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Incidence of Deep Venous Thrombosis in Hospitalized COVID-19 Patients in Isolated De Martini Hospital Mogadishu Somalia

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Abstract

➢ ***Background:***

Coronavirus (COVID-19) pandemic incidences of deep vein thrombosis (DVT) have been reported in considerable figures. This research aimed to assess the incidence of deep vein thrombosis (DVT) in COVID-19 patients admitted to De Martini Hospital Mogadishu, Somalia assigned for COVID-19 isolation cases.

➢ ***Method:***

All patients diagnosed with COVID-19 and performed venous ultrasounds by the radiology department between February 10 and April 10, 2021, in De-Martini hospital were enrolled. A retrospective data collected the demographic information and the participants' required clinical history, investigations, and treatment records. The study's primary step was the incidence of DVT in the in-hospital COVID-19 cases and its association with clinical and laboratory risk factors.

➢ ***Result:***

One hundred thirty-eight patients (Mean age was 62.58±13.12 years, 30.6% female, 56 ICU) participated in the study. More than 90% of the patients had at least one risk factor, and hypertension was the most prevalent condition (27.3%). While 39.9% were diagnosed with Deep Venous Thrombosis (DVT) after venous Doppler ultrasonography. Over 69.1% (38 patients) of the DVT group patients had lower extremity type, but 30.9% (17 patients) of the DVT patients had Upper extremity type. 78.9% (43 patients) of the DVT group were ICU patients, and 21.1% (12 patients) were admitted to the ward. Total ICU cases for advanced treatment were 55% patients. The DVT rate was higher in ICU (84%) than in Ward patients (16%). For 76 (55.1%) of the patients were admitted to the ICU for further care and the ICU patients in DVT group were significantly more than non-DVT group (85.0% vs 36.1%, P=0.002).

Heart rate, respiratory rate, oxygen saturation, white blood counts, D-dimer, CRP, and Anticoagulation use had significant statistical difference since P-value is less than 0.05

➢ ***Conclusion:***

Approximately, 39.9% incidence of DVT in COVID-19 is remarkably high, which can lead to high morbidity and mortality. Our findings suggest early screening of DVT and therapeutic anticoagulation of COVID-19 cases, especially ICU-admitted patients. Also, further research is required for identification of DVT risk factors in COVID-19 patients.

Keywords:- *Coronavirus disease (COVID-19), deep vein thrombosis (DVT), incidence rate, SARS- CoV-2.*

I. INTRODUCTION

On March 11, 2020, Word Health Organization declared COVID-19 a pandemic. Cases were increasing rapidly. Six months after the WHO announced a public health emergency on July 30, 2020, 16.8 million cases and 662,095 deaths had been reported worldwide. Coronavirus disease 2019 (COVID-19) provides an unprecedented threat to global health care systems, with more than 32730945 cases and over 991224 worldwide, as WHO confirmed in 2020. According to Somalia, its first case was confirmed in Mogadishu on March 16 2020, with 3588 points and 99 deaths as of September 26 2020 (1).

One hundred eighty million seven hundred fifty-six thousand three hundred forty-seven confirmed COVID-19 cumulative cases, 3,793,230 cumulative deaths globally, 14,867 points, and 775 fatalities in Somalia were reported by WHO and the Ministry of Health of Somalia. The severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) that causes coronavirus disease 2019 (COVID-19) can activate the systemic coagulation system, (2). The risk of venous thromboembolism and pulmonary artery thrombosis may rise because of the systemic stimulation of blood coagulation, pulmonary thrombo-inflammation, and local

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vascular damage brought on by COVID-19. Numerous researches have looked into the possibility of venous thromboembolism in COVID-19 hospitalized since the epidemic. While recent investigations indicated the risk might be as high as 85% despite all patients having pharmaceutical cardiovascular therapy, preliminary results suggested a 15–25% VTE incidence, (3).

The risk of venous thromboembolism and pulmonary artery thrombosis may rise because of the systemic stimulation of blood coagulation, pulmonary thrombo-inflammation, and local vascular damage brought on by COVID-19. Numerous research has investigated the possibility of venous thromboembolism in COVID-19 hospitalized since the epidemic. While recent investigations indicated the risk might be as high as 85% despite all patients having pharmaceutical cardiovascular therapy, preliminary results suggested a 15–25% VTE incidence. (4). Another study that included 3487 individuals from 30 trials and a systematic review and meta-analysis found that the incidence of VTE was 26% (95% PI, 6%-66%). In 12% of patients, PE with or without DVT occurred (95% PI, 2%-46%), and in 14% of patients (95% PI, 1%-75%), DVT alone, (5).

A high incidence of thrombotic events has been reported in hospitalized COVID-19 patients. Most patients suffer venous thromboembolic events with pulmonary embolism (PE) playing a major role; this can have a major impact on disease outcome. One hypothesis is that isolated pulmonary microcirculation lung thrombosis may be responsible for severe atypical ARDS cases of COVID-19 pneumonia. Still, PE may occur in COVID-19 patients—especially if the clinical suspicion is corroborated by the instrumental diagnosis of deep vein thrombosis (DVT) of the lower limbs. Few studies have specifically looked at the incidence of DVT in patients with COVID-19 pneumonia or at the role of blood assays like D-dimer in identifying DVT (6).

The incidence of VTE complications in COVID-19 patients ranged from 1.7 to 16.5% in 35 observational studies reported from around the world (total N=9249) (7). Researchers postulated that a severely activated inflammatory response to COVID-19 infection causes thrombo-inflammation; through mechanisms such as cytokine storm, complement activation, and endotheliosis. In addition, certain studies reported findings of microthrombi in autopsies of COVID-19 patients (8). Recent retrospective studies proposed several risk factors associated with higher mortality and higher severity of COVID-19, including inflammatory markers such as interleukin-6 (IL-6), D-dimer, ferritin, and lactate dehydrogenase (LDH). Moreover, many studies also showed VTE in COVID-19 is associated with severity of infection and mortality. Hence it is critical for physicians to identify the risk factors for the prevention and early management of VTE (8).

It is known that hospitalized, bedridden patients are particularly prone to development of deep venous thrombosis (DVT); in the absence of adequate prophylaxis, its overall incidence among in-hospital patients is 0.9%, rising up to 15% to 32% among intensive care unit (ICU) patients. However, a remarkable increase in the diagnosis of DVT has been noticed among non-ICU hospitalized patients as well due to the numerous cases of DVT observed among patients infected by coronavirus disease 2019 (COVID-19) (9).

II. METHODS

A. Study design and data collection

This study was single centered, and retrospective observational study, it was conducted at the Mogadishu Isolation Centre (De Martini hospital) Mogadishu, Somalia between February 10 and April 10, 2021. The patients were diagnosed for COVID-19 based on Diagnosis Treatment Protocols for Patients with Novel Coronavirus Pneumonia provided by World health organization (WHO).

B. Sample size determination

Patient's data were retrospectively reviewed from the day of admission to isolation hospital until one of the following outcomes (death, hospital discharge, transfer to another hospital).

Data were collected from patients admitted for COVID-19 to the De Martino Public hospital between February 10 and April 10, 2021. The study patients from medical records including (1) demographic information such as gender, age, weight, height, exposure history, clinical manifestations, date of onset of symptoms, and date of admission; (2) Co-morbidities; (3) vital signs and results of laboratory tests & the ultrasound; (4) the prophylaxis of venous thrombosis; and (5) outcomes. D-dimer levels were included if measured on or within 72 hours of admission.

C. Ethical approval

Formal approval from the Medical Ethics Review Committee not needed because Medical Research Involving Human Subjects Act does not apply for this observational study.

D. Patients

The patients reverse transcription-polymerase chain reaction (RT-PCR) test was performed on a nose/throat swab or sputum sample positive for SARS-CoV-2 to confirm COVID-19 cases. We excluded children, patients with incomplete data, re-admissions, and patients admitted for other medical conditions. Patients were classified as ICU patients if any time during hospital was spent in the ICU or Ward patients if not. The registry documented treatment protocols and ICU admission criteria for patients with COVID-19.

On the other hand, CBC count, Urea and Creatinine was measured daily; prothrombin time, activated partial thromboplastin time (aPTT), D-dimer and C-reactive protein (CRP) were measured at admission and at least every 3 days. Pharmacologic VTE prophylaxis was recommended for all patients, unfractionated heparin 4,000 International Units subcutaneously twice or three times daily, if not contraindicated or enoxaparin 40 mg subcutaneously daily. All the patients who underwent lower extremity venous ultrasound examinations by the ultrasound department were

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reviewed. After physician's decision, a totall of 196 patients with COVID-19 uunderwent venous ultrasound examinations during the study period but we excluded; 8 patients were excluded due to incomplete Venous ultrasound examinations, 10 patients were diagnosed with venous thrombosis before infected with SARSCoV-2. While 16 patients omitted due to incomplete clinical data and 5 transferred to another hospital with 19 children (<18 years old). Therefore, 138 patients were participated in this study.

Additionally, the lower extremity venous ultrasound examinations were conducted by specialized sonographers. All the patients were examined laying in a supine position with the legs extended. Then, the sonographer observed the common femoral vein plus the entire vein of the lower extremity directly using the compression method.

E. Exclusion & Inclusion Criteria

Inclusion and exclusion criteria for the study are shown in Fig. 1.

F. Statistical analysis

Categorical variables were described as number and percentage and continuous variables as mean and SD or median and interquartile range. The chi-square test compared DVT and non-DVT groups. All statistical analyses were performed using SPSS version 23.0 (Statistical Package for the Social Sciences, Chicago, IL). All tests were 2-tailed; P<0.05 was considered statistically significant.

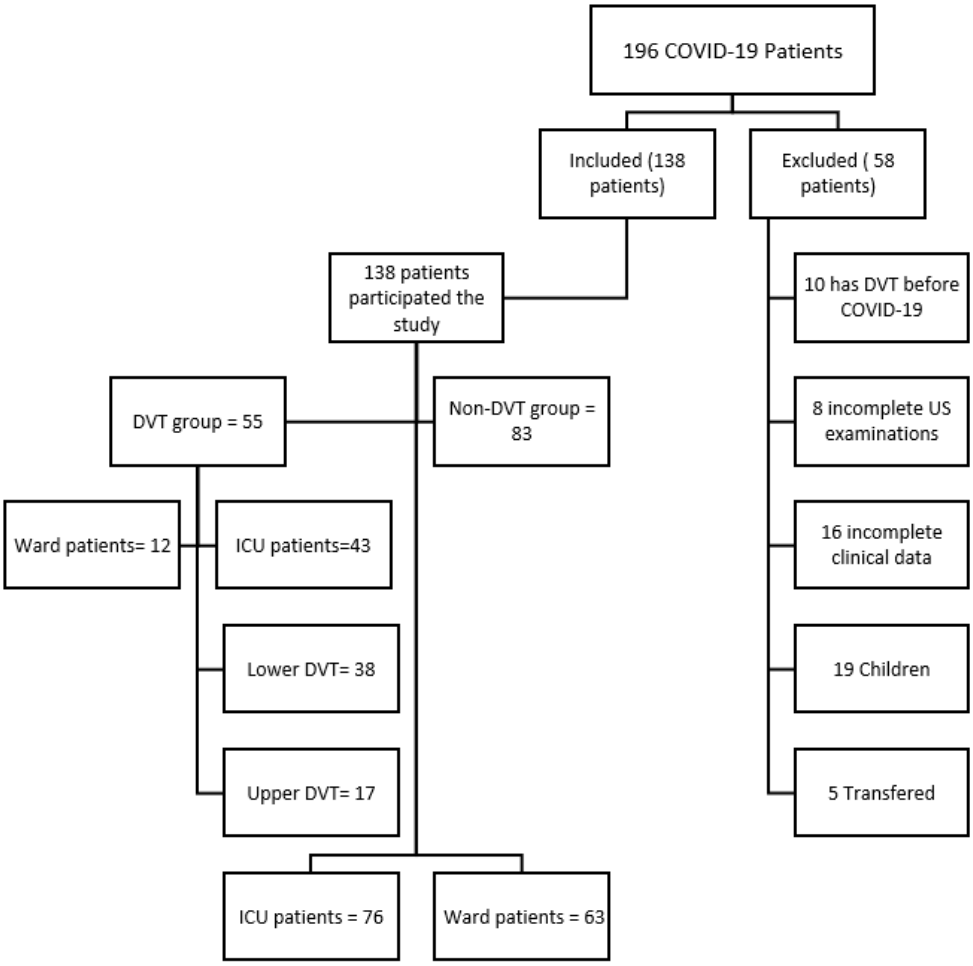

Fig 1:- Exclusion & Inclusion criteria of the study participants

III. RESULTS

Among 196 patients were hospitalized after COVID-19 confirmation by clinical features consistent with COVID-19 in combination with a reverse transcription polymerase chain reaction (RT-PCR) test on a nose/throat swab at national public health laboratory between February 10 & April 10, 2021. We excluded 19 children (<18 years old), 5 patients immediate transferred to another hospital, 8 patients with incomplete US examination, 16 patients with incomplete clinical data and 10 patients diagnosed with venous thrombosis before infected with SARSCoV-2. Of the remaining 138 patients were divide into DVT and Non DVT patients. 39.9% (55 patients) were diagnosed with Deep Venous Thrombosis (DVT) after venous Doppler ultrasonography. 69.1% (38 patients) of the DVT group patients had Lower extremity type while 30.9% (17 patients) of the DVT patients had Upper extremity type. 78.9% (43 patients) of the DVT group were ICU patients and 21.1% (12 patients) were admitted to the ward. 55% (76 patients) of the total patients participated our study were admitted to the ICU for advanced treatment.

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A. Demographic Data

The socio-demographic data of the participants are presented in Table 1. The means age was 62.58±13.12 years with only 42 (30.6%) were female. 15.5% of the study participants were obese (Body mass index greater than 30 Kilogram/meter square). Almost more than 90% of the patients had at least one risk factor, notably 5 most prevalent conditions were Hypertension 38 (27.3%), previous history of VTE 32 (23.2%), hyperlipidaemia 21 (15.2%), diabetic mellitus 20 (14.4%) and coronary artery diseases (CAD) 10 (7.2%). 14 (10.2%) of the patients can't walk before COVID-19 infection. For 76 (55.1%) of the patients were admitted to the ICU for further care and the ICU patients in DVT group were significantly more than non-DVT group (85.0% vs 36.1%, P=0.002).

B. Vital signs, Laboratory Tests and Treatment

Vitals signs, laboratory tests and treatment of the study participants are shown in Table 2.

Univariate analysis for comparing systolic blood pressure, haemoglobin concentration and mechanical ventilation use showed no statistical difference between DVT and Non-DVT group. On the other hand, heart rate, respiratory rate, oxygen saturation, white blood counts, D-dimer, CRP and Anticoagulation use had significant statistical difference.

C. Clinical Outcome

Around 55.1% of the patients were admitted to the ICU. Of those 60.5% had Deep Venous Thrombosis after Doppler ultrasound examination. 44.9% of the patients were ward patients with only 15% developed DVT. Out of total 55 DVT patients, 38 (69%) patients had lower extremity DVT.

D. Assessment Tools

Paradua prediction score; a simple prediction score for evaluating the risk of thromboembolism in patients admitted to Padua Hospital with 11 parameters was introduced in 2010. CURB 65 or CURB criteria is a clinical prediction rule that has been validated for predicting mortality in Community acquired pneumonia and ICU admitted patients, it was developed by Nottingham University and recommended by British Thoracic Society. For the assessment of severity of Pneumonia. CURB 65 is a scoring system that estimates the mortality severity.

Characteristics	Total (N=138)	DVT (N=55)	Non-DVT (N=83)	P-value
Age, mean+SD, years	62.6±13.0	63.3±12.9	62.19±13.2	0.146
Male Sex, n (%)	96 (69.4%)	42 (75.5%)	56 (67.8%)	0.451
BMI index (Kg/M2), mean+SD	22.5±2.5	24.1±2.3	22.1±2.1	0.133
HTN, n (%)	38 (27.3%)	22 (40.0%)	16 (19.3%)	0.401
DM	20 (14.4%)	7 (12.7%)	13 (15.7%)	0.712
Hyperlipidemia	21 (15.2%)	9 (16.4%)	12 (14.5%)	0.143
Smoking	8 (5.7%)	5 (9.1%)	3 (3.6%)	0.894
CAD	10 (7.2%)	4 (7.3%)	6 (7.2%)	0.546
ICU patients	76 (55.1%)	46 (85.0%)	30 (36.1%)	0.002
Previous history of VTE	32 (23.2%)	24 (43.6%)	8 (9.6%)	0.126
History of Asthma	6 (4.35)	4 (7.2%)	2 (2.4%)	>0.999
History of COPD	9 (6.5%)	5 (9.1%)	4 (4.8%)	0.928
Can walk before COVID-19	124 (89.8%)	44 (80.0%)	80 (96.4%)	>0.999

Table 1:- Baseline characteristics & co-morbid conditions of COVID-19 confirmed 138 patients enrolled the study.

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Vital signs	Total (N=138)	DVT (N=55)	Non-DVT (N=83)	P-value
Heart rate (beat pre minute), mean+SD	90.60±19.2	90.75 ±19.3	90.51± 19.2	0.032
Systolic blood pressure (mmHg), mean+SD	122.82±21.9	123.47±22.1	122.39±21.9	0.114
Respiratory rate (breaths per minute), mean+SD	18.26±2.9	18.42±2.8	18.16±2.9	<0.000
Saturation of pulse oxygen (%), mean+SD	96.49±4.7	89.44±4.9	92.53±4.6	0.003
Tests				
Hemoglobin (g/L)	10.0(8.5-11.5)	9.5 (8.8-12.0)	12.0(10.0-13.5)	0.06
White blood cell count ($\times 10^9$/L)	8.5 (6.5-10.4)	13.5 (8.2-20.3)	5.8 (4.2-6.1)	0.011
D-dimer (mg/L)	3.1(1.0-10.3)	7.4 (3.5-19.2)	0.8 (0.4-2.9)	<0.000
C-reactive protein (mg/dL)	14.5 (2.4-48.0)	29.2(4.8-91.2)	3.3(1.6-26.0)	0.001
Serum creatinine concentration (mmol /L)	0.84 (0.72-1.05)	0.96 (0.75-1.22)	0.75(0.54-0.98)	0.037
Treatment				
Mechanical Ventilation	59 (42.7%)	33 (60.0%)	26 (31.3%)	0.070
Anticoagulation use	65 (47.1%)	38 (69.0%)	27 (32.5%)	0.021

Table 2:- Vital signs, Laboratory tests and treatment of 138 COVI-19 patients

	ICU patients	Ward patients	TOTAL
Lower extremity DVT	30 (39.5%)	8 (13%)	38 (28%)
Upper extremity DVT	16 (21%)	1 (2%)	17 (12%)
Non DVT patients	30 (39.5%)	53 (85%)	83 (60%)
TOTAL	**76**	**62**	**138**

Table 3:- Clinical outcome of the patients enrolled the study; total 138 patients.

CURB-65 score			
	0-1	**2**	**≥3**
Total patients= 138	84 (60.9%)	36 (26.5)	18 (12.7%)
DVT patients	23 (41.5%)	21 (38.5%)	11 (20.0%)
Non-DVT patients	67 (80.7%)	13 (15.7%)	3 (3.6%)
P-value	0.001		
Paradua prediction score			
	<4	**≥4**	
Total patients=138	58 (42%)	80 (58%)	
DVT patients=55	12 (21.8%)	43 (78.2%)	
Non-DVT patients=83	49 (59.1%)	34 (40.9%)	
P-value	0.002		
General condition			
	Mild to Moderate	**Severe**	**Critical**
Total patients=138	47 (34%)	34 (25%)	57 (41%)
DVT patients=55	8 (14.6%)	31 (29.1%)	16 (6.4%)
Non-DVT patients=83	38 (45.8%)	29 (35%)	16 (19.2%)
P-value	<0.001		

Table 4:- Assessment criteria used for the evaluation of the selected patients

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IV. DISCUSSION

For 76 (55.1%) of the patients were admitted to the ICU for further care and the ICU patients in DVT group were significantly more than non-DVT group (85.0% vs 36.1%, P=0.002). Severe acute respiratory syndrome due to SARS-CoV-2 predisposes patients to thrombotic complications in the arterial and venous changes because of excessive inflammation, endothelial dysfunction, platelet activation, and stasis (10). Despite LMWH prophylaxis or full anticoagulant therapy, the incidence of DVT, mainly asymptomatic, in hospitalized COVID-19 patients was 14.5% (6). The observed risk for VTE in COVID-19 is high, particularly in ICU patients, which should lead to a high level of clinical suspicion and low threshold for diagnostic imaging for DVT or PE (11).

Although our current study concluded 39.9% incidence rate there is another study which found a 35.2% incidence rate of DVT in patients who undertook the lower extremity venous ultrasound examinations. Furthermore, the multivariate analyses showed that a high level of D-dimer, ICU admission, and without anticoagulant drugs were the risk factors of DVT (12).

Deep vein thrombosis (DVT) is a predominant complication of critically ill hospitalized COVID-19 patients. It is one of the major possibly preventable causes of death. A recent study has reported a Padua Prediction Score of 4 in 40% hospitalized COVID-19 patients, implying that they were at high risk of developing DVT (2), While in our study concluded that 58% of total participants had a Padua Prediction Score of 4 or above. Another study has been reported that, the rate of DVT complications in critically ill COVID-19 patients was as high as 69%, although all the patients received prophylactic or therapeutic anticoagulation (13). elsewhere, the rate of DVT incident was 27% in ICU patients. In current study, 39.9% of patients were diagnosed with DVT while the rate of DVT incident in ICU patients were 56%.

Diagnosis of DVT and PE are complex in patients with COVID-19. Symptoms of PE overlap with symptoms of COVID-19 and mild symptoms may be overlooked in a patient already suffering from shortness of breath. Similarly, clinical signs and symptoms of DVT may be harder to detect, especially in ICU patients, and when treating clinicians primarily focus on respiratory status and do not systematically assess lower extremities for signs of DVT (14). During our study, we faced the same challenges mentioned above but we confirmed not to underestimate or overestimate the cases.

A few studies have published a high incidence of VTE in patients with COVID-19. However, these studies were limited by the small numbers of patients undergoing duplex ultrasonography to confirm and characterize DVT (i.e., location, extent, and unilateral vs bilateral) (15). Of 34 patients with COVID-19 receiving antithrombotic therapy in the ICU, Nahum (15) demonstrated a DVT rate of 65%, predominantly bilateral (53%) and proximal (26%) in distribution.

In 81 ICU patients in China, Cui (16) showed that 25% of patients were diagnosed with DVT. However, the study was biased by patients not having received routine antithrombotic therapy unlike our study which received routine antithrombotic therapy. In European studies of patients receiving prophylactic antithrombotic therapy, the incidence VTE ranged from 18% to 31% (17) which is less according to our study. In a meta-analysis of observational studies, the prevalence of DVT in suspected PE is approximately 18%, and in proven PE 36–45% (18). Our study was not covered PE but the investigations showed that the incidence of DVT was very close. In a study conducted by Poissy (19) the incidence of DVT was 13.6% in patients with severe COVID-19 admitted to the intensive care unit.

Although our study was limited by a small sample size, there is a series of 362 patients the largest study reported to date of a cohort of non–critically ill patients with COVID-19 admitted to the intensive care unit and general wards. Among of them, DVT was confirmed in less than 1%, PE occurred in 10 patients (2.8%) (20).

Another prospective observational study by Franco-Moreno reported 7.7% Incidence of DVT patients. Patients with DVT had central and bilateral PE. there were diagnosed in the emergency department, so they did not receive previous prophylactic therapy with low-molecular-weight heparin. Patients without DVT had higher median d-dimer levels: 25,688 μg/dL (interquartile range, 80,000–1210 μg/dL) versus 5310 μg/dL ($P < .05$) (21). While, in our study the incidence 39.9% incidence Deep Venous Thrombosis (DVT) after venous Doppler ultrasonography including and ICU and Ward patients.

Another single-center study from Wuhan including 48 critically ill patients with COVID-19 reported an 85.4% rate of asymptomatic DVT (22) which is very high rate according to our study. Demelo (23) observed an incidence rate of 14.7% for asymptomatic DVT in a cohort of patients admitted to medical wards with COVID-19 pneumonia. However, in an Italian study, none of the 64 tested patients with COVID-19 admitted to the medical ward developed asymptomatic DVT (24). Although our study was limited to only DVT cases, a study in Germany that included 12 autopsies of patients who died of COVID-19 revealed PE as the cause of death in 4 patients, with the thrombi derived from the deep veins of the lower extremities. In another 3 patients, DVT was present in the absence of PE. In all cases with DVT, both legs were involved (25). Filippo Pieralli published another multicenter study, showed an overall incidence of DVT of 13.7%, 6.2% in proximal (6.2%) and 7.5% in distal venous district. Of note 94% of DVTs were asymptomatic, which means that they had been undetected without a serial ultrasound protocol of surveillance. This suggests a significant incidence of lower limb DVT in patients with COVID-19 pneumonia in non-ICU setting despite anticoagulation (26).

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Result of the recent meta-analysis by Jimenez reported an overall estimated pooled incidence of VTE of 17% (21). Demelo-Rodriguez and co-workers in a single-center study on patients hospitalized in non-intensive care units with COVID-19 pneumonia and D-dimers > 1000 ng/ml, described an incidence of DVT of 14.7%, of whom only 1 (0.6%) were proximal (23). Avruscio et al, in a series of 44 patients admitted to medical wards in Padua, Italy, described an overall occurrence of DVT of 22.7%; when the observation was limited to the lower limbs the prevalence of DVT was 13.6%, of which 9.1% were distal and 4.5% proximal (27). A recent study from a single center in Rome (Italy) on 84 patients with COVID-19 reported an incidence of DVT detected by systematic ultrasonography screening of 11.9% with higher incidence of distal (9.5%) versus proximal (2.4%) DVT (28). According to the above 4 studies, DVT incidence of COVID-19 patients in Somalia are different due to different methods of data collection.

In our study, a feature that differed substantially from the previous ones is the higher incidence of DVT compared to many studies. A possible explanation could be that in this study has many limitations including not only ICU patients which needs mechanical ventilation but also small sample size.

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