



Evaluation of the relationship between restless legs syndrome, mental status, and sleep disorders among Moroccan women during their third trimester of pregnancy

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Background: Restless legs syndrome (RLS) is a motor disorder encountered during pregnancy and leads to psychological and sleep impairments. The latter seems to be non-restorative and its occurrence alters the quality of life of pregnant women. The objective of this study was to evaluate the prevalence of RLS and its relationship with both anxio-depressive symptoms and sleep disorders among a population of Moroccan pregnant women during their third trimester of pregnancy.

Methods: A cross-sectional study was conducted in a population of pregnant women in their third trimester ($n = 178$) admitted to two health facilities in the city of Marrakech: Youssef Ibn Tachafine and Oasis. The face-to-face questionnaire was used to collect data including demographic and clinical characteristics, the four diagnostic criteria of RLS, the Pittsburgh Sleep Quality Index (PSQI), and the Hospital Anxiety and Depression Scale (HADS). Patients were divided into two groups RLS + (women with RLS) and RLS – (women without RLS).

Results: The prevalence of RLS was 59.5%; this syndrome was more common in the ninth month (74.15%) compared with the seventh and eighth months. Sleep impairment, including sleep efficiency, was significantly higher in RLS + than RLS – (P -value 0.05). Anxiety but not depression is significantly increased in RLS + compared to RLS – (48.11% versus 38.8%, $P = 0.000$). There were no significant differences between RLS + and RLS – in terms of socio-demographic and other clinical characteristics.

Conclusion: RLS is encountered during the prenatal period, with a higher prevalence in the last trimester. During this stage of pregnancy, women suffering from RLS were vulnerable to anxiety and sleep disorders. Prevention and early diagnosis of RLS could be a proactive healthcare management leading to better health outcomes and better conditions of pregnancy, which precedes childbirth.

Keywords: anxiety and depression disorders, restless legs syndrome, sleep disorders, third trimester of pregnancy

Background

Pregnancy is a period during which women are likely to develop certain pathologies, in particular restless legs syndrome (RLS) recognized as one of the causes of sleep disorders in pregnant women^[1]. The latter, also named Willis-Ekbom disease (WED), is a neurological, sensory motor disorder^[2]. It is characterized by

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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Annals of Medicine & Surgery (2024) 86:2626–2632

Received 22 December 2023; Accepted 8 March 2024

Published online 21 March 2024

<http://dx.doi.org/10.1097/MS9.0000000000001987>

HIGHLIGHTS

- Pregnant women are more vulnerable to the development of restless legs syndrome (RLS) due to the conditions of pregnancy.
- This syndrome occurred significantly during the last trimester of pregnancy.
- Women suffering from RLS at the time of pregnancy are more prone to sleep disorders and mental health disorders.

unpleasant and painful sensations, such as formication, most often localized to the lower limbs, associated with a compelling need to move the legs in order to obtain relief from the discomfort. This symptom is usually exacerbated during the rest and in the evening^[3,4]. The pathophysiology of the syndrome remains unknown and even elucidated. It is mostly primary, involving a very likely genetic component and/or associated with central dopaminergic dysfunction^[5]. It may be secondary, linked to a condition such as dysregulation of transmembrane iron passage, end-stage renal disease, pregnancy, or peripheral neuropathy^[6]. The prevalence of this disorder varies according to the stage of pregnancy and the characteristics of the target population, and is generally high in the last trimester, particularly in the seventh and eighth months. The development and the aggravation of RLS

during gestation is undetermined, but many hypotheses have been developed. A variety of endocrine changes occur, with increased estradiol, progesterone and prolactin secretion as well as deficiency of iron-serum and folate levels and ferritin during pregnancy^[7]. The prevalence of RLS during pregnancy is two to three times higher than in the general population and symptoms are usually relieved after delivery^[8]. The results of a study conducted in Saudi Arabia revealed that the prevalence of RLS in the third, second, and first trimester was 24.1%, 14.3%, and 13.6%, respectively^[9]. But in another study of Japanese women, they found that only a small percentage of orders (19.9%) suffered from RLS during pregnancy^[10]. In addition, gestational hypertension and preeclampsia are very common in women with RLS^[11,12].

Data from the literature showed that RLS influences quality of life, including social function, emotional role, and vitality, and exhibited significant mental health impairments^[13]. According to that, a link between RLS and anxiety-depressive disorders was reported; women who complained about signs of RLS before pregnancy had an increased risk of depression during and after pregnancy^[5]. However, no clinical studies have so far shown the relationship between RLS detected for the first time at gestation and its impact on mental state, especially the development of anxiety and depression disorders. Beside this, RLS significantly alters sleep quality through sleep deprivation, daytime sleepiness, and poor daytime function^[9]. Other studies suggested that RLS can be a major risk factor for maternal complications during pregnancy and childbirth as well as fetal complications^[14].

To our knowledge, there is no published data regarding the prevalence of RLS among Moroccan pregnant women and its association with other mental and neurological comorbidities. The aim of this study was to answer two research questions related to the following objectives: (i) to determine the prevalence of RLS among a sample of Moroccan pregnant women during their third trimester and (ii) to study the possible association between RLS and other clinical complications such as anxiety-depressive symptoms and sleep disorders.

Materials and methods

Population and setting

The present cross-sectional study was conducted over a period of 7 months in two different health structures in the province of Marrakech, a second-level health center named Youssef Ibn Tachafine and another first-level center named Oasis. Almost 200 pregnant women in the third trimester of pregnancy, who had received a service either through the pregnancy monitoring program or through delivery monitoring, were invited to collaborate in this study; only 178 women agreed to participate. The work has been reported in line with the STROCSS criteria for the cross-sectional study^[15].

Inclusion criteria were (1) women in their last 3 months of pregnancy, (2) aged 18 years or older, (3) pregnancy progressing normally with no history of hospitalization, (4) pregnancy well attended since the first trimester, and (5) written and signed informed consent.

Exclusion criteria: (1) Foreign pregnant women; (2) unable to understand, communicate, and speak Moroccan dialectal Arabic; (3) women with pregnancy-related or pre-pregnancy pathologies; (4) multiple pregnancies (twin pregnancies and triplets, etc.); (5)

cognitive or hearing impairments; and (5) a history of psychiatric disorders.

Patients were not included in the study if they had eclampsia or preeclampsia, renal insufficiency, diseases that can lead to peripheral neuropathy such as diabetes mellitus or thyroid disease, or a history of RLS before pregnancy.

Health professionals practicing in these health centers invited pregnant women to participate in the study. Pregnant participants were randomly chosen among those benefiting from medical follow-up or those coming for a general health check-up. After that, the principal investigator explains the aim of the study to the participants, then begins to read each question and the valid answers using pre-structured questionnaires, then ticked the answer chosen by women. This procedure takes ~25 min to complete the questionnaire.

Measurements

The collection tool used was a questionnaire administered during a face-to-face interview, which contained open and closed questions as well as scales allowing for a global evaluation:

- (1) Socio-demographic characteristics included age, height, body weight, education, economic level, parity, number of previous pregnancies, number of children, etc. Personal behavior (exercise, consumption of stimulants, iron, and vitamins) and previous medical diseases. Medical information was also obtained from the follow-up books of all participants, including demographic characteristics, course and evolution of the current pregnancy and previous pregnancies, and medical, gynecological, surgical, and family history.
- (2) Pittsburgh Sleep Quality Index (PSQI): This scale developed in English^[16], then translated and validated in Arabic^[17], allows to evaluate the different components of sleep during the previous month, including subjective quality, latency, duration, habitual efficiency, sleep disorders as well as the use of sleep medication, and poor form during the day. It contains 19 self-evaluation questions associated with 5 questions asked to the spouse or roommate. These 19 questions combine to give 7 'components' of the overall score, each component receiving a score from 0 to 3. These 7 components of the score add up to an overall score ranging from 0 to 21 points, with 0 meaning no difficulty and 21 indicating the presence of major difficulties. Usually, an overall score higher than 5 is an indicator of sleep disorders. The Cronbach's alpha for this study is 0.76, which demonstrated a very a good reliability of the used questionnaire.
- (3) The Hospital Anxiety and Depression Scale (HADS) allows to evaluate two dimensions of mental health at the same time: anxiety and depression, in a non-psychiatric sample. This scale was developed in English^[18] and then translated and validated in Arabic^[19]. The HADS has two subscales of 7 elements each, which give two results, the first for HAD-A anxiety and the second for HAD-D depression, and the two combine to interpret the anxiety-depression syndrome. A parturient with a total score less than 11 for HADS-A or HADS-D had no anxiety or depressive disorders, while a total score of 11 or higher for HADS-A or HADS-D shows a proven diagnosis of anxiety or depression. The Cronbach's alpha for this study is 0.88, which indicated a good reliability of the used questionnaire.

(4) The diagnosis of RLS is made on the basis of the criteria defined by the IRLSSG in 2003^[20]. This scale has been translated from English into Arabic and retranslated by translators/linguists in order to guarantee the credibility of the answers. In this work, the diagnosis is considered positive if the pregnant woman fulfilled the four diagnostic criteria and represents the symptoms related to this syndrome, particularly an irresistible urge to move the extremities, usually associated with a definable discomfort associated with motor agitation, in which the symptoms were harmful at rest, during the night, or later in the day with a temporary relief by activity. We also assessed the frequency of RLS symptoms in pregnant women with a positive diagnosis of RLS, as a woman is accepted as true positive if she encounters the aforementioned signs on at least three separate occasions in the same month.

Finally, all scales and firm questions underwent a standard translation-retranscription of a translation from English to Arabic and then a counter-translation by translators. These were then reviewed and validated by experts in the field to ensure the credibility and reliability of the translation and the validity of the content; they were then exposed to the parturient in a climate that meets the rules of ethics and, for a period, determines by explaining in detail each item in order to overcome any kind of confusion or absurdity. Finally, the data was collected subject to selection and analysis criteria.

Statistical analysis

Patients' socio-demographic and medical characteristics were statistically analyzed and displayed as numbers/percentage distribution. We tested for assumptions of normality and homogeneity of variances using the Shapiro–Wilks test. To assess the possible influence of demographic and other variables on the prevalence of RLS, we used Fisher's exact test and χ^2 test to compare categorical variables. All *P* values equal to or less than 0.05 were considered statistically significant. The statistical analysis was carried out using the SPSS version 20.0 for Windows.

Results

Identification of the population

Concerning the description of our target population, almost half of the women, 92 (51.68%), have an age ranging between 25 and 35 years, and the remaining 12.92% of the sample have an age higher than 35 years. In relation to the level of education, 39.88% of the participants had access to elementary school, contrary to a small fraction of 7.30% who achieved higher studies. Moreover, socio-economic status shows that more than half (52.80%) of the pregnant women earn a monthly income less than 2000 Dh (2000 Dh \approx 200\$) and only 7.86% of the women practice a professional activity. Concerning the evaluation of weight status before pregnancy, the results obtained showed that 107 (60.11%) of the pregnant women have a body mass index (BMI) more than 23.9 kg/m², which means that they suffer from an overweight condition. Regarding the number of pregnancies, 65.73% of the women had previous experiences of pregnancy, and 74.15% of the women in our sample are in the last month of pregnancy. This study also showed that 71.91% of the parturients had consumed

tea or coffee before the pregnancy, greater than or equal to 2 glasses per day (Table 1).

RLS and socio-demographic data

In this cross-sectional study, we found that the prevalence of RLS was about 59.5%, particularly elevated during the last month of pregnancy (75.47%), with a very high percentage in multiparous women (66.03%) compared to primiparous women (33.96%). Pregnant women complaining of obesity are more vulnerable to this pathology, with a percentage of 59.43%, as well as housewives are more prone to the symptoms described in this syndrome (90.56%). Compared to age, parturients with RLS were significantly younger than those without RLS; besides, 55.66% of women whose monthly income is less than 2000 Dh (2000 Dh \approx 200\$) suffer from this syndrome. In this study, 71.91% with RLS+ consumed more stimulants (≥ 2 cups). There were no significant differences and statistical associations when we compared the aforementioned clinical and socio-demographic characteristics between RLS+ and RLS- (Table 1).

Association between RLS, sleep quality, and mental health status

In this study, the prevalence of RLS was strongly recorded among women who complained of poor sleep quality in the third trimester (61.21%), while a fraction of 38.46% reported optimal sleep quality (Fig. 1).

The evaluation of different sleep components showed that sleep effectiveness and the frequency of sleep disorders such as nocturia, pain, sleep fragmentation, and early awakening were strongly and positively correlated with RLS (*P*-value less than 0.05). The majority of pregnant women (84.90%) with positive diagnostic criteria in the last trimester complained of sleep efficiency less than 65% (OR = 2.47), while more than half (69.81%) reported a frequency of rushed sleep disorders once or twice a week (OR = 2.31) (Table 2). However, if we set the *P*-value at 10%, sleep latency was found to be associated with RLS, and almost half (50.94%) of the parturients in the last 3 months of pregnancy suffer from an abnormal falling asleep (more than 60 min) (OR = 1.63). Finally, no significant association has been shown between the subjective quality of sleep, daytime functioning, and the development of RLS (Table 2).

Regarding mental health impairments, our data revealed that pregnant women with RLS in the third trimester of gestation were more exposed to anxiety with a percentage of 71.69% (OR = 3.35). Compared to depression, only 48.11% of women are diagnosed and no correlation between RLS and depression is statistically confirmed (*P*-value greater than 0.05) (Table 3).

Discussion

To our knowledge, this is the first study to assess the presence of RLS in a Moroccan population of pregnant women through face-to-face interviews during the prenatal period, particularly the third trimester. The prevalence of RLS recorded in our case is about 59.5%. The latter is very high compared to 13.5% in Brazil^[21], 26% in Turkey^[22], 26% in Italy^[23], 30% in Pakistan^[24], up to 31.2% in the USA^[25,1] and 34% in Norway^[26]. A study shows that RLS disappeared after childbirth in 64.8% of women, and less than 2 weeks after childbirth in half of them^[27].

Table 1
Restless legs syndrome according to socio-demographic characteristics.

	Total	RLS +	RLS -	P	OR and 95% CI
Age (years)					
Less than 25	63 (35.39%)	36 (33.96%)	27 (37.50%)	0.794	0.87 (0.36–2.10)
Between 25 and 35	92 (51.68%)	57 (53.77%)	35 (48.61%)		
More than 35	23 (12.92%)	13 (12.264%)	10 (13.88%)		
Education level				0.515	0.74 (0.27–2.02)
None	17 (9.55%)	9 (8.49%)	8 (11.11%)		
Elementary school	71 (39.88%)	43 (40.56%)	28 (38.88%)		
Middle school	51 (28.65%)	27 (25.47%)	24 (33.33%)		
High school	26 (14.60%)	19 (17.92%)	7 (9.72%)		
University level	13 (7.30%)	8 (7.54%)	5 (6.94%)		
Economic level (10 Dh ≈ 1\$)				0.480	1.33 (0.73–2.42)
Less than 2000 Dh	94 (52.80%)	59 (55.66%)	35 (48.61%)		
Between 2000 and 4000 Dh	71 (39.88%)	41 (38.67%)	30 (41.66%)		
Between 4000 and 10 000 Dh	13 (7.30%)	6 (5.66%)	7 (9.72%)		
Employment				0.345	1.77 (0.53–5.88)
Yes	14 (7.86%)	10 (9.43%)	4 (5.55%)		
No (housewife)	164 (92.13%)	96 (90.56%)	68 (94.44%)		
Pre-pregnancy BMI				0.927	0.93 (0.50–1.72)
< 18.5 kg/m ²	6 (3.37%)	4 (3.77%)	2 (2.77%)		
18.5–23.9 kg/m ²	65 (36.51%)	39 (36.79%)	26 (36.11%)		
> 23.9 kg/m ²	107 (60.11%)	63 (59.43%)	44 (61.11%)		
Parity				0.91	0.97 (0.51–1.81)
Primiparous	61 (34.26%)	36 (33.96%)	25 (34.72%)		
Multiparous	117 (65.73%)	70 (66.03%)	47 (65.27%)		
Pregnancy term				0.27	1.18 (0.60–2.33)
< 37 weeks of amenorrhea	46 (25.84%)	26 (24.52%)	20 (27.77%)		
≥ 37 weeks of amenorrhea	132 (74.15%)	80 (75.47%)	52 (72.22%)		
Consumption of tea or coffee before pregnancy				0.548	0.68 (0.34–1.35)
0 cup	47 (26.40%)	31 (29.24%)	16 (22.22%)		
1 cup	3 (1.68%)	2 (1.88%)	1 (1.38%)		
≥ 2 cups	128 (71.91%)	73 (68.86%)	55 (76.38%)		

Our data are in line with others found in the literature; thus, a cross-sectional study carried out in Brazil among 524 pregnant women showed that RLS is more frequent in the last trimester, and the probability that a pregnant woman is affected by this syndrome was 7.4 times higher at this time compared to the first trimester^[21].

Data related to socio-demographic, clinical factors and RLS showed that parity is a factor that contributes to the very high prevalence of this syndrome, but no significant difference

between multiparous and primiparous women was found (*P*-value greater than 5%). This result is confirmed by two different studies, the first one conducted by Manconi *et al.*^[2,3] and the second one by Alves *et al.*^[21]. Contrariwise, in the study published by Pantaleo *et al.*^[28], it has been shown that the prevalence of RLS is greater in parous women compared to nulliparous women.

Regarding age, level of education, and previous consumption of stimulants, especially coffee and tea, we have found that these characteristics do not contribute to the development of this syndrome. A similar study conducted in Taiwan in 2012 with a sample of 461 pregnant women also states that age, education, and BMI showed no difference between RLS+ and RLS-, but regular coffee consumption was significantly correlated with transient RLS but not chronic RLS^[29]. In contrast, previous studies affirm that RLS increases with the age of the pregnant women as well as having lower education^[21]. Furthermore, we could not find differences between women with and without RLS in terms of socio-economic status, gestational week, and pre-pregnancy BMI.

Concerning data related to sleep disturbance, we found that pregnant women who complained about RLS during the last 3 months of pregnancy revealed a repercussion of this syndrome on sleep efficiency, which alters physiological needs at rest and makes sleep unrepeatable, as well as an increase in the frequency of sleep disorders such as nocturia, early awakening, difficulty in adopting habitual sleep posture, back pain, and feeling hot or

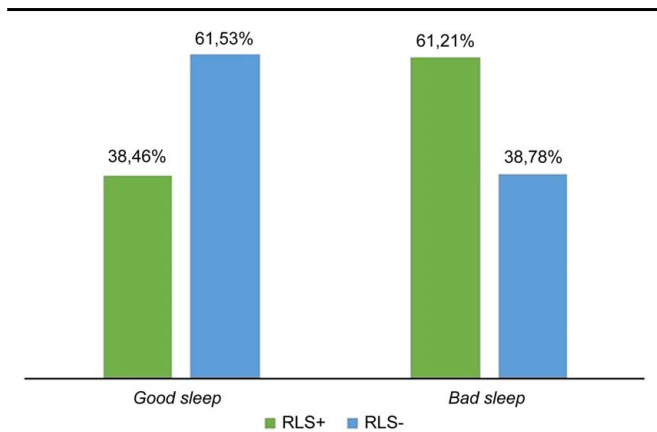


Figure 1. Prevalence of RLS and sleep quality.

Table 2
Distribution of women surveyed by RLS diagnosis and sleep disturbance during pregnancy.

	Total	RLS+	RLS-	P	OR and 95% CI
Sleep latency				0.078	1.63 (0.89–2.99)
≤ 15 min	43 (24.15%)	21 (19.81%)	22 (30.55%)		
16–30 min	5 (2.80%)	1 (0.94%)	4 (5.55%)		
31–60 min	48 (26.96%)	30 (28.30%)	18 (25%)		
> 60 min	82 (46.06%)	54 (50.94%)	28 (38.88%)		
Sleep efficiency				0.028	2.47 (1.19–5.14)
> 85%	15 (8.42%)	7 (6.60%)	8 (11.11%)		
75–84%	8 (4.49%)	5 (4.71%)	3 (4.16%)		
65–74%	15 (8.42%)	4 (3.77%)	11 (15.27%)		
< 65%	140 (78.65%)	90 (84.90%)	50 (69.44%)		
Subjective quality of sleep				0.131	2.6 (1.10–6.13)
Very good	19 (10.67%)	9 (8.49%)	10 (13.88%)		
Fairly good	120 (67.41%)	68 (64.15%)	52 (72.22%)		
Fairly poor	5 (2.80%)	3 (2.830%)	2 (2.77%)		
Very poor	34 (19.10%)	26 (24.52%)	8 (11.11%)		
Sleep disorders (occurrence)				0.009	2.31 (1.24–4.30)
Less than once a week	66 (37.07%)	30 (28.30%)	36 (50%)		
Once or twice/week	110 (61.79%)	74 (69.81%)	36 (50%)		
Three or four/week	2 (1.12%)	2 (1.88%)	0 (0%)		
Daytime function				0.124	1.51 (0.79–2.90)
Not a problem at all	26 (14.60%)	19 (17.92%)	7 (9.72%)		
Only a small problem	23 (12.92%)	13 (12.26%)	10 (13.88%)		
Some problem	70 (39.32%)	35 (33.01%)	35 (48.61%)		
A very big problem	59 (33.14%)	39 (36.79%)	20 (27.77%)		

cold. In addition, sleep latency can be correlated with RLS if a *P*-value of 10% is considered.

Our data are in line with others; thus, Dunietz *et al.*^[30] in 2017 found that pregnant women with RLS were more likely to have poor sleep quality, poor daytime function, and excessive daytime sleepiness. Moreover, a recent study conducted in Saudi Arabia confirms that 23.9% of pregnant women with this syndrome exhibited poor quality of sleep^[9]; this percentage is very low compared to the one shown in this analysis (61.21%). Sleep disorders seem to be higher in other populations with RLS; hence, a recent study carried out among pregnant women in Taiwan in 2012 shows that 81.2% of women suffering from RLS had sleep disorders^[29]. Furthermore, and according to our study, we found that sleep disorders such as increased sleep onset latency, reduced sleep time, insomnia, early waking, and excessive daytime sleepiness were significantly more common in pregnant women with RLS than in women without RLS in this study^[31].

In another context, this is the first survey to explore the association between RLS and anxio-depressive disorders among

Moroccan pregnant women. Concerning anxiety disorder, our study shows a significant manifestation between RLS+ and RLS-, but no depression was recorded. A similar study involving 119 participants in the second trimester of pregnancy is in agreement with our data; they found high levels of anxiety but no major depression^[32]. Meanwhile, a descriptive study to determine the extent of RLS in pregnant women and even its relationship to quality of life revealed that women with RLS sometimes avoid participating in social activities and may suffer from chronic sleep disorders and psychiatric problems such as depression and anxiety disorders^[33].

Dedicated studies on the association between RLS and psychiatric pathologies and sleep disorders, both in pregnant women and in the general population, have shown that their relationship goes beyond mere association and is based on reciprocal interactions and common pathophysiological mechanisms^[9,34]. Although the mechanisms of this association remain obscure and poorly understood, it could be that the various etiologies associated with this syndrome (dopamine deficiency, iron deficiency, endocrine deficiencies, etc.) are at the root of this deterioration in sleep and mental state. Controversy over the need to treat RLS in certain psychiatric or sleep-disordered patients remains, as does the need to screen for RLS as a differential diagnostic criterion and risk factor.

The present study has some limitations; firstly, it is conducted in two urban health structures in the city of Marrakech and cannot be truly representative of the Moroccan pregnant woman population. Secondly, during this work, no prospective follow-up of pregnant women with RLS was carried out during the first two trimesters or a few months after delivery. Thus, at the time of the design of the questionnaire, serum variables are not evaluated, such as ferritin, transferrin, or levels of other hormones.

Table 3
Evaluation of anxiety and depression versus RLS in third trimester pregnant women.

	Total	RLS+	RLS-	P	OR and 95% CI
Anxiety score (≥ 11)					
No	71 (39.88%)	30 (28.30%)	41 (56.94%)	0.000	3.35 (1.78–6.29)
Yes	107 (60.11%)	76 (71.69%)	31 (43.05%)		
Depression score (≥ 11)					
No	99 (55.61%)	55 (51.88%)	44 (61.11%)	0.224	1.46 (0.79–2.68)
Yes	79 (44.38%)	51 (48.11%)	28 (38.88%)		

Conclusion

During the last trimester of pregnancy, the majority of women were likely to develop symptoms of RLS, which is often underestimated and underdiagnosed during the prenatal period and can interfere with quality of life by altering the quality of sleep and the mental state of pregnant women. Hence the need to integrate this pathology into national strategies, to train professionals involved in pregnancy and childbirth monitoring programs in the particular characteristics of RLS, to raise awareness and ensure early detection, and to develop appropriate management protocols to prevent any associated health risks, refine the research profile by identifying predictive factors, measure the impact of this syndrome on maternal and fetal well-being, and elucidate the potential underlying mechanisms of the association between this syndrome, sleep quality, and psychological state.

Ethical approval

This study was conducted in a framework that respects the ethics and dignity of patients. Ethical approval was obtained from the Moroccan Association for research and ethics, Research Ethics Committee (No. 03/REC/20). All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee. Confidentiality and anonymity criteria were met as charted by the Declaration of Helsinki and its later amendments. Informed consent was obtained from all individual participants included in this study.

Consent

Written informed consent was obtained from the patient for the publication of this case report. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

Sources of funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Author contribution

M.G.: conception and design of the study; M.G., O.E., S.A., and A.A.: data collection; M.G., O.E., M.B., S.A., and A.A.: acquisition and data analysis; M.G., A.A., and A.E.: patient recruitment; A.E. and M.B.: interpretation of data; M.G. and A.E.: drafting of the work; M.B. and A.E.: revising the manuscript critically and final approval of the manuscript. All authors approved the final version of the manuscript to be submitted.

Conflicts of interest disclosure

None declared.

Research registration unique identifying number (UIN)

1. Name of the registry: Research Registry.

2. Unique identifying number or registration ID: research-registry9813.
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://www.researchregistry.com/browse-the-registry#home/?view_2_search=guerroumi&view_2_page=1

Guarantor

Abdeljalil Elgot.

Data availability statement

Available upon reasonable request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Acknowledgements

The authors are thankful for the support offered by the medical, the nursing, and midwifery staff of both Youssef Ibn Tachafine and Oasis health centers in Marrakech city who provided access to the participants. Our greetings also go to the participants, who voluntarily joined this study.

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