Long-Term Efficacy of Pre- and Post-Dilution Online Hemodiafiltration with Dialyzer Reuse

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Objective: *Growing evidence has demonstrated the potential survival benefit of online hemodiafiltration (HDF) over conventional hemodialysis (HD). Previous studies regarding online HDF utilized single-use dialyzer. The present study was conducted to compare the long-term clinical parameters between pre- and post-dilution online HDF with the reuse dialyzer.*
Material and Method: *This 2-year historical cohort study was conducted in 20 chronic hemodialysis patients who had undergone thrice-a-week pre-dilution online HDF for at least one year. The patients were switched to post-dilution online HDF for another year. Reuse dialyzers were utilized in both methods.*
Results: *No pyrogenic reactions had been detected throughout the 2-year study period. The C-reactive protein (CRP) and nutritional parameters were in good normal ranges. The normalization of protein equivalent of nitrogen appearance (nPNA) was significantly higher during the post-dilution period (1.25 $\pm$ 0.22 vs. 1.11 $\pm$ 0.14 g/kg/d, $p < 0.01$). Regarding adequacy of hemodialysis, the post-dilution online HDF showed significantly better Kt/V than the pre-dilution mode (2.46 $\pm$ 0.35 vs. 2.35 $\pm$ 0.35, $p < 0.05$) whereas the predialysis β_2-microglobulin levels were not different (23.43 $\pm$ 5.35 vs. 23.73 $\pm$ 5.55 mg/L, NS). The numbers of reuse were comparable (17.3 $\pm$ 2.6 vs. 16.4 $\pm$ 2.7, NS).*
Conclusion: *Utilizing reuse dialyzer in online HDF could provide efficacy, safety, cost saving, and environmental benefit. The post-dilution technique yielded the better adequacy and nutritional status without causing the limitation in the reuse number and would be the standard mode-of-choice for online HDF.*

Keywords: *Reuse dialyzer, Pre-dilution, Post-dilution, Online hemodiafiltration*

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In end-stage renal disease (ESRD) patients, online hemodiafiltration (HDF) technique, which can provide both diffusion and convection in a single therapy, has provided superiority in many aspects[1] including better survival[2-4] when compared with conventional hemodialysis (HD). Although, this online HDF is predominantly performed in Europe, a recent study in Southeast Asia by our group, also demonstrated that online HDF could offer several benefits including effective removal of higher molecular weight uremic toxins, improved nutritional status, and low inflammatory state[5]. Online HDF in these studies is mostly operated with single-use high-flux dialyzer. In several countries, especially developing countries, the reuse dialyzer program has been routinely practiced for the conventional HD. The benefits of the reuse program include not only the cost saving but also reducing the dialyzer waste that could provide the benefit for the environment[6]. Most of the previous studies regarding long-term effect of online HDF utilized single-use dialyzer[7-9]. There are very limited data in utilizing reuse dialyzer in online HDF[10,11].

Two standard methods of fluid replacement in online HDF comprise pre-dilution and post-dilution modes. Post-dilution online HDF is the more efficient mode in molecular clearance of uremic toxins but such efficiency is limited by hemoconcentration and high blood viscosity as plasma water is continually ultrafiltered along the length of the hollow dialyzer

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fibers. Such limitation and consequence do not occur in pre-dilution online HDF, in which the infusion rate of substitution fluid can be unlimitedly increased to augment clearance efficiency. However, this would cause dilution of the blood side solute concentration, leading to reduced clearances when compared with the post-dilution mode. Earlier studies comparing pre- and post-dilution online HDF were cross-sectionally designed and, were conducted in the single-use fashion[12-15]. Whether the hemoconcentration in post-dilution technique could reduce the number of the reuse dialyzers and, in contradiction, the reuse dialyzers could affect the efficacy of post-dilution mode compared with pre-dilution mode of online HDF have never been answered.

Therefore, the present historical cohort study was carried out to compare the long-term clinical parameters between pre- and post-dilution online HDF with the reuse dialyzer. Whether the hemoconcentration issue in the post-dilution mode could affect the dialyzer reuse process or not was also determined.

Material and Method

Patients

The present study was approved by the Ethical Committee for Research, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand. Twenty prevalent HD patients who had underwent thrice-a-week pre-dilution online HDF utilizing reuse dialyzer for at least one year were included into the prospective observational period of the present historical cohort study. The exclusion criteria included the patients who had the history of a limited number of dialyzer reuse and who were expected to have the technique survival below one year, such as living transplantation candidates and advanced stage of cancer. All of them were switched to thrice-a-week reuse post-dilution online HDF for another one year. The monthly clinical and laboratory data were systematically recorded during the two periods. The standard manual reprocessing protocol with peracetic agent was strictly performed as routine practice for both pre- and post-dilution online HDF periods without any differences. The criteria for discarding the dialyzer included the dropping of the total cell volume (TCV) below 80% of the first use, failure of the leaking test, or the maximum of 20 times of reuse was reached.

Both online HDF modes were operated on Fresenius 4008H (Fresenius Medical Care, Bad Homburg, Germany) HDF machine with Fresenius HF80S high-flux polysulfone 1.8 m^2 steam-sterilized dialyzer (Fresenius Medical Care, Bad Homburg, Germany). The dialysis time and blood flow rate were consistently set at 4 hours and 400 mL/min, respectively, with standard unfractionated heparin as the anticoagulant. The reinfusion fluid rate and dialysate flow rate were 170 and 630 mL/min for the pre-dilution mode and 100 and 700 mL/min for the post-dilution mode (the total dialysis fluid flow rate was 800 mL/min). The dialysis fluid purity utilized in the present study was met by the European Pharmacopoeia criteria for ultrapure water and dialysate indicated by total viable microbial counts of less than 0.1 CFU/mL and endotoxin concentrations of less than 0.03 EU/mL. The water and dialysate samples were monthly tested for biological contamination.

All clinical and laboratory data assessed in the present study were protocolized and obtained from the standard regular clinical service of the dialysis unit. The mean data of 1-year reuse pre-dilution online HDF, and 1-year reuse post-dilution online HDF were compared.

Statistical analysis

All data were expressed as mean $\pm$ SD. Comparisons between reuse pre-dilution online HDF and baseline single-use as well as between reuse pre- and post-diltution online HDF modes were performed by Student's paired t-test or the Wilcoxon signed-rank test's non-parametric test for non-normal distribution data. Statistical significant difference was defined when $p < 0.05$. All statistical tests were performed by using the SPSS statistical package (version 11.5 for Windows, SPSS Inc., Chicago, IL).

Results

Of the 20 chronic hemodialysis patients who had been treated with at least one year of reuse predilutional online HDF and included in the present study, there were seven male and 13 female subjects. The average age was 61.2 $\pm$ 13.2 years. The patient underwent reuse pre-dilutional online HDF for 2.16 $\pm$ 1.41 years (AV fistula = 75.0%, AV graft = 25.0%). The causes of ESRD in these patients were diabetes mellitus (20.0%), chronic glomerulonephritis (20.0%), lupus nephritis (5.0%), chronic tubulointerstitial disease (5.0%), chronic pyelonephritis (5.0%), and unknown (45.0%).

Table 1 details comparison of dialytic and biochemical parameters between reuse pre-dilution and reuse post-dilution online HDF modes. As expected, the reinfusion flow rate and total reinfusion

Table 1. Comparison of dialytic and biochemical parameters between reuse pre-dilution and reuse post-dilution online HDF

Parameter	Reuse pre-dilution online HDF study period	Reuse post-dilution online HDF study period
Blood flow rate (mL/min)	411.30 ± 48.90	397.10 ± 10.90[NS]
Dialysis fluid flow rate (mL/min)	800	800
Reinfusion flow rate (mL/min)	172.80 ± 14.00	98.10 ± 4.30*
Reinfusion fluid (L/session)	41.50 ± 3.40	23.60 ± 1.00*
Number of reuse	16.04 ± 2.70	17.30 ± 2.60[NS]
Dry weight (kg)	53.89 ± 11.33	53.49 ± 10.42[NS]
BMI (kg/m^2)	20.97 ± 3.24	20.79 ± 2.61[NS]
Pre-dialysis β_2M (mg/L)	23.73 ± 5.55	23.43 ± 5.35[NS]
Hemoglobin (g/dL)	11.61 ± 0.80	11.55 ± 0.74[NS]
Calcium (mg/dL)	9.21 ± 0.83	9.45 ± 0.73[NS]
Phosphorus (mg/dL)	4.43 ± 0.88	4.50 ± 0.78[NS]
iPTH (pg/mL)	395.10 ± 272.82	376.99 ± 347.15[NS]
CRP (mg/L)	5.02 ± 4.98	4.78 ± 3.14[NS]

NS = non significant
* $p < 0.01$ when compared with reuse pre-dilution online HDF

fluid volume per session in reuse pre-dilution online HDF were significantly greater than the reuse post-dilution mode ($p < 0.01$)

Of interest, the number of reuse in post-dilution mode was not lower than the pre-dilution mode. When compared with the pre-dilution period, the spKt/V values were significantly increased during the reuse post-dilution online HDF period ($p < 0.05$) (Fig. 1). The URR was also significantly increased ($p < 0.01$). The pre-dialysis β_2M levels were comparable.

Regarding nutritional parameters, nPNA was significantly increased after switching from the pre-dilution to post-dilution online HDF ($p < 0.01$) whereas the serum albumin levels were not significantly changed (Fig. 2). The BMI values were not different. Other parameters including hemoglobin, calcium, phosphorus, and iPTH were comparable (Table 1).

No pyrogenic reaction has been detected during all the study periods. The values of CRP in both groups were in good normal ranges (NS).

Discussion

The present study is the first to compare the efficacy and safety of the reuse dialyzer for online HDF between pre- and post-dilution mode. When compared with the pre-dilution mode, the post-dilution

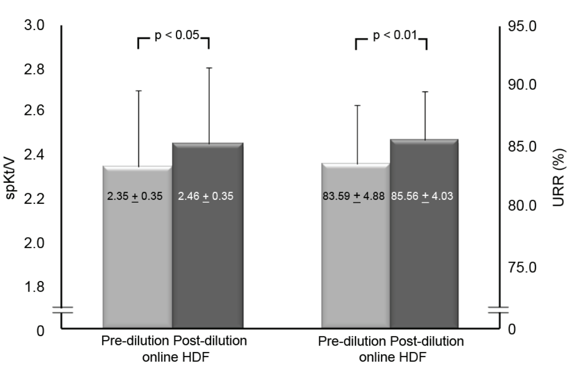

Fig. 1 Mean monthly single-pool Kt/V (left) and urea reduction ratio (URR) (right) between reuse pre-dilution and post-dilution online HDF periods

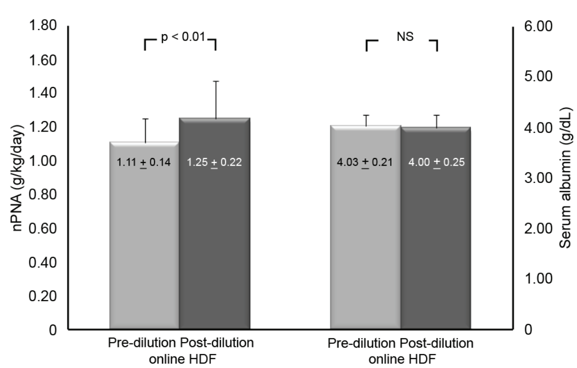

Fig. 2 Mean monthly nPNA (left) and serum albumin levels (right) between reuse pre-dilution and post-dilution online HDF periods

technique showed the better small molecule adequacy (Fig. 1). This was the crucial aspect of the post-dilution technique that the blood was not diluted before entering the dialyzer, leading to the maximal concentration difference between blood and dialysate. This greater concentration gradient in post-dilution online HDF when compared with pre-dilution online HDF results in the greater diffusive clearance, which is the important mechanism of small molecule clearance in HDF. When compared with previous long-term single-use online HDF studies, all of which were operated via post-dilution mode (Table 2), the online HDF with the reuse dialyzer in the present study provided better spKt/V values. This might be caused by both high BFR and high dialysate fluid flow rate (Table 1, 2) as well as relatively lower dry weight (correlated with volume of the distribution of urea of the patients) than other studies.

Although the clearance of β_2M was not determined in the present study, the pre-dialysis β_2M levels could reflex the long-term efficacy of middle molecule removal. Currently available data demonstrated the correlation between the pre-dialysis β_2M levels and mortality rate[16] and the pre-dialysis β_2M levels below 27.5 mg/L were correlated with the significantly lower mortality rate than the higher levels[16]. A previous study regarding online HDF showed a slightly decreased β_2M clearance after switching from single-use to reuse dialyzer[17]. Interestingly, the pre-dialysis β_2M levels during reuse pre- and post-dilution online HDF in this study were in the survival benefit range (Table 1, Fig. 1). The β_2M levels in post-dilution online HDF in the present study were not lower than the pre-dilution mode as shown in some previous cross-sectional clearance studies[12-15]. This might be caused by at least two factors. First, the higher β_2M clearance in the post-dilution mode might not be much enough to affect the plasma levels. The second possibility might be that the reuse process might cause more impaired β_2M clearance in the post-dilution than the pre-dilution technique. Further investigations are required to answer this question.

Theoretically, the hemoconcentration and high blood viscosity developing in post-dilution online HDF might cause intra-fiber clot and protein cake, possibly leading to decreased number of dialyzer reuse. It seems likely that the significant magnitude of this problem did not occur in the post-dilution mode

Table 2. Previous studies regarding single-use and reuse post-dilution online HDF

Parameter	Single-use post-dilution online HDF			Reuse post-dilution online HDF	
	Maduell[7] (Spain)	Ward[8] (Germany)	Munoz[9] (Spain)	Kerr[10] (France)	Lin[11] (Taiwan)
Number of patients	37	24	31	20	58
Blood flow rate (mL/min)	434.0 ± 68.0	281.0 ± 4.0	343	369.0 ± 24.0	322.1 ± 37.1
Dialysis fluid flow rate (mL/min)	654.0 ± 126.0	500	800	600	500
Reinfusion flow rate (mL/min)	121.0 ± 35.0	65-85	82.5	80-100	83.3-91.7
Reinfusion fluid (L/session)	22.5 ± 4.3	15.6-20.4	19.8	NA	20-22
Dialyzer	Vary	Polyflux 17S	Fresenius HF80	Fresenius HF60, HF80	Fresenius F80
Single-use or reuse	Single-use	Single-use	Single-use	Reuse (max 15)	Reuse (max 5)
spKt/V	1.56 ± 0.29	1.58 ± 0.09	1.58 ± 0.145	1.55 ± 0.32	1.4 ± 0.25
URR (%)	NA	NA	NA	NA	74.5 ± 6.4
Pre-dialysis β_2M (mg/L)	24.2 ± 6.5	23.0 ± 2.0	22.4 ± 5.36	30.5 ± 2.5	22.2 ± 5.3
nPNA (g/kg/day)	1.13 ± 0.24	NA	1.32 ± 0.29	1.11 ± 0.43	1.19 ± 0.26
Dry weight (kg)	NA	66.7 ± 2.9	68.8 ± 15.0	61.0 ± 12.3	NA
BMI (kg/m^2)	NA	22.9 ± 0.8	NA	NA	NA
Albumin (g/dL)	4.22 ± 0.3	NA	3.91 ± 0.298	NA	NA
Hemoglobin (g/dL)	11.36 ± 1.5	10.3 ± 0.2	12.3 ± 0.977	NA	NA
Calcium (mg/dL)	10.5 ± 1.0	9.2 ± 0.08	9.65 ± 0.507	9.96 ± 0.12	NA
Phosphorus (mg/dL)	5.0 ± 1.2	4.8 ± 0.2	5.27 ± 1.22	1.73 ± 0.09	NA
iPTH (pg/mL)	200 ± 216	NA	448.0 ± 326.2	NA	NA
CRP (mg/L)	NA	NA	NA	NA	NA

NA = not available

in the present study as the numbers of reuse in pre- and post- dilution modes were comparable (Table 1).

The beneficial effect of convective treatment to improve the nutritional status of HD patients has been described in some previous studies[5, 18]. In the present study, an improvement in nutritional intake as demonstrated by increased nPNA values in the post-dilution period was observed (Fig. 2). This might be caused by the loss via convection of several larger uremic toxins such as leptin (16,000 Da), which has negative effect on the appetite[19]. One of the markers of nutritional status is predialysis serum albumin, the low levels of which have been associated with both malnutrition and poor survival[20]. Although the online HDF technique increases albumin loss when compared with the conventional HD, the serum albumin was still maintained during both pre and post-dilution online HDF over the two-year study period (Fig. 2). Of note, the anthropometric parameters such as dry weight and BMI were not different.

The safety issue is usually a big concern about the reuse dialyzer policy. The strict adherence to the standard reprocessing protocols could prevent all the possible risks as obviously demonstrated in the present study, which showed no pyrogenic reaction and normal CRP levels throughout the present study.

Regarding dialyzer waste, each single-use hemodialysis session is estimated to produce 2.5 kg of solid clinical waste[21]. Thus, the amount of the waste generated by each patient on thrice-a-week hemodialysis utilizing single-use dialyzer is estimated at 390 kg per year, the significant portion of which is contributed by the dialyzer[21]. The yearly dialyzer-related polymer waste would be approximately ten times with the single-use policy when compared with the re-use strategy[6].

As such, online HDF should be promoted for worldwide use not only in the single-use unit but also in the reuse center. Despite the dialyzer cost issue, the online HDF platform does not cost much higher than high-flux hemodialysis. The post-dilution online HDF technique showed the better adequacy and appetite without causing the limitation in the reuse number. When compared with the pre-dilution technique, the post-dilution online HDF would be considered as the standard mode-of-choice for online HDF. However, the new techniques including mid- and mixed-dilution online HDF that combine the advantages of pre- and post-dilution modes might be the optimal therapeutic modalities in the future.

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Potential conflicts of interest

None.

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ประสิทธิภาพระยะยาวระหว่างการทำออนไลน์ฮีโมไดอะฟิลเตรชั่นโดยการเติมสารน้ำทดแทนชนิดก่อนและหลังตัวกรองโดยใช้ตัวกรองแบบใช้ซ้ำ

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วัตถุประสงค์*:* *การฟอกเลือดด้วยเครื่องไตเทียมแบบออนไลน์ฮีโมไดอะฟิลเตรชั่นมีหลักฐานจากการศึกษาหลายการศึกษาว่า ส่งผลดีต่ออัตราการรอดชีวิตมากกว่าการฟอกเลือดด้วยเครื่องไตเทียมปกติ การศึกษาต่าง ๆ ดังกล่าวจะใช้ตัวกรองไตเทียมแบบใช้ครั้งเดียวทั้งสิ้น การศึกษานี้จึงมีวัตถุประสงค์เพื่อเปรียบเทียบการเปลี่ยนแปลงทางคลินิกระยะยาว ระหว่างการทำออนไลน์ฮีโมไดอะฟิลเตรชั่นโดยการเติมสารน้ำทดแทนชนิดก่อนและหลังตัวกรองโดยใช้ตัวกรองแบบใช้ซ้ำ*

วัสดุและวิธีการ*:* *การศึกษาชนิดติดตามไปข้างหน้าเทียบกับข้อมูลย้อนหลังในระยะเวลาทั้งหมด 2 ปี ในผู้ป่วยไตวายระยะสุดท้ายที่ได้รับการรักษาด้วยออนไลน์ฮีโมไดอะฟิลเตรชั่นแบบการให้สารน้ำทดแทนก่อนตัวกรองเป็นเวลาอย่างน้อย 1 ปี ผู้ป่วยจะถูกเปลี่ยนเป็นแบบการให้สารน้ำหลังตัวกรองติดตามต่ออีก 1 ปี โดยทั้งสองช่วงเวลาใช้ตัวกรองชนิดใช้ซ้ำ*

ผลการศึกษา*:* *ระหว่าง 2 ปีของการศึกษาไม่พบภาวะแทรกซ้อนด้านไข้จากการติดเชื้อจากการใช้ตัวกรองซ้ำ ระดับของ CRP และภาวะทางโภชนาการอยู่ในเกณฑ์ปกติดี ค่า nPNA สูงขึ้นอย่างมีนัยสำคัญทางสถิติเมื่อเปลี่ยนมาเป็นการใช้การให้สารน้ำหลังตัวกรอง (1.25 $\pm$ 0.22 เทียบ 1.11 $\pm$ 0.14 กรัม/กก./วัน ค่า $p < 0.01$) ในแง่ของความเพียงพอในการฟอกเลือดนั้นการให้สารน้ำหลังตัวกรองได้ค่าความเพียงพอ Kt/V ที่ดีกว่าอย่างมีนัยสำคัญทางสถิติ (2.46 $\pm$ 0.35 เทียบ 2.35 $\pm$ 0.35 ค่า $p < 0.05$) แต่ค่าบีตาทูไมโครโกลบูลินไม่แตกต่างกัน (23.43 $\pm$ 5.35 เทียบ 23.73 $\pm$ 5.55 มก./ลิตร) จำนวนครั้งการนำตัวกรองมาใช้ซ้ำไม่แตกต่างกัน (17.3 $\pm$ 2.6 เทียบ 16.4 $\pm$ 2.7 ครั้ง)*

สรุป*:* *การใช้ตัวกรองซ้ำในการทำออนไลน์ฮีโมไดอะฟิลเตรชั่นมีประสิทธิภาพ ความปลอดภัย ประหยัด และประโยชน์ต่อสิ่งแวดล้อม การเลือกวิธีการให้สารน้ำทดแทนแบบหลังตัวกรองจะได้ความเพียงพอในการฟอกเลือด และประโยชน์ต่อภาวะโภชนาการที่ดีกว่า โดยไม่กระทบต่อจำนวนครั้งของการนำตัวกรองมาใช้ เมื่อเทียบกับแบบให้ก่อนตัวกรอง ดังนั้นจึงเป็นวิธีที่น่าจะเป็นตัวเลือกที่ดีกว่า*