

The Quality of Dialysis Water: A Case Study in the Educational Hospitals of Yazd, Iran

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Received: August 26, 2014; Revised: October 30, 2014; Accepted: November 19, 2014

Background: The chemical and physical quality of water used for dialysis fluid is a vital factor in the patients overall care who receive dialysis. Therefore, the water used for this purpose must be treated with advanced methods before being used for dialysis.

Objectives: The current study aimed to determine the chemical and physical quality of dialysis machines input water and compare it to the standards of Association for the advancement of medical instrumentation (AAMI) and European Pharmacopeia (EPH) in Yazd educational hospitals, i.e. Shahid Sadoughi and Shahid Dr. Rahnamoon.

Materials and Methods: This cross-sectional study is performed in three months (October to December) in 2013. This research was conducted on 24 samples of dialysis machines input water. The samples were tested by titrimetric method, turbid metric method, flame photometer, pH meter, and EC meter. The SPSS V16.0 software was used for statistical analyses.

Results: Based on results of the research, except chloride that its mean concentration was higher than the EPH standard, mean concentrations of cations and other compounds were significantly less than the standards ($P < 0.01$). Also there was a significant difference between the measured parameters in the dialysis machines input water in two educational hospitals with 99% confidence.

Conclusions: The evaluation of hemodialysis water quality showed that these hospitals were not significantly polluted and the water quality complied with AAMI and EPH standard limits.

Keywords: Water Quality; Pollution; Hemodialysis; Hospitals; Iran

1. Background

Patients with end-stage renal disease on regular hemodialysis treatment are exposed to approximately 400 liters of dialysis water in each week through the extracorporeal circulation (1). Furthermore, these patients have a limited urinary excretion as well as a compromised immune system and other disorders that make them susceptible to a number of specific diseases such as anemia, bone disease, hypertension, hypotension, acidosis, muscle weakness, nausea/vomiting and neurologic disturbances (1, 2). These diseases are caused via contaminated water by elements such as aluminum, calcium, magnesium, sodium and etc. (3). The dialysis fluids contain more than (99%) of reverse osmosis water and some chemical substances such as acids, salts and bicarbonates (4-6). Since the dialysis fluids are known as the largest volume of water consumption in medicine and pollution of drinking water enters bloodstream through the digestive system directly, compatible standards of physicochemical parameters for dialysis water is critical (2, 4). The consumption of urban water complying with drinking water standards is not confident without pretreatment

for patients (7). Therefore, the water used in dialysis centers needs treatment. Consequently, in the centers with dialysis machines, proper facilities for water treatment must be prepared and the quality of dialysis machines input water must be controlled (8, 9). In this regard, a number of studies are conducted worldwide on the quality of dialysis water and its importance for the patients. In a study, water quality in the UK healthcare centers was monitored weekly and researchers concluded that water quality depends on many factors, But If the data quality control are considered, the monitoring period must be more than one month (2). In a study in Australia conducted in seven dialysis units, the effects of all steps of water treatment were considered. In this study, microbial and chemical examinations were performed on the input water. The results showed that treatment process led to reduction of calcium and nitrate in water significantly, but sulfate reduction was not insignificant and the concentrations of heavy metals also reduced (10). In another study on the input water of dialysis machines in hospitals of Qom, Iran, regarding the concentration of cations,

potassium, sodium, magnesium, and calcium concentrations were examined. Researchers found that all the measured parameters were lower than the standard levels in these hospitals (11). The chemical and bacteriological characteristics of water used in hemodialysis were controlled over five years in Mexico and an investigation on 30 elements showed that the concentration of aluminum was higher than standard limits among the measured elements (12). According to an investigation by researchers on water quality of 36 hemodialysis centers located in Canada (Quebec) during a period of seven years, results determined that some of the chemical components in input water to the dialysis machines were higher than the standard level (13). In a study conducted in Iran, the chemical and microbial indexes of the water used in hemodialysis center in Zahedan educational hospitals were investigated. The results showed that the mean value of measured compounds were lower than standard levels (except calcium) (14). Recent studies showed that dialysis water with no contamination is an important factor to cure the patients. Since there were few such similar studies in Iran and especially in Yazd, Iran, two dialysis centers were selected. In the current study, physiochemical parameters of dialysis water were examined and treatment systems were checked. It was hoped that the results provided suitable background for health policy makers and help them to achieve community health goals.

2. Objectives

The current study aimed to determine the chemical and physical quality of dialysis machines input water and its compare it to the standards of Association for the advancement of medical instrumentation (AAMI) and European Pharmacopeia (EPH) standards in Yazd educational hospitals, i.e. Shahid Sadoughi and Shahid Dr. Rahnamoon.

3. Materials and Methods

This cross-sectional study was performed from October to December in 2013. This research was carried out on 24 samples of the input water to dialysis machines in Yazd educational hospitals, i.e. Shahid Sadoughi and Shahid Dr. Rahnamoon. These hospitals encompass six and twenty-two beds with dialysis machine purchased from Eurothechnic (Belgium) and BMA (Germany) with brands. The pressure applied by the reverse osmosis machines used in water treatment is 15 bars. Three membranes of two dialysis treatment machines were polyamide. The membranes life was four years and the mean age of dialysis water treatment systems were five and 3.5 years for Shahid Sadoughi, and Shahid Dr. Rahnamoon hospitals, respectively. Furthermore, the effluent discharge rate of reverse osmosis systems was 150 L and 350 L per hour for Shahid Sadoughi and Shahid Dr. Rahnamoon hospitals, respectively. The effluent of these systems usually includes more than 95% to 98% of dissolved salts and

more than 99% bacteria, and substances with molecular weights greater than 200 Dalton. Technicians evaluated the reverse osmosis systems monthly and reported the need to disinfection and replacement. The number of samples was obtained according to Cochran sampling adequacy; based on Equation 1:

$$n = \left(\frac{Z_{\alpha} \times \delta}{d} \right)^2$$

With a precision of 0.15 that standard deviation (SD) obtained from the pilot study. Therefore, 12 samples were collected. Four samples were collected from the input water to dialysis machines every month in complete sterile conditions using 240 mL clean plastic containers. The samples were kept at 4 °C before testing. Standard methods of chemical analyses were obtained from the standard methods of water and wastewater experiments book (15). Samples were randomly picked in different days without previous coordination. Some of the tests, such as pH and EC determination, were done using Metrohm pH meter (827) and conductivity meter (86503) at sampling site for all water samples. Other experiments, such as the concentration of calcium, magnesium, sodium, potassium, chloride and sulfate were conducted after transformation of the samples to the laboratory of sciences located in the collage. The titrimetric method with Ethylenediaminetetraacetic acid (EDTA) was used to determine calcium and magnesium, the flame photometer for sodium and potassium, the turbid metric method using spectrophotometry for sulfate, and the titrimetric with Ag-Nitrate method for chloride. The data were described using descriptive statistical tests such as mean, standard deviation, minimum and maximum. Data analyses were carried out using the sample t-test to compare the data with those of AAMI and EPH standards and independent t-test to compare the data between the hospitals. All the analyses were performed using SPSS Version 16 software.

4. Results

The results are showed with mean, standard deviation, minimum and maximum indexes, and are compared with those of AAMI and EPH (Tables 1 and 2). Also the normalization of the data is checked using 1-sample K-S at 1% level. There was no significant difference between the observed and expected frequencies. In other words, the distribution of data were normal with 99% confidence.

According to Table 1, there was no considerable hardness in any of the samples in Shahid Sadoughi Hospital. In other words, hardness was zero in all samples. A sample t-test showed significant difference between concentrations of the measured chloride with the EPH standard with 99% confidence limit. Also concentrations of chloride were higher than the standard in 83% of the

Table 1. Chemical and Physical Parameters in the Dialysis Machines Input Water in Shahid Sadoughi Hospital ^a

Parameters	Mean ± SD	Max	Min	AAMI St.	EPh St.	P Value ^b	P Value ^c	P Value, (K-S) ^d
Ca, mg/L	0 ± 0	0	0	2.00	2.00	< 0.0001	< 0.0001	-
Mg, mg/L	0	0	0	4.00	2.00	< 0.0001	< 0.0001	-
Na, mg/L	0.65 ± 0.60	1.93	0.15	70.00	50.00	< 0.0001	< 0.0001	0.300
K, mg/L	0 ± 0	0	0	8.00	2.00	< 0.0001	< 0.0001	-
TDS, mg/L	9.09 ± 4.16	21.05	6.31	-	-	-	-	0.412
So ₄ ²⁻ , mg/L	7.65 ± 1.82	11.34	5.55	100	50.00	< 0.0001	< 0.0001	0.588 (ns)
Cl ⁻ , mg/L	63.01 ± 13.88	71.00	35.50	-	50.00	-	0.008	0.058
TH, mg/L	0 ± 0	0	0	-	-	-	-	-
EC, µs/cm	14.21 ± 6.24	32.9	9.29	-	-	-	-	0.411
pH	7.73 ± 0.13	7.99	7.42	-	-	-	-	0.581

^a Abbreviations: Ca, calcium; Mg, Magnesium; Na, Sodium; K, Potassium; So₄²⁻, Sulfate; Cl⁻, Chloride; TH, total hardness; EC, electrical conductivity; ns, not significant difference at 1%.

^b Significant differences between concentration of parameters with AAMI standard at 0.01.

^c Significant differences between concentration of parameters with EPh standard at 0.01.

^d Kolmogorov-Smirnov P value.

Table 2. Chemical and Physical Parameters in the Dialysis Machines Input Water in Shahid Dr. Rahnamoon Hospital

Parameters	Mean ± SD	Max	Min	AAMI St.	EPh St.	P Value ^a	P Value ^b	P value, K-S
Ca, mg/L	0 ± 0	0	0	2.00	2.00	P < 0.0001	P < 0.0001	-
Mg, mg/L	0 ± 0	0	0	4.00	2.00	P < 0.0001	P < 0.0001	-
Na, mg/L	28.25 ± 16.5	51.52	12.02	70.00	50.00	P < 0.0001	P < 0.0001	0.256
K, mg/L	0 ± 0	0	0	8.00	2.00	P < 0.0001	P < 0.0001	-
TDS, mg/L	187.84 ± 40.31	220.16	130.56	-	-	-	-	0.062
So ₄ ²⁻ , mg/L	20.33 ± 9.01	36.06	10.17	100	50.00	P < 0.0001	P < 0.0001	0.902
Cl ⁻ , mg/L	84.31 ± 20.20	106.50	53.25	-	50.00	-	P < 0.001	0.150
TH, Total Hardness	0 ± 0	0	0	-	-	-	-	-
EC, µs/cm	293.5 ± 63.00	344	204	-	-	-	-	0.062
pH	7.30 ± 0.08	7.36	7.04	-	-	-	-	0.195

^a Significant difference between concentrations of parameters with AAMI standard limits was 1%.

^b Significant difference between concentrations of parameters with EPh standard limits was 1%.

measured samples. A sample t-test showed significant difference between the mean concentrations of sulfate with that of the standards with 99% confidence limit; the concentrations of sulfate were lower than the standards in 100% of the samples. A sample t-test showed significant difference between the mean concentrations of sodium with the standards with 99% confidence limit. Also the mean concentration of calcium, magnesium and potassium were zero in all of the samples. Therefore, concentrations of the four mentioned elements were lower than standards with 99% confidence limit in this hospital.

According to Table 2, there was no considerable hardness in any of the samples in Shahid Dr. Rahnamoon Hospital. In other words, hardness was zero in all of the samples, similar to those of Shahid Sadoughi Hospital. A sample t-test showed significant difference between the mean concentrations of chloride with EPh standard with 99% confidence limit. Also the mean concentration of chloride was higher than standard in 100% of the

measured samples. A sample T-test showed significant difference between the mean concentrations of sulfate with standards with 99% confidence limit and the mean concentration of sulfate was lower than standards in 100% of the samples. A sample t-test showed significant difference between the mean concentrations of sodium with standards with 99% confidence limit. Also, the concentration of calcium, magnesium and potassium were zero in all of the samples. Therefore, the concentrations of the four elements were lower than standards with 99% confidence limit in this hospital.

According to Tables 1 and 2, it was recognized that the mean concentrations of sodium, Total Dissolved Solid (TDS), So₄²⁻, Cl⁻ and mean value of Electrical conductivity (EC) in Shahid Dr. Rahnamoon Hospital were higher than those of Shahid Sadoughi Hospital.

In Table 3, the differences between the measured parameters in dialysis machines input water of the two hospitals are presented using independent t-test.

Table 3. Results of the Independent t-test

Parameters	P Value
Na, mg/L	< 0.0001
Cl ⁻ , mg/L	0.007 ^a
So ₄ ²⁻ , mg/L	< 0.0001
TDS, mg/L	< 0.0001
pH	< 0.0001
EC, µs/cm	< 0.0001

^a Significant differences at 0.01.

The results of independent t-test showed significant difference between the two educational hospitals in all the mentioned parameters of Table 3. In other words the dialysis machines input water in Shahid Sadoughi Hospital was purer than that of Shahid Dr. Rahnamoon Hospital.

5. Discussion

The findings of the current research showed that the values of measured parameters in the educational hospitals were lower than standards (except chloride). These findings were incompatible with the findings of Ibrahim in 2010 in Egypt on the amount of serum levels of some chemical parameters such as calcium and phosphorous in the patients receiving dialysis and the reported high values of these parameters (16). In the current study, the concentration of sulfate was lower than standard limits in all the samples. The result of the study regarding the concentration of sulfate was similar to the study by researchers in Mexico. Their study on 30 compositions in the dialysis water showed that the concentrations of anions such as sulfate were lower than standard limit (12). Also Arvanigidou et al. in Greece analyzed the samples in 85 dialysis centers of this country. The results of the few values of metals were higher than the standard level are compatible with those of the current study (1). Researchers evaluated the water quality regarding the concentration of cations and anions in dialysis machines input water in Qom, Iran. These researchers reported the value of 7.4 for mean pH which was the same as the results of the current study (11). In a study performed on some elements in the serum levels of the patients receiving dialysis in Italy, results showed that some metal levels were higher than the limits (17). In the current study the value of calcium and magnesium were zero. This finding was consistent with the study carried out in Qom and Zahedan, Iran (11, 14). In a study by Baseri et al. in Kashan, Iran, the characteristics of water quality of the hemodialysis machines in Akhavan Hospital were investigated. The results of this research showed that the mean concentration of chemical elements in all of the samples were not higher than standard limits, which comply with those of the current study (18). In a study by Shahryari et al. regarding the evaluation of reverse osmosis to improve water quality used for dialysis fluid in Isfahan hospitals,

the results showed that reverse osmosis significantly reduced the hardness, sodium, and potassium values in water outlet of the reverse osmosis that is in consistent with the results of the current study (19). Researchers investigated the chemical quality of dialysis machines input water and compared with standards in 22-Bahaman Hospital in Gonabad city in Khorasan Razavi Province, Iran. Results showed that the mean value of all the measured parameters were significantly lower than the standard values (except calcium) (20). These results were compatible with those of the current study (except calcium). The current study showed that the mean concentration of cations and measured parameters were lower than standards. Considering the point that a patient during the dialysis process needs 15000-30000 liters water yearly to exchange the harmful substances in the blood; therefore, this water must be treated and be free of harmful elements and substances. Since entering the substances into blood could be hazardous for the patients' health of it is suggested that the dialysis machines input water must be standard and with fixed characteristics. This requires a continuous monitoring of water by the health authorities of hospitals. Since the microbial quality of dialysis machines input water is important especially the endotoxins, conducting a study with this purpose in the educational hospitals is suggested.

Acknowledgements

Authors would like to thank the laboratory experts for their assistance.

Authors' Contributions

The overall implementation of this study, including experiments, data analyses, and manuscript preparation, conducted by those who have been listed as co-authors of this paper. All authors have made extensive contribution in the review and finalization of this manuscript.

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