2023 ASH Thrombophilia Testing Guideline

Wednesday, August 30, 2023

Anticoagulation FORUM

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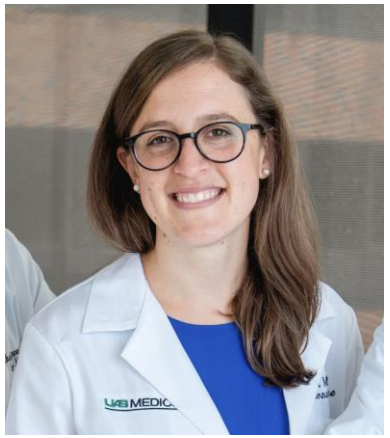

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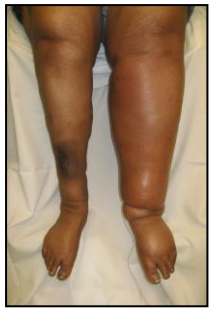
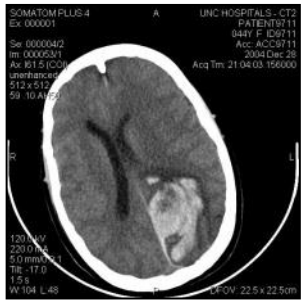
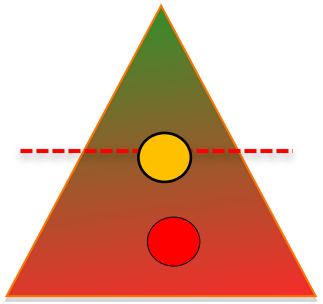




Thrombophilia Testing

ASH 2023 Guideline

Stephan Moll, MD

Medicine, Hematology-Coagulation

University of North Carolina, Chapel Hill

Anticoagulation Forum Webinar

Aug 30th,2023

Disclosures

Consultant to Diagnostica Stago

General Comments

- "*These guidelines are NOT intended to serve or be construed as a standard of care*"

- "*Clinicians must make decisions based on the clinical presentation of each individual patient*" "*…. ideally through a shared process that considers the patient's values and preferences with respect to the anticipated outcomes of the chosen option*"

- Almost all recommendations are based on "*very low certainty in the evidence, due to modelling assumptions"*

- Almost all recommendations are "suggestions", and they are "conditional"

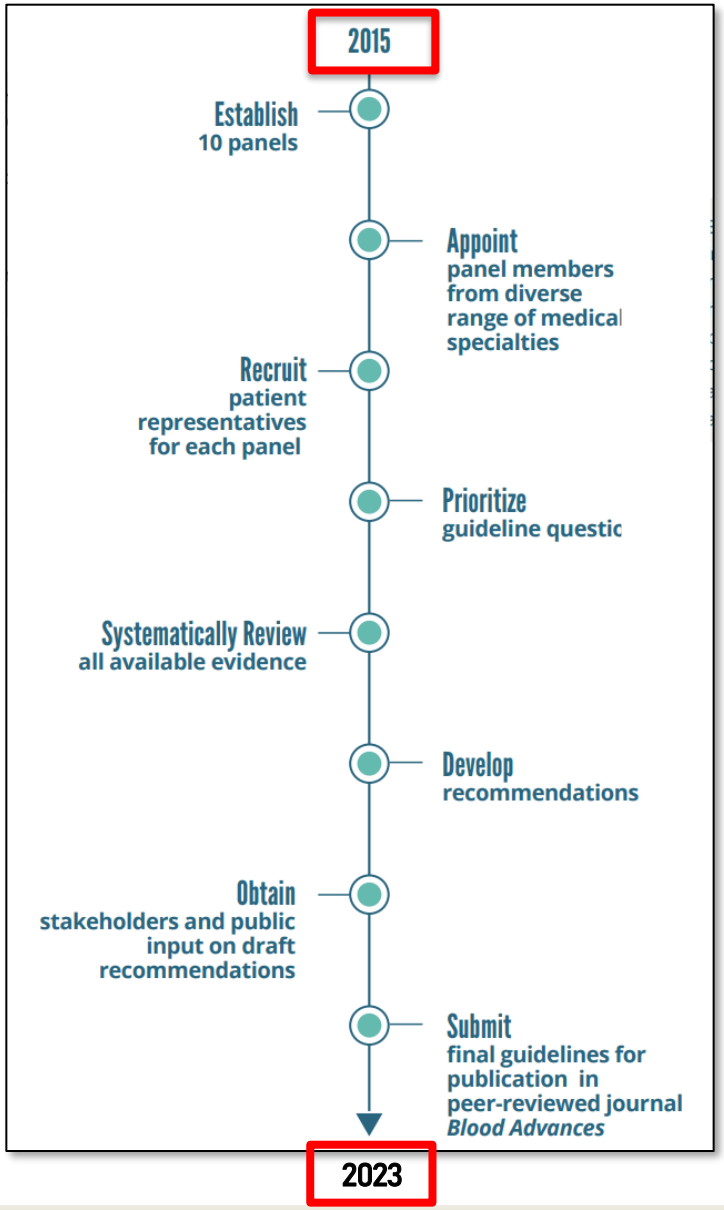
** Conditional = subject to one or more conditions or requirements being met*

[Middeldorp S et al. Blood Advances 2023; May 17. https://go.unc.edu/k4X2C]

Methods

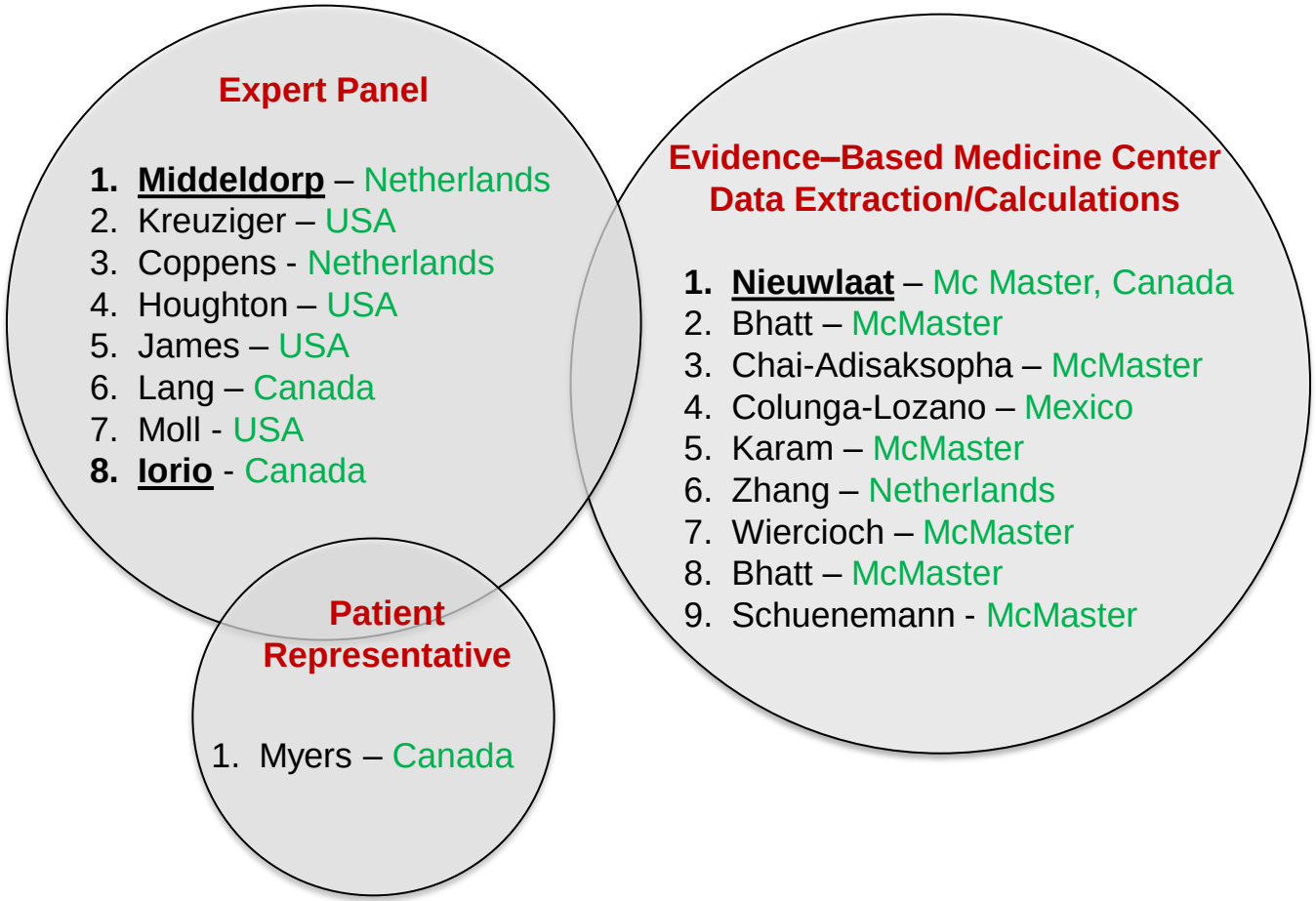
CONDITIONS/TOPICS ADDRESSED

Prevention of VTE in surgical and medical patients	Diagnosis of VTE	Treatment of VTE, including both DVT and PE
Optimal management of anticoagulation therapy	Thrombophilia testing	Heparin-induced thrombocytopenia
VTE and pregnancy	VTE in patients with cancer	Treatment of VTE in pediatric populations



[https://www.hematology.org/education/clinicians/guidelines-and-quality-care/clinical-practice-guidelines/venous-thromboembolism-guidelines]

Methods



American Society of Hematology 2023 Guidelines for Management of Venous Thromboembolism: Thrombophilia Testing

Saskia Middeldorp,[1] Robby Nieuwlaat,[2,3] Lisa Baumann Kreuziger,[4] Michiel Coppens,[5,6] Damon Houghton,[7] Andra H. James,[8] Eddy Lang,[9] Stephan Moll,[10] Tarra Myers,[11] Meha Bhatt,[2] Chatree Chai-Adisaksopha,[12] Luis E. Colunga-Lozano,[13] Samer G. Karam,[2,3] Yuan Zhang,[1,2] Wojtek Wiercioch,[2,3] Holger J. Schünemann,[2,3,14] Alfonso Iorio[3]

[Middeldorp S et al. Blood Advances **2023** May 17.2023010177. Online ahead of print]

Methods

- Calculate absolute risk of an event (VTE, bleeding, etc.)

[Wierioch W et al. J Clin Epidemiol 2022;143:91-104]
[Foroutan F et al. J Clin Epidemiol 2020;117:46-51]

- GRADE methodology (Grading of Recommendations, Assessment, Development and Evaluations)

[Wierioch W et al. J Clin Epidemiol 2022;143:91-104]

- Thrombophilia = inherited and acquired (APLA)
- Heterozygous and homozygous grouped together

- Forthcoming: ASH “clinical decision aids”

Methods

Background	Subgroup considerations	Justification	Implementation considerations

[https://guidelines.ash.gradepro.org/profile/XLPPdthsuBk]

Example: Q3

GRADE evidence profile | Summary of Findings table | Evidence to Decision framework | Interactive Summary of Findings

Open in new window

Author(s): Robby Nieuwlaat, Alfonso Iorio, Saskia Middeldorp
Question: In patients with symptomatic venous thromboembolism provoked by a non-surgical major transient risk factor who completed primary treatment, should thrombophilia testing and subsequent indefinite anticoagulant treatment in patients positive for thrombophilia and stopping anticoagulant treatment in patients negative for thrombophilia compared to no thrombophilia testing and stopping anticoagulant treatment in all be used?
Setting:
Bibliography: See reference list and footnotes.[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,43,44,45,46,47,48,49,50,51,52,53,54,55,56,57,58,59,60,61,62,63,64,65]

Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Recurrent VTE (assessed with: any DVT or PE)									
24[a,b,c,d,e,f,g]	observational studies	not serious	not serious	serious[h]	serious[i]	none	When testing 1,000 patients who completed primary treatment of symptomatic VTE provoked by a non-surgical major transient risk factor for any type of thrombophilia, and treating the 380 positives with indefinite anticoagulation (ranging from 216 to 595), 29 VTE recurrences will occur per year (ranging from 15 to 40). When not testing 1,000 patients for thrombophilia and stopping treatment in all of them, 50 VTE recurrences will occur per year. Therefore, a thrombophilia testing strategy is associated with 380 more patients treated with indefinite anticoagulation (ranging from 216 to 595) and **21 fewer VTE recurrences (ranging from 10 to 35)** per 1,000 patients per year compared with a no testing strategy. [j]	⨁◯◯◯ Very low	CRITICAL
Major Bleeding - Low (0.5% per year)[k]									
31[c,d,l,m,n]	observational studies	not serious	not serious	very serious[o]	not serious	none	When testing 1,000 patients with symptomatic VTE provoked by a non-surgical major transient risk factor who are at low risk of major bleeding for any type of thrombophilia, and treating the 380 positives with indefinite anticoagulation (ranging from 216 to 595), 7 major bleedings will occur per year (ranging from 5 to 12). When not testing 1,000 patients for thrombophilia and stopping treatment in all of them, 5 major bleedings will occur per year. Therefore, a thrombophilia testing strategy is associated with 380 more patients treated with indefinite anticoagulation (ranging from 216 to 595) and **2 more major bleedings (ranging from 0 to 7)** per 1,000 patients per year compared with a no testing strategy. [p]	⨁◯◯◯ Very low	CRITICAL
Major Bleeding - High (1.5% per year)[q]									
31[c,d,l,m,r]	observational studies	not serious	not serious	serious[o]	serious[i]	none	When testing 1,000 patients with symptomatic VTE provoked by a non-surgical major transient risk factor who are at high risk of major bleeding for any type of thrombophilia, and treating the 380 positives with indefinite anticoagulation (ranging from 216 to 595), 22 major bleedings will occur per year (ranging from 16 to 36). When not testing 1,000 patients for thrombophilia and stopping treatment in all of them, 15 major bleedings will occur per year. Therefore, a thrombophilia testing strategy is associated with 380 more patients treated with indefinite anticoagulation (ranging from 216 to 595) and **7 more major bleedings (ranging from 1 to 21)** per 1,000 patients per year compared with a no testing strategy. [s]	⨁◯◯◯ Very low	CRITICAL

CI: confidence interval; **RR:** risk ratio

Explanations

a. Number of studies used in calculations: Overall risk for VTE recurrence, 1 systematic review; Prevalence, 20 studies; Risk association for thrombophilia positive versus negative, 6 studies (all also reported Prevalence); Extended anticoagulation effect, 4 RCTs
b. Overall risk for VTE recurrence: Iorio 2010
c. Thrombophilia prevalence, used for calculation: Bezemer 2009, Di Minno 2014, Garcia-Fuster 2005, Heit 2010, Kearon 1999, Kearon 2008, Kearon 2018, Lim 2017, Mello 2010, Meyer 2015, Olie 2011, Palareti 2003, Prandoni 2007, Roldan 2009, Rossi 2008, Santamaria 2005, Schattner 1997, Schulman 2006, Sundquist 2015, Weingarz 2015
d. Prevalence of specific thrombophilia types, used to verify calculation estimate: Ahmad 2016, Ahmad 2016, Ahmad 2017, Asim 2017, Baarslag 2004, Baglin 2003, Brouwer 2009, Bruwer 2016, Cebi 2009, Christiansen 2005, De Stefano 1999, De Stefano 2006, Eichinger 1999, Eichinger 2002, Eischer 2017, Gonzalez-Porras 2006, Heijboer 1990, Hirmerova 2014, Hoibraaten 2000, Kearon 2008, Laczkovics 2007, Lee 2017, Lijfering 2010, Lindmarker 1999, Marcucci 2003, Mateo 1997, Miles 2001, Ridker 1995, Rodger 2008, Roupie 2016, Rupa-Matysek 2014, Simioni 2000, Sonnevi 2013, Strandberg 2007, Sveinsdottir 2012, The Procare group 2003, Wahlander 2006
e. Thrombophilia positive vs negative risk association, used for calculation: Kearon, 1999, Kearon 2018, Mello 2010, Santamaria 2005, Schulman 2006, Weingarz 2015
f. Risk association for specific thrombophilia types, used to verify calculation estimate: Baglin 2003, Brouwer 2009, Christiansen 2005, De Stefano 1999, De Stefano 2006, Di Minno 2014, Eichinger 2002, Gonzalez-Porras 2006, Hoibraaten 2000, Lijfering 2010, Lindmarker 1999, Marcucci 2003, Miles 2001, Palareti 2003, Prandoni 2007, Ridker 1995, Rodger 2008, Schattner 1997, Simioni 2000, Strandberg 2007, Wahlander 2006
g. Effect of extended anticoagulation treatment, used in calculation: Agnelli 2013, Bauersachs 2010, Schulman 2003, Schulman 2013
h. The effect was indirectly calculated using evidence from an indirect population (patients with any type of VTE), and using separate studies for thrombophilia prevalence, relative risk of thrombophilia positives vs negatives, and the effect of treatment
i. There is a clinically important difference between the smallest and largest possible effect of the testing strategy
j. Based on the following estimates: Overall risk for VTE recurrence, 50 per 1,000; Prevalence of any thrombophilia, 38.0% (min 21.6 - max 59.5); Relative risk for VTE recurrence in thrombophilia positives versus negatives, RR 1.65 (95%CI: 1.28-2.47); Relative risk of VTE recurrence with extended anticoagulation treatment versus discontinuation after the acute treatment period, RR 0.15 (0.10-0.23). To calculate the range of effects of a testing strategy versus a strategy without testing: 1) for a 'largest possible' difference between a strategy with testing vs without testing we used the maximum Prevalence, upper CI of the Relative risk for VTE recurrence, and the largest treatment effect (lower CI); 2) for a 'smallest possible' difference between a strategy with testing vs without testing we used the minimum Prevalence, lower CI of the Relative risk for VTE recurrence, and the smallest treatment effect (upper CI).
k. Among RCTs assessing the effect of extended treatment against limited treatment, the lowest observed rate of major bleeding with limited treatment was 0.5% (Agnelli 2001)
l. Number of studies used in calculations: Overall risk, 11 RCTs; Prevalence, 20 studies; Extended anticoagulation effect, 11 RCTs (same as for overall risk)
m. Effect of extended anticoagulation treatment, used in calculation: Agnelli 2001, Agnelli 2003, Agnelli 2013, Bauersachs 2010, Couturaud 2015, Eischer 2009, Kearon 1999, Palareti 2006, Ridker 2003, Schulman 2003, Schulman 2013
n. Overall risk for Major bleeding: Agnelli 2001
o. The effect was indirectly calculated using separate studies for thrombophilia prevalence and the effect of treatment
p. Based on the following estimates: Overall risk for Major bleeding of 5 per 1,000; Prevalence of any thrombophilia, 38.0% (21.6-59.5); Relative risk of Major bleeding with extended anticoagulation treatment versus discontinuation after the acute treatment period, RR 2.17 (1.40-3.35). To calculate the range of effects of a testing strategy versus a strategy without testing: 1) for a 'largest possible' difference between a strategy with testing vs without testing we used the maximum Prevalence, and the largest treatment effect (upper CI); 2) for a 'smallest possible' difference between a strategy with testing vs without testing we used the minimum Prevalence, and the smallest treatment effect (lower CI).
q. Among RCTs assessing the effect of extended treatment against limited treatment, the highest observed rate of major bleeding with limited treatment was 1.5% (Agnelli 2013)
r. Overall risk for Major bleeding: Agnelli 2013
s. Based on the following estimates: Overall risk for Major bleeding of 15 per 1,000; Prevalence of any thrombophilia, 38.0% (21.6-59.5); Relative risk of Major bleeding with extended anticoagulation treatment versus discontinuation after the acute treatment period, RR 2.17 (1.40-3.35). To calculate the range of effects of a testing strategy versus a strategy without testing: 1) for a 'largest possible' difference between a strategy with testing vs without testing we used the maximum Prevalence, and the largest treatment effect (upper CI); 2) for a 'smallest possible' difference between a strategy with testing vs without testing we used the minimum Prevalence, and the smallest treatment effect (lower CI).

[https://guidelines.ash.gradepro.org/profile/XLPPdthsuBk]

Example: Q3

Outcomes	Absolute Effect: With no thrombophilia testing and stopping anticoagulant treatment in all	Absolute Effect: With thrombophilia testing and subsequent indefinite anticoagulant treatment in patients positive for thrombophilia and stopping anticoagulant treatment in patients negative for thrombophilia	Relative effect (95% CI)	Certainty of the evidence GRADE
Recurrent VTE ○ Surgical Provoked VTE ○ Any Provoked VTE ◉ Non Surgical Provoked VTE	When testing 1,000 patients who completed primary treatment of symptomatic VTE provoked by a non-surgical major transient risk factor for any type of thrombophilia, and treating the 380 positives with indefinite anticoagulation (ranging from 216 to 595), 29 VTE recurrences will occur per year (ranging from 15 to 40). When not testing 1,000 patients for thrombophilia and stopping treatment in all of them, 50 VTE recurrences will occur per year. Therefore, a thrombophilia testing strategy is associated with 380 more patients treated with indefinite anticoagulation (ranging from 216 to 595) and 21 fewer VTE recurrences (ranging from 10 to 35) per 1,000 patients per year compared with a no testing strategy. Based on data from 6742 patients in 24 studies			⨁◯◯◯ VERY LOW Due to serious indirectness. Due to serious imprecision.
▸ **Major Bleeding - Low (0.5% per year)**				
▸ **Major Bleeding - High (1.5% per year)**				

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Major Bleeding - Low (0.5% per year)				
Major Bleeding - High (1.5% per year)				

[https://guidelines.ash.gradepro.org/profile/XLPPdthsuBk]

How Long to Anticoagulate?

Conglomerate decision of:

1. Risk of Recurrent VTE

A. ..., B. ..., C. ...

2. Risk for Bleeding

A. ..., B. ..., C. …

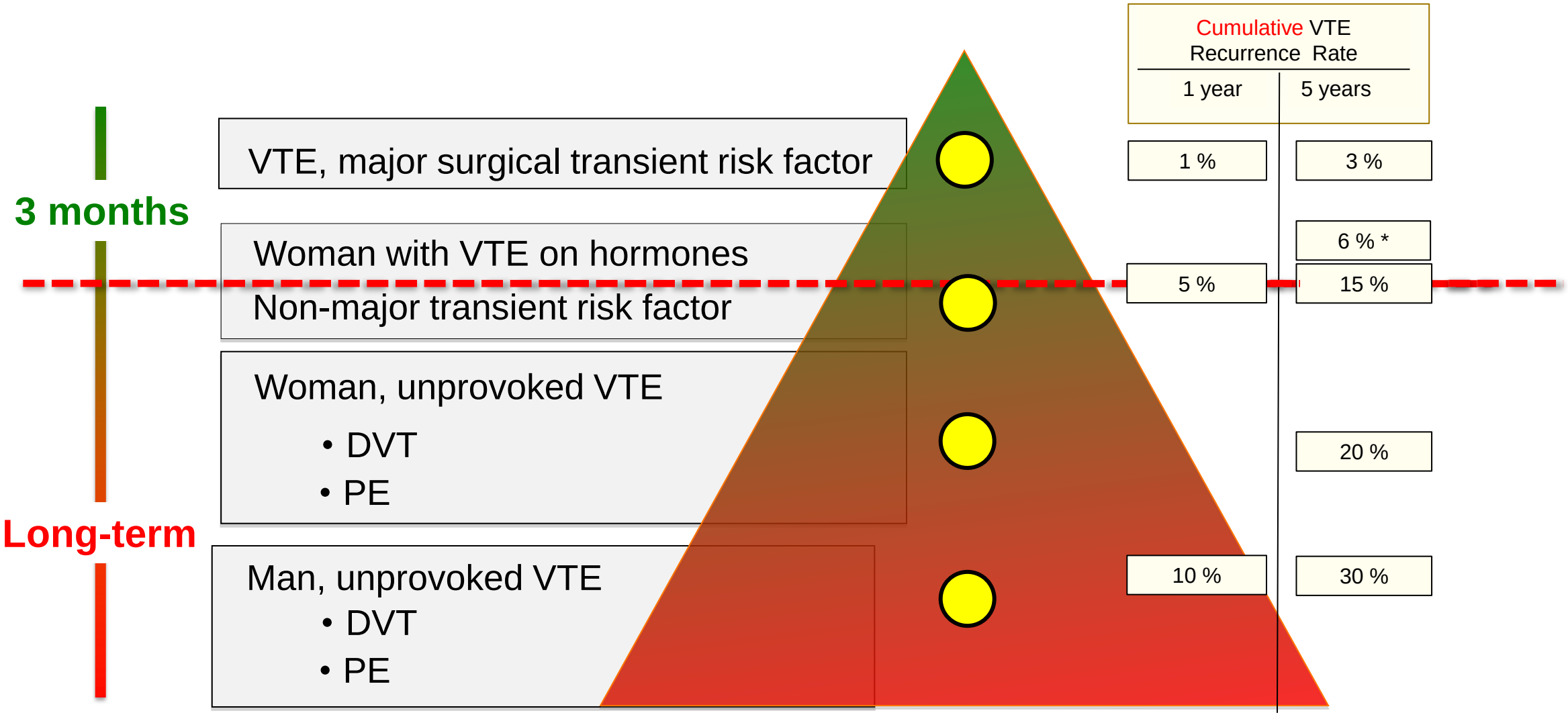
3. Patient Preference

Take-home points

VTE is multifactorial

VTE risk factors: A….., B….., C….

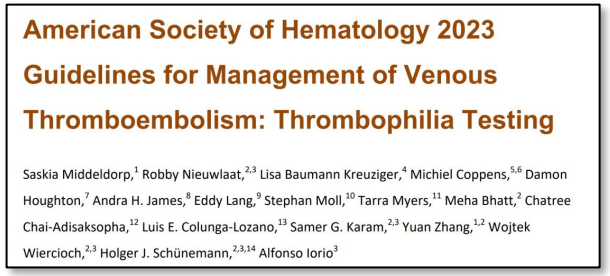
How Long to Treat? Recurrence Triangle



[Iorio A et al. Arch Intern Med. 2010;170(19):1710-1716] [Kearon C et al. Blood 2014;123:1794-1801] *[Douketis J et al. BMJ 2011;342:d813]

Recommendations

23 recommendations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[Middeldorp S et al. Blood Advances **2023**; May 17. https://go.unc.edu/k4X2C]

5

Conditional[1,2] suggestions when to test

1Conditional = subject to one or more conditions or requirements being met

[2] based on very low certainty of evidence about effects

1. Major non-surgery risk factor associated VTE
2. Hormone associated VTE
3. Unprovoked unusual site VTE
4. Pregnant woman never had VT, with Fam hx of VTE + strong thrombophilia
5. Cancer patient, never had VTE, at low to intermediate risk for VTE

Recommendation[1] when NOT to Test

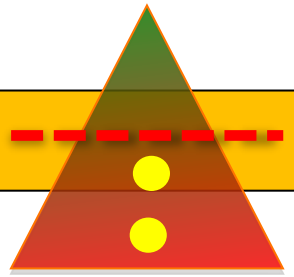
Q15

Women in general population considering combined oral contraceptives

[1] based on low certainty of evidence about effects

Q1

Unprovoked VTE

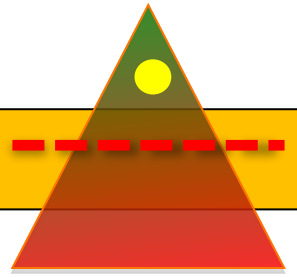


Case #1

[1] based on very low certainty of evidence about effects

Q2

Surgery-associated VTE



[1] based on very low certainty of evidence about effects

Conditional[1,2] Suggestion When to Test

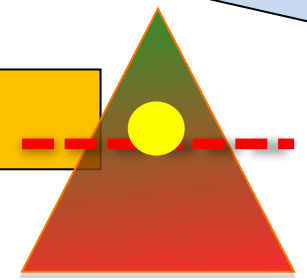
[1] based on very low certainty of evidence about effects

[2] Conditional = subject to one or more conditions or requirements being met

Q4,5

VTE with (a) pregnancy or postpartum, or (b) combined oral contraceptives.

Case #2



Conditional[1,2] Suggestion When to Test

[1] based on very low certainty of evidence about effects

[2] Conditional = subject to one or more conditions or requirements being met

Case #3

Q3

VTE with (a) non-surgical major transient risk factor or

(b) combination of minor transient risk factors.

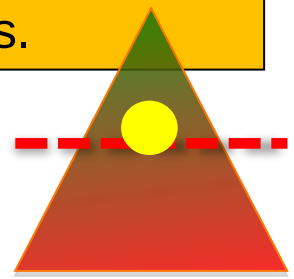


Table 3. Risk factors and venous thromboembolism

Transient risk factors (risk factors that resolve after they have provoked VTE)*
Major transient risk factors (occur within 3 mo of VTE diagnosis); examples include:
Surgery with general anesthesia for ≥30 min
Confined to bed in hospital for ≥3 d with an acute illness ("bathroom privileges" only)
Cesarean section
Minor transient risk factors (occur within 2 mo of VTE diagnosis); examples include:
Surgery with general anesthesia for <30 min
Admission to hospital for <3 d with an acute illness
Estrogen therapy (eg, oral contraceptives, hormone replacement therapy)
Pregnancy and puerperium
Confined to bed out of hospital for ≥3 d with an acute illness
Leg injury associated with decreased mobility for ≥3 d

[Ortel TL et al. Blood Advances 2020;Oct143:4(19)4693-4738]

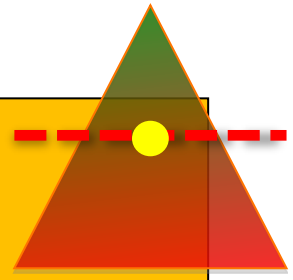
Conditional[1,2] Suggestion When to Test

[1] *Conditional = subject to one or more conditions or requirements being met*

[2] *based on very low certainty of evidence about effects*

Q7,9

Unprovoked unusual site VTE (Cerebral and sinus vein thrombosis; splanchnic vein thrombosis)



Q21

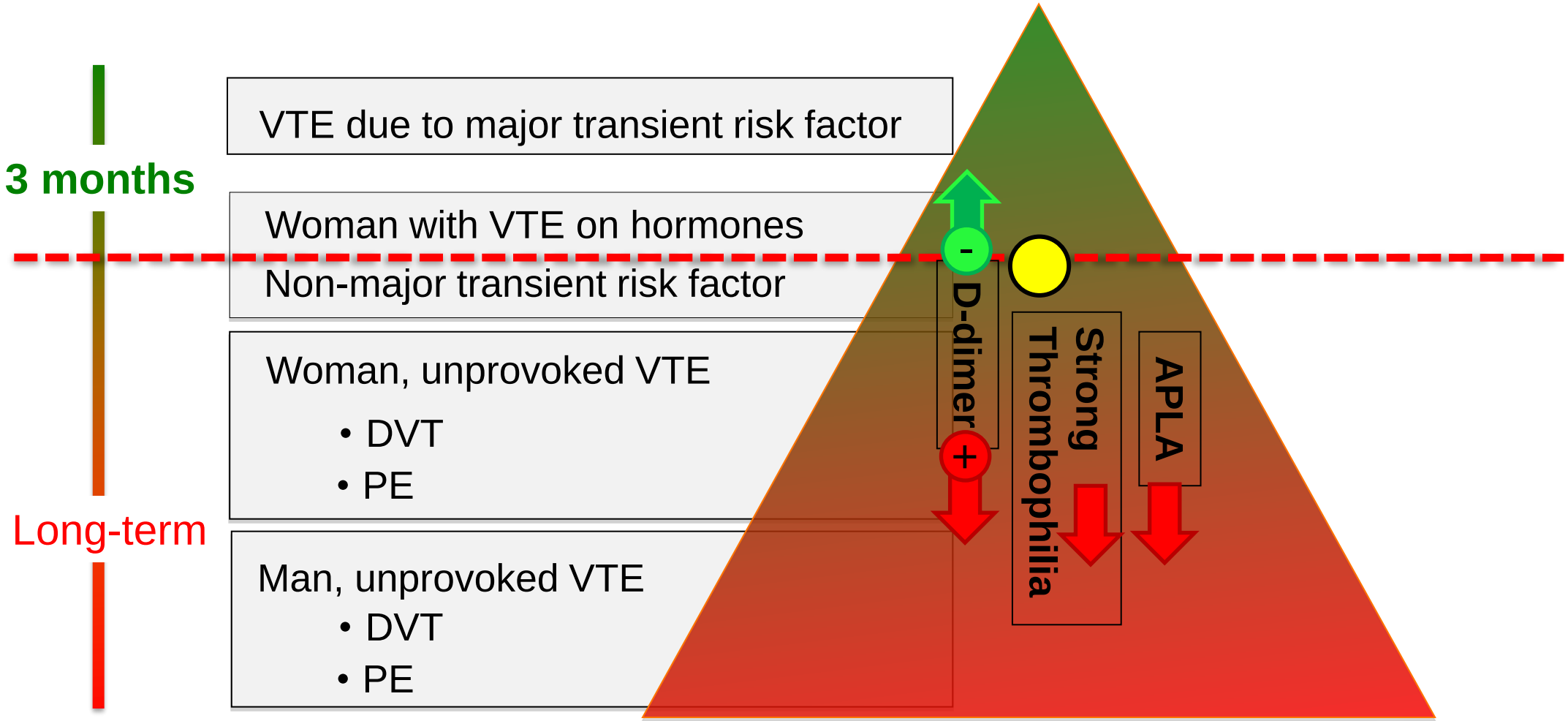
If Fam history of VTE AND strong thrombophilia: test the pregnant proband.

Q23

Cancer patient getting chemo, at low to intermediate risk for VTE + family history of VTE: suggest to test

Case #4

How Long to Treat? Recurrence Triangle



[My (S. Moll) personal general practice approach, 8/2023]

Which Family Members to Consider for Thrombophilia Testing?

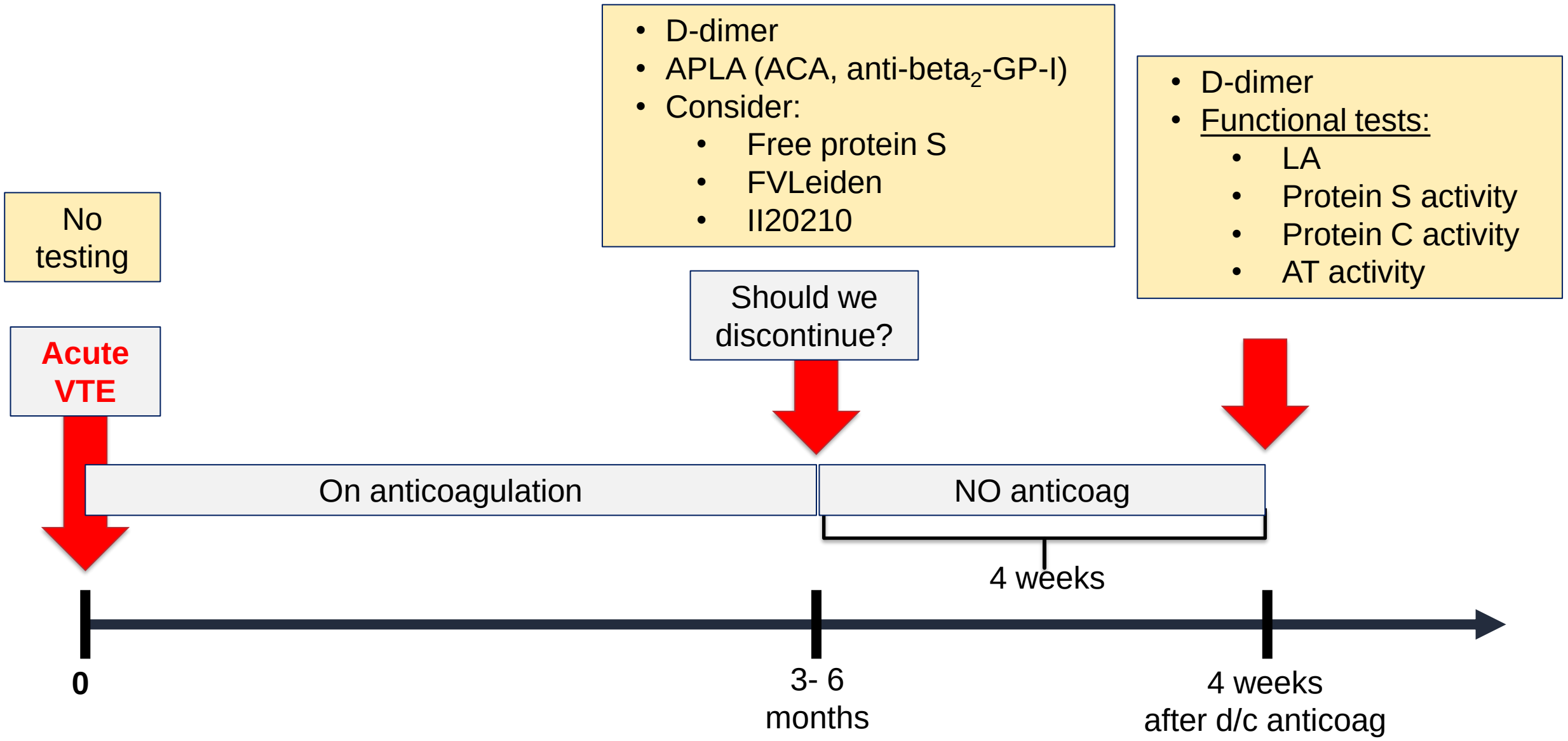
Proband's thrombophilia	Male Family Member		Female Family Member	
	Sons	Brothers	Daughters	Sisters
Hetero FVL or hetero prothrombin 20210	no	no	no	no
Homo FVL or homo prothrombin 20210	no	reasonable	no	yes
Double hetero	reasonable	reasonable	yes	yes
C, S, AT	reasonable	reasonable	yes	yes

"reasonable" because: consider DOAC/LMWH with airline travel, immobilizer/cast, non-major surgery; prolonged after major surgeries.

"yes" because: advice against estrogen contraceptives/hormone therapy; give ante- and postpartum anticoagulation.

[My (S. Moll) personal general practice approach 8/2023]

When to Test (if one tests)



When NOT to Test

Do NOT test ….

1. … during an acute thrombotic episode.
2. … a hospitalized patient.
3. … while patient is on an anticoagulant.
4. … if you don't know how to interpret test or what to do with results.

Take-home points

- Do not overvalue importance of thrombophilia testing
- Be aware of what influences test results (false pos., false neg.)

Summary

Take-home points

- VTE is multifactorial (VTE risk factors: A…., B…, C…)
- Bleeding is multifactorial
- Try the DOAC/Warfarin “Hate Factor” (scale from 0 to 10)

- Try the Recurrence triangle

- Don’t be dogmatic

Case 1

- 65-year-old female develops acute onset chest pain and shortness of breath, found to have **new pulmonary thromboembolism (PTE)**
  - No provoking factors are identified (i.e. the PTE was **unprovoked**)

- *Question*: Should she have **thrombophilia testing** to help determine how long to continue anticoagulation?

Guideline recommendation: *"In patients with unprovoked VTE who have completed primary short- term treatment, the ASH guideline panel suggests not to perform thrombophilia testing to guide the duration of anticoagulant treatment (conditional recommendation based on very low certainty of the evidence about effects)"*

Case 2

- 32-year-old female taking **estrogen containing oral contraceptive** (4th generation) for the past 7 months presents with **new proximal DVT**.
  - She has no first-degree relatives with a history of VTE
- *Questions:*
  - Should she have **thrombophilia testing** to guide AC duration?
  - If she is found to be heterozygous for Factor V Leiden (i.e., a **low-risk thrombophilia**), would you continue her anticoagulation indefinitely?
  - Would your approach to testing change if she was on the OCP for the past 15 years and/or on a 2nd generation estrogen containing OCP?

***Guideline recommendation**: "In women with VTE associated with combined oral contraceptives who have completed primary short-term treatment, the ASH guideline panel suggests testing for thrombophilia to guide anticoagulant treatment duration. The panel suggests indefinite anticoagulant treatment in women with thrombophilia and stopping anticoagulant treatment in women without thrombophilia (conditional recommendation based on very low certainty of the evidence about effects)"*

Case 3

- 75-year-old male develops left leg swelling, found to have **new proximal DVT**.
  - He was hospitalized for 3 days 1 month prior with pneumonia. He only got out of bed to use the bathroom during that time. (i.e., a **non-surgical major transient risk factor**)

- *Question*: Should he have **thrombophilia testing** to help determine how long to continue anticoagulation?

***Guideline recommendation**: "In patients with VTE provoked by a non-surgical major transient risk factor who have completed primary short-term treatment, the ASH guideline panel suggests testing for thrombophilia to guide anticoagulant treatment duration. The panel suggests indefinite anticoagulant treatment in patients with thrombophilia and stopping anticoagulant treatment in patients without thrombophilia (conditional recommendation based on very low certainty of the evidence about effects)"*

Case 4

- 52-year-old female with newly diagnosed **metastatic breast cancer** with a plan to initiate systemic chemotherapy.
  - The patient's **mother had a VTE** in her lifetime.
  - Khorana score is 0 (**low risk**).

- *Question:* Should she have thrombophilia testing to help determine if she should receive anticoagulation ***prophylaxis***?

Guideline recommendation: *"In ambulatory cancer patients receiving systemic therapy who have a family history of VTE and are otherwise determined to be at low or intermediate risk for VTE, the ASH guideline panel suggests testing for hereditary thrombophilia. The panel suggests ambulatory thromboprophylaxis in patients with thrombophilia and no thromboprophylaxis in patients without thrombophilia (conditional recommendation based on very low certainty of the evidence about effects)"*

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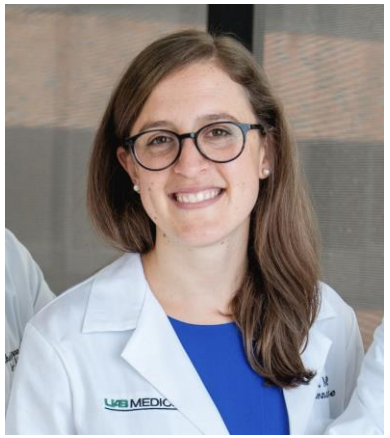

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