

Getting Treatment Right - COVID-19 and Venous Thromboembolism (VTE)



Faculty

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Early studies show that patients with COVID-19 appear to be at a higher risk for thrombotic complications like venous thromboembolism (VTE). VTE is already among the leading causes of death from cardiovascular disease. So, in addition to the traditional risk factors for VTE, practitioners must consider both the indirect effects as well as the direct effects of the COVID infection as they contribute to even greater risk of the consequences of VTE. This program will review the current literature and evidence regarding the frequency of VTE in patients with COVID, as well as the available guidance and evidence-based literature regarding the use of anticoagulation therapies in patients with COVID or patients recovering from COVID.

Learning Objectives

Pharmacist

1. Review the evidence-based literature and current assessment of the need for anticoagulation therapy for prevention of VTE in patients with COVID-19 and/or post COVID-19 patients.
2. Compare and contrast the indications, advantages and potential adverse effects of direct oral anticoagulants for the treatment of VTE.
3. Choose an anticoagulation treatment plan for VTE in COVID-19 positive patients based on patient specific factors and special considerations to improve patient outcomes.

Nurse

1. Review the evidence-based literature and current assessment of the need for anticoagulation therapy for prevention of VTE in patients with COVID-19 and/or post COVID-19 patients.
2. Compare and contrast the indications, advantages and potential adverse effects of direct oral anticoagulants for the treatment of VTE.
3. Choose an anticoagulation treatment plan for VTE in COVID-19 positive patients based on patient specific factors and special considerations to improve patient outcomes.

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Target Audience

Pharmacists, Nurses

Universal Activity Number

Pharmacist

0798-0000-20-256-H01-P

Nurse

0798-0000-20-256-H01-N

Credit Hours

1.0 Hour

Activity Type

Application-Based

CE Broker Tracking Number

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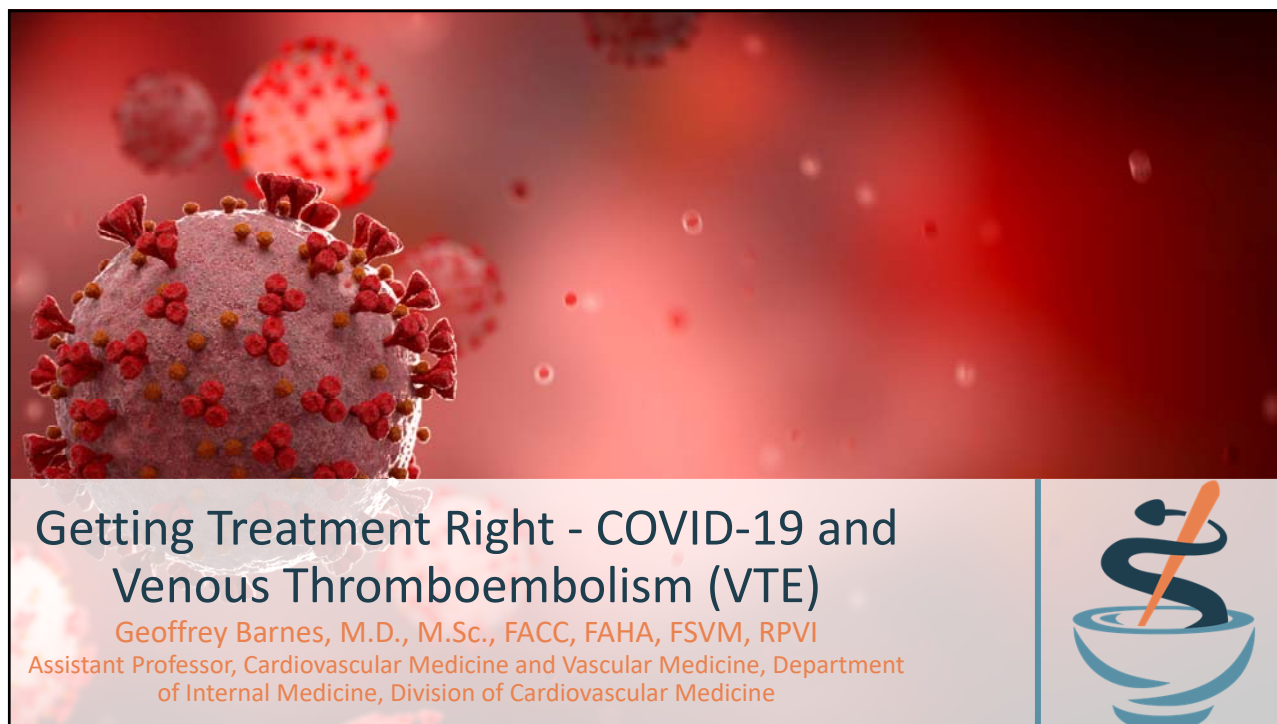
Consult full prescribing information on any drugs or devices discussed.

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Faculty Disclosure

- Dr. Geoffrey Barnes declares the following existence of financial interest in any amount related to the content of this activity:
 - Consulting fees from Pfizer/Bristol-Myers Squibb, Janssen, Portola, Acelis Connected Health
 - Board of Directors for Anticoagulation Forum and National Certification Board of Anticoagulation Providers
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2

Learning Objectives

At the conclusion of this activity, participants should be better able to:

1. Review the evidence-based literature and current assessment of the need for anticoagulation therapy for prevention of VTE in patients with COVID-19 and/or post COVID-19 patients.
2. Compare and contrast the indications, advantages and potential adverse effects of direct oral anticoagulants for the treatment of VTE.
3. Choose an anticoagulation treatment plan for VTE in COVID-19 positive patients based on patient specific factors and special considerations to improve patient outcomes.

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Case #1

- 49-year-old man admitted after 5 days of fever, progressive SOB
- PMH: obesity (BMI 38), DM2 on insulin, and stage 2 CKD
- ED: HR 98, BP 134/88, RR 24, SpO2 84% on room air → 94% on 2L
- No leg swelling
- D-dimer 8.4 mg/L (normal level <0.50)
- CXR: Bilateral patchy infiltrates
- CTPA: no PE, bilateral ground glass opacities and consolidation (RLL, LUL)
- Admit to the general medicine wards

RLL= Right Lower Lobe
LUL= Left Upper Lobe

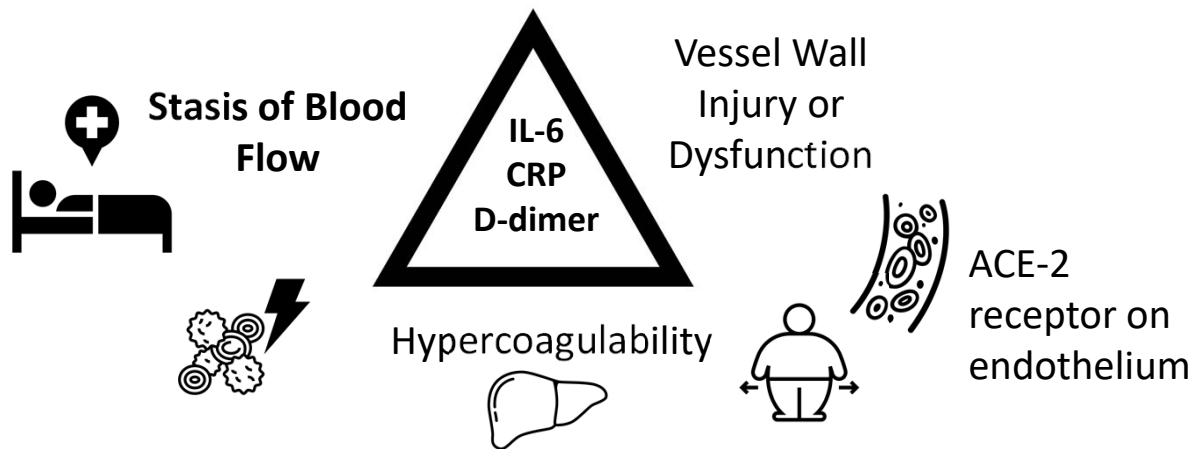
CTPA= CT pulmonary
angiogram

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Mechanisms of COVID-19 Thrombosis



JACC DOI 10/1016/j.jacc.2020.04.031

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Case #1 Continued

Case: 49-year-old man admitted with COVID-19

- 2L O₂
- Elevated D-dimer
- Negative PECT

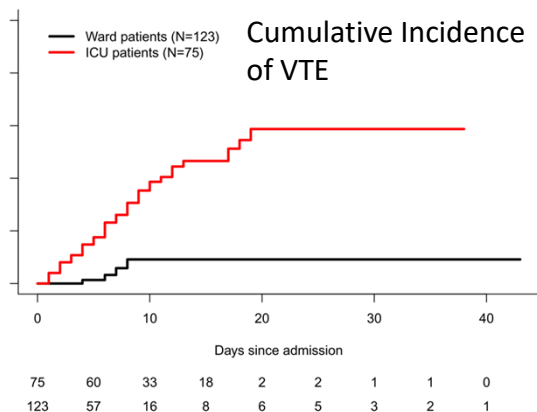
- What is VTE risk?
- What VTE prophylaxis would you use?

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D-dimer and COVID-19 Mortality Risk



VTE Risk Factors - Netherlands

	VTE (n=39)	No VTE (n=159)	HR
Mean age (SD)	62 (10)	60 (15)	1.05 (0.82-1.4)
ICU	35 (89%)	40 (25%)	8.9 (3.2-25)
Median D-dimer (IQR)	2.6 (1.1-18)	1.0 (0.7-1.7)	1.4 (1.1-1.9)

Middelorp S et al JTH 2020 ePub May 6. DOI 10.1111/jth.14888

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COVID-19 and VTE Risk in USA

	PE	DVT	Any Thromboembolism
All patients (n=3334)	106 (3.2%)	129 (3.9%)	533 (16.0%)
ICU patients (n=829)	52 (6.2%)	78 (9.4%)	244 (29.4%)
Floor patients (n=2505)	54 (2.2%)	51 (2.0%)	289 (11.5%)

NYU Langone Health System

JAMA 2020 DOI 10.1001/jama.2020.13372

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COVID-19 and Thrombosis (esp VTE)

Author	Country	Number of Patients	VTE Rate	Other Rates
Zhang	China	143	46.1% (DVT only)	
Middledorp	Netherlands	198 (75 ICU)	42% (25% symptomatic)	59% ICU 9.2% Floor
Klok	Netherlands	184 (all ICU)		All TE 49%
Longchamp	Switzerland	25 (all ICU)	32%	
Chui	China	81 (all ICU)	25%	
Helms	France	150 (all ICU)	16.7% (PE)	OR 6.2 vs. non-COVID ARDS
Al-Samkari	USA	400 (144 ICU)	4.8%	All TE 9.5%
Lodigiani	Italy	388 (61 ICU)	4.4% (8.3% ICU)	All TE 7.7%
Moll	USA	210 (102 ICU)	4.3%	
Bilaloglu	USA	3334 (829 ICU)	3.2% (PE) 3.9% (DVT)	All TE 16.0%

- 10.1161/circulationaha.120.046702. 10.1111/jth.14888. 10.1016/j.thromres.2020.04.041. 10.1002/rth2.12376. 10.1111/jth.14830.
- 10.1182/blood.2020006520. 10.1016/j.thromres.2020.04.024. 10.1016/j.chest.2020.07.031. 10.1007/s00134-020-06062-x.
- 10.1001/jama.2020.13372

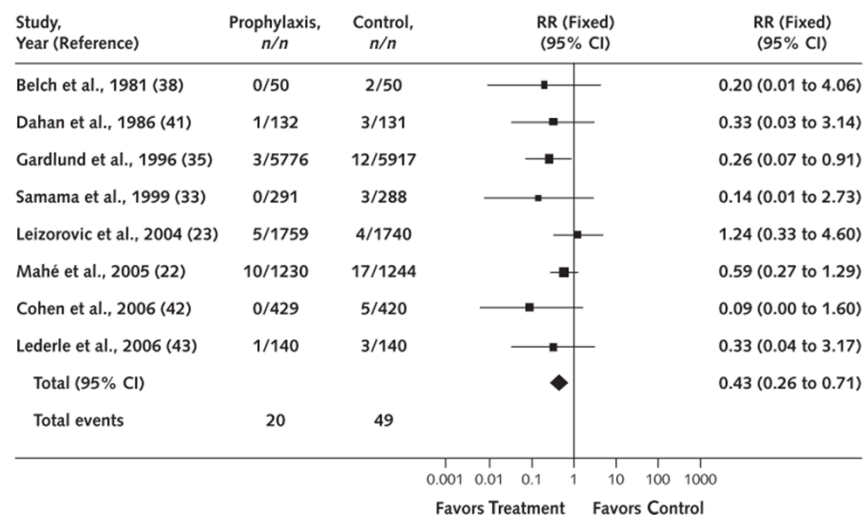
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Role of VTE Prophylaxis

Figure 2. Any pulmonary embolism during anticoagulant prophylaxis.



>50%
Relative
Risk
Reduction
for PE with
prophylaxis

Annals IM 2007;146:278-288

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Case #1 (Continued)

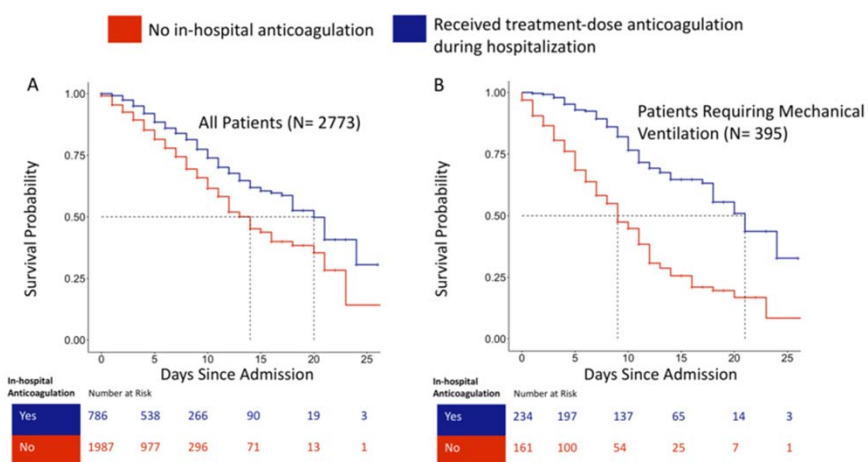
- On hospital day 4, his O2 requirement rapidly increases to 6L
- He is transferred to ICU for heated high-flow O2
- He develops acute on chronic renal insufficiency
 - Cr 2.2, CrCl <30ml/min
- Do you change his VTE prophylaxis regimen?

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What Dose of Anticoagulation?



DOI: 10.1016/j.jacc.2020.05.001

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- NYC Hospital System
- 2733 hospitalized patients with COVID-19
- Compare in-hospital treatment-dose anticoag vs. none

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Updated NYC Analysis

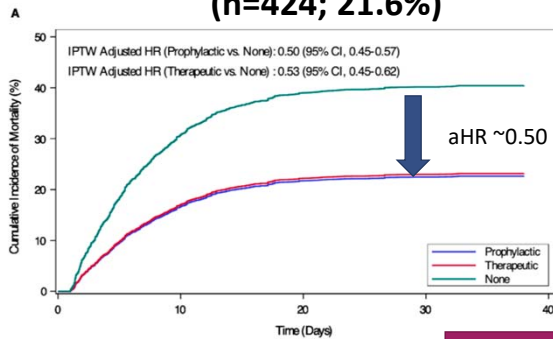
4389 patients total

900 therapeutic; 1959 prophylactic; 1530 "none"

Major bleeding in 89 patients

3.0% therapeutic, 1.7% prophylactic, 1.9% "none"

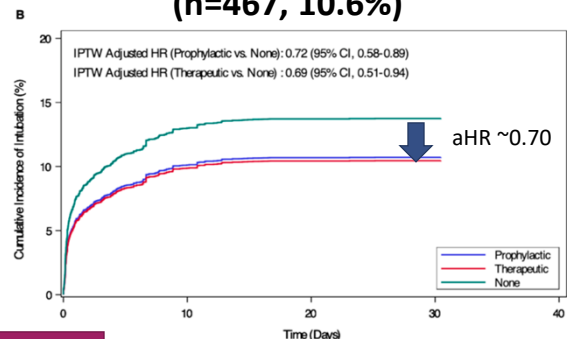
In-hospital Mortality (n=424; 21.6%)



10.1016/j.jacc.2020.08/041

aHR=adjusted hazard ratio

Intubation (n=467, 10.6%)

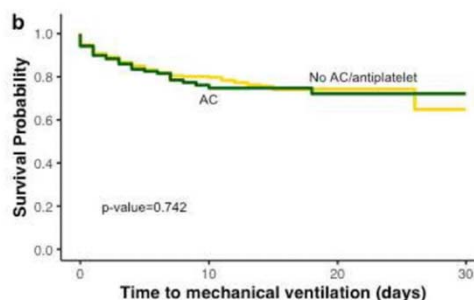
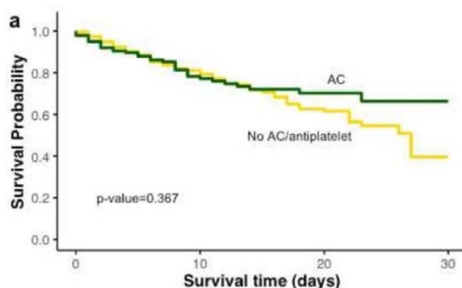


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Benefits of Therapeutic Anticoagulation?



■ Anticoagulation (AC)
■ No anticoagulation/antiplatelet

Tremblay D et al Blood 2020 ePub May 27, DOI: 10.1182/blood.2020006941

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- Same NYC Hospital System
- 3772 hospitalized patients with COVID-19
- Compare pre-hospital anticoag vs. no anticoag

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Which Anticoagulant to Use?

Drug Name	Hospitalized Medical VTE Prophylaxis Evidence	FDA Approval	Details
LMWH	Yes	Yes	Usual dose 40mg daily for 7-10 days, 30mg daily if CrCl<30ml/min
Unfractionated Heparin	Yes	Yes	5000 units every 8-12 hours, useful for advanced CKD
Apixaban	Yes	No	ADOPT Study: 2.5mg BID x30 days
Betrixaban	Yes	Yes	Discontinued commercialization
Dabigatran	No	No	
Edoxaban	No	No	
Rivaroxaban	Yes	Yes	10mg daily for 31-39 days, avoid if CrCl<15ml/min

Information for "hospitalized medical patients"

Drugs@FDA Website, accessed Sept 23, 2020 NEJM 2011;365:2167-217 © 2020 PharmCon 

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Ongoing Clinical Trials

46 RCT of Anticoag and COVID-19 on ClinicalTrials.gov (Aug 15, 2020)

Trial Name (NCT)	Details
ATTACC (NCT04372589)	Therapeutic UFH/LMWH vs. Usual Care (Bayesian, adaptive design). Up to 3000 patients.
HEP-COVID (NCT04401293)	Full vs. Prophyl/Intermediate LMWH in high-risk COVID-19. 308 patients
IMPROVE (NCT04367831)	Intermediate vs. prophyl dose anticoag in ICU. 100 patients
COVI-DOSE (NCT04373707)	Weight-adjusted intermediate vs. prophyl dose LMWH. 602 patients
COVID-PACT (NCT04409834)	(1) Therapeutic vs. prophyl anticoag and (2) clopidogrel vs. none. 750 ICU patients
RAPID COVID-COAG (NCT04362085)	Therapeutic UFH/LMW vs. usual care if D-dimer $\geq 2 \times$ ULN. 462 patients.

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Case #1 (Continued)

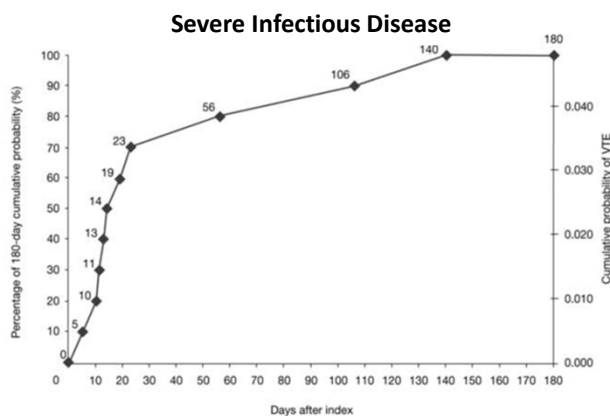
- After 3 days in the ICU, his O2 requirements improve, no longer febrile
 - He transfers to the floor for continued O2 weaning
 - Renal function improving (Cr 1.7)
- He is eventually discharged home on hospital day 10 (symptom day 15)
 - Still requiring 0.5-1L nasal canula
 - Back to baseline renal function (Cr 1.3)
 - D-dimer 2.5 mg/L (normal level <0.5)
- Do you consider post-hospital VTE prophylaxis?

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Risk of Post-hospital VTE



MarketScan Commercial and Medicare Dataset 2005-2008

DOI 10.1002/jhm.1002

NEJM 2013;368:513-523

NEJM 2016;375:534-544

	VTE Events	Major Bleeding
Rivaroxaban 10mg daily	4.4%	1.1%
Enoxaparin 40mg daily	5.7%	0.4%
Betrixaban 80mg daily	5.3%	0.7%
Enoxaparin 40mg daily	7.0%	0.6%

NEJM 2013;368:513-523

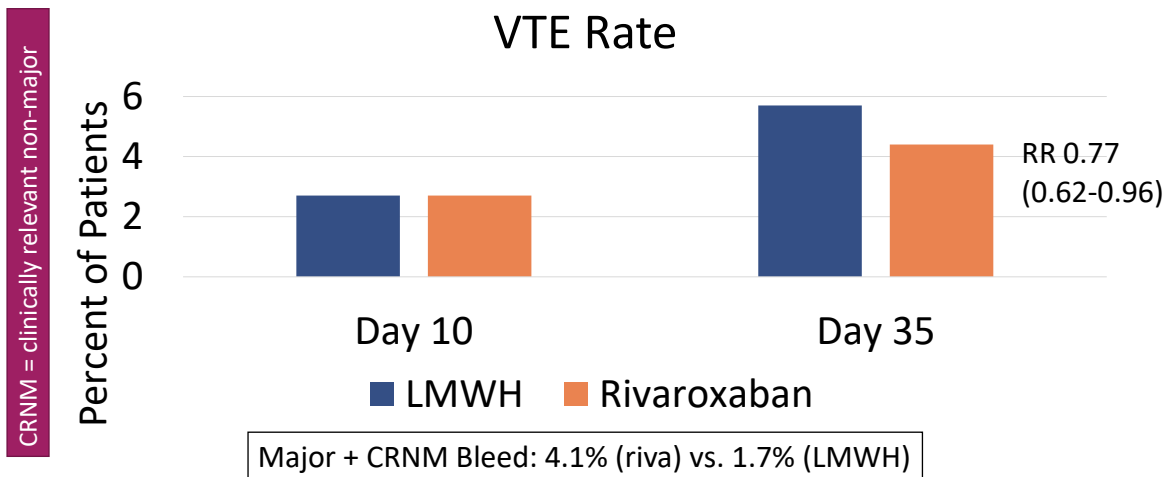
NEJM 2016;375:534-544

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Post-Hospital VTE Prophylaxis: MAGELLAN



NEJM 2013;368:513-523

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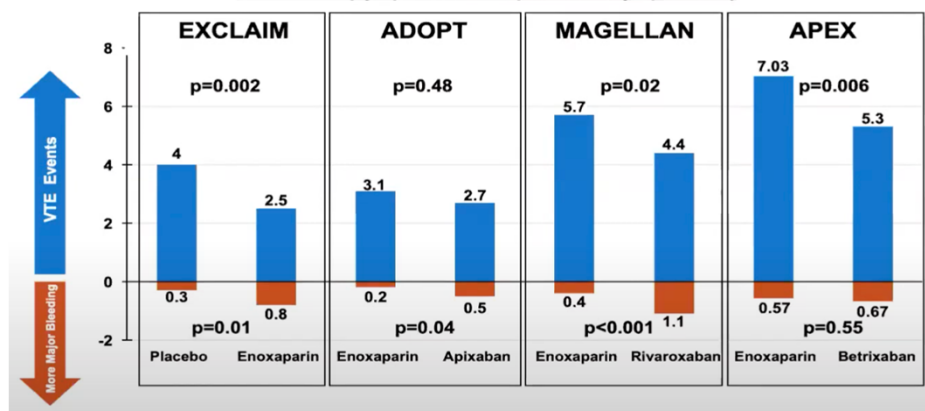


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Post-Hospital VTE Prophylaxis: DOAC Data

Trials Of Extended Thromboprophylaxis In Acute Medically Ill Patients

VTE events (symptomatic and proximal asymptomatic)



Ann Int Med 2010;153:8-18

NEJM 2011;365:2167-217

NEJM 2013;368:513-523

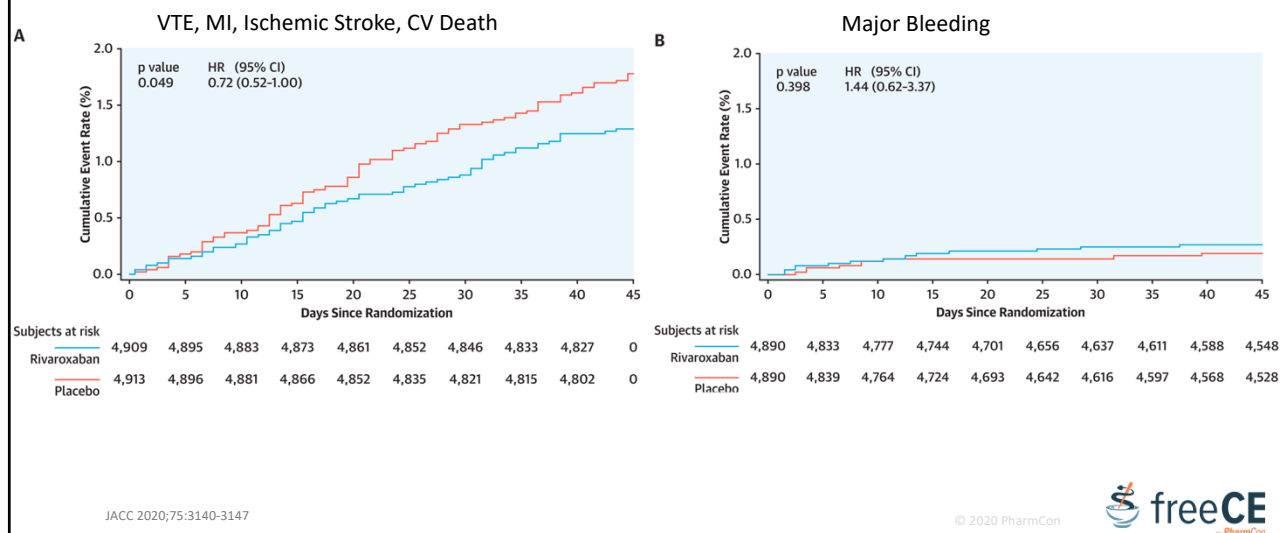
NEJM 2016;375:534-544

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Post-hospital VTE: More Selective at Discharge?



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Post-Hospital VTE and COVID

	COVID-19 London	2019 London	COVID-19 Boston
Total Discharges	1877	18,159	163
All Hosp-assoc VTE	84 (2.9%)		All TE: 4 (2.5%) (0.8-7.6%)
Post-hospital VTE (42 day)	9 (0.5%)	56 (0.3%)	0.6% at 30d
Time to VTE (median, days)	8 (range 3-33)	29 (IQR 16-51)	23 (IQR 12-33)

2 Hospitals in London, UK
March 3 – May 7, 2020

BI Deaconess
March-May 2020

10.1182/blood.202008086

10.1182/blood.202007938

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Guidelines for Post-Hospital VTE Prophylaxis

- AC Forum
 - Not for all patients
 - If used, follow clinical trial inclusion criteria
- CHEST
 - Not for all patients
 - If used, limit to patients at low bleeding risk if data shows potential benefit
- ISTH
 - Use if high-risk for VTE and low risk for bleed
 - Older age, ICU stay, cancer, prior VTE, elevated D-dimer, IMPROVE score ≥ 4

10.1007/s11239-020-02138-z 10.1016/j.chest.2020.05.559 10.1111/jth.14929

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What Dose of Anticoagulation?

Patient with COVID-19	Standard Dose VTE Prophylaxis	Intermediate or Escalated Dose VTE Prophylaxis	Therapeutic Anticoagulation
Floor patients	Yes		
ICU Patients		Yes	
ARDS Patients		Yes	
Confirmed VTE			Yes
Suspected PE			Yes

Mirrors AC Forum guidance
CHEST guidelines say standard dose for all

Connors and Levy Blood 2020 ePub Apr 28. 10.1007/s11239-020-02138-z. 10.1016/j.chest.2020.05.559

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Case #2

- 62-year-old woman is diagnosed with COVID-19 by her PCP
- PMH: surgically-provoked DVT 5 years ago, DM2, rheumatoid arthritis
- SH: Non-smoker
- Meds: metformin, methotrexate, naproxen
- Vital signs stable
- D-dimer 3x upper limit of normal
- She is managed at home with self-monitoring

- Is she at risk for VTE?
- Should she receive prophylaxis?

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Risk of VTE in Ambulatory Setting?

- Limited case reports/series for COVID-19 infection → unknown risk
- Other risk factors include
 - Prior VTE
 - Older age
 - Cancer
 - Venous insufficiency
 - Pregnancy
 - Trauma
 - Frailty and immobility
 - Smoking
 - Obesity

JACC 2010;56:1-7

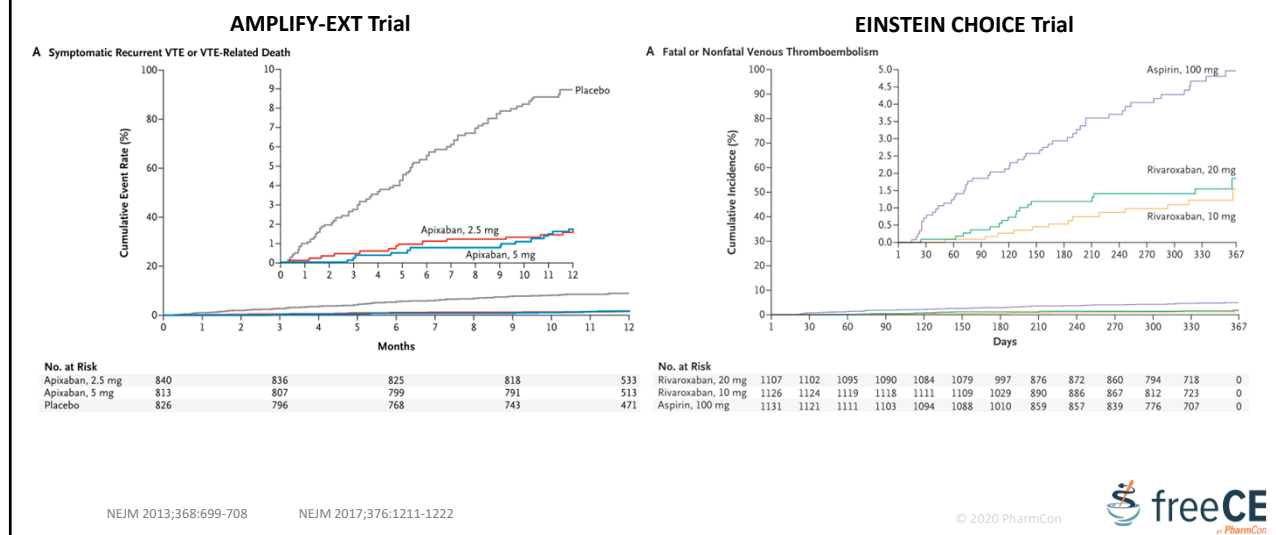
JAMA Cardiol 2019;4:163-173

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“Low Dose” DOAC for VTE Prevention?



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Outpatient VTE Prevention: Key Questions

- Is VTE risk high enough?
- Will low-dose DOAC reduce VTE risk?
- Would low-dose aspirin reduce VTE risk?
- Will bleeding risk outweigh thrombotic risk reduction?
- Are cost of DOACs too high?
- Warfarin and INRs → would DOAC be more convenient?

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Ongoing Clinical Trials

- COVID-19 Outpatient Thrombosis Prevention Trial (NCT04498273)
 - Patients 40-79 years old with COVID-19, elevated d-dimer and hsCRP
 - NOT hospitalized
 - 4 arms (apixaban 2.5 BID, apixaban 5 BID, aspirin 81 daily, placebo) x45days
 - Primary outcome: Hospitalization for CV/pulmonary events, symptomatic DVT, PE, arterial thromboembolism, MI, ischemic stroke, death
- PREVENT-HD Study (NCT04508023)
 - Patients 18+ years old with COVID-19 and 1+ risk factor for thrombosis
 - Age ≥60, prior VTE, thrombophilia, CAD, PAD, cerebrovascular disease, cancer, DM, CHF, BMI>35, elevated d-dimer
 - 2 arms (rivaroxaban 10mg daily, placebo)
 - Primary outcome: Symptomatic VTE, ischemic stroke, acute limb ischemia, systemic embolism, all cause hospitalization, all cause death

Clinicaltrials.gov

hsCRP = highly sensitive C-reactive protein

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Case #2 (Continued)

- 62-year-old woman with COVID-19, managed at home
- Multiple VTE risk factors
 - Prior VTE
 - Older age
 - Elevated d-dimer
 - Rheumatologic condition
- Consider short-term prophylaxis (recognize lack of data)
 - Only if bleeding risk is low
 - DOAC vs. aspirin
 - Encourage clinical trial enrollment if available
- Other advice
 - Ambulate when possible
 - Stay hydrated
 - Monitor for unilateral leg swelling, sudden onset shortness of breath or chest pain

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Other Common Questions: AC Forum Guidance

- Warfarin → DOAC switch?
 - Can reduce need for INR draw and travel to lab
 - Cost concerns, check renal function/drug-drug interactions, indications
- Reduce INR draws for warfarin-treated patients?
 - If stable, consider extended INR testing intervals (6-12 weeks)
 - Home INR testing

J Thromb Thrombolys 2020;50:72-81

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Key Takeaways

- COVID-19 is a key risk factor for hospital-associated VTE
 - Estimates vary widely
- Stick to evidence-based prophylaxis unless in a clinical trial
 - Consider intermediate-dose or escalated prophylaxis for sicker patients (or elevated d-dimer)
 - Heparin > DOAC for most hospitalized patients
 - Only rivaroxaban & betrixaban has FDA approval
 - Concerns with renal function change, need for procedures
- Consider role of post-hospital VTE prophylaxis
 - Overall VTE rates may not be markedly elevated
- Ambulatory VTE prophylaxis
 - Unclear risk, clinical trials to evaluate effective treatments

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VTE Prophylaxis and Oral Anticoagulants

- Confirmed VTE ← “Provoked” VTE
 - VKA or DOAC (any) for 3 months
- In-hospital prophylaxis ← Watch for renal dysfunction
 - LMWH > unfractionated heparin > DOAC
- Post-hospital prophylaxis ← Limited FDA approval
 - Rivaroxaban or betrixaban
- Non-hospitalized with COVID-19
 - Rivaroxaban or apixaban in clinical trial

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Thank You

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Activity Test

Getting Treatment Right - COVID-19 and Venous Thromboembolism (VTE)

Activity tests must be completed online at www.freeCE.com.

A passing grade of 70 or higher and completion of an online activity evaluation are required to earn credit.

1. Which of the following patients seen in a primary care clinic for COVID-19 is at highest risk for developing venous thromboembolism?
 - a. 55yo woman with a history of hyperthyroidism and surgery two months prior to remove uterine fibroids
 - b. 72yo man with a history of obesity, tobacco use, and has limited mobility
 - c. 69yo woman with a history of Von Willebrand disease, hypertension, and osteoarthritis
 - d. 61yo man with a history of moderate asthma, benign prostatic hypertrophy, and hyperlipidemia

2. Ms. N is a 62-year-old woman who was hospitalized for COVID-19 pneumonia. Her past medical history includes hypertension, and she is overweight (BMI 28). On hospital day 3, she had a sudden increase in oxygen requirement and tachycardia. Her medical team suspected a pulmonary embolism and initiated treatment-dose unfractionated heparin. She has continued to have normal renal function and has no signs of bleeding. She is now ready to leave the hospital after a 10-day stay. Which of the following is the best anticoagulation regimen for her upon hospital discharge?
- a. Apixaban 5mg twice a day for a 3-month course after a higher dose lead in
 - b. Dabigatran 75mg twice a day for a 6-month course after a higher dose lead in
 - c. Rivaroxaban 15mg twice a day for a 6-month course after a higher dose lead in
 - d. Warfarin with a goal INR of 1-2 for a 3-month course
3. Which of the following best describes how a patient hospitalized with COVID-19 may develop venous thromboembolism through one of Virchow's Triad categories of thrombosis risk?
- a. Use of anti-inflammatory medications
 - b. High levels of supplemental oxygen use
 - c. Accelerated blood flow due to dehydration
 - d. Vessel wall injury from activation of ACE-2 receptors
4. Which of the following patients with COVID-19 is at highest risk for venous thromboembolism?
- a. A 52yo man who is self-isolating at home
 - b. A 64yo woman hospitalized on the general medicine wards
 - c. A 59yo man who is admitted to the intensive care unit with acute respiratory distress syndrome
 - d. A 61yo woman currently living in a long-term care facility

5. In general, use of venous thromboembolism chemoprophylaxis is associated with approximately how much of a reduction in developing hospital-associated venous thromboembolism?
- 15% relative risk reduction
 - 25% relative risk reduction
 - 35% relative risk reduction
 - 55% relative risk reduction
6. Based on observational data from New York City, which of the following statements is true with regards to venous thromboembolism prophylaxis in patients hospitalized with COVID-19?
- Use of prophylactic- and treatment-dose anticoagulation is associated with similar reductions in in-hospital mortality as compared to no anticoagulation therapy.
 - Use of prophylactic anticoagulation is associated with a greater reduction in in-hospital mortality than treatment-dose anticoagulation
 - Use of prophylactic- and treatment-dose anticoagulation are not associated with a reduction in intubation risk
 - Use of treatment-dose, but not prophylactic-dose, anticoagulation is associated with a reduction in intubation risk
7. Which of the following anticoagulants is currently FDA approved for prophylaxis against venous thromboembolism in hospitalized medical patients?
- Apixaban
 - Dabigatran
 - Edoxaban
 - Rivaroxaban

8. Mr J is a 65yo man with a history of diabetes, chronic kidney disease, and chronic obstructive pulmonary disease. He uses 2 liters of home oxygen with exertion. His vital signs in the emergency department are: heart rate 85, respiratory rate 22, blood pressure 135/72, oxygenation 95% on 4L nasal cannula, and BMI 36. His admission labs include a white blood count of 12.0, hemoglobin of 14 g/dL, platelets of 175,000, and creatinine of 1.2 mg/dL. He is admitted to the hospital's general medicine wards for a diagnosis of COVID-19 pneumonia. Which of the following is the most appropriate regimen for venous thromboembolism prophylaxis?
- a. Unfractionated heparin 5000 units daily
 - b. Unfractionated heparin 7500 units daily
 - c. Enoxaparin 40mg daily
 - d. Enoxaparin 80mg daily
9. Mr J is a 55 year old man who was hospitalized for COVID-19 pneumonia. His past medical history includes hypertension and he is overweight (BMI 28). On hospital day 3, he had a sudden increase in oxygen requirement and tachycardia. His medical team suspected a pulmonary embolism and initiated treatment-dose unfractionated heparin. He has continued to have normal renal function and has no signs of bleeding. He is now ready to leave the hospital after a 10-day stay. Which of the following is the best anticoagulation regimen for him upon hospital discharge?
- a. Apixaban 2.5mg twice a day for a 3 month course
 - b. Dabigatran 75mg twice daily for a 6 month course
 - c. Rivaroxaban 15mg twice a day for a 6 month course
 - d. Warfarin with a goal INR of 2-3 for a 3 month course

10. Mrs. P is a 65yo woman with hypertension and diabetes takes warfarin for stroke prevention related to atrial fibrillation. She contacts her anticoagulation clinic asking if there are strategies she can use to minimize her risk of contracting COVID-19 when she goes for her monthly INR draw at her local laboratory. Which of the following is the best advice to help her minimize her COVID-19 exposure risk?

- a. Tell her that checking her INR can be done once every 3-6 months instead of monthly
- b. Tell her to eat a salad every day to balance the anticoagulant effect of warfarin and avoid the need for INR tests
- c. Stop warfarin and start aspirin for stroke prevention
- d. Check to see if she would qualify for home INR testing

11. Which of the following patients with a COVID-19 diagnosis is most appropriate to receive unfractionated heparin 7500 units three times daily as an “intermediate” dose venous thromboembolism chemoprophylaxis?

- a. 42 year old man admitted to the genal surgery service for appendectomy
- b. 52 year old woman recently transferred to the intensive care unit and intubated for acute respiratory distress syndrome
- c. 88 year old man admitted to cardiology service for a heart failure exacerbation
- d. 66 year old woman admitted to the pulmonary service for a COPD exacerbation requiring oxygen by nasal cannula

12. Which of the following patients seen in a primary care clinic for COVID-19 is at highest risk for developing venous thromboembolism?

- a. 55yo woman with a history of hyperthyroidism, uterine fibroids, and eczema
- b. 72yo man with a history of obesity, tobacco use, and a deep vein thrombosis 5 years prior
- c. 69yo woman with a history of benign colon polyps, hypertension, and osteoarthritis
- d. 61yo man with a history of asthma, benign prostatic hypertrophy, and hyperlipidemia