Ultrasound Evaluation for Extremity Deep Vein Thrombus in COVID-19-Positive Patients

Exam Positivity Rate and Association With D-Dimer Level

Hernan R. Bello, MD, Marta E. Heilbrun, MD, Omar N. Kallas, MD, Dean W. Thongkham, MD, Cindy D. Powell, MD, Courtney C. Moreno, MD

Objectives—Determine the rate of positive extremity ultrasound exams for DVT in patients with COVID-19 and assess for differences in laboratory values in patients with and without DVT, which could be used as a surrogate to decide the need for further evaluation with ultrasound.

Methods—Retrospective case control study with 1:2 matching of cases (COVID-19+ patients) to controls (COVID-19/- patients) based on age, gender, and race. Laboratory values assessed were serum D-dimer, fibrinogen, prothrombin time, international normalized ratio, and C-reactive protein. Demographic variables, comorbidities, and clinical variables including final disposition were also evaluated. P-values for categorical variables were calculated with the chi-square test or Fisher’s exact test. P-values for continuous variables were compared with the use of a two-tailed unpaired t-test.

Results—The rate of extremity ultrasound exams positive for DVT were similar in patients with (14.7%) and without (19.3%) COVID-19 (P = .423). No significant difference was observed in laboratory values including the D-dimer level in COVID-19 patients without (mean 9523.9 ng/mL (range 339 to >60,000)) or with DVT (mean 13,663.7 ng/mL (range 1193–>60,000)) (P = .475). No differences were found in demographic variabilities or co-morbidities among COVID-19 patients with and without extremity DVT.

Conclusions—We found no statistically significant difference in rate of positive DVT studies between COVID-19+ and COVID-19− patients. D-dimer levels are elevated, in some cases markedly, in COVID-19 patients with and without DVTs and therefore these data do not support their use as a surrogate when assessing the need for ultrasound evaluation.

Key Words—COVID-19; D-dimer; deep vein thrombosis; ultrasound

Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), can result in a hypercoagulable state and fibrinolysis shutdown leading to vascular thrombosis and thromboembolism with significant morbidity and mortality.\(^1\)\(^2\) Rates of venous thrombosis have been reported to range from 3.9% in COVID-19+ patients who underwent imaging as part of clinical care\(^3\) to 85.4% in a cohort of 48 critically ill COVID-19 patients who all underwent deep venous thrombosis (DVT) screening early in the pandemic.\(^4\)

Abbreviations
DVT, deep venous thrombosis; eIRB, Emory Institutional Review Board; EMR, electronic medical record; INR, international normalized ratio; LMWH, low molecular weight heparin; PPE, personal protective equipment; PT, prothrombin time; PUI, persons under investigation; RT-PCR, reverse transcription polymerase chain reaction

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At our institution, we observed an increase in requests for extremity Doppler ultrasound in COVID-19+ patients, raising concerns for ultrasound technologists’ safety and resource utilization. Clinical and/or laboratory criteria to guide extremity ultrasound utilization would therefore be useful in optimizing patient care, while minimizing sonographer exposure. For example, a prior publication suggested that imaging for DVT or PE should be considered in patients with a D-dimer < 1000 μg/L on admission that subsequently increased to levels above 2000 to 4000 during hospitalization.5

The purpose of this investigation was to evaluate the proportion of extremity ultrasound exams that demonstrated DVT in patients with COVID-19+ (cases) compared to patients without COVID-19− (controls), and to compare laboratory values, including serum D-dimer level, in COVID-19+ patients with and without DVT.

Materials and Methods

Institutional Review Board (Emory Institutional Review Board (eIRB)) approval was obtained, and a waiver of informed consent was granted, for this Health Insurance Portability and Accountability Act compliant retrospective study. Criteria for inclusion were extremity venous Doppler examination performed between February and May 2020 at [institution name blinded during the review process]. Patients who had been hospitalized for more than 60 days prior to the initial US exam were excluded. A search of our internal radiology data warehouse resulted in a list of 1003 consecutive extremity venous Doppler studies performed during the study period. After the exclusion criteria were applied, the cohort included 987 extremity venous Doppler studies performed in 808 unique patients. For each extremity ultrasound exam, study type (e.g. upper or lower extremity, unilateral, or bilateral) and test result (e.g. positive or negative for DVT) were recorded.

Laboratory values assessed were serum D-dimer, fibrinogen, prothrombin time (PT), international normalized ratio (INR), and C-reactive protein level. The most recent laboratory value prior to the extremity ultrasound was recorded. The D-dimer assay performed at our institution is HemosIL® D-Dimer HS500 (Instrumentation Laboratory Co., Lexington, MA) with a cut-off value of 500 ng/mL FEU. Peripheral blood is collected using a 21-gauge needle and transported using pneumatic tubes. Samples are tested within 4 hours of collection when stored at room temperature.

Demographic, clinical, and laboratory information was collected manually from the electronic medical record (EMR). Demographic variables recorded were patient age, gender, race, ethnicity, and body mass index at admission. Clinical variables recorded were final disposition (discharged alive, deceased, or remains hospitalized), intensive care unit stay, and length of stay. Presence or absence of co-morbidities including chronic kidney disease, cardiovascular disease (e.g. coronary artery disease, heart failure, stroke), chronic lung disease (e.g. chronic obstructive pulmonary disease, asthma, pulmonary hypertension), chronic liver disease (e.g. cirrhosis, chronic hepatitis, non-alcoholic steatohepatitis), diabetes mellitus, hypertension, and cancer under active treatment was recorded.

Extremity ultrasound examinations were performed by technologists employed by the Department of Radiology and Imaging Sciences, wearing personal protective equipment (PPE) as per institutional guidelines. All requests for ultrasound examinations in COVID-19+ patients and persons under investigation (PUI) were vetted by a staff radiologist or trainee prior to performance. Vetting typically included a phone discussion with the referring provider or review of the EMR to determine if performance of the exam would alter patient management. Only exams that would alter patient management were performed.

COVID-19 status was assessed by a reverse transcription polymerase chain reaction (RT-PCR) test on a nose/throat swab in our in-house laboratory. When no PCR test or mention of COVID-19 diagnosis was found in the medical record, the subjects were labeled as “no suspicion/never tested.”

Statistical Analysis
This study was a retrospective nested case–control study with 1:2 matching of cases to controls based on age, gender, and race. P-values for categorical
variables were calculated with the chi-square test or Fisher’s exact test. P-values for continuous variables were compared with the use of a two-tailed unpaired t-test. A P-value < .05 was considered statistically significantly different. Statistical analysis was performed using Stata (StataCorp LLC. College Station, TX).

Results

A total of 987 extremity Doppler ultrasounds performed on 808 unique patients during the study period comprised our initial cohort, including 104 extremity Doppler ultrasounds performed in 68 unique COVID-19+ patients. All 68 COVID-19+ patients were matched 2:1 with COVID-19- patients from the original cohort, resulting in a final dataset of 203 subjects: 68 COVID-19+ and 135 COVID-19-.

Demographic and clinical characteristics of all subjects are summarized in Table 1. Chronic lung disease (30.9% vs 16.3%, P = .016) and diabetes (45.6% vs. 31.9%, P = .034) were more frequent in the COVID-19+ group, as were higher ICU admission rate (80.9% vs. 25.9%, P = .0001), longer length of stay (18.5 days vs. 8.5 days, P < .0001), and higher mortality rate (25% vs. 8.1%, P = .001) compared to patients in the COVID-19− group.

There was no statistically significant difference in the proportion of positive extremity Doppler ultrasounds between patients with and without COVID-19. Out of the 68 scanned COVID-19+ patients, 10 were positive for DVT (14.7%), while of the 135 scanned COVID-19− patients, 26 were positive for DVT (19.3%) (P = .423). The mean time between subjects’ admission to the hospital and when an extremity Doppler ultrasound study was performed differed between groups, with 7.0 days for

| Table 1. Demographic and Clinical Characteristics by COVID-19 Status |
|---------------------------------------------------------------|
| **COVID-19 (+), n = 68**                                      |
| Mean age (years) 64.18 (SD = 15.24, 27–92)                   |
| Gender                                                       |
| Female 30 (44.1%)                                            |
| Male 38 (55.9%)                                              |
| Race                                                        |
| Black 47 (69.1%)                                             |
| White 20 (29.4%)                                             |
| Asian 1 (1.5%)                                               |
| Other 0                                                     |
| Ethnicity                                                   |
| Hispanic 0                                                  |
| Non-Hispanic 68 (100%)                                      |
| Mean BMI (kg/m²) 29.63 (SD = 8.27, 16–58)                   |
| Comorbidities                                               |
| Chronic kidney disease 20 (29.4%)                            |
| Cardiovascular disease 22 (32.4%)                            |
| Chronic lung disease 21 (30.9%)                              |
| Diabetes mellitus 31 (45.6%)                                 |
| Chronic liver disease 1 (1.5%)                               |
| Hypertension 44 (64.7%)                                      |
| Cancer under treatment 5 (7.4%)                              |
| ICU stay                                                    |
| No ICU 13 (19.1%)                                            |
| ICU 55 (80.9%)                                               |
| Mean length of stay (days) 18.51 (SD = 12.72, 0–60)         |
| Final disposition                                           |
| Discharged alive 50 (73.5%)                                  |
| Deceased 17 (25.0%)                                          |
| Remained hospitalized 1 (1.5%)                               |
| Mean time between admission and DVT study (days) 7.0 (SD = 8.43, 0–50) |
| **COVID-19 (−), n = 135**                                   |
| Mean age (years) 62.76 (SD = 16.62, 18–94)                   |
| Gender                                                       |
| Female 60 (44.4%)                                            |
| Male 75 (55.6%)                                              |
| Race                                                        |
| Black 94 (69.6%)                                             |
| White 40 (29.6%)                                             |
| Asian 1 (0.7%)                                               |
| Other 0                                                     |
| Ethnicity                                                   |
| Hispanic 4 (3.0%)                                            |
| Non-Hispanic 131 (97.0%)                                    |
| Mean BMI (kg/m²) 31.4 (SD = 9.01, 15.5–69.1)                 |
| Chronic kidney disease 37 (27.4%)                           |
| Cardiovascular disease 51 (37.8%)                            |
| Chronic lung disease 22 (16.3%)                              |
| Diabetes mellitus 43 (31.9%)                                 |
| Chronic liver disease 8 (5.9%)                               |
| Hypertension 81 (60.0%)                                      |
| Cancer under treatment 18 (13.3%)                            |
| ICU stay                                                    |
| No ICU 100 (74.1%)                                           |
| ICU 35 (25.9%)                                               |
| Mean length of stay (days) 8.50 (SD = 11.4, 0–59)            |
| Final disposition                                           |
| Discharged alive 121 (89.6%)                                 |
| Deceased 11 (8.1%)                                           |
| Remained hospitalized 3 (2.2%)                               |
| Mean time between admission and DVT study (days) 3.24 (SD = 8.00, −1.56–59) |
COVID-19+ patients, and 3.2 days for COVID-19− patients ($P = .0027$).

The laboratory tests included in the analysis were obtained more frequently in the COVID-19+ subgroup. For example, D-dimer levels were available for 65 out of 68 (95.6%) COVID-19+ patients, compared to 26 out of 135 (19.3%) COVID-19− patients. INR (1.21 vs. 1.43, $P = .0154$) and CRP (142.19 vs 70.75, $P = .0008$) were significantly higher in the COVID-19+ group. No statistically significant difference was found between the two groups for D-dimer ($P = .475$), fibrinogen ($P = .642$), and PT ($P = .5$), detailed in Table 2.

Further analysis of the 68 scanned COVID-19+ patients was performed dividing these subjects by the presence (n = 10) or absence (n = 58) of extremity DVT. A comparison of demographic and clinical characteristics in COVID-19+ patients by Doppler Ultrasound Results is shown in Table 3.

### Table 2. Doppler Ultrasound and Laboratory Results by COVID-19 Status

|                      | COVID-19 (+), n = 68 | COVID-19 (−), n = 135 | P Value |
|----------------------|----------------------|-----------------------|---------|
| Counts               | Mean                 | Counts               | Mean     |         |
| Positive DVT ultrasound |                     | 10 (14.7%)           | 26 (19.3%) | .423    |
| D-dimer (ng/mL)       | 9328.0 (SD = 12370.8, 0–60000) | 9705.5 (SD = 147179, 0–53847) | .475    |
| Fibrinogen (mg/dL)    | 574.5 (SD = 206.9, 182–977) | 763.7 (SD = 1536.2, 0–6262) | .642    |
| Prothrombin time (seconds) | 15.8 (SD = 4.4, 11–40) | 16.5 (SD = 79, 10.1–50.4) | .5       |
| International normalized ratio | 1.2 (SD = 0.4, 1–3) | 1.4 (SD = 0.7, 0.9–4.3) | .0154   |
| C-reactive protein (mg/L) | 142.2 (SD = 90.5, 2–333) | 70.8 (SD = 59.3, 3.6–198) | .0008   |

### Table 3. Demographic and Clinical Characteristics in COVID-19 (+) Patients by Doppler Ultrasound Results

|                      | DVT (−), n = 58 | DVT (+), n = 10 | P Value |
|----------------------|----------------|----------------|---------|
| Patient age          |                |                | .702    |
| <40                  | 6 (10.3%)      | 1 (10.0%)      | .494    |
| 40 to 49             | 3 (5.2%)       | 0              | .542    |
| 50 to 59             | 13 (22.4%)     | 1 (10.0%)      | .192    |
| 60 to 69             | 15 (25.9%)     | 5 (50.0%)      |         |
| 70 to 79             | 10 (17.2%)     | 3 (30.0%)      |         |
| 80+                  | 11 (19.0%)     | 0              |         |
| Gender               |                |                | .902    |
| Female               | 27 (46.6%)     | 3 (30.0%)      |         |
| Male                 | 31 (53.4%)     | 7 (70.0%)      |         |
| Race                 |                |                | .189    |
| Black                | 41 (70.7%)     | 6 (60.0%)      |         |
| White                | 16 (27.6%)     | 4 (40.0%)      |         |
| Asian                | 1 (1.7%)       | 0              |         |
| Final disposition    |                |                | .069    |
| Discharged           | 45 (77.6%)     | 5 (50.0%)      |         |
| Deceased             | 12 (20.7%)     | 5 (50.0%)      |         |
| Remained hosp.       | 1 (1.7%)       | 0              |         |
| Intensive care unit stay | 45 (77%)     | 10 (100%)      | .17    |
| Mean length of stay  | 17.0 (SD = 11.7, 0–44) | 27.3 (SD = 15.4, 5–60) | .17    |
| Mean body mass index | 29.1 (SD = 8.4, 16.1–58.4) | 32.7 (SD = 70, 22–45) | .17    |
| Chronic/end-stage renal disease | 17 (29.3%) | 3 (30.0%) | .1    |
| Cardiovascular disease | 18 (31.0%) | 4 (40.0%) | .717    |
| Chronic lung disease | 18 (31.0%)     | 3 (30.0%)      | .1    |
| Chronic liver disease | 1 (1.7%)       | 0              | .84    |
| Diabetes mellitus    | 27 (46.6%)     | 5 (50.0%)      | .476    |
| Hypertension         | 37 (63.8%)     | 8 (80.0%)      | .476    |
| Cancer under treatment | 5 (8.6%)      | 0              | .1    |
DVT. Demographic and clinical characteristics of COVID-19+ subjects are summarized in Table 3. There was no statistically significant difference in age ($P = .702$), gender ($P = .494$), race ($P = .542$), comorbidities ($P = .476–1.0$), or BMI ($P = .17$). Patients in the DVT (+) group were more frequently admitted to the ICU (100% vs. 77.6%) and had a higher mortality by the end of the study period (50.0% vs. 20.7%) although neither of these was statistically significant. Mean laboratory values, which are summarized in Table 4, were not significantly different between these two groups ($P = .102–.614$).

**Discussion**

We were surprised to find no significant difference in the proportion of extremity studies positive for DVT in COVID-19+ patients compared to other hospitalized patients. Early data from Wuhan, China, found the incidence of DVT in COVID-19+ patients to be as high as 46 to 85% even while on standard prophylactic anticoagulation. Subsequent European studies reported varied results, from 13% of hospitalized patients being diagnosed with DVT in one Dutch study to a 69% incidence of lower extremity DVT in French ICU patients undergoing screening. An investigation of 3334 consecutive, hospitalized COVID-19 patients in New York, most of whom were on low-dose (prophylaxis) anticoagulation, found that DVT occurred in 3.9% of patients. In this series, all patients did not undergo DVT screening, and diagnoses were made during routine clinical care.

A possible explanation for the relatively low rate of DVT in COVID-19+ patients at our institution may be the COVID-19 anticoagulation protocol in use at our institution during the period of this study. COVID-19+ patients received standard prophylactic dosing of low molecular weight heparin (LMWH) (0.5 mg/kg/day (min 40 mg, max 80 mg)) for patients without known thrombus and a D-dimer < 3000, intermediate dosing of LMWH (0.5 mg/kg/q12h or 1 mg/kg/day) for patients without known thrombus and D-dimer ≥ 3000, and therapeutic dosing of LMWH (1 mg/kg/q12h) for patients with known or suspected venous thromboembolism or otherwise unexplained increase in oxygen requirement or organ failure with concern for microvascular thrombi. In a limited number of selected patients with demonstrated severe clotting and organ failure, tissue plasminogen activator infusions were used.

We evaluated serum D-dimer levels and other laboratory values associated with hypercoagulable states and fibrinolysis shutdown but found no significant difference in laboratory values comparing COVID-19+ patients with extremity ultrasound exams positive for DVT to those negative for DVT. D-dimer is a degradation product of cross-linked fibrin and is a marker of endogenous fibrinolysis. DVT is one of several conditions including cancer, immobility, and pregnancy that can result in D-dimer elevation.

A normal D-dimer level can rule out DVT with a sensitivity of 95% in some series reported prior to the COVID-19 pandemic although D-dimer cut-off values vary based on assay used. By comparison, an abnormally elevated D-dimer level does not rule in DVT as many conditions can result in an elevated D-dimer level although a positive correlation has been found between the prevalence of PE and D-dimer level in the pre-COVID-19 era and also during the COVID-19 pandemic.

Elevations of D-dimer and fibrin/fibrinogen degradation products are thought to indicate that the coagulopathy seen in COVID-19+ patients is due to massive fibrin formation. In a study by Wright et al, fibrinolysis shutdown was found to predict VTE events in COVID-19+ patients. C-reactive protein is a marker of inflammation, and elevated C-reactive

| Table 4. Laboratory Data in COVID-19 (+) Patients by Doppler Ultrasound Results |
|-----------------|-----------------|-----------------|
| DVT (−), n = 58 | DVT (+), n = 10 | $P$ Value |
| D-dimer (ng/mL) | 9523.9 (SD = 13,012.5, 339–60,000) | 13,663.67 (SD = 16,347.6, 1193–60,000) | .346 |
| Fibrinogen (mg/dL) | 582.5 (SD = 1873, 182–977) | 488.00 (SD = 150.99, 272–652) | .102 |
| Prothrombin time (seconds) | 16.1 (SD = 5.1, 11.1–40.4) | 15.51 (SD = 2.78, 12.1–24.1) | .539 |
| International normalized ratio | 1.39 (SD = 0.44, 0.96–3.48) | 1.34 (SD = 0.24, 1.06–2.08) | .614 |
| C-reactive protein (mg/L) | 143.1 (SD = 897, 2.2–332.8) | 161.3 (SD = 68.3, 18.8–268.1) | .446 |

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protein level is associated with an increased risk of VTE. Prothrombin times have been found to be normal or slightly elevated in patients with COVID-19 coagulopathy. That no laboratory value differences were observed in COVID-19+ patients with and without DVT suggests that elevated D-dimer laboratory cutoffs may not be useful criteria for deciding when to perform an extremity ultrasound study. Additionally, that D-dimer cutoff levels vary by vendor further complicates the possibility of using elevated cut-off values to prompt imaging as it is difficult to compare research performed using one D-dimer assay to results from a different type of assay performed at a different institution. To the contrary, it may be that clinical scenario is the best determinant of when to perform extremity venous ultrasound exams including in patients with abnormal D-dimer levels. A June 2020 CHEST panel publication suggested that evaluation for DVT be performed based on clinical scenarios such as unexplained/refractory hypoxemia, unexplained right ventricular dysfunction, or in patients with suspected PE who are unable to undergo a CTA (i.e., unstable for transport or advanced renal failure). Performance of ultrasound exams necessitates close sonographer contact with patients for potentially prolonged periods of time with associated concerns related to the potential for nosocomial COVID-19 transmission to healthcare workers. Respiratory droplets encountered during close face-to-face contact are thought to be the primary mechanism of COVID-19 transmission along with possible spread via aerosolized particles. Sonographers should follow institutional guidelines for PPE when performing ultrasound exams during the COVID-19 pandemic. Various societies have published position statements and guidance for ultrasound practitioners during the COVID-19 pandemic addressing issues including PPE and machine cleaning as well as steps to take before, during, and after each ultrasound exam. Ultrasound exams should be performed with appropriate personal protective equipment if the exam results would result in a change in patient management and not solely based on the presence of elevated serum D-dimer level.

The limitations of our study include the fact that ultrasound studies were performed and serum laboratory values were assessed as part of clinical care. As not all patients with COVID-19 underwent extremity ultrasound evaluation, the true rate of extremity DVT in patients with COVID-19 could not be determined. Additionally, pharmacologic anticoagulation protocols were variable during the period of study and may have impacted the rate of positive ultrasound exams. Finally, there are many confounding factors that can affect D-dimer levels including conditions such as pregnancy, stroke, myocardial infarction, and recent surgery as well as substances resulting in analytical interference (most commonly paraproteins, bilirubin, lipids, and hemolysis), which were not recorded.

In summary, we were surprised to find the rate of extremity ultrasound exams positive for DVT to be similar in COVID-19+ patients and COVID-19-patients, possibly due to the anticoagulation protocols used for COVID-19+ patients at our institution. Additionally, as D-dimer levels were significantly elevated in COVID-19+ patients with and without DVT, decisions about whether to perform an extremity ultrasound exam should likely be based on clinical factors (e.g. high clinical suspicion of PE and inability to undergo a CTA chest) and whether or not the results of the exam will alter clinical management, rather than based on a D-dimer threshold.

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