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Impact of a protocol implementation in maternal mortality in High-Risk patients with postpartum hemorrhage: A cross-sectional study

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Abstract

Postpartum hemorrhage is the leading cause of maternal mortality and one of the main causes of maternal morbidity worldwide. The implementation of early alarms and unified management protocols allows for a quick, orderly, and sequential response to its management; and partly explains the different outcomes between high-income countries compared to low-income. We conducted a cross-sectional retrospective study in two institutions in Bogotá, Colombia. Eligible participants included all female patients between 12-49 years old with postpartum haemorrhage, defined as bleeding greater than 1000 mL, or clinical or hemodynamic instability that required medical attention, regardless of route of delivery. All patients were treated in accordance with obstetric hemorrhage protocols established in 2016 and updated in 2019 Medical records of patients with postpartum haemorrhage were reviewed from January 1, 2017, to December 31, 2021, with a total of 345 patients included. 71,6% of the population was Colombian, and 28.4% was migrating population; fifteen cases (5%) belonged to a specific ethnic group. Regarding level of education, 75,7% of the patients went to high school, and 3% had no education. 165 cases (48,2%) belonged to the subsidized regime and 94 (27,4%) didn´t have insurance. At the time of PPH, 134 patients (39.0%) had severe shock, 160 (46.6%) had moderate shock, and 50 (14.6%) had mild shock. The most used uterotonic was oxytocin, administered in 319 patients (92.8%). Our study reveals that the implementation of the protocol in the institution was related to better outcomes for patients and less maternal mortality.

Keywords: Postpartum hemorrhage, Labor, Shock, Route of delivery, Bleeding

Introduction

Postpartum hemorrhage is the leading cause of maternal mortality and one of the main causes of maternal morbidity in the world; timely diagnosis and appropriate management are essential to avoid fatal outcomes. The implementation of early alarms and unified management protocols allows for a quick, orderly, and sequential response to its management; and partly explains the different outcomes between high-income countries compared to low-income countries. The risk-based approach has the difficulty that a sizable percentage of postpartum hemorrhage (PPH) occurs in women without risk factors, and that not all patients with risk factors experience PPH. Moreover, the most relevant risk factors occur during labor and delivery.

There is no single and satisfactory definition of PPH. The World Health Organization (WHO) defines it as blood loss ≥500 ml after a vaginal delivery or more than 1000 ml after a cesarean section; however, in clinical practice, it is difficult to quantify blood loss in delivery rooms, and clinical estimation of blood loss is inaccurate. Moreover, bleeding is frequently underestimated by 30% to 50%. Other definitions of PPH include a 10% decrease in hematocrit, which is useful in research but not at the time of urgent care, or the need for transfusion, with the difficulty of the great variability in the attitude towards transfusions among medical staff. In the Subred Integrada de Servicios de Salud Centro-Oriente, it is defined as bleeding greater than 1000 ml, clinical or hemodynamic instability requiring medical intervention, regardless of the mode of delivery.

For the classification of severity, several models have been proposed. Minor bleeding if it is <1500 ml and major if >1500 ml, and massive obstetric hemorrhage when the loss is 30-40% (around 2 liters) of blood volume and very severe hemorrhage is a loss of 2500 ml or more. Massive PPH can also be considered as a

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loss of >30% of blood volume. The California Maternal Quality Care Collaborative classifies it into 4 stages: stage 0: Any woman in labor or delivery, stage 1: blood loss >500 ml after a vaginal delivery or >1000 ml after a cesarean; or a change in vital signs >15% or heart rate ≥110 beats/minute, blood pressure ≤85/45 mmHg or saturation <95%, stage 2: continuous bleeding with total blood loss <1500 ml, and stage 3: total blood loss >1500 ml or >2 units of packed red blood cells transfused; or unstable vital signs; or suspicion of disseminated intravascular coagulation.

The management of PPH is very variable, with multiple medical and surgical alternatives. Medical treatment includes medications such as oxytocin, tranexamic acid, methylergometrine, misoprostol, and recombinant factor VIIa, either alone or in combination. Resuscitation with crystalloids in high volumes or with controlled boluses. The most used surgical interventions are intrauterine hemostatic balloon, uterine curettage, lesion repair, compressive uterine sutures, ligation or embolization of uterine arteries, ligation of ovarian arteries, ligation of hypogastric arteries, uterine tourniquet, endovascular aortic balloon occlusion, hysterectomy, and pelvic packing.

To avoid variability in diagnosis and management, which increases the possibility of errors and fatal outcomes, in 2016 we unified the management algorithm in our institution according to the PPH classification.

Methods

Study design

We conducted a retrospective cross-sectional study. All patients admitted in the institutions of the Subred Integrada de Servicios de Salud Centro-Oriente in Bogota between 2017 and 2021 who met the eligibility criteria were included in the study. Data for all variables was collected in an anonymous database using REDCap electronic data capture tools. The study was reviewed and approved by our institution's ethics. Upon admission, patients provided written informed consent for the use of their clinical information in research. The study adhered to the checklist of essential items for cross-sectional studies (STROBE).

Study population

Eligible study participants included all the female patients between 12-49 years old with postpartum haemorrhage diagnosis, defined as a bleeding greater than 1000 mL, or clinical or hemodynamic instability that required medical attention, regardless of the route of delivery. We also included patients who underwent voluntary termination of pregnancy, and those patients whose delivery was conducted in another institution. All patients were treated in accordance with obstetric hemorrhage protocols established in 2016 and updated in 2019. The exclusion criteria were as follows: (i) insufficient follow-up and (ii) inability to provide informed consent during hospitalization.

Variables

The following variables were categorized and analyzed: demographic and clinical characteristics of the patients such as age, nationality, ethnicity, schooling, obstetric formula, body mass index (BMI), gestational history or previous diseases. Clinical variables related to labor: use of oxytocin or misoprostol, premature membrane rupture, duration of labor, complications, perineal tears, episiotomy, placental accretism or abruption and neonatal weight. Finally, the clinical variables regarding postpartum hemorrhage were evaluated: grade and duration of shock, mean bleeding volume, cause of the haemorrhage, packed red blood cells, platelets and plasma transfusions, need of reoperation and ICU admission

Statistical analysis

A description was made with demographic, clinical and outcome variables. Categorical variables were described as proportions and continuous variables as medians with their respective Interquartile Range (IQR). An analysis was performed using measures of central tendency and dispersion to describe the analyzed variables. There was no missing data from the records reviewed. The information was collected from clinical registries, and the analysis was performed using STATA/IC 15.1.

Sample size calculation

All patients who met the selection criteria during the study period were included in the analysis. A *post-hoc* sample power calculation was performed.

Table 1. Sociodemographic variables

Variable		N (n = 345)	Absolute frequency (%)
Age	≤15 years old	9	2.60%
	16-34 years old	307	89%
	≥ 35 years old	29	8.40%
Year of event	2017	57	16.50%
	2018	38	11.00%
	2019	87	25.20%
	2020	50	14.50%
	2021	113	32.80%
Insurance regime	Subsidized	166	48.10%
	Contributory	84	21.40%
	None	95	27.50%
Nationality	Colombian	248	71.90%
	Venezuelan	97	28.10%
Ethnicity	Indigenous	7	2.00%
	Afro	5	1.50%
	Gypsy	1	0.30%
	Raizal	1	0.30%
	Palenquero	1	0.30%
	None	330	95.70%
Educational level	Elementary	19	5.50%
	Highschool	260	75.40%
	Technician	21	6.10%
	Profesional	33	9.60%
	None	12	3.50%

Results

Medical records of patients with postpartum haemorrhage were reviewed from January 1, 2017, to December 31, 2021, with a total of 345 patients included in this study. 71,6% of the population was Colombian, and 28.4% was migrating population; fifteen cases (5%) belonged to a specific ethnic group. Regarding the level of education, 75,7% of the patients went to high school at least, and 3% had no education. 165 cases (48,2%) belonged to the subsidized regime and 94 (27,4%) didn´t have any type of insurance.

The mean age of the studied population was 24 years, of which nine cases (2,6) were patients under 15 years and twenty-nine cases (8,4%) were 35 years or older. In total, 138 cases (40%) were nulliparous and twenty-two patients (6,3%) had five or more pregnancies. The average gestational age was 37.6 weeks. Fourteen patients (4%) had a history of postpartum haemorrhage, and four (1.1%) had a history of a hematological disease. A total of 23% of patients presented with hypertension associated with pregnancy and 8.4% had hemorrhage after week twenty and before delivery. Eight patients (2.3%) had twin pregnancies. At the time of delivery, 147 patients (42.6%) were overweight and 117 (33.9%) were obese.

Regarding the route of delivery, 223 patients (64.6%) had vaginal delivery, 65 (18.8%) had an emergency cesarean section, 36 (10.4%) had an elective cesarean section, and 18 (5.2%) had instrumented delivery. In 54 cases (15.7%), cervical ripening was performed with misoprostol and in 266 (77.1%) induction with oxytocin was performed, with a mean labor duration of 4.1 hours, with an interquartile range of 0 to 24 hours. Only 52 (15%) patients had labor lasting longer than 14 hours. In 94.2% of deliveries, active management of labor was conducted. Episiotomy was done in 59 cases (17.1%) and 147 (42.6%) had some type of perineal tear. About placental abnormalities, 15 patients (4.4%) had placental accretism, 10 (2.9%) had placenta previa and 11 patients (3.2%) suffered from abruption.

Table 2. Variables related to pregnancy

Variable		N (n = 345)	Absolute frequency (%)	Variable		N (n = 345)	Absolute frequency (%)
Obstetric formula (Gravidity)	G1	138	40.00%	Gestational age	Mean	37.6 weeks	---
	G2	94	27.30%		Mediana	39 weeks	---
	G3	55	16.00%		SD	3.51	---
	G4	36	10.40%		Cardiopathy	6	1.70%

	≥ G5	22	6.40%	Gestational history	Diabetes mellitus	1	0.30%
Obstetric formula (Parity)	P0	2	0.60%		Hematologic disease	4	1.20%
	P1	160	46.40%		Postpartum hemorrhage	14	4.10%
	P2	93	27.00%		Obesity	42	12.20%
	P3	90	26.10%	Present gestation	Prenatal control < 4	152	44.10%
Obstetric formula (Cesarean section)	C0	243	70.40%		Prenatal control ≥ 4	193	55.90%
	C1	68	19.70%		Hemorragia <20 sem	19	5.50%
	C2	23	6.70%		Hemorragia >20 sem	29	8.40%
	≥ C3	11	3.20%		Gestational diabetes	6	1.70%
Obstetric formula (Abortion)	A0	277	80.30%		Hypertensive disorder	82	23.8
	A1	52	15.10%		Twin pregnancy	8	2.30%
	A2	12	1.20%	Body mass index (BMI)	Low weight (IMC < 18,5 kg/m2)	4	1.20%
	A3	4	1.20%		Normal weight (IMC 18,5-24.9 kg/m2)	77	23.30%
Obstetric formula (Fetal death)	O0	323	93.60%				
	O1	19	5.50%		Overweight (IMC 24.9-29.9 kg/m2)	147	42.60%
	O2	3	0.90%		Obesity (IMC ≥ 30 kg/m2)	117	33.90%
Obstetric formula (ectopic)	E0	341	98.80%	Delivery	Vaginal	223	64.60%
	E1	4	1.20%		Instrumented	18	5.20%
Obstetric formula (stillborn)	M0	1	99.70%		Elective C-section	36	10.40%
	M1	1	0.30%		Urgent C-section	65	18.80%
					Extra hospitalary	3	0.90%

At the time of activating the red code, 134 patients (39.0%) had severe shock, 160 (46.6%) had moderate shock, and 50 (14.6%) had mild shock. The mean bleeding volume was 1240 cc (IQR 300-6000). The mean initial hemoglobin value was 10.2 (IQR 3.6-15). The cause of postpartum hemorrhage was uterine tone in 283 patients (82.0%), tissue retention in 35 patients (10.1%), trauma in twenty-three cases (6.7%) and thrombin in four cases (1.2%). A total of 279 patients (81.1%) had massive fluid resuscitation. The most used uterotonic was oxytocin, which was administered in 319 patients (92.8%). In 206 case (59.9%), five simultaneous medications were used: oxytocin, misoprostol, methylergonovine, tranexamic acid and cefazolin. In 62 patients (17.9%), four simultaneous medications were used: oxytocin, misoprostol, methylergonovine, and cefazolin, in 3 cases (0.9%) three simultaneous medications were administered: oxytocin, misoprostol, and cefazolin, and in 29 (8.4%), only oxytocin and misoprostol were used. 82.3% of the patients (284) required at least one red blood cell unit transfusion, with a mean of 2 units (IQR 1-13), 31 cases (9%) received platelets (IQR 2-13), 32 patients (9.2%) were transfused with plasma (IQR 2-20), and 16 patients (4.4%) received a transfusion package of 6:6:6 units (red blood cells, plasma and platelets). Only 6 patients (1.7%) had fibrinogen less than 200.

Table 3. Variables related to labor

Variable		**N (n = 345)**	**Absolute frequency (%)**
Induction of labor	Yes	266	77.10%
	No	79	22.90%
Use of misoprostol only	Yes	54	15.70%
Variable		N (%)	Central tendency
Oxytocin infusion duration	0 - 6 hours	257 (74.5%)	Median = 3
	6 - 12 hours	73 (21.1%)	Mean = 4,1
	12 - 18 hours	11 (3.2%)	SD = 4,4
	> 18 hours	4 (1.2%)	IQR = 0 - 24
Prolonged membrane rupture	None (0-18 hours)	339 (98.3%)	Mean = 1
	Yes (> 18 hours)	6 (1.7%)	SD = 4,6
Duration of labor	0 - 14 horas	293 (84.9%)	Mean = 7,8
	> 14 horas	52 (15.1%)	SD = 7,4
Neonatal weight	0 – 500 gr	4 (1.2%)	Mean = 2924,7
	500 – 1499 gr	10 (2.8%)	Median = 3050
	1500 – 2499 gr	52 (15.1%)	SD = 635,4
	2500 – 3999 gr	275 (79.7%)	IQR = 590 - 4210
	≥ 4000 gr	4 (1.2%)	
Variable		N (n = 345)	Absolute frequency (%)
Active management with oxytocin	Yes	325	94.20%
	No	20	5.80%
Use of carbetocin	Yes	8	2.30%
Complications	Polihidramnios	7	2.00%
	Chorioamnionitis	9	2.60%
	Manual removal of placenta	73	21.20%
	Pelvic trauma	4	1.20%
Perineal tears during labor	None	198	57.40%
	1	55	15.90%
	2	59	17.00%
	3	3	0.90%
	4	1	0.30%
	Cervical	20	5.80%
	Parauretral	9	2.60%
Episiotomy	Yes	59	17.10%
	No	286	82.90%
Placental accretism	Yes	15	4.40%
	No	330	95.70%
Placenta previa	Yes	10	2.90%
	No	335	97.10%
Placental abruption	Yes	11	3.20%
	No	334	96.80%

In relation to outcomes and complications, a total of 76 patients (22%) required surgical management, in 75 cases (21.7%) a hysterectomy was performed and in only 1 (0.3%), uterine curettage was required. In 30 patients (8.7%) pelvic packing was performed as a second procedure. Only 35 patients (10.1%) presented any complications, the most frequent being infection and respiratory failure. The only maternal death (0.3%) was not due to postpartum hemorrhage, but due to liver failure.

Table 4. Variables related to postpartum hemorrhage and outcomes

Variable		**N (n = 345)**	**Absolute frequency (%)**	
Shock classification according to clinical record	Mild	50	14.60%	
	Moderate	160	46.60%	
	Severe	134	39.00%	
Shock classification according to clinical variables	Mild	24	7.00%	
	Moderate	179	52.00%	
	Severe	141	41.00%	
Cause of shock	Uterine tone	283	82.00%	
	Tissue retention	35	10.10%	
	Trauma	23	6.70%	
	Thrombin	4	1.20%	
Hospital stay (in days)	1 - 4 days	283	82.00%	
	> 4 days	62	18.00%	
Medicamentos usados durante el choque	Oxytocin	319	92.80%	
	Tranexamic acid	206	59.90%	
	Misoprostol	300	87.90%	
	Methergine	268	77.90%	
	Antibiotics	271	78.80%	
	Massive fluid resuscitation	279	81.10%	
Variable		N (%)	Central tendency	
Packed red blood cell units transfusion	0	61 (17.7%)	Mean = 2,0	
	1	45 (13.0%)		
	2	169 (49.0%)	Median = 2	
	3	19 (5.5%)		
	4	25 (7.2%)	S = 1,7	
	5	5 (1.4%)	IQR = 0 - 13	
	≥ 6	21 (6.2%)		
Platelets transfusion	0	314 (91.0%)	Mean = 0,5	
	3	1 (0.3%)	Median = 0	
	4	5 (1.4%)	SD = 1,8	
	5	1 (0.3%)	IQR = 0 - 12	
	≥ 6	24 (7.0%)		
Plasma transfusion	0	313 (90.7%)	Mean = 0,55	
	2	1 (0.3%)		
	3	1 (0.3%)	Median = 0	
	4	5 (1.4%)	SD =1,9	
	5	1 (0.3%)	IQR = 0 - 20	
	≥ 6	24 (7.0%)		
Variable		N (n = 345)		Absolute frequency (%)
Massive transfusion	Mild shock	15		62.50%
	Moderate shock	144		80.50%
	Severe shock	124		87.90%
	6:6:6 transfusion	16		4.70%
Surgical intervention	Hysterectomy	75		21.70%
	Curettage	1		0.30%
Number of reoperations	1	10		2.90%
	2	2		0.60%
	≥ 3	4		1.70%
Packing	Yes	30		8.70%
	No	315		91.30%
Traction	Yes	13		3.80%
	No	332		96.20%
Outcome	Survival	344		99.70%

	Death*	1	0.30%
Complications	Renal failure	3	8.60%
	DIC	5	14.30%
	Infection	11	31.40%
	Respiratory failure	9	25.70%
	Hydroelectrolyte alterations	5	14.30%
	Other	2	5.70%
Hemoglobin values	Lower hemoglobin	Median = 10,4	
		Mean = 10,2	
		SD = 2,2	
		IQR = 3,6 – 15	
	Hemoglobin at discharge	Median =11,2	
		Mean = 11,4	
		SD = 2,0	
		IQR = 6,8 - 22,3	

Variable		N (n = 345)	Absolute frequency (%)
Anemia	Mild (Hb 10 - 10,9)	39	24.68%
	Moderate (Hb 7,0 - 9,9)	33	20.89%
	Severe (< 7,0)	11	0.63%
Variable		N (%)	Central tendency
Fibrinogen levels	< 100 mg/dl	2	Median = 513
	101 - 200 mg/dl	4	Mean = 516,2
	> 200mg/dl	137	SD = 193,3
			IQR = 6,58 - 1436
ICU stay	None		Mean = 4,3
	< 7 days	39	Median = 2
	≥ 7 days	n = 7	SD = 5,8
			IQR = 1 - 32
Variable	Central tendency		
Duration of shock (minutes)	Median	24	
	Mean	32.7	
	SD	28.1	
	IQR	1 – 195	
Mean blood loss	Median	1000	
	Mean	1240	
	SD	629.51	
	IQR	300 – 6000	

Discussion

The main objective of our study was to describe and evaluate the outcomes of patients with postpartum hemorrhage in our high-volume centers following the implementation of an institutional protocol for the management of hemorrhage. Most patients included in this study have high social and economic vulnerability, considering that 75.6% did not have health insurance or were in the subsidized regime. In Colombia, this type of insurance is for women without formal economic income.

Our institutional protocol, which was implemented in 2016, included the following: active management of birth with oxytocin 10 IU at the time of birth of the anterior shoulder, regular clamping of the cord and traction and countertraction of the placenta, obstetric emergency activation (code red in bleeding greater than 1000 ml or clinical or hemodynamic instability that requires medical intervention, regardless of the route of delivery), permanent monitoring, massive fluid resuscitation, with 2 L of Ringer's lactate, initiation of oxygen and monitoring of urinary output, simultaneous use of oxytocin, misoprostol and methylergonovine, bimanual uterine massage, uterine and delivery examination and specific management according to etiology (4T), and in case of no response to initial management at minute 30, if severe shock or profuse bleeding persists, perform a

hysterectomy.

Regarding the clinical variables related to gestation, we found that most patients are between the ages of 16-34, accounting for 88.99% of our population. In contrast, the extremes of life, that is, those under 15 years (2.61%) and over 35 years (8.41%), constitute a smaller percentage of the study population but do pose a high-risk factor for presenting postpartum hemorrhage due to the age at which the event occurred. We also found that most patients are nulliparous, which is consistent with the findings of Combs and his collaborators (3), where postpartum hemorrhage was more frequent in nulliparous women. Multiparous patients, defined as those with two or more gestations (4), represent 59.3%, and like nulliparous women, they are under high-risk for obstetric complications. Fetal deaths were present in 6.32% of the patients; although this outcome is low in our population, it constitutes an important risk factor for PPH due to coagulopathies.

Most events in postpartum hemorrhage occurred with term pregnancies, interpreted as those pregnancies between 37/0 weeks and 41/0 weeks (5), with an average of 39 weeks. Among pregestational history, it is noteworthy that 19.42% of the patients had heart diseases, diabetes mellitus, hematological diseases, postpartum hemorrhage, and obesity, with the latter two being the most prevalent. According to the literature obesity represents a high-risk factor for postpartum hemorrhage, as found in a study recently conducted by Mendoza and collaborators, where obesity accounted for 59.3% in a population of 96 patients (6). However, according to the data obtained, obesity does not constitute a high-risk factor for postpartum hemorrhage in our population. Just like the history of postpartum hemorrhage in previous pregnancies, it is of utmost importance to highlight that 80.58% of the population had no significant pregestational history, data which aligns with what´s reported in literature.

This study has several notable strengths. To our knowledge, it is one of the biggest studies performed about postpartum hemorrhage in our country and our population. Additionally, it allows us to have an adequate overview of the sociodemographic characteristics of our population, their comorbidities, and risk factors, to identify them in a timely manner and implement evidence-based care protocols to prevent. However, this study also has several limitations. First, a major limitation is the descriptive nature of our project, as this limits the conclusions that can be obtained related to association between clinical variables and outcomes. Second, this study was conducted at a single center with a selected patient sample, which may limit the generalizability of the findings.

Conclusion

Our study describes the characteristics of the obstetric population in our hospitals, and the positive impact on outcomes following the successful implementation of a protocol for the management of postpartum hemorrhage in a very high-volume center. This experience is useful as a model for the implementation of guidelines and management protocols for this obstetric emergency to improve the quality of care and reduce maternal morbidity and mortality in our country. Additional studies are required to establish the association between the described variables and negative outcomes in this context.

Declarations

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Conflicts of interest: All authors declare no conflicts of interest.

Availability of data and material: The data used in the present study is available upon request to the corresponding author.

Author contribution

Jorge Eduardo Caro Caro: Study conception and design, analysis and interpretation of data, drafting of manuscript, critical revision of manuscript.

Eliana Maria Montoya Rubio: Analysis and interpretation of data, drafting of manuscript, critical revision of manuscript.

Jose Luis Rojas-Oviedo: Study conception and

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Juan Carlos Vallejo-Soto: Analysis and interpretation of data, drafting of manuscript, critical revision of manuscript.

All authors approved the definitive version of the manuscript.

Ethical standards

Ethical compliance with the Helsinki Declaration, current legislation on research Res. 008430-1993 and Res. 2378-2008 (Colombia) and the International Committee of Medical Journal Editors (ICMJE) were ensured under our Ethics and Research Institutional Committee (IRB) approval. Informed consent was filled out as required for the execution of this study

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