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Research Article

Development of an Assessment Scale for the Risk of Falling in Pregnant Women

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ABSTRACT

Introduction: In pregnant women, the rate of falling is similar to that of women older than 70 years. According to the literature review, there is no risk of falling assessment tool that is specific to pregnancy. The aim of the study was to develop a risk of falling assessment scale for pregnant women. **Methods:** This is a methodological study. The study's population consisted of pregnant women who sought follow-up care at a state hospital's maternity ward between November 2016 and November 2017. The study sample included 630 pregnant women who met the inclusion criteria and volunteered for the study. The Pregnant Women Information Form and Assessment Scale for Risk of Falling in Pregnant Women were used as data collection tools. **Results:** During the scale development process, an item pool draft of 63 questions was developed and submitted to 10 experts for feedback. The findings of the content validity analysis revealed that the average of the items was 0.95, validity was good, and the number of items on the scale was reduced to 42 according to the experts' suggestions. The Cronbach α coefficient of the scale was found to be 0.604 (moderately reliable). It was discovered that the CART and QUEST algorithms on the scale were successful models for estimating the status of falls in pregnant women. **Conclusion:** A 42-item assessment scale for the risk of falling in pregnant women was developed, and it was determined that the scale was a valid and reliable tool.

Keywords: fall risk, assessment tool, scale development, pregnant women

INTRODUCTION

During pregnancy, women undergo numerous physiologic, anatomic, and metabolic changes.[1] As pregnancy progresses, lumbar lordosis increases, symphysis pubis ligaments and sacroiliac joints loosen, and the pregnant woman's center of gravity shifts. In addition to these changes, pregnancy-related hypotension, frequent urination during pregnancy, and medication all contribute to pregnancy falls.[2,3]

The falling rate during pregnancy (27%) is considerably high.[4] This rate is similar to that of women older than 70 years (28%).[5] Pregnant women experience 25% more falls than nonpregnant women.[6] Pregnant women are hospitalized 2.3 times more because of falling compared with women of reproductive age.[7] Falls account for approximately 24% of all hospitalizations due to injury during pregnancy.[8]

Falling during pregnancy can result in joint sprains, muscle injuries, fractures, direct fetal injury, spontaneous miscarriage, early opening of membranes, premature delivery, cesarean delivery, placental separation, and uterine rupture.[5,9,10] Maternal mortalities can result from head trauma, shock, or rupture or bleeding of internal organs as a result of a fall.[5,10] At the same time, if a pregnant woman is hospitalized, treatment costs rise, the pregnant woman's quality of life decreases, and the pregnant woman and her family experience anxiety and fear as a result of the fall.[2,11]

Safety culture assessments are new tools in the field of patient safety.[12] Falling is a critical patient safety issue in healthcare facilities worldwide. It is also a critical public health issue concerning patient safety. Pregnant women can be protected from falling or have their chances of falling reduced with the help of midwives and nurses.[4,11] Midwives and nurses are responsible for

identifying pregnancy risks and taking precautions.[13,14] Midwives and nurses should use falling risk assessment tools to determine individuals' falling risks and develop interventions to reduce them.[13] Fall risk tools are used at hospitals to assess the risk of falling and to prevent falls.[11] In a study, falling was determined at a rate of 4.04% per 1000 patients daily, but this rate was reduced to 2.27% after the risk of falling assessment tool was used.[15]

The Itaki Fall Risk scale is used to determine the fall risk of pregnant women in gynecology clinics in hospitals in Turkey. This form is used for the elderly, those with chronic diseases, and patients in intensive care. Although the rates of falling in pregnant women and the elderly are similar in the literature, the causes and risk factors differ. For example, pregnant women experience falls due to pregnancy-specific weight gain, changes in their center of gravity, and hypotension, whereas the elderly experience falls due to factors such as increasing age, chronic disease history, multiple drug use, use of assistive devices, balance or gait disturbance, and poor vision.[5,14,16] Pregnant women do not usually have any other underlying factors that lead to falls apart from pregnancy-related factors.

Therefore, the fall risk forms used in clinics may not accurately reflect the fall risk of pregnant women. According to a review of the literature, although there is a risk of falling assessment tool for inpatients, children, the elderly, and neurology patients, there is no specific risk of falling assessment tool for pregnant women.[11,13,17] Therefore, this study was conducted to develop and validate a fall risk scale for pregnant women.

METHODS

The Province Public Hospitals Union Clinical Research Ethical Committee granted permission to conduct the research, and informed consent was obtained. This was a methodological study for health quality improvement. The study's population consisted of pregnant women who applied for follow-up care at a state hospital's maternity ward between November 2016 and November 2017. Among the groups defined in the population, women who were literate, who had not been diagnosed with a psychiatric disease, who did not have mental deficiency and communication problems, who did not have a medical risk in their pregnancy, and who volunteered to participate in the research were included in the research sample.

The Pregnant Women Information Form and Assessment Scale for Risk of Falling in Pregnant Women (PASRoF) were used to collect data. During scale development, a sample size of 5–10 times the number of items in the draft scale is often suggested in the calculation of the sample size.[18] Because the draft of the PASRoF contains 63 items ($63 \times 10 = 630$), 630 pregnant women were included in the study.[18] A quota was established for each trimester in terms of applicant application rates. Based on this rate, the study was conducted with 630 pregnant women, with 105 in the first trimester, 210 in the second trimester, and 315 in the third trimester.

Data Collection and Tools

The Pregnant Women Information Form consisted of 10 questions about the pregnant women, including their age, where they live, education, income, occupation, weight gain during pregnancy, height, gestational week, and pregnancy story.

The ASRoF scale consists of 42 items. Items are scored as 1 (*yes*) or 0 (*no*) based on the presence of the factor that may pose a risk of falling. Two items on the scale are scored inversely. To calculate the PASRoF score, inversely scored items must be converted first. After converting item scores, they are scored as 0 (*yes*) or 1 (*no*). After converting the two inversely scored items, the total score of all items in PASRoF equals the total score of the scale. The total score on the scale can range between 0 and 42. A higher PASRoF score indicates a higher risk of falling in pregnant women.

Scale Development Steps

First, an item pool of 63 questions was created for the draft assessment scale for pregnant women's risk of falling.[4–6,9,10,17,19–22] To assess the content validity, subject matter experts were asked for their opinions on the item pool for the draft assessment scale for risk of falls in pregnant women. A checklist was developed for experts to determine and evaluate the extent to which the items are or are not relevant to the objective of the matter. Experts were asked to score the items as *not applicable*: 1 point; *moderately applicable* (item or the expression should be made more suitable): 2 points; *applicable* (little change is required): 3 points; and *very applicable*: 4 points. They wereto clearly write their opinions, corrections, and suggestions on each item to assess the applicability of each item to the aim of the scale. Expert opinions were assessed using the content validity index (CVI), and a CVI score was assigned to each item. According to this calculation, although expert scores of 1 and 2 were deemed unacceptable, expert scores of 3 and 4 were deemed acceptable. Therefore, for an item to be valid, it is required to get at least 3 points from 80% of the responding experts.

As a result of the assessment, 15 items with a CVI score of less than 0.8 were suggested by experts to be removed from the scale. The number of items was then reduced to 42 by combining some of the questions in accordance with experts' suggestions, and thus PASRoF was created. According to the literature, the scale that is ready for implementation should be tested on a small group first. It is stated that a pilot implementation may be conducted on 10–15 people.[18,23] The scale's 42-item pilot study on 30 pregnant women led to the development of the final version of the scale after necessary analysis and corrections. The final version of the scale

Table 1. Relationship between Pregnant Women Information Form and Assessment Scale for Risk of Falling Scores and demographics($N = 630$)

Variable	Subgroup	Median (Min–Max)	Test Statistics	*p*
Age, y	18 and younger	7 (4–13)	$\chi^2 = 13.0$	0.001*
	19–34	6 (0–18)		
	35 and older	7.5 (0–19)		
Community	Village or town	7 (0–14)	$\chi^2 = 7.823$	0.020
	District	6 (0–19)		
	Province	6 (0–17)		
Education	Primary or Secondary	6 (0–19)	$\chi^2 = 3.389$	0.184
	High School	6 (0–16)		
	University and higher	6 (0–15)		
Income level	Income less than expenses	6 (0–19)	$\chi^2 = 0.619$	0.734
	Income equal to expenses	6 (1–16)		
	Income more than expenses	5.5 (1–13)		
Occupation	Housewife	6 (0–19)	$\chi^2 = 9.635$	0.022
	Employee officer	6 (2–15)		
	Employee private sector	7 (1–14)		
	Not working because of pregnancy	9 (2–16)		
Stage of trimester	First	5 (0–14)	$\chi^2 = 42.727$	0.001
	Second	5 (0–19)		
	Third	7 (1–18)		
Number of pregnancies	One	6 (0–14)	$U = 45944.5$	0.132
	Multiple	6 (0–19)		

χ^2 values are from Kruskal-Wallis test statistics; *U* values are from Mann-Whitney *U* test statistics.

was used on 630 pregnant women. Pregnant women who volunteered for the study provided written consent. Each form was completed face to face with pregnant women while respecting their privacy. Interviews took an average of 25–30 minutes.

Data Analysis

Data analysis was performed using SPSS (version 26; SPSS Inc.) software. Frequency analysis and descriptive statistics analysis were used in the data assessment for the Pregnant Women Information Form. Kruskal-Wallis Tests, Mann-Whitney *U* Test, CVI, Cronbach α reliability coefficient, frequency analysis, decision tree algorithms (CART and QUEST algorithms), and logistic regression analysis, Wald Test, and Standard Error were used in the development of the scale.

RESULTS

Descriptive Features of Pregnant Women

Of 630 total pregnant women included in the study, 85.4% were 19–34 years old, 61.4% lived in the city center, and 56.2% graduated from primary or secondary school. The income of 72.2% of the participants was less than their expenses, and 84.1% were housewives. Of the pregnant women who participated in the study, 49.5% were in the third trimester.

Relationship Between PASRoF Score and Demographics

The median values in Table 1 were used to calculate the average PASRoF score of each independent variable. The scale scores of pregnant women differed depending on their age group, their residence, their occupation, and the stage of trimester ($p < 0.05$). No significant difference was observed between the average scale score and education, income level, and number of pregnancies ($p > 0.05$). Multiple comparison tests were used for each independent variable with a significant difference. The mean PASRoF scores of pregnant women in the ≤ 18 and ≥ 35 age groups were significantly lower than those of pregnant women in the 19–34 age group ($p < 0.001$). As a result, pregnant women aged ≤ 18 and ≥ 35 years are at a higher risk of falling. There was a significant difference in scale scores between pregnant women living in villages or towns and those living in districts and city centers ($p = 0.020$). As a result, those living in villages or towns are at a higher risk of falling. There was a significant difference in mean PASRoF scores between individuals unable to work because of pregnancy, those who work in the private sector, government employees, and housewives ($p = 0.022$). Accordingly, pregnant women who are unable to work because of their pregnancies or who work in the private sector are at a higher risk of falling. The mean PASRoF scores of pregnant women in their third trimester differed significantly from those in their first and second trimesters ($p < 0.001$). Accordingly, pregnant women in their third trimester are at a higher risk of falling.

Content Validity of the Draft PASRoF

The CVI score assigned by reviewers to the 63 items included in the draft PASRoF ranges between 0.5 and 1. The average CVI score of all items on the scale was found to be 0.95.

Table 2. Accuracy estimation of falling based on CART-QUEST algorithm ($N = 630$)

Occurrence of Falling	Estimation of Falling		
	Yes	No	Accurate, %
Yes	0	69	0.0
No	0	561	100.0
Total %	0.0	100.0	89.0

The CART-QUEST algorithm is method that does not require assumptions when analyzing data, has no bias, uses decision trees, can be calculated very quickly, and offers wide possibilities in statistical analysis.[29]

Item Analysis Results

Supplemental Table 1 (available online) lists the names and descriptions of the items included in PASRoF. "Did you fall in the last 3 months?" item was used as the dependent variable. The scale contains 41 independent variables, which are thought to affect the dependent variable.

According to the item reliability analysis results, the corrected item-total correlation, scale average (which will be obtained if the item is deleted), scale variance, and the Cronbach α coefficient were all checked. In the first stage, *x*10, *x*35, and *x*37 items with negative correlations were removed. Later, *x*5, *x*18, *x*22, *x*29, *x*33, *x*34, and *x*40 items were removed from the analyses to significantly increase the Cronbach α coefficient. After removing 10 items from the analysis, a reliability analysis was performed again. According to the final stage analyses, no items were excluded from the analysis because there was no significant increase in the reliability coefficient when the item was deleted. According to the reliability analysis result, Cronbach α coefficient was 0.604.

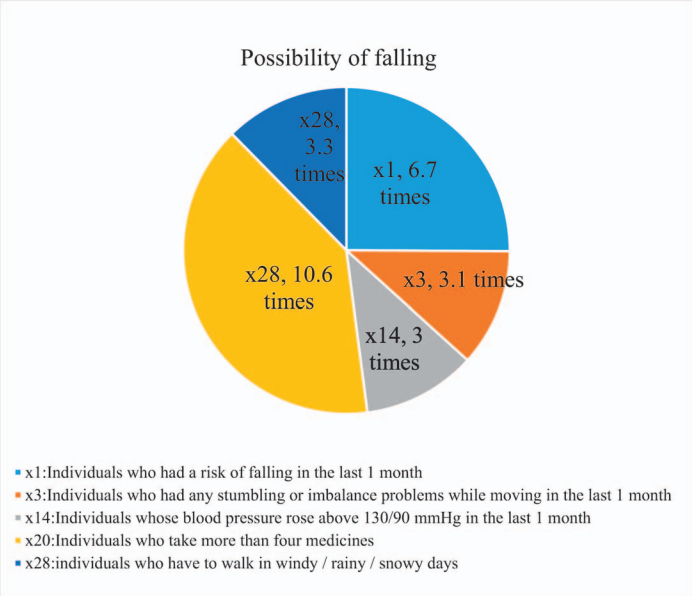

Figure 1. Items with a high probability of falling according to logistic regression analysis

Table 3. Accurate classification ratio for logistic regression analysis ($N = 630$)

Accurate	Estimation		
	Yes	No	Accurate, %
Yes	17	52	24.6
No	10	551	98.2
Total %	24.6	98.2	90.2

Estimation of Fall Risk

The decision trees of the CART and QUEST algorithms produced the same results. According to the decision tree generated by the CART and QUEST algorithms, the possibility of falling is 6.9% for those who did not have a risk of falling within the past 1 month and 26.1% for those who had a risk of falling within the past 1 month.

Table 2 shows the CART-QUEST algorithm's accurate estimation of falling in determining risk factors that affect falling. The rate of accurate estimation of falling by the decision tree model generated by the CART-QUEST algorithm is 89%. This ratio indicates that the CART-QUEST algorithm is a successful model for estimating the falling status of individuals.

According to the logistic regression model's test result, each regression coefficient has a statistically significant effect ($p < 0.05$) (Supplemental Table 2, available online). According to the logistic regression model's performance measures, Cox-Snell (0.158) and Nagelkerke R^2 (0.316) values indicate that independent variables can explain the dependent variable at a moderate level (–2 log likelihood, 327.214).

According to the logistic regression model's regression coefficients, the likelihood of falling of individuals who had a risk of falling within the previous month (*x*1) is approximately 6.7 times higher than other items. Individuals who had a stumbling or imbalance problem while moving within the past 1 month (*x*3) are approximately 3.1 times more likely to fall. Individuals whose blood pressure exceeded 130/90 mm Hg within the last month (*x*14) are approximately three times more likely to fall. Individuals who use more than four medicines (*x*20) are approximately 10.6 times more likely to fall. Individuals who have to walk on windy, rainy, or snowy days (28 days) are approximately 3.3 times more likely to fall. These ratios are shown in Figure 1.

Table 3 shows the accurate classification ratio for the logistic regression model. The accurate classification ratio of the logistic regression model is 90.2%. According to this result, the logistic regression model is a highly successful model to estimate the falling status of individuals.

DISCUSSION

Over the past century, maternal mortality from non-obstetric causes has increased, and maternal mortality from obstetric causes has decreased.[9] Traumas during

pregnancy are now reported to be the leading cause of nonobstetric maternal mortality.[13] The most common trauma during pregnancy is falling (25%).[2,22,24] A study conducted in Turkey found that this rate is much higher (54.9%).[25] Falls result in injuries, complications, increased hospitalization time, and thus higher healthcare costs for patients. It also causes premature birth, placental separation, uterine rupture, fetal development deficiency, and fetal and maternal mortality in pregnant women.[3,16] Midwives and nurses should identify the risk of falling in pregnant women ahead of time and take precautions against risk factors. However, although there are many risk of falling assessment tools in the literature for reviewing falling risk factors, there is no risk of falling assessment tool for pregnant women.[11] This shows the importance of developing PASRoF.

A scale is said to have content validity if a scale measures all the qualities to be measured, or if each item in a good scale has the ability to measure.[18,23] For content validity of the scale, the scale was restructured in accordance with the suggestions and criticisms of at least 3 and no more than 20 experts.[26] Therefore, the item pool of 63 items in the draft that was created to assess the content validity of the draft PASRoF was submitted for review by 10 experts. CVI was used to assess expert opinions. The CVI score is calculated for each item on the scale. In the literature review, it was determined that approximately 80% of the entire scale should receive a minimum of 3 points.[18,26] The CVI score assigned to the items in the item pool of 63 items in the draft assessment scale for risk of falling in pregnant women ranged between 0.5 and 1. The average CVI score of all items on the scale was found to be 0.95. This indicates that the content validity of the scale is quite good. In addition, 15 items with CVI scores of less than 0.8 that were suggested to be removed from the scale by experts were removed from the scale, some items were combined, and four new items were added, bringing the total number of items to 42.

When developing a scale, item-total score correlations are the most commonly used method of calculation during the item analysis process.[18,23] In this study, no items were excluded from the analysis, and there was no significant increase in reliability coefficient when an item was deleted. According to the reliability analysis results, the Cronbach α coefficient of 0.604 indicates that the scale is moderately reliable.

In the analysis of data obtained from scientific studies, the use of decision tree algorithms among classification and regression models used for forecasting the future based on existing data has increased recently.[27,28] This study was analyzed using commonly used decision tree algorithms, and it shows that the CART and QUEST algorithms are successful models for predicting the falling status of pregnant women.

Existing data should be statistically processed to determine a risk or make an estimate about the future. For this purpose, the most frequently used analysis is regression analysis.[18] To make an estimation, the relationship between dependent (y) and independent (x) variables must be measured. For cases in which the dependent variable is dual or categorized (e.g., alive or dead, sick or healthy), logistic regression is used. In logistic regression analysis, the model's suitability is tested first. If the model is statistically significant, the evaluation process is continued.[18] According to the results of this study, the logistic regression coefficient was statistically significant, so it was continued to be evaluated ($p < 0.001$). At the end of the assessment, it was determined that the accurate classification ratio of the logistic regression model was 90.2% and that the logistic regression model is a highly successful model for estimating the falling status of pregnant women.

Limitations of this work include that it was conducted in a public hospital in only one province and that data were collected cross-sectionally 5 years ago.

CONCLUSION

It is critical to limit falls and related complications that may occur during pregnancy. PASRoF was developed to help guide future studies on determining the risk of falling in pregnant women. It has been proposed that the PASRoF, which consists of 42 items, can be used as a valid and reliable scale for determining the risk of falling in pregnant women, and the results have been tested with studies conducted in different institutions and with different sample groups.

Midwives and nurses should use this assessment scale for risk of falling in pregnant women to determine individuals' falling risks and provide training and consultation to reduce falls. In this study, 42 risk factors for miscarriage were identified. Midwives and nurses can organize training for pregnant women and explain these risk factors to them (e.g., gaining weight quickly, being obese, being sleep deprived during pregnancy, suffering from advanced anemia problems, wearing high heels, not wearing slippers in the shower). Thus, awareness can be increased in pregnant women, risk factors for miscarriage can be reduced, and new strategies to prevent these risks can be developed.

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Supplemental Material

Supplemental materials are available online with the article.

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