SAFETY AND PERFORMANCE OF THE VIVIA HAEMODIALYSIS SYSTEM – RESULTS FROM THE FIRST IN-HUMAN CLINICAL STUDY

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Introduction and Objective

Despite the clinical and humanistic benefits associated with high dose haemodialysis (short daily or frequent nocturnal HD), relatively few patients receive this therapy. Among the many stated barriers to the growth of high dose HD is the absence of a HD device designed for the patient as the user, a device with intrinsic safety features to mitigate risks associated with HD in the home environment, and a device with features that limit the burden on the patient when performing independent HD.

Methods

We performed a first in-human, prospective, single arm clinical study with a novel HD device, VIVIA (Baxter Healthcare, Deerfield, IL, USA). Unique features of the VIVIA Haemo-dialysis System, including pneumatic blood pumps, infusion-quality dialysate, and extended use of the dialyser (2.1m^2, polyethersulfone membrane) and blood set, were tested over 10 weeks (2-week stabilization period and 8-week evaluable period) at two clinical sites in the United States.

Safety was assessed on all subjects who used the VIVIA Haemodialysis System at least once. Urea clearance was assessed using weekly standard Kt/V, values transformed from second generation estimates for single pool Kt/V. The association between fluid weight removed (as measured by the VIVIA Haemodialysis System) and weight change (determined using weight scales) was measured for each treatment. Dialysate was sampled at a minimum of once weekly for each subject throughout the study. Criteria for success was defined as a bacterial count of 0 CFU/mL and an endotoxin level of < 0.03 EU/mL, consistent with AAMI and ISO standards for dialysate for infusion.

Results: Baseline Characteristics

Of the 22 treated subjects, 54.4% were male. The mean ±SD age was 50.9 ± 9.5 years, with a range of 36 – 73 yrs. The mean weight ±SD was 81±16.7 kg (range of 58.6 – 123.4 kg). The time in years (ie, vintage) since first chronic dialysis treatment (ie, HD or PD) was 12.0 ±7.4 years (mean ±SD) with minimum of 3.4 years and maximum of 28.8 years.

Study Results:

1. PERFORMANCE

Figure 1: Dialysis Adequacy Measured by Weekly Standard Kt/V $_{urea}$ (KDQOI target ≥ 2.0)

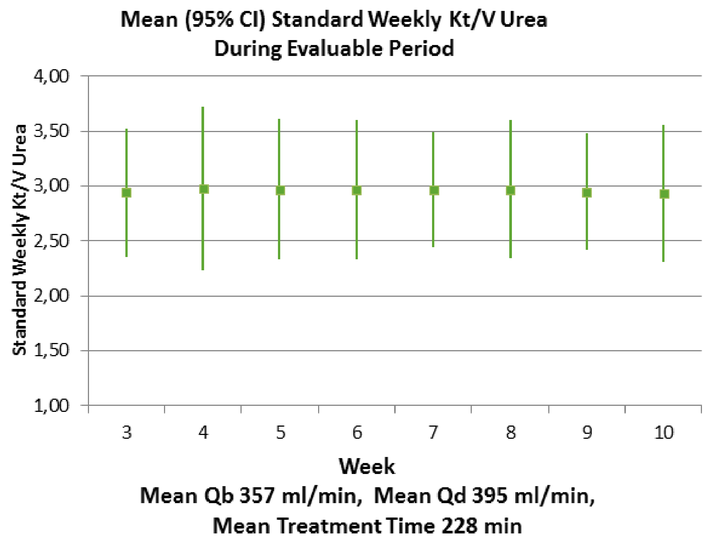
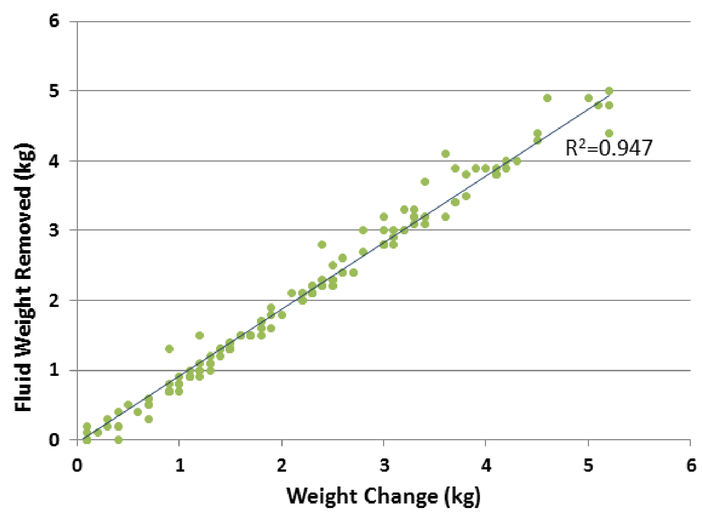


Figure 2: Association Between Fluid Weight Removed (VIVIA) and Weight Change



2. DIALYSER REUSE

Table 2: Treatments and Dialyser Use

Subject	No. of Treatments	No. of Dialysers	Maximum Use Count	Subject	No. of Treatments	No. of Dialysers	Maximum Use Count
1	2	2	1	12	32	11	9
2	35	23	5	13	30	26	5
3	34	26	4	14	31	9	11
4	35	4	24	15	34	12	17
5	33	11	9	16	31	4	24
6	32	5	23	17	33	8	18
7	32	6	13	18	32	9	16
8	32	9	19	19	32	2	20
9	34	20	8	20	30	5	23
10	31	7	8	21	31	4	16
11	32	4	13				

3. INFUSION QUALITY DIALYSATE

Table 3: Dialysate Quality and Extended use

Dialyser Use Count	Dialysate Culture No bacteria / Total Number of Samples	Dialysate Endotoxin < 0.03 EU/ml / Total Number of Samples
First use	121 / 121	121 / 121
Two to four times	62 / 62	62 / 62
Five to ten times	61 / 61	61 / 61
More than ten times	27 / 27	27 / 27

271 dialysate samples were obtained from active treatment devices: all samples met the ISO 11663:2009 standards

4. SAFETY

Table 4: Adverse Events

Total treatments: 817
• Total adverse events – 103 • Similar in type and number as HD literature reports • Microbiological – 0
• Device related adverse events – 8 • All were related to blood loss (ranging from 52 to 250 ml) and occurred during rinseback. • All underlying causes were corrected with updated software and hardware, and implemented during the study.
• Serious adverse events – 5 (all hospitalizations) • Asthma, anaemia, atrial arrhythmia, fractured ankle, anxiety • Device related serious adverse events – 0

SUMMARY: The VIVIA Haemodialysis System met acceptable targets for urea clearance and ultrafiltration performance. The VIVIA Haemodialysis System also produced dialysate that met quality standards for infusion, and in-situ extended use of the dialyser was performed safely. The overall adverse event profile during the study was also consistent with the adverse event profile observed in prevalent haemodialysis patients.

CONCLUSION: The VIVIA Haemodialysis System is safe and effective for 4-hour haemodialysis treatments.

Additional data from this Clinical Trial is provided in Poster SP444 "Effect of Hot Water Disinfection on Dialyser Solute Clearances with Extended Use in a New Haemodialysis Device"

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