International Journal of Nursing Studies 79 (2018) 114–121

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/locate/ijns

Development and validation of a predictive model for excessive postpartum blood loss: A retrospective, cohort study

Ana Rubio-Álvarez[a,*], Milagros Molina-Alarcón[b], Ángel Arias-Arias[c], Antonio Hernández-Martínez[d]

[a] "Mancha Centro" Hospital, Av. Constitución, 3, 13600, Alcázar de San Juan, Ciudad Real, Spain
[b] University of Castilla-La Mancha, Facultad de Enfermería, Edificio Benjamín Palencia, Campus Universitario, s/n. 02071, Albacete, Spain
[c] "Mancha Centro" Hospital, Av. Constitución, 3, 13600. Alcázar de San Juan, Ciudad Real, Spain
[d] "Mancha-Centro" Midwifery Teaching Unit, Av. Constitución, 3, 13600. Alcázar de San Juan, Ciudad Real, Spain

ARTICLE INFO

Keywords:
Postpartum haemorrhage
Predictive model
Vaginal birth
Validation

ABSTRACT

Background: postpartum haemorrhage is one of the leading causes of maternal morbidity and mortality worldwide. Despite the use of uterotonics agents as preventive measure, it remains a challenge to identify those women who are at increased risk of postpartum bleeding.
Objective: to develop and to validate a predictive model to assess the risk of excessive bleeding in women with vaginal birth.
Design: retrospective cohorts study.
Setting: "Mancha-Centro Hospital" (Spain).
Participants: the elaboration of the predictive model was based on a derivation cohort consisting of 2336 women between 2009 and 2011. For validation purposes, a prospective cohort of 953 women between 2013 and 2014 were employed. Women with antenatal fetal demise, multiple pregnancies and gestations under 35 weeks were excluded
Methods: we used a multivariate analysis with binary logistic regression, Ridge Regression and areas under the Receiver Operating Characteristic curves to determine the predictive ability of the proposed model.
Results: there was 197 (8.43%) women with excessive bleeding in the derivation cohort and 63 (6.61%) women in the validation cohort. Predictive factors in the final model were: maternal age, primiparity, duration of the first and second stages of labour, neonatal birth weight and antepartum haemoglobin levels. Accordingly, the predictive ability of this model in the derivation cohort was 0.90 (95% CI: 0.85–0.93), while it remained 0.83 (95% CI: 0.74–0.92) in the validation cohort.
Conclusions: this predictive model is proved to have an excellent predictive ability in the derivation cohort, and its validation in a latter population equally shows a good ability for prediction. This model can be employed to identify women with a higher risk of postpartum haemorrhage.

What is already known about the topic?

- Postpartum haemorrhage (PPH) is one of the most serious complications arising from birth.
- Reducing the cases of PPH has become an objective for health-related international communities.
- Identifying women at higher risk of postpartum bleeding is a key element in the prevention of this complication.
- Four models of prediction have been developed previously, but none of them have validated their results in other populations.

What this paper adds

- A validation model available to professionals to help identify women with higher risk of bleeding.
- This tool can allow professionals to anticipate and implement more intensive bleeding assessment and control systems in those women with a higher riskof bleeding.
- The possibility of using a predictive model to reduce the morbidity of mothers in relation to postpartum bleeding.

* Corresponding author. Permanent address: Ana Rubio Álvarez +34 646628933 Address: C/Agen 7, 2°B | 45005 Toledo, Spain.
E-mail addresses: a.rubio.alvarez@hotmail.es (A. Rubio-Álvarez), milagros.molina@uclm.es (M. Molina-Alarcón), aariasa@sescam.jccm.es (Á. Arias-Arias), antomatron@gmail.com (A. Hernández-Martínez).

https://doi.org/10.1016/j.ijnurstu.2017.11.009
Received 25 March 2017; Received in revised form 21 November 2017; Accepted 24 November 2017

1. Introduction

Postpartum haemorrhage (PPH) is one of the most serious complications of birth. In fact, it is responsible for 27% of deaths related to pregnancy, according to data published by the World Health Organization (Say et al., 2014). Although the rates of PPH tend to vary depending whether high or low incomes countries are considered, it is estimated that PPH affects 6% of births (Carroli et al., 2008; Smit et al., 2014) and it is still the main cause of preventable maternal morbidity and mortality all across the world (Grobman et al., 2014; Ramler et al., 2017; Say et al., 2014; Zhang et al., 2005). Despite the use of uterotonics agents as preventive measure for postpartum haemorrhage (Mavrides et al., 2016; Westhoff et al., 2013), there has been an increase in the global rates of PPH during the last 25 years in well-resourced countries such as Australia, Canada, the United Kingdom, Ireland or the United States (Knight et al., 2009; Lutomski et al., 2012).

Due to its high impact on both the mother and newborn health, reducing the cases of PPH has become a major objective for health-related international communities. One of the strategies that has been put forward deals with properly identifying those women with higher chances of excessive postpartum blood loss in the attempt to promote a stricter vigilance on the aforementioned collective. Although obstetric haemorrhages can occur unexpectedly, some research has identified specific risk factors (Al-Zirqi et al., 2008; Bais et al., 2004; Briley et al., 2014; Combs et al., 1991; Ekin et al., 2015; Kramer et al., 2013; Nyflot et al., 2017; Sheldon et al., 2014; Sosa et al., 2009; Waterstone et al., 2001).

Some authors have made their contribution by means of models to predict the risks of bleeding, shedding light on both maternal and obstetric features that can be linked to this event. Nonetheless, only four models of this sort have been published. More specifically, three of these models have a very limited predictive ability, not even validating its effectiveness among different populations (Biguzzi et al., 2012; Helman et al., 2015; Koopmans et al., 2014; Prata et al., 2011).

The objective of the present study was first to develop and then validate a predictive model to assess excessive postpartum blood loss in women undergoing vaginal birth.

2. Methodology

2.1. Design and participants

An observational, analytical study of retrospective cohorts methodology was used. In order to elaborate the predictive model, we used a historical cohort consisting of 2336 women who had vaginal birth between 2009 and 2011. For validation purposes, we gathered information deriving from a prospective cohort involving by 953 women who had vaginal birth taking place between 2013 and the first semester of 2014 (Fig. 1).

The study population consisted of women with singleton pregnancies who had a vaginal birth at “Mancha-Centro Hospital”. Women with antenatal fetal demise, multiple pregnancies and gestations under 35 weeks were excluded because these situations present special clinical conditions whose behaviour might vary with respect to the normal situations.

In the attempt to estimate the size of the sample, we followed the maximum modeling principle (Perduzzi et al., 1996). This requires 10 events (women with haemorrhages in this particular case) per each incorporated variable. Taking into account that haemorrhage itself happens in 6% of births (Carroli et al., 2008; Smit et al., 2014), an initial model of 14 independent variables would require a minimum of 1666 women with vaginal births and approximately half of this amount (this is, 833 women) to satisfy the validation process.

2.2. Data collection and sources of information

The main tool we employed in order to collect the relevant data for this study was medical case histories from which the following variables were collected:

- Primary outcome variable: excessive postpartum blood loss, defined as a reduction in haemoglobin levels (Hb) greater than 3.5 g/dL between the outset of birth and 24 h after it.
- Independent variables were:
  - Maternal: maternal age, body mass index (BMI) and antepartum haemoglobin.
  - Obstetric: previous cesarean-section, primiparity, instrumental birth, duration of first and second stage of labour, use of regional analgesia, active management (use of 5 international unit intraoperative oxytocin upon the fetus' elbow birth and consequent controlled umbilical cord traction), manual removal of placenta, episiotomy and vaginal tear.
  - Fetal: gestational age and neonatal birth weight.

Different units of measurement and categories used for each variable are detailed in Table 1.

2.3. Statistical analysis

First of all, a descriptive statistics analysis was performed using absolute and relative frequencies for qualitative variables and arithmetic means and standard deviation (SD) for quantitative ones.

A bivariate analysis of potential predictive factors that previously were identified in the literature as risk factors of postpartum haemorrhage was carried out by using Chi-square and Student's *t*-test to calculate qualitative and quantitative variables respectively. Of these variables, and following Lemeshow's statistical criteria, associations with *p*-values of < 0.25 were chosen to be included in the multivariate binary logistic regression model (Hosmer and Lemeshow, 2000; Mickey and Greenland, 1989) (Table 1). This model was constructed by using backward elimination (RV in SPSS).

Using this model as reference (Model 1), we developed different models using final haemoglobin levels as the differentiating criterion. In other words, we considered as cases higher loss of 3.5 g/dL in Hb levels and also that the final levels of Hb were < 11 g/dL (Model 2), < 10 g/dL (Model 3), < 9 g/dL (Model 4) and < 8 g/dL (Model 5), respectively. For model 5, due to the low number of events, a complementary analysis was performed by Ridge Regression (Table 2).

Likewise, parameters of statistical reliability were presented: $-2LL$; Cox-Snell R2; Nagelkerke R2, for each of the 5 models (Table 2), with the values of sensitivity (Se), specificity (Sp), positive predictive value (PPV), negative predictive value (NPV) and likelihood ratio positive (LR +) for different probabilities of model 5 both the derivation cohort and the validation cohort (Table 3).

From among the eligible models, those that best fulfilled the following characteristics were chosen: suitable calibration (Hosmer-Lemeshow), area under the ROC curve (AUC of ROC), parsimony (small number of explanatory variables), ease of interpretation and clinical plausibility. In order to assess the prediction qualitatively, we used Swets's criteria, which values range from 0.5-0.6 (bad), 0.6-0.7 (poor), 0.7-0.8 (satisfactory), 0.8-0.9 (good), and 0.9-1.0 (excellent) (Swets, 1988).

We compared both the derivation cohort and the validation cohort carried out by using Chi-square and Student's *t*-test to calculate qualitative and quantitative variables respectively (Table 4) and finally the AUC of ROC in the validation cohort was calculated for the different models we created (Table 2).

A tool for automatically calculating the risk of excessive bleeding according to individual characteristics was designed in the attempt to make its application easier for clinic purposes (Appendix 1 in