

## Original Article

# Restless Legs Syndrome and Quality of Life in Chronic Hemodialysis Patients

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### ABSTRACT

**Context:** Restless legs syndrome (RLS) is a sensorimotor disorder that often has a profound impact on sleep and one of the most troublesome conditions experienced in hemodialysis patients. **Aims:** The aim of study was to search frequency of RLS and effects of RLS on quality of life (QoL) in chronic hemodialysis patients. **Settings and Design:** Chronic hemodialysis patients of classical hemodialysis units were chosen. Length of the study was approximately 1 year. **Subjects and Methods:** Two hundred and thirty-seven patients were investigated. RLS was diagnosed using to international the RLS questionnaire. The International RLS (IRLS) rating scale was used to calculate RLS severity. QoL was assessed using the World Health Organization QoL brief version (WHOQOL-BREF) instrument. **Statistical Analysis Used:** Student's *t*-test, Chi-square test or Fisher's exact test, Bonferroni correction for multiple comparisons, and Pearson or Spearman correlation analysis were used. Significance level was  $P < 0.05$ . **Results:** The overall prevalence of RLS according to the four essential criteria was 18.6% ( $n = 44$ ). According to IRLS, 22.7% of the patients with RLS were mild ( $n = 10$ ), 63.6% were moderate ( $n = 28$ ), and 13.7% were severe ( $n = 6$ ). The parameters of QoL were compared in RLS-positive and negative patients. There was no significant difference in psychological health ( $P = 0.971$ ), social relationships ( $P = 0.462$ ), and environment ( $P = 0.483$ ) between two groups. Only the physical health scores were higher in without RLS than patients with RLS ( $P = 0.027$ ). **Conclusions:** This study revealed that the frequency of RLS among chronic hemodialysis patients is 18.6% and RLS leads to physical life quality disturbances.

**KEYWORDS:** Hemodialysis, quality of life, restless legs syndrome

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## INTRODUCTION

Restless legs syndrome (RLS)/Willis-Ekbom disease (WED) is a chronic sensorimotor neurological disorder. The estimated prevalence for diagnosed RLS/WED is 3.5%–4.4% of adult patients treated by this cohort of primary care doctors in these six western European countries.<sup>[1]</sup> It is characterized by leg discomfort with nocturnal aggravation, and the symptom severity aggravates with age. Therefore, RLS/WED patients commonly complain of both sleep disturbance and somatic symptoms.<sup>[1-3]</sup> Due to these clinical features, the quality of life (QoL) of RLS/WED patients is worse than that of healthy individuals.<sup>[4-8]</sup>

RLS/WED is also associated with renal insufficiency, pregnancy, iron deficiency anemia, diabetic neuropathy, and Parkinson's disease. RLS/WED is associated with increased prevalence of mood disturbances, sleep disturbances, and an impaired QoL.<sup>[8-11]</sup>

In 1995, the International RLS (IRLS) study group developed standardized criteria for the diagnosis of RLS/WED.<sup>[12]</sup> Since that time, additional scientific scrutiny and clinical experience have led to a better

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understanding of the condition.<sup>[13]</sup> The four minimal criteria must be present to diagnose RLS/WED.<sup>[13,14]</sup>

RLS/WED does not directly lead to life-threatening complications, but its symptoms may manifest chronically as considerable impairments to the patient's QoL.<sup>[8,15]</sup> There are only few studies available which have assessed the impact of RLS/WED on health-related QoL (HRQoL). These studies used established questionnaires such as the 36-Item Short Form Health Survey (SF-36), the RLS/WED QoL questionnaire (RLSQoL), and visual analog scales. It has been reported that the QoL (QoL) in RLS/WED patients is lower than in healthy controls. The higher disease severity was associated with the lower QoL scores.<sup>[5,6]</sup>

Up to now, there are no published studies which used the World Health Organization QoL Instrument (WHOQOL-BREF) to assess the HRQoL in patients with RLS/WED.

In this study, we aimed to evaluate the frequency and severity of RLS/WED and impact of RLS/WED on QoL using WHOQOL-BREF questionnaires in the chronic hemodialysis patients.

## SUBJECTS AND METHODS

### Study design, setting, and population

The study protocol was approved by the local ethics committee (protocol number = 2012/234). The participants were duly informed, and written and oral consent was obtained according to the principles of the Helsinki Declaration. To participate in the study, the patients had to have received regular hemodialysis for at least 6 months. Patients who refused to participate in the study or who were unable to communicate were excluded from the study. We excluded pregnant women, those with chronic neurological diseases (such as multiple sclerosis and Parkinson's disease) and rheumatologic diseases, and all participants with a history of chronically painful conditions such as arthritis, neuropathy, or muscle pain.

A questionnaire investigating demographic characteristics (age, gender, duration of dialysis therapy, renal disease history, and comorbid disease history), RLS questionnaire (RLSQ), and WHOQOL-BREF were filled by face-to-face interview technique.

Clinical information and dialysis-related data were obtained from the patient's file records. To assess the frequency of RLS/WED, we used the RLSQ. The IRLS rating scale was used to calculate RLS/WED severity.

### Restless legs syndrome questionnaire

Since the introduction of the four minimal criteria for RLS/WED in 1995 by the IRLS Study Group,<sup>[12]</sup> the

number of published studies in RLS/WED during the past 10 years has substantially increased. The presence of RLS/WED was diagnosed using internationally recognized criteria.<sup>[13]</sup> Participants who responded positively to all four questions were diagnosed as having RLS/WED.<sup>[12,14]</sup>

### The International Restless Legs Syndrome rating scale (International Restless Legs Syndrome Study Group)

The RLS/WED-positive patients completed the International Restless Legs Syndrome Study Group (IRLSSG) questionnaire. This questionnaire also included questions regarding the severity of RLS/WED symptoms. It consists of 10 questions about RLS/WED symptoms and their impact on daily activities and mood. All responses are graded in the range 0–4 (0 absence of a problem; 4 very severe problem) giving a maximum score of 40.

Participants with IRLS scores of <10 were categorized as mild, 11–20 as moderate, 21–30 as severe, and  $\geq 31$  as very severe.<sup>[12,13]</sup>

### Quality of life

The QoL was assessed using the WHOQOL-BREF questionnaire. The WHOQOL-BREF is a self-report scale that consists of 26 items. The WHOQOL-BREF includes four domains related to QoL: physical health, psychological health, social relationships, and environment. In addition, two items are examined separately, namely, the perception of overall QoL and overall health. The WHOQOL-BREF has been demonstrated to have satisfactory discriminant validity, internal consistency, and test-retest reliability.<sup>[16]</sup>

### Data analysis

Statistical analyses of the data were performed using the International Business Machines (IBM) Statistical Package for the Social Sciences (SPSS) software version 21.0 (IBM Corp. New York, USA). Comparison of the means was performed using Student's *t*-test and categorical variables were analysed with Chi-square test or Fisher exact test, as appropriate. Analysis of variance testing with Bonferroni correction for multiple comparisons was used to analyze the relationship between continuous and categorical variables. Univariate analysis was performed using the Pearson or Spearman correlation analysis, as appropriate. The results were interpreted using a 95% confidence interval and at a significance level of  $P < 0.05$ .

## RESULTS

This descriptive study was constituted of 237 (M:126, F:111) chronic hemodialysis patients. The mean age of the patients was  $59.8 \pm 14.3$  years. The mean

**Table 1: The evaluation of quality of life by the World Health Organization Quality of Life Instrument-BREF in patients with and without restless legs syndrome**

Parameters	RLS		Total (n=237), n (%)	$\chi^2$	P
	Positive (n=44), n (%)	Negative (n=193), n (%)			
Very bad	6 (50)	6 (50)	12 (100)	7.73	0.102
Not so bad	5 (14)	31 (86)	36 (100)		
Moderate	27 (17)	135 (83)	162 (100)		
Quite good	6 (23)	20 (77)	26 (100)		
Very good	0	1 (100)	1 (100)		

RLS=Restless legs syndrome

**Table 2: Feelings about various aspects from patients' life**

Parameters	RLS		Total (n=237), n (%)	$\chi^2$	P
	Positive (n=44), n (%)	Negative (n=193), n (%)			
Not satisfied at all	4 (44)	5 (56)	9 (100)	4.39	0.35
A little satisfied	7 (19)	30 (81)	37 (100)		
Moderately satisfied	27 (16)	137 (84)	164 (100)		
Quite satisfied	6 (23)	20 (77)	26 (100)		
Extremely satisfied	0	1 (100)	1 (100)		

RLS=Restless legs syndrome

**Table 3: Evaluation of life quality by World Health Organization Quality of Life Scale-BREF in the patients with and without restless legs syndrome**

WHOQOL-BREF parameters	RLS		t	P
	Positive (n=44), n (%)	Negative (n=193), n (%)		
Physical field	47.3 (20.6)	54.0 (17.4)	-2.22	0.02
Mental field	52.2 (13.6)	52.1 (12.1)	0.03	0.97
Social field	52.2 (15.6)	54.2 (16.6)	-0.73	0.46
Environmental field	62.9 (9.8)	64.0 (9.4)	-0.70	0.48

WHOQOL=World Health Organization Quality of Life Scale; RLS=Restless legs syndrome

dialysis duration was  $5.4 \pm 3.7$  years (range: 1–19 years). Nearly 32.1% of the patients had diabetes mellitus.

The overall prevalence of RLS/WED according to the four essential criteria in the all participants was 18.6% ( $n = 44$ ).

In the patients with diabetes mellitus ( $n = 76$ ), RLS/WED was determined in 15 patients (19.7%). In the nondiabetic patients ( $n = 161$ ), RLS/WED was determined 29 patients (18%). There was not statistically different ( $\chi^2: 0.102, P = 0.75$ ).

Age, gender, body mass index, blood pressure, education, smoking, dialysis duration, and some blood biochemistry levels including creatinine, urea, and calcium were not significantly related to RLS/WED ( $P > 0.05$ ).

According to the IRLSSG severity scale for RLS/WED (IRLS), of the RLS/WED-positive patients, 22.7% was found as mild ( $n = 10$ ), 63.6% as moderate ( $n = 28$ ), and 13.7% as severe categories ( $n = 6$ ). Of the participants, the mean score of the RLS/WED symptom severity was  $15.1 \pm 4.9$  (range: 6–26). The patients with moderate or severe

RLS/WED ( $n = 34$ ) were compared the patients with mild RLS/WED ( $n = 10$ ) for QoL. Physical, mental, social, and environment field parameters of WHOQOL-BREF were not different between the two groups ( $P > 0.05$ ).

Approximately, 63.6% of 44 RLS/WED patients had the disturbance of onset and maintenance of sleep. Roughly, a person with RLS/WED is 32 times more likely to have insomnia than RLS/WED-negative patients (OR = 32.025, %95CI [13.223–77.561]), ( $\chi^2 = 90.942, P = 0.0001$ ). A positive family history was found only two hemodialysis patients. None of the RLS/WED-positive participants had been previously diagnosed or treated for RLS/WED.

#### Impact of restless legs syndrome on quality of life

When we compared the perception of overall health and the QoL in the patients with ( $n = 44$ ) and without RLS/WED ( $n = 193$ ), there was no significant difference between two groups, statistically ( $\chi^2 = 7.734, P = 0.102$ ) [Table 1]. When we compared the perception of overall health and satisfaction from

life in with and without RLS/WED, there was no significant difference between two groups, statistically ( $\chi^2 = 4.398$ ,  $P = 0.355$ ) [Table 2].

When we compared the QoL parameters in RLS/WED-positive and RLS/WED-negative patients, there was no statistically significant difference in psychological health ( $P = 0.971$ ), social relationships ( $P = 0.462$ ), environment ( $P = 0.483$ ) between two groups, only there was an important difference in the physical health ( $P = 0.027$ ). The physical health scores were higher in without RLS/WED than RLS/WED-positive patients [Table 3].

## DISCUSSION

RLS/WED is an extremely distressing problem experienced by chronic hemodialysis patients; the prevalence appears to be greater than in the general population. In this study, the overall prevalence of RLS/WED according to the four essential criteria in the all participants was 19% ( $n = 44$ ).

Salman declared that RLS/WED frequency was seen in 20.3% of the hemodialysis patients in Syria.<sup>[17]</sup> Tuncel *et al.* published that RLS/WED was seen in 12% of hemodialysis patients.<sup>[18]</sup> Micozkadioglu *et al.* reported that the prevalence of RLS/WED was 4.7% in the hemodialysis patients.<sup>[19]</sup> Mucsi *et al.* presented that the prevalence of RLS/WED was 14%.<sup>[20]</sup>

Unruh *et al.* reported that 15% of dialysis patients were classified as having severe restless legs.<sup>[21]</sup> Merlino *et al.* found 19% to the prevalence of RLS/WED in chronic hemodialysis patients.<sup>[22]</sup>

On the other hand, Kim *et al.* published that RLS/WED was present in 46 (28.0%) of 164 dialysis patients.<sup>[23]</sup>

Al-Jahdali *et al.* reported that the overall prevalence of RLS/WED was 50.2% in 227 hemodialysis patients. This frequency was higher than our result. Approximately, 63.6% of 44 RLS/WED patients had the disturbance of sleep onset and maintenance of sleep. Roughly, a person with RLS/WED is 32 times more likely to have insomnia than RLS/WED-negative patients. Al-Jahdali *et al.* emphasized that the patients with RLS/WED were found to be at increased risk of having insomnia and excessive daytime sleepiness (EDS).<sup>[24]</sup>

In our study and other studies, it was determined that RLS/WED is a common problem in hemodialysis population and was significantly associated with other sleep disorders, particularly insomnia, and EDS.

Wesstrom and *et al.* stated that RLS/WED-positive women had an impaired mental HRQOL compared to RLS/WED-negative women in the studied population.<sup>[25]</sup>

In Abetz' study, comparison of the SF-36 scores of patients with RLS/WED and the normative general population suggests that the RLS/WED has a significant impact on patients' QOL.<sup>[26]</sup>

Lee issued that the scores for the subscales of QoL in patients with RLS were lower than the normal group for general health, physical functioning, role limitations due to emotional problems, role limitation due to physical problems, social functioning, bodily pain, vitality, and mental health.<sup>[27]</sup>

The physical health scores were higher in without RLS/WED than RLS/WED-positive patients in our study. That is, physical health scores of life quality that is measured by WHOQOL-BREF were bad in chronic hemodialysis patients with RLS/WED. Musci *et al.* in their study found that RLS/WED patients were twice as likely to have significant insomnia as patients without RLS/WED (35% vs. 16%;  $P < 0.05$ ). Furthermore, RLS/WED was associated with impaired overall sleep quality and poorer QoL.<sup>[21]</sup>

Cho *et al.* showed that RLS/WED has a considerable impact on the QoL of Koreans, which is comparable with studies of western countries. The QoL impairment relates to the degree of depression with RLS/WED for Koreans.<sup>[28]</sup>

In the study of Kawauchi *et al.*, it was found that RLS/WED frequency was 23% in hemodialysis patients, and health-related QoL (KDQOL-SF) was significantly lower in the RLS/WED group.<sup>[29]</sup> In another study, RLS/WED prevalence was found 42% in hemodialysis patients, and QoL was low in patients with RLS/WED.<sup>[30]</sup>

As similar to findings of these studies, we also found that RLS/WED led to poor QoL in the hemodialysis patients. In addition, to investigate impact of RLS/WED on QoL, WHOQOL-BREF questionnaires were firstly used in literature.

## CONCLUSIONS

We founded that the frequency of RLS/WED (19%) among chronic hemodialysis patients is similar to literature. The presence of RLS/WED in hemodialyzed patients negatively affects QoL. RLS/WED is associated with poor sleep and impaired QoL in patients on maintenance dialysis.

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## Conflicts of interest

There are no conflicts of interest.

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