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Construction of a New Predictive Model and Scoring System for Hypertensive Disorder Complicating Pregnancy

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Abstract

Objective: To construct a new predictive model and scoring system for hypertensive disorder complicating pregnancy by using a combination of simple clinical variables that can easily be obtained at antenatal visit, and evaluate its clinical diagnostic value.

Study design: Included in this study were 2,466 nulliparous pregnant women at the gestational age of 16~20 weeks who came to our hospital for the first antenatal visit between 2011 and 2013. They were classified as a derivation cohort (*n*=1,421) and a validation cohort (*n*=1,045). A predictive model was developed from a logistic regression model, scoring system was developed by using the regression coefficients obtained from the new model and then internally and externally validated.

Results: The predictive model comprised 8 variables: body mass index (BMI), mean arterial pressure (MAP), drinking history, gestational diabetes, occupational physical activity, family history of hypertension, platelet count (PLT) and uric acid (UA), with a scoring system ranging from 0 to 13. The risk of HDCP in participants with low-risk (≤ 4 scores) or high-risk (>4 scores) in the validation cohort was 4.5% and 24.4% respectively (P<0.001), indicating that the predictive model had good discrimination (area under the receiver operating characteristic curve = 0.783), 95% confidence interval (0.746, 0.820) and calibration (P=0.745). The sensitivity and specificity were 76.6% and 67.7% respectively.

Conclusion: We have developed and validated a new predictive model comprising 8 variables: BMI, MAP, drinking history, gestational diabetes, occupational physical activity, family history of hypertension, PLT and UA. Due to cost/effectiveness and cost/utility, the new model can be applied to clinical screening of HDCP.

Keywords: Hypertensive disorder complicating pregnancy; Predictive model; Logistic regression; Scoring system

Introduction

Hypertensive disorder complicating pregnancy (HDCP) is a pregnancy-specific disease of pregnant women. According to current guidelines, hypertensive disorders during pregnancy may be classified into four categories: gestational hypertension (GH), preeclampsia (PE), eclampsia and PE with superimposed upon chronic hypertension (PE-SCH) [1]. The disease affects approximately 9.4%~10.4% of pregnant women in China. PE affects about 2% of pregnancies [2]. Approximately 10%~15% of direct maternal deaths are associated with PE and eclampsia [3]. It is important to predict HDCP early and strengthen monitoring and management to reduce maternal and child mortality.

The accurate etiology of HDCP remains unclear. Accumulating evidence suggests that abnormal cytotrophoblast invasion and spiral artery remodeling lead to placental ischemia/hypoxia, endothelial and vascular dysfunction [4,5]. Because of placental ischemia and hypoxia, abnormal secretion of the placenta enter the maternal blood stream and causes symptomatic phase disorder [6]. Failure of trophoblastic invasion leads to a higher placental resistance, this results in altered Doppler ultrasound blood flow pattern [7], the pulsatility index (PI) in the uterine arteries is increased in the first and second trimester of pregnancy [8]. In addition, there is strong evidence that an imbalance between angiogenic and antiangiogenic factors exists in preeclampsia [9]. So numerous candidate biomarkers have been proposed for prediction of HDCP, including placental hormones such as pregnancy-associated plasmaprotein-A (PAPP-A), placenta-protein 13 (PP-13) and β-human chorionic gonadotropin (β-HCG) [10-12], and angiogenic factors such as vascular endothelial growth factor (VEGF), placental growth factor (PlGF) and soluble fms-like tyrosine kinase-1(Flt-1) [12-14]. But no single predictor can predict the disease accuracy.

Presently, there is no single screening test that is definitely reliable and cost-effective for routine use in clinical practice due to a lack of sensitive specific indicators [15]. However, more recent studies suggested a combination of maternal factors and biomarkers to improve the accuracy of multivariable predictive models for HDCP. In terms of screening by maternal characteristics, uterine artery mean pulsatility index (PI) and mean arterial pressure (MAP) detected 90% of cases of PE requiring delivery before 34 weeks and 54% of all cases of PE at a fixed false-positive rate of 10% [16]. A combination of maternal factors, lowest uterine artery PI (L-PI), MAP and biochemistry (PlGF, activin-A and P-selectin) detected 90% of early PE, 45% late PE, 35%GH at a fixed false-positive rate of 10% [17]. As it is difficult to get these predictors, they are unsuitable for using in clinical practice. A recent survey [18] showed that weight, systolic and diastolic blood pressure obtained at the antenatal booking visit prior to 16 weeks may be suitable to stratify the risk of becoming hypertensive before 36 weeks of gestation, but the

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data used in this study were obtained between 1990 and 1994, and the model was not validated in recent cohorts.

In view of these limitations, they are not suitable for routine clinical use. Our aim is to construct a new predictive model by using a combination of simple clinical variables that can easily be obtained at antenatal visit.

Material and Methods

Patient population

The study protocol was approved by the institutional review board of the hospital. Pregnant women came to the hospital for the first antenatal visit at the gestational age of 16~20 weeks between September 1, 2011 and July 31, 2013. Pregnant women who had heart, liver and kidney diseases, severe anemia (Hb<60 g/L) and endocrine disorders (pheochromocytoma and primary aldosteronism psychosis) that could increase the risk of HDCP were excluded. Studies [15] showed that chronic hypertension in pregnancy complicated by preeclampsia increased by 9 times, chronic hypertension complicating pregnancy was also excluded, because this population are high-risk pregnancy, requiring intensive care. A total of 2,466 nulliparous were enrolled into this study, they classified as a derivation cohort (n=1,421) and a validation cohort (n=1,045), All of them were followed up till delivery. The case group included GH, PE and eclampsia, and the control group was normal pregnancy.

Age, height and weight, ethnicity, singleton or multiple birth, education background, blood pressure, smoking and drinking history before pregnancy, history of hypertension and diabetes, family history of hypertension and complications of pregnancy were recorded. Blood samples were taken at the same time for measurement of white blood cell (WBC), red blood cell (RBC), basophilic granulocytes (BG), total bilirubin (TB), aspartate aminotransferase (AST), platelet count (PLT), human chorionic gonadotropin (HCG), alpha fetal protein (AFP) and uric acids (UA). Urine samples were taken for measurement of urinary protein. Gestational diabetes screening was performed at 24-weeks gestation.

The subjects enrolled were occupationally classified as heavy manual laborers (such as porters, cleaners, agricultural workers and farm workers); manual laborers (such as domestic workers, waiters, cooks and nurses); light workers (such as teachers, hairdressers and beauty salon workers; wholesalers and staff) and sedentary workers (such as cashiers, receptionists and secretaries). Smoking was classified as Yes (average one pack of cigarettes per week over one year) and No (occasionally or never smoking). Drinking was classified as Yes (average > 500ml white or red wine per week over two years) and No (<500 ml white or red wine per week or never drinking). Calcium supplementation was classified as Yes (use of calcium supplements >3 months) and No (use of calcium supplements < 3 months).

Methods

Univariate analysis was performed in the derivation cohort to assess associations of each potential risk factor with HDCP, using the chi-square test for categorical variables and the unpaired t test for continuous variables. Multivariable logistic regression with backward stepwise selection with P<0.05 was performed for entry of variables to identify independent predictors of HDCP. Independent variables were selected according to the purposeful method described by Hosmer and Lemeshow [19]. Initial candidate variables were those with P < 0.20 in univariate analysis. Discrimination and calibration of the models were assessed by area under the receiver operating characteristic curve (AUC) and the Hosmer-Lemeshow chi-square statistics respectively [20,21].

To predict the presence of HDCP in a given individual, a predictive model with the independent variables selected by the multivariate analysis was designed. Continuous variables were converted into categorical variables. A new logistic regression model was run with these transformed variables, the score-based predictive model was developed from the new logistic regression equations by using a regression coefficient-based scoring method. To generate a simple integer-based point score for each predictor variable, we assigned scores by dividing beta coefficients by the absolute value of the smallest coefficient in the model and rounding up to the nearest integer; the total score for each participant was calculated by adding each component together. We then performed receiver operating characteristic (ROC) curve analysis and computed the AUC and its corresponding 95% confidence interval. In the derivation cohort, the risk for HDCP was measured for each score level. In developing an ordinal set of categories of risk, we combined score levels with similar magnitudes of risk; the proportions of people with HDCP in each risk category were compared by using the chi-square test. We chose the score that discriminated between a low-risk category and a high-risk category as the cut-off value and then calculated the sensitivity and specificity of the predictive model.

The predictive model was validated internally using the bootstrap method in the original data set by sampling with replacement for 1,045 iterations [21,22]. The predictive model was also externally validated in the independent validation cohort, with the same risk categories defined in the derivation cohort, the absolute risk for HDCP and the number needed to screen for each category were measured. To compare risk across categories, P values and AUC were measured; the sensitivity and specificity of the predictive model in the validation cohort were also calculated to evaluate the predictive accuracy.

To evaluate the impact of different sets of variables on the performance of the predictive model, sensitivity analysis was conducted by entering a different set of variables one at a time into a new logistic regression model and then recalculating AUC and the Hosmer-Lemeshow chi-square statistics. One set of variables based on the strongest and most consistent risk factors for HDCP included body mass index (BMI), MAP, drinking history, gestational diabetes, occupational physical activity, family history of hypertension, PLT and UA.

All statistical analyses were performed by using SPSS 19.0. All P values were 2-tailed, with statistical significance defined by P<0.05.

Results

Of the 2,466 pregnant women included in this study, the derivation cohort comprised 1,421 women and the validation cohort comprised 1,045 women. The rate of HDCP in derivation cohort and validation cohort were 12.1% (173/1421) and 9.1% (95/1045) respectively.

Predictive model construction

The result of univariate analysis showed that 19 variables were associated with HDCP (P<0.20) (Table 1). The result of multivariate analysis showed that BMI, MAP, drinking history, gestational diabetes, occupational physical activity, family history of hypertension, PLT and UA were significantly and independently associated with the risk for HDCP (P<0.05) (Table 1). The regression model showed good discrimination for HDCP with an AUC of 0.794 (95% confidence interval (CI): 0.757, 0.831) (p<0.001).

Variable	Total Cohort (n=1,421), no.	HDCP (n=173)		Normal pregnancy (n=1248)		*P* Value	Adjusted OR (95% CI)	*P* Value
		No.	%	No.	%			
BMI (Kg/m^2)						<0.001		
≤22.27	711	55	7.7	656	92.3		1	
>22.27	710	118	16.6	592	83.4		1.49 (1.03, 2.17)	0.037
MAP (mmHg)						<0.001		
≤83	855	46	5.4	809	94.6		1	
>83	566	127	22.4	439	77.6		4.01 (2.74, 5.86)	<0.001
WBC(10^9/L)						0.022		
≤8.89	712	73	10.3	639	89.7			
>8.89	703	100	14.2	603	85.8			
Gran(10^9/L)						0.081		
≤6.8	710	76	10.7	634	89.3			
>6.8	706	97	13.7	609	86.3			
LYM(10^9/L)						0.154		
≤1.67	718	79	11.0	639	89.0			
>1.67	697	94	13.5	603	86.5			
RBC(10^{12}/L						0.001		
≤3.94	717	67	9.3	650	90.7			
>3.94	701	106	15.1	595	84.9			
HGB(g/L)						<0.001		
≤120	719	64	8.9	655	91.1		1	
>120	699	109	15.6	590	84.4		1.37 (0.95, 1.98)	0.090
HCT(L/L)						0.067		
≤35	740	79	10.7	661	89.3			
>35	678	94	13.9	584	86.1			
PLT(10^9/L)						0.001		
≤200	717	67	9.3	650	90.7		1	
>200	701	106	15.1	595	84.9		1.56 (1.09, 2.25)	0.016
UA(mmol/L)						0.002		
≤0.22	707	67	9.5	640	90.5		1	
>0.22	705	104	14.8	601	85.2		1.69 (1.18, 2.44)	0.004
Urea(mmol/L)						0.003		
≤2.9	724	106	14.6	618	85.4		1	
>2.9	689	65	9.4	624	90.6		0.72 (0.50, 1.03)	0.074
TBIL(μmol/L)						0.149		
≤7.9	880	114	13.0	766	87.0			
>7.9	539	59	10.9	480	89.1			
IBIL(μmol/L)						0.163		
≤5.5	742	97	13.1	645	86.9			
>5.5	677	76	11.2	601	88.8			
AST(U/L)						0.200		
≤20	733	95	13.0	638	87.0		1	
>20	686	78	11.4	608	88.6		0.73 (0.51, 1.04)	0.082

GDM						<0.001		
No	1238	122	9.9	1116	90.1		1	
Yes	183	51	27.9	132	72.1		2.46 (1.61, 3.76)	<0.001
Drinking						<0.001		
No	1366	151	11.1	1215	88.9		1	
Yes	55	22	40.0	33	60.0		3.83 (1.70, 8.63)	0.001
Smoking						<0.001		
No	1398	161	11.5	1237	88.5		1	
Yes	23	12	52.2	11	47.8		2.56 (0.76, 8.57)	0.128
Physical activity						0.032		
Low	763	106	13.9	657	86.1		1	
Medium & High	658	67	10.2	591	89.8		0.61 (0.42, 0.87)	0.007
Family history of hypertension						0.010		
No	1098	120	10.9	978	89.1		1	
Yes	323	53	16.4	270	83.6		1.63 (1.10, 2.42)	0.015

Abbreviations

CI: Confidence Interval; HDCP: Hypertensive Disorder Complicating Pregnancy; OR: Odds Ratio; GDM: Gestational Diabetes Mellitus; BMI: weight (kg)/height (m). MAP: Mean Arterial Pressure; Gran, neutrophilic granulocyte; LYM: Lymphocyte; HB: Hemoglobin; HCT: Haematocrit; UA: Uric Acid; TBIL: Total Bilirubin; IBIL, indirect bilirubin; PLT: Platelet; AST: Aspartate aminotransferase

Smoking was classified as Yes (average one pack of cigarettes per week over one year) and No (occasionally or never smoking).

Drinking was classified as Yes (average > 500 ml white or red wine per week over two years) and No (<500 ml white or red wine per week or never drinking).

Calcium supplementation was classified as Yes (use of calcium supplements >3 months) and No (use of calcium supplements < 3 months).

P values refer to comparison between normal pregnancy and HDCP groups in the univariate analysis.

For variables not significant ($P > 0.20$) in the Univariate analysis are not shown

For variables not significant ($P > 0.05$) in the logistic regression model, multivariable data are not shown

Occupational Classification:

Heavy manual labor (porters, cleaners, agricultural workers and farm workers)

Manual labor (domestic workers, waiters, cooks and nurses)

Light work (teachers, hairdressers, beauty salon workers, wholesalers and staff)

Sedentary work (cashiers, cashiers, receptionists and secretaries)

Table 1: Univariate and Multivariable Analyses in the Derivation Cohort (*n* = 1421), China, 2011–2013.

All independent variables selected by the multivariate analysis were entered into a new logistic regression model (Table 2). In the new model, occupational physical activity heavy manual laborer and manual labor were combined into heavy & manual laborer; light workers and sedentary workers were combined into light & sedentary workers. The new model showed sound discrimination (AUC = 0.784, 95% CI: 0.747, 0.821).

Establishment of the scoring system

A predictive model including 8 variables that independently predicted HDCP in multivariate analysis was then developed by using the regression coefficients obtained from the new model (Table 2), a regression coefficient of 0.442 corresponded approximately to 1 point. Scoring system also had good discrimination (AUC = 0.783, 95% CI: 0.746, 0.820), the risk for HDCP increased with the risk score increasing (Table 3). On the basis of similar magnitudes of risk, scores 0 through 4 were combined into a low-risk category, and scores more than 4 were combined into a high-risk category (Table 3). The respective risk for HDCP in persons at low or high risk was 4.5% and 24.4% respectively (P<0.001), the sensitivity and specificity were 76.6% and 67.7% respectively, the high-risk category contained 76.6% of all person with HDCP.

Internal and external validation

The results showed that the mean AUC obtained from internal validation was the same as that from the derivation cohort, indicating that the predictive model had good discrimination. In the validation cohort, the risk for HDCP also increased with increasing of the risk score (Table 3), with the same risk categories as defined in the derivation cohort. The respective risk for HDCP in persons at low and high risk was 2.1% and 16.5% respectively (P < 0.001) ,which was similar in magnitude to the risk estimated in the derivation cohort. The sensitivity was 88.4% and the specificity was 55.3%, the high-risk category contained 88.4% of all people with HDCP, the AUC was 0.807 (95% CI: 0.763, 0.851), which was not different significantly from that of the derivation cohort (P = 0.407).

Discussion

The pathophysiology of HDCP is complex and is likely to be multifactor. Apart from placental ischemia/hypoxia, imbalance between angiogenic and antiangiogenic, which were mentioned in introduction, insulin resistance, hyperlipidemia, hypercoagulability, inflammation and a hyper dynamic circulation were associated with it. Study [23] showed that normal pregnancy is a state of systemic inflammation, and preeclampsia may represent an exaggerated response, maternal obesity and diabetes might enhance this response.

Our multivariable analysis showed that BMI, MAP, drinking history, gestational diabetes, occupational physical activity, family history of

Variable	Regression Coefficient	Adjusted OR	95%CI	*P* Value	Points Assigned
BMI (Kg/m^2)					
≤22.27		Referent			0
>22.27	0.442	1.56	(1.07, 2.26)	0.020	1
MAP(mmHg)					
≤83		Referent			0
>83	1.441	4.22	(2.90, 6.15)	<0.001	3
PLT(10^9/L)					
≤200		Referent			0
>200	0.458	1.58	(1.11, 2.26)	0.012	1
UA(mmol/L)					
≤0.22		Referent			0
>0.22	0.467	1.60	(1.12, 2.28)	0.010	1
GDM					
No		Referent			0
Yes	0.948	2.58	(1.71, 3.90)	<0.001	2
drinking					
No		Referent			0
Yes	1.715	5.56	(2.93, 10.56)	<0.001	4
Occupation					
Sedentary & light	0.482	1.62	(1.13, 2.32)	0.008	1
Heavy manual & manual		Referent			0
family hypertension					
No		Referent			0
Yes	0.461	1.59	(1.07, 2.35)	0.021	1

All independent variables selected by the multivariate analysis were entered into the new logistic regression model, in which all continuous variables were converted into categorical variables.

Points were assigned by dividing the regression coefficients by the absolute value of the smallest coefficient in the model and rounding up to the nearest integer. A regression coefficient of 0.442 corresponded approximately to 1 point.

Table 2: Predictors of HDCP in the New Logistic Regression Model and the Associated Predictive model (*n* = 1421).

Risk Score	Total No.	HDCP		Risk category	Total.		HDCP	
		No.	%		No.	%	No.	%
Derivation cohort					1421	100.0	173	12.2
0	42	1	2.4	Low(0-4)	885	62.3	40	4.5
1	181	5	2.8					
2	258	7	2.7					
3	238	13	5.5					
4	166	14	8.5					
5	185	27	14.7	High>4	536	37.7	131	24.4
6	159	33	20.9					
7	97	26	27.1					
8	42	17	41.5					
9	26	11	44.0					
10	19	11	57.9					
11	5	3	60.0					
12	2	2	100.0					
13	1	1	100.0					
Validation cohort					1045			
0	28	0	0.0	Low(0-4)	536	51.3	11	2.1
1	85	1	1.2					
2	166	1	0.6					
3	112	4	3.6					

4	145	5	3.4					
5	166	15	9.0	High>4	509	48.7	84	16.5
6	167	19	11.4					
7	96	15	15.6					
8	42	13	31.0					
9	23	10	43.5					
10	11	8	72.7					
11	2	2	100.0					
12	1	1	100.0					
13	1	1	100.0					

The prevalence rate of HDCP in both derivation and validation cohorts. There was a significant difference in HDCP prevalence across the 2 risk categories ($P < 0.001$). Proportion relative to all participants of the derivation or validation cohort.

Table 3: Risk for HDCP by Risk Score and Risk Category ($n = 2466$).

hypertension, PLT and UA are predictors of HDCP (Table 1), which is consistent with the results from previous investigations [15,24-34].

It was found in our study that gestational diabetes was the greatest risk of the others for HDCP occurrence, which is consistent with a recent finding that HDCP and gestational diabetes have common pathological insulin resistance [24]. Obese women are at higher risk for metabolic syndrome and insulin resistance, the risk of gestational preeclampsia has been found to double as the BMI rises from 21 to 26 [25], it is consistent with our findings. In our research the family history of hypertensive disorders and MAP are predictors of HDCP, which is supported by ample evidence from other studies [26,27]. Uric acid is a terminal metabolite of the degradation of nucleotides, which increases in patients with preeclampsia eclampsia, because the damage and death of trophoblastic cells and decreased urinary excretion due a lower glomerular filtration rate. Current Studies [28] showed that UA was an independent predictor of HDCP, which is consistent with our finding. Freitas et al. [29] showed that PLT was a good candidate predictor for PE. Yang et al. [30] reported that the platelet count in women with hypertensive disorders during pregnancy was remarkably high before the second trimester, our study also showed that the risk of HDCP was increased in women with a platelet count $>200\times10^9$/L at the gestational age of 16~20 weeks. Our result showed that drinking before pregnancy increased the risk of HDCP, supporting the previous idea about an association between HDCP and drinking history [31,32]. Our result also showed that sedentary and light work increased the risk of HDCP, on the contrary, heavy and manual occupational physical activities reduced the risk of HDCP, the reason may be that appropriate exercise may increase vascular compliance [33,34].

In addition, several studies reported that calcium supplements may reduce the risk of HDCP [35]. Age>35 [36] and elevated β-HCG [37] were associated with HDCP. However, we did not find a significant association between HDCP and these factors in our study.

In addition, the predictive model developed in this study compares favorably with other 2 predictive models [17,18]. The predictive model of Nijdam et al. [18] had good discrimination also (AUC=0.78 95% CI: 0.75-0.82), but the model only for GH, the prediction of eclampsia/PE was not evaluated. The predictive model of Poon et al. [17] had better discrimination than ours, but it is not reality to get these predictors. The predictors of our model are simple clinical variables that can easily be obtained at antenatal visit.

There are good reasons to believe that the new predictive model is accurate and can be applied in Chinese populations, our results showed that the predictive model had good discrimination and calibration in derivation and validation cohorts, which were also mentioned on internal validation, the performance indices obtained from internal and external validation were almost the same as those from the derivation cohort.

In addition, scoring system comprises only 8 readily available components and the score is easy to be computed, this simplicity will promote the use of the model in clinical care and research settings. Our sensitivity analysis showed that the Scoring system based on the statistical criteria had better discrimination too, When the cut off was risk score 4, the risk for HDCP in people at low and high risk were 4.5% and 24.4% respectively (P<0.001), the sensitivity and specificity were 76.6% and 67.7% respectively, the high-risk category contained 76.6% of all persons with HDCP. A pregnant woman will be classified based on a scoring system when she comes to the hospital for the first antenatal. Pregnant women with BMI >22.27 Kg/m (score 2), MAP>83 mmHg (score 3), PLT count>200×10^9 (score 1), UA>0.22 mmol/L (score 1), drinking history (Yes, score 4), occupational physical activity (sedentary and light work, score 1), history of family hypertension (Yes, score 1), If be diagnosed as GDM at 24 -weeks gestation, (score 2, this part of pregnancy accounted for 30% of HDCP in our study), total score>4 are classified as high-risk groups of HDCP, whose care and monitoring should be strengthened to reduce maternal and child morbidity and mortality.

Finally, we derived the predictive model by using the recommended methods that are widely used in derivation and validation of a predictive model [21,22], our sensitivity analysis showed that a predictive model based on statistical criteria had better discrimination. The eight-predictor logistic regression model was typical for epidemiological studies [38], in our derivation sample, 173 patients had confirmed HDCP, and the final Scoring system comprised 8 variables.

Conclusion

We have developed and validated a new predictive model consisting of 8 items: BMI, MAP, drinking history, gestational diabetes, occupational physical activity, family history of hypertension, PLT and UA. Due to cost/effectiveness and cost/utility, the new model can be applied to clinical screening of HDCP.

Limitation

There are two limitations in this study that should be acknowledged.

First, the study would be perfect if it is to be done in multicenter. The study population was composed of women from the same hospital, which may not representative of the entire female population. Second, more patients should be enrolled in this study. We could not determine the type of HDCP and its severity.

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