ATELIER MTEV

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Déclaration d’intérêts (Disclosure)

Financial compensation for participation on advisory board with speaking engagement sponsored by Bayer Healthcare (Xarelto), Novartis (Lixiana), Bristol-Myers Squibb SA (Eliquis)

ATELIER

OBJECTIFS

1) Reconnaitre une TVP et le risque thrombo-embolique
2) Connaitre les recommandations de traitement et prévention de la maladie thrombo-embolique
3) Cancer et Thrombose (CAT)
4) Risque hémorragique

Présentation clinique de MTE

- Swelling
- Tenderness
- Discoloration
- Pitting edema

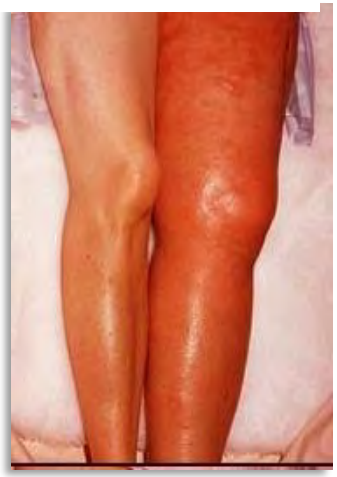
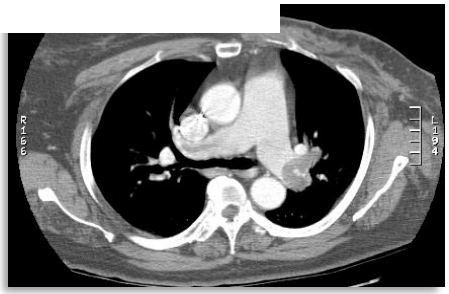


image from National Blood Clot Alliance.
http://www.stoptheclot.org/learn_more/learn_thrombosis.htm.
Accessed September 1, 2012.

- Shortness of breath
- Cough
- Chest pain
- Tachycardia
- Hypotension
- Low-grade fever



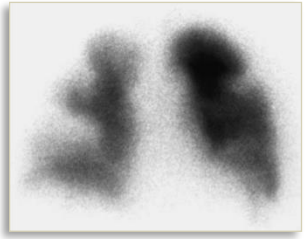


Image courtesy of
RF Schneider, Pfizer

Image

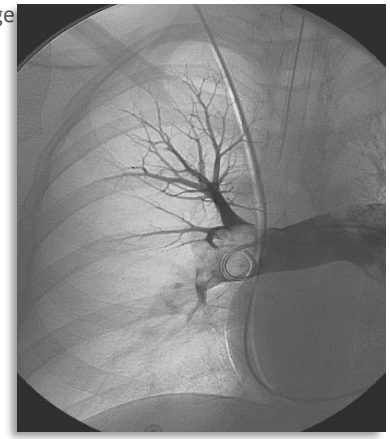


Image from Schümichen C.

1. Moll S. *Arterioscler Thromb Vasc Biol*. 2008;28(3):373-9;
2. Pai M *et al.* http://www.uptodate.com/contents/deep-vein-thrombosis-dvt-beyond-the-basics - Accessed July 2013;
3.Thompson *et al.* http://www.uptodate.com/contents/pulmonary-embolism-beyond-the-basics - Accessed July 2013;
4. Goldhaber SZ. Pulmonary Embolism. In: Bonow RO, et al. *Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine*, 9th ed. Philadelphia, PA: Elsevier, 2012

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Complications à long terme de MTE

Syndrome Post-Thrombotique[1]

~30% of VTE patients experience a post-thrombotic syndrome[1]

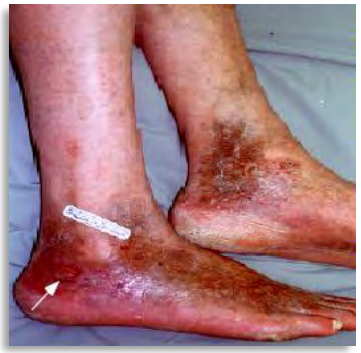


Image from UpToDate. http://www.uptodate.com/contents/diagnostic-evaluation-of-chronic-venous-insufficiency. Accessed September 1, 2012.

Hypertension pulmonaire thromboembolique chronique[2,3]

- Can occur after PE and is associated with significant morbidity and mortality[2]
- Frequency: 3.8% at 2 years[3]

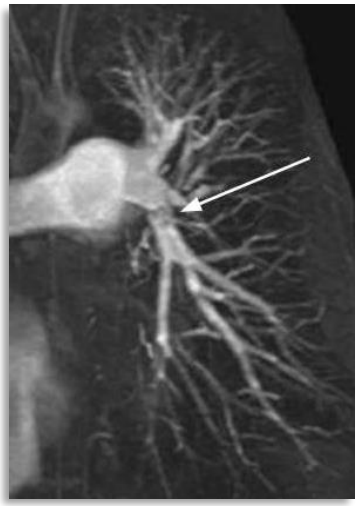
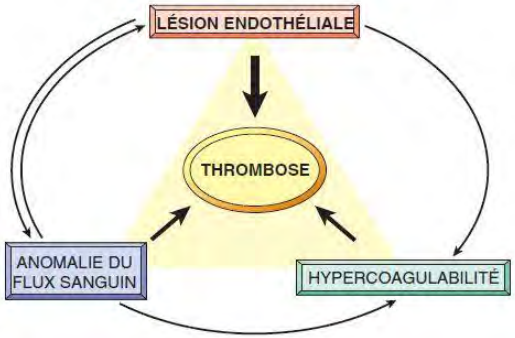


Image from McNeil K. *Heart* 2007; 93:1152-1158.

1. Kahn and Ginsberg, *Arch Intern Med* 2004;164:17-26
2. McNeil K and Dunning, *J Heart* 2007;93:1152-8
3. Pengo *et al. N Engl J Med* 2004;350:2257-64

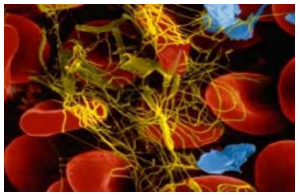
Physiopathologie



Système veineux

facteurs déclencheurs

stase sanguine — **hémostase secondaire** — thrombocytes



TVP, EP et AVC chez les patients atteints de fibrillation auriculaire

anticoagulants

Tableau 2. Score de Genève révisé

	Point
Facteurs de risque	
– Age > 65 ans	1
– Antécédents de thrombose ou embolie	3
– Chirurgie sous anesthésie générale ou fracture des membres inférieurs dans le mois précédent	2
– Cancer solide ou hématologique actif ou en rémission depuis moins d'un an	2
Symptômes	
– Douleur unilatérale d'un membre inférieur	3
– Hémoptysie	2
Signes cliniques	
– Douleur à la palpation d'un trajet veineux et œdème unilatéral d'un membre inférieur	4
– Fréquence cardiaque 75-94 batt/min	3
> 94 batt/min	5
→ Probabilité clinique d'EP : Bas	0-3
Intermédiaire	4-10
Elevé	> 10

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REVIEW INTERNAL MEDICINE JOURNAL

Acute pulmonary embolism: a concise review of diagnosis and management

Morgan Hepburn-Brown [1,2] Jai Darvall[3,4] and Gary Hammerschlag[2] Internal Medicine Journal 49 (2019) 15–27

Taux d'admission pour EP aiguë

- ↗ 80% depuis 1998 à 2006

Wiener R et al. Time trends in pulmonary embolism in the United States; Arch Intern Med 2011;171:831-7

- ↗ 237% depuis 1993 à 2016

Smith S et al. Analysis of national trends in admissions for pulmonary embolism. Chest 2016;150:35-45

Acute **pulmonary embolism** (PE) is a common cause of death, accounting for 50,000 to 200,000 deaths annually. It is **the third most common cause of mortality** among the cardiovascular diseases, after coronary artery disease and stroke.

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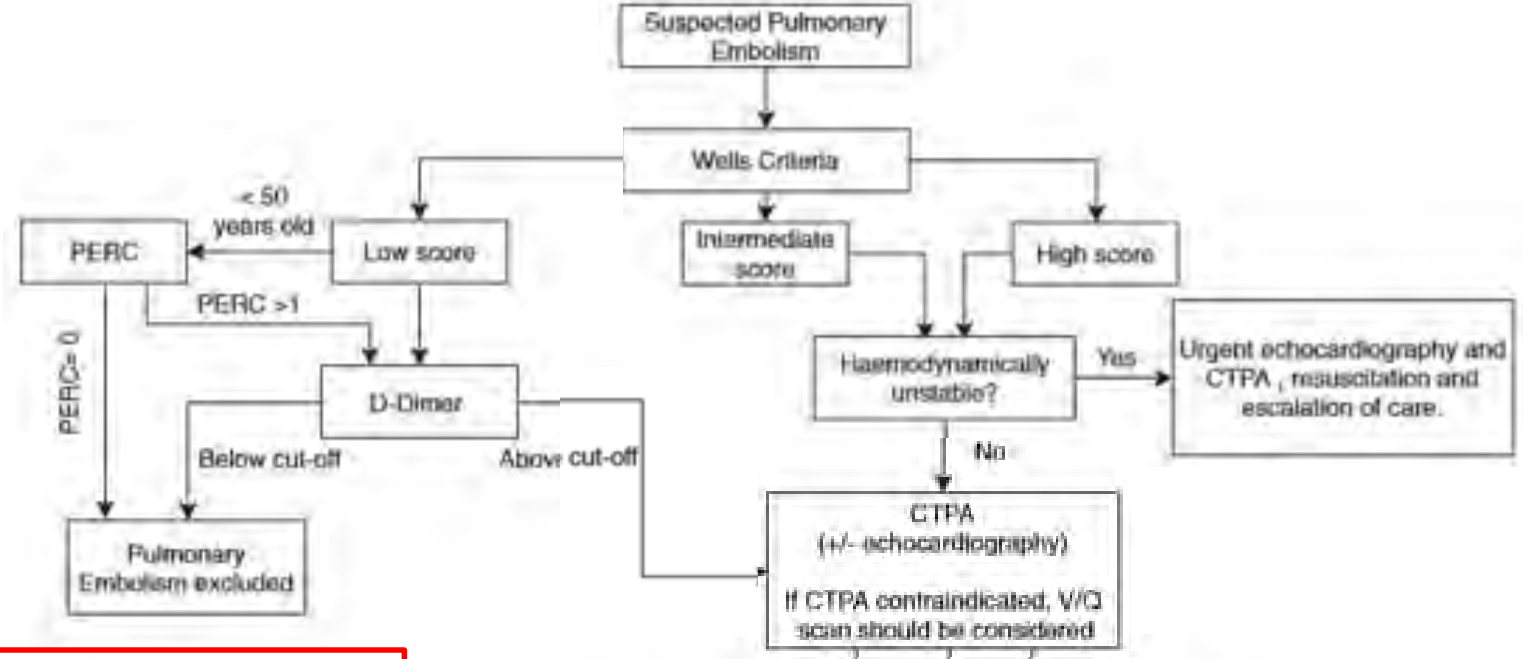
Figure 1 A suggested diagnostic pathway for acute pulmonary embolism based on services available in most Australian hospitals.



Pulmonary embolism rule-out criteria	Scoring: 0 = PE ruled out, >1 = PE unable to be ruled out
1 point	Age ≥ 50
1 point	Heart rate >100/min
1 point	Arterial oxygen saturation <95% on room air
1 point	Unilateral leg swelling
1 point	Haemoptysis
1 point	Recent surgery or trauma (within 4 weeks) requiring general anaesthesia
1 point	Prior PE of DVT
1 point	Hormone use (i.e. OCP, HRT)

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Table 3 The recommended duration of anti-coagulation for pulmonary embolism based on risk factor contributing to venous thromboembolism (VTE) event

Risk factor classification	Example precipitant	Recommended duration	Recommended anti-coagulant	References
Provoked reversible (major, transient)	Orthopaedic surgery, trauma, intravascular catheter	3 months	Rivaroxaban, apixaban or warfarin	ESC guidelines, 2014[5]; AHA guidelines, 2011[16]; CHEST guidelines, 2016[18];
Provoked reversible (non-major, transient)	Oral contraceptive pill, long haul flight, immobilisation, hormone replacement therapy, pregnancy	3 months minimum, but careful evaluation of the bleeding versus recurrence risk. Consider extension to 6 or 12 months (recurrence risk estimated at 5% at 12 months, 15% at 5 years)	Rivaroxaban, apixaban or warfarin	Choosing Wisely guidelines[71]; Agnelli *et al.*, 2013[90]; Couturaud *et al.*, 2015[95]; Enea *et al.*, 2017[91]
Provoked irreversible	Cancer	Indefinite	Rivaroxaban, apixaban or warfarin (consider Aspirin after 3 months if anti-coagulation not appropriate)	ESC guidelines, 2014[5]; AHA guidelines, 2011[16]; CHEST guidelines, 2016[18]; Agnelli *et al.*, 2013[90]; Becattini *et al.*, 2012[93];

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Risk factor classification	Example precipitant	Recommended duration	Recommended anti-coagulant	References
Unprovoked	Unknown at time of diagnosis	Indefinite	Rivaroxaban, apixaban or warfarin (consider aspirin after 3 months if anti-coagulation not appropriate)	Brighton *et al.*, 2012[94]; Couturaud *et al.*, 2015[95]; Enea *et al.*, 2017[91]; Marik *et al.*, 2015[97]; Weitz *et al.*, 2017[98]
Recurrent or second VTE	Any precipitant previously listed	Indefinite	Rivaroxaban, apixaban or warfarin (consider aspirin after 3 months if anti-coagulation not appropriate)	

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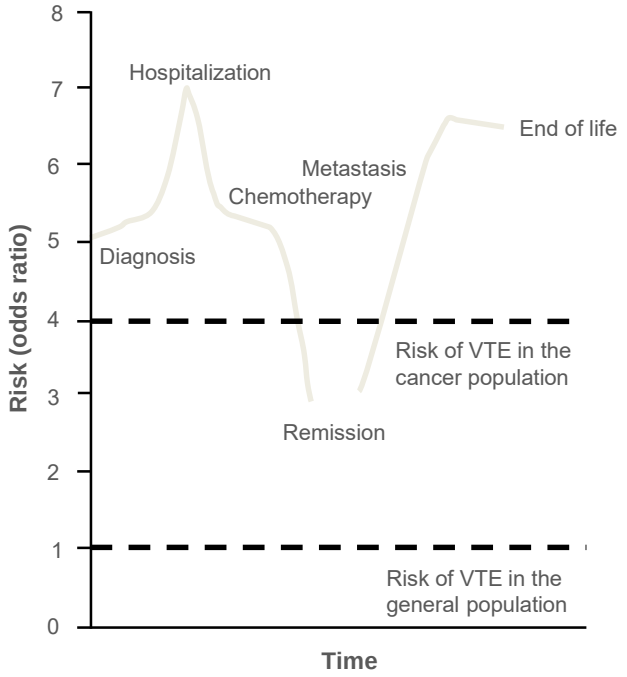
Recurrent or second VTE	Any precipitant previously listed	Indefinite	Rivaroxaban, apixaban or warfarin (consider aspirin after 3 months if anti-coagulation not appropriate)	

\, American Heart Association; DOAC, direct oral ar Society of Cardiology.

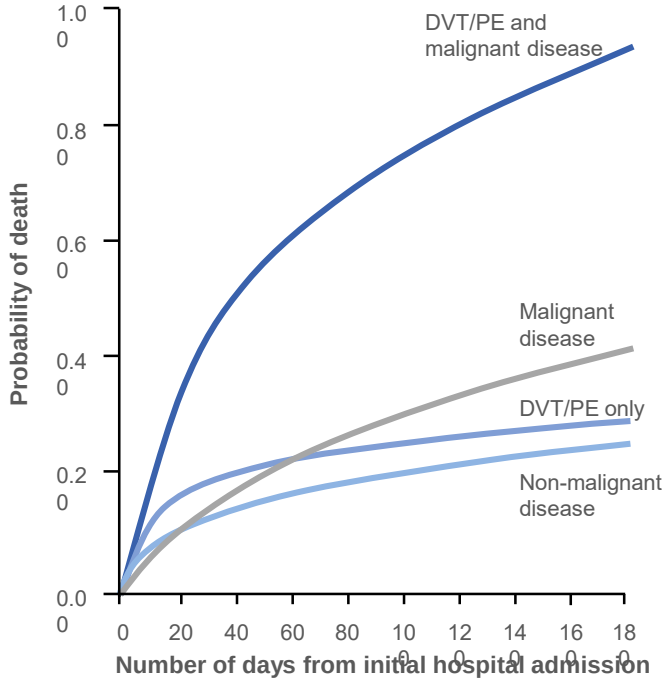
Cancer Associated Thrombosis

In Cancer Patients: Risk of VTE is Higher & Associated with Reduced Survival

Risk of VTE varies during the natural history of cancer care[1,2]



Thrombosis and cancer increases risk of death[3]



1. Lyman GH et al, Cancer 2011;7:1334–1349; 2. Rao MV et al, in *Cancer-Associated Thrombosis*. (Khorana and Francis, Eds) 2007; 3. Adapted from Levitan N et al, *Medicine* 1999;78:285–291

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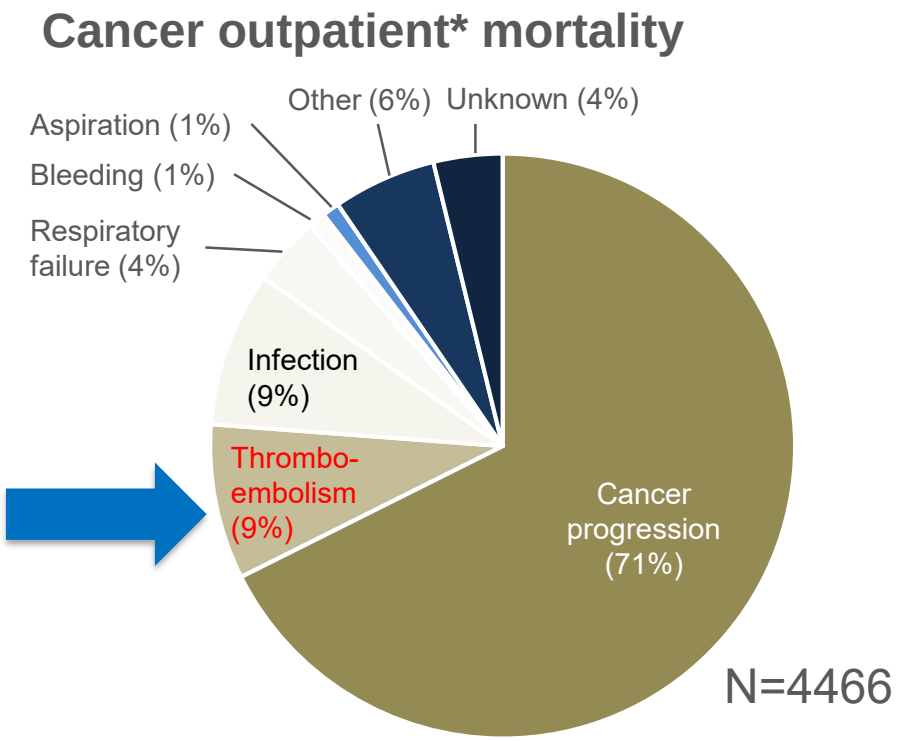
Thromboembolism Is a Leading Cause of Death in Cancer Patients Receiving Outpatient Chemotherapy

- Thromboembolism is the **second leading** cause of death in patients with cancer
- 4466 patients from 117 US centres, receiving chemotherapy, were enrolled in a prospective observational study
- Annual death rate for VTE was 448 per 100,000 cancer outpatients
  - **47-fold increase** over the general population



*Receiving chemotherapy

Khorana AA *et al*, *J Thromb Haemost* 2007;5:632–634

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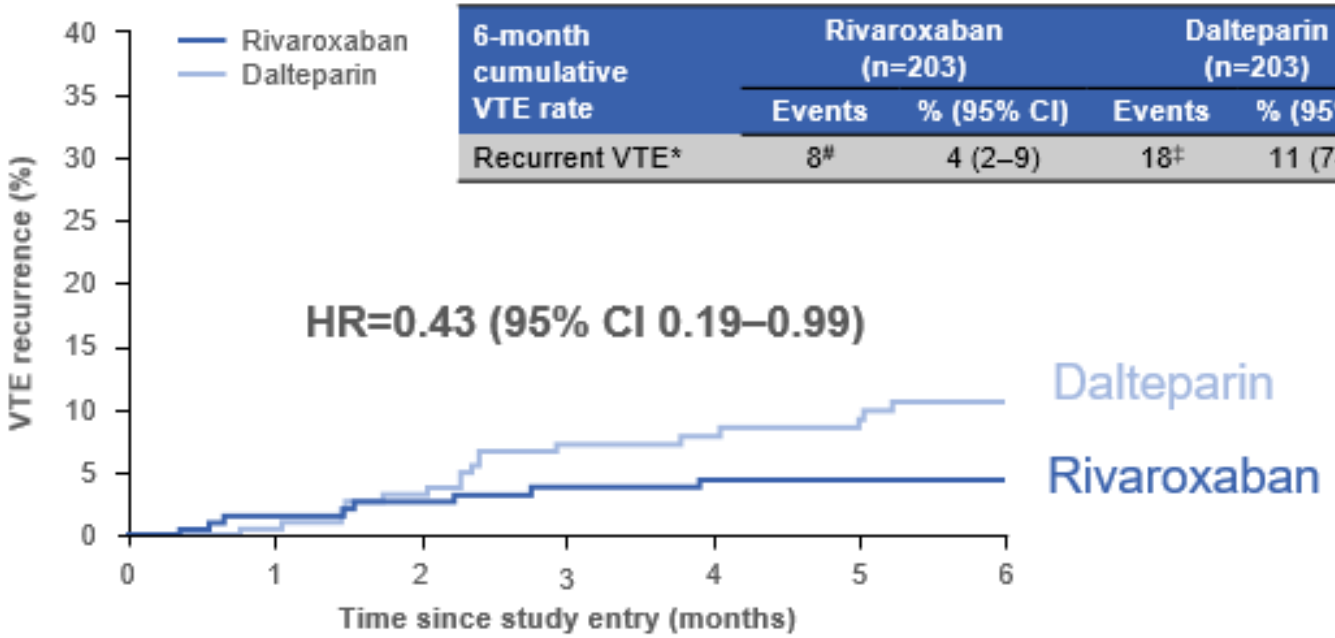
Comparison of an Oral Factor Xa Inhibitor With Low Molecular Weight Heparin in Patients With Cancer With Venous Thromboembolism: Results of a Randomized Trial (SELECT-D)

Annie M. Young, Andrea Marshall, Jenny Thirlwall, Oliver Chapman, Anand Lokare, Catherine Hill, Danielle Hale, Janet A. Dunn, Gary H. Lyman, Charles Hutchinson, Peter MacCallum, Ajay Kakkar, F.D. Richard Hobbs, Stavros Petrou, Jeremy Dale, Christopher J. Poole, Anthony Maraveyas, and Mark Levine

JOURNAL OF CLINICAL ONCOLOGY

36 (20) (July 10 2018); 2017-2023



6-month cumulative VTE rate	Rivaroxaban (n=203)		Dalteparin (n=203)	
	Events	% (95% CI)	Events	% (95% CI)
Recurrent VTE*	8#	4 (2–9)	18‡	11 (7–16)

Number of patients at risk				
Dalteparin	203	171	139	115
Rivaroxaban	203	174	149	134

*One fatal PE in each arm; #including 2 patients with symptomatic PE and one patient with incidental PE; ‡including 2 [illegible] symptomatic PE and 6 patients with incidental PE

al, J Clin Oncol 2018;36:2017-23

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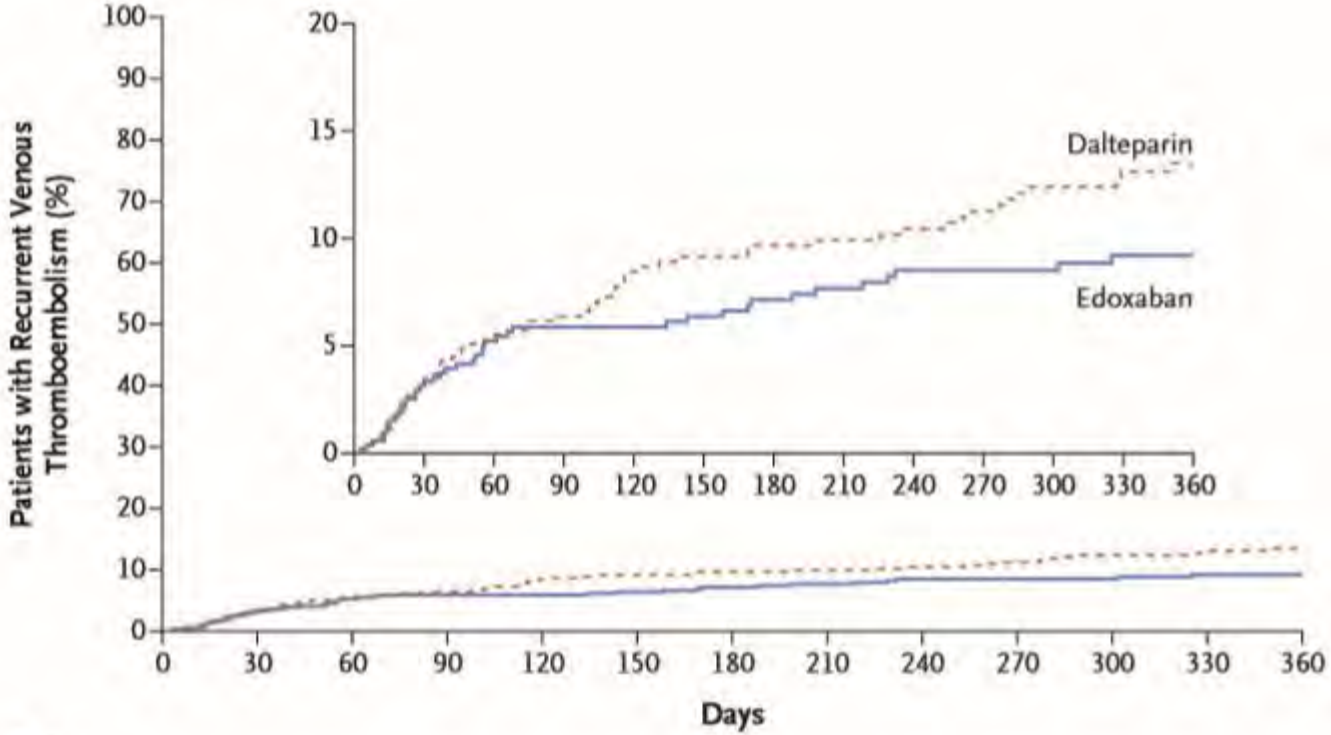
Edoxaban for the Treatment of Cancer-Associated Venous Thromboembolism

N Engl J Med 2018;378:615-24.

Gary E. Raskob, Ph.D., Nick van Es, M.D., Peter Verhamme, M.D., Marc Carrier, M.D., Marcello Di Nisio, M.D., David Garcia, M.D., Michael A. Grosso, M.D., Ajay K. Kakkar, M.B., B.S., Michael J. Kovacs, M.D., Michele F. Mercuri, M.D., Guy Meyer, M.D., Annelise Segers, M.D., Minggao Shi, Ph.D., Tzu-Fei Wang, M.D., Erik Yeo, M.D., George Zhang, Ph.D., Jeffrey I. Zwicker, M.D., Jeffrey I. Weitz, M.D., and Harry R. Büller, M.D., for the Hokusai VTE Cancer Investigators*

The NEW ENGLAND JOURNAL of MEDICINE



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RSEULTATS SELECT-D et HOKUSAI

No head to head comparison!

	select-d[1]		Hokusai VTE Cancer[2]	
	Dalteparin (n=203)	Rivaroxaban (n=203)	Dalteparin (n=524)	Edoxaban (n=522)
Recurrent VTE	11%	4%	8.8%	6.5%
Major	4%	6%	3.2%	5.6%
CRNM Bleedings	4%	13%	8.2%	12.3%

bleeding. Edoxaban was found to be noninferior to dalteparin. Over the first 6-month period, the recurrent VTE rate was 6.5% with edoxaban and 8.8% with dalteparin, but rates were 5.6% and 3.2% for major bleeding and 12.3% and 8.2% for CRNMB, respectively. Although there are limitations to between-study comparisons, the results of our trial are consistent with those of this study.

1 Young A et al, J Clin Oncol. 2018;36:2017-2023. 2 Raskob GE et al. Edoxaban for the Treatment of Cancer-Associated Venous Thromboembolism. N Engl J Med. 2018;378:615-624 – Supplementary ndix, Table S5: Clinical Outcomes during First Six Month-Study Period

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2016 ACCP Guidelines pour le traitement anti-thrombotique de la MTEV

	ACCP recommendation	Grade of recommendation
Initial anticoagulation		
Acute DVT or haemodynamically stable PE and no cancer	NOAC preferred to VKA	2B
	LMWH/VKA preferred to LMWH alone	2C
PE with hypotension	Thrombolytic therapy (systemic rather than catheter-directed unless bleeding risk is high)	2B (2C)
DVT or PE with cancer	LMWH suggested over NOAC or VKA	2C
Duration of anticoagulant therapy		
Proximal DVT or PE	3 months recommended over shorter duration	1B
First proximal DVT or PE provoked by surgery	3 months	1B
Unprovoked DVT or PE	Extended therapy if bleeding risk is low/moderate	2B
	3 months if bleeding risk is high	1B
DVT or PE associated with active cancer	Extended therapy recommended over 3 months' therapy	1B (2B if high bleeding risk)

Faible niveau de preuve scientifique, niveau 2

Présomption scientifique, niveau 1, 2

Kearon C *et al, Chest* 2016;149:315–352

Summary of Guidelines for the Treatment of CAT

	ISTH SSC 2018[1]	ASCO 2019[2]	ITAC 2019[3]	NCCN 2019[4]	ESC 2019[5]
Anticoagulant choice	NOACs (edoxaban and **rivaroxaban**) and LMWH are the preferred agents Choice dependent on the risk of bleeding (LMWH preferred in patients with a high risk of bleeding) and potential for DDIs	Initial anticoagulation (first 5–10 days): LMWH or **rivaroxaban** preferred Long-term (<6 months): LMWH, edoxaban or **rivaroxaban** (VKAs are acceptable alternatives for long-term therapy if LMWH/NOACs are not available) Extended therapy (≥6 months): LMWH, edoxaban or **rivaroxaban** or VKAs	Initial anticoagulation (first 5–10 days): LMWH, **rivaroxaban** or edoxaban following ≥5 days of parenteral anticoagulation Long-term (<6 months): LMWH or NOACs (to date evidence is only available for edoxaban and **rivaroxaban**) Extended therapy (≥6 months): LMWH or NOACs	Lists appropriate monotherapy/combined therapy options, including edoxaban, **rivaroxaban** and apixaban	Long-term for patients with PE and cancer (<6 months): LMWH are preferred over VKAs Edoxaban or **rivaroxaban** should be considered as an alternative to LMWH, with a word of caution for patients with GI cancer due to the increased risk of bleeding with NOACs
Duration of therapy	No recommendations provided	Extended therapy beyond 6 months can be considered for selected patients with active cancer	Treatment for a minimum of 6 months, following which termination or continuation of anticoagulation should be based on individual evaluation	Minimum 3 months. For non-catheter-associated DVT or PE indefinite anticoagulation is recommended while cancer is active, under treatment, or if risk factors for recurrence persist	Extended therapy beyond 6 months should be considered for an indefinite period or until the cancer is cured

1. Khorana AA *et al*, *J Thromb Haemost* 2018;16:1891–1894; 2. Key NS *et al*, *J Clin Oncol* 2019; doi:10.1200/JCO.19.01461; 3. Farge D *et al*, *Lancet Oncol* 2019;20:e566–e581;
4. NCCN guidelines v. 1. 2019. https://www.nccn.org/store/login/login.aspx?ReturnURL=https://www.nccn.org/professionals/physician_gls/pdf/vte.pdf [accessed 23 Oct 2019];
5. Konstantinides SV *et al*, *Eur Heart J* 2019;40:3453–3455

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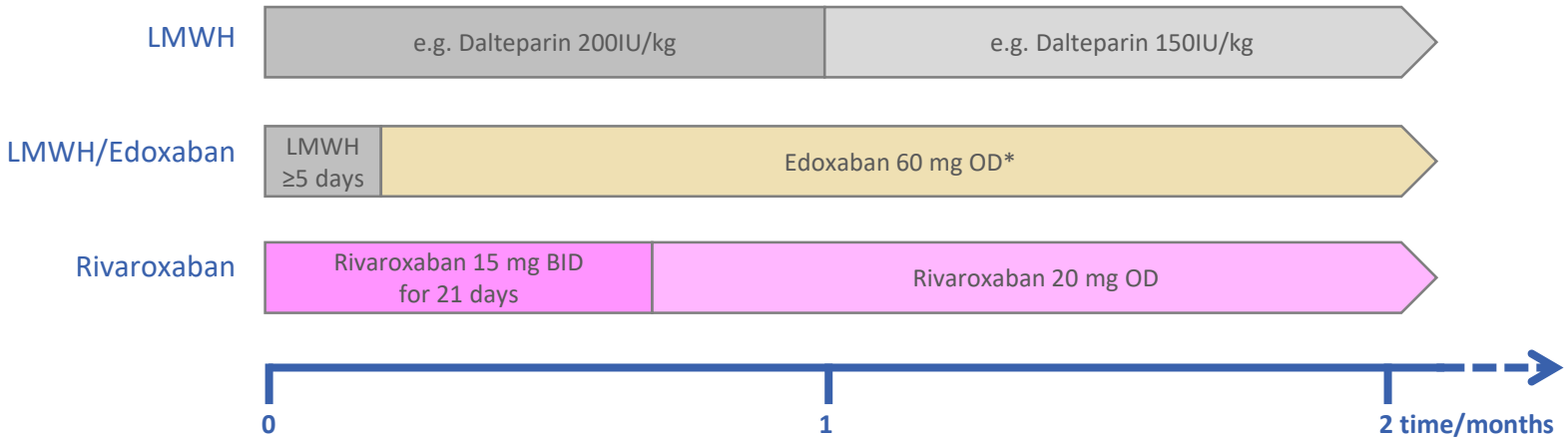
- Recommandations du SSC de l'ISTH suggèrent :

  usage de spécifiques AODs pour les patients avec cancer et un diagnostic de MTEV et à bas risque de saignement et sans interactions médicamenteuses avec le traitement habituel[2] :

  - LMWHs sont une alternative acceptable.
  - Actuellement, edoxaban and rivaroxaban sont les seuls AODs avec une preuve (basée sur une RCT) comparée avec LMWH chez les patients avec cancer

Khorana AA *et al*. Role of direct oral anticoagulants in treatment of cancer-associated venous thromboembolism: guidance from the SSC of the ISTH. J Thromb Heamost 2018;16:1891-4



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RISQUE HEMORRAGIQUE

Contrindications versus précautions en cas d'anticoagulation

1. Risque hémorragique
    - Hémorragie active (Ulcère, SNC)
    - Chirurgie récente (neurochirurgie)
    - Traumatisme important récent
    - HTA mal contrôlée
2. Insuffisance hépato-cellulaire
3. Insuffisance rénale
4. Thrombopénie sévère

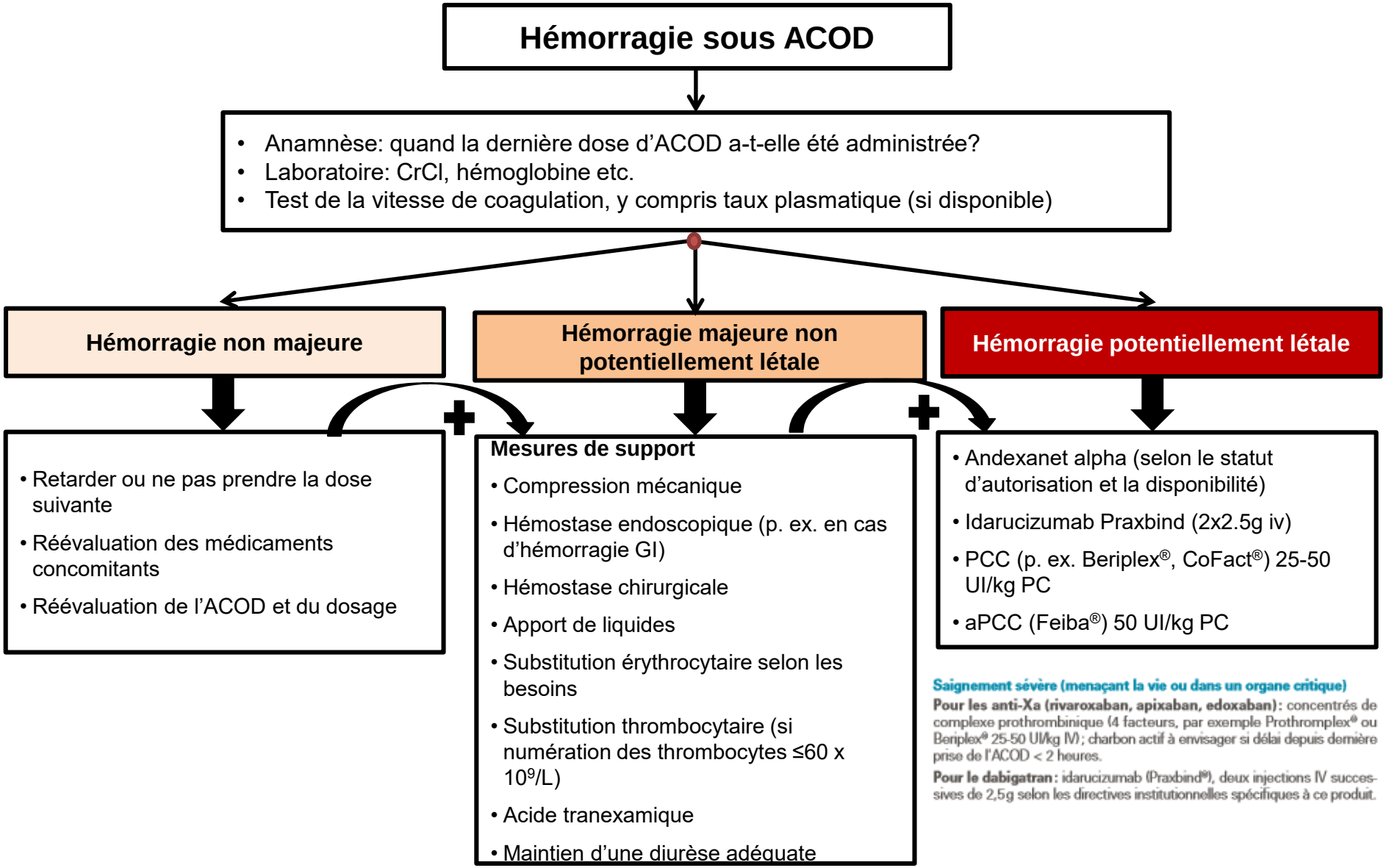
HAS-BLED

Points			Definition
1	H	Hypertension	Sys BP > 160
1 or2 (1pt each)	A	Abnormal Renal and/or liver function	dialysis/transplant cirrhosis/T. Bili 2x or AST/ALT 3x normal
1	S	Stroke	
1	B	Bleeding	previous bleed/predisposition
1	L	Labile INR	< 60% in therapeutic range
1	E	Elderly (> 65 yrs)	
1 or2 (1pt each)	D	Drugs or alcohol excess	antiplatelet or NSAID's

A score of ≥ 3 is considered "high risk"
ESC recommends "caution" using warfarin[1]

[1] *"ESC" Guidelines for the management of atrial fibrillation. 2011*

Prise en charge des hémorragies aiguës chez les patients traités par ACOD



Comment procéder en cas d'hémorragie et de prise d'AOD ?

Hémorragie mineure

→ Traitement symptomatique (p. ex. compression mécanique, application locale d'acide tranéxamique)

Hémorragie modérée ou sévère

→ Stopper la prise d'AOD jusqu'à ce que la situation se stabilise et qu'aucun risque de saignement ne subsiste

→ Envoyer le patient à l'hôpital

- Appliquer les mesures d'urgence
- Préciser quelle dose le patient a pris et à quel moment
- Dans les situations d'urgence, mesurer les paramètres de coagulation (TP/Quick, aPTT, test chromogénique de l'activité anti-Xa) et déterminer le taux plasmatique de rivaroxaban
- Procéder dans la mesure du possible à une hémostase chirurgicale, à une substitution volémique (y compris transfusion de plasma) et à une assistance circulatoire
- Envisager éventuellement l'utilisation d'acide tranéxamique ou de la desmopressine (DDAVP)
- Si ces mesures ne suffisent pas à contrôler le saignement, l'administration de concentré de complexe prothrombinique, FEIBA® ou de facteur VII activé (NovoSeven®) peut être envisagée

Prise en charge péri-interventionnelle*

En principe, nous ne proposons pas de relais avec de l'héparine, à l'exception des patients à très haut risque thrombotique (par ex.: MTEV < 3 mois, FA avec antécédent d'AIT ou d'AVC < 3 mois) et qui vont avoir une procédure à haut risque hémorragique.

Dans la phase aiguë d'une MTEV, d'un AIT ou d'un AVC (< 1 mois), le tableau ci-dessous ne s'applique pas et une stratégie personnalisée doit être discutée par une équipe multidisciplinaire.

Les délais proposés ci-dessous sont valables pour les **ACOD à dose thérapeutique**.

	Risque hémorragique faible	Risque hémorragique élevé		
Avant le geste	Pas de prise la veille au soir ni le matin de l'acte invasif [7]	Rivaroxaban Apixaban Edoxaban	Dernière prise[7] à J-3*	
		Dabigatran	ClCr C-G > 80 ml/min	Dernière prise[7] à J-3
			ClCr C-G 50-80 ml/min	Dernière prise[7] à J-4
			ClCr C-G < 50 ml/min	Dernière prise[7] à J-5
Après le geste	Reprise le soir de l'acte invasif (délai min de 6h) ou le lendemain matin	Anticoagulant à dose prophylactique au moins 6 heures après l'acte invasif, jusqu'à l'obtention d'une hémostase permettant la reprise d'un anticoagulant à dose thérapeutique		

Anesthésie neuraxiale et ponction lombaire*

Pour les ACOD à dose thérapeutique

Se référer aux délais d'arrêt proposés ci-dessus pour les interventions à risque hémorragique élevé. Envisager un dosage de l'activité spécifique du médicament avant le geste ou un arrêt à J-5 pour tous les ACOD si ClCr C-G < 50 ml/min.

Pour les ACOD à dose prophylactique

	Rivaroxaban, apixaban, edoxaban	Dabigatran
Délai entre la dernière dose et la ponction, la pose ou le retrait d'un cathéter	24 heures	36 heures
Délai entre la ponction, la pose ou le retrait d'un cathéter et la reprise de l'anticoagulation	6 heures (24 heures si ponction traumatique)	

* Propositions communes avec le Service d'anesthésiologie des HUG.

[7] Quelles que soient les doses et les modalités d'administration (1x/j matin ou soir, ou 2x/j matin et soir)

* Dans certains cas, une dernière prise le matin de J-2 peut être envisagée.

MERCI DE VOTRE ATTENTION

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