departments.

3.7.2 Exclusion criteria

- Active bleeding disorders
- Clinical suspicion of PE
- Patient on anti-coagulation therapy i.e. heparin

For patients with more than one Compression duplex ultrasound scan performed during the same clinical encounter or admission, only the first scan was included for analysis to avoid duplication.

3.8 Study variables

3.8.1 Dependent variable

Diagnostic accuracy of the Modified Wells Score was assessed by comparing its results to the first line standard (compression duplex ultrasound).

3.8.2 Independent variables

- Socio-demographic characteristics (age in years, sex, highest level of education attained, occupation, access to health-care, education and awareness etc.)
- Clinical characteristics (Primary complaint, duration of symptoms, relevant medical history, risk factors, presence of comorbidities)
- Operator factors (professional cadre, years of experience)
- Type of the diagnostic test used (Both MWS and compression duplex ultrasound)

3.9 Ethical considerations

Eligible study patients were provided with a detailed explanation of the study and its purpose, was given to the patient, and assured that their decision to accept or refuse participation would not affect the care they receive at the facility. To mitigate fear and anxiety, participants were offered assurance and detailed explanations before undergoing MWS assessment and compression duplex ultrasound. Once each participant had understood the information provided, they were asked to grant consent (written in both Swahili and English) to take part in the study. The nondisclosure agreement was sustained throughout the study timeline. Each participant was given a distinct identifier, and study procedures were conducted only after obtaining their voluntary agreement to participate. Research data collection assistants helped to ensure a conducive environment for privacy during data collection, all patient-related information and research data were securely protected, ensuring that personally identifiable information was accessible only to authorized personnel.

To achieve this, Physical copies of the data collection tools were safely kept in a locked cabinet, with access limited to authorized personnel only, including Principal Investigator, Research assistant and radiologist. Meanwhile, digital records were stored on secured computers with password access, guaranteeing restricted access to the Principal Investigator.

3.10 Ethical clearance

Ethical approval was granted by the Institutional Research Ethics Committee (IREC) of Kairuki University, and authorization to carry out the study was sought from MNH. Before enrollment in the study, each client or caretaker was given the opportunity to grant verbal consent for study participation, in accordance with the informed consent procedures.

3.11 Validity and Reliability of the Data Collection Instrument

To ensure the validity and reliability relating to study instrument, a pre-designed questionnaire was used to collect data on socio-demographics, clinical characteristics, diagnostic tool usage, and operator factors. The validity of the questionnaire was ensured by reviewing its content to confirm it accurately measures the intended variables and by consulting experts in the field. Reliability was assessed through pilot testing on a small sample, allowing for test-retest or inter-rater reliability checks to ensure consistent responses. Any required modifications were implemented based on the pilot study findings to enhance the instrument prior to the main data collection.

3.12 Plan for Data Management

3.12.1 Data entry and refinement

Completed questionnaire were reviewed for accuracy and consistency at the end of each working day to ensure the data is correctly recorded and any discrepancies are addressed promptly.

3.12.2 2 Approach to Data Analysis

The collected data were cleaned prior to analysis, which was conducted using the Statistical Package for the Social Sciences (SPSS) version 23. Frequencies and percentages were used to summarize discrete variables, and the results were displayed in tables. The Receiver Operating Characteristic (ROC) curve was used to assess the validity of the Modified Wells Score and Compression Duplex Ultrasound in distinguishing between positive and negative DVT cases, along with calculating the area under the curve (AUC). Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for each diagnostic tool to assess their individual accuracy. Likewise, McNemar test was used to compare the two diagnostic modalities. A p-value of less than 0.05 was considered statistically significant when appropriate.

3.13 Dissemination of the Research findings

The outcomes of this study will be presented to the Department of Surgery at Kairuki University and Muhimbili National Hospital, and also at national and international conferences. The dissertation report will be submitted to Kairuki University as part of the requirements for the Master of Medicine in Surgery degree. The report will be archived in the Kairuki University library and the Department of Surgery. Furthermore, a manuscript will be developed and forwarded for review, consideration, and publication in a peer-reviewed journal.

CHAPTER FOUR

4.0 RESULTS

4.1 Socio-demographic and clinical characteristics of the patients

4.1.1 Socio-demographic characteristics of patient

A total of 227 clients were included in this study. The majority were females (125, 55.1%). More than three quarters had attained a secondary education or higher (207, 91.2%), Table 1.

Table 1: Socio-demographic characteristics of patient

Variables	Frequency	Percentage
Age category		
18-44	52	22.9
45-49	62	27.3
60+	113	49.8
Age (years) – median (IQR)	**56.9(46-68)**	
Sex		
Male	102	44.9
Female	125	55.1
Occupation		
Employed	66	29.1
Self-employed	161	70.9
Education level		
None	1	0.4
Primary	19	8.4
Secondary	124	54.6
University/College	83	36.6
Residence		
Rural	40	17.6
Urban	187	82.4

4.2 Clinical characteristics of the Patients

It was revealed that just a few (5, 2.2%) of the clients had a previous history of DVT. More than a half of the patients had Hypertension (139, 61.2%) while Diabetes Mellitus was noted in 92 (40.5%) of the patients. Likewise, Obesity was noted in 33(14.5%) of the patients, Table 2.

4.2.1 Symptoms of the study participants

The major symptoms among patients were leg swelling (210, 92.5%) and leg pain (187, 82.4%), table 2 and figure 1.

Table 2: Symptoms among patients

Variables	Frequency	Percentage
Leg pain		
Yes	187	82.4
No	40	17.6
Leg swelling		
Yes	210	92.5
No	17	7.5
Redness/Warmth		
Yes	85	37.4
No	142	62.6
Duration of symptoms		
<1 week	55	24.2
1-2 weeks	94	41.4
>2 weeks	78	34.4

Symptoms

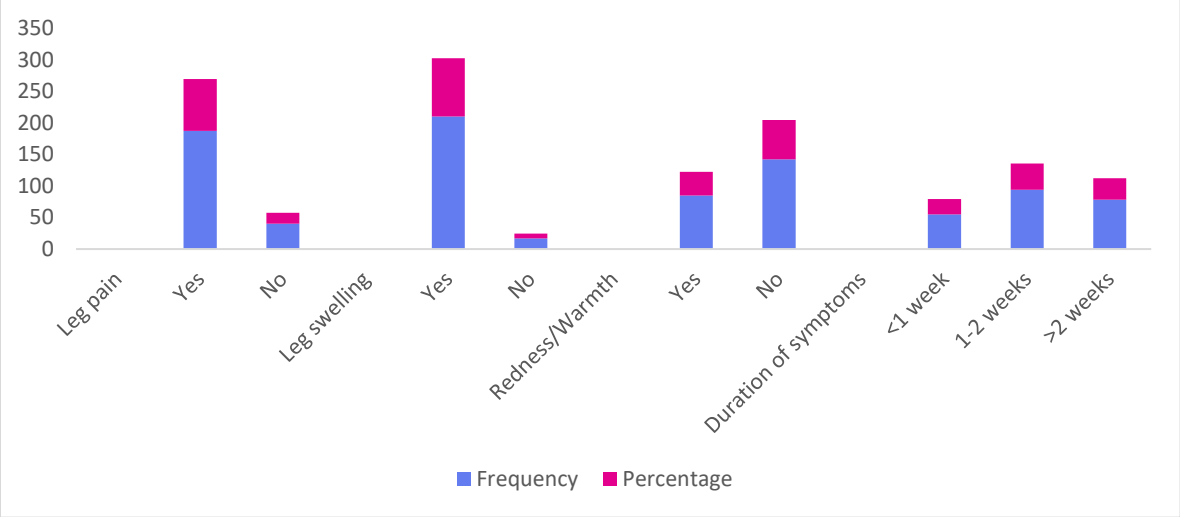


Figure 6: Symptoms of the patients

4.2.2 Medical history of the study participants

The majority of patients had a previous history of a recent surgery (42, 18.5%), followed by active cancer (11, 4.8%), table 3 and figure 2.

Table 3: Medical History of the patients

Variables	Frequency	Percentage
Active cancer		
Yes	11	4.8
No	216	95.2
History of DVT		
Yes	5	2.2
No	222	97.8
Known clotting disorder		
Yes	7	3.1
No	220	96.9
Recent surgery		
Yes	42	18.5
No	185	81.5

Medical history

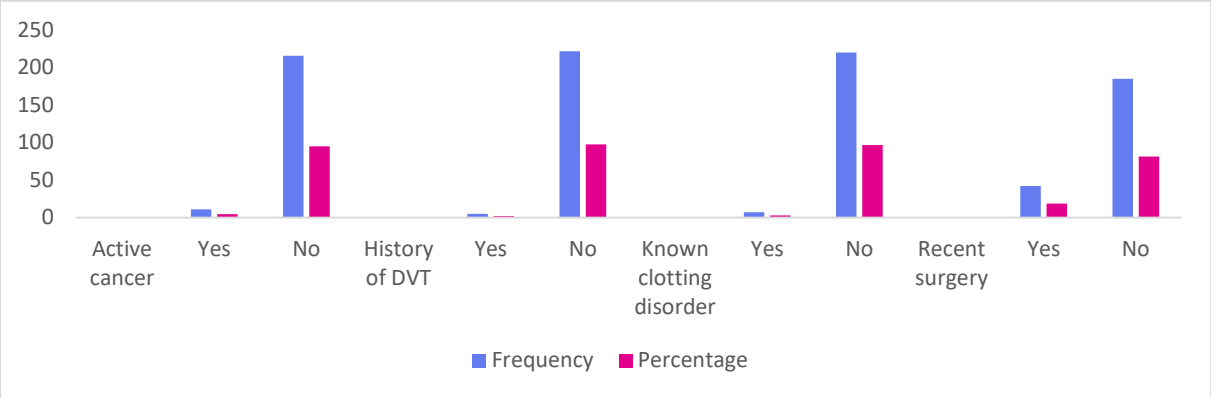


Figure 7: Medical History of the patients

4.2.3 Risk factors associated with development of DVT among study participants

Prolonged immobility emerged as the major risk factor (115, 50.7%) followed by hormonal therapy (58, 25.6%), table 4 and 3.

Table 4: Risk factors associated with development of DVT among patients

Variables	Frequency	Percentage
Recent trauma		
Yes	31	13.7
No	196	86.3
Prolonged immobility		
Yes	115	50.7
No	112	49.3
Hormonal therapy		
Yes	58	25.6
No	169	74.4
Smoking		
Yes	17	7.5
No	210	92.5

Risk factors

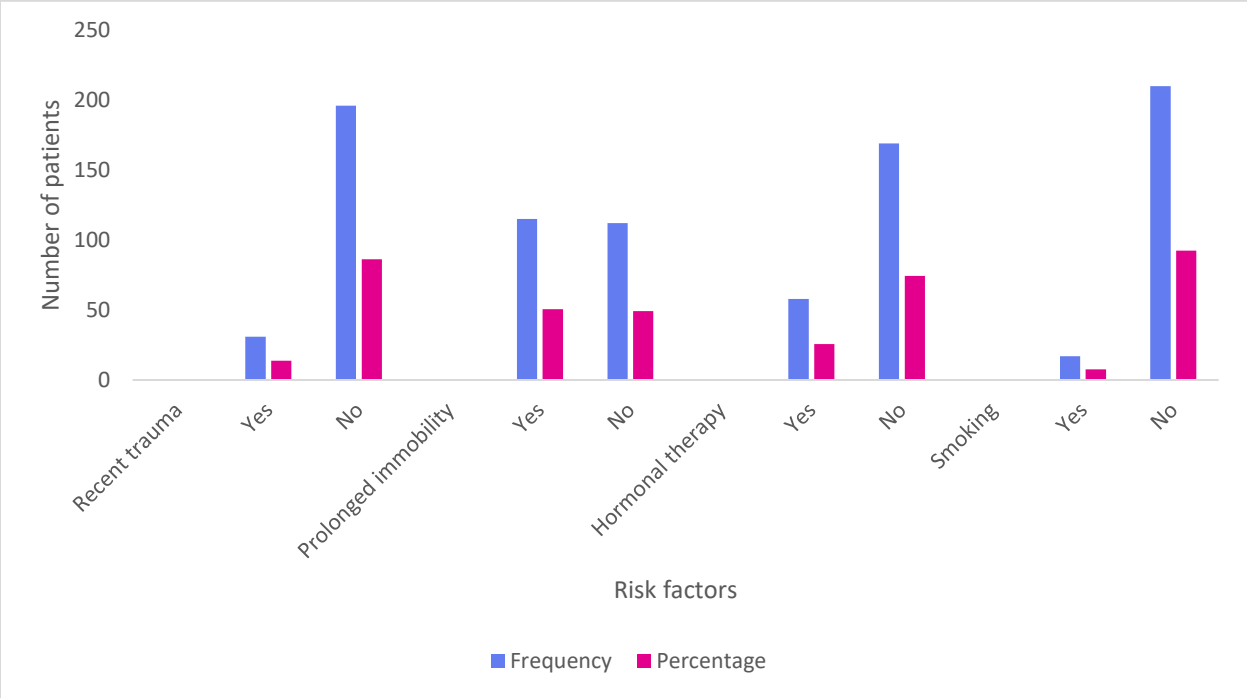


Figure 8: Risk factors associated with development of DVT among study participants

4.2.4 Comorbidities among patients

The majority of patients had hypertension (139, 61.2%) followed by renal disorders (41, 18.1%), table 5 and figure 4.

Table 5: Comorbidities among patients

Variables	Frequency	Percentage
BMI > 30		
Yes	33	14.5
No	194	85.5
Hypertension		
Yes	139	61.2
No	88	38.8
Diabetes Mellitus		
Yes	92	40.5
No	135	59.5
Cardiac disorder		
Yes	20	8.8
No	207	91.2
Renal Disorders		
Yes	41	18.1
No	186	81.9
Pregnancy		
Yes	12	9.6
No	113	90.4
NA	102	0

Comorbidities among patients

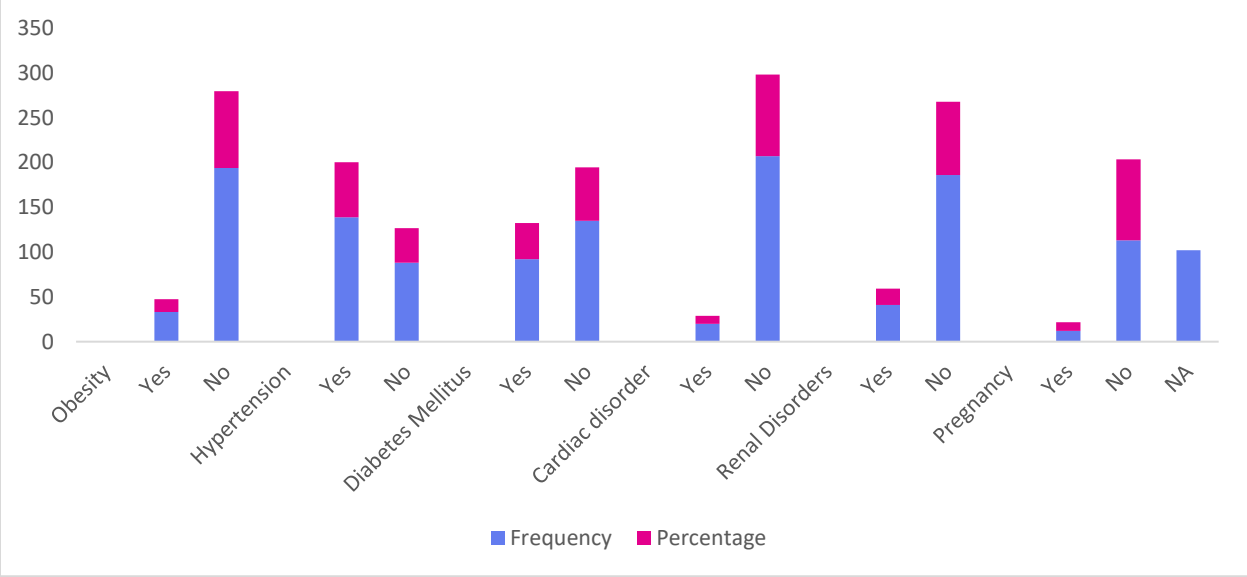


Figure 9: Comorbidities among patients with DVT

4.3 Distribution of Modified Wells Scores and Corresponding Compression Duplex Ultrasound Results

Patients with lower Wells Scores (e.g., -2 to 1) predominantly tested negative for DVT on Compression Duplex Ultrasound, while those with higher scores (2 and above) had progressively higher proportions of confirmed DVT. For instance, among patients scoring 1 or below, only a small fraction were Compression duplex ultrasound positive, whereas scores of 3 or higher were associated with a majority of patients confirmed to have DVT. This trend illustrates the increasing likelihood of DVT with rising Modified Wells Score and supports the score's predictive validity in clinical assessment, Table 4.

Table 6: Distribution of Modified Wells Scores and Corresponding Compression Duplex Ultrasound Results.

Modified Wells' Score	DVT Positive n (%)	DVT Negative n (%)	Total n (%)
-2	0 (0.0)	2 (1.5)	2 (0.9)
-1	0 (0.0)	5 (3.6)	5 (2.2)
0	1 (1.1)	10 (7.3)	11 (4.8)
1	9 (10.0)	73 (53.3)	82 (36.1)
2	15 (16.7)	20 (14.6)	35 (15.4)
3	20 (22.2)	12 (8.8)	32 (14.1)
4	18 (20.0)	8 (5.8)	26 (11.5)
5	10 (11.1)	5 (3.6)	15 (6.6)
6+	17 (18.9)	2 (1.5)	19 (8.4)
Total	**90 (100)**	**137 (100)**	**227 (100)**

4.4 The association between the Compression Duplex USS study and the Modified Wells' Score

According to the Modified Wells' score, 100 patients (44.1%) were classified as unlikely to have DVT, while 127 patients (55.9%) were classified as likely. Compression Duplex ultrasound confirmed DVT in 80 patients (88.9%) within the likely group, compared to 10 patients (11.1%) in the unlikely group, and this difference was statistically significant ($p = 0.001$), Table 7.

Table 7: The association between compression duplex ultrasound study and Modified Wells' Score

Modified Wells' Score	Compression Duplex Ultrasound Study		P-value
	DVT	No DVT	
Likely to have DVT (≥2)	**80**	**47**	**0.001**
Unlikely to have DVT (<2)	**10**	**90**	

- **Unlikely DVT (MWS <2):** 10 had DVT (FN), 90 did not (TN).
- **Likely DVT (MWS ≥2):** 80 had DVT (TP), 47 did not (FP).

So:

- True Positive = 80
- False Positive = 47
- False Negative = 10
- True Negative = 90

4.5 Diagnostic validity of Modified Wells' Score using ROC Analysis

The ROC curve analysis showed that the Modified Wells Score had good diagnostic accuracy for predicting DVT with an AUC of 0.849(95% CI: 0.79-0.90, p=0.001), figure 5.

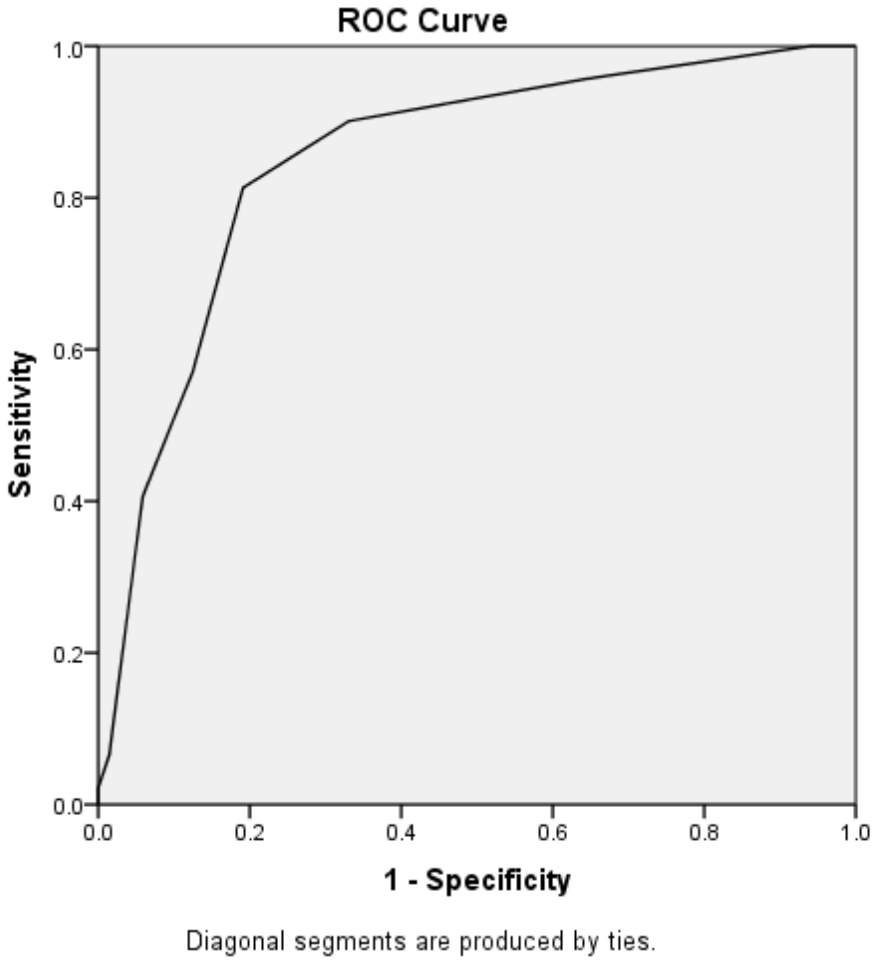


Figure 10: ROC curve showing the diagnostic performance of the Modified Wells Score compared to Compression Duplex Ultrasound for the Diagnosis of DVT

Similarly, sensitivity was 88.9% and specificity was 65.7%, yielding an overall accuracy of 74.9%. NPV (90%) exceeded PPV (63%), supporting its role as a screening rather than confirmatory tool for DVT, Table 8.

Table 8: Diagnostic validity of Modified Wells' Score using ROC Analysis

Diagnostic metric	Value
Sensitivity	88.9%
Specificity	65.7%
Positive predictive value	63.0%
Negative predictive value	90%
Accuracy	74.9%
Area under the curve	0.849(0.79-0.90)
Optimal cut point	>1
P-value	0.001

CHAPTER FIVE

5.0 Discussion

This study involved patients with clinical suspicion of deep vein thrombosis (DVT) presenting at the study site. The participants' sociodemographic characteristics reflected a population commonly affected by DVT, with most being adults in the middle to older age groups (66,67). This finding aligns with existing evidence that DVT incidence increases with age due to reduced mobility, venous valve incompetence, and comorbidities. (68). Females comprised a slightly higher proportion of the study population, consistent with prior studies suggesting hormonal factors, pregnancy, and contraceptive use as important risk determinants. Clinically, the most common presentations included unilateral leg swelling, pain, and tenderness, which are classical symptoms of DVT described in other clinical investigations. (69). These findings collectively illustrate that the study population's characteristics were typical of patients at risk of venous thromboembolism.

The Modified Wells Score (MWS) demonstrated good diagnostic performance in identifying patients with and without DVT. In this study, the MWS achieved an area under the curve (AUC) of 0.849, with a sensitivity of 88.9%, specificity of 65.7%, positive predictive value (PPV) of 63%, and negative predictive value (NPV) of 90%. These results indicate that the MWS has a strong capacity to rule out DVT in low risk patients while maintaining reasonable discrimination between positive and negative cases. The findings are consistent with those reported by Goodacre et al. (2005), who demonstrated that the MWS performs well in ruling out DVT with high sensitivity and acceptable specificity (70). Similarly, several other studies (71–73) have shown comparable diagnostic metrics, highlighting the robustness of the score across diverse populations and settings. The similarity in sensitivity across studies can be attributed to the score's design, which incorporates key clinical variables strongly associated

with DVT. However, minor differences in specificity may arise from variations in patient selection, disease prevalence, and local diagnostic thresholds.

The moderate specificity (65.7%) observed in this study, while consistent with previous reports, represents a notable limitation. This implies that a proportion of patients without DVT were incorrectly classified as "DVT likely," potentially leading to unnecessary imaging or treatment. The finding aligns with the observations of Goodacre et al. (2005), who also reported moderate specificity and highlighted that while high sensitivity is desirable to avoid missed diagnoses, it comes at the cost of lower specificity. (70). Studies conducted in other clinical environments, including emergency and outpatient settings, have reported slightly higher or lower specificity. (71–73), possibly due to differences in case mix, examiner experience, and underlying prevalence of DVT. For instance, populations with higher baseline risk, such as hospitalized or post-surgical patients, tend to produce higher positive predictive values, whereas community based cohorts show higher negative predictive values. Such differences emphasize the need for local validation of the MWS to ensure that its predictive capacity remains accurate and clinically relevant within specific healthcare contexts.

The results of this study showed that the MWS correctly classified a substantial proportion of patients when compared with compression duplex ultrasound, which served as the reference standard. The good discriminatory ability (AUC 0.849) observed is comparable to previous studies reporting moderate to good performance (74,75), confirming that the MWS remains a reliable screening tool for DVT risk stratification. Differences in AUC values across studies can often be explained by variations in sample size, case selection, and operator expertise in conducting the reference ultrasound. Despite such variability, the overall pattern across the literature supports the MWS as a useful triaging tool, particularly in resource limited settings where imaging availability may be constrained.

The higher NPV compared to PPV in this study reinforces the clinical utility of the MWS as a safe method for excluding DVT among patients categorized as low risk. This finding aligns with earlier reports. (76) Showing that the MWS is particularly valuable for ruling out DVT rather than confirming it. The relatively low PPV observed suggests that a positive MWS alone is insufficient for diagnosis and must always be followed by confirmatory imaging, such as compression duplex ultrasound. This interpretation supports the current understanding that while clinical scores are excellent for screening, definitive diagnosis should rely on imaging to avoid false positives and unnecessary treatment.

In summary, this study confirms that the Modified Wells Score is a reliable, easy-to-use, and clinically valuable tool for assessing DVT probability. Its high sensitivity and negative predictive value make it effective for ruling out disease in low-risk individuals, thus optimizing imaging use. The performance metrics obtained are consistent with findings from previous studies, with differences largely attributable to contextual factors such as disease prevalence and study setting. The findings support the continued use of the MWS in clinical practice, particularly as a triaging instrument in settings where diagnostic resources are limited.

5.1 Conclusion

This study demonstrated that the Modified Wells Score is a useful and reliable clinical tool for assessing the probability of deep vein thrombosis among patients with suspected disease. The score showed good ability to identify patients unlikely to have DVT, supporting its role in guiding the use of compression duplex ultrasound. The findings also indicated that DVT was more common among older adults and females, with typical presentations of leg pain, swelling, and tenderness. Overall, the study confirms that the Modified Wells Score can enhance clinical decision-making by improving diagnostic efficiency and reducing unnecessary imaging, particularly in resource-limited settings.

5.2 Recommendations

Clinicians should continue using the Modified Wells Score as an initial screening tool for patients with suspected DVT, particularly to safely exclude DVT in low-risk individuals and guide the use of imaging resources and possible referral to a nearby hospital for further evaluation in case of immediate urgency. Positive scores should always be followed by a confirmatory compression duplex ultrasound to ensure accurate diagnosis and management. Healthcare institutions are encouraged to conduct local Application studies in diverse groups of patients to further evaluate the accuracy of the study. Future research should assess the applicability and accuracy of the Modified Wells Score across wider populations and healthcare environments to strengthen evidence-based use.

5.3 Limitations and Mitigation's

One limitation of this study was the use of convenient sampling, which may have introduced selection bias and limited the generalizability of the findings to the wider population. To mitigate this, efforts were made to recruit participants who closely represented the typical patient population encountered in routine clinical practice. Another limitation was the subjectivity of the Modified Wells' Score, as it relied on clinical judgment, which may have varied between clinicians. To minimize this variability and enhance consistency, standardized training sessions and clear application guidelines were provided before and during the study. Additionally, the operator dependency of Compression Duplex Ultrasound posed a limitation, as its accuracy could be influenced by the skill level of the operator. To address this, all compression duplex ultrasound examinations were conducted by a radiologist using standardized protocols, with ongoing quality assurance monitoring to ensure reliability.

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APPENDICES

Appendix I: Diagnostic applicability of Modified Wells Score with Compression Duplex Ultrasound in predicting Deep Vein Thrombosis among suspected cases at Muhimbili National Hospital

(English Version)

Participant Details:

- Participant ID: _____
- Date of Data Collection: _____
- Research Assistant Name: _____

Section 1: Sociodemographic Information

1. Age (years): _____
2. Gender: Male / Female
3. Occupation: Employed / Unemployed / Self-employed / Retired
4. Level of Education: No formal education / Primary education / Secondary education / Tertiary education
5. Residence: Urban / Rural

Section 2: Clinical Characteristics

6. Primary complaint (select all applicable):
    - Leg pain
    - Leg swelling
    - Redness or warmth in the leg
    - Other (specify): _____

7. Duration of symptoms: Less than 1 week / 1–2 weeks / More than 2 weeks

8. Relevant medical history:
    - Active cancer: Yes / No
    - History of DVT: Yes / No
    - Known clotting disorder: Yes / No
9. Risk factors present:
    - Recent surgery or trauma (within 4 weeks)
    - Prolonged immobility (bed rest or travel longer than 3 hours in the past month)
    - Hormonal therapy (e.g., contraceptives, HRT)
    - Obesity (BMI greater than 30)
10. Presence of comorbidities (indicate all that apply):
    - Hypertension
    - Diabetes
    - Cardiac disease
    - Renal disease
    - Other (specify): _____

Section 3: Modified Wells Score for DVT Assessment

For each item, indicate whether the condition is present:

B: Modified Wells Score

1. Active cancer (treatment ongoing, within 6 months, or palliative): Yes / No
2. Paralysis, paresis, or recent plaster immobilization of the lower extremities: Yes / No
3. Recently bedridden for more than 3 days, or major surgery within the past 4 weeks requiring general or regional anesthesia: Yes / No

4. Localized tenderness along the distribution of the deep venous system: Yes / No
5. Entire leg swollen: Yes / No
6. Calf swelling by more than 3 cm compared to the asymptomatic leg (measured 10 cm below tibial tuberosity): Yes / No
7. Pitting edema confined to the symptomatic leg: Yes / No
8. Collateral superficial veins (non-varicose): Yes / No
9. Previously documented DVT: Yes / No
10. Alternative diagnosis at least as likely as DVT: Yes / No

Total Modified Wells Score: _____

Interpretation of Modified Wells Score:

- DVT likely (≥2 points)
- DVT unlikely (<2 points)

Section 4. Operator Information (FOR RADIOLOGIST)

- Role of the individual conducting the Doppler ultrasound: Radiologist
- Other (please specify): _____
- Years of experience: _____
- Quality assurance protocols in place for diagnostic procedures: Present / Absent

Section 4: Compression Duplex Ultrasound

- DVT present YES/NO: _____
- **Site of DVT:**
    - Distal DVT YES/NO
    - Proximal DVT YES/NO
    - Vein/s involved
    - Other diagnosis

Appendix II: Dodoso la Utafiti Kuhusu, Uhalisia na uwezo wa utumiaji wa utambuzi wa Alama ya Wells iliyorekebishwa ikilinganishwa na uchunguzi wa Mawimbi sauti ya Duplex ya Msukumo katika kutabiri Kifumbato cha Mshipa wa Ndani kwa Wagonjwa wanaoshukiwa katika Hospitali ya Taifa ya Muhimbili.

(Swahili Version)

Maelezo ya Mshiriki:

• Kitambulisho cha Mshiriki: _____

• Tarehe ya Ukusanyaji wa Taarifa: _____

Sehemu ya 1: Taarifa za Kijamii na Kidemografia (KUJAZWA NA MGONJWA)

1. Umri (miaka): _____

2. Jinsia: Mwanaume / Mwanamke

3. Kazi: Ajira rasmi / Hana ajira / Kujiajiri / Mstaafu

4. Kiwango cha Elimu: Hakuna elimu rasmi / Elimu ya Msingi / Elimu ya Sekondari / Elimu ya Juu

5. Makazi: Mjini / Vijijini

Sehemu ya 2: Tabia za Kliniki (ITAJAZWA NA MGONJWA)

6. Malalamiko makuu (chagua yote yanayohusika):

- Maumivu ya mguu
- Kuvimba kwa mguu
- Kuwa na wekundu au joto kwenye mguu
- Nyinginezo (fafanua): _____

7. Muda wa dalili: Chini ya wiki 1 / Wiki 1–2 / Zaidi ya wiki 2

8. Historia ya matibabu inayohusika:

- Saratani iliyo hai: Ndio / Hapana
- Historia ya DVT: Ndio / Hapana
- Ugonjwa wa kuganda damu unaojulikana: Ndio / Hapana

9. Vihatarishi vilivyopo:

- Upasuaji au jeraha la hivi karibuni (ndani ya wiki 4)
- Kukaa bila kusogea kwa muda mrefu (kupumzika kitandani au kusafiri kwa zaidi ya masaa 3 katika mwezi uliopita)
- Matumizi ya homoni (mfano, vidonge vya uzazi wa mpango, tiba ya homoni mbadala)
- Unene kupita kiasi (BMI zaidi ya 30)

10. Uwepo wa magonjwa yanayoambatana (weka alama kwa yote yanayohusika):

- Shinikizo la damu
- Kisukari
- Ugonjwa wa moyo
- Ugonjwa wa figo
- Nyinginezo (fafanua): _____

Sehemu ya 3: Vigezo vya Alama ya Wells Iliorekebishwa kwa Tathmini ya Kifumbato Cha Mshipa wa Ndani (DVT)

Kwa kila kipengele, onyesha ikiwa hali ipo:

B: Alama, ya Modified Wells Score Iliyorekebishwa

i. Saratani iliyo hai (matibabu yanaendelea, ndani ya miezi 6 iliyopita, au tiba ya kupunguza maumivu): Ndio / Hapana

ii. Kupooza, udhaifu wa misuli, au kuwekwa kwenye kifaa cha kubana (plasta) cha sehemu za chini za mwili hivi karibuni: Ndio / Hapana

iii. Kulazwa kitandani kwa zaidi ya siku 3, au kufanyiwa upasuaji mkubwa ndani ya wiki 4 zilizopita ukihitaji ganzi ya jumla au ya sehemu: Ndio / Hapana

iv. Maumivu mahususi kwenye mfumo wa vena za ndani: Ndio / Hapana

v. Kuvimba kwa mguu mzima: Ndio / Hapana

vi. Kuvimba kwa ndama kwa zaidi ya sentimita 3 ikilinganishwa na mguu usio na dalili (kipimo kinafanyika sentimita 10 chini ya kitako cha tibia): Ndio / Hapana

vii. Kuvimba kwa edema kwenye mguu wenye dalili pekee: Ndio / Hapana

viii. Mishipa ya juu ya damu inayoonekana (isiyo ya varikosi): Ndio / Hapana

ix. DVT iliyorekodiwa hapo awali: Ndio / Hapana

x. Utambuzi mbadala unaowezekana kama DVT: Ndio / Hapana

(KUJAZWA NA MTOA HUDUMA)

Jumla ya Alama za Modified Wells Score: _____

Ufafanuzi wa Alama za Modified Wells Score:

- **Inawezekana kuwa na DVT (alama ≥2)**
- **Haielekei kuwa na DVT (alama <2)**

Sehemu ya 4: Uchunguzi wa mawimbi sauti wa duplex ya msukumo (ITAJAZWA NA MTAALAMU WA MIONZI)

• DVT ipo NDIYO/HAPANA: _____

• Sehemu ya DVT: _____

• DVT ya sehemu ya chini NDIYO/HAPANA

• DVT ya sehemu ya juu NDIYO/HAPANA

• Mishipa iliyoathirika: _____

• Utambuzi mwingine: _____

Appendix III: Informed consent to take part in the study (English Version)

Principal Investigator(s): Dr. Briella Nyanyama Sure Mabusi

This information is provided to inform you about the research study and your participation in it. Please read this form carefully, ask any questions you may have about this study and the information given below, and be sure you receive answers to your questions before signing this consent form (a copy of which will be given to you).

Study Title: Diagnostic applicability of Modified Wells Score with Compression Duplex Ultrasound in predicting Deep Vein Thrombosis among suspected cases at Muhimbili National Hospital

1. Purpose of this study:

This study aims to find the diagnostic accuracy, sensitivity, specificity, and cost-effectiveness of the Modified Wells Criteria and Compression Duplex ultrasound to provide evidence-based guidance for clinicians and improve diagnostic strategies for better patient outcomes.

2. The approximate duration of your participation in the study:

The exercise will last for less than an hour

3. Procedures to be followed for this study:

You will be asked several questions, and you will be required to respond as appropriate. The responses will be jotted down.

4. Experimental procedure(s) involved in the study (if any):

There are no experimental procedures involved in this study

5. Description of the discomforts, inconveniences, and/or risks that can be reasonably expected because you participated in this study:

There could be physical trauma during the exercise. Therefore, any time you experience such kindly let me know. Besides, you have the right to withdraw from the exercise at any time you feel uncomfortable to proceed.

6. Good effects or benefits that might result from this study:

There is no direct material benefit as such for individuals who volunteer to participate in this study.

7. Privacy and Confidentiality: All efforts, within reason, will be made to keep your personal information confidential. All information and issues relating to your participation in the study will be treated confidentially, and no unauthorized persons will have access to your personally identifiable information. To ensure that, the hardcopies of the data collection tools/records will be stored in a locked cupboard where only an authorized person can have access. Additionally, the soft copies of the records will be stored in computers that are password-protected. Thus, users with login and password credentials will be the only ones able to access the information.

8. Rights to refuse or withdraw: Your participation in this research study is voluntary. You are free to withdraw from this study at any time without penalty.

9. Contact information: If you have any questions about this research study, your rights, or experiences any study-related effects, please contact the:

1. Principal Investigator's Information : Dr. Briella Nyanyama Sure Mabusi

Email : briellasure@yahoo.com

Address: P.O. Box 10190, Dar es Salaam, Tanzania.

Phone #: 0686-549509

2. Chair Person of KU-IREC : Prof. Columba Mbekenga

Address: P.O Box 63500, Dar es Salaam, Tanzania.

Phone #: 0784-645777

Email: irec@ku.ac.tz

STATEMENT BY PERSON ASSENTING TO PARTICIPATION IN THIS STUDY:

I have read this informed consent document, and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to consent to participate in this study.

Signature of the participant and Date:

Signature of person obtaining consent and Date:

Printed name of person obtaining consent:

This consent form will be kept by the researcher for at least one year beyond the end of the study.

Appendix IV : Ridhaa ya Taarifa (Swahili Version)

Mtafiti Mkuu: Dk. Briella Nyanyama Sure Mabusi

Taarifa hii inatolewa kukujulisha kuhusu utafiti na ushiriki wakondani yake. Tafadhali soma fomu hii kwa makini, uliza maswaliyoyote unayoweza kuwa nayo kuhusu utafiti huu na taarifazilizotolewa hapa chini, na uhakikishe umepata majibu yamaswali yako kabla ya kusaini fomu hii ya ridhaa (nakala yakeutapewa).

Jina la Utafiti : Uhalisia na uwezo wa utumiaji wa utambuzi wa Alama ya Wells iliyorekebishwa ikilinganishwa na uchunguzi wa Mawimbi sauti ya Duplex ya Msukumo katika kutabiri Kifumbato cha Mshipa wa Ndani kwa Wagonjwa wanaoshukiwa katika Hospitali ya Taifa ya Muhimbili.

1. **Madhumuni ya utafiti huu:** Utafiti huu unalenga kulinganisha usahihi wa utambuzi, unyeti, upekee, na ufanisi wa gharama wa Vigezo vya Wells Vilivyorekebishwa na Ultrasound ya Doppler ili kutoa mwongozo unaotegemea ushahidi kwa madaktari na kuboresha mikakati ya utambuzi kwa matokeo bora ya wagonjwa.
2. **Muda wa karibu wa ushiriki wako katika utafiti:** Zoezihili litachukua chini ya saa moja
3. **Taratibu za kufuatwa kwa utafiti huu:** Utaulizwa maswalikadhaa na utahitajika kujibu ipasavyo. Majibu yataandikwa.
4. **Taratibu za majaribio zinazohusika katika utafiti (ikiwazipo):** Hakuna taratibu za majaribio zinazohusika katikautafiti huu
5. **Maelezo ya usumbufu, usumbufu, na/au hatarizinazoweza kutarajiwa kutokana na ushiriki wa mtotowako katika utafiti huu:** Kunaweza kuwa na maumivu kidogo. Kwa hiyo, wakati wowote upotapo changamoto yoyote niarifu. Aidha,

una haki ya kujitoa kwenye zoezi wakati wowote unapojisikiakutokuwa na starehe kuendelea.

6. **Matokeo mazuri au faida zinazoweza kutokana na utafitihuu:** Hakuna faida ya moja kwa moja kwa watu wanaojitoleakushiriki katika utafiti huu.
7. **Faragha na Usiri:** Juhudi zote, kwa mantiki, zitafanywakuweka siri taarifa zako binafsi katika kumbukumbu za utafiti. Taarifa zote na masuala yanayohusiana na ushirikiwako katika utafiti yatashughulikiwa kwa usiri, hakuna watuwasioidhinishwa watakuwa na uwezo wa kufikia taarifa zakozinazokutambulisha kibinafsi. Ili kuhakikisha hilo, nakala za karatasi za zana za kukusanya data/kumbukumbuzitahifadhiwa kwenye kabati lililofungwa ambapo ni mtualiyeidhinishwa tu anaweza kufikia. Aidha, nakala laini za kumbukumbu zitahifadhiwa kwenye kompyuta zilizolindwakwa nywila. Kwa hivyo, watumiaji wenye vitambulisho vyakuingia na nywila ndio watakuwa na uwezo wa kufikia taarifahizo.
8. **Haki ya kukataa au kujitoa:** Ushiriki wako katika utafitihuu ni wa hiari. Uko huru kujitoa katika utafiti huu wakatiwowote bila adhabu.
9. **Taarifa za mawasiliano:** Ikiwa una maswali yoyote kuhusuutafiti huu, haki zako, au uzoefu wowote unaohusiana nautafiti, tafadhali wasiliana na:

1. Mtafiti Mkuu : Dkt. Briella Nyanyama Sure Mabusi

Namba ya simu: 0686-549509

Anuani: S.L.P 10190, Dar es Salaam, Tanzania

Barua pepe: briellasure@yahoo.com

2. Mwenyekiti wa KU-IREC : Prof. Columba Mbekenga

Anuani: SLP 63500, Dar Es Salaam, Tanzania.

Simu: 0784-645777

Barua pepe: irec@ku.ac.tz

TAARIFA YA MTU ANAYETOA RIDHAA YA KUSHIRIKI KATIKA UTAFITI HUU:

Nimesoma waraka huu wa ridhaa na maelezo yaliyomo ndaniyake yameelezwa kwangu kwa mdomo. Maswali yangu yote yamejibiwa, na kwa hiari yangu mwenyewe nachagua kutoaridhaa ya kushiriki katika utafiti huu.

Sahihi ya mshiriki _____ Tarehe_____

Sahihi ya mtu anayepata ridhaa _____ Tarehe_____

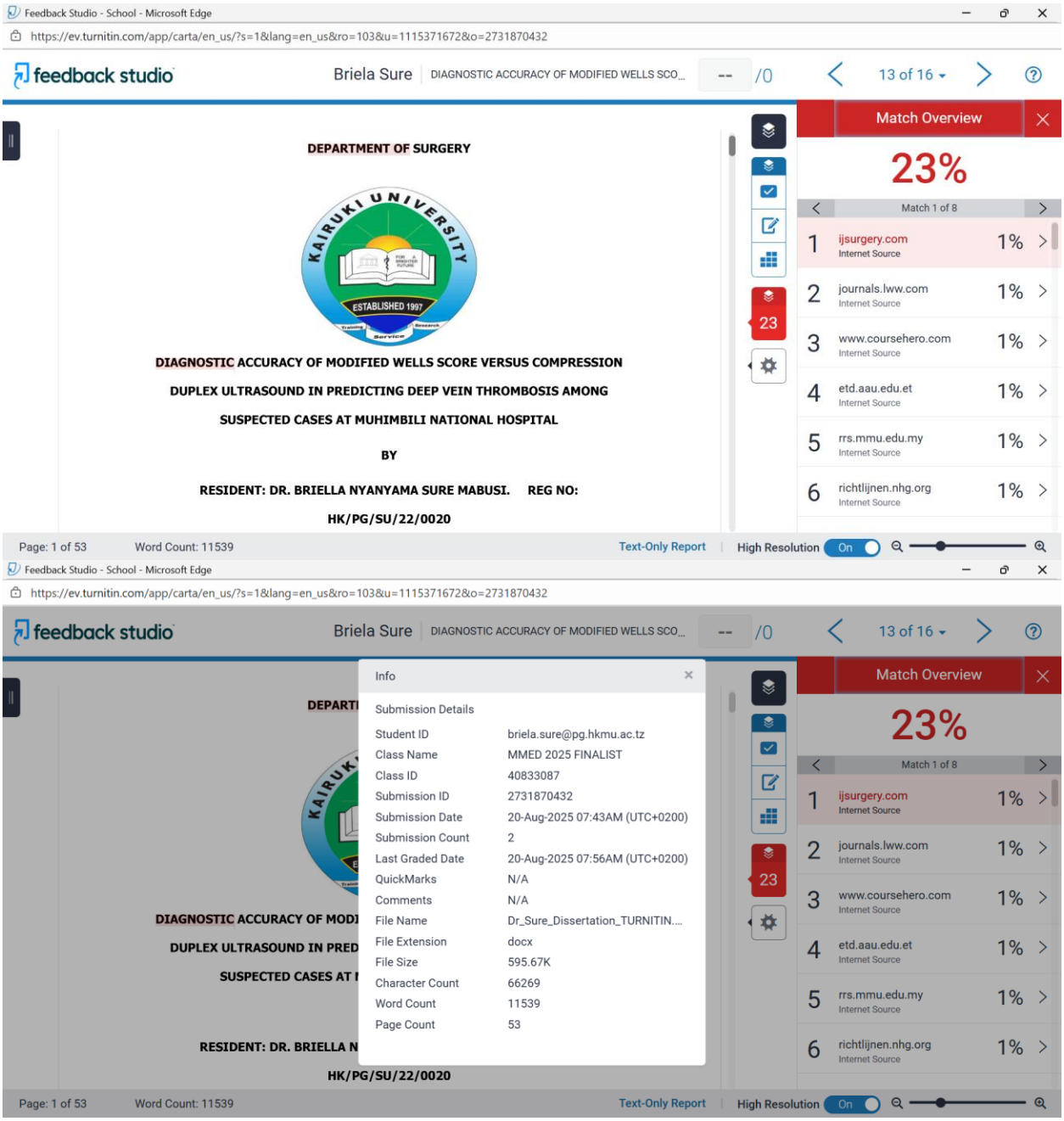
Jina la mtu anayepata ridhaa (kwa herufi kubwa) _____

Fomu hii ya ridhaa itahifadhiwa na mtafiti kwa angalau mwakammoja baada ya kumalizika kwa utafiti.

Appendix V: Modified Wells Score Chart

Table 9: Modified Wells Score Chart

RISK FACTORS	POINTS	TICK
Active cancer (ongoing treatment, within the last 6 months, or palliative care): Yes / No	1	
Paralysis or recent plaster immobilization of the legs: Yes / No	1	
Bedridden for over 3 days or had major surgery within the last 4 weeks that needed general or regional anesthesia: Yes / No	1	
Localized tenderness related to the deep venous system: Yes / No	1	
Swelling present in the entire leg: Yes / No	1	
Calf swelling exceeding 3 cm compared to the unaffected leg (measured 10 cm below the tibial tuberosity): Yes / No	1	
Pitting edema limited to the affected leg: Yes / No	1	
Non-varicose collateral superficial veins: Yes / No	1	
Prior documented DVT: Yes / No	1	
An alternative diagnosis that is at least as likely as DVT: Yes / No	-2	
TOTAL		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DUPLEX ULTRASOUND IN PREDICTING DEEP VEIN THROMBOSIS AMONG
SUSPECTED CASES AT MUHIMBILI NATIONAL HOSPITAL
BY
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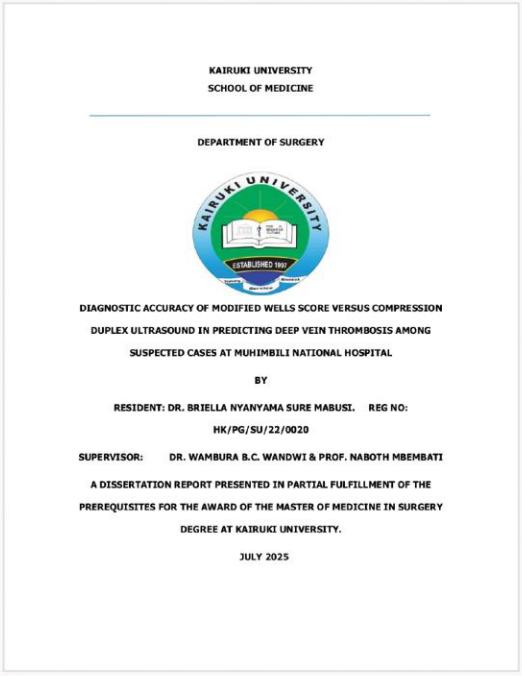

KAIRUKI UNIVERSITY
SCHOOL OF MEDICINE

DEPARTMENT OF SURGERY

DIAGNOSTIC ACCURACY OF MODIFIED WELLS SCORE VERSUS COMPRESSION DUPLEX ULTRASOUND IN PREDICTING DEEP VEIN THROMBOSIS AMONG SUSPECTED CASES AT MUHIMBILI NATIONAL HOSPITAL

BY

RESIDENT: DR. BRIELLA NYANYAMA SURE MABUSI. REG NO: HK/PG/SU/22/0020

SUPERVISOR: DR. WAMBURA B.C. WANDWI & PROF. NABOTH MBEMBATI

A DISSERTATION REPORT PRESENTED IN PARTIAL FULFILLMENT OF THE PREREQUISITES FOR THE AWARD OF THE MASTER OF MEDICINE IN SURGERY DEGREE AT KAIRUKI UNIVERSITY.

JULY 2025