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Original Article

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Development, Validation, and Reliability of Medication Knowledge Assessment Questionnaire Among Hemodialysis Patients

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ABSTRACT

Objective: The study aimed to prepare, validate, and test the reliability of the Medication Knowledge Assessment Questionnaire and assess the patients' knowledge about their medications.

Methods: The Medication Knowledge Assessment Questionnaire was prepared subsequently, referring to primary, secondary, and tertiary resources. An expert panel validated the content of the Medication Knowledge Assessment Questionnaire. The validated Medication Knowledge Assessment Questionnaire was translated into Kannada and Malayalam languages. The test–retest reliability was conducted on day 1 and after a week among 15 patients. During the interview, the patients' medication knowledge was assessed based on 10 parameters: name, indication, dose, time and frequency of administration, storage, refilling, pre- and post-prandial directions, side effects, and missed dose.

Results: The Cronbach's alpha reliability values of the Medication Knowledge Assessment Questionnaire were in the range of 0.716-1.00, which shows that the Medication Knowledge Assessment Questionnaire is reliable for evaluating the medication knowledge among hemodialysis patients. Patients had comparatively very low-level knowledge about the side effects and actions to be taken if a dose is missed among the knowledge parameters surveyed. The average number of medications prescribed per patient was 7.65.

Conclusions: In the present study, the maximum medication knowledge scores have been accounted for drug administration sequence with respect to food (95.39) and storage of medications (95.27). The Medication Knowledge Assessment Questionnaire is a vital tool for assessing patients' medication knowledge and improving patients' therapeutic outcomes.

Keywords: Patient medication knowledge, kidney failure, kidney replacement therapy

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INTRODUCTION

End-stage kidney disease (ESKD) is a terminal illness with a glomerular filtration rate of less than 15 mL/min, which necessitates hemodialysis (HD), peritoneal dialysis, and kidney transplantation.[1] In India, approximately a 100 000 new patients develop ESKD annually. These patients receive 11 ± 4 medications per day, contributing to non-adherence and medication-related problems (MRPs), leading to poor quality of life.[2,3] Forgetfulness, inconvenience, and scheduling problems also play vital roles in medication non-adherence.[4] Several studies conducted among HD patients estimated 1 MRP per 15.2 drug exposures.[5] The studies reported evidence of a high rate (67%) of non-adherence to orally prescribed medications.[6-8] Health-related quality of life is usually poor in HD patients due to the risk of comorbidities and complications.[1] Strict adherence to the medication regimen contributes to the effective management of ESKD patients on HD.[9]

The World Health Organization determined that only 50% of chronic diseases take medications systematically. In

HD patients, non-adherence has resulted in uncontrolled hypertension, increased medications, and hospitalizations.[10] Many patients were unaware of the name, use, dosage, frequency, and side effects of their prescribed medications, contributing to non-adherence.[11]

Medication knowledge is defined "as the patient's ability to completely comprehend the information about the medication for safer and effective results," including the understanding of the medication's use, dose, frequency, and other special considerations. This is critical in achieving fewer MRPs, better patient compliance, and decreased hospital visits that reflect positive clinical outcomes.[12] Therefore, assessing medication knowledge among HD patients using a valid and reliable questionnaire is very important.[13,14]

The appropriate tool for assessing the medication knowledge in Asian patients is lacking. The study's objective is to prepare, validate, and test the reliability of MKAQ and evaluate the patient's knowledge about their medications among the South Indian HD patients.

METHODS

Study Design and Patient Population

A cross-sectional study was carried out in an HD Unit of a Charitable Hospital for 6 months from October 2017 to March 2018. The present study is a 6-month time-bound hospital-based study. The sample size estimated at the beginning of the study (n = 80) was arrived at by considering previous records of patients visiting the hospital's outpatient HD unit in the preceding years. During this study period, 66 patients visited the outpatient HD unit. Out of 66 patients, 63 patients have given consent for participation in the study. Hence, the analysis was carried out for a sample size of 63. The study protocol approval was obtained from the Institution Ethics Committee (Ref No. NGSMIPS/IEC/27/2017-18). Patients aged 18-65 years undergoing maintenance HD were included, and critically ill and uncooperative patients were excluded from the study.

MAIN POINTS

- The appropriate tool for assessing medication knowledge in Asian hemodialysis patients is lacking.
- The study developed, validated, and tested the reliability of the medication knowledge assessment questionnaire for hemodialysis patients.
- Healthcare providers could utilize the developed questionnaire to assess medication knowledge in hemodialysis patients.
- Based on assessing patients' knowledge of medications, health care professionals can educate the patients, further enhancing the rational use of medications and improving the therapeutic outcomes.

Preparation, Validation, and Translation of MKAQ

The Medication Knowledge Assessment Questionnaire (MKAQ) was prepared based on the primary, secondary, and tertiary resources. The content of MKAQ has been validated by experts (physicians and academic pharmacists). After preparing the English version of MKAQ, it was translated into Kannada and Malayalam languages by 2 bilingual experts. This translated MKAQ was then validated after the forward translation, backward translation, and pilot testing.[14]

Reliability Testing of MKAQ

The reliability test has been conducted on 15 randomly selected patients as per the requirements of the study. All 15 patients were interviewed 1 week after their first interview using the MKAQ. Both the patients' responses (test and re-test knowledge) have been compared, and Cronbach's alpha test has been applied to assess the questionnaire's reliability.

Data Collection

All participants were informed beforehand about the aim of the study. Consent was obtained from all the patients and assured the confidentiality and freedom to withdraw from the study. The demographic characteristics like age, sex, social habits, educational status, domiciliary status (Rural/Urban), alternative treatment, duration of dialysis, number of dialysis patients have undergone per week, comorbidities, and coexisting conditions were recorded in the data collection form. The MKAQ is an interviewer-administered questionnaire that takes 15-20 minutes to complete. Medication knowledge was assessed for the patients prescribed with different categories of medications such as antihypertensive, calcium and phosphate binders, vitamin D3 analogs, erythropoietin, folic acid, iron preparations, hypoglycemic agents, and drugs used for other comorbidities. During the interview, the medication knowledge of the patients was assessed based on 10 parameters of medication such as name, indication, dose, time and frequency of administration, storage, next refill date, side effects, actions to be made if a dose is missed, and pre and post-prandial directions. The MKAQ is depicted in the Figure 1. The MKAQ scores were calculated by using the formula given below:

$$\text{MKAQ Scores} = \frac{\text{Number of correct responses of patients}}{\text{Total number of actual responses}} \times 100$$

Based on the response, the knowledge scores ranged from 0 to 100, with 0 being the minimum score and 100 being the maximum score.

Statistical Analysis

The reliability of the MKAQ was assessed by applying Cronbach's alpha test. The mean and standard deviation of knowledge scores were calculated and presented. Demographic characteristics and prescription patterns were

Medications	Could you name the medications currently taken by you?	Do you know the use of this medication?	When do you take this medication? (morning/after noon/night)	Do you know the dose of this medication?	How frequently do you take this medication in a day?	Do you know any of the side effects of this medication ?	How do you take this medication with regard to food? (with/before /after)	Where do you store this medication?	When is the next refill date for this medication?	What would you do if a dose is missed?

Figure 1. Medication Knowledge Assessment Questionnaire.

analyzed using counts and percentages. The non-parametric Kruskal–Wallis test analyzed age groups, educational status, HD vintage, and no HD sessions per week on the medication knowledge scores. The analysis of sex and domiciliary status on the medication knowledge scores was analyzed by a non-parametric Mann–Whitney *U* test. A *P*-value less than .05 was considered statistically significant. The data analysis was computed using the Statistical Package for Social Sciences software for Windows version 20.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Demographics Details of the Patients

A total of 63 HD outpatients were included in the study, out of which 49 (77.77%) were males. The predominant number of patients were in the age group of 30-60 years, 37 (58.71%), and the study population's mean age was 52.31 $\pm$ 13.12 years. Most of the patients resided in rural areas, 39 (61.9%), and the remaining were from urban areas, 24 (38.1%). Most of the patients in the study have been undergoing HD for 2-4 years, and most of them had twice a week HD [46 (73.02%)]. Hypertension has been the most common comorbid condition observed in 62 patients (98.41%), followed by diabetes in 25 patients (39.68%). Anemia (95.23%) is the most common coexisting condition, followed by bone and mineral disorder (60.31%) and uremic encephalopathy (4.76%). The demographic characteristics of the patients are shown in Table 1.

Test-retest Reliability Results of MKAQ

The Cronbach's alpha reliability values of MKAQ were in the range of 0.716-1.00, which shows that the MKAQ is a reliable tool for evaluating the medication knowledge among HD patients. The test–retest reliability results of MKAQ are shown in Table 2.

Prescription Pattern in HD Patients

The most prescribed medications in the study were erythropoi etin-stimulating agents (n = 56), followed by calcium channel blockers (n = 52) and iron supplements (n = 42). The average number of medications prescribed per patient in the study was 7.65.

Medication Knowledge Assessment among HD Patients

The maximum medication knowledge score has been accounted for drug administration sequence with respect to food (95.39) and storage of medications (95.27). The minimum knowledge has been accounted for medication side effects (0.62) and actions to be taken if a dose is missed (5.39). The mean medication knowledge of HD patients is shown in Table 3.

Comparison of Knowledge Scores Between the Age Groups, Sex, Educational Status, Domiciliary Status, Vintage of HD, and the Number of HD Sessions Per Week

There is no statistically significant difference among the age groups and male and female patients' medication knowledge. The results analysis for comparing knowledge scores between age groups and sex are shown in Table 4.

Table 1. Demographics of the HD Patients

Demographics		No. of Subjects, n = 63 (%)
Age group	<30	6 (9.52%)
	30- 60	37 (58.73%)
	>60	20 (31.74 %)
Gender	Males	49 (77.77%)
	Females	14 (22.22%)
Social habits	Alcohol	6 (9.5%)
	Smoking	2 (3.17%)
Educational status	Illiterate	13 (20.63%)
	Primary	21 (33.33%)
	Secondary	24 (38.09%)
	Graduate	5 (7.93%)
Alternative treatment	Ayurveda	14 (22.22%)
	Homeopathy	2 (3.17%)
Domiciliary status	Urban	24 (38.1%)
	Non-urban	39 (61.9%)
Duration of HD (years)	<2	25 (39.68%)
	2-4	26 (41.26%)
	4-6	8 (12.69%)
	>6	4 (6.34%)
Comorbidities	Hypertension	62 (98.41%)
	Diabetes mellitus	25 (39.68%)
	IHD	10 (15.87%)
	COPD	2 (3.17%)
	Chronic liver disease	1 (1.58%)
Coexisting conditions	Anemia	60 (95.23%)
	CKD-MBD	38 (60.31%)
	Uremic encephalopathy	3 (4.76%)
	Hepatitis	2 (3.17%)
	Hypothyroidism	1 (1.58%)
	LV dysfunction	1 (1.58%)
	Uremia	1 (1.58%)
	UTI	1 (1.58%)
	Hyponatremia	1 (1.58%)
	Hyperparathyroid disease	1 (1.58%)

COPD, chronic obstructive pulmonary disease; CKD-MBD, chronic kidney disease-mineral bone disorder; IHD, ischaemic heart disease; LV dysfunction, left ventricular dysfunction; UTI, urinary tract infection.

Statistically significant differences have been observed between patients educational status in knowing the name of the medications, use, and dose of the medications with a *P*-value < .05. The results analysis for comparing knowledge scores between educational status and domiciliary status of the patients is shown in Table 5.

There is no statistically significant difference among the HD vintage and the number of HD per week. The results analysis for comparing knowledge scores between the HD vintage and the number of HD sessions per week is shown in Table 6.

Table 2. Test–Retest Reliability Results of MKAQ

Items	Test Scores	Re-test Scores	Cronbach's Alpha Reliability Value
Name	48.26 ± 41.42	49.85 ± 41.01	0.997
Use	63.06 ± 36.85	65.06 ± 37.23	0.995
Time	89.73 ± 21.37	89.73 ± 21.37	1.000
Dose	21.60 ± 31.22	21.60 ± 31.22	1.000
Amount	90.13 ± 25.82	90.13 ± 25.82	1.000
Side effects*	-	-	-
Food	96.53 ± 7.71	98.66 ± 3.51	0.716
Storage	97.33 ± 10.32	94.53 ± 10.23	0.798
Refill	97.33 ± 10.32	97.33 ± 10.32	1.000
Missed dose	13.33 ± 35.33	13.33 ± 35.33	1.000

*None of the patients were aware of side effects of the medications.
MKAQ, Medication Knowledge Assessmant Questionnaire.

Table 3. Medication Knowledge Score of HD Patients

Items	Mean ± Std. Deviation
Name	32 ± 37.07
Indication/use	55.43 ± 30.91
Time of administration	91.78 ± 16.24
Dose	19.74 ± 29.02
Frequency	89.61 ± 22.68
Side effects	0.62 ± 3.59
Food	95.39 ± 10.7
Storage	95.27 ± 16.08
Refill	90.52 ± 26.28
Missed dose	5.4 ± 21.91

DISCUSSION

In our study, the Cronbach's alpha reliability values of MKAQ ranged from 0.716 to 1.00. Similar results were attained in the study conducted by Sathvik et al.[15] where the questionnaire's test-retest reliability alpha coefficient was more than 0.70. The literature study revealed that the Cronbach's alpha value of 0.7 and more of an instrument is reliable.

Table 4. Comparison of Medication Knowledge Scores Between the Age Groups and Sex

Medication Knowledge Items	Age Groups (Mean Knowledge Scores)			*P* (Kruskal–Wallis Test)	Sex (Mean Knowledge Scores)		*P* (Mann–Whitney *U* test)
	<30 Years	30-60 Years	>60 Years		Male	Female	
Name	39.00	31.38	31.03	.849	30.93	32.30	.674
Use	61.50	57.98	48.90	.553	51.82	56.46	.654
Time	97.17	91.75	90.23	.651	91.54	91.85	.591
Dose	23.83	20.24	17.59	.853	23.07	18.79	.957
Amount	89.17	88.24	92.28	.874	88.82	89.83	.849
Side effects	0	.68	0.70	.814	0	0.80	.446
Food	88.83	97.29	93.85	.205	90.71	96.73	.304
Storage	85.00	95.30	98.30	.131	89.29	96.98	.565
Refill	85.00	93.05	87.50	.391	82.14	92.92	.328
Missed dose	6.67	5.41	5.00	.607	7.14	4.90	.876

Table 5. Comparison of Medication Knowledge Scores Between Patient's Educational Status and Domiciliary Status

	Educational Status (Mean Knowledge Scores)				*P* (Kruskal–Wallis Test)	Domiciliary Status (Mean Knowledge Scores)		*P* (Mann–Whitney *U* test)
	Illiterate	Primary	Secondary	Graduate		Rural	Urban	
Name	5.08	27.84	46.83	48.20	.003*	33.38	29.75	.686
Use	34.20	49.85	60.13	70.83	.005*	54.89	56.31	.771
Time	89.79	87.76	95.46	96.20	.801	90.85	93.29	.831
Dose	6.78	13.27	26.84	46.53	.011*	18.17	22.30	.335
Amount	90.71	82.33	94.38	94.40	.051	89.62	89.58	.246
Side effects	0	1.19	0.58	0	.842	0.36	1.04	.709
Food	94.62	94.33	96.98	94.20	.966	94.25	97.25	.246
Storage	98.69	95.19	92.50	100	.779	93.82	97.63	.551
Refill	84.62	94.43	88.33	100	.804	90.85	90	.798
Missed dose	0	4.76	5.83	20	.441	5.13	5.83	.639

*P-value < .05 represents statistical significance.

The patients' mean age was 52.31 ± 13.12 years, with most age groups ranging from 30 to 60 years. This study's results were quite closely associated with the study findings conducted by Rani et al.[13] as the mean age of patients in that study was 50.52 ± 13.28 years. However, in the study carried out by Ghimirey et al.[16] the patients' studied mean age was found to be 46.66 ± 14.37 years. In this study, the medication knowledge item scores were comparatively less for older patients than those of 30 years. Still, there is no significant difference in the medication knowledge scores among the different age groups. This might be due to an unequal number of patients in each group.

In our study, male (77.77%) patients outnumbered females (22.22%). These findings were closer to the study carried out by Ibrahim et al.[7] whereas slighting deviating from the study conducted by Chakraborty et al.[8] in which 57% of patients were males and 43% were of female gender. In this study, gender had no significant impact on the medication knowledge scores. The medication knowledge was comparatively less among males

Table 6. Comparison of Medication Knowledge Scores Between the Vintage of HD and No. of HD Sessions Per Week

	Vintage of HD Groups (Mean Knowledge Scores)				*P* (Kruskal–Wallis Test)	No. of HD Sessions Per Week (Mean Knowledge Scores)			*P* (Kruskal–Wallis Test)
	<2 Years	2-4 Years	4-6 Years	>6 Years		1	2	3	
Name	20.16	32.54	40.96	84.50	.02*	14.25	31.76	38.28	.513
Use	51.68	52.96	56.92	92.00	.082	54	55.22	56.64	.994
Time	89.92	90.77	98.38	96.75	.256	86	92.02	92.69	.644
Dose	11.28	18.84	27.10	63.75	.1	15.50	18.85	24.20	.780
Amount	88.21	89.62	88.75	100.00	.291	86	91.44	84.23	.872
Side effects	1.00	0.54	0	0	.923	0	0.85	0	.687
Food	92.68	96.25	98.75	100.00	.595	88.75	95.75	96.15	.510
Storage	91.72	96.50	100.00	100.00	.54	95.75	95.85	93.08	.567
Refill	91.72	92.69	87.50	75.00	.871	50	93.33	93.08	.064
Missed dose	5.60	7.69	0	0	.804	25	5.22	0	.195

*P-value < .05 represents statistical significance.

because females are pivotal to communication about their health and treatment.

In the present study, 38.09% of the patients had a secondary level of education, 33.33% had a primary level of education, and 7.93% were graduates, whereas 20.63% involved in the study were illiterate. Similar results were observed in the study conducted by Ibrahim et al[7] in which 31.3% of the study group had secondary education and 23.4 % were illiterate. In contrast, the percentage of illiterates was 6.7 in the study conducted by Sathvik et al.[15] A statistically significant difference was observed between the educational status of the patients and the knowledge of the name of the medications, use, and dose of the medicines with a *P*-value < .05. There was an exponential improvement in medication knowledge scores among graduates, followed by secondary and primary educational status. Hence, the pharmacist must know the patient's education level to provide drug information and counseling to improve the knowledge, attitude, and practice of safe medication use.

In this study, 61.9% of the patients resided in rural areas and the remaining 38.1% belonged to urban areas. However, in a study conducted by Sathvik et al[15], most of the patients (77.8%) resided in urban and semi-urban areas and the remaining 22.2% were in rural areas.[15] Domiciliary status (rural/urban) of patients had no statistical impact on the medication knowledge scores. This might be due to rural and urban patients keen to seek medication information to improve their health.

Most of the HD patient's vintage ranged from 1 to 4 years (80.9%). This study's results were quite closely related to the study conducted by Ghimirey et al.[16] in which 65.6% of the patients had a vintage of HD ranging from 1 to 5 years.[16] In our study, the vintage of HD has no impact on medication knowledge. The medication knowledge is relatively more, as the vintage of patients' dialysis increases due to the prolonged use of the same drugs for years than the lower dialysis vintage. In the study, most of the patients underwent HD twice a week [n = 46 (73.02%)], followed by thrice a week HD [n = 13 (20.63%)]. These findings are in concordance with the study results conducted by Rani et al.[13] in which 78.82% of the patients underwent HD twice in a week and 17.64% underwent HD thrice in a week. There is no statistically significant difference between the number of HD sessions per week and medication knowledge. However, as observed in the study, medication knowledge possessed by patients who underwent multiple times a week dialysis schedule was higher than those who had once a week schedule attributable to an increased number of counseling that they could receive at each visit.

The average number of medications prescribed for each patient in the study was found to be 7.65. Similar findings were observed in the study conducted by Rani et al.[13] where each patient takes the average medication was 6.47. On the contrary, the average number of drugs prescribed for each patient was 10 in the study performed by Chakraborty et al.[8] The reason medication knowledge declined might be due to the polypharmacy or complexity of the medications. In the present study, the medication knowledge scores for the name of medicines, indication, dose, and the number of doses to be taken per day were 31.99, 55.43, 19.74, and 89.6, respectively. In contrast, the medication knowledge scores reported in the study conducted by Sathvik et al[15] for the parameters surveyed like name, indication, strength, and the number of medication doses were 39.03, 20.49, 9.80, and 55.28, respectively, at the baseline.

Less availability of HD patients than previous studies, difficulty in willingness to give the study's consent, and less duration were the study's limitations.

CONCLUSION

In this study, MKAQ was prepared and validated by the expert panel of the relevant field and for which a reliability test was performed by collecting data from HD patients. The maximum medication knowledge score was accounted for drug administration sequence with respect to food, whereas the minimum knowledge scores were for medication side effects. This questionnaire was found to be a reliable and valid instrument for assessing medication knowledge among HD patients.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Nitte University Date: August 31, 2017, Decision No: NGSMI PS/IE C/27/ 2017- 18).

Informed Consent: Obtained written informed consent from the patients and their legally accepted representatives.

Peer-review: Externally peer-reviewed.

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