Dialyzer reuse and single use: pyrogenesis and bacteremia episodes

Reutilização do dialisador e uso único: episódios de pirogenia e bacteremia

Reutilización del dializador y uso único: episodios de reacciones pirógenas y bacteriemias

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Abstract

Objectives: To compare dialyzer reuse with its single use for biochemical, hematological markers, pyrogenesis and bacteremia episodes.

Methods: A longitudinal study with retrospective data collection from medical records of patients on dialysis in a public university hospital. The investigation was conducted six months with dialyzer reuse and six months with single use. Data were analyzed using SPSS Version 18.0. To compare the tests means, paired t-test and Wilcoxon were used. Pyrogenesis and bacteremia episodes were analyzed using the Wilcoxon test and *Odds Ratio* (OR) as association strength measures. Categorical variables were analyzed using McNemar and Fisher's Exact tests. The study was approved by the hospital's Research Ethics Committee.

Results: Five thousand five hundred eight dialysis sessions of predominantly male patients were analyzed, 21 (62%), with mean age of 58 (± 14) years, hypertensive 14 (41%), with mean treatment time 6 ± 3 years. During single use, a reduction in urea after dialysis, creatinine, phosphorus, ferritin, hematocrit and hemoglogin was identified in relation to reuse ($p<0.05$) and 91% less risk of pyrogenesis compared to dialyzer reuse (*Odds Ratio*=0.091; 95% CI: 0.002-0.625). There was no significant difference in the occurrence of bacteremia.

Conclusion: The results suggest greater removal of biochemical biomarkers and fewer pyrogenics episodes when the dialyzer is a single use.

Resumo

Objetivos: Comparar a reutilização do dialisador com o uso único deste material para marcadores bioquímicos, hematológicos, episódios de pirogenias e bacteremias.

Métodos: Estudo longitudinal com coleta de dados retrospectiva em prontuários de pacientes em hemodiálise, em hospital público universitário. A investigação foi conduzida seis meses com a reutilização do dialisador e seis meses com uso único. Os dados foram analisados no SPSS Versão 18.0. Para comparação das médias dos exames utilizou-se teste t pareado e Wilcoxon, episódios de pirogenia e bacteremia foram analisados pelo teste de Wilcoxon e Razão de Chances (RC) como medida de força de associação. Variáveis categóricas foram analisadas pelos testes de McNemar e Exato de Fisher. O estudo foi aprovado pelo Comitê de Ética e Pesquisa.

Resultados: Foram analisadas 5.508 sessões de hemodiálise de pacientes predominantemente masculinos 21(62%), média de idade 58(± 14) anos, hipertensos 14(41%), tempo médio de tratamento 6±3 anos. Durante uso único identificou-se redução da ureia pós diálise, creatinina, fósforo, ferritina, hematócrito e hemoglogina em relação ao reutilizado ($p < 0,05$) e 91% menos risco de pirogenia comparado a reutilização do dialisador (Razão de Chance= 0,091; IC 95%: 0,002-0,625). Não houve diferença significativa na ocorrência de bacteremias.

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Conflicts of interest: nothing to declare.

Conclusão: Os resultados sugerem maior remoção de biomarcadores bioquímicos e menos episódios de pirogenias quando o dialisador é uso único.

Resumen

Objetivos: Comparar la reutilización del dializador con el uso único de este material en marcadores bioquímicos, hematológicos, episodios de reacciones pirógenas y bacteriemias.

Métodos: Estudio longitudinal con recolección de datos retrospectiva en historias clínicas de pacientes en hemodiálisis, en un hospital público universitario. La investigación fue conducida seis meses con la reutilización del dializador y seis meses con un único uso. Los datos fueron analizados en SPSS Versión 18.0. Para comparar los promedios de los análisis, se utilizó el Test-T pareado y prueba de Wilcoxon, los episodios de reacciones pirógenas y bacteriemia fueron analizados mediante la prueba de Wilcoxon y Razón de Momios (RM) como medida de fuerza de asociación. Las variables categóricas se analizaron con la prueba de McNemar y la prueba exacta de Fisher. El estudio fue aprobado por el Comité de Ética e Investigación.

Resultados: Se analizaron 5.508 sesiones de hemodiálisis de pacientes predominantemente masculinos 21 (62 %), promedio de edad 58 (±14) años, hipertensos 14 (41 %), tiempo promedio de tratamiento 6±3 años. Durante el uso único del dializador, se identificó una reducción de la urea posdiálisis, creatinina, fósforo, ferritina, hematocrito y hemoglobina respecto al dializador reutilizado ($p < 0,05$) y un 91 % menos de riesgo de reacción pirógena comparado con la reutilización del dializador (Razón de Momios = 0,091; IC 95 %: 0,002-0,625). No hubo diferencia significativa en episodios de bacteriemias.

Conclusión: Los resultados sugieren mayor eliminación de biomarcadores bioquímicos y menos episodios de reacciones pirógenas cuando el dializador se utiliza una única vez.

Introduction

Capillary dializer reuse in dialysis is a practice carried out in many countries where resources are limited,[1.2] although there is no consensus on its safety and effectiveness compared to disposable devices, termed single use.[3] A systematic review that included 14 studies involving 956,807 patients pointed out that there is no evidence that accurately proves the effectiveness or not of dialyzer reuse compared to single use, especially regarding mortality. These authors report that even with contradictory evidence, the reuse technique is common practice in some services.[4] In addition to the concern attributed to mortality risk, there are also concerns about dialyzer reuse in relation to its performance reduction, biochemical and immunological effects, and infection risk.[5] In this perspective, after alerting to cases of bloodstream infections (BSI) caused by gram-negative bacteria in dialysis clinics in California, a group of researchers conducted a case control study to observe dialyzer reuse in the institutions. In one year, 17 confirmed cases of growth of Gram-negative microorganisms, and 12 suspicions were observed. The symptoms associated with the presence of these microorganisms were manifested in the form of chills and fever during dialysis. Thirty-five percent of patients were hospitalized, and the pyrogenic reactions were associated with the number of reuses.[6] Hospital medical device reuse poses a potential risk to the patient if it is contaminated or damaged.[2] In first world countries such as those of the European Union and Japan, dialyzer reuse is prohibited by law, due to the potential risks to patients.[7] In Brazil, a developing country, dialyzer reuse is regulated as a standard practice.[8] However, studies that have compared dialyzer reuse and single use in Brazil are non-existent. In order to fill this gap, this study aimed to compare the effect of dialyzer reuse with single use for biochemical, hematological markers, rates of pyrogenic reactions and bacteremia variables and describe antibiotic use after positive blood culture results during dialyzer reuse and single use.

Methods

Type of study and period

This is a longitudinal study with retrospective data collection from medical records of patients on a conventional dialysis program in a public university hospital. The dialyzer's manual reuse started from the establishment of the dialysis service, in June 1975, until March 2013. After this period, all patients started using single-use dialyzers. Thus, the observation period of patients was from September 2012 to February 2013 (six months of reuse) and from April to September 2013 (six months of single use), March was not counted because it was the period technique transition. The study complied with the guidelines and regulatory standards for research involving human beings, being submitted to the *Hospital de Clínicas de Porto Alegre*'s Ethics

Committee and approved under nº 924,238 on 12/16/2014.

Participants

All patients diagnosed with Chronic Kidney Disease (CKD) undergoing conventional dialysis of the unit by means of a catheter, fistula or graft, with blood flow of at least 300 ml/min, with a prescribed dialysis time of three to four hours and who underwent dialysis in the two study periods were considered eligible. Patients on daily dialysis, with positive Human Immunodeficiency Virus (HIV), patients with hepatitis B and those with dialysis treatment time equal to or less than three months were excluded, resulting in 35 patients.

Outcome variables

The outcomes of interest were: - Laboratory tests: urea pre- and post- dialysis, Kt/v, creatinine, calcium, potassium, phosphorus, albumin, ferritin, iron, hematocrit, hemoglobin, and parathormone**.**

- Pyrogenic reaction: Defined by a sudden episode of at least one of the signs and symptoms of fever, chills, tremors, sweating, hypotension, without justifiable cause and negative blood culture. [9]
- Bacteremia: defined by the absence of clinical evidence of an alternative source of infection and in the presence of fever and chills, with growth of bacteria in the blood, collected from the peripheral route or catheter, resulting from positive blood culture. [10]
- Use of antibiotics: Antibiotics used empirically and/or after a positive blood culture result, considering the number of days and doses**.**

Unit protocol in the event of pyrogenesis

In the event of episodes of pyrogenic reactions or suspicion of bacteremia observed by the presence of tremors, fever and chills during dialysis sessions, the conduct in the unit under study was administration of antipyretic, as prescribed, and perform blood culture collection requesting antibiogram. When a patient using an AVF, two peripheral blood samples at five-minute intervals, during the rise of the febrile peak. When a central venous catheter, two pairs of blood cultures were collected (at least one in a peripheral vein). The method of processing blood cultures is automated. After collection and if prescribed, antibiotics were administered. Dialyzer and lines were discarded.

Data collection

From the data collection in the electronic medical records, the venous access in use by the patient was considered to be the date on which the pyrogenic reaction occurred. When there was a description of the AVF and catheter in the chart, only the venous catheter was considered. Patients who did not show pyrogenic reactions, access in use was recorded on the first collection date of laboratory tests in each period.

Laboratory tests were grouped every two months, generating a mean, and inserted in a spreadsheet, accounting for three test records for each group of patients. To calculate Kt/V, the second generation Daugirdas equation was used.

Pyrogenesis episodes were recorded according to the number of times presented. In cases of two or more episodes, these were recorded in a new form, and identified as 1st episode, 2nd episode, successively, both in the dialyzer reuse and single use period.

Statistical analysis

For data analysis, the program Statistical Package for Social Sciences (SPSS) Version 18.0 was used. Categorical variables were described in percentage and absolute numbers. A Kolmogorov-Smirnov normality test was performed. According to data distribution, continuous variables were expressed as means and standard deviation or median and interquartile range. The comparison of the mean results of laboratory tests was performed in the two periods of the study using the t test. Variables with asymmetric distributions were used the Wilcoxon test. Pyrogenesis and bacteremia episodes between the two periods were compared using the Wilcoxon test. Later, the *Odds Ratio* (OR) was used as a measure of association strength to assess the risk in pyrogenic and bacteremic episodes. For categorical variables, when comparing the periods to verify positive blood culture, the McNemar test and Fisher's exact

test were applied to compare the type of venous access. A p<0.05 value was considered significant.

Results

Of a total of 48 patients undergoing dialysis treatment, 35 met the inclusion criteria. Of these, one was excluded during the study because he was using antifungal (Amphotericin). Five thousand five hundred eight dialysis sessions of 34 chronic renal patients were analyzed; 21 (62%) were male, with mean age of 58 (± 14) years. Hypertension was the most common cause of CKD with 14 (41%), with an average treatment time of 6 ± 3 years. Predominantly, dialysis sessions in the two analyzed periods took place in four hours, with a blood flow of 300 ml/min to a dialysate flow of 500 ml/min. Venous access route for the treatment was similar between the two periods. During the reuse period, the dialyzer used was Diacap LOPS by B. Braun, while in the single use period, Polyflux L-Gambro was used. The membranes used in both periods were biocompatible and the sterilization process in manual reuse occurred with proxitane (0.2% peracetic acid) (Table 1).

Table 1. Clinical characteristics of the sample and hemodynamic and volemic parameters according to dialyzer use

Features	Reuse (n=34) n (%)	Single use (n=34) n (%)
Hours per dialysis session (4h)	33(97)	33(97)
Blood flow of 300 (ml/min)	28(82)	28(82)
Dialysis bath flow of 500 (ml/min)	32(94)	32(94)
Arteriovenous access		
Arteriovenous fistula	29(85)	28(82)
Permanent catheter	3(9)	4(12)
Temporary catheter	1(3)	2(6)
Graft	1(3)	
Dialyzer		
Diacap LOPS	34(100)	---
Poliflux L-Gambro	----	34(100)

Laboratory tests

In the comparison between laboratory tests in the analyzed periods of dialyzer use, there was a statistically significant reduction in the values of post-dialysis urea, creatinine, phosphorus, ferritin, hematocrit and hemoglobin when single-use dialyzer was used in relation to dialyzer reuse (Table 2).

Table 2. Comparison of laboratory results between the two periods

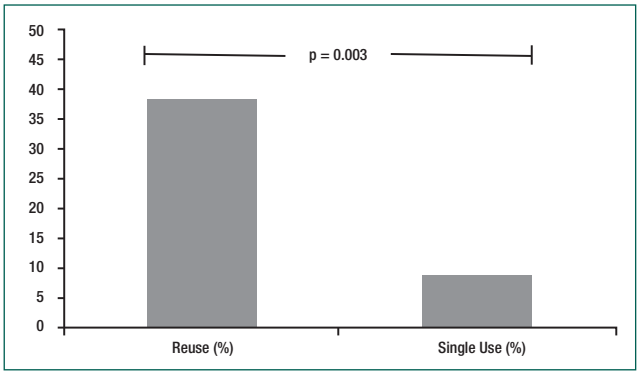
Laboratory data	Reuse (n=34)	Single use (n=34)	P value
Pre-dialysis urea (mg/dl)	140±31	134±27	0.078*
Post-dialysis urea (mg/dl)	40±14	37±11	0.015*
Kt/V	1.3±0.2	1.4±0.2	0.655*
Creatinine (mg/dl)	10±2	8±2	<0.001*
Calcium (mg/dl)	9±0.5	9±0.4	1.120*
Potassium (mEq/l)	5±0.5	5±0.5	0.616*
Phosphorus (mg/dl)	6±1.1	5±1.2	<0.001*
Albumin (g/dl)	4± 0.2	4± 0.6	0.143*
Ferritin (ng/ml)	556(314-782)	479(349-646)	0.008†
Iron (µm/dl)	61(46-75)	61(43-70)	0.192†
Hematocrit (%)	34±3	32±3	0.008*
Hemoglobin (g/dl)	11±1	10±1	0.008*
Parathormone (pg/ml)	562.9±396.6	561.8±398.4	0.976*

Kt/V- Fractional urea clearance; *Continuous variables expressed in (mean ± standard deviation); p: comparison between groups by test t paired; †Variables presented as median (25th to 75th percentile); p: Wilcoxon test

Pyrogenesis and or bacteremias episodes

Of the 34 patients followed, 20 (59%) did not present pyrogenesis/bacteremia in any of the two periods of the study. Of the 14 (41%) patients who presented pyrogenesis/bacteremia, 13 (32%) presented it during the reuse period and one during the single use period. There was a significant difference in pyrogenesis episodes between the two groups, Figure 1. In single use, 91% less risk of pyrogenesis is observed compared to the reuse period of the capillary dialyzer (OR=0.091; 95% CI: 0.002-0.625).

In the analysis of the two study periods, 22 fever and chills episodes occurred in 14 patients; 19 episodes were recorded in the reuse period in 13 patients, while in single use only one episode of fever and chills was found in three patients. Of the 22 episodes that occurred in 14 patients, seven showed positive blood culture, six (18%) in reuse, and one (3%) in single use. There was no significant difference (p=0.125) in the presence of bacteremia when comparing the different dialyzer uses. Of the 13 patients who presented pyrogenesis/bacteremia in the reuse period, four (31%) were using a central venous catheter, while nine (69%) patients had arteriovenous fistula (AVF) (p=0.015). In the period of single use of the dialyzer, there was a greater use of central venous catheters in the group that presented bacteremic pyrogenesis (p=0.074), but with no significant



* p is the result of the comparison by number of patients.

Figure 1. Percentage of pyrogenesis and or bacteremia in the period of the study of dialyzer reuse and single use. *p** Wilcoxon test.

difference. The microorganisms found in the results of the blood samples of the six patients with positive blood culture in the reuse period were *Staphylococcus sp coagulase* negative, one (3.0%), *Staphylococcus aureus*, one (3.0%), *Burkholderia cepacea* Complex, two (6.0%), *Ralstonia Piketti,* two (6.0%). During the dialyzer reuse and single use period, bacteremia was confirmed in only one of the three patients who presented with an episode of chills and fever, with the presence of *Escherichia Coli*, one (3.0%) in the blood culture result. As for the analysis of the presence of microoganisms in dialysis water, during reuse, in one record, heterotrophic bacteria (> 5700 CFU/ml) were found after dialysis filter, in another patient, there was development of heterotrophic bacteria at the outlet of the charcoal filter activated (> 5700 CFU/ml), for the other results, the water quality obeyed the parameters recommended by the current legislation, as well as the analyzes during the single use. The antibiotic most used empirically to treat pyrogenesis was vancomycin. Only one patient used this antibiotic after the blood culture result using seven doses of the drug. The presence of another outbreak of infection during the pyrogenic episode was confirmed in two patients during the reuse period, while in single use it was associated with 100% of the pyrogenic episodes.

Discussion

This is one of the few studies developed in a Brazilian public and university hospital that evaluated dialyzer reuse with that of single use for variables such as biochemical, hematological, pyrogenic and bacteremic reactions. Their findings demonstrated a statistically significant reduction in post-dialysis serum urea, creatinine, phosphorus, ferritin, hematocrit and hemoglobin levels, although the clinical relevance of these markers should be interpreted with caution. There was a reduction in the rates of pyrogenic and bacteremic reactions when changing dialyzer reuse to single use.

In addition to urea, other small solutes that must be removed during dialysis to ensure patient survival are acreactinin and phosphorus, which in the present study, both showed a better reduction during single use.

Another significant finding was the maintenance of albumin for both types of dialyzers, analogous to a study.[11] who indicated that there was no difference in the average albumin between the processed and single-use dialyzer. Although, in chronic renal patients undergoing dialysis, it is common to observe a fall in their serum levels, due to the association of conditions of metabolic acidosis, reduced protein intake and inflammation.[12]

CKD alone is an inflammatory state, which is associated with anemia, which is shown by hematocrit and hemoglobin indices. In the present study, the levels of these markers had a statistically significant reduction during the period of single use of the dialyzer. In a recent cross-over clinical trial, no significant difference was found when comparing these blood components in reuse and single dialyzer.[13]

In this study, when analyzing the presence of pyrogenesis in dialysis patients, it was observed that 14 (41%) of the patients presented signs and symptoms characteristic of a pyrogenic reaction or bacteremia during the study. Of these, 13 (38%) were during dialyzer reuse. During single use, only three patients presented pyrogenesis, accounting for three episodes. Two of the patients who exhibited pyrogenic reactions in single use had presented in reuse, and one patient presented only in single use of the dialyzer, conferring a significant difference (p=0.003) between the groups. However, for the analysis of the results, the number of patients

was counted and not of the pyrogenesis episodes. This means that the difference in the result between the periods is even greater, that is, there is a lower risk of pyrogenic reactions when using the dialyzer single use.

The risks to the exposure of microorganisms by dialyzer reuse affirm that there is an association between a greater number of reuse of the dialyzer and the occurrence of pyrogenic reactions.[6] Thus, when investigating an outbreak of bacterial infections in patients in dialysis clinics, and after thoroughly reviewing environmental factors, reuse technique and medical records, they observed that the growth of microorganisms occurred due to inadequate head cleaning and disinfection dialyzer, as a result of the disinfectant not reaching portions of the O-ring during disinfection.[14]

In reinforcing these findings, a recent study evaluated the effectiveness of manual and automated reuse methods on microbial contamination after multiple dialyzer reuse in two dialysis services in Brazil. Of a total of 11 dialyzer samples with automatic reuse, three (27.3%) showed growth of microorganisms in the blood chambers and all samples showed microbial growth in the dialysate compartment. Of the four samples of the manually reused dialyzer, a sample (25%) of gram-positive bacteria was found in the blood chamber and a sample (25%) of *Burkholderia cepacia in the* dialysate chamber. Signaling that dialyzer reuse may represent safety risks for the patient due to exposure to microorganisms, regardless of the manual or automated method.[15]

When advancing in the analysis of pyrogenesis, when analyzing the two periods of the present study to identify among those how many were effectively diagnosed as bacteremias, no statistical difference was demonstrated when comparing the different uses of the dialyzer. It is reinforced that this result was presented by the number of patients, and not by the number of pyrogenic reactions, thus, patients who presented more than one episode, were not counted for the calculation. It should be noted that in both periods, all patients were considered for the analysis of confirmation of bacteremia, since all were exposed to the possibility of having an episode.

Pyrogenesis or bacteremia during the reuse period occurred in patients using AVF, whereas in the single use of the dialyzer, there was greater use of the central venous catheter for the group that presented pyrogenesis/bacteremia. Recently, a European cohort, investigated the risk and fatal cases of bloodstream infection among chronic dialysis patients, during the period 1995-2010, found that the creation of an AVF was associated with a lower risk of bloodstream infection.[16] This evidence reinforces the results of the present study, inferring to dialyzer reuse the possibility of being the potential causative agent of the episodes and exempting the association with venous access.

Among the microorganisms found in these patient samples, the *Burkholderia Cepacea* and *Ralstonia Piketti* Complex stands out. Both are possible to be found in water systems for dialysis, and when in contact with the bloodstream they cause pyrogenic or bacteremic reactions.[17]

In order to determine if the microorganisms were associated with the dialysis water reservoir, water cultures were observed during the dialyzer reuse period, and a record of heterotrophic bacteria (> 5700 CFU/ml) was found after dialysis filter, which culminated in development Complex *Burkholderia Cepacea,* proven by blood culture. In another patient who found heterotrophic bacteria at the outlet of the activated carbon filter (> 5700 CFU/ml), *Staphylococcus aureus* was confirmed in the blood culture. The other records of water culture maintained quality standards of microscopic analysis, supporting the opinion, that water was not associated with pyrogenic and bacteremic reactions confirmed by negative culture.

Pyrogenic and bacteremic reactions were treated with vancomycin empirically, and only one patient during the single use made use of the antibiotic after the result of blood culture. Explanation for the other patients not to use the antibiotic after the result can be in the delay of the release of the result, which induces the permanence of the use of the empirical medicine until completing the planned cycle.

In a study that investigated an outbreak of vancomycin-resistant enterococci in southern Brazil, it showed that all patients investigated

used some type of antimicrobial therapy before isolating the microorganism. All isolates were identified as resistant to vancomycin and most patients who died were from the dialysis unit.[18] Moreover, dialyzer reuse is a concern in increasing infection rates, since the extensive and sometimes inappropriate use of antibiotics added to the patients' immunosuppression and the delay in the diagnosis of bacterial infections can culminate. in microbial resistance.

In summary, the development of this study brought relevant information in the comparison between dialyzer reuse and the single use, mainly when signaling the potential risks of pyrogenic reactions with reuse, which compromise the patient's safety. However, the results regarding the reduction of laboratory parameters when single-use dialyzer is used, should be considered with caution, because although some have shown a statistically significant reduction when the single-use dialyzer is used, it is necessary to consider whether this difference is clinically is relevant.

Some limitations are important to highlight, such as, for example, the sample size, absence of information in the medical records of C-reactive protein tests, in addition to possible confusion biases regarding the occurrence of pyrogenesis and bacteremia. For these, we tried to define the criteria for bacteremia and pyrogenesis, research the presence of central venous catheter and water culture in order to isolate possible confounders.

Conclusion

The results suggest greater removal of biochemical biomarkers and fewer pyrogenics episodes when the dialyzer is a single use. Additionally, antibiotics have been used empirically to treat infections.

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Collaborations

Silva OM, Karohl C, Proença MCC, Vicari AR, Fengler KPM, Rabelo-Silva ER collaborated with the study design, analysis and interpretation of data, relevant critical review of the intellectual content and approval of the final version to be published.

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