



Investigation of the reverse osmosis system efficiency in supplying water to the hemodialysis center in Khoy city and comparing the quality of this water with the international standard

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Abstract

Background & Aims: Ensuring the quality of water for hemodialysis is crucial for the safety of dialysis patients. In this study, we evaluated the suitability of water from the reverse osmosis (RO) system for the Khoy Hemodialysis Center, comparing it with the American Medical Equipment Administration (AAMI).

Materials & Methods: We collected laboratory data related to hemodialysis water samples. These experiments were carried out by the reference laboratory of Khoy Medical Sciences Faculty from 2021 to 2022. Parameters such as pH, total dissolved solids, hardness, nitrate, and various metals were analyzed using SPSS software. Then the results were compared with AAMI standards.

Results: The average concentrations of pH, total dissolved solids, total hardness, nitrate, calcium, magnesium, sodium, and potassium were determined to be 6.2 ppm, 7.8 ppm, 21 ppm, 0.27 ppm, 0.93 ppm, 3.8 ppm, 3.7 ppm, and 0.07 ppm, respectively. The average concentrations of aluminum, copper, zinc, lead, and arsenic were found to be 3.4 ppb, 2.6 ppb, 5 ppb, 3.7 ppb, and 4.8 ppb, respectively. Importantly, the average concentration of all variables was below the AAMI standard. Statistical analysis tests of Bivariate and Canonical correlation indicated that the removal rate of heavy metals in the RO system was independent of the removal rate of other impurities, such as total dissolved solids. Moreover, residual chlorine, coliform, and heterotrophic plate count were zero in all samples.

Conclusion: Urban water purification using the RO system significantly enhances water quality at the Khoy Hemodialysis Center, aligning it with AAMI standards. However, it is emphasized that continuous monitoring is indispensable to ensure the sustained efficiency of the system.

Keywords: AAMI Standard, Hemodialysis, Reverse osmosis, Water quality

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Introduction

Kidney failure is a common disease in Iran, which causes insufficient kidney function in blood detoxification (1). For this reason, patients need regular hemodialysis to continue living. Dialysis fluid contains a mixture of electrolytes and water (2). Electrolytes are produced on an industrial scale and are of the same quality; however, the water used may vary in quality. In general, this water must be free of impurities and meet the quality standards of treatment. Urban drinking water is usually used to prepare dialysis water worldwide (3). There is a possibility of microbial and chemical contamination of hemodialysis water due to several factors: poor quality of urban drinking water, such as high total dissolved solids (TDS); inappropriate water treatment system for dialysis; lack of regular cleaning and chemical disinfection in the water treatment system; and biofilm formation on treatment equipment (4). Therefore, this contaminated water can be very dangerous for dialysis patients. During hemodialysis, pollutants enter the blood directly and, in the presence of pathogenic microorganisms or toxic substances such as heavy metals, patients can become infected, and the poisoning can be fatal. The quality of this water also influences the quality of dialysis and thus the health and longevity of the patients. Therefore, compliance with microbial, chemical, and physical standards for dialysis water is vital (5).

Dialysis water is particularly sensitive in high-flow filtration dialysis (6). There are various methods for purifying dialysis water. This water is generally made following these steps: pretreatment and microfiltration, reverse osmosis (RO), disinfection, and activated carbon. It is important to use the dialysis water directly, i.e. not to store it, as there is a risk of microorganisms developing in the reservoir and secondary contamination of the water (7). According to research, chemical and biological pollutants in the dialysis fluid can pass through the diaphragm. If the dialysis fluid is contaminated with microorganisms, patients will suffer from sepsis or endotoxemia (8). According to the study by Abbaszadeh et al. in 2018, titled "Investigating the quality of water consumed in three dialysis centers of Tabriz hospitals", it was found that except for calcium, magnesium, fluoride, and nitrate, the concentration of the remaining cations and anions in all the water samples was lower than the European hemodialysis water standard. The samples were contaminated with coliform in 9.4% of cases, and there was no fecal coliform in any of them. However, despite the danger of heavy metals to the health of dialysis patients, determining of heavy metals concentration is not performed on dialysis water (5). In a study conducted in 2020 at a dialysis center in Al Jazeera, dialyze water, an average of 182 bacterial colonies were detected in 1 mL of the water. Of this amount, 4.3 to 6.7 colonies per mL were related to the biofilm formed in dialysis water treatment facilities. Additionally, 50% of the bacteria isolated from the biofilm were Bacillus bacteria, and 24% were Enterobacter cloaca, Staphylococcus, Klebsiella pneumonia, and Pseudomonas aerogenes bacteria. The results of the research showed that the water purification system should be disinfected periodically (9).

In Khoy Madani Hospital, where the only hemodialysis center of the city is located, urban water and RO water treatment system are used to prepare dialysis water. However, raw water (urban water) can be contaminated with chemical and microbial substances. This contamination can occur during treatment and transportation due to biofilm growth and insufficient washing and disinfection of the system and pipes. Therefore, its quality, especially microbial quality, should be checked regularly. Since the quality of Khoy hemodialysis water has not been measured completely, especially in terms of heavy metals, and it has not been compared with relevant international standards, we conducted this study. This research was conducted to investigate the chemical and microbial quality of hemodialysis water during the years 2022 and 2023 and compare it with the American International Medical Equipment Standard (AAMI) (10). We also checked the efficiency of the system in supplying this water. The innovation of this research was to determine the relationship between the rate of heavy metal removal in RO and other common water quality parameters.

Materials & Methods

Study area:

This research was conducted in the hemodialysis center of Khoy city, located in Shahid Madani Hospital. The Khoy dialysis center's water treatment system includes: a water storage tank, a pressurized sand filter, zeolite hardener, activated carbon filter, microfiltration, and RO. The produced water is consumed in line. To investigate water quality, we collected data from routine water tests, including chemical and microbial analysis of the water samples from two years ago. The Central Laboratory of Khoy University of Medical Sciences conducted these tests. In addition, we performed instant chemical sampling of the RO output on a monthly basis and measured the concentration of certain heavy metals (Al, Cu, Zn, Pb, and As) according to the standard method of water and wastewater tests by the chemical laboratory of the Water and Wastewater Company of West Azarbaijan province (Urmia). The heavy metals were chosen because they were commonly found in dialysis water in previous studies (7, 15). The number of microbial and chemical samples of dialysis water used each year was 45, and they were taken every 2 weeks from the outflow of the RO system instantaneously and tested immediately.

Anion, cation, and heavy metals detection:

To measure the concentrations of Na and K, a Jenway flame photometer (PFP7) was used, while pH was measured using a Metrohm pH meter (826). Electrical conductivity and soluble salts were measured using an EC&TDS meter WTW (3310). Ca and Mg concentrations were determined by the titration method, NO₃ by a UV spectrophotometer, and turbidity

by a WTW (550) turbidity meter. The concentrations of Al, Cu, Zn, Pb, and As were measured using an OES-730 ICP device, while total coliform and HPCs microbial tests were conducted using Most Probable Number (MPN) and Heterotrophic plate counts (HPC), respectively.

Accuracy and precision:

The validity and reliability of the data are confirmed by regular calibration of the instruments used in the laboratories and repetition of the tests. In addition, these two laboratories are reference laboratories, and competent authorities regularly calibrate all their equipment to confirm the accuracy and precision of the data.

We used Excel software version 22 and SPSS software version 25 for statistical analysis. Statistical indicators, including: mean and standard deviation of the data and their statistical relationships were analyzed using Bivariate and Canonical correlation tests. We considered an error value of 5% and compared the results with the standard (AAMI). The lack of an internal standard caused this comparison.

Results

Table 1 shows the average results conducted on chemical tests of the dialysis water. As depicted, all parameters except pH fall below the standard. The overall average of the values significantly differs from the AAMI standard, with the average of the measured parameters being lower than the standard. The standard deviation is higher in TH and EC, indicating a high dispersion of data around the average of these two parameters. The observed dispersion is most likely caused by the operation of the purification system, such as RO and filter backwashing. The p values in comparing the average values of the parameters and their standards were all less than 0.05 except for calcium, which was 0.31.

Table 1. Descriptive Results of Parameters in Samples Obtained from Dialysis Water

Parameter	Turbidity NTU	Na mg/l	K mg/l	Mg mg/l	Ca mg/l	NO ₃ mg/l	TH mg/l	EC μs/cm	TDS mg/l	рН
Mean	1.12	3.67	0.07	3.76	0.93	0.27	21.2	16.9	7.8	6.2
Standard deviation	0.61	2.24	0.05	1.92	1.13	0.12	14.6	13	6.08	0.78

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Parameter	Turbidity NTU	Na mg/l	K mg/l	Mg mg/l	Ca mg/l	NO3 mg/l	TH mg/l	EC μs/cm	TDS mg/l	pН
Min	0.04	0.00	0.00	1.9	0.00	0.2	8	5.7	3	5.4
Max	2.42	7	0.1	7	3.2	1.1	56	43.4	20	7.6
Standard permit value (10)	-	70	8	4	2	2	35	100	60	6.5-7.5
out of standard samples percentage	-	-	-	13	8	-	-	-	-	78

The average concentration of the variables is much lower than the standard, except for Ca, Mg, and turbidity. The amount of residual chlorine, the MPN, and HPC Tests were also zero in all 45 samples. The pH was lower than the standard, indicating a greater reduction of cations than anions and the absence of bicarbonate alkalinity in RO output water. Additionally, late RO membrane replacement can cause acidification of the produced water. This acidification can affect the corrosion of metal equipment, such as the water transferring pipes to the

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hemodialysis machine. This corrosion can lead to toxic metals entering the patient's blood.

Table 2 shows the average concentration of the heavy metals. All the concentrations are lower than the standard. The p values in comparing the average values of the parameters and their standards were all less than 0.05. The highest concentration is aluminum ion, and the lowest concentration is lead. Even the highest values are lower than the standard, which indicates that the RO system has a high ability to remove heavy metals from water and produces higher quality water than the hemodialysis AAMI standard.

Table 2. Comparison of the average concentration of heavy metals with the standard value (all concentrations in

ppb)					
Parameter	As	Pb	Zn	Cu	Al
Mean	3.8	2.6	5	3.7	4.8
Standard deviation	1.9	1.6	2.3	1.9	2.4
Min	0.9	1.3	3.6	2.5	4
Max	6.3	3.9	7.5	6.5	7.6
Standard permit value(10)	10	5	100	100	10
out of standard samples percentage	0	0	0	0	0

Table 3 indicates the statistical relationship between the chemical characteristics of the dialysis water. According to Table 3, there was no significant relationship among any of the parameters. However, the correlation coefficient (R) between Cu and K, Zn and pH, as well as arsenic and TDS, had the highest value. This may be because the RO filter removes ions and large molecules such as heavy metals without

interfering with other chemical impurities in the water. Considering that the sample size was 45, these correlation coefficients are significant and can help determine the concentration of heavy metals in RO outflow by using a model. This model can predict the concentration of heavy metals from other parameters such as TDS and TH.

Table 3. Statistical correlation of heavy metal concentrations with water chemical parameters by Canonical test

Heavy metal	Parameters	рН	Ca mg/l	K mg/l	Na mg/l	Mg mg/l	TH-mg/l CaCo3	TDS mg/l
A 1	R	0.48	0.31	0.44	0.207	-0.06	0.108	0.34
AI	P value	0.24	0.45	0.27	0.62	0.88	0.8	0.41

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Heavy metal	Parameters	рН	Ca mg/l	K mg/l	Na mg/l	Mg mg/l	TH-mg/l CaCo3	TDS mg/l
Cu	R	0.37	0.3	0.68	0.41	0.33	0.21	0.1
Cu	P value	0.36	0.47	0.06	0.31	0.42	0.61	0.8
Zn	R	0.57	0.47	0.51	0.20	0.17	0.31	0.03
Zn	P value	0.13	0.24	0.19	0.63	0.68	0.45	0.94
D1	R	0.25	0.32	0.34	0.05	0.15	0.16	0.014
Pb	P value	0.55	0.43	0.4	0.89	0.72	0.705	0.97
٨	R	0.15	0.08	0.35	0.206	0.57	0.04	0.6
As	P value	0.73	0.84	0.38	0.62	0.14	0.92	0.117

Table 4 shows the statistical relationship of the heavy metal concentrations in dialysis water. According to the table and p values, there is a significant relationship between Al and Zn, with a p value of 0.038 and a correlation of 0.73. There is a direct relationship between removal efficiency and the

output concentration of the parameters, allowing for the calculation of the concentration of these two elements from each other. In addition, it seems that there is a significant relationship between Zn and Cu, with a correlation of 0.7, indicating that these two heavy metals are removed almost equally.

 Table 4. Statistical correlation of heavy metal concentrations with each other using correlation bivariate test (concentrations in ppb)

Heavy metal	Parameters	As	Pb	Zn	Cu
Al	R	0.701	0.581	0.733	0.444
	P value	0.053	0.131	0.038	0.27
As	R		0.62	0.334	0.476
	P value		0.101	0.418	0.233
Pb	R			0.342	0.554
Pb	P value			0.407	0.154
7	R				0.704
Zn	P value				0.05

Table 5 shows the statistical relationship between the chemical characteristics of water. According to the reported p value, there is a significant relationship between TDS and Na, Na and K, Na and total hardness, as well as pH and Ca (with a correlation coefficient of 0.7 to 0.9), as the most significant correlation is between pH and calcium. This indicates a linear relationship between the concentrations of these substances. For example, by reducing TDS, Na will increase, or by reducing pH, the removal of Ca will increase. This is because the decrease in pH causes more solubility of Ca and Mg salts, and increases their removal in RO. On the other hand, it reduces the deposition of Ca and Mg salts on the RO membrane.

Table 5. Statistical correlation of chemical	parameters of dialysis water with each other using the Biv	ariate test

Test type	Parameters	pH	Ca mg/l	K mg/l	Na mg/l	Mg mg/l	TH mg/ICaCo ₃
TDS	R	0.17	0.057	0.366	0.74	0.487	0.257
	P value	0.686	0.893	0.372	0.036	0.221	0.539
Total hardness	R	0.387	0.48	0.082	0.3	0.48	
	P value	0.344	0.228	0.848	0.47	0.228	

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Test type	Parameters	рН	Ca mg/l	K mg/l	Na mg/l	Mg mg/l	TH mg/lCaCo3
Mg	R	0.126	0.065	0.168	0.173		0.48
	P value	0.766	0.879	0.69	0.682		0.228
	R	0.126	0.065	0.722		0.173	0.74
Na	P value	0.766	0.789	0.043		0.68	0.036
17	R	0.526	0.528		0.722	0.168	0.366
K	P value	0.18	0.178		0.043	0.69	0.372
Ca	R	0.95		0.528	0.283	0.065	0.48
Ca	P value	0.00		0.178	0.497	0.879	0.228

Discussion

The results of this study showed that the RO system outflow has very good quality and is in accordance with the AAMI standard. This shows that this system has the ability to remove heavy metals completely from water. The findings indicate that the RO system has a good ability to produce dialysis water. These results are consistent with the study conducted by Baseri et al. in 2013 on the quality of hemodialysis water in a hospital. The comparison of raw water and purified water quality results in Baseri's study showed that with correct design and optimal management of RO, this system is fully effective in removing mineral salts and microbial contamination from water (11).

According to Alizadeh et al.'s study, conducted to investigate hemodialysis water quality in Zahedan city hospital, the results showed that all water cations and anions concentrations, except Ca, were lower compared to the AAMI standard. In addition, no type of microbial contamination was seen in this study. The water treatment system of this center was also RO (12).

In the study of microbial and chemical indicators investigation of dialysis water in one of Sanandaj hospitals, the results showed that this water has no microbial pollution, but the concentrations of NO₂, Ca, and Mg were higher than the AAMI standard in less than 50% of the samples (13).

The review study accomplished in Brazil focused on hemodialysis water quality. The study emphasized the importance of permanent control and adherence to water quality standards. It also highlighted the need for appropriate laboratory methods to determine microbial indicators (14).

A study conducted by Chaoui et al., in 2022, evaluated the presence of bacteria resistant to disinfection in the treatment system of dialysis water. Gram-negative bacilli species, such as Pseudomonas, were detected in the water. These bacteria can produce endotoxins, leading to infections in dialysis patients. Therefore, permanent microbial monitoring of this water and optimization of its purification system were suggested (15).

In a study by Anversa et al. in 2022 on the water of hemodialysis centers, Pseudomonas aeruginosa bacteria was detected in the purified water. They concluded that the bacteria became resistant to disinfectants due to biofilm formation on the water treatment system. They stated that the filtration and transfer system of the water need regular maintenance and cleaning to prevent biofilm formation (16).

The results of another study showed that the quality of the water entering the RO treatment system is better than the AAMI standard, and the average concentration of heavy metals in the hemodialysis water of Qorveh city Shahid Beheshti Hospital is lower than this standard (17).

The results of another study showed that the produced water quality from the RO device meets AAMI and EPH (European standard) standards for heavy metal concentration. The results indicated that water poses no danger to dialysis patients. In addition, RO is very effective in removing heavy metals from city water (18) During a study in Isfahan hemodialysis centers, the RO system significantly reduced the amount of residual chlorine, hardness, Na, K, F, NO₃, SO₄, and Mn in the outflow water but did not have a significant effect on reducing the amount of Cu, Zn, Kd, Cr, Pb, and Al. Consequently, the concentration of Pb and Al in the RO outflow was higher than the hemodialysis water standard. The opposite result in current research is likely due to three factors. These factors include not flushing the water filtration system, end of the useful life of the RO membranes, and the presence of internal leakage in the RO connections. Therefore, most researches confirm the effectiveness of the RO system in removing heavy metals to a lesser extent than the hemodialysis water standard (13).

Based on the findings of the study on dialysis water of Kermanshah province hospitals, the RO system's efficiency in removing Zn and Cr was 61.5% and 2.1%, respectively, and it was not effective in Pb and Kd removal, resulting in higher concentrations of Pb and Kd compared with their concentration in the RO inflow water. This indicates that the RO membrane has become filled by sediments, and as a result, the membrane must be washed or replaced (19).

The results of most researches showed that various factors are involved in the purification of water by RO. These factors include the sampling method, the type of water purification system, and the quality of its performance. For example, periodic flushing of the treatment system or the quality of the used raw water can greatly improve the permeate water. The similar reported results can be attributed to the use of the same water purification process in the hemodialysis centers of Iran and the world. Factors such as the retention time of water in the filtration system, the age and type of pipes and system connections, and even the age of the system are effective for releasing substances from the piping and leaking into the water. The results proved that the type, design, installation, service, and maintenance of water purification systems in hemodialysis centers play a vital role and can be effective in preventing primary and secondary contamination of hemodialysis water (20, 21).

The results of this study, as with most previous studies, showed that the outflow of the RO system has a much better quality than the AAMI standard, and the RO system can almost completely remove heavy metals. This indicates that the RO system has a good ability to produce hemodialysis water. This issue is in line with the study conducted by Baseri et al. in 2012 on the quality of hemodialysis water in a hospital. The comparison of raw water and purified water by RO quality in Baseri's study showed that in the case of correct design and optimal management of RO, this system is about 100% effective in removing mineral salts and microbial contamination of water (10).

At last, we suggest that the concentration of heavy metals in the water of hemodialysis centers in the country be monitored. Additionally, the chemical characteristics of the RO outflow water from the hemodialysis centers should be statistically analyzed. This will allow for the establishment of a relationship between the water's chemical parameters, especially heavy metals. Therefore, this relationship can be modeled and the heavy metal concentration can be predicted based on the usual water parameters. This model will eliminate the need to measure heavy metals.

Conclusion

The findings show that the quality of hemodialysis water at Khoy Dialysis Center meets AAMI standards. The removal percent of heavy metals in the RO independent of the removal percent of other water chemical impurities, such as TDS and TH, etc. The RO system can produce water with better quality than the AAMI standard and even remove heavy metals almost completely, so this system has good performance for the preparation of dialysis water. However, the efficiency of this system may be impaired if timely servicing and washing are neglected. Therefore, this emphasizes the need for continuous chemical and microbial monitoring of water in hemodialysis centers.

Practical implications

One of the practical consequences of the current research is increasing the sensitivity of hospital

managers regarding the regular quality control of water treatment system performance in dialysis centers. Also, in the country the results of the present study can be used for develop national standards of hemodialysis water

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Conflict of interest

The authors declare no conflicts of interest.

Ethical statement

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Data availability

The raw data supporting the conclusions of this article are available from the authors upon reasonable request.

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