

The background of the slide is a reproduction of the famous Japanese woodblock print 'The Great Wave off Kanagawa' by Katsushika Hokusai. The image depicts a massive, curling blue wave with white foam, about to crash over a small boat. In the distance, the snow-capped Mount Fuji is visible under a pale sky. The overall style is characteristic of Edo-period ukiyo-e art.

**Edoxaban for the
Treatment of Acute
Symptomatic Venous
Thromboembolism the
HOKUSAI-VTE study**

*On behalf of the HOKUSAI -VTE
Investigators*

Baseline characteristics

	Edoxaban (N=4118)	Warfarin (N=4122)
Mean age, years (SD)	56 (16)	56 (16)
Male gender, n (%)	2360 (57)	2356 (57)
Qualifying diagnosis, n (%)		
DVT	2468 (60)	2453 (60)
PE	1650 (40)	1669 (40)
Clinical presentation and risk factors, n (%)		
Unprovoked	2713 (66)	2697 (65)
Cancer	378 (9)	393 (10)
Previous VTE	784 (19)	736 (18)
Dose of 30 mg (e.g. 60 kg, CrCl 30-50 ml/min), n (%)	733 (18)	719 (17)

Efficacy outcomes

	Edoxaban (N=4118)	Warfarin (N=4122)	Hazard ratio (95% CI)	P Value
First recurrent VTE - no. (%)				
Overall study period	130 (3.2)	146 (3.5)	0.89 (0.70-1.13)	<0.001 Noninferiority
Patients with index DVT*	83 (3.4)	81 (3.3)	1.02 (0.75-1.38)	
Patients with index PE**	47 (2.8)	65 (3.9)	0.73 (0.50-1.06)	
On-treatment period	66 (1.6)	80 (1.9)	0.82 (0.60-1.14)	<0.001 noninferiority)
Subgroup severe PE (RV dysfunction ProBNP) n/N (%)	15/454 (3.3)	30/485 (6.2)	0.52 (0.28 to 0.98)	

* Denominator is number of patients with index DVT: 2468 and 2453 in edoxaban and warfarin group respectively

** Denominator is number of patients with index PE : 1650 and 1669 in edoxaban and warfarin group respectively

Safety outcomes

	Edoxaban (N=4118)	Warfarin (N=4122)	Hazard ratio (95% CI)	P Value
First major or clinically relevant non major – no. (%)	349 (8.5)	423 (10.3)	0.81 (0.71-0.94)	0.004 superiority
Major – no. (%)	56 (1.4)	66 (1.6)	0.84 (0.59-1.21)	0.35 superiority
Fatal	2 (<0.1)	10 (0.2)		
Intracranial	0	6 (0.1)		
Non-Fatal in Critical Sites	13 (0.3)	25 (0.6)		
Intracranial	5 (0.1)	12 (0.3)		
Non-Fatal in Non-Critical Sites	41 (1.0)	33 (0.8) †		
Clinically Relevant Non-Major – no. (%)	298 (7.2)	368 (8.9)	0.80 (0.68-0.93)	0.004 superiority

† some patients have more than 1 bleeding

Conclusion

(LMW)heparin/edoxaban regimen

- non-inferior to standard therapy for preventing recurrent VTE**
- consistent efficacy in patients with DVT and PE**
- clinically significant reduction in recurrent VTE in right ventricular dysfunction subgroup**
- less clinically relevant bleeding**
- constant effect over center TTR quartiles**
- dose adaptation (30 mg) effective and safer**

Attractive regimen for full spectrum of VTE- patients