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1 CLINICAL ARTICLE

Validation of specific questionnaires to assess nausea and vomiting of ³ pregnancy in a French population

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ABSTRACT

Objective: To validate the modified Pregnancy-Unique Quantification of Emesis and Nausea (PUQE) score and the18Health-Related Quality of Life for Nausea and Vomiting of Pregnancy (NVP-QOL) score in a French population.19Methods: A retrospective study was conducted of data for women who delivered at a tertiary care hospital20in La Roche sur Yon, France, between November 1, 2012, and April 1, 2013. Only women who reported21nausea and vomiting of pregnancy (NVP) in the first trimester were invited to respond to the two questionnaires.22Results: Overall, complete questionnaires were available from 399 women, 238 (59.6%) of whom reported NVP in23the first trimester. The modified-PUQE score was associated with the self-reported symptom severity (P<0.001).</td>24A relationship was also noted when either the NVP-QOL score or the modified-PUQE score was associated26with a high modified-PUQE score (P < 0.001).</td>Conclusion: The modified-PUQE and NVP-QOL scores provided27valid indices for assessing NVP severity and alterations in quality of life. Owing to its simplicity, the modified-28PUQE score might be used routinely among women experiencing NVP in the first trimester of pregnancy.29© 2016 Published by Elsevier Ireland Ltd. on behalf of International Federation of Gynecology and Obstetrics.30

44 1. Introduction

Nausea and vomiting of pregnancy (NVP) occurs in 50%-80% of all 45pregnancies worldwide, particularly during the first trimester [1]. A se-46vere form of NVP, known as hyperemesis gravidarum, is reported 47 among a small proportion of affected individuals (0.3%-3.6%); this con-48 dition can lead to weight loss, dehydration, electrolyte disorders, and 49 50 even hospitalization [2,3]. By contrast, the symptoms associated with most cases of NVP are generally mild, although they can still affect qual-51ity of life (QOL), with substantial morbidity and cost to society [4-6]. 52Multiple scores have been developed to accurately describe patients' 5354symptoms, but they are rarely used in clinical practice, because they are little known by physicians or take too long to complete [7]. 55

Two scores are available for use among pregnant women. Koren et al. [8] created the Pregnancy-Unique Quantification of Emesis and Nausea (PUQE) score, which evaluates NVP symptoms occurring in the previous 12 hours. This method has proven useful to evaluate the effectiveness of an anti-emetic agent, but its utility is limited for longer periods, such as during the first trimester of pregnancy. In 2008, Lacasse and al. [9] produced the modified-PUQE score, which combines all

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symptoms occurring from the beginning of the current pregnancy. 63 A second score—the Health-Related Quality of Life for Nausea and 64 Vomiting in Pregnancy (NVP-QOL)—was developed by Magee et al. 65 [10]. This score was compared with the 12-item Short Form Health 66 Survey and found to be effective for use during the first trimester of 67 pregnancy [11]. Other studies have confirmed the utility of this score 68 in the evaluation of QOL during episodes of NVP [12,13]. Nevertheless, 69 few studies have been published concerning the use of these two scores 70 among pregnant women [14]. 71

The aims of the present study were to assess the modified-PUQE 72 and NVP-QOL scores according to the severity of NVP and any alteration 73 in QOL, and to analyze the correlation between these two scores in a 74 French population. 75

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2. Materials and methods

A cross-sectional study was conducted at Centre Hospitalier 77 Departemental, La Roche sur Yon, France. The study center is a tertiary 78 care hospital that records more than 2600 deliveries each year. 79 Women who delivered between November 1, 2012, and April 1, 2013, 80 and who reported NVP during their first trimester were enrolled. Exclusion criteria were delivery before 24 weeks, intrauterine fetal death, 82 elective induced abortion, inability to speak or read French, and refusal 83 to fill out the questionnaires. The protocol was performed in accordance 84 with the Declaration of Helsinki and approved by the Ethics Committee 85

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of the National College of Obstetricians and Gynecologists (Comité
d'Ethique de la Recherche en Obstétrique et Gynécologie, Paris, France;
CEROG OBS 2015-07-09). All women provided informed oral consent
before participation.

Data were obtained for demographic variables, lifestyle, treatment
used during pregnancy, and QOL. Participants completed the modified PUQE and NVP-QOL questionnaires in the obstetrics department after
delivery. The French linguistic versions were used [9,11] and incomplete
questionnaires were excluded from the analysis.

95 The modified-PUQE questionnaire [9] was used to evaluate three specific symptoms of NVP occurring since the beginning of pregnancy. 96 This tool uses a five-point Likert scale that measures the duration 97 of nausea, vomiting frequency, and the frequency of retching or dry 98 99 heaves. Scores were calculated by assigning a value to each response from "causing the least possible discomfort" (score of 1) to "causing 100 the most possible discomfort" (score of 5). The total score was obtained 101 by summing the responses to each of the three items, which ranged 102 from no symptoms (score of 3) to maximal symptoms (score of 15). 103This measure was used to define mild MVP (score of 3–6), moderate 104 NVP (score of 7–12), and severe NVP (score of \geq 12). 105

The NVP-OOL guestionnaire [10] uses a seven-point Likert scale cov-106 ering 30 items of potential importance for QOL. The items were catego-107 108 rized into four general domains: physical symptoms and/or aggravating factors (n = 9), fatigue (n = 4), emotions (n = 7), and limitations 109 (n = 10). Scores were calculated by assigning a value to each response, 110 from 1 ("none of the time") to 7 ("all the time"), although scores for 111 question 20 were reversed (a score of 1 indicated the patient felt 112 113 reassured that she had the usual symptoms of a normal pregnancy "all the time" and a score of 7 indicated that she felt reassured "none of the 114 time"). The total score was obtained by summing the responses of each 115of the 30 items. The minimum score was 30 (corresponding to good 116 117QOL) and the maximum score was 210 (corresponding to poor QOL).

118 After name coding, all information was transferred to a computerized database and analyzed using Excel 2000 (Microsoft, Redmond, 119WA, USA) and SPSS version 17.0 (SPSS Inc, Chicago, IL, USA). Maternal 120and neonatal characteristics were described according to presence 121 or absence of NVP, and according to NVP severity (mild, moderate, 122 123 and severe). Qualitative variables were expressed as numbers and percentages; quantitative variables were expressed as means and standard 124deviations. The modified-PUQE scores were described as means and 125standard deviations according to NVP status and treatment. Continuous 126 127variables were compared using the Student t test or the Wilcoxon-

t1.1 Table 1

t1.2 Maternal and neonatal characteristics.^a

Table 2
Treatment of nausea and vomiting of pregnancy during the first trimester $(n = 238)$

Treatment of nausea and vomiting of pregnancy during the first trimester $(n = 238)$. ^a	t2.2

Treatment	No. (%)	Modified-PUQE score	P value	
Medications			< 0.001	-
Yes	144 (60.5)	8.2 ± 2.6		
No	94 (39.5)	7.0 ± 2.1		
Non-pharmacological methods			0.03	
Yes	120 (50.4)	7.8 ± 2.5		
No	118 (49.6)	7.1 ± 2.2		
Non-pharmacological methods used ^b			0.93	
Acupressure	5 (2.1)	8.4 ± 2.1		
Homeopathic treatment	73 (30.7)	8.2 ± 2.6		
Dietary changes	85 (35.7)	8.0 ± 2.6		
Phytotherapy	7 (2.9)	8.7 ± 2.9		
Hospitalization for severe nausea and			< 0.001	
vomiting of pregnancy				
Yes	3 (1.3)	11.3 ± 1.5		
No	235 (98.7)	7.4 ± 2.3		

Abbreviations: NVP, nausea and vomiting of pregnancy; PUQE, Pregnancy-Unique Quantit2.19 fication of Emesis and Nausea. t2.20

 a Values given as number (percentage) or mean \pm SD, unless indicated otherwise. t2.21 b More than one method was used for some women who received non-pharmacological t2.22 treatment.

Mann–Whitney test. The qualitative variables were compared using 128 the χ^2 or Fisher test as appropriate. The association between self- 129 reported symptom severity and the NVP-QOL and modified-PUQE 130 scores, and the association between modified-PUQE (measure of NVP 131 severity) and NVP-QOL scores, were described using box plots and 132 tested using the Kruskal–Wallis test and Spearman rank correlation. 133 P < 0.05 was considered statistically significant. 134

3. Results

A total of 835 women who had delivered during the present study 136 period were eligible for inclusion. Questionnaires were recovered 137 for 461 (55.2%) women; 62 (7.4%) had incomplete questionnaires 138 and were excluded from the analysis. Therefore, the final sample 139 comprised 399 women. 140

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Overall, 238 (59.6%) women reported NVP in the first trimester of 141 pregnancy. The presence of NVP in a previous pregnancy was associated 142 with recurrence of NVP in the following pregnancy (P<0.001) (Table 1). 143 By contrast, smoking during the first trimester was associated with 144

t1.3	Characteristic	Patients with NVP ($n = 238$)	Patients without NVP ($n = 161$)	Crude OR (95% CI)	P value
t1.4	Age, y	30.5 ± 4.0	29.9 ± 4.6	1.03 (0.98-1.08)	0.22
t1.5	Living arrangement				
t1.6	With spouse or with someone else	233 (97.9)	159 (98.8)	Ref.	NA
t1.7	Alone	5 (2.1)	2 (1.2)	1.70 (0.33-8.61)	0.71
t1.8	Work status				
t1.9	Student or not working	24 (10.1)	27 (16.8)	Ref.	NA
t1.10	Working	214 (89.9)	134 (83.2)	1.08 (1.00-1.17)	0.07
t1.11	NVP in a previous pregnancy	124 (52.1)	20 (12.4)	4.19 (2.73-6.43)	< 0.001
t1.12	Smoking during first trimester	45 (18.9)	45 (28.0)	0.68 (0.47-0.97)	0.04
t1.13	Pre-pregnancy body mass index ^b	24.2 ± 5.7	24.0 ± 4.8	1.01 (0.97–1.04)	0.71
t1.14	Maternal weight gain, kg	10.4 ± 4.8	11.3 ± 5.0	0.96 (0.92-1.00)	0.09
t1.15	Nulliparity	83 (34.9)	72 (44.7)	0.66 (0.44–1.00)	0.06
t1.16	Gestational diabetes mellitus	24 (10.1)	13 (8.1)	1.25 (0.66-2.38)	0.60
t1.17	Cesarean delivery	48 (20.2)	19 (11.8)	1.71 (1.05-2.80)	0.03
t1.18	Length of pregnancy at delivery, wk	39.6 ± 1.5	39.9 ± 1.1	0.85 (0.73-0.99)	0.04
t1.19	Singleton	237 (99.6)	159 (98.8)	1.01 (0.99–1.03)	0.57
t1.20	Male neonate	113 (47.5)	82 (50.9)	0.93 (0.76-1.14)	0.54
t1.21	Birth weight, g	3281 ± 502	3329 ± 426	0.89 (0.72-1.11)	0.32
t1.22	Breastfeeding	109 (45.8)	71 (44.1)	1.04 (0.83–1.30)	0.76

t1.23 Abbreviations: NVP, nausea and vomiting of pregnancy; OR, odds ratio; CI, confidence interval; NA, not applicable.

t1.24 ^a Values given as mean \pm SD or number (percentage), unless indicated otherwise.

t1.25 ^b Calculated as weight in kilograms divided by the square of height in meters.

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