

## Periprocedural management of patients on edoxaban undergoing pacemaker and cardiac monitoring device implantation - a sub-analysis of the EMIT-AF/VTE study

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**Background:** Periprocedural management of patients on direct oral anticoagulants undergoing insertion of permanent pacemaker (PPM) and cardiac monitoring devices is mainly based on pharmacokinetic considerations, clinical experience, and expert opinion.

**Purpose:** To describe the characteristics, periprocedural management, and events of edoxaban patients undergoing implantation of PPM/monitoring devices.

**Methods:** From the global EMIT-AF/VTE registry, which includes edoxaban patients undergoing any diagnostic or therapeutic procedures, those with PPM/cardiac monitoring device implantation were observed from five days prior to 30 days post procedure. Events documented included the incidence of International Society on Thrombosis and Haemostasis defined Major Bleeding, Clinically Relevant Non-Major Bleeding (CRNMB), acute thromboembolic events (ATE) and perioperative edoxaban interruption times.

**Results:** PPM or invasive cardiac monitoring devices were implanted in 136 patients. Conformance with European Heart Rhythm Association Guidance for the interruption of anticoagulation was variable: of the cardiac monitoring patients, 62.5% had interruption of treatment, whereas in PPM procedures 23.4% had no interruption. One case of CRNMB and two cases of minor bleeding were documented. All bleedings seem non procedure-related since they occurred > three days post procedure. There were no ATE.

**Conclusions:** Relevant complications for edoxaban treated patients undergoing PPM or invasive cardiac monitoring procedures were rare. This population of patients is apparently well managed in routine practice, but further investigation of risk factors is justified.

**Table:** Patient characteristics

Parameter	All subjects N = 136	All pacemaker N = 128	Insertion first pacemaker N = 89	Change pacemaker N = 39	Monitoring device N = 8
Age, mean (SD)	75.1 (10.1)	75.0 (10.3)	75.7 (9.9)	73.5 (11.2)	76.3 (4.3)
Male, n (%)	85 (62.5)	83 (64.8)	57 (64.0)	26 (66.7)	2 (25.0)
BMI, mean (SD)	27.1 (5.5)	27.2 (5.6)	27.2 (6.0)	27.3 (4.5)	25.2 (4.3)
AF, n (%) <sup>‡</sup>	135 (99.3)	127 (99.2)	89 (100.0)	38 (97.4)	8 (100.0)
VTE, n (%) <sup>‡</sup>	3 (2.2)	3 (2.3)	1 (1.1)	2 (5.1)	0
CrCL, mean (SD)	63.8 (26.4)	64.1 (26.7)	62.3 (26.2)	68.3 (27.9)	58.9 (21.8)
CrCL, ≤50, n (%)	43 (31.6)	41 (32.0)	33 (37.1)	8 (20.5)	2 (25.0)
HAS-BLED Score, mean (SD)	2.0 (1.2)	1.9 (1.2)	1.9 (1.0)	2.1 (1.6)	2.6 (0.5)
CHA <sub>2</sub> DS <sub>2</sub> -VASc Score, mean (SD)	3.7 (1.6)	3.7 (1.6)	3.7 (1.5)	3.8 (1.9)	3.1 (0.6)
Edoxaban 30 mg/day, n (%)	49 (36.0)	46 (35.9)	32 (36.0)	14 (35.9)	3 (37.5)
Edoxaban 60 mg/day, n (%)	86 (63.2)	81 (63.3)	56 (62.9)	25 (64.1)	5 (62.5)

AF, atrial fibrillation; BMI, body mass index; CrCL, creatinine clearance; VTE, venous thromboembolism. <sup>‡</sup>Two patients had both AF and VTE.