A Composite Index of Compliance for Chronic In-Center Hemodialysis Patients

Karen S. Servilla,[1] Antonios H. Tzamaloukas,[1] Charles Carter,[1] Glen H. Murata[2]

Renal Section[1] and General Internal Medicine Section,[2] New Mexico Veterans Affairs Health Care System and Department of Medicine, University of New Mexico School of Medicine, Albuquerque, New Mexico, U.S.A.

We developed a composite compliance index as the sum of the compliance scores for interdialytic weight gain (IDWG), pre-dialysis serum potassium and phosphorus concentrations (each scored from zero to 3, with 3 indicating the poorest compliance), and skipping hemodialysis sessions (scored from zero to 9, with 9 indicating the poorest compliance). We used this composite score to prospectively evaluate compliance in 25 prevalent hemodialysis patients over a period of 1 year. We then followed these patients for another 3.5 years. The patients studied were divided into two groups: group A (poor compliance) consisted of 9 subjects with composite score ≥ 9 (13.2 ± 3.2); group B (better compliance) consisted of 16 subjects with composite score < 9 (4.7 ± 1.8). Age, duration of hemodialysis, and frequency of diabetes mellitus did not differ between the groups. Group A contained higher fractions of subjects with history of alcoholism (66.7% vs 12.5%, p = *0.010), other substance addiction (44.4% vs 0%,* p = *0.010), and severe psychosocial problems (88.9% vs 18.8%,* p = *0.002). Mean survival from the beginning of observation, estimated by actuarial life-table survival analysis, was 1.19 years in group A and 2.60 years in group B (*p = *0.0265). A composite compliance index incorporating domains indicating adherence to diet, medications, and dialysis schedule identified other behavioral problems in poorly compliant patients. Hemodialysis patients characterized by this composite index as poorly compliant had shortened survival.*

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Key words

In-center hemodialysis, compliance, interdialytic weight gain, potassium, phosphorus, skipping hemodialysis

Introduction

Chronic hemodialysis (HD) imposes multiple lifestyle limitations on patients with end-stage renal disease. The demands on the patient are dietary, pharmaceutical, time-related, and secondary to feeling ill. It is not surprising that compliance of the patients with these multiple demands varies greatly in chronic HD. Non-compliance is associated with adverse outcomes [1–3] in most but not all [4] studies. In an analysis of data from the United States Renal Data System, poor compliance was associated with increased risk of death [3]. In that study, young age (20 – 39 years), black race, and smoking were identified as predictors of poor compliance, and older age (> 60 years) predicted better compliance [3].

In the present report, we analyzed compliance with various aspects of treatment in HD patients followed in the same HD center (New Mexico VA Health Care System). Our purposes were to develop a composite index of compliance incorporating aspects of compliance known from previous studies to affect the outcome of HD, and to test whether this compliance index is related to patient survival.

Patients and methods

We prospectively followed for a period of 12 months the clinical course of 25 prevalent patients (1 woman, 24 men) that had been on dialysis on January 1, 1997, at the dialysis unit of the Albuquerque Veterans Affairs Medical Center. All these patients were American veterans. Renal failure was caused by diabetes mellitus in 11 patients and by other diseases in 14.

Frequency of dialysis prescription was three times weekly for all patients and duration of each HD session was 3.86 ± 0.22 (mean ± standard deviation) hours. All patients were dialyzed using modified cellulose hollow-fiber dialyzers (Terumo Medical Corporation, Elkton, MD, U.S.A.) with various surface areas, in single-pass dialysis machines (Gambro Cobe Centrysystem 3; Gambro Renal Products, Lakewood, CO, U.S.A.) at a 600 mL/min dialysate flow rate and varying blood flow rate. The dialysate contained bicarbonate as its buffer. Target single-pool Kt/V_{urea} was set at > 1.2.

The subjects were prospectively evaluated for four indicators of compliance: interdialytic weight gain (IDWG), pre-dialysis serum potassium and phosphorus concentrations, and skipping HD sessions. Interdialytic weight gain is an index of compliance with diet, specifically with the prescription of dietary salt [5]. Pre-dialysis serum potassium is also affected by compliance with the prescription of diet; pre-dialysis serum phosphorus reflects compliance with both dietary prescription and, primarily, drug prescription. Skipping dialysis is a direct measure of non-compliance with a life-sustaining treatment. The degree of compliance of each patient for each item discussed was given a score.

Correspondence to:
Antonios H. Tzamaloukas, MD, Renal Section (111C), New Mexico VA Health Care System, 1501 San Pedro, SE, Albuquerque, New Mexico 87108 U.S.A.
email: Tzamalouka@aol.com

The domains included in the composite compliance score included IDWG, calculated prior to each dialysis session (potential total of 156 measurements in 1 year), pre-dialysis serum potassium and phosphorus concentrations measured twice per month (potential total of 24 measurements per year each), and skipping HD sessions. Table I shows the scoring for each domain. The cutoff values for IDWG [3], K [6], P [3], and skipping [7] were obtained from the literature. The composite compliance score of each patient was derived by adding the scores for IDWG, potassium, phosphorus, and skipping. Potential composite scores range between zero (perfect compliance) and 18 (extreme non-compliance with different aspects of treatment).

We then divided the patients into two groups: group A (poor compliance) contained patients with composite compliance scores ≥ 9; group B (better compliance) contained patients with composite compliance score < 9. Group A was compared to group B. Categorical variables were compared using Fisher's exact test. Continuous variables, which are presented as mean ± standard deviation, were compared using the two-tailed unpaired Student's t-test. Mean survival from the beginning of the study was calculated by actuarial life-table analysis. Survivals in group A and group B were compared using the Mantel–Cox statistic.

TABLE I Compliance scoring.

Domain	*Score*	*Definition*
IDWG	0	<3% of dry weight in all dialysis sessions in the observation period
	1	Mean gain in the observation period ≥3% and <5.7% of dry weight
	2	≥7.5% of dry weight in one or more dialysis sessions
		Mean gain in the observation period ≥5.7% but <7.5% of dry weight
	3	Mean gain ≥7.5% of dry weight in the observation period
Potassium	0	<5 mmol/L in all measurements in the observation period
	1	≥5 mmol/L in one or more measurements
		No measurement ≥6 mmol/L
	2	≥6 mmol/L in one or more measurements
		Mean value <6 mmol/L in the observation period
	3	Mean value ≥6 mmol/L in the observation period
Phosphorus	0	<5.0 mg/dL in all measurements in the observation period
	1	≥5.0 mg/dL in one or more measurements
		No measurement ≥7.5 mg/dL
	2	≥7.5 mg/dL in one or more measurements
		Mean value <7.5 mg/dL in the observation period
	3	Mean value ≥7.5 mg/dL in the observation period
Skipping	0	No skipping throughout the observation period
	3	Skipping <1 dialysis session per month
	6	Skipping an average of ≥1, but <2 dialysis sessions per month
	9	Skipping ≥2 dialysis sessions per month

IDWG = interdialytic weight gain.

Results

Table II shows compliance scores. Perfect compliance with IDWG and pre-dialysis serum potassium and phosphorus control was seen in only 8% – 12% of patients, while compliance with the HD schedule was seen in 68% of patients. Severe and repeated non-compliance ranged between 8% (skipping HD sessions) and 20% (hyperkalemia and hyperphosphatemia).

The composite scores ranged between 1 (1 patient) and 18 (1 patient). Nine patients (36%) had composite scores of 9 or higher and were classified as group A, while 16 patients (64%) had composite scores less than 9 and were classified as group B. Table III shows the compliance scores of the non-compliant patients. Several patients exhibited severe non-compliance to several aspects of HD.

Table IV shows the comparison of groups A and B. Age at the beginning of the study, duration of HD, and the fraction of patients with diabetes mellitus did not differ between the poorly compliant and better compliant groups. The poorly compliant group contained relatively more patients with ethanol abuse, other substance abuse, and severe psychological problems. Measured Kt/V_{urea} did not differ between the groups. In each group, more than 85% of the Kt/V_{urea} measurements were above the target value of 1.2. However, these measurements do not reflect underdialysis caused by skipping.

The percent of patients that died between January 1, 1997, and August 15, 2001, was not different between the two groups (group A 88.9%, group B 62.5%). However, the deaths

TABLE II Compliance scores.

	Grade 0	*Grade 1*	*Grade 2*	*Grade 3*
IDWG [*n* (%)]	3 (12)	9 (36)	10 (40)	3 (12)
Hyperkalemia [*n* (%)]	2 (8)	10 (40)	8 (32)	5 (20)
Hyperphosphatemia [*n* (%)]	2 (8)	8 (32)	10 (40)	5 (20)
	Grade 0	*Grade 3*	*Grade 6*	*Grade 9*
Skipping dialysis [*n* (%)]	17 (68)	3 (12)	3 (12)	2 (8)

IDWG = interdialytic weight gain.

TABLE III Non-compliant patients.

			Score		
Patient	*IDWG*	*K*	*P*	*Skipping*	*Composite*
A	3	1	0	9	13
B	3	3	3	3	12
C	3	3	3	0	9
D	3	3	3	3	12
E	3	3	3	0	9
F	2	2	3	9	16
G	3	1	3	9	16
H	3	3	3	9	18
J	0	3	1	9	13
Mean ±SD	2.6±1.0	2.4±0.9	2.4±1.1	5.7±4.1	13.2±3.2

IDWG = interdialytic weight gain; K = potassium; P = phosphorus.

TABLE IV Comparison of poorly compliant patients (Group A) and better compliant patients (Group B).

	Group A	*Group B*	p *Value*
N	9	16	
Composite score	13.2±3.2	4.7±1.8	<0.001
Age[a] (years)	67.7±13.0	67.6±12.4	NS
Hemodialysis[b] (years)	4.1±2.3	6.3±5.0	NS
Diabetic patients [*n* (%)]	6 (66.7)	5 (33.3)	NS
Ethanol abuse [*n* (%)]	6 (66.7)	2 (12.5)	0.010
Other substance abuse [*n* (%)]	4 (44.4)	0	0.010
Psychosocial problems[c] [*n* (%)]	8 (88.9)	3 (18.8)	0.002
Kt/V_{urea}	1.41±0.27	1.43±0.17	NS
Mean survival[d] (years)	1.19	2.60	0.0265

[a] Age at beginning of observation period (January 1, 1997).
[b] Until death or August 15, 2001.
[c] Requiring psychiatric or psychological follow-up.
[d] From beginning of observation period until August 15, 2001.

occurred earlier in group A and, calculated by actuarial life-table analysis, mean (50%) survival was statistically different, with group A having shorter mean survival (Table IV).

Discussion

Compliance affects the outcome of HD. The risk of death increases by 14% – 25% when patients skip one or more HD sessions per month [1,3], by 35% in patients with IDWG exceeding 5.7% of dry weight, or 4 kg in a 70-kg person [3], and by 13% in patients with serum phosphorus exceeding 7.5 mg/dL [3]. Studies of compliance patterns focus on these three parameters as well as on serum potassium, elevation of which can lead to cardiac death [1,4,8–12]. Few of these studies have addressed all four indices of compliance [3]. The need to incorporate compliance indices with predictors of outcome on HD has been stressed [13].

Studies on compliance in HD can be classified into three broad categories: descriptive studies demonstrating the magnitude of non-compliance and its effects on the outcomes of HD; studies analyzing psychosocial factors affecting compliance, such as family interaction, denial, self-concept, interaction with nurses, duration of dialysis, health focus of support, neuroticism, ethnicity, demographic variables, education, age, stress, degree of physical impairment, depression, coping style, and medication knowledge; and studies describing specific interventions to improve compliance. Several studies can be classified in more than one category.

Collaboration between different disciplines conducting compliance studies in HD has been infrequent. This can lead to wrong targets of therapeutic interventions. Interdialytic weight gain illustrates this point. Weight gain between HD sessions may be associated with better nutrition indices [14–16]; however, small IDWG is associated with prolonged survival [17], and large IDWG leads to hypertension [18] and is associated with increased mortality risk [3,19]. Therefore, large IDWG must be prevented. Interventions to reduce IDWG routinely focus on restricting fluid intake. However, the major cause of thirst and fluid intake in HD patients is the amount of salt in the body [20]. Observational studies strongly suggest that IDWG is secondary to salt intake [5,21–23]. Large IDWG secondary to primary fluid intake is much less frequent and results in pre-dialysis hyponatremia [23]. Large IDWG secondary to fluid intake occurs primarily in beer drinkers. Primary fluid intake may be significant in dialysis patients with alcoholism [24]. Nevertheless, it is clear that the primary focus of interventions designed to reduce IDWG should be restriction of salt, not fluid, intake.

There appears also to be a lack of correlation between different indicators of compliance [8,9,25] and between predictions of compliance by different health-care workers, or between psychological profiling and actual compliance measurements [25–29]. There is a need for a "global" index of compliance. Such an index should be easily measured and verified, reproducible, clear, and accurate, and should have meaning for the patient, independent pathophysiologic significance, and association with HD outcomes [30]. We attempted to satisfy these premises with the compliance index developed in this study. This index used objective measurements of items directly related to the prescription of HD.

Our compliance index was weighed in favor of skipping HD sessions (Table I) because adherence to the prescribed HD schedule is central and specific to the issue of compliance with this treatment, while adherence to the other aspects of the prescription (diet, medications) is generic to compliance issues and, although important, supportive of HD as a life-sustaining treatment. The patients are aware of this distinction. For example, many patients who never miss a HD session allow themselves dietary indiscretions. Furthermore, we have encountered patients who demand increased dialysis time or extra dialysis sessions after dietary indiscretions. Skipping or shortening HD treatments affects the adequacy of HD [31]. We suggest that any discussion of compliance in HD populations start with adherence to the dialysis schedule.

One deficit of the compliance index developed in this study was the absence of accounting for shortening HD treatments, for which we had incomplete data. The findings of this study are relevant to men on HD since this study contained only one woman, who was classified as compliant. The patients studied are members of a population with a high incidence of substance dependence [32], mortality due to this substance dependence [33], and psychosocial problems related to substance dependence [34]. It is possible that our findings are not applicable to other populations (*e.g.*, women or populations with a low incidence of substance abuse). However, our study is relevant to American patients on HD, since skipping HD is more frequent in American than in Japanese or Swedish patients [35].

The compliance index developed in this study was associated with survival, despite the small number of patients studied. Since we studied a prevalent rather than an incident HD population, the estimates of survival in Table IV do not rep-

resent the actual survival in this dialysis unit. Nevertheless, among prevalent patients of the same age and similar duration of HD, survival was longer in patients with better compliance.

In conclusion, the compliance index developed in this study appears to be predictive of survival in a small number of HD patients. This index will be modified to include a score for shortening HD sessions. Prospective studies in larger cohorts of incident HD patients will then be needed to establish the usefulness of this index of compliance as a predictor of outcome on HD. This index could be incorporated in multivariate analyses of survival in large HD cohorts and could be used to evaluate the psychosocial attributes of non-compliance and the effectiveness of interventions designed to improve compliance in HD populations.

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