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Introduction and Objective

Clotting during hemodialysis occurs when blood comes in contact with the extracorporeal circuit (ECC) consisting of the blood set and dialyser. To optimize anticoagulation during hemodialysis, targeting the activated partial thromboplastin time (aPTT) to 1.5-2.5 is recommended(1,2). The VIVIA Hemodialysis System, a novel home hemodialysis (HHD) system, allows up to 30 *in-situ* non-chemical re-uses of the ECC, decreasing burden of treatment and, thus, enables more patients to dialyse at home. The studies aim to characterize the anti-coagulation profile of extended use in the VIVIA HHD System.

Methods

Extended use of the ECC was studied in two clinical trials. The First-in-man study included 22 patients on 4 hour HD, 4X per week for 8 weeks. The Extended- duration study involved 17 patients who received HD 8 hours at night 3X per week for 6 weeks. Unfractionated heparin (UFH) was administered as a bolus followed by hourly infusion. aPTT was measured at baseline (Pre), after initial infusion (Inf) and at the end of treatment (End). aPTT ratio was calculated as: Inf aPTT/Pre aPTT (InfR) and End aPTT/Pre (EndR). Extended use was assessed by ECC appearance, presence of clotting, urea reduction ratio (URR) and dialyzer clearance.



Results

Characteristic	First-in-man study (n = 22)	Extended-duration study (n = 17)
Mean age, years (SD)	50.9 (9.5)	54.9 (14.2)
Female, n (%)	10 (45.5)	6 (35.3)
Mean target dry weight, kg (SD)	80.2 (16.8)	81.7 (17.5)
Mean time since first dialysis treatment, years	12.0 (7.4)	9.6 (8.2)
Cause of ESRD (n(%))		
Diabetic nephropathy	4(18.2)	6(35.3)
Hypertension	11(50.0)	0(0)
Glomerulonephritis	2(9.1)	6(35.3)
Polycystic kidney disease	3(13.6)	0(0)
Other	2(9.1)	5(29.4)

Table 1. Baseline patient characteristics and treatment parameters

Characteristic	First-in-man study (n = 22)	Extended-duration study (n = 17)
Prestudy prescription		
Mean treatment time/session, hours (SD)	3.48 (0.4)	7.3 (0.6)
Treatment frequency/week, n	3	3
Mean blood flow rate, mL/min (SD)	473 (43)	302 (22)
Mean dialysate flow rate, mL/min (SD)	700 (126)	500 (61)
Mean heparin bolus, units (SD)	2175 (2759)	1324 (683)
Mean heparin infusion, units/hour (SD)	815 (882)	935 (453)
In-study prescription		
Mean treatment time/session, hours (SD)	3.9 (0.2)	7.0 (0.6)
Treatment frequency/week, n	4	3
Mean blood flow rate, mL/min (SD)	358 (21)	293 (23)
Mean dialysate flow rate, mL/min (SD)	395 (9)	318 (27)

Table 2. Baseline and in-treatment study parameters

FIRST-IN-MAN STUDY

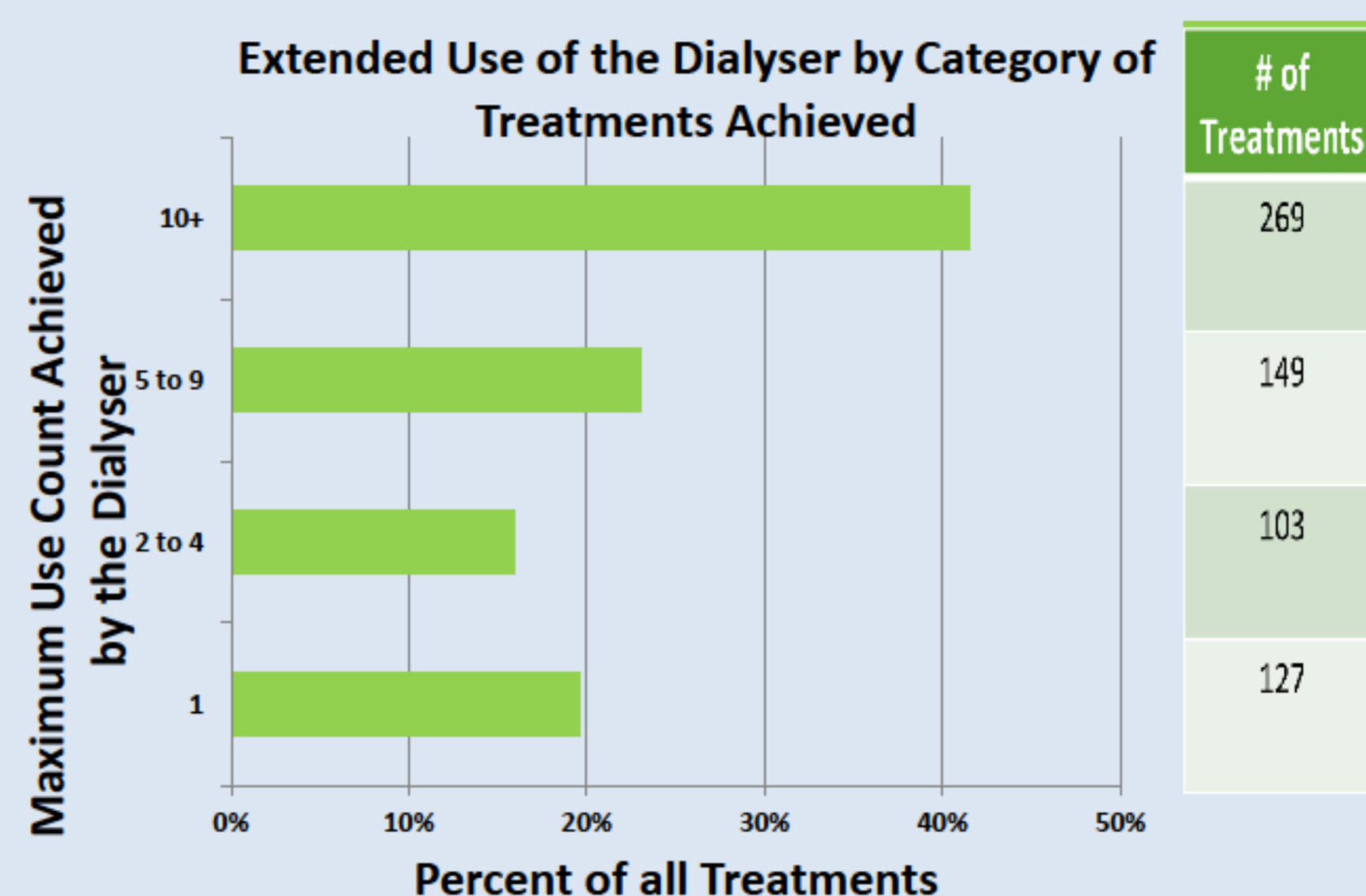


Figure 1. Percent of extended use achieved

Reason for ECC Change	Percent (%)
Physical Appearance	67.3
Study End	10.1
Unknown	6.7
Device Last Use	4.3
Clotting	2.9
Clearance Alert	1.4
Miscellaneous	2.4
Device Issue	1.9

Table 3. Reasons for ECC Change

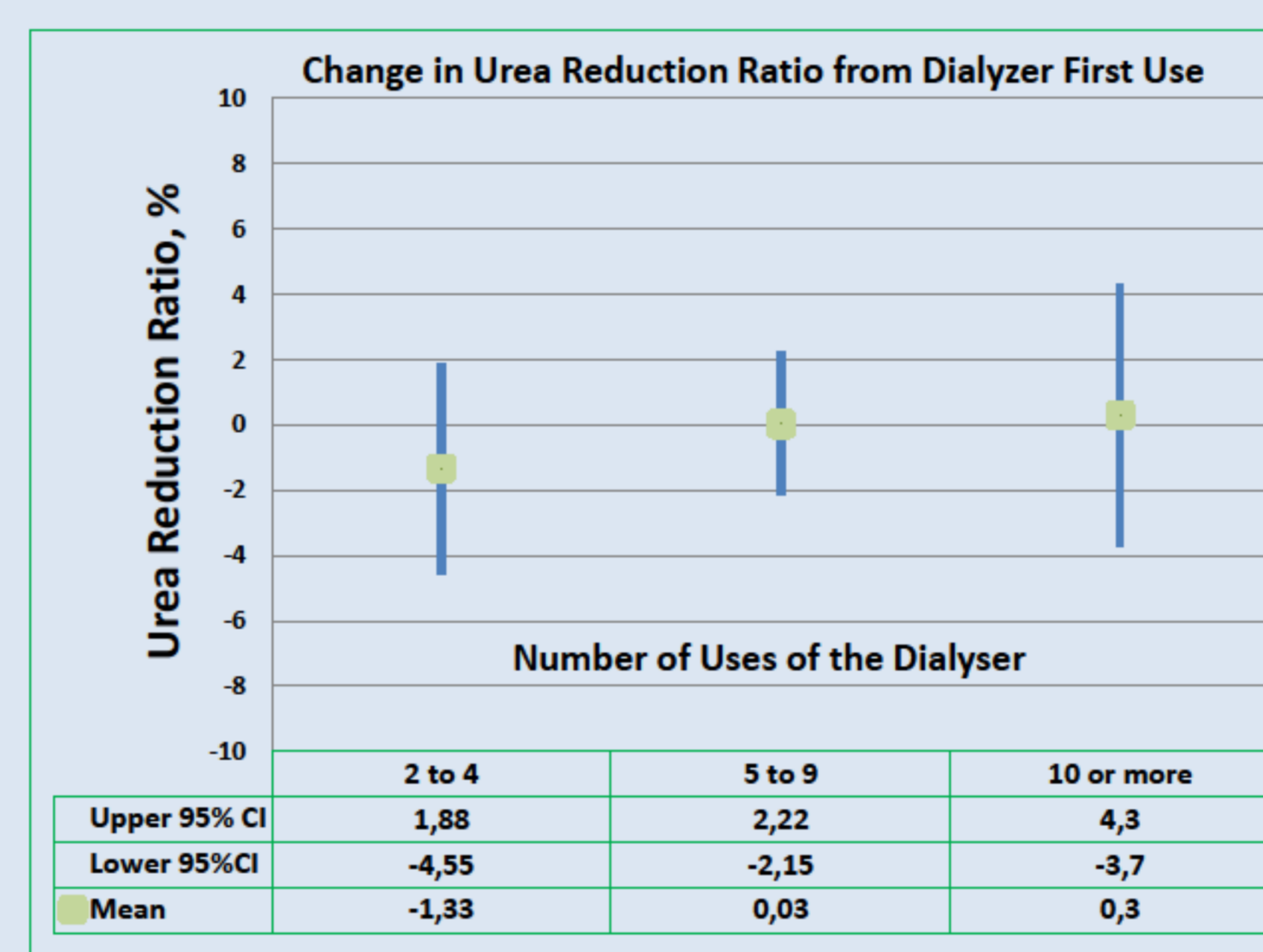


Figure 2. Change in Urea Reduction Ratio from Dialyzer First Use

	PRE	INITIAL	END
aPTT Ratio vs Baseline	1*	2.42±0.59	1.64±0.45

* Baseline

Table 4. Activated Partial Thromboplastin Time Ratio

EXTENDED DURATION STUDY

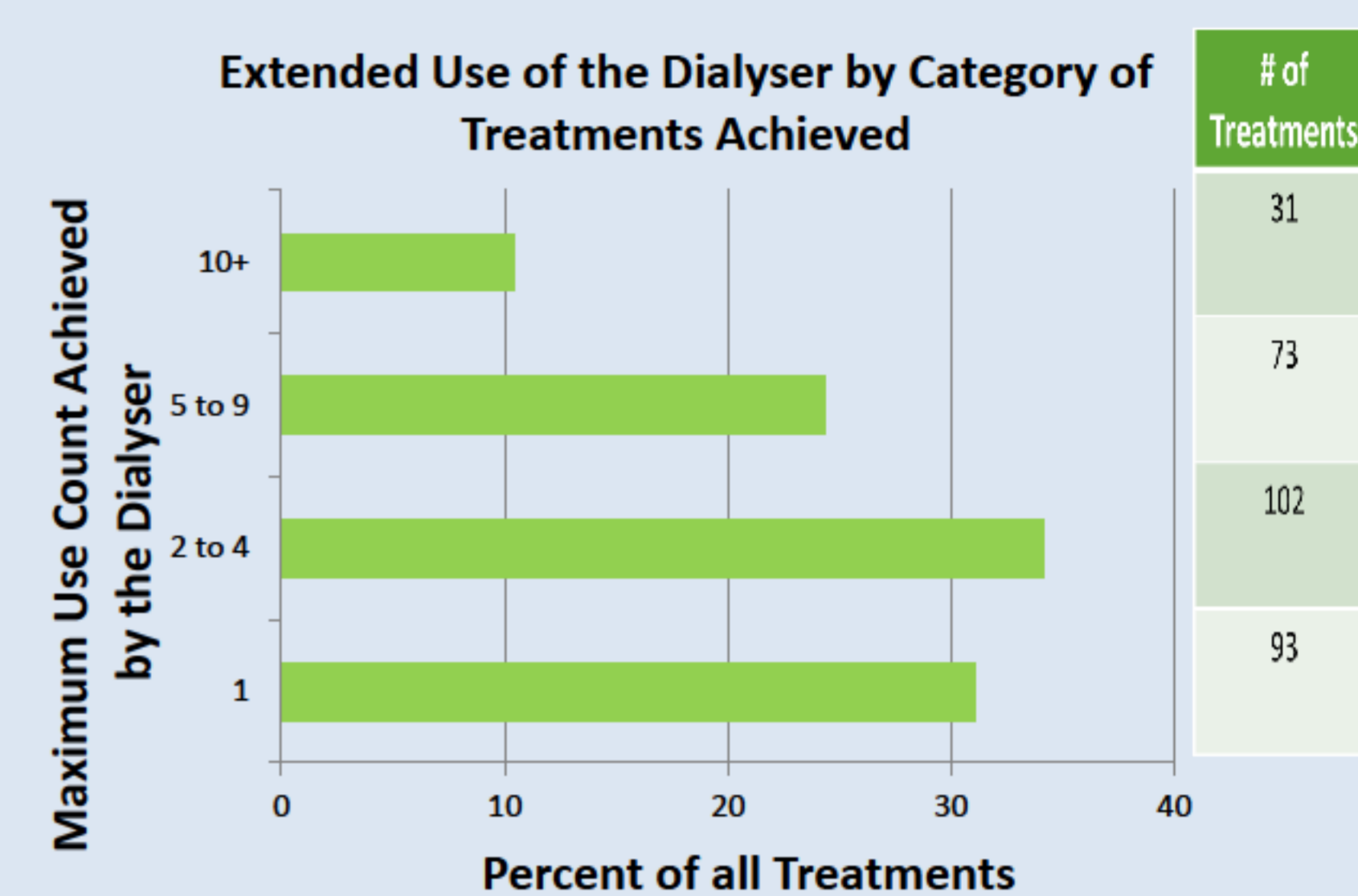


Figure 3. Percent of extended use achieved

Reason for ECC Change	Percent (%)
Physical Appearance	45
Study End	18
Clotting	9
Device Last Use	7
Clearance Alert	8
Device issue	7
Unknown	6

Table 5. Reasons for ECC Change

	PRE	INITIAL	END
aPTT Ratio vs Baseline	1*	2.26±1.01	2.42±1.32

* Baseline

Table 6. Activated Partial Thromboplastin Time Ratio

	First-in-man Study	Extended Duration Study
Heparin Bolus (Mean±SD)	3078 ±1106	1854±696
Heparin Infusion (Mean±SD)	1061±510	1564±498

Table 7. Heparin Dose by Clinical study

Conclusion

Optimization of anticoagulation using aPTT as recommended in practice guidelines resulted in extended use of the ECC in the VIVIA Hemodialysis System with no bleeding complications.

References

- European Best Practice Guidelines Section V. Chronic intermittent haemodialysis and prevention of clotting in the extracorporeal system. European Best Practice Guidelines Expert Group on Hemodialysis, European Renal Association. Nephrol Dial Transplant. 2002;17 Suppl 7:63-71.
- Davenport A. What are the anticoagulation options for intermittent hemodialysis? Nat Rev Nephrol. 2011;7:499-508.

