



**Clinical Characteristics of Pulmonary Thromboembolism and Rate of
Computed Tomographic Pulmonary Angiography Confirmation among
patients treated for Pulmonary thromboembolism at St Paul's Hospital
Millennium Medical College, Addis Ababa, Ethiopia**

By: Azazhu Datiko (MD)

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By: Azazhu Datiko (MD)

Advisors:

Dr. Afework Hagos (Internist, Consultant Hematologist)
Mrs. Fatimetu Mohammed (B.Sc. MPH)

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ACRONYMS

BP-Blood pressure

CTEP-Chronic thromboembolic pulmonary hypertension

CTPA -Computed tomographic pulmonary angiography

CUS -Compression venous ultrasonography

DVT-Deep vein thrombosis

E.C-Ethiopian calendar

ECG-Electrocardiography

Echo-Echocardiography

G.C-Gregorian calendar

HIMS - Health information management system

IRB – Institutional review board

MICU-Medical intensive care unit

PTE, PE–Pulmonary thromboembolism

PTP-Pretestprobability score (wells score)

RVI-Retroviral infection

SPHMMCS-Saint Paul’s Hospital Millennium Medical College

SPSS - Statistical Package for the Social Sciences

TB-Tuberculosis

VTE-Venousthromboembolism

ABSTRACT

BACKGROUND: Venousthromboembolism is a major cause of morbidity and mortality worldwide. It is also the most common complication in hospitalized patients. Although there is available data on clinical characteristics & use confirmatory Gold standard diagnostic modality of PTE in hospitalized patients in developed countries, there is a limited information in developing countries especially in Ethiopia

OBJECTIVE: To assess the clinical characteristics of Pulmonary thromboembolism& rate of Computed tomographic pulmonary angiography confirmation in inpatientstreated as PTE at St Paul's hospital millennium medical college

METHODS: A descriptive cross-sectional retrospective chart review study was done, Data from HIMS registration book who have been admitted to St Paul's hospital internal medicine departmentward and MICU with a diagnosis of PTE & those diagnosed to have PTE after admissionfrom January 2016 to December 2018 GCwere randomly selected. Datawas analyzed using SPSS version 25.0. Thedescriptive analysis was done by simple frequency & proportion &the resultsare presented by tables, graphs and pie chart.

RESULT: From a total 150 patients treated as PTEfrom January 2016 to December 2018 GC,64 cases were randomly selected for this study &58 cases who fulfil the inclusion criteria were analyzed.70.7 % (41) were females, the mean age was38.3($\pm$ 16 SD)&69% of the patients were under 40 years. The most common clinical presentations were dyspnea (96.6%)& chest pain (70.7%) & DVT was the common comorbidity (27.5%). Therate of CTPA confirmation was 71%(CTPA was done for 38 cases & it confirmed PTE in 27 cases (46. 6% of 58). 33.3%(n=9) of confirmed cases were cases of massive PTE. Wells score is documented in only 3 cases (5%)

CONCLUSSION& RECOMMENDATION:our study reported high rate of PTEamong the young and middle aged with female predominance of 70%.There is also underutilization of wells score &CTPA. 33.3% of confirmed cases were massive PTE.PTE presents in various clinical settings, and poses a great diagnostic challenge to the physician. A high degree of clinical suspicion with close observation of key clinical symptoms & signs, awareness & adherence to guideline directed workup is very important to properly identify &treat this entity.**Key words:** clinical characteristics, CTPA confirmation, PTE, Ethiopia.

1.INTRODUCTION

1.1 Background

Venous thromboembolism (VTE) which encompasses deep venous thrombosis (DVT) & its complication pulmonary thromboembolism (PTE) is a major cause of morbidity and mortality worldwide. It is also the most common complication in hospitalized patients in high income settings [1,2]. Pulmonary thromboembolism (PTE) is a common clinical disorder associated with high morbidity and mortality [1]. Pulmonary embolism is the third most common acute cardiovascular disease after myocardial infarction and stroke and results in thousands of deaths each year because it often goes undetected [3,4].

The overall economic burden of pulmonary embolism in the United States is estimated to be over \$1.5 billion a year in healthcare costs. Some estimates suggest that pulmonary embolism results in healthcare costs of more than \$30,000 per incident [5]. Several studies have determined that prevention of pulmonary embolism in hospitalized patients is cost-effective, costing just \$3,000 per pulmonary embolism event avoided [6,7].

It displays geographical and ethnic differences [8, 9]. In Europe PTE is a major public health burden [10]. In the USA it is estimated that the annual incidence of PE is 1–2 per 1000 persons [11]. Although there is limited data in Africa, existing data show that its prevalence & mortality is higher than Europeans & Asians [12].

In Sub-Saharan Africa, with changing lifestyles and increase in cardiovascular risk factors rise in its prominence is largely expected. Preliminary reports indicate that it is not uncommon. In Cameroon, for example, it accounts about 40% of the VTE in-hospital incidence of 4.4 per 1000 admissions [1,13,14].

In Kenya, it is a frequent cause of cardiovascular death [15].

VTE is a multifactorial condition resulting from a complex interaction between genetic predispositions and acquired risk factors, leading to thrombosis and subsequently embolism [16]. although there is no published study about PTE in Ethiopia, one small study done on DVT in Tikur anbessa tertiary hospital shows that the major risk factors were malignancy, immobilization, pregnancy related & trauma [17]. Pulmonary embolism (PE) is a potentially life threatening clinical condition that is fairly non-specific in presentation; sharing

overlapping features with various other clinical conditions including acute myocardial infarction, pneumonia, chronic obstructive pulmonary disease and even anxiety spectrum disorders. some patients may even present with sudden cardiac arrest or syncope& sudden unexplained death [18,19,20]. Massive PE which is PE with hypotension is associated with a 30% mortality and where PE causes cardiac arrest the associated mortality may be as high as 95%. [21,22]

Since it is a disease with high morbidityand mortality if not treated, early diagnosis& proper management isof vital importance. CTPA- gold standard confirmatory diagnostic test for PE should be performed selectively in patients in whom there is high likelihood of PE b/c of logistic restrains, may be expensive, not alwaysavailable, has risk of radiation, contrast exposure&its yield may be low in some patients [19,23,24,25]

Since CTPA can only be used conservatively, the use of pretest score (wells score) in conjunction

with D-dimer levels can be a useful guide for patient selection and for all patients with possible PE should have wells score documented. [19,25]. If CTPA is not available,Echocardiographic examination is recommended as part of thediagnostic work-up for patients with suspected PE with hypotension (massive PTE) in which the absence of echocardiographic signs of RV overload or dysfunction practically excludes PE as the cause ofhemodynamicinstability&also echocardiography maybe of further help in the differential diagnosis of the cause of shock,by detecting pericardial tamponade, acute valvar dysfunction, severe global or regional LV dysfunction, aortic dissection, or hypovolemia. It also justifies emergency reperfusion treatment for PE if immediate CT angiography is not feasible [19,23,25]. If echo is also not available, presence of leg DVT on CUS can confirm PTE in any patient suspected of PTE [19,23,25].

1.2 Statement of the problem

VTE globally is the third most common acute cardiovascular disease after myocardial infarction and stroke and results in thousands of deaths each year because it often goes undetected. Pulmonary thromboembolism (PTE) is a common clinicalcardiovascular disorder associated with high morbidity and mortality[3].

According to European guideline, Massive PE which is PE with hypotension is associated with a 18%-65% mortality and where PE causes cardiac arrest, the associated mortality may be as high as 95%.sub massive PE is associated with 5-25% mortality but with proper treatment this mortality is decreased to < 20% for massive PE & <8% for submassive PE. About 4% of patients with PTE will develop chronic thromboembolic pulmonary hypertension (CTEP) resulting in chronic exertional dyspnea & Cor pulmonale, there is also ~8% rate of recurrence at one year.

According to Frederikus et al, this adverse outcomes (death, recurrent PTE & CTEP) occurs in half of PTE patients within 04 years of follow-up [19,25].

The hospital prevalence of PTE in developed countries is <1 % & in developing countries like in Africa, the prevalence, the morbidity & mortality is higher than the estimates in Europe. and this may be due to failure of early proper diagnosis & management [12,67]

Since it is a disease with high morbidity & mortality & its prognosis depends on its presentation (massive vs submassive) and proper management, data on its characteristics & early diagnosis (clinical suspicion & imaging) is very important to prevent this adverse outcome.

As many studies done abroad shows, PTE is not a rare disease in hospitalized patients though there is inter set up variability. Nowadays it is not unusual to encounter patients with the diagnosis of PTE on treatment without confirmatory diagnosis & there are also death reports ascribed to PTE in St Paul Hospital Millennium Medical College. If it is due to high exact prevalence or over diagnosis is not studied.

1.3 Significance of the study

The aim of the study is to identify the clinical characteristics & rate of CTPA confirmation in patients treated as PTE, assess the rate of use of clinical decision rules for all suspected cases of PTE, suggest evidence based workup & create awareness to health professionals and policy makers. This will be the first study to be done in our hospital with this title and help as a stepping stone for future interventional studies.

2. LITERATURE REVIEW

2.1 PTE& its characteristics

pulmonary thromboembolism refers to obstruction of the pulmonary artery or one of its branches by thrombus (clotted blood) that originated elsewhere in the body [19,25].

Venous thromboembolism (VTE) which encompasses DVT & its complication PTE is a major cause of morbidity and mortality worldwide. The Global Burden of Diseases, Injuries, and Risk Factors (GBD) Study 2010 documents that VTE causes a major burden of disease globally following ischemic heart disease & stroke [34]

It is also the most common complication in hospitalized patients in high income settings [1,2]. The epidemiology of PE is difficult to determine because it may remain asymptomatic, or its diagnosis may be an incidental finding & in some cases, the first presentation of PE may be sudden death [27-30,35].

A 25-year retrospective chart review study at Olmsted county Minnesota 1966-1990 among patients with diagnosis of PTE, the incidence of PE was determined according to age, sex, and race. The incidence of PE was 400 of 175,730 (0.23%; 95% CI, 0.21 to 0.25%). The incidence was linearly related to age ($r = 0.94$). African Americans showed an incidence of 0.26%, and whites showed an incidence of 0.21% ($p < 0.05$) [66]

A 21-month prospective study at a tertiary care general hospital shows that The estimated prevalence of acute PE in hospitalized patients was 526 of 51,645 (1.0%; 95% confidence interval [CI], 0.9 to 1.1 %). Based on extrapolated data from autopsy, PE was estimated to have caused death in 0.2%; 95% CI, 0.19 to 0.29%). [8]

Although there are limited data in Africa, a systematic review of African continental studies (one prospective cohort study, two case-control studies, and 18 cross-sectional studies) show that the prevalence of pulmonary embolism (PE) in medical patients varied between 0.14% and 61.5%, highest among TB & COPD patients with a mortality rate of PE between 40% and 69.5%. The case-fatality rate after surgery was 60% [12]

A 5-year retrospective study (January 2005 - December 2009) done in Kenya tertiary hospital on pattern of PTE of 128 cases shows that the mean age at diagnosis was 40.8 years (range 5–86 years) with a peak between 30 and 50 years. Male: female ratio was 1:1.13. All the patients were treated with anticoagulants and thrombolytic with only one having embolectomy. Ninety-two patients (71.9%) recovered, 18.8% of them with Cor pulmonale, while 28.1% died. Common comorbidities were DVT (36%), HIV (10.9%) & TB (12.5%) [67]

A 6 year & 4 months descriptive cross-sectional study done in Cameroon tertiary hospital concluded that among VTE patients (78 cases), almost half are PTE (41 cases) & the most clinical presentation is dyspnea (80%), chest pain (65%), syncope (9.8%), shock (4.9%) obesity & HTN (in 29% of VTE patients) are main comorbidities. DVT with PTE occurred in 12.8% & there were 10% in hospital deaths [71]

PE has a wide variety of presenting features, ranging from no symptoms to shock or sudden death [27-30]. The most common presenting symptom is dyspnea followed by chest pain (classically pleuritic but often dull) and cough. However, many patients, including those with large PE, have mild or nonspecific symptoms or are asymptomatic. For example, a meta-analysis of 19 studies (25,343 patients) found that clinical impression alone had a sensitivity and specificity of 85 and 51 percent, respectively, for the diagnosis of PE [31]. Thus, it is critical that a high level of suspicion be maintained such that clinically relevant cases are not missed.

The most common symptoms in patients with PTE were identified in the Prospective Investigation of Pulmonary Embolism Diagnosis (PIOPED) group a multicenter (8 centers) study in different countries in Europe 2001-2003. GC sample size of 365 (117 PTE cases & 248 non PTE). Includes: Dyspnea at rest or with exertion (73 percent), Pleuritic pain (66 percent), Cough (37 percent), Orthopnea (28 percent), Calf or thigh pain and/or swelling (44 percent), Wheezing (21 percent), Hemoptysis (13 percent). They were 54 ± 17 years of age (mean $\pm$ standard deviation) & 49% of the cases were male patients. [28].

Less common presentations include transient or persistent arrhythmias (e.g. atrial fibrillation), presyncope, syncope, and hemodynamic collapse (<10 percent each) [32,33].

The onset of dyspnea is frequently (but not always) rapid, usually within seconds (46 percent) or minutes (26 percent) [30]

Importantly, symptoms may be mild or absent, even in large PE [27,30,35]. Although the true incidence of asymptomatic PE is unknown, one systematic review of 28 studies found that, among the 5233 patients who had a deep vein thrombosis (DVT), one-third also had asymptomatic PE [35].

Common presenting signs on examination include:

Tachypnea (54-70 percent), Calf or thigh swelling, erythema, edema, tenderness, palpable cords (47 percent), Tachycardia (30 percent), Rales (18 percent), Decreased breath sounds (17 percent, an accentuated pulmonic component of the second heart sound (15 percent), Jugular venous distension (14 percent), Fever, mimicking pneumonia (3 %) [28,30]

PE is a common cause of sudden cardiac arrest or circulatory collapse (8 percent), especially among patients younger than 65 years old [8,30,65]. Among such patients, either dyspnea or tachypnea is present in 91 percent. Massive PE may be accompanied by acute right ventricular failure manifested by increased jugular venous pressure, a right-sided third heart sound, a parasternal lift, cyanosis, and obstructive shock. However, shock may also develop in patients with smaller PE who have severe underlying pulmonary hypertension. these are considered massive PTE, has mortality of 30-50% compared to sub massive PTE whose mortality is 10-30% which can be decreased by systemic thrombolytic&anticoagulation. [19]

Laboratory tests are not diagnostic but alter the clinical suspicion for PE, confirm the presence of alternative diagnoses, and provide prognostic information in the event that PE is diagnosed

Electrocardiogram (ECG) abnormalities, although common in patients with suspected PE, are nonspecific [29]. The most common findings are tachycardia and nonspecific ST-segment and T-wave changes (40-70 percent) [28,29]

Abnormalities historically considered to be suggestive of PE (S1Q3T3 pattern, right ventricular strain, new incomplete right bundle branch block) are uncommon (less than 10 percent) [36,37]

In the Cameron study, among the 41 PTE cases ECG was done for 37 cases & the common ECG findings were sinus tachycardia 46.3%, anterior T wave inversion 31.7% & S1Q3 pattern 26.8% [71].

Chest radiograph — Nonspecific abnormalities on chest radiography are common (eg, atelectasis, effusion) in PE, but a normal chest radiograph can be seen in 12 to 22 percent of patients [25,29,38]

PE is stratified into massive &sub massive based upon the presence or absence of hypotension and right ventricular dysfunction or dilation. This stratification is associated with mortality risk [39,40]

2.2 Wellsscore &rate of CTPA confirmation

Different guidelines& studies recommend that Whenever PE is suspected, pretest score like the Wells score has to be done [31,41,42,43-48]. when combined with D dimer, wells score hashigh specificity [31,48] and increase the diagnostic yield of CTPA [62]

Despite validation of the Wells criteria, for unclear reasons, clinicians do not use them or use them incorrectly in 50 percent of patients [63,74]. In addition, they may not be as accurate in older patients [46]. Wells criteria have best validated in outpatients presenting with suspected PE. However, a system review of hospitalized patients (12 studies encompassing 3,942 hospitalized patients) reported walls score of ≤ 4 has a sensitivity and specificity of 72 and 62 percent, respectively [49]; the addition of D-dimer improved the sensitivity and specificity to 99 and 11 percent, respectively.

European PTE guideline &British thoracic society recommend that for patients in whom the probability of PE is high or in whom the suspicion is low or moderate and the D-dimer level is elevated (≥ 500 ng/mL [fibrinogen equivalent units]), CTPA should be performed [19,25]

Support for preference of CTPA-based algorithms is derived from a prospective, multicenter cohort study (Christopher study) Netherlands, 12 centers 2002-2004 of 3306 patients with clinically suspected PE [41]. Patients were from an inpatient or outpatient setting and categorized according to the modified Wells score as PE "likely" (score >4) or PE "unlikely" (score ≤ 4). Patients classified as PE unlikely underwent sensitive D-dimer testing; PE was considered excluded when the D-dimer level was <500 ng/mL (fibrinogen equivalent units). PE unlikely patients who had a D-dimer level ≥ 500 ng/mL (fibrinogen equivalent units) and PE likely patients underwent CTPA. When the CTPA confirmed PE, patients were anticoagulated; when it

excluded PE or was inconclusive (rarely), patients were not treated. At three months' follow-up, the rates of venous thromboembolism during follow-up were low, as evidenced by the following:

- ✓ Among 1028 untreated patients in whom PE was excluded by clinical assessment plus D-dimer testing, there was one DVT (0.1 percent), four nonfatal PE (0.4 percent), and no fatal PE.
- ✓ Among 1436 untreated patients in whom PE was excluded by CTPA, there were eight DVT (0.6 percent), three nonfatal PE (0.2 percent), and seven fatal PE (0.5 percent).
- ✓ Among 674 treated patients in whom PE was detected by CTPA, there were six DVT (0.9 percent), three nonfatal PE (0.4 percent), and 11 fatal PE (1.6 percent).

A similarly designed prospective, multicenter study (Belgium, France, Netherlands & Switzerland b/n January 1 2010 & February 28, 2013)

of 3346 patients with suspected PE in an emergency department setting reported comparable results using age-adjusted D-dimer cutoffs (ADJUST-PE) [50]. In ADJUST-PE, patients were classified as PE unlikely or likely. Those who were PE unlikely underwent age-adjusted D-dimer testing (age [if over 50] multiplied by 10 [e.g., normal D-dimer at 60 years is <600 mg/mL]). When the age-adjusted value was negative, no further testing was performed. All other patients underwent CTPA. When CTPA was positive, PE was confirmed and when CTPA was negative. At three months' follow-up, rates of venous thromboembolism were low, as evidenced by the following:

- ✓ Among the 1141 untreated patients in whom PE was excluded by clinical assessment plus age-adjusted D-dimer testing, there were only two cases (0.2 percent) of nonfatal PE. Compared with using a fixed D-dimer level of <500 mg/mL, use of age-adjusted cutoffs resulted in a 12 percent increase in the number of patients in whom a diagnosis of PE could be safely excluded without further imaging.
- ✓ Among the 673 untreated patients ≥ 75 years in whom PE was excluded by clinical assessment plus age-adjusted D-dimer testing, there were no thromboembolic events.
- ✓ Among the 1481 untreated patients in whom PE was excluded by CTPA, there was one DVT (0.1 percent), four cases of nonfatal PE (0.2 percent), and two indeterminate events.

Most studies report that CTPA is >90 percent sensitive and specific for the diagnosis of PE especially in the low and intermediate clinical risk groups. The highest sensitivities are reported when CTPA is combined with a moderate to high clinical probability assessment for PE (≥ 96 percent), but lower for those with a low suspicion for PE [51,64]. The PIOPED II study reported that the sensitivity and specificity of multidetector CTPA was 83 (90 percent when combined with high suspicion) and 96 percent, respectively, using catheter-based pulmonary angiography as the reference standard. PIOPED II also highlighted the influence of clinical probability on the predictive value of MDCT. In patients with a low or intermediate clinical probability of PE as assessed by the Wells rule, a negative CT had a high negative predictive value for PE (96% and 89%, respectively), whereas this was only 60% in those with a high pre-test probability. The rate of PTE confirmation in moderate & high clinical probability PTE is 92% & 96% respectively [51].

However, numerous cohort studies that use technically advanced scanners and specific CTPA protocols have since consistently reported a low incidence (<2 percent) of PE in patients with low to moderate clinical suspicion and a negative CTPA [52-56]. Nevertheless, there is a risk of PE in those with a negative CTPA and a high clinical suspicion for PE (up to 5 percent when a ≤ 64 detector row multidetector CT [MDCT] is used) [57].

One commonly cited benefit of CTPA is its ability to detect alternative pulmonary abnormalities that may explain the patient's presenting symptoms and signs [58-61]. In one observational study, 9 percent of CTPA examinations confirmed PE, while 33 percent identified an alternative cause of the patient's symptoms [60]. In another retrospective review of 641 patients who underwent CTPA for suspected PE, an alternate diagnosis was discovered in 14 percent of patients who did not have PE, and 15 percent of these findings required immediate attention [61].

Also there are many pretest scoring systems to be used, the wells score is good one b/c it is simple and based on information that is easy to obtain; on the other hand, the weight of one subjective item ('alternative diagnosis less likely than PE') may reduce the inter-observer reproducibility of the Wells rule. the proportion of patients with confirmed PE can be expected to be around 10% in the low probability category, 30% in the moderate-probability category,

and 65% in the high-clinical probability category when using the three-level classification. When the two-level classification is used, the proportion of patients with confirmed PE in the PE-unlikely category is around 12%. [68]

A study done in Turkey on emergency 196 suspected cases of PTE, comparing 4 scoring rules (empirical, Geneva, Wells & Miniati) included 107 males (54.6%) and 89 females (45.4%) suspected of PE. It was concluded that the Wells method was found to have the highest specificity. There was no PE in any patient with a normal D-dimer level and a low probability score in any scoring system. [69]

Miniati et al compared the performance of 3 models in 215 consecutive patients (both in & outpatients) with suspected pulmonary embolism in Italy in 2017. The clinical probability predicted by the models was categorized as low, intermediate, or high. In all patients, pulmonary angiography was used as the reference diagnostic standard. The frequencies of pulmonary embolism in the low, intermediate, and high probability categories were compared. In low probability score is The Wells score has the highest negative predictive value of the three models 88% (95% CI, 77%–94%) highest of the three models The positive predictive values of the Wells model were 64% [70]

Since the introduction of multi-detector computed tomographic (MDCT) angiography with high spatial and temporal resolution and quality of arterial opacification, computed tomographic (CT) angiography has become the method of choice for imaging the pulmonary vasculature in patients with suspected PE. [19,23,25]

Studies on characteristics of PTE (massive & submassive), rate of use of clinical pretest scores (Wells score) to diagnose PTE & use of confirmatory CTPA is a neglected topic in our country and in our hospital in particular. So this study will help understand the clinical characteristics of PTE in our hospital & rate of CTPA confirmation in patients treated as PTE. Above all it paves the way for future interventional studies.

3.OBJECTIVES

3.1 General objective

- Asses the clinical characteristics&rate of CTPA confirmation in inpatients treated as PTE at SPHMMC

3.2 Specific objectives

- To describe the clinical presentation of PTE
- To determine the rate of CTA confirmation in patients treated as PTE
- To assess the rate of use of wells score for diagnosis of PTE
- To describe comorbidities

4. Methodology

4.1 Setting

This study was conducted in the in-patient department of internal medicine at SPHMMC. SPHMMC is one of the two biggest specialized referral hospitals in Addis Ababa and in the country at large. It is a hospital on fast expansion especially after it started working as a medical college since 2000 E.C/2007G.C. Currently it is a huge residency and sub specialization center in many fields. It is a center of excellence in medical services for renal center providing dialysis and also the first hospital in the country with renal transplantation center. one of the department is internal medicine with many subunits (nephrology, cardiology, gastroenterology

hematology, pulmonology& endocrinology). it has a burn, emergency and trauma center& also outreach services to fulfill the community demand in health. The hospital has over 45 beds in medical ward and 6 bed in ICU, with over 1200 admission per year. The study was conducted in medical ward and MICU.

4.2 Study design

Using descriptive cross-sectional retrospective study, Patient charts admitted to SPHMMC ward and medical ICU were collected using data from HIMS registration book, discharge summaries& death certificates. All patients admitted from January 2016 to December 2018 with a diagnosis of PE/PTE, patients admitted with other diagnosis but who are found to have PTE after admission started on treatment regardless of CTPA and patients whose cause of death is documented PTE were included & by using simple random sampling technique study subjects were selected. The study period was on Jun& July 2019GC.

4.3 Source population

All Patients above age of 16 years admitted to MICU and medical ward at St Paul hospital millennium medical college with a diagnosis of PTE, all patients in medical inpatient with diagnosis of PTE who started on treatment (regardless of imaging), patients whose cause of death is documented PTE from January 2016 –December 2018

4.4 Study population

Randomly selected patients from the source population who are fulfilling the inclusion criteria.

4.5 Inclusion & exclusion criteria

4.5.1 Inclusion criteria

- age 16 years & above
- Patients admitted to the ward or MICU with admission diagnosis of PTE & started on treatment
- all patients after admission with other diagnosis but suspected to have PTE & started on treatment
- Patients who had chest imaging documented on the chart or obtained from electronic data from radiology department
- Patients with clearly known outcome (discharge or death)

4.5.2 Exclusion criteria's

- patients whose chart is lost

4.6 Sample size

As to the knowledge of the investigator, there are no published hospital based studies on PTE in Ethiopia, Abah et al. found a PTE prevalence of 0.96% among patients admitted to a Cameroonian hospital in Bamenda [65]. assuming prevalence of 0.96, taking margin of error 4% and 95% confidence (sample size, $n = Z^2(p(1-p)/d^2) = 1.96^2(0.96\%(1-0.96))/0.04^2 = 92$ b/c the source population is <10,000, there is a need to use population correction formula

sample size = $n / (1 + n/N)$ N-source population=150 , n=corrected sample size will be 58. d= margin of error=4%. Z = Confidence interval creep to 95% & CI = 1.96

P = Estimates prevalence (Abah et al. Prevalence of PTE is 0.96% among patients admitted to a Cameroonian hospital in Bamenda 2016). considering non response rate of 10%, the final total sample size is 64.

4.7 Sampling technique:

First the card number of all admitted patients with diagnosis of PTE from January 2016-december 2018 GC were identified, then by using simple random sampling study subjects were selected.

4.8 Data collection:

Data was collected by two trained data collector's (medical residents) & the principal investigator after being trained ahead of data collection. Data collection was done on Jun & July 2019 GC after retrieving patient cards from card room. By using format containing important variables the data was collected.

4.9 Study variables

- ✓ clinical characteristics of PTE
- ✓ rate chest CT angiography confirmation of PTE
- ✓ Age
- ✓ sex
- ✓ wells score / pretest score
- ✓ co morbidity

4.10 Operational Definitions

- **chest CT angiography confirmation of PTE-** radiology comment suggestive of pulmonary embolism.
- **Clinical decision rule/ wells score-** pre CTPA test scoring
- **DVT-** is defined as a case identified for having the disease by the clinician
- **Massive PTE-** case of PTE with BP < 90/60 mmHg at the time of diagnosis
- **PTE-** is defined as a case identified for having the disease by the clinician
- **Submassive PTE-** PTE with BP ≥ 90/60 mmHg
- **sudden cardiac arrest/sudden death-** is defined as a diagnosis labeled by a clinician
- **Rate of CTPA confirmation-** proportion of CTPA confirmed cases of PTE for whom CTPA was done from January 2016–December 2019 GC.

4.11 Data Processing and Analysis:

The data was analyzed by using SPSS version 25.0 software. The data was cleaned and rechecked for its consistency. The descriptive analysis was done by simple frequencies and proportions, and the results are presented by tables, pie charts and graphs.

4.12 Ethical clearance:

The study was conducted after ethical clearance is obtained from the college institutional review board(IRB).Confidentiality of information collected from charts was respected and only used for this study purpose.

4.13 Dissemination:

The results of this study will be presented as one of the partial fulfillments of residency program in internal medicine department.The manuscript will also be sent to local journals for possible publication.

5. RESULTS

5.1. Sociodemographic characteristics

From a total of 150 cases documented PE, 64 cases were randomly selected for the study. From this 6 cases were excluded (b/c we couldn't get their charts). Then, 58 patients treated for PTE from January 2016 –December 2018 were analyzed. out of this 70.7 % (41) were females and 21.1%(17) were males, giving male to female ratio 1:2.4. The mean and median ages of years 38.3 ± 16 SD and 33 years respectively. The minimum age was 18 & the maximum was 80 years. The majority (69%) of the patients were aged under 40 years, of this 46.6% were in the 31-40 years' age group. These patients were hospitalized in the internal medicine ward 33 cases (56.9%) and in the ICU 25 cases (43.1%).

The diagnosis of PTE was made at the time of admission in 35 (60.3%) patients & after admission in 23(39.7%) of patients. Table 1 shows the sociodemographic characteristics of the study subjects.

Table 1: sociodemographic characteristics of patients treated for PTE at SPHMMC Jan 2016-Dec 2018(N=58)

sociodemographic characteristics		Frequency	Percent(%)
Age category	16-30	27	46.6
	31-40	13	22.4
	41-50	5	8.6
	51-60	5	8.6
	≥ 61	8	13.8
	Total	58	100
Sex	Male	17	29.3
	Female	41	70.7
	Total	58	100
Timing of diagnosis of PTE	At admission	35	56.9
	After admission	23	39.7
Site of admission	MICU	25	43.1%
	Medical ward	33	56.9%

5.2. Clinical characteristics (symptoms, signs)

At the time diagnosis of PTE made, the most common presentations were dyspnea in 56(96.6%) cases, chest pain in 41 (70.7%) cases& hemoptysis in 15(25.9%). Sudden cardiac arrest occurred in 1 patient (1.7%). On physical examination, 19(32.9%)patients were hypotensive (BP< 90/60) & the majority of patients were tachypnea(94.8%),tachycardia (82.8%)&desaturation(91.1%).Table 2 shows the symptoms & signs of the patients.

Table 2: symptoms & signs patients treated for PTE at SPHMMC from January 2016-dec 2018 (N=58)

Symptoms and signs		Frequency	Percent
Dyspnea	Yes	56	96.6
	No	2	3.4
Chest pain	Yes	41	70.7
	No	17	39.3
Hemoptysis	Yes	15	25.9
	No	43	74.1
Cough	Yes	7	12.1
	No	51	87.9
Leg swelling	Yes	5	8.6
	No	53	91.4
Easy fatigability	Yes	2	3.4
	No	56	96.5
Syncope	Yes	1	1.7
	No	57	98.3
Sudden cardiac arrest	Yes	1	1.7
	No	57	98.3
BP	< 90/60	19	32.8
	≥ 90/60	39	67.2
PR	≤ 100	10	17.2
	>100	48	82.8
RR	≤ 20	3	5.2
	>20	55	94.8
SO ₂	<90	53	91.4
	≥90	5	8.6

5.4. Rate of use of pretest score (wells score)

Among the patients treated for PTE, it is in only 3 cases (5.2%) that wells score is documented on the chart. The 3 patients had wells score of 4, 5.5 & 6. In All of the 3 patients,CTPA was not done.

5.3. Rate of CTPA confirmation& other investigations

Among the 58 patients treated as PTE, CTPA was done for only 38 patients (65.5%). From the 38 patients,10 patients were hypotensive at presentation &27 patients (46.5% of total, 71% of the 38)wereCTPA confirmed cases of PTE.from which 6 patients (10.3%) were male & 21 patients (36.2%) were females. In the 10hypotensivepatients, CTPA confirmed the presence of PTE in 9 cases (33.3% of confirmed cases, 15.5%of the study subjects). The rate of CTPAconfirmation in clinically diagnosed PTE patients is 71%(27/38).Among the 20 patients for whom CTPA was not done, 3 patients have AKI, 3 patients can't afford the investigation & in the remaining 14 cases there is no documented reason why CTPA was not done.ECG was performed in 32(55.2%) patients& it is abnormal in 27 cases (84,3%). The most frequent findings were sinus tachycardia in 18(56.2% of ECG cases ,18/32),anterior T-wave inversion (RV strain) in 9 (28%) cases and S1Q3T3 pattern in 2 cases (6.25%).Of the 27confirmed cases, ECG was done for 15 patients & the most common findings were sinus tachycardia 7cases (46.7%,7/15, 4 cases have isolated sinus tachycardia, 2 cases have sinus tachycardia with RV strain & 1 case sinus tachycardia with S1Q3T3) &RV strain 5 cases (33.3%, 5/15. 2cases have isolated RV strain; 2 cases have RV strain with sinus tachycardia & 1 case has RV strain with S1Q3T3) & S1 Q3 T3 is found in 2 cases (1 case with sinus tachycardia & in the other with RV strain.) & in 3 cases the ECG was normal.See table 3& figure 1.

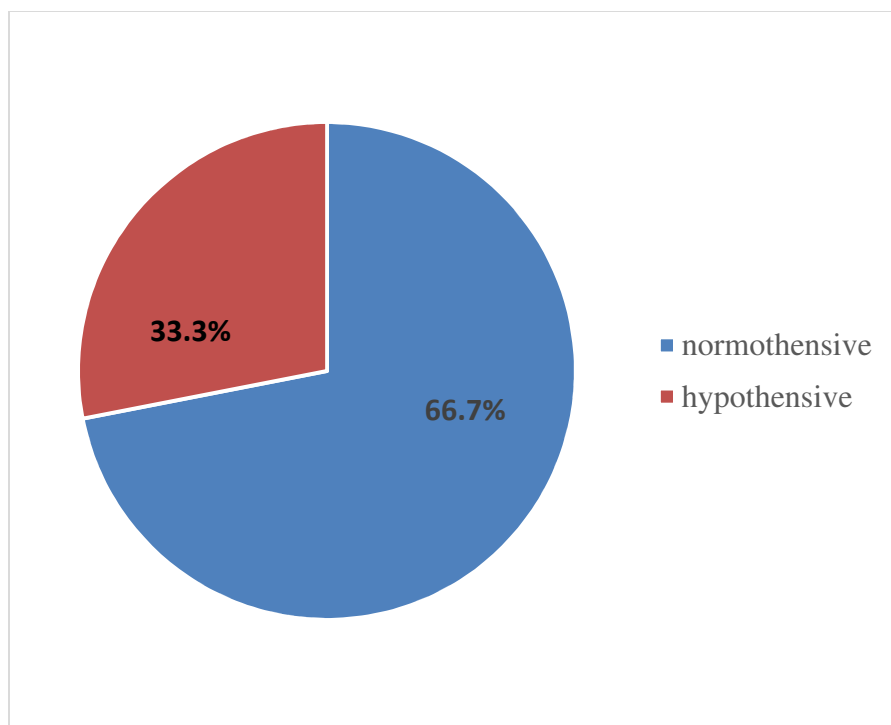


Figure 1:BP at presentation of CTPA confirmed cases of PTE (n=27)

Table 1: ECG finding of the study subjects for whom ECG was done at SPHMMC Jan2016-Dec 2018(N=32, confirmed cases n=15)

	Finding	Frequency	Percent(%)
ECG finding for treated as PTE	Normal	5	15.6
	Isolated Sinus tachycardia	15	46.9
	Only RV strain	6	18.7
	RV strain + sinus tachycardia	2	6.25
	RV strain +S1Q3T3	1	3.125
	Sinus tachycardia+S1Q3T3	1	3.125
	Atrial fibrillation	2	6.25
	Total ECG done	32	100
ECG finding in	Normal	3	20
	Isolated Sinus tachycardia	4	26.7
	RV strain	2	13.3

confirmed cases	RV strain + sinus tachycardia	2	13.3
	RV strain + S1Q3T3	1	6.7
	Sinus tachycardia + S1Q3T3	1	6.7
	Atrial fibrillation	2	13.3
	Total	15	100

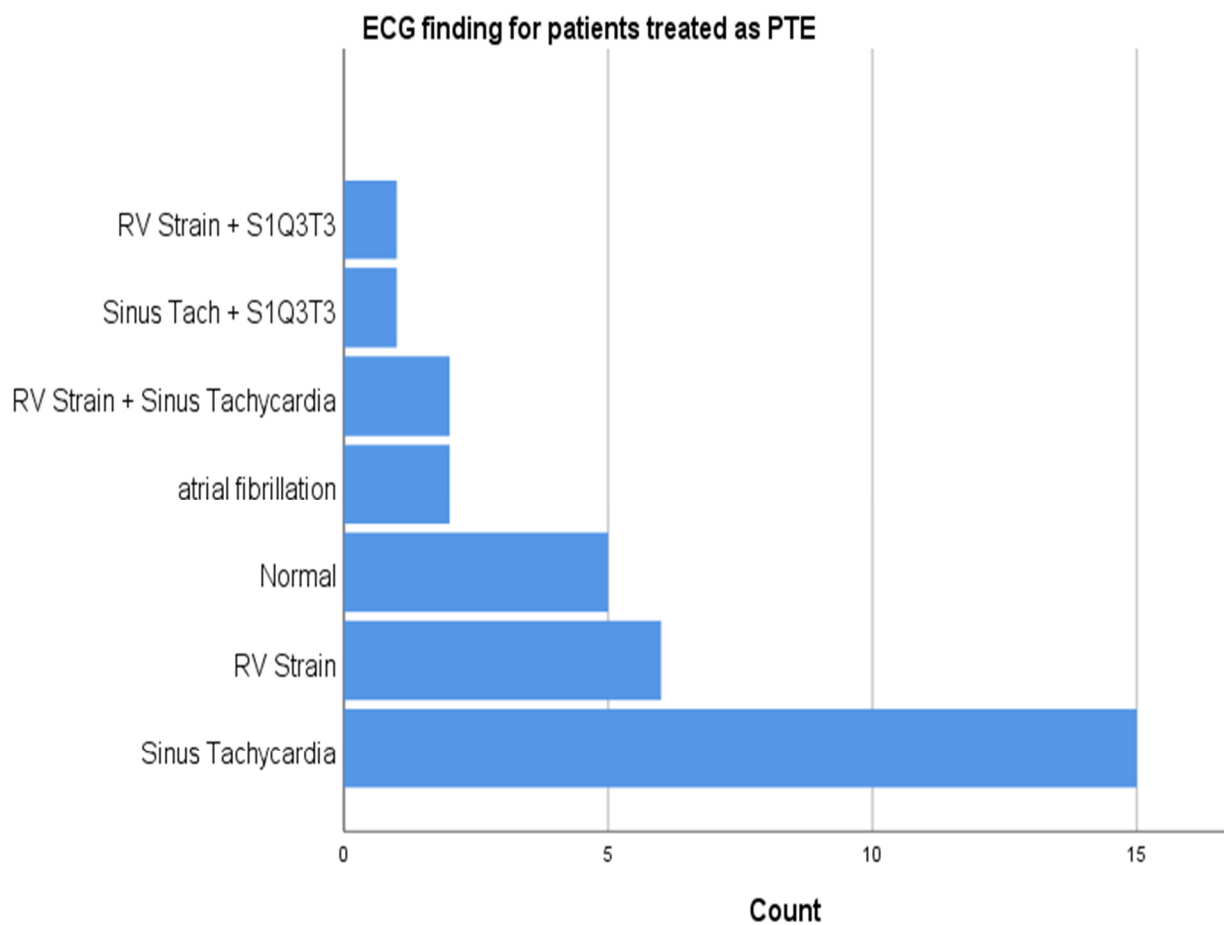


Figure 2: ECG finding of study subjects

CUS was done for a total of 19 patients (32.7%). From this 16 patients (27.5%) have DVT & 3 patients have normal CUS. From this, CTPA confirmed cases account for 2 normal CUS & 4 DVT cases (14.8%)

Echocardiography was done for 28 patients (48.3%) from which 14 patients (50%, 14/28) were CTPA confirmed cases & the most common finding was pulmonary hypertension found in 9 cases of the study (15.5% which is equivalent to 32% of echo findings) & in 5 cases (35.7%) of CTPA confirmed cases., Cor pulmonale was found in 2 patients (14.3%) of CTPA confirmed cases for whom Echocardiography was done. Table 4: shows Doppler us & echocardiography of the patients.

Table 4: Doppler us & echocardiography of study patients at SPHMMC Jan 2016- Dec 2018GC

	Finding	frequency	Percentage
DOPPLER US OF LEG	Normal	3	16
	DVT	16	84
	Total	19	100
ECHOCARDIOGRAPHY	Normal	8	28.5
	Cor pulmonale	5	17.8
	Pulmonary HTN	9	32.2
	Others(VHD,IHD)	6	21.4
	Total	28	100

Others = VHD (valvar heart disease), IHD (ischemic heart disease), DCM (dilated cardiomyopathy)

For patients with hypotension (19 patients=32.7%) at presentation, CTPA was not done in 9 patients (15.5%). Among these 9 patients neither CUS nor echocardiography was done for 3 patients (5%), echo is done for 1 patient & it showed rheumatic valvar heart disease & CUS was done for 5 patients which shows DVT.

5.4. Comorbidities & other characteristics

Among the comorbidities in patients treated as PTE, 16 patients have DVT (27.5%), 5 (8.6%) patients have tuberculosis (1 patient is RVI with TB), 7 (12.1%) patients have malignancy, 3 patients have AKI, 3 patients have valvar heart disease (2 chronic rheumatic & 1 degenerative

valvar heart disease), 2 patients have stroke&HTN (3.4%), 2 patients have ADPKD. 15patients(25.8%) were post-partum& 13 (22.4%)patients were in post-operative period.

Even in the CTPA confirmed groups, the most common comorbidity was DVT in 4 cases (14.8%) & malignancy in 3 cases (11.1%).

Of the total 58 patients, 49 patients were discharged cases & 9 patients were deaths (15.5%). among the deaths, 3cases (5% total cases, 33.3% of PTEdeaths were from CTPA confirmed group).

6. DISCUSSION

The objective of this retrospective cross-sectional descriptive study was to describe the clinical characteristics & rate of CTPA confirmation of patients treated as PTE at SPHMMC. About 58 cases treated as PTE were analyzed, Majority of the patients were females (70.7%) & the most common age group was below 40(accounting for 69% of the cases.). The most common clinical presentation was dyspnea (96.6%) & chest pain (70.7%). The most common clinical findings were tachypnea (94.8%)&tachycardia (82.8%). During the time clinical diagnosis of PTE was made, 19 cases (32.7%)were hypotensive. Sinus tachycardia (with &without other ECG finding) was the most common ECG finding (56.3%)&DVT was the most common comorbidity (26.6%) followedby malignancy& tuberculosis. Wells score was documented in only 3 cases (5%).

Of the 58 cases, 27(46.6%) were CTPA confirmed cases of PTE(9 cases=33.3% were cases of massive PTE) & rate of CTPA confirmation was 71%(27 /38 from January 2016-december 2018GC).

Of the 58 cases, 49 patients were discharged cases& 9 patients were death cases (3 cases were from the CTPA confirmed group=11.1% of CTPA confirmed PTE,33.3% of PTE deaths)

Our study shows female predominance of 70%, this study is similar toOgeng'o et al. at Kenya tertiary referral hospital which reported female predominance of about 53.1%(67)& is different from that reported by Cameron tertiaryhospital (71) which reported male accounted for 53.8% of VTE cases.

The variation of PTE prevalence in relative to the mean age of our patients were similar to that of Ogengo'o et al. [67] who reported a mean 40.8 years & Nagamalesh etal (72) single center

prospective study in India reported that of the 31 patients enrolled in their study, 71% (n = 22) of the patients belonged to the age range 20–50.

But compared to PIOPED study (28) which reported mean age of 54 ± 17 years (mean $\pm$ SD), our patients are too young.

The majority being young in our study may be due to the majority of the cases were females & about 15 cases were in the post-partum which indicates females in the reproductive age group. Or it may be due to increment in prevalence among the young unlike told previously (disease of the old)

The clinical presentation & signs are nonspecific & are similar to those reported by Cameroon (71), U.M. Nagamalesh et al (72) & landmark trials like PIOPED (28) all reported the common presenting symptoms were dyspnea & chest pain accounting for >60% of the symptoms & tachypnea being the most common sign.

Massive PTE in our study among the CTPA confirmed cases is 33.3% which is higher than the 8% (9 of 117 cases) reported by PIOPED (28), the 4.9% (2 cases of 41) Duala hospital study in Cameroon (71) & 26% (8 cases of 31) by U.M. Nagamalesh et al (72). This may be due to late consideration of PTE in patients at high risk for PTE or it may be due to high prevalence of massive PTE in our setup b/c PTE has variety of clinical presentation which are unpredictable.

In our study, 25 cases (43%, confirmed cases were 11 = 19% of 58) were ICU admissions indicating cases of hemodynamically unstable patients & severe hypoxia requiring ventilator support. This is very higher than Korean tertiary hospital study which reports 4.8% (28 cases of 591 PTE admissions in a 10-year retrospective review (73) & Duala hospital Study-Cameroon which report 9.7% (4 cases of 41 PTE admissions.) (71). Although from the 25 cases, 14 cases were not CTPA confirmed cases, 11 cases (19% of 58) were CTPA confirmed cases of ICU admission indicating high rate of severe forms of PTE in our setup or presence of other comorbidities making the patient too critical b/c about 39.7% PTE (23/58) occurred after admission for other illness. This may also indicate our poor hospital based preventive strategies of VTE.

Regarding rate CTPA confirmation, from our study, the rate of confirmation was 71% (only 27 out of 38 cases for whom CTPA was done were CTPA confirmed) which is very lower than that of PIOPED study (30,51) (rate of confirmation was 92-96%), Christopher study (41) rate of confirmation was 99.3%, study done in Cameroon (71) rate of confirmation was 94.6%. The

lower confirmatory rate in this study may be due to the poor guideline directed investigation of patients by their physicians or maybe they were critical having other comorbidities mimicking PTE (b/c 25 cases of the 58 Patients were medical ICU Admissions.) & absence of investigation like D-dimer which increases likelihood of PTE in moderate probability clinical PTE.

Another striking finding in this study was underutilization of wells score (done for only 5% of the cases). This is in opposite to landmark trials like the Christopher study (41), ADJUST-PE study (50) & PIOPED II study (51) in which in all patients suspected of PTE, pretest score (wells score) is done for every patient. Although studies on rate of use of wells score is scarce, a retrospective chart audit of 88 cases undergoing CTPA for suspected PTE at Timaru hospital New Zealand (74) identified that it is in only 3% of the cases that wells score is documented on the chart & about 26 scans were ordered inappropriately (had low wells score). They concluded that adherence to guideline recommendations may have reduced the total number of scans from 88 to 62, it is estimated that the positive yield of CTPA can improve from 14% to as high as 19%. This would improve cost effectiveness and reduce the risk of contrast and radiation exposure.

From our study, the low rate of use of wells score may be due to poor chart documentation or lack of knowledge about its importance & the lack of institutional guidelines.

The British Thoracic society (19) & the European PTE guidelines 2014 (25) recommends to have documentation of wells score in any patient suspected of PTE. They also recommend that echocardiography or CUS (leg venous Doppler u/s) must be done in all patients with hypotension & suspected of PTE who are unable to undergo CTPA. But in this study, in 3 cases initially presenting with hypotension, they have no CTPA, Echo or CUS.

These guidelines also recommend to give thrombolytic for patients with massive PTE but in my study about 9 cases were CTPA confirmed cases of massive PTE (33.3% of the confirmed cases, 15.5% of the total cases) & all were not given thrombolytic b/c it is not available in our hospital.

7. LIMITATION OF THE STUDY

Although attempts were made to elaborately discuss most of the clinical characteristics & issues concerned with diagnosis of PTE, it is a retrospective descriptive cross sectional chart review study & some of the investigations not documented may be lost. This study will not generalize to all Ethiopian hospitals b/c it is a single center study.

8.CONCLUSION

pulmonary thromboembolism (PTE) is lethal form of venous thromboembolism (VTE) commonly encountered in clinical practice.

PTE which was previously told disease of old and frail is now increasingly becoming common among the young and middle aged with female predominance of 70%. PTE still masquerades itself presenting in various clinical settings, and posing a great diagnostic challenge to the physician. About 43.1% cases PTE were MICU admissions, 39.7% were in hospital PTE & rate of CTPA Confirmation is 71%. High risk PTE (massive PTE) which accounted for 33.3% CTPA confirmed cases is an alarm to policy makers & hospital administrators to pave way for further management strategies. Our clinicians are also underutilizing wells score (done only in 5%) & CTPA (done in 65.5%) in a patient suspected of PTE & there is low confirmatory rate of CTPA in our setup. So, high degree of clinical suspicion with close observation of key clinical symptoms & signs, awareness & adherence to guideline directed workup & management is very important to properly identify & treat this medical problem.

9. RECOMMENDATIONS

1. Physicians should be adherent to guideline directed workup of patients with PTE & they have to document the wells score of every patient suspected of PTE in order to reduce over diagnosis.
2. Physicians should increase screening and risk scoring of all admitted patients for VTE to prevent in-hospital PTE
3. The hospital should avail tests like D-dimer to help in the decision making in combination with clinical decision rules (like wells score) to increase yield of CTPA confirmation.
4. We should adopt institutional guideline for VTE management
5. The hospital administrators & responsible bodies should avail drugs(thrombolytic) for treatment of patients with massive PTE.
6. Further studies should be done to justify barriers why clinicians don't assess & document pretest scores (wells score) for all patients suspected of PTE.
7. A prospective study should be done to better clarify the rate of confirmation of PTE, treatment outcome and complications.

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ANNEX

Question	Response
Card no	
Age(in years)	
Sex	1.male 2.female
BP at diagnosis of PTE & other vital signs.	1.<90/60 3, PR >100 5. RR >20 7. SaO ₂ ----- ? 2.≥90/60 4,PR ≤ 100 6, RR ≤20
How diagnosis of PTE made?	1.clinical 2.imaging done A. CTPA B. echocardiography C-Doppler u/s of leg D-ECG specify the findings-----?
Clinical presentation at time of dx of PTE	1, Dyspnea 2, chest pain 3, hemoptysis 4, sudden cardiac arrest/death 5, syncope 6, others. Specify -----?
Timing of PTE diagnosis:	1.at admission 2.after admission
Site of Admission	1.medical ward 2.MICU
<i>Well's score documented before imaging or initiation of treatment?</i>	A. Yes B. NO
<i>If yes, what is the score?</i>	-----?
Medical co morbidity?	1.yes Specify -----? 2.No
Patient Out come	1.discharge 2.death
Comment	

