

Hemodialysis Adequacy and Treatment in Iranian Patients

A National Multicenter Study

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Introduction. Assessment of the hemodialysis adequacy is one of the key factors in evaluating health service system. This would provide a good background for effective future planning by healthcare authorities. In this study, we aimed to evaluate the hemodialysis adequacy in Iran.

Materials and Methods. One hundred and twenty-seven hemodialysis centers affiliated to 30 medical universities in Iran participated in this cross-sectional multicenter national study. All demographic data as well as hemodialysis prescription data, including blood flow rate, length of the hemodialysis session, hemodialysis membrane type, and composition of the dialysis solution were recorded for each patient. In addition, urea reduction ratio and Kt/V were calculated to determine the hemodialysis adequacy.

Results. A total of 4004 patients were included in this study, 2345 men (58.6%) and 1659 women (41.4%). Bicarbonate-based solutions and low-flux membranes were prescribed for 77.0% and 97.6% of the patients, respectively. The mean blood flow rate was 242.9 ± 39.2 mL/min. The mean length of hemodialysis session was 229.2 ± 22.2 minutes. The mean urea reduction ratio and Kt/V were calculated to be $61.0 \pm 11.8\%$ and 1.2 ± 0.4 , respectively. A Kt/V less than 1.2 and a urea reduction ratio less than 65% were found in 56.7%, and 65.2% of the hemodialysis patients, respectively.

Conclusions. This study showed a substantial inadequate hemodialysis in Iran as compared with the Kidney Disease Outcomes Quality Initiative guidelines. Considering the impact of dialysis adequacy on quality of life and survival rates, as well as healthcare costs, rigorous attempts to achieve the desired goals are necessary.

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INTRODUCTION

There are about 1.8 million patients with end-stage renal disease (ESRD) all over the world that need a kind of renal replacement therapy (RRT), including hemodialysis, peritoneal dialysis, or transplantation.¹ Hemodialysis is one the main modalities in RRT, and according to published statistics in 2006, about 12 500 Iranian patients with

ESRD (48.5%) are on maintenance hemodialysis.² The prevalence and incidence rates of ESRD in Iran have increased from 238 and 49.9 patients per million populations (pmp) in 2000 to 357 and 63.8 pmp in 2006, respectively.² Thus, ESRD and its consequences, like the need for RRT are emerging public health problems that will require more active policy attention of healthcare.^{1,3}

Despite notable improvements in medical managements and dialysis delivery, the mortality and hospitalization rates of patients have not significantly changed in the past 20 years, they have remained unacceptably high. The annual mortality rate of patients on maintenance hemodialysis is approximately 18%. Hospitalization rate is about 1.94 times greater than that in general population, which lasts approximately 14 days each time.⁴

Updated information and statistics about hemodialysis patients, including patients population, treatment modalities, and outcomes, particularly in a national scale, is a required background for better planning to overcome these obstacles.⁵ Achievement of the global goals to improve quality of life, healthcare costs, and morbidity and mortality rates in hemodialysis patients is our desired goal. In this way, considering the intermediate outcomes that have an established association with these targets are also worth a plan.⁶ Urea reduction ratio (URR) and Kt/V, which are indicators of dialysis adequacy, are among these intermediary outcomes. According to the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines, a URR greater than 65% and a Kt/V greater than 1.2 are recommended for adequate hemodialysis.⁷ Each 0.1 decrease in Kt/V is associated with approximately 7% increase in the relative risk of death and 11% increase in the annual rates of hospitalization.^{8,9} We aimed to evaluate the management protocol and dialysis adequacy in Iranian patients on maintenance hemodialysis.

MATERIALS AND METHODS

This multicenter national study was carried out between September 2007 and March 2008. One hundred and twenty-seven hemodialysis centers affiliated to 30 medical universities in Iran participated in this study. For this purpose, a package containing a brochure about the study and its objectives, a sample data collecting form, in addition to an instruction for sampling, recording data and working with our designed computer program (Kt/V and URR calculator) was sent to these centers through the Management Center for Transplantation and Special Diseases of the Iran Ministry of Health. The study was performed in accordance with the Declaration of Helsinki and subsequent modifications, and its protocol was

approved by the ethics committee of the Ministry of Health of Iran.

Demographic data of all patients as well as the adequacy of hemodialysis protocols and prescriptions, including blood flow rate, length of hemodialysis session, type of hemodialysis membrane, dialysis solution, and calculated Kt/V and URR were recorded in the forms. Blood samples were drawn to measure postdialysis blood urea nitrogen (BUN) through the arterial sampling port at the end of dialysis. Before blood sampling, blood flow rate decreased to 50 mL/min for 20 seconds. A computer program was designed to facilitate the calculation. Urinary reduction ratio and a single-pool Kt/V were calculated based on the standard formulas^{10,11} as follows:

Urinary reduction ratio = $100 \times [1 - (\text{urea after hemodialysis} / \text{urea before hemodialysis})]$

Single-pool Kt/V = $-\ln(R - 0.008 \times t) + (4 - 3.5 \times R) \times UF / W$

where \ln represents the natural logarithm, R is the ratio of postdialysis to predialysis BUN, t is the length of a dialysis session in hours, UF is the ultrafiltration volume in liters, and W is the patient's postdialysis weight in kilograms.

Data were presented as mean \pm standard deviation for numeric variables and as percentages and frequency rates for categorical variables. The Student t test was used to compare continuous variables, and categorical variables were assessed by the chi-square or the Fisher exact test, as appropriate. P values less than .05 were considered significant. The data were analyzed with the SPSS software (Statistical Package for the Social Sciences, version 13.0, SPSS Inc, Chicago, Ill, USA).

RESULTS

A total of 4004 adult hemodialysis patients were included, consisting of 2345 men (58.6%) and 1659 women (41.4%). Two thousand and three patients were on hemodialysis in large equipped centers of the capital of states, and 2001 patients were on hemodialysis in small local areas.

Hemodialysis treatment data are shown in Table 1. Bicarbonate-based dialysis solution was used for 77% of the patients. Low-flux membranes were used in 97.6% of the patients, while 2.4% of patients were on hemodialysis with high-

Table 1. Data of Hemodialysis Treatment*

Characteristic	Value
Bicarbonate-based dialysis solution	2683 (67.0)
Blood flow rate, mL/min	242.90 ± 39.21
Length of hemodialysis session, min	229.16 ± 22.16
Low-flux membrane	
Polysulfone	
0.4 m ²	5 (0.1)
0.7 m ²	144 (3.6)
1.0 m ²	1886 (47.1)
1.3 m ²	919 (23.0)
Micro-endolated polysulfone	
1.0 m ²	653 (16.3)
1.3 m ²	155 (3.9)
Hemophan	
1.0 m ²	70 (1.7)
1.3 m ²	53 (1.3)
Cuprophan	
1.0 m ²	3 (0.1)
1.3 m ²	4 (0.1)
High-flux membrane	
Polysulfone	
0.7 m ²	10 (0.2)
1.0 m ²	87 (2.2)

*Values in parentheses are percents.

flux membranes. The mean blood flow rate was 242.9 ± 39.2 mL/min. The mean duration length of the hemodialysis was 229.16 ± 22.16 minutes. The mean single-pool Kt/V and URR in the studied population was 1.17 ± 0.4 and $61 \pm 11.8\%$,

respectively. The single-pool Kt/V was less than 1.2 in 56.7% of the patients. Also, URR was less than 65% in 65.2% of the patients. The mean Kt/V and URR were significantly lower in the men than the women (1.13 ± 0.3 versus 1.24 ± 0.4 , $P < 0.001$ and $59.7 \pm 11.8\%$ versus $62.9 \pm 11.6\%$, $P < 0.001$; respectively).

Table 2 compares characteristics of the hemodialysis patients on high-flux dialysis with low-flux dialysis. The mean single-pool Kt/V and URR were significantly higher in the patients who received high-flux dialysis compared to those who received low-flux dialysis (1.36 ± 0.29 versus 1.17 ± 0.36 , respectively; $P < .001$ and $68.2 \pm 11.2\%$ versus $60.9 \pm 11.8\%$, respectively; $P < .001$). Similarly, a significantly higher blood flow rate was reached during treatment with high-flux dialysis compared with low-flux dialysis (283.76 ± 43.86 mL/min versus 241.90 ± 38.53 mL/min, respectively; $P < .001$).

There was no significant difference between patients who underwent hemodialysis with bicarbonate-based dialysis solution and those with acetate-based dialysis solution regarding the single-pool Kt/V and URR (1.18 ± 0.36 versus 1.15 ± 0.37 , respectively; $P = .06$ and $61.1 \pm 11.9\%$ versus $60.9 \pm 11.4\%$, respectively; $P = .71$). Table 3 shows hemodialysis treatment in patients on different types of dialysis solution.

Table 2. Comparison Between High-flux and Low-flux Membranes in Hemodialysis*

Variable	High-flux Membrane	Low-flux Membrane	P
Number of patients	97	3892	...
Male gender	73 (75.3)	2272 (58.4)	.001
Bicarbonate-based dialysis solution	89 (91.8)	2995 (76.7)	< .001
Blood flow rate, mL/min	283.76 ± 43.86	241.90 ± 38.53	< .001
Length of dialysis session, min	225.77 ± 20.12	229.25 ± 22.21	.13
Single-pool Kt/V	1.36 ± 0.29	1.17 ± 0.36	< .001
Urinary reduction ratio, %	68.21 ± 11.18	60.85 ± 11.78	< .001

*Values in parentheses are percents.

Table 3. Comparison Between Different Types of Dialysis Solutions*

Variable	Dialysis Solution		P
	Bicarbonate-based	Acetate-based	
Number of patients	3084	920	
Male gender	1811 (58.7)	534 (58.0)	.71
High-flux membrane	89 (2.9)	8 (0.9)	< .001
Blood flow rate, mL/min	244.48 ± 40.05	237.83 ± 35.86	< .001
Length of dialysis session, min	230.22 ± 21.79	225.70 ± 23.05	< .001
Single-pool Kt/V	1.18 ± 0.36	1.15 ± 0.37	.06
Urinary reduction ratio, %	61.07 ± 11.93	60.90 ± 11.41	.71

*Values in parentheses are percents.

Table 4. Comparison Between Equipped Hemodialysis Centers and Small Local Centers With Few Facilities

Variable	Equipped Facilities	Small Facilities	P
Number of subjects	2003	2001	
Male gender	1164 (58.1)	1181 (59.0)	0.56
High-flux membrane	80 (4.0)	17 (0.8)	< 0.001
Blood flow rate, mL/min	247.25 ± 35.5	238.63 ± 42.1	< 0.001
Length of dialysis session, min	227.44 ± 20.9	230.84 ± 23.1	0.04
Single-pool Kt/V	1.17 ± 0.3	1.17 ± 0.4	0.84
Urinary reduction ratio, %	61.30 ± 11.8	60.75 ± 11.9	0.16

*Values in parentheses are percents.

We compared hemodialysis treatments in large equipped hemodialysis centers with hemodialysis facilities in small local areas (Table 4). There was no significant difference between these two kinds of centers regarding the single-pool Kt/V, URR, and length of the hemodialysis session. Patients in large equipped hemodialysis centers underwent higher blood flow rates than patients in small hemodialysis centers (247.25 ± 35.49 mL/min versus 238.63 ± 42.15 mL/min, respectively; $P < .001$). Moreover, they underwent more frequently a high-flux dialysis (4% versus 0.8%, respectively; $P < .001$).

DISCUSSION

According to the KDOQI guidelines for hemodialysis patients, the minimally adequate dose of dialysis should be a single-pool Kt/V of 1.2 or a URR of 65%, and the recommended target dose should be a Kt/V of 1.4 or a URR of 70%.¹² In the present study, the mean single-pool Kt/V and URR were 1.17 and 61%, respectively. The single-pool Kt/V was over 1.2 only in 43.3% of hemodialysis patients. These findings indicate a substantial inadequate hemodialysis treatment in Iranian patients. In contrast, we did not find any significant difference in hemodialysis adequacy between patients in large equipped and small local hemodialysis centers with fewer facilities. These findings point to the well distribution of hemodialysis treatment in Iran. To evaluate the adequacy of hemodialysis in Iran, Pourfarziani and

colleagues¹³ carried out a study on 338 patients in 6 hemodialysis centers from different areas of Iran. The mean Kt/V and URR were determined as 1.17 and 62.6%, respectively. Mahdavi-Mazdeh and coworkers³ conducted another study on 2630 hemodialysis patients from 56 hemodialysis centers in Tehran, Iran. They assessed hemodialysis adequacy and treatment. The mean Kt/V was determined 0.97 in their study. Considering the existence of diversity in conditions, facilities, and studied populations, both studies interpreted the results acceptable. Malekmakan and colleagues¹⁴ compared the hemodialysis treatment in Fars province of Iran with the KDOQI targets. They evaluated 632 hemodialysis patients in 15 hemodialysis centers and reported a mean Kt/V of 0.97.

Although our study revealed similar findings to those carried out in other developing countries such as Brazil, Nigeria, Nepal, and Pakistan,¹⁵⁻¹⁹ they differ from those reported from developed countries (Table 5). In the United States, according to the 2007 annual report, the mean delivered single-pool Kt/V was more than 1.5 and over 90% of patients had a Kt/V greater than 1.2.²⁰ Similarly, the Euro-Dialysis Outcomes and Practice Patterns Study (DOPPS), which assessed dialysis practices in the years 1998 to 2000 in 5 European countries consisted of France, Germany, Italy, Spain, and UK, found that the mean delivered Kt/V varied from 1.28 to 1.50.²¹ The substantial discrepancy in hemodialysis adequacy between aforementioned

Table 5. Adequacy of Hemodialysis in Iran Compared With Five European Countries and the United States

Variable	Iran	France*	Germany*	Italy*	Spain*	UK*	USA†
Mean single-pool Kt/V	1.17	1.51	1.30	1.32	1.32	1.38	1.55
Single-pool Kt/V < 1.2, %	56.7	16	40	34	35	28	10
Length of dialysis session, min	229	249	251	221	216	230	217
Blood flow rate, mL/min	243	292	251	307	322	311	296
High-flux membrane, %	2.4	60	54	28	49	19	...

*Based on the Euro-Dialysis Outcomes and Practice Patterns Study.²¹

†Based on the 2007 annual report of end-stage renal disease clinical performance measures project.²⁰

developed countries and Iran at least, to some extent, may be resulted from more frequent use of high-flux dialysis and higher blood flow rates in those countries than in Iran (19% to 60% versus 2.4%, and 251 to 322 mL/min versus 243 mL/min, respectively).²¹ More rapid reduction in blood urea nitrogen in high-flux dialysis overestimates the true rate of urea removal, because there has not been sufficient time for intracellular urea to diffuse out of the cells and equilibrate with extracellular pool. Thus, the calculated Kt/V in this setting may exceed the true value by approximately 0.2.^{10,22} In this way, the 0.19 difference in Kt/V between high-flux and low-flux membranes (1.36 versus 1.17, respectively) that was observed in our study may have negligible clinical significance. However, high-flux membranes were associated with substantial higher blood flow rate than low-flux membranes in our study (283.76 mL/min versus 241.90 mL/min, respectively). Port and coworkers²³ reported that delivering a same dialysis dose in higher blood flow rates was associated with the lower mortality rate. This correlation has been observed consistently in Euro-DOPPS, as well as in US-DOPPS and Japan-DOPPS.²¹ Concordantly, the use of high-flux synthetic membranes has been associated with mortality risk reduction with the same Kt/V.²⁴ The mentioned evidence calls for attention of health authorities to consider the extent use of high-flux dialysis to improve outcomes in hemodialysis patients.

There are numerous observational studies supporting the positive association between the length of hemodialysis session and survival rate.^{25,28} However, our study revealed marked short length of hemodialysis sessions in Iranian patients. Considering that 97.6% of Iranian hemodialysis patients were on low-flux dialysis, our patients received significantly shorter hemodialysis treatments (229 minutes) than patients in developed countries with more use of high-flux dialysis like France (249 minutes) and Germany (251 minutes).²¹ In fact, hemodialysis prescription, including length of treatment is rarely individualized in Iran. Almost all patients are prescribed to receive hemodialysis four hours a day, thrice a week that seems to be insufficient considering the high extent use of low-flux dialysis. Thus, increasing the length of hemodialysis sessions may play an important role in improving the outcomes of hemodialysis

in Iran. There are some barriers to increase the length of hemodialysis sessions. The first and the most common barrier is the compliance of patients.²⁹ Thus, education is the crucial step to bring about understanding and acceptance.^{29,30} It is well known that dialysis with bicarbonate-based solutions compared to acetate-based solutions is less likely associated with hypotension, headache and other complications during hemodialysis.³¹ As a result, higher blood flow rate, consistent with longer length of hemodialysis sessions and higher dialysis adequacy is anticipated by bicarbonate based dialysis. These rationales need more attention of health authorities to extend the usage of bicarbonate-based dialysate in Iran.² In spite of our expectations, we did not encounter any significant difference in tolerability of long length hemodialysis sessions and high blood flow rates during hemodialysis between patients on bicarbonate based vs. acetate based dialysate (mean difference in length of sessions and blood flow rates was 5 minutes and 6 mL/min, respectively). Similarly, dialysis adequacy did not differ with administration of bicarbonate based dialysate vs. acetate based solution in our study (1.18 versus 1.15, respectively).

Prescription a fixed hemodialysis protocol with little attention to differences between individuals like body mass index, increases the likelihood of inadequate hemodialysis.³² In this way, it is supposed to have a greater risk of delivering inadequate hemodialysis dose in men than women. Thus, individualizing the hemodialysis prescription based on monthly assessment of single-pool Kt/V would be a useful and practical tool to provide a safe and cost-effective hemodialysis treatment.

There are some limitations in our study. Limited participation and low compliance of the patients in some hemodialysis centers restricted our data, including the existence of concordant disorders like diabetes mellitus, hypertension, and heart failure as well as the cause of ESRD. In addition, we assessed hemodialysis adequacy for each patient just once instead of measuring Kt/V and URR in several occasions and this is another limitation of our study.

CONCLUSIONS

This multicenter study revealed the available evidence about the hemodialysis treatment in Iran.

Our study showed a substantially low hemodialysis adequacy in Iranian patients with ESRD. Regarding a considerable impact of dialysis adequacy on quality of life and survival rate of hemodialysis patients, a continuous evaluation system in management is necessary. This might help to track closely the efficiency and performance of hemodialysis centers as well as to present practical guidelines based on different conditions.

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CONFLICT OF INTEREST

None declared.

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