NOCTURNAL HAEMODIALYSIS WITH THE VIVIA HAEMODIALYSIS SYSTEM

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Introduction and Objective

The VIVIA Haemodialysis System (Baxter Healthcare, Deerfield, IL, USA) was designed for the patient as the primary operator in a home environment. To reduce the burden associated with performing frequent and / or long haemodialysis (HD) in the home, the VIVIA Haemodialysis System includes features not typically available in traditional HD devices. These unique features include (1) extended use of the dialyser (2.1m^2 polyethersulfone membrane) and blood set, facilitated by in-situ hot water disinfection between treatments; (2) generation of on-line infusible quality dialysate to allow automated priming, rinseback, and hemodynamic support during hypotensive episodes; and (3) a fully integrated access disconnect system to mitigate the risk associated with venous access disconnections. Given these unique features, we sought to determine the safety and efficacy of the VIVIA Haemodialysis System in a controlled clinical environment.

Methods

Prevalent in-centre nocturnal HD patients were enrolled in this prospective, single arm clinical study at two clinical sites in Canada. All subjects received HD from trained nurses for six to ten hours per session, three times per week, for six weeks. Safety was assessed in all subjects who used the VIVIA Haemodialysis System at least once. Urea clearance was assessed using second generation estimates for single pool Kt/V. Anticoagulation was obtained with unfractionated heparin with adjustments to maintain intra-dialysis activated partial thromboplastin times (aPTT) levels between 1.5x and 2.0x pre-dialysis values. The association between fluid weight removed (as measured by VIVIA) and weight change (determined using weight scales) was calculated for each treatment. Dialysate was sampled at a minimum of three times per subject throughout the study. Dialysate 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

65% of the 18 treated subjects were male. The mean ± SD age was 55 ± 14 years, with a range of 33-80 yrs. The mean weight ±SD was 85±18 kg (range of 60-113 kg). The time in years (ie, vintage) since first chronic dialysis treatment (ie, HD or PD) was 10 ± 8 years (mean ±SD) with minimum of 2 years and maximum of 30 years.

Study Results:

1. PERFORMANCE

Figure 1: Dialysis Adequacy Measured by Single Pool Kt/V_{urea}

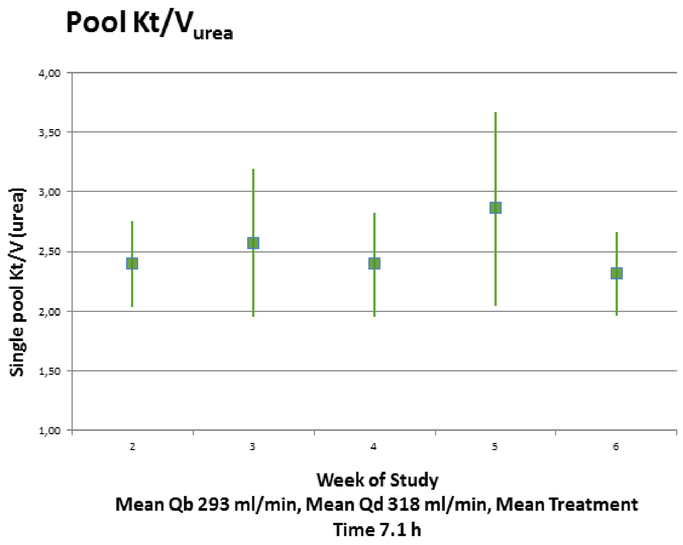
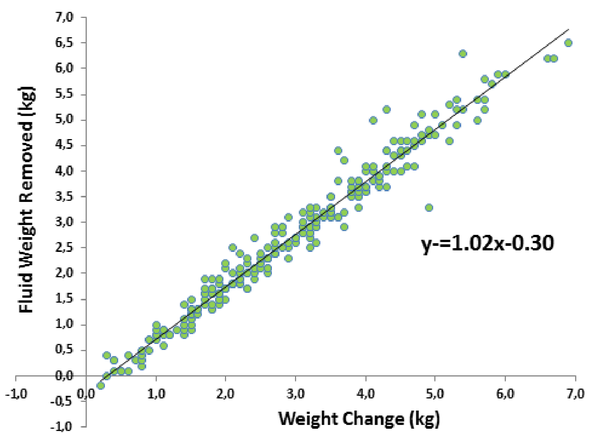


Figure 2: Association Between Fluid Weight Removed (VIVIA) and Weight Change)



2. DIALYSER REUSE

Table 2: Treatments and Dialyser Use

Subject	No. of Treatments	No. of Dialyzers	Maximum Use Count
1	19	3	17
2	15	9	5
3	18	13	3
4	18	7	10
5	18	2	13
6	18	2	17
7	16	8	4
8	18	3	15
9	18	3	10

Subject	No. of Treatments	No. of Dialyzers	Maximum Use Count
10	18	3	13
11	17	5	10
12	18	4	12
13	18	5	7
14	17	10	5
15	17	7	5
16	18	3	11
17	18	5	6

3. INFUSION QUALITY DIALYSATE

Table 3: Dialysate Quality

Dialysate for Infusion- Total number of Samples: 90
Sampling Strategy • At Time of Installation of Vivia HD System • Treatment Day 1 • Treatment Day 10 • End of Study Treatment (day 18) or End of study)
Bacterial Count 88 samples : No growth 2 samples: 0.02 CFU/mL • *B lentus* on training device, unassigned to patient Touch contamination- On repeat sampling: negative • *S warnieri* on back-up device unassigned to patient Touch contamination- On repeat sampling : negative
Endotoxin **87 samples : < 0.03 EU/mL** Three positive samples had the following values: 0.03 EU/mL, 0.035 EU/mL, and 0.035 EU/mL All three samples, when re-tested in quadruplicate, were < 0.03 EU/ml

4. SAFETY

Table 4: Reported Adverse Events

Total treatments: 298
• Total adverse events – 52 events observed in 16/17 subjects • Similar in type and number as HD literature reports. Most common AE was 'hypotension' – 14 events were observed in 7 subjects • Microbiological AE – 0
• Device related adverse events – 3 • 2 events related to blood loss (in one subject) and occurred towards the end of treatment • 1 event related to an elevated CRP level in a subject with an acute respiratory illness
• Serious adverse events – 1 (hospitalization) • AVF thrombosis • Device related serious adverse events – 0

5. ANTICOAGULATION

Table 5: Mean Unfractionated Heparin Dose

	Baseline	Throughout the Study	Percent Change
Heparin bolus, Units	1324	1855	40%
Heparin infusion, Units/hr	935	1564	67%

SUMMARY: The VIVIA Haemodialysis System achieved dialysis adequacy target and ultrafiltration accuracy. During nocturnal treatments, the VIVIA Haemodialysis System produced infusible dialysate and performed safe extended use of the dialyser. Observed adverse events are typical for end stage renal disease patients on hemodialysis.

CONCLUSION: The VIVIA Haemodialysis System performed safely and effectively during nocturnal haemodialysis.

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