

**DIAGNOSTIC YIELD, CLINICAL PROBABILITY SCORE AND
UTILITY OF COMPUTERIZED TOMOGRAPHIC PULMONARY
ANGIOGRAPHY AT MOI TEACHING AND REFERRAL
HOSPITAL.**

BY

JOSPHAT KIPROTICH SANG

**A RESEARCH THESIS SUBMITTED TO THE SCHOOL OF
MEDICINE IN PARTIAL FULFILLMENT OF THE AWARD OF
THE DEGREE OF MASTER OF MEDICINE IN RADIOLOGY
AND IMAGING OF MOI UNIVERSITY.**

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DECLARATION

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Dr. Josphat Kiprotich Sang

Reg No SM/PGR/09/18

Department of Radiology and imaging

Signature:..... Date:.....

Supervisor's Declaration

This research thesis has been submitted for consideration with our approval as university supervisors.

Dr. Loice Sitienei

Lecturer, Department of Radiology and Imaging

School of medicine, College of health sciences

Signature:..... Date:.....

Dr. Andrew Wandera

Lecturer, Department of Surgery and Anesthesiology.

School of medicine, College of health sciences.

Moi University

Signature:..... Date:.....

DEDICATION

I dedicate this work to my wife Mercy Jepchumba Tanui who through her unending love and sacrifice has encouraged me in my educational journey and enabled me to write this thesis. I also acknowledge my children Diphath, Divine and Darvine for giving me purpose in life and motivation to achieve my dreams.

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ABSTRACT

Background: Pulmonary embolism (PE) is a major cause of cardiovascular mortality in the world ranking third after myocardial infarction and cerebrovascular accidents. Diagnosis of PE is challenging as the symptoms of PE are non-specific. Computed tomographic pulmonary angiography (CTPA) has emerged in recent years as the imaging modality of choice. However, the wide availability of Computed tomography (CT) has led to concerns about the overutilization of CTPA. Use of D dimers and clinical probability scoring tools like the revised Geneva scores are invaluable in stratifying patients according to the probability of PE. However, this has not been explored and no previous studies on clinical probability scores and yield of CTPA exists in our region. Therefore, the study aimed to calculate the diagnostic yield, clinical probability scores and overutilization of CTPA in patients with suspected PE.

Objective: To determine the diagnostic yield, clinical probability score, utility and overutilization of CTPA in patients with suspected pulmonary embolism at Moi Teaching and Referral Hospital (MTRH).

Methods: This was a cross-sectional study conducted at the MTRH between September 2022 and August 2023. A consecutive sampling technique was applied and recruited 102 adult patients. CTPA were performed using either the 32 slice Siemens and 64 slice Philips CT machines. Demographics, revised Geneva scores and D dimers results were recorded in a questionnaire form. Patients were subsequently categorized into low, intermediate and high probability for PE. CTPA images were uploaded to the Picture Archiving and Communication System (PACS) and interpreted by the principal investigator and 2 radiologists blinded to the clinical probability categories. The diagnostic yield of CTPA was calculated for the low, intermediate and high probability groups and then an overall diagnostic yield for the whole cohort. Data was analyzed using STATA software version 13. Descriptive statistics were summarized as frequencies and percentages, whereas categorical data was analysed using chi square test and fisher's exact test. A P value of 0.05 was considered statistically significant.

Results: The majority of the study participants were female at 62 (60.8%) and a mean age of 53.2 years. The diagnostic yield was 29.4%. On the Revised Geneva score, 7 (6.9%) were low risk, 84 (82.4%) moderate risk and 11 (10.8%) high risk. 0%, 25% and 81% in the low intermediate and high risk groups were diagnosed with PE respectively. 50 (49.0%) of participants had positive conventional D dimers while 52 (51.0%) were negative. The revised Geneva score had a sensitivity, specificity, positive predictive value and negative predictive value of 83.3%, 44.4%, 38.5% and 86.5% respectively. 7 patients (6.9%) had negative D dimers, low risk on the revised Geneva score and no PE on CTPA.

Conclusion: The use of D dimers combined with the revised Geneva clinical probability score will stratify patients into risks groups for PE and help to reduce overutilization of CTPA.

Recommendation: Stratification of patients using the revised Geneva scores combined with D dimers in low-risk patients should be adopted. Protocols on the diagnostic schema in patients with suspected PE should be developed.

LIST OF ABBREVIATIONS.

AO	Ascending Aorta.
CT	Computed tomography
CTPA	Computed tomographic pulmonary angiogram.
DVT	Deep venous thrombosis.
HU	Hounsfield units
IREC	Institutional research and ethics committee
MDCT-PA	multidetector computed tomographic pulmonary angiography
MPA	Main pulmonary artery
MTRH	Moi Teaching and Referral Hospital.
PACS	Picture Archiving and Communication Systems.
PE	Pulmonary Embolism.
PERC	Pulmonary Embolism Rule-out Criteria.
PIOPED	Prospective investigation on pulmonary embolism diagnosis.
V/Q	Ventilation perfusion Radionuclide scanning.
VTE	Venous thrombo-embolism.

OPERATIONAL TERMS

Computerized tomographic pulmonary angiography (CTPA) is a modification of computerized pulmonary angiography in which the computer software optimizes the view of the pulmonary arteries. It's also known as SVCT (spiral volumetric computerized tomography)

Pulmonary embolism (PE) it's a partial or complete occlusion of pulmonary artery (s) by a blood clot.

Deep venous thrombosis DVT It's the presence of blood clots in the deep veins of the lower limbs and pelvis.

Embolus it's a blood clot that dislodges and is propagated through the blood stream.

Overutilization is defined as the delivery of tests and procedures that provide little or no clinical benefit, are unlikely to have an impact on clinical decisions, increase health care spending without improving health outcomes or risk patient harm in excess of potential benefits (Macleod S et al 2018).

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CHAPTER ONE

1.0 INTRODUCTION

1.1 Introduction and General Background

Pulmonary embolism refers to the total or partial occlusion of one or more central or peripheral pulmonary arteries by emboli which typically originate from veins in the lower limbs or pelvis. Pulmonary embolism is a potentially fatal condition if not properly managed. Mortality of untreated Pulmonary embolism (PE) is high and complications can occur with extended treatment with anticoagulants. In an Australian study the annual crude incidence rate of pulmonary embolism was found to be 0.31 per 1000 (Wai RH et al 2012). The one-year mortality rate for PE varies according to studies. In the Prospective Investigation of Pulmonary Embolism Study (PIOPED) the one-year mortality rate for Pulmonary Embolism was approximately 24% (Worsley DF 1995) while in the Quebec-Venous thromboembolism(Q-VTE) study it was 23% (Tagalakis V et al 2013). In contrast the pulmonary embolism registry of Gottingen (PERGO) study reported a one-year mortality rate of 19.7% (Eckelt J et al 2023).

Pulmonary embolism presents with several cardiorespiratory symptoms including chest pain, cough, hemoptysis, dyspnea and hypoxia. However, none of the symptoms are specific to this disease and that's why PE is referred to as the 'great masquerader' (Sharma GV et al. (1976). This therefore necessitates the use of imaging studies to arrive at a conclusive diagnosis. Clinical evaluation and accurate diagnostic testing are required to decrease delays in initiating therapy which will result in reduction of morbidity and mortality due to Pulmonary embolism.

Clinical probability scoring tools such Wells score, modified Wells score, revised Geneva classification and Pulmonary embolism rule out scores (PERC) scores are

necessary to aid clinical evaluation and optimize the use of diagnostic modalities especially in the emergency departments.

Pulmonary angiography has been used historically for diagnosis of Pulmonary embolism, but due to its invasiveness has now been largely replaced by less invasive modalities. Use of multi detector computed tomography technology results in fast acquisition of images and enables 3D reconstruction. The short scan times reduces motion artifacts, making vessels close to the heart easier to visualize. Thinner slices results in improved depiction of segmental and sub segmental arteries. With faster scans less contrast is administered, a factor beneficial in patients with renal or cardiac impairment. Use of Computed tomography potentially minimizes delays in diagnosis and results in improved patient care. Computed Tomographic Pulmonary Angiogram (CTPA) additionally enables direct visualization of blood clot as well as assessment of cardiac and pulmonary function. This will aid in quantifying the degree of pulmonary obstruction and the severity of Pulmonary embolism. Apart from pulmonary embolism, Computed Tomographic Pulmonary Angiogram can pick alternative diagnoses such as pleural effusion, pneumonia, atelectasis, emphysema and pulmonary masses. However, despite being the investigation of choice for diagnosis of Pulmonary embolism, Computed Tomographic Pulmonary Angiogram requires administration of contrast media which is potentially nephrotoxic and deposits a large amount of radiation in tissues which may predispose to malignancies in the long run. To mitigate these effects an alternative modality like ventilation perfusions scans is occasionally considered especially for patients with severe renal impairment, pregnancy and in younger patients.

The widespread availability of Computed tomography has resulted in an increase in the use of Computed tomographic pulmonary angiogram to diagnose pulmonary embolism. Usage has increased especially in the emergency departments in the United States of America (Chandra S et al 2013). This has led to concern of overutilization of Computed Tomographic Pulmonary Angiogram which has largely been fueled by data from emergency departments in the USA where PE yields are low largely below 10%. These low yields are obtained despite the large increase in the number of investigations in the last decade. In the USA up to 3% of all adult patients seen in the emergency department have a Computed tomographic pulmonary angiogram recommended (Chandra S et al 2013). This increased use may result in potential harm including radiation, contrast induced nephropathy, allergies and results in increased health care costs and potentially delays care (Ong CW et al 2013, Segers T et al 2013)

1.2 Problem Statement

CTPA is the gold standard for diagnosis of pulmonary embolism and its requisitions have increased as CT scans have become widely available. It has high sensitivity for diagnosing PE, however the diagnostic yield varies according to different studies with most in the USA below 10%. Overuse of CTPA in diagnosing pulmonary embolism is a common problem especially where CT is widely available. Increasing availability of CTPA is resulting in overutilization in the diagnostic workup of patients presenting with cardiorespiratory symptoms. It is possible to reduce unnecessary CTPA requests by adherence to protocols developed as a result of recommendations from studies and by doing a detailed clinical risk assessment. Excessive use of CTPA also potentially overdiagnoses clinically insignificant cases of PE.

Clinical probability scores helps to categorize patients into low, intermediate and high probability for Pulmonary embolism or alternatively into Pulmonary embolism

likely and pulmonary embolism unlikely groups. This will guide clinicians on the next appropriate course of action. If well utilized these scores alone or in combination with D dimers can result in a reduction in the number of CTPA requisitions. A pulmonary embolism diagnostic pathway that utilizes clinical probability scoring, D dimers and Computed Tomographic Pulmonary Angiography or ventilation perfusion scans has been adopted worldwide. However, the utilization of this diagnostic pathway has not been explored in our set up. In addition, there are no previous studies in our region which have studied the utilization of clinical probability scores combined with D dimers and Computed Tomographic Pulmonary Angiography in patients with suspected pulmonary embolism.

The aim of the current study was to compare the D-dimer test and modified Geneva criteria, which is used for clinical probability assessment, with the results of CTPA in patients who had CTPA requisitions for suspected PE, and consequently, to investigate the applicability of these tests to reduce the excessive use of CTPA.

1.3 Justification

There is a paucity of data locally on studies that have combined the clinical probability scores, D dimers and CTPA results such a study is important to determine if there is overutilization of CTPA in diagnosis of PE. This has been a concern in Emergency departments in western countries where the diagnostic yields are low. We hypothesize that over testing for PE remains a problem.

CTPA is associated with a risk of radiation exposure and complications like contrast induced nephropathy. Radiation is associated with an increased risk of malignancies. Estimates of the risk vary, a 2007 review estimated that 1.5-2% of malignancies could be because of medical imaging radiation (Brenner JD et al, 2007).

Pulmonary CT angiography has attracted particular attention because evidence suggests that nearly one-third of CT studies ordered to evaluate patients for suspected pulmonary embolism (PE) may be inappropriately ordered, and more than six million patients are evaluated for suspected PE in EDs in the United States annually (Venkatesh H et al 2017)

Clinical probability scores are used to categorize patients into low, intermediate and high risk of pulmonary embolism. Others categorize patients into PE likely or PE unlikely. This categorization will guide the clinician in determining the next appropriate course of management. When appropriately utilized this can reduce the number of CTPA requisitions.

1.4 Research Question.

What are the revised Geneva clinical probability scores and the diagnostic yield rate of CTPA in diagnosis of PE in patients at Moi Teaching and Referral Hospital?

1.5 Objectives of the study

1.5.1 Broad objective

- To determine the clinical probability scores using the revised Geneva score and the diagnostic yield rates of CTPA in diagnosing PE.

1.5.2 Specific objectives

1. To determine the clinical probability scores using the revised Geneva clinical probability score of patients referred for CTPA at MTRH
2. To calculate the overall diagnostic yield of CTPA in diagnosing of PE in patients suspected of PE at MTRH.
3. To establish if there is overutilization of CTPA in diagnosis of PE at MTRH

CHAPTER TWO

2.0 LITERATURE REVIEW

Definition

Pulmonary embolism is the partial or complete occlusion of a central or peripheral pulmonary arteries by material such as thrombus, tumor, air or fat that originated elsewhere in the body (Vyas V et al (2024). Most commonly thrombi originate in the large veins of the lower limbs or pelvis. It has nonspecific symptoms which mimic other conditions and its diagnosis is challenging to clinicians and radiologists (Mishra S et al (2025). Pulmonary embolism is classified based on several parameters which include presence or absence of hemodynamic compromise, presence or absence of symptoms, the pattern of occurrence and also on the vessels that are occluded. On the first parameter of hemodynamic compromise PE is classified into massive, sub massive and low risk PE. Likewise, it can be classified into acute, subacute and chronic PE based on the time of presentation. On vessel involvement PE is classified into saddle, lobar and segmental and types.

2.1 Epidemiology

It is a common disease in adults with an annual incidence rate of 23-69 per 100,000 people. In the United States, 600,000-630,000 cases are reported annually. It is the third most common cardiovascular condition in adults after acute myocardial infarction and stroke. It is often undetected, hence causing considerable mortality. If untreated, PE is associated with a 15-30% mortality (Eckelt et al 2023) Management may include long term anticoagulation therapy which carries the risk of bleeding, hence it's important to exclude or confirm PE before initiating anticoagulation therapy. The incidence of PE varies with age being rare in children (<5 per 100,000) and rising with age. Among the elderly the incidence approaches 1 in 100.

Worldwide the incidence of PE is estimated to be 60-70 per 100,000 inhabitants (Behlovalek et al 2013). In hospitalized patients, venous thromboembolism is common and was reported in 60% of patients in a study by Otellini PS et al in 2011. In Europe the annual incidence of VTE is estimated to be 5-10 per 10,000 inhabitants (Behlovalek et al 2013) while in the US it's approximately 10 per 10,000 people and accounts for 5-10% of all hospital mortalities (Anderson et al 2007).

In Africa the prevalence of PE varies widely as reported in a systematic review by Danwag C et al in 2017 which found a prevalence of PE in medical patients of 0.14%-61.5%. The mortality rate was also variable ranging between 40%-69.5%. In sub-Saharan Africa, Tambe et al in 2012 reported a CTPA PE prevalence of 32.4% among patients with suspected PE in Cameroon. In Kenya an autopsy study by Ogengo et al in 2011 reported an incidence rate of 0.032% in black African population over a 5-year period. PE also accounts for 14.21% of all cardiovascular mortalities in Kenya. The true incidence of PE is not known since 80% of patients with PE on autopsy studies are unreported or undiagnosed when alive (Stein et al 2006).

2.2 Pulmonary vascular anatomy.

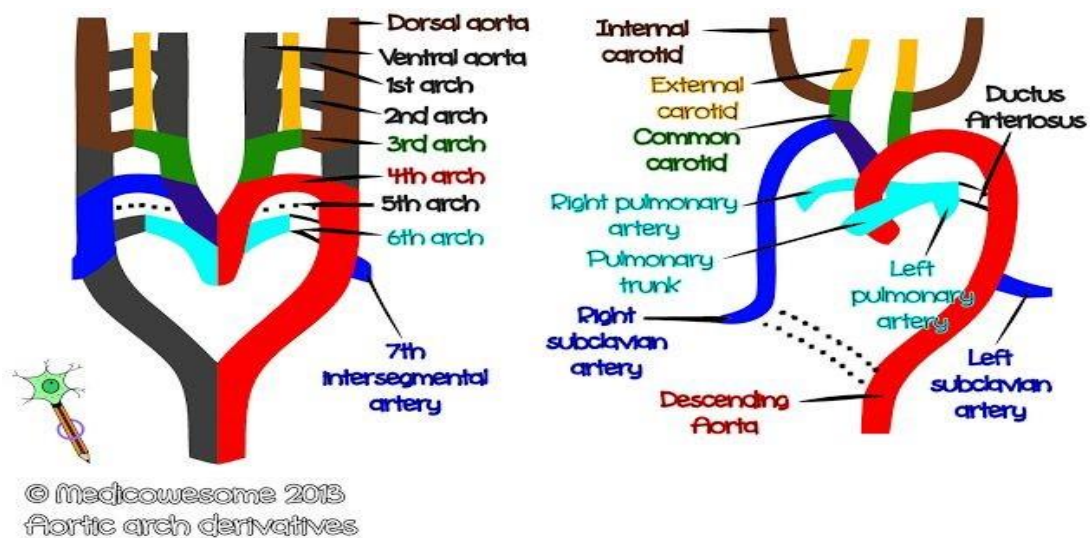
Embryology.

The early arterial system begins as a bilaterally symmetrical system of aortic arched vessels. These then undergo extensive remodelling to form the major arteries that exit the heart.

The derivatives of the aortic arches are summarised in the table below.

Table 1: The derivatives of the aortic arches

1st arch	Contributes to the maxillary, hyoid and stapedius arteries
2nd arch	Contributes to maxillary, hyoid and stapedius arteries.
3rd arch	Forms the common carotid artery and part of the proximal Internal carotid artery
4th arch	Right arch forms the right subclavian artery .left arch forms part of the arch of the aorta.
5th arch	Forms incompletely and regresses
6th arch.	Right forms the right pulmonary artery. Left forms the left pulmonary artery and ductus arteriosus.

**Figure 1: Diagram depicting the derivatives of the aortic arches.**

Each lung is supplied by a pulmonary artery which arises from the pulmonary trunk at the level of the sternal angle. Each artery carries blood to the lung for oxygenation. Each lung also has two corresponding pulmonary veins which drain blood from it. At the left or right lung root each pulmonary artery divides into secondary lobar arteries.

The right and left superior lobar arteries arise first before entering the hilum. They supply the superior lobes of the lung. The left pulmonary artery then descends posterolateral to the main bronchus as the inferior lobar artery. The right pulmonary artery divides into the middle and inferior lobar arteries. The lobar arteries subsequently divide into tertiary segmental branches.

Each artery is paired with its corresponding bronchi and branch simultaneously and run a parallel course. A paired secondary lobar artery and bronchus supply each lobe. A paired tertiary segmental artery and bronchus supply each bronchopulmonary segment of the lung.

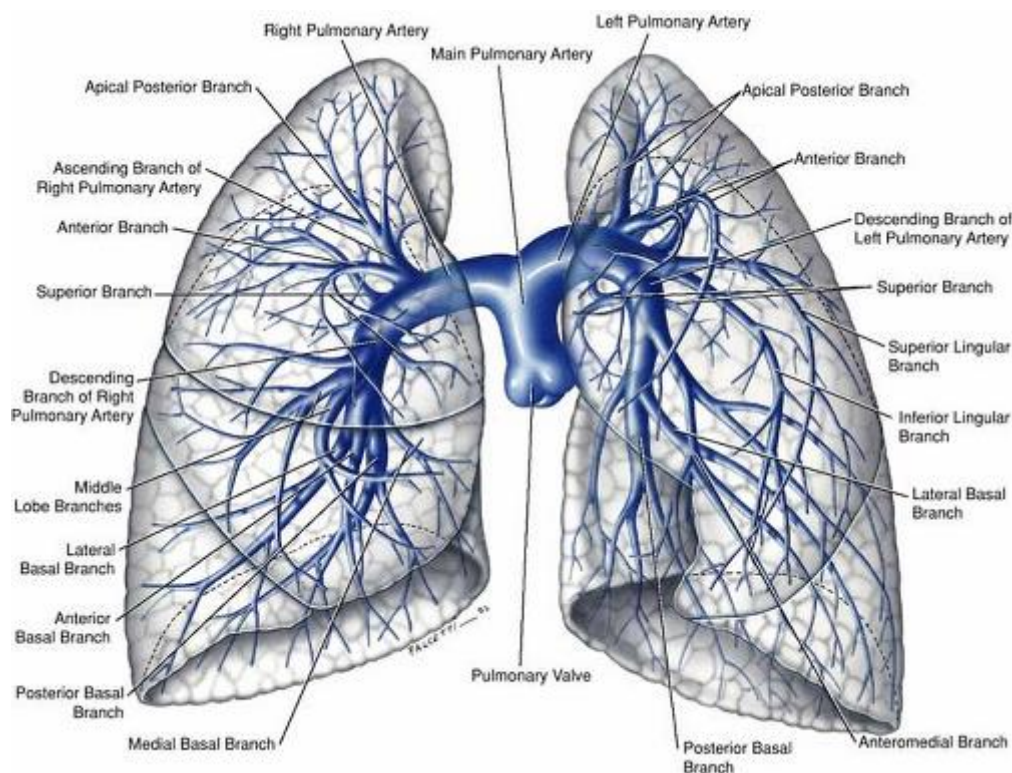


Figure 2: Diagram of the distribution of the pulmonary arteries in both lungs.
Uflaker R ,ed .atlas of vascular anatomy: an angiographic approach,2nd edition.

2.3 Clinical presentation

The clinical presentation of pulmonary embolism is nonspecific and mimics other conditions and as a result the diagnosis maybe difficult to diagnose and may be missed. The most common symptoms include cough, chest pain, dyspnea and hemoptysis. Other less common symptoms include tachycardia, syncope, leg swelling and cyanosis. Knowledge of the features of PE is critical so that clinicians may make a prompt diagnosis and appropriate management.

Chest pain can result from impairment of coronary circulation, disturbance of pulmonary circulation or pleural irritation because of pulmonary infarction. (Islam M et al 2018). Patients may present with angina which is a result of right ventricular ischemia. Dyspnea occurs because of multiple mechanisms which include bronchospasm or vasospasm, disturbances in pulmonary circulation, reduced respiratory movement of the diaphragm, immobility, lung collapse resulting in pulmonary infarction, anoxia and impairment of cardiac function. Patients with underlying heart failure or pulmonary disease may present with worsening dyspnea as a result of PE while patients with anoxia will manifest clinically with cyanosis. Sudden cardiac arrest/ death can also present as the initial clinical presentation in patients with PE and can occur in the presence of acute coronary syndromes, developing ventricular arrhythmia or during non-shockable rhythm.

Non cardiogenic pulmonary oedema or acute respiratory distress syndrome can occur in various clinical settings and has been recognized as a complication of pulmonary embolism. This occurs as a result of release of vasoactive substances from clots leading to venous constriction and increased capillary hydrostatic pressure. In addition, a fibrin micro embolus may injure capillaries which results to reactive oedema downstream of the obstruction. Typical respiratory failure (hypoxia and

hypercapnia) is a typical finding of acute pulmonary embolism. This is demonstrated on blood gas analysis as hypoxemia. These patients also present with dyspnea as the first symptom of respiratory failure. Patients also develop hemodynamic disturbance which results in low cardiac output and eventually leads to desaturation of mixed venous blood flow. This combined with areas of reduced flow secondary to obstruction led to ventilation perfusion mismatch. PE is known to precipitate bronchial asthma like symptoms. The mechanism of bronchoconstriction is not fully understood but is thought to be due to the release of agents such as acetylcholine, histamine, serotonin and plasma kinins at the thromboembolic sites. PE maybe accompanied with fever and pulmonary infiltrates on chest radiographs. In this scenario exclusion of other differentials such as pneumonia is critical. The clinical features will be important to make a conclusive diagnosis. Pneumonia has a progressive onset with prominent cough, sputum production and fever which appears early. Pulmonary embolism on the other hand has a sudden onset, with dyspnea that is more prominent than cough and sputum. In addition, PE is not responsive to antibiotics. When fever is present it tends to present early in pneumonia as compared to PE. Usually, chest pain is present in PE. A clear differentiation between PE and pneumonia should be made to ensure timely and appropriate treatment.

Patients with massive PE or high-risk pulmonary embolism may present with hypotension/shock. When present this is a predictor of poor outcome. Normotensive patients with right ventricular dysfunction on echocardiography are categorized as intermediate risk of poor outcome. Patients with myocardial injury or shock index (heart rate/systolic blood pressure (mm/Hg) >1 have the worst prognosis.

Syncope is the transient loss of consciousness due to global cerebral hypoperfusion. It's characterized by rapid onset and spontaneous recovery. The prevalence of

pulmonary embolism among patients with syncope is not well documented. However, a study by Duplyakov et al 2015 and the German register, Management Strategy and prognosis of pulmonary embolism registry (MAPPET) demonstrated rates of syncope of 29.9% and 35% respectively. Mechanism of syncope is thought to be due to thrombosis of more than 50% of the lung arterial system, resulting in marked reduction of cardiac output and subsequent arterial hypotension and decreased cerebral blood flow. Other mechanisms include activation of the vasovagal reflex and right ventricular overload, heart arrhythmias and conduction disturbance.

Delirium, an acute confusional state, is a potentially reversible cognitive disturbance and is recognized as a sign of serious underlying illness. PE is a common cause of hypoxia which in turn is a risk factor for delirium.

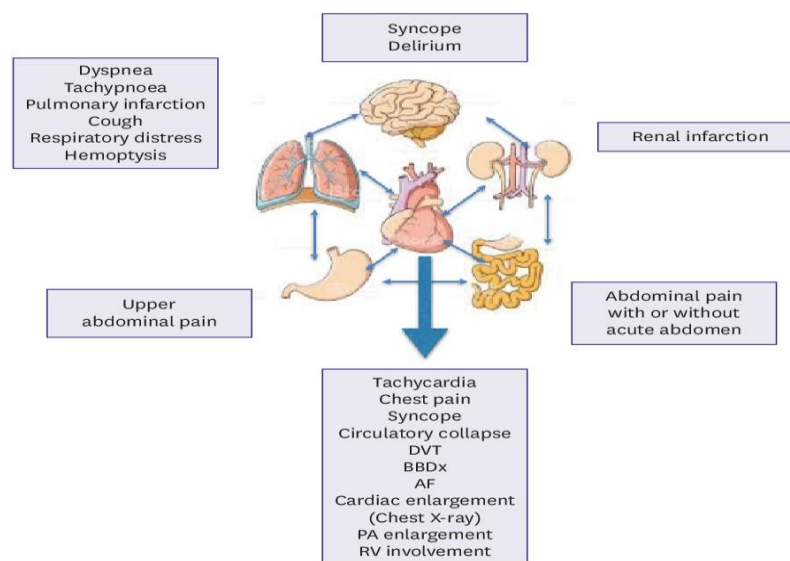


Figure 3: Apparatus involvement in PE

PE may present under several clinical pictures. Careful patient evaluation is the key role in order not to miss the diagnosis

AF= atrial fibrillation, DVT=deep venous thrombosis; PA= Pulmonary artery;

PE=Pulmonary embolism RV=right ventricle

Pulmonary embolism is commonly caused by a thrombus dislodged from the deep veins in the lower limbs. Thrombosis in the deep veins originates from the calf veins and is propagated proximally to the leg veins. DVT originates less frequently from the iliac veins and propagates distally. Pelvic DVT occurs in association with pelvic masses and pregnancy and in postoperative patients who have undergone urological, abdominal and gynecological surgery. A thrombus formed in the deep veins is propagated proximally from the deep veins, via the inferior venacavae and to the right side of the heart. From the heart the thrombus is propagated proximally to the pulmonary trunk and lodges within the artery or its divisions and branches. Prolonged use of upper limb indwelling catheters may also predispose to PE arising from the upper limb veins. Less common causes of PE are emboli from fat, air, amniotic fluid, tumor and tricuspid or pulmonary valves in patients with infective endocarditis. (Mehmet SA et al 2012, Kadriye KY et al (2011).

2.4 Pathophysiology of PE

Risk factors for development of PE are well established and have been described as the Virchow triad (Preto et al 2010). The triad consists of endothelial injury, impaired venous return and hypercoagulable venous states. Hypercoagulation results from dysfibrinogenemia, plasminogen deficiency, prothrombin gene mutation, factor V Leiden mutation, antithrombin III deficiency and protein C and S deficiency. Acquired factors for development of PE include obesity, oral contraceptives, immobility, long distance travel including flights, road, train or cruise ship, pregnancy, smoking, hormone replacement therapy, trauma and surgery. It also includes medical conditions like Chronic Obstructive Pulmonary Disease (COPD), systemic arterial hypertension, malignancy and antiphospholipid antibody syndrome. Ethnicity is also a risk factor for venous thromboembolism with higher incidences

reported among Caucasians and blacks than among Hispanics and Asians in the USA. However, 25-50% of patients diagnosed with venous thromboembolism for the first time have no identifiable risk factors as demonstrated in the emergency medicine pulmonary embolism in the real-world registry (EMPEROR) and the international cooperative pulmonary embolism registry (ICOPER) (White RH et al 2003).

Approximately 50-60% of patients with DVT also develop PE. PE and DVT are collectively referred to as venous thromboembolism (VTE) (Kostadima 2007).

Table 2: Predisposing factors for venous thromboembolism (data modified from Rogers et al and Anderson and Spencer

Strong risk factors (OR > 10)
Fracture of lower limb
Hospitalization for heart failure or atrial fibrillation/flutter (within previous 3 months)
Hip or knee replacement
Major trauma
Myocardial infarction (within previous 3 months)
Previous VTE
Spinal cord injury
Moderate risk factors (OR 2-9)
Arthroscopic knee surgery
Autoimmune diseases
Blood transfusion
Central venous lines
Intravenous catheters and leads
Chemotherapy
Congestive heart failure or respiratory failure
Erythropoiesis-stimulating agents
Hormone replacement therapy (depends on formulation)
In vitro fertilization
Oral contraceptive therapy
Post-partum period
Infection (specifically pneumonia, urinary tract infection, and HIV)
Inflammatory bowel disease
Cancer (highest risk in metastatic disease)
Paralytic stroke
Superficial vein thrombosis
Thrombophilia
Weak risk factors (OR < 2)
Bed rest >3 days
Diabetes mellitus
Arterial hypertension
Immobility due to sitting (eg. prolonged car or air travel)
Increasing age
Laparoscopic surgery (eg. cholecystectomy)
Obesity
Pregnancy
Varicose veins

2.5 Clinical Prediction Scores

While there are numerous clinical prediction criteria, Wells and revised Geneva are the most frequently used, validated, standardized and simplified criteria nowadays (Douma R A et al 2011).

When Wells, Modified Wells, Geneva and Modified Geneva criteria are combined with normal D-dimer results, their performance is similar in eliminating acute PTE (Douma R A et al 2011)

2.5.1 PERC rule for PE

The pulmonary embolism rules out criteria (PERC) rules out PE if all variables are negative and the patient has a low risk of pulmonary embolism corresponding to <15%. The rule is applied to patients when PE is suspected but the probability is considered low. A patient is considered low risk if the patient meets all the following criteria: is <50 years old, pulse rate <100 beats per minute, SpO₂ >95%, no hemoptysis, no history of estrogen use, no history of trauma or surgery in preceding 4 weeks, no prior PE/DVT and no current signs of DVT. The PERC rule out variables must return 0 in all criteria to be considered negative. In this case there is no need for further workup as the PE chance is <2%. The PERC scores are used to help low risk patients avoid unnecessary risks associated with imaging and treatment of PE. The criteria is summarized in the table below

Table 3: The PERC scores are

Criteria	NO	YES
Age >50 years	0	1
Heart rate >100	0	1
O ₂ saturation at room air >95%	0	1
Unilateral leg swelling	0	1
Hemoptysis	0	1
Recent trauma/surgery in last 4 weeks	0	1
Prior PE or DVT	0	1
Hormone use, oral contraceptives, hormone replacement or estrogenic hormones	0	1

2.5.2 Revised Geneva score for PE.

The revised Geneva score is used to categorize patients into low, intermediate or high risk for PE. This is based on history and clinical examination findings alone. It can be used in place of the Wells criteria to identify low risk patients who are then subjected to D dimer tests only hence avoiding the use of CTPA and its attendant risks. It is not meant as a diagnostic tool but is used to guide testing and subsequent workup by predicting the probability of PE. It has several advantages: it does not require imaging or serum studies for assessment of risk and does not require clinical gestalt for risk stratification. It helps in reducing unnecessary imaging studies by identifying low probability for PE patients who are then recommended for D dimer tests. Together with the Wells criteria, they are the most widely applied scores to rule out PE. The revised Geneva score is preferred by some physicians because it is objective unlike the Wells criteria which uses the subjective "PE is unlikely primary diagnosis or very likely". The original Geneva scores required chest x-ray and arterial blood gas analysis and fell out of favour because of these requirements.

Table 4: a summary of the criteria and its corresponding score.

Criteria	No	Yes
Age >65 years	0	1
Previous DVT or PE	0	3
Surgery (under general anaesthesia) or lower limb fracture in last one month	0	2
Active malignant condition	0	2
Unilateral lower limb pain	0	3
Hemoptysis	0	2
Pain on lower limb palpation and unilateral oedema	0	4

Table 5: Heart rate <75 bpm

Heart rate < 75 BPM	--	0
Heart rate 75-94 BPM	-	3
Heart rate >95 BPM	-	5

2.5.3 interpretation of scores.

Patients with a score of 0-3 are categorized as low risk with an incidence of pulmonary embolism of less than 10%.

A score of 4-10 is categorised as intermediate risk .These patients have a 20-30% incidence of PE. Further workup is not considered if D dimer test is negative. However if positive consider CTPA.

Patients with a score of 11 or more are classified as high risk and the incidence of PE is more than 60%.Further workup with CTPA is recommended in this instance.

Wells score for PE

The Wells criteria stratifies patients and estimates the pretest probability of PE. This guides the clinicians on the next appropriate course of action whether D dimers or CTPA.

The table below gives a summary of the criteria and scores for each component of the Wells score.

Table 6: a summary of the criteria and scores for each component of the Wells score.

Clinical signs and symptoms of DVT	No 0	Yes 3
PE is #1 diagnosis or equally likely	No 0	Yes 3
Heart rate >100	No 0	Yes 1.5
Immobilization of at least 3 days or surgery in previous 4 weeks	No 0	Yes 1.5
Previous objectively diagnosed PE or DVT	No 0	Yes 1.5
Hemoptysis	No 0	Yes 1
Malignancy treatment within 6 months or on palliative care	No 0	Yes 1

Table 7: Score interpretation.

Score	risk category.
Three tier model	
0-1	low risk
2-6	moderate risk
>6	high risk
Two tier model	
<4	PE unlikely
>5	PE likely

A multi centre randomized European clinical trial study by Anderson et al sought to determine if CTPA could be used as an alternative diagnostic method to ventilation perfusion scanning in patients with acute symptoms of PE. The results indicated that CTPA is superior to ventilation perfusion scanning diagnosing 133 patients with PE as opposed to 101 patients by V/Q scanning. In conclusion the study indicated that V/Q scans was not superior to CTPA in ruling out PE and additionally concluded that CTPA was more sensitive than V/Q scanning (Anderson DR et al 2007).

Pulmonary angiography as a gold standard diagnostic criterion for PE has several limitations: it is invasive, expensive, time and labour consuming and not widely available. Its mortality risk is 0.2-0.5% (Stein PD et al 1992). In addition, the level of interobserver agreement is 83% and 92% for excluding and including diagnosis of PE respectively This is a potential source of false positive and false negative results (PIOPED JAMA 1990).

The European multicenter trial, done to compare spiral CT and conventional pulmonary angiography demonstrated sensitivity of spiral CT of between 75-92%. In this study sensitivity of ventilation perfusion scans varied between 36-65%. Fewer non-diagnostic scans were also performed with spiral CT than V/Q scans. The interobserver agreement was 72% and 39% for CT and V/Q scans respectively and

much higher than conventional pulmonary angiography at 46 % (Herald C et al 1998). Remy-Jardin et al conducted the first study to evaluate PE using spiral CT. The diagnosis of PE was made on direct visualization of blood clots. Among the 135 patients, 51 had complete filling defects, 41 partial filling defects, 23 normal findings 14 had mural defects and 6 had railway tract signs. 100% of patients with normal findings on CT also had normal findings on conventional pulmonary angiography. The study had a sensitivity of 100% and specificity of 96 % (Remy J et al 1992). The advent of MDCT has improved CT imaging technique with the whole lung being imaged during a single breath hold. A study by Winer M et al demonstrated sensitivity, specificity and accuracy of MDCT OF 100%, 93% and 95% respectively. Conventional angiography findings were 86%, 100% and 97% respectively (Winer M et al 2004).

Modified wells criteria.

Features	Score (points)
Clinical signs and symptoms of DVT	3.0
No alternative diagnosis	3.0
Heart rate >100 beats/min	1.5
Immobilization $\geq$ 3 days or surgery in the previous 4 weeks	1.5
Previous DVT or PE	1.5
Hemoptysis	1.0
Malignancy with active treatment in the past 6 months or under palliative care	1.0
Pretest clinical probability	
PE unlikely	≤ 4.0
PE likely	>4.0

PE = Pulmonary embolism, DVT = Deep vein thrombosis

2.6 Diagnostic approach of PE

The diagnostic algorithm for PE involves assessment of clinical risk scores with Wells score, modified Wells score, revised Geneva scores and PERC scores. Combined with D dimer levels they help to determine the likelihood of PE (Wells P S et al 2000). Patients with a Wells score of >6 are considered likely for PE and confirmatory imaging tests with CTPA is recommended. A Wells score of 2-6 is considered indeterminate risk and D Dimers are recommended. If D dimers is negative no further radiological workup is warranted. Low risk patients have low Wells score of <2 and D dimers maybe recommended to exclude PE. The components of well score for clinical assessment for PE include clinical symptoms of DVT, heart rate >100 , immobilization $\geq$ three days or surgery in the previous four weeks, previous DVT/PE hemoptysis malignancy and other diagnosis less likely than pulmonary embolism

In patients with low clinical probability of PE, pulmonary embolism rules out criteria (PERC) has been demonstrated to be useful to rule out PE (Freund et al 2018). PERC uses eight items in the clinical criteria and all eight must be fulfilled for PERC to rule out PE in low-risk patients. The eight are: arterial oxygen saturation of $>95\%$, heart rate <100 beats/min, patient age <50 years, no unilateral leg swelling, no hemoptysis, no recent trauma or surgery, no prior PE or DVT and no exogenous estrogen use. New diagnostic algorithms use PERC in patients with low test probability for PE to determine if D dimer testing will be required. If all the eight criteria are not fulfilled, then D dimer testing is recommended.

Wells criteria.

Wells criteria for PE is a risk stratification score and clinical decision rule to estimate the probability of acute pulmonary embolism in patients in whom history and clinical examination suggests PE is a possible diagnosis. It provides a pretest probability

which if deemed unlikely can then be used together with a negative D dimer to rule out PE pulmonary imaging.

The components of Wells score are clinical symptoms of DVT, heart rate >100 beats/min, immobilization of more than three days or surgery in the preceding four weeks, history of previous DVT/PE, history of hemoptysis, active malignancy and other diagnosis less likely than PE.

Wells score has a sensitivity of 63.8%-79.3% and specificity of 48.8%-90%.
(Crawford F et al 2016)

Clinical decision rule		Points	
Well score		original version	simplified version
Previous PE or DVT	1.5	1	
Heart rate 100 beats/min	1.5	1	
Surgery or immobilization within 4 weeks	1.5	1	
Hemoptysis	1	1	
Active cancer	1	1	
Clinical signs of DVT	3	1	
Alternative diagnosis less likely than PE	1	1	
Clinical probability			
PE unlikely	≤ 4		≤ 1
PE likely	> 4		> 1
Revised Geneva score			
Previous DVT or PE	3	1	
Heart rate			
75-94 beats / min	3	1	
95 beats/min	5	2	
Surgery or fracture within 1 month	2	1	
Hemoptysis	2	1	
Active cancer	2	1	
Unilateral lower limb pain	3	1	
Pain on lower limb deep venous palpation and unilateral edema	4	1	
Age 65 y	1	1	
Clinical probability			
PE unlikely	≤ 5		≤ 2
PE likely		> 5	> 2

Original Geneva score.

It ranges from 0 to 16 points and results in 3 clinical probability categories, low intermediate and high risk.

Variable	Score
Age	
60-79 years	1
80+ years	2
Previous venous thromboembolism	
Previous DVT or PE	2
Previous surgery/ Recent surgery within 4 weeks	3
Heart rate	
Heart rate > 100 beats per minute	1
PaCO₂ (partial pressure of CO₂ in arterial blood)	
<35 mm Hg	2
35-39 mm Hg	1
PaO₂ (partial pressure of O₂ in arterial blood)	
<49 mm Hg	4
49-59 mm Hg	3
60-71 mm Hg	2
72-82 mm Hg	1
Chest X-ray findings	
Band atelectasis	1
Elevation of hemidiaphragm	1
<5 Points indicates a low probability of PE.	
5-8 Points indicates a moderate probability of PE.	
>8 Points indicates a high probability of PE.	

Revised Geneva score

It's a clinical prediction rule used to determine the pretest probability of PE. It's based on the patient's risk factors and clinical findings. It uses eight parameters which include age over 65 years, previous history of PE /DVT, surgery within the preceding 4 weeks, active malignancy, unilateral lower limb pain, hemoptysis, heart rate, unilateral lower limb oedema.

Patients with scores of 0-3 points are deemed low probability, those with scores of 4-10 points are intermediate while scores of over 10 points are high probability.

These scores are useful in determining the need for further investigations.

The sensitivity of the revised Geneva score for PE is 58.3%-73.6%. (Crawford F et al 2016)

Simplified revised Geneva score.

Uses a one-point stratified scoring system to replace the previously weighted scores for each parameter. This was done to reduce the likelihood of error. When the score is used in clinical settings' simplified Geneva score does not lead to a decrease in diagnostic utility when compared to previous Geneva scores.

Table 9: Simplified revised Geneva score.

Predictive variables	Revised Geneva score	Simplified Revised Geneva score
Age >65 years	1	1
Active malignancy (or considered cure <1 year)	2	1
Recent surgery or fracture of the lower limbs within 1 month	2	1
Previous PE or DVT	3	1
Hemoptysis	2	1
Unilateral lower limb pain	3	1
Tenderness on lower limb deep venous palpation and unilateral oedema	4	1
Heart rate		
75-94 bpm	3	1
≥95 bpm	5	2

Pulmonary embolism rule out criteria.

The PERC helps to evaluate patients in whom pulmonary embolism is suspected but unlikely. These were developed for emergency department patients with the aim of selecting on clinical grounds patients whose probability of having PE is low. Such patients were then not subjected to further imaging.

Unlike the Wells score and Geneva score which are clinical prediction rules intended to risk stratify patients with suspected PE, the PERC rule is designed to rule out the risk of PE in low-risk patients. In 2008, a study by Kline et al demonstrated that PERC rule had a sensitivity of 97.4% a specificity of 21.9% and a false negative rate of 1%

The PERC scores utilize eight clinical variables. These are age<50years, pulse rate<100 beats/min, spo2 >94%, no unilateral leg swelling, no hemoptysis, no recent trauma or surgery, no history of venous thromboembolism and no history of hormonal use.

All eight parameters should be positive to rule out likelihood of PE.

YEARS algorithm for pulmonary embolism.

In 2017, the YEARS algorithm established a simplified algorithm for evaluation with a two-tiered D-dimer threshold in an effort to reduce the number of patients getting CTPA (van der Hulle 2017). The YEARS algorithm asks three questions: 1) Are there clinical signs of DVT? 2) Does the patient have hemoptysis? and 3) is PE the most likely diagnosis. If the answer to all 3 questions is no, the D-dimer threshold is set at 1000 ng/mL and if the answer is “yes” to any of the 3 questions, the D-dimer threshold is set at 500 ng/mL. The YEARS algorithm departs from traditional PE CDRs in two ways: (1) D-dimers are completed for all patients investigated for PE, not just low-risk patients and (2) The negative D-dimer threshold is increased from 500 to <1000 µg/L when all risk factors are absent.

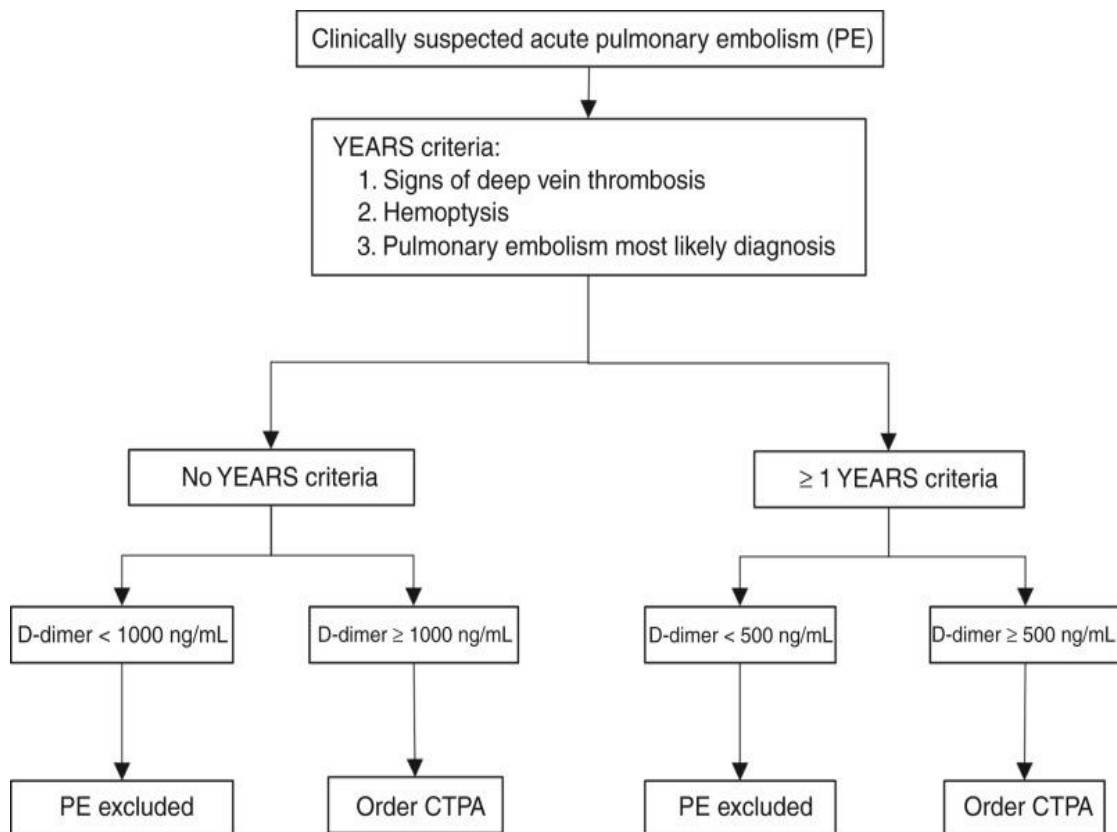
The Years criteria is simple and efficient rendering it useful in clinical practice. Apart from helping to rule out embolism, it's also validated in pregnant patients with clinically suspected PE. The Years criteria has several exclusion criteria as enumerated in the table below.

INSTRUCTIONS

Use in hemodynamically stable patients ≥ 18 years old.

Take note of the following exclusion criteria:

1. Treatment with therapeutic doses of anticoagulants initiated 24 hours or more before eligibility assessment.
2. Life expectancy less than 3 months.
3. Geographic inaccessibility precluding follow-up.
4. Pregnancy (be sure to use pregnancy-adapted YEARS algorithm in the calc).
5. Allergy to intravenous contrast agent.



Application.

If a patient has 0 YEARS items use a D dimer threshold of 1000ng/ml. However, if the patient has one or more YEARS items use a D dimer threshold of 500mg/dl.

Interpretation

0 YEARS items and D-dimer <1000 ng/mL - PE is considered excluded.

1+ YEARS items and a D-dimer <500 mg/mL - PE is considered excluded.

All other patients not included above will require a CTPA to exclude PE. As a result of the binary D dimer cutoffs utilized in YEARS the number of CTPA requested are projected to reduce. This is confirmed in a study by Van der Hulle et al in 2017. This is of great benefit to younger patients in whom the unnecessary exposure to radiation has a more significant lifetime risk. Importantly the algorithm was not associated with an increase in missed clinically significant pulmonary embolisms.

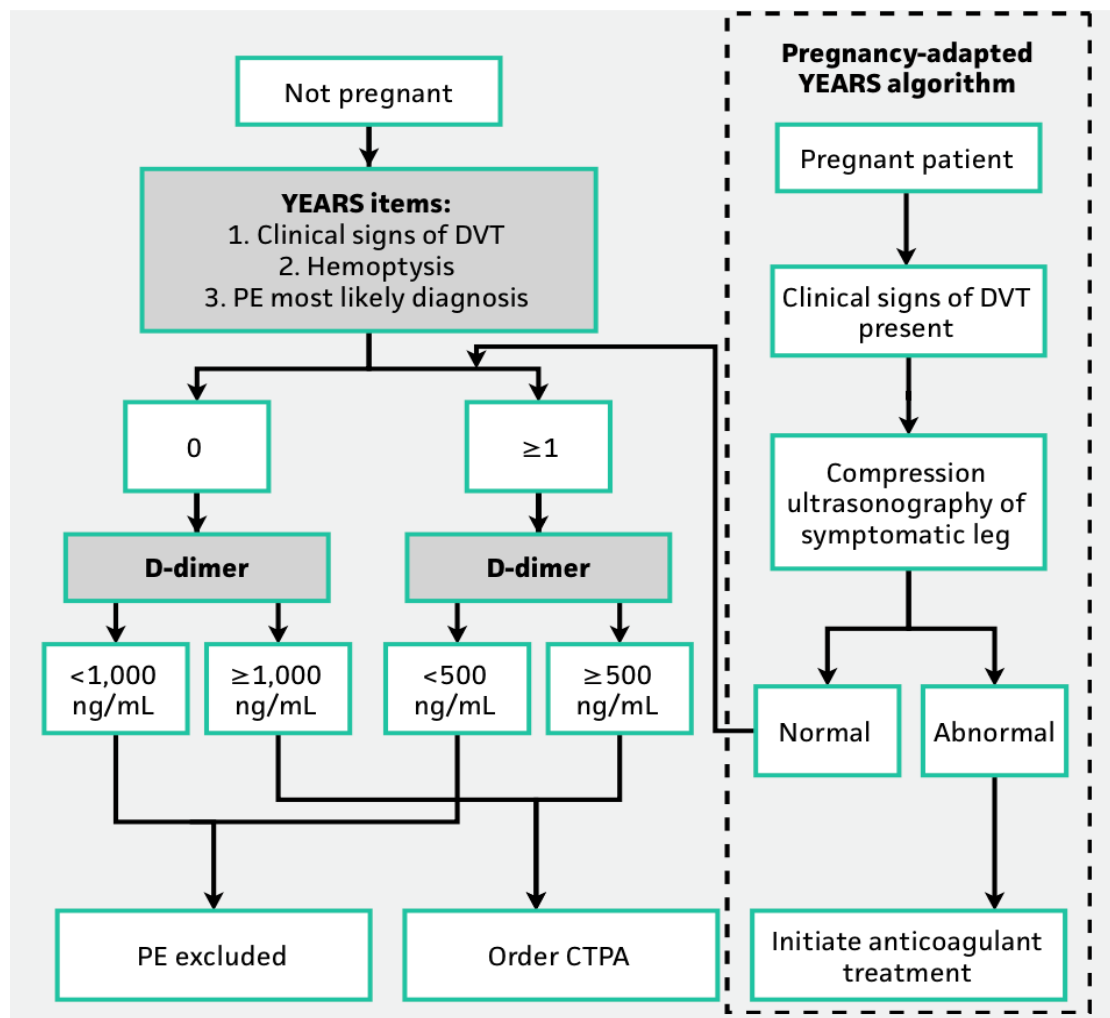
Pregnancy adapted YEARS criteria.

A pregnancy adapted YEARS Criteria is one of the few tools for risk stratification of PE in pregnancy. It uses three components from the Wells criteria: hemoptysis, clinical signs of DVT and PE as the most likely diagnosis. A positive response to any of the three criteria yields a score of 1 while a negative response gives a score of zero. In total the scores ranges from 0-3. In addition, compression ultrasonography and D dimers are included. If there is evidence of DVT on ultrasound, patients are treated as having PE without further diagnostic imaging. The tool produced an absolute reduction in CT scans by 11% when compared to other strategies (Al Oweidat et al 2020). There are several exclusion criteria's to be considered. These include treatment with therapeutic doses of anticoagulants initiated within 24 hours or more, life expectancy of less than 3 months, geographic inaccessibility precluding follow-up and allergy to contrast material.

Application

If no YEARS criteria are met and the D dimer results is less than 1000ng/ml, PE is ruled out and no CTPA is recommended. However, if one or more YEARS criteria are met and the D dimer is less than 500ng/ml, PE is also ruled out. Patients with one or more positive YEARS criteria and D dimer of > 1000 ng/ml are recommended for imaging to rule out PE. Patients with elevated D dimer levels or positive compression ultrasonography results are evaluated further with CTPA.

The diagnostic algorithm is summarized in the flow diagrams below.



Legend score

The legend score synthesizes Wells, PERC, Geneva, D Dimer and predicts acute pulmonary embolism prior to imaging tests. The score comprises active cancer, D dimer with a cutoff of $> 1000\text{ng/ml}$, DVT symptoms and signs, previous venous thromboembolism, VTE history, surgery, trauma or immobilization in the past one month.

It has yielded excellent diagnostic efficiency with good safety and more reduction in unnecessary imaging tests than Wells combined with D dimer, PERC combined with D dimer, Geneva score combined with D dimer or YEARS with D dimer in the pretest prediction of acute PE prior to imaging tests (Yunfeng Z et al 2023)

The legend prediction rule for acute pulmonary embolism.

Items	Original version	Simplified version.
Active cancer	1	1
D dimer $>1000\text{ng/ml}$	3	1
DVT symptoms/signs	2	1
Previous VTE history	2	1
Surgery, trauma or immobilization	2	1
Clinical probability		
PE unlikely	<1	0
PE likely	>2	>1

2.7 Imaging tests for pulmonary embolism

2.7.1 Ventilation perfusion (V/Q) scans

Ventilation perfusion scans consist of a perfusion study where macroaggregated albumin labelled radionuclide are injected intravenously and transported to the pulmonary capillary bed where they are trapped and a ventilation study performed with radiolabeled technetium 99 inhaled gases like Krypton and Xenon.

Ventilation perfusion scans were used as the first line test to diagnose PE before introduction of CTPA (Wiener RS et al 2013). There is no direct visualization of PE with V/Q scans, but inference of PE is made on the basis of mismatches of ventilation and perfusion in the lung fields. The probability of PE is graded as high, intermediate and low using criteria from the PIOPED study (JAMA 1990). Pretest probability scores of PE can be combined with findings from ventilation perfusion scans to arrive at correct interpretation (Jha S 2015). Often ventilation perfusion scans do not rule out the presence of PE as intermediate probability is commonly reported. In the PIOPED study, intermediate probability was reported in 35% of patients with suspected PE of which only one third of these patients had PE confirmed on pulmonary angiography (JAMA PIOPED study 1990). Ventilation perfusion scans are largely indicated in patients with contraindication to intravenous contrast and in pregnant patients where ionizing radiation is undesirable. PE is diagnosed if there is a perfusion scan defect but normal ventilation (Leung a w et al 2011). The diagnostic value of V/Q scans is improved if the chest radiograph for a patient with suspected PE is normal (P. Robin et al 2011).

2.7.2 Computed tomographic pulmonary angiography (CTPA)

CTPA was introduced in 1998 and is now the first line test for pulmonary embolism. It has a sensitivity of 83% and specificity of 96% according to the Prospective Investigation of Pulmonary Embolism Diagnosis (PIOPED) II study and has been recommended as the first line imaging modality for suspected PE by the Kenya national guidelines for cardiovascular disease (2018). CTPA is faster and is not operator dependent (Riedell 2004). An additional advantage of CTPA is that it can assess presence or absence of right ventricular heart strain, an indirect assessment of PE severity which is not possible with pulmonary angiography. There is good

interobserver agreement with CTPA as opposed to scintigraphy and also picks alternative diagnoses such as pleural effusion, pneumonia, atelectasis, emphysema or pulmonary masses. It can provide direct visualization of partial or complete occlusion of the pulmonary arteries and its segmental divisions. It also allows for investigation of possible differential diagnoses in patients with cardiorespiratory symptoms.

CTPA has a major disadvantage of depositing high doses of radiation which is injurious to young children, expectant mothers and adolescents who are twice or thrice as likely to develop radiation induced malignancies. In these instances, alternative imaging modalities like ventilation perfusion scans are considered.

Features of PE on CTPA include complete occlusion of the vessel, filling defects which form an obtuse angle with the vessel wall and intravascular filling defect in the lumen of the vessel. Parenchymal findings include ground glass opacities, oligemia and peripheral wedge-shaped opacities (Mazilu et al 2015). With availability of CT, the use of CTPA has increased significantly resulting in detection of clinically insignificant PE which are small emboli with no acute physiologic effects and may lyse immediately or resolve within hours or a few days. (Scheissler et al 2013).

Acute pulmonary embolism.

CTPA will demonstrate filling defects within the pulmonary vasculature with acute pulmonary emboli. When the artery is viewed in its axial plane the central filling defect from the thrombus is surrounded by a thin rim of contrast which has been called the polo mint sign.

Emboli maybe occlusive or non-occlusive, the latter is seen with a thin stream of contrast adjacent to the embolus. Typically, the embolus makes an acute angle with the vessel in contrast to chronic emboli. The affected vessel may also enlarge. Acute

pulmonary thromboemboli can rarely be detected on non-contrast chest as intraluminal hyper densities. Pulmonary infarction can occur when the pulmonary artery branches which are less than 3mm are occluded due to inadequate bronchopulmonary anastomosis at this level. Larger infarctions can occur with concomitant heart failure.

Chronic pulmonary embolism.

In contrast to acute PE, chronic thromboemboli are often complete occlusions or non-occlusive filling defects in the periphery of the affected vessel which form an obtuse angle with the vessel wall. The thrombus may also be calcified. The features which are associated with chronic thrombi include webs or bands, intimal irregularities, abrupt narrowing or complete occlusion of the pulmonary arteries. There are also indirect signs which may suggest a chronic embolus. These include mosaic perfusion, vascular calcification and bronchial or systemic collateralization. CT is also critical in demonstrating complications of emboli. These include Right ventricular dysfunction which is characterized by abnormal position of the interventricular septum, inferior vena cavae contrast reflux, right ventricular to left ventricular diameter ratio of >1 on reconstructed four chamber views.

Subacute and chronic emboli may also result in pulmonary infarction, pulmonary hypertension, pulmonary arterial sclerosis and cor pulmonale.

2.7.3 Chest x-ray

A chest x-ray is commonly the initial imaging modality requested in patients with suspected PE (Coche E et al 2004), Abnormal chest radiograph findings are common in patients with PE according to a study by Elliot et al in 2000. Abnormalities detected on a chest radiograph include atelectasis, cardiomegaly, elevated hemi

diaphragm, pleural effusion and parenchymal opacities. Peripheral wedge shaped triangular opacity (Hamptons hump), focal oligemia (Westermarck sign) and enlarged right descending pulmonary artery (Pallas sign) are the classical radiological findings of pulmonary embolism (Goldhaber et al 2005). The accuracy of chest x-ray alone in diagnosis of PE is variable and in a study by Greenspan RH et al found an accuracy rate of 33% .The indication for chest radiograph is mainly to exclude other diagnoses which mimic PE such as pneumothorax ,congestive cardiac failure, rib fracture, costochondritis, pulmonary edema and chronic obstructive pulmonary disease (Moore et al 2018). Chest x-ray findings in PE evolve over time with normal findings or pulmonary oligemia (Westermarck sign) initially. Gradually pleural effusion, elevated hemidiaphragm, atelectasis and parenchymal infiltrates appear.

Hamptons hump and Pallas sign are late presentations (Preto et al 2010, Abbas et al 2013, Hsu et al 2017).

Chest X-ray is neither sensitive nor specific for PE. It is used to assess the differential diagnostic possibilities such as pneumonia and pneumothorax rather than for direct diagnosis of PE. Pleural effusions are associated in approximately 35% of cases. There are several described chest radiographic signs. Fleischer sign refers to enlarged pulmonary artery. Hamptons hump describes the peripheral wedge shaped opacity and implies lung infarction. The Westermarck sign describes regional oligemia and has the highest positive predictive value. Others include the Palla sign which refers to an enlarged right descending pulmonary artery. The loosely related Chung sign describes a dilated right descending pulmonary artery with sudden cutoff. In the PIOPED study the sensitivity and specificity of these signs was explored. The Westermarck sign had a sensitivity of 14%, specificity of 92%, positive predictive value of 38% and a negative predictive value of 76%. A finding of vascular redistribution had a

sensitivity of 10%, specificity of 87% and a positive predictive value and negative predictive value of 21% and 74% respectively. Hamptons hump, pleural effusion and elevated diaphragms had sensitivity, specificity, PPV and PPV of 20-36%,70-85%28-30% and 76% respectively.

2.7.4 Compression ultrasonography

Lower limb Doppler relies on loss of vein compressibility as the major criteria for diagnosis of DVT. Other features include absent colour flow if completely occluded, no phasic flow on Valsalva, no flow augmentation with squeeze of calf muscles and prominence of superficial veins due to increased flow. An acute thrombus is suggested by increased venous diameter, presence of soft and deformable intraluminal material and smooth surface. Doppler ultrasound is relatively easy to perform and interpret and has been advocated by some practitioners as part of the workup for PE. The management of DVT and PE is largely similar and a positive finding of DVT on Doppler ultrasonography may not require further imaging. There is limitation to the usefulness of this strategy in that missed diagnosis of PE in the setting of VTE will result in overdiagnosis of PE recurrence during subsequent visits especially if V/Q scintigraphy is performed (Schoepf et al 2004).If DVT had been diagnosed on compression ultrasonography and no further imaging was done to investigate for PE, subsequent V/Q scans may pick PE .This may be incorrectly stated as a recurrence yet it could have been missed because no further imaging in addition to compression ultrasonography had been done.

2.7.5 Echocardiography

Acute pulmonary embolism

Point of care ultrasonography is not recommended for a hemodynamically stable patient with suspected PE. In the presence of hemodynamic compromise, echocardiography may be of value to assess for the presence of severe right ventricular dysfunction. If absent another cardiopulmonary derangement is likely responsible. If unequivocally present it can establish the need for emergent treatment.

The echocardiographic features which may be suggestive include thrombus in transit. This usually presents the embolic propagation of deep venous thrombosis and is usually intracavitary and freely mobile. It's visualized in the right atrium, right ventricle and the main pulmonary artery and is typically associated with signs of right heart strain. If an intracardiac shunt is present it may result in paradoxical embolism. In addition there may be right ventricular dysfunction which results in a hypercontractile and dilated ventricle. Other features of acute pulmonary embolism include flattening and dyskinesis of the interventricular septum. In echocardiography a 60/60 sign may be visualized. This refers to the coexistence of a truncated right ventricular outflow tract acceleration time ($AT < 60\text{ms}$ with pulmonary arterial systolic pressure of less than 60mmHg (but more than 30mmHg). In the presence of right ventricular failure, it is consistent with an acute elevation of afterload, commonly due to acute pulmonary embolism. A regional pattern of acute right ventricular dysfunction seen on trans thoracic echocardiography has been observed in patients with acute pulmonary thromboembolism and is referred to as the McConnell sign. Of note is that transesophageal echocardiography has a reported sensitivity of 81% and a specificity of 97% for ruling in acute pulmonary embolism after the detection of right ventricular overload on transthoracic echocardiography.

Chronic pulmonary embolism.

Echocardiography is not recommended as part of the first line workup. Cumulative damage from repeated emboli insults is a common cause of chronic thromboembolic pulmonary hypotension which demonstrates a variable degree of the afore mentioned signs but with significantly higher right ventricular pressures, right ventricular hypertrophy and diastolic dysfunction and a higher degree of tricuspid regurgitation.

2.7.6 MR angiography

Maybe performed by centres that are technically advanced and in patients in whom the standard tests are excluded. It has many disadvantages in that it is not widely available, is highly technical, is time consuming and has poor spatial resolution (Preto et al 2010). Often MR angiography results in technically inadequate images (Stein PD et al PIOPED III 2010). The sensitivity and specificity for proximal PE ranges from 77-87% and 95-97% respectively. It's lower for segmental and sub segmental PE (Schoepf and Costello 2005). The significant development of MRI technology has enabled faster sequences with high contrast and spatial resolution. MRI can provide both morphological and functional information. MRI protocols consist of free breathing steady state free precession sequence for PE, Post contrast T1 weighted 3D contrast enhanced MRA for pulmonary embolism, T1 weighted 4D contrast enhanced first pass perfusion study involving perfusion and T1 weighted volumetric interpolated 3D gradient echo for mediastinal and pleural disease.

MRA findings of PE include filling defects, complete absence of vessel enhancement, dilatation of the MPA and caliber change with post stenotic dilation. In comparison with CTPA, MRPA has lower sensitivity for detecting PE especially in peripheral arteries. According to the PIOPED III study MRPA has a sensitivity of 78% and

specificity of 99% for detecting venous thromboembolism. The sensitivity was also noted to decrease according to the anatomical locations ranging from 79% in the main/lobar arteries, 50 % in the segmental arteries and 0% in the subsegmental arteries. MRPA is not routinely used in clinical practice because of technically inadequate studies, less robustness, long examination times and contraindications in patients with implanted devices.

2.7.7 CT Venography

Can also be used in the detection of deep venous thrombosis in the extremities and can be obtained at the same time as the CTPA thus eliminating the need for additional time-consuming studies. CTV has several advantages over ultrasound. Firstly, it can be performed adequately in patients with overlying casts, surgical material or wounds. In addition, it also allows imaging of the more central venous structures which can be challenging with lower extremity ultrasound and additional sources of leg pain can be identified beyond the realm of vascular structures. Combining CTPA and CTV has been noted to increase the sensitivity for thromboembolic disease. This was demonstrated in the PIOPED II trial where sensitivity for thromboembolic disease increased from 83-90%. Moreover, it was also recommended in combination with CTPA as part of that study conclusion.

The radiation dose of CTPV ranges from 4.8 to 9.7mSv effectively doubling the total radiation dose compared to CTPA alone. CTV also requires the use of greater volume of intravenous contrast material. CTV when performed as part of a diagnostic algorithm for PE is obtained following CTPA and is sometimes referred to in literature as indirect CTV. In the PIOPED II trial, a helical acquisition using 7.5mm reconstruction, pitch 1.5, tube current 180mA and 120KVP was utilized. Images were

obtained from the iliac crest through to level of the tibial plateau at a delay of 3 to 3.5 minutes.

Acute DVT on CTV appears as a complete or partial filling intraluminal hypodense filling defect in a deep vein. The vein is typically expanded and a rim of enhancing venous wall maybe seen. Secondary signs include edema in the adjacent tissues.

Chronic DVT manifests on CTV with small vessels, recanalization or thrombus calcifications, and thickened veins. The mean CT attenuation of DVT is between 31-65 Hounsfield units.

2.8 Laboratory investigations

2.8.1 D Dimer

D dimer is a fibrin degradation product. Its level rises in PE due to breakdown of fibrin. It is a biological marker that is produced by the enzymatic breakdown of fibrin which forms the fibrous mesh of a blood clot. The measurement of Dimer in blood serves as a marker of coagulation and fibrinolysis which is useful in diagnosis of certain diseases. There are several validated uses of D dimers. These include 1) excluding the diagnosis of pulmonary embolism or venous thromboembolism in combination with clinical decision tools such as wells criteria, Geneva score and pulmonary embolism rule out criteria. Secondly it can be used in determining the optimal duration of anticoagulation therapy in patients with venous thromboembolism. Thirdly it can be used together with the coagulation profile findings like prothrombin time, platelet count and fibrinogen to diagnose and monitor disseminated intravascular coagulation (DIC). In addition, it's also useful for determining patients at high risk of thrombosis among cancer and hospitalized patient. Raised D dimer levels are associated with several conditions including stroke, venous

thromboembolism, aortic dissection, atrial fibrillation, and DIC. Other conditions include normal pregnancy, preeclampsia/eclampsia, increasing age, severe liver disease, congestive heart failure, renal disease., malignancy, sepsis and surgery or trauma.

Ultra-high d dimer levels >5000ng/ml are encountered in various clinical conditions like VTE, cancer and COVID 19. Progressive rise in D dimer levels were associated with increasing mortality as demonstrated in a study by Schafer et al (2021). Ultrahigh D dimer levels carry a high predictive value for serious disease (Schutte T et al 2016).

D dimer elevations are not specific to clot formation and are linked to other conditions like inflammation, sepsis and malignancy, therefore the indication for D dimer is to rule out and not rule in venous thromboembolism (Konstantinidis SV et al 2019).

D dimer levels are elevated in plasma in presence of acute thrombosis because of activation of the coagulation system. It's also elevated in patients with cancer, hospitalized patients, severe infections, during pregnancy and in inflammatory diseases.

Normal D dimer levels render acute PE or DVT unlikely. Quantitative Elisa derived assays have a diagnostic sensitivity of >95% and can be used to exclude PE in patients with either low or intermediate pretest probability. However, specificity decreases with advancing age and therefore age adjusted cut offs may be utilized to improve the performance in the elderly.

D dimers have high sensitivity, low specificity and high negative predictive value for PE. Previous studies reported that D dimer levels in patients with acute PE are increased significantly (Righini M et al (2015). A meta-analysis by Crawford et al

reported D dimer sensitivity of between 80-100% while specificity ranged between 23-63% (Crawford F et al (2016)).

It has been reported that when D-dimer and clinical scoring are used in combination, the diagnosis can be excluded in approximately 30% of the patients suspected of having PE without the need for imaging methods (Van belle et al 2006)

2.9 Approach of PE

2.9.1 Over testing of PE

Numerous guidelines and algorithms have been developed to prevent over testing of PE in patients with low risk. However there is evidence that CTPA is often inappropriately ordered without using clinical probability scores or D Dimers and ignoring evidence of low pretest probability of PE (Perera M et al 2018,Osman M et al 2018).There are also large variations in over testing practices among clinicians (Booker M T et al 2017).In the recent past attention has been drawn to over testing with CTPA with a recommendation that CTPA should be avoided in patients with low pretest probability, negative D dimers and negative PERC scores.(Wiener RS et al 2014).D Dimer tests are recommended to rule out PE in patients with low probability of PE and hence reduce inappropriate use of CT PA. The D dimer has a high negative predictive value and low specificity. If the D dimer test is negative, the clinician should be overly confident that the patient doesn't have PE. A positive D dimer test is non-specific therefore it should not be used indiscriminately in patients with very low probability of PE. Recently evidence has shown that it's safe to use PERC scores without additional tests hopefully leading to decrease in CTPA investigations and D dimer testing.

Several studies have been done to assess the interventions required to reduce inappropriate use of CTPA. A review of 17 studies found evidence that clinical decision support reduced imaging use by 8 to 25.4% and increased the diagnostic yield (Deblois S et al 2018). Overuse of CTPA to test for PE results in overdiagnosis and resultant overtreatment of PE. It also results in increased detection of incidental findings with no clear significance. Approximately one in four CTPA tests detects incidental findings such as adenopathy, pulmonary nodules or thyroid nodules which likely turnout to be insignificant (Anjum O et al 2019).

2.9.2 Avoidable imaging

Routine use of CTPA has risks and significant costs. As a result, European and American societies have developed guidelines to help physicians better allocate resources. PIOPED II and European society of cardiology guidelines recommend imaging in patients with intermediate or high risk of PE. In low-risk patients D dimers levels of <500ng/ml can accurately exclude PE (Terbicki et al 2008). Despite the development of algorithms, many CTPAs are requested in low-risk patients with no D dimer or negative D dimer tests. (Venkatosh et al 2012).

2.9.3 Overutilization /underuse

Diagnosis of patients with suspected PE is still a challenge. Over and under diagnosis could result in significant morbidity or mortality. To establish diagnosis clinical probability scores, CTPA and serum D dimer levels are utilized. Wells scores and revised Geneva scores are accepted criteria used to categorize PE probability into likely and unlikely groups (Wells PS et al 2000). Alternatively modified Wells score combined with D dimer levels is utilized. .Modified Wells score is simpler and efficient and has been validated in several studies (Van belle A 2006).Combination of

low Pretest clinical probability and low D dimer excludes the diagnosis of PE with a negative predictive value of 99% (Wells PS 2001). Crichlow et al studied 152 patients with suspected PE in Pennsylvania and concluded that 9.2% and 13.8% of the CTPAs performed were avoidable if PERC and D dimers were utilized respectively. (Crichlow A et al overuse of CTPA in evaluation of patients with PE 2012).

Adherence to guidelines helps physicians identify high risk patients who will benefit from further testing and low risk patients who can avoid radiation and contrast exposure hazards of CTPA.

2.10 Diagnostic yield

The diagnostic yield is calculated as the number of patients with positive test results among all people for whom testing was performed. This has been suggested as a metric of appropriateness of use . A definitive positivity rate has not been globally established with a rate of 10% accepted as the threshold under which overuse of CTPA is considered in North America .The British royal college of radiologists consider a threshold of 15.4% as ideal. There is a wide range of diagnostic yields for pulmonary embolism in literature ranging from 4.7% to 31%(Kornblum J et al 2021, De Boer 2022).

The diagnostic yield of CTPA is variable depending on the studies. Low Diagnostic yield of CTPA have been reported especially in the USA. This is despite using a lower cutoff of 10% as the acceptable threshold. However, yields can be raised up to 30% if pretest assessment tools and scores are used (Reagle Z et al, 2012, Walen S et al, 2016). Previous studies in the USA had yields ranging from 5.7-9.0 % (Weir ID et al 2010, Hall WB et al, 2009). One study in the USA by Reagle et al reported an overall CTPA yield of 8.2%. The patients were grouped into three categories using

the revised scoring system: low probability, intermediate and high probability. Out of 1514 patients examined, 447 were categorized as low probability and when subjected to CTPA, only 4.5% were diagnosed with PE. There were 1012 (68%) patients with an intermediate score and on CTPA 9% were diagnosed with PE. Only 55 patients were categorized as high probability. In this group 25.4% had PE on CTPA (Reagle Z et al 2012). Similarly, a recent retrospective study in a tertiary academic center in Canada reported a positive PE yield of 15.9% (Chen z et al 2019).

Studies done in the developing countries in Asia and Africa however have reported higher diagnostic yields. One such study by Alshumrani et al 2021 in Saudi Arabia reported a diagnostic yield of 33%. (177/534 patients.

Hanieh R et al conducted a similar study in Iran on 112 patients and reported an overall CTPA diagnostic yield of 39%. However, the yields varied markedly when the patients were categorized into three groups using the Wells criteria. In the low clinical probability group, 18% were positive for PE, while the intermediate and high probability groups had yields of 44% and 82% respectively. When the revised Geneva score was utilized 20/65 in the low probability group, 16/36 of the intermediate and 8/11 of the high probability group were positive for PE (Hanieh R et al 2018). in Malaysia a cross-sectional study done to determine the yield of CTPA and identify predictive factors yielded a positive score of 26.5% among the 351 patients enrolled. Factors such as male gender, discipline and history of trauma, were associated with a positive CTPA result. Patients with covid 19 infection and pneumonia had a lower chance of positive CTPA results (Low C L et al 2023).

In Thailand, a study by Vongchaiudomchoke T et al reported positive PE on CTPA of 7.95%, 39.3% and 59.3% for the low, intermediate and high probability categories

respectively. (Vongchaiudomchoke T et al, 2012). In yet another study of 602 patients with suspected PE who subsequently had CTPA done,

Stojanovska et al concluded that use of PERC reduced the need for CTPA and missed fewer cases of PE compared to Wells criteria. They therefore considered PERC as an efficient tool to make a decision (Stojanovska J et al, 2015). The diagnostic yield of CTPA in this study was 10% (61/602). Additionally, 17.6% and 45% CTPA examinations could have been avoided if PERC and modified Wells scores were applied respectively.

Data from Australia and New Zealand is limited, with reported yields ranging from 6-14 % (Sud R et al 2013, Ong CW et al 2012). A study by Al Alawi et al in Australia on 249 patients reported a diagnostic yield of 13.7%. In a retrospective study at a single tertiary centre in Victoria the CTPA yield was 12.9% (56/434) (Uthuman A et al 2023). Further analysis indicated a positive association of PE with patients age and history of DVT/unilateral lower limb swelling. Female gender had a negative association for pulmonary embolism. A larger regional study in 4 centres in Tasmania involving 2758 patients reported a similar diagnostic yield of 12.4%. (Thurlow L e et al 2023). In Queensland Australia another retrospective study of CTPAs ordered reported a diagnostic yield of 12.4%. Further stratification of patients using wells score into low, moderate and high risk had yields of 4.0%, 18.5% and 41% respectively. In addition, 25 patients who had low Pretest probability and had CTPA requested could have been excluded with the pulmonary embolism rule our criteria. Use of age adjusted D dimers could have prevented 26 CTPA with no false negatives whereas Pretest probability approach may have prevented 128 CTPA with four false negatives. (Kumar Saaransh et al 2024). In 2017 a multi-site observational Australia

study had demonstrated average yield of 14.6% with sizeable intra site variations. more recent data have demonstrated reduced yields raising concerns about over testing (Youens D et al 2023).

In Europe and Canada yields are higher compared to the USA ranging between 12-20%. The definitions of a low or unacceptable yield have not been universally agreed however the British College of Radiologists have targets of 15.4%-37.4 %. (Royal College of radiologists: appropriateness of usage of CTPA investigation for PE).

Diagnostic yields in Sub-Saharan Africa were reported as 23.3% in the PIOPED II study (Stein PD et al 2007). A study by Tambe et al in Cameroon also in 2012 reported a PE prevalence of 32.4% (Tambe et al 2012). In South Africa Ramlakhan et al in 2017 reported a diagnostic yield of 26.2%. Another retrospective study in south Africa at a regional hospital reported a yield of 32% (Bulajic B et al 2019. clinical probability scores were not routinely done. Only 13% of patients with suspected PE had the wells score documented and none had the revised Geneva scores performed. while Lomamba et al in the Democratic Republic of Congo had a diagnostic yield of 26.0%.

In Kenya Amunga L et al recruited 103 patients with suspected PE out of whom 34.0 had positive PE findings on CTPA. (Amunga L et al N et al, 2021).

Adams et al in 2013 did a study to evaluate the adherence of PIOPED II recommendations in patients with suspected PE and found that 54.5% of all CTPAs performed were in patients with low or intermediate clinical risk or had negative D dimers. Similarly, Molaee S et al in Iran found that 50.6% of patients with suspected PE and who underwent CTPAs had low clinical probability of PE (Molaee S et al

2015). These two studies highlight the overuse of CTPA, subjecting patients to potential harm and increasing costs of health care to the patients.

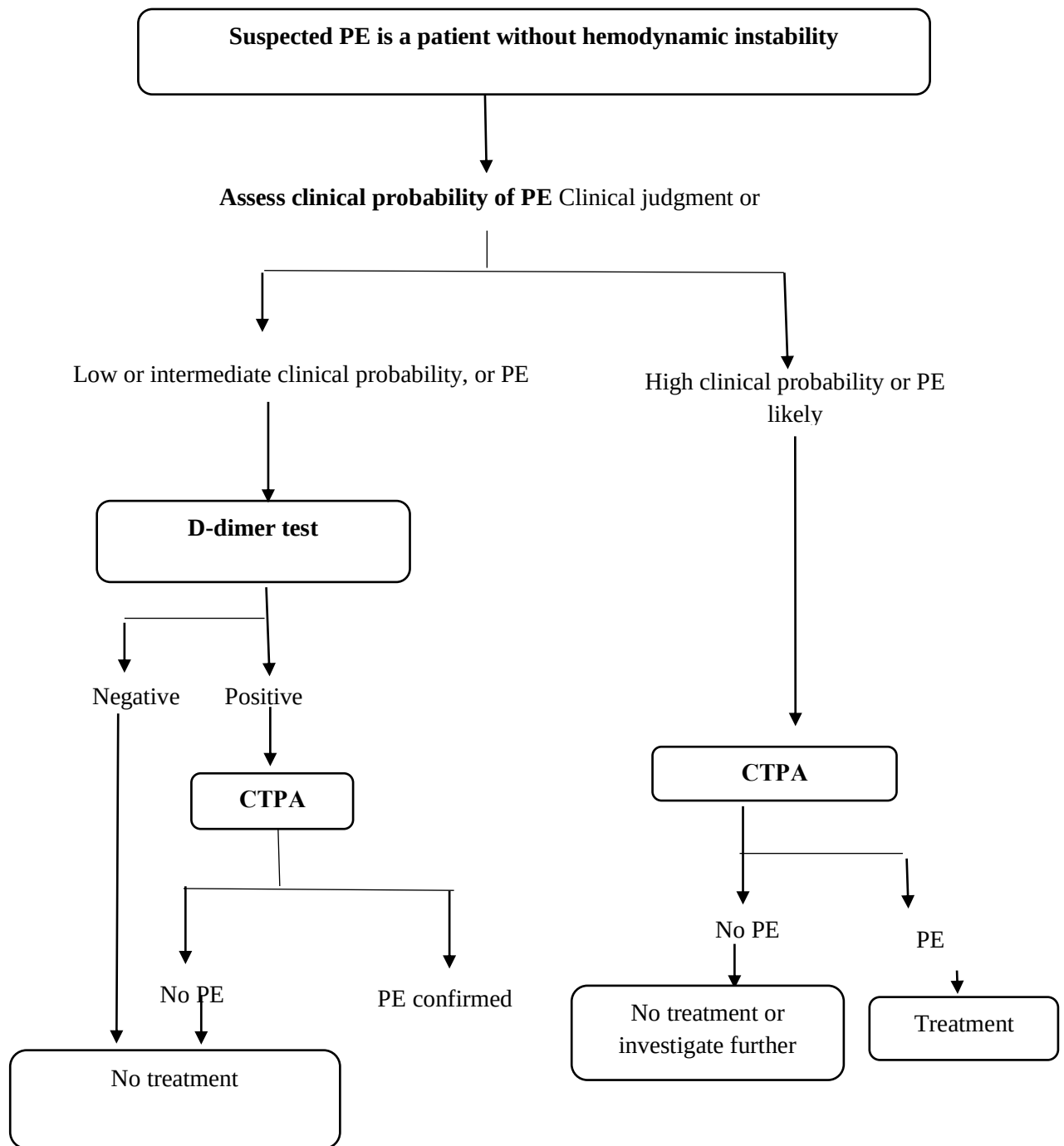


Figure 4: Diagnostic algorithm for patients with suspected pulmonary embolism. 2019 European Society of cardiology guidelines for the diagnosis and management of acute pulmonary embolism. European heart journal 41(4).

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Site

The study was conducted at the Moi Teaching and Referral Hospital Radiology and Imaging department at the CT imaging rooms.

The Moi Teaching and Referral Hospital is located along Nandi Road in Eldoret town. Eldoret is in the North Western side of Kenya, about 310 km Northwest of the capital city Nairobi. Moi Teaching and Referral Hospital is the second largest referral hospital in Kenya after Kenyatta National Hospital. Its catchment area is counties in the Western and North Rift regions of Kenya, parts of Eastern Uganda, South Sudan, Northern Tanzania, and Democratic Republic of Congo with a population of over 25 million.

It has a bed capacity of 991. MTRH offers a wide range of services which include outpatient and inpatient medical services, surgical, obstetric mental health, comprehensive care services and AMPATH oncology which caters for the oncology patients. It also serves as the teaching hospital for Moi University College of Health Sciences and offers both undergraduate and post graduate medical programs across several specialties.

The radiology and imaging department offers a wide range of imaging services both routine and specialized. This includes general x ray examinations special x ray procedures such as barium studies micturating cysto-urethrogram, intravenous urogram and pyelogram. It has an ultrasound room with two ultrasound machines. the computerized tomography unit has two CT machines 32 slice CT scan machine (Siemens Germany) and a 64 slice CT scan (Philips Netherlands) It has twelve radiologists and offers both diagnostic and interventional radiology services. It has one 1.5 tesla Magnetic Resonance Imaging (MRI) machine.

3.2 Study Population

The study was undertaken over a 12-month period and included all adult patients with suspected pulmonary embolism referred to the radiology department for Computed tomographic pulmonary angiography and also had D dimers performed.

3.3 Study Design

This was a cross-sectional study undertaken over a period of one year from September 2022 to August 2023.

3.4 Eligibility Criteria

3.4.1 Inclusion Criteria

1. Adult patients 18 years and above
2. Clinically suspected to have pulmonary embolism, referred to radiology department for CTPA and had D dimer tests performed.

3.4.2 Exclusion Criteria

1. Patient with confirmed pulmonary embolism who are on treatment and sent for rescanning.
2. Patients who declined consent.

3.5 Study period

This study was conducted for a period of 12 months between September 2022 and August 2023.

3.6 Sampling and Sampling Procedures:

3.6.1 Sample Size determination

A census study was undertaken due to the low numbers of patients referred for CTPA in the preceding years. These average for 2020 and 2021 was 93 patients.

3.6.2 Sampling Method

Consecutive sampling technique was applied to this study. Every patient suspected to have pulmonary embolism and referred for CTPA was recruited after obtaining informed consent. A clinical history with emphasis of risk factors was obtained and entered into a questionnaire. Pretest probability scoring using revised Geneva score was done and patients classified as low, intermediate and high probability for PE. The revised Geneva score was selected as it is widely used in Europe and has similar performance to Wells scoring in the risk stratification of patients with suspected PE (Shen JH et al 2016, Ma Y et al 2016). The Wells and Geneva scores have a similar yield for diagnosing acute pulmonary embolism (Robert -Ebad H et al 2017). The score would also be fully standardized without any variable requiring physician clinical assessment. In addition all patients with low or intermediate pretest probability can undergo a D dimer test which will rule out PE if negative. A requisition for D dimers was made. All patients subsequently had a CTPA performed. Data was then analyzed for the whole group of patients.

3.6.3 Study Schemer

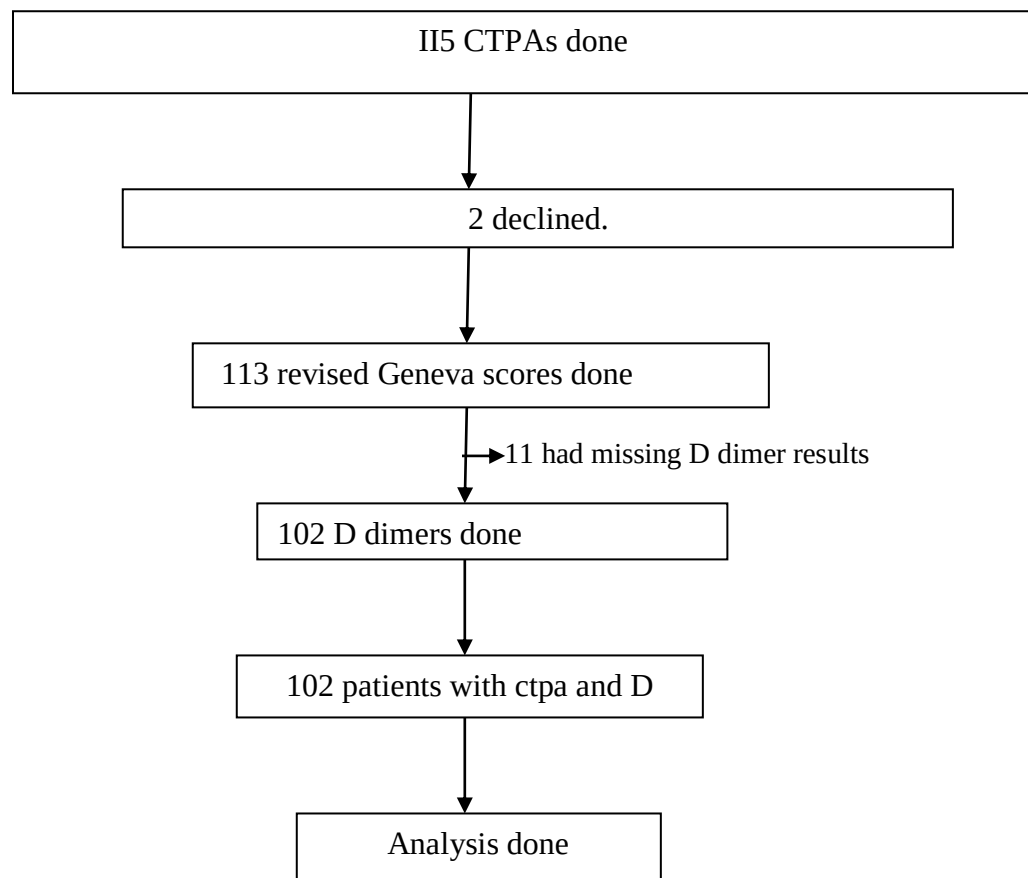


Figure 5: Study Schemer

The components of the revised Geneva score were collected at the point of consent and entered into the questionnaire. This information was then used to calculate the revised Geneva score for each patient. Informed consent was at the point of recruitment mainly in the CT room.

3. 7 Study Procedure

Patients who were referred to the radiology department for CTPA were recruited into the study after informed consent was obtained. Clinical history with special emphasis on symptoms such as cough, chest pain, dyspnea or difficulty in breathing and hemoptysis was obtained and entered into the questionnaire (**Appendix vi**) Patients

were also asked about the presence /history of eight risk factors for PE. These included history of or current DVT, history of surgery, trauma, immobility of more than 3 days, malignancy, oral contraceptive pills and blood clotting disorders. Their responses were then entered into the questionnaire (appendix VI)

Risk factors for PE were also explored. These included history of immobility, current malignancy, history of previous surgery, history of DVT and use of oral contraceptives.

Information on patient's demographics age and sex were obtained and entered into the questionnaire.

Patient's vital signs SPO2 heart rate was taken and entered into the questionnaire. They were usually taken at the point of first contact with the patient and before any intervention. The revised Geneva score clinical scoring system was applied and patients categorized into low, intermediate and high risk for PE (**Appendix VII**).

CTPA procedure.

Patient preparation.

Intravenous access was obtained from the referring unit or in the CT rooms within the radiology departments. This was required for intravenous contrast administration, fluids and for resuscitation. The CTPA requisition form was checked for completeness and for urea, electrolyte and creatinine results.

The patient was positioned on the CT machine in a supine position with their arms above their heads. The table was raised to a height of 160 cm and then moved into the gantry. Position was aided by laser lights. Next the dual injector pump was connected.

Next 60-100mls of contrast media (Iohexol 350mg/ml) at the rate of 1ml/kg body weight was injected followed by a saline chaser equivalent in volume to 50% of the contrast volume.

Image acquisition was triggered when opacification at the main pulmonary artery was at least 250 Hounsfield units (HU).

Images were acquired, processed, saved and uploaded to the picture archiving and communication (PACS) system for interpretation by the radiologists in the image reading room.

Post op observation.

Patients were advised to report any complaints to their attending clinicians. After the procedure the patients were taken back by the patient attendants or nurse to the referring departments.

CTPA SCANNING TECHNIQUE (Philips Netherlands)

For intravenous access, introduction of an 18- or 20-gauge catheter into an antecubital vein was done. The patient was positioned supine within the CT gantry with both arms extended and resting comfortably below the head.

The chest field of view is the widest rib to rib distance acquired during breath hold after suspended inspiration and from the lowest pleural recess to the apices of the lungs. Images of the thorax were acquired in a cranial caudal direction with a standard algorithm at 120 peak kilovoltage (kVp), tube current 350 (mAs) and slice thickness of 2 millimeters. A scanogram of the entire thorax was first obtained after which serial axial pre-contrast scans were acquired.

The syringe pump with contrast was then fixed to the intravenous cannula after which 60-100 ml (1ml/kg body weight) of iodine concentration water soluble contrast media (Iohexol 350) was infused at 5ml/second by use of a dual injector pump. This was followed by a saline chaser equivalent to 50% of the iodine dose administered. A bolus tracking technique was utilized (with region of interest at the main pulmonary artery) and scanning was triggered when opacification at the MPA was at least 250HU.

From each dataset multi-planar reconstructions were generated as 2.5 mm thick slices with 1mm spacing on the standard three orthogonal planes—axial, coronal and sagittal. Images were displayed and viewed on the workstation with a computer software in three different gray scales for interpretation of lung window (window width/level [HU] = 1500/600), mediastinal window (400/40) and pulmonary embolism-specific (700/100) which aids in differentiating between a sharp margined embolus and an ill-defined artifact. The lung algorithm is a high spatial frequency reconstruction used to improve the quality of images of the pulmonary vessels, bronchi, and interstitium.

CT PULMONARY ANGIOGRAPHY PROCEDURE (Siemens somatom perspective, Germany)

The entry point for the study was at the CT scan room MTRH. The scans were performed using a 32-slice Multidetector CT scanner). The scanning protocol included a bolus intravenous injection of 1mls/kg body weight iodinated contrast (Iohexol 350mg I/ml) at 5 mL/sec via an antecubital vein along with a saline wash out (half the volume of the contrast given). Using a bolus-tracking technique (region of interest over the main pulmonary artery with a threshold of 250 Hounsfield units [HU]), the scan was triggered at the point of maximal pulmonary arterial

enhancement (250 HU). A spiral CT scan of the thorax from the lung apices to the adrenal glands was acquired during this phase (kVp, 100–120; mAs 120; pitch, 0.9; rotation time, 0.5 seconds; collimation, 32 _ 0.6 mm).

Images were reconstructed at 2mm slice thicknesses: (a) for primary routine image interpretation, 5-mm axial slices were reformatted of the entire dataset; (b) in addition, for evaluation of the pulmonary arteries, contiguous thin (1.5 mm) slices of the thorax were systematically reformatted. Images were displayed with three different gray scales for interpretation of lung window (window width/levels [HU]1200/-600), Mediastinal window (350/50), and pulmonary embolism–specific windows (700/80 HU).

All images were archived electronically and evaluated by the principal investigator and two consultant radiologists independently.

D dimers.

D dimers were requested as part of the routine patient care and results obtained by the principal investigator from the hematology laboratory or from the patients' files.

3.8 Measurements

3.8.1 Main pulmonary artery and ascending aorta

Measurements of the main pulmonary artery and ascending aorta were performed on axial CT scans in mediastinal window. The measurements were taken at the level of the bifurcation of the main pulmonary artery into the right and left pulmonary arteries perpendicular to its long axis. At the same level, the diameter of the ascending aorta was also measured. The outer limit of the contrast column was considered to determine the vessel diameters. The normal MPA/AO ratio is less than 1.

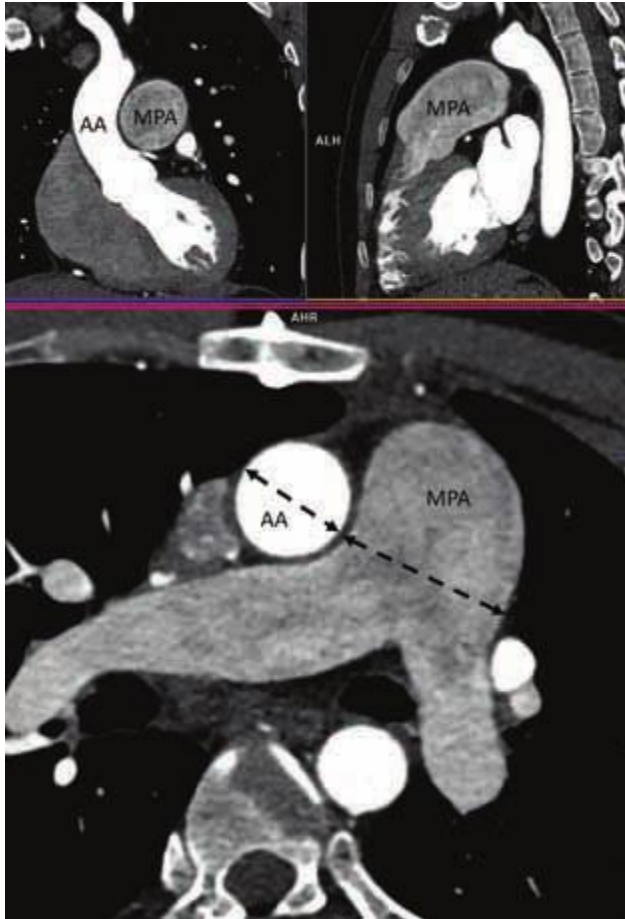


Figure 6: Technique of measurement of main pulmonary artery and the aorta.

Pulmonary arterial dilatation: imaging evaluation using MDCT the Indian journal of radiology and imaging 31(10/93).

3.8.2 Right ventricle//left ventricle ratios.

These were assessed in axial plane at the widest point between the inner surface of the free wall and the surface of the interventricular septum by measuring the minor axes of the right and left ventricles in the transverse plane. The ventricular diameters were determined by identifying the maximum distance perpendicular to the long axis of the heart between the ventricular endocardium and the interventricular septum. The normal left ventricular diameters are 39-53mm in females and 42-59mm in males. The right ventricular diameters are between 27-35 mm. (Kathiria N et al 2015).

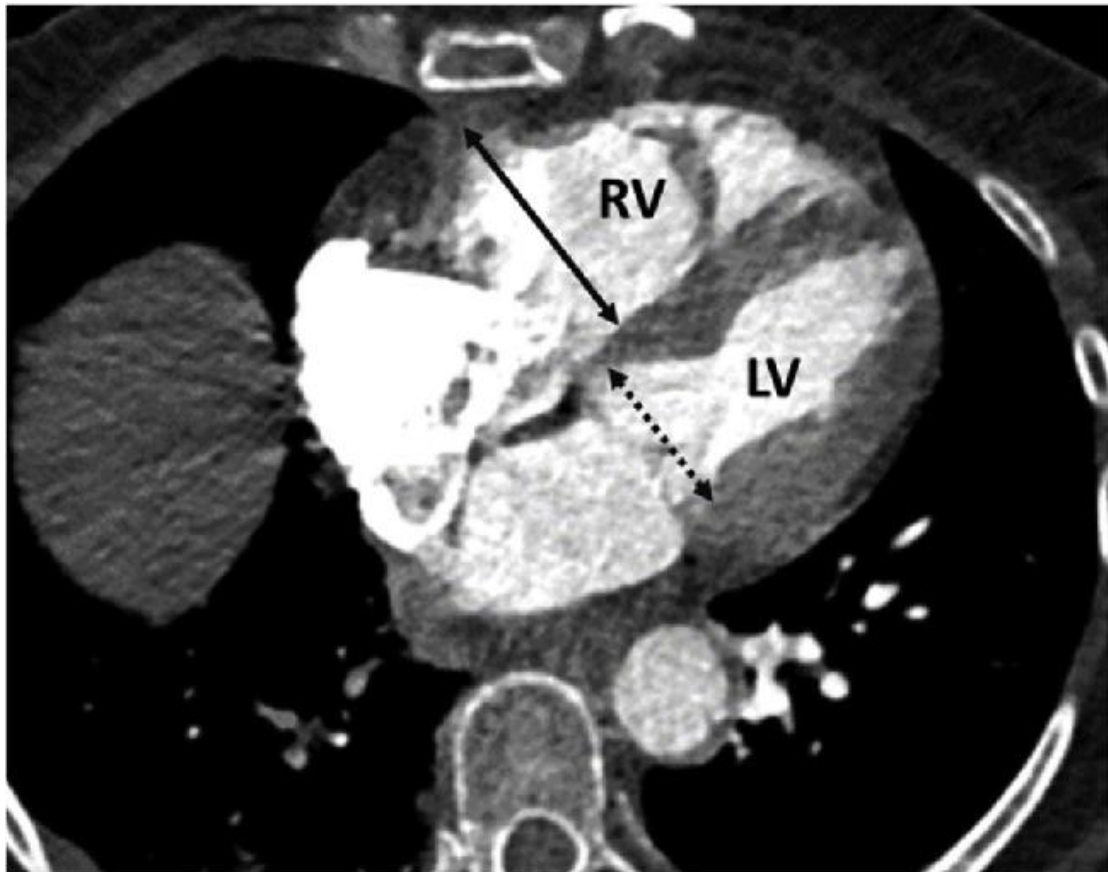


Figure 7: Measurement of right and left ventricular diameters on axial CTPA image. The ventricular diameters were determined by identifying the maximum distance perpendicular to the long axis.

European journal of radiology open 8(4):100340

CT PULMONARY ANGIOGRAPHY PROTOCOL

The patients are positioned supine and scanned in a craniocaudal direction from the level of the lung apices to the diaphragm. The scanning protocol includes a bolus intravenous injection of iodinated contrast media (Iohexol 350mgI/ml) at a dose of 1mls/kg body weight at a rate of 5 mL/sec via an antecubital vein (preferably gauge 18) followed by a saline wash equivalent to half the volume of contrast administered. A bolus-tracking technique is utilized with the region of interest placed over the main pulmonary artery with a threshold of 250 Hounsfield units (HU). The scan is

triggered at the point of maximal pulmonary arterial enhancement (250 HU). A spiral CT scan of the thorax from the lung apices to the adrenal glands is acquired during this phase (kVp, 100– 120; mAs 120; pitch, 0.9; rotation time, 0.5 seconds; collimation, 32 _ 0.6 mm). Patients are instructed to hold their breath and images acquired.

Images are reconstructed at 2mm slice thicknesses: (a) for primary routine image interpretation, 5-mm axial slices are reformatted of the entire dataset; (b) in addition, for evaluation of the pulmonary arteries, contiguous thin (1.5 mm) slices of the thorax are systematically reformatted. Images are then displayed with three different gray scales for interpretation of lung window (window width/levels [HU] 1200/-600), Mediastinal window (350/50), and pulmonary embolism-specific windows (700/80 HU).

All images are then archived electronically and evaluated by the principal investigator and two consultant radiologists. In the case of discrepancy, consensus was reached through discussion with a third radiologist (chief radiologist). The diagnosis of PE was confirmed by the presence of at least one filling defect in the pulmonary tree.

CTPA Diagnostic criteria for acute pulmonary embolism (Conrad Wittram et al 2004) either one of the following

1. Intraluminal filling defect with non-enhancement of the vessel
2. Incomplete filling defect surrounded by contrast material, resulting in the “polo mint” or “railway track”
3. A marginal embolus which forms an acute angle with the vessel wall.



Figure 8: Acute pulmonary embolism in 27-year-old woman. CT pulmonary angiogram shows thrombus (arrow) that expands diameter of right posterior basal subsegmental artery compared with pulmonary arteries of same order of branching (arrowheads). Conrad wittrram.AJR: 188, May 2007.

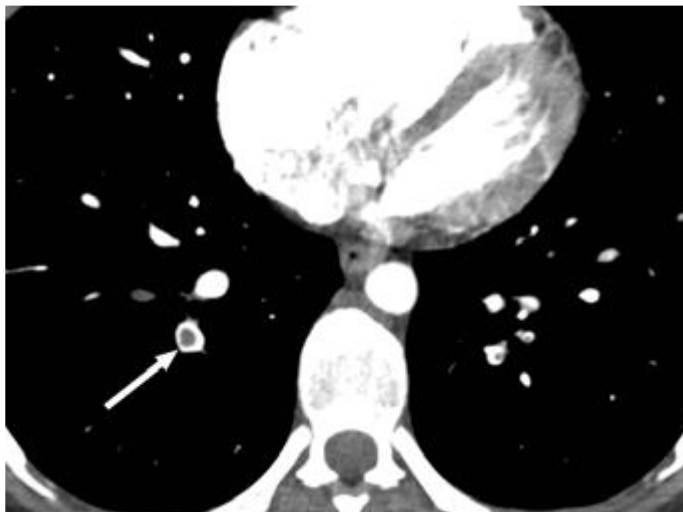


Figure 9: Acute pulmonary embolism in 27-year-old woman. A centrally located thrombus, in right posterior basal segmental artery, has well-defined margins and is completely surrounded by contrast material (arrow). Acute emboli are also noted in right lateral basal segmental and left posterior basal subsegmental arteries.

Conrad wittrram.AJR: 188, May 2007.

Diagnostic criteria for chronic pulmonary embolism (Conrad Wittram et al 2004):
one of the following

a. Obstruction of a vessel by a thrombus that appears small in size compared to nearby vessels.

- b. A marginal embolus which forms an obtuse angle with the vessel wall
- c. Thickened and small sized vessels allowing contrast to pass through it due to recanalization.
- d. A web within a contrast material–filled artery

Supportive signs include calcifications, collateral vessel formation especially bronchial arteries and mosaic lung parenchymal pattern.

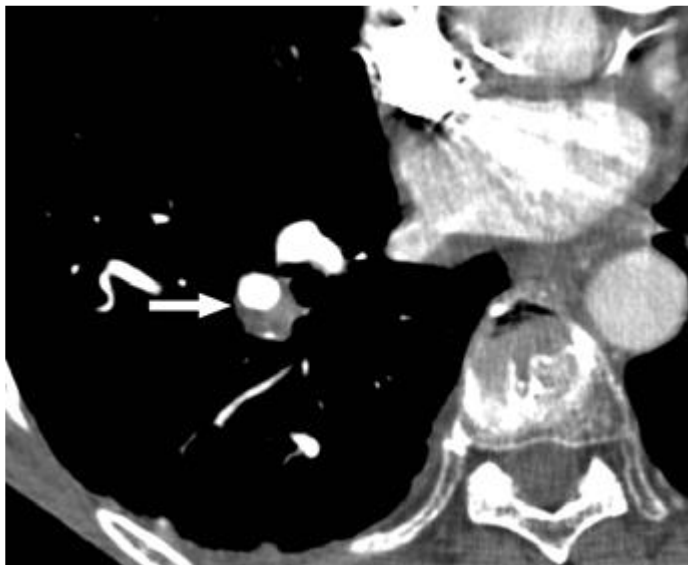


Figure 10: Chronic pulmonary embolism in 60-year-old man. Axial CT image obtained at level of right lower lobe pulmonary artery shows broad-based, smoothly margined, eccentric filling defect (arrow) that forms obtuse angle with vessel wall.

NOTE. Thrombi refers to the formation of a blood clot in the circulatory system commonly in a vein and may impede blood flow. Most often it occurs in veins especially of the lower limbs or pelvis. When this clot is dislodged and is propagated through the vessels most often through the heart to the lungs then it's referred to as an embolus.

3.9 Data Management Data Management, analysis and presentation.

The data was collected using questionnaires that had no patient names. Instead a study code number was used. The questionnaires were kept in a study file and placed under lock and key to ensure that the study information provided was kept confidential. To ensure that the quality of data was maintained ,the principal investigator checked the completeness of questionnaire daily before entering the data into a Microsoft access database.

Data was then imported into SPSS version 16.Subsequently coding, cleaning and analysis was done.

Descriptive statistics such as mean, standard deviation median and interquartile range were used to summarize continuous data for example age. Frequencies and percentages were used to summarize categorical data such as sex.

Sensitivity ,specificity, positive and negative predictive values were calculated for D dimers and revised Geneva scores as compared to CTPA findings.

Sensitivity ,specificity, positive and negative predictive values for D dimers as compared to CTPA findings. Were calculated using a two-by-two table.as depicted below.

	pulmonary embolism	no pulmonary embolism
D dimers >500ug/ml	True positive	False positive
D dimers <500ug/ml	False negative	True negative
Total		

sensitivity was calculated as true positive/ (true positive +false positive). specificity as true negative/ (true negative + false positive). positive predictive value was

calculated as true positive/ (true positive +false positive) and the negative predictive value as true negative/ (false negative + true negative).

The sensitivity, specificity, positive predictive value and negative predictive value of revised Geneva score against CTPA results were e calculated likewise in a similar manner using the two-by-two table below.

	Pulmonary embolism	No pulmonary embolism
PE likely	True positive	False positive
PE unlikely	False negative	True negative.
Total		

The data is presented in tables ,graphs and prose forms.

3.10 Ethical consideration.

Ethical approval was sought and obtained from Moi university/MTRH institutional and ethics research committee (IREC) ref no.**0004240** and NACOSTI (National commission for science, technology and innovation) ref no.**579277**

Permission was sought from the CEO of MTRH for permission to carry out the study in the facility.

Informed, written consent was sought directly from the patients enrolled into the study.

Consent. Written informed consent was obtained from all patients enrolled in the study. Participation in the study was voluntary and participants were informed that they could withdraw from the study at any time. Patients information was kept confidential by using codes instead of patients names.

Confidentiality. The information obtained from the study participants and that obtained from their records was kept confidential. The data was entered into

questionnaires which were kept in a study file and stored in study cabinet under lock and key. Data was entered into a password protected computers and codes were used in place of patients names.

Benefits. There were no monetary benefits to participants in the study. However the information gathered on use of D dimers and clinical probability scores will be useful in categorizing and managing patients with suspected PE.

Risks .there were no risks associated with participating in the study. Data was closely guarded to ensure no leaks of patients data.

3.11 Data Dissemination Plan

The findings of the research will be presented to the department of Radiology and Imaging Moi University and MTRH Radiology department. A manuscript will be prepared for publishing in a reputable regional medical journal. The results will also be presented in local radiology meetings, conferences and seminars including the annual Kenya association of radiologist's conference. It will also be made available to the Moi University Library. The results of this research shall be availed for publication in a reputable journal of medicine for use in improving diagnosis and management of pulmonary embolism.

CHAPTER FOUR

4.0 RESULTS

4.1 Sociodemographic characteristics

Table 8: Sociodemographic characteristics

Variable	N	Frequency (n)	Percent (%)
	102		
Gender			
Male		40	39.2
Female		62	60.8
Age in Years			
Mean 53.2			
SD 19.4			
Median Age 54			
Interquartile range 28			
Below 36		20	19.61
36-45		22	21.57
46-55		15	14.71
56-65		17	16.67
> 65		28	27.45
Total		102	100.0

During the study period a total of 102 patients who presented to the radiology department for CTPA and who consented were enrolled. The youngest participant was 18 years old while the oldest was 97 years old. The mean age was 53.2 (S. D+ - 19.4) years with a median age of 54 years (IQR=28). A total of 62 participants were female comprising 60.8% while male patients were 40 comprising 39.2%. The male to female ratio was 1:1.55. A total of 30 patients had positive PE findings on CTPA giving a diagnostic yield of 29.4%. This information is summarized in table 8 above.

Table 9: Distribution by age.

VARIABLE	PE POSITIVE	PE NEGATIVE	TOTAL	P VALUE
Age (mean+S.D)	52.7(19.0)	53.5(19.7)		0.865
<36 years	5(25.0%)	15(75.0%)	20(19.61%)	
36-45years	7(31.82%)	15(68.18%)	22(21.57%)	
46-55years	5(33.33%)	10(66.67%)	15(14.71%)	
56-65years	4(23.53%)	13(76.47%)	17(16.67%)	
>65 years	9(32.14%)	19(67.86%)	28(27.45%)	
Total	30(29.41%)	72(70.59%)	102(100%)	

The average age of those patients diagnosed with PE was 52.7 +- 19.0 years while those who had negative PE results was 53.5+-19.7 years. However, there was no statistically significant difference in age among the two groups (p value 0.865). As demonstrated in the table above, the age category of 65 years and above had the most patients suspected of PE (28/102) and subsequently confirmed positive on CTPA (9/30)

Gender.

More female patients presented for CTPA with symptoms suggestive of pulmonary embolism as indicated in the table below.

Table 10: Distribution by gender.

VARIABLE	PE POSITIVE	PE NEGATIVE	TOTAL	PVALUE
Gender				0.5824
Male	13(32.5%)	27(67.5%)	40(39.2%)	
Female	17(27.42%)	45(72.58%)	62(60.8%)	
Total	30(29.41%)	72(70.59%)	102(100%)	

among the 30 PE positive patients 17 were female accounting for 56.67% of the participants while males accounted for 43.33%. However, the difference in gender was not statistically significant with a p value of 0.5824.

Clinical history

An inquiry was made into the presence of four main symptoms which when present could be suggestive of PE. These were cough, chest pain, hemoptysis and dyspnea. All the patients enrolled presented with cough while 101(99%) presented with chest pain. Just under half (49.0%) of the patients presented with a history of hemoptysis. In addition, a large number of 82 patients (80.4%) reported difficulty in breathing(dyspnea) as one of their complaints.

Variable	Frequency	percentage
Cough	102	100
Chest pain	101	99
Dyspnea	82	80.4
Hemoptysis	50	49

Apart from the four main symptoms listed above, some of the patients presented with additional symptoms which are depicted in the table below. 42 patients had additional symptoms. seventeen patients presented with leg swelling and twelve had history of fever. Smaller numbers of patients presented with weight loss, dysphagia, breast mass and bone pains which could point towards malignancies which is one of the risk factors for PE.

Table 11: Additional clinical history

Leg swelling	17
Fever	12
Weight loss	3
Dysphagia	1
Breast mass	1
Easy fatiguability	3
Bone pain	3
Wheeze	1
Hemiparesis	1

Risk factors.

Table 12: Risk factors

Variable	Frequency	P value
History of blood clot in the lower limbs	15	0.001
History of surgery	11	0.373
History of trauma	8	0.448
Immobility more than 3 days	12	0.005
History of cancer	10	0.236
History of contraceptive use	19	0.619

History of DVT was assessed as part of the history and clinical presentation of patients suspected of. A total of 15(14.67%) patients gave a history of DVT. Out of

this number 8(53.3%) were diagnosed with PE on imaging. DVT history was clinically significant with a p value of 0.002. History of trauma or surgery were also assessed but found to be statistically insignificant. Among the female patients 19 gave a history of oral contraceptive use. On analysis however it was found to be statistically insignificant. 10 and 12 patients reported history of malignancy within the last 6 months and immobility respectively. On analysis they were found to be statistically insignificant.

objective 1: To determine the clinical probability scores using the revised Geneva clinical probability score of patients referred for CTPA at MTRH.

The clinical presentation of the patents confirmed to have PE had the following distribution.

Table 13: Frequency of presentation of the revised Geneva score criteria in patients with pulmonary embolism.

Clinical presentation	Frequency
Previous PE or DVT	8
surgery or fracture in last one month	4
Heart rate >94 beats/min	17
Hemoptysis	16
Age >64years.	13

Current malignancy or treatment within last 6 months. 3

On the assessment of the different characteristics that are used in the clinical history from the table above it is clear that the most common presentation of the patients who were suspected to have PE was tachycardia (HR>94) in 17/30(56.7%). On the other hand, only 10.0% (3/30) had a history of DVT or PE.

Clinical features	PE +VE	PE-VE	ODDS	P Value
Previous DVT	8	7	3.58(1.17-10.940)	0.004
OR PE				
HEART RATE >95	17	17	5.93(6.42-15.18)	0.006
Surgery or fracture in 1 month	4	7	1.43(0.39-5.31)	0.727
Hemoptysis	16	36	1.14(0.49-2.66)	0.829
Cancer	3	7	1.03(0.25-4.14)	0.9
Age>65 yrs	13	19	2.13(0.88-5.21)	0.106

Patients diagnosed with pulmonary embolism were likely to present with the following components of the revised Geneva scores heart rate >94 beats/min, age >65 years and history of DVT/PE all of which had an odds ratio of 5.93,3.58 and 2.13 respectively. History of DVT/PE also demonstrated a significant p value of less than 0.05.

Revised Geneva score (N=102)

Score	Frequency	Percentage
2	2	2.0
3	5	4.9
4	12	11.8
5	18	17.6
6	10	9.8
7	10	9.8
8	8	7.8
9	11	10.8
10	15	14.7
11	4	3.9
12	3	2.9
13	1	1.0
14	2	2.0
15	1	1.0

As depicted in the table above the patients had revised Geneva scores ranging from 2 to 15. the largest number of patients (18/102) had a score of 5 while only 1 patient each had scores of 13 and 15 respectively. The mean score of all the patients was 7 with an interquartile range of 5-10 as depicted in the table below.

	Mean	Range
Revised Geneva score	7(IQR 5-10)	2-15

Revised Geneva score classification.

Variable	Frequency	Percentage
Low risk	7	6.9%
Moderate risk	84	82.4%
High risk	11	10.8%

The participants were stratified into three categories of low risk, intermediate risk and high risk with 7,84 and 11 patients respectively. None of the low-risk patients had PE on CTPA, while 25% (21/84) and 81% (9/11) in the moderate and high-risk groups respectively had PE.

Revised score	Geneva	PE positive	PE negative	P value
Revised score	Geneva	PE positive	PE negative	P value
				0.004
Low risk		0	7	
Intermediate		21	63	
High risk		9	2	
Total		30	72	

Stratification of patients using the revised Geneva score into low, intermediate and high-risk groups as depicted above was found to be statistically significant with a p value of 0.004.

Revised Geneva score	PE present	PE absent
PE likely	25	40
PE unlikely	5	32
Total	30	72

The revised Geneva score was used to calculate the sensitivity and specificity of clinical stratification. When tested against CTPA findings, the revised Geneva score had a sensitivity of 83.3%, specificity of 44.4%, PPV of 38.5% and negative predictive value of 86.5%.

Objective 2: To determine the overall diagnostic yield of CTPA in diagnosing of PE in patients suspected of PE at MTRH.

Table 14: CTPA outcomes.

	Variable	Frequency	Percentage
Conclusion	Normal	3	2.9
	Pulmonary embolism	12	11.7
	PE+additional diagnosis	18	17.6
	Alternative diagnosis	69	68.1
	Total	102	100

A large number of the participants 69(68.1%) had no PE but had other alternative findings as depicted in the table above. A small number of 3 patients had normal CTPA findings. In total 30 patients had PE, out of whom 12 had only PE with no additional findings while 18 had PE and other additional findings on CTPA.

Additional diagnoses and alternative diagnoses.

69 patients were not diagnosed with pulmonary embolism but had other additional findings which could explain their symptoms. In addition, 18 patients among the 30 diagnosed with pulmonary embolism had other additional findings. These are depicted in the tables below

Radiological findings in the negative CTPAS and additional findings present in the positive CTPAS done as represented in the following table.

Table 15: Radiological findings in the negative CTPAS and additional findings present in the positive CTPAS

Variable	Frequency	Percentage
Pneumonia	11	48
Interstitial lung disease	1	4
Pulmonary hypertension	3	13
Pulmonary tuberculosis	1	4
Right heart failure	4	17
Lung mass	1	4
Aspergillosis	1	4
Metastases	1	4

Table 16: Alternate diagnoses

Variable	Frequency	Percentage
Heart failure	12	20
Emphysema	1	2
Interstitial lung disease	5	8
Pneumoniae	17	28
Pulmonary tuberculosis	7	11
Lung mass	3	5
Pericardial effusion	3	5
Pulmonary oedema	3	5
Thrombi	3	5
Others bronchiectasis, COPD, PCP, PHT etc.	15	11

COPD chronic obstructive pulmonary disease PCP pneumocystis pneumonia, PHT pulmonary hypertension.

For the patients who had negative CTPAs for PE (72) alternative diagnoses to explain their symptoms included pneumonia, heart failure, pulmonary tuberculosis, pulmonary hypertension, interstitial lung disease, lung masses and metastases, pericardial effusion among others. A small number (3) also had normal CTPA with no other findings,

Table 17: Anatomical location of PE.

Variable	Category	Frequency	Percentage
Right lung	Right pulmonary artery	11	36
	Right lobar artery	17	56
	Right segmental/subsegmental arteries	23	77
Left lung	Left pulmonary artery	9	30
	Left lobar artery	11	36
	Left segmental/subsegmental arteries	24	80
	Main pulmonary artery	2	7

As depicted in the table above, many of the thrombi were located in the left and right segmental/subsegmental arteries at 80% and 77% respectively. A smaller number of thrombi were in the right and left lobar arteries, accounting for 56% and 36% respectively. The least number was in the main pulmonary artery at only 7%. Of note is that some patients presented with thrombi in more than one location, hence the numbers and percentages sum up to more than 100%.

Table 18: MPA/ascending aorta diameters and right ventricle/left ventricle diameters ratio.

		CT FINDINGS			P value
Variables	Category	No embolism	embolism	Total	
MPA/AO diameter	<1	33	7	40	0.0098
	>1	39	23	62	
Total		72	30	102	
Right ventricle diameter/Left ventricle diameter	<1	57	13	70	0.002
	>1	15	17	32	
Total		72	30	102	

Ratio of MPA diameter to ascending aorta diameter.

A ratio of MPA/AO >1 is a marker of pulmonary hypertension whereby the MPA is dilated due to PE.

In this study the ratio of MPA diameter to ascending aorta diameter was found to be statistically significant with a p value of 0.0098. there was also a wide variation in the MPA/AO diameter ratio among patients found to have PE with the majority having a ratio equal to or greater than 1. this ratio is important as it's an indicator of pulmonary hypertension attributable to PE. However, the variation in the ratio among the PE Negative patients was narrow with most patients found to have ratio less than 1. Main pulmonary artery to ascending aorta diameter ratio greater than 1 was found in 61% of all patients and 77% of those who turned out positive for PE. This ratio is important as it's a marker of pulmonary hypertension. 39% of patients had MPA/AO ratio of less than 1.

ratio of RV/LV diameter.

A ratio of the right ventricle to the left ventricle diameter >1 was significantly associated with PE on MDCTPA (P value 0.02) as depicted in table 16 above. This ratio is important as it is an indicator of right ventricular strain due to Pulmonary hypertension attributable to PE. There was wide variation in the RV/LV ratio among patient found to have PE with the majority having a ratio greater than 1 and a median of 1.2. however, the variation in the RV/LV ratio in the negative patients was narrow with the majority of patients found to have a ratio less than 1. In total 23/30 of PE positive patients had RV/LV ratio of greater than 1. This finding was significant with a p value of 0.02.

Table 19: CTPA outcomes

	PE positive	PE negative	Total
Number	30	72	102
Percentage	29.4	70.6	100

As depicted in the table above 30 patients from a total sample of 102 were diagnosed with pulmonary embolism on CTPA. This gives a diagnostic yield of 29.4%.

Objective 3: To determine if there is overuse of CTPA in diagnosis of PE at MTRH

Table 20: D dimers.

Variable	Frequency	Percentage
>500u/l	50	49.0
<500u/l	52	51.0
Total	102	100

Out of the 102 patients ,50 had conventional D dimer levels above 500ug/l. This accounted for 49.0% of all the participants. On analysis this was found to be significant with a p value of less than 0.05.

	PE positive	PE negative	Total
D dimers >500ug/l	26	24	50
D dimers <500ug/l	4	48	52
Total	30	72	102

The sensitivity of D dimers to diagnose PE was found to be 86.7%, while the specificity, positive predictive value and negative predictive value were 66.7%, 52% and 92.3% respectively. The accuracy was 72.5%. The sensitivity, specificity, positive predictive value, negative predictive value and accuracy of D dimers to diagnose pulmonary embolism were calculated using a 2x2 table as indicated above. There were 26 true positives,24 false positives,4 false negative and 48 true negatives. The sensitivity of D dimers to diagnose PE was found to be 86.7%, (26/26+4), specificity

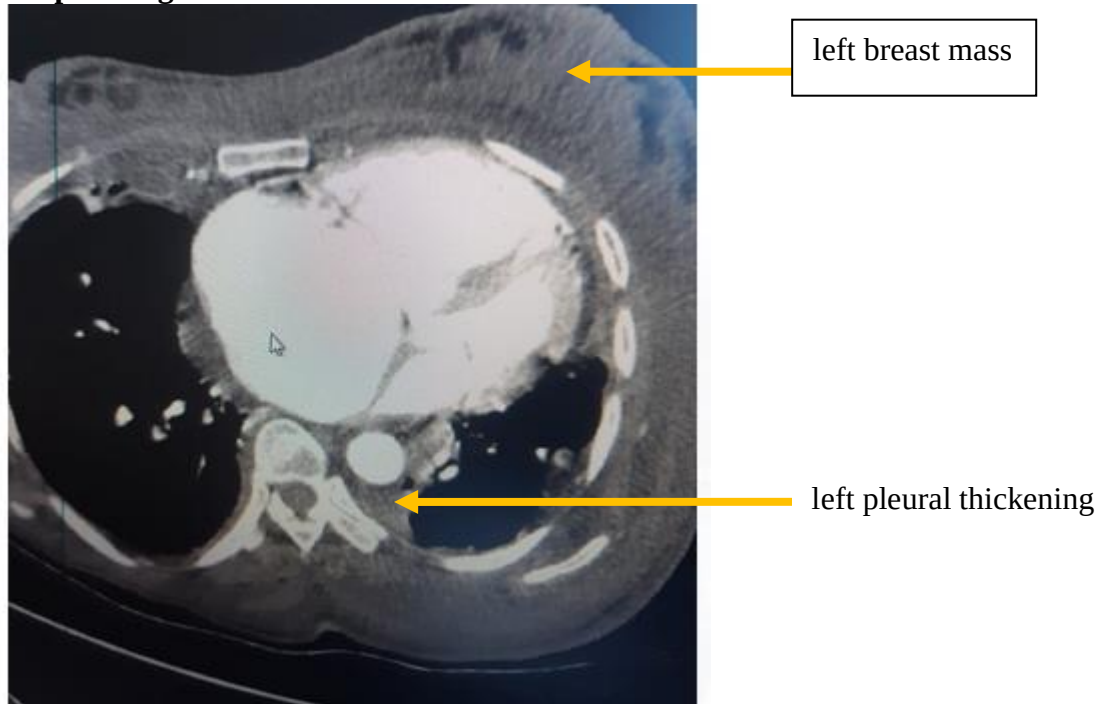
66.7% (48/48+24), positive predictive value of 52% (26/26+24) and negative predictive value of 92.3% (48/48+4)

The accuracy was 72.5%. (26+48/48+24+4+26)

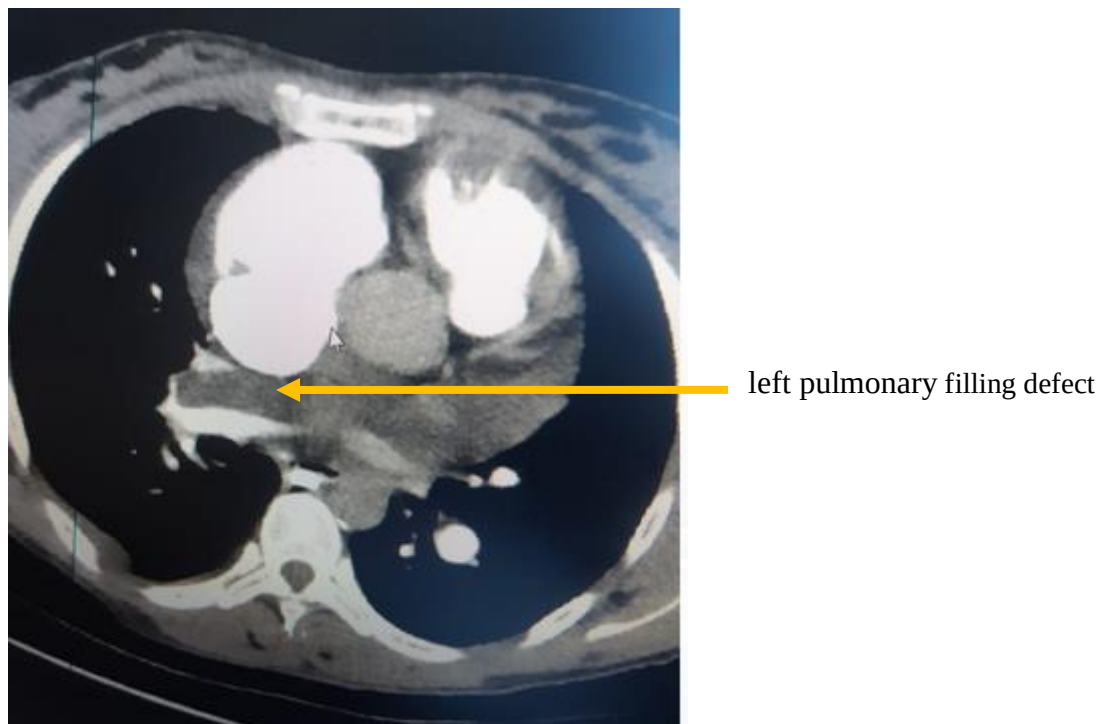
Table 21: Overutilization of CTPA

	Total
	N=102
Pulmonary embolism	
Absent	72 (70.6%)
Present	30 (29.4%)
D dimers	
<500	52 (49.0%)
>500	50 (51.0%)
Revised Geneva score classification	
Low risk	7 (6.9%)
Moderate risk	84 (82.4%)
High risk	11 (10.8%)
PE if D dimers <500 & Geneva score is low score (n=7)	
Absent	7 (100%)
Present	0

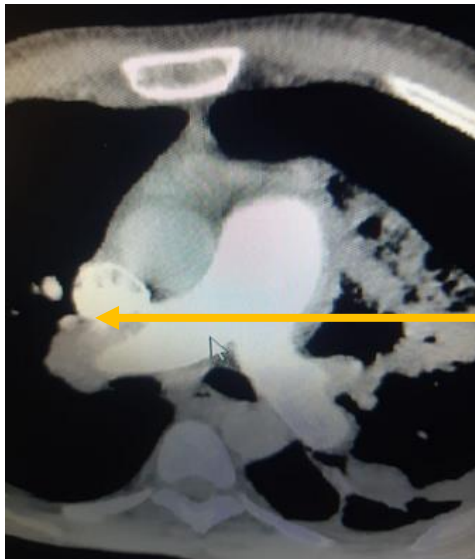
The overuse of CTPA in diagnosis of PE at MTRH is 7/102 that is, 6.9%.

Sample Images

Sample images 1: Chest CT scan of a 60-year-old patient with left breast mass, left pleural effusion and thickening. CTPA was negative for PE.

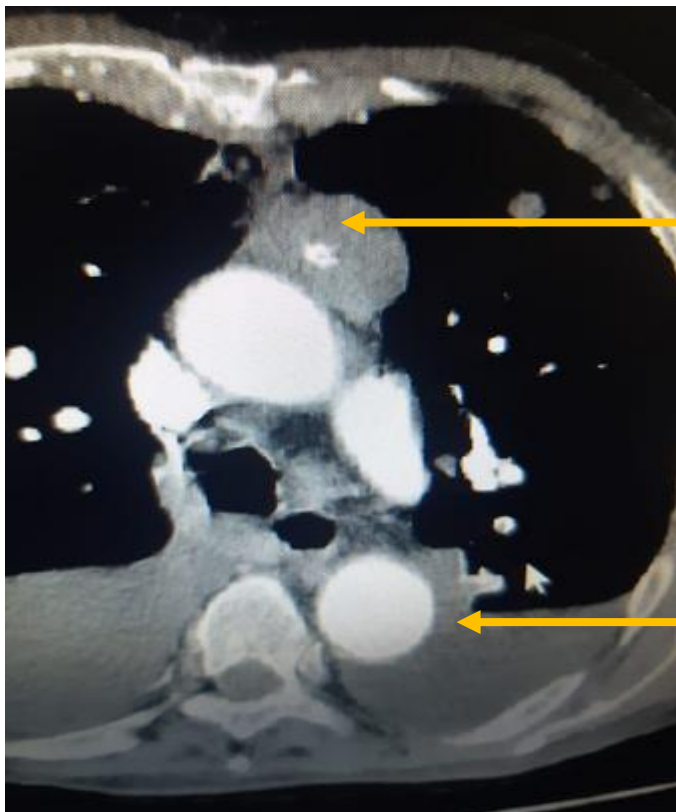


Sample Image 2: CTPA of a 46-year-old male Patient demonstrating filling defects involving the pulmonary trunk at its point of bifurcation and extending to both main pulmonary arteries.



right main pulmonary artery filling defect

Sample image 3: CTPA of a 39-year-old patient demonstrating a filling defect of the right main pulmonary artery consistent with a pulmonary embolism.



anterior mediastinal mass

Pleural effusion.

Sample image 4: CTPA image of 65 year of patient with anterior mediastinal mass and bilateral pleural effusion.

CHAPTER FIVE

5.0 DISCUSSION

5.1 Introductions

The introduction of standardized guidelines and diagnostic protocols which utilizes clinical probability scores, D Dimers and radiological investigations to determine the clinical probability of PE has improved the diagnostic workup of patients with suspected PE. A clinical decision rule result of PE unlikely in combination with normal D dimer result can exclude PE in a sizeable population of patients who present for evaluation (approximately 20-40%) (Van belle et al (2006.) This reduces the need for additional imaging in these patients and ultimately anticoagulant drugs can be safely withheld.

A total of 102 patients with clinically suspected pulmonary embolism were recruited into the study after giving informed consent. There were more female participants (62) in the study with men accounting for 40 participants indicating a male to female ratio of 1:1.55. Although there is no clear sex difference in overall age adjusted incidence of PE, men and women have different patterns of PE incidence. Among patients between 20-40 years of age, women develop PE at a rate that is twice that of men (Spencer FA 2009) while between 60-80 years, the incidence of PE is higher for men (Engbers MJ 2010). However current available data on sex-related disparities in pulmonary embolism (PE) are limited and controversial. For example, the nation-wide inpatient sample of the United States of America (with > 276,000 patient discharge files) showed a higher incidence of PE in females compared to males. Although a review by Jarman et al. reports a similar overall age-adjusted incidence of PE between the sexes, most observational studies and reviews in the literature have found men to have a higher overall age-adjusted incidence of PE compared to females.

The mean age of the study participants was 52.6 years with a range of 18 to 97 years. This finding is significant as the prevalence of PE increases with advancing age (Andersen FH et al 1991, White RH et al 2003, Stein PD 2006). PE incidence, prevalence, morbidity and outcome generally increase with age with older patients being at higher risk although PE can occur at any age. Also, older individuals often have multiple underlying medical conditions (comorbidities) that can further increase the risk of developing PE. These risk factors include smoking, obesity, trauma, surgery, prolonged travel, oral contraceptives, pregnancy, post-partum period and hormone replacement therapy. Further the burden of malignancy increases with age and its treatment is known to be thrombogenic.

The findings of this study were comparable to a thesis study done by Wainaina N et al (2013). Patterns of findings on MDCT pulmonary angiography in patients with PE in Nairobi which reported a mean age of 52.6 years and a male to female ratio of 1:2. Another study by Amunga et al in Nairobi (2021) reported a male to female ratio of 1:1.4, very close to our findings but with a slightly lower mean age of 46.2 years. The lower mean age could be because the study excluded a sizeable number of patients 40 (26.6%) who didn't consent or had other conditions which excluded them from the study. The study also included patients of all age groups with suspected PE potentially resulting to a younger population recruited. This however contrasts with a retrospective study by Almarshad F et al (2023) in Saudi Arabia involving 422 patients which reported a mean age of 59.6 years and a male to female ratio of 1:2.4. The higher mean age could be due to the bigger sample size and higher life expectancy.

The mean age for patients with PE was 52.9 year while those negative for PE had a mean age of 52.2 years. These findings agree with a study by Tambe J et al (2017) in

Cameroon which reported no significant mean age differences between the PE and non-PE patients (47.6 years and 48.9 years). However, this contrasts with a thesis study done by Ibrahim A et al (2019) in Kenya which reported a mean age of 51.48 for PE positive patients and a mean age of 43.43 among those who turned out negative for PE. In a study in Poland by Skrabaka M et al (2019), the PE negative patients had a mean age of 62 years, and the PE positive patients had a mean age of 66 years while in Spain Pilar s et al 2014 reported a mean age of males with PE at 70.1 years while those without had a mean of 65.9 years. The females patients with PE in this study had a mean age of 71.5 and PE negative had a mean of 67 years. Age is not a critical factor in deciding whether a patient is likely to have PE or not. This is because PE affects people of all age groups only that its prevalence increases with age.

The rate of PE was commoner in females in our population. This could be due to several factors including health seeking behaviors as more women were recruited overall. There are also women only risk factors like oral contraceptive use, pregnancy and post-partum states which induce a coagulable state. It may also be related to physiological changes such as reduced mobility and higher rates of obesity.

Objective 1: To determine the clinical probability scores using the revised Geneva clinical probability score of patients referred for CTPA at MTRH.

In our study patients were stratified into two and three tier categories using the revised Geneva score probability score. The revised Geneva score was chosen because it uses only objective criteria as opposed to the wells score. Out of the 102 patients ,7 were low risk,84 moderate risk and 11 high risks for PE. when the two-tier category was utilized 37 were categorized as PE unlikely (36%) and 65 (64%) PE likely. The PE prevalence among the low, intermediate and high probability groups

was 0%, 25% and 81.8% respectively. The low PE prevalence among the low probability group and high PE yield in the high probability group may point to adequate stratification of patients for CTPA. Most patients in our study 84/102(83%) fell into the moderate risk category. This agrees with a study done by Abolfotouh MA et al (2020) in Saudi Arabia where 1254/2010 (62%) were categorized as moderate risk for PE

Similar studies in world have yielded contrasting results. For example, a study by Bulajic B et al (2019) in South Africa reported 79% (100/127) of the participants as PE unlikely and 21% as PE likely. This contrasts with our study where 36% and 64% of study participants were categorized as PE unlikely and PE likely respectively. This could be due to the retrospective nature of the South African study and the fact that the revised Geneva scores were calculated retrospectively and compared poorly to the CTPA results. Similarly, a study by Douma et al (2011) classified 69% of the patients as PE unlikely. The difference could be due to the different population characteristics, multicentre nature of the study and exclusion of patients who could be lost to follow-up and those with life expectancy of less than 3 months.

Several studies however yielded similar results to ours. These include Gogulakrishna et al (2023) in India where 36/65(55%) were categorized as PE likely and 29/65(45%) as PE unlikely and Bylinka et al (2022) in Poland who reported an almost equal split of PE likely 345(49%) and PE unlikely 355(51%) patients.

Most patients in our study 84/102(83%) fell into the moderate risk category. This agrees with a study done by Abolfotouh MA et al (2020) in Saudi Arabia where 1254/2010 (62%) were categorized as moderate risk for PE. This however contrasts with a study done by Raji H et al (2018) in Iran where 58% of patients were

categorized as low risk and 32% moderate risk. This could be due to the small number of patients enrolled.

The PE prevalence among the low, intermediate and high probability groups was 0%,25% and 81.8% respectively. This agrees with results of a study by Abolfotouh M et al (2020) in Saudi Arabia where the PE prevalence was 0%,25.8% and 88.9% respectively. Similarly, a study by Raji H et al (2018) yielded rates of 18%,44% and 82% among the low, intermediate and high-risk groups respectively.

The revised Geneva scores performance was calculated as a clinical prediction rule. When tested against CTPA findings, the revised Geneva score had a sensitivity of 83.3. %, specificity of 44.4. %, PPV of 38.5. % and negative predictive value of 86.7%. This is in agreement with literature where the revised Geneva score is reported to have a high sensitivity and negative predictive value and a low specificity and positive predictive value. Due to its low specificity and positive predictive value, it is useful to rule out PE and should be combined with D dimers and imaging for diagnostic workup of patients with suspected PE.

Our results are in agreement with a study by Gogulakrishnam R et al (2023) in India which reported the sensitivity, specificity, PPV and NPV of the revised Geneva score as 70%,52%,44% and 76% respectively. However, this contrasts to a South African study (Bulajic et al 2019) in which the clinical probability score had a sensitivity of 29%, specificity of 83%, positive predictive value of 44% and negative predictive value of 71%. This could be explained by the fact that the revised Geneva scores were calculated retrospectively.

The Revised Geneva score utilizes eight components, these include age of 65years, previous DVT or PE, surgery or lower limb fracture in last 1-month, active

malignancy, hemoptysis, pain on lower limb palpation/unilateral lower limb oedema and heart rate. This has been summarized in table 4 on page 17.

The actual revised Geneva scores ranged from 2-15 with a mean of 7. this is depicted on the table revised Geneva scores page 67.

When these patients were stratified 7,84 and 11 patients fell into the low, intermediate and high-risk groups respectively.

The referring clinicians were sensitized on the study, and they indicated the presence of the components of the revised Geneva score which were then used to calculate the scores.

A total of 50/102 patients (49%) in our study had positive D dimers. This contrasts to a study done by Hadid et al (2023) in the United Arab Emirates where a majority 250/276 (90%) of patients tested for D dimers were positive. This could be explained by the fact that 210 patients out of the total enrolled population of 486 were excluded from D dimer testing due to low risk. An additional study by Kennedy N et al (2015) in New Zealand yielded positive D dimers in 56/63 patients in whom D dimers were requested. However, the total enrolled population was 105, hence 42 patients had no D dimer results.

The sensitivity, specificity, positive predictive value and negative predictive values of D dimers in our study were 86.7%,66.7%,52% and 92.3% respectively. These metrics indicate that although D-dimer is highly sensitive for detecting PE, its low specificity implies that it is less adept at differentiating PE from other conditions that also raise D-dimer levels. The PPV indicates that 52% of patients with elevated D-dimer levels had PE, whereas the NPV shows that 92.3 % of patients with low D-dimer levels were correctly identified as not having PE.

D dimers and have a high sensitivity and low specificity and are utilized to rule out PE. Clinical decision rules like revised Geneva scores also have high sensitivity and low specificity and are best used to stratify patients into PE likely /unlikely groups and not used for diagnosis of PE. Combination of D dimers and the clinical decision rules improves the stratification of patients and guides on who requires a CTPA. The gold standard for diagnosis of PE remains computerized tomographic pulmonary angiography (CTPA).

The reported specificity of D-dimer has varied somewhat between published studies, but in general ranged from 23-63% in studies that used cut-off values of 0.5-1.2 µg/ml (Crawford F et al 2016), Importantly, the specificity varies with the D-dimer cut-off value chosen; for example, one study reported a specificity of 41% for a threshold value of 0.5 µg/ml and 93% for a threshold value of 4 µg/ml (Perrier et al 1997).

A limited number of studies to evaluate the diagnostic accuracy of D dimer tests in patients with suspected PE have been done in Africa. However, one small study of 30 patients in Egypt by Abdel Rahem et al (2013) examined this link. On analysis the sensitivity, specificity, PPV, NPV and accuracy of D dimers were 90%,37.5%,80%,60% and 26.6% respectively.

The sensitivity, specificity, negative predictive value and positive predictive value of the revised Geneva score and D dimers was performed against the CTPA findings. This was done to assess its utility in ruling out PE in patients with low or intermediate risk of PE and determine the number who could safely be excluded from imaging. The two (revised Geneva score and D dimers) are used for stratifying patients into PE risk categories and are not alternative diagnostic tests as CTPA still remains the current gold standard for diagnosis of PE. The number of patients enrolled in the study were few and hence was not powered to perform a validation study.

Objective 2: To determine the overall diagnostic yield of CTPA in diagnosing of PE in patients suspected of PE at MTRH.

The diagnostic yield of CTPA in our study was 29.4%. This falls within the 15.4 - 37.4% range (Royal College of Radiologists 2007) This range is a recommendation by the Royal College of Radiologists and was arrived at by the British thoracic society standards of care committee pulmonary embolism guidelines development group. Thus far, there is no consensus on the acceptable positive rate of CTPA in diagnosing PE. While the Royal College of Radiologists suggests a minimum yield of 15.4% as the acceptable positive rate of CTPA, certain centres use 10% as the accepted threshold under which overuse of CTPA should be considered [Chen Z et al 2019)]. (Low CL et al 2023).

There is a wide range of diagnostic yields of CTPA for PE in the literature, ranging from 4.7% to 31% (Kornblum j et al 2021). Despite using a lower cut-off (10%) as the acceptable threshold in North America, there are a few studies that report a yield lower than the threshold (Alshumrani G et al 2021, De Boer H et al 2022)

Several African studies have reported yields that are in close range with our study. Wainaina et al (2013) in KNH and Mater hospitals in Nairobi, Kenya reported a diagnostic yield of 27.3%. Similar findings were also reported by Meer S et al (2018) in South Africa. This however contrasts to a study by Esiene A et al (2019) in Cameroon which examined the diagnostic performance of four clinical probability models for diagnosing of acute PE. The diagnostic yield of CTPA was 53.3% (16/30 patients). The higher yield could be due to different population and the study protocol in that they performed ECG and excluded patients with coronary syndromes or heart blocks. Still in Cameroon, another study by Tambe et al (2012) involving 37 patients with suspected PE out of whom 12(32.4%) were positive for PE. All these studies had

diagnostic yields falling within the 15.4 -37.4% range. (Royal College of Radiologists 2007)

In the Middle East two studies in Iran and UAE gave contrasting CTPA diagnostic yields. The first study by Hanieh R et al (2018) in Iran evaluated the utilization and diagnostic yield of CTPA and utilized the wells and revised Geneva clinical probability scores. Of the 112 patients enrolled in the study ,44 were diagnosed with pulmonary embolism on CTPA giving a diagnostic yield of 39%. In the UAE a study by Hadid et al (2023) retrospectively investigated 486 patients out of whom only 9.47% were diagnosed with PE. This contrasts with our study results and could be due to the different population demographics, inappropriate use of the PE diagnostic pathway and the retrospective nature of the study.

In a seven-hospital prospective cohort study in the Netherlands ,807 patients were enrolled and the results of the clinical decision rules were compared with prevalence of PE identified by CTPA. The diagnostic yield of CTPA was 23 %. Similar findings were reported by Marco J et al 2003 and Haap M et al (2012). The yields in the European studies were double or triple the American studies.

In the developed world the diagnostic yield of CTPAS in emergency departments has been low raising concerns about overuse of CTPA and non-adherence to diagnostic protocols. This is especially so in the USA where the PE prevalence is routinely under 10%. A study from a secondary hospital by Kennedy N et al (2015) in New Zealand demonstrates these findings. Among 105 patients enrolled the mean age was 63.7 years with 60% females. The commonest risk factors were history of previous thromboembolism at 18%,11% malignancy,22% immobility or recent surgery. The prevalence of PE in this study was 15%. These results contrast with the findings of

our study due to different population demographics, higher life expectancy. Other studies yielded PE prevalence's between 15.4-37.4% as recommended by the royal college of radiology include Ozakin E et al (2016) in Turkey and Bylinka A et al (2022) in Poland.

In contrast, studies in the USA have demonstrated low yields of CTPA. A study by Mohammed O et al (2018) in Michigan involving 395 patients had a diagnostic yield of 5.4%. this is in tandem with most studies in the USA which have demonstrated yield of less than 10%. the low diagnostic yields in USA medical centres have raised the possibility of concern for malpractice litigation (costa AF et al 2014). it can also be partly explained by the greater accessibility of CTPA in USA. In contrast European studies demonstrate higher yield that are two or three times higher than American studies. the difference could be due to differences in physician practices, access to CTPA and application of diagnostic algorithms. (Kauppi J N et al 2022). Physicians also maintain a low threshold for suspected PE potentially leading to deviation from guideline recommended algorithms and unnecessary CTPA (Alagha Z et al 2024). in a study conducted from 2016 to 2019 at 27 emergency room in the USA, 5.3% of 1828010 patient encounters had PE tests performed. 25870 (59%) of all PE tests had CTPA performed without a D dimer test. From the CTPA scans only 3.1% had pulmonary embolism (Kline et al 2020) In another study, also in the USA 8449 patients with suspected PE were enrolled over 3 years. On clinical probability score, 96% were categorized as low risk and only 4% were intermediate or high risk for PE. D dimer was only obtained in 37% of the low-risk patients. Despite low wells score and normal D dimers 260 patients underwent CTPA testing none of whom were diagnosed with PE. (Dhakal p et al 2019). The clinical practice guidelines for

diagnosis of pulmonary embolism in the USA involve assessment of clinical probability, use of D dimers and imaging studies such as CTPA and V/Q scans.

Many patients in our study presented with cough, chest pain and dyspnea at 100%,99% and 80% respectively. The large number of patients who presented with cough was surprising as most of the patients with PE present with breathlessness or chest patient at a higher rate than cough.in the PIOPED study only 37% of patients presented with cough while in the Pessinaba study (Pessinaba et al 2017) it was 60.8%. the difference could be due to patient selection in our set up where patients with respiratory systems especially cough were referred for CTPA,71% of whom were negative for PE on imaging. Close to half (49%) presented with hemoptysis. This agrees with the literature which states the common symptoms of PE to include dyspnea, chest pain, cough, hemoptysis, syncope (Konstantinidis 2014, Zhan et al 2014). Worldwide dyspnea and chest pain are the two most common presenting complaints (Mccaig LF et al 2006).

In sub-Saharan Africa, a retrospective study at a district hospital in Cape town by Bulajic B et al (2019) enrolled 127 patients over two years. 41/127 patients were confirmed positive on CTPA giving a diagnostic yield of 32%. The mean ages were 43 and 45 years for PE negative and PE positive patients respectively. In addition, the most common reported presenting symptoms was dyspnea at 83% followed by chest pain at 50%.

This agrees with results in our study where 80% of patients presented with dyspnea. Similarly, the EMPEROR study (Pollack CV et al 2011) found dyspnea, chest pain and lower limb swelling suggestive of DVT as the most common presentation. These

results correspond to our study probably due to a similar population group and associated risk factors such as TB and HIV which are hypercoagulable states

Other African studies that reported on the clinical presentation of patients with PE include Pessinaba et al (2017) in Lomé, Togo who reported the commonest symptoms as dyspnea (98.0%), chest pain (78.4%), cough (60.8%), hemoptysis (31.4%) and syncope (29.4%) and Ngahane et al (2019) reported the commonest symptoms as dyspnea (83.4%), chest pain (78.6%) and syncope (5.8%).

Objective 3: To determine if there is overutilization of CTPA in diagnosis of PE at MTRH

Overuse of CTPA in patients suspected of PE has been a concern especially in emergency departments in western countries. In this study the rate of overuse of CTPA was found to be 7%. This could point to underutilization of D dimers and clinical scores or non-adherence to clinical guidelines. In our facility there are guidelines regarding diagnosis of DVT and venous thromboembolism developed by the national ministry of health and adopted by MTRH. However, they are not widely utilized and almost all patients sent to radiology department for imaging have no D dimers or clinical prediction scores for PE. done.

There are several possible explanations for the excessive use of CTPA in the world. Among them are concerns regarding missing potentially life-threatening PE; risk of litigation, underestimation of adverse consequences associated with the use of CT, the ease with which this mode of investigation can be used; and an insufficient policy for utilizing prediction rules (Rohacek et al 2012, Takahashi et al 2013).

This is in agreement to a study done in Michigan USA by Mohammed Osman et al (2018) involving 395 patients where they established that 41% of the patients were

inappropriately referred for CTPA. The diagnostic yield was also low at 5.4% but in concordance with similar USA studies. This could be due to greater accessibility of CTPA in the USA and lack of adherence to guidelines. In contrast yields in European countries are double or triple the American yields. (Marco J L et al (2003), Michael M Haap et al (2012).

A study by Amanda Crichlow, Adam Cuker and Angela M Mills in USA (2012) also arrived at a similar conclusion that 13.8% of CTPA could have been avoided if clinical probability scores and D dimers were utilized.

Adil Shujaat et al (2012) did a retrospective study on 231 patients in Florida with a view to determining overuse of CTPA. He arrived at a conclusion that 24.3% of CTPA could be avoided if D dimers and clinical probability scores were done. Almost similar findings were reported in a study by Hadid et al (2023) in the United Arab Emirates where he established that 15.4% (75/486) of patients enrolled in his study received unnecessary CTPAs. This is as per the recommended clinical decision pathway.

A study in Saudi Arabia by Al Marshad F et al (2023) retrospectively examined the use of clinical probability scores and D dimers with a view to determining overuse/overutilization of CTPA. 30 patients (D dimer negative and low probability of PE) could have had CTPAs avoided giving a rate of 7.1%. This is in agreement with the results of our study which found 6.9% of CTPAs could be avoided.

Another study by Bylinka A et al (2022) in Poland demonstrated that the combination of revised Geneva score with standard D dimers were associated with 2.5-9.3% reduction of CTPA use. Similarly, a study in Italy by Mirabile M et al (2021) also

established that 43/437(9.84%) CTPAs could be avoided if clinical probability scores and D dimers were fully utilized to stratify suspected PE patients.

The results of our study demonstrated a CTPA diagnostic yield of 29.4%. This is within the British Association of Radiologists threshold of 15.4% -37.4% and is similar to most studies in Africa, Middle East and Asia. It is higher than most studies in North America. This implies that utilization of CTPA is within acceptable limits in the developing countries while in the North America its overutilized.

There was a 6.9% (7 patients /102) overutilization of CTPA. Similar results have been obtained in Saudi Arabia and Poland. This could point to underutilization of D dimers and clinical scores.

If clinical probability scores are strictly followed the diagnostic yields would be within the recommended rates by the royal college of radiologists of 15.4%-37.4% which is not what currently obtains in North America. This is corroborated by several studies in recent years that have shown positivity rates in MDCT of less than 10% in patients with suspected PE, while prospective clinical trials conducted two decades ago, in which Pretest clinical evaluations were carried out before V /Q scan, revealed the disease in at least one third of the patients. (Miniati et al 1996).

Conclusion: In the diagnosis of pulmonary thromboembolism, modified Geneva score, and D-dimer test have high negative predictive values. Other clinic diagnoses can be considered primarily in patients who have low modified Geneva scores with negative d-dimer results. This may contribute to the reduction of the overuse of pulmonary CT angiography. (Turnoglu H et al 2020).

Moreover, our results corroborate the necessity to make the request for CTPA according to the clinical decisions based on various clinical criteria.

The wells score and the revised Geneva scores have been validated as clinical prediction tools for PE. In a study by Claudis B et al (2025), Wells score had a sensitivity of 84,3% and specificity of 71.4% while revised Geneva had a sensitivity of 82.3% and specificity of 69%. Both also showed a clear correlation with confirmed PE 77,4%(Wells) and 81.5% (revised Geneva) in the high-risk groups. Concluded that both the wells and revised Geneva are effective in stratifying PE risk. In another study Tang L et al (2024) demonstrated that the well score combined with PERC and Revised Geneva score combined with PERC had outstanding PE rule out criteria with near perfect sensitivity and negative predictive values. There was also no difference in the AUC between the well score combined with D dimer and Revised Geneva score with d Dimers probability scores.

Similarly, Klok F et al (2008) assessed the performance of the wells score and revised Geneva score and conclude that the performance of the revised Geneva score is equivalent to that of the wells rule. Studies comparing the diagnostic performance of wells and revised Geneva scores have shown variable results across different populations. Some research suggests that the wells score may have slightly better sensitivity in emergency settings (Goldhaber Z et al 2005), while others advocate for the revised Geneva score in standardized environments where physician experience may vary (Di Marcia et al 2015, Penaloza A et al 2012). A systematic review by Ceriani E et al (2010) concluded that no single clinical prediction rule is universally superior and clinical context remains crucial.

However, I have not come across any study in literature that demonstrates that the revised Geneva score is superior to the well score.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS.

6.1 CONCLUSION

1. Combination of clinical probability scores and D dimers helps to guide on the course of management and reduces the number of patients who require CTPA for suspected pulmonary embolism. Patients with low probability on Revised Geneva scores most likely don't have PE. In our study no patient out of 11 in this category had PE.

2. The diagnostic yield of CTPA in our study was 29.4% which falls in the 15.4%-37.4% range recommended by the Royal College of Radiologists.

3. 7/102 patients had low probability on revised Geneva score, negative D dimers and no PE. This corresponds to an overutilization rate of 6.9%.

6.2 LIMITATIONS

1. The study limited itself to the utility of the revised Geneva scores in decision making on PE management algorithm to decide on whether a patient requires CTPA or not. A further study to combine other clinical probability scoring D dimers and lower limb Doppler may give added benefit.
2. The study was limited to one center due to resource and time constraints; it also had a smaller sample size.
3. The pretest probability score did not consider the bradycardic effects of beta blockers which may lead to misclassification.

6.3 RECOMMENDATIONS

1. Patients suspected to have pulmonary embolism should be clinically stratified according to the probability of PE being present with the goal of reducing the number of unnecessary CTPA being done in patients who are unlikely to have PE.
2. A multicenter study across different regions /health facilities to determine differences in diagnostic yields and overuse.
3. The rate of overutilization in our study was 6.9% (7/102) patients who could safely have been excluded from imaging. We propose integrating an algorithm-based checklist with validated tools like the revised Geneva scores to guide appropriate CTPA referrals.

REFERENCES

- Abbas, A., St Joseph, E. V., Mansour, O. M., & Peebles, C. R. (2014). Radiographic features of pulmonary embolism: Westermarck and Palla signs. *Postgraduate medical journal*, 90(1065), 422-423.
- Abolfotouh MA, Almadani K, Al Rowaily MA. Diagnostic Accuracy of D-Dimer Testing and the Revised Geneva Score in the Prediction of Pulmonary Embolism. *International Journal of General Medicine*. 2020 Dec 15;13:1537-1543.
- Al Oweidat, K., Al Ryalat, S. A., Al Husban, N., Alhawari, H., Ghareeb, R., Ribie, M., Jwaied, S., Al Yasjeen, S., & Juweid, M. E. (2020). Additive evidence of the competence of pregnancy-adapted YEARS algorithm in reducing the need for CTPA, Q and/or V/Q scintiscan. *Hellenic journal of nuclear medicine*, 23(2), 165–172.
- Almarshad, F., Alaklabi, A., Al Raizah, A., AlZahrani, Y., Aljohani, S. A., AlShammari, R. K., ... & Ram, D. (2023). Diagnostic approach and use of CTPA in patients with suspected pulmonary embolism in an emergency department in Saudi Arabia. *Blood research*, 58(1), 51-60.
- Alshumrani, G., Al Bshabshe, A., & Mousa, W. F. (2021). Diagnostic yield of CT pulmonary angiography for pulmonary embolism in clinically suspected patients. *Medicine*, 100(22), e26213.
- Anderson, D. R., Kahn, S. R., Rodger, M. A., Kovacs, M. J., Morris, T., Hirsch, A., ... & Wells, P. S. (2007). Computed tomographic pulmonary angiography vs ventilation-perfusion lung scanning in patients with suspected pulmonary embolism: a randomized controlled trial. *Jama*, 298(23), 2743-2753.
- Anderson, D. R., Kahn, S. R., Rodger, M. A., Kovacs, M. J., Morris, T., Hirsch, A. & Dennie, C. (2007). Computed tomographic pulmonary angiography vs ventilation-perfusion lung scanning in patients with suspected pulmonary embolism: a randomized controlled trial. *Jama*, 298(23), 2743-2753.
- Anderson, F. A., Wheeler, H. B., Goldberg, R. J., Hosmer, D. W., Patwardhan, N. A., Jovanovic, B., ... & Dalen, J. E. (1991). A population-based perspective of the hospital incidence and case-fatality rates of deep vein thrombosis and pulmonary embolism: the Worcester DVT Study. *Archives of internal medicine*, 151(5), 933-938.
- Andersson and Söderberg *BMC Cardiovascular Disorders* (2017) 17:155
- Angiography in Kenyatta National Hospital. East African collection. 2009; RC 683.5. A5K34. (Unpublished data).
- Aydın, M. S., Hazar, A., & Demirkol, A. H. (2013). Massive right main pulmonary embolism caused by tricuspid valve infective endocarditis. *Heart Asia*, 5(1), 128-129.

- Bělohávek, J., Dytrych, V., & Linhart, A. (2013). Pulmonary embolism, part I: Epidemiology, risk factors and risk stratification, pathophysiology, clinical presentation, diagnosis and nonthrombotic pulmonary embolism. *Experimental & Clinical Cardiology*, 18(2), 129.
- British Thoracic Society Standards of Care Committee Pulmonary Embolism Guideline Development Group. (2003). British Thoracic Society guidelines for the management of suspected acute pulmonary embolism. *Thorax*, 58, 470-483.
- Castañer, E., Gallardo, X., Ballesteros, E., Andreu, M., Pallardó, Y., Mata, J. M., & Riera, L. (2009). CT diagnosis of chronic pulmonary thromboembolism. *Radiographics*, 29(1), 31-50.
- Ceriani, E., Combescure, C., Le Gal, G., Nendaz, M., Perneger, T., Bounameaux, H., ... & Righini, M. (2010). Clinical prediction rules for pulmonary embolism: a systematic review and meta-analysis. *Journal of thrombosis and haemostasis*, 8(5), 957-970.
- Ceriani, E., Combescure, C., Le Gal, G., Nendaz, M., Perneger, T., Bounameaux, H., ... & Righini, M. (2010). Clinical prediction rules for pulmonary embolism: a systematic review and meta-analysis. *Journal of thrombosis and haemostasis*, 8(5), 957-970.
- Chen, Z., Deblois, S., Toporowicz, K., Boldeanu, I., Francoeur, M. O., Sadouni, M., ... & Chartrand-Lefebvre, C. (2019). Yield of CT pulmonary angiography in the diagnosis of acute pulmonary embolism. *BMC Research Notes*, 12(1), 41.
- Cladius, S., Chaudhari, S. S., Mohanty, S., & Cladius, A. (2025). Correlation of Wells Score and Revised Geneva Score with Confirmed Pulmonary Embolism Diagnosis: A Prospective Observational Study. *European Journal of Cardiovascular Medicine*, 15, 214-218.
- Coche, E., Verschuren, F., Hainaut, P., & Goncette, L. (2004). Pulmonary embolism findings on chest radiographs and multislice spiral CT. *European radiology*, 14(7), 1241-1248.
- Contractor, S., Maldjian, P. D., Sharma, V. K., & Gor, D. M. (2002). Role of helical CT in detecting right ventricular dysfunction secondary to acute pulmonary embolism. *Journal of computer assisted tomography*, 26(4), 587-591.
- Costa, A. F., Basseri, H., Sheikh, A., Stiell, I., & Dennie, C. (2014). The yield of CT pulmonary angiograms to exclude acute pulmonary embolism. *Emergency radiology*, 21(2), 133-141.
- Crawford F et al D dimer testing for excluding diagnosis of pulmonary embolism Cochrane database systrev. *Cochrane Database of Systematic Reviews*, (8).
- Dalen, J. E. (2006). New PIOPED recommendations for the diagnosis of pulmonary embolism. *The American Journal of Medicine*, 119(12), 1001-1002.
- Dalrymple, N. C., Prasad, S. R., El-Merhi, F. M., & Chintapalli, K. N. (2007). Price of isotropy in multidetector CT. *Radiographics*, 27(1), 49-62.

- Danwang, C., Temgoua, M. N., Agbor, V. N., Tankeu, A. T., & Noubiap, J. J. (2017). Epidemiology of venous thromboembolism in Africa: a systematic review. *Journal of Thrombosis and Haemostasis*, 15(9), 1770-1781.
- De Boer, H. C., Rajaram, S., Chopra, A., Hurdman, J. A., & Maclean, R. M. (2022). 10,589 CT pulmonary angiograms: evaluating the yield of acute pulmonary embolism. *The British Journal of Radiology*, 95(1137), 20220254.
- Di Marca, S., Cilia, C., Campagna, A., D'Arrigo, G., ElHafeez, S. A., Tripepi, G., ... & Malatino, L. (2015). Comparison of Wells and Revised Geneva Rule to Assess Pretest Probability of Pulmonary Embolism in High-Risk Hospitalized Elderly Adults. *Journal of the American Geriatrics Society*, 63(6), 1091-1097.
- Douma, R. A., Mos, I. C., Erkens, P. M., Nizet, T. A., Durian, M. F., Hovens, M. M., ... & Prometheus Study Group*. (2011). Performance of 4 clinical decision rules in the diagnostic management of acute pulmonary embolism: a prospective cohort study. *Annals of internal medicine*, 154(11), 709-718.
- Duffett, L., Castellucci, L. A., & Forgie, M. A. (2020). Pulmonary embolism: update on management and controversies. *Bmj*, 370.
- Duplyakov, D., Kurakina, E., Pavlova, T., Khokhlunov, S., & Surkova, E. (2015). Value of syncope in patients with high-to-intermediate risk pulmonary artery embolism. *European Heart Journal: acute cardiovascular care*, 4(4), 353-358.
- Ergan, B., Ergün, R., Çalışkan, T., Aydın, K., Tokur, M. E., Savran, Y., ... & Gökmen, N. (2016). Mortality related risk factors in high-risk pulmonary embolism in the ICU. *Canadian respiratory journal*, 2016(1), 2432808.
- Estrada-Y-Martin, R. M., & Oldham, S. A. (2011). CTPA as the gold standard for the diagnosis of pulmonary embolism. *International journal of computer assisted radiology and surgery*, 6(4), 557-563.
- Findik, S., Erkan, L., Light, R. W., Uzun, O., Atici, A. G., & Akan, H. (2008). Massive pulmonary emboli and CT pulmonary angiography. *Respiration*, 76(4), 403-412.
- Garg, K., Sieler, H., Welsh, C. H., Johnston, R. J., & Russ, P. D. (1999). Clinical validity of helical CT being interpreted as negative for pulmonary embolism: implications for patient treatment. *AJR. American journal of roentgenology*, 172(6), 1627-1631.
- Geersing, G. J., Takada, T., Klok, F. A., Büller, H. R., Courtney, D. M., Freund, Y., ... & van Es, N. (2022). Ruling out pulmonary embolism across different healthcare settings: a systematic review and individual patient data meta-analysis. *PLoS Medicine*, 19(1), e1003905.
- Germini, F., Zarabi, S., Eventov, M., Turcotte, M., Li, M., & de Wit, K. (2021). Pulmonary embolism prevalence among emergency department cohorts: a systematic review and meta-analysis by country of study. *Journal of Thrombosis and Haemostasis*, 19(1), 173-185.

- Germini, F., Zarabi, S., Eventov, M., Turcotte, M., Li, M., & de Wit, K. (2021). Pulmonary embolism prevalence among emergency department cohorts: a systematic review and meta-analysis by country of study. *Journal of Thrombosis and Haemostasis*, 19(1), 173-185.
- Gogulakrishnan, R., & Ramakrishnan, G. A. (2023). Comparison of various clinical scoring systems in assessing the probability of pulmonary thromboembolism in adults in a tertiary care hospital in South India. *Journal of Association of Pulmonologist of Tamil Nadu*, 6(2), 39-44.
- Group, B. T. S. S. o. C. C. P. E. G. D. (2003). British Thoracic Society guidelines for the management of suspected acute pulmonary embolism. *Thorax*, 58, 470-484.
- Hamad, M. M. A., Bhatia, P., Ellidir, E., Abdelaziz, M. M., & Connolly, V. (2011). Diagnostic approach to pulmonary embolism and lessons from a busy acute assessment unit in the UK. *Breathe*, 7(4), 315-323.
- Hartmann, I. J., & Screatton, N. J. (2020). Pulmonary circulation and pulmonary thromboembolism. In *Grainger & Allison's Diagnostic Radiology, 2 Volume Set E-Book*. Elsevier.
- Hartmann, I. J., Wittenberg, R., & Schaefer-Prokop, C. (2010). Imaging of acute pulmonary embolism using multi-detector CT angiography: an update on imaging technique and interpretation. *European journal of radiology*, 74(1), 40-49.
- Heuschmid, M., Mann, C., Luz, O., Mahnken, A. H., Reimann, A., Claussen, C. D., & Kopp, A. F. (2006). Detection of pulmonary embolism using 16-slice multidetector-row computed tomography: evaluation of different image reconstruction parameters. *Journal of computer assisted tomography*, 30(1), 77-82.
- Ho, W. K., Hankey, G. J., & Eikelboom, J. W. (2008). The incidence of venous thromboembolism: a prospective, community-based study in Perth, Western Australia. *Medical journal of Australia*, 189(3), 144-147.
- Hoang, J. K., Lee, W. K., & Hennessy, O. F. (2008). Multidetector CT pulmonary angiography features of pulmonary embolus. *Journal of Medical Imaging and Radiation Oncology*, 52(4), 307-317.
- Horlander, K. T., Mannino, D. M., & Leeper, K. V. (2003). Pulmonary embolism mortality in the United States, 1979-1998: an analysis using multiple-cause mortality data. *Archives of internal medicine*, 163(14), 1711-1717.
- Hsu, C. W., & Su, H. Y. (2017). Palla's sign and Hampton's hump in pulmonary embolism. *QJM : monthly journal of the Association of Physicians*, 110(1), 49-50.
- Huisman, M. V. (2006). Effectiveness of managing suspected pulmonary embolism using an algorithm combining clinical probability, D-dimer testing, and computed tomography. *JAMA: Journal of the American Medical Association*, 295(2).

- Hurwitz, L. M., Yoshizumi, T. T., Goodman, P. C., Nelson, R. C., Toncheva, G., Nguyen, G. B., ... & Anderson-Evans, C. (2009). Radiation dose savings for adult pulmonary embolus 64-MDCT using bismuth breast shields, lower peak kilovoltage, and automatic tube current modulation. *American Journal of Roentgenology*, 192(1), 244-253.
- Ibrahim MA (2019) comparison of chest radiograph findings to CT pulmonary angiography among adults with suspected PE at Eldoret, Kenya.
- Islam, M., Filopei, J., Frank, M., Ramesh, N., Verzosa, S., Ehrlich, M., ... & Steiger, D. (2018). Pulmonary infarction secondary to pulmonary embolism: An evolving paradigm. *Respirology*, 23(9), 866-872.
- Janata, K., Holzer, M., Domanovits, H., Mullner, M., Bankier, A., Kurtaran, A., ... & Laggner, A. N. (2002). Mortality of patients with pulmonary embolism. *Wiener klinische Wochenschrift*, 114(17-18), 766-772.
- Kaguthi, J. N. (2009). *The pattern of vascular pathology on multidetector computerised tomography angiography In Kenyatta National Hospital* (Doctoral dissertation, University of Nairobi).
- Karabulut, N., & Kiroglu, Y. (2008). Relationship of parenchymal and pleural abnormalities with acute pulmonary embolism: CT findings in patients with and without embolism. *Diagnostic and interventional radiology*, 14(4), 189.
- Kathiria, N. N., Devcic, Z., Chen, J. S., Naeger, D. M., Hope, M. D., Higgins, C. B., & Ordovas, K. G. (2015). Assessment of left ventricular enlargement at multidetector computed tomography. *Journal of computer assisted tomography*, 39(5), 794-796.
- Keller, K., Hobohm, L., Ebner, M., Kresoja, K. P., Münzel, T., Konstantinides, S. V., & Lankeit, M. (2020). Trends in thrombolytic treatment and outcomes of acute pulmonary embolism in Germany. *European heart journal*, 41(4), 522-529.
- Kingue, S., Bakilo, L., Mvuala, R., Pay Pay, E., Ze Minkande, J., Fifen, I., ... & Nwadinigwe, C. (2014). Epidemiological African day for evaluation of patients at risk of venous thrombosis in acute hospital care settings: cardiovascular topic. *Cardiovascular journal of Africa*, 25(4), 159-164.
- Kline, J. A., Courtney, D. M., Kabrhel, C., Moore, C. L., Smithline, H. A., Plewa, M. C., ... & Nordenholz, K. (2008). Prospective multicenter evaluation of the pulmonary embolism rule-out criteria. *Journal of Thrombosis and Haemostasis*, 6(5), 772-780.
- Klok, F. A., Kruisman, E., Spaan, J., Nijkeuter, M., Righini, M., Aujesky, D., ... & Huisman, M. V. (2008). Comparison of the revised Geneva score with the Wells rule for assessing clinical probability of pulmonary embolism. *Journal of Thrombosis and Haemostasis*, 6(1), 40-44.
- konstantinides S. V. (2014). 2014 ESC Guidelines on the diagnosis and management of acute pulmonary embolism. *European heart journal*, 35(45), 3145–3146.

- Konstantinides, S. V., Meyer, G., Becattini, C., Bueno, H., Geersing, G. J., Harjola, V. P., ... & Zamorano, J. L. (2020). 2019 ESC Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS) The Task Force for the diagnosis and management of acute pulmonary embolism of the European Society of Cardiology (ESC). *European heart journal*, 41(4), 543-603.
- Kornblum, J., Daugherty, R. J., Bounds, R., Vance, A. Z., & Graif, A. (2021). Diagnostic yield of computed tomographic pulmonary angiography for suspected pulmonary embolism varies across settings within a community-based health system. *Emergency Radiology*, 28, 291-296.
- Kostadima, E., & Zakynthinos, E. (2007). Pulmonary embolism: pathophysiology, diagnosis, treatment. *Hellenic J Cardiol*, 48(2), 94-107.
- Kumamaru, K. K., Lu, M. T., Niri, S. G., & Hunsaker, A. R. (2013). Right ventricular enlargement in acute pulmonary embolism derived from CT pulmonary angiography. *The International journal of cardiovascular imaging*, 29(3), 705-708.
- Le Gal, G., Righini, M., & Wells, P. S. (2015). D-dimer for pulmonary embolism. *Jama*, 313(16), 1668-1669.
- Leung, A. N., Bull, T. M., Jaeschke, R., Lockwood, C. J., Boisselle, P. M., Hurwitz, L. M., Paidas, M. J. (2011). An official American Thoracic Society/Society of Thoracic Radiology clinical practice guideline: evaluation of suspected pulmonary embolism in pregnancy. *American journal of respiratory and critical care medicine*, 184(10), 1200-1208.
- Lim, W., Le Gal, G., Bates, S. M., Righini, M., Haramati, L. B., Lang, E., ... & Mustafa, R. A. (2018). American Society of Hematology 2018 guidelines for management of venous thromboembolism: diagnosis of venous thromboembolism. *Blood advances*, 2(22), 3226-3256.
- Lomamba, F. W., Tshibola, J. M., & Tshikwela, M. L. (2017). Clinical and Demographic Predictors of Acute Pulmonary Embolism in Central Africa Using 64-Rows Multi-Detector Computed Tomography Angiography. *Research in Health Science*, 2(2), 185.
- Lombard, J., Bhatia, R., & Sala, E. (2003). Spiral computed tomographic pulmonary angiography for investigating suspected pulmonary embolism: clinical outcomes. *Canadian Association of Radiologists Journal*, 54(3), 147.
- Loud, P. A., Grossman, Z. D., Klippenstein, D. L., & Ray, C. E. (1998). Combined CT venography and pulmonary angiography: a new diagnostic technique for suspected thromboembolic disease. *AJR. American journal of roentgenology*, 170(4), 951-954.

- Ma, Y., Huang, J., Wang, Y., Wu, T., Cai, D., Liu, Y., ... & Shi, Y. (2016). Comparison of the Wells score with the revised Geneva score for assessing pretest probability of pulmonary embolism in hospitalized elderly patients. *European Journal of Internal Medicine*, 36, e18-e19.
- Mayo, J. R., Aldrich, J., & Müller, N. L. (2003). Radiation exposure at chest CT: a statement of the Fleischner Society. *Radiology*, 228(1), 15-21.
- Mazilu, L., Adam, T., Suceveanu, A., Baz, R., & Tofolean, D. (2015). Pulmonary thromboembolic disease—clinical and etiological aspects in internal medicine department. *ARS Medica Tomitana*, 21(2), 67-74
- Mishra, S., Jagaty, S. K., Mohapatra, S. K., Gupta, S., Laha, S., Sahoo, K. C., & Rath, S. S. (2025). Atypical Presentation of Pulmonary Embolism in Patients with Refractory Hypoxemia and Dyspnea. *European Journal of Cardiovascular Medicine*, 15, 12-14.
- Mitchell, A. M., Jones, A. E., Tumlin, J. A., & Kline, J. A. (2012). Prospective study of the incidence of contrast-induced nephropathy among patients evaluated for pulmonary embolism by contrast-enhanced computed tomography. *Academic Emergency Medicine*, 19(6), 618-625.
- Moore, A. J., Wachsmann, J., Chamrathy, M. R., Panjikaran, L., Tanabe, Y., & Rajiah, P. (2018). Imaging of acute pulmonary embolism: an update. *Cardiovascular diagnosis and therapy*, 8(3), 225.
- Nduta, W. A. (2013). *The pattern of findings on multidetector computed tomographic pulmonary angiography for suspected pulmonary embolism in Nairobi* (Doctoral dissertation, University of Nairobi).
- Ng, C. S., Wells, A. U., & Padley, S. P. (1999). A CT sign of chronic pulmonary arterial hypertension: the ratio of main pulmonary artery to aortic diameter. *Journal of thoracic imaging*, 14(4), 270-278.
- Ogeng'o, J. A., Gatonga, P., & Olabu, B. O. (2011). Cardiovascular causes of death in an east African country: an autopsy study. *Cardiology Journal*, 18(1), 67-72.
- Ogeng'o, J. A., Obimbo, M. M., Olabu, B. O., Gatonga, P. M., & Ong'era, D. (2011). Pulmonary thromboembolism in an East African tertiary referral hospital. *Journal of thrombosis and thrombolysis*, 32(3), 386-391.
- Oser, R. F., Zuckerman, D. A., Gutierrez, F. R., & Brink, J. A. (1996). Anatomic distribution of pulmonary emboli at pulmonary angiography: implications for cross-sectional imaging. *Radiology*, 199(1), 31-35.
- Parker, J. A., Coleman, R. E., Siegel, B. A., Sostman, H. D., McKusick, K. A., & Royal, H. D. (1996). Procedure guideline for lung scintigraphy: 1.0. *Journal of Nuclear Medicine*, 37(11), 1906-1910.

- Pastakia, S. D., Crisp, W. I., Schellhase, E. M., Manji, I., Ouma, M. N., & Akwanalo, C. (2010). Implementation of a pharmacist managed anticoagulation clinic in Eldoret, Kenya. *Southern Med Review*, 3(2).
- Penaloza, A., Melot, C., & Motte, S. (2011). Comparison of the Wells score with the simplified revised Geneva score for assessing pretest probability of pulmonary embolism. *Thrombosis research*, 127(2), 81-84.
- Perrier, A., Desmarais, S., Goehring, C., de MOERLOOSE, P. H. I. L. I. P. P. E., Morabia, A., Unger, P. F., ... & Bounameaux, H. (1997). D-dimer testing for suspected pulmonary embolism in outpatients. *American journal of respiratory and critical care medicine*, 156(2), 492-496.
- Pessinaba, S., Atti, Y. D. M., Baragou, S., Pio, M., Afassinou, Y., Kpélafia, M., ... & Damorou, F. (2017). L'embolie pulmonaire au centre hospitalier universitaire Campus de Lomé (Togo): étude rétrospective à propos de 51 cas. *The Pan African Medical Journal*, 27(129).
- Preto, A. S., Rocha, D. M., Campos, J. T., Carneiro, A. L., & Gonçalves, J. F. (2010). Pulmonary Thromboembolism Revisited: The Radiologist's View.
- Prologo, J. D., Gilkeson, R. C., Diaz, M., & Asaad, J. (2004). CT pulmonary angiography: a comparative analysis of the utilization patterns in emergency department and hospitalized patients between 1998 and 2003. *American Journal of Roentgenology*, 183(4), 1093-1096.
- Raksha Ramlakhan, R. R., Andronikou, S., & Ashmitha Rajkumar, A. R. (2017). The prevalence and radiological findings of pulmonary embolism in HIV-positive patients referred for computed tomography pulmonary angiography in the Western Cape of South Africa.
- Rashidi, F., Sate, H., Dourandish, N., & Tabrizi, A. (2017). Evaluation of incidence of chronic thromboembolic pulmonary hypertension after acute pulmonary embolism in patients admitted to Imam Reza Hospital, Tabriz, Iran (primary results). *Journal of Research in Clinical Medicine*, 5(4), 122-127.
- Raskob, G. E., Angchaisuksiri, P., Blanco, A. N., Bueller, H., Gallus, A., Hunt, B. J., ... & Weitz, J. I. (2014, October). Thrombosis: a major contributor to global disease burden. In *Seminars in thrombosis and hemostasis* (Vol. 40, No. 07, pp. 724-735). Thieme Medical Publishers.
- Raskob, G. E., Angchaisuksiri, P., Blanco, A. N., Buller, H., Gallus, A., Hunt, B. J., ... & Weitz, J. I. (2014). Thrombosis: A major contributor to global disease burden ISTH Steering Committee for World Thrombosis Day. *THROMBOSIS AND HAEMOSTASIS*, 112(5), 843-852.
- Refaat, R., & El-Shinnawy, M. A. (2013). Does the anatomic distribution of acute pulmonary emboli at MDCT pulmonary angiography in oncology-population differ from that in non-oncology counterpart?. *The Egyptian Journal of Radiology and Nuclear Medicine*, 44(3), 463-474.

- Remy-Jardin, M., Remy, J., Wattinne, L., & Giraud, F. (1992). Central pulmonary thromboembolism: diagnosis with spiral volumetric CT with the single-breath-hold technique--comparison with pulmonary angiography. *Radiology*, 185(2), 381-387.
- Riedel, M. (2004). Diagnosing pulmonary embolism. *Postgraduate medical journal*, 80(944), 309-319.
- Robert-Ebadi, H., Mostaguir, K., Hovens, M. M., Kare, M., Verschuren, F., Girard, P., ... & Le Gal, G. (2017). Assessing clinical probability of pulmonary embolism: prospective validation of the simplified Geneva score. *Journal of Thrombosis and Haemostasis*, 15(9), 1764-1769.
- Rohacek, M., Buatsi, J., Szucs-Farkas, Z., Kleim, B., Zimmermann, H., Exadaktylos, A., & Stoupis, C. (2012). Ordering CT pulmonary angiography to exclude pulmonary embolism: defense versus evidence in the emergency room. *Intensive care medicine*, 38(8), 1345-1351.
- Scheres, L. J., Lijfering, W. M., & Cannegieter, S. C. (2018). Current and future burden of venous thrombosis: not simply predictable. *Research and practice in thrombosis and haemostasis*, 2(2), 199-208.
- Schissler, A. J., Rozenshtein, A., Kulon, M. E., Pearson, G. D., Green, R. A., Stetson, P. D., ... & Einstein, A. J. (2013). CT pulmonary angiography: increasingly diagnosing less severe pulmonary emboli. *PloS one*, 8(6), e65669.
- Schoepf, U. J., & Costello, P. (2005). Spiral computed tomography is the first-line chest imaging test for acute pulmonary embolism: yes. *Journal of Thrombosis and Haemostasis*, 3(1), 7-10.
- Schoepf, U. J., Holzknacht, N., Helmberger, T. K., Crispin, A., Hong, C., Becker, C. R., & Reiser, M. F. (2002). Subsegmental pulmonary emboli: improved detection with thin-collimation multi-detector row spiral CT. *Radiology*, 222(2), 483-490.
- Shah, A. A., Davis, S. D., Gamsu, G., & Intriere, L. (1999). Parenchymal and pleural findings in patients with and patients without acute pulmonary embolism detected at spiral CT. *Radiology*, 211(1), 147-153.
- Sharma, G. V. R. K., Sasahara, A. A., & McIntyre, K. M. (1976). Pulmonary embolism: the great imitator. *Disease-a-Month*, 22(7), 1-38.
- Shen, J. H., Chen, H. L., Chen, J. R., Xing, J. L., Gu, P., & Zhu, B. F. (2016). Comparison of the Wells score with the revised Geneva score for assessing suspected pulmonary embolism: a systematic review and meta-analysis. *Journal of thrombosis and thrombolysis*, 41(3), 482-492.
- Silverstein, M. D., Heit, J. A., Mohr, D. N., Petterson, T. M., O'Fallon, W. M., & Melton, L. J. (1998). Trends in the incidence of deep vein thrombosis and pulmonary embolism: a 25-year population-based study. *Archives of internal medicine*, 158(6), 585-593.

- SL, Longo DL, Jameson JL, editors. *Harrison's principles of internal medicine* 16 ed. (Vol.II). New York, NY: McGraw; 2005. 1561–1565.
- Sostman, H. D., Stein, P. D., Gottschalk, A., Matta, F., Hull, R., & Goodman, L. (2008). Acute pulmonary embolism: sensitivity and specificity of ventilation-perfusion scintigraphy in PIOPED II study. *Radiology*, 246(3), 941-946.
- Stein, P. D., Beemath, A., Matta, F., Weg, J. G., Yusen, R. D., Hales, C. A., ... & Woodard, P. K. (2007). Clinical characteristics of patients with acute pulmonary embolism: data from PIOPED II. *The American journal of medicine*, 120(10), 871-879.
- Stein, P. D., Fowler, S. E., Goodman, L. R., Gottschalk, A., Hales, C. A., Hull, R. D., ... & Woodard, P. K. (2006). Multidetector computed tomography for acute pulmonary embolism. *New England Journal of Medicine*, 354(22), 2317-2327.
- Stein, P. D., Fowler, S. E., Goodman, L. R., Gottschalk, A., Hales, C. A., Hull, R. D., ... & Woodard, P. K. (2006). Multidetector computed tomography for acute pulmonary embolism. *New England Journal of Medicine*, 354(22), 2317-2327.
- Stein, P. D., Hull, R. D., Patel, K. C., Olson, R. E., Ghali, W. A., Brant, R., ... & Kalra, N. K. (2004). D-dimer for the exclusion of acute venous thrombosis and pulmonary embolism: a systematic review. *Annals of internal medicine*, 140(8), 589-602.
- Stein, P. D., Woodard, P. K., Weg, J. G., Wakefield, T. W., Tapson, V. F., Sostman, H. D., ... & Buckley, J. D. (2007). Diagnostic pathways in acute pulmonary embolism: recommendations of the PIOPED II Investigators. *Radiology*, 242(1), 15-21.
- Sverzellati, N., De Filippo, M., Quintavalla, M., Randi, G., Franco, F., Cobelli, R., ... & Zompatori, M. (2014). Interobserver reliability of the chest radiograph in pulmonary embolism. *Clinical and Applied Thrombosis/Hemostasis*, 20(2), 147-151.
- Tagalakis, V., Patenaude, V., Kahn, S. R., & Suissa, S. (2013). Incidence of and mortality from venous thromboembolism in a real-world population: the Q-VTE Study Cohort. *The American journal of medicine*, 126(9), 832-e13.
- Takahashi, E. A., & Yoon, H. C. (2013). Four-year cumulative radiation exposure in patients undergoing computed tomography angiography for suspected pulmonary embolism. *Radiology Research and practice*, 2013(1), 482403.
- Tambe, J., Moifo, B., Fongang, E., Guegang, E., & Juimo, A. G. (2012). Acute pulmonary embolism in the era of multi-detector CT: a reality in sub-Saharan Africa. *BMC medical imaging*, 12(1), 31.
- Tang, L., Hu, Y., Min, M., Gu, J., Pan, D., Lin, X., & Tong, C. (2024). Comparisons of clinical scoring systems among suspected pulmonary embolism patients presenting to emergency department. *Health Science Reports*, 7(8), e70003.

- Tapson, V. F., & Humbert, M. (2006). Incidence and prevalence of chronic thromboembolic pulmonary hypertension: from acute to chronic pulmonary embolism. *Proceedings of the American Thoracic Society*, 3(7), 564-567.
- The PIOPED Investigators: value of the ventilation/perfusion scan in acute pulmonary embolism: *Results of the Prospective Investigation of Pulmonary Embolism Diagnosis (PIOPED)*. *JAMA* 1990; 263:2753-2759.
- Truong, Q. A., Massaro, J. M., Rogers, I. S., Mahabadi, A. A., Kriegel, M. F., Fox, C. S., ... & Hoffmann, U. (2012). Reference values for normal pulmonary artery dimensions by noncontrast cardiac computed tomography: the Framingham Heart Study. *Circulation: Cardiovascular Imaging*, 5(1), 147-154.
- Turnaoglu, H., Keskin, S., Ozcetin, A., Becer, B., Eybatova, L., & Durukan, E. (2020). Value of revised Geneva criteria and d-dimer levels in reducing overuse of pulmonary CT angiography in the diagnosis of pulmonary thromboembolism. *Annals of Medical of Research*, 27(3).
- Van der Hulle, T., Cheung, W. Y., Kooij, S., Beenen, L. F., van Bommel, T., van Es, J., ... & del Sol, A. I. (2017). Simplified diagnostic management of suspected pulmonary embolism (the YEARS study): a prospective, multicentre, cohort study. *The Lancet*, 390(10091), 289-297.
- Van Erkel, A. R., Van Rossum, A. B., Bloem, J. L., Kievit, J., & Pattynama, P. M. (1996). Spiral CT angiography for suspected pulmonary embolism: a cost-effectiveness analysis. *Radiology*, 201(1), 29-36.
- Venkatesh, A. K., Agha, L., Abaluck, J., Rothenberg, C., Kabrhel, C., & Raja, A. S. (2018). Trends and variation in the utilization and diagnostic yield of chest imaging for Medicare patients with suspected pulmonary embolism in the emergency department. *American Journal of Roentgenology*, 210(3), 572-577.
- Venkatesh, A. K., Kline, J. A., Courtney, D. M., Camargo, C. A., Plewa, M. C., Nordenholz, K. E., ... & Kabrhel, C. (2012). Evaluation of pulmonary embolism in the emergency department and consistency with a national quality measure: quantifying the opportunity for improvement. *Archives of internal medicine*, 172(13), 1028-1032.
- Victor F Tapson. Acute PE. *N Engl J Med* 2008; 358:1037-1052.
- Viera, A. J., & Garrett, J. M. (2005). Understanding interobserver agreement: the kappa statistic. *Family Medicine* 37(5), 360-363.
- Vyas, V., & Goyal, A. (2023). Acute Pulmonary Embolism.[Updated 2022 Aug 8]. *StatPearls [Internet]*. Treasure Island (FL): StatPearls Publishing.
- Wildberger, J. E., Mahnken, A. H., Das, M., Küttner, A., Lell, M., & Günther, R. W. (2005). CT imaging in acute pulmonary embolism: diagnostic strategies. *European radiology*, 15(5), 919-929.

- Winer-Muram, H. T., Rydberg, J., Johnson, M. S., Tarver, R. D., Williams, M. D., Shah, H., ... & Kopecky, K. K. (2004). Suspected acute pulmonary embolism: evaluation with multi-detector row CT versus digital subtraction pulmonary arteriography. *Radiology*, 233(3), 806-815.
- Wittram, C., Maher, M. M., Yoo, A. J., Kalra, M. K., Shepard, J. A. O., & McLoud, T. C. (2004). CT angiography of pulmonary embolism: diagnostic criteria and causes of misdiagnosis. *Radiographics*, 24(5), 1219-1238.
- Worsley, D. F., Alavi, A., Aronchick, J. M., Chen, J. T., Greenspan, R. H., & Ravin, C. E. (1993). Chest radiographic findings in patients with acute pulmonary embolism: observations from the PIOPED Study. *Radiology*, 189(1), 133-136.
- Yasar, K. K., Pehlivanoglu, F., Gursoy, S., & Sengoz, G. (2011). Tricuspid endocarditis and septic pulmonary embolism in an intravenous drug user with advanced HIV infection. *Oman Medical Journal*, 26(5), 365.
- Zhan, Z. Q., Wang, C. Q., Nikus, K. C., He, C. R., Wang, J., Mao, S., & Dong, X. J. (2014). Electrocardiogram patterns during hemodynamic instability in patients with acute pulmonary embolism. *Annals of noninvasive electrocardiology*, 19(6), 543-551.
- Zubairi, A. B. S., Husain, S. J., Irfan, M., Fatima, K., Zubairi, M. A., & Islam, M. (2007). Chest radiographs in acute pulmonary embolism. *Journal of Ayub Medical College, Abbottabad: JAMC*, 19(1), 29.

APPENDICES

Appendix I: IREC Approval



MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 334711/2/3

Reference: IREC/229/2022
Approval Number: 0004240

Dr. Josphat Kiprotich Sang,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET- KENYA.

Dear Dr. Sang,



MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 334711/2/3
7th September, 2022

DIAGNOSTIC YIELD, CLINICAL PROBABILITY SCORE AND UTILITY OF COMPUTERIZED TOMOGRAPHIC PULMONARY ANGIOGRAPHY AT MOI TEACHING AND REFERRAL HOSPITAL

This is to inform you that **MTRH/MU-IREC** has reviewed and approved the above referenced research proposal. Your application approval number is **FAN: 0004240**. The approval period is **7th September, 2022- 6th September, 2023**. This approval is subject to compliance with the following requirements;

- i. Only approved documents including (informed consents, study instruments, Material Transfer Agreements (MTA) will be used.
- ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by **MTRH/MU-IREC**.
- iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to **MTRH/MU-IREC** within 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to **MTRH/MU-IREC** within 72 hours.
- v. Clearance for export of biological specimens must be obtained from **MOH at the recommendation of NACOSTI** for each batch of shipment.
- vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
- vii. Submission of an executive summary report within 90 days upon completion of the study to **MTRH/ MU-IREC**.

Prior to commencing your study; you will be required to obtain a research license from the National Commission for Science, Technology and Innovation (NACOSTI) <https://oris.nacosti.go.ke> and other relevant clearances from study sites including a written approval from the CEO-MTRH which is mandatory for studies to be undertaken within the jurisdiction of Moi Teaching & Referral Hospital (MTRH) and its satellites sites.

Sincerely,

PROF. E. WERE
CHAIRMAN

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE



cc	CEO	-	MTRH	Dean	-	SOP	Dean	-	SOM
	Principal	-	CHS	Dean	-	SON	Dean	-	SOD

Appendix II: Hospital Approval (MTRH)



An ISO 9001:2015 Certified Hospital



MOI TEACHING AND REFERRAL HOSPITAL

Telephone : (+254)053-2033471/2/3/4
Mobile: 722-201277/0722-209795/0734-600461/0734-683361
Fax: 053-2061749
Email: ceo@mtrh.go.ke/directorsofficecmtrh@gmail.com

Nandi Road
P.O. Box 3 – 30100
ELDOR ET, KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

9th September, 2022

Dr. Josphat Kiprotich Sang,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDOR ET-KENYA.

DIAGNOSTIC YIELD, CLINICAL PROBABILITY SCORE AND UTILITY OF COMPUTERIZED TOMOGRAPHIC PULMONARY ANGIOGRAPHY AT MOI TEACHING AND REFERRAL HOSPITAL

You have been authorised to conduct research within the jurisdiction of Moi Teaching and Referral Hospital (MTRH) and its satellites sites. You are required to strictly adhere to the regulations stated below in order to safeguard the safety and well-being of staff, patients and study participants seen at MTRH.

- 1 The study shall be under Moi Teaching and Referral Hospital regulation.
- 2 A copy of MTRH/MU-IREC approval shall be a prerequisite to conducting the study.
- 3 Studies intending to export human bio-specimens must provide a permit from MOH at the recommendation of NACOSTI for each shipment.
- 4 No data collection will be allowed without an approved consent form(s) to participants unless waiver of written consent has been granted by MTRH/MU-IREC.
- 5 Take note that data collected must be treated with due confidentiality and anonymity.

The continued permission to conduct research shall only be sustained subject to fulfilling all the requirements stated above.

The approval period is 9th September, 2022 – 8th September, 2023.

Chao 09/09/2022
DR. WILSON K. ARUASA, *MBS, EBS*
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL
c.c. - Senior Director, Clinical Services
- Director, Nursing Services
- HOD, HRISM



All correspondence should be addressed to the Chief Executive Officer

Visit our Website: www.mtrh.go.ke

TO BE THE LEADING MULTI-SPECIALTY HOSPITAL FOR HEALTHCARE, TRAINING AND RESEARCH IN AFRICA

Appendix III:Nacosti Approval

 REPUBLIC OF KENYA	
Ref No: 579277	Date of Issue: 17/October/2022
RESEARCH LICENSE	
	
This is to Certify that Dr. JOSPHAT KIPROTICH SANG of Moi University, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Uasin-Gishu on the topic: DIAGNOSTIC YIELD, CLINICAL PROBABILITY SCORE AND UTILITY OF COMPUTERIZED TOMOGRAPHIC PULMONARY ANGIOGRAPHY AT MOI TEACHING AND REFERRAL HOSPITAL for the period ending : 17/October/2023.	
License No: NACOSTI/P/22/20566	
579277	
Applicant Identification Number	Director General NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION
Verification QR Code	
	
NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.	
See overleaf for conditions	



Appendix IV: Informed Consent Form

MOI TEACHING & REFERRAL HOSPITAL / MOI UNIVERSITY COLLEGE OF

HEALTH SCIENCES -INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE(MTRH/MU-IREC)

INFORMED CONSENT FORM

STUDY TITLE: DIAGNOSTIC YIELD, CLINICAL PROBABILITY SCORE AND UTILITY OF COMPUTERIZED TOMOGRAPHIC PULMONARY ANGIOGRAPHY AT MOI TEACHING AND REFERRAL HOSPITAL.

Name of Principal Investigator(s): Josphat Sang

Co-investigator(s): Dr. Loice Sitienei
Dr. Andrew Wandera

Name of Organization: Moi University

Address: 4606-30100
538

Telephone Number: 0721 788

Name of Sponsor/Funding Agency: self

Informed Consent Form for: Patients with suspected Pulmonary Embolism at Moi Teaching and Referral Hospital

This Informed Consent Form has two parts:

- Part I: Information Sheet [to share information about the study with you]
- Part II: Certificate of Consent [for signatures if you choose to participate]

PART I: INFORMATION SHEET

Introduction: You are being asked to take part in a research study. This information is provided to tell you about the study. Please read this form carefully. You will be given a chance to ask questions.

Taking part in this research study is voluntary. Saying no will not affect your rights to health care or any other services. Your treatment/payment or enrollment in any health plans or eligibility for benefits will not be affected if you decide not to take part. You are also free to withdraw from this study at any time. If after data collection you choose to quit, you can request that information provided by you be destroyed under supervision. This would be before data is de-identified and aggregated. You will be notified if new information becomes available about the risks or benefits of this research. You will receive a copy of this form after it is signed

Purpose of the study: To determine the diagnostic yield rates of CTPA in diagnosing PE with a view to determining under/overuse among patients suspected of PE at MTRH.

Study site: Department of radiology and imaging at the Moi Teaching and Referral Hospital Eldoret, Kenya.

Study population: Adult patients suspected to have pulmonary embolism referred to radiology department for Computed tomographic pulmonary angiography

Study procedures: All patients referred to the radiology department for CTPA will be interviewed and given an explanation of the study with a view of obtaining informed consent. Patients biodata including age and gender will be obtained. A clinical history will be obtained with emphasis on clinical symptoms like cough, chest pain, difficulty in breathing and hemoptysis. Risk factors for PE will be explored and indicated if present or absent on a questionnaire. Clinical probability scoring will be done and patients categorized as low, intermediate and high probability for PE. D dimers will be performed and lastly all patients will be referred for CT pulmonary angiography.

If you agree you will do the following: You will be required to answer some structured questions in form of questionnaires like age and gender .Clinical history with emphasis on symptoms of cough, chest pain, difficulty in breathing and hemoptysis will be obtained and filled in the questionnaire. Risk factors for PE like previous surgery, immobility, use of contraceptives, history of cancer will be obtained. A blood sample for D Dimers will be taken, finally will be sent to the radiology department for an imaging test called CTPA which is used to determine if you have a blood clot in your pulmonary arteries.

Benefits: This is a research project and the findings may be used by the MTRH management, Government's policy makers and health providers to design appropriate policies and plans to provide better health services for PE management. Your participation will help us to gain a better understanding of PE.

Risks/Discomforts: I am aware of the fact that some of the questions regarding research participation are not convenient to you. Everything you will tell me will be kept

confidential. Under no circumstance will we link your name to the data during analysis and dissemination of the study findings.

Payments and Reimbursements: There is no payment or reimbursement for participating in the study

Confidentiality: All reasonable efforts will be made to keep your protected information (private and confidential). Using or sharing (“disclosure”) of such information will follow National privacy guidelines. By signing the consent document for this study, you are giving permission (“authorization”) for the use and disclosure of your study information. We may need to share your protected information with the community advisory board, MTRH//MU-IREC, NACOSTI or the healthcare team. We will retain your research records for at least six years after the study is completed. At that time, the research information is destroyed [Inform the participant how the records will be destroyed]. If you decide to withdraw your permission for use of your personal data, contact the [PI] in writing and let them know your decision. At that time, we will stop further collection of any information about you. However, the health information collected before this withdrawal may continue to be used for the purposes of reporting and research quality.

[OPTIONAL]: For studies involving biological materials, specify the storage location and procedures and duration for handling specimens.

[OPTIONAL]: For studies involving patients, explain that their information will be added to their medical record and that any research information entered into their medical record will be kept indefinitely.

[OPTIONAL]: You have the right to see and copy your personal information related to the research study for as long as the study team holds this information

Compensation for injury: In the event of an injury resulting from participating in this study, medical expenses will be covered for treatment of that injury.

PART II: CONSENT OF PATICIPANT:

I have read or have had someone read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all the questions I have at this time. I have been told of the potential risks, discomfort, and possible benefits (if any) of the study. I freely volunteer to take part in this study.

[This section must be written in the first person. If the participant is illiterate, or for some reason is unable to write, they should provide a thumbprint and a competent witness must be engaged during the consent process]

_____	_____	_____
Name of Participant	Signature of participant/Thumbprint	Date & Time
_____	_____	_____
Name of Witness [Optional]	Signature of Witness	Date & Time
_____	_____	_____
Name of the person obtaining consent	Signature of person obtaining consent	Date & Time
_____	_____	_____
Printed name of the investigator	Signature of Investigator	
	Date	

A NOTE ON STUDIES USING VERBAL CONSENT/ASSENT:

Verbal consent/assent means that the person obtaining consent or assent verbally explains the study using a study information sheet, and that consenting individuals give their verbal consent/assent in place of written consent to participate. They should be given the opportunity to ask questions and invited to keep a copy of the study information sheet. The PI should submit a copy of the study information sheet showing this consent script and how the research team will document in their research files when the consent discussion took place, who did it, and if there were any emergent issues.

Contacts for questions about the study

Questions about the study: PI Contact Information [Name: Josphat Sang, Phone Number: 0721 788 538: Email address josphatsang20@gmail.com]

Questions about your rights as a participant: You may contact the Institutional Ethics and Research Committee (MTRH//MU-IREC) 0787723677 or email irec@mtrh.go.ke or irecoffice@gmail.com. The MTRH//MU-IREC is a group of people that review studies for safety and to protect the rights of participants.

APPENDIX V: KISWAHILI VERSION

HOSPITALI YA UALIMU NA RUFAA MOI / CHUO KIKUU CHA MOI CHA

SAYANSI YA AFYA -UTAFITI WA TAASISI NA

KAMATI YA MAADILI (MTRH/MU-IREC)

FOMU YA RIDHAA INAYOFAHAMISHWA

KICHWA CHA SOMO: MAVUNO YA KITAMBUZI NA MATUMIZI AU

MATUMIZI KUBILI YA CTPA KATIKA UCHUNGUZI WA EMBOLISM YA

MPAFU KATIKA HOSPITALI YA MAFUNDISHO NA RUFAA MOI.

Jina la Wapelelezi Mkuu: Josphat Sang

Wapelelezi-wenza: Dk. Loice Sitienei

Dkt Andrew Wandera

Jina la Shirika: Chuo Kikuu cha Moi

Anwani: 4606-30100 Nambari ya Simu: 0721 788 538

Jina la Mfadhili/Wakala wa Ufadhili: binafsi

Fomu ya Idhini Iliyoarifiwa kwa: Wagonjwa walio na tuhuma ya Embolism ya Mapafu katika Hospitali ya Mafunzo na Rufaa ya Moi.

Fomu hii ya Idhini iliyo na Taarifa ina sehemu mbili:

- Sehemu ya I: Karatasi ya Taarifa [kushiriki nawe taarifa kuhusu utafiti]
- Sehemu ya II: Cheti cha Idhini [kwa saina ukichagua kushiriki]

SEHEMU YA I: KARATASI YA HABARI

Utangulizi: Unaombwa kushiriki katika utafiti wa utafiti. Taarifa hii imetolewa ili kukuambia kuhusu utafiti. Tafadhali soma fomu hii kwa makini. Utapewa nafasi ya kuuliza maswali.

Kushiriki katika utafiti huu ni kwa hiari. Kusema hapana hakutaathiri haki zako za utunzaji wa afya au huduma zingine zozote. Matibabu/malipo au uandikishaji wako

katika mipango yoyote ya afya au ustahiki wa manufaa hautaathiriwa ukiamua kutoshiriki. Pia uko huru kujiondoa kutoka kwa utafiti huu wakati wowote. Ikiwa baada ya kukusanya data utachagua kuacha, unaweza kuomba kwamba maelezo uliyotoa yaharibiwe chini ya usimamizi. Hii itakuwa kabla ya data haijatambuliwa na kujumlishwa. Utaarifiwa iwapo taarifa mpya itapatikana kuhusu hatari au manufaa ya utafiti huu. Utapokea nakala ya fomu hii baada ya kusainiwa

Madhumuni ya utafiti: Kuamua viwango vya mavuno ya uchunguzi wa CTPA katika kuchunguza PE kwa lengo la kuamua chini ya / matumizi ya kupita kiasi kati ya wagonjwa wanaoshukiwa na PE katika MTRH.

Tovuti ya utafiti: Idara ya radiolojia na picha katika Hospitali ya Kufundishia na Rufaa ya Moi Eldoret, Kenya.

Idadi ya waliofanyiwa utafiti: Wagonjwa watu wazima wanaoshukiwa kuwa na embolism ya mapafu walitumwa kwa idara ya radiolojia kwa angiografia ya mapafu ya kompyuta.

Taratibu za utafiti: Wagonjwa wote waliorejelewa kwa idara ya radiolojia kwa CTPA watahojiwa na kupewa maelezo ya utafiti kwa nia ya kupata kibali cha habari. Data ya kibaolojia ya wagonjwa ikijumuisha umri na jinsia itapatikana. Historia ya kliniki itapatikana kwa kusesitiza dalili za kliniki kama kikohozi, maumivu ya kifua, ugumu wa kupumua na hemoptysis. Sababu za hatari kwa PE zitachunguzwa na kuonyeshwa ikiwa zipo au hazipo kwenye dodoso. Uwekaji alama za uwezekano wa kimatibabu utafanywa na wagonjwa kuainishwa kama uwezekano wa chini, wa kati na mkubwa wa PE. Vipimo vya D vitafanywa na mwishowe wagonjwa wote watapewa rufaa kwa angiografia ya mapafu ya CT.

Ukikubali utafanya yafuatayo: Utahitajika kujibu baadhi ya maswali yaliyopangwa kwa namna ya dodoso kama umri na jinsia .Historia ya kliniki yenye msisitizo wa dalili za kikohozi, maumivu ya kifua, ugumu wa kupumua na hemoptysis itapatikana na kujazwa. dodoso. Sababu za hatari kwa PE kama upasuaji wa awali, kutokuwa na uwezo, matumizi ya uzazi wa mpango, historia ya saratani itapatikana. Sampuli ya damu ya D Dimers itachukuliwa, hatimaye itatumwa kwa idara ya radiolojia kwa kipimo cha picha kiitwacho CTPA ambacho kitatumika kubaini kama una damu iliyoganda kwenye ateri zako za mapafu.

Manufaa: Huu ni mradi wa utafiti na matokeo yanaweza kutumiwa na usimamizi wa MTRH, watunga sera wa Serikali na watoa huduma za afya kubuni sera na mipango inayofaa ya kutoa huduma bora za afya kwa usimamizi wa PE. Kushiriki kwako kutatusaidia kupata ufahamu bora wa PE.

Hatari/Masumbuko: Ninafahamu ukweli kwamba baadhi ya maswali kuhusu ushiriki wa utafiti hayakufai. Kila kitu utakachoniambia kitawekwa siri. Kwa hali yoyote hatutaunganisha jina lako na data wakati wa kuchanganua na kusambaza matokeo ya utafiti.

Malipo na Marejesho: Hakuna malipo au fidia kwa kushiriki katika utafiti.

Usiri: Juhudi zote zinazofaa zitafanywa ili kuweka maelezo yako yaliyolindwa (ya faragha na ya siri). Kutumia au kushiriki (“kufichua”) kwa maelezo kama haya kutafuata miongozo ya faragha ya Kitaifa. Kwa kutia sahihi hati ya idhini ya utafiti huu, unatoa ruhusa ("idhini") kwa matumizi na ufichuaji wa maelezo yako ya utafiti. Huenda tukahitaji kushiriki habari zako zinazolindwa na bodi ya ushauri ya jamii, MTRH//MU-IREC, NACOSTI au timu ya afya. Tutahifadhi rekodi zako za utafiti kwa angalau miaka sita baada ya utafiti kukamilika. Wakati huo, taarifa za utafiti

huharibiwa [Mfahamishe mshiriki jinsi rekodi zitakavyoharibiwa]. Ukiamua kuondoa ruhusa yako ya kutumia data yako ya kibinafsi, wasiliana na [PI] kwa maandishi na uwajulishe uamuzi wako. Wakati huo, tutasimamisha mkusanyiko zaidi wa maelezo yoyote kukuhusu. Hata hivyo, maelezo ya afya yaliyokusanywa kabla ya uondoaji huu yanaweza kuendelea kutumika kwa madhumuni ya kuripoti na ubora wa utafiti.

[SI LAZIMA]: Kwa tafiti zinazohusisha nyenzo za kibaolojia, taja mahali pa kuhifadhi na taratibu na muda wa kushughulikia vielelezo.

[SI LAZIMA]: Kwa tafiti zinazohusisha wagonjwa, eleza kuwa maelezo yao yataongezwa kwenye rekodi zao za matibabu na kwamba taarifa zozote za utafiti zitakazowekwa kwenye rekodi zao za matibabu zitawekwa kwa muda usiojulikana.

[SI LAZIMA]: Una haki ya kuona na kunakili maelezo yako ya kibinafsi yanayohusiana na utafiti kwa muda wote ambao timu ya utafiti inashikilia maelezo haya.

Fidia ya jeraha: Katika tukio la jeraha linalotokana na kushiriki katika utafiti huu, gharama za matibabu zitalipwa kwa matibabu ya jeraha hilo.

SEHEMU YA PILI: RIDHAA YA MGONJWA:

Nimesoma au kuna mtu amenisomea maelezo ya utafiti huu. Mpelelezi au mwakilishi wake amenieleza utafiti na amejibu maswali yote niliyo nayo kwa wakati huu.

Nimeambiwa kuhusu hatari zinazowezekana, usumbufu, na manufaa yanayoweza kutokea (ikiwa yapo) ya utafiti. Ninajitolea kwa hiari kushiriki katika utafiti huu.

[Sehemu hii lazima iandikwe kama mtu wa kwanza. Iwapo mshiriki hajui kusoma na kuandika, au kwa sababu fulani hawezi kuandika, wanapaswa kutoa alama ya kidole gumba na shahidi mwenye uwezo lazima ashirikishwe wakati wa mchakato wa idhini]

Jina la Mshiriki

Sahihi ya mshiriki/Alama ya Kidole

Tarehe na Wakati

Jina la Shahidi [Sio lazima]

Sahihi ya Tarehe na Saa ya Shahidi

Jina la mtu anayepata

kibali Sahihi ya mtu

Tarehe & Saa

kupata kibali

Jina lililochapishwa la mpelelezi

Sahihi ya Tarehe ya Mpelelezi

DONDOO KUHUSU MASOMO KWA KUTUMIA RIDHAA/RIDHAA YA

MANENO:

Ridhaa ya mdomo/kibali kinamaanisha kwamba mtu anayepata kibali au kibali anaeleza kwa mdomo utafiti huo kwa kutumia karatasi ya taarifa ya utafiti, na kwamba watu walioidhinishwa wape kibali/kibali chao cha mdomo badala ya kibali cha maandishi kushiriki. Wapewe nafasi ya kuuliza maswali na kualikwa kuweka nakala ya karatasi ya taarifa za utafiti. PI inapaswa kuwasilisha nakala ya karatasi ya maelezo ya utafiti inayoonyesha hati hii ya idhini na jinsi timu ya utafiti itakavyoandika katika faili zao za utafiti wakati mjadala wa idhini ulifanyika, ni nani aliyefanya, na ikiwa kulikuwa na masuala yoyote yanayojitokeza.

Anwani kwa maswali kuhusu utafiti

Maswali kuhusu utafiti: PI Maelezo ya Mawasiliano [Jina: Joshat Sang, Nambari ya Simu: 0721 788 538; Barua pepe josphatsang20@gmail.com]

Maswali kuhusu haki zako kama mshiriki: Unaweza kuwasiliana na Kamati ya Maadili na Utafiti ya Kitaasisi (MTRH//MU-IREC) 0787723677 au barua pepe irec@mtrh.go.ke au irecoffice@gmail.com. MTRH//MU-IREC ni kundi la watu wanaopitia tafiti kwa ajili ya usalama na kulinda haki za washiriki.

APPENDIX VI:QUESTIONNAIRE

1 PATIENTS BIO DATA

Serial No. _____ Age _____ Gender Male _____ Female _____

2. CLINICAL HISTORY do you have the following symptoms (tick where applicable)

I.Difficulty in breathing yes ☐ no ☐

II.Chest pains yes ☐ no ☐

III.Cough yes ☐ no ☐

IV.Coughing out blood strained sputum yes ☐ no ☐

V.Others (specify).....

VI.None.....

3. RISK FACTORS (tick where applicable and specify)

I.Do you suffer a clot in your lower limb's vessels? yes ☐ no ☐

II.Have you ever suffered a clot in your lower limb vessels? yes ☐ no ☐

III.Have you been operated before? yes ☐ no ☐

IV.Any history of trauma? yes ☐ no ☐

V.Have you ever remained immobile for 3 or more consecutive days? yes ☐
no ☐

VI.Do you suffer from any cancer? yes ☐ no ☐

VII.Do you suffer from any blood clotting disorder? yes ☐ no ☐

VIII.Have you ever used birth control pills? yes ☐ no ☐

If yes specify

IX.Other(s).....

X.None

4. D dimers requested yes ☐ no ☐

D dimers level

5. Heart rate

6. Spo2

7. Revised Geneva score

Pulmonary Angiography Report

Clinical information:

Findings:

Lungs and airways-----

Pleura-----

Heart and pericardium-----

Mediastinum and hila-----

Chest wall and lower neck-----

Vessels

Aorta-----

Pulmonary arteries

Pulmonary embolus

(tick): present

Absent

If present, specify the location of pulmonary embolism. **(Tick and specify)**

Right Lung	Right	Lobar Arteries	Segmental /Sub
	pulmonary		segmental
	artery		arteries
Left lung	Left pulmonary		
	artery		

Main pulmonary artery

Other site (specify) -----

Evidence of acute pulmonary embolism?

Tick Yes

No

Evidence of chronic pulmonary embolism? Tick

Yes

No

Are there signs of right heart strain? Tick

Yes

No

State diameter in millimeters of:

MPA diameter/ AO diameter _____

Right ventricle diameter/left ventricle diameter _____

Other findings	PRESENT	ABSENT
-----------------------	----------------	---------------

1. Pulmonary artery enlargement
2. Hampton hump
3. Westermarck sign(oligemia)
4. Pleural effusion
5. Atelectasis
6. Consolidation
7. others specify

Conclusion (i) Normal

(ii)No pulmonary embolism

(iii)Pulmonary Embolism

(iv)Additional diagnosis

(v)Alternate diagnosis.

APPENDIX VII: REVISED GENEVA SCORES

Variable	Score
Age 65 years or over	1
Previous DVT or PE	3
Surgery or fracture within 1 month	2
Active malignant condition	2
Unilateral lower limb pain	3
Haemoptysis	2
Heart rate 75–94 beats per minute	3
Heart rate 95 or more beats per minute	5
Pain on deep palpation of lower limb and unilateral edema	4
0–3 Points indicates low probability.	
4–10 Points indicates intermediate probability.	
11 Points or more indicates high probability.	

Revised Geneva Score.

Variable	Score
Predisposing factors	
<i>Age > 65 years</i>	+1
<i>Previous DVT or PE</i>	+3
<i>Fracture or surgery in the previous month</i>	+2
<i>Active malignancy</i>	+2
Symptoms	
<i>Unilateral leg pain</i>	+3
<i>Hemoptysis</i>	+2
Clinical signs	
<i>Heart rate</i>	
75–94bpm	+3
≥95bpm	+5
<i>Pain in deep veins of lower limbs on palpation and unilateral edema</i>	+4
Total clinical probability	
<i>Low</i>	0–3
<i>Intermediate</i>	4–10
<i>High</i>	≥11

PE, pulmonary embolism; DVT, deep venous thrombosis; bpm, beats per minute.

APPENDIX VIII:STUDY TIME LINES

[illegible]

APPENDIX IX:BUDGET

Item.	Quantity	Cost per unit.	Total (Kshs)
Internet bundles.	50 GB	1000	Kshs.50000
Printing	5000pages	10	Kshs.50000
Photocopy	3000pages	5	Kshs.15000
Binding	20	500	Kshs.10000
Communication			Kshs 10000
Biostatistician	1	50000	Kshs 50000
Miscellaneous			Kshs.15000
Grand total.			Kshs.200,000