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Diagnostic Value of Risk Nomogram for the Prediction of Postpartum Hemorrhage Following Vaginal Delivery

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Abstract

Background: Postpartum hemorrhage (PPH) is considered as one of the major causes of maternal mortality worldwide. The most effective risk factors have been suggested in various studies on risk nomogram for the prediction of PPH.

Aim: This study aimed to determine the diagnostic value of the risk nomogram for the prediction of PPH.

Method: This study was performed prospectively using diagnostic methods on 600 women admitted to Omolbanin Hospital, Mashhad, Iran, from May to October 2017. The researcher measured and recorded the loss of blood volume in mothers using plastic blood collection bags and pads within 4 h after delivery. Subsequently, risk nomogram was completed for each study sample and the probability score for PPH was calculated by the researcher's assistants. The obtained data were analyzed in SPSS software (Version 25). Ultimately, the receiver operating characteristic (ROC) curve of risk nomogram was plotted in this study.

Results: The PPH occurred in 33.3% (n=200) of deliveries in this study. The area under the ROC curve was estimated at 81.2%. The point of 0.1 with 85.5% sensitivity and 51.5% specificity was also selected as the proposed cut-off point for this nomogram.

Implications for practice: According to the results, the risk nomogram was considered as an appropriate method for the prediction of PPH. Therefore, it was recommended as a simple and noninvasive approach in childbirth for the prediction of PPH.

Keywords: Nomogram, Postpartum Hemorrhage, Risk Factor, Specificity and Sensitivity

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Introduction

Postpartum hemorrhage (PPH) is a known emergency situation in midwifery (1) characterized by 500 ml or more blood loss from genital tract within 24 h following vaginal delivery (2). The incidence of PPH has been reported to vary from 0.8% to 28.9% in numerous studies (3, 4) and it has also been reported about 27% in an investigation conducted in Ahvaz, Iran (5). The PPH is also considered as one of the major causes of maternal mortality across the world (6). This bleeding mostly occurs within 4 h after childbirth (7, 8) and the highest rate of maternal mortality (88 %) happen at this time (9, 10).

Three approaches, including the prevention of augmentation of bleeding, early recognition of bleeding and the estimation of loss of blood volume, and correct management of postpartum bleeding are considered to deal with PPH (11, 12). Given that 77% of hemorrhages happen at the presence of risk factors, it is necessary to identify such factors for the prediction of the hemorrhage incidence. The risk factors acknowledged in most studies include race (Asian mothers), maternal age and weight before delivery, a number of deliveries, hemoglobin and platelet levels, instrumental labor, uterine fundal pressure, episiotomy, perineal tears, retained placenta and its weight, as well as neonatal birth weight (13-15).

With regard to the strong correlation between the given risk factors and PPH in numerous studies, it seems that it is possible to use a model encompassing a number of factors for the prediction of PPH (13). Some guidelines have been developed for the classification of mothers into high-risk and low-risk groups following the results of studies for the evaluation of PPH risk factors. However, the instruments used in these studies have not been provided with high diagnostic values or such values have not been specified for them. Accordingly, these instruments do not have the required efficiency to be employed in hospitals (16, 17).

All the studies conducted on the understanding of the PPH risk factors have been retrospective and accomplished by the information provided in records. Such administrative data have not been able to review all the potential factors involved in childbirth. Accordingly, clinical data are needed to better understand the relationship between delivery factors and PPH (4).

The ROC curve is plotted for each model to measure the predictive value that can be measured according to the area under the curve (AUC). According to Swets's criteria and Zhu et al. (2010), the predictive value of models based on AUC domain can be divided into four categories. If 1>AUC>0.9, the predictive value of a model is excellent. This value is assumed good if 0.9>AUC>0.8. In addition, the predictive value of a model is worthless and the given value is reported bad if 0.8>AUC>0.7 and 0.7>AUC>0.6, respectively (18, 19). The points with the highest sensitivity are of utmost priority to determine the cut-off point in screening tests (20). Five models have been invented so far to predict the bleeding using risk factors; however, most of these models have had limited predictive power and the credibility of none of them has been measured in various communities (13, 17, 21-23).

According to a study conducted by Bigguzi et al. on Italian women from 2007 to 2009 (2012), a significant relationship was observed between the number of deliveries, episiotomy, retained placenta, hemoglobin levels, neonatal birth weight, race, Kristeller maneuver, placenta weight, genital tract tears, maternal age, vacuum-assisted delivery, and platelet levels.

They also proposed a nomogram to predict PPH with 71% predictive value (13). With regard to the suggestion by Bigguzi et al. for determining the validity of this nomogram in different environmental conditions and the absence of reports about establishing the diagnostic value of this nomogram in Iran, the present study was conducted in order to determine the diagnostic value of risk nomogram in the prediction of PPH in pregnant women admitted to Omolbanin Hospital in Mashhad, Iran, from May to October 2017.

Methods

This study was performed prospectively using diagnostic methods on a total number of 600 nulliparous and multiparous women admitted to the maternity ward of Omolbanin Hospital in Mashhad, Iran, from May to October 2017. All participants met the inclusion criteria in this study. The inclusion criteria were: 1) age range of 15 to 50 years, 2) gestational age of 37 weeks or more, 3) cervical dilatation of 4-6 cm during admission, 4) selective vaginal delivery, 5) fetal vertex presentation, 6) singleton pregnancy, and 7) lack of uterine scars.

On the other hand, the participants with emergency cesarean section, oxytocin intake by more than 20 units through infusion, and 10 units intramuscular as prophylaxis at the third stage of labor were

excluded from the study. Initially, 653 individuals were recruited in this study. However, 28, 23, and 2 of them were excluded due to emergency cesarean section, oxytocin intake at the third stage of labor, and urine leaks, respectively. Eventually, the final analysis was done on 600 study samples.

The study protocol was approved by the Ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran. Subsequently, the onset of the active phase of the first stage of labor and the objectives of the study were explained to the participants.

Moreover, written consent forms were obtained from mothers according to ethical codes followed by sampling. The PASS software was used to determine the sample size. Accordingly, the AUC and power were obtained at 0.7 and 0.5, respectively. Eventually, the sample size was calculated about 600. The tools used in this study included plastic blood collection bags, a digital scale, a hemoglobin and platelet analyzer, a risk nomogram, and information forms of individual characteristics, midwifery, and stages of labor.

This nomogram contained 12 quantitative variables (i.e., maternal age and weight, neonatal and placental weight, and prenatal hemoglobin and platelet levels) and qualitative ones (i.e., parity, race, perineal tears, episiotomy, vacuum-assisted delivery, Kristeller maneuver, and retained placenta). A score was assigned to each variable and a total score was calculated using sum of the scores. Finally, the probability of PPH for each participant was reported by numbers ranging from 0.1 to 0.9. In this respect, the scores lower than 136, by 136, and from 136 to 236 showed the probability of zero, 0.1, and 0.1 to 0.9, respectively (Figure1).

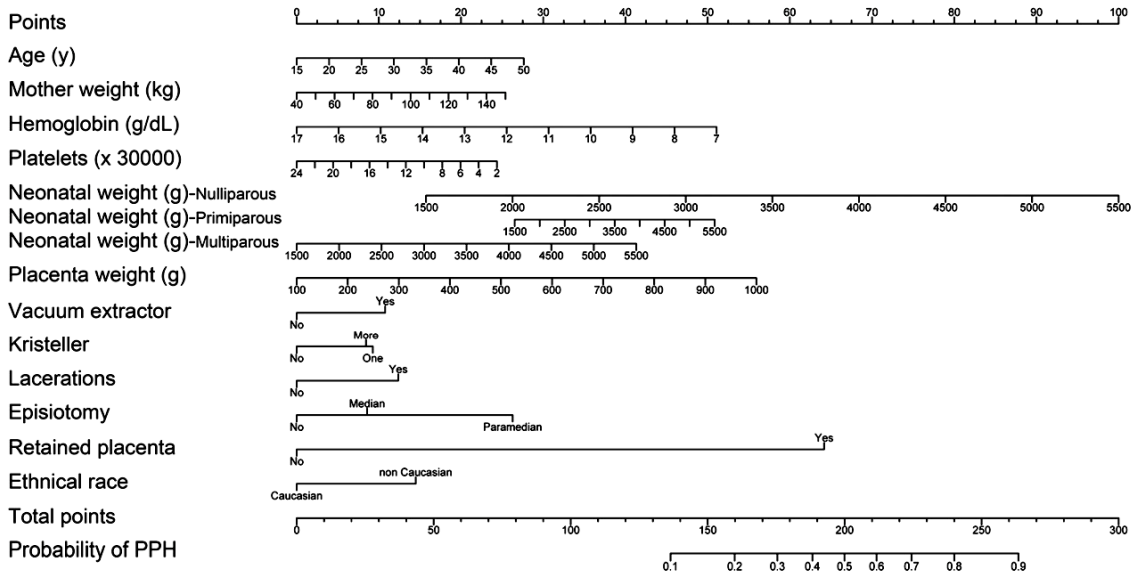

Figure 1: Risk nomogram predictive of postpartum hemorrhage

The content validity was also used to determine the validity of the individual characteristics. In addition, the content validity of the information forms of midwifery and stages of labor as well as the nomogram were approved by seven faculty members of Mashhad University of Medical Sciences, Mashhad, Iran.

The validity of the plastic blood collection bag had been also proved in various studies by Abbaspoor et al. (2010), Tourne et al. (2004), Patel et al. (2006), and Ambardekar et al. (2014). It was determined by comparison with a gold standard method (5, 24-26). The hemoglobin and platelet levels were also measured by Sysmex KX-21N analyzer in the laboratory of Omolbanin Hospital. The reliability of the risk nomogram was similarly verified by inter-rater agreement method. Therefore, the scores of risk nomograms of 20 study samples were calculated by the researcher and her assistants.

In the next stage, the reliability of the risk nomogram was confirmed (r=0.92). The reliability of plastic blood collection bag was also confirmed by inter-rater agreement method (r=0.98).

The blood samples of 15 individuals whose hemoglobin and platelet levels had been measured by the hospital laboratory in the morning, evening, and night shifts (5 samples per shift) were sent again to hospital laboratory (with fake names) to corroborate the reliability of hemoglobin and platelet.

Afterward, the laboratory results of these two samples were authorized using the agreement between evaluators by a correlation coefficient of r=0.84 and r=0.87 for hemoglobin and platelet, respectively. The study protocol was approved by the Ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran, on March 14, 2017 (IRCT code: 951233). The researcher explained the research objectives and methodology of the research process. The plastic blood collection bag was put under the parturient immediately after the neonate birth and it was taken out and weighed after one hour. Then, the weight of the bag subtracted from the initial weight of the empty bag (70 g) and it was recorded in the bleeding data form. Following this step, every 15 min within the second hour after birth and every 30 min during the third and fourth hours, a weighed pad in which the lost blood had been collected was given to the mother.

The pad was then removed after 15 min in the second hour and 30 min during the third and fourth hours. The pad weight and the result of the subtracted weight from the initial weight was recorded in bleeding data form.

Finally, the risk nomogram for each participant was drawn by the researcher's assistants using data in the forms and then its score was calculated and recorded in SPSS software (Version 25). After the completion of data, the ROC curve was plotted to determine the percentage of subjects who were correctly classified in PPH group by the risk nomogram. In addition, the AUC was calculated and sensitivity and specificity were determined in this study. The data were analyzed using the Mann-Whitney U test, independent t-test, and the Chi-square test. P-value less than 0.05 was considered significant and p-value less than 0.15 was also considered as the criteria for inclusion of a variable in logistic regression.

Results

The mean of the lost blood for four hours after delivery was 449.65± 266.97. Out of 600 study samples, the blood loss volume of 400 samples was less than 500 ml and 200 people (33.3%) had bleeding equal to 500 ml or higher. To determine the percentage of correctly classified subjects in PPH group by the risk nomogram, the ROC curve was plotted and the AUC was calculated by 0.812±0.020 with the probability of <0.001 and confidence interval of 95% (0.772-0.851) (Figure 2).

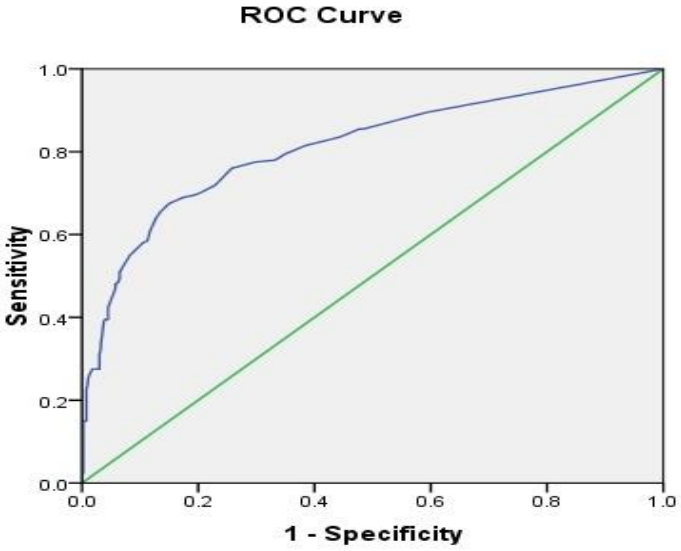

Figure 2: ROC curve of the predictive nomogram of postpartum hemorrhage

Sensitivity, specificity, and accuracy of various cut-off points in the nomogram were also determined. The point of 0.1 had the highest sensitivity (85.5%) while the points of 0.8 and 0.9 obtained the highest specificity.

Moreover, the cut-off point of 0.2 had the highest accuracy (75.75%) for predicting PPH. The least sensitivity and specificity equal to 0.5% and 51.5% were at the cut-off points of 0.9 and 0.1, respectively. The cut-off point of 0.9 also had the lowest validity or accuracy (50.25%) for predicting PPH. Since this nomogram was considered as a screening test and among the sensitivity and specificity of different points of the nomogram, the maximum of sensitivity was selected as the best

cut-off point with a value of 0.1 and higher as well as sensitivity and specificity of 85.5% and 51.5%; respectively (Table 1).

Table 1: Diagnostic value of proposed cutting points in risk nomogram for the prediction of postpartum hemorrhage

Cut-off points	Sensitivity %	Specificity %	(Accuracy)
0.1	85.5	51.5	68.5
0.2	69	82.5	75.75
0.3	51	93.5	72.25
0.4	39	96.3	67.65
0.5	26	98.8	62.4
0.6	16	99.3	57.65
0.7	7.5	99.8	53.65
0.8	2	100	51
0.9	0.5	100	50.25

The results of the comparison of quantitative variables of the nomogram in both groups were equal to and more than 500 ml and less than 500 ml as calculated by independent t-test and Mann-Whitney U test. In addition, there was a statistically significant difference between these groups in terms of age, maternal weight, platelet levels, neonatal birth weight, and placental weight (Table 2).

Table 2: Demographic and reproductive characteristics of pregnant women in the two study groups and Predictive factors of postpartum hemorrhage on the logistic regression analysis.

Variable	Bleeding equal to and more than 500 ml (N=200)	Bleeding less than 500 ml (N=400)	P- value	(OR)	95% CI
	Mean ± SD	Mean ± SD			
Age (Year)	25.8±5.9	27.2±6.3	P=0.007*	1.040	1.010-1.069
Mother's weight(Kg)	77.2±11.1	72.3±10.3	P<0.001**	1.047	1.011-1.083
Mother's Platelets (×1000)	197.7±50.6	207.4±54.5	P=0.037**	0.989	0.981-0.996
Mother's Hemoglobin(g/dl)	12.8±1.2	13.0±1.1	P=0.027*	1.160	0.999-1.347
Neonatal weight(g)	3284.3±509.0	3138.7±487.2	P<0.024*	4.025	3.641-6.850
Placental weight(g)	608.3±130.7	548.0±125.1	P<0.001*	1.003	1.003-1.011
	N (%)	N (%)	P- value	(OR)	95% CI
Race Caucasian Non- Caucasian	 164 (31.3) 36 (48.0)	 361 (68.7) 39 (52.0)	P=0.006***	 0.645 -	 1.141-11.644 -
Parity Nulliparous Primiparous Multiparous	 113(46.6) 44(24.8) 43(23.7)	 129(53.4) 133(75.2) 138(76.3)	P<0.001***	 5.987 - 1.219	 1.870-21.821 - 2.144-11.125

Table 2 Continued.

Uterine fundus pressure No One time More than one time	127 (26.8) 14 (63.7) 59 (57.3)	348 (73.2) 8 (36.3) 44 (42.7)	P<0.001*	- 1.964 2.688	- 1.964-11.764 2.688-6.896
Use of vacuum Yes No	19 (86.4) 181 (31.3)	3 (13.6) 397 (68.7)	P<0.001**	13.698 -	4.000-47.619 -
Episiotomy Yes No	132 (39.1) 68 (26.2)	207 (60.9) 192 (73.8)	P=0.001**	3.921 -	1.041-14.705 -
Genital tract tears Yes No	100 (42.8) 27 (21.3)	134 (57.2) 80 (37.4)	P<0.001**	17.857 -	2.041-16.666 -

* Mann-Whitney U test
** Independent t-test
*** Chi-Square test
**** Fisher's exact test

Moreover, the results of the comparison of qualitative variables in these two groups based on the findings of Mann-Whitney U test, the Chi-square test, and Fisher's exact test showed a statistically significant difference between parity, fundal pressure, use of vacuum, episiotomy, genital tract tears, retained placenta, and maternal race.

The results of the logistic regression test in this study showed that maternal age, race, parity, maternal weight, platelet levels, uterine fundal pressure, use of vacuum, episiotomy, neonatal birth weight, as well as placental weight were each associated with an increased odds of PPH. The risk of PPH in the women who had episiotomy was 3.921 times more than those who had not experienced this condition. Furthermore, perineal tears could increase the risk of PPH by 17.857 times (Table 2).

Discussion

After plotting the ROC curve in the present study, the risk nomogram could predict 81.2% of PPH (AUC=81.2). According to Swets's criteria, these findings showed that the given nomogram was endowed with a good percentage of subjects who were correctly classified. The point of 0.1 had the maximum sensitivity for predicting PPH, which was introduced as a cut-off point.

In a study conducted by Bigguzi et al. (2012) on 100 women in Italy, the nomogram predicted 70% of PPH (13). Alvarez et al. (2018) also proposed the predictive model of severe PPH in Australia. The variables affecting this model included maternal age, nulliparity, and duration of the first and the second stages of labor, neonatal birth weight, and prenatal hemoglobin levels. The predictive value of this model was estimated at 90% in a retrospective study on 2336 singleton term women and 83% in a prospective study on 953 women (23). The results of the study performed by Alvarez et al. were

consistent with the findings of the present study due to the similarity of the examined variables such as maternal age, neonatal weight, and hemoglobin levels before delivery.

According to a study carried out by Prata et al. in Egypt, (2011), the risk factors of PPH were divided into antepartum and intrapartum groups. Based on their model, the predictive risk factors of PPH included hemoglobin levels less than or equal to 11 mg per deciliter before delivery, previous history of PPH, and augmented and prolonged labor.

However, this model was able to predict only 10% of the bleeding. According to this model, if the person had only one of the risk factors mentioned above, the model could have the highest sensitivity (100%) and the least specificity (9.01%). If the person had all of the four mentioned risk factors, this model could have the least sensitivity (13.79%) and the highest specificity (98.92%). Accordingly, PPH could not be predicted (21). The results of the study revealed by Prata et al. were not in line with the findings of the present study due to the difference in the variables of the model proposed by Prata et al. and the given risk nomogram.

Two predictive models of PPH in women with gestational hypertension or mild preeclampsia were similarly proposed by Koopmans et al. (2014). The first model included prenatal variables, such as maternal age and platelet level; however, the second model contained variables during delivery, such as gestational age, duration of first and second stage of labor, neonatal birth weight, episiotomy, type of delivery, retained placenta, as well as manual removal of placenta.

Based on the AUC of the ROC curve, the first and the second model could predict 59% and 64% of PPH in women with gestational hypertension or mild preeclampsia, respectively (17). Therefore, the models presented in the study by Koopmans et al. failed to provide good predictive values. The results of the study by Koopmans et al. were not in agreement with the findings of the present study due to the differences in the study samples as well as separation of pre- and postpartum risk factors in the proposed model.

In this regard, Helman et al. (2015) conducted a study in Israel in order to predict severe PPH. In their study, multiple pregnancies, labor induction, cesarean section, and instrumental delivery were considered as the risk factors for severe PPH and the receipt of more than or equal to 5 units of red blood cells. The model provided was able to predict 91.9% of severe PPH (22). According to Swets's criteria, the predictive value of the model proposed by Helman et al. was excellent; however, the findings of the study were not consistent with those in the present investigation due to the difference in the studied variables as well as the definition provided for PPH.

In this study, PPH occurred in 33.3% of the study samples; however, its prevalence rate varied from 0.8% to 28.9% in different studies. In fact, the difference in the incidence of bleeding with other studies was due to discrepancies in the demographic status of study samples as well as levels of care in hospitals. Among the limitations of the present study was lack of access to similar investigations as well as no trust in responses provided by study samples in terms of the history of infliction with clinical diseases, gynecologic infection and problems, mental illnesses, as well as weight disorders before delivery.

Implications for practice

It was recommended to determine the predictive value of this nomogram for severe postpartum hemorrhage. Moreover, the predictive value of this nomogram was compared with other predictive models, such as those in the studies performed by Álvarez et al., Helman et al., and Koopmans et al. According to the results of this study, approximately 1 out of 3 pregnant women suffers from PPH. As well, the present nomogram had 81.2% predictive value. Considering the high rate of PPH and according to the fact that PPH could cause mortality, there is a need for a test or nomogram with the lowest false negative. However, this nomogram has about 15% false negative at its best condition for the prediction of postpartum hemorrhage.

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Conflict of Interests:
None declared

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