ARTICLE

Effect of reuse of hollow fiber dialyzers upon Kt/V (Urea): a prospective study

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Abstract

Dialyzer reuse is known to reduce costs of dialysis. This prospective study was undertaken to determine the effect of manual reprocessing on the delivered dose of dialysis, safety & cost saving. Thirty patients undergoing maintenance haemodialysis between November 1999 and April 2000, were included in the study. Twenty one patients completed the study. Sixteen patients were dialyzed using cellulose acetate dialyzers 1.3m² [NiproFB-13OT] and 5 patients using polysulfone dialyzers 1.3m² [Fresenius F-6]. Dialyzers were reprocessed manually by a standard technique consisting of pre-rinsing, [treated water] cleaning [3% hydrogen peroxide] reverse ultrafiltration, rinsing, total cell volume [TCV] estimation, sterilization [4% formaldehyde] storage and priming prior to the next dialysis. Dialyzers were discarded if the total cell volume (TCV) fell below 80% of the initial value. Kt/V was estimated using pre and post-dialysis BUN, post dialysis weight and ultrafiltration. The average number of reuses of FB-13OT dialyzers was 6.73 and that of F-6 dialyzers was 11.92 [p<0.05]. No significant difference was noted between Kt/V obtained by new or reused FB-13OT and F-6 dialyzers. A good correlation was noted between the TCV and Kt/V for both FB-13OT dialyzers [R=0.70] and F-6 dialyzers [R=0.69]. Two febrile episodes during 166 reuses and 1 episode during 21 first uses were noted. A cost saving per session of Rs.645/- was achieved for F-6 dialyzers and Rs.546/- for FB-13OT dialyzers due to reuse, compared to new dialyzers. This manual method of reuse does not compromise efficacy or safety and results in significant cost saving. The Kt/V correlates well with the TCV.

Key words: Dialyzer- reuse, Kt/V, TCV, Cost saving

Introduction

Dialyzer reuse, first introduced in the 1960s, as a cost saving measure is now practiced in most centers of the world, except where it is proscribed by law. Studies of adequacy and safety of dialysis using re-used dialyzers have yielded equivocal results and a centre specific effect of reuse on delivered KT/V has been noted raising concerns, about monitoring the reuse process[1].

Centers in India reuse dialyzers between 5 and 8 times[2], manual reprocessing and subjective visual estimates of dialyzer quality, instead of total cell volume (TCV) measurement are common, and can result in inadequate delivered dose of dialysis[3] .

This study was undertaken to determine delivered dose of dialysis as estimated by Kt/V(urea) and its relation to (TCV) of reused dialyzers reprocessed manually in our unit in patients who had chosen maintenance hemodialysis as their renal replacement therapy. Safety of the method in the short term was also noted. The cost of dialysis using new and reused dialyzers was calculated.

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Patient and Methods

30 patients were included in the study from November, 1999 to April, 2000.

Inclusion criteria

1. Patients having end stage chronic renal failure on thrice-weekly hemodilaysis of at least 6 months.
2. Permanent vascular access yielding at least 250-300ml per minute blood flow.

Exclusion criteria

1. Access failure [2 patients]
2. Hepatitis B carrier state [3 patients]
3. Early transplantation [2 patients]
4. Lost to follow up [2 patients]

21 patients out of initial 30 completed the study. 16 used cellulose acetate dialyzers [FB-130T (Nipro)] and 5 used polysulfone dialyzers [F-6 (Fresenius)], having surface areas of 1.3m^2. All patients were dialysed with bicarbonate dialysate and machines having volumetric control of ultrafiltration [TR-321X(Toray) and NCU-10E (Nipro)]. Anticoagulation was maintained by a loading dose of heparin followed by hourly boluses, to maintain the Lee-White clotting time at 1.5 times the baseline. The target Kt/V in our unit is 1.2. nPCR was calculated from Kt/V and pre-HD BUN every week.

Procedure of reprocessing

The manual method of reprocessing used in our centre is as follows:

1. Reprocessing was started immediately after termination of the dialysis.
2. Blood was returned from the circuit to the patient with 200 ml of saline using the machines blood pump.
3. The entire circuit was then pre-rinsed with treated water, maintaining a pulsatile flow by periodic clamping of the venous outflow line to dislodge adherent blood products .
4. At the reprocessing area the arterial and venous tubings, were disconnected, the dialysate compartment was filled with 3% hydrogen peroxide, for2-3 minutes
5. After closing one outlet, reverse ultrafiltration using a Hansen's connector and treated water at 3.0 liters per minute was carried out in 3 cycles of 12 minutes each. The direction of flow was reversed with each cycle and the blood compartment rinsed for 2 minutes during alteration of flow.
6. The dialysate compartment was then filled with treated water and closed at both ends.
7. The dialyzer was inspected for large clots in the headers or discolored fibres in which case it was discarded. During this study no dialyzer was discarded for this reason. The total cell volume [TCV] was estimated by displacing the water from the blood compartment into a measuring cylinder using a sphygmomanometer bulb as previously described[4].
8. Dialysers were discarded if the TCV fell to < 80% of its initial value.
9. The blood compartment was again rinsed with treated water using pulsatile flow to remove air, and then reconnected to the tubing. The blood compartment, tubings and drip chambers were filled with 4% formalin using the machine blood pump.
10. Dialysers were labeled with the patients name, registration number, and number of reuse and stored in an individual compartment at room temperature until the subsequent dialysis session.
11. During priming for subsequent dialysis the dialysate compartment was filled with heparinized saline, the tubings connected, and dialysate circulation started at 500ml per minute.
12. Formalin was removed from the circuit using 3 liters or more of heparinized saline until the effluent gave a reading of trace or less on Serim reagent test strips or less than 5ppm using Schiff's reagent.

Estimation of Kt/V

The delivered dose of dialysis was estimated from the pre and post dialysis BUN values and ultrafiltration achieved using the Daugirdas 2nd generation formula.

$$\frac{Kt}{V} = -\ln [R - 0.03] + [4 - 3.5R] \times \frac{UF}{W}$$

Where $R = \frac{\text{Post BUN}}{\text{Pre BUN}}$

UF = Achieved ultrafiltration

W = Post dialysis weight

The pre-dialysis sample was drawn at insertion of the arterial needle and the post-dialysis sample just prior to patient disconnection using the slow flow technique recommended by the NKF working group (1997)[1]. Computational software available on the Up to Date programme was used to calculate Kt/V for each and every use of all dialyses during the study and the results were analyzed by the Student's paired 't' test.

Observations

twenty one patients completed the study. Nine patients were withdrawn from the study and not included in the analysis because two developed vascular access problems, requiring temporary catheter insertion, 2 were taken for early transplantation, 1 patient became hepatitis B surface antigen positive and 2 patients were lost to follow up.

The patient and dialyzer characteristics including priming volumn as specified by the manufacturers are shown in Tables 1 & 2.[5,6] During the study period 16 cellulose acetate FB-130T dialyzers and 5 polysulfone F-6 dialyzers were used to do 187 dialysis sessions.

The average number of reuses obtained with F-6 dialyzers, 11.92 [range 10-17] was significantly higher than that with FB-130T dialyzers 6.73 [range 5-12] [p<0.01].

13 out of 16 FB-130T and 4 out of 5 F-6 dialyzers were discarded because the TCV decreased to <80% of its initial value, 2 FB-130T dialyzers were discarded because the patients developed pyrexia and 1FB-130Tand 1 F-6 were discarded because of complaints of pruritis, during the 6th and 10th reuse respectively

despite TCV being maintained. During the same period one episode fever occurred during first use of FB-130T dialyser. There were no episodes of pruritus during first use. The mean Kt/V for all uses and TCV values and their relation is shown in Tables 3 and 4.

During 13 out of 107 dialysis [9.1%] sessions with reused FB-130T dialyzers the Kt/V fell below 1.2 [the target in our unit and also in the NKF working group guideline] and in 3 out of 59 reuses [5%] of F-6 dialyzers. KT/V during 1st use of dialyzers was compared with that of reused dialyses by the paired t-test and the results are shown in table 5. No significant difference was noted in the KT/V obtained with new dialyzers and with reused dialyzers during this study as long as the TCV was maintained at or more than 80% of its initial value.

A positive correlation was noted between the TCV for both cellulose acetate and polysulfone dialyses [R=0.70] and [R=0.69] respectively as shown in Figures 1 and 2.

The serum albumin was 3.75 ± 0.34 g/dl at the start of the study and 3.69 ± 0.45 g/dl at the end of the study. The mean nPCR was 0.85 ± 0.21g/kg/day at the start of the study and 0.82 ± 0.16g/kg/day at the end of the study. The difference was not statistically significant.

The cost of first use of FB-130T dialyser was Rs.949 per session whereas the same for F-6 dialyser was Rs.1014 per session. The cost of reusing F-6 dialyzers was Rs.369 and that of FB-130T was Rs.403 per session thus leading to a cost saving of Rs.546 using FB-130T dialyzers and Rs.645 per session using F-6 dialyzers respectively as shown in Table 6.

Discussion

The practice of reusing dialyzers results in satisfactory delivery of dialysis dose and cost saving. However several studies have reported an increased mortality among centers that reused dialyzers[7, 8]. This has been attributed to a decreased dose of dialysis with reused dialyzers[7, 8], exposure to the chemicals used in reprocessing[7], breach of sterility and increased incidence of infections[9] and qualitative and quantitative changes in the dialyzer membrane due to the reprocessing technique[8, 9].

In this prospective study, we studied the Kt/V (urea) of dialyzers manually reprocessed in our dialysis department. Decrease in the delivered Kt/V [urea] from a value of 1.05 increased the relative risk of death[8,10], and hence Kt/V (urea) is an important indicator of the adequacy of dialysis, and outcome. We also attempted to correlate the KT/V [urea] with the TCV of new and reused dialyzers. The TCV estimated manually in this study is the simplest test of dialyzer performance, and is recommended as a surrogate for urea clearance both of cellulose and synthetic [polysulfone] membranes[1, 11,12,13].

We found that the TCV of the 16 new cellulose acetate dialyses [FB-130T] varied between 70 and 74ml, and that of the 5 polysulfone [F6] dialyzers was 74ml when estimated manually. The manufacturers data for the TCV of these 2 dialyzers was 75 and 82ml. respectively. Using this data as a baseline value, or using an average value for a particular batch of dialyzers would have resulted in discarding of the dialyzers early and in a lower mean and individual number of reuses. This variation in the TCV of individual dialyses has been previously reported for both cellulosic membranes[14] and polysulfone membranes, with a coefficient of variation of 2.4% for the TCV of cellulosic membranes and 1.9% for polysulfone membranes.[13]

The TCV was maintained above 80% of its initial value for an average of 6.73 reuses for FB-130T dialyzers and 11.92 reuses for the F-6 dialyzers, while the maximum number of reuses that could be obtained, was 13 with the FB-130T and 18 with the F-6 dialyzers.

After assessing the Kt/V [urea] at all dialysis sessions performed during the study period we found no significant difference between that of new dialyzers and

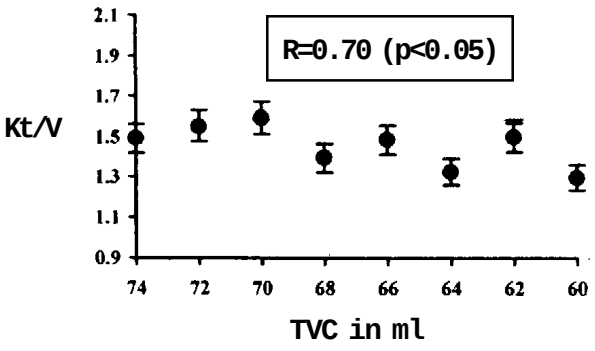

Fig 1 - Correlation of TVC & Kt/v for FB-130T dialysers

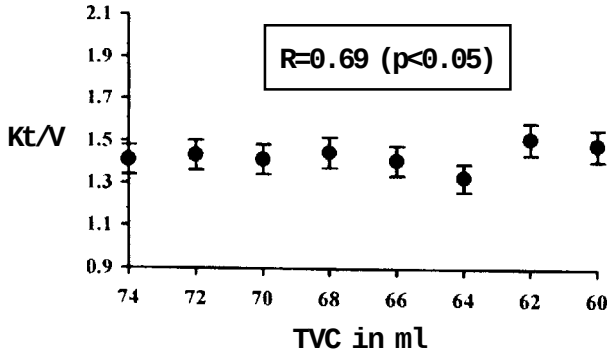

Fig 2 - Correlation of TVC & Kt/v for F6 dialysers

of FB-130T dialyzers reused 6 times, 8 times and in 1 case 13 times, and for F-6 dialyzers reused 10 to 12 times. Similar findings in 104 patients using manually reprocessed standard low flux dialyzers on average 6.74 times[4] and high-flux cellulose acetate and polysulfone membranes reprocessed by an automated technique[13]. The Kt/V [urea] and TCV were not significantly changed over 12 uses of cellulose acetate and 10 & 15 reuses of polysulfone dialyses in the above study. Similarly others have found that the Kt/V [urea] & TCV was well maintained over 8 reuses of both cellulose acetate and polysulfone dialyzers reprocessed automatically[15]. A countrywide survey covering 20,000 patients in the USA found that delivered KT/V tended to be higher in centers that reused dialyzers [1.22 vs. 1.19][16].Conversely others found a significant decrease in KT/V [urea] between a mean 3.8 reuses and 13.8 reuses [1.10 vs 1.05][17].

The most significant decrease in their study occurred during reuse with formalin [1.18 vs 1.08]. Similar findings of a significant difference in urea and creatinine clearance between new and reused dialyzers reprocessed with formalin and bleach were reported[9]. The Kt/V [urea] dropped by > 10% in 15 of 156 reuses with cellulose acetate dialyses reprocessed manually using 4% formalin, and inadequate dialysis [Kt/V of < 1.2] resulted in 5 cases in an Indian study[3]. In this study however, the TCV was not estimated, but a visual impression of the dialyzer was used as a criteria for discarding dialyzers. In our study also we found the Kt/V to fall to <1.2 in 13 of 123 reuses(9.7%) with FB-130T dialyzers and 3 of 64 reuses (5%) with F-6 dialyzers. When the variables like decreased blood flow, stoppage time for hypotension, dialysate conductivity failure were excluded, the number of dialysis sessions where Kt/V was <1.2 decreased to 7 of 117 reuses with FB-130Tcellulose acetate dialyzers [6.06%] and 1 of 61 reuses [1.67%] with F-6 dialyzers.

A positive co-relation was noted between TCV and KT/V [urea] for both cellulose acetate [R=0.70] and polysulfone dialyses [R=0.69]. Only one study reported a very significant decrease in urea clearances of 48% with reused dialyzers, despite a TCV maintained above 80% of the starting value for low-flux cuprophan membranes[18]. They found that non-uniform flow of dialysate in a batch of dialyzers was responsible for this

Table 1 - Patient characteristics

Patient parameters	Parameters studied
No. of patients included for analysis	21
Patient using FB-130T dialyzers	16
Patients using F-6 dialyzers	5
Dialysis with FB 130T dialyzers	123
Dialysis with F-6 dialyzers	64
Blood flow	250-300ml/min
Dilaysate flow	500ml/min
Time on dialysis	240 minutes
Vascular access	
Radiocephalic AV fistula	16
Breachioephalic AV fistula	3
Sephaneous vein jump graft	2
Mean serum albumin before study period	3.75±0.34 g%
Mean serum albumin after study period	3.6±0.45 g%
Mean nPCR at start of study	0.85+0.21g kg/day (range 0.72-1.05)
Mean nPCR at end of study	0.82+0.16 g/kg/day (range 0.78-0.99)

Table 2 - Dialyzers characteristics during the study

Parameters studied	FB-130T dialyzer	F-6 dialyzer
Priming volume (manufacturers data)	85 ml	82 ml
Initial TCV	70.75 ml range (70-74)ml	74 ml
TCV <80%	12	4
Pyrexia	2	1
Pruritis	2	0

Table 3 - Delivered dialysis dose Kt/V of New & Reused dialyzers

FB 130T dialyzers			F-6 dialyzers		
Reuses	Patients	KT/V mean±SD	Reuses	Patients	KT/V mean±SD
New	16	1.56±0.35	New	5	1.50±0.15
2	16		2		
4	16	1.36±0.35	4	5	1.25±0.20
6	12	1.26±0.33	6	5	1.40±0.38
8	3	1.59±0.39	8	5	1.46±0.14
10	1	1.40	10	5	1.54±0.16

Table 4 - Relation of TCV & Kt/V

FB-130T dialyzers			F-6 dialyzers		
TCV	Dialysis in ml	Kt/V mean±SD sessions	TCV	Dialysis	Kt/V mean±SD session
74	3	1.49±0.11	74	4	1.41±0.16
72	5	1.55±0.25	72	6	1.43±0.17
70	23	1.59±0.45	70	8	1.41±0.21
68	16	1.57±0.39	68	8	1.44±0.21
66	15	1.68±0.26	66	8	1.40±0.32
64	21	1.32±0.33	64	7	1.32±0.22
62	13	1.49±0.24	62	7	1.50±0.22
60	16	1.30±0.24	60	6	1.47±0.20
58	4	1.21±0.21			
56	8	1.39±0.27			

Table 5 - Comparison of Kt/V of new & reused dialyzers

Cellulose acetate dialyzers			Polysulfone dialyzers		
Reuses	t-value	P value	Reuses	t-value	p-value
[0,3]'	0.47	0.32	[0,3]	0.89	0.20
[0,5]	0.07	0.47	[0,7]	0.68	0.26
[0,7]	0.13	0.45	[0,11]	0.68	0.26
[0,6]	0.02	0.49	[1,8]	0.84	0.21
[2,7]	0.58	0.28	[2,9]	0.33	0.37
[3,6]	0.16	0.44	[3,11]	0.84	0.21

0* = New dialyses. Subsequent reuses designated by numbers in sequence.

phenomenon. This effect was attributed to possible errors in fibre length, geometry or number and was believed to be batch-specific and has not since been reported.

The use of bleach as a cleaning agent has been shown to increase the ultrafiltration co-efficient of polysulfone dialyzers and lead to significant loss of albumin in the dialysate[19]. In our study, although we did not estimate protein in the spent dialysate, the plasma albumin of the patients was maintained during the study period, as shown in table 1.

2 of the 16 FB-130-T dialysers were discarded because of febrile episodes, 1 of which was due to malaria. Only 1 episode of fever occurring in 166 dialyses with reused dialyzers could be attributed to the reprocessing procedure itself, an incidence of 0.6%.

In contrast to this, an outbreak of M.chelonei infection in patients using reprocessed dialyzers due to tap water contamination has been reported[20]. In our study all the water used for reprocessing was treated with 3 column de-ionization a process, which may have contributed to the low incidence of febrile reactions.

Conclusion

In conclusion the manual method of reprocessing dialyzers using hydrogen peroxide as cleaning agent and formalin as sterilant, does not appear to significantly change the Kt/V [urea] over the period of reuse provided the TCV is maintained above 80%.

The F-6 dialyzers maintained the TCV above 80% for a mean of 11.92 reuses and the FB-130T dialyzers for a mean of 6.73 reuses.

No increased incidence of febrile reactions was noted over the study period with reused dialyzers

The Kt/V [urea] co-related with the manually measured TCV.

Thus, manual reprocessing of dialyzers appears to be safe, efficient and results in significant cost saving, of around 60% in terms of materials.

Table 6 - Material costs of new & reused dialyzers

Material	FB-130T New	FB-130T 6.7 reuses	F-6 New	F-6 11.9 reuses
Dialyses	520	75	585	49
Dialyze tubing's	162	27	162	14
Bicarboante solution (5 litres)	80	80	80	80
Fistula needles	28	28	28	28
I/V sets	9	9	9	9
Saline 3 liters	36	36	36	36
Heparin 2 vials	60	60	60	60
2 hypodermic needles	2	2	2	2
2 disposable syringes	3	3	3	3
Inj. Xylocaine 2%	11	11	11	11
Anhydrous dextrose [300mg]	20	20	20	20
Hydrogen peroxide 3%	-	5	-	10
Formalin 4% [150ml]	-	12	-	12
Reagent strip	-	17	-	17
1 venous transducer	14	14	14	14
Micropore 1	4	4	4	4
Total	Rs.949	Rs.403	Rs.1014	Rs.369

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