Restless Legs Syndrome among End Stage Renal Disease Patients Undergoing Hemodialysis

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1.ABSTRACT

Restless legs syndrome is a prevalent medical problem; it can be classified into 2 types primary and secondary. It is a common hemodialysis complication that has been linked to decreased quality of life and an increased risk for additional complications. Therefore, ***the aim*** was to describe the phenomenon of Restless Legs Syndrome among End Stage Renal Disease Patients Undergoing Hemodialysis. ***Method and Subjects***, A cross sectional research design has been utilized. Sample of this study comprised of 245 ESRD Patients who was undergoing long-term hemodialysis in hemodialysis units at Mansoura University Hospital, this study included three tools . Tool I: Interviewing questionnaire: The researcher designed this tool after reviewing relevant literature; it consisted of 2 parts; to assess personnel and medical data related to study participants, tool II: International Restless Legs Syndrome Study Group Rating Scale for Severity of Restless Legs Syndrome, it was adapted to assess severity of RLS, tool III: Medical Outcomes Study Questionnaire Short Form 36 Health Survey (SF-36) used to evaluate overall health status. ***Results*** *indicate that* less than half had severed RLS. ***Conclusion,*** there was a significant relation between RLS and overall health status for patients undergoing hemodialysis.

Keywords: End Stage Renal Disease, Hemodialysis, Patients, Restless Legs Syndrome.

2.Introduction:

Restless legs syndrome (RLS) is a prevalent neurological condition, RLS can be classified into 2 types primary and secondary. Primary RLS related to positive family history and more common in people older than 45 years. Secondary RLS related to other conditions such as uremia, pregnancy, DM, Rheumatoid arthritis, and iron deficiency state (Saraji., Hami., Boostani., & Mojahed., 2017).

RLS symptoms are Uncomfortable or strange sensations in the arms or legs, along with a need to move the limbs, Movement can briefly ease the symptoms, which typically occur during rest and at night. RLS has a deleterious effect on patient's quality of life and is linked to mental health issues like anxiety and depression. (Lin., Zhang ., Qiu., Nil., Yu., *et al* 2019).

The prevalence of RLS where between 3 and 9% of people, depending on their age and gender. However, ESRD, which is defined as a persistent loss of renal function and demanding renal replacement treatment or dialysis, has a 6.6 - 70% prevalence of RLS, that is significantly greater than the overall population (Lin., Wu ., Li., SY., Wu., *et al.,* 2013).

The symptoms of RLS comprise parathesis, creeping or crawling sensations, or even discomfort in the calves and legs that only happens while the legs are immobile, like during hemodialysis (Sathish., & Pavan., 2014). There are many reports that discussed the relation between RLS and mental health, depression, decrease quality of life, increase mortality in patients undergoing hemodialysis (Giannaki ., Hadjigeorgious ., |Karatzaferi ., Pantzaris ., Stefanidis ., *et al* 2014).

2.1- Aim of the study was:

To describe the phenomenon of Restless Legs Syndrome among End Stage Renal Disease Patients Undergoing Hemodialysis.

2.2Research Questions:

Q1. What is the severity of Restless Legs Syndrome among End Stage Renal Disease Patients Undergoing Hemdialysis?

Q2. What are the correlates of Restless Legs Syndrome among End Stage Renal Disease Patients Undergoing Hemdialysis?

3-Subjects &Method:

3-1 Research design: The study Utilized a cross sectional research design.

3-2 Setting: This study was carried out at Main Mansoura University Hospitals' hemodialysis unit., Egypt. The unit composed of large hall with 20

hemodialysis machines, in addition to medical department 3 and other parts beside neurology department include 17 hemodialysis machines. Every unit served three shifts \ day.

3-3 Subjects: About 245 End Stage Renal Disease Patients who was undergoing long-term hemodialysis in hemodialysis units at Main Mansoura University Hospital were enrolled as the following, based on a previous study by Lin et al. (2019), Patients with ESRD had a prevalence of RLS of 20.44% and it also reported that 89.3% vs 67.0%, p = 0.02, having higher risks of sleep problems according to PSQI sum scores. A total of randomly selected 246 ESRD patients from a presumed infinite population will be enrolled in this study to achieve 5% precision, 20% prevalence and accordingly 95% confidence interval specified limits of 15% - 25% with a design effect = 1.0. This was calculated by Epi Info™ software (version 7.2.3.1). Group sample sizes of 42 in group 1 (the RLS group) and 204 in group 2 (the control group) riche 92.7% power to detect a difference between the group proportions of 0.2230. The proportion in group 1 (the RLS group) is assumed to be 0.6700 under the null hypothesis and 0.8930 under the alternative hypothesis. The proportion in group 2 (the control group) is 0.6700. The test statistic used is the one-sided Z-Test with unpoled difference. The significance level of the test is 0.050 and was measured by G*Power software (version 3.1.9.6).

3-4 Tools:

The following three instruments were utilized in this research:

Tool I: Interviewing questionnaire: This tool was designed by the researchers after reviewing related literature; it include 2 parts;

Part 1: Demographic data sheet. It used for collection of personal data such as gender, age, marital status, education level, duration of dialysis, frequency of dialysis, causes of renal disease, and BMI.

Part 2: laboratory blood tests: It used to assess blood results such as, serum hemoglobin, platelet level, hematocrit, serum calcium, phosphorus, and creatinine.

Tool II: International Restless Legs Syndrome Study Group Rating Scale for Severity of Restless Legs Syndrome.

It was adapted from (International Restless Leg Syndrome Study Group, 2003). It consisted of 10 questions and has rating for their symptoms ranged from 0 to 4 for each question, total score ranged from 0 to 40 and divided into mild "from 0

to 10", moderate "from 11 to 20", sever "from 21 to 30" and very sever from "31 to 40".

Tool III: Medical Outcomes Study Questionnaire Short Form 36 Health Survey (SF-36).

It adapted from (McHorney., Ware., Lu., & Sherbourne., 1994), The SF-36 measures general health status. The scaled scores on the SF-36 are the weighted sums of the questions in each part. There are eight scaled scores. Scores are between 0 and 100. Higher scores equal less disability whereas lower scores indicate greater disability Indicators of general health views, physical role functioning, emotional role functioning, social role functioning, and mental health were included

3-5 Validity : Five experts from the Mansoura University's faculties of nursing and medicine evaluated the developed tool for clarity, relevance, understanding, and suitability for implementation before testing it for content-related validity. Minor modifications were made in response to their criticisms.

3-6 Reliability: Internal consistency reliability and construct validity for the IRLS total score, symptoms and symptoms effect subscales were acceptable (alpha=0.81, 0.80, and 0.76, respectively)" (Abetz ., Arbuckle., Allen., Borreguero., Hening., *et al*, 2006). Most of research that assess the reliability of the SF_36 have exceeded 0.80. determining reliability in the physical and mental sections are typically above 0.90.

3-7 A pilot study was carried out on 10% of subjects before starting of data collection to test the tool for its relevance, feasibility, applicability, reliability, clarity and to verify the length of time needed to gather the data from each participant.

3-8 Ethical considerations: Ethical approval was granted from the Research Ethics Committee of the Faculty of Nursing at Mansoura University Reference No. (p.0218). This study was conducted with permission from the administrators of Hospitals after explaining the aim of study.

3-9 Field work: The researchers introduced themselves to the participants, explained the aim of the study and how to fill the questionnaire, consent was taken from participants and asked them for their cooperation.

3.10Statistical analysis: Data were enrolled and interpreted using IBM-SPSS software (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.), and Stat. Qualitative data were presented as frequency and percentage. Quantitative data were firstly tested for

normality using Shapiro-Wilk's test with data being normally distributed if p>0.050. The significant outliers (extreme values) was investigated for by inspecting boxplots. Quantitative data were expressed as median and interquartile range (IQR). To assess quantitative data for two groups, Mann-Whitney U test was utilized. Reliability testing (Internal consistency) was performed using Cronbach's Alpha. Point biserial correlation was used to assess the association between a dichotomous variable (nominal with two categories) and a continuous variable. Spearman's correlation was used to assess the association between two continuous variables. Results for any test used were determined statistically significant if the p value was less than 0.050. When necessary, appropriate charts were developed to display the data graphically.

4.Results:

Table 1: This table illustrated demographic and medical data of the studied cases, about (49.4%) of participants aged from 50 to 60 years old, (55.1%) were male. About level of education (31%) were illiterate, the majority of studied sample (71%) were married. Hypertension was more prevalent in (71.4 %), (82.9%) hasn't family history related to chronic diseases. Regarding daily habits, (56.3%) drinking a lot of tea, more than half (56.3%) have normal body weight.

Concerning quantitative lab results, the median for hemoglobin level (9), median for hematocrit (46), median level for platelet (190), serum creatinine level (7.9), serum calcium level (8.2), and serum phosphorus (4.5).

Table (2): This table showed ESRD and hemodialysis characteristics, regarding suffering from ESRD (78.4%) suffering more than 2 years. (81.6%) doing hemodialysis is more than 2 years ago. Concerning times of dialysis per week, (97.6%) perform dialysis 3 sessions per week. The duration of dialysis session for the majority of participants (99.6%) take 4 hours. The most common shift for dialysis session (54.3%) was morning shift. About (88.6%) using fistula for dialysis and about (18.8%) have uremic pruritus. There were lowering into SBP, DBP, MAP post dialysis session where the median (110,70, 83.3 respectively).

Table (3): This table illustrated distribution of severity of RLS, about (44.9%) of cases has severed RLS.

Table (4): This table shows that IRLS was statistically significantly correlated with the

following parameters: Presence of diabetes (higher score in presence of DM, median IRLS = 26.5 vs. 24 in those with and without DM, respectively). Drinking a lot of tea (higher score in drinking a lot of tea, median IRLS = 25 vs. 22 in those drinking and not drinking a lot of tea, respectively). Smoking (higher score in non-smokers vs. smokers, median IRLS = 25 vs. 21 in non-smokers vs. smokers, respectively). Presence of uremic pruritus (higher score in those suffering from uremic pruritus, median IRLS = 26 vs. 24 in uremic pruritus vs. no pruritus, respectively).

A statistically significant positive correlation of low strength with age, and BMI. A statistically significant negative correlation of low strength with serum creatinine, and of medium strength with serum phosphorus.

Table (5): This table showed a statistically significant positive correlation od medium strength between IRLS total score and pain score, and a statistically significant negative correlation between IRLS total score and all other SF-36 domains of low strength with social functioning, and medium strength with other domains.

5.Discussion:

Restless legs syndrome, which is common phenomena among hemodialysis patient, have been linked to worse quality of life and a greater risk of complications. This syndrome causes patients to have a strong, irrational urge to move their legs, which is primarily brought on by an uncomfortable sensation that gets worse while they are resting.

Regarding demographic characteristics of participants, slightly less than half were aged between 50 years to 60 years. This may relate to that RLS happened more for elderly dialysis patients. In relation to sex, above half were male, this may relate to Male patients exhibit much higher rates of ESRD incidence and CKD prevalence than those seen in female patients. *(Yang., Xie ., Anderson., Joffe., Greene., et al, 2014)*. In contrast to *(Saraji ., Hami ., Boostani ., Mojahed ., 2017)* who reported that the majority of it study were female.

Concerning education level, less than one third were illiterate, but *(Lin ., Zhang ., Qiu ., Ni ., Yu ., et al., 2019)* proved that above half reached to middle school learning. About marital status less than three quarter were married, in the same point *(Tsai ., Chen., Lin., Tsai., Han., et al., 2021)* proved that the majority of participants were married.

Concerning history of disease, hypertension prominent in majority of patient and this is in the

same line with Teo etal .,(2021)who reported that the hypertension is the prevalent risk factor in ESKD patient . Above three quarter of studied participants have negative family history, in the same line *(Lin ., Zhang ., Qiu ., Ni ., Yu ., et a l., 2019)* who reported that the majority were without family history. Regarding daily habits, above half drinking a lot of tea, Also *(Lin ., Zhang ., Qiu ., Ni ., Yu ., et a l., 2019)* found that the largest proportion has the daily habit of drinking tea, but **(** *Chavoshi., Einollahi., Haghighi., Saraei., & Izadianmehr., 2015)* illustrated that the majority were smoking. About BMI *(Samavat ., Fatemizadeh ., Fasihi ., & Farrokhy ., 2017)* illustrated that BMI were (25.4 ± 5.2). In this presented study above the half has normal body weight. This result didn't approve the relation between weight gain and occurrence of RLS. The serum hemoglobin level showed lower value 9 and this is in line with *(Castillo-Torres., Ibarra-Sifuentes ., Sánchez-Terán., Sánchez-Martínez,., Chávez-Luévanos., et al., 2018).* who found that the RLS patients had low hemoglobin level .

The largest proportion of studied sample suffering from ESRD since more than 2 years. Also the majority of participants performed dialysis more than 2 years ago, in the same line *(Achmad., & Rusmai.., 2021)* who reported that above half perform dialysis for more than one year. About number of dialysis session per week, the majority of participants perform 3 times per week, also (*Lin ., Zhang ., Qiu ., Ni ., Yu ., et a l., 2019)* proved that the majority perform 3 session per week for dialysis.

Regarding duration of each session, approximately all participants take 4 hours for each dialysis session, and *(Chavoshi., Einollahi., Haghighi., Saraei., & Izadianmehr., 2015)* found that time for each session take 3.90 . About dialysis shift, above half of study sample perform dialysis into morning shift, this is in accordance with *(Samavat ., Fatemizadeh ., Fasihi ., & Farrokhy ., 2017)* who found the same results. Regarding type of dialysis access, above three quarter used fistula for dialysis, on other hand *(Torres ., Sifuentes., Teran., Martinez.., Luevanos., et al., 2018)* who illustrated that all participants used intravenous catheter.

As regard to, uremic pruritis less than one quarter suffering from it, *(Torres., Sifuentes., Teran., Martinez.., Luevanos., et al., 2018)* recommended that less than half had uremic pruritis.

The finding of this study showed that, there was a significant lowering in all blood pressure measurements after HD session. This is in agreement with *(Teama ., Soliman., Elsharkawy., & Elsharabasy., 2012)* who revealed that dialysis is efficient tool to remove excess sodium & water. Longer HD sessions result in greater improvements in UF volume, mean SBP & DBP, pre-dialysis SBP & DBP, and post-dialysis SBP & DBP. It is necessary to raise awareness about the benefits of longer and frequent HD.

Concerning severity of RLS, the finding of current study presented that   less than half had sever RLS, this goes with *(Samavat ., Fatemizadeh ., Fasihi ., & Farrokhy ., 2017)* who releaved that less than half had sever and very sever RLS. Also *(Lin ., Zhang ., Qiu ., Ni ., Yu ., et a l., 2019)* described RLS a common complication in patients with ESRD and linked to significant morbidity.

A study carried out by (Bathla*., Ahmed., Gupta., & Ahmad., 2016)* who illustrated that no significant relation between RLS and DM. According to our study, there was a significant correlation between DM and IRLS. Regarding correlation between RLS and drinking a lot of tea and smoking, the current study proved a significant correlation between IRLS and drinking a lot of tea and smoking, but *(Araujo., Bruin.,Nepomuceno.,Maximo.,Daher., et al, 2010)* reported that no significant association between smoking , drinking tea or coffee and RLS.

A study carried out by *(Torres., Sifuentes., Teran., Martinez.., Luevanos.,   et al., 2018*), stated a significantly higher prevalence of uremic pruritus among patients with RLS. In the same line, current study found significant correlation between presence of uremic pruritus and RLS. This might be because uremic pruritus is among the most uncomfortable symptoms in people with chronic renal failure.

The results of study also revealed that a statistically significant correlation of low strength with age, this was in harmony with (*Saraji ., Hami ., Boostani ., & Mojahed ., 2017)* who reported that RLS happened more in older dialysis patients. In the present study, there was a statistically significant positive correlation of low strength with BMI. This goes in line with *(Wali ., & Alkbouli ., 2015)* who indicated that BMI as a risk factor linked to a greater chance of RLS.

According to *(Araujo., Bruin., Nepomuceno., Maximo., Daher., et al, 2010)* who shown that an investigation of much bigger series is required to fully understand the relationship between anomalies in calcium, phosphorus, and parathormones and their relationship to RLS. But the findings of the present study found a negative

significant correlation of low strength with serum creatinine and medium strength with serum phosphorus.

Regard correlation between IRLS and SF-36 domains, there was positive correlation between IRLS total score and pain score, and negative correlation between IRLS total score and all other SF-36 domains. This goes with (*Akbas., & Sazbir., 2019*) who proved that all SF-36 subscales, except for "mental health" and "overall health perception," had a negative connection with RLS severity, indicating that a rise in RLS severity is linked with a fall in quality of life. Also, (*Kubo., Sugawara., Kaneda., Takahashi., & Nakamura ., 2016)* reported a significant and negative association between symptoms of RLS and physical functioning, role – physical functioning, bodily pain, social functioning, and the physical composite summary score. These results indicated to the importance for early screening and treatment for RLS symptoms.

6.Conclusion: The study found association between RLS and health status among ESRD Patients.

7.Recommendation: The following recommendations are proposed based our study findings:

- Workshops to increase Awareness of health care providers about symptoms of RLS
- Further studies need to verify the possible risk factors for RLS.
- Other studies need to apply for fully understanding causes and consequences of RLS in dialysis patients.
- Further studies need to apply for investigating the relation between RLS and quality of life in different groups.
- Appropriate intervention and management will make difference into quality of life for patients with RLS undergoing dialysis.

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Table (1): Demoghraic and Medical Characteristics of the Studied Cases (N=245)

Categorical characteristic	N (%)
• **Age (years)**	
20 year to <30 year	18 (7.3%)
30 year to <40 year	36 (14.7%)
40 year to <50 year	70 (28.6%)
50 year to 60 year	121 (49.4%)
• **Sex**	
Male	135 (55.1%)
Female	110 (44.9%)
• **Educational level**	
Illiterate	76 (31%)
Read and write	69 (28.2%)
Middle education	63 (25.7%)
University education	37 (15.1%)
• **Marital status**	
Single	41 (16.7%)
Married	174 (71%)
Widow	27 (11%)
Divorced	3 (1.2%)
• **History of DM**	72 (29.4%)
• **History of Hypertension**	175 (71.4%)
• **History of Anemia**	39 (15.9%)
• **Family history of chronic disease**	
Family history of DM	25 (10.2%)
Family history of Hypertension	17 (6.9%)
No family history	203(82.9%)
• **Daily habits**	
Drinking a lot of coffee	12 (4.9%)
Drinking a lot of tea	138 (56.3%)
Smoking	29 (11.8%)
No related habits	66(27%)
• **BMI**	
Underweight	56 (22.9%)
Normal weight	138 (56.3%)
Overweight	51 (20.8%)
Quantitative characteristics	**Median (IQR)**
Hemoglobin level (g/dl)	9 (8 – 10.2)
Hematocrit value	46 (32.5 – 72.3)
Platelet count	190 (155 – 222)
Serum creatinine (mg/dl)	7.9 (6.3 – 8.9)
Serum calcium (mg/dl)	8.2 (7.3 – 9)
Serum phosphorus (mg/dl)	4.5 (3.7 – 5.3)

Notes: IQR is presented as 25th and 75th percentiles (IQR = 75th percentile *minus* 25th percentile).

Table (2): End Stage Renal Disease and Hemodialysis Characteristics of the Studied Cases (N=245):

Categorical characteristic	N (%)
How long have you been suffering from the end stage renal disease?	
<1-year	26 (10.6%)
1-2 years	27 (11%)
>2-years	192 (78.4%)
How long have you been doing dialysis?	
<1-year	20 (8.2%)
1-2 years	25 (10.2%)
>2-years	200 (81.6%)
How many dialysis times per week?	
3 per week	239 (97.6%)
4 per week	6 (2.4%)
What is the duration of dialysis session?	
4-hours	244 (99.6%)
5-hours	1 (0.4%)
What is the period of (shift) dialysis?	
Morning shift	133 (54.3%)
Afternoon shift	46 (18.8%)
Night shift	66 (26.9%)
Type of dialysis catheter	
Fistula	217 (88.6%)
Catheter	24 (9.8%)
Other	4 (1.6%)
Uremic pruritus	46 (18.8%)
Quantitative characteristics	**Median (IQR)**
Pre-dialysis blood pressures (mmHg)	
SBP	130 (110-140)
DBP	80 (70-90)
Mean arterial pressure (MAP)	96.7 (83.3-106.7)
Post-dialysis blood pressures (mmHg)	
SBP	110 (110-120)
DBP	70 (70-80)
Mean arterial pressure (MAP)	83.3 (83.3-93.3)

Notes: IQR is presented as 25th and 75th percentiles (IQR = 75th percentile *minus* 25th percentile).

Table (3): Distribution of Study Participant According to Severity of RLS in the Studied Cases (N=245):

Grade of severity	N (%)
• **Mild** (IRLS = 0-10)	9 (3.7%)
• **Moderate** (IRLS = 11-20)	73 (29.8%)
• **Sever** (IRLS = 21-30)	110 (44.9%)
• **Very sever** (IRLS = 31-40)	53 (21.6%)

Table (4): Correlation between IRLS among End Stage Renal Disease Patients Undergoing Hemodialysis with their Demographic and Medical Data:

Parameter	Correlation coefficient	P value
	r_{pb}	
• Sex	-0.033	0.611
• Presence of DM	0.165	**0.010**
• Presence of hypertension	0.056	0.380
• Presence of anemia	-0.025	0.693
• Drinking a lot of coffee	0.044	0.493
• Drinking a lot of tea	0.148	**0.021**
• Smoking	-0.154	**0.016**
• Uremic pruritus	0.139	**0.030**
• HD times / week	0.040	0.538
	r_s	
• Age category	0.226	**<0.001**
• Education level	-0.094	0.144
• BMI	0.266	**<0.001**
• CKD duration	0.084	0.192
• HD duration	0.008	0.901
• Hemoglobin level (g/dl)	0.063	0.323
• Hematocrit value	0.013	0.835
• Platelet count	-0.083	0.194
• Serum creatinine (mg/dl)	-0.268	**<0.001**
• Serum calcium (mg/dl)	-0.082	0.199
• Serum phosphorus (mg/dl)	-0.374	**<0.001**

Notes: r_{pb} = Point biserial correlation coefficient. r_s = Spearman's correlation coefficient.

Table (5): Correlation between IRLS Total Score and SF-36 Domains:

Domains	r_s	P value
• Physical functioning	- 0.446	**< 0.001**
• Role functioning/physical	- 0.483	**< 0.001**
• Role functioning/emotional	- 0.435	**< 0.001**
• Energy/fatigue	- 0.354	**< 0.001**
• Emotional well-being	- 0.406	**< 0.001**
• Social functioning	- 0.283	**< 0.001**
• Pain	0.350	**< 0.001**
• General health	- 0.294	**<0 .001**

r_s = Spearman's correlation coefficient.