

Tromboembolismo venoso: aspetti clinici e diagnostici

CLINICAL SAFETY AND MONITORING OF APIXABAN IN HEMODIALYSIS PATIENTS: A PROSPECTIVE STUDY

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Background and Aims. The use of direct oral anticoagulants (DOACs) in patients with end-stage renal disease (ESRD) on dialysis remains controversial due to bleeding concerns. Dialysis patients have been excluded from randomized clinical trials, and data in this setting are limited. Among DOACs, apixaban appears to have the most favorable profile in this population. We aimed to describe our clinical experience with apixaban in hemodialysis patients, focusing on drug levels, safety, and clinical outcomes.

Methods. We conducted a prospective analysis of hemodialysis patients receiving apixaban 2.5 mg twice daily for atrial fibrillation (AF) or venous thromboembolism (VTE). Apixaban plasma levels (via anti-Xa calibrated assay) were measured at trough (12 hours after drug administration) and peak (4 hours after drug administration) on dialysis days and, when feasible, on non-dialysis days after 10–15 days of treatment. Data included demographic and clinical characteristics, indication for anticoagulation, hemoglobin, and renal function. At follow-up visits scheduled every 6 months, bleeding events (major and clinically relevant non-major, according to ISTH criteria), thrombotic and cardioembolic events, and all-cause mortality were recorded.

Results. Between February 2025 and April 2026, 8 patients (F/M 6/2) were included; median age was 77 years (IQR 68–81). Four patients had AF and 4 VTE. On dialysis days, apixaban levels measured after a median of 12 days from treatment initiation were within the therapeutic range at trough in 6 patients (75%) and at peak in 3 (37.5%); in the remaining patients, levels were slightly elevated. Measurements on non-dialysis days (3 patients) were within range in two (both peak and trough) and slightly increased in one. Laboratory parameters and apixaban levels are reported in Table 1. During a median follow-up of 6 months (IQR 3–7), one major bleeding event occurred (hematemesis with a hemoglobin drop of 2.0 g/dL due to a gastric polyp) in a patient with prior VKA-related bleeding. The incidence rate of bleeding in our cohort was 0.27 events/person-year (IC95%: 0.07 – 1.49 events/person-year). No cardioembolic or thromboembolic events were observed. One death occurred, unrelated to cardioembolic or thromboembolic events or bleeding.

Conclusions. In this small cohort of hemodialysis patients, apixaban appeared safe and effective. Plasma levels were mostly within the therapeutic range, suggesting that, with careful monitoring, apixaban may represent a viable option in this complex clinical setting. Larger studies are needed to confirm pur findings in this high-risk population.

	Pt. 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt. 6	Pt. 7	Pt. 8	Median (IQR)	Therapeutic range
Age (years)	93	67	69	67	85	77	81	77	77 (69 – 81)	-
Sex (M/F)	F	F	F	M	F	F	M	F		-
VTE/AF	AF	AF	TEV	TEV	AF	AF	TEV	TEV		-
Months FU in DOAC	3	6	14	7	8	3	1	5	6 (3 – 7)	-
Hb (g/dL)	9.1	11.5	11.4	11.4	11.4	11.0	12	14.2	11.4 (11.3 – 11.6)	-
Creatinine (mg/dL)	7.5	8	10	10	7.56	5.82	3.5	7.44	7.5 (7 – 8.5)	-
Urea (mg/dL)	80	194	167	102	146	143	90	148	144 (99 – 152)	-
Apixaban dialysis trough (ng/mL)	96.8	139	33	43	166	68	46	49	59 (45 – 107)	**11 – 90 ng/mL**
Apixaban dialysis peak (ng/mL)	211	184	193	77	209	69	**96**	85	140 (83 – 197)	**30 – 153 ng/mL**
Apixaban no-dialysis trough (ng/mL)	-	-	104	58	-	47	-	-	-	**11 – 90 ng/mL**
Apixaban no-dialysis peak (ng/mL)	-	-	176	74	-	73	-	-	-	**30 – 153 ng/mL**
VTE/cardioembolism	0	0	0	0	0	0	0	0	-	-
Bleeding	0	0	0	0	1	0	0	0	-	-
Death	1	0	0	0	0	0	0	0	-	-