



## ORIGINAL ARTICLE

## Adherence to Therapeutic Regimen in Adults Patients Undergoing Hemodialysis: The Role of Demographic and Clinical Characteristics

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### Abstract

**Purpose:** This study aimed to measure the adherence levels among patients undergoing hemodialysis and correlate the adherence levels with demographic and clinical characteristics.

**Methods:** To conduct the study, 350 patients undergoing hemodialysis completed the GR-Simplified-Medication Adherence Questionnaire-Hemodialysis (GR-SMAQ-HD). Demographic and clinical data were recorded. Statistical data analysis was performed using the IBM SPSS Statistics Version 19. Multiple linear regression test, stepwise method and logarithmic transformations were used. The level of statistical significance was set at  $p < 0.05$ .

**Results:** The mean age of patients was 56.5 years (SD = 10.0 years). The whole score of GR-SMAQ-HD was 6.05 (SD = 1.54) while for the dimensions of "Medication Adherence" was 3.01 (SD = 1.01), for "Attendance at HD Session" 1.75 (SD = 0.51) and for "Diet/Fluid Restrictions" was 1.3 (SD = 0.70). The educational level and the absence of children were independently associated with the "Attendance at HD Session" ( $P = 0.001$  and  $P = 0.007$ , respectively). The daily number of pills was independently associated with "Attendance at HD Session" ( $P = 0.020$ ) and "Medication Adherence" score ( $P = 0.026$ ). Vascular access site was independently associated with the total score of adherence scale ( $P < 0.001$ ) and the "Medication Adherence" score ( $P < 0.001$ ).

**Conclusions:** Adherence levels among patients undergoing hemodialysis are moderate while the role of demographic and clinical characteristics is crucial.

### Keywords

Adherence, Clinical characteristics, Demographic characteristics, Hemodialysis

### Introduction

It is widely accepted that End Stage Renal Disease (ESRD) entails significant changes in the patients' life. In addition, patients experience many changes that affect the outcome of the disease. Adherence to treatment regimen plays an indisputable role in the management of chronic kidney disease [1].

According to National Kidney Foundation-Kidney Disease Outcomes Quality Initiative (NKF-KDOQI) [2], non-adherence in hemodialysis (HD) includes: (a) Non-adherence to pharmaceutical treatment; (b) Omitting or shortening the time of HD session; (c) Excessive intake of fluids and foods containing potassium and phosphorus. ESRD under HD is a long-term illness that deprives patients of living a normal life. Factors, which influence HD patient adherence, vary and may be treatment-related, condition-related, health system-related or socioeconomic [3].

Most of the HD patients also experience other chronic diseases including hypertension, diabetes mellitus, cardiovascular disease, osteodystrophy requiring long-term medication [4]. The average of prescribed medications received by HD patients is 10-12, while the average number of pills per day is 19 [5]. In addition, substitution of renal function through HD is associated with strong stressors such as attendance at HD session and diet/fluid restrictions. Non-adherence to

diet restrictions can lead to chronically elevated levels of potassium or phosphorus levels which, in turn, play a major role in the onset of cardiac arrest or renal osteodystrophy, respectively. Moreover, shortening or skipping an HD session can reduce the adequacy of HD and increase the risk of death.

For the above reasons, the need for early identification and assessment of non-adherence levels among HD patients is vital. However, given the complexity of the pathogenicity of adherence and the lack of multidimensional tools, an effective intervention by nephrology nurses is difficult. Hence, nurses and health-care professionals of hemodialysis units and nephrology clinics should be alert to detection of non-adherence in order to improve the care plan and help patients develop contingency strategies [6]. Because of their contact with HD patients, nephrology nurses could help improve adherence levels by creating a relationship of trust with patients through their approach.

According to studies, factors of patient non-adherence vary [7]. Sabaté (2003) has ranked potential non-adherence factors in five categories: Treatment-related, disease-related, health-system related and finally, socio-economic [8]. More specifically, in the international literature the causes of non-compliance may be the beliefs of the patient [9], the poor relationship between a healthcare professional and a patient [10] the personality of the patient [11], the educational level or economic reasons [12]. Most of these studies agree that all potential determinants should be considered in order to improve the patient's ability to follow the treatment regimen.

In adult patients undergoing HD, demographic factors that may affect adherence to medication, diet and fluid intake, include young age [13-15], black race [16-18], female [16,18,19] absence of family support [12,20,21], and low educational level [22,23]. Most of these studies agree that all potential determinants should be considered in order to improve the HD patients' ability to follow the treatment regimen.

Despite the extended research on the topic of adherence, our knowledge on adherence among HD patients is still limited. Thus, the aim of the study was to examine the levels of adherence in ESRD patients undergoing HD. This study is the first one exploring the adherence levels in Greek HD patients. Based on prior research findings highlighting the effect of demographic and clinical characteristics on patient adherence, it was decided to investigate, also, the association between these variables and adherence.

The research hypothesis of this study was that adherence levels are low among HD patients while it is expected an important impact of demographic on the clinical characteristics.

## Methods

### Design

This is a descriptive and analytic study. Patients were from three hemodialysis centers in the area of Athens and Peloponnese region: (i) "Iatriko Therapeftirio Iliou Medifil A.E." (Athens), (ii) General Hospital of Athens "G. Gennimatas" (Athens) and, (iii) Panarkadiko Hospital of Tripolis "Evaggelistria" (Peloponnese region). All 371 patients on maintenance HD from these Hemodialysis Units were asked to participate in this study. The inclusion criteria were: (a) Aged > 18 years; (b) Undergoing hemodialysis for at least 6 months and (c) Ability to write and read the Greek language. Patients with history of mental illness, cognition problems, serious mobility or eye problem were excluded from the study. Finally, 350 patients met the criteria (response rate 94.3%). The study was conducted from June 2017-August 2017.

### Measurements

Researchers provided the questionnaire to patients during HD session. A self-administered questionnaire included demographic and clinical variables (age, gender, marital status, having children, educational level, years on HD, vascular access site, co-existing diseases, the daily number of pills) was given followed by the GR-Simplified Medication Adherence Questionnaire-Hemodialysis (GR-SMAQ-HD). The questionnaire used had been validated for the respective Greek HD population [18]. As GR-SMAQ-HD is the only one tool for subjective measuring of adherence among Greek HD patients, an effort was performed in order to measure adherence using this scale. The questionnaire consists of eight items exploring the three dimensions of adherence in hemodialysis: (i) "Medication Adherence" (items 1-4), (ii) "Attendance at Hemodialysis Session" (items 5 & 6) and "Diet/Fluid Restrictions" (items 7 & 8). Three of the items are dichotomous (Yes/No) while five are scored on a 5 point Likert-type scale. The internal consistency of the scale has been studied (Cronbach's Alpha 0.751) [24]. The score ranges from 0-8. Higher scores indicate higher adherence to HD regimen. This is the first time GR-SMAQ-HD is used in Greek HD patients.

### Ethical considerations

The current study was approved by the scientific councils of the hospitals and Hellenic Data Protection Authority (Approval number ΓΝ/ΕΞ/240-3/11-02-2016). Patients were informed about the aim of the study, the anonymity and the safety of the data and that they can quit the study whenever they wish. Informed consent was obtained.

### Statistical analysis

Quantitative variables were described using the means, standard deviations, median and interquartile ranges. Qualitative variables were described using the

absolute (N) and relative (%) frequencies. Linear regression analysis by stepwise was used to find independent factors associated with the study scale from which dependency factors ( $\beta$ ) and their standard errors (SE) occurred.

## Results

In total, 350 patients undergoing hemodialysis participated in this study. The mean age of patients was 56.5 years (SD = 10.0 years). Analytically, sociodemographic and clinical characteristics of patients are presented in Table 1.

### Descriptive statistics of adherence

The total score of all participants' adherence ranged

**Table 1:** Sociodemographic and clinical characteristics of patients (N = 350).

		N	%
Age, Mean (SD <sup>a</sup> )		56.5 (10.0)	
Gender	Male	230	65.7
	Female	118	33.7
Marital Status	Unmarried	79	22.5
	Married	194	55.4
	Divorced	30	7.71
	Widows	47	13.4
Children	No	99	28.2
	Yes	250	71.4
Living alone	Yes	56	16.0
	No	294	84.0
Educational level	Illiterate	22	6.2
	Primary School	114	32.5
	Secondary School	78	22.2
	High School	79	22.5
	University Student	12	3.4
Employment	University Graduate	44	12.5
	Unemployed	55	15.7
	Household	39	11.1
	Self-employed	25	7.1
	Private employee	19	5.4
	State employee	12	3.4
Co-existing diseases	Retired	199	56.8
	Diabetes mellitus	79	22.5
	Hypertension	93	26.5
	Glomerulonephritis	65	18.5
	Polycystic disease	40	11.4
	Other	70	20.0
Years on Hemodialysis, Mean (SD <sup>a</sup> )		6.5 (5.3)	
Daily number of pills, Mean (SD <sup>a</sup> )		7.1 (5.4)	
Vascular access site	Fistula	226	64.5
	Graft	49	14.0
	Central Venous Catheter	74	21.1

Notes: <sup>a</sup>Standard Deviation.

from 1-8 (Mean = 6.05, SD = 1.54). The following table gives the participants' scores on adherence dimensions. Means, standard deviations, minimum and maximum scores of all dimensions of adherence are presented in Table 2.

### Multiple linear regression

Then, a multifactorial linear regression was performed. The overall adherence score, the score of "Medication Adherence", the score of "Attendance at HD Session" and "Diet/Fluid Restrictions" were used as dependent variables. The demographic and clinical data of the participants was used as independent variables. Using the stepwise method and using logarithmic transformations, the results of the table below were found (Table 3).

The educational level was independently associated with the total adherence score of participants, with the "Medication Adherence" score and "Attendance at HD Session" scores. Educational level and years on HD was independently associated with the adherence to "Diet/Fluid restrictions". Vascular access site was independently associated with the total adherence score of participants and with the "Medication Adherence" score. The daily number of pills was independently associated with the "Medication Adherence" score and "Attendance at HD session" score while the having children was independently associated with the "Attendance at HD session" score.

## Discussion

This study was carried out in the broad area of Athens and Peloponnese region and aimed to assess the adherence among 350 patients on maintenance HD. It, also, targeted to explore the relationship between demographic and clinical characteristics of patients with adherence levels.

The mean score of the whole adherence scale was 6.05 (SD = 1.54). According to our findings, the low levels of adherence are common among HD patients and are affected by several demographic and clinical variables.

In our study an important aspect which affected the adherence was the educational level. This study found that high school graduates had significantly higher score in all domains of adherence in comparison to the illiterate and primary school graduates. Similarly, University students and graduates had a significantly higher score compared to the illiterate and primary school students.

**Table 2:** Mean values, standard deviations and minimum and maximum scores of patients' adherence (N = 350).

	Min.	Max.	Mean (SD <sup>a</sup> )	Median (IR <sup>b</sup> )
Total Score of GR-SMAQ-HD	1	8	6.05 (1.54)	7 (5-8)
Medication Adherence	0	4	3.01 (1.01)	3 (2-4)
Attendance at HD Session	0	2	1.75 (0.51)	2 (2-2)
Diet/Fluid Restrictions	0	2	1.3 (0.70)	2 (1-2)

Notes: <sup>a</sup>Standard Deviation; <sup>b</sup>Interquartile Range.

**Table 3:** Multifactorial linear regression.

		B <sup>a</sup>	SE <sup>b</sup>	p
<b>Total Score of GR-SMAQ-HD</b>				
<b>Educational level</b>	Illiterate/Primary School (reference group)			
	Secondary/High School	0.08	0.02	< 0.001
	University Student/University Graduate	0.10	0.02	< 0.001
<b>Vascular access site</b>	Fistula (reference group)			
	Graft	0.02	0.02	0.433
	Central Venous Catheter	-0.07	0.02	< 0.001
<b>Medication Adherence</b>				
<b>Educational level</b>	Illiterate/Primary School (reference group)			
	Secondary/High School	0.08	0.02	< 0.001
	University Student/University Graduate	0.10	0.02	< 0.001
<b>Vascular access site</b>	Fistula (reference group)			
	Graft	0.02	0.02	0.603
	Central Venous Catheter	-0.07	0.02	< 0.001
<b>Daily number of pills</b>		-0.004	0.002	0.026
<b>Attendance at HD Session</b>				
<b>Daily number of pills</b>		0.004	0.002	0.020
<b>Educational level</b>	Illiterate/Primary School (reference group)			
	Secondary/High School	0.05	0.01	0.001
	University Student/University Graduate	0.06	0.02	0.003
<b>Having Children</b>	No (reference group)			
	Yes	0.04	0.01	0.007
<b>Diet/Fluid Restrictions</b>				
<b>Educational level</b>	Illiterate/Primary School (reference group)			
	Secondary/High School	0.07	0.02	0.001
	University Student/University Graduate	0.03	0.03	0.202
<b>Years on HD</b>		0.004	0.001	0.001

Notes: <sup>a</sup>Beta coefficient; <sup>b</sup>SE: Standard Error.

Several studies have found that a high level of education can lead to better adherence rates [16,17,22]. The higher the educational level, the higher the level of knowledge and adherence [14]. Some researchers suggest that a patient with a high educational level can more easily understand the usefulness of the therapy [14] while other authors [25] report that it is difficult for high educational level patients to comply due to employment and occupational obligations.

We, also, found that the longer the duration (years) on HD, the higher the adherence of level they had. However, this finding contrasts with the results of other studies [15,26] which refer that the longevity of HD may be significantly associated with non-adherence. Moreover, HD patients who are under dialysis for many years have great knowledge on HD and, therefore, are more likely to be adherent than the new ones. In view of this, health professionals of HD Units should identify the knowledge base of each subject.

Participants using a central venous catheter to undergo hemodialysis had a significantly lower score compared to the participants who performed hemodialysis with a graft. This finding may be correlated to the previous one as the new HD patients of our sample (and therefore the less compliant) initiate dialysis using a central venous catheter while the graft is usually the last choice for vascular access.

The mean number of pills in the total of 350 patients in the sample was 7.1. This number appears to be lower than the overall average (10-12 pills) mentioned in the literature [27]. Despite all this, the number of pills is a predictor of adherence in this study. In particular, the higher burden of pills, the lower adherence scores both to "Medication Adherence" and "Attendance at HD Session". A study related to the effect of the number of pills on adherence reported similar results [28] while another study conducted in Italy using questionnaires noted that the larger the number of pills the lower the adherence level [29]. A study [30] using the Simplified Medication Adherence Questionnaire reported that of the 165 dialysis patients, 40% had low compliance with medication (21% in phosphorus and 13% in antihypertensive agents). Patients had selective non-adherence to phosphate binders, as these should be taken during meals, at least 3 times a day. Therefore, they coincide with working hours or the social life of patients, especially young [30]. The contribution of various drugs to the daily pill burden in hemodialysis patients has not been investigated so far. The serum phosphate level has now been shown to be an independent factor of death risk [31]. Clinicians' experience suggests that phosphate binders are probably the largest factor in the daily pills number [32].

Participants with children had a significantly higher score compared to participants without children. The



marital status and family support (existence of children) seems to be positively correlated with the adherence levels as in previous studies [33,34]. However, marital status was not found to be correlated to patient adherence in two studies [35,36]. Lack of social/family support is sometimes a barrier to adherence to HD regimen according to the literature [23]. In North America, patients without family support were more likely to omit or shorten the duration of HD session [20]. Therefore, social support can affect positive results and is a link between hemodialysis patients and adherence to treatment [37].

At this point, it is important to emphasize that the items of GR-SMAQ-HD don't record the cases of adherence/non-adherence due to clinical complications but only those due to personal initiative of the patient.

GR-SMAQ-HD is the modified version of GR-SMAQ [24] which has been translated in Greek language and culturally adapted for Greek lung cancer patients [38]. The first version of SMAQ was used to measure adherence levels on the dimension of medication among HIV patients [39].

Regarding the limitations of the study it is noted that that interference of external variables (interruption by others, room temperature, noise level and fatigue of the participants and persons with underlying disease), probably influenced the answers of respondents. Results cannot be generalized for all Greek patients undergoing HD as the study was conducted in Athens and Peloponnese region even if these areas are two major geographic regions of Greece. Therefore, more studies using the GR-SMAQ-HD are needed.

This study was an attempt to assess for first time adherence among Greek HD patients using subjective measures. Future studies could combine subjective with objective measures (pill count, laboratory tests). Due to the lack of a world guideline on adherence measures of HD patients, there is a need for research on which tool (subjective, objective or a combination of them), is the most suitable for this special target group.

## Conclusion

According to the findings of this study, adherence levels among HD patients are moderate while the role of demographic and clinical characteristics is crucial. Results of this study could be used in Hemodialysis Units implementing programs focused on the investigation of adherence levels, patients' behavior and factors of non-adherence. Therefore, health care professionals of HD Units should be aware of the non-adherence issues.

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## Conflict of Interest

None declared.

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