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Incidence of symptomatic venous thromboembolism following hospitalization for coronavirus disease 2019: Prospective results from a multi-center study

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ABSTRACT

Background: Thrombosis and pulmonary embolism appear to be major causes of mortality in hospitalized coronavirus disease 2019 (COVID-19) patients. However, few studies have focused on the incidence of venous thromboembolism (VTE) after hospitalization for COVID-19.

Methods: In this multi-center study, we followed 1529 COVID-19 patients for at least 45 days after hospital discharge, who underwent routine telephone follow-up. In case of signs or symptoms of pulmonary embolism (PE) or deep vein thrombosis (DVT), they were invited for an in-hospital visit with a pulmonologist. The primary outcome was symptomatic VTE within 45 days of hospital discharge.

Results: Of 1529 COVID-19 patients discharged from hospital, a total of 228 (14.9%) reported potential signs or symptoms of PE or DVT and were seen for an in-hospital visit. Of these, 13 and 12 received Doppler ultrasounds or pulmonary CT angiography, respectively, of whom only one patient was diagnosed with symptomatic PE. Of 51 (3.3%) patients who died after discharge, two deaths were attributed to VTE corresponding to a 45-day

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cumulative rate of symptomatic VTE of 0.2% (95%CI 0.1%–0.6%; n = 3). There was no evidence of acute respiratory distress syndrome (ARDS) in these patients. Other deaths after hospital discharge included myocardial infarction (n = 13), heart failure (n = 9), and stroke (n = 9).
Conclusions: We did not observe a high rate of symptomatic VTE in COVID-19 patients after hospital discharge. Routine extended thromboprophylaxis after hospitalization for COVID-19 may not have a net clinical benefit. Randomized trials may be warranted.

1. Introduction

Coronavirus disease 2019 (COVID-19) is characterized by a broad spectrum of manifestations ranging from the absence of symptoms to acute respiratory distress syndrome (ARDS) and multiple organ dysfunction syndrome (MODS) [1]. Extrapulmonary vascular manifestations may include endothelial dysfunction [2] with stroke, acute kidney injury, pneumopathy-induced local coagulopathy [3], microvascular thrombosis [4], and venous thromboembolism (VTE) [5,6]. It remains unclear how thrombotic complications influence the course of COVID-19, but they appear to increase the risk of death and VTE [7–9].

Anticoagulant prophylaxis might reduce thrombotic events and mortality in COVID-19 patients [10]. However, no data from randomized controlled trials and prospective cohort studies are available to date, and three largely debated questions remain unanswered: whether selected ambulatory patients should receive thromboprophylaxis, if a therapeutic-dose parenteral anticoagulation should be given to most severe inpatients, and if the post-discharge VTE rate is high enough to mandate extended thromboprophylaxis [11].

In a survey of hospital charts integrated in an institutional quality program in London, the authors described a 0.5% rate of VTE within 42 days of hospital discharge [12]. In a retrospective cohort of 163 hospitalized patients, the 30-day post-discharge cumulative incidence of VTE was 0.6% [13]. These numbers suggest that post-discharge VTE rates are comparable in COVID-19 and non-COVID-19 patients. However, given that these data are rather preliminary, they call for confirmation in the setting of large cohort studies before recommending routine post-discharge thromboprophylaxis after COVID-19 hospitalization.

In this study, we investigated the 45-day rate of VTE following hospital discharge in COVID-19 patients enrolled at three Iranian referral centers and followed according to a standardized two-step diagnostic process consisting of a telephone follow-up and an in-hospital visit in case of signs or symptoms of VTE.

2. Methods

The study population consisted of hospitalized patients who had a diagnosis of COVID-19 at one of three major referral centers in Iran (Tabriz University of Medical Sciences, Zanjan University of Medical Sciences, and Qom University of Medical Sciences) between February 20 and April 10, 2020. The patients were enrolled consecutively, without any selection.

The diagnosis of COVID-19 was made in symptomatic patients based either on high throughput sequencing or real-time reverse-transcriptase polymerase chain reaction (RT-PCR) assay of nasopharyngeal swab specimens or on chest computer tomography (CT) scan based on most common findings in COVID-19, with bilateral and peripheral ground glass opacity that could be unequivocally attributed to COVID-19. Ground glass opacity and consolidation were the most common radiologic abnormalities, reported in 94.5% of the patients in previous studies [14]. Given that we saw these patients during a severe epidemic, the prior probability for COVID-19 having clinical symptoms was quite high. Further radiologic confirmation with ground glass opacity and consolidation made the posterior probability for diagnosis very high. A radiologist and a pulmonologist assessed the accuracy of the diagnoses made based on the CT scan findings. Research protocol and data collection was approved by the Ethics Committee of the Tabriz University of Medical Sciences (approval number IR.TBZMED.REC.1399.304).

The primary study outcome was symptomatic DVT or PE within 45 days of hospital discharge. The diagnostic process of DVT and PE, their definition and the process of prospective collection of data are described thereafter.

The participants were followed for a minimum of 45 days after hospital discharge. The initial follow-up was in the form of phone interview performed by a trained physician 45 to 55 days after hospital discharge. The interviewer used a structured questionnaire that included data on patient demographics and relevant risk factors, including history of hypertension, diabetes, collagen vascular diseases, ischemic heart disease, chronic kidney disease (CKD), heart failure, cancer, obesity, oral contraceptive pill use, DVT and PE. The patients were also asked about clinical symptoms of PE or DVT after recovery, including sudden shortness of breath, exertional dyspnoea, pleuritic chest pain, lightheadedness, palpitations, and swollen, painful, and erythematous limbs. Patients were divided into three groups based on the aforementioned symptoms: 1) in individuals who had displayed none of these symptoms, symptomatic PE or DVT was considered absent (Group 1); 2) individuals who had visited a physician during this period (i.e. before the telephone follow-up) due to these symptoms and had been diagnosed with PE or DVT were asked to provide relevant documents, such as pulmonary CT angiography, or ultrasonography to verify the diagnosis (Group 2); 3) individuals who had displayed at least one of the above symptoms but did not undergo work up for VTE diagnosis were invited for an in-hospital visit and, if deemed necessary based on local diagnostic algorithms, assessed with specific VTE imaging (Group 3). The diagnostic criteria for acute pulmonary embolism included: 1) Arterial occlusion with failure to enhance the entire lumen due to a large filling defect; the artery may be enlarged compared with adjacent patent vessels; 2) A partial filling defect surrounded by contrast material, producing the "polo mint" sign on images acquired perpendicular to the long axis of a vessel and the "railway track" sign on longitudinal images of the vessel; 3) A peripheral intraluminal filling defect that forms acute angles with the arterial wall. Patients with a contraindication to contrast agents underwent pulmonary ventilation-perfusion (V/Q) scans and were classified according to the Prospective Investigation of Pulmonary Embolism Diagnosis (PIOPED) criteria. In case of death occurred between hospital discharge and telephone follow-up, the cause of death was obtained using information from the next-of- kin or medical documentations.

We show number and percentages for all categorical variables, and median (10^{th} and 90^{th} percentiles) for age, as a continuous variable. We used logistic regression models to study the relation of baseline demographic factors (age and sex), certain co-morbidities (history of recent cancer, chronic obstructive pulmonary disease, chronic kidney disease, cardiac disease, diabetes mellitus, hypertension), and habits (smoking) with odds of death after discharge. All analyses were done in Stata 16.1 (College Station, Texas).

3. Results

We included 1694 consecutive survivors discharged from hospital after hospitalization for COVID-19. Of these, complete follow-up data were available for 1529 patients: of these, 119 (7.8%) required intensive

care management during hospitalization. The diagnosis of COVID-19 had been confirmed in 985 (64.4%) using RT-PCR and by the combination of typical symptoms plus unequivocal radiographic evidence in 544 (35.6%). The patients were seen Tabriz (n = 881), Zanjan (n = 497), and Qom (n = 151). Median (10^{th}–90^{th} percentile) age was 56 (32–80) years and 832 (54.4%) were men. An overview of the baseline characteristics is presented in Table 1. A total of 71 patients (4.6%) received anticoagulation after discharge for VTE emerged during hospitalization (n = 53), prior VTE (n = 8), heart failure (n = 2) or atrial fibrillation (n = 8).

During the follow-up period after discharge, 1301 patients reported no symptoms of DVT or PE (Group 1) whereas none was diagnosed with DVT or PE during external medical evaluation (Group 2). A total of 228 patients reported potential symptoms of DVT or PE at telephone contact (Group 3), including exertional dyspnoea (n = 134, 8.8%), palpitation (n = 54, 3.5%), pleuritic chest pain (n = 32, 2.1%), and lower-extremity oedema (n = 18, 1.2%). All of these 228 patients were seen by a pulmonologist during an in-person visit. During this visit, the pulmonologists asked further probing questions and determined that the symptoms reported by 176 of the patients appeared to not have been related to VTE; most of these symptoms were non-specific, including fatigue, musculoskeletal disorders, obesity, anxiety, other organ disorders, yet the patients had been invited to the interview for completeness. The pulmonologists had a higher suspicion for potential VTE in the remaining 52 patients and further evaluated them clinically or radiologically for the presence of VTE: 13 received Doppler ultrasounds, 12 pulmonary CT angiography and 5 perfusion/ventilation scan. Acute PE was confirmed in only one patient.

After hospital discharge, 51 (3.3%) patients died prior to the telephone interview (Table 2). An interview with the next-of-kin and review of the legal and medical documents indicated these as the most likely or proven causes of death: myocardial infarction (n = 13), congestive heart failure (n = 9), cerebrovascular events (n = 9), cancer (n = 3), PE (n = 2), n = 11 due to other reasons, and n = 4 due to unknown causes (Table 2).

Considering fatal and non-fatal VTE events, we obtained a 45-day cumulative rate of symptomatic VTE of 0.2% (95%CI 0.1%–0.6%; n = 3) among recently hospitalized patients with COVID-19.

In a multivariable model evaluating potential predictors of mortality after discharge, older age was associated with a higher risk of death after discharge (OR 2.86 for 10-year interval, 95%CI 2.17–3.78), as well as a history of recent cancer (OR 5.61, 95%CI 1.78–17.8) and a history of diabetes mellitus (OR 2.58, 95%CI 1.26–5.29) (Table 3).

Table 1
Demographic and baseline clinical characteristics of the patients.

Total number of patients	1529
Age (year) – median (10^{th}–90^{th} percentile)	56 (32–80)
Men, n (%)	832 (54.4)
Medical history, n (%)	
Hypertension	438 (28.7)
Diabetic mellitus	274 (17.9)
Obesity[a]	206 (13.5)
Ischemic cardiac disease	149 (9.7)
Chronic obstructive pulmonary disease	146 (9.6)
Oral contraceptive use	116 (7.6)
Chronic renal dysfunction	72 (4.7)
Heart failure	41 (2.7)
Recent cancer[b]	28 (1.8)
Systemic lupus erythematosus	8 (0.5)
Prior pulmonary embolism	5 (0.3)
Prior deep vein thrombosis	3 (0.2)
Antiplatelet therapy	214 (14)
VTE prophylaxis (enoxaparin 40–60 mg/daily, unfractional heparin 5000 IU/QID)	1490 (97)
Duration of follow up	45–55 days

[a] Obesity = BMI > 30 kg/m^2.
[b] Recent cancer = histologically confirmed solid cancer or hematologic malignancy, which were diagnosed or treated within the previous 6 months.

Table 2
Causes of death after hospital discharge.

Total number of death	51 of 1519 (3.3%)
Myocardial infarction, n	13
Heart failure, n	9
Stroke, n	9
Cancer, n	3
Pulmonary embolism, n	2
Other, n	11
Unknown, n	4

4. Discussion

In this multicenter study with prospectively-collected data, we report a less than 0.5% incidence of confirmed VTE among recently hospitalized patients with COVID-19. Due to the low number of events, we could not identify any risk factor for post-discharge VTE, whereas age, history of diabetes, and history of recent cancer were associated with early all-cause death. These data further confirm preliminary evidence suggesting that, whereas the burden of VTE may be substantial during the acute phase of COVID-19, the individual risk of VTE after recovery from COVID-19 and discharge seems to be comparable to patients hospitalized for reasons other than COV ID-19. Based on this observation, routine prescription of extended thromboprophylaxis in this patient population may not lead to a net clinical benefit. While prophylaxis may reduce the risk of VTE, it may increase the risk of bleeding, and hence the net benefit is unclear.

Early evidence of COVID-19-associated coagulopathy was reported in Wuhan, China, showing increases in the levels of inflammatory markers and D-dimer [15]. Further investigations showed that higher D-dimer levels were associated with more severe disease and higher mortality [3]. Autopsy results from the United States and Italy suggested important role of thrombosis in pathogenesis and pathophysiology of COVID-19 [4,16] and several observational studies reported a high in-

Table 3
The association between baseline demographic and clinical risk factors and death after discharge.

	Survived (n = 1478)	Died (n = 51)		
	N (%)	N (%)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Age (10-year increase)	–	–	2.62 (2.05–3.35)	2.86 (2.17–3.78)
Male sex	799 (54.1)	33 (64.7)	1.56 (0.87–2.79)	1.72 (0.89–3.33)
Recent cancer	23 (1.6)	5 (9.8)	6.88 (2.50–18.9)	5.61 (1.78–17.8)
COPD	132 (8.9)	14 (27.5)	3.85 (2.03–7.31)	1.83 (0.51–6.64)
CKD	66 (4.5)	6 (11.8)	2.85 (1.18–6.92)	1.32 (0.47–3.74)
Cardiac disease	175 (11.8)	11 (21.6)	2.05 (1.03–4.06)	0.80 (0.36–1.76)
Smoking	215 (14.6)	18 (35.3)	3.20 (1.77–5.79)	1.46 (0.45–4.74)
Diabetes mellitus	258 (17.5)	16 (31.4)	2.16 (1.18–3.96)	2.58 (1.26–5.29)
Hypertension	421 (28.5)	17 (33.3)	1.26 (0.69–2.27)	0.56 (0.28–1.11)

OR: odds ratio. CI: confidence interval; COPD: chronic obstructive pulmonary disease; CKD: chronic kidney disease; Cardiac disease included ischemic heart disease and heart failure.

hospital rate of VTE, particularly in severely ill patients, despite standard VTE prophylaxis [17–20] and possibly contributing to the high death rates [21,22]. These findings resulted in guidelines suggesting (at least) prophylactic anticoagulation for all COVID-19 hospitalized patients, regardless of VTE risk assessment score (e.g. IMPROVE, Padua, Caprini, etc.) [23,24], and trials evaluating the efficacy of higher dosage regimens [25–28].

Preliminary analyses tested whether the risk of VTE extends after the acute phase and, consequently, a post-discharge thromboprophylaxis may be recommended [12,13]. Our study, the largest to the best of our knowledge, confirmed that the rate of VTE appears low after hospital discharge, similar to other unselected populations of medically ill patients. Indeed, the recent American guidelines recommend against routine extended VTE prophylaxis in medically ill patients [29], which, to date, might be considered only in carefully selected patients. Our data suggest that no deviations from standard practice should be made for COVID-19 patients, despite the transient pro-thrombotic and pro-inflammatory state observed during hospitalization [30,31]. Previous studies included D-dimer as an indicator of fibrin formation and a criterion to administer anticoagulation: its predictive role remains unknown for COVID-19 patients in the post-discharge setting [32].

There are limitations to our study. First, ethnicity and median age of patients likely play some role on the low rate of VTE in this population. Indeed, this patient group was at least five to ten years younger than previously described cohorts of COVID-19 patients studied for the rate of in-hospital VTE [6,8,18]. Moreover, as shown in epidemiological studies, the incidence and mortality of VTE varies across ethnicities [9,33,34] and is three- to four-fold lower in Asia compared to Caucasian individuals, while the VTE risk in African Americans appears to be higher than that in Caucasians. This may be due to genetic factors, but also to underdiagnosis. The latter point cannot be excluded, as we largely relied on medical and legal documents with no routine autopsy been performed. Moreover, we had no follow-up information of more than 150 patients (of a total of 1629). The reasons for lack of follow up included wrong phone number or not answering the phone despite repeated (at least 3) calls. Finally, not all hospitalized patients had a RT-PCR confirmation of COVID-19, although the radiological findings should be considered reliable in a time period where COVID-19 represented the major cause of hospitalization.

In conclusion, we observed a low rate of symptomatic VTE and all-cause death in COVID-19 patients after hospital discharge. These data appear to confirm what described in recent analysis of smaller retrospective cohorts or studies based on administrative data. Taken together, the current evidence suggests that routine extended thromboprophylaxis after hospital discharge of COVID-19 patients may not have a net clinical benefit. However, given the methodologic limitations of this study and other studies, a randomized clinical trial may be needed.

Declaration of competing interest

S.B. reports personal fees from Biocompatibles Group UK and Bayer HealthCare, non-financial support from Bayer HealthCare and Daiichi Sankyo, institutional grants from Sanofi, outside the submitted work. The other authors have no conflicts of interest to disclose.

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