

# EFFECT OF HOT WATER DISINFECTION ON DIALYSER SOLUTE CLEARANCES WITH EXTENDED USE IN A NEW HAEMODIALYSIS DEVICE

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## Introduction and Objective

Conventional reuse of dialysers creates potential exposure to the toxic effects of chemicals, and some chemical-based reuse methods do not maintain dialyser solute clearances, depending on membrane and chemical. A new haemodialysis (HD) system, VIVIA (Baxter Healthcare Corporation, Deerfield, IL, USA), was designed to permit extended or multiple use of the dialyser and blood tubing set by in-situ, non-chemical hot water disinfection, thereby eliminating chemical exposure and the risk of infections due to blood circuit disconnections.

The objective of this study was to evaluate the effects of hot water disinfection on dialyser solute clearances by performing a clinical study with VIVIA to assess the effects of extended use on urea and  $\beta_2$ -microglobulin ( $\beta_2M$ ) clearances.

## Methods

### Data Collection

A prospective, single arm clinical study was performed on 22 chronic HD patients using the VIVIA Home Haemodialysis System. Hot water disinfection (exposure to 85°C for 1 hour) was performed prior to every use of the dialyser, including first use. Over the course of this 8-week evaluation, HD treatments were performed with a 2.1 m<sup>2</sup> polyethersulfone membrane dialyser for 3.9 ± 0.2 hours, 4 times per week. Dialysers were replaced if in-situ dialyser sodium clearance was <90% of the initial dialyser sodium clearance or if there were abnormalities in physical appearance.



Predialysis and postdialysis blood samples were obtained at first use, second use and then weekly; the urea reduction ratio (URR) and dialyser  $\beta_2M$  clearance were calculated to assess extended use dialyser performance. Abnormalities in physical appearance, primarily residual clots in the venous header of the dialyser or the blood set, most often terminated extended use (67.3% of occurrences). Overall, dialyser performance was evaluated at a blood flow rate of 357 ± 21 mL/min and a dialysate flow rate of 395 ± 9 mL/min.

### Calculations

URR:

$$URR = 1 - \frac{[urea]_{post}}{[urea]_{pre}}$$

Dialyser  $\beta_2M$  clearance of  $K_{\beta_2M}$ : (Leypoldt et al, ASAIO J 1997; Cheung et al, J Am Soc Nephrol 1999):

$$K_{\beta_2M} = Q_f \left( 1 - \ln \left( \frac{[\beta_2M]_{post}}{[\beta_2M]_{pre}} \right) \right) \div \ln \left( 1 + Q_f \times T / V_{post} \right)$$

In these equations,

[urea] = urea concentration

[ $\beta_2M$ ] =  $\beta_2M$  concentration

$Q_f$  = predialysis body weight – postdialysis body weight

$V_{post}$  = 20% of postdialysis body weight

T = treatment time

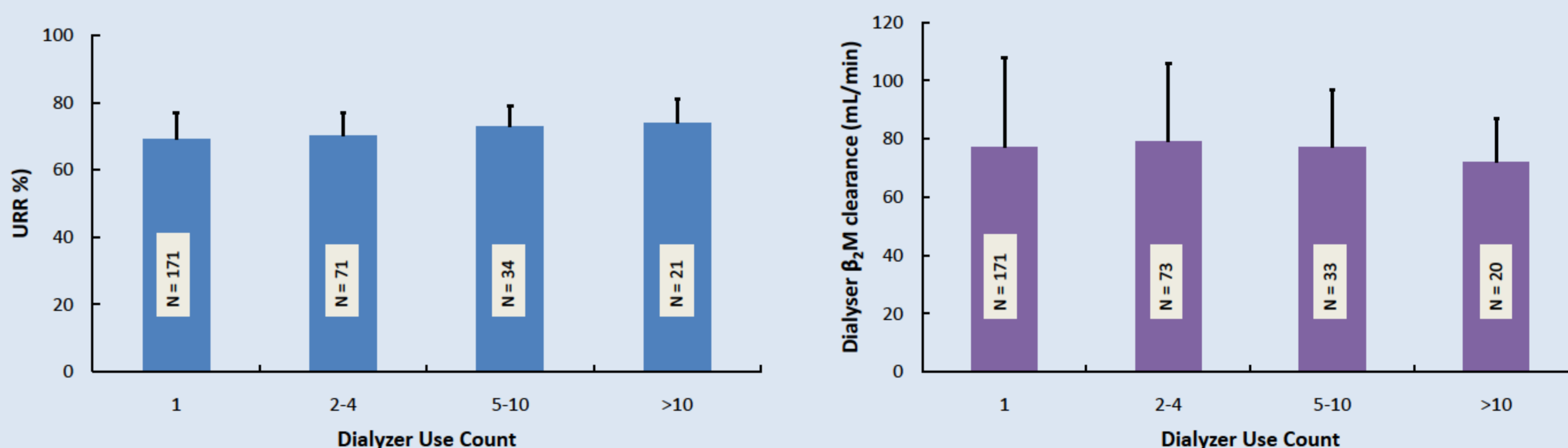
## Results

**Table 1: Patient and extended use characteristics: summary.**

Characteristics	Mean ± Standard Deviation (or N or %)
Age (years)	50.9 ± 9.5
Female Sex (N, %)	10, 44%
Race (Black/White/Taino Indian)	16/5/1
No. of dialysers evaluated	207
No. of URR and dialyser $\beta_2M$ clearance measurements	648
% of dialysers used multiple times	39%
% of treatments delivered by dialysers that achieved 5 or more uses	42%

**Table 2: Dialyser extended use treatment details by patient.** Thirteen of 21 (61.9%) patients were able to use a dialyzer more than 10 times.

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



**Figure 1: Efficacy of Dialyser Solute Clearances During Extended Use.** Post-hoc repeated measures analysis of URR and  $\beta_2M$  clearance on dialyser use count for dialysers used at least 10 times in 12 patients was also performed. In that analysis, URR was independent of dialyser use count (P = 0.7), but the estimated dialyser  $\beta_2M$  clearance decreased (P = 0.02) by 0.74 (standard error of 0.27) mL/min for each dialyser use.

## Conclusions

- ✓ Hot water disinfection during extended use of large surface area polyethersulfone dialysers in the VIVIA Haemodialysis System has no effect on dialysis adequacy as assessed by URR.
- ✓ Extended use decreases dialyser  $\beta_2M$  clearance; however, these effects are small and likely not clinically significant given the high baseline  $\beta_2M$  clearance rates.

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