

Original Research Article

Safety and efficacy of dialyzer reuse by manual reprocessing: an observational study

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ABSTRACT

Background: Haemodialysis is the main form of RRT in the patients of CKD. Haemodialysis is a costly procedure and is not afforded by many. Reuse of components of Haemodialysis circuit helps in reducing cost but may be associated with decreased efficacy and side effects.

Methods: Prospective observational study. Manual reprocessing of dialyzer was done with either formaldehyde or peracetic acid. Single brand (Fresenius) dialyzer were used across all patients. Dialysis efficacy was calculated by URR and side effect and toxicity monitored in a predefined proforma.

Results: A total 50 patients were studied (39 male and 11 female) with age ranging from 31-60 years. The mean urea reduction ratio after four dialysis session with the same dialyzer was 62.93% which is below KDOQI recommendation. The findings in our study suggest that URR was adequate upto three session of haemodialysis by reprocessed dialyzer but not beyond that. The choice of chemical for reprocessing did not affect the efficacy. As compared to F6 dialyzer F8 dialyzer had better initial URR and this was maintained upto fourth reuse. Serum albumin levels correlated with the fall in efficacy of dialyzers. There were no significant complications of reuse of dialyzers across both methods of reprocessing and there was no dialyzer first use syndrome.

Conclusions: ESRD affects a younger age group in our country. Use of large membrane area results in better efficacy. Dialyzer reuse with manual reprocessing is safe and also effective upto third and fourth use. Dialyzer reuse is associated with economic benefits.

Keywords: CKD (Chronic Kidney Disease), RRT (Renal Replacement Therapy), URR (Urea Reduction Ratio)

INTRODUCTION

Chronic kidney disease includes a spectrum of different pathophysiologic processes associated with abnormal kidney function and a progressive decline in glomerular filtration rate. There are approximately 7.45 million patients suffering from chronic kidney disease in India and the number is increasing day by day.¹ Haemodialysis the mainstay of the renal replacement therapy in end stage renal disease is expensive and not affordable by many. Reuse of various disposable used in haemodialysis

has been practised to reduce cost.² Dialyzer disinfection and reuse was the norm when the dialyzer needed to be assembled, as it saved time.³

This practice continued as dialyzer was the most expensive component of haemodialysis and reprocessing was the most effective way to save money. The reprocessing of dialyzer has come a long way since then, and although modern dialyzer are for single use but are routinely being reprocessed, more so in countries like ours where cost is a major concern.¹

Reprocessing can affect both the efficacy and safety of dialysis. The technique of reprocessing of dialyzers also make a difference in the efficacy and safety of reuse. Manual reprocessing is still being used in most of centres in India with a variety of chemical. Review have not shown any adverse effect of reuse whereas the literature on efficacy is varied with center specific observation.⁴⁻⁶ The efficacy and safety of reuse of dialyzer has not been studied in Indian scenario. The current study was done to assess the safety and efficacy of dialyzer reuse by manual reprocessing with formaldehyde or peracetic acid in patients undergoing dialysis in a tertiary care hospital in Eastern UP which caters to a predominantly poor socioeconomic population.

METHODS

Prospective observational study was conducted during one academic year from 2016-2017 at Nehru hospital, B.R.D. Medical collage Gorakhpur. All CKD patients undergoing Haemodialysis of any aetiology were included after taking informed consent. The study was approved by institutional ethical committee. A brief history taking, and clinical examination was performed. All enrolled patients of CKD were dialysed twice weekly with vascular access (either with AVF or other). yielding at least 250-350ml per min blood flow. Each dialysis session lasted for four hours. All the patients were monitored for any intra-dialytic symptoms (i.e. fever, sweating, rigors, nausea/vomiting, chest pain and hypotension) during dialysis session. At the same time the blood samples were collected at the baseline, pre- and post- haemodialysis session were used for the estimation of biochemical variables including, serum urea, creatinine, albumin and CRP using standard laboratory techniques. Urea reduction ratio (URR) was calculated and was used as a measure of haemodialysis adequacy. It was calculated for each dialysis session by using the formula i.e. $(1 - \frac{U_{post}}{U_{pre}}) \times 100$, where U_{pre} = pre-dialysis urea concentration and U_{post} = post dialysis urea concentration. Each patient was dialysed four times using same dialyzer after reprocessing manually with either formaldehyde (41 patients) or peracetic acid (9patients). F-6 and F8 polysulfone dialyzer were used. Anticoagulation was maintained by a loading dose of heparin 5000 IU followed by hourly boluses, to maintain the activated clotting time at 1.5 times the baseline. Data collected was analyzed using statistical package for social sciences (SPSS) version 22. Frequencies and percentages were calculated, Student t test (independent t test and paired sample t test) was used for comparison of data.

RESULTS

Fifty CKD patients were enrolled in the study in which 39 (78%) were male and 11 (22%) were female. The mean age of the patients with ESRD was young with 62% of all cases in 31-60 age group. Diabetic nephropathy was the commonest cause of ESRD (50%) followed by Hypertensive nephropathy (28%) and (22%) patients had

an unknown etiology. The value of mean URR among male and female were 71.12 ± 0.73 and 72.48 ± 0.99 respectively but there was no significant statistical difference. The mean URR with new dialyzer was 71.42 ± 0.61 and after fourth dialysis session was 62.93 ± 1.09 . There was significant difference in mean URR achieved by F6 and F8 dialyzer both at first use and at fourth use (Table 1).

Table 1: Comparison of means of URR with different type of dialyzer.

Dialyzer type	URR1	URR4
F8 (N=16)	73.77 ± 1.6	66.19 ± 1.36
F6 (N=34)	70.31 ± 0.5	61.39 ± 1.34
P value	<0.05	<0.05

Table 2: Comparison of means of URR with different type of access.

Access	URR1	URR4
Fistula (n=45)	71.84 ± 0.66	63.52 ± 1.16
Others (femoral, juglar, permacath) (n=5)	67.68 ± 1.18	57.62 ± 3.12
P value	<0.05	>0.05

Table 3: Comparison of means of URR of different dialysis session.

URR	UR R1	URR 2	URR 2	URR 3	URR 3	URR 4
Mean	71.4	68.30	68.30	65.99	65.99	62.93
P value	<0.05		<0.05			<0.05

Patients with AV fistula had better mean URR as compared to patients with other forms of access (Table 2).

There was a decline in URR on each dialyzer reuse and this was statistically significant by paired t test (Table 3).

There was no difference in mean URR levels amongst patients with a high CRP or low CRP (Table 4) but there was a significant decline in serum albumin levels after fourth dialysis session (Table 5).

Table 4: Comparison of means of URR with CRP.

CRP	URR1	URR4
<6 (n=31)	71.34 ± 0.74	63.37 ± 1.17
>6 (n=19)	71.55 ± 1.09	62.20 ± 2.18
P value	>0.05	>0.05

Table 5: Comparison of means of serum albumin.

S. Albmin (After first session)	S. Albmin (After Fourth session)	P value
4.18 ± 0.76	3.80 ± 0.83	<0.05

Though values appears to be different, but there was no significant difference in dialysis efficacy with use of formaldehyde and peracetic acid (Table 6).

Table 6: Comparison of means of URR1-4 with various reagent use.

Reagent	URR1	URR4
Formaldehyde(n=41)	71.18	61.97
Peracetic acid(n=9)	72.50	67.30
P Value	>0.05	>0.05

All the patients were observed for intradialytic symptoms like fever, sweating, rigors, nausea/vomiting, chest pain and hypotension during each session of dialysis. None of the patient had intradialytic complication during first to third session of dialysis, while one patient had hypotension during 4th session of dialysis session.

DISCUSSION

In our study of 50 CKD patients the mean age is younger as compared to the western literature.^{7,8} The overall mean URR after fourth dialysis was below the Kidney Disease Outcome Quality Initiative guidelines (KDOQI) for dialysis efficacy but there was a difference when analysed according to type of dialyzer. The mean URR was maintained above the recommended guidelines with F8 dialyzer but not with F6. This would be expected as F8 dialyzer has a larger surface area. Other studies have also found F8 dialyzer to be more effective even in patients with average body weight.⁶

Studies from India with reuse of dialyzers have found F6 to be efficacious upto three uses with manual reprocessing.¹ They did not use it beyond that and hence we cannot compare with our results. However, efficacy of F6 dialyzer has been maintained upto 20 times in western studies.⁵ There were 90% patients who had an AV fistula and 10% patients who had other form of access. AV fistula showed statistically significant better URR in the first dialysis session and although difference was maintained after fourth session, it was not significant. Better URR with use of AV fistula has been shown in different studies and probably related to a higher blood flow in AV fistula compared to other type of access.^{9,10}

Dialyzer reuse resulted in a significant reduction of URR with each session. Studies on reduction in URR with dialyzer reuse are varied, some studies have found efficacy to be maintained upto 13-20 reuses and other have found decreased efficacy.^{4,6} Long term outcome studies of dialyzer reuse have not shown an adverse effect on morbidity and mortality.^{1,5,6}

The reduction in efficacy of dialyzer has been co-related to the presence of inflammation. Patients with higher CRP, used as a marker of inflammation and having a more reduction in efficacy.¹¹⁻¹³ There was no significant

difference in dialyzer efficacy in our study amongst patients with high or low CRP.

Reduction in dialyzer efficacy is believed to be due to clogging of pores of membrane.² This also leads to less loss of albumin in the dialysate. We did not measure albumin level in the dialysate but there was a significant decrease in Serum albumin at the fourth session. This may be due to the fact that albumin itself may be depositing on the membrane due to use of chemicals during reprocessing. The low albumin could also be due to enhanced catabolism and poor nutrition in patient undergoing haemodialysis. The fall in serum albumin can be used as an indirect marker of decrease efficacy of dialyzer.

None of the patients had significant intradialytic complications. Dialyzer first use syndrome was more with previous generation cellulose membrane dialyzer and method of sterilisation used. Present day dialyzers have a very low probability of these reactions. Reaction due to reuse can occur either due to chemical used in reprocessing or due to infections.¹⁴⁻¹⁶ Only one patient had hypotension during fourth session whereas none of the patients had any intra dialytic complications like sweating, nausea/vomiting, chest pain, hypotension, fever and rigors during first, second and third dialysis session. The requirement of heparin also did not increase with subsequent reuse. This suggest that dialyzer reuse is safe even by manual reprocessing.

CONCLUSION

To conclude, ESRD affects a younger age group in our country. Dialyzer reuse with manual reprocessing with Formaldehyde and peracetic acid though safe, does not maintain dialysis efficacy for long. Dialyzer reuse continues to be practised because of the economic benefits. Further studies to determine the best method and the maximum number of reuses at which efficacy will be retained without compromising safety are required.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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