

**Are new anticoagulants a  
safe and reasonable  
alternative to low molecular  
weight heparins?**

**My task: to defend YES**

I always greatly respect nobility



Sir Noble, my opponent

# Safe?

There are three perspectives for answering the question

- The skin
- The risk of recurrent VTE
- The risk of serious bleeding

# Skin hematoma





**Are the new anticoagulants a  
safe and reasonable alternative  
to low molecular weight  
heparins?**

For the skin: yes

# Safe?

There are three perspectives for answering the question

- The skin
- **The risk of recurrent VTE**
- The risk of serious bleeding

A Randomized, Open-Label, Blinded Outcome Assessment  
Trial Evaluating the Efficacy and Safety of  
LMWH/Edoxaban versus Dalteparin  
For Venous Thromboembolism Associated with Cancer

## **Hokusai VTE - Cancer Study**

G Raskob, N van Es, P Verhamme, M Carrier,  
M Di Nisio, D Garcia, M Grosso, A Kakkar, M Kovacs,  
M Mercuri, G Meyer, A Segers, M Shi, T Wang, E Yeo,  
G Zhang, J Zwicker, J Weitz, H Buller

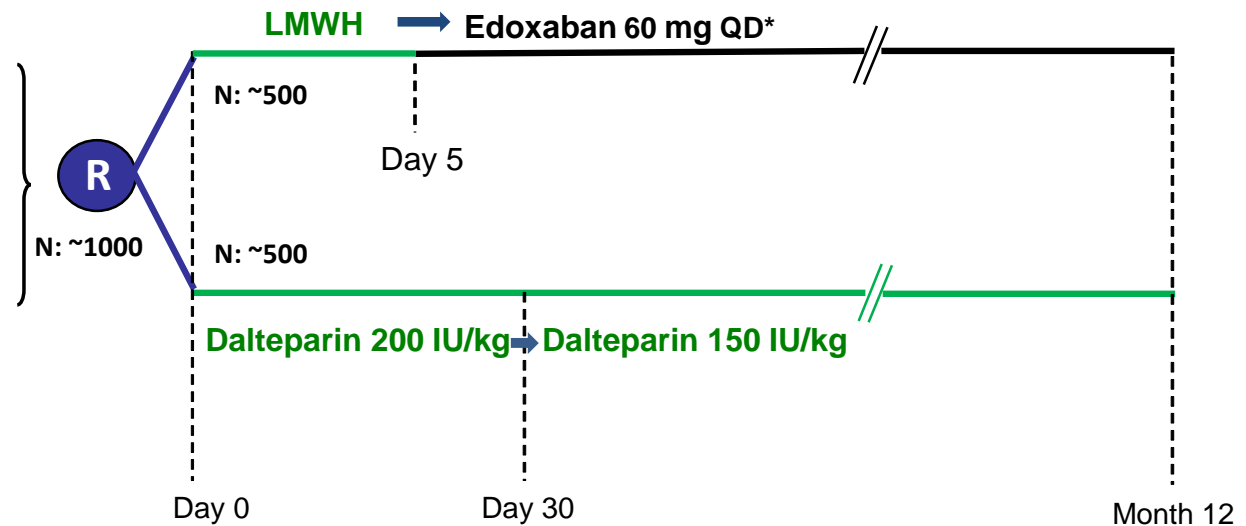
on behalf of the Hokusai-VTE Cancer Investigators

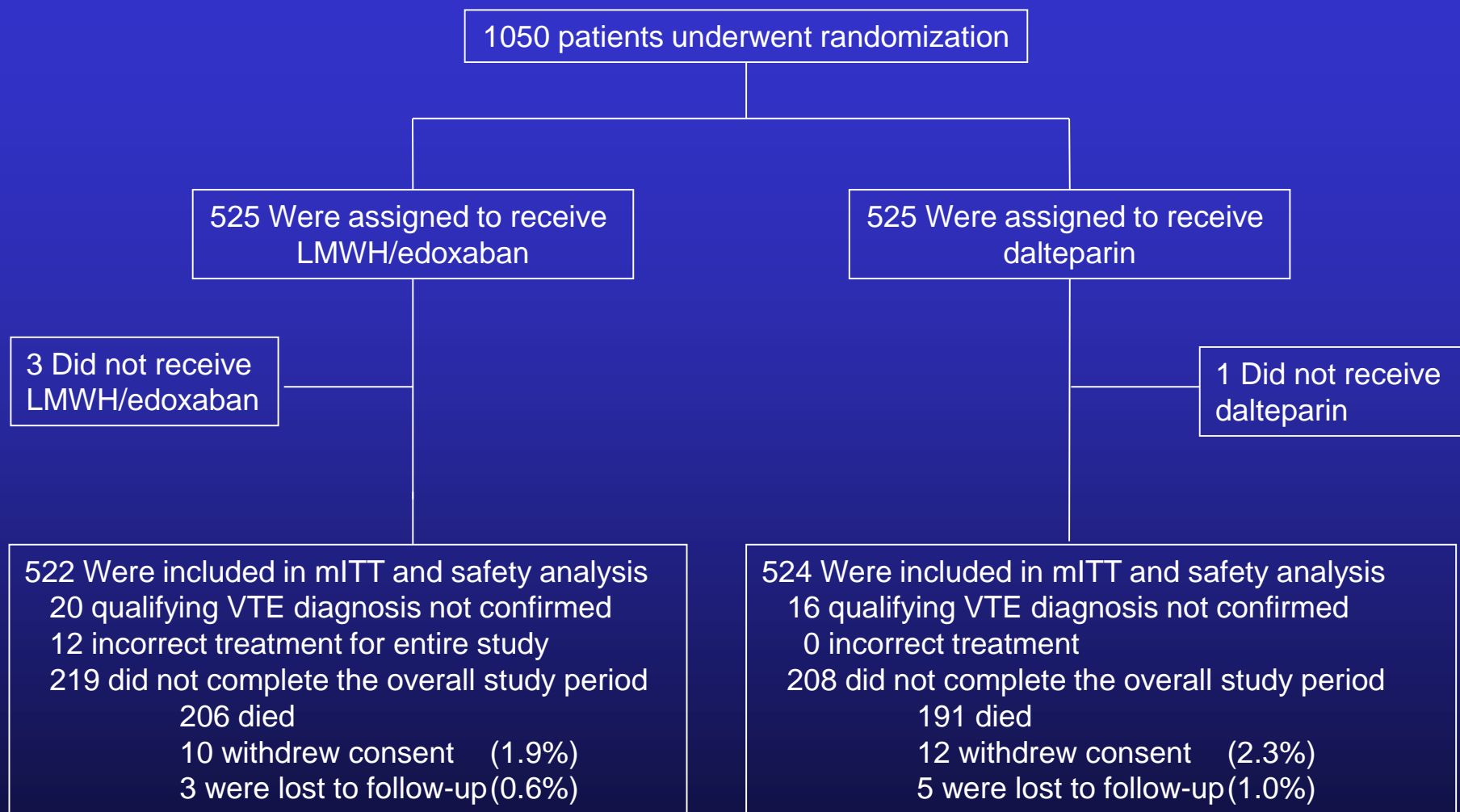


# Hokusai VTE - Cancer Study Design

## Objectively Confirmed VTE

- Stratified randomization for
  - Bleeding Risk
  - Dose Adjustment
- PROBE design
- 114 sites North America, Europe, Australia, New Zealand



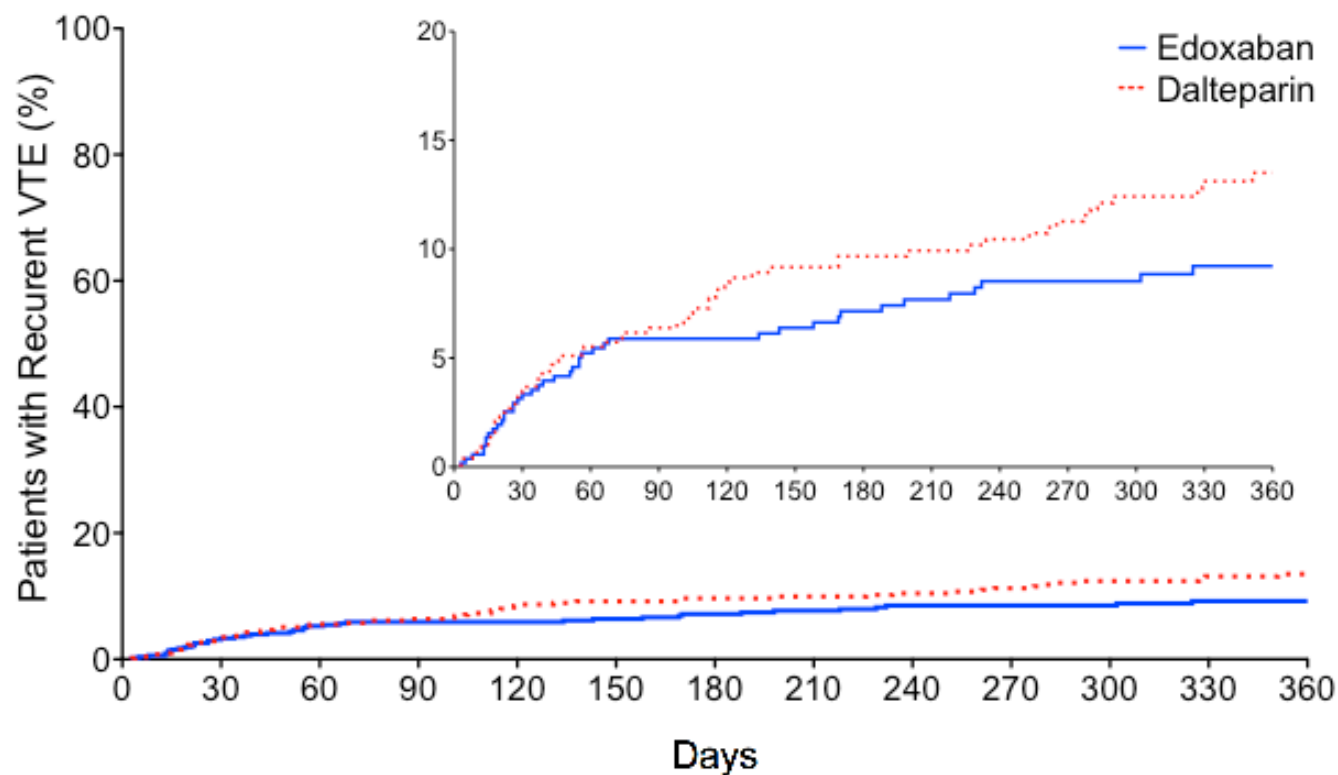


# Primary Outcome

**First recurrent VTE or Major bleeding event**

Recurrent VTE			
	Edoxaban (N=522)	Dalteparin (N=524)	Risk difference
All events	34 (6.5%)	54 (10.3%)	-3.8 (-7.1 - -0.4)
Fatal	0	0	
DVT only	13	30	
Symptomatic	22 (65%)	40 (74%)	

# Recurrent VTE



## No. at Risk:

Edoxaban:	522	480	437	415	395	370	356	340	320	307	281	245	168
Dalteparin:	524	488	452	423	389	370	358	348	333	321	282	246	174

**Are the new anticoagulants a  
safe and reasonable alternative  
to low molecular weight  
heparins?**

For recurrent VTE: yes

# Safe?

There are three perspectives for answering the question

- The skin
- The risk of recurrent VTE
- **The risk of serious bleeding**

# Primary outcome

First recurrent VTE or Major bleeding event

Major Bleeding			
	Edoxaban (N=522)	Dalteparin (N=524)	Risk difference
All events	33 (6.3%)	17 (3.2%)	3.1 (0.5 – 5.7)
Fatal	0	2	
Intracranial	2	4	
GI-upper	17	3	
GI-lower	3	3	

# Severity of Major Bleeding

Severity	Edoxaban (33 major bleeds)	Daltaparin (17 major bleeds)
1	0	0
2	21 (64%)	5 (29%)
3	12 (36%)	11 (65%)
4	0	1 (6%)
3 or 4	12 of 522 (2.3%)	12 of 524 (2.3%)



**Are the new anticoagulants a  
safe and reasonable alternative  
to low molecular weight  
heparins?**

For major bleeding: no, but for severe  
bleeds: yes

Hence, but much to my regret given my respect for Sir Noble, the conclusion of my assessment is that DOACs are a safe and more than reasonable alternative to LMWH in CAT

