Online Clearance Monitoring With Electrical Conductance (Dt/V) Versus Blood-driven (Kt/V) of Urea: A Compressional Study

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Introduction. The rates of morbidity and mortality in patients receiving routine hemodialysis have been demonstrated to be significantly affected by the dose of HD. As the national and international standards for determination of dialysis adequacy vary among countries, it is necessary to investigate the optimum criteria for HD adequacy. In this study, we aimed at comparing HD adequacy, through two methods of OCM with electrical conductance, and blood-driven Kt/V of urea, in the largest hemodialysis center in Iran.

Methods. The value of UC, as an indicator of HD adequacy, was measured 301 times in 120 HD patients via two methods of OCM and blood-driven clearance of urea. For urea- driven Kt/V, two blood samples, each 2 milliliters, were taken from the patient, one before and one after a HD session. For OCM, Fresenius 4008 dialysis machine was set online once the patient was receiving HD. The results of these two methods were analyzed regarding the correlation with patients' demographics, BMI, required weekly HD sessions, type of HD access, type of dialyzers, hematocrit, UDV, ultrafiltration, and blood flow rate.

Results. The mean values of UC obtained from blood samples and OCM were almost similar and not significantly different (1.20 vs. 1.11, P = .50). UC values, measured by laboratory assessments were significantly associated with gender, BMI and UDV, while UC values from OCM were significantly associated with gender, BMI, dialyzer type, UDV and ultrafiltration.

Conclusions. We conclude that OCM can be used as an effective substitute for laboratory assessment in HD centers to assess HD adequacy.

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INTRODUCTION

Chronic diseases are currently among the most serious health issues around the world, which could adversely affect patients' lives in terms of physical and mental health, quality of life, and economic status.[1-3] End-stage kidney disease (ESKD) is the terminal stage of renal failure and one of the most severe types of chronic kidney disease, caused by progressive uremia, which compromises body fluid and electrolytes balance.[4] It is a global public health issue, due to its considerable morbidity and mortality rates. Furthermore, the need for acute care, dialysis or kidney transplantation, to save patients with ESKD, imposes a significant economic burden on healthcare system.[5,6] Iran is one of the countries with a high prevalence of ESKD and it has been shown that, 48 percent of Iranian patients with kidney failure, require hemodialysis (HD).[7,8]

Since the adequacy of HD is related to the incidence of morbidity and mortality in patients with ESKD, it is now well accepted that the quantification of HD dose is a key factor in the surveillance of HD treatment efficacy and clinical management of ESKD patients.[9,10] An adequate delivery of HD dose requires both an appropriate prescription of HD dose and regular and accurate monitoring of delivered HDtreatments.[11] The prescription of HD dose is mainly based on Kt/V formula, where K, t and V represent the urea clearance (UC) (milliliters per minute), duration of a HD session (minutes), and volume of urea distribution (milliliters), respectively.[12,13] The accuracy of adequate delivered value of Kt/V to patients depend on its regular monitoring. Urea- driven Kt/V with laboratory assessments of pre-and-post HD samples of arterial line, are considered as classic monitoring methods.[14] In recent years, online clearance measurement (OCM) has become popular, as a useful method for determination of HD adequacy. Online hemodiafiltration machines are equipped with OCM and provide easy, fast, continuous, and effective monitoring of adequate dialysis delivery in every HD session, through automatic measurements of K values.[15,16] Conductivity clearance measurement is a method, for monitoring HD adequacy, with the help of the dialysis machine. In this approach, the HD machine, gradually and episodically increases and decrease the inflow dialysate conductivity. All changes in conductivity of dialysate inflow and outflow, which might affect the dialysate electrolyte concentration, are calculated by dialyzer clearance.[17-19] The OCM uses electrical conductance to provide a safe and reliable method, for constant monitoring of total UC, which is an indicator of HD adequacy, at every HD session. Therefore, this method eliminates, or greatly reduces, the need for disposables containers or reagents, undesirable blood sampling, laboratory services workload, as well as, healthcare expenses, associated with HD procedures.[15,20,21]

Due to the variations in national standards of HD adequacy, across countries, and insufficient published literature, it is important to conduct and publish studies, on different methods of HD adequacy measurement, in order to introduce the best guidelines applicable to the country of study.[20,22] Despite the advantages of OCM in measuring HD adequacy, it is not included in national HD guidelines, and laboratory tests remain the most preferred tool for monitoring of HD adequacy. As a result, we sought to compare OCM with electrical conductance, with laboratory determination of urea reduction ratio (URR) techniques, in order to offer the most effective method for estimating HD adequacy in our regional settings.

MATERIALS AND METHODS

In this study, we calculated and compared the HD adequacy with two methods: the OCM method with electrical conductance and the blood urea- driven Kt/V method. A total of 301 sample were obtained from 120 patients with ESKD, on maintenance hemodialysis, who were referred to Emam Reza teaching hospital HD center in Tabriz, which is the largest hemodialysis center in Iran, in 2019.

Participants

Patients with ESKD, who required at least two sessions of HD per week, and had a permanent HD access, were included in this study. The patients who required any change in their HD profile, such as ultrafiltration, session length, blood flow rate, sodium, and temperature were excluded from the study. Sample collection was performed between May and September 2019.

Procedures

All patients referred to Emam Reza teaching hospital in 2019 for HD treatment, were evaluated for acquisition of eligibility criteria. The HD adequacy values was examined for each eligible patient, at each HD session using the two mentioned methods, i.e. the blood urea- driven Kt/V and the OCM method with electrical conductance. In the first method, the national protocol for measuring HD adequacy, which is currently used in almost all dialysis centers in Iran, was applied. In this method 2 milliliters of blood is drawn from the arterial line, before starting HD and another 2 mL blood sample is drawn, at the end of HD session, when ultrafiltration is stopped, and blood flow rate is reduced to 100 mL/min, for last 10 to 20 seconds. Both pre- and post-HD blood samples are sent to laboratory, for separation of serum, and laboratory determination of URR (as an indicator for UC).

URR is calculated as: predialysis urea – postdialysis urea / predialysis urea × 100. Dialysis adequacy is assessed monthly using the second-generation Daugirdas formula to calculate the single pool Kt/V.

In the second method, OCM with electrical conductance is performed online for the same patient with a Fresenius 4008 dialysis machine upon the initiation of the HD session. The dialysis machine uses electrical conductance to assess urea variations, based on sodium alterations, and displays HD adequacy is shown as a value of Dt/V, as indicator for UC, on its monitor.

Demographic data, BMI, weekly required HD sessions, type of HD access, type of dialyzers, hematocrit level, urea distribution volume, UF and blood flow rate were also collected for each patient, along with acquired UC values by each study method.

Statistical Analysis

Data was analyzed, using SPSS software version 24. Kolmogorov–Smirnov test was used to verify the normal distribution of data. Quantitative data was reported as mean (± Standard Deviation) and qualitative data was presented as percentage (%). The correlations between UC values and other research variables were determined, using chi square test, Pearson coefficient correlation test and independent samples t test. The results were considered statistically significant, if the *P* value was < .05.

Ethical Considerations

The study protocol was approved by the ethical committee of Tabriz University of Medical Sciences, (IR.TBZMED.REC.1399.787). An informed written consent was signed by all patients, after they met the eligibility criteria.

RESULTS

Patient's Characteristics and HD Information

The study comprised 301 samples derived from 120 HD patients, who met the inclusion criteria. The mean age of the patients was 60.7 ± 14.6 years, 202 (67.1%) were males, 99 (32.9%) were females and the mean BMI was 20.8 ± 3.9. As shown in Table 1, the majority of enrolled patients (81.4%) needed three HD sessions per week. Arteriovenous fistula was the most frequent (66.8%) type of HD access, and high flux dialyzer was the most frequently used dialyzer (57.8%). The mean hematocrit level, urea distribution volume, ultrafiltration (UF) and blood flow rate were 35.8 ± 5.5, 36.7 ± 13.3, 2.5 ± 1.2, and 275.2 ± 19.6; respectively (Table 1).

HD Adequacy Using Two Measurement Methods

The mean amount of UC was 1.20 ± 0.23, as evaluated by urea measurement method and 1.11 ± 0.21, as measured by OCM with electrical conductance. The mean values of UC did not differ significantly between the two methods (*P* = .50), indicating that the amount of UC levels calculated by urea measurement were comparable with those reported by OCM technique (Figure 1).

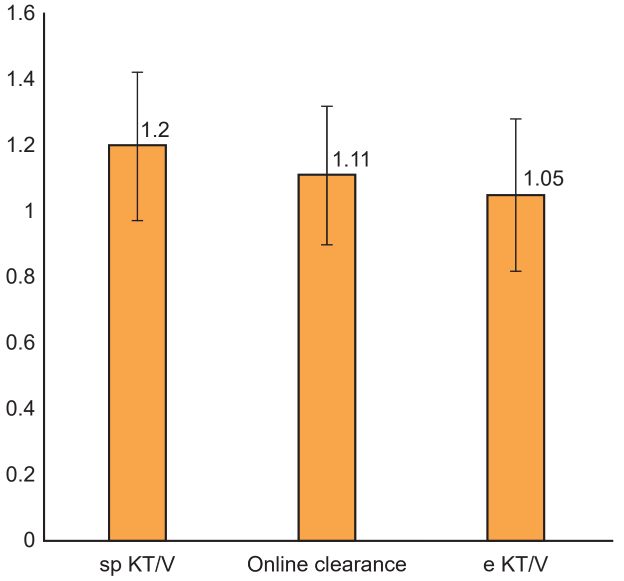
The correlation studies showed that the UC values of blood urea- driven Kt/V method were significantly associated with gender, BMI, and urea distribution volume (*P* < .05), with females having significantly higher UC levels than males (1.25 vs. 1.17) (Table 2). Additionally, the patients with lower BMIs and urea distribution volumes had significantly higher UC values.

The UC values driven from OCM with electrical conductance method were significantly associated with gender, BMI, dialyzer type, urea distribution volume and UF (*P* < .05) (Table 3). The mean value of UC was significantly higher in females

Table 1. HD Information (n = 301)

	Statistics
Weekly HD Sessions†	
2 Sessions	56 (24.9)
3 Sessions	245 (81.4)
Access†	
Catheter	100 (33.2)
Arteriovenous Fistula	201 (66.8)
Hematocrit, %*	35.8 (5.5)
Urea Distribution Volume*	36.7 (13.3)
Ultrafiltration*	2.5 (1.2)
Blood Flow Rate, mL/min*	275.2 (19.6)
Dialyzer†	
High Flux	174 (57.8)
Low Flux	127 (42.2)

*Data are presented as mean (± SD).
†Data are presented as n (%).



Comparison of KT/V Results (Online, e KT/V, and sp KT/V)

Table 2. The Correlations Between the UC Values From Laboratory Assessments and the Study Variables (n = 301)

Study Variables	Value of UC	*P*
Gender		
Male	1.17 (0.20)*	< .05§
Female	1.25 (0.26)*	
Age	0.019†	> .05‡
BMI	-0.312†	< .000‡
Weekly HD Sessions		
≤ 2	1.17 (0.20)*	> .05§
> 2	1.20 (0.24)*	
Access		
Catheter	1.22 (0.27)*	> .05§
Arteriovenous Fistula	1.19 (0.21)*	
Dialyzers		
High Flux	1.18 (0.22)*	> .05§
Low Flux	1.22 (0.24)*	
Hematocrit	0.090†	> .05‡
Urea Distribution Volume	-0.409†	< .000‡
Ultrafiltration	-0.003†	> .05‡
Blood Flow Rate, mL/min*	0.050†	> .05‡

*Mean (± SD)
§Independent Student t Test
†Correlation Coefficient
‡Pearson Correlation Test

Table 3. The Correlations Between the UC Values From OCM With Electrical Conductance and the Study Variables (n = 301)

Study Variables	Value of UC	*P*
Gender		
Male	1.07 (0.20)*	0.001§
Female	1.18 (0.19)*	
Age	0.010†	> .05‡
BMI	-0.436†	< .001‡
Weekly HD Sessions		
≤ 2	1.08 (0.19)*	> .05§
> 2	1.11 (0.22)*	
Access		
Catheter	1.08 (0.23)*	> .05§
Arteriovenous Fistula	1.12 (0.20)*	
Dialyzers		
High Flux	1.07 (0.20)*	< .05§
Low Flux	1.15 (0.22)*	
Hematocrit	-0.052†	> .05‡
Urea Distribution Volume	-0.530†	< .000‡
Ultrafiltration	-0.140†	< .05‡
Blood Flow Rate, mL/min*	0.030†	> .05‡

*Mean (± SD)
§Independent Student t Test
†Correlation Coefficient
‡Pearson Correlation Test

than males (1.18 vs. 1.07), and in low flux- highly efficient dialyzers than high flux dialyzer (1.15 vs. 1.07). Furthermore, patients with lower BMI, urea distribution volume, and UF had significantly higher values of UC.

DISCUSSION

Although HD is now considered as the most available treatment for ESKD, the high risk of mortality, disability and hospitalization still threaten the lives of HD patients and reduce their quality of life.[23] By administrating an appropriate and adequate HD treatment, it may be possible to avoid unnecessary prolonged dialysis sessions as well as additional sessions between inadequate scheduled weekly dialysis. This would improve patient compliance and reduce the financial healthcare burden in terms of personnel, services, and instruments.[22,24,25]

Despite the fact that Current Kidney Disease Outcomes Quality Initiative Guidelines obligate the application of pre-and-post-dialysis blood samples, at least once a month, for measuring the HD adequacy in HD patients, many studies declared that the majority of patients are not treated with even the minimum required HD dose.[26,28-32] Such ineffective HD treatments have called for alternative monitoring methods to achieve a better HD adequacy.

The European Best Practice guideline recommends OCM, as a valid method for assessing the HD adequacy.[33] The current study demonstrates that, the measured values of UC were not significantly different between two methods of OCM and blood sampling for determination of single pool KT/V.

Pre- and post-dialysis blood samples are used in the traditional method of determining HD adequacy in urea- driven Kt/V assessments technique. However, this method has several flaws and limitations, such as the monthly (or less) frequency, that is often insufficient for measuring HD adequacy, and high cost of logistics, laboratory, and nursing services.[20,26,33] On the other hand, OCM method provides continuous feedback on the effectiveness of HD, constant monitoring of HD dose, accompanied by appropriate prescriptions for any change during a HD session towards the targeted HD dose. It also offers a timely and effective detection of consequences, following any prescribed change in HD treatment, such as decrease in blood flow, and has the capability of immediate tracking of vascular access dysfunction, such as access recirculation, once they occur.[16,20,34] The HD adequacy results have also been compared between OCM and conventional blood-sampling methods in various studies conducted around the world. These studies have introduced the OCM as a safe, more reliable, more effective, and less expensive option for patients, clinicians and health systems.[11,15,16,20,34] According to Steil *et al,* effective ionic dialysance (EID) of sodium is directly proportional to in vitro urea clearance in six patients undergoing maintenance HD. The correlation between blood side urea clearance and K in the in vitro trials was found to be 0.998.[35]

In our study, the mean value of UC, detected through urea- driven Kt/V, were slightly higher than that, detected by OCM (1.20 vs. 1.11). Since, the post-HD samples are immediately drawn at the end of the HD session, when arterial line concentrations of urea are still decreasing in response to ongoing urea removal, the value of UC may be overestimated compared to relatively equilibrated value of UC from OCM, which is continuously measured during the HD session.[36] On the other hand, the Dt/V from OCM corresponds to Equilibrated KT/V, which is slightly lower than standard single pool KT/V (1.2 vs. 1.05). McIntyre *et al.* reported a similar correlation between the values of UC from blood samples and OCM.[37] While double-pool measurements of UC from post-HD samples, which are taken 30 minutes after the HD session, will present more reliable measurements of HD adequacy, they showed that such sampling protocols are very difficult to apply, primarily due to the inconvenience that they cause to the patients.[11,37]

There are additional problems associated with these post-HD samples; being drawn during a busy time right after the HD session, requires special protocols to protect them from the interference with access recirculation. [26,33]

The UC values from both OCM and blood sampling methods were significantly associated with patients' gender, BMI and urea distribution volume. Our findings from OCM showed further correlations between UC values and variables of dialyzer type and ultrafiltration; where UC values were significantly higher when using low flux dialyzer than using high flex dialyzer. Furthermore, higher UC values were associated with lower amounts of ultrafiltration, which was consistent with previous study findings.[38]

Hemodialysis machines, equipped with high flux membrane, are more capable of transmitting moderate-sized molecules, such as inflammatory proteins and lipoproteins, compared to those with low flux dialyzers,[39,40] Several studies reported considerably higher UC values and adequate HD adequacy achievement for the HD machines with high flux dialyzer, and recommended the application of these dialyzers in HD centers.[41-43] Use of a low flux but highly effective dialyzer with higher mass transfer area (KoA), in our dialysis patients, may help to explain the difference in HD adequacy between our study and prior studies. Further research is required to determine the impact of ultrafiltration, as well as its accurate assessment, on HD adequacy. [44] It should be noted that, KT/V and protein catabolic rate (PCR) are two important determinant of dialysis adequacy. Unfortunately, OCM is unable to measure PCR. Additionally, Kt/V > 1.2 and PCR > 1.0 g/kg/d are necessary, but insufficient criteria, for determination of dialysis adequacy. Other parameters such as phosphate, acid-base and electrolytes management and elimination of middle and high molecular solutes, are crucial components of effective dialysis therapy.[45]

Our study has several advantages and limitations. The sample size was larger than the majority of previous similar studies. In addition, in our investigation, all dialysis machine were identical. Measurement of dialysis adequacy by OCM was limited to the patients with fixed HD profiles during the HD sessions; hence, it was unable of addressing HD adequacy in patients whose HD profiles changed during their prescribed scheduled HD treatment. In addition, we did not record the differences in the efficacy of dialyzers in this trial. As far as variations in HD profile can impact the UC values, additional studies are required to determine the optimal methods for measuring HD adequacy in various groups of HD patients.[20]

CONCLUSION

OCM can be considered as a reliable, effective, available and non-expensive alternative substitution for urea- driven Kt/V in monitoring of HD adequacy in HD patients, with a prescription of a predefined profile.

CONFLICT OF INTEREST

Authors did not claim any conflict of interest.

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