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# Characteristics of Fatigue and Restless Leg Syndrome on Dialysis and Non-Dialysis Days among Patients with Chronic Kidney Disease on Maintenance Haemodialysis: Findings from Southern India: A Cross-Sectional Study

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## **ABSTRACT**

**Background:** Patients with Chronic kidney disease (CKD) patients on maintenance haemodialysis may have fatigue and restless leg syndrome which may impact their overall quality of life and activities of daily living. We aimed to characterise and compare the fatigue and restless leg syndrome between dialysis and non-dialysis days.

Materials and Methods: This cross-sectional study was conducted at two dialysis centres in Puducherry. 112 subjects who fulfilled the eligibility criteria were selected conveniently and the data collected using standardised instruments namely Fatigue Assessment scale and RLS questionnaire by self-report method. Data analysed by SPSS-20 software, using descriptive and inferential statistics.

**Results:** Out of 112 subjects, 79 (70.54%) comprised males and 33(29.46) were females. The average age was  $50.12 \pm 13.87$  years. The prevalence of RLS in the range of 6.25% (11/112)  $\cdot 9.82\%$  (7/112) and 31 (27.68%), 47 (41.96%) had fatigued in non-dialysis and dialysis days. The mean fatigue score was found to be  $23.12 \pm 4.56$  and  $21.5 \pm 3.89$  on dialysis and non-dialysis day respectively which was statistically significant at p<0.05, suggesting fatigue was high on dialysis days compare to non-dialysis days. Among the participants, the average RLS score was  $9.82 \pm 5.13$  and  $9.35 \pm 4.68$  on dialysis and non-dialysis day respectively which was not statistically significant at p<0.05, suggesting no difference in RLS experienced by the patients on dialysis days compared to non-dialysis days.

Conclusion: RLS and fatigue are prevalent and debilitating symptoms in CKD patients on both dialysis than non-dialysis days. These findings illuminate the necessity for healthcare providers to routinely screen and managing these symptoms, can enhance the overall quality of life for CKD patients.

Key words: Chronic kidney disease, Haemodialysis, Fatigue, Restless Leg Syndrome

#### **INTRODUCTION:**

Chronic Kidney Disease (CKD) is a progressive and irreversible condition characterised by gradual and permanent loss of kidney function due to a range of causal factors making kidneys incapable to effectively excrete metabolic waste and carry out normal renal processes. Chronic kidney disease is a global public health problem and affects millions of individuals about 10% of the global population, leading to various complications that significantly impact the health and overall quality of life. <sup>2</sup>

Hemodialysis (HD) is the most widely used renal replacement therapy to extend the life span of patients with CKD. However, enhanced dialysis techniques have resulted in longer survival in patients with CKD in recent years, these patients suffer from several adverse effects and a heavy burden of symptoms that result from either CKD or HD treatment, such as restless legs syndrome (RLS), depression, insomnia, and fatigue. <sup>3</sup>

Among these complications, Restless Leg Syndrome (RLS) and fatigue are prevalent issues that often go unrecognized.

As kidney function declines, patients may experience various systemic symptoms including RLS and fatigue which can further complicate their management. Restless legs syndrome (RLS) is a neurological sensory-motor disorder that is associated with reduced life quality and feelings of discomfort mostly occurring during sleeping hours. <sup>4, 5</sup>

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Restless legs syndrome (RLS), is one of several complications that patients on hemodialysis suffer from, it is a neurological sensory motor disorder, causing sleep disturbances, and other problems, which affects the activities of daily living.

Fatigue is a common complaint among CKD patients and may arise from multiple factors, including anemia, metabolic disturbances, and the burden of chronic illness.

As CKD progresses to advanced stages, patients often require dialysis to maintain their health. The burden of CKD is not limited to physical health; it extends to psychological and emotional well-being. Two common yet often under looked complications in CKD patients are Restless Leg Syndrome (RLS) and fatigue.

Considering the paucity of such work from the Indian context, this study is planned to assess the characteristics of fatigue and restless leg syndrome on dialysis and non-dialysis days among patients with chronic kidney disease on maintenance haemodialysis and the findings will help the health care personnel to plan care effectively.

The objectives of the study were

- 1. To determine the prevalence of RLS and fatigue among CKD patients on dialysis and non-dialysis days.
- 2. To explore the relationship between RLS and fatigue in CKD patients.
- 3. To find out the association between RLS and fatigue with selected socio-demographic and clinical variables.

### MATERIALS AND METHODS:

This study was conducted in two dialysis centres of selected hospitals of Puducherry adopting quantitative research approach and cross-sectional research design. This study was carried out between September 2024 and March 2025 and the study protocol was approved by the Institute Ethics Committee. The study population consisted of patients with CKD on HD in the last 3 months or more at selected hospitals. A total of 112 CKD patients were recruited by convenience sampling method based on the eligibility criteria. The inclusion criteria were (i) Patients aged from 18 years to 80 years; (ii) diagnosed with CKD stage 4 and 5 and had been receiving HD 3 times/week, 4 hours per time for 3 months or more; (iii) those who willing to participate in the study, and able to understand Hindi or English language; and (iv) those who were in stable condition during the study.

The exclusion criteria were as follows: (i) those were not willing to participate, (ii) suffered from critical conditions, and were cognitively unable to participate. (iii) Incapable of providing information. The nursing personnel in the HD centres, helped in gaining access to the study settings and participants at the centres. All subjects provided information about the study and informed written consent was obtained from them.

## Data collection

The data was collected using standardized tools, namely, International Restless Legs Syndrome Study Group (IRLSSG), fatigue assessment scale as well as socio-demographic profile among the participants. All the tools were translated to Tamil and back translation was done, pretested and found feasible to use. Socio-demographic Profile:

We collected the basic demographic parameters like gender, age in years, religion, marital status, education, occupation, type of family, family monthly income, area of residence and clinical details like body mass index, smoking status, alcohol intake, duration of undergoing HD since, duration of illness, no. of hemodialysis cycle in a week and co-morbidity, history of renal transplantation, and laboratory indices including blood urea nitrogen, hematocrit, hemoglobin (Hb), serum albumin and serum creatinine.

# International Restless Legs Syndrome Study Group (IRLSSG) criteria for the diagnosis of RLS:

This scale consists of 10 questions and each items rated on a 4 point Likert scale according to severity; none (0 points), mild (1 point), moderate (2 points), severe (3 points) and very severe (4 points). Thus, a total score ranging from 0-40 is obtained. Patients with RLS grouped according to the total score, 1-10 points: mild, 11-20: moderate, 21-30: severe, 31-40 very severe.

The RLS patients were diagnosed according to the criteria of the IRLSSG.<sup>6,7</sup> The four minimal criteria include: (i) Urge to move the legs, usually accompanied or caused by uncomfortable leg sensations; (ii) temporary relief with movement, partial or total relief from discomfort by walking or stretching; (iii) onset or worsening of symptoms at rest or inactivity, such as when lying down or sitting; and (iv) an aggravation or onset of symptoms in the evening or at night. To assess the severity of RLS, we used the IRLSSG

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severity scale. Severity classification is as follows: Mild (1 – 10 points), moderate (11 – 20 points), severe (21 – 30 points), and very severe (31 – 40 points).

## Fatigue Assessment Scale:

The fatigue assessment scale, a self-reporting questionnaire, was used to evaluate fatigue. The FAS consisted of 10 questions; each one required a response on a scale of 1 to 5 (never to always). The total FAS value was determined by adding the results of all questions. The overall score was between 10 and 50. A value of 10-21 meant no fatigue; a score of 22-34 meant fatigued, and an FAS score of  $\geq$  35 meant extreme fatigue. <sup>8</sup>

#### **Data Collection Procedure**

Subjects were screened for eligibility and explanation about the study was given to the subjects. After obtaining informed written consent, data were collected in the hospital setting as per the convenience of the subjects for time and place (a private room or a bedside) during dialysis and non dialysis days using selected standardised instruments by self-report method and semi structured interview schedule. Each participant completed the "Dialysis Day" questionnaire within the first hour of dialysis session. The "Non-dialysis Day" questionnaires were completed on the following day within the same timeframe – approximately 24 h later. Depending on the day (dialysis or non-dialysis), reporting time was fixed to the specific day.

**Statistical Analysis:** The data were analysed using the Statistical Package for Social Science (SPSS) version 22.0(SPSS, Inc., Chicago, IL). Descriptive statistics (i.e. frequency, percentage, mean, range and standard deviation) and inferential statistics (i.e. t test, one way ANOVA and Pearson correlation coefficient test) were used. Level of significance was set as p<0.05.

#### **RESULTS:**

The socio-demographic characteristics of the study subjects are shown in Table 1. The mean age was 50.12 ± 13.87 years and 70.54% were male. The majority of the subjects belonged to Hindu religion (81.25%), married (88.40%), had secondary or higher secondary level of education (49.11). Among the study population, 31.15 % of the patients were unemployed and were engaged in professional/trained work, untrained work 19.64% and home maker (17.86%). About 75.89% of the subjects belonged to nuclear family, were residing in urban area (56.25%) and 49.11% had monthly family income in the range of Rs.10001-30000.

Table 1: Socio-demographic profile of CKD patients on hemodialysis (n = 112)

| Socio-demographic Variable                        | Mean ± SD                      |
|---|--------------------------------|
| Age in years                                      | 50.12 ± 13,87                  |
|   | Frequency (Percentage) / f (%) |
| • Less than 35                                    | 28 (25.00)                     |
| • 35-50   | 52 (46.43)                     |
| <ul> <li>More than 50</li> </ul>                  | 32 (28.57)                     |
| Sex   |                                |
| • Male  | 79 (70.54)                     |
| • Female  | 33(29.46)                      |
| Religion  |                                |
| • Hindu   | 91 (81.25)                     |
| • Muslim  | 9 (8.35)                       |
| • Christian                                       | 12(10.70)                      |
| Marital status                                    |                                |
| <ul> <li>Married</li> </ul>                       | 99 (88.40)                     |
| • Unmarried                                       | 9 (8.03)                       |
| • Others  | 4(3.57)                        |
| Educational status                                |                                |
| <ul> <li>No formal education</li> </ul>           | 12 (10.71)                     |
| • Primary   | 25(22.32)                      |
| <ul> <li>Secondary or Higher Secondary</li> </ul> | 55 (49.11)                     |
| Graduation or more                                | 20 (17.85)                     |

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| Occupation                  |            |
|-----------------------------|------------|
| Unemployed                  | 35 (31.25) |
| Trained/Professional        | 35 (31.25) |
| Untrained                   | 22 (19.64) |
| Home maker                  | 20(17.86)  |
| Type of family              |            |
| Nuclear                     | 85 (75.89) |
| • Joint                     | 27 (24.11) |
| Family monthly income in Rs |            |
| • Less than 10000           | 35 (31.25) |
| • 10001-30000               | 55 (49.11) |
| • 30001 or more             | 22 (19.64) |
| Area of residence           |            |
| • Urban                     | 63 (56.25) |
| Rural                       | 49 (43.75) |

Table 2: Clinical profile of CKD patients on hemodialysis (n = 66)

| Clinical Variable                        | Frequency (Percentage) / f (%) |  |  |
|--|--------------------------------|--|--|
| Body mass index BMI (kg/m2)              |                                |  |  |
| <18.5                                    | 31 (27.68)                     |  |  |
| 18.5-24.9                                | 57 (50.89)                     |  |  |
| 25-29.9                                  | 13 (11.61)                     |  |  |
| ≥30                                      | 11 (9.82)                      |  |  |
| Smoking Status                           |                                |  |  |
| Non-smoker                               | 78 (69.64)                     |  |  |
| Ex smoker (Quit)                         | 25 (22.32)                     |  |  |
| Smoker (Active)                          | 9 (8.04)                       |  |  |
| Use of Alcohol                           |                                |  |  |
| Yes                                      | 17 (15.18)                     |  |  |
| No                                       | 81 (72.32)                     |  |  |
| Past History                             | 14 (12.50)                     |  |  |
| History of renal transplantation         |                                |  |  |
| Yes                                      | 3 (2.68)                       |  |  |
| No                                       | 109 (97.32)                    |  |  |
| Co-morbid health conditions <sup>a</sup> |                                |  |  |
| Yes                                      | 98 (87.50)                     |  |  |
| Diabetes                                 | 65 (58.04)                     |  |  |
| Hypertension                             | 82 (73.21)                     |  |  |
| Glomrulonephritis                        | 23(20.54)                      |  |  |
| Others                                   | 25(22.32)                      |  |  |
| No                                       | 14(12.50)                      |  |  |
| HD cycles in a week                      |                                |  |  |
| Two                                      | 95 (84.82)                     |  |  |
| Three                                    | 17 (15.18)                     |  |  |
| Clinical Variable                        | Mean ± SD                      |  |  |
| Duration of illness                      | 3.85 ± 2.81                    |  |  |
| Age at onset of Dialysis                 | 48 ± 12.15                     |  |  |
| Duration of dialysis in years            | 3.12 ± 1.89                    |  |  |
| BUN (mg/dl)                              | 51.02 ± 18.62                  |  |  |
| HCT (%)                                  | $33.65 \pm 3.35$               |  |  |
| Hb (g/dl)                                | 11.15 ± 1.64                   |  |  |
| S. creatinine (mg/dl)                    | $7.5 \pm 2.3$                  |  |  |
| S. albumin (g/dl)                        | $3.8 \pm 0.85$                 |  |  |

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<sup>a</sup> Multiple response questions. BMI: Body mass index; CKD: Chronic kidney disease; Hb: Hemoglobin; HD: Hemodialysis; SD: Standard deviation; HCT: Hematocrit; BUN: Blood urea nitrogen; S.: Serum; f: frequency.

Table 2 depicts the clinical profile of patients with CKD. Half of the subjects, or 57 (50.89%), had a normal BMI (18.5–24.9 kg/m2). Further, nearly two third of the subjects, 78 (69.64) were non-smokers, 25 (22.32) quit smoking. In addition, majority of the participants 81 (72.32) did not consume alcohol and 14 (12.50) stopped taking alcohol. Majority of the CKD patients, 98 (87.50%), had associated comorbid health conditions, the most prevalent co-morbid conditions were hypertension (73.21%) and diabetes mellitus (58.04%). About 97.32% of the subjects had no history of kidney transplantation. Notably, the majority of subjects underwent three hemodialysis cycles per week (84.82%).

The mean duration of CKD was  $3.85 \pm 2.81$  years and average duration of undergoing dialysis was  $3.12 \pm 1.89$  years. The mean age at onset of dialysis was  $48 \pm 12.15$ . Lab indices showed that the mean Hb level of participants was  $11.15 \pm 1.64$  g/dl. Blood urea nitrogen (BUN) level had an average of  $51.02 \pm 18.62$  mg/dl, which was increased along with S. creatinine levels of  $7.5 \pm 2.3$  mg/dl. The mean serum albumin and haematocrit levels of the study participants were  $3.8 \pm 0.85$  g/dl, and  $33.65 \pm 3.35$  g/dl, respectively.

Table 3. Characteristics of RLS and Fatigue among Patients with CKD on dialysis and non-dialysis days

| Parameters                              | Dialysis day    | Non Dialysis day | t value / x2 | p value |  |  |
|---|-----------------|------------------|--------------|---------|--|--|
|   | Mean ± SD       | Mean ± SD        | value        |         |  |  |
| Fatigue#                                | 23.12 ± 4.56    | 21.5± 3.89       | 3.45         | 0.001** |  |  |
| RLS#                                    | 9.82 ± 5.13     | 9.35 ± 4.68      | 1.24         | 0.62    |  |  |
| RLS                                     | f (%)           | f (%)            |              |         |  |  |
| No RLS                                  | 101/112 (90.18) | 105/112 (93.75)  | 0.5437       | 0.46    |  |  |
| RLS                                     | 11/112 (9.82)   | 7/112 ((6.25)    |              |         |  |  |
| No RLS                                  | 101/112 (90.18) | 105/112 (93.75)  | 4.167        | 0.244   |  |  |
| RLS                                     | 11/112 (9.82)   | 7/112 ((6.25)    |              |         |  |  |
| Mild                                    | 7/11 (63.63)    | 6/7 (85.71)      |              |         |  |  |
| Moderate                                | 3/11(27.27)     | 1/7(14.29)       |              |         |  |  |
| Severe                                  | 1/11(9.09)      | 0/7(0.00)        |              |         |  |  |
| Very Severe                             | 0/11(0.00)      | 0/7 (0.00)       |              |         |  |  |
| Fatigue                                 | f (%)           | f (%)            |              |         |  |  |
| No fatigue                              | 65 (58.03)      | 81 (72.32)       | 87.539       | 0.001** |  |  |
| Fatigued                                | 47 (41.96)      | 31 (27.68)       |              |         |  |  |
| No fatigue                              | 65/112 (58.03)  | 81/112 (72.32)   | 8.612        | 0.013*  |  |  |
| Fatigued                                | 44/47 (93.62)   | 31/31 (100.00)   |              |         |  |  |
| Extreme fatigue                         | 3/47 (6.38)     | 0/31 (0.00)      |              |         |  |  |
| # Paired t test * p > 0.05 ** p > 0.001 |                 |                  |              |         |  |  |

The prevalence and characteristics of fatigue and restless leg syndrome on both dialysis and non-dialysis days are presented in Table 2. It revealed that the mean fatigue score was  $23.12 \pm 4.56$  and  $21.5 \pm 3.89$  on dialysis and non dialysis day respectively which was statistically significant at p<0.05. It can be interpreted that fatigue was high among the subjects on dialysis days compared to non dialysis days.

Out of 112 participants, 58.04% reported no fatigue and 41.96% had fatigue on dialysis day whereas 72.32% reported no fatigue and only 27.68% had fatigue on non-dialysis days which was statistically significant at p<0.05. 93.62% of the patients were fatigued and 6.38% had extreme fatigue on dialysis days whereas all the subjects (100%) had reported fatigued and none reported extreme fatigue on non dialysis days. This indicates that patients experienced more fatigue on dialysis days than non dialysis days. Among the participants, the mean average RLS score was  $9.82 \pm 5.13$  and  $9.35 \pm 4.68$  on dialysis and non dialysis day respectively which was not statistically significant at p<0.05. It can be interpreted that there was no difference in RLS experienced by the patients on dialysis days compared to non dialysis days. Out of 112 participants, 90.18 reported no RLS and only 9.82% of the subjects had RLS on dialysis day whereas 93.75% reported no RLS and only 6.25% had RLS on non dialysis days which was not statistically

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significant at p<0.05. Seven subjects had mild RLS, Moderate (3), severe (1) and no one reported very severe RLS on dialysis days whereas 6 patients (mild), 1 (moderate) RLS and no one reported severe or very severe RLS on non dialysis days. This indicates that patients experienced similar RLS on dialysis and non dialysis days.

#### **DISCUSSION**

This study highlights the significant prevalence and characteristics of RLS and fatigue among CKD patients, particularly on dialysis and non-dialysis days. Findings revealed a similar trend, moderate level of fatigue experienced by patients with CKD both during dialysis and non-dialysis days with a mean fatigue score of 23.12 ± 4.56 and 21.5± 3.89 respectively measured by FAS scale. This finding was consistent with the previous study findings experiencing fatigue as one of the most prevalent complaints by the patients with CKD. <sup>9,10</sup> The occurrence of fatigue in our study participants was 41.96% on dialysis day and 27.68% in non-dialysis day which was consistent with the study done by Khemchandani et al. <sup>11</sup> Our study results also demonstrated that severity of fatigue is significantly greater on a dialysis day than on a non-dialysis day. This finding was similar to the previous study done by Debnath et al in 2021. <sup>12</sup> These findings illuminate the significant burden of fatigue in this patient population. The exacerbation of fatigue symptoms on dialysis days may be attributed to factors such as fluid overload, electrolyte imbalances, and the physical toll of dialysis itself. The findings of our study illustrated that fatigue is an important hidden feeling of constant tiredness that most patients do not share with their family, friends, or doctors. The identification of multiple factors associated with fatigue can help healthcare providers in risk stratification and targeted interventions.

One of the most debilitating issues that haemodialysis individuals encounter is restless legs syndrome and more common than the general population.<sup>13</sup> In individuals receiving HD treatment, RLS is seen at varying frequencies. Global literature reveals a wide range of RLS prevalence in dialysis patients, from 6.6% to 70%.

The main finding of the current study is that RLS prevalence was 9.82% (11 patients) on the day of dialysis and 6.25% (7 patients) on non-dialysis days according to IRLSSG criteria and most of the subjects had mild RLS symptoms. Similar finding was reported by the previous study done by Ramachandran, et al in 2018 as the prevalence of RLS among patients with CKD was 10.3%. <sup>14</sup> On contrary to our study observations, higher prevalence of RLS have been reported by Pervez M et al and Amrish S. <sup>15, 16</sup>

There could be several reasons for this wide variation in frequency, first the heterogeneity of the study populations that is genetically variable, second the different definitions used for RLS and the tools used for diagnosis, third and the most important is the associated factors which could lead to the precipitation of RLS like Iron deficiency, diabetes mellitus, peripheral neuropathy and inadequacy of HD.<sup>17</sup>

RLS is many times unrecognized or underreported by this population. Early identification and treatment would help to prevent morbidity because of RLS and mortality in these patients. Our study provides the insight of presence and severity of RLS was congruent on dialysis and non-dialysis days among patients with CKD which calls urgent attention and intervention among this group.

The limitations of the current study are small sample size, single point of data collection, single study setting and data collection by self-report method. Therefore, multicentre studies with large sample size can be done to generalize the study findings.

The current study paves a path for implement routine screening and develops integrated care plans for RLS and fatigue in CKD patients. Future research should explore interventions targeting RLS and fatigue to improve patient outcomes.

## Conclusion

Restless Leg Syndrome and fatigue are prevalent and debilitating symptoms in CKD patients, particularly on dialysis than non-dialysis days. These findings underscore the necessity for healthcare providers to routinely screen for RLS and assess fatigue levels in CKD patients. By recognizing and managing these symptoms, healthcare providers can enhance the overall quality of life for CKD patients.

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