Venous Thromboembolism in Patients with Cancer: Assessment of Risk and Safe Prophylaxis

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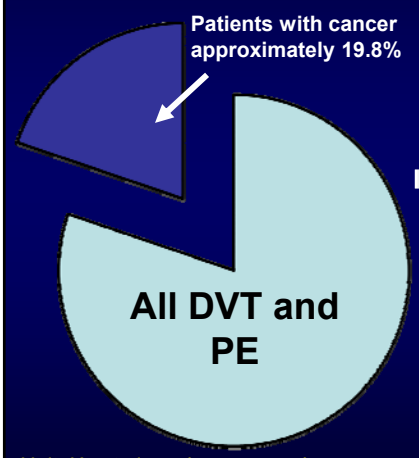
Learning Objectives

- Discuss the link between cancer and thrombosis.
- Define the cancer treatment settings in which VTE risk should be assessed and VTE prophylaxis considered.
- Describe how to risk stratify patients undergoing cancer surgery, and implement NCCN recommendations for prevention of venous thromboembolism (VTE).
- Develop strategies for risk-directed prophylaxis against VTE in patients with cancer.
- Review results of landmark clinical trials focusing on novel VTE treatments in patients with cancer.

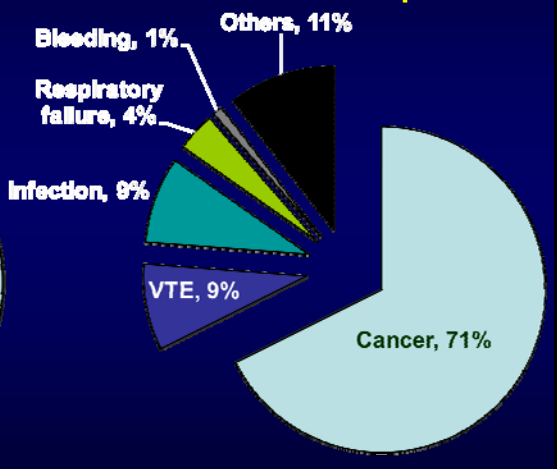
Cancer, VTE, and Mortality

Cancer accounts for 1/5 of all VTE cases



Heit JA, et al. *Arch Intern Med*. 2002;162:1245-8.

VTE is the 2nd leading cause of death in cancer patients



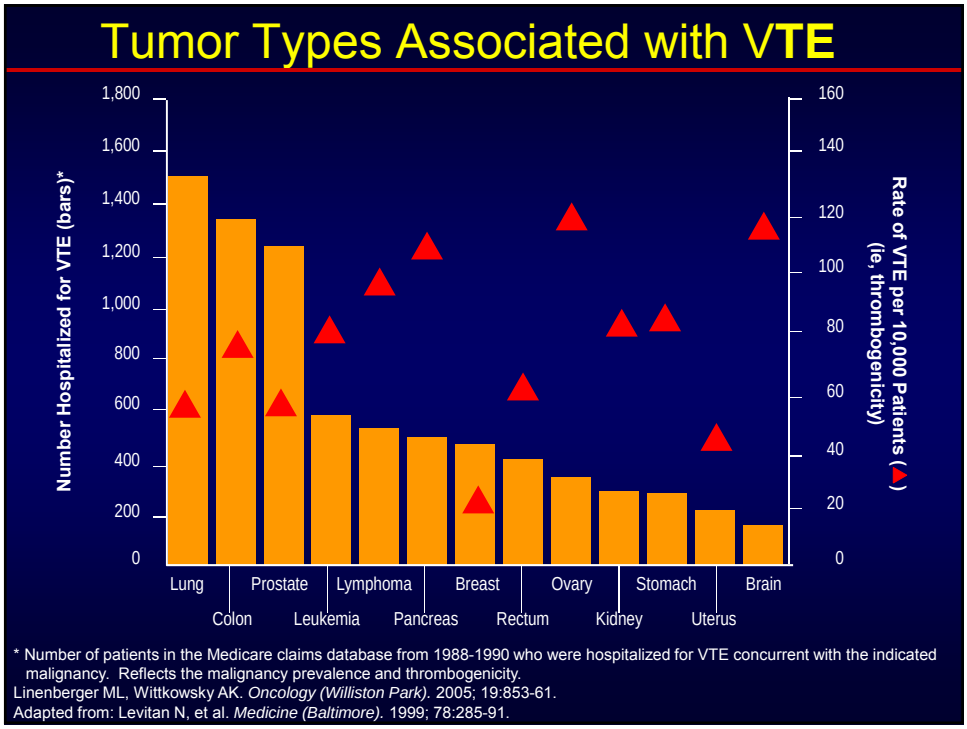
Khorana AA, et al. *J Throm Haemost*. 2007;5:632-4.

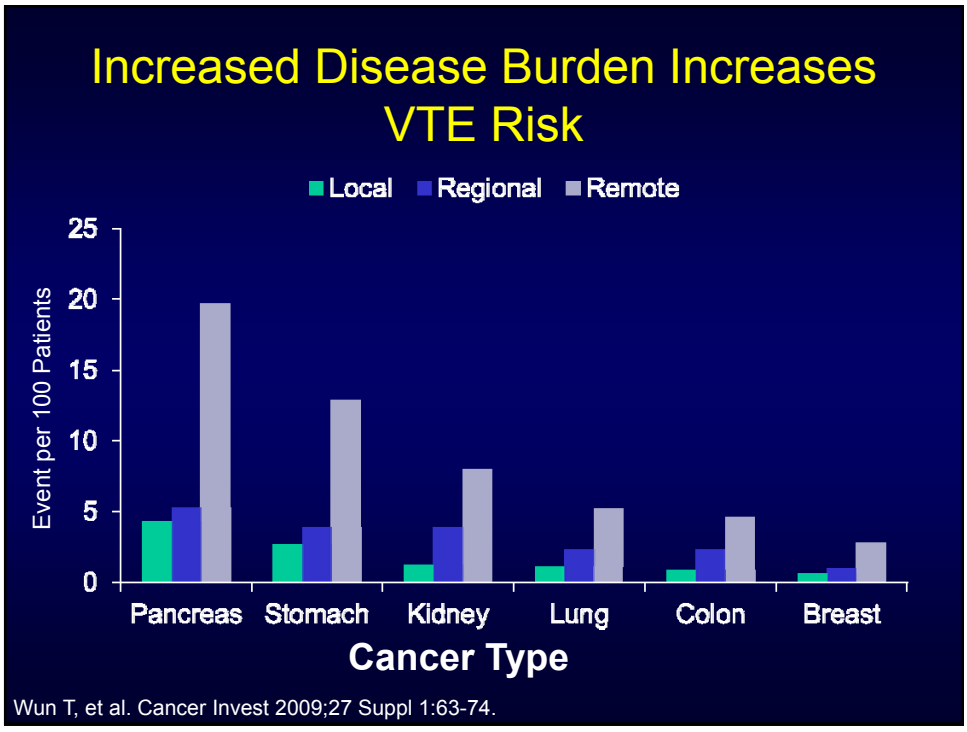
DVT, deep vein thrombosis; PE, pulmonary embolism.

Cancer, VTE, and Mortality

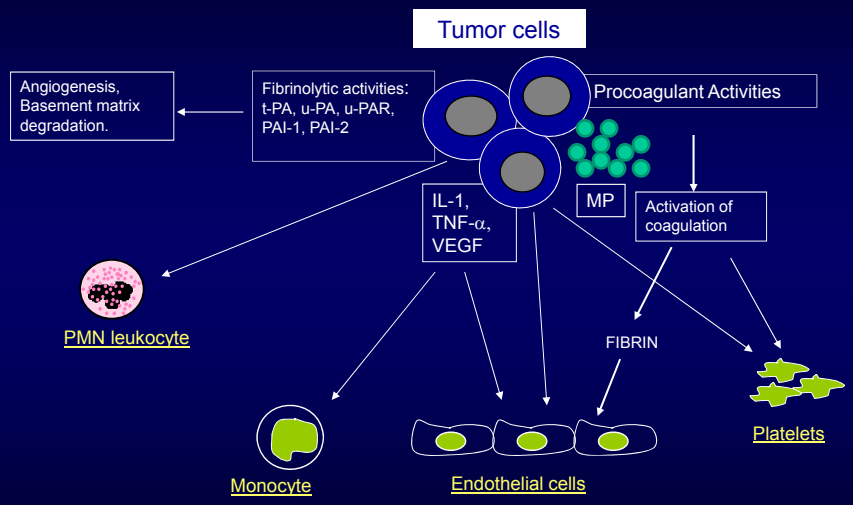
- Annual incidence of VTE in US population: 117 in 100,000
- Cancer increases risk of thrombosis 4.1-fold
- Recurrence of VTE 3-fold higher in patients with cancer
- Chemotherapy increases risk of thrombosis 6.5-fold
- Death rate from cancer 4-fold higher if concurrent VTE
- Additive risk factors: surgery, radiation therapy, central venous catheters, other antitumor and supportive therapies

Silverstein MD, et al. *Arch Intern Med.* 1998;158:585-93.
Heit JA, et al. *Arch Intern Med.* 2000;160:809-15.
Prandoni, et al. *Blood.* 2002;100:3484-8.
White R, et al. *Thromb Haemost.* 2003;90:445-55.
Sorensen HT, et al.*N Engl J Med.* 2000;343:1846-50.
Levitan N, et al. *Medicine.* 1999;78:284-91.
Khorana A, et al. *J Thromb Haemost* .2007;5:632-4.



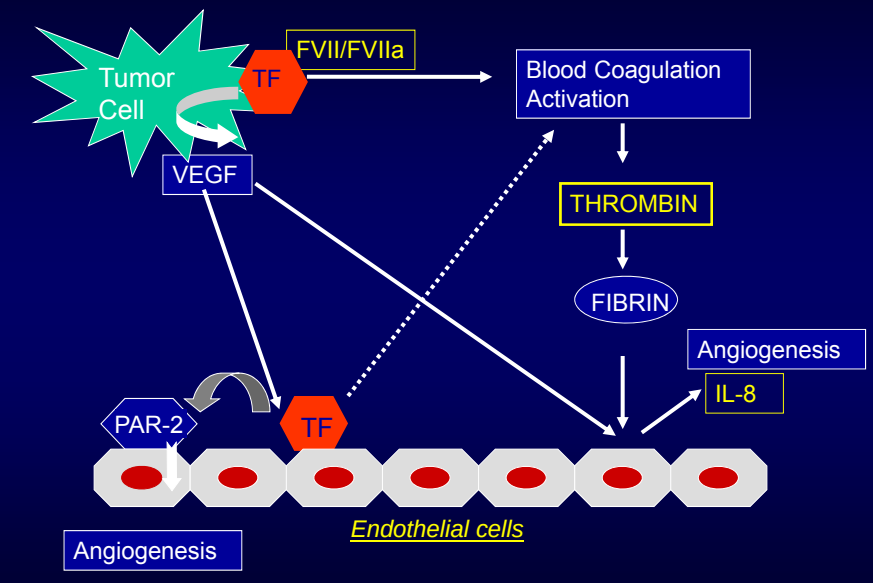


Interface of Hematology and Cancer



IL, interleukin; MP, tumor microparticles; PMN, polymorphonuclear; TNF, tumor necrosis factor; VEGF, vascular endothelial growth factor.
Falanga, A. Thrombosis Research 2013;131:Suppl 1, S59-S62.

Interface of Clotting Activation and Tumor Biology



IL, interleukin; TF, tissue factor; PAR-2, protease-activated receptor 2; VEGF, vascular endothelial growth factor.
Falanga, A. Thrombosis Research 2013;131:Suppl 1, S59-S62.

Cytotoxic Chemotherapy and VTE

- Cisplatin: meta-analysis of 8216 patients, 38 randomized controlled trials
  - Increases VTE risk (1.92% vs. 0.79%; RR 1.67, 95% CI 1.25-2.23)
  - Increased with cisplatin dose >30 mg/m^2 (RR 2.71)
- L-asparaginase: 238 adult ALL patients
  - 4.2% developed VTE
  - Median 11 days after start of treatment

ALL, acute lymphoblastic leukemia.
Seng S, et al. J Clin Oncol 2012;30:4416-4426; Gugliotta L, et al. Eur J Haematol 1992;49:63-66.

Hormonal Therapy and VTE

- Tamoxifen
  - Increases risk 2-3 fold vs. control
  - Increases risk 3-5 fold when added to chemo over chemo alone and 20-fold over no treatment
  - Risk 3-fold higher in post-menopausal women
  - Thrombosis risk clustered at initiation of therapy
- Aromatase inhibitors (AI)
  - AI associated with lower risk of thrombosis vs. tamoxifen: 1.6% versus 2.8% (OR = 0.55, 95% CI = 0.46 to 0.64)

Haddad TC, et al. Thromb Res 2006;118:555-568; Onitilo AA, et al. Thromb Res 2012;130:27-31; Amir E, et al. J Natl Cancer Inst 2011;103:1299-1309.

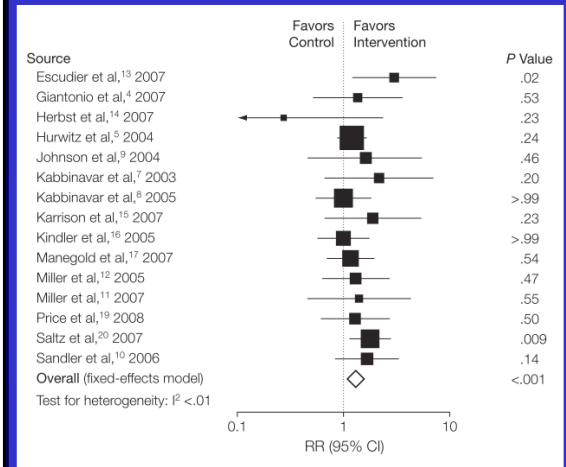
Immunomodulators and VTE

- Thalidomide: 11 RCT, 50 cohort studies
  - Thalidomide alone: 1.3 VTE per 100 patient cycles
  - Thalidomide + dexamethasone: 4.1 VTE per 100 patient cycles
- Lenalidomide + dexamethasone: 2 RCT, 3 cohort studies
  - Lenalidomide + dexamethasone: 0.8 VTE per 100 patient cycles
- Pomalidomide
  - Pomalidomide alone: 2% DVT
  - Pomalidomide + dexamethasone: 3% DVT

DVT, deep venous thrombosis; RCT, randomized controlled trials

Carrier M, et al. J Thromb Haemost 2011;9:653-663; Richardson PG, et al. Blood 2014;123:1826-1832.

Bevacizumab and Thromboembolism



Adapted from: Nalluri SR, et al. JAMA 2008;300:2277-2285.

Bevacizumab:

- 2-fold increased risk of arterial events.
- Increased risk of VTE: RR 1.33 (95% CI, 1.13-1.56; P<.001).
- Not significant if adjusted for exposure time: RR 1.10 (95% CI, 0.89-1.36; p=NS).

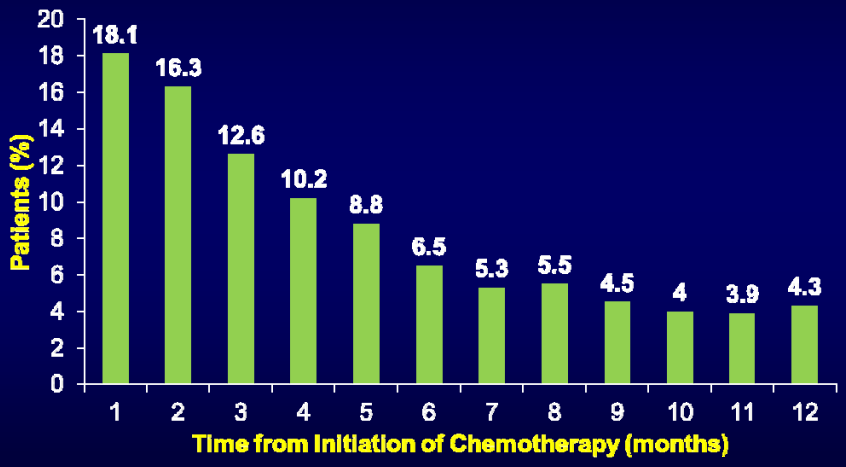
Scappaticci FA, et al. J Natl Cancer Inst 2007;99:1232-1239.
Nalluri SR, et al. JAMA 2008;300:2277-2285.
Chu S, et al. JAMA 2009;301:1434-1436.
Hurwitz HI, et al. J Clin Oncol 2011;29:1757-1764.

Thrombosis Risk with other Growth Factor Receptor Antagonists

- VEGF-R-TKIs (pazopanib, sunitinib, sorafenib, vandetanib) are not associated with VTE: 64/3332 vs. 54/2364; RR 0.91 (95% CI, 0.61-1.34; p=.64).
- Anti-EGFR agents are associated with an increased risk of VTE: RR 1.32 (95% CI, 1.07-1.63; p=.01)
  - Risk with antibodies (cetuximab, panitumumab; RR 1.34; p=.01) rather than oral TKIs (erlotinib and gefitinib; RR 1.16, p=.065)

EGFR, epidermal growth factor receptor; TKIs, tyrosine kinase inhibitors; VEGFR, VEGF receptor.
Choueiri TK, et al JCA 2010:28:2280-2285. Qi WX, et al. Int J Ca 2013;132(12):2967-2977. Petrelli F, et al. Ann Oncol 2012;23:1672-1679; Sonpavde G, et al. Crit Rev Oncol Hematol 2013;87:80-89.

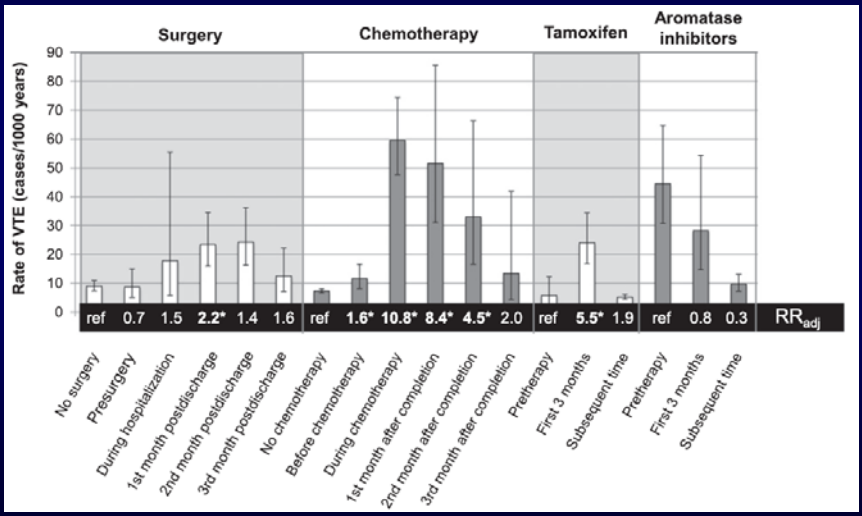
Timing of VTE After Initiation of Chemotherapy



Khorana AA, et al. Cancer 2013;119:648-655.

Treatment and Thrombosis Timing in Breast Cancer

- >13,000 women diagnosed with breast cancer
- Highest VTE rates during chemotherapy
- 2-fold increase following surgery



Adapted from: Walker AJ, et al. Blood 2016;127:849-857.

Medical Patient VTE Risk Assessment: The Padua Risk Score

- Prospective Cohort study of 1180 consecutive patients
- Exclusion criteria: anticoagulant therapy, contraindication to prophylaxis, pregnant, age <18 years
- Blinded outcome assessment
- Follow up for 90 days
- The Padua risk score identifies patients at high risk for VTE

Risk Factor	Points
Active Cancer	3
Previous DVT/PE	3
Reduced mobility (3 or more days)	3
Thrombophilia	3
Recent surgery/trauma	2
Age ≥ 70	1
Heart/Lung Failure	1
Acute MI or stroke	1
Acute infection/inflammation	1
Obesity	1
Hormonal therapy	1

High risk ≥4 patients

Barbar S, et al. J Thromb Haemost 2010;8:2450-2457.

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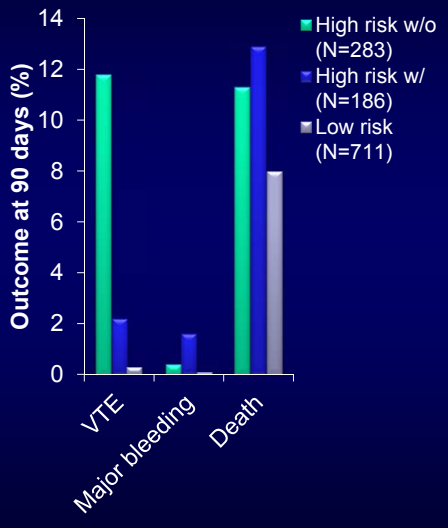

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Barbar S, et al. J Thromb Haemost 2010;8:2450-2457.

Medical Patient VTE Risk Assessment: The IMPROVE VTE Risk Model

- Multicenter observational cohort
- Exclusion criteria: Age <18 years, anticoagulation, surgery/trauma within 3 months, length of stay <3 days
- Outcome: VTE within 3 months (90% follow up)
- The IMPROVE Risk score appears to be useful for VTE risk assessment

Risk Factor	HR (95% CI)	Points
Previous VTE	4.7 (3.0-7.2)	3
Thrombophilia	3.5 (1.1-11)	2
Limb paralysis	3.0 (1.6-5.7)	2
Active Cancer	2.8 (1.9-4.2)	2
Immobile ≥ 7 days	1.9 (1.3-2.7)	1
ICU stay	1.8 (1.1-2.9)	1
Age > 60	1.7 (1.1-2.6)	1

Spyropoulos AC, et al. Chest 2011;140:706-714; Mahan CE, et al. Thromb Haemost 2014;112:692-699.

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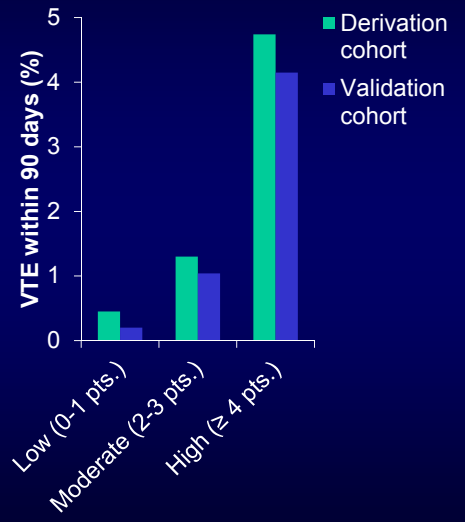
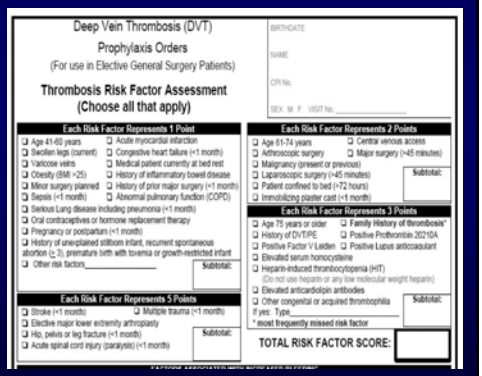


Spyropoulos AC, et al. Chest 2011;140:706-714; Mahan CE, et al. Thromb Haemost 2014;112:692-699.

Surgical Patient VTE Risk Assessment: The Caprini VTE Score

- Expert opinion based risk model
- Advantages: validated in multiple surgical types
- Disadvantages: complex, evidence-based?, no oncology validation


Deep Vein Thrombosis (DVT)
Prophylaxis Orders
(For use in Elective General Surgery Patients)
Thrombosis Risk Factor Assessment
(Choose all that apply)
Each Risk Factor Represents 1 Point
Each Risk Factor Represents 2 Points
Each Risk Factor Represents 3 Points
Each Risk Factor Represents 5 Points
TOTAL RISK FACTOR SCORE:

Caprini JA, et al. Semin Hematol 2001;38:12-19; Bahl V, et al. Ann Surg 2010;251:344-350.

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Total Risk Factor Score	Risk Level	Incidence of DVT	Prophylaxis Regimen
0-1	Low Risk	2%	❑ Early ambulation
2	Moderate Risk	10-20%	Choose the following medication OR compression devices: ❑ Sequential Compression Device (SCD) ❑ Heparin 5000 units SQ BID
3-4	Higher Risk	20-40%	Choose ONE of the following medications + / - compression devices. ❑ Sequential Compression Device (SCD) ❑ Heparin 5000 units SQ TID ❑ Enoxaparin/Lovenox: ❑ 40mg SQ daily (WT < 150kg, CrCl > 30mL/min) ❑ 30mg SQ daily (WT < 150kg, CrCl = 10-29mL/min) ❑ 30mg SQ BID (WT > 150kg, CrCl > 30mL/min) (Please refer to Dosing Guidelines on the back of this form)
5 or more	Highest Risk	40-80%	Choose ONE of the following medications PLUS compression devices. ❑ Sequential Compression Device (SCD) ❑ Heparin 5000 units SQ TID (Preferred with Epidurals) ❑ Enoxaparin/Lovenox (Preferred): ❑ 40mg SQ daily (WT < 150kg, CrCl > 30mL/min) ❑ 30mg SQ daily (WT < 150kg, CrCl = 10-29mL/min) ❑ 30mg SQ BID (WT > 150kg, CrCl > 30mL/min) (Please refer to Dosing Guidelines on the back of this form)

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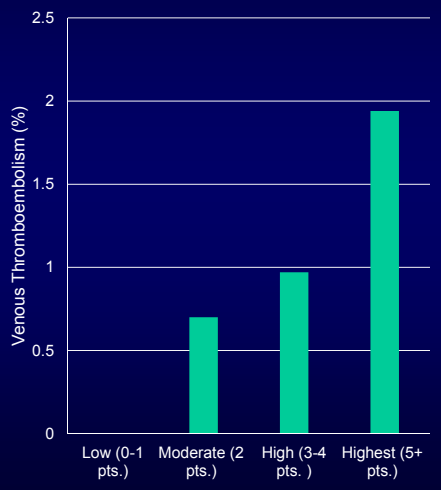

Caprini JA, et al. Semin Hematol 2001;38:12-19; Bahl V, et al. Ann Surg 2010;251:344-350.

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NCCN Guidelines Version 1.2015
Cancer-Associated Venous Thromboembolic Disease

CONTRAINDICATIONS TO PROPHYLACTIC OR THERAPEUTIC ANTICOAGULATION TREATMENT

Absolute
- Recent central nervous system (CNS) bleed, intracranial or spinal lesion at high risk for bleeding
- Active bleeding (major): more than 2 units transfused in 24 hours

Relative
- Chronic, clinically significant measurable bleeding >48 hours
- Thrombocytopenia (platelets <50,000/mcL)
- Severe platelet dysfunction (uremia, medications, dysplastic hematopoiesis)
- Recent major operation at high risk for bleeding
- Underlying hemorrhagic coagulopathy
- High risk for falls (head trauma)
- Neuraxial anesthesia/lumbar puncture

CONTRAINDICATIONS TO MECHANICAL PROPHYLAXIS

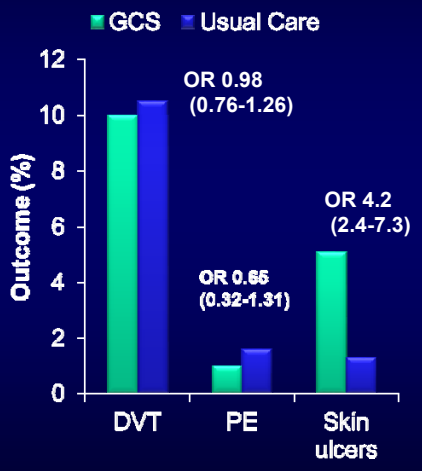
Absolute
- Acute DVT
- Severe arterial insufficiency (pertains to GCS only)

Relative
- Large hematoma
- Skin ulcerations or wounds
- Thrombocytopenia (platelets <20,000/mcL) or petechiae
- Mild arterial insufficiency (pertains to GCS only)
- Peripheral neuropathy (pertains to GCS only)

VTE-B

CLOTS Trial 1: Graduated Compression Stockings (TEDS) May Not Reduce VTE But Cause Skin Ulcers

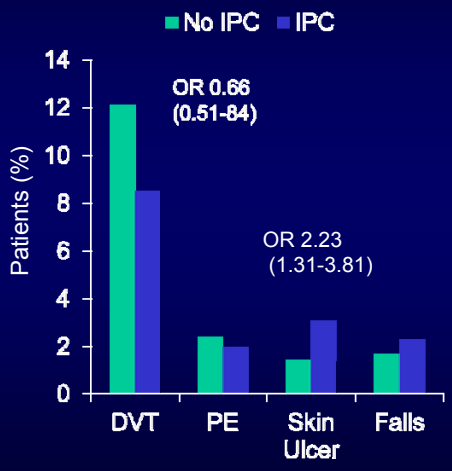
- Open-label randomized controlled trial of 2518 patients with stroke
- Thigh-high graduated compression stockings (GCS) vs. usual care up to 30 days
- Outcome: Duplex ultrasound at 7-10 days and 25-30 days
- Conclusion: GCS do not reduce VTE but increase skin complications



DVT, deep vein thrombosis; PE, pulmonary embolism; TEDS, thromboembolism deterrent hose.
CLOTS Trials Collaboration, et al. Lancet 2009;373:1958-1965.

CLOTS 3 Trial: Pneumatic Compression Devices Reduce DVT

- Multicenter randomized controlled trial of intermittent pneumatic compression (IPC) versus no IPC
- 2876 immobile patients with acute stroke
- Outcome: Duplex ultrasound at 7-10 days and 25-30 days
- Conclusion: IPC reduces DVT but increases skin complications



DVT, deep vein thrombosis; PE, pulmonary embolism.
CLOTS Trials Collaboration, et al. Lancet 2013;382:516-524.

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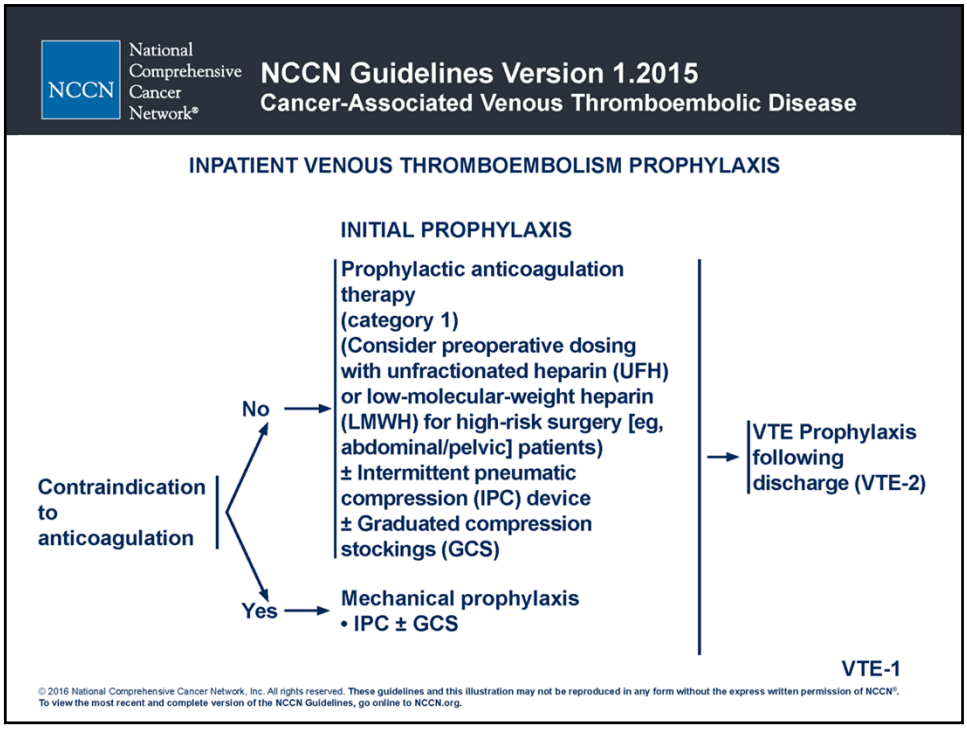
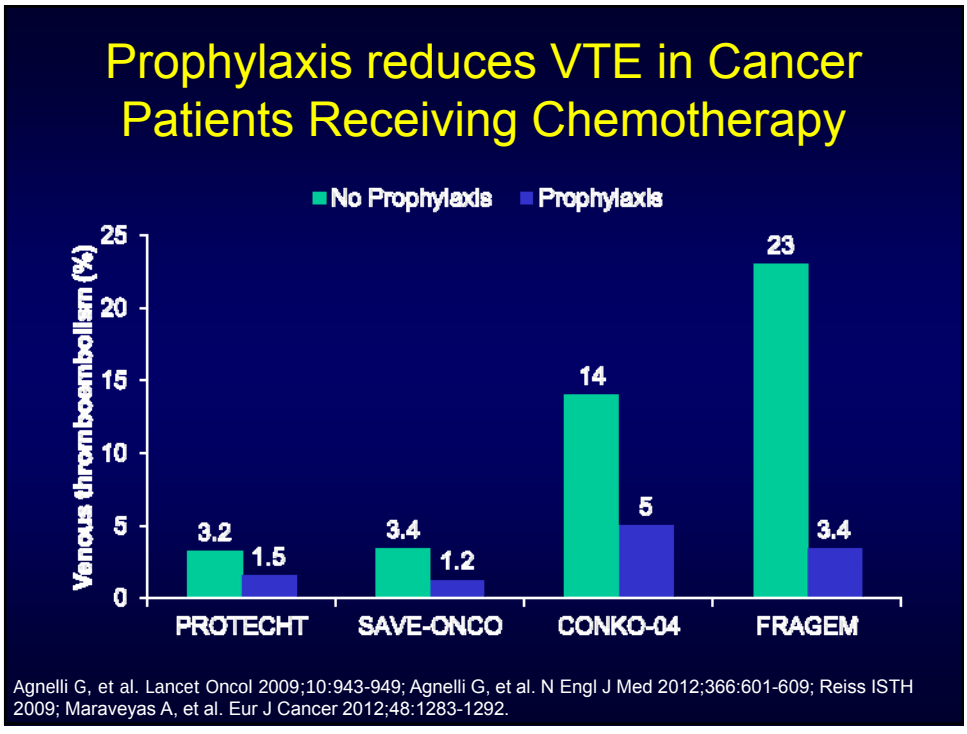
Cancer-Associated Venous Thromboembolic Disease

INPATIENT VENOUS THROMBOEMBOLISM PROPHYLAXIS

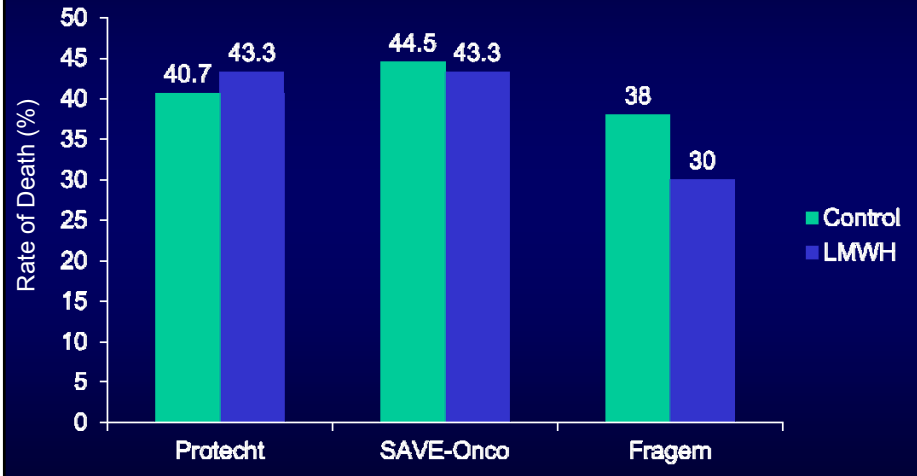
AT-RISK POPULATION	WORKUP
• Adult medical or surgical patient • Diagnosis of cancer or clinical suspicion of cancer • Providers are encouraged to discuss VTE risk factors, VTE prevention, and the importance of patient adherence to care programs	Initial Workup: • History and physical • Complete blood count (CBC) with platelet count • Prothrombin time (PT) • Activated partial thromboplastin time (aPTT) • Liver and kidney function tests

VTE-1





VTE Prophylaxis Does Not Reduce Mortality

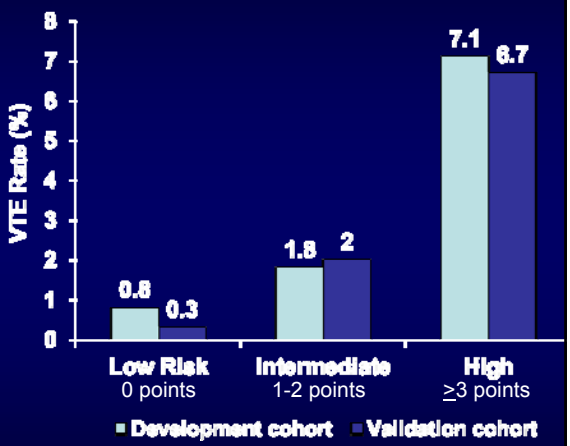


LMWH, low-weight molecular heparin.

Agnelli G, et al. Lancet Oncol 2009;10:943-949; Agnelli G, et al. N Engl J Med 2012;366:601-609; Maraveyas A, et al. Eur J Cancer 2012;48:1283-1292.

VTE Risk Assessment Model for Cancer

Patient Characteristic	Point Score
Site of Cancer • Very high risk (stomach or pancreas) • High risk (lung, lymphoma, GYN, bladder, testicular)	 2 1
Pre-chemotherapy platelet count ≥350,000/mm^3	1
Hemoglobin <10 g/dL or use of red cell growth factors	1
Pre-chemotherapy leukocyte count >11,000/mm^3	1
BMI ≥35 kg/m^2	1



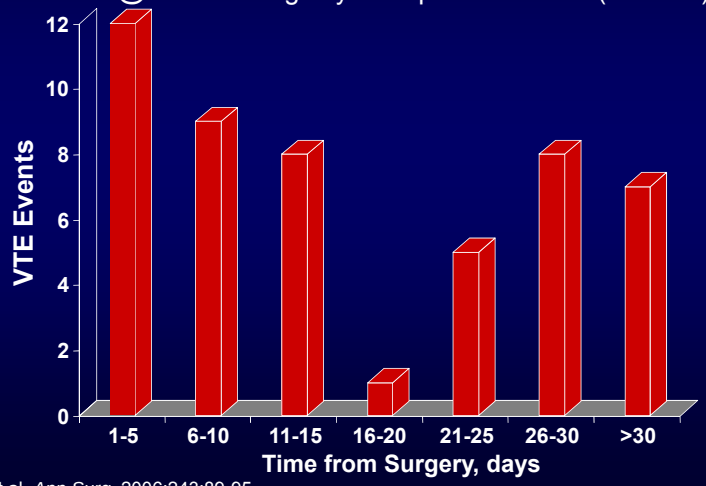
BMI, body mass index; GYN, gynecologic.

Khorana AA ,et al. Blood 2008;111:4902-7.

Time Distribution of VTE After Cancer Surgery

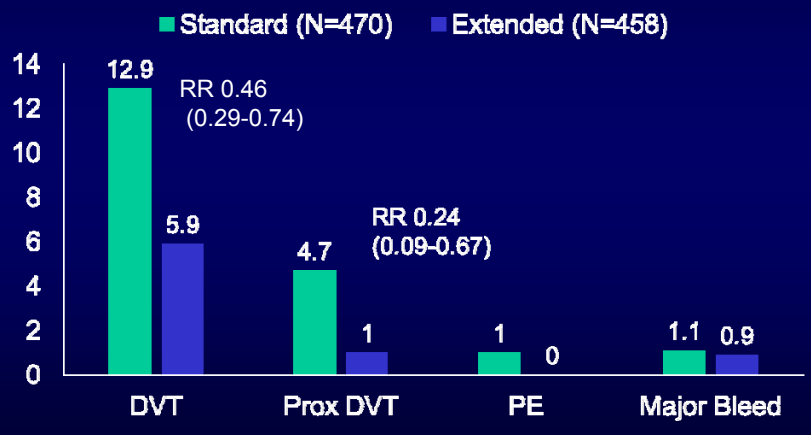
- Symptomatic VTE: 2.1%
- Overall mortality: 1.7%–46% due to fatal PE

@RISTOS Registry: Prospective Cohort (N=2373)

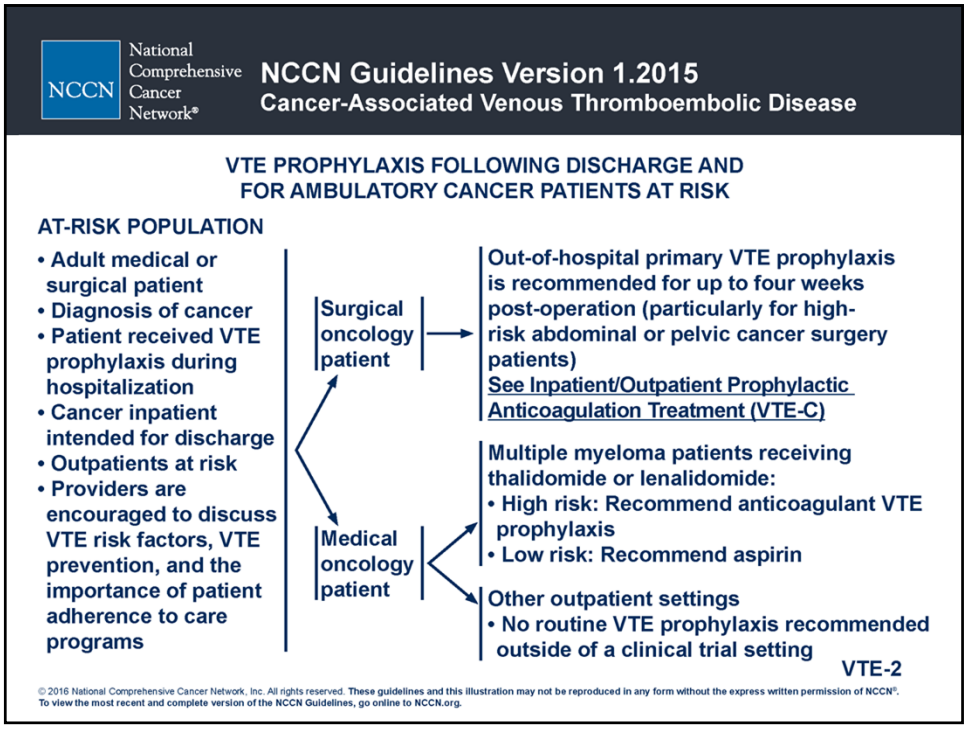


Agnelli G, et al. *Ann Surg.* 2006;243:89-95.

Extended Perioperative Prophylaxis Reduces VTE



DVT, deep vein thrombosis; PE, pulmonary embolism; Prox DVT, proximal deep vein thrombosis
Bottaro FJ, et al. Thromb Haemost 2008;99:1104-1111.

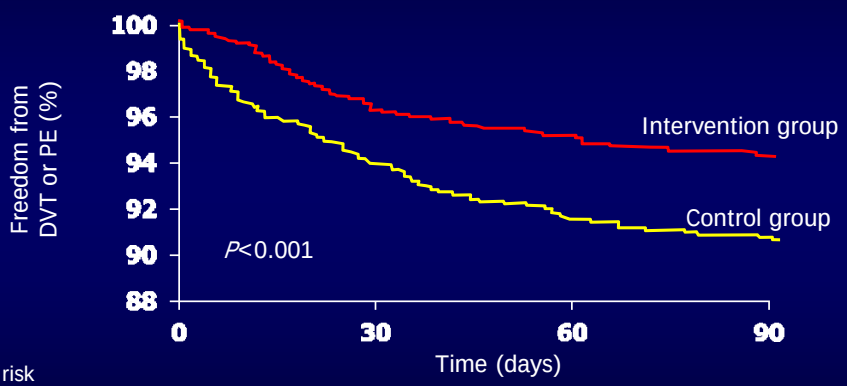


How to implement a VTE Prevention Program: Principles of Success

- Standardize VTE and anticoagulant risk assessment into the process of admission and transfers
  - "Opt out" of default choices (not opt in)
  - Keep it simple to access and use
  - Don't interrupt the workflow
  - Allow for variation from the protocol based on patient characteristics (rather than providers)
- Monitor use of your protocol
  - % admissions with VTE prophylaxis order set
  - Use real-time interventions
- Improve protocol based on feedback and justifiable variation
  - Fail faster (pilot small scale with ongoing feedback and refinement before wider implementation)
  - Monitor % reduction in hospital-acquired VTE

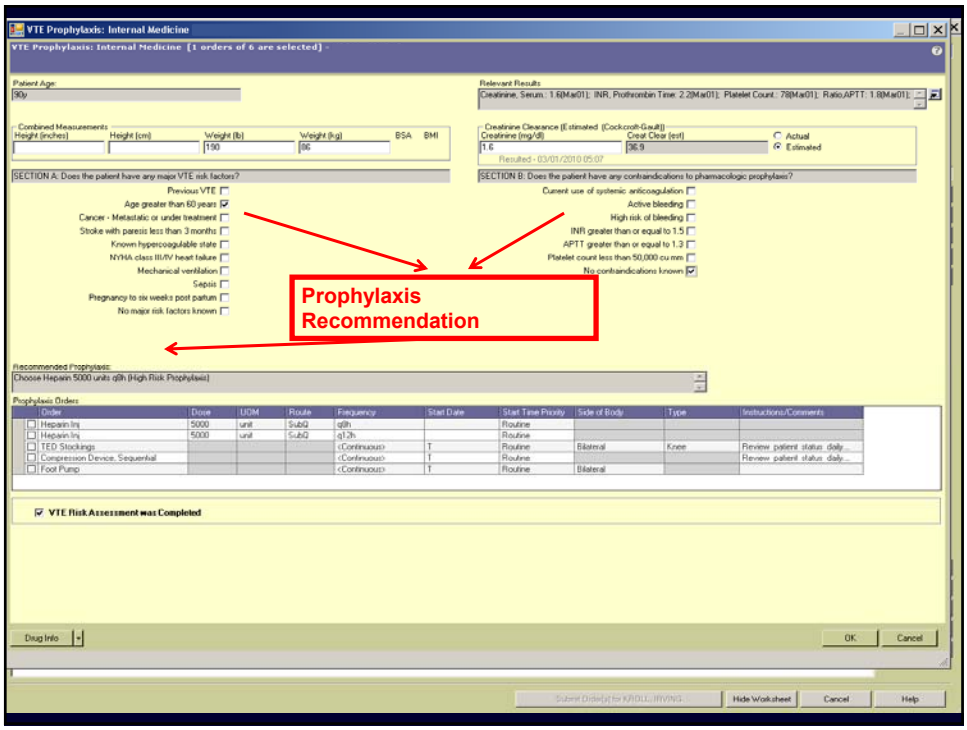
Maynard G, Stein J. *J Thromb Thrombolysis*. 2010; 29:159-66.

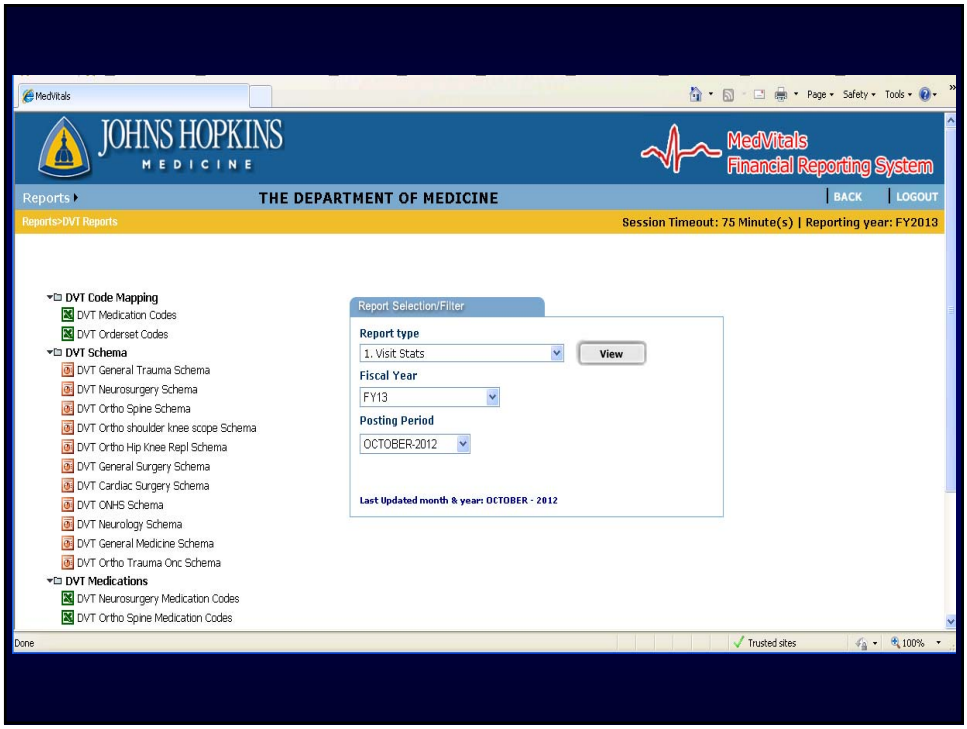
Electronic Alerts to Prevent VTE in Medical Patients

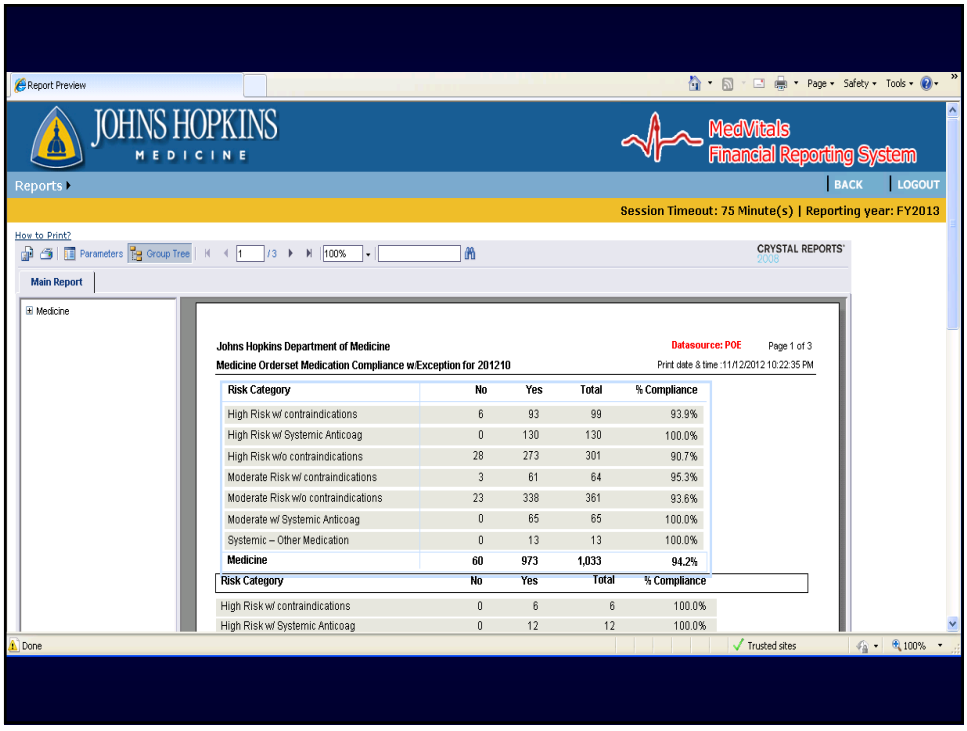


No. at risk				
Intervention group	1,255	977	900	853
Control group	1,251	876	893	839

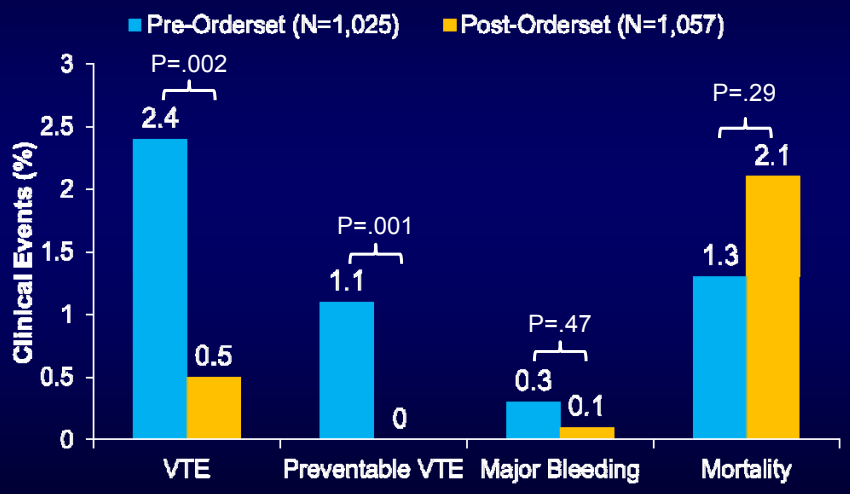
Kucher N, et al. *N Engl J Med*. 2005;352:969-77.





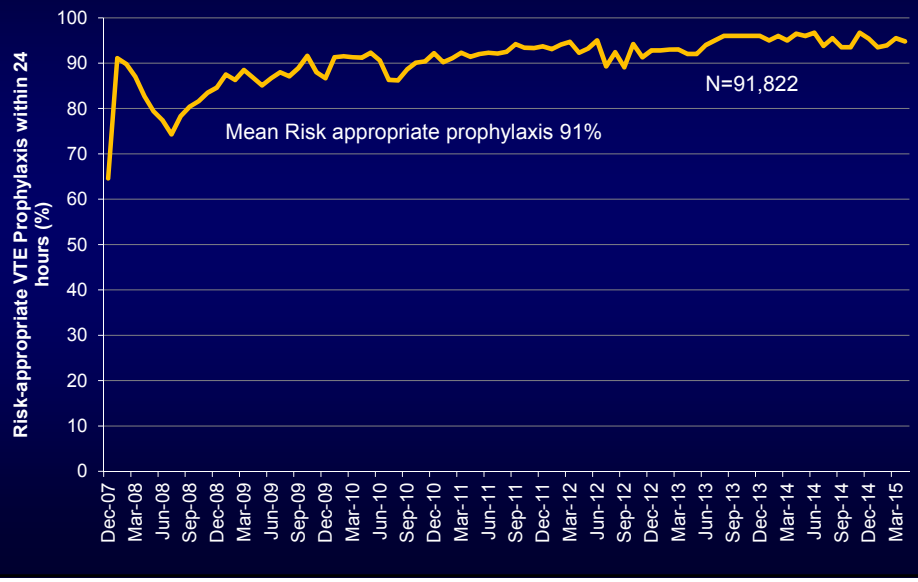


Impact of Mandatory "Smart Order Sets": Fewer Clots, No Increase in Bleeding



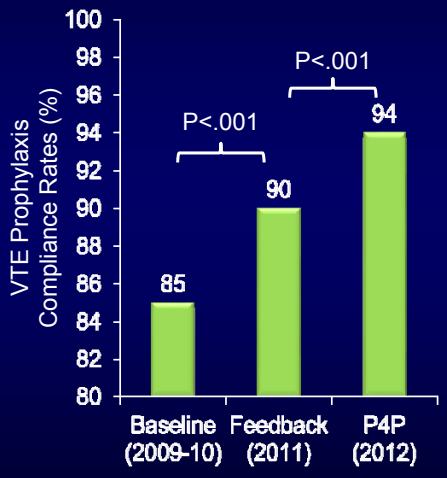
Zeidan AM, et al. Am J Hematol 2013;88:545-54.

VTE Performance 2008-2015

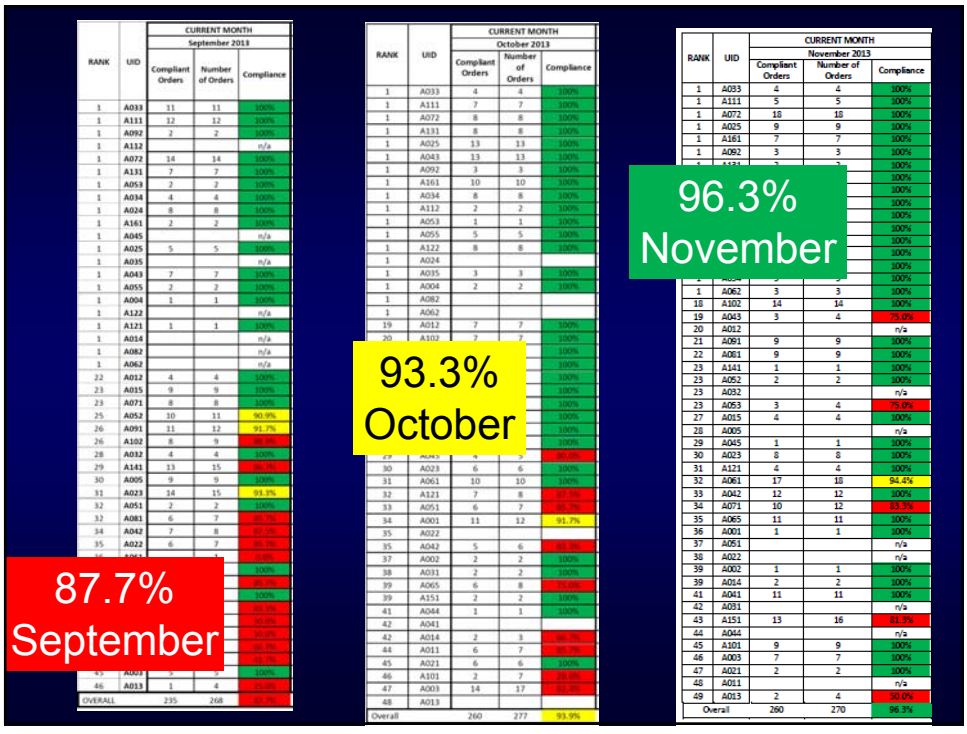


Individual Feedback and Pay-for-Performance to Improve Compliance

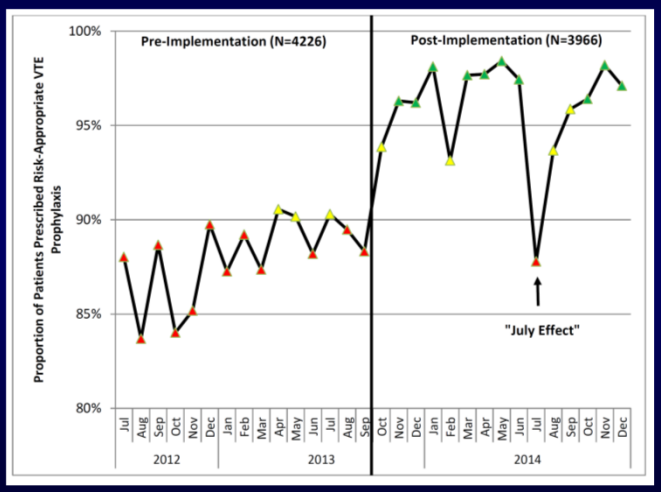
- Problem: suboptimal VTE prophylaxis performance
- Solution:
  1. Share performance data with individuals
  2. Pay-for-performance (P4P)
- Conclusion: Individual feedback and P4P can be effective strategies to improve performance



Michtalik HJ, et al. J Hosp Med 2015;10:172-178.



Surgery Resident Feedback Improves VTE Prophylaxis



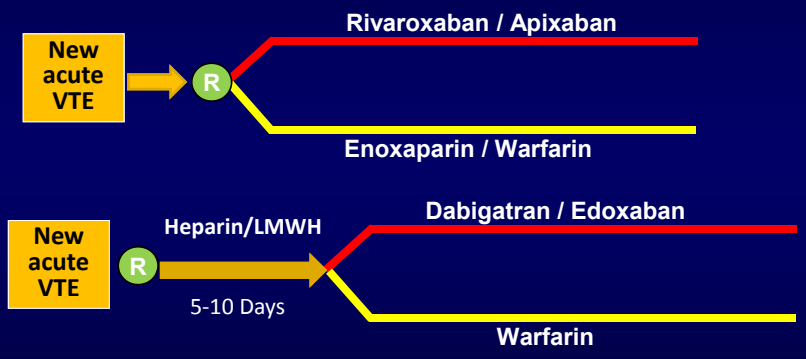
Lau BD, et al. Ann Surg 2015.

Direct Oral Anticoagulants vs. Warfarin

Drug	Target	Dose	Monitor	Onset (h)	Half-Life (h)	Renal Clearance (%)	Interactions
Dabigatran	Factor IIa Thrombin	150 mg BID	No	2	14-17	100	P-glycoprotein
Rivaroxaban	Factor Xa	15 mg BID X 21 d then 20 mg QD	No	2.5-4	9	65	CYP3A4 and p-glycoprotein
Apixaban	Factor Xa	10 mg BID X 7 d then 5 mg BID	No	3	9-14	25	CYP3A4 and p-glycoprotein
Edoxaban	Factor Xa	30-60 mg QD	No	2		50	P-glycoprotein
Warfarin	Vitamin K epoxide reductase	2.5-10 mg QD	Yes	72-96	40	0	Multiple drugs, dietary vitamin K

Eikelboom JW, et al. Circulation 2007;116:131-133.

DOAC Should be Used as They Were in the VTE Clinical Trials



DOAC, direct oral anticoagulants; R, randomization.

A Comparison of the DOAC VTE Trial Populations

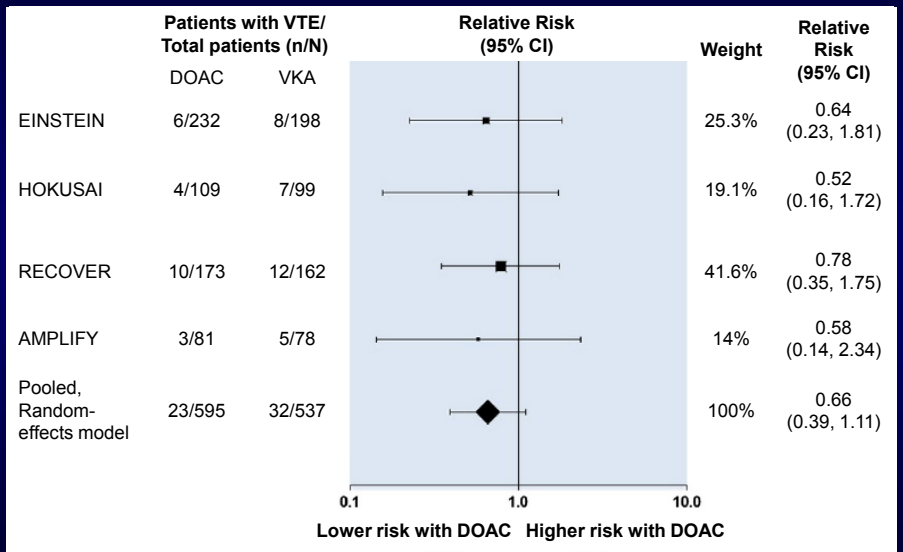
Patient Characteristics	Dabigatran (Re-Cover)	Rivaroxaban (Einstein)	Apixaban (Amplify)	Edoxaban (Hokusai-VTE)
Thrombophilia	?	223 (6.4%)	Excluded	?
Patients with cancer (%)	121 (4.8%)	430 (5.2%)	Excluded	208 (2.5%)
Pregnancy/ Lactation	Excluded	Excluded	Excluded	Excluded
Platelets	?	?	<100 K	?
Hemoglobin	?	?	<9 g/dL	?
Kidney	<30 ml/min	<30 ml/min	<25 ml/min	<30 ml/min
Liver	2X ULN	3X ULN	>2X ULN	>2X ULN
Anti-platelets	ASA = 100 mg	ASA = 100 mg or CLOP = 75	ASA <165 mg or CLOP 75	ASA >100 mg

ASA, aspirin; CLOP, clopidogrel; DOAC, direct oral anticoagulant.

Schulman S, et al. N Engl J Med 2009;361:2342-2352; Buller HR, et al. N Engl J Med 2012;366:1287-1297; Hokusai VTE Investigators, et al. N Engl J Med 2013;369:1406-1415; Agnelli G, et al. N Engl J Med 2013;369:799-808; Agnelli G, et al. N Engl J Med 2013;368:699-708.

Meta-Analysis

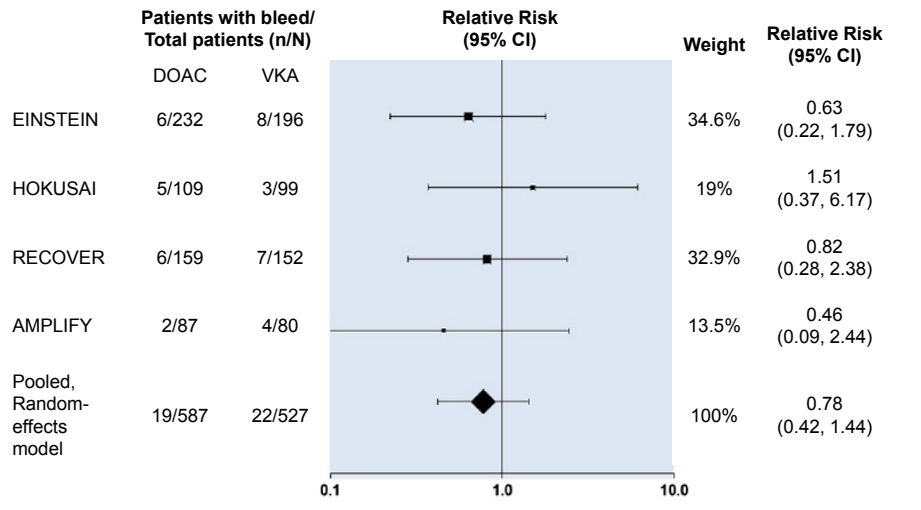
Risk of Recurrent VTE in Cancer Patients



DOAC, direct ora anticoagulant; VKA, vitamin K antagonist.
Carrier M, et al. Thromb Res 2014;134:1214-1219.

Meta-Analysis

Risk of Major Bleeding in Cancer Patients



DOAC, direct ora anticoagulant; VKA, vitamin K antagonist.
Carrier M, et al. Thromb Res 2014;134:1214-1219.

Trials Testing DOACs for Treating VTE: Conclusions from Meta-Analysis of Cancer Patient Data

- **Patient populations from LMWH cancer trials have substantially different VTE & bleeding risks (↑) compared to the populations in DOAC trials.**
- **Limitations of DOAC trials:**
  - **Under powered to show effects in cancer patients**
  - **Selection bias**
  - **Need cancer characteristics of patients included in these trials: tumor type, stage, treatment status**
- **Remaining questions about using DOACs in cancer patients:**
  - **What cancer patients will benefit?**
  - **Compatibility with chemotherapy?**
  - **Periods of thrombocytopenia?**
- **Need studies dedicated to cancer patients**

DOAC, direct oral anticoagulant; LMWH, low-molecular-weight heparin; VKA, vitamin K antagonist.
Carrier M, et al. Thromb Res 2014;134:1214-1219..
Vedovati MC, et al. Chest 2015;147:475-483.

Clinical Trials

Study	Agent	Comparator	Population	Status
Hokusai-VTE Cancer NCT02073682	Edoxaban 60 mg QD	Dalteparin	Treatment of VTE	Recruiting
AVERT NCT02048865	Apixaban 2.5 mg x 6 months	Placebo	VTE prevention	Recruiting
CALLISTO NCT02555878	Rivaroxaban	None, Placebo	VTE prevention	Recruiting
CONKO-011 NCT02583191	Rivaroxaban	LMWH	VTE treatment	Recruiting
CALLISTO	Rivaroxaban	-	VTE treatment	Development

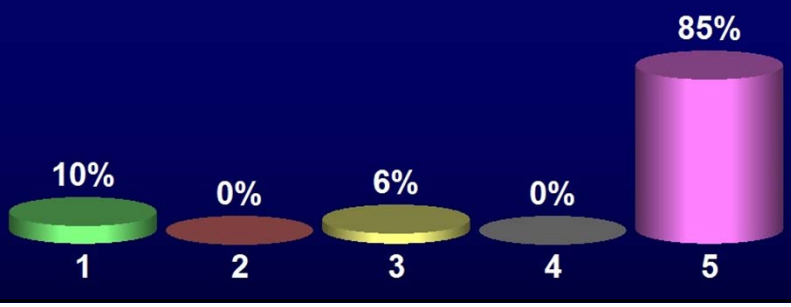
Summary

- Patients with cancer are at increased risk for venous thromboembolism
- VTE prophylaxis is recommended for medical and surgical patients with cancer
  - Risk assessment models need further validation in cancer patient populations
  - Post-discharge prophylaxis is recommended for patients with cancer undergoing surgery
- Direct oral anticoagulants warrant further investigation in cancer patients before routine use
  - Unknowns: drug interactions, use in patients with liver/kidney dysfunction, thrombocytopenia

Audience Polling Results

1. Which of the following statements is correct?

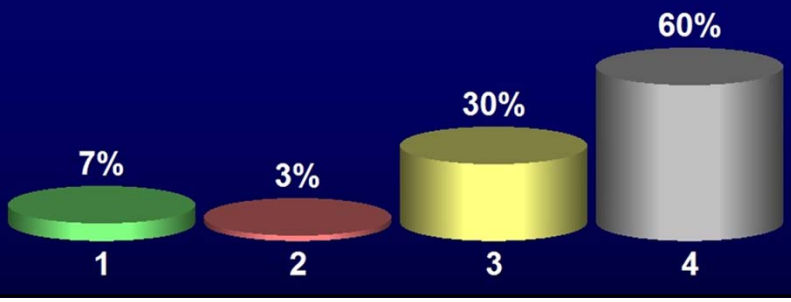
1. VTE is more common in patients with cancer.
2. Recurrent VTE is more common in patients with cancer.
3. Mortality is higher in patients with cancer and VTE.
4. Bleeding is more common in patients with cancer receiving an anticoagulant.
5. **All of the above**



Audience Polling Results

2. Randomized trials of new direct oral anticoagulants (DOAC) in patients and venous thromboembolism:

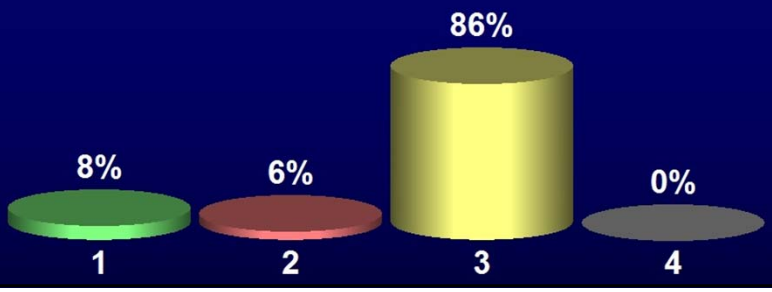
1. Have all shown a significant reduction in recurrent VTE
2. Have all shown significant reduction in rates of major hemorrhage
3. **Have enrolled a small number of patients with cancer**
4. All of the above



Audience Polling Results

3. A 67-year-old female with colon cancer is admitted for surgical resection. She does not have any contraindications to anticoagulation. What is a prudent course of action for VTE prophylaxis?

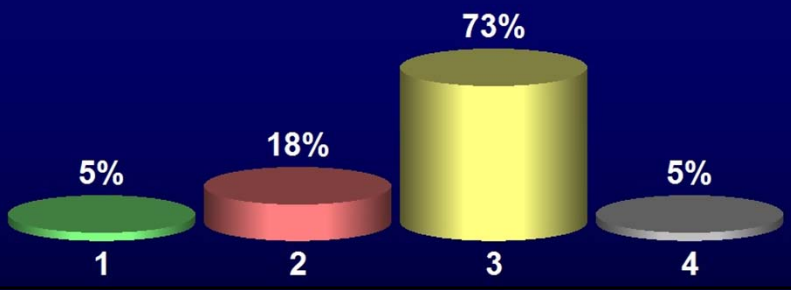
1. Provide pharmacologic prophylaxis with aspirin
2. Provide pharmacologic prophylaxis with rivaroxaban
3. **Provide pharmacologic prophylaxis with low- molecular-weight heparin (LMWH) and intermittent pneumatic compression**
4. All of the above



Audience Polling Results

4. A 67-year-old female with colon cancer is admitted for surgical resection. What is a prudent course of actions for VTE prophylaxis?

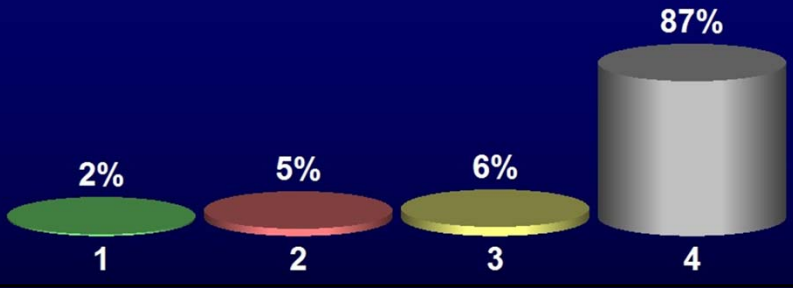
1. Limit pharmacologic prophylaxis to hospitalization
2. Extend pharmacologic prophylaxis until patient is mobile
3. **Extend pharmacologic prophylaxis for up to 4 weeks after hospital discharge**
4. All of the above



Audience Polling Results

5. A 78-year-old woman is diagnosed with breast cancer. She will receive a paclitaxel-based regimen on an ambulatory basis. She does not have any contraindications to anticoagulation. Her VTE risk warrants:

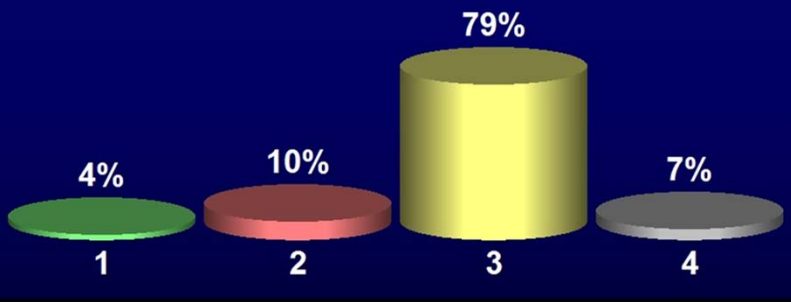
1. Initiating aspirin and clopidogrel for primary VTE prevention
2. Initiation of warfarin for primary VTE prevention
3. Initiation of rivaroxaban for primary VTE prevention
4. **No VTE prophylaxis is required**



Audience Polling Results

6. An 82-year-old male with lung cancer develops calf acute deep vein thrombosis (DVT). What is his best option?

1. Dabigatran 75 mg twice daily
2. Rivaroxaban 15 mg twice daily
3. **Low-molecular-weight heparin (LMWH) once or twice daily**
4. None of the above



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