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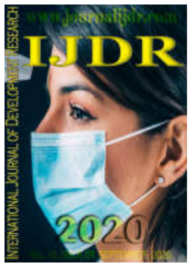

RESEARCH ARTICLE OPEN ACCESS

IMPACT OF TREATMENT AND MONITORING OF WATER QUALITY IN HEMODIALYSIS THERAPY

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ABSTRACT

Chronic Kidney Disease (CKD) is caused by kidney damage, which causes a loss of function. In the most advanced form, it generates to the patient the need for renal replacement therapies, such as hemodialysis (HD). One of the HD quality indicators is water quality. This study's objective was to demonstrate, discuss, and synthesize the importance of monitoring HD water treatment and verify the incidents of adverse events caused by contaminants. The literature review carried out using articles in Portuguese, published in the last 20 years, fit the study's theme, taken from the electronic databases: *LILACS*, *SciELO*, *Redalyc*, and official websites of the Ministry of Health. Health descriptors were used: hemodialysis, monitoring of Water, and Reverse Osmosis. Dialysis water has organoleptic properties that must be evaluated daily to ensure that it is free of contaminants that may cause adverse reactions to patients. The monitoring of HD water treatment must be used strictly to obtain greater efficiency in the treatment. Therefore, monitoring is essential to guarantee HD treatment, requiring specific care, avoiding organic and inorganic complications that can cause loss of effectiveness.

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INTRODUCTION

Considered a public health problem due to the growing number of patients undergoing hemodialysis, CKD is characterized by a progressive and irreversible loss of renal function. The body's ability to maintain metabolic and hydro electrolytic balance fails, resulting in uremia or azotemia (1). In its most advanced stage, it is defined as Chronic Renal Insufficiency (CRF), and the kidneys cannot maintain their functionality anymore (2,3). In Brazil, according to a census by the Brazilian Society of Nephrology (SBN) of 2019, the distribution of patients is 93.2% in hemodialysis (HD) and only 6.8% in peritoneal dialysis (PD). It is estimated that the number of new dialysis patients per year in Brazil is around 42,500, with these indicators only tending to increase (4,5). Chronic Kidney Disease (CKD) is considered to have high morbidity and mortality and has five stages of evolution. In the final stage, the patient is deemed to have Chronic Renal Insufficiency (IRCT).

When then, the patient needs renal replacement therapy (RRT) to live. The existing RRTs are hemodialysis (HD), peritoneal dialysis (PD), and kidney transplantation (TX) (1). Specialized clinics carry out this treatment. The dialyzer or "artificial kidney" does the whole blood purification process. The dialyzer has a complex of semipermeable membranes that allow, through the opposition flow, the displacement of substances between the patient's blood and the dialysis solution—thus promoting diffusion, the filtration of blood. After this process, the "pure" blood returns to the patient (6). The therapeutic efficacy directly influences the morbidity and mortality of hemodialysis patients and the water treatment performed. The increase in patients subjected to hemodialysis therapy highlights the importance of monitoring water, allowing it to be linked to contaminants that cause possible adverse events (1). The water used in the hemodialysis treatment plays a crucial role, since 95% of the solution that purifies the blood is made up of water. For water treatment, the Reverse Osmosis (OR) process is the most efficient to achieve the necessary degree of purity (7). Water treatment avoids bacteremia and pyrogenesis in the process. The verification of water quality and purification equipment is essential for the microbial and chemical containment of water, following established standards (8). Following the national literature and the norms established by the quality and patient safety management, this work seeks to demonstrate, discuss, and synthesize the importance of monitoring treated water. According to the norms established for hemodialysis, it is intended to emphasize those adverse events caused by organic and inorganic contamination. The events can occur when monitoring is not adequate, causing irreversible damage to patients undergoing hemodialysis.

Literature Review

The work was developed using the literature review method, based on published articles that provided a discussion of the topic addressed to gather and synthesize other research conclusions, thus collaborating to deepen knowledge about the investigated topic. This study sought to analyze Brazil's publications in Portuguese in the last 20 years. Twenty-eight publications were selected that fit the proposed theme, in the following electronic databases: *LILACS (Latin American and Caribbean Literature in Health Sciences), SciELO (Scientific Electronic Library Online), Redalyc (Network of Scientific Journals of America Latina)*. Official websites of the Ministry of Health was used in this review. After reading the publications, three of them were excluded because they did not contribute consistently to the study. As descriptors, the keywords were used: Hemodialysis, "Water Monitoring Program," and "Reverse Osmosis." A significant number of researches were detected regarding monitoring, and the quality of the water offered to patients undergoing hemodialysis. However, few highlighted the adverse events caused to these patients. Thus demonstrating the importance of continuity in monitoring, the water is free from any contamination, ensuring patients' safety, whose health status must be preserved. This study was approved by the Ethics and Research Committee (CEP) nº of the University Center of Fundação Hermínio Ometto / FHO under protocol 665/2019.

Context of the situation: For dialysis, the water used until the end of the 70s was drinking water. However, chemicals and microbiological already demonstrated contaminants harmful to hemodialysis and especially to patients in therapy. Thus, it was necessary to adapt filtering systems to the best condition of this water. Until 1995, there were no standards for water quality control by ANVISA. However, in 1996 the country experienced two outbreaks of human contamination related to dialysis water (9,10).

Caruaru – Pernambuco: In February 1996, Brazil faced the first outbreak of human poisoning involving cyanotoxins in a dialysis clinic, a situation that caused everyone to change their views regarding dialysis water treatment. This year, northeastern Brazil's region went through a long period of drought, which led the municipality of Caruaru to need tank trucks to guarantee water for hemodialysis. This water from the Tabocas reservoir, after that receiving chlorination, undergoes filtration with the exchange of sand, carbon, and cationic/anionic exchange, followed by filtration by micropores, to then be used for hemodialysis. Do not receive Reverse Osmosis (OR) treatment at the time. This situation generated reactions and complications in 116 patients at the dialysis clinic. In addition to the negative national repercussions of this case of water-related contamination, 100 cases of acute liver failure and 52 deaths were recorded among the 131 patients at the clinic. As it became known, the "Caruaru Syndrome" generated complaints of headache, eye pain, blurred vision, nausea, and vomiting, followed by liver complications and, in the most severe cases, death. In the research with water, blood, and liver tissue, these patients were performed. It can be seen the intoxication could have been caused by the release of microcystins from the cyanobacteria cells - or blue algae -, which were lysed by the chlorination in the tank trucks (11.12).

Campinas: In September 1996, in a dialysis clinic in the city of Campinas, an outbreak of infection by Pseudomonas aeruginosa took place. It is being found in several dialysis water points, such as machines and filter capsules, and four blood samples from patients. This situation led to the need for interdiction and sealing by the Health Surveillance and transfer of patients to other clinics until new free samples of the bacteria were collected. The clinic's dialysis water analysis showed that it was operating in inappropriate situations about water quality (12,13). After these disastrous situations, in October 1996, the Ministry of Health launched the first ordinance regarding dialysis services quality. Ordinance Nº. 2,042, of October 11, 1996, which in its annex has two tables: one is containing physical and organoleptic characteristics of drinking water and the other the standard of quality of treated water used in the preparation of dialysis solution. This also brought water conductivity conditions, and the recommendation to analyze bacteriological qualities when cases of pyrogenesis and/or septicemia occurred in patients (14). In 2000, the Ministry of Health launched Ordinance Nº. 82, of January 3, 2000, which dictated new regulations on the service and registration of services with the Unified Health System (SUS). Its main difference was the increase in the number of dialyzes reuses - from 6 to 12, when only the internal capillary volume was measured and 20 when a reprocessing machine with fiber integrity tests was used. Regarding water treatment, only the conductivity parameter has changed (15).

Calderaro and Heller (2001) reported the outbreak that occurred in a dialysis clinic, in the state of Minas Gerais, related to chlorine and chlorine concentration. In this situation, patients who presented symptoms of chest pain, low back pain, abdominal pain, diarrhea, hemolysis, coagulation, heat, and redness. These symptoms were occurring simultaneously or not, or the patient whose capillary was changed and/or washed during the session due to undesirable complications. They were considered as possibly intoxicated by chlorine, and confounding factors inherent to the health situation of patients undergoing dialysis therapy were discarded. This fact made it possible to show the effect of high concentrations of chlorine and chloramine. In most cases, these are above the values determined by current legislation, and induce severe hemolysis reactions in the patient, with possible damage to health (16,17). Also, we cannot forget about events of contamination by bacteria, the most common situations in dialysis. Infections are directly related to the high mortality rates in this population. In 2004, the MS launched RDC Nº. 154, of June 15, 2004, which was associated with water quality monitoring: water samples for purposes of physical-chemical and microbiological analysis must be collected at points adjacent to the machine hemodialysis and reuse. They should be one of the points in the most distal part of the distribution loop (loop) (Art. 8.5.1) (18). These microbiological analysis criteria refer to the microbial load present in the water and which are related to the occurrence of bacteremias and pyrogenic reactions. Bacteremia cases may be associated with the integrity of the dialyzer membrane or the process of reuse thereof. High microbial rates generate a high concentration of endotoxins, which release cytokines that stimulate the patients' immune response, developing more severe bacteremia and pyrogenesis (19). Bugno et al., 2007, analyzed samples of treated water and dialysate and found that the most frequent Gram-negative bacteria isolated were: Burkholderiacepacia, followed by Stenotrophomonas maltophilia. The Burkholderiacepacia complex was the most prevalent in all types of samples, followed by Stenotrophomonas maltophilia and Ralstoniapickettii, in treated water and Pseudomonas fluorescens, in dialysates (20).

The author takes into account that even after OR, distillation, and deionization Gram negative bacteria can develop in the water, favoring the release of endotoxins, even when the microbial load is within the levels established by ordinances and resolutions. Thus demonstrating the importance of monitoring chemical and microbial concentrations, and maintaining and monitoring the water purification system (12,20). We draw attention here to fungal infections and water-related yeasts for dialysis. Although there is no standardization established by national and international bodies, it is essential to assess their presence due to the high pathogenic capacity of some fungi and yeasts (21). In 2004, Ruvieri et al. developed research in the State of São Paulo, in which he investigated cyanobacteria for a year. They to be able to monitor their flowering and whether their seasonal concentration influenced water contamination by releasing microcystin (cyanotoxins). After the Caruaru incident, concern about their presence increased exponentially across the country. Finally, the authors were able to verify that in the State of São Paulo, there is a presence of cyanobacteria in the water samples of springs. However, in the dialysis water samples, no microcystins were found. Thus emphasizing that the requirements of Ordinance MS 518/04, when followed, plus the system's maintenance, effectively prevent contamination of renal patients by these (22). Thus, we see that regardless of the agent that causes the contamination, it is necessary to maintain the entire water treatment system for dialysis, as well as to carry out periodic analyzes of its components. The analysis of interdialytic complications helps identify causal agents, whether microbiological, chemical, or structural. It and can dictate whether these are caused by water-related contamination.

Monitoring of Water Quality for Hemodialysis: Hemodialysis water needs strict control and monitoring to avoid complications arising from this medium (23). Hemodialysis is applied to correct the electrolyte balance and remove toxic elements from the body, through a dialyzer and a solution of dialysis (dialysate), composed mainly of water (9) The dialyzer is the device through which blood purification occurs through diffusion and ultrafiltration, consisting of two divisions separated by semipermeable membranes: the dialysate and the blood flow, which follow in contrary, after this process, the purified blood returns to the patient (6). The water offered by the hemodialysis centers must have a quality and effective treatment, in which the main objective is to provide quality dialysis avoiding complications transmitted by this means. ANVISA standards and guidelines must be strictly followed to maintain the water quality standard, as well as guarantee recovery or continuity in patient treatment (6) According to RDC nº 11, of March 13, 2014 (BRASIL, 2014) in the modality of hemodialysis, the average volume of water used per patient in each HD session is around 120 liters (8) and with sessions usually held three times a week or according to the patient's need for dialysis (6,24). Regarding water quality standards, Technical Note 06/2017 GVIMS / GGTES of ANVISA establishes permitted limits for organic and inorganic contamination of the water used in dialysis. Thus, the water quality will not be compromised at any stage of the treatment. The storage and distribution of this water contain steps to measure the microbiota and its chemical characteristics, in which they are monitored by the laboratories responsible for analyzing this water, whether monthly or semi-annually, according to the availability of the Brazilian Network of Laboratories (REBLAS / ANVISA) (25). The occurrence of outbreaks of contamination related to dialysis water exposes the high capacity they have to generate complications and increase mortality rates due to infections in dialysis patients. Proper water treatment and effective disinfection of the treatment system and dialysis machines can prevent contamination from occurring. Adherence to dialyzer reuse protocols and strict monitoring of the quality of treated water help prevent adverse events (8).

Acute intoxication causes are vertiginously identified, and the causal link is usually clearly determined. However, the cases of chronic exposure of HD-dependent patients to these elements are still the subject of great debate, and it is immensely difficult to determine the relationship with the pathological condition (10). Dialysis health services, whether public, private, philanthropic, civil or military, must fill out a form on a monthly basis (Notification of national indicators of anger - dialysis) on the FormSus system, in which information on the dialysis service is reported to obtain indicators for monitoring Health-Related Infections (IRAS) (26). Despite the principles and standards determined by law, the precarious inspection is due to the lack of infrastructure and monetary funds for its exact action. This, indeed, prevents a concrete standardization of the quality of the water used in the treatment of HD, and makes it impossible to have a real knowledge of the adverse events caused in the patients, which is an essential point for the growth of the expectation and the quality of life of the chronic kidney patients (8). Thus, the occurrence of adverse events caused by failure to monitor water treatment in patients undergoing HD therapy should be rigorously investigated and treated as a priority. Their relationship with the patient's pathological condition can be determined (27).

Water Treatment System: According to RDC nº 11, of March 13, 2014, from ANVISA, drinking water must follow a standard of acceptable physical and organoleptic characteristics for consumption and HD performance and be inspected and analyzed by Organs competent bodies. The physical and organoleptic water characteristics for HD should be examined daily, where turbidity, color, appearance, taste, odor, free residual chlorine, and pH will be evaluated (24). According to Resolution nº January 08, January 02, 2001, the hemodialysis solution has three fractions: water, acidic fractions, and basic fractions. The acidic fraction contains sodium chloride, calcium chloride, potassium chloride, magnesium chloride, acetic acid, and water, while in the basic fraction, there is only sodium bicarbonate (28). Water is a primary resource for maintenance and segment of life and is the most extensive input consumed during an HD session's performance, and this must follow a quality standard. To achieve this standard, HD water must undergo a purification process (8). The water purification process is divided into three phases: 1°) the first is called pre-treatment, where the water undergoes mechanical filtration, softening, and an activated carbon filter. In mechanical filtration, corpuscles and residues are removed, using cartridge filters of varying porosity, from 5 to 25 microns, or quartz filter (sedimentation filter), to remove impurities and sediments in the water. In this process, softeners are needed to remove calcium, magnesium ions, and other polyvalent cations by exchanging with sodium, present in the softening resin, and the activated carbon filter. The latter has a high affinity for organic matter. If not treated correctly, the risk of contamination and proliferation of bacteria is increased since its function is to absorb chlorides, chloramines, and organic substances present in water (23,29).

The second phase of water purification is Reverse Osmosis. According to Teixeira and Silva (2011), the process of water purification by Reverse Osmosis (OR) is the most effective (7). OR is a process that separates water from mineral salts, and is found by two solutions, one of higher concentration and one of lower concentration, especially by a semipermeable membrane. The solution with the highest concentration tends to migrate to the solution with the lowest concentration. This is due to the mechanical pressure exerted being more significant than the osmotic pressure applied by the most concentrated solution. Thus, the low-weight molecules pass through the semipermeable membrane, separating the water into two parts: permeate and tailings. The waste runs through the membrane but does not cross it, thus forming what will be neglected. The permeate (which crosses the membrane), on the other hand, will have a high degree of purity and will be an integral part of the dialysate (the solution used for dialysis) (30). As an alternative to OR, deionization can be used, but in most cases, it is used to purify water after the OR process further. Deionization does not remove bacteria, endotoxins, or anionic contaminants. Deionizers contain cationic and anionic resins, which can be configured in two beds, one for cationic resins and the other for anionic resins or in the form of a single bed containing both. Cationic resins are regenerated with hydrochloric acid or sulfuric acid in which the hydrogen ions (H +) are exchanged for another cation: sodium, calcium, and aluminum. Anionic resins exchange hydroxyl ions (OH-) for anions such as chloride, phosphate, and fluoride (29). After the entire purification process, it is necessary to distribute the water to prepare the dialysis solution for each dialysis machine, thus producing a contaminant-free solution. This is considered the third stage of the purification process (29).

Water Contaminants: Various reactions can be caused by chemical and biological residues to which patients are exposed in hemodialysis sessions. The primary contaminants in water are of chemical and microbiological origin. Chemical contaminants are capable of causing several complications, among which cardiovascular ones can present different etiology, such as the origin of bacterial products, presence outside the standards of calcium, magnesium, copper, fluorides, nitrate, and zinc. Nausea and vomiting are related to low concentrations of magnesium, nitrate, sulfate, and zinc. Neurological complications often have aluminum as the principal causative agent and fluoride, which can also be responsible for such complications. Hemolytic reactions are caused by chlorine and chloramines. Bone disease can be accompanied by the presence of aluminum, fluorides, and strontium. Finally, anemia may be associated with the presence of aluminum, bacterial products, chloramine, copper, nitrate, and zinc (8). Several microorganisms can be listed regarding microbiological contaminants, such as *Burkholderia, Pseudomonas sp, Flavubacteriumsp, Acinetobacter sp, Alcaligenes sp, Aeromonas sp. Biofilms caused by Serratia sp, Moraxella sp, Stenotrophomonas,* fungi and yeasts, coliforms*, and Leifsoniashinshuensis* are also crucial in this context. Therefore, microbiological contaminants have endotoxin capable of causing infections, pyrogenesis, cardiovascular problems, vomiting, nausea, hypotension, and other chronic symptoms such as malnutrition and chronic systemic inflammation (6). The death of the patient undergoing hemodialysis related to water contamination is associated with the presence of aluminum, fluorine, the presence of chloramine, and bacterial endotoxin. A long period of exposure of patients on hemodialysis to endotoxins, can cause chronic inflammatory responses, determining new events of pyrogenic reactions. Therefore, indicating the need for measures to identify the contamination focus with the disinfection of the reverse osmosis membranes to eliminate the problem (8). This review can detect limited studies regarding the descriptions of complications and adverse events in patients undergoing HD treatment, caused by not monitoring the water quality. This stems from the fact that most complications are underreported, little analyzed, without understanding for sure what the problem is, and if this is related to contact with toxic substances to the organism.

Dialysis water treatment quality programs: According to the Ordinances and Resolutions of the MS, the dialysis water needs intense control. Thus, numerous studies have been showing situations of satisfaction or dissatisfaction with this water quality control over the years. Lima et al. 2005, in the State of Maranhão, in three dialysis services found that in 100% of the pre-treatment samples from all units analyzed and in 33% of the post-treatment, endotoxins were identified. Thus suggesting the need to monitor all stages of processing. According to Ordinance of the Ministry of Health No. 518 of March 25, 2004, when the affluents have cyanobacteria, a weekly collection of samples of water from the treatment outlet and water entering the dialysis clinic is required (Art 18. § 5) (31 , 32) Barreto, 2013, performed a water analysis of eight dialysis services in the State of Maranhão. The collections took place in the reservoir, after osmosis, at the most distant point from the lopping and the reuse room, and were carried out in six months. Of the 32 samples, 11 had non-standard microbiological values, one had altered nitrate values , and four had altered fluoride and chlorine concentrations. All clinics had at least one-month unsatisfactory values in some parameters concerning current legislation. This demonstrates the need for strict control of the estimated values in the ordinances to guarantee safe care for patients (33). Costa et al., 2018, in a dialysis clinic in the city of Belo Horizonte-MG, assessed at each monitoring point, according to the current legislation, if they presented values of satisfaction and dissatisfaction of the chemical and microbiological indicators. Regarding the chemical parameters, he observed mild changes in the variable pH and arsenic concentration, both of which situations, even with slight deviation, must be corrected as they can cause severe damage to patients' health. Concerning microbiological parameters, unsatisfactory samples were found at the dialysis machine (dialysate) and in the reprocessing room. Even if they present values a little far from the recommended ones, all of these situations need correction and monitoring to avoid adverse events and severe complications to the patients' health (10). We could see that, over the years, countless researches and situations culminated in resolutions and ordinances that adapted the water treatment for dialysis. As in other states, in São Paulo, in 1999, the Health Surveillance Center, in partnership with the Adolfo Lutz Institute (IAL / CCD / SES-SP), started the Water Quality Standard Monitoring Program. This aims to develop all necessary measures to ensure the quality of the water used in dialysis treatment, in compliance with the current legislation's specifications. This Program has been applied throughout the State, managing to transparently identify regions with a higher risk of adverse events and certify large centers with positive results.

At times this project was interrupted, however in 2008, Marcatto et al. reported that 80% of the treated water samples used in dialysis, in the Capital and Greater São Paulo, presented non-conformities in at least one of the sampling points. The main irregularities are bacterial endotoxin, heterotrophic bacteria, inorganic contaminants (sodium, potassium, magnesium, calcium, chromium, arsenic, aluminum), fluorides, nitrates, and conductivity. In 2010, the author brought data to the interior of the State, with the participation of 104 clinics, where the results were favorable in 71 (68.27%) and unfavorable in 33 (31.73%) of them (34, 35). Almodovar et al. 2018, presented the outline of the last years of the Program in the State. After the Resolution of RDC 11/2014, collection points and parameters were changed (24). In the years 2010 to 2013, the first harvest's satisfactory results were 80% and 87%, respectively. In 2017 and 2018, there was a decrease in quality, registering 77% of acceptable parameters. This situation may be linked to the period of the water crisis that the State was a pass. Bacterial endotoxins, conductivity, and physical-chemical parameters were parameters with the highest incidence of unsatisfactory results in each round of the Program. Periods of water crises also contribute to the worsening of quality parameters, due to the need to use secondary tributaries, which have less favorable conditions due to the eutrophication and proliferation of algae in the water sources, due to the intrusion of salt water into water supplies. Underground sweet, due to biological and chemical contamination accumulated in the soil. Another important fact of the article was the retraction of the percentages of dissatisfaction with water quality in the states of Rio de Janeiro, Bahia, Rio Grande do Norte, and the Federal District, showing in these States worse values than the São Paulo scenario. With that, we want to emphasize here the importance of applying for water quality monitoring programs, as they diagnose the real situation, contributing to the best risk prevention outcome for patients on hemodialysis (36).

FINAL CONSIDERATIONS

The importance of monitoring water quality for hemodialysis can be verified, since it guarantees the treatment result, avoiding possible organic and inorganic complications, which compromise its effectiveness and adequate dialysis treatment for patients with chronic kidney disease. With the significant increase in patients undergoing hemodialysis therapy, the influence of water treatment that is necessary is emphasized, since water is the main input for carrying out this complex treatment. The water treatment process requires specific care and verification of the percentages of its components. In this way, there is the prevention of risks and assistance so that the treatment reaches the main objective - to safeguard hemodialysis patients' quality of life.

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