

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)

Young AM et al, Journal of Clinical Oncology 2018

Background

- VTE in cancer is a major challenge
- Cancer patients are at increased risk of recurrent VTE and major bleeding on anticoagulant therapy¹
- LMWH is the recommended standard for treatment and prevention of recurrent VTE in cancer patients
- Direct oral anticoagulants (DOACs) are recommended for the management of patients with VTE *without* cancer
- Limited data for DOACs in patients with cancer-associated thrombosis

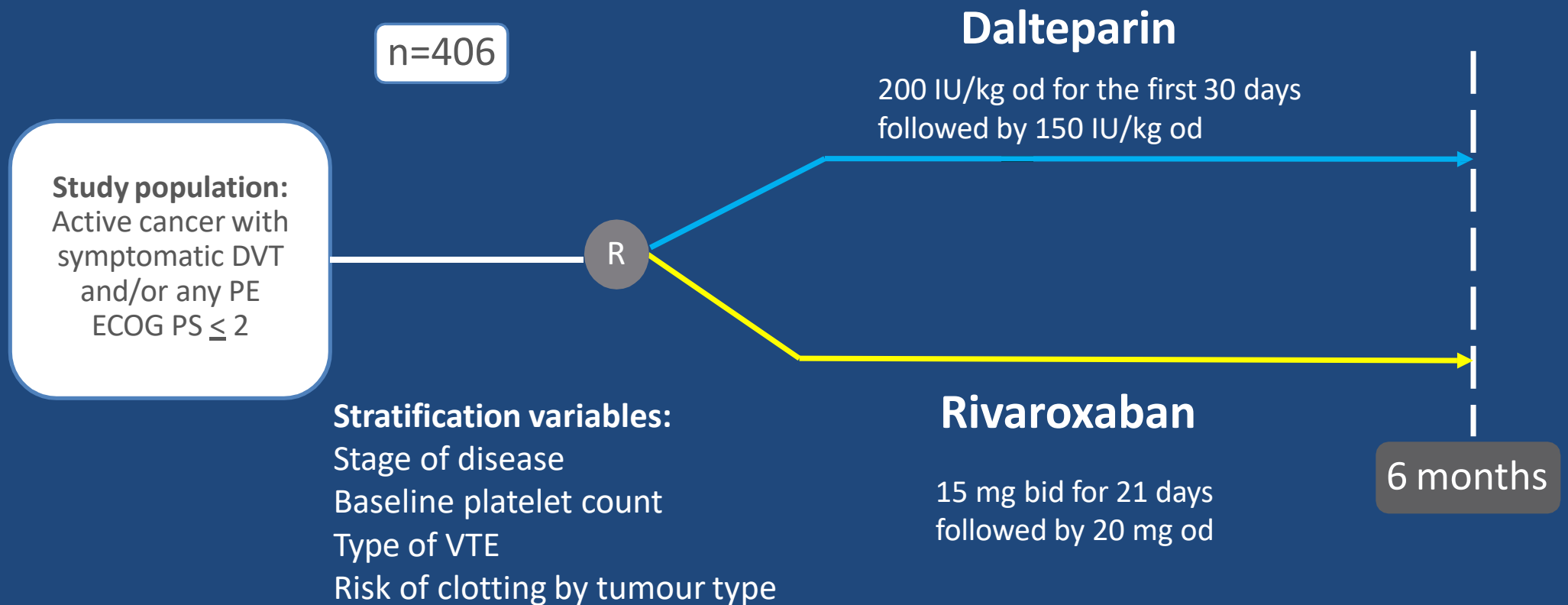
¹Hutten et al. *Journal of Clinical Oncology* 2000; 18, 3078-3083

Main research objectives

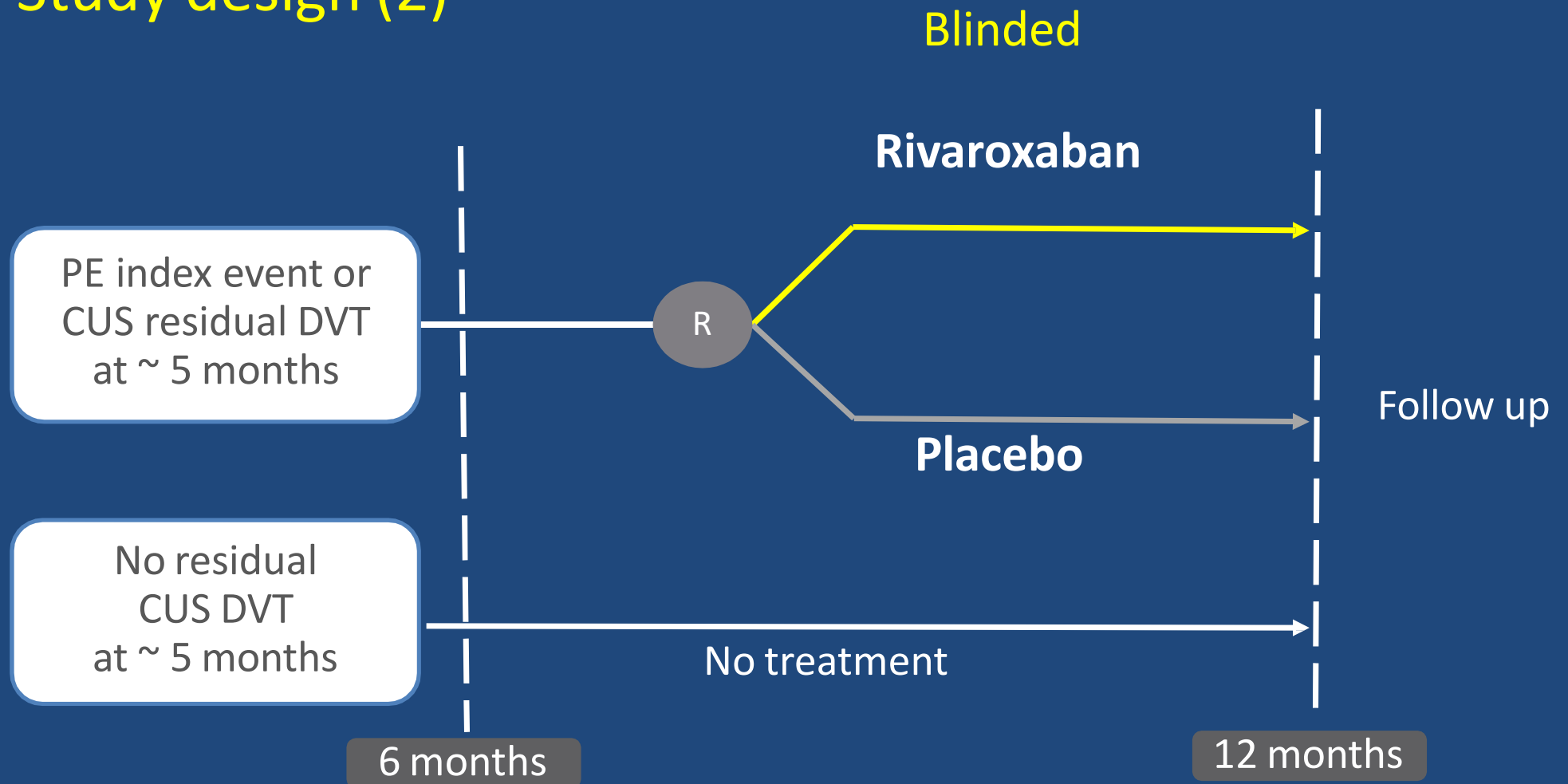
- **To assess VTE recurrence in cancer patients with a first VTE, treated with rivaroxaban or dalteparin**
- To assess rates of major and clinically relevant non-major bleeding
- To assess extended anticoagulation treatment beyond 6 months in selected patients

Study design (1)

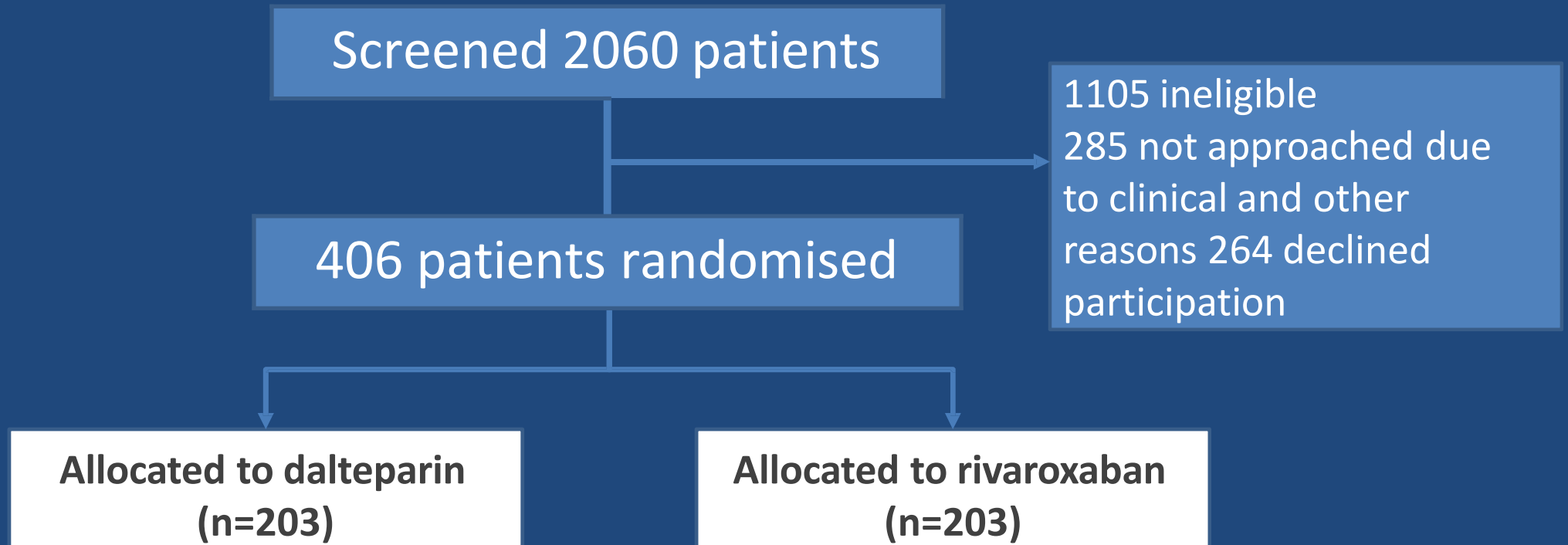
Prospective, randomised, open-label, multicentre pilot phase III



Study design (2)



Recruitment



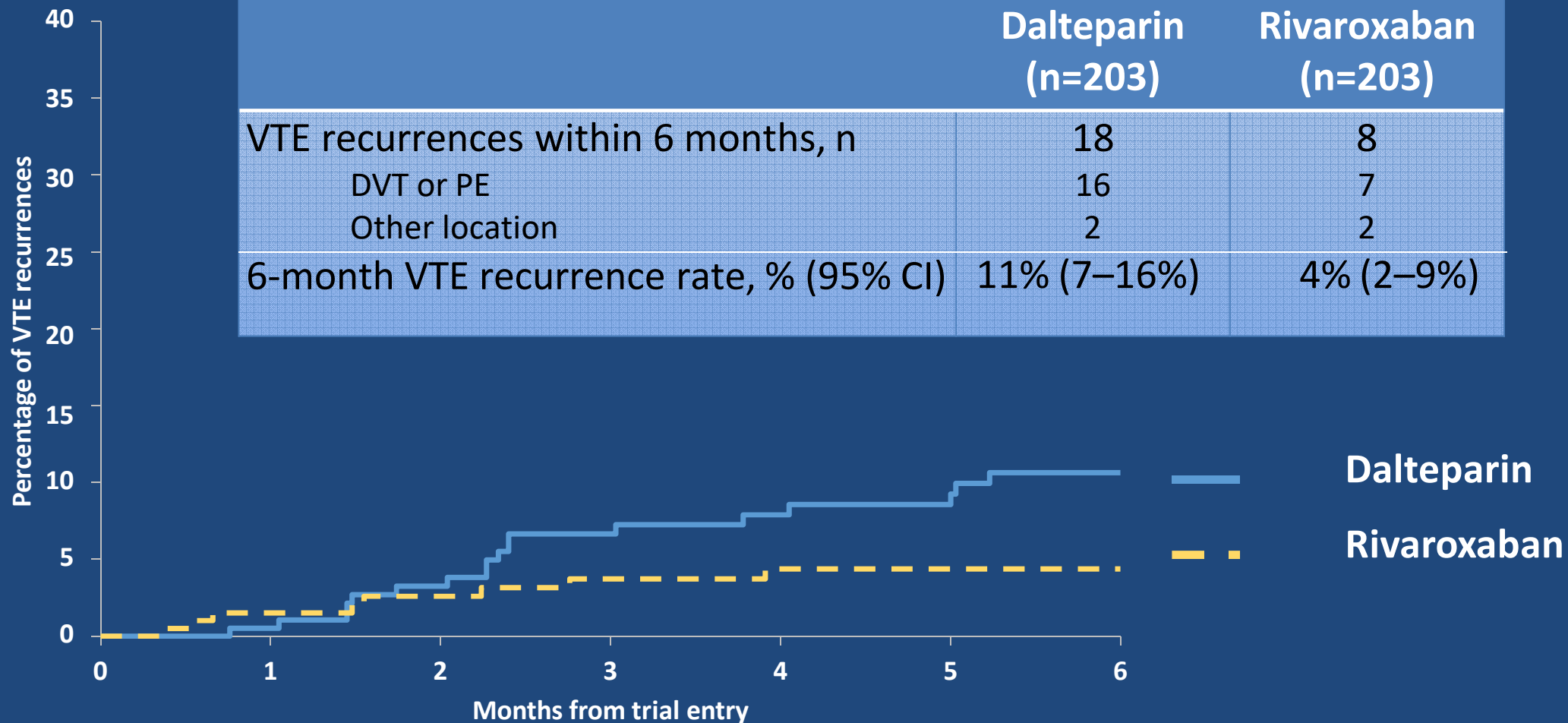
Baseline characteristics

Factor	Dalteparin % (n=203)	Rivaroxaban % (n=203)
Age: years, median (range)	67 (34–87)	67 (22–87)
Gender: male	48	54
Stage of Cancer: - metastatic	58	58
ECOG PS: - 0,1	77	73
- 2	21	26
Qualifying VTE: - symptomatic VTE	48	47
- incidental PE	52	53

Primary tumour type

	Dalteparin, % (n = 203)	Rivaroxaban, % (n = 203)
Colorectal	23	27
Lung	12	11
Breast	10	10
Ovarian	9	6
Pancreatic	5	9
Lymphoma	6	5
Esophageal/gastro-esophageal	9	5
Prostate	4	7
Bladder	2	5
Other	23	21

VTE recurrence



Numbers at Risk:

Dalteparin	203	171	139	116
Rivaroxaban	203	174	149	134

Bleeding - number of patients (%)

Category	Dalteparin (n=203)	Rivaroxaban (n=203)
Major*	6 (3%)	11 (5%)
Clinically relevant non-major	7 (3%)	25 (12%)

*1 fatal bleeding event in each arm

Most major bleeding events were gastrointestinal bleeding; no CNS bleeds

Most CRNMBs were gastrointestinal or urological

Overall survival

	Dalteparin	Rivaroxaban
6-months overall survival, % (95% CI)	70% (63–76%)	75% (69–81%)

- Overall 104 (26%) patients died
- 92 (88%) died from progressive cancer
- 2 (2%) fatal PEs

Conclusions

- The results of the trial provide evidence that rivaroxaban is an effective alternative to LMWH for the treatment of VTE in cancer
- Rivaroxaban reduced the rate of recurrent VTE compared with LMWH, but at the cost of more bleeding
- Rivaroxaban should be used with particular caution in patients with esophageal cancer
- In terms of therapeutic decision making, a patient's preference for a specific anticoagulant drug is based on a careful discussion between patient and physician about the benefits and risks of the treatment alternatives