

Supplementary materials

Title: Real-World Safety and Effectiveness of a 4-Factor Prothrombin Complex Concentrate in Japanese Patients Experiencing Major Bleeding: A Post-Marketing Surveillance Study

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S-Table 1 Patient characteristics at baseline (Overall study populations and VKA treatment)

Characteristics		Overall study populations (n=1381)	With VKA treatment (n=1271)
Sex, male, n (%)		848 (61.4)	776 (61.1)
Age, years, mean (SD)		74.0 (14.2)	74.3 (14.0)
Age group, years, n (%)	<65	236 (17.1)	213 (16.8)
	≥ 65 to <75	347 (25.1)	315 (24.8)
	≥ 75 to <85	507 (36.7)	469 (36.9)
	≥ 85	290 (21.0)	273 (21.5)
Weight, kg, mean (SD)		56.0 (12.9)	56.0 (12.9)
BMI, mean (SD)		21.9 (3.9)	21.9 (3.9)
Comorbidity, n (%)		1126 (81.5)	1040 (81.8)
Dose of 4F-PCC, IU/kg (SD)		28.4 (9.7)	28.5 (9.4)
Baseline PT-INR, median (minimum, maximum)	Median	2.6 (0.92-27.11)	2.6 (0.92-7.11)
Distribution of baseline PT-INR, n (%)	<1.6	134 (9.7)	78 (6.1)
	1.6-<2.0	153 (11.1)	137 (10.8)
	2.0-<4.0	727 (52.6)	705 (55.5)
	4.0-6.0	140 (10.1)	137 (10.8)
	6.01-<10.0	94 (6.8)	89 (7.0)
	≥10.0	57 (4.1)	56 (4.4)

	Not available	76 (5.5)	69 (5.4)
Reasons for the utilization of VKA, n (%)	Atrial fibrillation		619 (48.7)
	Valvular heart disease		210 (16.5)
	Cerebral infarction		105 (8.3)
	VTE		79 (6.2)
	Other		231 (18.2)
	Not available		107 (8.4)

BMI, body mass index; IU, international units; PT-INR, prothrombin time international normalized ratio; SD, standard deviation; VKA, vitamin K antagonist; VTE, venous thromboembolism.

S-Table 2 Types of 31 TEEs of 20 patients who experienced TEEs

		31 TEEs
Type of TEE, n	Cerebral infarction	6
	Embolic stroke	3
	Deep vein thrombosis	3
	Haemorrhagic cerebral infarction	2
	Thrombosis in device	2
	Carotid arterial embolus	1
	Cerebral artery embolism	1
	Hemiplegia	1
	Monoplegia	1
	Carotid artery occlusion	1
	Embolic cerebral infarction	1
	Myocardial infarction	1
	Intracardiac thrombus	1
	Embolism arterial	1
	Iliac artery embolism	1
	Venous thrombosis limb	1
	Arterial occlusive disease	1
	Femoral artery embolism	1
	Pulmonary artery thrombosis	1
Renal infarct	1	

TEEs, Thromboembolic events.