Development of a New Psychometric Assessment Tool for Predicting Hepatitis B Virus Infection in Pregnant Women

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Abstract
Objectives: Hepatitis B virus (HBV) infection in pregnant women can lead to the development of serious complications in neonates. Therefore, this study aimed to develop a new tool for predicting this infection in pregnant women and to assess the psychometric properties of this scale.
Materials and Methods: This methodological study was carried out on 220 pregnant women visiting Al-Zahra and Taleghani hospitals of Tabriz, Iran in 2019. First, the relevant items were formulated and the respective questionnaire was developed and then, the validity (i.e., face, content, and construct) and reliability of the questionnaire were assessed as well. The data were analyzed in SPSS 21 using descriptive statistics, exploratory factor analysis (EFA), dependent t test, and Cronbach alpha coefficient.
Results: A 22-item questionnaire was designed and the items were scored using a five-point Likert-type scale (Min=22, Max=120). Finally, the Kaiser-Meyer-Olkin value, Bartlett's test of the Sphericity value, the internal consistency of the tool based on Cronbach's alpha coefficient, and the intra-cluster correlation coefficient were 0.801, 4035.810, 0.811, and 0.81, respectively.
Conclusions: In general, the present tool can reliably predict HBV infection in pregnant women thus its application is recommended in preventing relevant complications.
Keywords: Validity, Reliability, Pregnant women, HBV

Introduction

Women in different conditions (e.g., disease, pregnancy, cancer, and the like) are at a higher risk of developing various infections compared to men (1-4). Hepatitis B virus (HBV) infection is one of the most prevalent infections worldwide occurring during pregnancy (5). The US Preventive Services Task Force made recommendations in 2009 regarding screening for hepatitis B infection during pregnancy, and these recommendations were updated in 2019. Women's infection and its transmission to children (the high risk of all kinds of diseases and infections after being born) should always receive special attention (6). According to the World Health Organization (WHO), about two billion people have been infected with this virus throughout the world, and about 600 000 people die each year due to its complications (7-9). According to statistics, the moderate prevalence of HBV in Iran is about 1.5 million infected people (10) and perinatal transmission is considered as one of the most common routes for HBV transmission (11). More than 52% of HBV carriers have been infected through mother-to-child transmission in Iran. Therefore, it is one of the most common routes of HBV transmission in Iran (12, 13).

HBV can cause serious neonatal diseases and its transmission to infants can be prevented if it is diagnosed during pregnancy and before childbirth (14). HBV infection can also create major maternal problems. Accordingly, it is necessary to develop a tool for identifying relevant risk factors, screening pregnant women, and predicting the development of this infection in the target population. Thus, this study sought to develop a new tool for predicting HBV infection in pregnant women and to evaluate the psychometric properties of this tool.

Materials and Methods

This methodological study was conducted on 220 pregnant women visiting Al-Zahra and Taleghani hospitals affiliated with Tabriz University of Medical Sciences, Tabriz, Iran, in 2019. These women were selected from the clinics affiliated to the aforementioned hospitals during 2019. Self-report questionnaires were also completed, and the study was conducted in two phases. Necessary items were formulated and the questionnaire was developed in the first phase and then the validity and the reliability of the questionnaire were assessed in the second phase. All pregnant women within the age range of 18-35 years old were enrolled in this study. Women who were unwilling to participate in the study, illiterate women, and infertile

women who had become pregnant using treatments such as in vitro fertilization were excluded from the present study.

First Phase: Formulating the Items and Designing the Questionnaire

The research literature was reviewed and relevant researcher-made tools were examined in the first phase. Three new tools made in Iran were similar to our study in terms of their method, which was considered as our working model (15-17). Therefore, all articles associated with HBV in pregnant women were reviewed and relevant items were prepared considering the two above-mentioned studies. This task was performed by two members of the research group. The prepared items were then provided to three researchers who were experienced in developing research tools, and they made some comments. The items were subsequently given to two epidemiologists to examine the conformity of the items with the Iranian culture. Finally, 26 items were approved for inclusion in the questionnaire.

Second Phase: Assessing the Validity and Reliability of the Questionnaire

The face, content, and construct validity and reliability of the questionnaire were assessed in this phase.

Face Validity

The face validity was assessed using qualitative and quantitative methods. In the qualitative part, face-to-face interviews were conducted with 12 individuals in the target group to examine the difficulty of the used terms and expressions, as well as the relationships of different aspects of the questionnaire and the possibility of ambiguities or wrong interpretations. The items were then corrected based on interviewees' viewpoints. In the quantitative part, an impact score of ≥1.5 for an item was considered suitable. Finally, the items were edited by three experts who were experienced in the translation and edition of scientific papers.

Content Validity

To assess the content validity of the questionnaire, 8 faculty members were selected, including three gynecologists, three infectious disease specialists, and two epidemiologists who were experienced in developing relevant research tools, and the questionnaire was provided to them in order to submit their comments as documentary. The content validity of the scale was assessed using the content validity ratio (CVR) and content validity index (CVI). To calculate the CVR, the experts were asked to comment on the necessity of each item using a three-point scale ("necessary," "useful but not necessary," and "not necessary"). The Lawshe table for the minimum values of CVR was used and items with values smaller than 0.56 were omitted from the questionnaire. Further, the CVI value for each item was calculated using Waltz and Bausell's CVI (18). These values were computed as the proportion of items given a rating of quite/very relevant by the experts, and values above 0.79 were considered appropriate. Then, the overall content validity of the questionnaire was calculated, where scores ≥0.90 were considered acceptable.

Construct Validity

Factor and exploratory factor analyses were used to assess the construct validity of the questionnaire. Factor analysis evaluates inter-item correlations and categorizes correlated items. Moreover, the minimum sample size for conducting factor analysis is 10 people per item (19). In factor analysis, Bartlett's test of Sphericity and the Kaiser-Meyer-Olkin (KMO) test are used to measure the adequacy of sampling. Additionally, KMO values >0.9 and Bartlett's test at the significance level of <0.001 confirm the adequacy of data for factor analysis. In this study, eigenvalues were used to determine the number of items. An eigenvalue of a factor is defined as the sum of its squared factor loadings for all variables. In the next step, exploratory factor analysis (EFA) was performed after creating the factor correlation matrix. In addition, a correlation coefficient of 0.35 was determined as the minimum acceptable correlation. To further simplify the results, the extracted factors were rotated using orthogonal rotation. After extracting factors, they were given titles with regard to respective items, and their correlation with HBV development was examined as well. Eventually, the known-groups validity of the assessment tool was used to distinguish between distinct groups.

Reliability

Internal consistency and stability were used to assess the reliability of the questionnaire. Internal consistency was assessed by calculating the Cronbach's alpha coefficient (acceptable range: 0.7-0.8). To examine the stability of the questionnaire, the test-retest method was used with a two-week interval.

Major ethical considerations were considered in this study, included ensuring the confidentiality of information, along with obtaining an ethics code from the Regional Ethics Committee (IR.TBZMED.REC.1398.736)

and the participants' written informed consent.

Finally, the Kolmogorov-Smirnov test was used to examine the normality of the data and the data were analyzed by SPSS 21 using descriptive statistics, EFA, a dependent *t*-test, and the Cronbach's alpha coefficient.

Results

The mean (standard deviation) age of study participants was 28.19 05-05.18 years and all women had given birth at least once and all had only one sex partner. The birth record showed that none of them had an infection after pregnancy, and the educational attainment was 189 university-wide.

First Phase

A large item pool was extracted following the literature review. To select appropriate and district items, the research team analyzed the item pool in three stages and omitted or integrated similar or duplicate items accordingly. Finally, 26 items were selected for inclusion in the questionnaire.

Second Phase
Qualitative and Quantitative Face Validity

In this phase, some changes were made to items 9, 15, and 21 in order to clarify their meaning. Item 11 was also omitted due to the impact score of less than 1.5 (Table 1).

The construct validity of the questionnaire was assessed using EFA on 25 items. The KMO and Bartlett's test values were 0.801 and 4035.810, respectively, which was significant at $P < 0.001$. Therefore, the model was suitable for conducting factor analysis. The principal component analysis was carried out to extract the factors, and the scree plot was used to determine the number of factors. Since a correlation coefficient of 0.35 was determined as the minimum acceptable correlation for keeping items in factor analysis, 3 out of the remaining 25 items were omitted due to the small size of their factor loadings, and 22 items were assigned to 5 factors (Table 2).

Finally, internal consistency and stability were used to assess the reliability of the questionnaire and the Cronbach's alpha coefficient was 0.811 for the entire questionnaire (Table 3). The test-retest method was applied to examine the stability of the questionnaire, and the intra-cluster correlation coefficient was calculated as 0.81 in SPSS.

Scoring Items

Eventually, a 22-item questionnaire was designed and the items were scored using a five-point Likert-type scale (Min = 22, Max = 120). The scores ranged from 1 to 5. High overall scores (close to 120) indicated an increased risk of HBV infection and the immediate need for treatment before pregnancy.

Discussion

The present study was conducted to develop a new tool for predicting HBV infection in pregnant women and to assess the psychometric properties of this tool. The design of this questionnaire, as well as the framework of this study was based on the US Preventive Services Task Force protocol and its main parts followed this protocol. However, it should be noted that the Iranian culture has attempted in the design of the questionnaire (6). Given that the questionnaires should be based on the culture of each country, it is necessary to construct the questionnaire for the Iranian culture (making the questionnaire for the first time in Iran). A 22-item questionnaire was ultimately designed with 5 main factors including the history of infectious disease, insecure sex, insecure sex partner, the use of preventive materials, health, and observance. Studies on the factors influencing hepatitis B in pregnancy are close to the design factors in our study and it is clear that the design factors in our study have been also discussed in other studies. For example, Azami et al found that unsafe sex and the lack of preventive measures and hygiene are the main causes of this virus during pregnancy, which are similar to the results of our study (5). Other meta-analysis studies, such as our study, have pointed to similar factors,

Table 1. Effect Sizes, CVR, and CVI Values

Question Number	Effect Size	CVR	CVI	Question Number	Effect Size	CVR	CVI
Q1	04/03	1	1	Q14	04.20	0.72	1
Q2	01/91	1	1	Q15	03.25	1	1
Q3	04/66	1	1	Q16	03.21	1	1
Q4	04/03	0.73	1	Q17	03.81	1	1
Q5	05/22	0.5	1	Q18	01.77	0.70	1
Q6	04/20	1	1	Q19	04.30	0.55	1
Q7	03/33	1	1	Q20	02.91	1	1
Q8	03/33	1	1	Q21	02.10	0.74	1
Q9	04/91	1	1	Q22	02.77	0.74	1
Q10	03/51	1	1	Q23	03.51	1	1
Q11	0/58	-	-	Q24	04.15	1	1
Q12	02/71	1	1	Q25	03.88	1	1
Q13	04/44	1	1	Q26	01.59	1	1

Note. CVR: content validity ratio; CVI: content validity index.

Table 2. Factors Extracted Using the Orthogonal Rotation Method

Question Number	Factors				
	First	Second	Third	Fourth	Fifth
Q1	0.531				
Q2	0.589				
Q3	0.581				
Q4	0.636				
Q5	0.714				
Q6	0.750				
Q7		0.656			
Q8		0.723			
Q9		0.710			
Q10			0.471		
Q11		0.451		0.109	
Q12		0.726			
Q13			0.496		
Q14					
Q15			0.811		
Q16			0.891		
Q17			0.811		
Q18					
Q19					
Q20					0.239
Q21					0.494
Q22					0.801
Q23				0.603	
Q24				0.501	
Q25				0.119	

Table 3. Cronbach's Alpha Coefficient of the HBV Prediction Questionnaire

Factors	Cronbach's Alpha
First	0.781
Second	0.901
Third	0.821
Fourth	0.753
Fifth	0.803

Note. HBV: Hepatitis B virus.

which corroborates with the results of some other studies (20-22). The results confirmed the validity and reliability of the designed questionnaire. To the best of our knowledge, this is the first study to develop a tool for predicting HBV infection in pregnant women. Accordingly, it was impossible to compare the results with other articles, and this study merely analyzed the discussion. This tool can yield reliable results because various infections in women can lead to different complications. HBV is among these infections. Children born to mothers with +HBsAg and +HBeAg have a 70-90% chance of developing HBV infection, of whom more than 85% will eventually become the chronic carriers of the disease and about 25% of them will die from chronic liver disease or liver cancer (23-25). Therefore, the correct diagnosis of the possibility of HBV infection in pregnant women or those planning to become pregnant can prevent the occurrence of serious and even deadly infant diseases. Thus, this issue highlights the necessity of developing a prediction tool.

Validity is of great importance when developing scientific tools. As mentioned earlier, the face, content, and construct validity of the questionnaire were confirmed, and the result was a prediction tool with acceptable scientific validity and high understandability for the target population.

In addition, the Cronbach's alpha coefficient was 0.811 for the entire questionnaire, indicating that the designed tool had an acceptable internal consistency and high internal consistency demonstrates great reliability. This tool was developed by a group of researchers based on the opinions of some gynecologists and infectious disease specialists. Therefore, it seems to reliably predict HBV infection in pregnant women. Finally, it should be noted that this tool was found to have good reliability and reliability after being developed and reviewed by relevant experts and is therefore usable for everyone. On the other hand, any tool that is first made will definitely be used if it has high reliability and validity and its effectiveness depends on appropriate reliability and validity.

Limitations
The designed tool has not been used on a large-scale level. In addition, the sample consisted of Azeri-speaking women. Therefore, it was difficult for researchers to easily communicate with them.

Suggestions for Future Studies
It is recommended that relevant specialists use this tool to better calculate the likelihood of HBV infection in pregnant women. It is also suggested that this tool be used in other provinces of Iran to screen women with different cultures and backgrounds.

Conclusions
The prediction of dangerous infections such as HBV, which can cause undesirable complications, guarantees maternal and neonatal health. The prediction tool designed in this study can reliably predict HBV infection in pregnant women. Therefore, its application is recommended for preventing relevant complications.

Conflict of Interests
Authors declare that they have no conflict of interests.

Ethical Issues
The research project was approved by the Ethics Committee of Tabriz University of Medical Sciences (ethics no. IR.TBZMED.REC.1398.736).

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