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SLEEP QUALITY IN END-STAGE RENAL DISEASE PATIENTS ON MAINTENANCE HEMODIALYSIS: A SIX MONTH PROSPECTIVE SURVEY

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ABSTRACT: Objective: The aim of this study was to evaluate the sleep quality and to identify risk factors for poor sleep quality in hemodialysis population. An additional aim of the study was to identify number of patients treated for their sleep problems. **Method:** 126 patients undergoing hemodialysis treatment were enrolled into the study. Subjective sleep quality was measured using Pittsburgh Sleep Quality Index. All the participants also completed Beck Depression Inventory questionnaire for evaluation of depressive symptoms. The pharmacotherapy and clinical, demographic and socioeconomic variables were also investigated. **Results:** Among the enrolled patients, poor sleep quality was reported in 67% (n=85). Depressive symptoms were identified in 75% (n=62) of the poor sleepers. Significant association was observed between variables like being single, female gender, older age, low socioeconomic status, increased financial reliability, spending more than INR 10,000 (\$ 166) per month for treatment, overweight, morning dialysis shift and dialysis duration more than 3 years. Clinical conditions like depression, diabetes, limb pain, fatigue, hypertension, hypoalbuminemia, hypocalcaemia and hypophosphatemia and use of medications like clonidine, erythropoietin, metoprolol and prazosin were also found to be associated with poor quality of sleep. Out of 67% (n=85) of the patients identified with sleep problems, 13% (n=17) were on sleep medications. **Conclusion:** The quality of sleep is impaired in hemodialysis population. Therefore, evaluation of sleep quality during regular clinical practice should be taken into consideration.

INTRODUCTION: Poor sleep complaints are common in patients with end-stage renal disease (ESRD) on hemodialysis (HD). The prevalence of sleep abnormalities in this population (50-80%) ^{1, 2} is substantially greater than that reported in the general population ³. Patients with poor sleep may have more difficulty with intellectual, social and vocational functioning. They may have impaired cognitive performance. Defects in sleep decrease the patient's ability to enjoy family and social life. It also decreases job satisfaction and productivity resulting in poorer performance and increased absenteeism.

Studies point out that impaired sleep is a risk factor for new onset and recurrent major depressive disorder (MDD). Substance abuse is twice more common among these individuals ³. Impaired sleep is found to be significantly associated with longer recovery time from dialysis ⁴. It increases morbidity and mortality due to cardiovascular diseases and infectious complications ⁵ and is also associated with reduced health related quality of life (HRQOL) ^{1, 4}. Thus, it is important to study the risk factors associated with sleep disorders that can help directly to improve the sleep quality (SQ) in HD patients.

Although few studies have assessed the prevalence of poor sleep among HD patients, its relation with depression and other clinical conditions, pharmacotherapy, demographic and socioeconomic variables has not been completely established, especially in Indian HD population. Moreover, the

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prevalence of sleep problems among dialysis patients varies from country to country⁶, thereby reflecting the need for study in a nationally representative population. This study was undertaken to evaluate the quality of sleep in a large population of HD patients and to identify risk factors related to poor sleep symptoms. The number of patients who received treatment for their poor SQ was also estimated.

MATERIALS AND METHODS:

This cross sectional study was carried out over a period of 6 months, Nov 2012 to Apr 2013, at the outpatient dialysis department of two tertiary care hospitals in Mysore, India. Patients who had been on HD sessions for ESRD at least 3 times per week, lasting 4 hours each, for at least 3 consecutive months were included in the study. The patients were excluded if they were not willing to participate or sign the informed consent, were undergoing HD for conditions other than ESRD, or had hearing, speech or cognitive defects that would interfere with their ability to understand and answer questions from the screening tools used in the study. Additionally, patients with delirium, dementia or history of psychiatric disorders prior to undergoing HD were also excluded.

Ethical approval:

The protocol was approved by the institutional human ethical review board of JSS institution prior to commencement of the study.

Procedures:

Participants were interviewed when they came for their dialysis sessions. Using appropriate data collection form designed for the study, relevant socio demographic data, details regarding laboratory examinations, clinical conditions, medications and other dialysis details were recorded.

Evaluation of sleep quality:

To evaluate SQ, Pittsburgh Sleep Quality Index (PSQI) was applied. It is a well validated, widely used 19 item self-report measures developed in 1989 to examine SQ over the previous month⁷. It contains seven subscales measuring domains such as subjective SQ, sleep latency, sleep duration, and sleep disturbance, which combine to yield a global score of SQ. Global SQ scores are continuous (range 0-21), with higher scores reflecting poorer

SQ, and scores less than 5 indicating good sleep. PSQI has been demonstrated to have high internal consistency, test-retest reliability as well as a diagnostic sensitivity (80-100%) and specificity (80-83%) in distinguishing good and poor sleepers⁷.

Evaluation of depressive symptoms:

Depressive symptoms were evaluated using the Beck Depression Inventory (BDI). It is a validated 21 item screening tool to detect depression in ESRD, with sensitivity and specificity rates of more than 90%⁸. This instrument has been used extensively for the assessment of depression in patients with ESRD⁹. It covers affective, cognitive, motivational, and physiological areas of depressive symptomatology. According to BDI, grading of depression was done based on the score levels: mild depression (14-19), moderate depression (20-28) and severe depression (29-63).

Evaluation of socioeconomic status:

The socioeconomic status of the patients was evaluated using modified Kuppaswamy's socioeconomic status scale, which takes into consideration their education, occupation and monthly income. It is a widely used tool in hospital and community based research to measure socioeconomic status of families in urban areas of India¹⁰. Grading of socioeconomic status was based on score levels: upper class (> 26), middle class (11-25) and lower class (< 10).

Evaluation of body mass index:

The body mass index (BMI) of the participants were calculated using the patients estimated dry weight and were divided into 3 categories, overweight (BMI: > 25), normal weight (BMI: 18.5-24.9) and underweight (BMI: < 18.5). Before interviewing the patients, researchers underwent adequate training by the psychiatrist with respect to administration of PSQI and BDI. Although the questionnaires were largely self-administered, it was read out to illiterate patients and their responses were recorded. The data was collected privately and confidentiality was maintained on all data collection forms.

Statistical analysis:

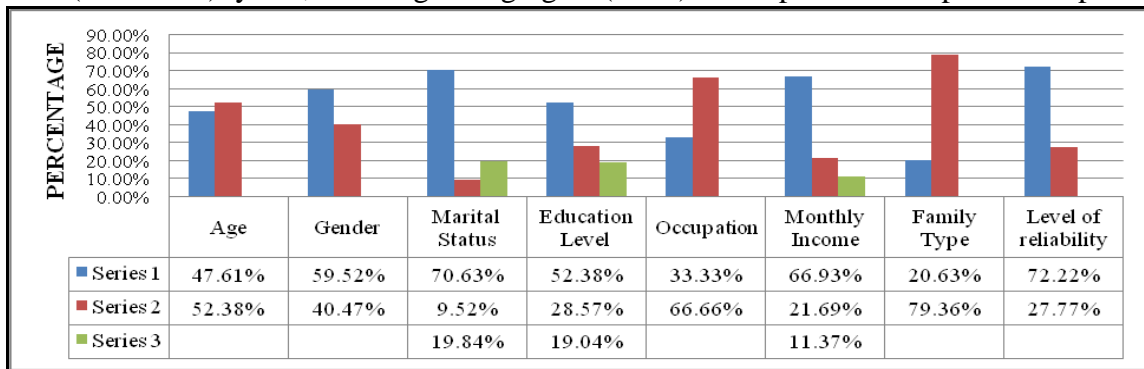
Data was verified and analysed using Statistical Package for Social Sciences (SPSS) for windows

version 20.0. Results were evaluated using percentage value and mean ± standard deviation (mean±SD). Comparisons between categorical variables were done using the chi squared test. A p value < 0.05 was considered statistically significant.

RESULTS:

The mean age of the dialysis population were 48.42±14.47 (mean±SD) years, with age ranging

between 20 years and 85 years. Patients were undergoing HD for mean duration of 3.89±2.49 (mean±SD) years. The ESRD patients attending the outpatient dialysis units had an average glomerular filtration rate (GFR) of 8.51±1.52 (mean±SD) ml/min/1.73 m². In **Figure 1**, the sociodemographic characteristics of the participants are presented. The average value from PSQI was found to be 8.98±10.17 (mean±SD) %. About 67% (n=85) of the patients complained of poor sleep.



LEGEND FOR FIGURE 1

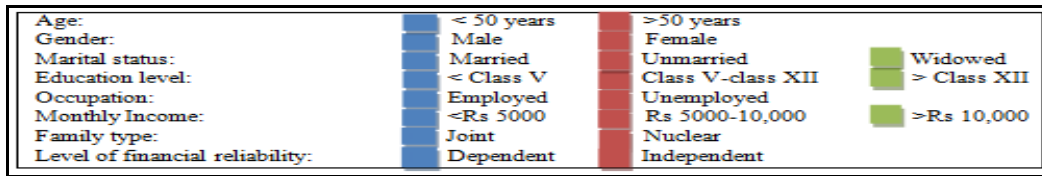
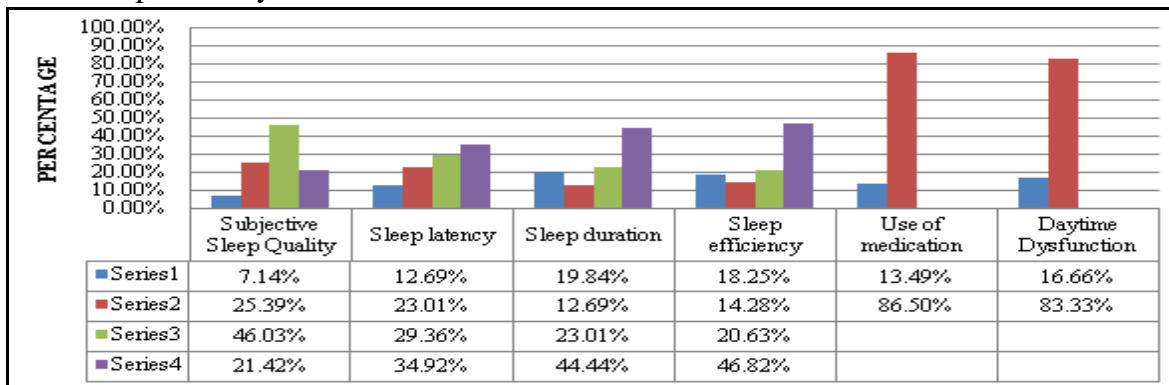


FIGURE 1: THE DEMOGRAPHIC AND SOCIOECONOMIC CHARACTERISTICS OF THE STUDY POPULATION (N=126)

The pattern of sleep experienced by the study patients is shown in **Figure 2**. 35% (n=44) of the patients reported sleep latency more than 60 minutes and 44% (n=56) had sleep duration less than 5 hours. Approximately 47% (n=59) of the patients had sleep efficacy less than 65%. 17%

(n=21) of HD patients had problems with their functionality during daytime, which may affect their daytime alertness, activity level, incidence of accidents and overall wellbeing. 13% (n=17) were on sleep medications.



LEGEND FOR FIGURE 2

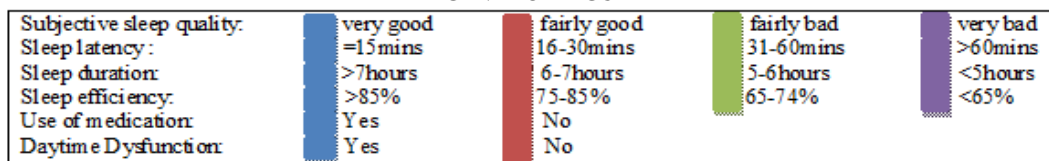


FIGURE 2: QUALITY OF SLEEP IN THE STUDY POPULATION ACCORDING TO PITTSBURGH SLEEP QUALITY INDEX (PSQI) (N=126)

Table 1 summarises the sociodemographic characteristics of patients with poor SQ. Among the study subjects, poor sleep was significantly more among patients who were financially dependent on others and had to spend more than INR 10,000 (\$ 166) per month for their HD treatment and medications. It was significantly lower in males

and younger patients and among those who were married. Patients who had poor SQ tended to belong to the lower socioeconomic class. The relationship between poor SQ and BMI is depicted in **Table 2**. As the table shows, patients who were overweight had more sleep problems.

TABLE 1: SOCIODEMOGRAPHIC AND ECONOMIC CHARACTERISTICS OF POOR SLEEPERS

Demographics variables	Categories	Total patients (n=126) n (%)	Poor sleepers (n=85) n (%)	p value
Age	<50 years	60 (47.61)	33 (55.00)	0.0044*
	>50 years	66 (52.38)	52 (78.78)	
Gender	Male	75 (59.52)	37 (49.33)	0.0000*
	Female	51 (40.47)	48 (94.11)	
Marital status	Married	89 (70.63)	52 (58.42)	0.0031*
	Unmarried	12 (9.52)	10 (83.33)	
	Widowed	25 (19.84)	23 (92.00)	
Family type	Joint	26 (20.63)	15 (57.69)	0.2327
	Nuclear	100 (79.36)	70 (70.00)	
Level of financial reliability	Dependent	91 (72.22)	76 (83.51)	0.0000*
	Independent	35 (27.77)	9 (25.71)	
Cost of treatment per month (including HD and medications)	< INR 10,000 (\$ 166)	80 (63.49)	41 (51.25)	0.0000*
	> INR 10,000 (\$ 166)	46 (36.50)	44 (95.65)	
Kuppuswamy's SES scale	Upper class	4 (3.17)	0 (0.00)	0.0005*
	Middle class	28 (22.22)	14 (50.00)	
	Lower class	94 (74.60)	71 (75.53)	

* Indicates significant p value at 95% level of confidence interval ($p \leq 0.05$). HD - Hemodialysis, Kuppuswamy's SES Scale - Kuppuswamy's socioeconomic status scale

TABLE 2: ASSOCIATION BETWEEN POOR SQ AND BMI OF THE PATIENTS

Variable	Categories	Total patients (n=126) n (%)	Poor sleepers (n=85) n (%)	p value
BMI Categories	Underweight	61 (38.88)	52 (85.24)	0.0000*
	Normal weight	51 (50.00)	20 (39.21)	
	Over weight	14 (11.11)	13 (92.85)	

* Indicates significant p value at 95% level of confidence interval ($p \leq 0.05$). BMI - Body mass index, SQ - Sleep quality

Association between time of dialysis and duration of dialysis with SQ is shown in **Table 3**. Notable relation was observed between impaired sleep and

patients who had been on mid-day dialysis shift for a period more than 36 months.

TABLE 3: ASSOCIATION BETWEEN POOR SQ AND TIME AND DURATION OF DIALYSIS

Variables	Categories	Total patients (n=126) n (%)	Poor sleepers (n=85) n (%)	p value
Time of dialysis	Morning (6am-10am)	42 (33.33)	35 (83.33)	0.0114*
	Mid-day (11am-3pm)	44 (34.92)	29 (65.90)	
	Evening (4pm-8pm)	40 (31.74)	21 (52.50)	
Duration of dialysis	< 12 months	45 (35.71)	21 (46.66)	0.0000*
	13-24 months	36 (28.57)	23 (63.88)	
	25-36 months	16 (12.69)	14 (87.50)	
	>36 months	29 (23.01)	27 (93.10)	

* Indicates significant p value at 95% level of confidence interval ($p \leq 0.05$). SQ - Sleep quality

With regard to the clinical variables, poor sleep was significantly higher among patients with

clinical conditions like depression, diabetes, fatigue, limb pain and hypertension (**Table 4**).

TABLE 4: ASSOCIATION BETWEEN POOR SQ AND CO-MORBIDITIES IN PATIENTS

Co-morbidities	Yes/No	Total patients (n=126) n (%)	Poor sleepers (n=85) n (%)	p value
Depression	Yes	82 (65.07)	62 (75.60)	0.0076*
	No	44 (34.92)	23 (52.27)	
Diabetes	Yes	49 (38.88)	48 (97.95)	0.0000*
	No	77 (61.11)	37 (48.05)	
Fatigue	Yes	108 (85.71)	77 (71.29)	0.0243*
	No	18 (14.28)	8 (44.44)	
Limb pain	Yes	115 (91.26)	81 (70.43)	0.0212*
	No	11 (8.73)	4 (36.36)	
Hepatitis C virus	Positive	11 (8.73)	9 (81.81)	0.2873
	Negative	115 (91.26)	76 (66.08)	
Hypertension	Yes	123 (97.61)	85 (69.10)	0.0115*
	No	3 (2.38)	0 (0.00)	

* Indicates significant p value at 95% level of confidence interval ($p \leq 0.05$). SQ - Sleep quality
Statistical analysis of results obtained showed serum albumin, calcium and phosphate levels significant association between poor SQ and lower (Table 5).

TABLE 5: ASSOCIATION BETWEEN POOR SQ AND LABORATORY PARAMETERS OF PATIENTS

Laboratory Parameters	Abnormalities	Total patients (n=126) n (%)	Poor sleepers (n=85) n (%)	p value
Hemoglobin	Normal	0 (0.00)	0 (0.00)	0.0001*
	Low	126 (100.00)	85 (67.46)	
Albumin	Normal	50 (39.68)	24 (48.00)	0.0066*
	Low	76 (60.31)	61 (80.26)	
Calcium	Normal	23 (18.25)	10 (43.47)	0.0136*
	Low	103 (81.74)	75 (72.81)	
Phosphorous	Normal	21 (16.66)	19 (90.47)	0.5946
	High	105 (83.33)	66 (62.85)	
Sodium	Normal	89 (70.63)	59 (66.29)	0.2446
	High	2 (1.58)	2 (100.00)	
	Low	35 (27.77)	24 (68.57)	
Potassium	Normal	37 (29.36)	28 (75.67)	0.5628
	High	87 (69.04)	55 (63.21)	
	Low	2 (1.58)	2 (100.00)	
Chloride	Normal	39 (30.95)	24 (61.59)	0.5628
	High	82 (65.07)	58 (70.73)	
	Low	5 (3.96)	3 (60.00)	

* Indicates significant p value at 95% level of confidence interval ($p \leq 0.05$). SQ - Sleep quality

Correlation between pharmacotherapy of the strong link was observed between poor sleep and patients with sleep quality is shown in Table 6. use of clonidine, erythropoietin, metoprolol and Among the medications patients were receiving, prazosin.

TABLE 6: ASSOCIATION BETWEEN POOR SQ AND PHARMACOTHERAPY

Drugs	Yes/No	Total patients (n=126) n (%)	Poor sleepers (n= 85) n (%)	p value
Alprazolam	Yes	3 (2.38)	3 (100.00)	0.2234
	No	123 (97.61)	82 (66.66)	
Clonidine	Yes	22 (17.46)	22 (100.00)	0.0003*
	No	104 (82.53)	63 (60.57)	
Erythropoietin	Yes	52 (41.26)	52 (100.00)	0.0000*
	No	74 (58.73)	33 (44.59)	
Levothyroxine	Yes	6 (4.76)	5 (83.33)	0.3951
	No	120 (95.23)	80 (66.66)	
Lorazepam	Yes	2 (1.58)	2 (100.00)	0.3221
	No	124 (98.41)	83 (66.93)	
Metoprolol	Yes	22 (17.46)	22 (100.00)	0.0003*
	No	104 (82.53)	63 (60.57)	
Phenobarbital	Yes	3 (2.38)	1 (33.33)	0.2016
	No	123 (97.61)	84 (68.29)	
Prazosin	Yes	23 (18.25)	23 (100.00)	0.0002*
	No	103 (81.74)	62 (60.19)	
Prednisolone	Yes	2 (1.58)	1 (50.00)	0.5952
	No	124 (98.41)	84 (67.74)	

* Indicates significant p value at 95% level of confidence interval ($p \leq 0.05$). SQ - Sleep quality

Out of 67% (n=85) patients with defective SQ, according to PSQI, 13% (n=17) were on sleep medications.

DISCUSSIONS: Our study identifies that large number of HD patients suffer from poor sleep. The incidence of poor sleep in the present study was 67.4% (n=85), using PSQI. The incidence of poor sleep symptoms in our study was almost similar to that reported by Tel et al, who determined 78.7% of their HD patients as having poor quality of sleep². In the present study, majority of the patients complained of difficulty in getting sleep, having shorter sleep time and less efficient sleep. Few patients also reported significant day time dysfunction. Williams et al observed the sleeping behaviour of HD patients and found that more than 50% of the patients woke up from sleep frequently and about 55% of the patients woke up too early¹¹. Other evidence also suggest that HD patients were three times more likely to sleep less than 5 hours per night, and have more difficulty getting back to sleep, waking up too early, feeling tired and not getting enough sleep¹².

Many risk factors have been ascertained in literature to have significant relationship with the development of impaired sleep. Knowledge about these risk factors may be helpful in designing preventive and therapeutic strategies for sleep disorders in HD patients. In our study, age of the HD patients negatively correlated with the SQ. It was determined that elderly patients were more likely to report poor quality of sleep. Similarly, studies by Yoshioka et al⁵ and Tel et al¹³ found that advanced age significantly affected patients experiencing sleep problems. This may also be due to age related changes in sleep, or due to increased prevalence of physical diseases, multiple drug use or lifestyle modification⁵.

Regarding gender, quality of sleep of female patients in the study population were worser than that of male patients. This could be explained by fluctuating hormone levels or because women tend to ruminate on their problems at night whereas men are able to distract themselves from their thoughts¹⁴. However, other studies have reported variable effects of gender on SQ. Unruh et al¹⁵ reported that male patients complained of more sleep problems than female patients, while Chang et al¹⁶ reported

the opposite. However, Rodriguez et al in his study reported an equal percentage of men and women to have sleep problems². Concerning marital status, patients who were single reported higher PSQI scores. Previous research on patients with impaired sleep also reported that being single negatively affects sleep¹⁷.

Patients belonging to the lower socioeconomic class had more defects in sleep. The socioeconomic status of most of the study patients was low. Greater number of our patients were unemployed and had low monthly income due to their low educational levels and work disability due to fatigue and limb pain as a result of dialysis. Sleep defects were more common among patients with low monthly income and had to pay more than their gross monthly salary towards their medications and dialysis treatment. Since majority of these patients had no insurance cover and could not afford the treatment cost, they were financially reliable on others and many of these patients had impaired sleep. According to research, increased sleep disturbances are associated with predictors like lower socioeconomic status, lower education, income or being unemployed¹⁷. Anders et al in his study also reported that individuals in lower socioeconomic groups may be at higher risk for sleep disturbances¹⁸. Guney et al states that employment status is an important predictor of SQ in HD patients¹⁹. However, previous studies have not evaluated the effect of treatment cost and financial dependence on the quality of sleep.

Some studies found association between cigarette smoking and sleep diseases. They found that nicotine exposure and withdrawal may negatively affect the SQ^{4,20}. However, our study sample was not large enough for such comparison. We only had 3% (n=4) patients who were smoking in the last 3 months. Thus no relation could be established between smoking and SQ. Similar to other studies^{5, 21}, we found that study patients with high BMI, had the most defects in sleep. Evidence from sleep restriction studies reveals that short sleep duration is associated with elevated BMI and increased prevalence of obesity²¹. However, Unruh et al observed no difference in SQ by BMI²⁰. An association between morning dialysis shift and poor SQ in HD population is reported in some studies^{5,22}. We also found morning dialysis shift as

an independent predictor of poor SQ. This may be because HD patients tend to sleep under the device and during the day which results in sleep problems at night¹¹. However, Hui-hua et al did not identify an association in this regard²³. In our study, significant correlation was found between how long patients have been on dialysis and their SQ. Other studies also found that length of dialysis was positively correlated with the sleep problems of dialysis patients^{2, 5}. HEMO study demonstrated that nearly 30% of their participants experienced a clinically significant decline in SQ over a course of 3 years⁴.

According to the results of our study, there was strong correlation between co-morbidities and SQ. Many studies reports quality of sleep to be associated with the physical and mental status of the patients^{1, 20}. Study by Hayashino et al demonstrated that co-morbidities are correlated positively with sleep disturbance²⁴. However, according to Sabet et al²⁵ and Unruh et al²⁰ there are no associations between PSQI score and clinical conditions. We found that one of the major problem study population faced was depression. The relation between quality of sleep and mood disorder like depression is well established and has been reported in HD patients. Studies suggests that higher BDI score is one of the predictors for poor SQ in dialysis patients^{1, 4, 19}. According to Iliescu et al, dialysis patients with PSQI score greater than 5 have a prevalence of overt depression of 20%, while among ESRD patients reporting normal sleep, prevalence of depression is almost nil⁵. Since the patient's psychological status may influence the onset of poor sleep¹², early psychiatric assessment of the patients undergoing HD should be done to detect depression and initiate appropriate treatment program. It is also important because depression is treatable using either cognitive behavioural therapy or antidepressant medications⁴.

Limb pain was another complaint of the dialysis patients. Similar to several other reports^{4, 20}, we found negative correlation between SQ and limb pain. Research suggests that disturbed sleep can lower the pain threshold and thus leading to higher pain perception². In addition, the results also found statistically significant differences in SQ between patients with and without diabetes, with impaired

sleep more common among diabetic patients. The results were in acceptance with the study by Lou et al²⁶. Concerning fatigue, we demonstrated association between fatigue and poor SQ, however previous studies have not established any relation between the two variables. We also found negative correlation between blood pressure and SQ. Calhoun et al also reports short sleep duration to be associated with increased hypertension risk²⁷.

With regards to laboratory parameters, HD patients with poor sleep had lower levels of serum albumin and calcium levels and higher serum phosphate levels. Iliescu et al reported negative correlation between PSQI score and hypoalbuminemia¹. However, Mujais et al found that hypoalbuminemia has no effect on sleep²⁸. Previous studies have not found an association between serum calcium and quality of sleep in dialysis patients. However, evidence states that calcium has a sedative and relaxing effect on the body and its deficiency may result in restlessness and wakefulness²⁹. Results from study by Cengic et al demonstrated association between poor sleep and high serum phosphate level³⁰. Anemia is another possible mechanism that has been proposed as a possible risk factor for sleep defects in HD patients. Association between hemoglobin and SQ has been indicated in previous studies^{1, 31}. However, no statistically significant difference in patients SQ was found according to their hemoglobin levels in the current study.

Medications may interfere with sleep. Benzodiazepines, antidepressants, opioids, anticonvulsants, non-benzodiazepine hypnotics⁴, beta-blockers, bronchodilators, corticosteroids, CNS stimulants, cardiovascular drugs, alcohol, caffeine, nicotine and erythropoietin therapy⁵ are known to impair sleep and induce various sleep problems. We also found that medication use with clonidine, erythropoietin, metoprolol and prazosin negatively contributed to SQ. However, further studies needs to be conducted in larger HD population to confirm this relation.

Findings from our study suggest that sleep characteristics of HD patients' needs to be routinely evaluated. Early identification of sleep problems and interventions to improve the quality of sleep should be included in overall plan of

patient care, because sleep problems present for a long time can decrease the general health and functioning. Evidence supports the effectiveness of both therapeutic interventions and dialysis modifications for the management of sleep problems in dialysis population⁵. However, the presence of frequent comorbidities and drug interactions may limit the use of sleep medications in this population. In our study, relatively small percentage of the patients received sleep medications.

There clearly exist some limitations to the study. First, sleep diaries were not utilized. There was no separate group from the general population to serve as control group. The study was conducted only for a short period and was conducted at only two study sites. So the study population was limited. Moreover, self-reported measures were used for assessing sleep. Finally because of the cross sectional nature of the study, we were not able to establish a cause and effect relationship in examining associations.

CONCLUSIONS: Results of this study showed that poor SQ is highly frequent in uremic patients on HD and while evaluating sleep problems in dialysis patients, physicians along with dialysis pharmacists and nurses should identify and assess the contribution made by these predictors. We found that being single, female gender, older age, low socioeconomic status, increased financial reliability, spending more than INR 10,000 (\$166) monthly for treatment, overweight, morning dialysis shift and dialysis duration more than 3 years are independent predictors of quality of sleep in these patients. Clinical conditions (depression, diabetes, limb pain, fatigue and hypertension), lab parameters (hypoalbuminemia, hypocalcaemia and hypophosphatemia) and use of medications (clonidine, erythropoietin, metoprolol and prazosin) all contribute to poor quality of sleep in HD patients. Majority of these patients were not treated. Further studies are required for better understanding of association between these risk factors and SQ and also to assess the best possible treatment options in these patients.

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