



Outpatient-Identified COVID-19 and Subsequent Hospitalized Thrombotic Events

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Disclosures

- The views expressed in this presentation represent those of the presenters and do not necessarily represent the official views of the U.S. FDA.
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Introduction

BACKGROUND: SARS-CoV-2 infection is associated with thrombotic complications. The risk of thrombotic events for outpatient COVID-19 cases is unknown

OBJECTIVE: To describe hospitalized thrombotic events following outpatient COVID-19 diagnosis among patients aged 40-79 years without known pre-existing risk factors for thrombosis

Methods

DATA SOURCE: Electronic health records from 64 health care organizations (HCO) in the TriNetX Live™ USA Network

PARTICIPANTS: Patients with outpatient-identified COVID-19 aged 40-79 years from February 20 through September 11, 2020

- Index date (Day 0): The first date of COVID-19 diagnosis (ICD-10-CM: B97.29, U07.1, B34.2, B97.2, J12.81) or positive test result (antigen or PCR)
- Exclusion criteria*:
 - Hospitalization [-2, 0]
 - Evidence of pregnancy [-84, 0];
 - Intracranial hemorrhage, ischemic stroke, bronchiectasis, or cancer [-30, 0];
 - Anticoagulant, antiplatelet, or thrombolytic use [-183, -2]; or
 - Use of strong P-glycoprotein (p-gp)/cytochrome P450 3A4 (CYP3A4) inhibitors or inducers [0, 45]

MAIN OUTCOMES AND MEASURES: Number (%) of patients with subsequent hospitalization records, those with hospitalized thrombotic events (deep vein thrombosis, pulmonary embolism, myocardial infarction, or ischemic stroke), and those with hospitalized thrombotic events or death up to **45 days after index date**

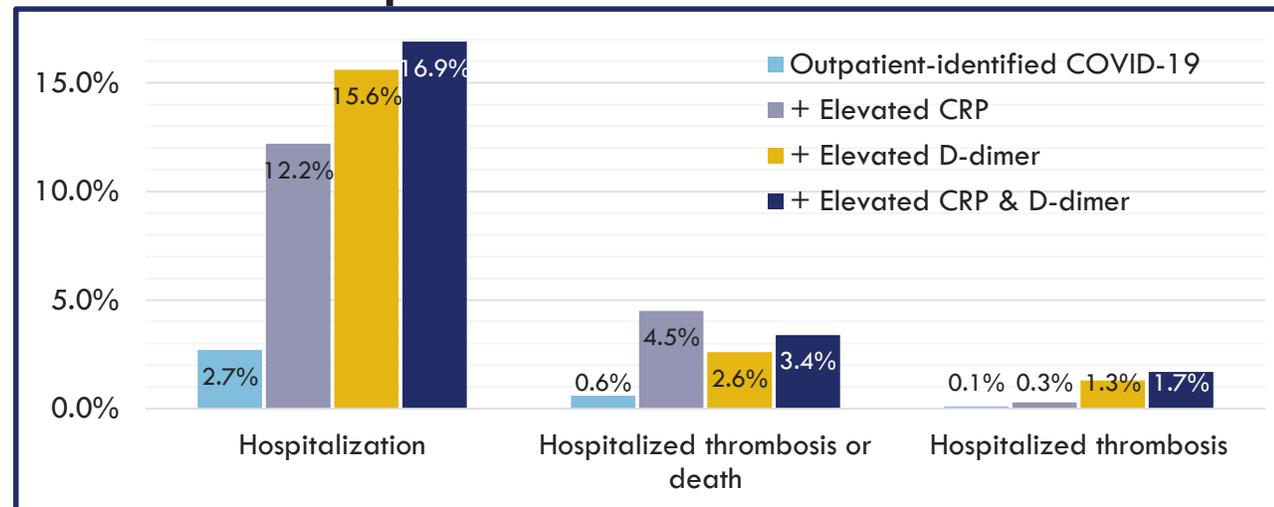
- Overall
- Stratified by C-Reactive Protein (hs-CRP/CRP) and D-dimer levels

*Consistent with the ACTIV-4b trial protocol (available at <https://fnih.org/sites/default/files/2021-03/activ-4b.pdf>)

Baseline characteristics of patients with outpatient-identified COVID-19

| | N*/Mean | %/Std. Dev. |
|--|---------|-------------|
| Total Patients | 89,640 | 100.0% |
| Age, mean | 55 | 10 |
| Female | 50,199 | 56.0% |
| Anticoagulant, antiplatelet, or thrombolytic use [0, 1 days] | 3,310 | 3.7% |
| Biomarkers of inflammation or coagulation [0, 7 days] | | |
| Any CRP/hs-CRP | 4,490 | 5.0% |
| Elevated [‡] | 3,120 | 3.5% |
| Any D-dimer | 4,260 | 4.8% |
| Elevated [§] | 770 | 0.9% |
| D-dimer and CRP/hs-CRP elevated [¶] | 590 | 0.7% |

Outcomes on days 1-45 after outpatient-identified COVID-19



- Hospitalized thrombotic events were uncommon among adults with COVID-19 identified while not currently hospitalized and without evidence of pre-existing risk factors for thrombosis
- Among those who were subsequently hospitalized, the frequency of thrombotic events was comparable to other published reports
- There may be misclassification of patients due to incomplete laboratory data and/or outcome ascertainment since events occurring outside of participating HCOs were not captured. This would limit temporal evaluation of clinical outcomes relative to index event.
- Further studies should assess risk of thrombotic events following outpatient COVID-19 diagnosis in patients with and without known risk factors for thrombosis

* All values are rounded up to the highest 10 to protect patient privacy

[‡]CRP/hs-CRP >10mg/L

[§] D-dimer >500 ng/mL for fibrinogen equivalent units (FEU) or >250 ng/mL for d-dimer units (DDU)

[¶] D-dimer >500 ng/mL [FEU] or >250 ng/mL [DDU] and CRP/hs-CRP >10mg/L