



Automated Dialyzer'S Reuse: A Safe and Cost-Effective Strategy

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Abstract

Introduction: Dialyzer's reuse is common due to economical restraints related to ESRD. In Mexico up to twelve reuses per dialyzer are permitted. Previous studies have reported no difference in mortality among patients with dialyzer reuse vs. single use. The aim of this study was to evaluate the clinical impact of dialyzer's reuse in HD patients in Mexico.

Methods: Retrospective, cross-sectional study in HD patients. Only patients who had a Kt/V \geq 1.2 were included. High flux dialyzers were used. Reuse was automated with Renatron II 100 Series™ and Renalin™ was the cleaning agent. Data was collected through 16 HD clinics data base. Analysis was performed by the statistical package SPSS 22.

Findings: 2,561 patients were evaluated. Only 597 patients (23.3%) with Kt/V \geq 1.2 were included. 80.7% were in dialyzer reuse program. Average reuse was 5.5 times per dialyzer (range 1 to 12). Hemoglobin, urea pre and post values were statistically better for patients with dialyzer reuse. Laboratory values (serum electrolyte, creatinine, uric acid, albumin, and PTH and iron kinetics) did not differ among reuse vs. single use. Time to death and mortality did not differ among both groups. No significant differences were identified in dialysis treatment prescription (dialysate flow, ultrafiltration, blood flow, sodium conductivity).

Conclusion: Less than 1 every 4 patients achieve a Kt/V >1.2, regardless the fact of reusing dialyzer or not. Reuse is a common practice in our settings and is carried out in eight of every ten patients. Automated dialyzer's reuse is a controversial practice, but according to these findings, it is safe. Further studies are needed to assess the long-term clinical impact of this practice.

Keywords: Hemodialysis; Dialyzer; Reuse automated; Mortality

Introduction

Dialyzers reuse was very popular during the 1980s through 1990s [1]. It had been reported to be a safe and cost-effective procedure for high-flux and high-urea removal dialyzers [2,3]. But even though previous studies have reported no difference in mortality among patients with dialyzer reuse vs. one single use, nowadays dialyzer reuse is rare in the United States and most resource-rich countries, but it is still performed in other parts of the world, particularly in countries with limited resources to dedicate to renal replacement therapies [4]. The practice declined due to concerns about the risk of infection to patients or staff, loss of performance with impairment in clearance and/or ultrafiltration, and exposure of patients or staff to germicide [5,6]. Dialyzers reuse remains a controversial yet indispensable practice in countries with economic constraints to deliver renal replacement therapy to a growing number of patients. The Mexican Health Institute is responsible to deliver renal replacement therapy to roughly 73% of the Mexican End-Stage Renal Disease (ERSD) patients and expends an average of \$9,091 USD per patient per year in dialysis. In 2014, the treatment of ESRD represented 15% of the total annual expenditure for the Institute; this expense was invested in only 0.8% of the beneficiaries (population with ESRD) [7]. That is why it is important to look for cheaper options in the care of patients with ESRD, without neglecting safety and quality. In Mexico, dialyzers reuse practice is regulated by the Ministry of Health, allowing only up to twelve reuses per dialyzer if the dialyzer passes the performance tests: Membrane integrity (absence of leaks in the dialyzer casing, membrane, and supporting materials); clearance (fiber bundle volume at least 80% of original measured volume or urea clearance at least 80% of original measured clearance);

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Received Date: 08 Nov 2021

Accepted Date: 03 Dec 2021

Published Date: 07 Dec 2021

Citation:

Karina R-L, Gabriela A-M, Mónica J-C, Marisol L-C, Daniel M-B. Automated Dialyzer'S Reuse: A Safe and Cost-Effective Strategy. *J Clin Nephrol Kidney Dis.* 2021; 6(1): 1030.

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and ultrafiltration capability [8]. The dialyzer represents the most expensive disposable medical supply per hemodialysis treatment (approximately 30% of the total cost of disposable supplies). For each patient admitted into the reuse program, significant savings are achieved (an average of 24% savings in disposable medical supplies) [9]. In addition to savings, dialyzer’s reuse has a positive impact on caring for the environment, since it reduces the amount of biological waste per hemodialysis session. Dialyzer processing may be performed manually or with the use of automated equipment. Currently, most reprocessing in Mexico is done using automated methods, which is supposed to be more reliable and predictable since it is less prone to human error [4,10]. Cleaning agents include peracetic acid-based products such as Renalin™, which is a combination of peracetic acid, acetic acid hydrogen peroxide. Renalin™ is the most used cleaning and sterilizing agent for dialyzers reuse [11]. The aim of this study was to assess the impact of automated dialyzer reuse with on mortality in prevalent hemodialysis patients in Mexico.

Materials and Methods

Design

A cross-sectional, multicenter study of patients belonging to 16 hemodialysis clinics in Mexico. Reuse protocol was explained to every new patient admitted (rinsing, cleaning, performance testing, disinfection/sterilization, and labeling/storage). Informed consent was mandatory to include patients in the reuse program. Patients who refuse to sign informed consent were allocated in the single use group Figure 1.

Dialyzers

All dialyzers were high flux, hollow fiber polysulphone (Bellco BLS™), surface range 1.4 thru 2.1 m². All dialyzer’s were reused with automated Renatron™ II 100 Series device and peracetic acid (Renalin™).

Patients

Subjects with chronic renal failure who attended hemodialysis and with Kt/V <1.2 were included. Those who had any contraindication for reuse (ongoing bacterial or fungal infection, positive test for HIV, hepatitis B or C and any other clinical circumstance determined by the nephrologist) were excluded.

Obtaining data

Data was collected through data base from sixteen clinics across the country. The general characteristics of the patients, laboratory parameters and those related to the prescription of dialysis were analyzed separately.

Statistics

The variables were analyzed in a multivariate study, where chi square and “t” of student were applied to determine statistical significance.

Results

2,561 medical record were evaluated, 1964 were excluded (Kt/V <1.2), only 597 patients (23.3%) had Kt/V ≥ 1.2 and were included for analysis, of which 482 patients (80.7%) accepted to be in the dialyzer reuse program. Variables demographic were recorded, dialysis

Table 1: Baseline characteristics of the patients.

Base line characteristics*	Overall n=597	Reuse n=482	Single use n=115	P**
Male, n (%)	258 (43.2)	212 (44)	46 (40)	0.43
Age (years) media (SD)	46.8 (18.1)	47.2 (18.3)	45.4 (16.9)	0.33
Insured, n (%)	564 (94.5)	452 (93.8)	112 (97.4)	0.12
CKD etiology, n (%)				
Diabetes mellitus, n (%)	153 (25.6)	130 (27)	23 (20)	0.12
Hypertension, n (%)	54 (9)	47 (9.8)	7 (6.1)	0.21
Number of vascular access, media (SD)	2.3 (1.4)	2.17 (1.3)	2.83	<0.01
Functional vascular access, n (%)	572 (95.8)	459 (95.2)	113 (98.3)	0.14
Exhaustion VA syndrome, n (%)	4 (0.7)	4 (0.8)	0	0.32
Vascular access				
Native AV fistulae, n (%)	275 (46.1)	207 (42.9)	68 (59.1)	0.002
Prosthetic AV fistulae, n (%)	16 (2.7)	14 (2.9)	2 (1.7)	0.48
Tunneled CVC, n (%)	191 (32)	159 (33)	32 (27.8)	0.28
Untunneled CVC, n (%)	115 (19.3)	102 (21.2)	13 (11.3)	0.01
Prior peritoneal dialysis, n (%)	373 (62.5)	304 (63.1)	68 (60)	0.54
Prior kidney transplant, n (%)	81 (13.6)	62 (12.9)	19 (16.5)	0.3
Hemodialysis vintage, months media (SD)	41.6	40.8 (34.8)	44.74 (32.1)	0.31
Time to death, months media (SD)	7.59 (8.6)	7.64 (9.2)	7.33 (6.4)	0.054
End points				
Death, n (%)	21 (3.5)	18 (3.7)	3 (2.6)	0.55
Transfer to another facility, n (%)	8 (1.3)	8 (1.7)	0	0.16
Kidney transplant, n (%)	8 (1.3)	5 (1)	3 (2.6)	0.18

*CVC: Central Venous Catheter; HD: Hemodialysis; AV: Arteriovenous; VA: Vascular Access

**chi square, t Student

Table 2: Laboratory values*

Variables	Overall n=597	Reuse n=482	Single use n=115	p**
Hemoglobin, gr/dL	9.9 (2.2)	10 (2.4)	9.3 (2.2)	0.01
Hematocrit, %	28.8 (6.1)	28.9 (6.7)	27 (6.1)	0.007
Glucose, mg/dL (SD)	110.2 (60.5)	110.1 (62.7)	107.9 (52.8)	0.72
Sodium, mEq/L (SD)	139.3 (5.6)	139.4 (5.8)	139.1 (4.5)	0.6
Potassium, mEq/L (SD)	6 (6.7)	6 (7.4)	5.6 (1.1)	0.5
Phosphate, mg/dL (SD)	5.7 (8.6)	5.8 (9.5)	5.1 (1.8)	0.45
Calcium, mg/dL (SD)	9 (1.1)	8.9 (4.8)	8.7 (1.7)	0.65
Chlorine, mEq/L (SD)	102 (37.8)	101.1 (43.2)	99.9 (10.7)	0.78
Cholesterol, mg/dL (SD)	65.7 (76.6)	76.1 (77.8)	26.6 (57.1)	<0.01
Triglycerides, mg/dL (SD)	67.7 (92.3)	46.1 (80.8)	23.1 (71.5)	0.005
Albumin, g/dL (SD)	3.7 (0.7)	2.9 (1.7)	2.8 (1.64)	0.3
TGO, U/L (SD)	22.4 (19.5)	12.6 (19.4)	13.7 (13.9)	0.5
TGP, U/L (SD)	22 (14.1)	21.7 (14.7)	22.1 (9.4)	0.9
Uric acid, mg/dL (SD)	6.6 (1.4)	6.3 (1.9)	6.7 (1.9)	0.06
Creatinine, mg/dL (SD)	9.7 (5.7)	9.7 (6.1)	9.7 (3.4)	0.9
Urea pre-HD, , mg/dL (SD)	134 (41)	132.2 (41.4)	141.7 (40)	0.02
Urea post-HD, mg/dL (SD)	42.6 (13.9)	42 (13.9)	45 (14)	0.04
URR, media (SD)	70.5 (9.6)	70.7 (10)	69.7 (7.7)	0.31
Iron saturation, % (SD)	67.9 (71.8)	54.9 (70.2)	46.9 (66)	0.26
Serum iron, µg/dL (SD)	108.5 (95.1)	88.4 (95.2)	78.7 (96.3)	0.32
Ferritin, ng/mL (SD)	396.3 (367.1)	295.9 (372.9)	293.4 (306.8)	0.98
Parathormone, pg/dL (SD)	177.2 (305.6)	185.7 (310.9)	160.9 (300.4)	0.73

*Expressed in media; (SD): Standard Deviation; URR: Urea Reduction Rate

**chi square, "t" Student

Table 3: Hemodialysis prescription.

Variables*	Overall n=597	Reuse n=482	Single use n=115	p**
Number of HD treatments/week, media (SD)	2.96 (0.1)	2.96 (0.18)	2.9 (0.2)	0.6
HD hours/week, media (SD)	9.68 (1.1)	9.6 (1.2)	9.7 (1.2)	0.4
EPO use/week, IU (SD)	11886 (6738)	11850 (7139)	12034 (4723)	0.79
Intradialytic iron dose/week, mg (SD)	98.7 (27.2)	44.1 (52.9)	55.2 (51)	0.04
Heparin bolus, IU (SD)	1242.3 (567.1)	1273.8 (557)	1110.4 (592)	0.05
Heparin per hour, IU (SD)	525.9 (308)	540.8 (308.3)	463.4 (299.8)	0.01
Dialyzate flow, ml/min				
300 ml/min, (%)	0	0	0	NA
500 ml/min, (%)	208 (34.8)	176 (36.5)	32 (27.8)	0.07
800 ml/min (%)	389 (65.2)	306 (63.5)	83 (72.2)	0.07
Blood flow, ml/min				
200 ml/min -249 ml/min, (%)	4 (0.7)	4 (0.8)	0	0.32
250 ml/min -299 ml/min, (%)	5 (0.8)	3 (0.6)	2 (1.7)	0.23
300 ml/min -349 ml/min, (%)	39 (6.5)	33 (6.8)	6 (5.2)	0.52
350 ml/min -399 ml/min, (%)	209 (35)	173 (35.9)	36 (31.3)	0.35
400 ml/min - 449 ml/min, (%)	316 (52.9)	247 (51.2)	69 (60)	0.9
>450 ml/min, (%)	24 (4)	22 (4.6)	2 (1.7)	0.16
Sodium conductivity, (SD)	13.7 (0.14)	137.2 (1.5)	136.9 (1.25)	0.8
Ultrafiltrate, L (SD)	0.6 (1.1)	0.51 (0.99)	0.67 (1.18)	0.1

*Expressed in media; (SD): Standard Deviation; L: Liters; IU: International Units; EPO: Erythropoietin

**chi square, "t" Student

Table 4: Multivariate analysis with binary logistic regression.

Multivariate analysis	p*	OR	IC 95%
Number of vascular accesses	<0.01	1.2	1.1-1.4
AV fistulae	0.038	1.6	(1.02-2.5)
Hemoglobin	0.58	0.9	0.6-1.2
Hematocrit	0.83	0.98	0.86-1.1
Urea pre-HD	0.48	1	0.9-1
Urea post-HD	0.69	1	0.9-1
Weekly IV iron	0.16	1	1-1.09
Heparin bolus	0.23	1	0.99-1
Heparin per hour	0.65	1	0.99-1

*chi square, "t" Student

prescription parameters, type of vascular access, biochemical results and withdrawal from treatment were recorded (Table 1). Multivariate analysis was performed; chi-square and Student's t-test were applied to identify statistical significance. Average reuse was 5.5 times per dialyzer (range 1 to 12). Overall average hemoglobin was below the recommended level of 10.5 gr/dL but was significantly better in the reuse group than in the single use group (10 and 9.3 gr/dL respectively, p=0.001). Urea pre and post hemodialysis values were statistically better for patients with dialyzer reuse. Other laboratory values (serum electrolyte, creatinine, uric acid, albumin, parathormone and iron kinetics) did not differ among patients who underwent reuse of dialyzer vs. those with single use urea reduction rate did not vary among both groups (Table 2). The weekly iron dose was significantly lower in the reuse group. No significant differences were identified in dialysis treatment prescription (dialysate flow, ultrafiltration, blood flow, sodium conductivity) nor in the multivariate analysis (hemoglobin, urea pre and post, weekly IV iron dose, heparin initial and hourly dose) (Table 3). Multivariate analysis with binary logistic regression only found a significant difference in the number of vascular accesses, p<0.01 (Table 4). Overall, twenty-one patients died (3.5%): Eighteen in the reuse group (3.6%) and three in the single use group (2.6%). Time to death and mortality did not differ among both groups (p>0.05).

Discussion

Mexico registers one of the highest incidences and prevalence of ESRD worldwide [7,11]. Economic burden is a mayor incentive to promote actions to lower costs in the care of ESRD. Dialyzers reuse is a strategy than can significantly lower costs if done properly. Experience has been generated over the years in the reuse of dialyzers and reprocessing has been protocolized, so more dialysis providers in Mexico are currently looking to get patients into the reuse program. One of the limitations to admitting more patients to the reuse program is the belief that the patient will not receive the same quality of hemodialysis as with a new dialyzer in each session (loss of performance with impairment in clearance and/or ultrafiltration) [4]. Our findings show that patients in the reuse program do not present lower values in the dialysis dose or in laboratory parameters such as hemoglobin, phosphorus, and urea reduction. Another concern is cross usage and the increased in infection risk to patients or staff. There are still no studies that have shown an increase in the risk of cross-infection due to the reuse of dialyzers, and there is no evidence that dialyzer reuse is associated with viral hepatitis or Human Immunodeficiency virus (HIV) transmission to patients or dialysis personnel if appropriate guidelines are followed by the medical staff. Although the purpose of this study was not to assess the risk of cross

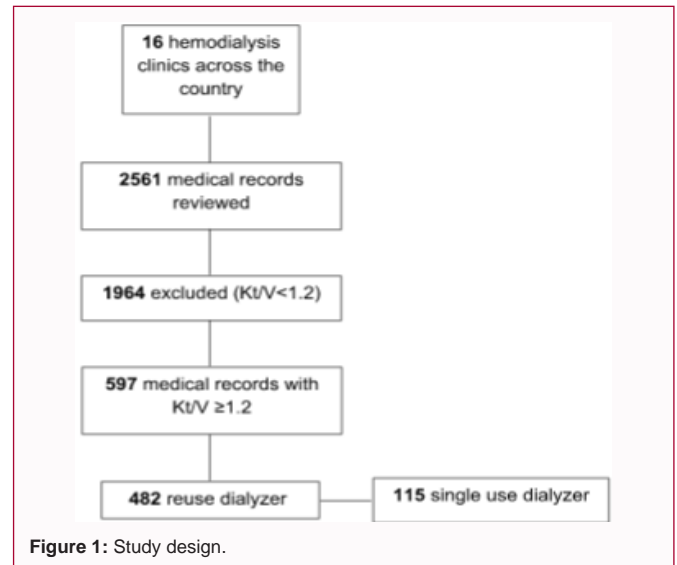


Figure 1: Study design.

contamination, when reuse is done properly, cross usage should not be a concern and nor infection risk. Also, Mexican health authorities prohibit the reuse of dialyzers in patients with hepatitis B, C or HIV, and international guidelines advice that patients with an infectious disease, bacteremia or sepsis are temporarily excluded from the reuse program until the infectious process is resolved. If we take these two precautions into account, these risks can be minimized [8,12]. Exposure of patients or staff to germicide has been another limitation for the generalized practice of reuse. Higher neutrophil superoxide bursts and anaphylactoid reactions have been reported in patients treated with reprocessed dialyzers sterilized with peracetic acid, but the clinical implication of these observations is still unclear [13-15]. We only used Renalin™ for the chemical disinfection and sterilization of dialyzers. Unfortunately, we did not include a record of adverse or anaphylactic reactions due to the use of peracetic acid in patients undergoing reuse, but we found no difference in the mortality of patients subjected to reuse. As for mortality outcomes, increase, decrease, and no change in mortality have been reported [16,17]. In a 2012 meta-analysis that included 14 studies and 956,807 patients, automated and manual reuse, and different chemicals for disinfection and sterilization, no significant differences were identified for the superiority or inferiority of dialyzer reuse vs. single use when assessing the mortality of patients with ESRD [4]. Although our sample was significantly smaller, we did not find differences in the mortality of patients subjected or not to reuse. Another concern about dialyzer's reuse is clotting. Dialyzer clotting tends to increase with reuse and contributes to the decline in dialyzer performance. One should expect that reuse patients would have lower hemoglobin levels due to increased clotting, but surprisingly in our study we observed better hemoglobin levels at lower doses of intravenous weekly iron and with the same average dosage of erythropoietin. This might be explained by the fact that we do increase the heparin dose per protocol when reusing dialyzers. Ouseph et al., reported that even though the heparin dose may need to be increased with reused dialyzers, the heparin prescription is generally not adjusted automatically but rather on indication (i.e. in the setting of clotting) [18]. Positive effects of reuse it to improve dialyzer membrane biocompatibility and reduce the risk of first use syndrome like first-use syndrome and biocompatibility have been reported, but these positive effects can now also be achieved with dialyzers without reprocessing by thorough rinsing of the dialyzer and blood lines before use and with

the use of biocompatible membranes like polysulphone [4,10,19]. So, for now, it is not possible to identify beneficial clinical effects of reuse, but economic ones. Dialyzer reuse continues to emerge as an integral part of hemodialysis due to financial savings, adequate overall safety, and better membrane biocompatibility. Dialyzer reuse is an efficient method that saves costs and enables the use of more efficient and expensive biocompatible synthetic membranes, thus providing high-quality dialysis to people living in countries with limited medical resources without compromising the safety or effectiveness of the treatment [20]. Our study has the limitation of having been carried out retrospectively. Suspected adverse events, anaphylaxis, cross contamination, and infectious events that could be related to dialyzer reprocessing were omitted. Given that the Mexican Health authorities do not allow reuse in patients with a suspected or confirmed diagnosis of Hepatitis B, C or VHI, neither can we know the risk of infection by these viruses with the practice of reuse. We also did not investigate possible adverse events or bleeding related to increased heparin dose in patients undergoing reuse. It will be necessary to carry out prospective studies to evaluate not only the impact of reuse on mortality, but also its impact on the incidence of adverse events, cross-infection, and anaphylactic reactions to show whether the current protocol that we use in the reuse of dialyzers is effectively safe for patients and staff.

Conclusion

Reuse is a common practice in our settings and is carried out in eight of every ten patients. Less than one every four patients in our settings achieved a $Kt/V \geq 1.2$, regardless the fact of reusing dialyzer or not. Actions to improve Kt/V delivery are urgently needed. Higher doses of heparin are needed in patients undergoing dialyzer reuse to prevent clotting and blood loss. Hemoglobin level was higher in the dialyzers group at lower weekly intravenous iron. Automated dialyzers reuse is a controversial practice, but according to these findings, it is safe. The financial panorama of ESRD points to an urgent and generalized need to optimize economical resources and to provide safe treatments to more patients at lower costs. Actions to improve the reuse technique to extend the dialyzers life to its maximum allowed are needed. Dialyzers reuse is a cost-effective alternative to maximize resources to treat ESRD patients, but further studies are needed to assess the long-term clinical impact of this practice in patients and staff.

Statement of Ethics

We conducted this study in accordance with the tenets of the World Medical Association Declaration of Helsinki. Informed consent written was mandatory. The data record is kept confidential and no public data of the patients is displayed.

Study Limitations

This is a retrospective study. Suspected adverse events of anaphylaxis, cross-contamination, and infectious events that could be related to dialyzer reprocessing were omitted. Given that in Mexico dialyzers are not reused in patients with hepatitis B, C or VHI, it is not possible to know the risk of infection by these viruses with the practice of reuse. Possible adverse events or bleeding related to the increased use of heparin were not investigated, although no cases were known.

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