RESEARCH ARTICLE

PREVALENCE OF TREATMENT ADHERENCE AMONG ATTENDANCE AT HEMODIALYSIS IN MAKAH

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ABSTRACT

Background: There are remarkable paucity in the studies which identify prevalence of adherence and non-adherence risk factors in hemodialysis patients in Saudi Arabia. Despite the importance of this issue, there are very limited studies which discuss our topic in Saudi Arabia.

Aims & Objective: To identify the prevalence of adherence to (hemodialysis attendance, medications, fluid restrictions, and diet restrictions) among hemodialysis patients at governmental kidney centers in Makah city in Saudi Arabia in the year 2013.

Materials and Methods: Based on a cross section study design, a sample of 361 hemodialysis patients were selected randomly (stratified random sample) from the list of available patients in three hemodialysis centers at three major governmental hospitals in Makah city, and they were invited to be enrolled in the study after taking their consent. Clinical measures and a valid, reliable Questionnaire (ESRD-AQ) were used to assess adherence of patients to (hemodialysis attendance, medications, fluid restrictions, and diet restrictions).

Results: The prevalence of hemodialysis patients' adherence to Dietary, fluid restrictions recommendations and medication prescription were 88.37%, 87.78% and 87.99%, respectively and nearly half of patients were adherent to dialysis sessions (55.96%). The highest adherence rate was for diet restriction (88.37%) and the lowest was for attendance to dialysis sessions (55.96%).

Conclusion: The overall adherence rates in our study population were thought to be within the range of most published international studies.

Key Words: Prevalence; Hemodialysis, Adherence; Treatment; Saudi Arabia

Introduction

Adherence can be defined as: following medical or health advice (Denhaerynck et al., 2007)[1] or "the extent to which a person's behaviour corresponds with the agreed recommendations of a healthcare provider in terms of taking medicines, following the recommended diet and/or executing lifestyle changes[2]. End-stage renal disease (ESRD) is defined as irreversible decline in kidney function, when renal replacement therapy (RRT) is needed for survival of patients. There are two major types of renal replacement therapy, which include dialysis and kidney transplantation.[3]

Despite the importance of our topic there are remarkable paucity in the studies which identify prevalence of adherence in hemodialysis patients in Saudi Arabia. According to the researchers' extensive research, there are very limited studies which discuss our topic in Saudi Arabia.

The first dialysis session in Saudi Arabia took place in 1971 and the first renal transplant in 1979.[4] In Saudi Arabia, there is consistent increase in prevalence and in the incidence of newly-diagnosed individuals with end-stage renal disease (ESRD), especially over the last 3 decades, this rise exceed those reported from many countries. Those patients requires renal replacement therapy in each year, fuelled by the large expansion of the aged population as well as the rapid emergence of diabetic nephropathy disease.[5]

The increase in the number of dialysis patients has been seen in virtually all countries; the annual increase in dialysis patients has been around 8%. In the KSA, the incidence and prevalence of dialysis patients have 10-15 fold increase when compared to 1983.[6] The incidence of chronic renal disease is 260 per one million of world population and increases 6% annually.[7] The dialysis statistics performed by the Saudi Center for Organ Transplantation (SCOT) at the end of year 2012 showed there were a total of 14,171 patients were on dialysis, 12,844 of them were treated by hemodialysis (HD) and the remaining 1,327 by peritoneal dialysis (PD).[8] The prevalence of end stage renal failure treated by dialysis was estimated to be 499 cases/PMP (per million populations). Total death was 1638 (11.6%), while the incidence of treated ESRD was estimated at 129 cases/PMP. However, the incidence of end-stage renal disease (ESRD) in Saudi Arabia is not well documented; The few reports that exist are either single hospital studies or retrospective data from limited areas or age-groups.[9-14]

In view of the rapidly increased of ESRD in Saudi Arabia, there is a need to determine the adherence rate to therapeutic regimen among patients undergoing hemodialysis. Data on adherence to treatment regimens (fluid, dietary, medication and dialysis attendance) is however not available. Furthermore, medical staff services in HD centers in Saudi Arabia are generally focused on physical care. Holistic care is either not performed or is inadequate.

The majority of patients use center-based hemodialysis as treatment modality thus offering a unique opportunity to examine adherence behaviour in this population. Hemodialysis patients are asked to adhere to a very difficult treatment regimens consisting of fluid and diet restrictions, several daily medications, and, mostly, 3- or 4-hour hemodialysis sessions three times in each week. Most of hemodialysis patients fail to adhere to their recommended treatment. Even though these regimens are difficult, it is necessary for patients to adhere to their prescribed regimens for optimal health and well-being.[15] Poor adherence to complex multimodal therapies is a widely recognized problem in the daily care of hemodialysis patients, which contribute to excess morbidity and mortality of this population.[16] There is evidence that good adherence to the treatment can reduce hospitalization risk in HD patients.[17] There is solid evidence that adherence of ESRD patients' correlates with morbidity and mortality.[18] Specifically, skipping treatment and poor dietary adherence are strongly associated with greater risk for death.[19]

Treatment adherence of patients on maintenance hemodialysis, which is the most common therapy [renal replacement therapy (RRT)](United States Renal Data System [USRDS], 2009[20]; the Saudi Center for Organ Transplantation data, 2012[8] usually consists of four components, which include attendance at hemodialysis sessions, adherence to the recommended medications, and fluid and diet restrictions.

The current study aimed at assessing the prevalence of adherence to (hemodialysis attendance, medications, fluid restrictions, and diet restrictions) among hemodialysis patients at governmental kidney centers in Makah city in Saudi Arabia in the year 2013.

Materials and Methods

This cross-sectional study was conducted in three hemodialysis (HD) centers at three major governmental hospitals in Makah city. It is located at the Western Region of the Kingdom of Saudi Arabia and it is the capital of Makah Province. According to the preliminary results of the population and housing census taken on 2010, the total population of Makah city was roughly 1.6 million.[21] The population got their health care services through governmental and private health facilities. There are 8 governmental hospitals and many other private hospitals and private polyclinic. Our registered patients are in three HD centers in three major governmental hospitals in Makah city are estimated to be around 2000.

The study population of the cases included all patients with ESRD requiring MHD. These patients were registered in the hemodialysis unit of kidney centers. The centers accommodate for patients infected by HCV, HBV and HIV. Patients who are HBV and HIV positive are kept in isolated wards during treatment. The HD machines are kept busy through the year with four shifts daily. Sometimes a fifth shift has to be arranged to overcome the heavy workload as usual, there is a large influx of patients during the Holy months of Ramadan and Hajj due to a large number of visitors from outside the city of Makah and there is an arrangement for visitors who have ESRD and need dialysis to do it in governmental hospitals. Small HD units are also available in other governmental and private hospitals, which accommodate for only a small percentage of patients.

Inclusion criteria were any adult patients above 18 year, conscious, understand, able to give an informed consent and regular on hemodialysis. Individuals who agreed to participate and met the eligibility criteria were included in the study. Patients on peritoneal dialysis were excluded.

The sample size was calculated by using Epi-Info program version 6.04. There are around 2000 patients (population size) in hemodialysis centers in Makah city and the estimated proportion for prevalence of adherence from literature was about 50%, so the required sample size was 385 patients, with 95% CI and allowable error of 5%.Using the single proportion equation for dichotomous variables:

$$N = \frac{Z^2 \times P\,(1 - P)}{C^2}$$

Where, N= Sample size; P = Percentage of population; C = Confidence level; Z = Z-Value (e.g., 1.96 for a 95 percent confidence level). Accordingly, the estimated sample size was 385. Patients who responded and participated in our study were 361. So, our response rate was 361/385=93.8%. The sample was selected through stratified random sampling approach to obtain an equal number of male and female patients.

The available (770) patients at the HD centers in our three hospitals undergo HD for an average of 3 times a week, with a small percentage undergoing hemodialysis only twice a week. The hemodialysis sessions take place in four shifts. The researchers comprised the study group, which included 361 patients through stratified random sample from the list of available patients at each HD center in each hospital. This method of sample collection allowed the researcher to cover patients from all the wards, including male and female wards, the isolation section, both hepatitis C positive and negative patients and at different times of the day.

We took our sample from each hospital according to proportion of available patients present in each hospital. We take half of available patients present in each hospital. The sample selected from each hospital through stratified random sample approach according to gender from the available patients` list to obtain an equal number of male and female patients. We take a list of male patients and through systematic random sample we select our sample. And we take a list of female patients and through a systematic random sample we select our sample.

Adherence to treatment regimens in patients with ESRD was measured by a variety of methods, with no one method being superior.[1,15,22] Questionnaire (ESRD-AQ) and clinical measures were used to evaluate treatment adherence or non-adherence in patients with ESRD on maintenance HD (Hemodialysis).

Clinical Measures

Each patient's adherence behaviours were rated by the researcher based on IDWGs, dialysis attendance, serum potassium and phosphorous levels over the last month. These criteria were used separately to distinguish between adherer and non-adherer.[17] Dry weight (weight at the end of dialysis treatment) in dialyzed patient is the lowest weight which patient can tolerate at the end of dialysis treatment without the development of symptoms or hypotension.[23] Inter Dialytic Weight Gain (IDWG) is calculated as the difference between the patient's weight obtained at the onset of a dialysis treatment and the weight obtained at the end of the previous dialysis.[24-26]

Questionnaire

The End-Stage Renal Disease-Adherence Questionnaire (ESRD-AQ) for patients requiring in-center HD was used to measure treatment adherence behaviours in four dimensions: HD attendance, medication use, fluid restrictions, and diet restrictions.[27,28] The ESRD-AQ instrument is a self- administrated questionnaire consist of 46-item, completion of the instrument took approximately 20 to 40 minutes.[27,28] The ESRD-AQ is the first self-report instrument to address all components of adherence behaviours of patients with ESRD. The findings support that the instrument is reliable and valid, and is easy to administer.[27,28]

The original English version of questionnaire was translated to Arabic then the Arabic version was back translated to English and the English version was compared with the original English version to see if they were identical, if they were not identical, they were translated again till they become identical and to ensure lexical equivalence. However, it was subjected to validity testing after being translated into Arabic language by consultant of family medicine, consultant of community medicine and nephrology consultant.

The End-Stage Renal Disease-Adherence Questionnaire (ESRD-AQ) for patients requiring in-center HD was designed to measure treatment adherence behaviours in four dimensions: HD attendance, medication use, fluid restrictions, and diet restrictions recommendations. The final version of the ESRD-AQ consists of 46 questions/items divided into five sections. The first section pursues general information about patients' ESRD and RRT related history (5 items), and the remaining four sections ask about treatment adherence to HD treatment (14 items), medications (9 items), fluid restrictions (10 items), and diet restrictions recommendations (8 items). Responses to the ESRD-AQ utilize a combination of Likert scales and multiple choice, as well as “yes/no” answer format. The adherence behaviour subscale was scored by summing the responses to questions 14, 17, 18, 26, and 46. The weighting system for scores was determined based on the degree of importance relevant to clinical outcome of each dimension. The attitude/perception subscale was scored by summing the responses to questions 11, 12, 22, 23, 32, 33, 41, and 42. The remaining questions obtain information about patients' ESRD and RRT related history. The ESRD-AQ was designed such that higher scores indicate better adherence.[27]

Pilot Study

A pilot study was carried out in Jeddah kidney center at King Fahd general hospital (referral center for HD patients in western province) on about 10% of our sample size who were not included in the main study. The aim of the pilot trail was to test for clarity and feasibility of the tools, it also helped to estimate the time needed for filling the questionnaire, taking clinical measures and conducting the

health educational program, re-evaluate the intervention process, re-evaluate tools of the study (the questionnaire and clinical measures), gain an idea of the cost required, and foresee any problems that may be encountered during the study so that solution could be promptly found.

Statistical Analysis

All data were coded and entered in a personal computer. Under supervision of an expert biostatistician. Statistical analysis was performed using Statistical Package for Social Science (SPSS) program, version 16. The data was checked and corrected for errors at the stages of coding and data entry and quality control was ensured. Initially, the frequency distribution and simple descriptive statistical analysis and percentages for qualitative variables and mean, median and range for quantitative variables were done for the study population.

Results

As shown in table 3, the mean age of subjects was 50.05±15.81 years old; range between (14 to 95 years). About half of patients (47.6%) were males. The majority of patients were Saudis (93.9%. About two-third of patients (67.3%) were form Al-Noor Specialist hospital (ANSH), 20.8% from King Abdul-Aziz hospital (KAH) and 11.9% from King Faisal hospital (KFH). About two-third of patients were married (62.3%). About half of patients (44%) had secondary school and above. The mean duration of dialysis was 74.83 ± 64.43 months range between (2 to 336 months) and half of them (50.3%) did their dialysis for 60 months or greater, compared to (21.2%) between 13 to 36 months, (15.9%) for 12 months or less and (12.6%) between 37 to 60 months. The mean inter-dialytic weight gain was 2.24 ±1.11 kg; range between (0 to 6.500 kg).

The mean number of daily tablet(s) taken by patients was 6.09 ± 3.710; range between (1 to 26). The presence of co-morbidities was common in this sample, the mean number of co-morbid disease was 3.04 ± 1.7; range between (0 to 10) disease(s). Unknown cause (32.4%), hypertension (23.0%), diabetes mellitus (21.9%), glomerulonephritis (3.6%) were the four major etiology of renal failure; other (19.1%) of cases were caused by other causes. Most of patients (93.6%) did not had a prior kidney transplant history, compared to (6.4%) had a prior kidney transplant history. Half of patients (49.9%) had hepatitis c virus (HCV) disease, compared to (50.1%) did not had that disease. Most of patients (93.9%) were diagnosed with HTN. About (39.6%) of patients were diagnosed with DM. Only 10.2% of patients had a psychiatric disease.

Table-1: Explanation for our study population

Hospital	Registered Patients	Available Patients	Required Sample	Response Sample
ANSH	1346	518	259	243
KAH	416	162	81	75
KFH	238	90	45	43
Total	2000	770	385	361

Table-2: Explanation of sampling technique for stratified sample

	ANSH		KAH		KFH	
Available patients	518		162		90	
Gender	Male	Female	Male	Female	Male	Female
Available patients	266	252	74	88	28	62
Required sample	133	126	37	44	14	31
Response Sample	125	118	34	41	13	30

Table-3: Socio-demographic and clinical characteristics of the study group (n=361)

Characteristics		%
Age (years)	< 65 years	78.9
	> 65 years	21.1
	Mean (SD)	50.05 (15.81)
	Range	14-95
Gender	Male	47.6
	Female	52.4
Marital status	Married	62.3
	Single	21.3
	Others (divorced, widowed)	16.3
Education	Illiteracy	31.3
	Primary school	24.7
	≥ Secondary school	44
Causes of kidney failure	Diabetes mellitus	21.9
	Hypertension	23
	Glomerulonephritis	3.6
	Others	19.1
	Unknown	32.4
Duration of Dialysis (months)	12 months or less	15.9
	13 to 36 months	21.2
	37 to 60 months	12.6
	60 months or greater	50.3
	Mean (SD)	74.83 (64.43)
	Range	2-336
Interdialytic weight gain (kg)	Mean (SD)	2.24(1.11)
	Range	0-6.500
Nationality	Saudi	93.9
	Non-Saudi	6.1
Patients hospital	ANSH	67.3
	KAH	20.8
	KFH	11.9
Presence of co-morbid disease	Yes	99.2
	No	0.8
Number of co-morbid disease	Mean (SD)	3.04 (1.7)
	Range	0-10
Daily tablet(s)	Mean (SD)	6.09 (3.71)
	Range	1-26
Kidney transplant history	Yes	6.4
	No	93.6
HCV	Yes	49.9
	No	50.1
HTN	Yes	93.9
	No	6.1
D.M	Yes	39.6
	No	60.4
Hospitalization history	Yes	77
	No	23
Pre-hemodialysis Serum potassium (mmol/L)	Mean (SD)	5.10 (0.91)
	Range	2.70 – 10.20
Pre-hemodialysis Serum phosphorus (mg/dl)	Mean (SD)	5.33 (1.76)
	Range	1.30 – 11.60
Psychiatric disease(s)	No	89.8
	Yes	10.2

Table-4: Prevalence of adherence behaviour (n=361)

Adherence behaviour indicator	Clinically determined adherence rates
Dietary	88.37%[1]
Fluid	87.78%[2]
Medications	87.99%[3]
Attendance to dialysis	55.96%[4]

1-Serum potassium achieved adherence criteria; 2-IDWG achieved adherence criteria; 3-Serum phosphorus achieved adherence criteria; 4-Subjects skipped at least one dialysis session (data derived from dialysis record).

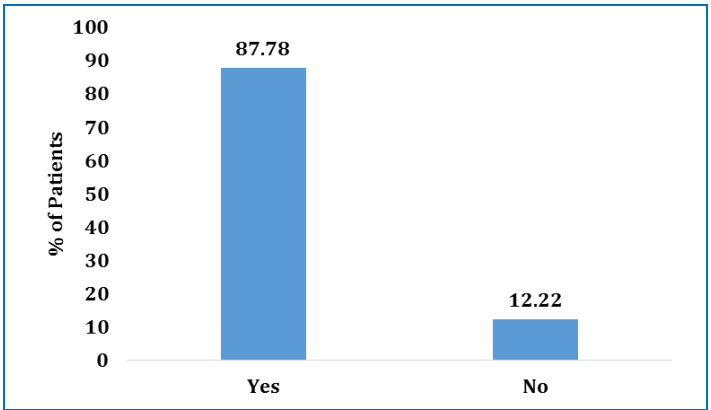

Figure-1: Adherence to fluid restrictions recommendations among the study group

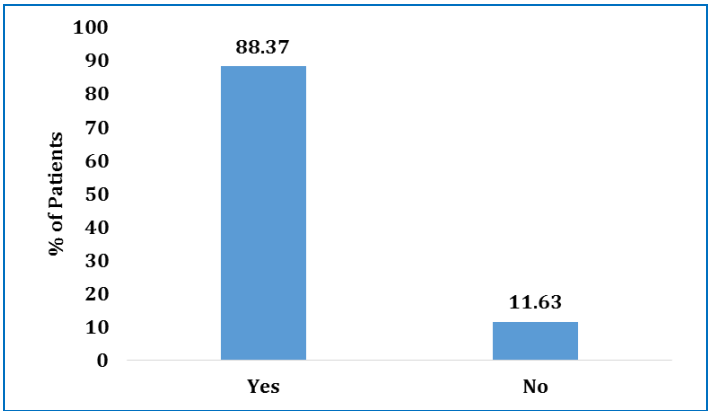

Figure-2: Adherence to diet restriction recommendations among the study group

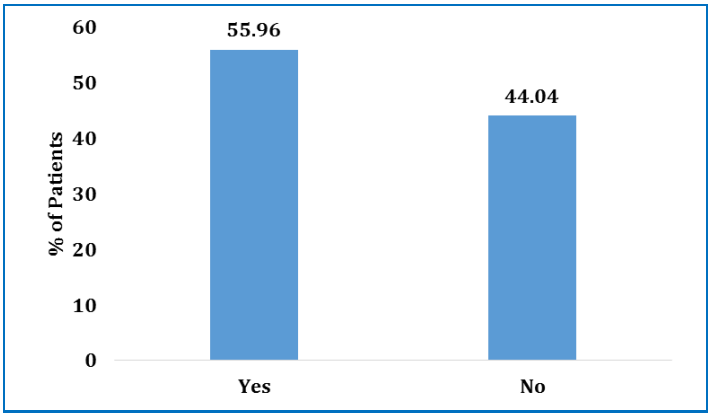

Figure-3: Adherence to hemodialysis sessions attending among the study group

More than two third of patients (77%) had a hospitalization history. The mean level of pre-hemodialysis serum potassium (K+) was 5.10374 ± 0.906054 mmol/L; range between (2.700 to 10.200 mmol/L). The mean level of pre-hemodialysis serum phosphorus (po4) was 5.32851 ± 1.756836 mg/dl; range between (1.300 to 11.600 mg/dl).

Prevalence of Adherence Behavior

The table shows that, the prevalence rate of adherence were high among all four categories (dietary, fluid, medications and attendance to dialysis sessions) being the highest adherence rate was for diet (88.37%) and the lowest was for attendance to dialysis sessions (55.96%); the majority of patients were adhere to diet, fluid and medications (88.37%, 87.78% and 87.99%, respectively) and nearly half of patients were adherent to dialysis sessions (55.96%).

Figure 1 shows that the majority of patients (87.78%) were adherent to their fluid restrictions recommendations and only (12.22%) of them were non-adherent to those recommendations. Figure 2 displays that most of patients (88.37%) were adherent to their diet restrictions recommendations and only (11.63%) of them were non-adherent to those recommendations. From figure 3, it can be seen that about half of patients (55.96%) were adherent to attending to their hemodialysis sessions compared to (44.04%) of them were non-adherent to attending to their sessions. Figure 4 demonstrate that the majority of patients (87.99%) were adherent to their medications recommendations and only (12.01%) were non adherent to those recommendations.

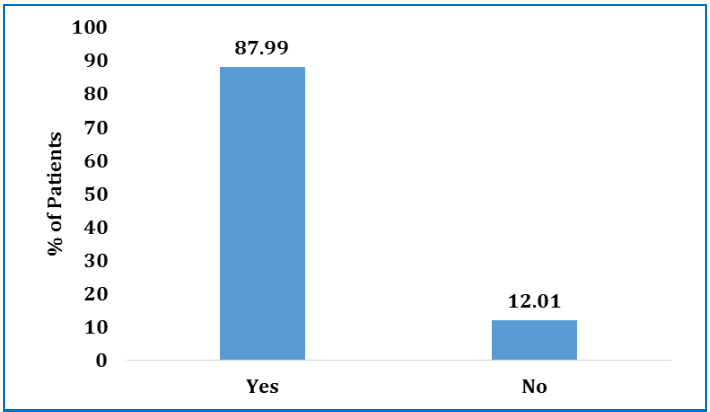

Figure-4: Adherence to medications among the study group

Discussion

To determine the frequency and prevalence of non-adherence in patients with ESRD undergoing HD, a clear-cut and consistent definition of these terms is essentially needed. Owing to the inconsistencies in uniform definitions, widely divergent results have been obtained in different studies, so that as many as 80% of HD patients may be considered noncompliant with oral

medication.[24,29] The data of the previous studies revealed that the calculated median is closer to 50%.[22]

Standardized adherence parameters that can be easily measured and verified would be desirable to achieve reproducible and accurate rates of non-adherence. Non-adherence to treatment by HD patients is quite common, but it is difficult to quantitatively measure this condition, and there is no agreement regarding how exactly to define noncompliance.

The prospective observational Dialysis Outcomes and Practice Patterns Study (DOPPS) used skipping of more than 1 dialysis session, shortening a dialysis session by>10 minutes, serum potassium concentration of >6.0mEq/L, phosphate level of >2.4 mmol/L or IDWG >5.7% of body weight as measures of non-adherence.[30] In our study, we also measured skipped and shortened HD sessions, serum phosphorus and potassium level and IDWG.

Hemodialysis places multiple and unavoidable demands on a patient's lifestyle, related to the dialysis regimen, dietary and fluid restrictions, the requirement for multiple medications with potential side effects, as well as management of multiple co-morbid conditions. Adherence with various aspects of management is uncommon and is understandable from the patient's perspective.[17]

Our study was conducted to describe adherence behaviours of patients on maintenance HD in a comprehensive way by identifying the prevalence of adherence behaviours, and determining non-adherence risk factors in patients on maintenance HD.

Based on the demographic findings of our study, the majority of the study sample had poor socioeconomic status, as reflected in high levels of unemployment (66.20%), low monthly incomes(72.85% had less than 3000 RS), and low educational levels. Ward (2008)[31] examined the incidence in 747,556 adults with ESRD in the U.S. population from January 1, 1996, to June 30, 2004, and reported that incidence of ESRD was different according to socioeconomic status. The incidence of ESRD caused by all primary kidney diseases was greatest in those in the lowest socioeconomic score and decreased with higher socioeconomic status. Thus, the current sample adequately reflects the general Saudi population from the socioeconomic standpoint where individuals with lower socioeconomic status were at greater risk for ESRD.

Adherence rates to HD (missing and shortening HD), medication, and fluid and diet restrictions in the current study population were 55.96%, 87.99%, 87.78%, and 88.37%, respectively. Previous studies reported adherence rates to attendance at HD, medications, and fluid and diet restrictions from 100% to 67.7%, 98.8% to19%, 96.6% to 26%, and 98.8% to 17.6%, respectively.[30,32-35]

Since the previously reported adherence rates have been extremely varied, it is difficult to compare measured adherence rates in this study to those reported by others. When compared to the reported adherence rates using self-report instruments, the study conducted by Kugler and colleagues (2005)[36] reported non-adherence rates as high as 74.6% and 81.4% to fluid and diet restrictions from916 patients in Germany and Belgium, respectively. They used the Dialysis Diet and Fluid Non-Adherence Questionnaire (DDFQ), the only available self-report instrument with proven validity and reliability. Overall adherence rates in this study population are thought to be higher than our study. Perhaps this is related to the different study settings, measurement instruments, and/or the recruitment procedures employed for the study. Another study conducted by Chan, et al 2012[37] in Malaysia and found the adherence rates of dietary, fluid, medication and dialysis were 27.7%, 24.5%, 66.5% and 91.0%, respectively.

Prevalence of adherence behaviour of patients varied between studies according to the cut-point used to establish compliance criteria, where more stringent cut-points inflated the percentage and more lenient cut-points reduced the percentage. Thus, there is a need to establish uniform criteria in order to test real differences in compliance between patient groups vs. simply differences in measurement). The reported adherence rate for our sample is high, but the rates of adherence to HD (missing and shortening HD), were relatively low. It is speculated that this findings are related to the increased degree of difficulty following treatment recommendations for HD sessions guidelines; perhaps following HD sessions recommendations require more appropriate knowledge and skill and more willpower of patients.

Among limitations of the current study, some of patients might have not enough time to complete the questionnaire; therefore, the tools were as concise as possible. Language barriers as some patients do not speak Arabic, therefore the questionnaires were bilingual. The main limitation of this study is its cross-sectional design for the first two objectives. A longitudinal design might be better suited to explore indications of causal relationships and would help to display changes of over time.

Conclusion

In conclusion, the study showed that the prevalence of adherence among our HD patients was within the range of most published international studies.

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