ARTICLE

Comparative analysis of hemodialysis adequacy on multiple-use dialyzers in a pediatric hemodialysis unit: a prospective cohort

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OBJECTIVES: This study aims to determine the hemodialysis adequacy of dialyzer reuse in pediatric patients undergoing maintenance HD. Specifically, the study aims to determine the median urea reduction ratio (URR) and single pool Kt/V (sp Kt/V) in relation to number of dialyzer reuse, as well as the percentage of patients receiving adequate hemodialysis for each subsequent dialyzer reuse based on the median URR and sp Kt/V.

MATERIALS AND METHODS: A total of 17 CKD patients who used 25 dialyzer samples were included in the study. Blood samples for determination of pre- and post-HD blood urea nitrogen were extracted from the hemodialysis access (i.e. central venous access, arteriovenous fistula) prior to initiation and after termination of HD treatment. Additional data such as HD duration (in hours), ultrafiltration volume (in liters), and post-dialysis weight were also noted for the computation of hemodialysis adequacy based on URR and sp Kt/V.

RESULTS: There was a marked reduction in adequacy rate based on URR observed at 4th use (78.9%) which further declined until 50% adequacy rate only at 10th use. Moreover, there was a marked reduction in the median URR observed at 4th use (69.79) which further declined until a median URR of 65.08 at 10th use. There was also a marked reduction in adequacy rate based on sp Kt/V at 4th use (78.9%) which further declined until 50% adequacy rate only at 10th use. In addition, there was a marked reduction in median sp Kt/V observed at 4th use (1.37) which further declined until a median sp Kt/V of 1.30 at 10th use.

CONCLUSION: Among pediatric patients on HD, the adequacy rates based on URR and sp Kt/V both showed a decline over multiple uses of the dialyzer, particularly after 3rd use and with occasional fluctuations between 6th to 7th use. These findings suggest the need for closer monitoring and potential adjustments to improve dialysis efficiency and patient outcomes. Further studies are needed to explore the factors contributing to the decline in adequacy rates over multiple uses of the dialyzer in this patient population.

KEYWORDS: *hemodialysis, hemodialysis adequacy, dialyzer reuse*

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INTRODUCTION

Chronic Kidney Disease (CKD) is a growing cause of morbidity among pediatric patients. It is defined as abnormalities of kidney structure or function, present for more than three months, with implications for health. Different from the adult population, the most common cause of CKD among children is congenital anomalies of the kidney and urinary tract (CAKUT). The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (NKF K/DOQI) has formulated a classification for CKD which is made up of five stages depending on the cause, glomerular filtration rate (GFR), and presence of albuminuria. This is applicable to children who are over two years old.[1] End-stage Renal Disease (ESRD) is the final stage of CKD, and renal replacement therapy (RRT) is necessitated among patients classified in this category. There are two options for Renal Replacement Therapy (RRT) modality among pediatric patients - hemodialysis and peritoneal dialysis. Peritoneal dialysis (PD) is preferred among pediatric patients. However, due to reasons such as caregiver burden, unfavorable living conditions, perceived higher risk for infection, some families still prefer hemodialysis (HD) over PD.[2] A 2023 census of the Philippine Society of Nephrology reveals that a majority of adult Filipino patients with ESRD prefer hemodialysis as their RRT.[3] Hemodialysis adequacy significantly impacts patients' quality of life, influencing the control of complications like anemia, mineral bone disorder, and cardiovascular disease in CKD patients. In the Philippines, economic constraints and reliance on the government's PhilHealth coverage lead to the common practice of reusing dialyzers during hemodialysis therapy, as opposed to the single -use approach in developed countries. Despite a June 2023 increase in PhilHealth coverage for patients undergoing hemodialysis, budget limitations persist, preventing the adoption of single-use dialyzers for all treatment sessions.[4] Limited data, especially in the pediatric population, exists on the effects of dialyzer reuse on hemodialysis adequacy. Additionally, the long-term impact of exposure to chemicals in dialyzer reprocessing remains insufficiently studied.

There are several determinants of dialysis adequacy, including efficient solute removal, blood pressure control, acidosis correction, fluid and electrolyte homeostasis, biocompatibility, anemia correction, and good nutrition.[5] Hundreds of toxins accumulate in kidney failure, and urea is the most abundant organic solute in these patients. It has also been correlated with morbidity and mortality among these patients. As such, urea clearance has become a widely used measure of dialysis adequacy.[6] The dialysis dose, and subsequently, dialysis adequacy, is determined by measuring the blood urea nitrogen at the beginning and end of the treatment. Usual methods include calculating the urea reduction ratio (URR) and single pool Kt/V.[7]

Issues in the vascular access, dialyzer, bloodlines, needles, or the dialysis equipment may affect the delivered dialysis dose.[8] Studies on the effect of reusing dialyzers on hemodialysis adequacy have conflicting results. After a comprehensive search, there are no local studies available regarding the effect of dialyzer reuse on hemodialysis adequacy.

This study aims to determine the hemodialysis adequacy of dialyzer reuse in pediatric patients undergoing maintenance HD. Specifically, the study aims to determine the median urea reduction ratio and single pool Kt/V in relation to number of dialyzer reuse, as well as the percentage of patients receiving adequate hemodialysis for each subsequent dialyzer reuse based on the median urea reduction ratio and single pool Kt/V.

Materials and Methods

Research Design

This was a single-center prospective cohort study.

Study Setting

The study was conducted at the hemodialysis unit (HDU) of the Philippine Children's Medical Center (PCMC). This is the first and only pediatric-dedicated hemodialysis unit in the country and provides treatment for patients with acute and chronic renal failure. The PCMC HDU catered to a total of 64 patients in the year 2023. The hemodialysis unit (HDU) is operated by one physician and four to six nurses per shift.

Inclusion and Exclusion Criteria

The participants were recruited using convenience purposive sampling from the hemodialysis unit (HDU) of the Philippine Children's Medical Center (PCMC). The participants included in the study were patients aged 12 – 18 years old diagnosed with CKD Stage 5 on outpatient maintenance hemodialysis for at least three months. The patients who were clinically unstable and/ or showing signs and symptoms of an active infection and those with vascular access problems who were unable to complete the prescribed treatment were excluded from the study.

Data from particular sessions of enrolled patients who presented with signs of active infection and/or vascular access problems during the data collection period were excluded from the analysis.

Withdrawal criteria

Patients who were unable to complete the treatment.

Sample Size Computation

Given the small number of expected eligible cases (less than 20 patients with multiple dialyzer use), total enumeration sampling was employed wherein all eligible patients based on inclusion and exclusion criteria were included.

Outcome Assessment and Data Collection

The Hemodialysis Unit Census was reviewed to determine the patients eligible for enrollment in the study. Data was collected from these patients starting from use of a new dialyzer until it has been deemed unfit for use or until the 10^{th} use (or 9^{th} reuse), whichever came first. The patients used the same dialyzer and dialysis prescription during the data collection period.

Blood samples for determination of pre- and post-HD blood urea nitrogen were extracted from the hemodialysis access (i.e. central venous access, arteriovenous fistula) by their respective nurses in charge prior to initiation and after termination of HD treatment.

A form was used during the data collection process. The information gathered was deidentified and assigned specific codes. The following were noted in the data collection form: age, sex, cause of CKD, number of months undergoing HD, number of dialyzer use, pre- and post-HD BUN, HD duration (in hours), ultrafiltration volume (in liters), post-dialysis weight, and blood flow rate. These values were used to compute for the URR and sp Kt/V. The data collection forms will be shredded and disposed of properly three years after the study was concluded.

Data Processing and Analysis

Qualitative variables were described using frequency and proportion distribution, while quantitative variables were described using percentages, median with interquartile range (IQR) and range. Shapiro-Wilk test demonstrated non-normal distribution of data. Cut-off values of at least 65% and 1.2 were used to categorize hemodialysis adequacy for urea reduction ratio and sp Kt/V, respectively, based on KDIGO guidelines. The number of patients receiving adequate hemodialysis based on these values was presented as percentage of the total samples collected.

Ethical Considerations

The study was conducted in accordance with the Good Clinical Practice guidelines. An informed consent form to join the study was obtained from the parent/legal guardian of the patients. Additionally, an assent form was also obtained from eligible patients prior to the conduct of the study. The patients were allowed to withdraw anytime in the study. The research methodology was submitted to and approved by the Ethics Committee of the institution.

RESULTS

A total of 17 CKD patients who used 25 dialyzer samples were included in the study. The median age was 16 years old and ranged between 14 to 18 years. About half were males (52.9%) and had chronic glomerulonephritis as cause of CKD (52.9%). The median duration of HD was 6 months and ranged between 6 to 44 months.

Table 3. Incidence of Moderate to Severe Pain using FLACC Scoring

Variable	N=17
Age (Median, Range)	16 (IQR= 2, Range=14-18)
Male Female	9 (52.9%) 8 (47.1%)
Cause of CKD Chronic glomerulonephritis Reflux nephropathy Others	 9 (52.9%) 4 (23.5%) 5 (29.4%)
Months on HD	6 (6-44)

Figure 1 below showed that only 20 (80.0%) dialyzers had 3rd repeat use, while 16 (64.0%) had 5th repeat use, and only 10 (40.0%) had 10th repeat use of dialyzer. It can be observed that a marked reduction in adequacy rate based on URR was observed at 4th use (78.9%) which further declined until 50% adequacy rate only at 10th use.

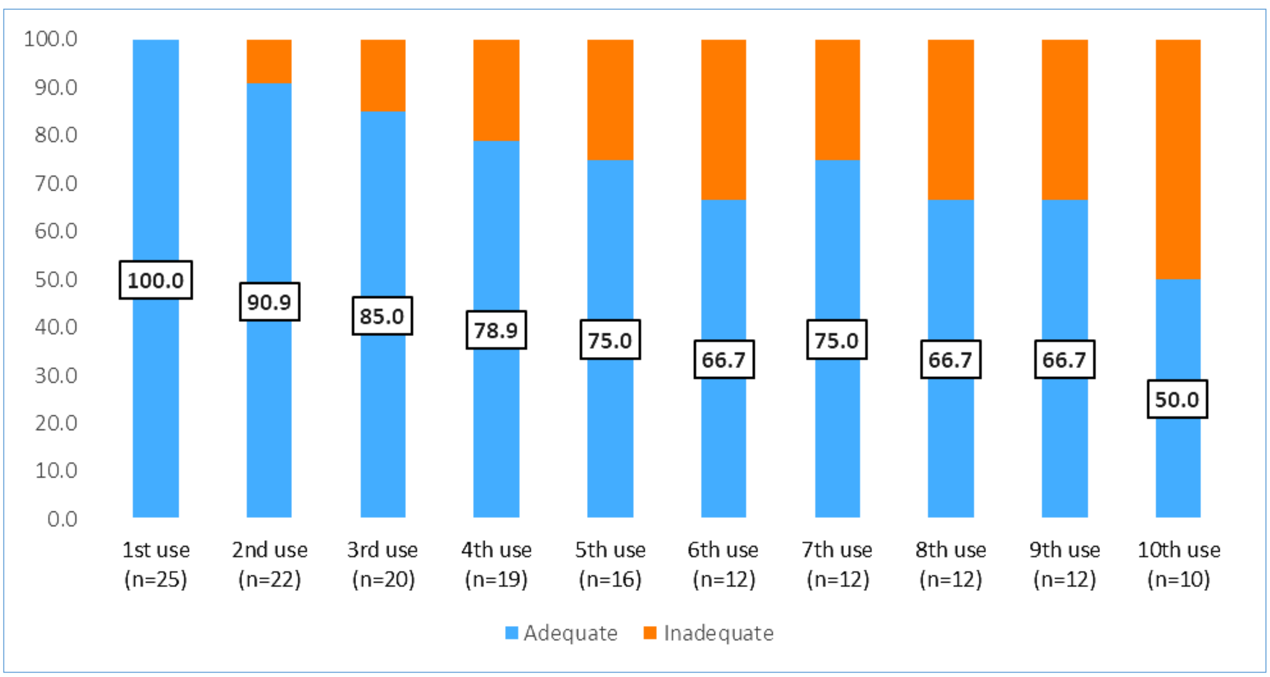
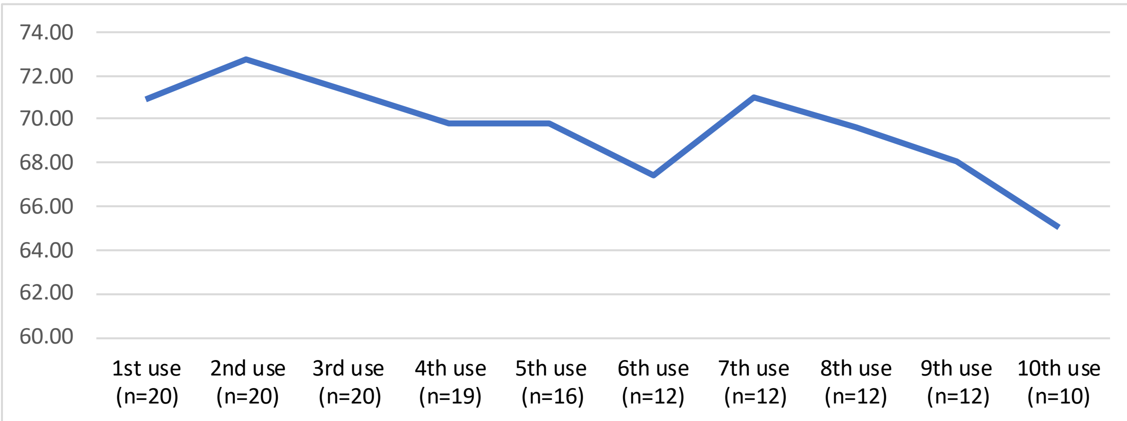


Figure 1. HD Adequacy Rate Based On Urea Reduction Ratio By Number Of Dialyzer Use

The median and interquartile range (IQR) were used to summarize URR and Kt/V. Figure 2 showed a marked reduction in median URR observed at 4th use (69.79), which further declined until a URR median of 65.08 at 10th use. Although there was an increase in median URR between 6th to 7th use, the increase in value (70.78) did not reach the values seen between 1st and 3rd use.



	1st	2nd	3rd	4th	5th	6th	7th	8th	9th	10th
Medi-an	70.86	72.70	71.29	69.79	69.73	67.35	70.78	69.57	68.01	65.08
IQR	6.86	7.41	3.14	8.52	7.47	15.84	8.32	16.24	7.94	12.36
Min	66.40	42.62	58.67	55.53	45.36	46.82	50.95	48.60	3.38	52.03
Max	79.79	78.98	79.45	75.95	80.62	77.7	80.47	78.09	78.42	78.03

Figure 2. Median Urea Reduction Ratio By Number Of Dialyzer Use

For normally distributed data, a paired t-test was applied, whereas the Wilcoxon signed-rank test was used for non-parametric data to compare dialyzer performance between the first use and subsequent reuses. N represents the number of patients who reached the specified reuse threshold (e.g., 6th, 7th, 8th, 9th, or 10th reuse). Patients who did not meet the threshold were excluded from the respective analysis. A two-tailed test was used, and a p-value of <0.05 was considered significant.

Table 2 showed that there was a significant difference in the URR between the 1st use and the 8th to 10th dialyzer reuses. This comparison indicated that the dialyzer's performance, as measured by URR, changed after several reuses.

Table 2. SEQUENTIAL COMPARISONS OF URR: First Use vs. Subsequent Reuses (6th to 10th)

N= number of patients who reached each respective dialyzer reuse				
Use	Median (IQR)	Use	Median (IQR)	P-value
1st Use vs 5th Re-use (N=16)				
1st	72.57 (69.3 - 78.5)	5th	69.73 (66.7 - 74.5)	0.2
1st Use vs 6th to 9th Re-use Cycles (N=12)				
1st	72.57 (69.7 - 78.5)	6th	67.3 (59.5 - 75.3)	0.1
		7th	71.0 (65.4 - 73.8)	0.1
		8th	69.6 (58.9 - 75.1)	**0.04**
		9th	68.0 (63.7 - 71.6)	**0.02**
1st Use vs 10th Re-use (N=10)				
1st	74.2 (70.4 - 78.6)	10th	65.1 (59.5 - 71.9)	**<0.05**

Figure 3 showed a marked reduction in adequacy rate based on sp Kt/V at 4th use (78.9%) which further declined until 50% adequacy rate only at 10th use.

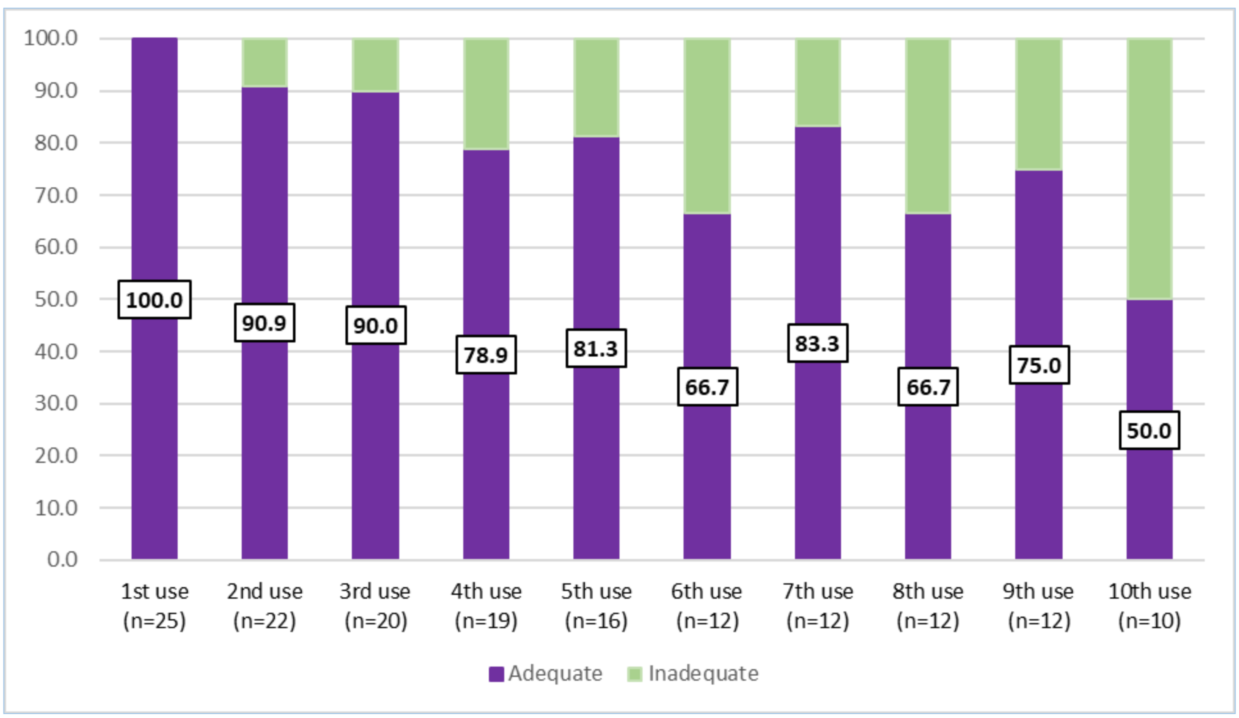
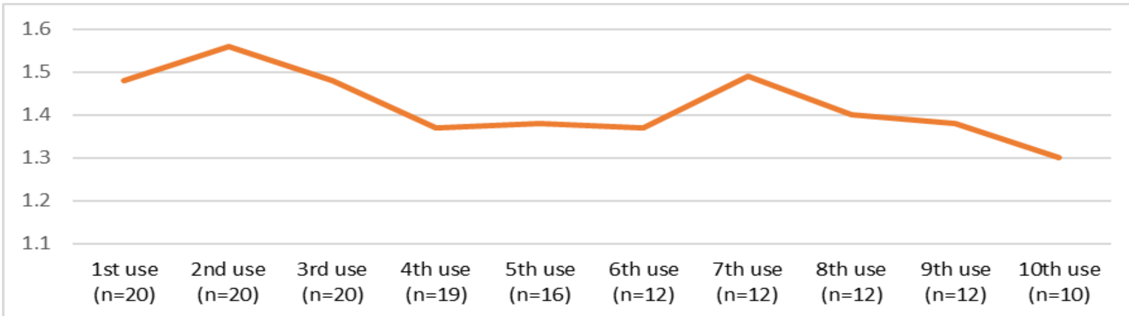


Figure 3. HD Adequacy Rate Based On Single-Pool Kt/V By Number Of Dialyzer Use

Figure 4 showed a marked reduction in median sp Kt/V observed at 4th use (1.37) which further declined until a sp Kt/V median of 1.30 at 10th use. Although there was an increase in median sp Kt/V between 6th to 7th use, the increased value (1.49) was marginal only compared to the 1st to 3rd use



	1st	2nd	3rd	4th	5th	6th	7th	8th	9th	10th
Medi-an	1.48	1.56	1.48	1.37	1.38	1.37	1.49	1.40	1.38	1.30
IQR	0.33	0.25	0.18	0.30	0.29	0.57	0.29	0.58	0.29	0.41
Min	1.31	0.69	1.07	1.00	0.72	0.78	0.88	0.82	0.09	0.90
Max	1.87	1.89	1.99	1.78	2.06	1.89	1.92	1.84	1.80	1.78

Figure 4. Median Single-Pool Kt/V By Number Of Dialyzer Use

The comparison began between the Kt/V values of the 1st and 3rd reuses, as a significant difference was observed starting from the 4th use. Table 3 shows that Kt/V values differed significantly between the initial use and the 4th through subsequent reuses. Although the 7th and 8th reuses did not reach the conventional threshold for statistical significance ($p < 0.05$), with p-values of 0.07 and 0.052, they suggested a trend toward significance, indicating a potential but less robust difference in Kt/V.

Table 3. SEQUENTIAL COMPARISONS OF KT/V: First Use vs. Subsequent Reuses (3rd to 10th)

N= number of patients who reached each respective dialyzer reuse				
Use	Median (IQR)	Use	Median (IQR)	P-value
1st Use vs 3rd Re-use (N=20)				
1st	1.48 (1.4 - 1.7)	3rd	1.48 (1.4 - 1.6)	0.5
1st Use vs 4th Re-use (N=19)				
1st	1.47 (1.4 - 1.7)	4th	`1.37 (1.3 - 1.6)	**0.01**
1st Use vs 5th Re-use (N=16)				
1st	1.51 (1.41 - 1.8)	5th	1.38 (1.2 - 1.5)	**0.02**
1st Use vs 6th to 9th Re-use Cycles (N=12)				
1st	1.51 (1.24 – 1.54)	6th	1.37 (1.12 – 1.7)	**0.03**
		7th	1.49 (1.3 – 1.6)	0.07
		8th	1.4 (1.08 – 1.7)	0.052
		9th	1.38 (1.21 – 1.5)	**0.01**
1st Use vs 10th Re-use (N=10)				
1st	1.6 (1.5 – 1.85)	10th	1.3 (1.1 – 1.52)	**<0.05**

Discussion

For ESRD patients, hemodialysis is a typical renal replacement therapy, although it comes with a significant financial cost. Reusing hemodialyzers was first introduced more than 50 years ago for financial reasons, and it was then widely used.(10) Hemodialysis, a frequent renal replacement therapy for end-stage renal disease (ESRD), has been shown in narrative reviews to be more biocompatible and cost-effective; however, the dangers of infections, adverse reactions, poor technique, and changes in membrane permeability and clearance efficiency have also been emphasized. Reusing dialyzers has become less common over time, however, certain emerging and underdeveloped counties still do so for financial reasons and have reported effective dialysis. Reuse of the dialyzer raises three main issues: infection risk; biochemical and immunologic consequences; and performance loss due to reduced clearance and/or ultrafiltration. (11)

The impact of multiple-use dialyzer on the loss of acceptable performance was examined in this study. Results show that the dialyzer solute clearance decreases with increased reuse frequency as observed in the decreased median urea reduction ratio and single pool Kt/V, and dialyzer reprocessing leads to a decline in administered dialysis.

Several studies were similarly conducted previously on this topic. A study conducted in Saudi Arabia over a decade ago showed that the dialyzer's ability to clear low molecular weight solutes is unaffected by its reuse. Small solute clearance, including those of urea, creatinine, and phosphate, was consistently maintained for the duration of the trial. Reuse has been shown to be helpful in reducing complement activation and the first use effect, even if it does not entirely eliminate the protein adsorbed to the fiber. Nevertheless, this might lessen the elimination of bigger solutes like β2 microglobulin and additional proteins like albumin. (12) In a more recent study, results show that the HD adequacy metrics remained unchanged even after using the dialyzer seven times. (13)

On the other hand, similar results with the current study were seen in other studies. In a prospective study involving 68 patients, improved dialysis adequacy was noted as indicated by significantly lower urea following the HD session, a highly significant increase in the urea reduction ratio, and a tendency to rise in Kt/V one year after the non -reuse of the dialyzer.(14) Reprocessing dialyzers may impair the delivery of the recommended dialysis dose, as demonstrated by the earlier study by Sherman et al. in a larger prospective study of 436-patients. Specifically, measured Kt/V for urea during dialysis with a high (median 14th reuse) number of reuse is significantly lower than dialysis with a low (median 4th reuse) number of reuse.(15) Although the exact cause of this is unknown, it may be connected to the increasing intradialytic loss of effective surface area and fiber bundle volume (FBV) that is missed in post dialysis FBV measurements performed on the reprocessing machine.(14)

When measuring dialysis delivery, it is important to regularly record the number of dialyzer usage. Different investigations can be used to determine variations in the safe reuse dialyzer usage limitations. Kashem et al. found that using dialyzers up to six times did not affect their effectiveness in blood urea clearance.(16) Aggarwal and colleagues found that reuse did not impact sufficiency value until the third usage.(17) Dewi et al. concluded that using the fifth and sixth dialyzers is still adequate.(18) In the current study, adequate hemodialysis declines significantly after the 3rd dialyzer reuse and was noted to be lowest on the 9th and 10th use. With regards to the abrupt incline in dialyzer performance in the 7th re-use where a decline in performance was expected, this could just be because of two outlier samples demonstrating more than 75% URR. Given the non-normal distribution, the central tendency can be greatly affected by outlier values. Further investigation of the two cases offered no physiologic explanation of the higher than usual URR. It is suggested that routine quantification of dialysis adequacy in patients at the beginning and end of a dialyzer's life may be useful.

Moreso, the chemicals and protocols used in reusing dialyzers should also be noted. Reusing dialyzers 13.8 times led to decreased dialysis dose delivery, urea and creatinine clearance, and similar solute clearance trends in several studies.(19) However, it should be emphasized that these outcomes were observed in dialyzers that had undergone formaldehyde and bleach reprocessing.(20) Several investigations found insignificant differences in small molecule clearance in dialyzers reconditioned with Renalin.(10,19,21) Comparable outcomes were noted in the study of Manandhar et al. after dialyzer was reprocessed nine times, and in the study of Dewi et al. after dialyzer was reused seven times.(18,22) If established procedures, developed by the Association for the Advancement of Medical Instrumentation (AAMI) are followed, dialyzers can be securely reused and give effective dialysis. The effectiveness and safety of dialyzers that are reused could be jeopardized by a lack of quality control and protocol breaches. (20)

In the current study, we may not be able to conclude that dialyzer reuse makes it impossible to provide adequate or even optimal dialysis. However, our results suggest the fact that dialyzer efficiency is decreased by reuse. If the reuse of dialyzers cannot be prevented, e.g. financial constraints, and the benefits outweigh the risks, it is recommended that the effects be mitigated by properly adjusting the dialysis prescription. (15)

This study also has some limitations. It is a single-centered study with a limited sample size. It should be emphasized that the performance and the administration of dialysis doses vary throughout centers. A larger, prospective, randomized, multicenter study is needed to validate the results of this investigation. Furthermore, evaluation of intradialytic symptoms, infection frequency, other dialysis efficacy measurements (e.g. bio-chemical tests including phosphorus, iron, hemoglobin, etc.), and hospitalizations were lacking; therefore, it is not possible to rule out these possible risks associated with dialyzer reuse. Nevertheless, the study still provides relatively good information on the use and efficacy of multiple-use dialyzers in the chosen hospital.

Another limitation of this study was the use of dialyzer size which was bigger than what was appropriate for all patients. Although the use of a bigger dialyzer size benefited these patients in terms of clearance, this may also be a source of bias. An increase in dialyzer membrane surface area also increases solute transport and in turn, clearance. [23] As a result, the observed clearance rates could be higher than we would have expected in patients using the correct dialyzer size. Given these constraints, generalizability of results is limited to patients with similar profile and context to that of our study. Nonetheless, we still observed a decreasing trend of URR and sp Kt/V in our study sample.

Conclusion

Among pediatric patients on HD, the adequacy rates based on URR and sp Kt/V both showed a decline over multiple uses of the dialyzer, particularly after 3rd use and with occasional fluctuations between 6th to 7th use. These findings suggest the need for closer monitoring and potential adjustments to improve dialysis efficiency and patient outcomes. Further studies are needed to explore the factors contributing to the decline in adequacy rates over multiple uses of the dialyzer in this patient population.

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