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Kertas Asli/*Original Article*

Development, Validity and Reliability of a Pregnancy Symptoms Questionnaire (PSQ)

(Penghasilan, Validiti dan Kebolehpercayaan Borang Soal Selidik Simptom Kehamilan)

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ABSTRACT

This study aimed to develop and examine the validity and reliability of a pregnancy symptoms questionnaire. A total of 214 pregnant women aged 19 to 40 years old were purposive randomly recruited from December 2009 to January 2010 in Antenatal Clinic, Hospital Universiti Sains Malaysia. Pregnant mothers at second and third trimesters were interviewed to complete the Pregnancy Symptoms Questionnaire (PSQ). The PSQ was developed by experts in nutrition, obstetrics and statistics. The PSQ consists of 38 items on frequency and severity of pregnancy symptoms. Factor analysis was done using Promax rotation method to check for construct validity. A total of 16 items which had poor correlation (<0.3) and less important content were removed during the final revise. The 22 remaining items were found to be loaded on the three components (general, constitutional and somatic pain). The overall Cronbach's alpha coefficient was 0.93 and for each three components ranges from 0.70–0.87. The results suggest that the final PSQ consisting of 22 items is valid and reliable for measuring the frequency and severity of the symptoms experienced during pregnancy. It can be used in nutritional studies related to pregnancy and its outcome.

Keywords: Pregnant mothers, Pregnancy symptoms, Questionnaire, Validation

ABSTRAK

Kajian ini bertujuan untuk menghasilkan soal selidik simptom semasa hamil serta mengkaji validiti dan kebolehpercayaannya. Seramai 214 ibu hamil yang berusia di antara 19 hingga 40 tahun telah dipilih secara rawak bertujuan bermula dari Disember 2009 hingga Januari 2010 di Klinik Antenatal, Hospital Universiti Sains Malaysia. Ibu-ibu hamil pada trimester kedua dan ketiga telah ditemubual untuk melengkapkan Pregnancy Symptoms Questionnaire (PSQ). PSQ telah dihasilkan daripada perbincangan pakar-pakar dalam bidang pemakanan, obstetrik dan statistik. PSQ mengkaji kekerapan dan tahap keterukan sejumlah 38 simptom semasa hamil. Setelah faktor analisis menggunakan kaedah Promax rotation dilakukan untuk menguji validiti kandungan PSQ, sebanyak 16 simptom dengan perkaitan yang lemah (<0.3) telah dikeluarkan. Seterusnya baki 22 simptom dibahagikan mengikut tiga komponen utama; umum (general), gejala alahan (constitutional) dan kesakitan badan (somatic pain). Bacaan Cronbach's alpha bagi keseluruhan PSQ ialah 0.93 sementara bacaan untuk setiap komponen adalah di antara 0.70 hingga 0.87. Hasil kajian menunjukkan PSQ dengan 22 simptom adalah valid dan boleh dipercayai untuk mengukur kekerapan dan tahap keterukan simptom semasa hamil. Seterusnya dapat digunakan di dalam kajian pemakanan yang berkaitan dengan kehamilan dan hasil kehamilan.

Kata kunci: Ibu-ibu hamil, Simptom semasa hamil, Soal selidik, Validiti

INTRODUCTION

Maternal physiology changes remarkably throughout the pregnancy to support the development of the fetus and to prepare the mother for labour and lactation (Coad & Dunstall 2005). The physiological changes of pregnancy such as in respiratory, gastrointestinal and renal systems may exacerbate many irritating symptoms which can be troublesome on a day-to-day basis (Baker 2006). This can be a wide range of discomforts, from fatigue and headache to more severe pregnancy symptom like hyperemesis gravidarum which requires hospitalization. Each stage of pregnancy has its associated pregnancy-related physical symptoms which are unpleasant and cause profound effects to mother and infant (Kamysheva et al. 2009). Nausea and vomiting tend to occur at the early trimester while somatic pain symptoms e.g. pelvic pressure and Braxton Hicks are common during the third trimester of pregnancy. As proposed by the 'Developmental Origins Hypothesis,' the maternal nutritional, metabolic and hormonal environments are critical to fetal growth and later adult disease (Barker 2003). Therefore, considering that these aspects are correlated with the pregnancy symptoms, thus it is important and appropriate to measure and identify the symptoms among pregnant mothers.

Disturbances of gastrointestinal function are the most common cause of complaints in pregnancy (Coad & Dunstall 2005). These gastrointestinal changes include nausea, vomiting, appetite preference, constipation and heartburn (Stephenson & Connor 2000). Various degree of nausea and vomiting, known as 'morning sickness' are probably the most common symptoms of early pregnancy which can occur at any time of the day in about 80% of pregnant mothers (Kalnins & Saab 2006). Even though there are some studies suggesting that nausea and emesis in early pregnancy were associated with favorable birth outcomes and positive role in early placental growth (Huxley 2000; Lumey 1998), the suggestion has not been confirmed (Lee et al. 2004). Furthermore, a study in marginally nourished mothers with nausea and vomiting during pregnancy (NVP) showed later nutritional stress and adverse pregnancy outcomes (Pike 2000).

Besides NVP, there are varying degree of unpleasant sensations and pains during pregnancy which may have relationship with the nutritional status among pregnant mothers. Pregnant mothers who experienced low back pain and pelvic pain were reported to have significantly higher body mass index (BMI) during pre-pregnancy and end-pregnancy periods (Morgan & Pohjanen 2005), while mothers who suffered leg cramp during pregnancy were probably associated with lower regulation of blood calcium level due to the increased demand of calcium by growing fetus (Steer 2005). Hence, it is important to use a questionnaire which is valid and reliable to assess the pregnancy symptoms experienced by the mothers during pregnancy in order to enhance our understanding of the association of related symptoms with maternal and infant nutritional status.

In the present study, we aimed to design a Pregnancy Symptoms Questionnaire (PSQ) to be used in a prospective birth cohort study in pregnant mothers. Both frequency and severity of symptoms are crucial to be included in the questionnaire as they equally play a major role to the pregnancy outcomes. Pregnant mothers with higher symptoms frequency were shown to have greater discomfort and effect in life (Kamysheva et al. 2009), and there are many studies reported the unpleasant effects of symptoms severity on pregnancy outcomes (Lee et al. 2004; Padua et al. 2001; Dodds et al. 2006). To establish the validity of the PSQ, face, content and construct validity were examined. In addition, we sought to determine the internal consistency reliability of the PSQ based on Cronbach's alpha.

MATERIALS AND METHODS

There were two phases in the study. First phase was aimed to develop the PSQ and pre-test it. Second phase was aimed to validate and examine the reliability of the PSQ. A total of 62 mothers participated in phase 1 and 214 mothers participated in phase 2.

PHASE 1: DEVELOPMENT AND CONTENT VALIDATION OF THE PSQ

There were three major steps in developing the PSQ. Firstly, the construction of symptom items list; secondly, the assignment of frequency occurrence; and thirdly, the definition of symptom severity. A team of experts in nutrition, obstetrics and statistics reviewed literatures on pregnancy related physical symptoms. The extensive reviews included the possible items to be listed in the questionnaire as well as the methods used for self-reported questionnaire of pregnancy symptoms and the appropriate measurement scales (Kamysheva et al. 2009; Wallace et al. 1986). The newly developed questionnaire consists of two main components i.e. the frequency and the severity of the symptoms. The frequency of symptoms was given three response options i.e. 'per day,' 'per week' and 'per month.' There were four levels of severity, which were 'none,' 'mild,' 'moderate' and 'severe.' Mothers were asked to choose the level of severity from either one of these four options. The initial version of PSQ consisted of 26 items in semi-quantitative form. An open-ended additional question on 'other symptoms' were asked at the end of the interview to identify pregnancy minor problems which were not included in the questionnaire.

The initial version was pretested on 62 mothers aged 19 to 40 years old who were at least 12 weeks pregnant in Antenatal Clinic, HUSM. The questionnaire was face to face interview-administered. As pre-test was completely done, the PSQ was rephrased and finalized by the team experts in term of content and construct based on the feedback, responses and comments from the mothers. An expert in questionnaire development and validation reviewed the final version of PSQ for the overall construct.

After the pre-test, the second version of PSQ was presented in a quantitative form with 38 items of symptom. Frequency of occurrence was ranked in 0 – 5 scales, which were '0 = never,' '1 = rarely,' '2 = sometimes,' '3 = often' and '4 = very often.' 'Rarely' was defined as once per week, 'sometimes' was defined as three to five times per week, 'often' was defined as once per day and 'very often' was defined as more than once per day. Level of severity was ranked on 0 – 5 scale, which were '0 = none,' '1 = mild,' '2 = moderate,' '3 = severe,' '4 = very severe' and '5 = extremely severe.' The rating definition was based on clinical significance of the pregnancy symptoms as suggested by the obstetrician.

PHASE 2: FACE VALIDATION, CONSTRUCT VALIDATION AND RELIABILITY OF THE PSQ

All participants in Phase 2 were not the same participants in Phase 1. A total of 214 antenatal mothers attending antenatal clinic, HUSM who aged 19 to 40 years old, in second and third trimester were interviewed using the second version PSQ. All of them were given written consent. Ethical approval was granted by the Universiti Sains Malaysia Human Research Ethics Committee.

Maternal sociodemographic and obstetrics data were also obtained.

Face validity was assessed by asking the mothers to rate overall PSQ as 'very relevant,' 'relevant' or 'not relevant' for them to answer with regards to frequency and severity of pregnancy symptoms. Factor analysis statistical procedures were used to measure the construct validation. For the questionnaire reliability, the internal consistency coefficients (Cronbach's alpha) were computed for the overall PSQ, frequency and severity scales as well as each distinct domain, to ensure that the items of the distinct domains related to the total assessment.

STATISTICAL ANALYSIS

Data were analyzed using the Statistical Package for Social Sciences (SPSS 12.0). Descriptive statistics were used to summarize maternal characteristics. The construct validity of the PSQ was measured using factor analysis (principle axis factoring). Factor analysis for each frequency and severity of the symptoms was performed based on 38 items. In determining the number of factors to retain, eigenvalues of more than one, scree plot and percentage of variance of the factors were considered. Promax rotation method was used to determine the construct components. The derived factors were named based on team of expert discussion. The internal consistency reliability was expressed as Cronbach's alpha coefficients (α).

RESULTS

MATERNAL CHARACTERISTICS AND RESPONSE RATES

Of the mothers approached and invited to participate in the validation study, a total of 214 mothers completed the questionnaire with the response rate of 94% and refusal rate to participate was 4%. The sociodemographic and clinical characteristics of mothers in the validation study were presented in Table 1. Two hundred and one mothers were Malay (98.10%), while the rest were Chinese. Almost all mothers were receiving formal education. A total of 163 mothers were multiparous while one third of the sample had been admitted to the ward at least once before the study interview.

CONSTRUCT VALIDITY

Sixteen items were removed due to poor correlation with other items (Pearson correlation coefficient < 0.3), less important content, redundancy with other items as well as floor and ceiling effects. The eliminated items were frequency and severity of smell hypersensitive, excessive saliva, increased urination, hemorrhoids, fainting, mood swing, depression, increased appetite, non food cravings, congestion, nose bleeds, bleeding gums, tender breasts, vaginal discharge, vaginal bleeds and varicose veins. The 22 remaining items were used in the principal axis factoring analysis. The items were frequency and severity of headache, dizziness, food cravings, shortness of breath, hot flushes, insomnia, heartburn, bloating, constipation, nausea, vomiting, lost appetite, food hypersensitive, non food hypersensitive, Carpal tunnel, pelvic pressure or discomfort, Braxton Hicks, groin pain, backache, leg cramps, leg edema and fatigue.

The Keiser-Meyer-Olkin (KMO) for sampling adequacy was 0.74, while the scree plot suggested three domains to be used. The 22 items were found to be loaded in the three domains which were named as 'General,' 'Constitutional' and 'Somatic pain.' General domain consisted of 9 items, Constitutional domain consisted of 5 items and Somatic pain domain included 8 items (Table 2). The cumulative percent of three domains was 40.81% (Table 3).

TABLE 1. Maternal characteristics (n = 214)

Characteristics	Mean (SD)
Maternal age – yr	30.14 (5.07)
Gestational age – wk	32.43 (6.15)
Pre-pregnancy Body Mass Index (BMI)	24.20 (5.11)
	n (%)
Marital status	
Married and living together	183 (85.50)
Married and living separately	30 (14.00)
Divorced/Widow	1 (0.50)
Employment status	
Employed	132 (61.68)
Unemployed	82 (38.32)
Monthly household income (RM)*	
400 – < 700	23 (10.75)
700 – < 1000	17 (7.94)
1000 – < 2000	41 (19.16)
2000 – < 3000	32 (14.95)
3000 – < 4000	30 (14.02)
4000 – < 5000	22 (10.28)
≥ 5000	47 (21.96)
Undetermined	2 (0.94)
Gravidity	
Primigravida	51 (23.80)
Multigravida	135 (63.10)
Grand multigravida	28 (13.10)
Co-morbidities in pregnancy**	
Gestational Diabetes Mellitus (GDM)	26 (12.10)
Pregnancy-induced Hypertension (PIH)	12 (5.60)
GDM and PIH	4 (1.90)
Chronic illness	32 (15.00)

* range based on NHMS III report
** cases maybe overlapped

TABLE 2. Factor loadings for the pregnancy symptoms questionnaire items

Items	General	Constitutional	Somatic pain
Severity of heartburn	0.732		
Frequency of heartburn	0.708		
Severity of shortness of breath	0.656		
Frequency of shortness of breath	0.649		
Severity of bloating	0.602		
Severity of headache	0.586		
Severity of insomnia	0.582		
Severity of hot flushes	0.582		
Frequency of hot flushes	0.574		
Frequency of insomnia	0.552		
Frequency of headache	0.530		
Frequency of dizziness	0.515		
Severity of dizziness	0.514		
Frequency of bloating	0.496		
Severity of constipation	0.391		
Frequency of constipation	0.372		
Frequency of food cravings	0.349		
Severity of food cravings	0.280		
Severity of nausea		0.902	
Severity of vomiting		0.808	
Severity of lost appetite		0.776	
Frequency of nausea		0.771	
Severity of food hypersensitive		0.723	
Frequency of vomiting		0.698	
Frequency of lost appetite		0.677	
Frequency of food hypersensitive		0.642	
Severity of non food hypersensitive		0.625	
Frequency of non food hypersensitive		0.587	
Severity of Braxton Hicks			0.647
Severity of pelvic pressure			0.642
Frequency of Braxton Hicks			0.577
Severity of backache			0.575
Severity of leg cramps			0.568
Frequency of fatigue			0.551
Frequency of backache			0.548
Frequency of pelvic pressure			0.547
Severity of fatigue			0.528
Severity of carpal tunnel			0.503
Severity of groin pain			0.487
Frequency of leg cramps			0.486
Frequency of carpal tunnel			0.451
Frequency of groin pain			0.396
Severity of leg edema			0.254
Frequency of leg edema			0.247

FACE VALIDITY AND RELIABILITY

The vast majority (93.93%) of mothers indicated that the PSQ was relevant to them in the time of pregnancy period. The Cronbach's alpha coefficient was 0.93 for the whole PSQ and range for 0.70-0.87 for each domain (Table 3).

DISCUSSION

The present study was intended to develop and design a validated questionnaire of pregnancy symptoms for a use in the nutritional studies with a concern that pregnancy outcomes are greatly influenced by the maternal condition throughout the pregnancy period (Barker 2003). The early trimester of pregnancy is critical for the fetal growth and health status as this is when the major organ and systems begin to develop. Apparently most mothers experienced discomforts particularly morning sickness during their early pregnancy (Flaxman & Sherman 2000) which was then associated with reduced energy and nutrient intake and later results to impaired nutritional quality, less maternal weight gain and poor infant outcomes (Lee et al. 2004). Therefore, it is vital to measure the symptoms and discomforts during pregnancy to better understand the correlation between the pregnancy symptoms and pregnancy outcomes in the scope of nutritional status.

The content of PSQ was developed from a thorough literature review with the major concern on nutritional studies. Besides anticipating mothers' response from pre-test study, the content was also built up from advices and reviews of experts. Content validity that has been undertaken during the process of developing questionnaire helped to ensure that the content of PSQ is appropriate and relevant to the study purpose.

To ascertain that the content of PSQ seems appropriate for the mothers thus capable to measure the intended purpose, the face validation was carried out by asking the mothers the relevancy of the questions. Even though face validity is the weakest type of validity (Parsian & Dunning 2009), the result of eighty-five percents agreed that the PSQ is relevant during their pregnancy period further supported by high response rate, indicates the PSQ's acceptability with the average of only 10-15 minutes spent for each interview.

Construct validity of PSQ was supported by the factor analysis. Results of analysis showed high factor loadings in each domain, except three items with factor loadings less than 0.3. Instead of being eliminated, these three items (frequency and severity of leg edema and severity of food cravings) were meaningful to be retained since the correlation matrix of factors showed that all domains were correlated (correlation coefficient > 0.3). In addition, those three items were fairly contributed to the nutritional and health status of both mother and infant.

Food cravings were responsible for an increasing intake of certain foods during pregnancy (Pope et al. 1997). The most commonly craved items among pregnant mothers were fruit and fruit juices, sweets, pickles, fast foods, ice cream, and pizza (Pope et al. 1997; Bayley et al. 2002), which were most of them contained a high number of calories per serving or also referred as high density foods. According to a study (Crystal et al. 1999), mothers who experienced more severe symptoms of nausea during pregnancy were shown to self-reported more cravings for salty foods than mothers with no or mild symptoms.

TABLE 3. Construct validity and reliability of the pregnancy symptoms questionnaire

Domain	Subdomain	Score range	Factor loading	Cumulative Eigen value %	Cronbach's Alpha
General	Frequency	0-4	0.35-0.71	15.42	0.76
	Severity	0-5	0.28-0.73		0.79
Constitutional	Frequency	0-4	0.59-0.77	30.37	0.79
	Severity	0-5	0.63-0.90		0.87
Somatic pain	Frequency	0-4	0.25-0.58	40.81	0.70
	Severity	0-5	0.25-0.65		0.75

The changes of dietary patterns that mainly took place in early pregnancy might put the mothers at high risk of deficient or excess intake of energy and certain nutrients. Meanwhile, the contrasting view of food cravings that was proposed as a way of fetal protection (Flaxman & Sherman 2000), suggested that devouring for certain foods during pregnancy period was not only a reason to compensate but to diversify the diets and to consume higher-quality foods for the fetus growth. Given the conflicting and contrasting views of food cravings, it would be essential to include food cravings in the questionnaire to further investigate the potential dimensions of cravings in the nutritional studies. In view of the fact that the PSQ was developed with concern to the nutrition and health, hence those three items were subsequently retained in the questionnaire according to their respective domains.

Factor analysis (principle axis factoring) using Promax rotation was performed to assess the unique relationship and the correlations between items. The analysis showed that the items were correlated in which each item in a domain correlates to other items in other domain. In the mean time, factor analysis (principal component) using Varimax rotation was also performed. However the results showed lower factor loadings for certain items and since the orthogonal rotation (Varimax) does not permit correlations between items, then the factor analysis using Promax rotation was found to be more appropriate for the study. Moreover, the correlation matrix of factors in Promax rotation demonstrated the correlations coefficient of > 3.

The intercorrelation between symptoms of pregnancy was also shown in the previous studies. A study among the Australian pregnant mothers investigated the relationship between sleep disorder and physical symptoms during pregnancy and the result demonstrated that the mothers with greater frequency, severity and effect of physical symptoms on life during earlier pregnancy, tend to suffer from poorer sleep quality at later pregnancy (Kamysheva et al. 2010). Besides, more severe heartburn was observed to correlate with increased severity of nausea and vomiting during pregnancy (Ali & Egan 2007; Gill et al. 2009). One study reported that even though edema alone is not dangerous, but it could lead to discomforts and night cramps to the pregnant mothers (Young & Jewell 1997), while the favorable effect of reflexology technique to alleviate edema on reduced pain (Stephenson et al. 2000) explained that severe edema might caused pain sensations and poorer quality of life.

Morning sickness is characterized by nausea and vomiting. In the present study, nausea and vomiting were found loaded in the same domain (Constitutional) which revealed that they were highly correlated and equally measured the same variable. Food hypersensitivity in the PSQ is signified food aversion. A study demonstrated that mothers with more severity of vomiting during pregnancy had experienced significantly higher of food aversion/ food hypersensitivity (Crystal et al. 1999). In addition, a study by Lawson et al. (2004) which correlated nausea, vomiting and appetite loss with a decrease in caffeine consumption, supported the appetite loss as one of the items loaded in constitutional domain together with nausea and vomiting.

As the questionnaire relies on the mothers' memory, recall bias during the interview was our limitation. The extent to which mothers might have underreported or over reported their frequency of symptoms was unknown. However, the limitation can be reduced with the high reliability and repeatability of the questionnaire since the whole PSQ and each distinct domain demonstrated acceptable internal consistencies.

The mothers' information bias might also arise which was probably caused by wrongly defined the symptoms or by the misunderstanding of what interviewer has requested. We were aware of the limitations and to minimize the possible errors, the standard interviewing technique was developed by the interviewers before the interview session and there were only two interviewers involved in the study. The strength of the study is the application of both frequency and severity measurements in the questionnaire that eventually will help to increase our understanding to the regularity and intensity of symptoms experienced by the mothers during their pregnancy period. Lacasse et al. 2009 suggested that health practitioners should address important factor such as symptom severity to improve the management of symptoms such as nausea and vomiting in pregnancy.

As a conclusion, the PSQ is valid and reliable for measuring the frequency and severity of the pregnancy

symptoms, and therefore can be a useful tool in the nutritional studies related to pregnancy and its outcome.

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