Original Article

Construction and Validation of the Pregnancy Sleep Disorders Assessment Scale (EETSE)

Construcción y validación de la Escala de Evaluación de Trastornos del Sueño en Embarazadas (EETSE)

Iris Pineda-Mújica,[*] *Lilia S. Gallardo-Vidal,*[**] *María del C. Ponce-Martínez.*[***]

Summary

Objective: to construct and validate a scale to assess sleep disorders in pregnant women. **Method:** cross-sectional study, an instrument was constructed in Spanish with questions aimed at investigating sleep disorders that occur during pregnancy. A pilot test was applied to one hundred pregnant women, randomly selected, who attended the Family Medicine Unit no. 8, in El Marqués, Querétaro, from February to May 2021. The questionnaire was submitted to three rounds of expert judges and a reliability analysis was performed to obtain correlation coefficients. **Results:** a high degree of intelligibility and relevance per question was determined using Delphi methodology. A confirmatory factor analysis was performed for the correlation between variables with the Bartlett's Test of Sphericity ($p<0.001$). A feasible degree of intercorrelation between variables was identified, Kaise-Meyer-Olkin = 0.840. The 20 factors of the instrument were distributed in four principal components that yielded the total variance explained. These items presented factor loading >0.30 and communalities >0.35. The item correlation was found between 0.844 and 0.309. Cronbach's alpha reliability analysis for internal consistency was 0.927. **Conclusion:** The Pregnancy Sleep Disorders Assessment Scale fulfills the objective of measuring sleep disorders that occur during pregnancy in Mexican women.

Keywords: Pregnancy; Sleep Disorders; Validation Study

Received: 01/31/2022
Accepted: 04/12/2022

[*]Family Medicine, Mexican Institute of social Security, Querétaro, México.
[**]Family Medicine Unit No. 13, Mexican Institute of Social Security, Querétaro, México.
[***]Family Medicine Unit No. 8, Mexican Institute of Social Security, Querétaro, México.

Correspondence:
María del C. Ponce-Martínez, Lilia S. Gallardo-Vidal
maría.poncem@imss.gob.mx
susana.gallardo@imss.gob.mx

Suggestion of quotation: Pineda-Mújica I, Gallardo-Vidal LS, Ponce-Martínez MC. Construction and Validation of the Pregnancy Sleep Disorders Assessment Scale (EETSE). Aten Fam. 2022;29(4):104-210. http://dx.doi.org/10.22201/fm.14058871p.2022.4.83410

Aten Fam. 2022;29(4):104-210. http://dx.doi.org/10.22201/fm.14058871p.2022.4.83410

Resumen

Objetivo: construir y validar una escala para medir trastornos del sueño en mujeres gestantes. **Método:** estudio transversal, se construyó un instrumento en español con preguntas dirigidas a investigar los trastornos del sueño que se presentan durante la gestación. Se aplicó una prueba piloto a cien mujeres embarazadas, seleccionadas de forma aleatoria, que acudieron a la Unidad de Medicina Familiar No. 8, en El Marqués, Querétaro, de febrero a mayo de 2021. El cuestionario fue sometido a tres rondas de jueces expertos y se realizó análisis de confiabilidad para obtener los coeficientes de correlación. **Resultados:** se determinó un alto grado de inteligibilidad y de pertinencia por pregunta mediante la metodología Delphi. Se realizó un análisis factorial confirmatorio para la correlación entre variables con la prueba de esfericidad de Bartlett ($p < 0.001$). Se identificó un grado factible de intercorrelación entre variables, Kaiser-Meyer-Olkin = 0.840. Los 20 factores del instrumento se distribuyeron en cuatro componentes principales que arrojó la varianza total explicada. Estos ítems presentaron cargas factoriales > 0.30 y comunalidades > 0.35. La correlación ítem - total se encontró entre 0.844 y 0.309. El análisis de confiabilidad alfa de Cronbach para la consistencia interna fue de 0.927. **Conclusión:** la Escala de Evaluación de Trastornos del Sueño en Embarazadas, cumple con el objetivo de medir los trastornos del sueño que se presentan durante el embarazo en mujeres mexicanas.

Palabras clave: embarazo, trastornos del sueño, estudio de validación

Introduction

It has been globally reported that 70 to 94% of the pregnant population has some type of sleep disorder, its prevalence is higher than in the general population.[1] Population studies report an annual prevalence of insomnia of 30 to 45% in adults,[2] while 75% of pregnant women report changes in their usual sleep patterns.[3] The sleep modifications suffered by pregnant women are secondary to physical, hormonal and physiological changes associated with pregnancy.[1]

Sleep disorders are classified into four categories: dyssomnias, parasomnias, those associated with medical or psychiatric illnesses, and others. Dyssomnias are disturbances of the circadian cycle; the main symptoms are insomnia and hypersomnia. Three types of insomnia are recognized, depending on when they occur during sleep: insomnia of conciliation, insomnia of continuity, and insomnia of premature awakening.[4,5]

Poor sleep quality is a risk factor of depression. Sleep disturbance during late pregnancy is related to high levels of interleukin-6 and C-reactive protein which condition a proinflammatory state. Pregnant women who sleep four hours or less have a higher risk of gestational diabetes, with a ratio of 5.6:1 than those who sleep nine hours or more. Each hour less sleep is associated with a 4% increase in glucose levels; likewise, it is related to hypertensive disease in late pregnancy and a higher risk of preterm births. It increases the likelihood of decreased pain tolerance during labor and of requiring an emergency surgical procedure by 20%.[6]

Sleep restriction during critical period of *in utero* renal growth increases blood pressures in the male fetus and reduces the number of nephrons. It has been identified to increase the risk of low-birth-weight and alterations in the sensitivity of cardiac baroreceptors response.[6,7]

Evaluation of maternal sleep is not currently part of prenatal care, despite evidence suggesting that sleep disturbances are associated with complications during pregnancy and fetal disorders. Screening, diagnosis, and appropriate treatment of these sleep disorders potentially offer benefits that may decrease the risk of gestational complications, improve maternal postpartum health, and reduce short-and long-term health disorders in the newborn.[8]

The gold standard for sleep disorders diagnosis is polysomnography. However, this study is not very accessible, so the diagnosis of insomnia is inferred through a sleep diary or questionnaires.

There are multiple scales to assess sleep patterns, the Pittsburgh Sleep Quality Index (PSQI) contains a total of 19 questions grouped into seven dimensions, they probe sleep quality and efficiency, sleep latency and duration, sleep disturbances, medication use and daytime dysfunction. Each of the dimensions has a minimum score of 0 points, a maximum score of 3 and a total of 21 points.[9] The Insomnia Symptom Questionnaire (ISQ) consists of 13 questions aimed at the perception of sleep symptoms experienced in the past month and how these symptoms affect daily life.[10] The Epworth Sleepiness Scale (ESE) contains eight items and is used to assess the propensity to fall asleep in different monotonous situations. It has a total score of 24 and a cut-off point of 12, above which drowsiness is suggested.[11] Despite the existence of these scales, there is no instrument oriented to the Mexican population that can serve as

diagnostic support for sleep disorders in pregnant women, so it is considered pertinent to construct an instrument that can improve the care of this specific population.[6,8-11]

The validity of an instrument can be calculated through content, criterion and construct validity, and can be tested using factor analysis studies. Reliability is expressed in degrees and ranges from 0 (no correlation) to 1 (perfect correlation). An instrument is reliable with a reliability coefficient greater than 0.7 degrees, which can be calculated by computing internal consistency.[12,13]

Due to the lack of specific instruments for the referred group, the objective of this study was to construct and validate a scale to measure sleep disorders in pregnant women.

Methodology

Cross-sectional study conducted at Family Medicine Unit (FMU) No. 8, in the municipality of El Marqués, Querétaro; from February to May 2021. Pregnant patients who attended for prenatal care, follow-up of comprehensive services or procedures participated with prior informed consent. The Nunnally formula in Psychometric Theory was used to calculate the sample size, resulting in one hundred study subjects,[14] the selection of participants was random. Women with pregnancy confirmed by ultrasound or positive blood or urine pregnancy test, regardless of gestational age, were included. Patients with a diagnosed sleep disorder or those taking medications that cause drowsiness (e.g., anticonvulsants), as well as patients identified without vitality of the product and those who decided not to complete the instrument were excluded.

The Assessment of Sleep Disorders in Pregnant Women Scale (EETSE) was constructed based on the analyzed sections of the ISQ and the PSQI. Four of the dimensions used by both questionnaires were considered and the items were adapted taking into account the activities and conditions of the general population of Mexican pregnant women. In this way, a series of questions were written in Spanish, using simple and clear language with the aim of identifying any sleep disorder and at what stage of sleep they were in. These questions were grouped into four dimensions, each dimension consisting of five items randomly dispersed to avoid biased responses. The conciliation dimension refers to the ability to fall asleep; the continuity dimension assesses nocturnal awakenings with significant interruption of sleep and the ability to recover it; daytime dysfunction measures the lack of ability to perform activities regularly; parasomnias are abnormal and involuntary physiological phenomena that occur during sleep and reduce its quality, such as leg movements, somniloquy and nightmares.

Each question involves a closed response to facilitate coding. Using the Likert psychometric scale, where 0 refers to never, 1 occasionally or once a month, 2 sometimes or two to three times a month, 3 refers to frequently or one to three times a week, and finally 4 is very frequently or more than three times a week.[15] In this way, 0 to 4 points are added for each question. Thus, a score of 40 or more on the total questionnaire suggests insomnia. The total of the 20 items adds up to a maximum of 80 points.

Following, in strict order, the steps for the construction of an instrument, the questionnaire was submitted to three review sessions by a panel of experts (content and construct validity), who were selected and invited to participate, after signing an informed consent; academic degree, publications, experience, reputation, availability and impartiality were considered. These contributions and suggestions were taken into account in the final format of the scale.[16] Finally, the reliability analysis of the instrument was carried out with the SPSS v. 22 statistical program to obtain the correlation coefficients. The protocol of this project was submitted for review and obtained the approval of the Local Research and Ethics Committee, folio number 2020-2201-051, R-2021-2201-006.

Results

One hundred pregnant patients were considered for the pilot test, with an average age of 26.5 years (95% CI; 25.59-27.41). Of these, 50% were in their third trimester (95% CI; 40.2-59.8). 66% of the pregnant women were classified as low obstetric risk (95% CI; 56.7-75.3) and 27% as high risk (95% CI; 18.3-35.7).

By Delphi methodology, a high degree of intelligibility and relevance per question was determined. Content validity was considered by means of expert rounds. Regarding construct validity, a confirmatory factor analysis was carried out for the correlation between the variables of the instrument by means of Bartlett's test of sphericity, with $p < 0.001$, which demonstrates sense in the factor analysis. A feasible degree of intercorrelation between variables was identified, calculating Kaiser-Meyer-Olkin (KMO) of 0.840, see Table 1. The total variance explained yields four principal components (>1) in which the total of the twenty factors contained in the instrument are distributed, with an accumulated percentage of 64.01%, see Table 2. All items presented factor

Aten Fam. 2022;29(4):104-210. http://dx.doi.org/10.22201/fm.14058871p.2022.4.83410

Table 1. Construct Validity

Validity Testing	EETSE	A. Sleep Conciliation	B. Continuity	C. Daytime Dysfunction	D. Parasomnias
KMO	0.84	0.83	0.69	0.827	0.737
Bartlett's Test of Sphericity	χ^2 1201.0950 sig. <0.001	χ^2 311.803 sig. <0.001	χ^2 142.712 sig. <0.001	χ^2 242.415 sig. <0.001	χ^2 87.712 sig. <0.001
%Variance		70.257	51.385	66.396	46.991

Table 2. Explained Total Variance, Extraction Method: Main Component Analysis

Component	Initial Eigenvalues			Extraction Sums of Squared Loads			Rotation Sums of Squared Loads		
	Total	Variance %	Cumulative %	Total	Variance %	Cumulative %	Total	Variance %	Cumulative %
1	8.519	42.596	42.596	8.519	42.596	42.596	4.615	23.077	23.077
2	1.838	9.188	51.784	1.838	9.188	51.784	3.748	18.74	41.817
3	1.394	6.971	58.755	1.394	6.971	58.755	2.435	12.173	53.989
4	1.052	5.258	64.013	1.052	5.258	64.013	2.005	10.024	64.013
5	0.998	4.989	69.001						
6	0.869	4.345	73.346						
7	0.791	3.957	77.303						
8	0.704	3.518	80.821						
9	0.62	3.102	83.923						
10	0.554	2.771	86.694						
11	0.494	2.472	89.166						
12	0.392	1.96	91.126						
13	0.364	1.822	92.948						
14	0.291	1.457	94.405						
15	0.258	1.29	95.695						
16	0.249	1.245	96.939						
17	0.223	1.114	98.053						
18	0.2	0.999	99.053						
19	0.104	0.521	99.574						
20	0.085	0.426	100						

Table 3. Communalities by Dimension

Item		Extraction
A. Sleep Conciliation		
8	I have hard time falling asleep	0.844
12	I have trouble falling asleep	0.765
4	I have difficulties falling asleep	0.759
1	When I go to bed at night, it takes me 30 minutes or more to fall asleep	0.705
16	When I lie down, I think about things that keep me from falling asleep	0.440
B. Continuity		
20	Any sound, of any intensity, causes me to wake up while asleep	0.843
13	I wake up when hearing low intensity sounds (e.g., trees moving outside, door cracking)	0.815
17	Once I wake up at night, I can no fall asleep again	0.783
5	At night, I wake up for 30 minutes or more	0.714
9	I wake up one hour before my alarm clock goes off in the mornings	0.428
C. Daytime Dysfunction		
10	I feel tired when doing my daily activities at home or at work	0.743
6	I feel tires to finish my daily activities	0.701
3	I feel tires while perming my daily activities	0.643
14	I do not feel like doing my activities	0.621
18	I do not have strength to do my daily activities	0.613
D. Parasomnias		
11	I have been told that when I am asleep, I move my legs a lot or jump up and down	0.570
19	When I am asleep, I fight or get angry	0.550
15	I have nightmares during sometime in the night while I am asleep	0.495
7	I have been told that when I am asleep, I walk, talk, grind my teeth, or act violently or strangely	0.426
2	I suddenly wake up, startled, and feel afraid for no reason	0.309

Table 4. Inter-class Correlation Coefficient, Inter-item Correlation Matrix

Dimensions	Sleep Conciliation	Continuity	Daytime Dysfunction	Parasomnia
Sleep Conciliation	1.000	0.717	0.623	0.531
Continuity	0.717	1.000	0.687	0.621
Daytime Dysfunction	0.623	0.687	1	0.557
Parasomnias	0.531	0.621	0.557	1.000

loadings greater than 0.30 and communalities greater than 0.35. The item-total correlation was found to be between 0.844 and 0.309, see Table 3. The 20 items-internal consistency was carried out using Cronbach's alpha and a result of 0.927 was obtained. An interclass correlation test was also performed, finding the highest correlation between the dimensions of conciliation and continuity, see Table 4.

Discussion

The high percentage of pregnant women suffering from sleep disorders, as well as the impact on their health and their products, obliges health systems to pay special attention to this vulnerable group, since, regardless of the cause, insomnia in this specific population implies preventable risks if identified in a timely manner.

There are numerous validated instruments by means of which the existence of insomnia can be suggested. The PSQI is a scale that evaluates the specific characteristics and quality of sleep, i.e., it identifies good or bad sleep, but not whether or not insomnia exists. Neither does it assess the frequency with which symptoms occur, nor does it provide information regarding the following day consequences of these symptoms. It has a high degree of internal consistency ∝ Cronbach's ∝ of 0.83; the validity of this instrument lies in the ability to discriminate between patients and controls supported by similar results with polysomnography.[9] On the other hand, the ISQ is an instrument that defines a case of insomnia in a similar manner to

information obtained through a medical consultation, provides dichotomous results regarding the presence or absence of insomnia based on a list of established diagnostic criteria, is useful in studies in which clinical interviews are not feasible, and allows the researcher to confidentially categorize participants.[10]

In 2015, in Pittsburgh, validation of the ISQ was published in 14 pregnant women at 12 weeks' gestation, reporting a Cronbach's ∝ = 0.86.[17] While the ESE is an instrument that measures the patient's overall level of sleepiness, regardless of brief variations in sleepiness, time of day and from day to day; it contains a Cronbach's ∝reliability coefficient of 0.89. [11] Notwithstanding the existence of the referred instruments, the Pregnant Women's Sleep Disorders Assessment Scale focuses specifically on the pregnant population, since it investigates the presence of sleep disorders during the entire pregnancy, in addition to considering the frequency these symptoms occur, as well as the consequences the day after, while the rest of the instruments investigate specific periods (last trimester). However, the different trimesters are subject to well-identified hormonal changes that imply a symptomatology that may contribute to poor sleep quality or poor sleep satisfaction.[3] The EETSE, despite being a self-application instrument, does not replace medical consultation; on the contrary, it enriches it by providing extremely important information in a targeted and practical way.

Other non-validated instruments that aim the identification of sleep disorders are also found in the literature. In Poland, a study was published on 7207 pregnant patients to analyze the relationship between sociodemographic factors, pregnancy-associated symptoms and sleep difficulties, applying a questionnaire composed of questions taken from the PSQI, the Insomnia Severity Index, the Stanford Sleep Questionnaire and the Berlin Questionnaire, in which 77.09% (5556) of the women reported at least one sleep problem. The most common sleep disturbances were continuous awakening with 52.77%, insomnia of conciliation with 20.23%, early awakening with 18.56% and 9.82% poor quality sleep.[18]

In 2020, a systematic review both in English and Spanish, focused on determining which sleep disturbances occurred during pregnancy, their causes and consequences, pointed out the need to inquire about sleep habits during pregnancy in order to promote sleep hygiene strategies that benefit the health of the mother and the newborn, and prevent the early development of certain diseases.[3] It is essential to consider these aspects at the Primary Care level in order to avoid major complications for both the mother and the newborn.

The EETSE had a high reliability (Cronbach's ∝ of 0.927) and has a high degree of validity, since it effectively measures what it intends to measure (relevance of 0.84), likewise, it contains relevant items that provide content validity and reflect a feasible intercorrelation, keeping an adequate variability between each question. Due to its characteristics, this scale can be applied to Mexican pregnant patients; it has a comfortable and easy-to-read structure, designed to be filled out personally by the pregnant woman; for this reason, it is an appropriate tool to quickly and practically determine the existence of a sleep disorder in pregnant women during prenatal control visits. As it is a screening and follow-up instrument, it allows timely intervention of the sleep disorder and its reevaluation at a later stage. The use of these tools in daily clinical practice improves the quality of care for this vulnerable group of the population under the family physician care, projecting a decrease in health risks inherent to these disorders.

Conclusion

The Pregnancy Sleep Disorders Assessment Scale is intended to measure sleep disorders that occur during pregnancy in Mexican women. It can be applied in pregnant women who speak, understand and read Spanish of any age and in any gestational trimester. The purpose is to integrate this tool to the regular prenatal control consultation in our country as a screening for insomnia, as well as to reevaluate its evolution.

Authors' contributions

I P-M: construction, pilot testing, data analysis, development, and writing; L.S G-V: data analysis and review; M. del C P-M: methodology, data, and writing review. All authors approve the publication of this paper.

Funding

The present research did not receive external funding.

Conflicts of interest

The authors declare having no conflicts of interest.

Acknowledgments

We would like to thank Manuel Enrique Herrera Ávalos, MD, and Celeste Cedeño Vidal, MD, for all their support.

References

1. Ruiz GI, Valenza M, Molina C, Torres SI, Cabrera MI, González-Jiménez E. Prevalencia de alteraciones del sueño y diabetes gestacional en el último trimestre del embarazo. Nutr Hosp. 2015;32(3):1139-1144. DOI:10.3305/nh.2015.32.3.9365
2. Chan-Chan E, Cisneros-Dorantes C, Martín-Arcero S, Reyes-León A. El insomnio como factor de riesgo para la depresión en mujeres embarazadas. Perinatol Reprod Hum. 2013;27(3):171-176.
3. Aguilar Cordero MJ, Fajardo Gaitán M, Pérez Castillo IM, Rojas Carvajal AM, Latorre García J, Núñez Negrillo AM Alteraciones y efectos del sueño durante el embarazo. JONNPR. 2020;5(12):1558-74. DOI: 10.1923/jonnpr.3979
4. Hashmi AM, Bhatia SK, Bhatia SK, Khawaja IS. Insomnia during pregnancy: Diagnosis and rational interventions. Pak J Med Sci. 2016;32(4):1030-1037. DOI: http://dx.doi.org/10.12669/pjms.324.10421
5. American Psychiatric Association, editor. Guía de consulta de los criterios diagnósticos del DSM-5. Arlington, VA: American Psychiatric Publishing; 2014.
6. Reichner CA. Insomnia and sleep deficiency in pregnancy. Obstet Med. 2015;8(4):168-171. DOI: 10.1177/1753495X15600572
7. Argeri R, Nishi EE, Volpini RA, Palma BD, Tufik S, Gomes GN. Sleep restriction during pregnancy and its effects on blood pressure and renal function among female offspring. Physiol Rep. 2016;4(16):4-11. DOI: 10.14814/phy2.12888
8. Romero R, Badr MS. A role for sleep disorders in pregnancy complications: challenges and opportunities. Am J Obstet Gynecol. 2014;210(1):3-11. DOI: 10.1016/j.ajog.2013.11.020
9. Buysse DJ, Reynolds CF 3rd, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. Psychiatry Res. 1989;28(2):193-213. DOI: 10.1016/0165-1781(89)90047-4
10. Okun ML, Kravitz HM, Sowers MF, Moul DE, Buysse DJ, Hall M. Psychometric evaluation of the Insomnia Symptom Questionnaire: a self-report measure to identify chronic insomnia. J Clin Sleep Med. 2009;5(1):41-51
11. Johns MW. A new method for measuring daytime sleepiness: The Epworth sleepiness scale. Sleep. 1991;14(6):540-5. DOI: 10.1093/sleep/14.6.540
12. Supo J. Cómo validar un instrumento. 2013 [Internet]. [Citado 2022 Ene 04]. Disponible en: http://www.cua.uam.mx/pdfs/coplavi/s_p/doc_ng/validacion-de-instrumentos-de-medicion.pdf
13. Bravo P, Contreras A, Dois A, Villarroel L. Adaptación y validación del instrumento genérico CollaboRATE™ para medir la participación de mujeres en la toma de decisiones en salud durante el proceso reproductivo. Aten Primaria. 2018;50(5):274-281. DOI: 10.1016/j.aprim.2017.04.003
14. Nunnally J, Bernstein I. Teoría psicométrica. 3ª edición. México, D.F.: Editorial Mc Graw-Hill Latinoamericana; 1995.
15. Joshi A, Kale S, Chandel S, Pal D. Likert Scale: Explored and explained. Br J Appl Sci Technol. 2015;7(4):396-403. DOI: 10.9734/BJAST/2015/14975
16. Skjong R, Wentworth B. Expert judgment and risk perception. Proc Int Offshore Polar Eng Conf. 2001;4:537-544.
17. Okun ML, Buysse DJ, Hall MH. Identifying insomnia in early pregnancy: Validation of the insomnia symptoms questionnaire (ISQ) in pregnant women. J Clin Sleep Med. 2015;11(6):645-654. DOI: 10.5664/jcsm.4776
18. Smyka M, Kosińska-Kaczyńska K, Sochacki-Wójcicka N, Zgliczyńska M, Wielgoś M. Sleep problems in pregnancy—A cross-sectional study in over 7000 pregnant women in Poland. Int J Environ Res Public Health. 2020;17(15):5306. DOI: 10.3390/ijerph17155306