VTE

Venous Thromboembolism

Toolkit for Health Professionals

WHAT YOU NEED TO KNOW ABOUT BLOOD CLOTS

VENOUS DISEASE COALITION

AN INITIATIVE *of the* VASCULAR DISEASE FOUNDATION

Chapter One
Venous Disease Coalition

Venous Thromboembolism
Toolkit for Health Professionals

VTE Toolkit

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Venous Disease Coalition

- The Venous Disease Coalition (VDC) is a collaborative alliance of over 35 leading health professional organizations and patient advocacy groups committed to improving the survival rates and quality of life for individuals with, or at risk for, venous disease
- The VDC provides peer-reviewed educational materials for the general public and health care professionals
- www.vasculardisease.org/venousdiseasecoalition/

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VDC Goals

1. To develop a national, participatory, diverse coalition that is firmly committed to improving public health via venous disease awareness and education;
2. To create media awareness of venous thromboembolism as an urgent public health hazard;
3. To provide a public forum for VDC member organizations, the National Institutes of Health (NIH) and Centers for Disease Control (CDC) to make one another aware of their existing programs and future plans for venous disease education.

VDC Member Organizations

American Academy of Physician Assistants
American Academy of Nurse Practitioners
American College of Cardiology
American College of Chest Physicians
American College of Phlebology
American Osteopathic Association
American Radiological Nurses Assoc.
American Society of Health-System Pharmacists
American Society of Hematology
American Society for Clinical Oncology
American Thrombosis Hemostasis Network
American Venous Forum
Anticoagulation Forum
APS Foundation of America
Canadian Chapter Society for Vascular Nursing
Canadian Society for Vascular Surgery
Canadian Cardiovascular Society
Case Management Society
Hemophilia & Thrombosis Research Society
Institute for Safe Medication Practices
National Alliance of Thrombosis and Thrombophilia
National Gerontological Nursing Association
North American Thrombosis Forum
Preventive Cardiovascular Nursing Association
Society for Cardiovascular Angiography and Interventions
Society for Clinical Vascular Surgery
Society of Critical Care Medicine
Society of Interventional Radiology
Society for Vascular Medicine and Biology
Society for Vascular Nursing
Society of Vascular Ultrasound
Spirit of Women
Thrombosis Interest Group of Canada
Vascular Disease Foundation

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www.vasculardisease.org/venousdiseasecoalition/

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Chapter Two
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Pathogenesis and Consequences of VTE

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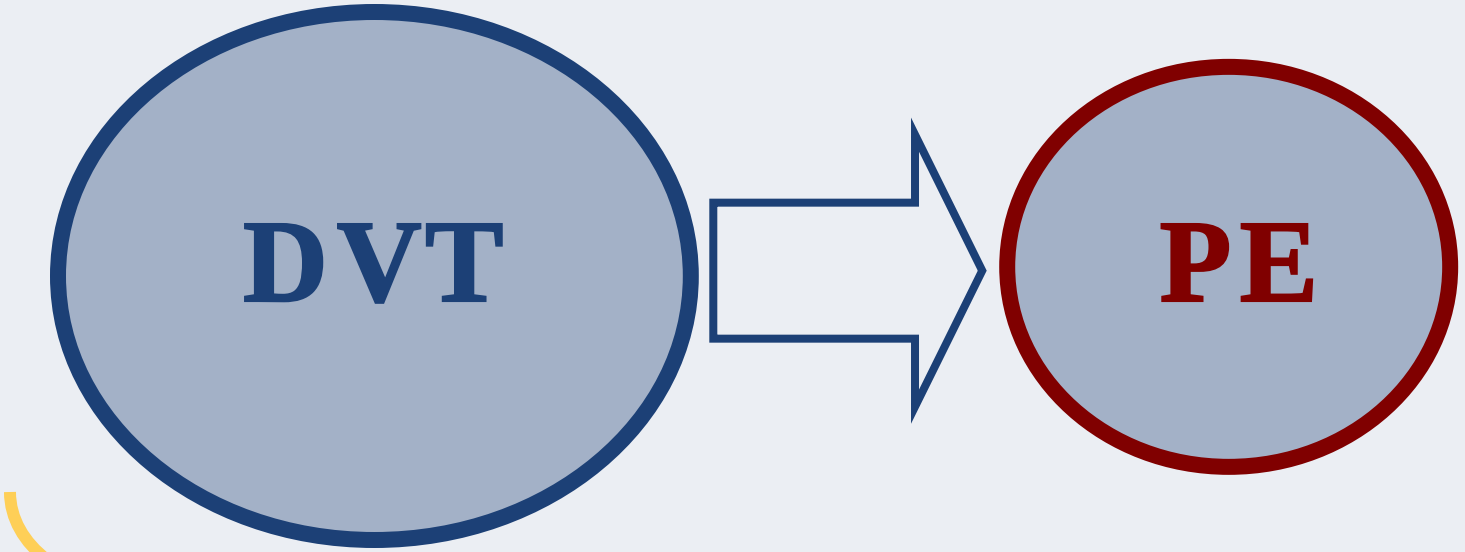
Venous Thromboembolism (VTE)

=

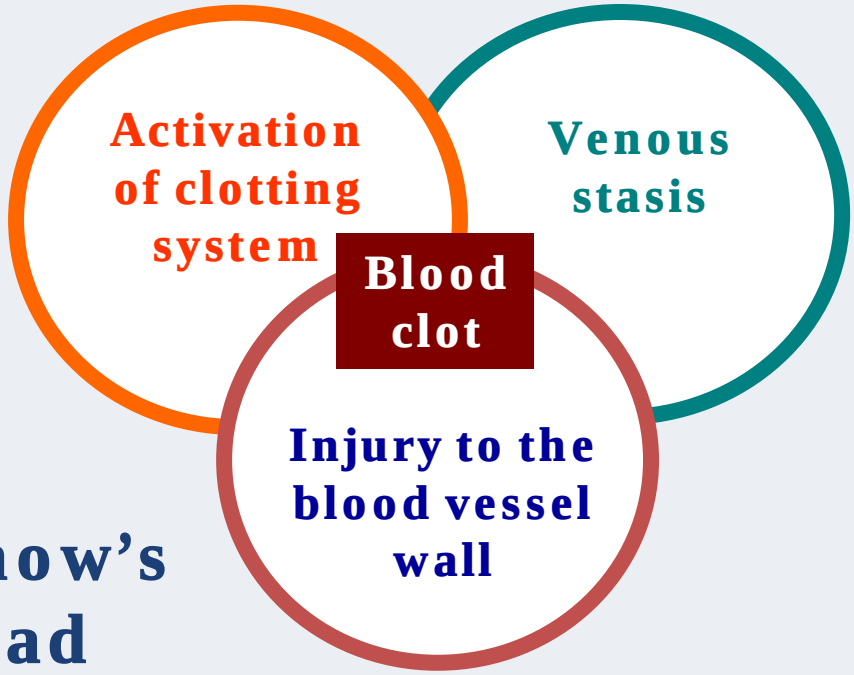
1. Deep vein thrombosis (DVT)
2. Pulmonary embolism (PE)

Definition



VTE (venous thromboembolism)

What Causes the Blood to Clot When it Shouldn't?



Virchow's Triad

Virchow's Triad

1) Activation of clotting system (hypercoagulability)

2) Venous stasis

3) Endothelial injury/vessel wall injury

Dr. Rudolf Virchow 1856

Virchow's Triad

Activation of Coagulation (Hypercoagulability)

Congenital Hypercoagulability Disorders

- Factor V Leiden
- Prothrombin G20210A Polymorphism
- Protein C and/or Protein S deficiency
- Dysfibrinogenemia
- Antithrombin deficiency

Virchow's Triad

Activation of Coagulation (Hypercoagulability)

Pregnancy:

- Risk of thrombosis during postpartum period is 5 times greater than during pregnancy
- It takes ~ 2 months after delivery for the coagulation and fibrinolytic systems to return to normal

Segal JA & Liem TK. Congenital and Acquired Hypercoagulable Syndromes. In Bergan JJ (ed.) The Vein Book. Burlington, Elsevier 2007; 339-346.

Virchow's Triad

Activation of Coagulation (Hypercoagulability)

Pregnancy:

- Increases in Factors I, VII, VIII, IX, X, XI
- Increased platelet count
- Decreased Protein S and Antithrombin
- Inhibition of fibrinolytic system by factors from placenta
- Increased venous stasis secondary to compression of pelvic veins by gravid uterus

Segal JA & Liem TK. Congenital and Acquired Hypercoagulable Syndromes. In Bergan JJ (ed.) The Vein Book. Burlington, Elsevier 2007; 339-346.

Virchow's Triad

Activation of Coagulation (Hypercoagulability)

Malignancy:

- VTE is a major complication in cancer patients
- 1 in 5 cancer patients experience a thrombotic event
- Cancer patients are at 7 times greater risk than general population for VTE - greatest risk with hematologic cancers followed by lung and GI tract cancers

Khorana – J Clin Oncol 2009;27:4839

Virchow's Triad

Activation of Coagulation (Hypercoagulability)

Malignancy:

- Risk for VTE in cancer is greater if patient also has distant metastases, Factor V Leiden or Prothrombin 20210A mutation
- Chemotherapy increases the risk for VTE by multiple mechanisms: direct toxicity to vascular endothelium, release of procoagulants from activated cancer cells, suppression of natural anticoagulants and fibrinolytics

Khorana – J Clin Oncol 2009;27:4839

Virchow's Triad

Venous Stasis

Varicose Veins:

- Thrombosis occurs commonly in the varicose veins and can migrate to deep venous system

Virchow's Triad

Venous Stasis

Travel and VTE:

- Long Haul Travel – "economy class syndrome"
- Velocity of venous blood decreases by 2/3 in the seated position

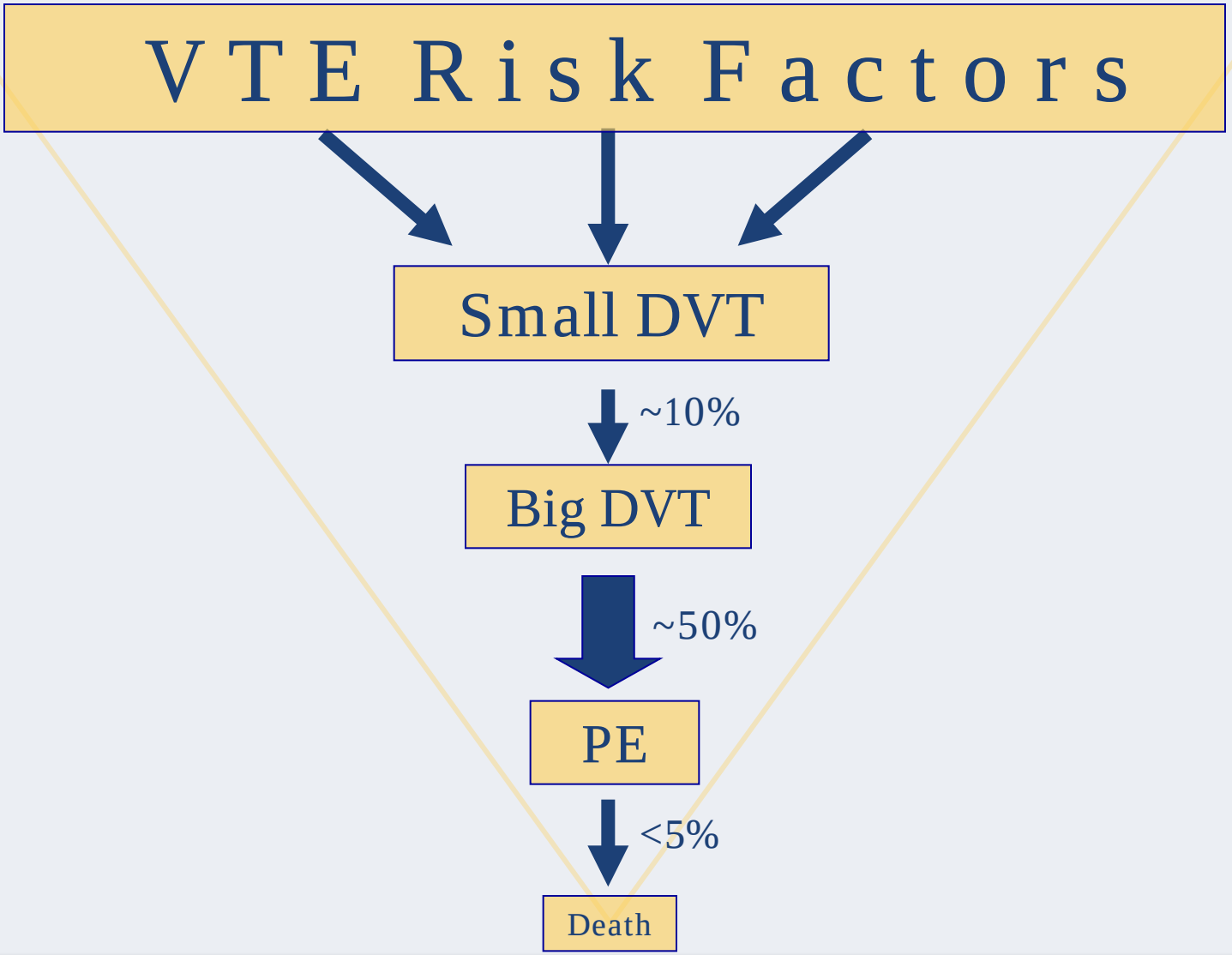
Ferrari - Travel as a risk factor for venous thromboembolic disease:
A case-control study. Chest 1999;115:440

Virchow's Triad

Endothelial Injury

- Partial rupture of calf muscles and knee ligament injury were more strongly associated with VTE than were contusions or simple sprains
- Risk of VTE was increased 50 fold in those who had injury **and** Factor V Leiden mutation
- Risk of VTE was increased 9 fold in those who had injury **and** Prothrombin 20210A mutation

Van Stralen - Arch Intern Med 2008;168:21



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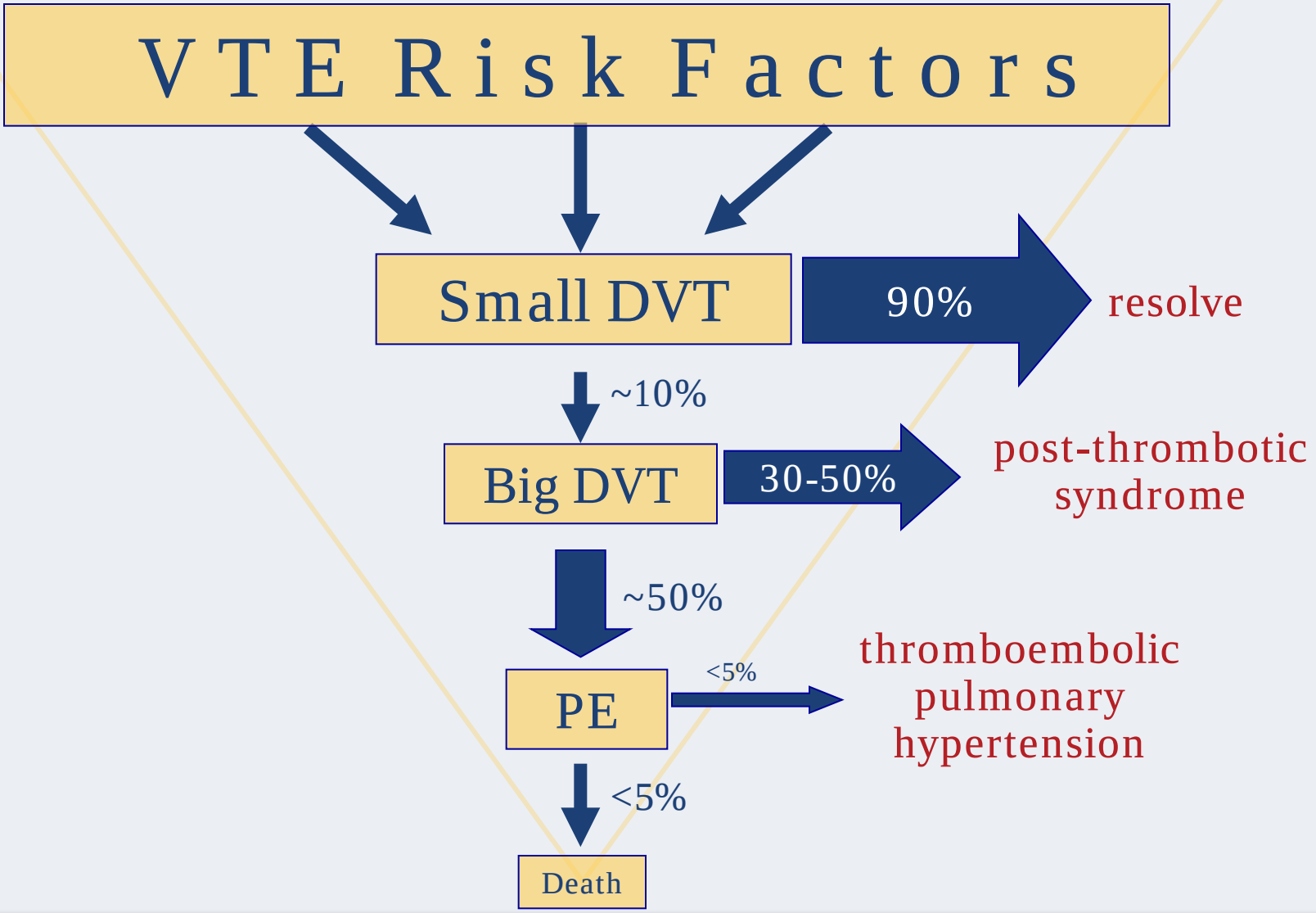

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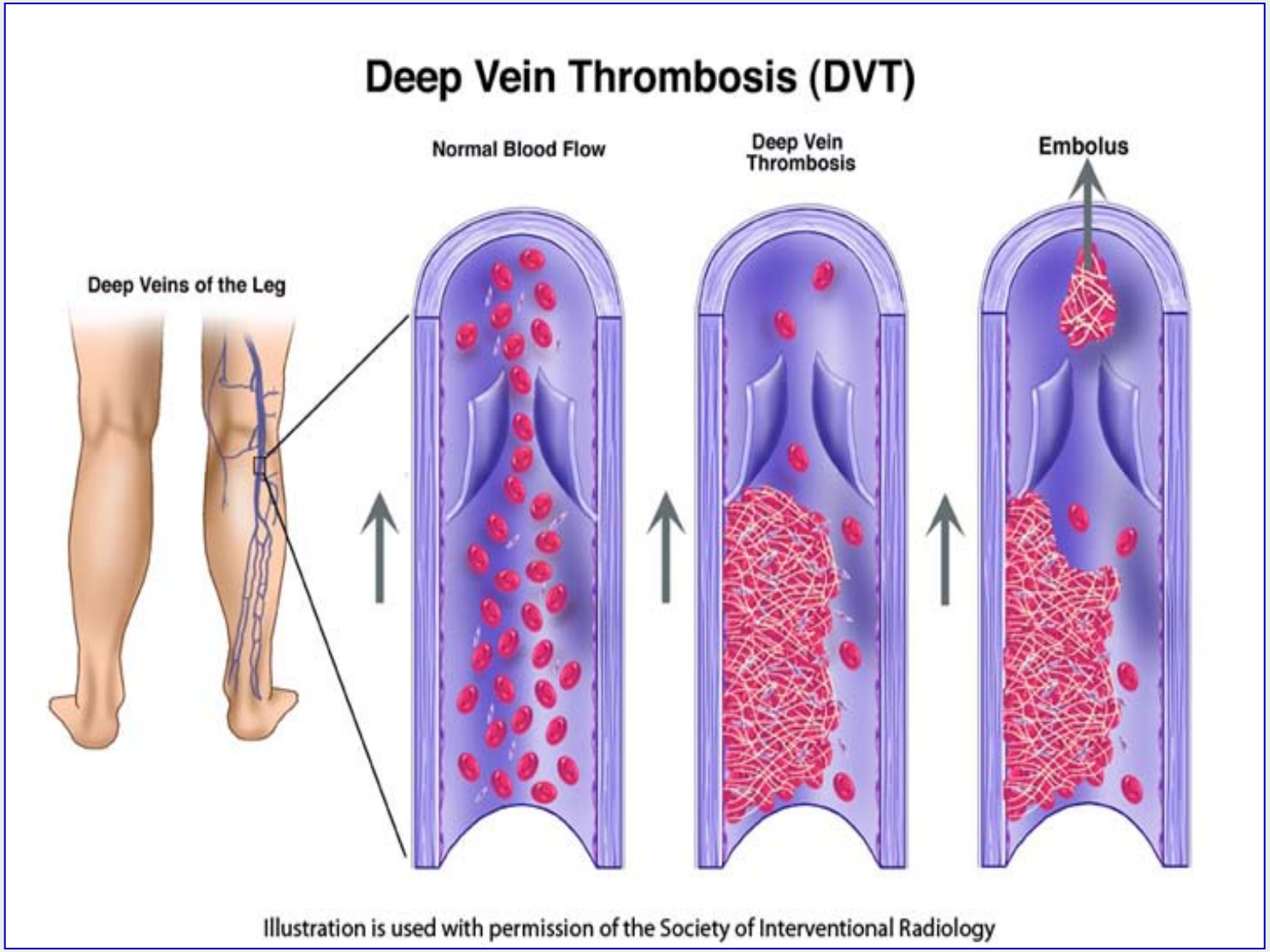

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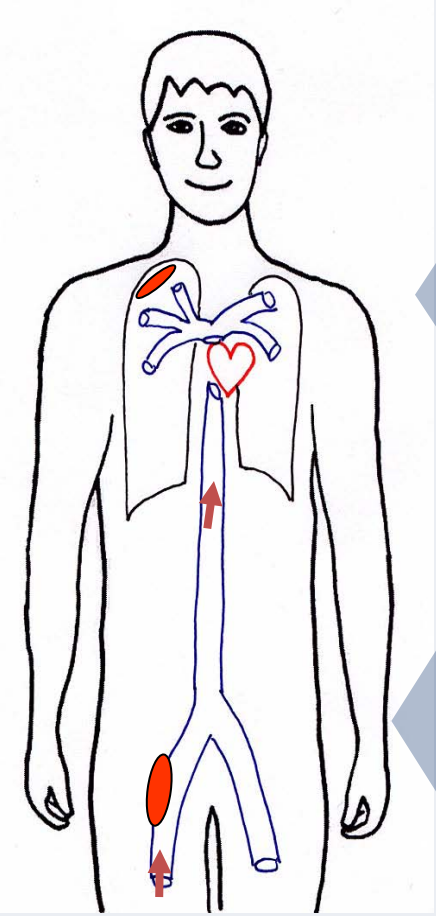
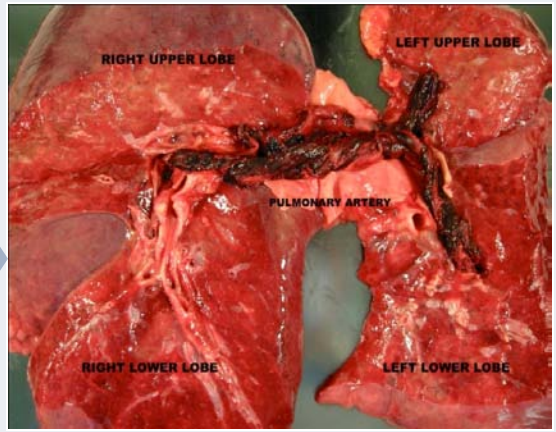
Venous Thromboembolism (VTE) = DVT+PE



Pulmonary Embolism (PE)



Deep Vein Thrombosis (DVT)

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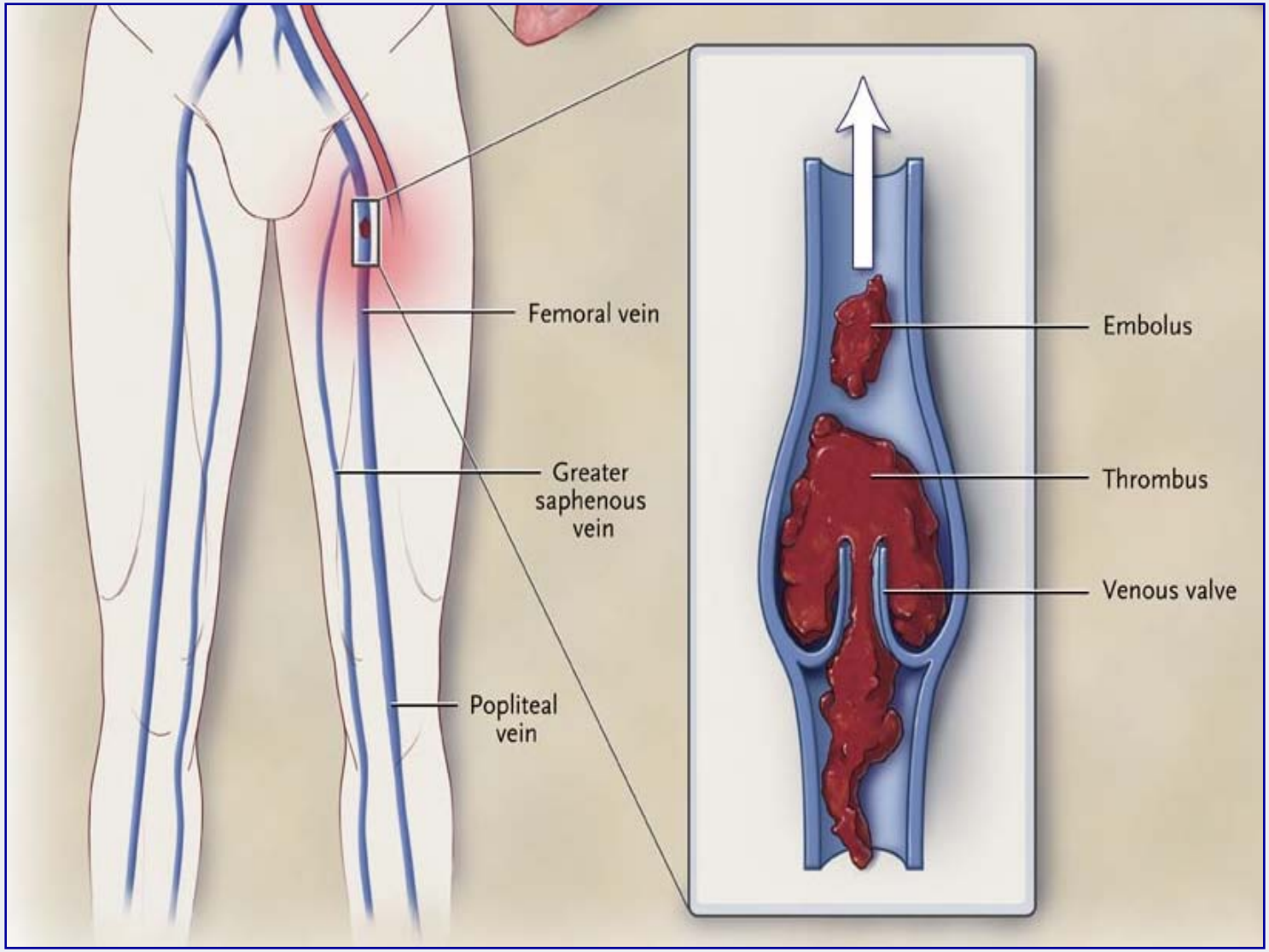

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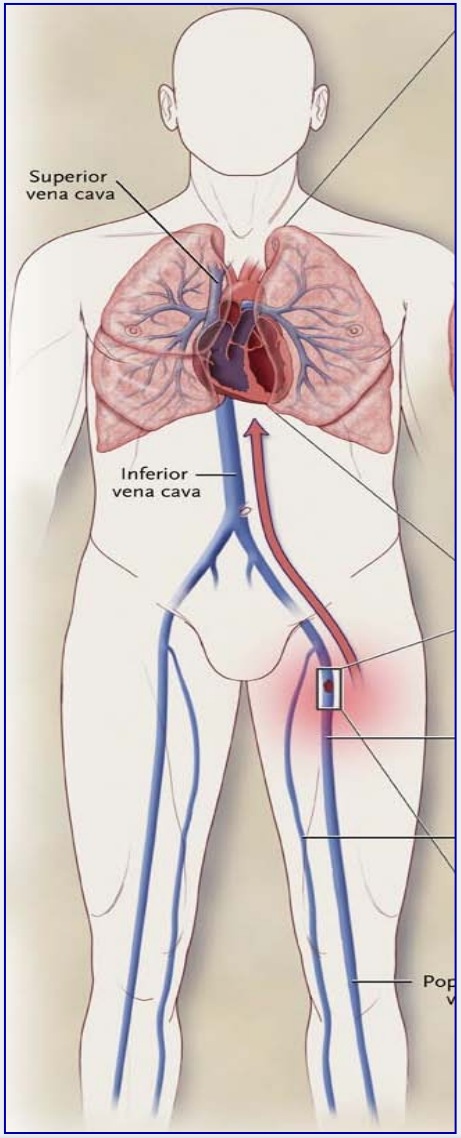

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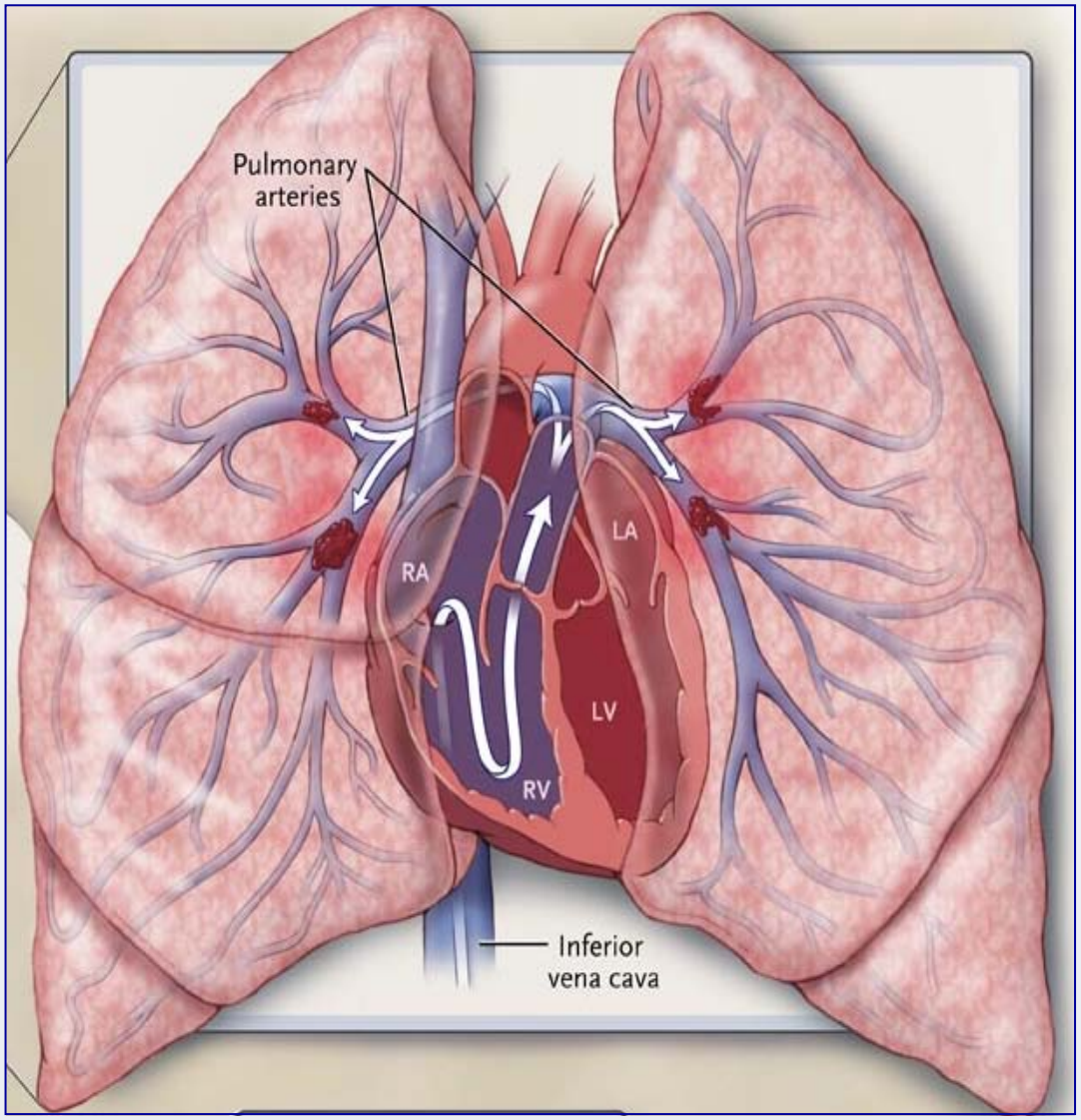

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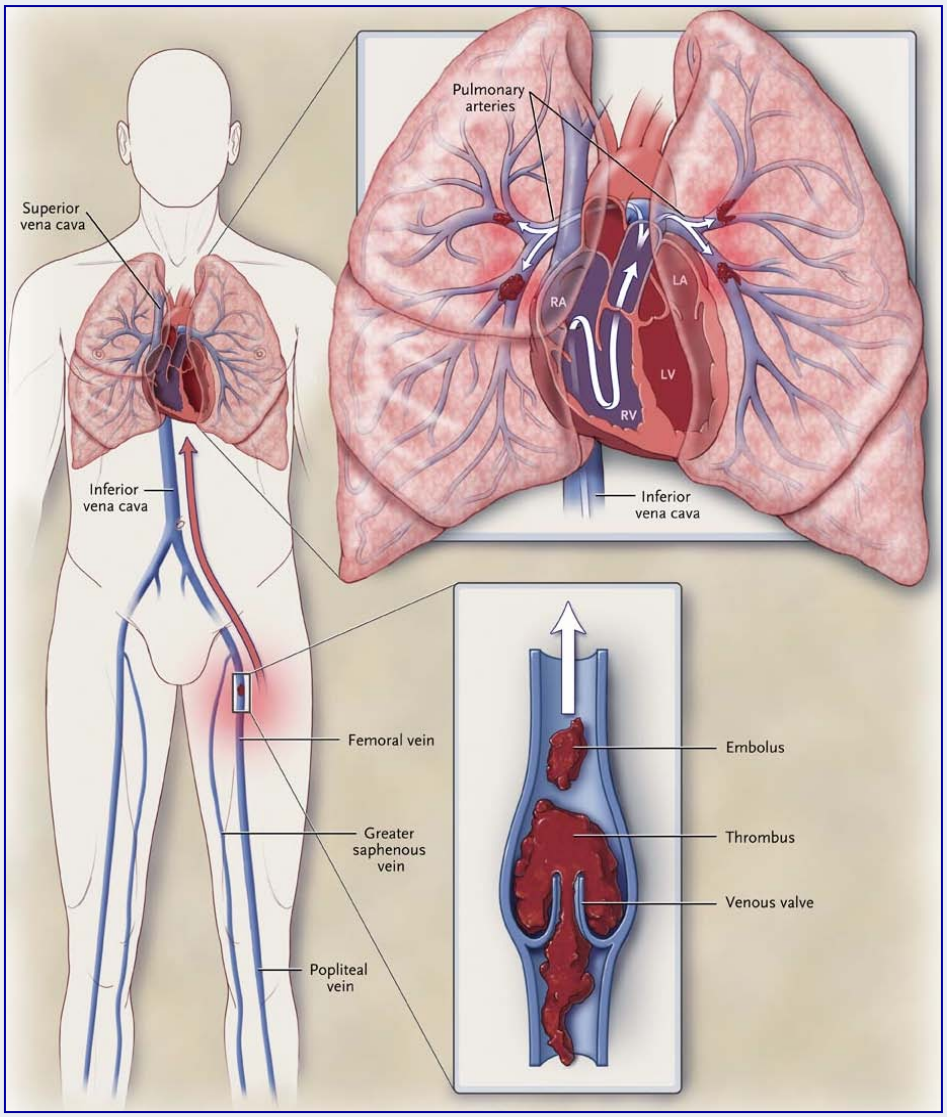

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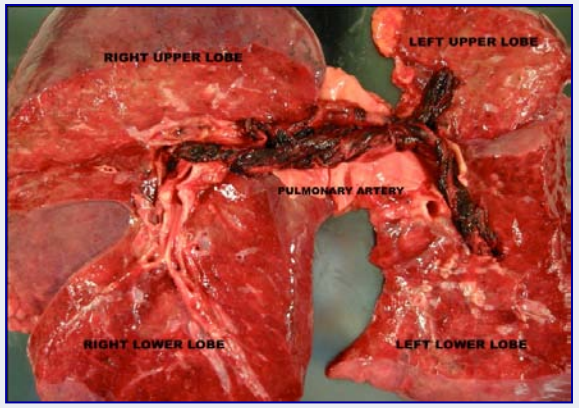
Consequences of DVT and PE



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Deep Vein Thrombosis (DVT)

Thrombosis in one or more deep veins

** leg is the most common site**

can also be the arm

portal, splenic, mesenteric, cerebral, renal veins

Proximal DVT
- Popliteal, femoral or iliac veins
- >90% of pulmonary emboli derive from proximal DVT

Distal or calf DVT
- Below the popliteal vein
- Posterior tibial, peroneal veins
- Lead to <5% of PE

Pulmonary Embolism (PE)

Thrombus embolizes from a deep vein (usually a proximal leg vein) to the pulmonary arteries

Massive PE (~5% of cases)	- Hemodynamic compromise - Shock, cardiac arrest
Submassive PE (~30% of cases)	- Right heart dysfunction - Normal BP
Nonmassive PE (~65% of cases)	- No right heart dysfunction

Natural History of VTE

- Most DVTs in calf veins undergo spontaneous lysis
- ≤10% of untreated calf DVTs extend into the proximal veins
- 50% of untreated proximal DVTs extend
- 50-70% of untreated proximal DVTs cause PE
- Untreated PE 10-30% fatal

Chapter Three
Venous Disease Coalition

Epidemiology of VTE
Risks, Risk Factors

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Thromboembolic Disorders

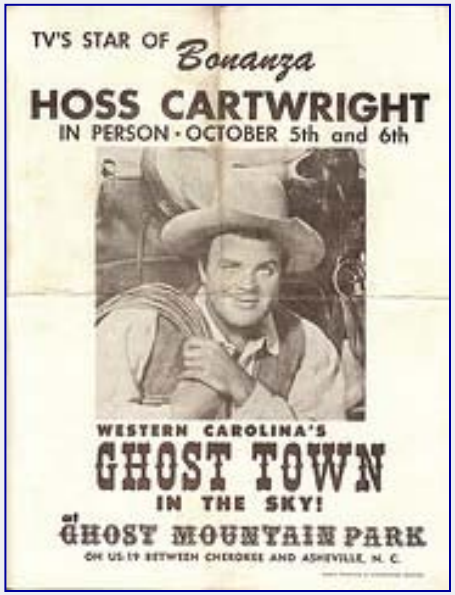
- Acute coronary syndrome, ischemic or cardioembolic stroke, venous thromboembolic disease, acute limb ischemia
- Acute vascular diseases are the commonest cause of death
- VTE (DVT, PE) 3rd commonest vascular disease
- More deaths from PE than AIDS, breast cancer and motor vehicle crashes *combined*
- Risk of VTE increases with age

Thromboembolic Disorders

- Affects approximately 1/1,000 people annually
- DVT alone accounts for 300,000–600,000 hospitalizations each year in the USA
- PE causes nearly 200,000 deaths per year in the USA
- Major costs of diagnosis, treatment

Who Is This?

Dan Blocker (Hoss Cartright)



- Of the hit TV show, Bonanza
- Died of pulmonary embolism after gall bladder surgery
- Age 43

Who Is This?

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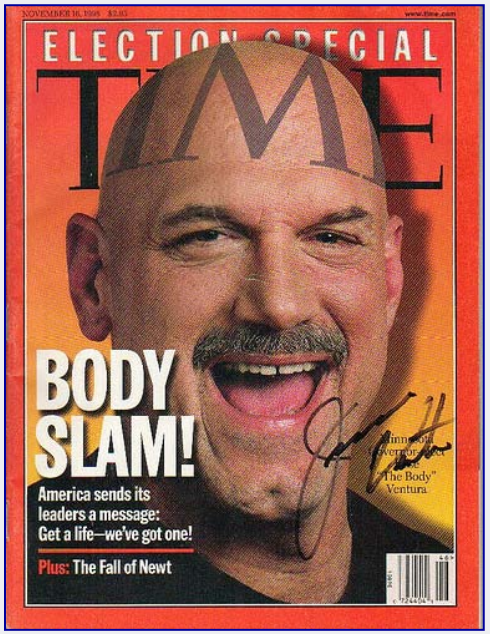
General George S. Patton

"May God have mercy on my enemies, because I won't."

- One of the greatest generals of all time – "Old Blood and Guts"
- WWII commander of the US 3rd army in Europe and North Africa
- December 1945 – car accident near Heidelberg
- Died of pulmonary embolism 12 days later
- Age 60

Which of these politicians have had blood clots?



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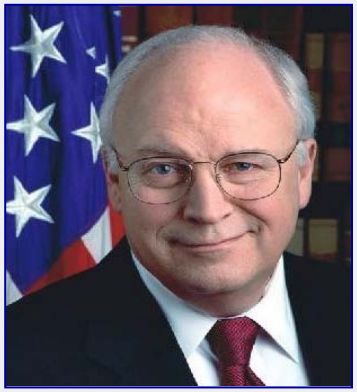
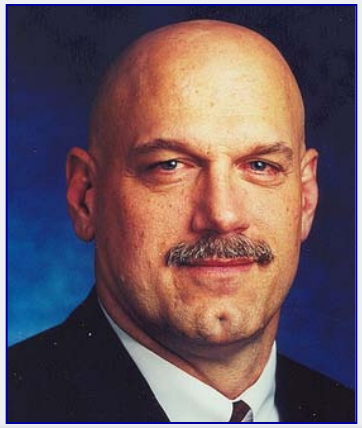
All of them had a blood clot!



Dick Cheney
Vice President
2001-2009

Richard Nixon
President
1969-1974

Dan Quayle
Vice President
1989-1993



Jesse Ventura
Gov. of Minnesota
1999-2003

Hillary Clinton
Secretary of State
2009-present

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Who is at risk for VTE?

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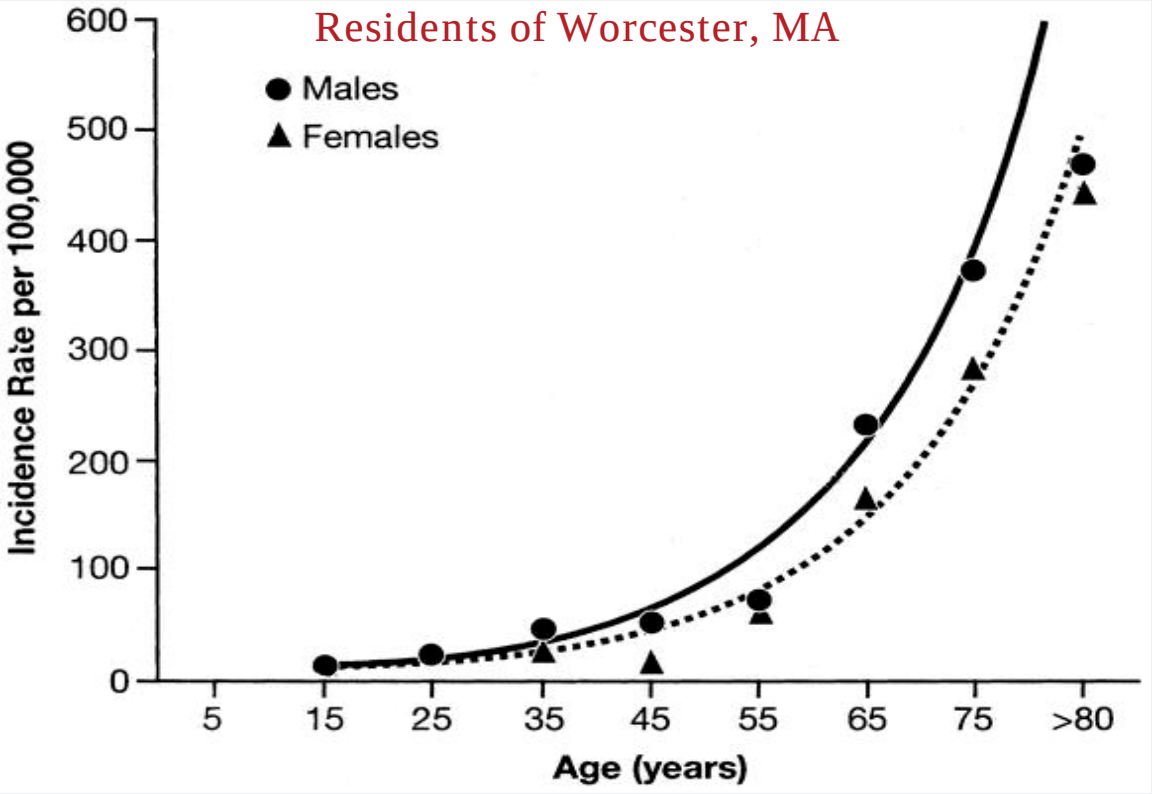
Risk Factors

- Surgery
- Trauma (major trauma or leg injury)
- Immobilization (bedrest, stroke, paralysis)
- Cancer and its treatment (CTX, RTX, hormonal)
- Acute medical illness (heart or respiratory failure, infection, inflammation)
- Previous DVT or PE
- Increased age
- Estrogen use (BCP, HRT), pregnancy, postpartum
- Central venous lines
- Blood clotting disorders (thrombophilia)

VTE Risk Increases with Age



Anderson - Arch Intern Med 1991;151:933

Population Attributable Risk for VTE

Risk factor	Adjusted AR
Hospitalization with surgery	24%
Hospitalization without surgery	22%
Active cancer	18%
Nursing home	13%
Trauma	12%
Prior CVC or pacemaker	9%
Neurologic disease with leg paresis	7%

(case-control study/adjusted for age, sex, year)

Heit - Arch Intern Med 2002;162:1245

Symptomatic VTE after Surgery

- California Patient Discharge Database (N = 1,653,275)
  - VTE during surgical admission or within 3 months
    - Thromboprophylaxis data was not available

Benign disease	
Hip replacement	2.4%
Craniotomy	2.3%
Knee replacement	1.7%
Coronary bypass	1.1%
Colectomy	1.1%
Hysterectomy	0.3%
TUR prostate	0.3%
Lap. Cholecystectomy	0.2%

Malignant disease	
Craniotomy	3.6%
Colectomy	1.7%
Pneumonectomy	1.6%
Rad. Prostatectomy	1.5%
Hysterectomy	1.2%
Mastectomy	0.4%

White - Thromb Haemost 2003;90:446

Postoperative VTE is Associated With Increased Mortality

- 118,258 surgical patients in 120 VA hospitals

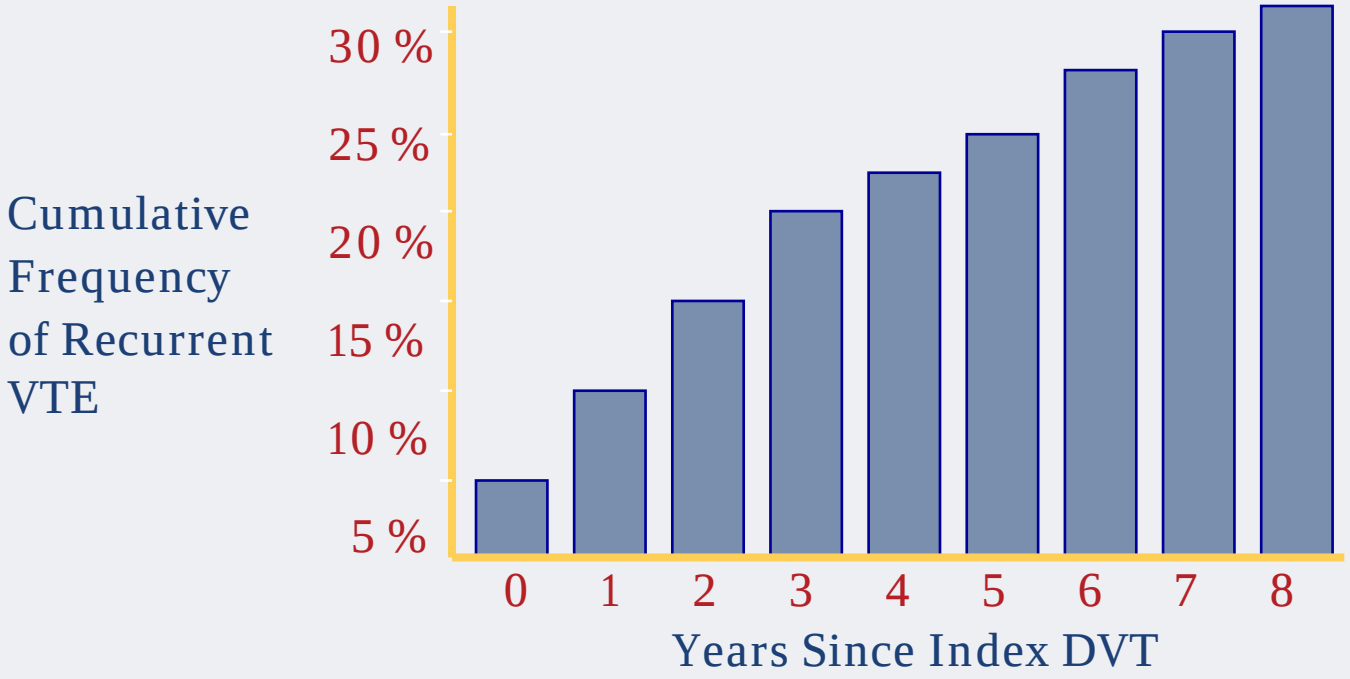
VTE	30-day Mortality	
No	4.4%	p<0.0001
Yes	16.9%	

- *Symptomatic VTE is associated with significantly increased 30-day mortality*

Gangireddy - J Vasc Surg 2007;45:335

Recurrent VTE is Common

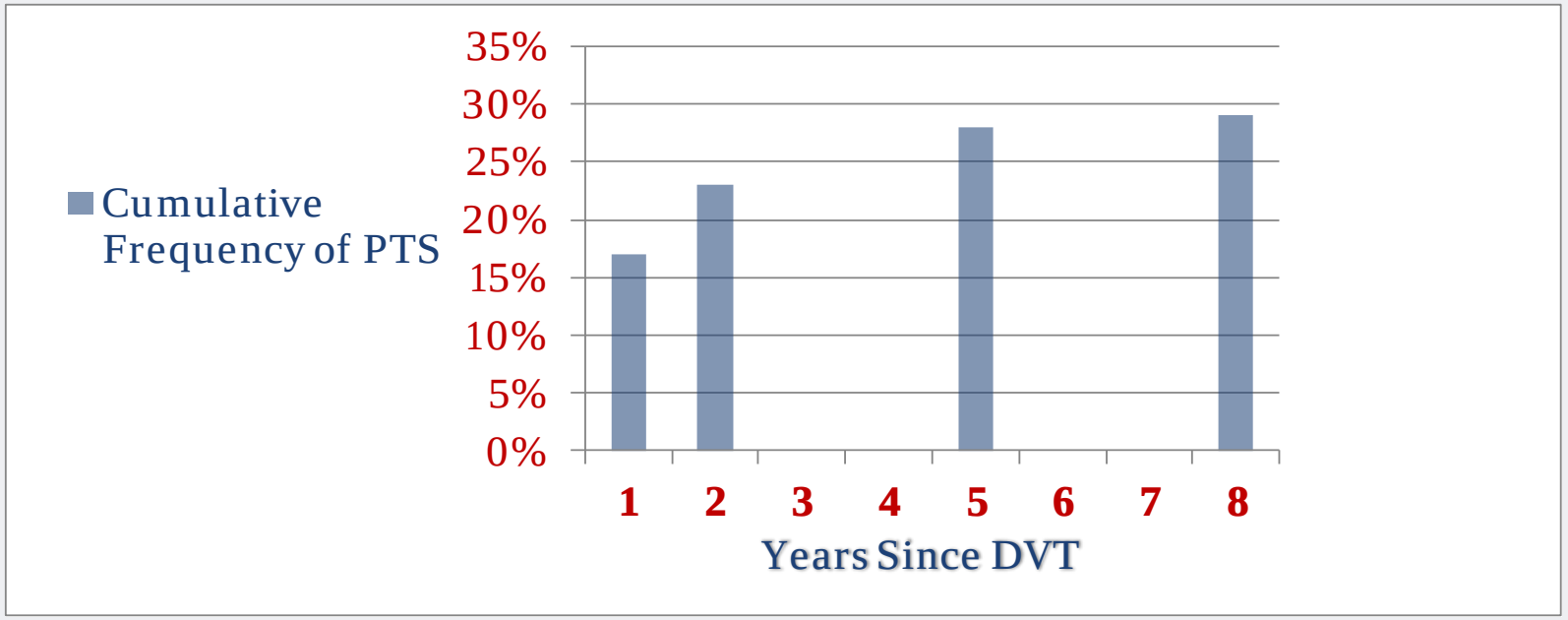
VTE is often a chronic disease



Prandoni - Ann Intern Med 1996;125:1

Post-Thrombotic Syndrome is Common

- Prospective study of 355 patients with DVT
- All patients advised to wear 40 mmHg stockings



Pradoni – Ann Intern Med 1996; 125:1

Chapter Four
Venous Disease Coalition

Clinical Presentations of VTE

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Symptoms of VTE

- Leg swelling
- Leg pain
- Arm swelling or pain
- SVC syndrome

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Symptoms of PE

- Sudden shortness of breath
- Gradual shortness of breath
- Pleuritic chest pain
- Hemoptysis
- Unexplained fever
- Presyncope
- Hypotension/shock
- Cardiac arrest/death

Chapter Five
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Investigation of Suspected VTE

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Investigation of Suspected DVT

- Ascending contrast venography
- Impedance plethysmography
- Radioactive fibrinogen scan

No longer used

- **Doppler ultrasonography** (Duplex scan): sensitive and specific for symptomatic proximal DVT

- **CT venography:** contrast timing critical
- **MR venography:** may be useful for pelvic vein thrombosis

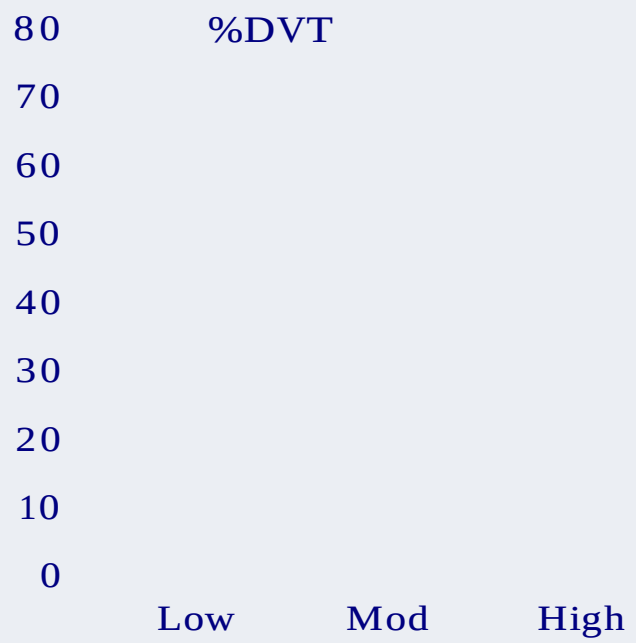
Investigation of Suspected DVT

- Try to never miss acute PROXIMAL DVT
- Some Doppler labs over-call DVT (especially calf DVT)
- No one knows if / how calf DVT should be managed
- Be aware of CLINICAL-IMAGING DISCORDANCE (the clinical features don't fit with the imaging results)

Clinical Predictive Model for DVT

Active cancer ≤ 6 mos	1
Paralysis, paresis, recent plaster cast	1
Bedridden > 3 d or major surgery < 1 mo	1
Localized tenderness along deep vein	1
Entire leg swollen	1
Calf swelling 3 cm > asymptomatic side	1
Pitting edema symptomatic leg	1
Collateral superficial veins	1
Alternative diagnosis > likely	-2

Low = ≤ 0 Mod = 1-2 High = ≥ 3

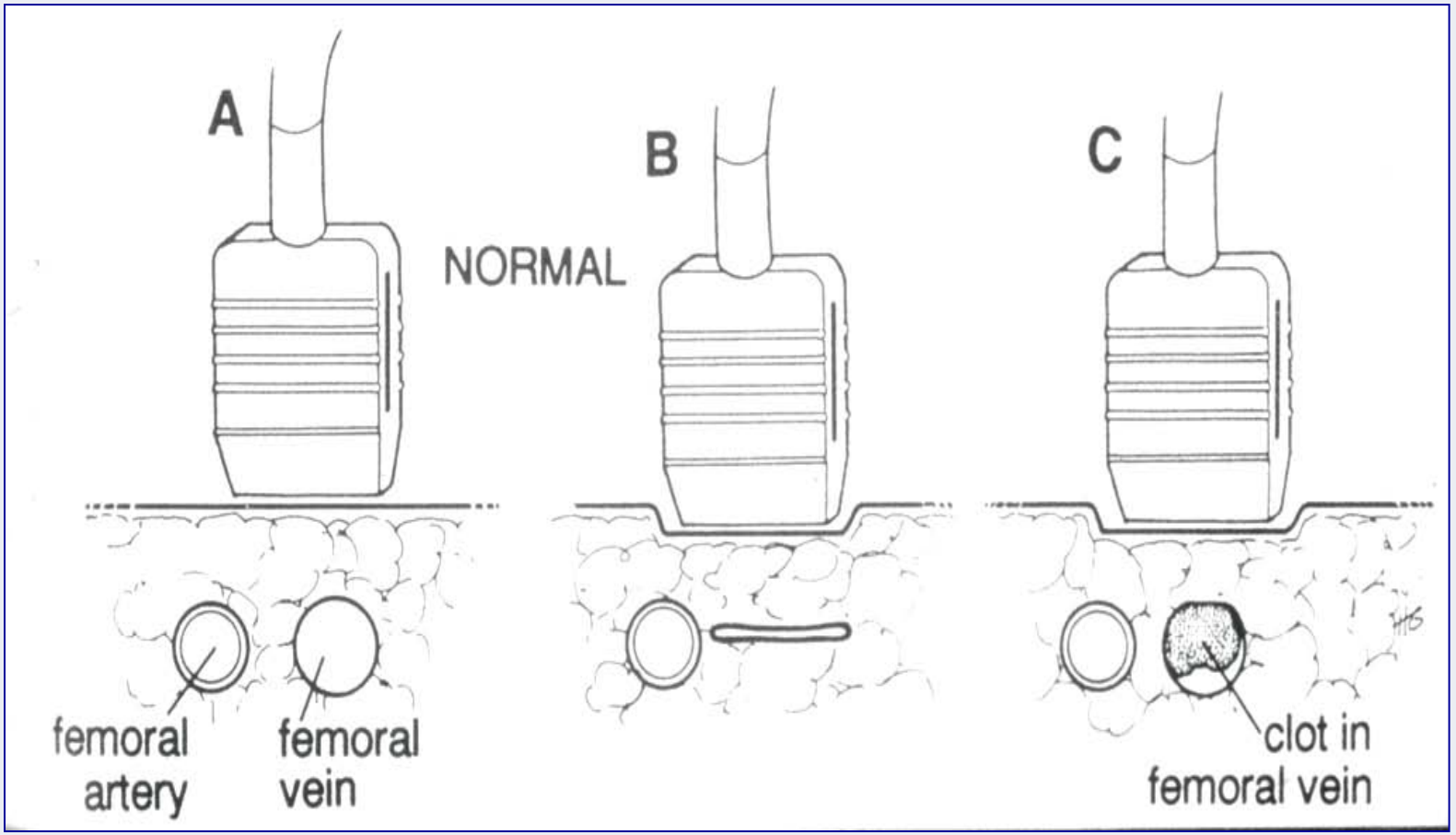


Wells - Lancet 1997;350:1795

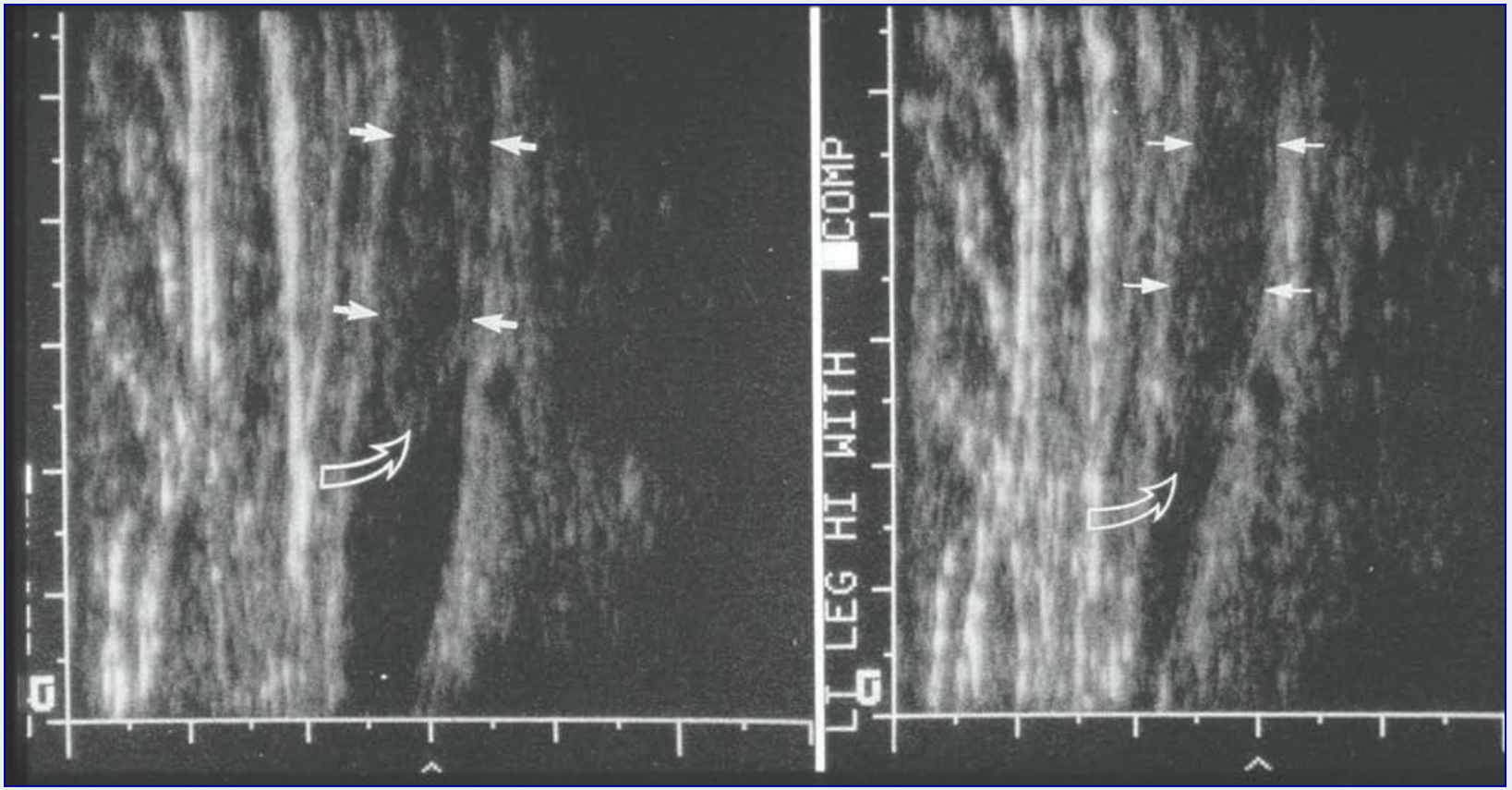
D-dimer in Suspected VTE

- D-dimers are degradation products resulting from the action of plasmin on fibrin
- The presence of D-dimer indicates initiation of blood clotting but many conditions other than DVT give a positive D-Dimer test result
- Therefore, a **positive D-dimer** does NOT rule in DVT, but a **negative D-dimer** can help exclude the diagnosis
- D-dimer may be useful in outpatients with low pre-test probability for VTE as part of a formal algorithm

Compression Doppler Ultrasound



Compression Doppler Ultrasound



Without Compression

With Compression

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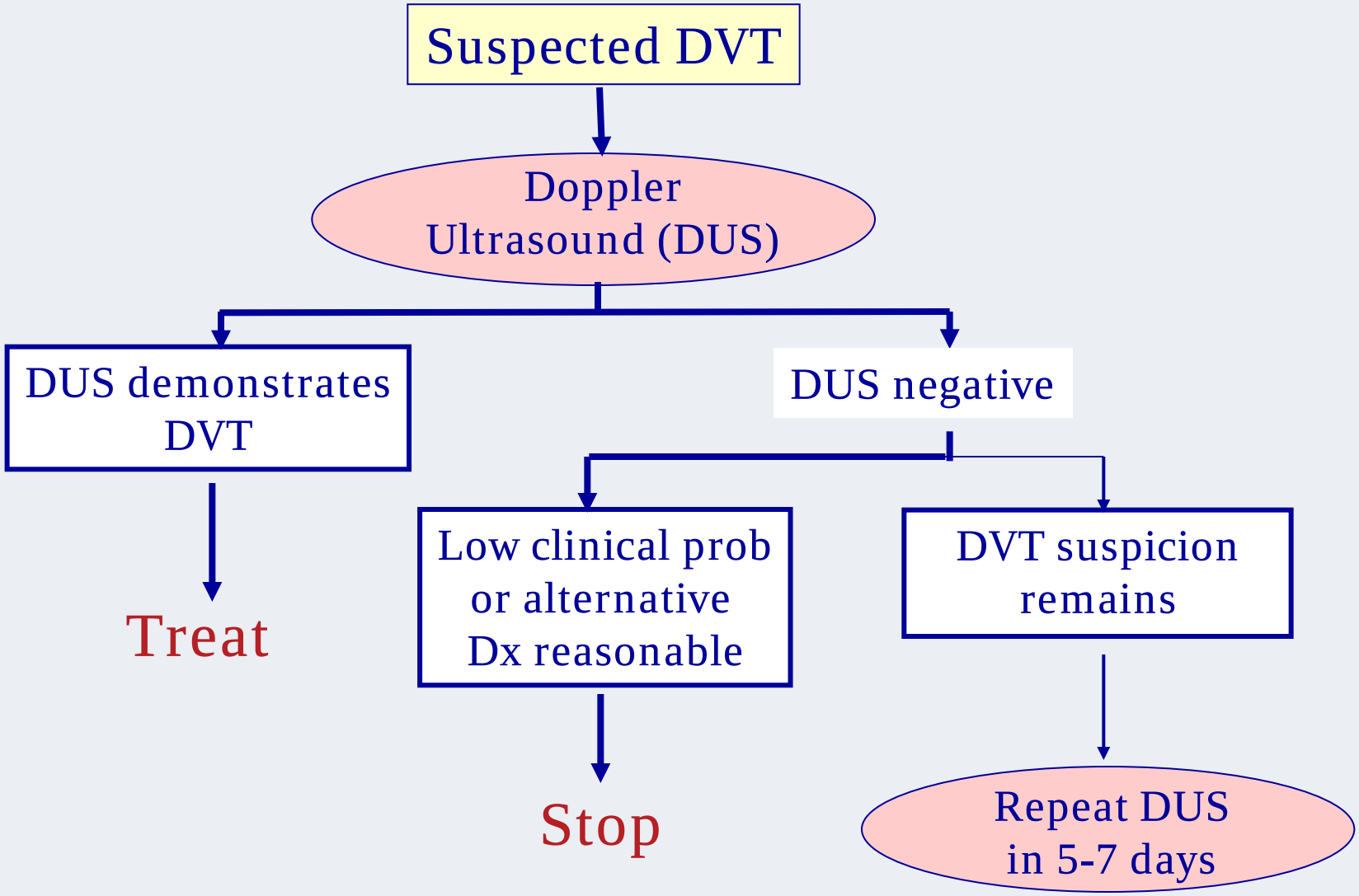
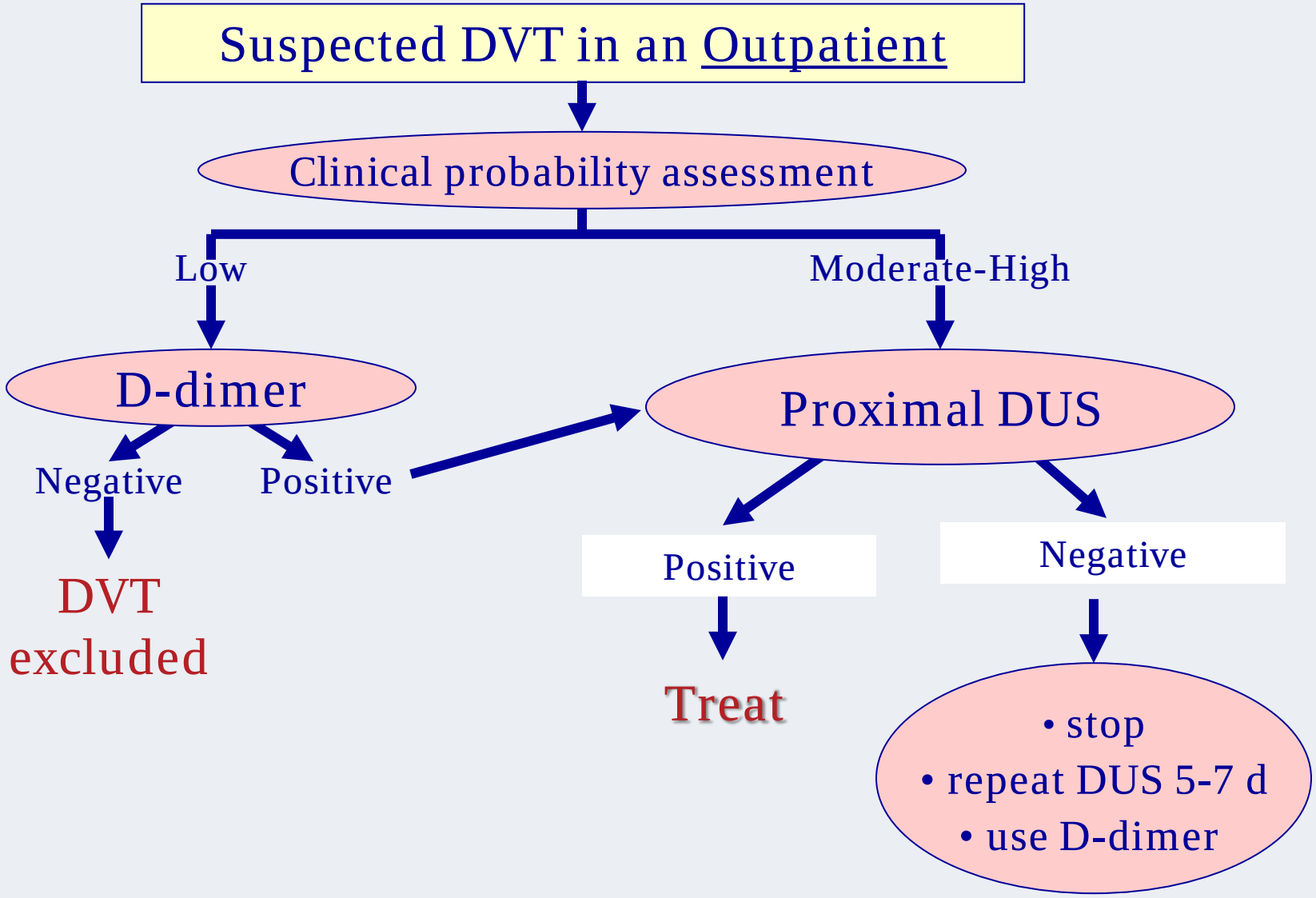
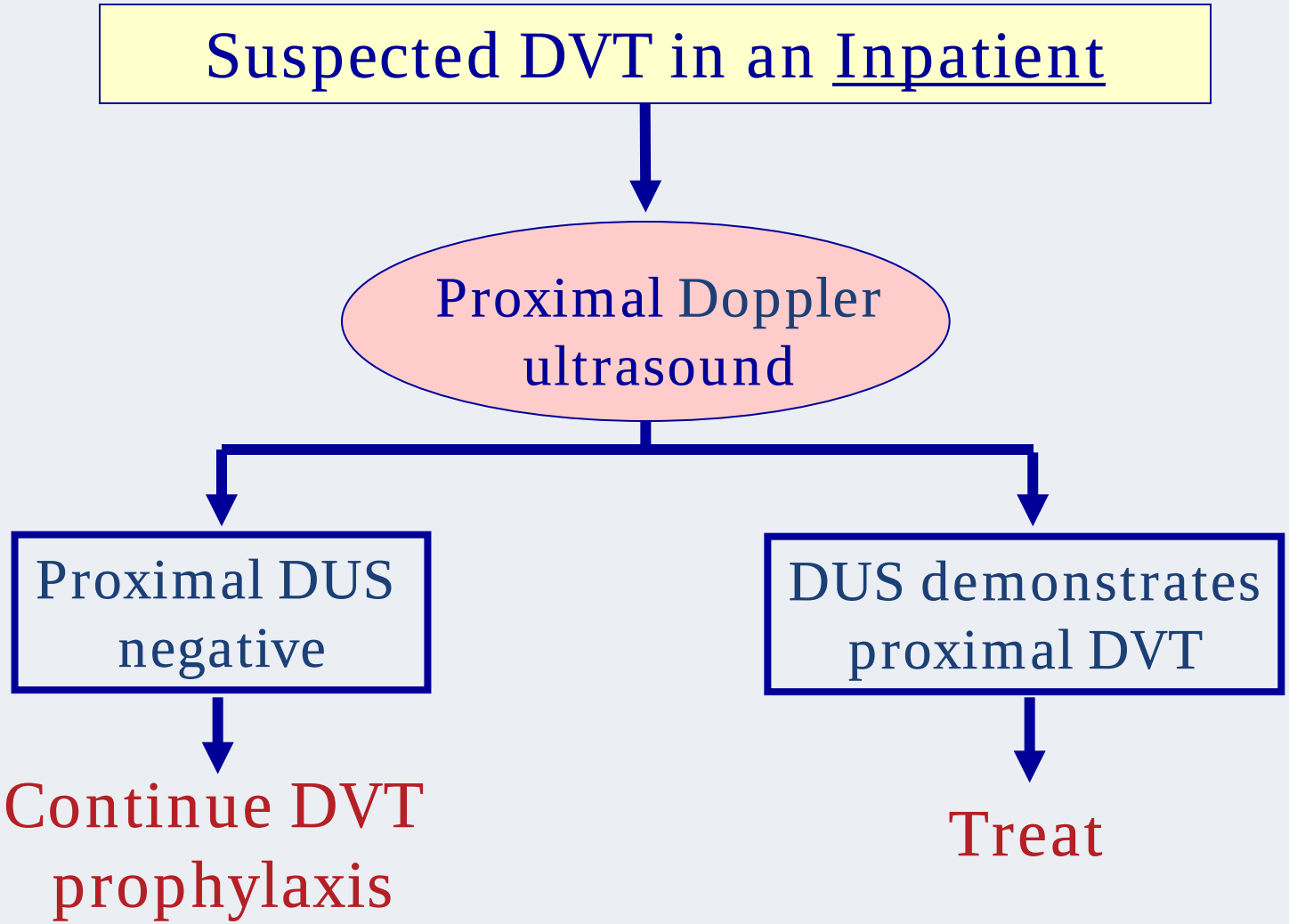
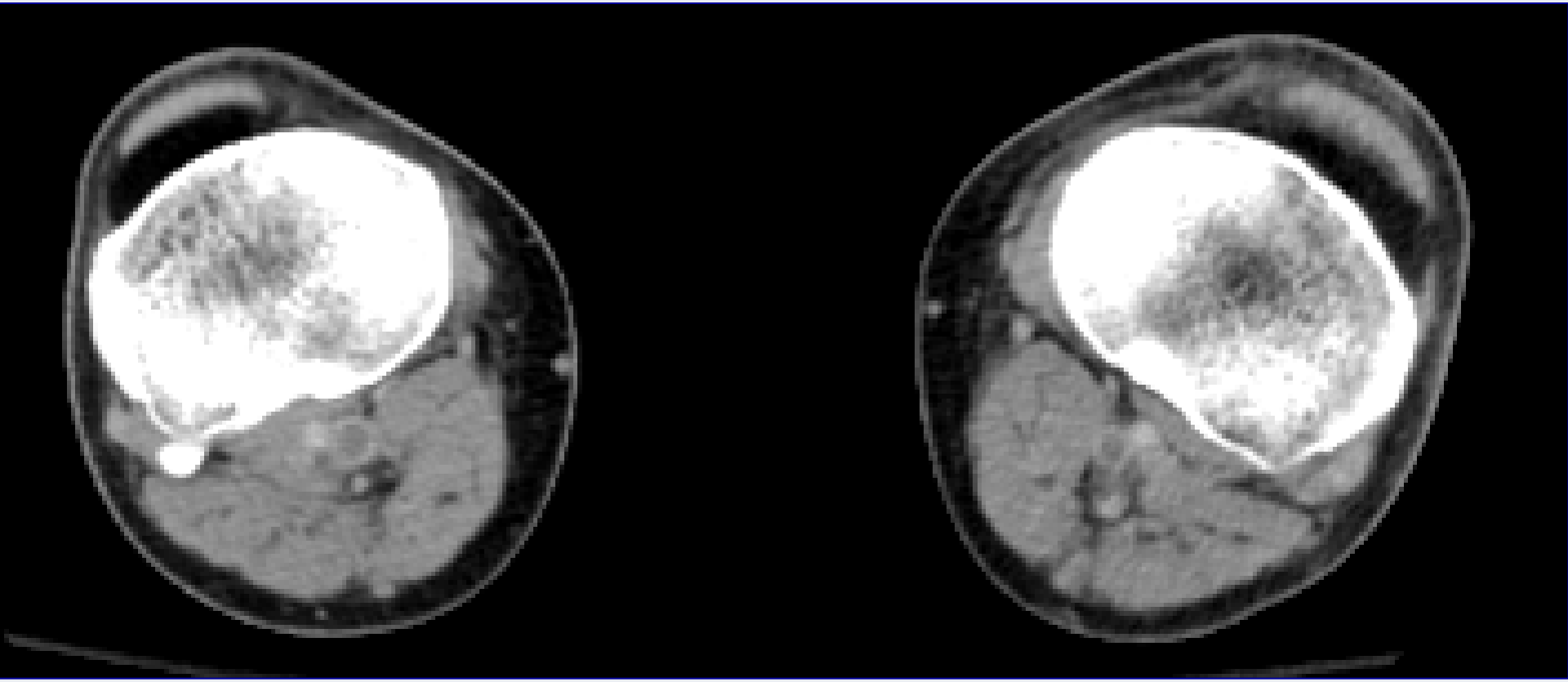

Suspected DVT
Doppler Ultrasound (DUS)
DUS demonstrates DVT
Treat
DUS negative
Low clinical prob or alternative Dx reasonable
Stop
DVT suspicion remains
Repeat DUS in 5-7 days


Suspected DVT in an Outpatient
Clinical probability assessment
Low
Moderate-High
D-dimer
Proximal DUS
Negative
Positive
DVT excluded
Positive
Negative
Treat
• stop
• repeat DUS 5-7 d
• use D-dimer


Suspected DVT in an Inpatient
Proximal Doppler ultrasound
Proximal DUS negative
DUS demonstrates proximal DVT
Continue DVT prophylaxis
Treat

CT Can Diagnose Proximal DVT



VTE Toolkit

VENOUS DISEASE COALITION
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Investigation of Suspected PE

- No diagnostic value of blood gases in suspected PE
- V/Q scans:
  - At least 60% are non-diagnostic
  - Consider in some patients with renal dysfunction or severe contrast allergy
  - Reasonable option for outpatients with normal CXR, and either very high probability of PE or low probability
  - Role in pregnancy and young women (because of reduced radiation dose)
- CT Pulmonary Angiogram ("Spiral CT"):
  - Accurate for segmental or larger PE
  - Accuracy and clinical relevance of sub-segmental abnormalities is uncertain

Wells Clinical Predictive Model for PE

History	
Previous proven DVT or PE	1.5
Immobilization ≥ 3 d or surgery prev. month	1.5
Malignancy (current or ≤ 6 mos.)	1
Hemoptysis	1
Physical exam	
Signs of possible DVT (leg swelling, tenderness	3
HR > 100	1.5
Alternative diagnosis	
PE as likely or more likely than alternative	3

Pre-test probability score		VTE
High	>6.0	41-50%
Moderate	2.0-6.0	16-19%
Low	<2.0	1-2%

Wells -
Thromb Haemost (2000)
Ann Intern Med (2001)

Revised Geneva Score for PE Assessment

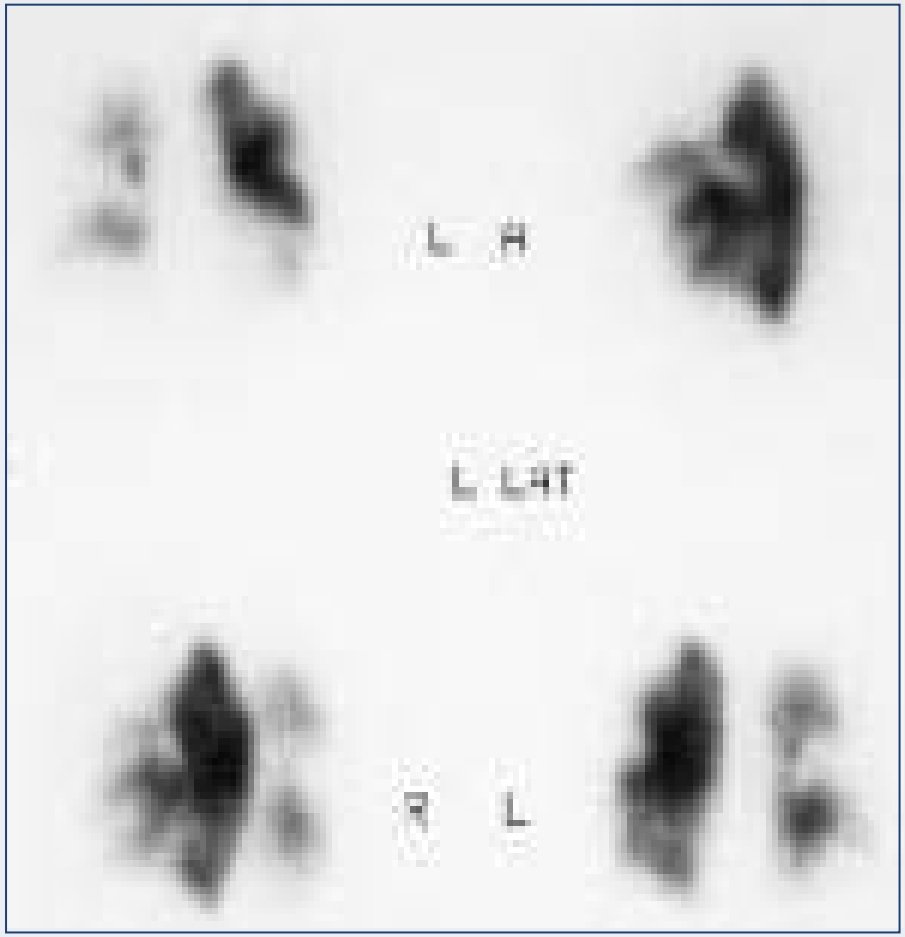
based on 8 clinical variables (not on clinical judgment)

	Points
Age > 65	1
Surgery/fracture past month	2
Active cancer	2
Hemoptysis	2
Previous DVT/PE	3
Unilateral leg pain	3
HR 75-94	3
HR ≥ 95	5
Unilat. edema + tenderness	4

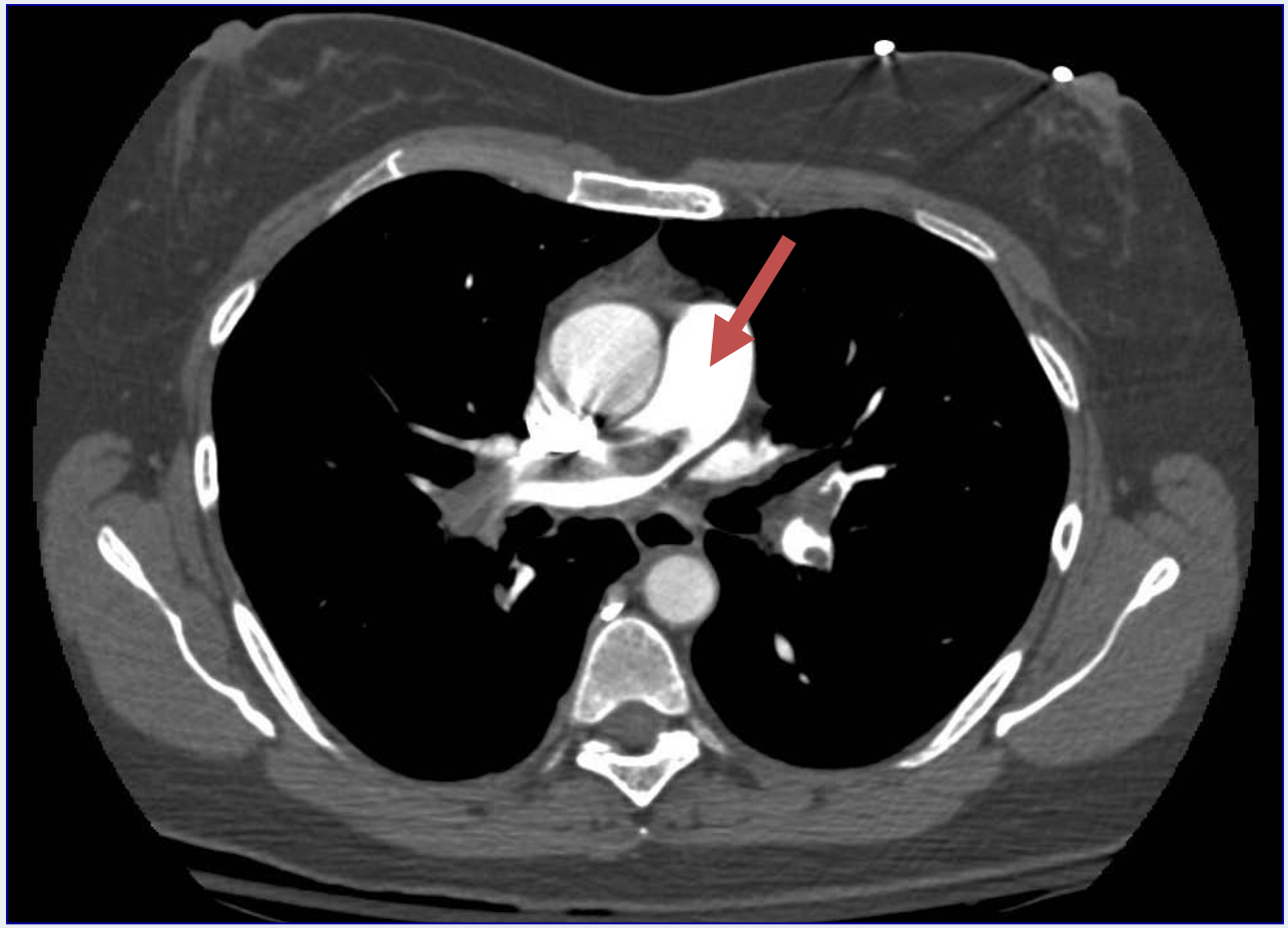
Risk	Points	PE prevalence
Low	0-3	8 %
Intermediate	4-10	29 %
High	≥ 11	74 %

Le Gal – Ann Intern Med 2006;144:165

Highly Abnormal Perfusion Scan



CT Pulmonary Angiogram



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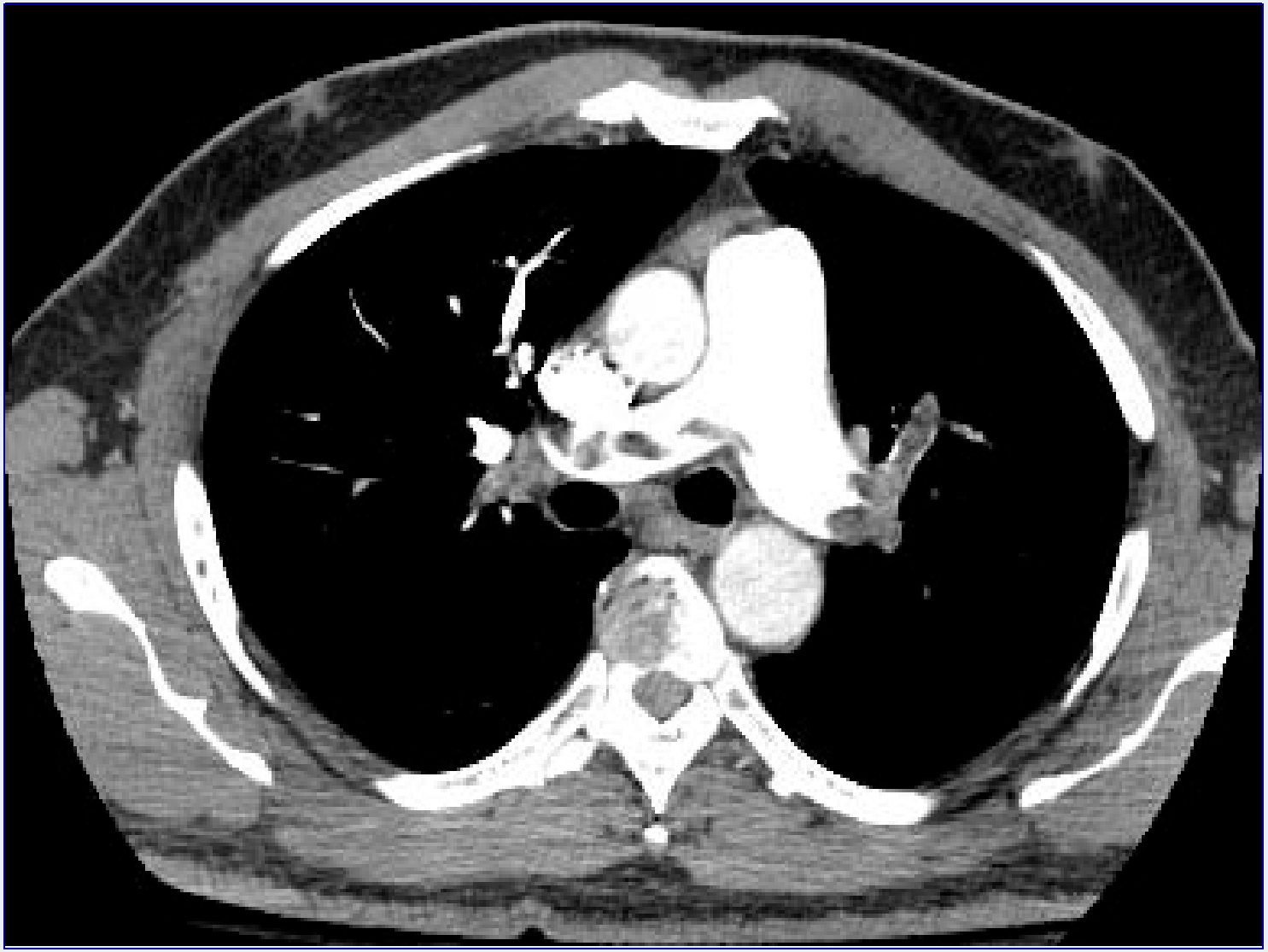

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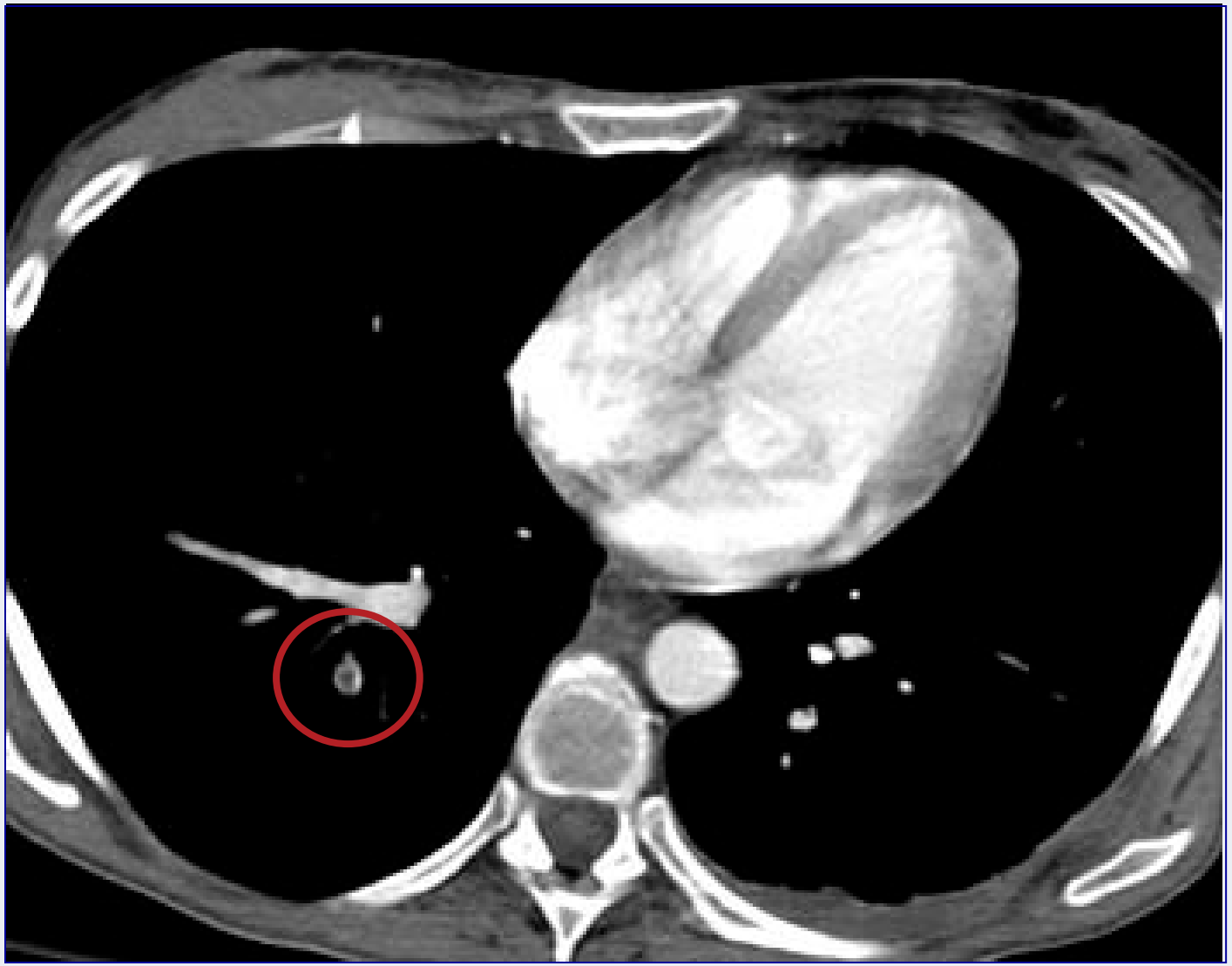

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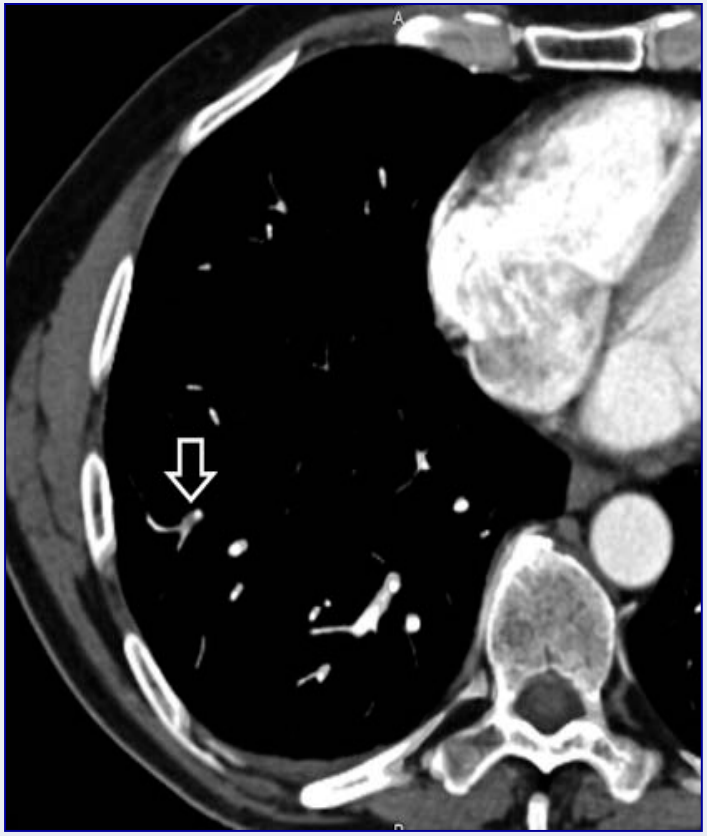
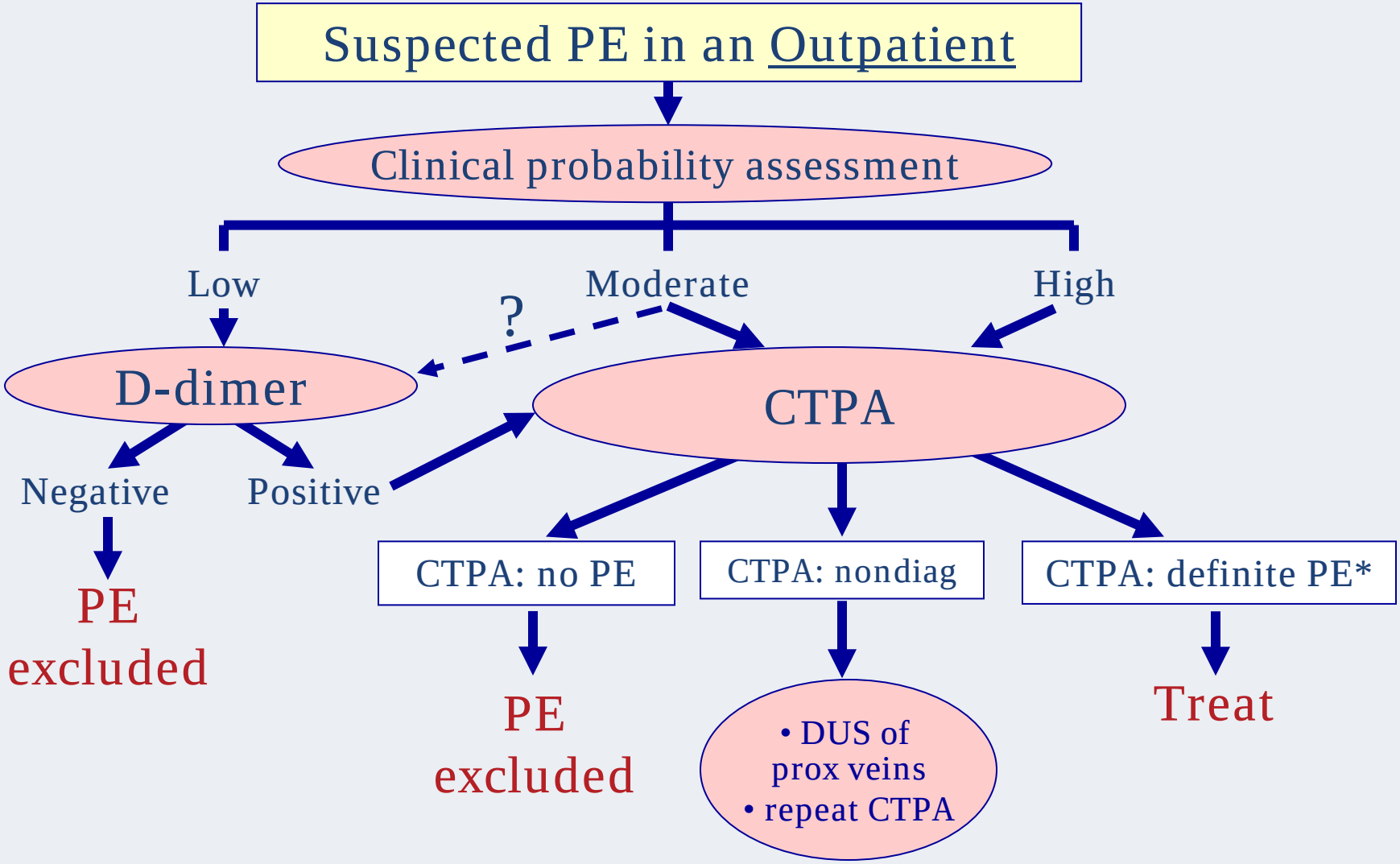
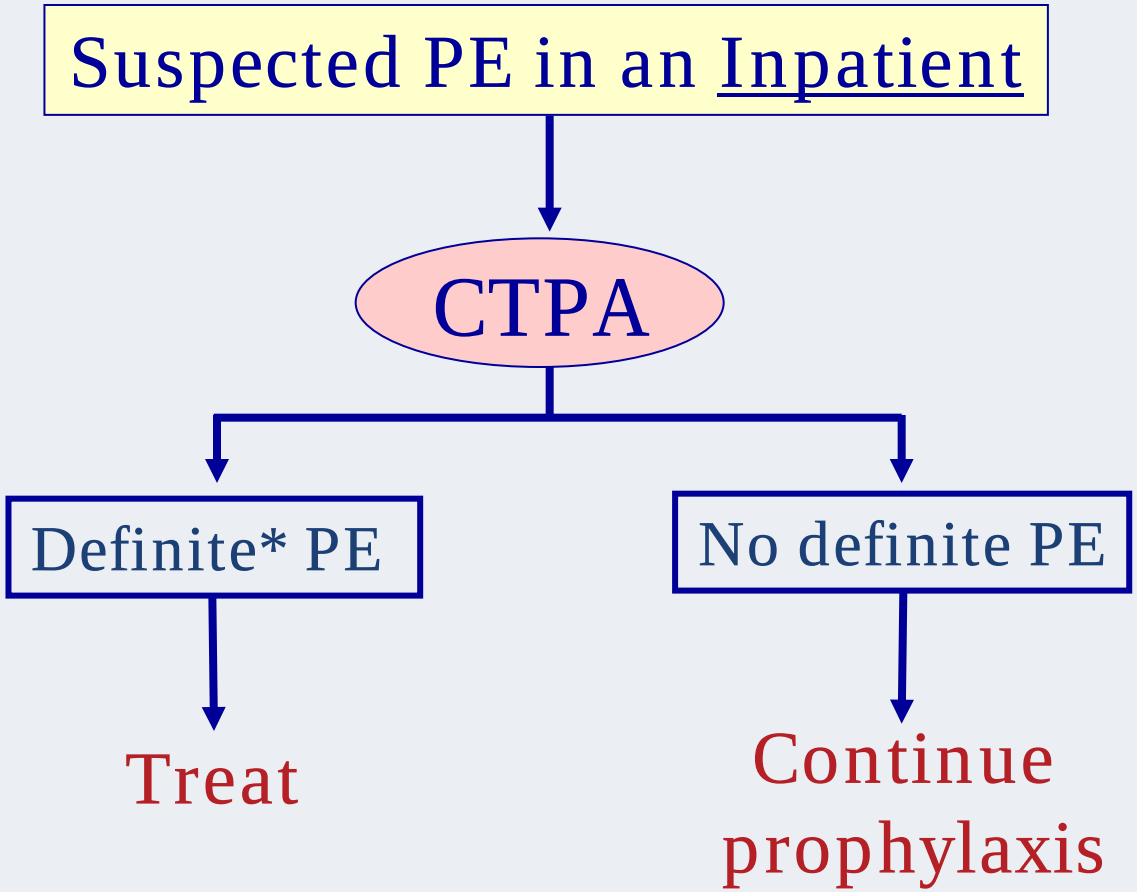
Subsegmental "Something"
Is it PE? Is it important?





*At least segmental filling defect and "reasonable" clinical suspicion



*At least segmental filling defect and “reasonable” clinical suspicion

Chapter Six
Venous Disease Coalition

Acute Management of VTE

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Objectives of VTE Treatment

- Prevention of PE
- Prevention of DVT extension
- Prevention of recurrent VTE
- Prevention of post-thrombotic syndrome

Principles of Acute VTE Treatment

- Early, rapid therapeutic anticoagulation
  - IV heparin; weight-adjusted SC heparin
  - Weight-adjusted SC LMWH
  - SC fondaparinux
  - Not warfarin alone
- Encourage early ambulation

Low Molecular Weight Heparin

(dalteparin or Fragmin®; enoxaparin or Lovenox®)

Advantages:

- more predictable response than heparin
- no dosage adjustment
- no need for lab monitoring
- at least as effective as IV heparin
- safer than heparin
- many patients can be treated as outpatients
- cheaper than using heparin

Disadvantages:

- subcutaneous injection daily
- accumulation in renal dysfunction

Initial Treatment of VTE

- **LMWH SC rather than heparin IV** for most
  - dalteparin (Fragmin®) 200 U/kg SC once daily
  - enoxaparin (Lovenox®) 1 mg/kg SC BID
- Use **pre-filled syringes** *(and round up to that dose)*
- **NO maximum** *(dose not capped for weight)*
- Most patients with DVT and many with PE can be managed entirely as **outpatients** *(if out-patient LMWH can be arranged)*
- Most patients can **do their own injections**

Prophylactic and Treatment doses of LMWHs are NOT the same

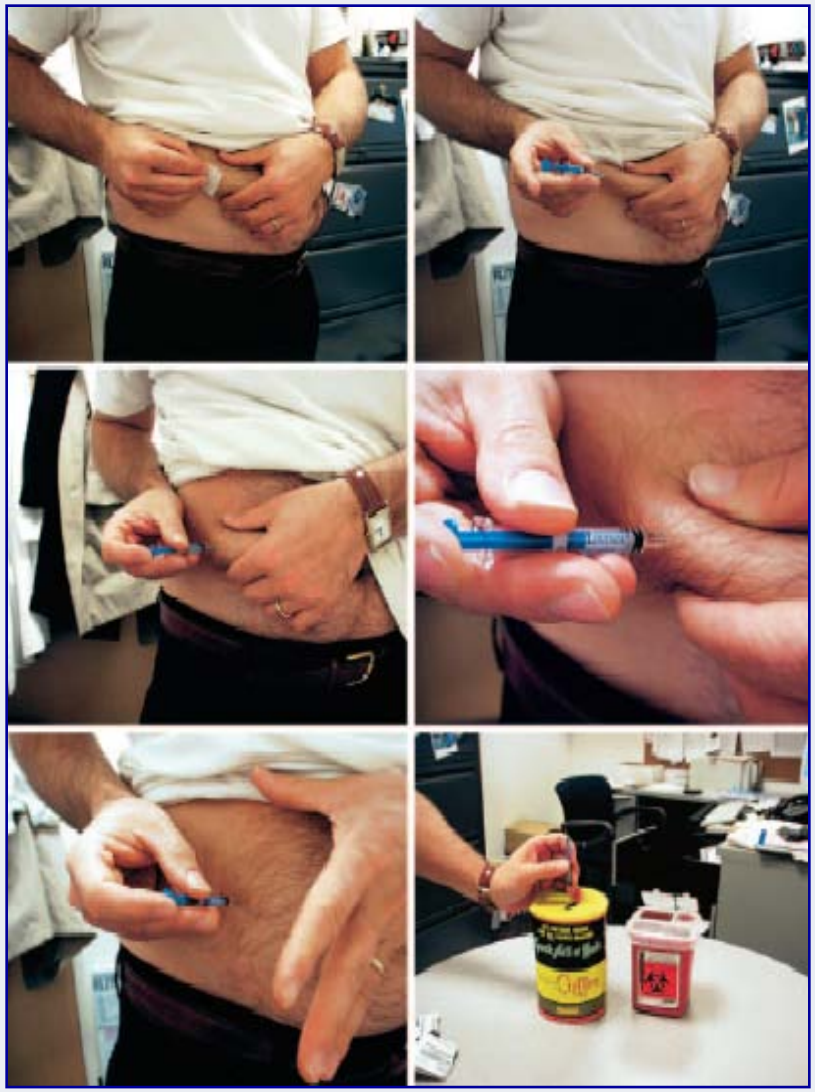
(for a 75 kg patient with normal renal function)

LMWH	Prophylaxis dose	Treatment dose
dalteparin (Fragmin®)	5,000 U QD	15,000 U QD *(200 U/kg QD*)*
enoxaparin (Lovenox®)	30 mg bid or 40 mg QD	80 mg BID *(1.0 mg/kg BID*)*

*no maximum

Injection of LMWH

Patients can do their own injections with minimal instruction



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Use of Unfractionated Heparin Therapy for DVT or PE

- Dose varies markedly among patients
- APTT target = 2.0 – 3.0 times control
- Aim to obtain target APTT ASAP
  - Failure to achieve therapeutic APTT within 24 hours is associated with 23% recurrence of VTE compared to 5% in those therapeutic within 24 hours!!

Initial IV Heparin Therapy for DVT or PE

- **Indications** (rare)
  - Massive PE, during lytic therapy
  - severe renal dysfunction
  - unstable patient
  - failed LMWH
- **Bolus:** 5,000 units
- **Starting infusion:** 20 units/kg/hr
- **Target aPTT:** 2 - 3 times control (~70-90 sec)
- Use a **nomogram**

Heparin-Induced Thrombocytopenia (HIT)

- Occurs in 1-5% of patients given therapeutic heparin for more than 5 days (less common with LMWH)
- HIT leads to venous and/or arterial thrombosis in approximately 50% of patients as well as amputations and deaths
- Is the most hypercoagulable state known

Management of Heparin-Induced Thrombocytopenia (HIT)

1. Stop heparin (and LMWH) in all forms

2. Start a HIT-safe alternative anticoagulant
   - Argatroban
   - Bivalirudin
   - Lepirudin
   - Fondaparinux

3. Confirm the diagnosis

Initial Treatment of VTE

- Start **warfarin** on the same day as LMWH or heparin (if warfarin is an appropriate option)
- Continue LMWH **at least 5 days** and until **INR ≥2.0 for 2 days**
- **Early mobilization** is very important

Admission Criteria for Acute VTE

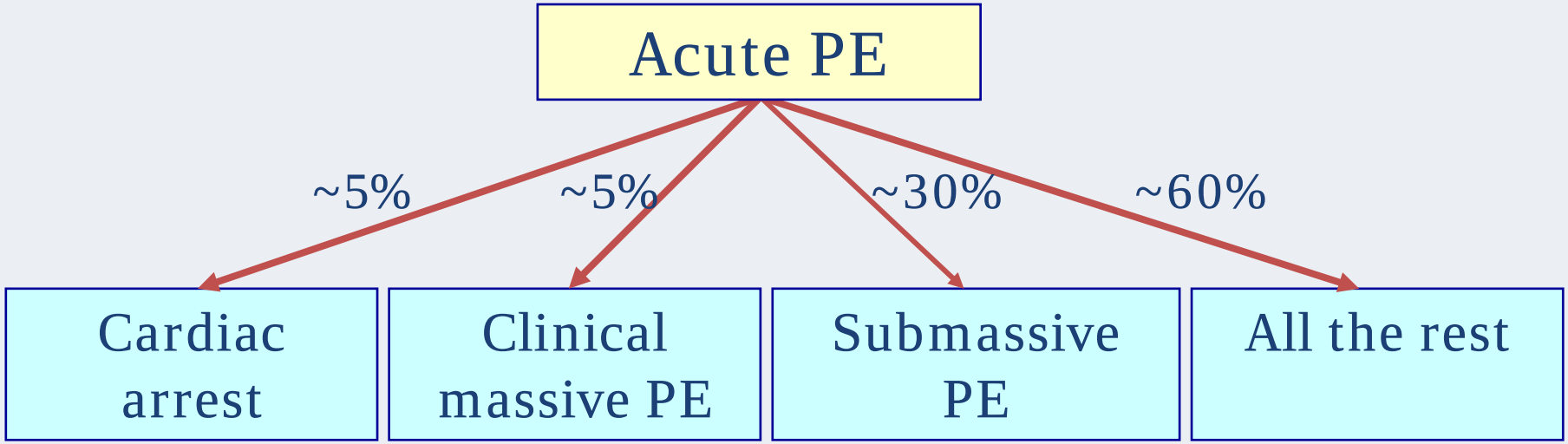
DVT: (few need to be admitted*)

- Very high bleeding risk
- Severe renal dysfunction
- Patients with extensive iliofemoral DVT who are considered for catheter thrombolysis

PE: (many can be treated as outpatients*)

- Hemodynamically unstable
- Requires O_2 or parenteral narcotics
- Very high bleeding risk
- Severe renal dysfunction
- Massive PE requiring catheter thrombolysis

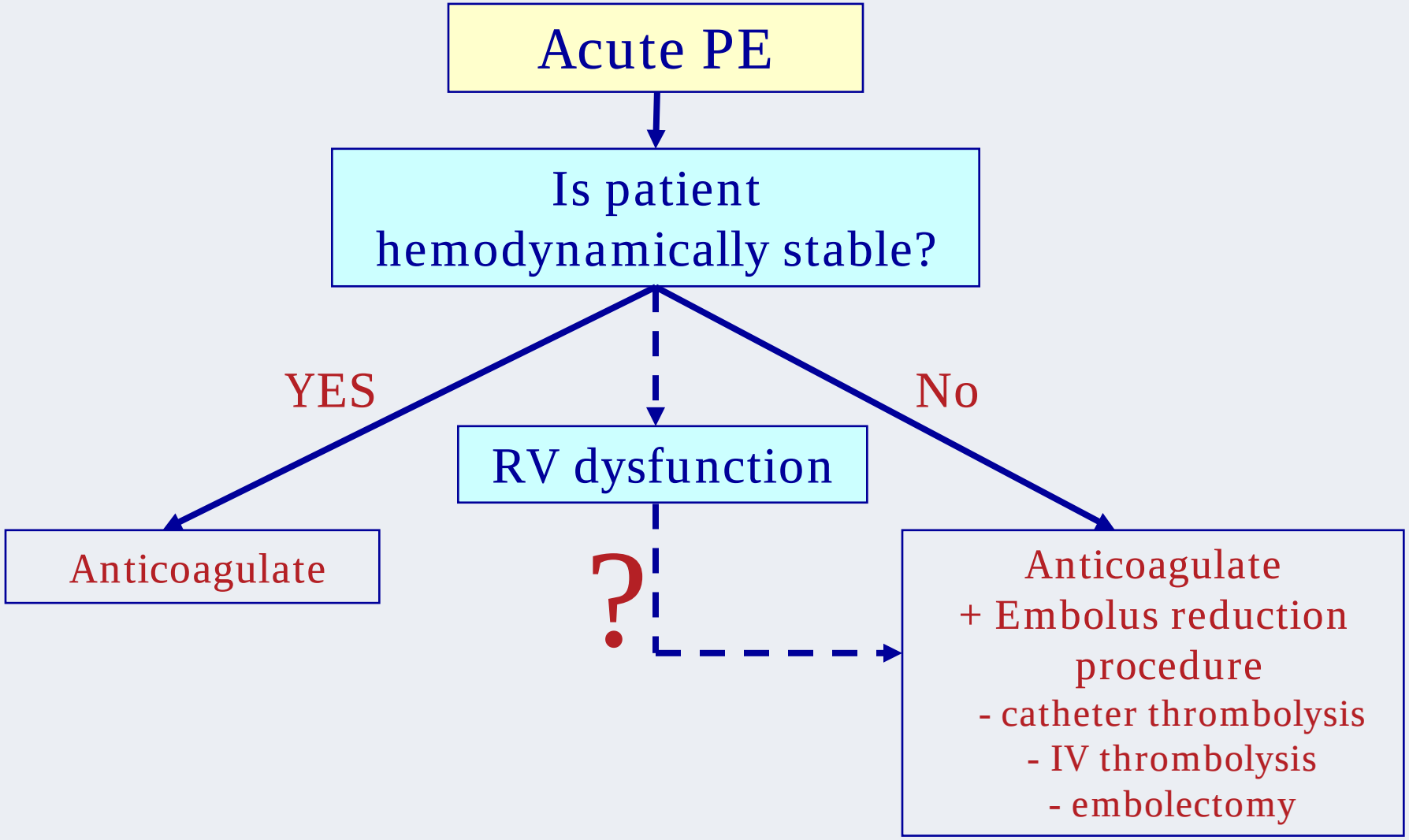
*if outpatient low molecular weight heparin can be arranged



Mortality:

70-95%	20-50%	5-10%	≤ 3%

BNP = brain natruiretic peptide; RHF = right heart failure; RVD = right ventricular dysfunction; Tp = troponin


Acute PE
Is patient hemodynamically stable?
YES
No
RV dysfunction
Anticoagulate
?
Anticoagulate
+ Embolus reduction procedure
- catheter thrombolysis
- IV thrombolysis
- embolectomy

Treatment Options for Massive PE

Surgical embolectomy

- Available in very few centers & when needed
- High mortality and morbidity

IV thrombolysis

- Contraindicated in 70% of patients
- Often small benefit
- Definite increased bleeding risk

Catheter-directed thrombus reduction

- Few contraindications
- Appears to be highly effective but no RCTs
- Appears to be safe

Meta-Analysis of Randomized Trails of IV Thrombolytic Therapy for PE

11 RCTs, 748 patients

Outcome	Heparin		Lysis	Odds Ratio
Recurrent PE, death	9.6 %	~	6.7 %	0.7 [0.4-1.1]
Death	5.9 %	~	4.3 %	0.7 [0.4-1.3]
Bleeding - major	6.1 %	~	9.1 %	1.4 [0.8-2.5]
- nonmajor	10.0 %	<	22.7 %	2.6 [1.5-4.5]

Wan – Circulation 2004;110:744

Accepted Indication for an IVC Filter

Recent PROXIMAL DVT or PE
PLUS an absolute contra-indication to full anticoagulation

Uncertain (controversial) indications:

- Big DVT ± poor cardiopul. reserve
- "Recurrent" VTE/failure of Rx
- Primary prophylaxis

Retrievable IVC Filter

- Up to 80% are NOT removed!
- No data about long-term implications
- Require 2 central venous procedures
  - ↑ cost
  - ↑ radiology time
  - ↑ risks
  - ↑ radiation

8th ACCP Conference on Antithrombotic Therapy

IVC Filter Use:

- Recommend AGAINST IVCF in addition to anticoagulation [Grade 1A]
- Recommended if acute proximal DVT with contraindication to anticoagulation [Grade 1A]
- When high bleeding risk resolves, use conventional anticoagulation as for patients without a filter [Grade 1C]

Kearon – Chest 2008

Chapter Seven
Venous Disease Coalition

Long-Term Management of VTE

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Long-Term Treatment of DVT/PE: 2 options

1

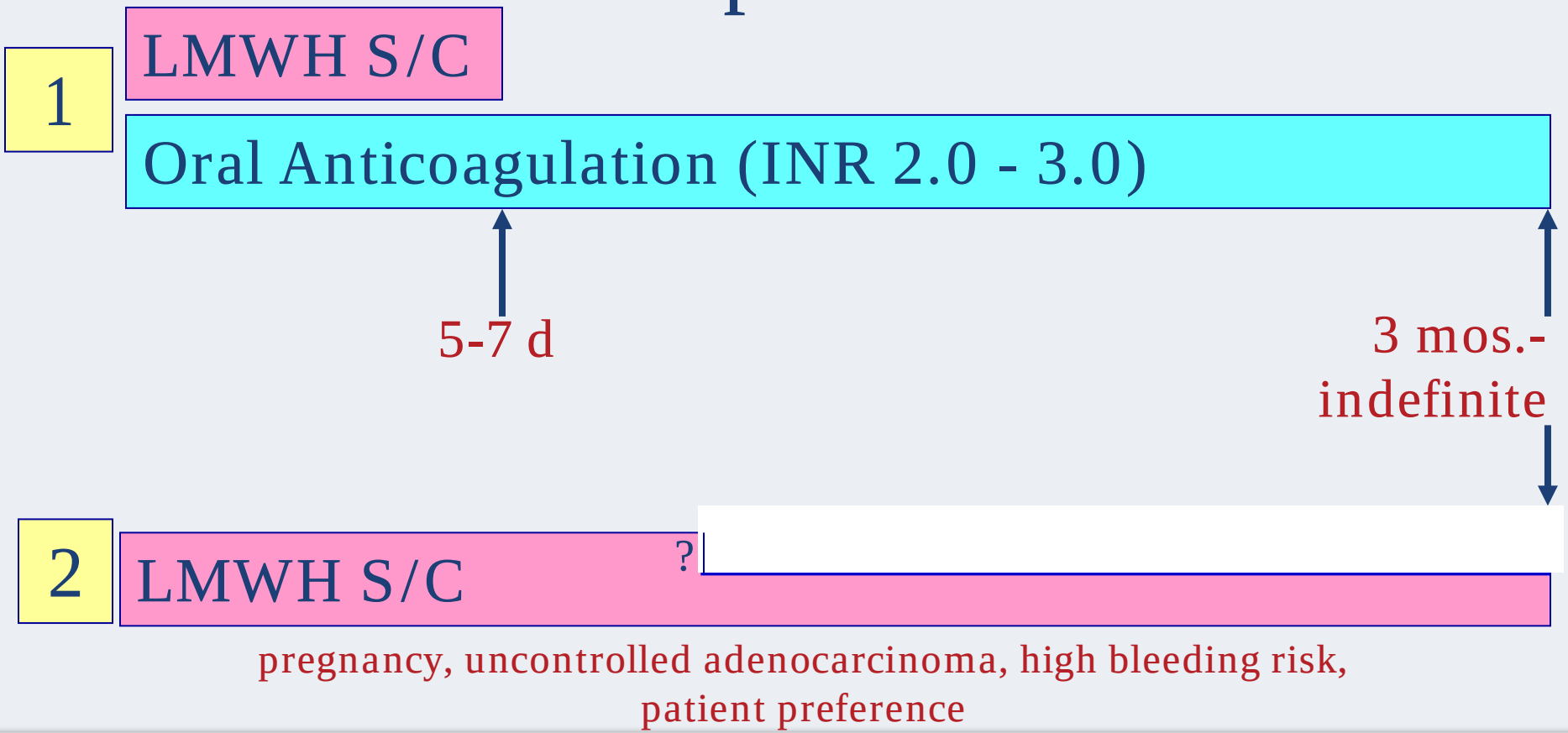
LMWH S/C

Oral Anticoagulation (INR 2.0 - 3.0)

5-7 d

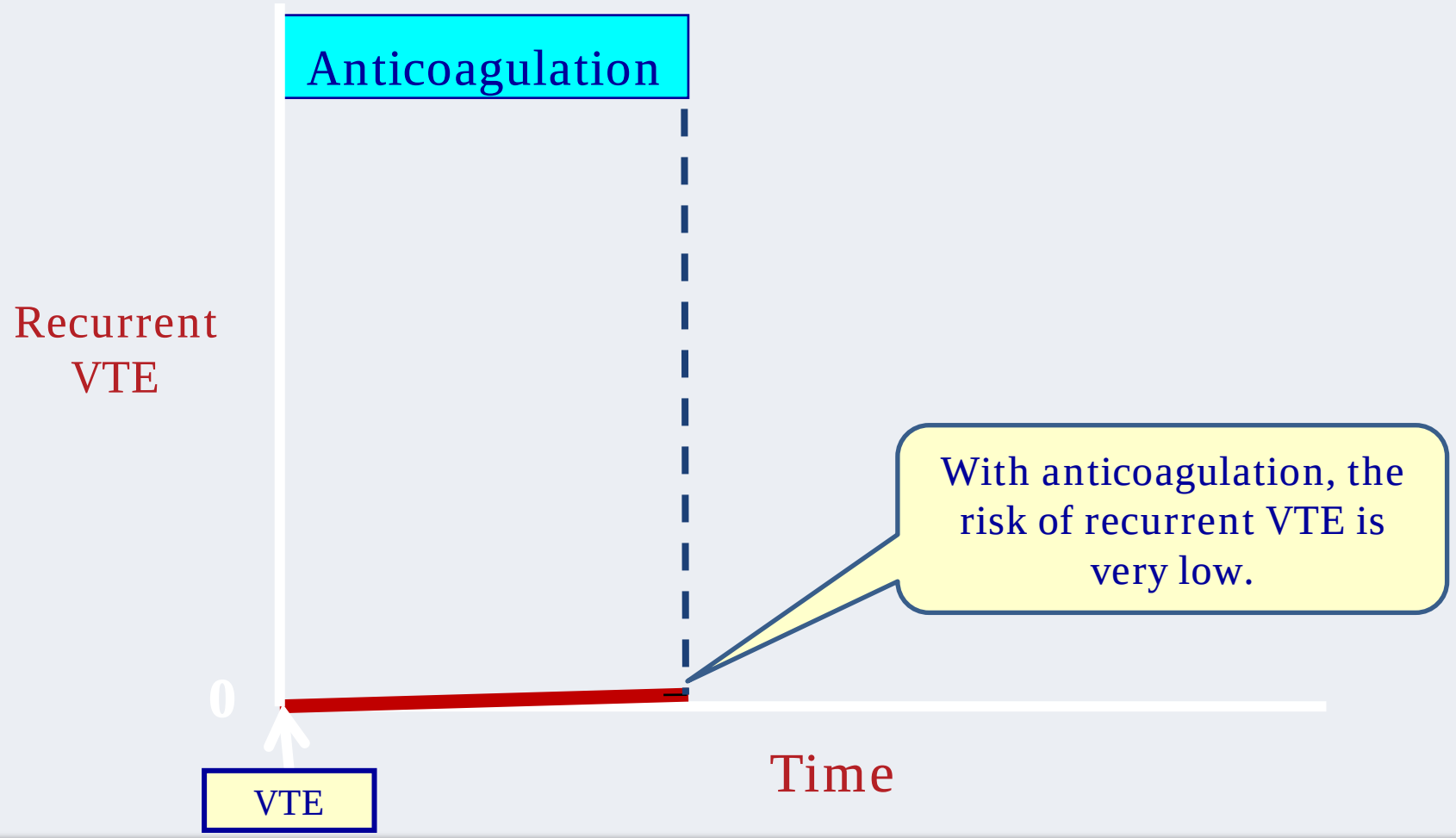
3 mos.- indefinite

Long-Term Treatment of DVT/PE: 2 options

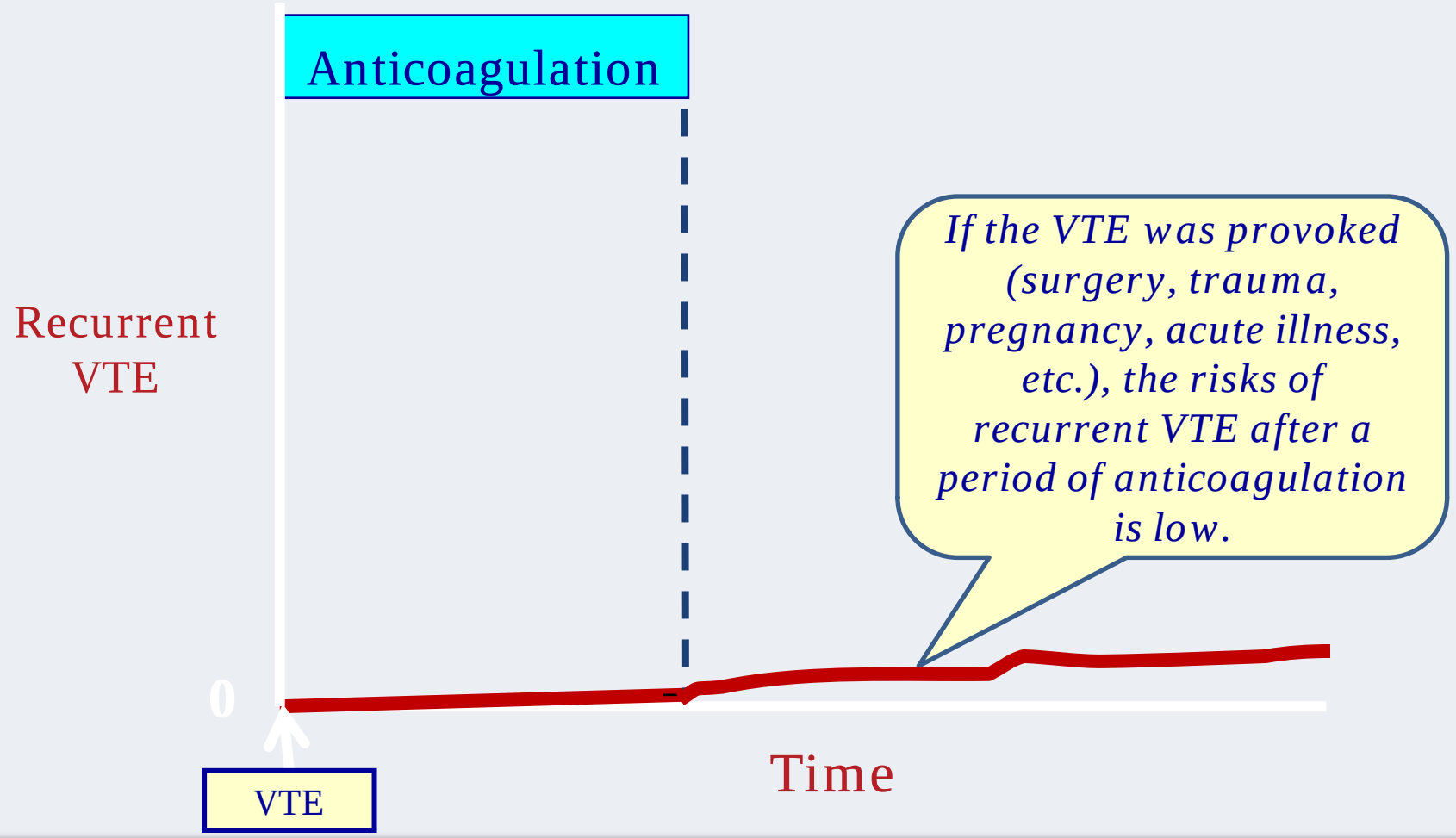


pregnancy, uncontrolled adenocarcinoma, high bleeding risk, patient preference

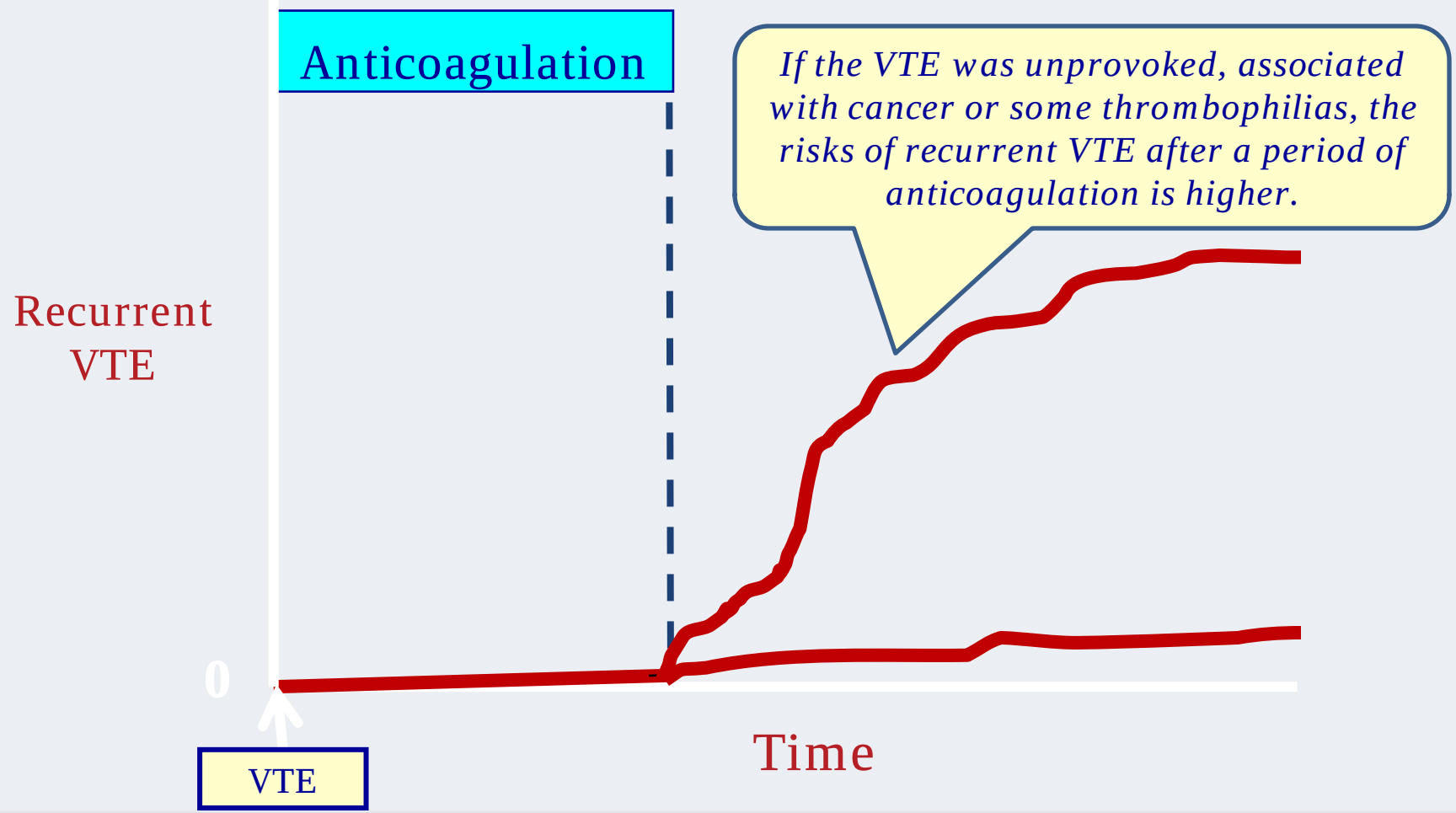
Treatment of VTE



Treatment of VTE



Treatment of VTE



D-Dimer to Predict VTE Recurrence

Patients with abnormal D-Dimer one month after discontinuation of anticoagulation have a significantly greater incidence of recurrent VTE than patients with a normal D-dimer.

Palareti - D-Dimer testing to determine the duration of anticoagulation therapy.
N Engl J Med 2006;355:1780

Predictors of Recurrent VTE

- Ongoing risk factors – cancer, immobility, high risk thrombophilia (APLA, AT deficiency)
- Unprovoked initial VTE
- Older age
- Male gender
- Obesity
- Residual DVT
- Elevated D-dimer 1 month after stopping anticoagulants

Duration of Treatment for VTE

1st Episode:	
Transient, reversed risk	3 - 6 mos.
Unprovoked	12 mos → indefinite*
Ongoing risk (unresolved cancer, AT deficiency, APLA)	indefinite*
Recurrent Episodes:	indefinite*

* Periodic reassessment to discuss:

1) Patient risk factors for bleeding and thrombosis
2) New knowledge about risk of recurrence
3) Patient preference

Chapter Eight
Venous Disease Coalition

Safe Use of Oral Anticoagulants

VTE Toolkit

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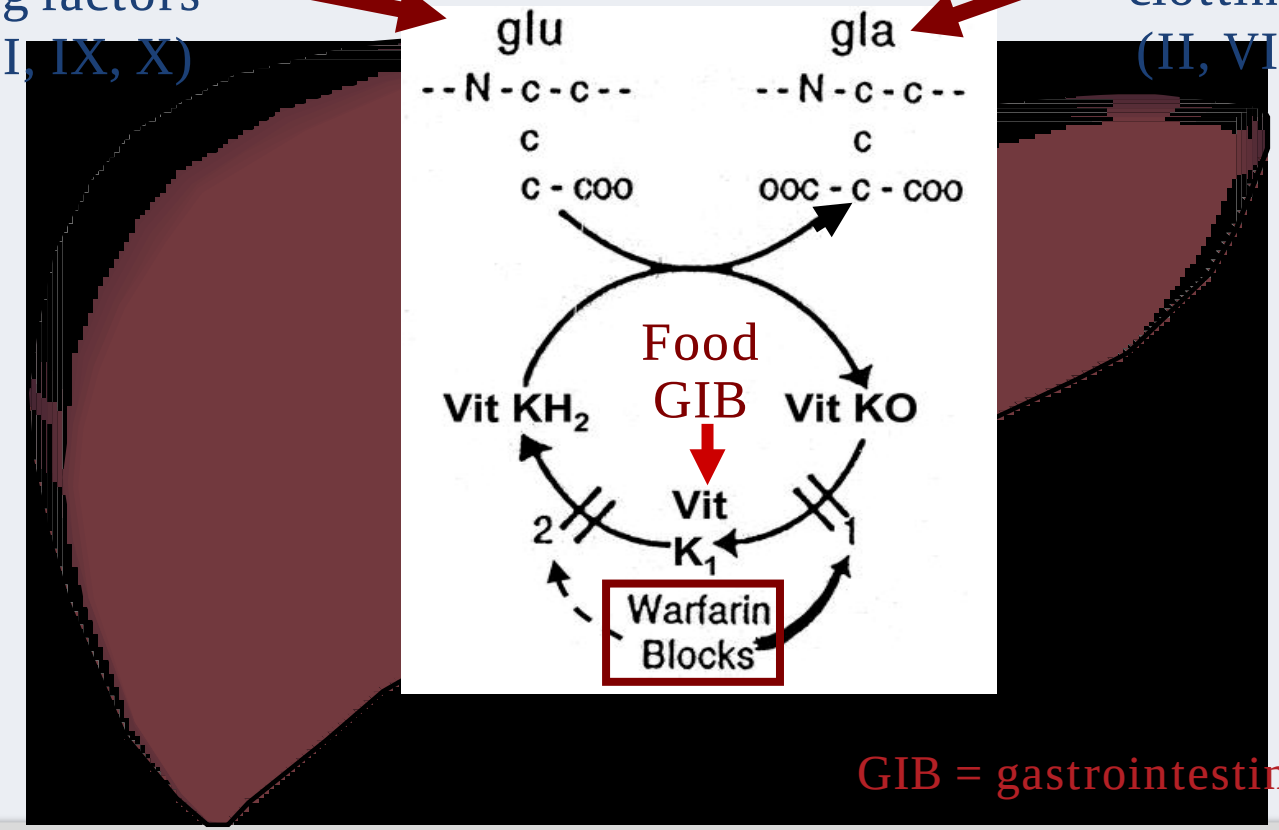
Action of Vitamin K Antagonists *(Warafin)*

- Inhibit the production of functional vitamin K dependent clotting factors II, VII, IX, X
- Also inhibit the anti-clotting factors Protein C & S
- Initial changes in INR reflect inhibition of Factor VII (shortest half-life); other factors take nearly a week to decrease to thrombosis-preventing levels
- 20-fold or greater range in maintenance dose among groups of patients (<1 mg/day to >20 mg/day)
- Contraindicated in pregnancy

Mechanism of Action of Warafin

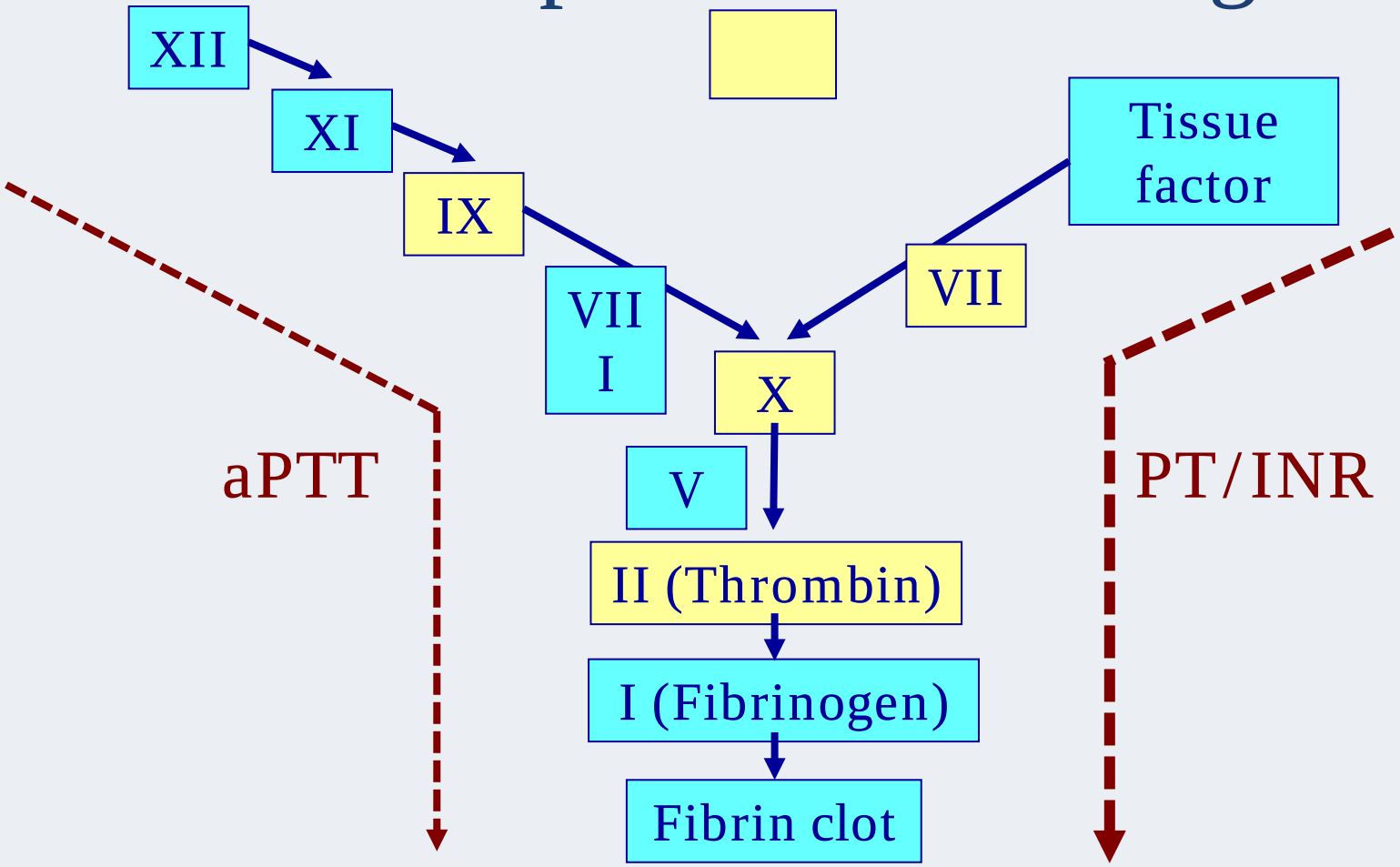
Hypofunctional clotting factors (II, VII, IX, X)

Functional clotting factors (II, VII, IX, X)



GIB = gastrointestinal bacteria

Vitamin K Dependent Clotting Factors



Factors Contributing to Patient Variability in Warafin Dose

- Age
- Weight
- Race
- Liver disease
- Heart failure
- Genetics:
  - cytochrome P450 2C9 polymorphisms (CYP 2C9)
  - vitamin K epoxide reductase (VKOR) polymorphisms
- Alcohol intake
- Nutritional status
- Diet
- Activity level
- Drug interactions
- Patient compliance
- Who's supervising anticoagulation

Factors Increasing Bleeding Risk on Oral Anticoagulants

1. Age > 75
2. Also receiving antiplatelet drugs
3. Uncontrolled hypertension
4. History of bleeding (GI, intracranial)
5. Cancer
6. Chronic renal failure
7. Poorly controlled / poorly supervised anticoagulant therapy

Long-Term Treatment of VTE with a Vitamin K Antagonist (Warafin)

- Target INR = 2.0 - 3.0
- Lower INR (1.5-1.9) is associated with increased VTE recurrence, but NOT decreased risk of bleeding

Warafin Therapy - Principles

- Patient and physician must be **obsessive**
- **Do not order daily INR** – use long-term trends
- Use a **warfarin dosing sheet** (for both MD and patient) = a longitudinal record of doses, INR results, next INR date
- **Don't over-react** to just out-of-range INR values
- **Stop ASA/clopidogrel** unless indicated
- **Manage hypertension** aggressively
- **Encourage vitamin K intake**

Diet and Warafin Use

- Do NOT advise restriction of vitamin K-containing food – this is associated with less stable INR values
- Encourage foods high in vitamin K (broccoli, spinach, brussel sprouts)
- "Let me know if you plan a major change in your usual diet"

Warafin and Alcohol

- Binge drinking → increases INR
  - → may reduce compliance
  - → increases UGI bleed risk
  - → reduces the stability of anticoagulation
- **Recommend moderation NOT abstinence**

New Drugs and Warafin

- Assume new drugs might affect the INR
- For a known interaction (or uncertain):

  - get INR 4-5 days after starting

- If INR was increased previously with the same antibiotic, reduce warfarin dose for a few days

ASA and Warafin Use

- Generally **AVOID**
- No additional benefit for most patients
- Definite increase in bleeding risk
- There must be a good reason for the ASA, e.g. coronary artery stent, high-risk mechanical heart valve, acute coronary syndrome, TIA/stroke on warfarin
- Therefore, the combination of an antiplatelet agent and warfarin must be an **ACTIVE decision**

NSAIDs and Warafin Use

- Not anticoagulants; minimal platelet inhibition
- Effect on INR unpredictable (may ↑ it)
- Like all meds, there should be a good reason for the NSAID
- If starting <u>regular</u> NSAID use, check INR 4-5 days later (if using PRN, don't bother)
- If high-risk of GI bleeding → avoid or add PPI (age >60, previous PUD, GERD, steroids)

What to do if INR is not what was expected

If the INR value is not what you expected, ask the question,

“Why did this happen?”

INR Higher than Expected

- Miscommunication about dosing by the doctor or patient

  "Tell me what doses you've taken since the last INR"

- New medication – antibiotics, high dose acetaminophen, amiodarone, NSAIDs, statins, omeprazole, over-the counter drugs, herbals
- Substantial alcohol excess
- Inter-current illness
- Nutrition change – decrease vitamin K intake

INR Lower than Expected

- Compliance
- Compliance
- Compliance
- Miscommunication about dosing by the doctor or patient

  "Tell me what doses you've taken since the last INR"
- Nutrition change – increase vitamin K intake
- New medication – ginseng, green tea

Reducing Warafin-Related Bleeding in Practice

1. **Things you CANNOT change**
   - age
   - comorbid conditions
2. **Things you CAN influence**
   - careful management of hypertension
   - avoid combined ASA, other antiplatelets if possible
   - excellent patient education
   - obsessive supervision and tracking
   - appropriate management of elevated INR

Chapter Nine
Venous Disease Coalition

New Therapies for VTE

VTE Toolkit

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Iliofemoral DVT

- Iliofemoral DVT has more serious long-term consequences than infra-inguinal DVT
- After 5 years:
  - 95% develop chronic venous insufficiency
  - nearly ½ have venous claudication
  - 15% develop venous ulcers
  - substantially reduced Quality of Life

Iliofemoral DVT

Potential Benefits of Clot Removal:

- More rapid relief of obstruction
- Preservation of valve function
- Reduction in clot recurrence
- Reduction in post-thrombotic morbidity

Iliofemoral DVT

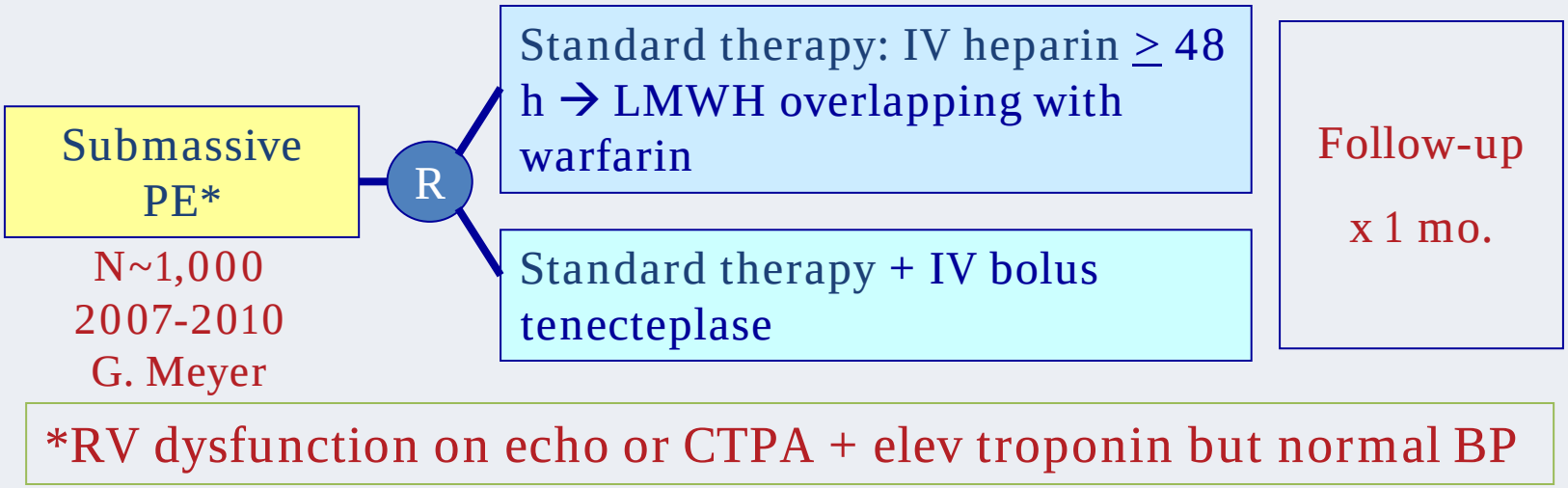
Catheter-Directed Thrombus Reduction:

- Successful thrombolysis →
  - more rapid return to function
  - reduced chronic post-thrombotic symptoms
  - improved quality of life
- Bleeding →
  - Major bleeding <5%
  - Intracranial bleeding <1%
- Clinical pulmonary embolism <1%

Catheter-Directed Thrombolysis in Acute DVT (ATTRACT)

Primary efficacy outcome: incidence of PTS at 24 mos (Villalta scale)
Secondary efficacy outcomes: severity of PTS; QOL (disease-specific and general); symptoms; valvular reflux & residual thrombus (at 1 year); cost-effectiveness; predictors of response
Safety outcomes: major bleeding, symptomatic PE, rec VTE, death

Thrombolysis in Acute PE (PEITHO)



*RV dysfunction on echo or CTPA + elev troponin but normal BP

Primary outcome: composite of all-cause mortality + hemodynamic collapse (CPR, sBP <90 ≥15 min) within 7 days

Secondary outcomes: death, hemodynamic collapse, recurrent symptomatic PE, stroke, major bleeding within 7days; death ≤30 days

Sponsors: Assistance Publique – Hopitaux de Paris, German Ministry of Education & Research, Boehringer-Ingelheim

Chapter Ten
Venous Disease Coalition

Hypercoagulability

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Thrombophilia = Hypercoagulability

- Factor V Leiden
- Prothrombin 20210A variant
- Antiphospholipid Ab syndrome
  - lupus anticoagulant
  - anticardiolipin antibody

- Deficiencies of:
  - Antithrombin
  - Protein C
  - Protein S
  - Heparin cofactor II
- ↑ Factor VIII, IX, XI, II

- Hyperhomocysteinemia
- Fibrinolytic dysfunction
- Myeloprolif. disorders:
  - PRV, ET
- Dysfibrinogenemia
- DIC

DIC = disseminated intravscular coagulation;
ET = essential thrombocytosis; PRV = polycythemia rubra vera

Which patients have an increased risk of having a hypercoagulable state?

- Unprovoked VTE at a **young age**
- **Recurrent**, unprovoked VTE events
- VTE with positive **family history**
- VTE at an **unusual site**

Which patients have an increased risk of having a hypercoagulable state?

- Unprovoked VTE at a **young age**
- **Recurrent**, unprovoked VTE events
- VTE with positive **family history**
- VTE at an **unusual site**

AND ALSO

- **Any unprovoked** VTE event
- VTE with **minor risk factor** such as BCP, HRT, pregnancy, travel, bedrest only
- Unexplained, recurrent **pregnancy losses**

General Indications for Hypercoagulability Testing

ONLY **if patient management will be affected** by the result:

	Management affected?
1. Duration of anticoagulation	(rarely)
2. Another medical intervention	
– pregnancy prophylaxis	(sometimes)
– BCP, HRT avoidance	(possibly)
3. Family counseling	(virtually never)

Principles of Hypercoagulability Testing

1. **Should only by <u>done by experts</u>**
   - both in hypercoagulability + in the provision of evidence-based patient counseling
2. **Only if <u>management is (should be) affected</u> by the result = rare**
3. **Almost never test <u>relatives</u>**
   - net harm generally greater than net benefit

Chapter Eleven
Venous Disease Coalition

Chronic Venous Insufficiency

VTE Toolkit

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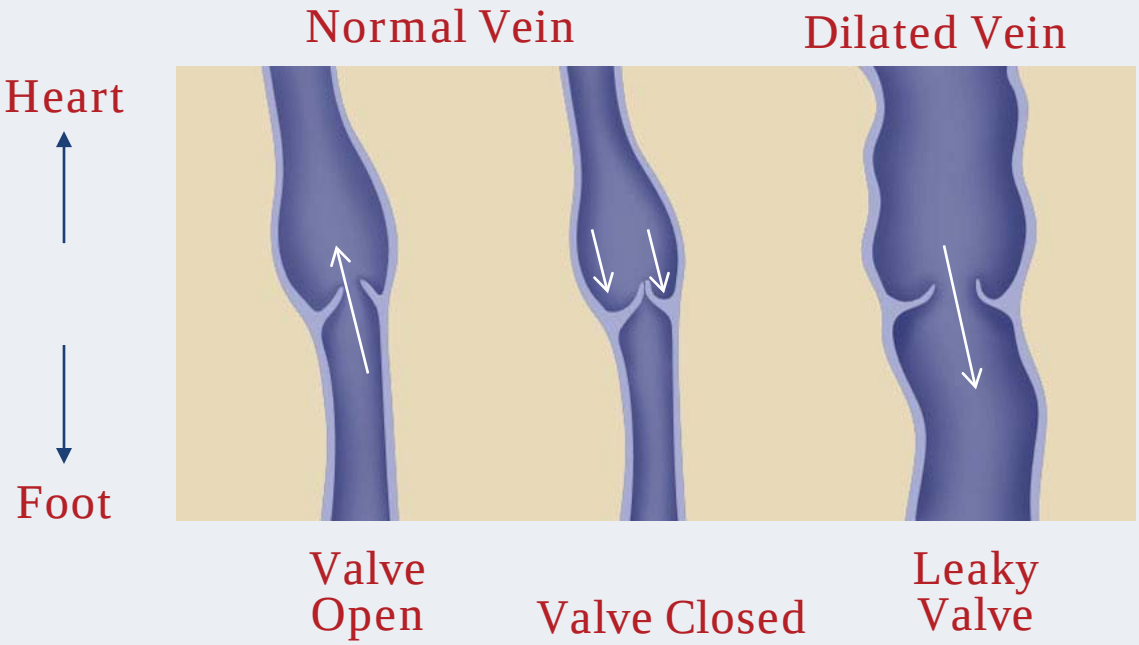
Post-Thrombotic Venous Reflux Disease

Seen in 20-50% of patients after DVT[1]



1. Deep vein valves become damaged by DVT resulting in venous valve failure
2. Reflux or backward flow in the deep veins occurs
3. Pooling of blood causes increased pressure in leg veins, edema, hyperpigmentation

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1. Antithrombotic and Thrombolytic Therapy 8th edition, ACCP Guidelines

Chronic Venous Disease

VTE Toolkit

VENOUS DISEASE COALITION
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Telangiectases
C_1

Varicose veins
C_2

Pigmentation
C_4

Active Ulceration
C_6

Bergan – NEJM 2006;355:488

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Post-Thrombotic Syndrome

- Prospective study of 355 patients with DVT
- All patients advised to wear 40 mmHg stockings

Years since DVT	Cumulative Incidence of PTS
1	17 %
2	23 %
5	28 %
8	29 %

↑ PTS - recurrent, ipsilateral DVT
NOT - extent of DVT

Prandoni - Ann Intern Med (1996)

Prevention and Management of Post-Thrombotic Syndrome

- Prevent recurrent DVT with anticoagulation
- Encourage the obsessive use of good quality compression stockings = ESSENTIAL
- Encourage regular exercise
- Encourage normal body weight
- Avoid local trauma to the legs
- Aggressive management of stasis dermatitis
- Urgent expert treatment of early ulcers

Chapter Twelve
Venous Disease Coalition

Prevention of VTE

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Symptomatic VTE after Surgery

- California Patient Discharge Database (N = 1,653,275)
- VTE during surgical admission or within 3 months
- Thromboprophylaxis data was not available

Benign disease	
Hip replacement	2.4%
Craniotomy	2.3%
Knee replacement	1.7%
Coronary bypass	1.1%
Colectomy	1.1%
Hysterectomy	0.3%
TUR prostate	0.3%
Lap. cholecystectomy	0.2%

Malignant disease	
Craniotomy	3.6%
Colectomy	1.7%
Pneumonectomy	1.6%
Rad. Prostatectomy	1.5%
Hysterectomy	1.2%
Mastectomy	0.4%

White - Thromb Haemost 2003;90:446

Postoperative VTE is Associated with Increased Mortality

- 118,258 surgical patients in 120 VA hospitals

VTE	30-day mortality	
No	4.4%	p<0.0001
Yes	16.9%	

- Symptomatic VTE is associated with significantly increased 30-day mortality

Gangireddy - J Vasc Surg 2007;45:335

VTE is a Common Complication After Surgery

(review of 7.5 million discharges from 994 US hospitals)

Postoperative DVT or PE:

- 2nd most common **medical complication** overall
- 2nd most common cause of **excess length of stay**
- 3rd most common cause of **excess mortality**
- 3rd most common cause of **excess charges**

Zhan - JAMA 2003;290:1868

Thromboprophylaxis Reduced Mortality after Hip Fracture 50 Years Ago!!

(randomized trial)

	Controls n=150		Phenindione* n=150
Symptomatic DVT	29 %	>>	3 %#
Symptomatic PE	5 %	>>	0
Total deaths	28 %	>>	17 %
Autopsy - DVT	83 %	>>	14 %
- major PE	41 %	>>	10 %

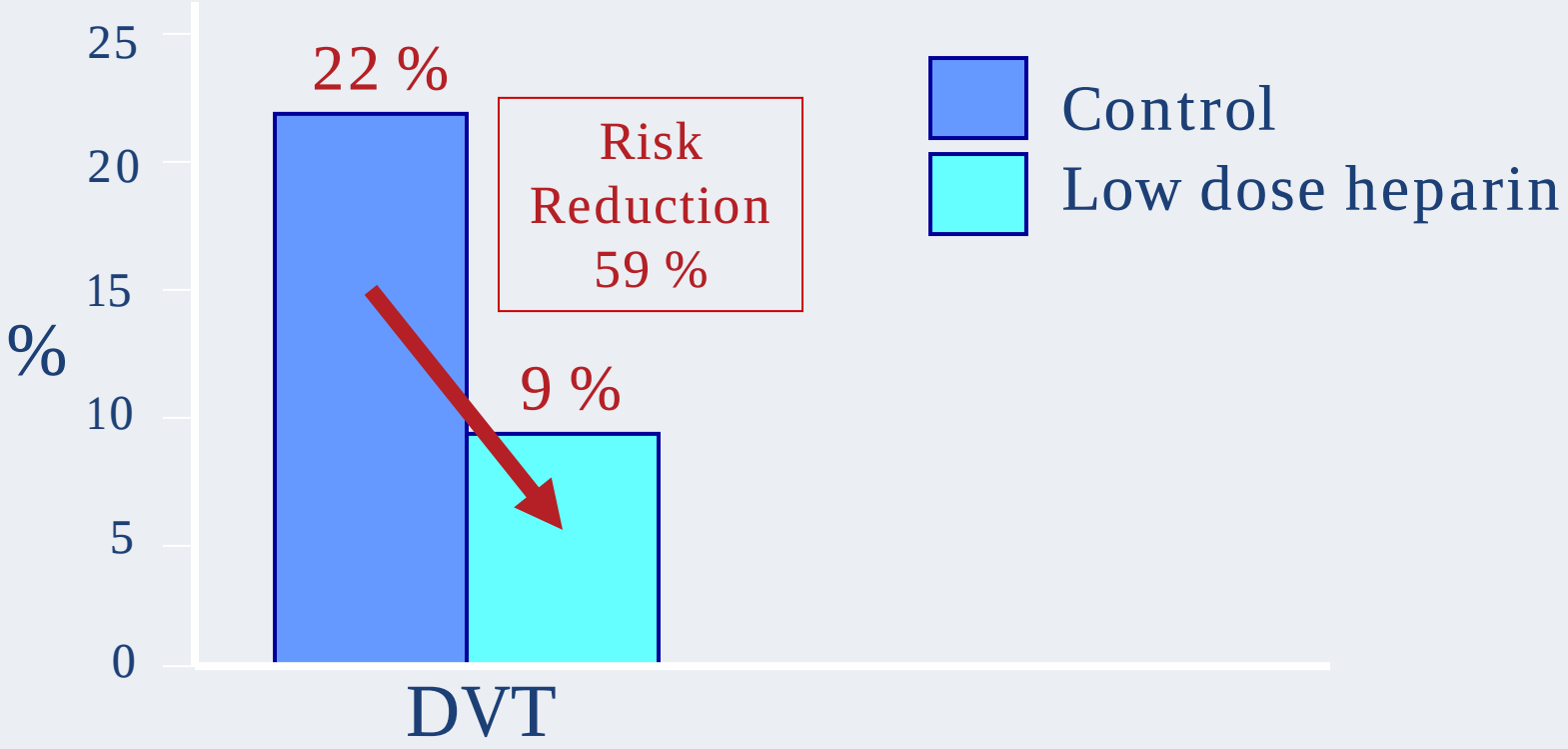
* from admission to ambulation (~5 weeks); PT 25-40 sec

all after phenindione stopped

Sevitt & Gallagher – Lancet 1959:2:981

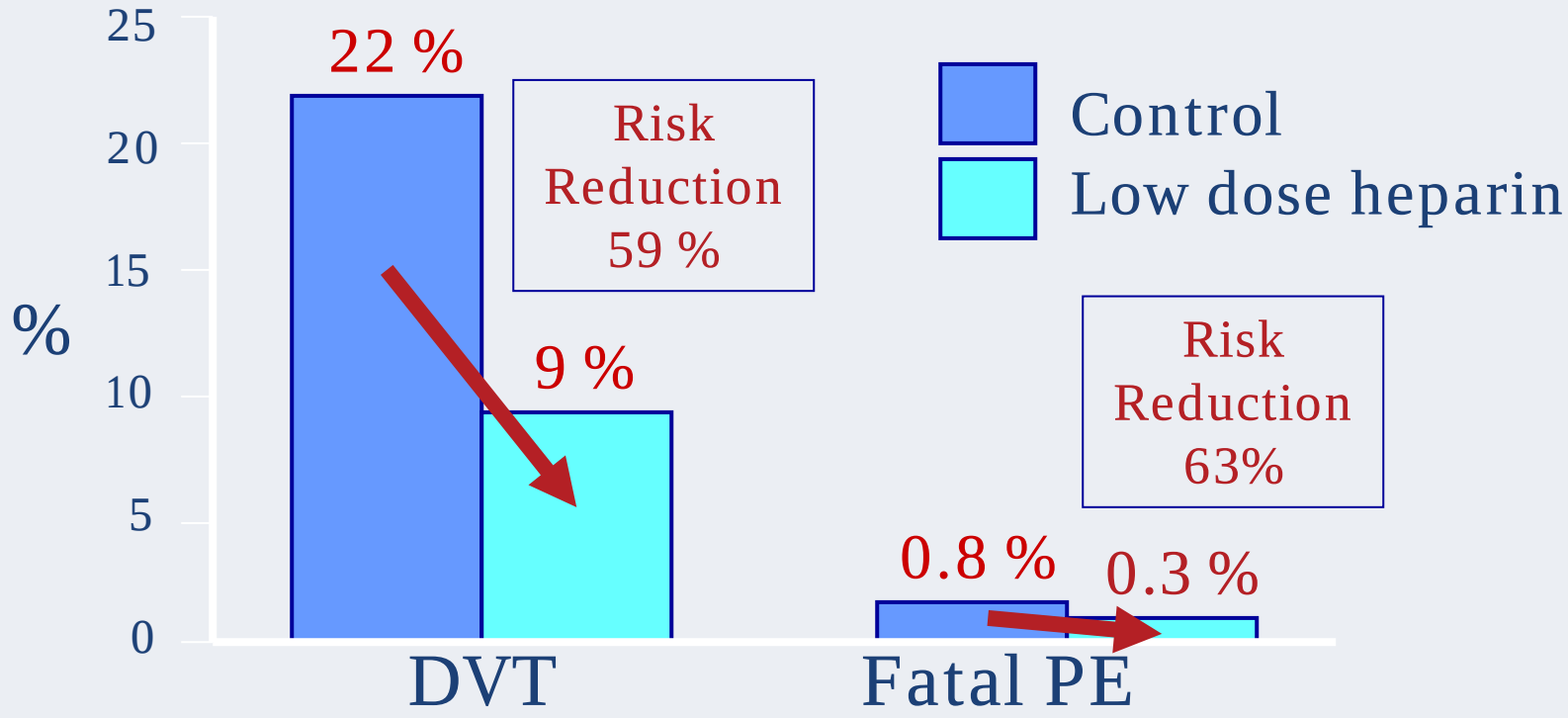
Low Dose Heparin Reduced DVT in 46 RCTs of Surgical Patients

(n=15,598)

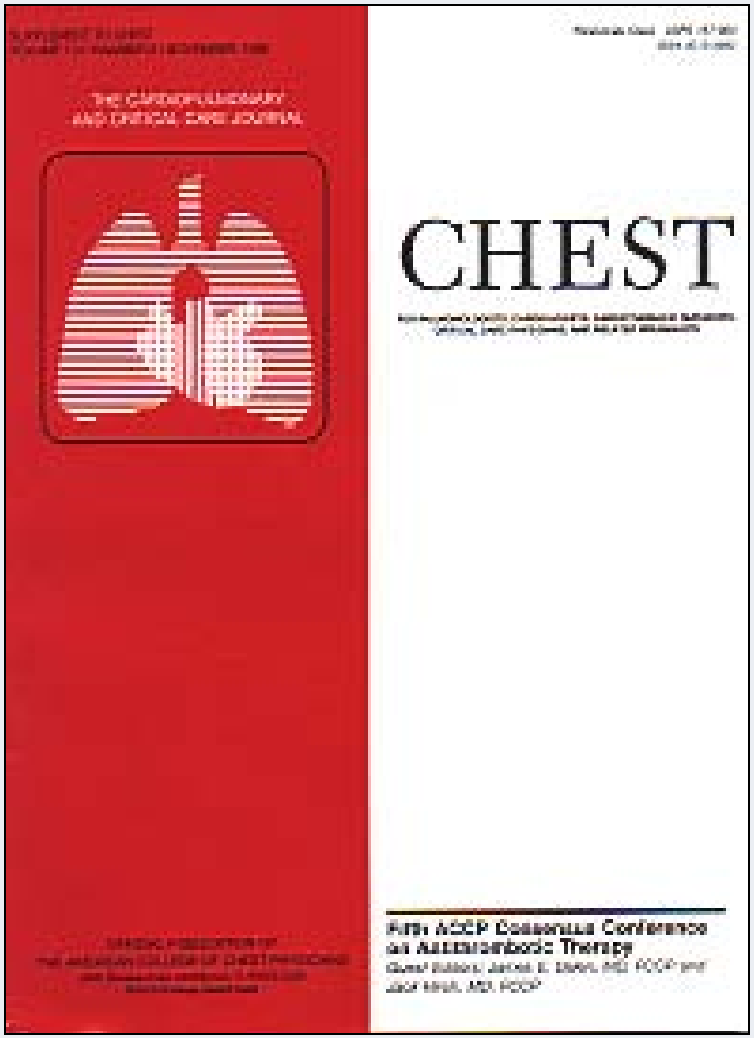


Collins – NEJM 1988;318:1162

Reduction in DVT Correlated with Reduction in Fatal PE in 46 RCTs of 16,000 Surgical Patients



Collins – NEJM 1988;318:1162



Prevention of Venous Thromboembolism

1986

1989

1992

1995

1998

2001

2004

Chest – June 2008

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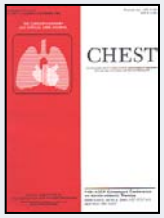
Thromboembolism Risk Groups

8th ACCP Guidelines on the Prevention of VTE

- General surgery
- Vascular surgery
- Gynecologic surgery
- Urologic surgery
- Thoracic surgery
- Bariatric surgery
- Laparoscopic surgery
- Coronary bypass surgery
- Hip arthroplasty
- Knee arthroplasty
- Knee arthroscopy
- Hip fracture surgery
- Spine surgery
- Lower extremity injuries
- Neurosurgery
- Major trauma
- Spinal cord injuries
- Burn patients
- Medical patients
- Cancer patients
- Central venous catheters
- Critical care patients
- Long distance travel

Geerts – Chest 2008;133:381S



8th ACCP Guidelines on Antithrombotic Therapy

1.2 VTE Prophylaxis Policy

1.2.1 We recommend that **every general hospital** develop a **formal, active strategy** that addresses the **prevention of VTE** [Grade 1A]

Geerts – Chest 2008;133:381S

How Can VTE be Prevented in Hospitals?

1. Getting patients up and walking as early as possible helps . . .

   but this is not enough

2. Giving patients low doses of an anticoagulant every day

The Myth of Mobility and DVT

- Immobility ALONE rarely results in DVT
- Immobility does increase the risk of symptomatic VTE after another risk factor (surgery, trauma, acute medical illness, cancer, etc.)
- After another thrombosis insult, mobilization does NOT eliminate or substantially reduce the VTE risk for some time

∴ The duration of prophylaxis should not be determined by mobility status alone

Mechanical Methods of Prophylaxis

- ✓ Graduated compression stockings (medical grade stockings, ?TEDS™
- ✓ Intermittent pneumatic compression devices (SCDs™, leg squeezers)
- ✓ Foot pumps

If used properly, **these methods work in <u>some</u> patient groups**,
<u>but</u>
They generally **don't work as well as anticoagulants,**
<u>and</u>
They require a **big effort to work** at all

Mechanical Methods of Prophylaxis

Who should receive mechanical prophylaxis?

1. Patients at high risk for bleeding

2. ? Along with an anticoagulant method to try to improve protection

Mechanical Methods of Prophylaxis

1. Ensure they fit properly
2. Start ASAP
3. Have on ~24 hours/day – only remove for leg washing and when patient is actually walking
4. Ensure optimal compliance
5. Only stop at discharge

Pharmacologic (anticoagulant) Methods of Prophylaxis

1. Low dose heparin / minidose heparin
   - heparin 5,000 U SC Q12H or Q8H
2. Low molecular weight heparin
   - enoxaparin (Lovenox) 40 mg SC QD or 30 mg SC Q12H
   - dalteparin (Fragmin) 5,000 U SC QD
   - tinzaparin (Innohep) 3,500 or 4,500 U SC QD
3. Fondaparinux (Arixtra) 2.5 mg SC QD
4. Warfarin (Coumadin)
5. Oral Factor Xa inhibitors, IIa inhibitors
   - rivaroxaban (Xarelto), dabigatran (Pradax)*

*not approved in USA

Pharmacologic (anticoagulant) Methods of Prophylaxis

Using Anticoagulant Prophylaxis:

1. **Start as soon as safe - once bleeding stopped**
   - usually day after admission or surgery
2. **Try to avoid missing any doses**
   - don't hold for most procedures
   - consider routine qhs dosing
3. **Continue at least until discharge**

DVT Prophylaxis: 3 Patient Groups

Low risk

Moderate risk

High risk

NO prophylaxis

ROUTINE prophylaxis

8th ACCP Conference on Antithrombotic Therapy - Chest 2008

Thromboprophylaxis in Moderate Risk Medical or Surgical Patients

Patients	Medical: bedrest, sick Surgical: general, gynecologic, urologic, thoracic, bariatric, neurosurgery
Options	- Low molecular weight heparin - Low dose heparin - Fondaparinux - Mechanical if high bleeding risk
Duration	Until discharge

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Thromboprophylaxis in High Risk Patients

Patients	Major orthopedic: (hip and knee arthroplastyhip fracture repair) Major trauma
Options	- Low molecular weight heparin - Fondaparinux - Warfarin (INR 2-3) - Mechanical if high bleeding risk
Duration	At least 10 days (2-5 weeks)

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LDH vs LMWH

Factor	LDH	LMWH
Efficacy	++ to +++	+++
Safety	+++	+++
Dosing	2-3 x/day	once daily
Accum. in renal insuff.	No	? - no
HIT potential	low	very low
dost	+	+ to ++
Indicated for all pts	no	yes

Thromboprophylaxis in Major Orthopaedic Surgery

	THR	TKR	HFS
Routine Prophylaxis	**yes**	**yes**	**yes**
Recommended	**LMWH** [1A] **fonda** [1A] **warfarin** [1A]	**LMWH** [1A] **fonda** [1A] **warfarin** [1A] **?IPC** [1B]	**fonda** [1A] **LMWH** [1B] **warfarin** [1B] **LDUH** [1B]
Not Recommended	**ASA** [1A] **LDUH** [1A] **GCS** [1A] **VFP** [1A]	**ASA** [1A] **LDUH** [1A] **VFP** [1B]	**ASA** [1A]

Geerts – Chest 2008;133:381S

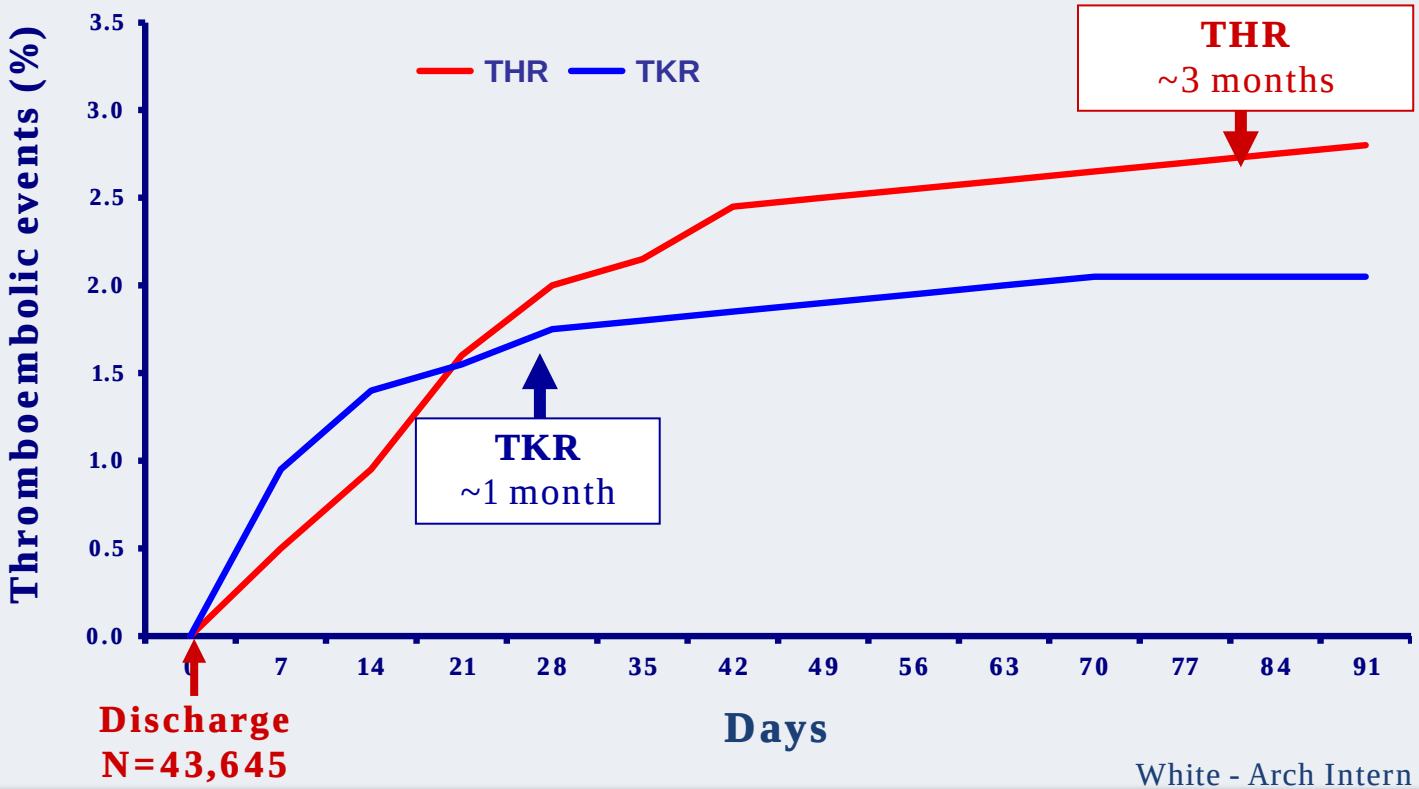
LMWH vs Warfarin in Arthroplasty

	Warfarin	LMWH
Onset of action	delayed 3-5 days	rapid 1-3 hours
Anticoag. effect	unpredictable	predictable
Lab monitoring	yes	no
Efficacy	++	+++
Effectiveness	+++*	+++
Early bleeding	+/-	+/-
Late bleeding	+	+/-
Drug cost	+/-	++
Total cost	++	++
Complexity	yes	no

*assumes optimal use

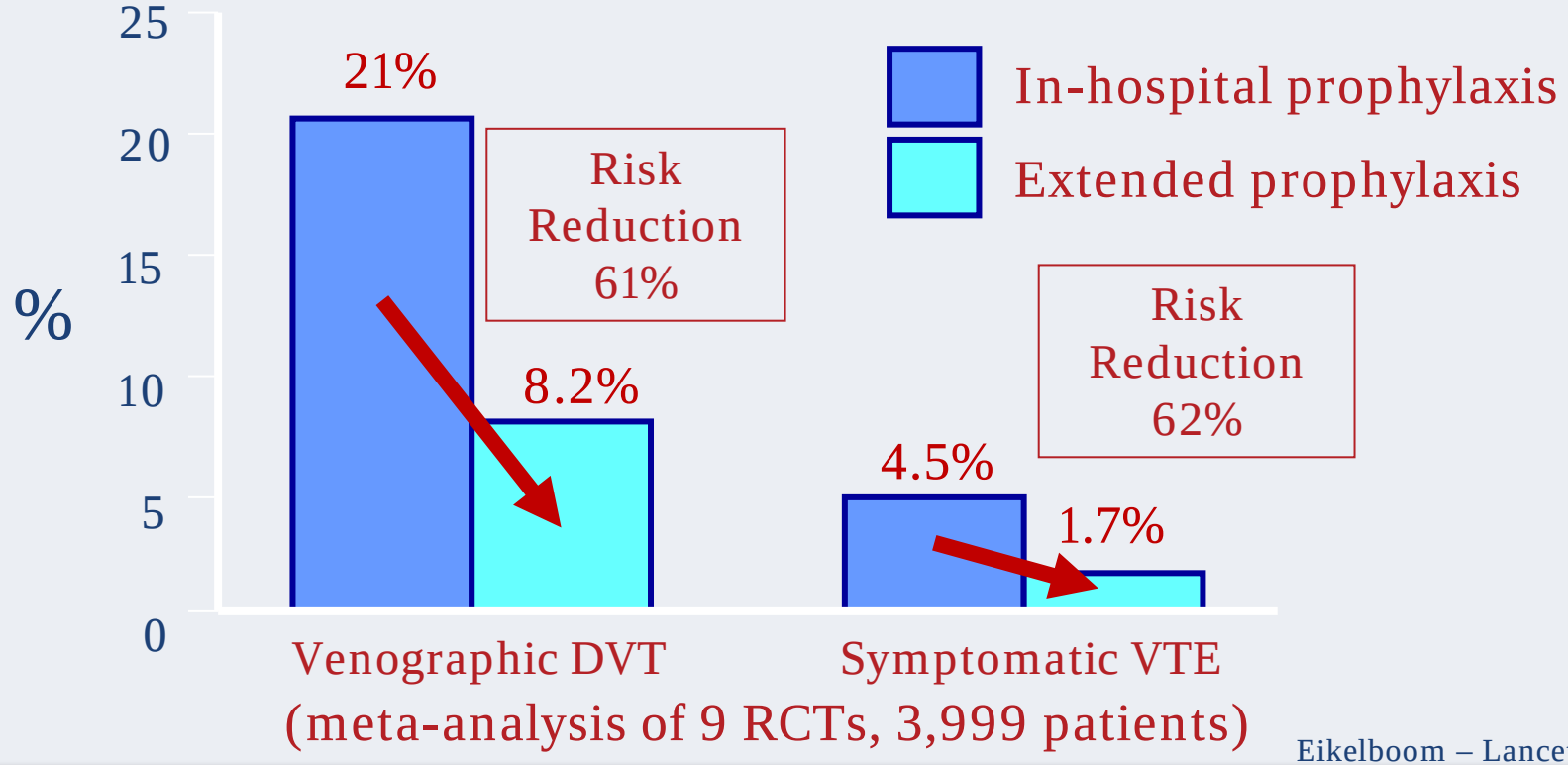
Some Patients Need Post-Discharge Thromboprophylaxis

(Readmissions to Hospital for VTE)



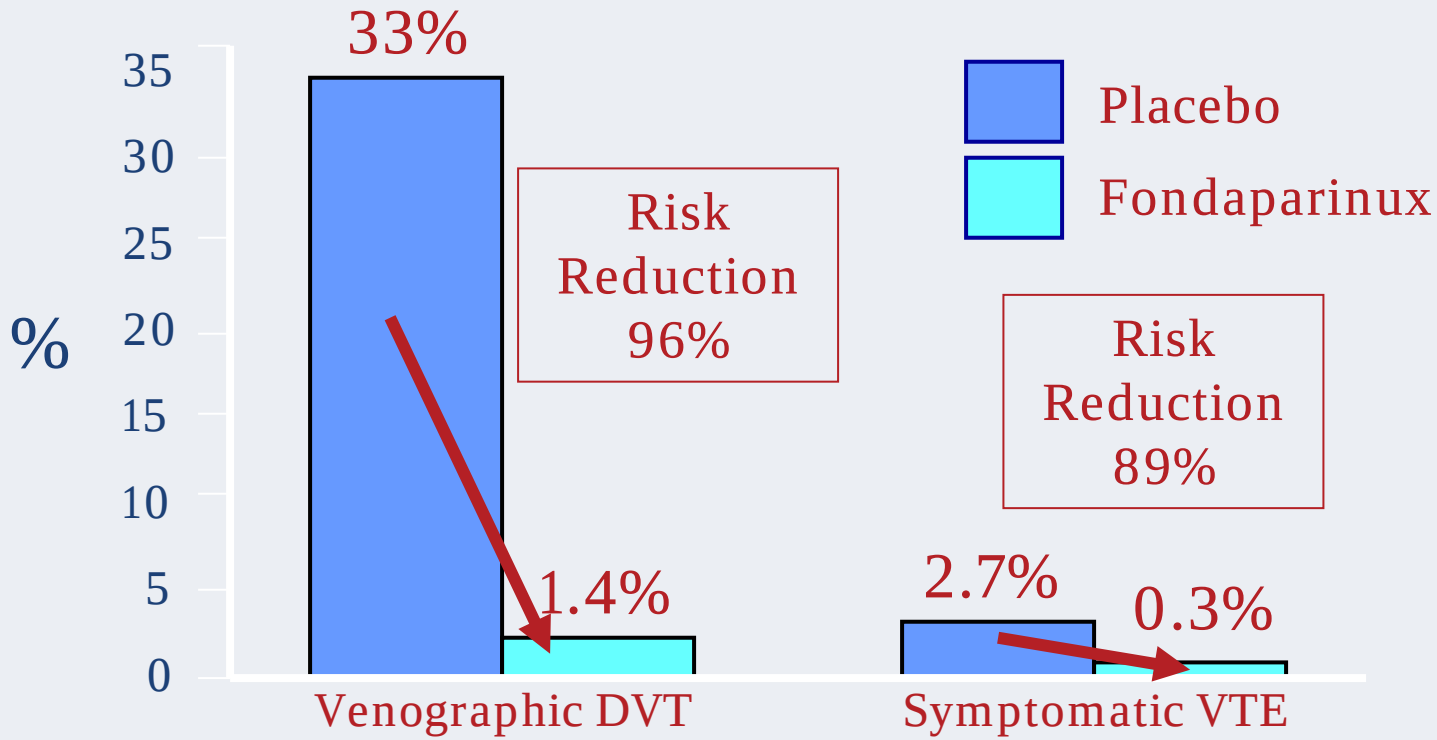
White - Arch Intern Med (1998)

Extended Prophylaxis Reduces Both Asymptomatic DVT and Symptomatic VTE after Arthroplasty



Eikelboom – Lancet 2001;358:9

Extended Prophylaxis Reduces Both Asymptomatic DVT and Symptomatic VTE in Hip Surgery



Eriksson – Arch Intern Med 2003;163:1337

Duration of Thromboprophylaxis in Major Orthopaedic Surgery

	THR	TKR	HFS
At least 20 days	**yes** [1A]	**yes** [1A]	**yes** [1A]
Beyond 10 days - up to 35 days	**yes** [1A]	**yes** [1A]	**yes** [1A]
Options	**LMWH** [1A] **OVKA** [1A] **fonda** [1C]	**LMWH** [1C] **OVKA** [1C] **fonda** [1C]	**fonda** [1A] **LMWH** [1C] **OVKA** [1C]

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Which Hospital Patients Should Receive Thromboprophylaxis?

- Sick medical patients
- General surgical
- Major gynecologic
- Major urology
- Neurosurgery
- Orthopedics
- Trauma
- ICU

i.e. most patients in hospital

Simplifying DVT Prophylaxis: 2 Patient Groups

Low risk
= no prophylaxis

At risk
= routine evidence-based prophylaxis

Which Thromboprophylaxis Options Do We Have to Choose From?

Anticoagulant Options:

- LDH – BID or TID
- LMWH – dalteparin, enoxaparin, tinzaparin
- Fondaparinux
- Rivaroxaban

Choose 1 (or possibly 2):

☐ _____

☐ _____

Mechanical Options:

- GC stockings
- Seq compr. devices

Choose 1:

☐ _____

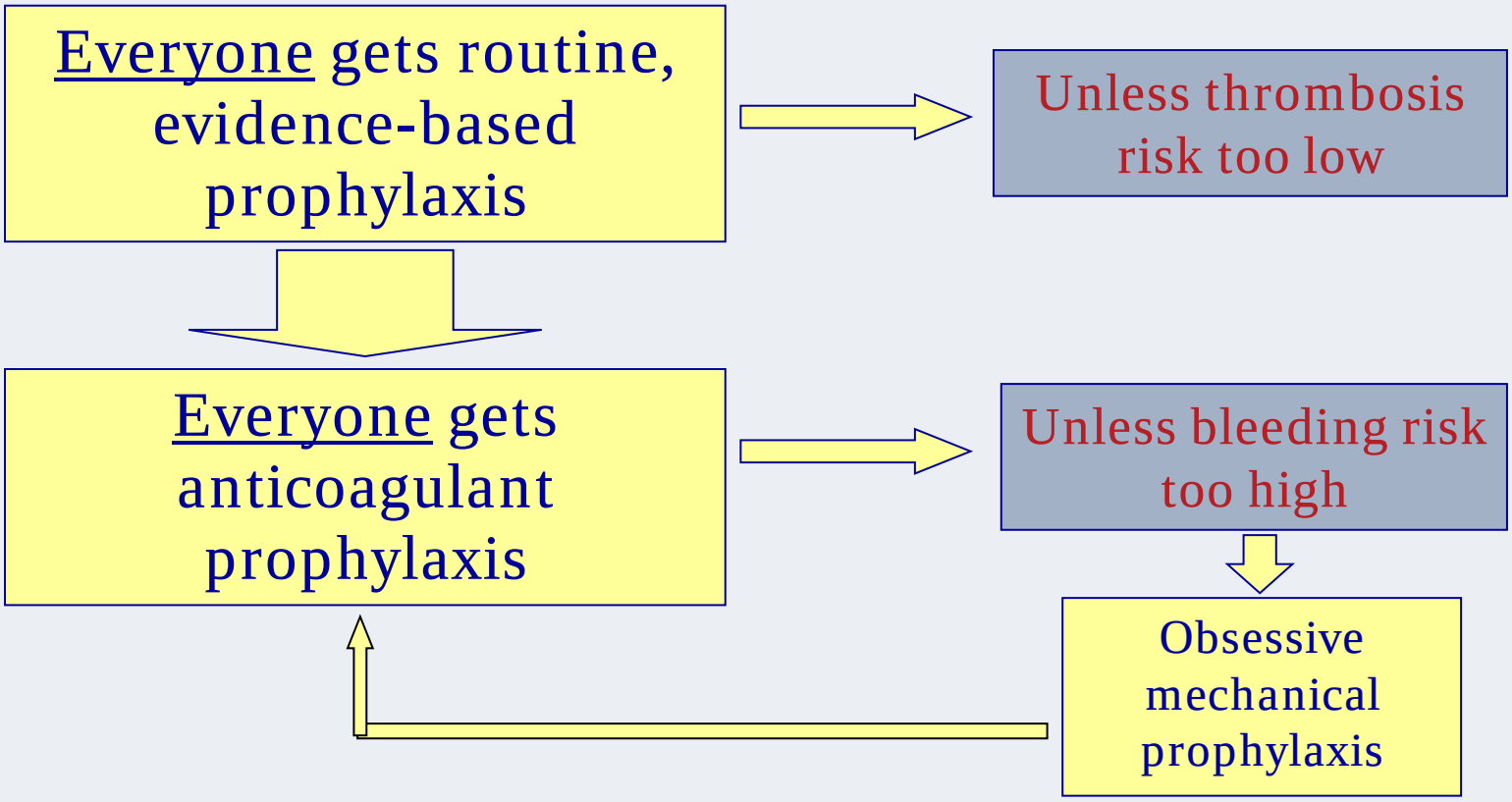
i.e. only 2 or 3 options

ACCP Thromboprophylaxis Recommendations

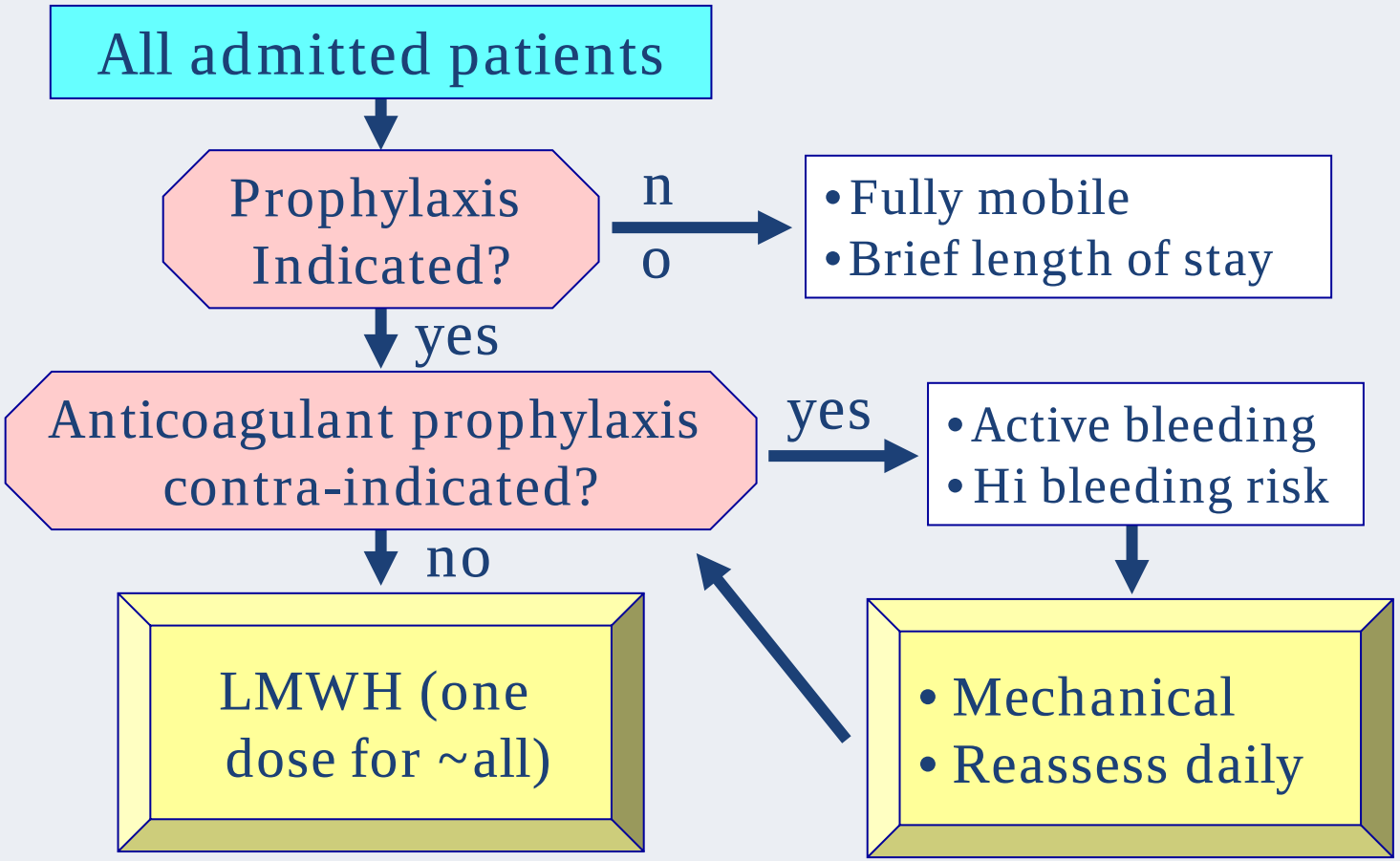
	LDH	LMWH	Fonda	Warfarin
General surgery	1A	1A	1A	no
Gynecologic surgery	1A	1A	1C	no
Urologic surgery	1B	1C	1C	no
Coronary art bypass surgery	1C	1C	no	no
Hip replacement	no	1A	1A	1A
Knee replacement	no	1A	1A	1A
Hip fracture surgery	1B	1B	1A	1B
Neurosurgery	2B	2A	no	no
Major trauma	no	1A	no	no
Medical patients	1A	1A	1A	no
Critical care patients	1A	1A	no	no

Geerts – Chest 2008;133:381S

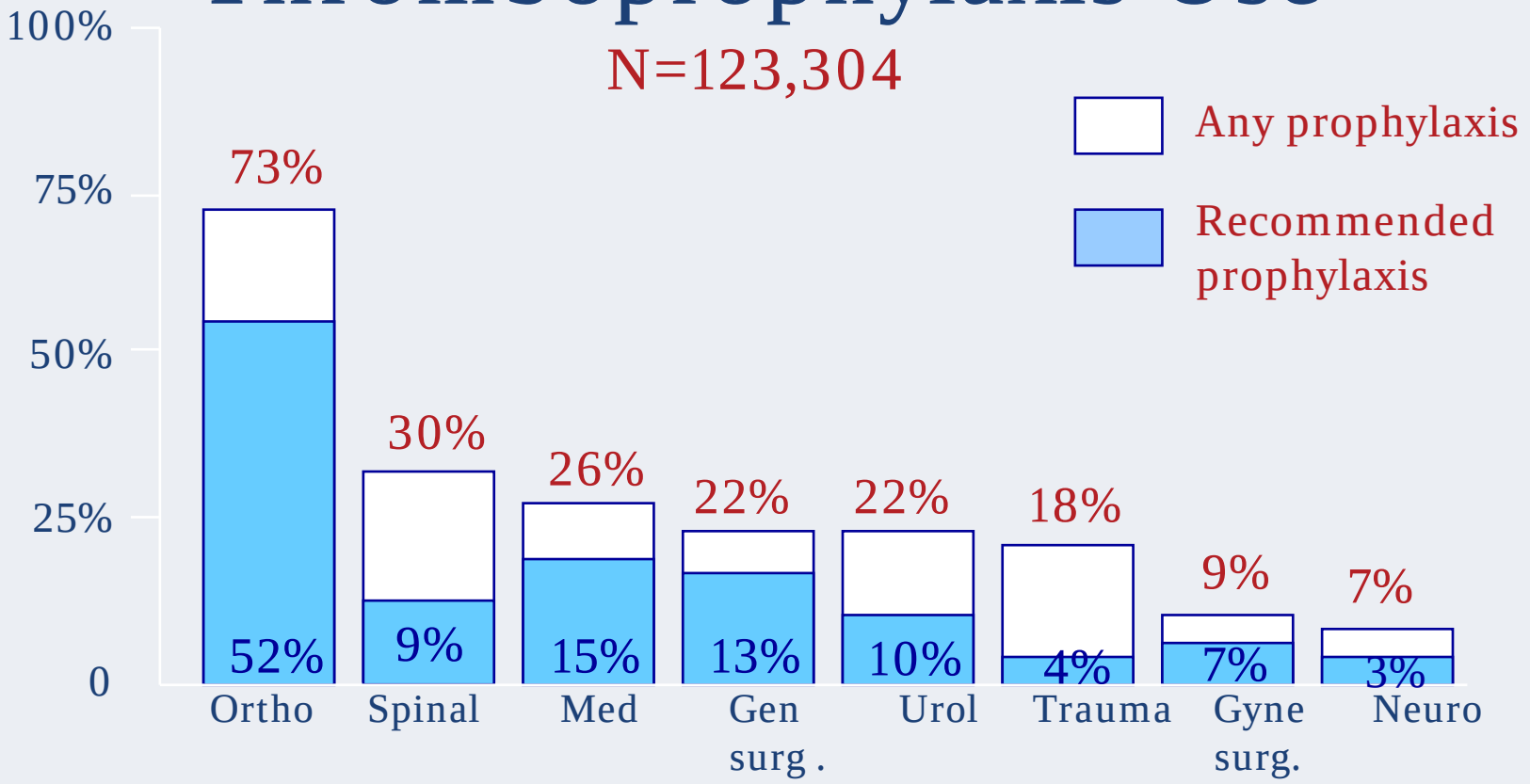
Default ("opt-out") Prophylaxis



Thromboprophylaxis Approach



ANY and RECOMMENDED Thromboprophylaxis Use



Yu – Am J Health-Syst Pharm 2007;64:69

International Thromboprophylaxis Use

- Surgical and medical patients admitted to 358 randomly selected, acute care hospitals in 32 countries on 6 continents
- Cross-sectional chart audit on one particular day

	Surgical (N=30,827)	Medical (N=37,356)
At risk for VTE*	64%	42%
Any prophylaxis given	64%	48%
Recommended Prophylaxis*given	59%	40%

*using 2004 ACCP recommendations (type of prophylaxis only)

Cohen – Lancet 2008:371:387

Thromboprophylaxis Used After THR/TKR: Geographic Variation

100 hospitals in 13 countries

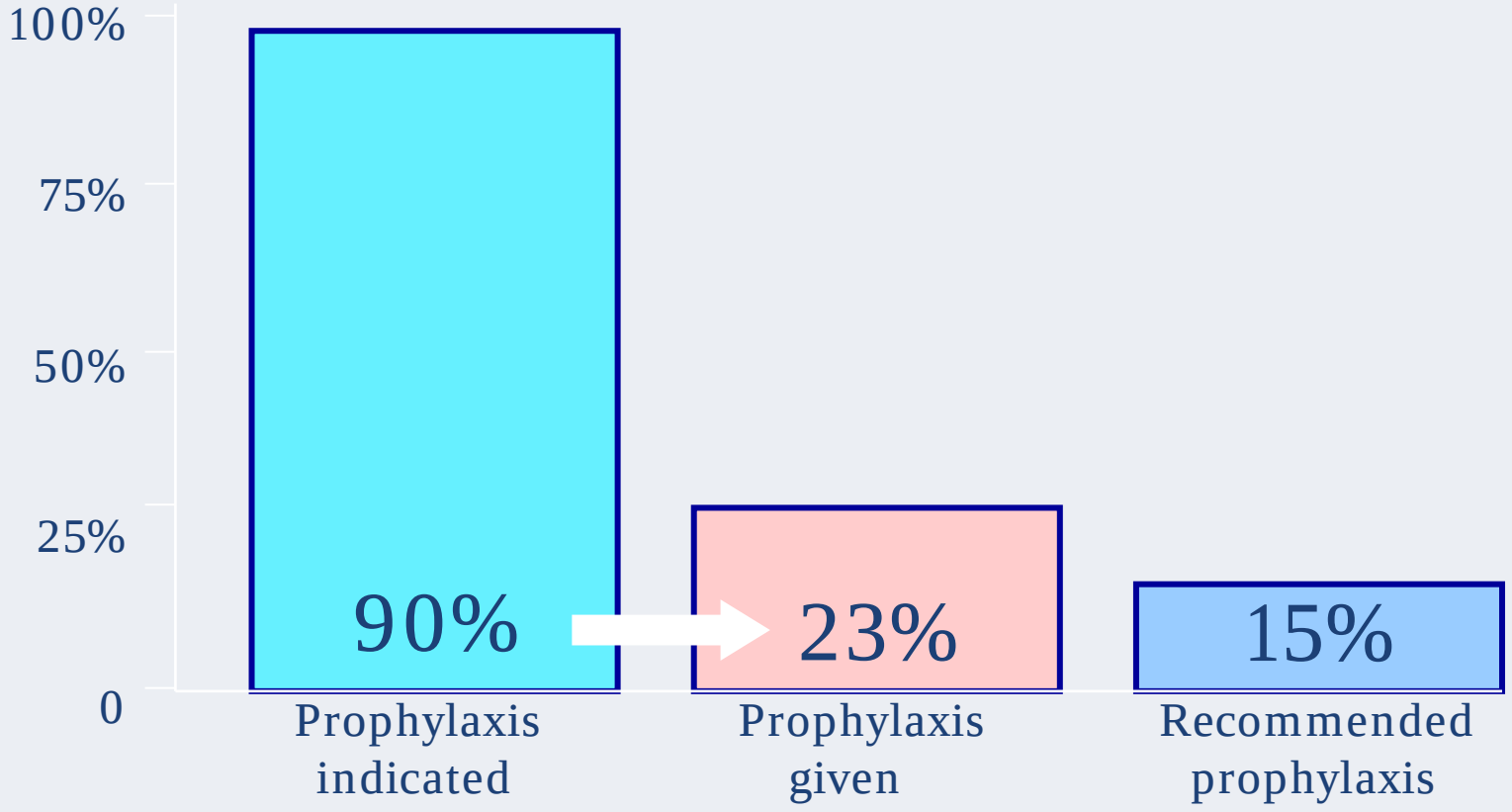
Prophylaxis on Day 1	USA (n=7,008)	Others (n=6,007)
LMWH	42%	100%
Warfarin	58%	<<1%

Australia
Brazil
Bulgaria
Canada
Columbia
Germany
Italy
Japan
Poland
Spain
Turkey
UK

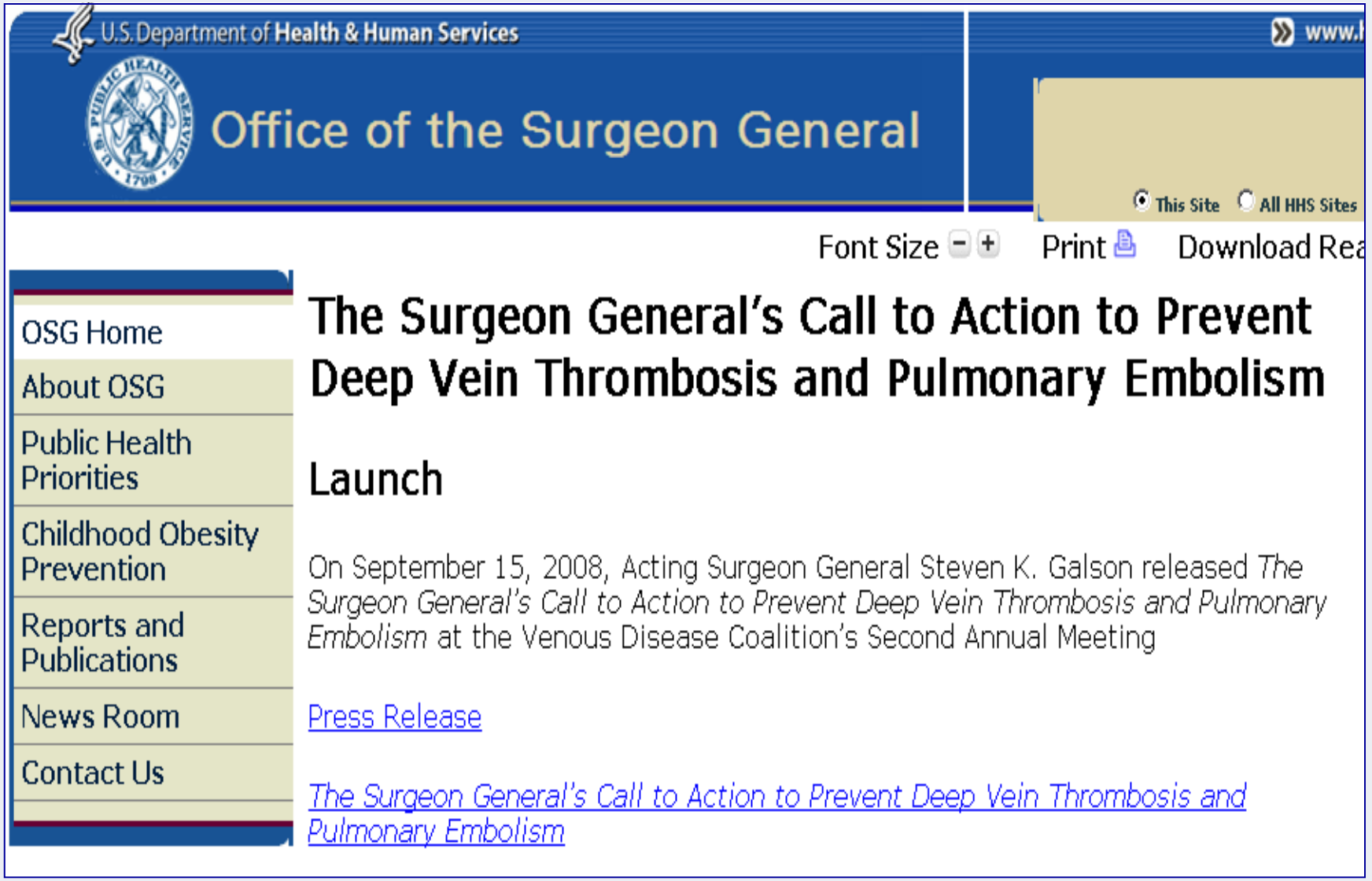
Warwick - JBJS 2007;89-B:799

Prophylaxis Use in Medical Patients

1,894 medical patients in 29 hospitals in Canada



Khan – Thromb Res 2007;119:145



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Surgeon General's Call to Action

Venous Thromboembolism (VTE)

- Estimated that 350,000 to 600,000 Americans are afflicted by VTE each year
- Also, estimated that **at least** 100,000 deaths each year are related to VTE

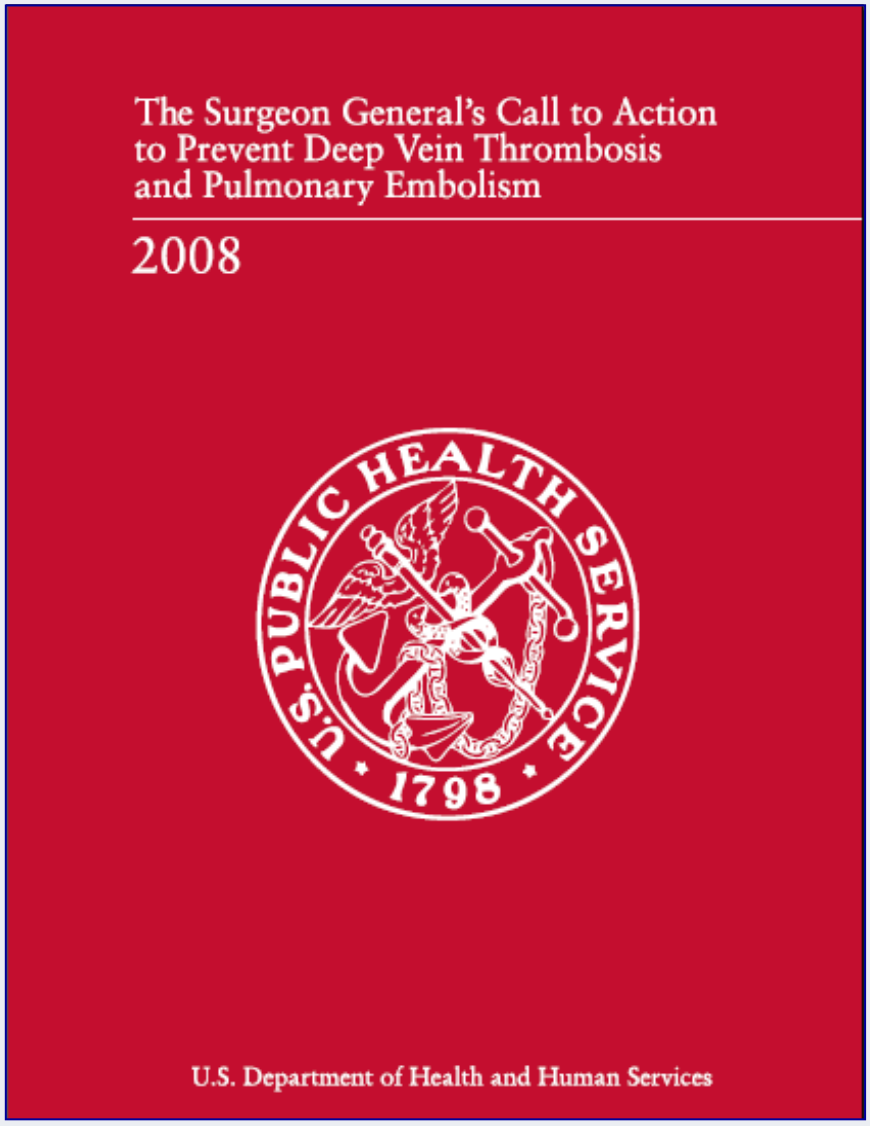
The Surgeon General's Call to Action To Prevent DVT/PE 2008

Surgeon General's Call to Action

Dr. Galson laid out recommendations for the prevention of two common, yet deadly major public health threats: DVT and PE

The plan emphasized the need for:

- Increased awareness about DVT/PE
- Evidence-based practices for DVT
- More research on the causes, prevention and treatment of DVT



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Improving Thromboprophylaxis

What does NOT work?

- Education
- Grand rounds
- Reminders
- Hospital policy
- Local champion
- Producing order sets

Improving Thromboprophylaxis

What DOES work?

- ✓ Having a hospital *thromboprophylaxis policy*
- ✓ PLUS *KEEP IT SIMPLE*
- ✓ PLUS local *champion/leader*
- ✓ PLUS *education* of docs, pharmacists, nurses
- ✓ PLUS *mandatory use of order sets*
- ✓ PLUS empower *everyone to be involved* – nursing, pharmacist ("It's what we do here")
- ✓ PLUS *audit and feedback*

Thromboemolism in Hospitals

1. We know **who's at risk** for VTE

2. We know the **consequences** of unprevented VTE

3. We know **how to prevent** VTE with effective, safe, simple, and inexpensive interventions, **So . . .**

Just do it!

Venous Disease Coalition

www.vasculardisease.org/venousdiseasecoalition/

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