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Factors associated with acute postpartum hemorrhage in low risk women delivering in rural India

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Abstract

Objective—Postpartum hemorrhage (PPH), a major cause of maternal mortality and morbidity in low-income countries, can occur unpredictably. This study examined the sociodemographic, clinical, and perinatal characteristics of low-risk women who experienced PPH.

Methods—This analysis was conducted using data on 1620 women from a randomized trial testing oral misoprostol for prevention of PPH in rural India.

Results—Of the women, 9.2% experienced PPH. No maternal or sociodemographic factors and few perinatal factors differed between women with PPH and those without, other than treatment with misoprostol. Having fewer than 4 prenatal visits and lack of iron supplementation increased the risk for PPH ($P<0.001$ and $P=0.037$, respectively). Several factors unknown until the second stage of labor (perineal tear and birth weight) were also associated ($P=0.003$).

Conclusions—Among women at low risk for PPH, there were few factors associated with further risk. Given that PPH can occur without warning, rural communities should consider ways to increase both primary prevention (iron supplementation, AMTSL) and secondary prevention of PPH (availability of obstetric first aid, availability of transport, and availability of emergency obstetric care).

Keywords

India; Maternal mortality; Postpartum hemorrhage

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Synopsis: Among rural Indian women at low risk for postpartum hemorrhage, medical prophylaxis and the ability to stabilize and transfer to higher levels of care are crucial.

1. Introduction

Postpartum hemorrhage (PPH) is the leading cause of maternal death, with one woman dying every 4 minutes [1]. Postpartum hemorrhage accounts for 30% of these deaths [1]. The leading cause of PPH is uterine atony, generally preventable by use of conventional uterotonics, among which oxytocin is preferred in hospital-based settings [2–4]. However, use of oxytocin is not feasible in low-income countries where births still occur at home with untrained birth attendants who do not practice active management of the third stage of labor (AMTSL) [3, 5–8]. Other uterotonic agents such as oral misoprostol have been shown to be effective for prevention of PPH but have yet to be implemented as standard care in low-resource settings [9, 10].

Factors known to put a woman at higher risk for acute PPH include a history of PPH; prolonged, augmented or rapid labor; pre-eclampsia; operative delivery; chorioamnionitis; and overdistended uterus due to macrosomia, twins, or hydramnios [11]. Many of these risk factors can be identified during prenatal care or in early labor so that, ideally, women are referred to a hospital-based facility where prophylaxis and treatment are available. This is especially important in low-resource settings lacking adequate preventive options utilized during labor and delivery, as well as referral systems and access to emergency obstetric care.

However, PPH generally occurs without warning and the majority of women affected present with no known risk factors [11, 12]. Therefore, this study examined the characteristics, determined during prenatal care and early delivery, of women in rural India at low risk for PPH, but who did in fact experience PPH.

2. Methods

This study is a post hoc analysis of data from a randomized placebo controlled clinical trial (RCT) conducted in rural India to test whether use of 600 µg oral misoprostol was safe and effective for the prevention of acute PPH (> 500 mL) in a low-risk population of women. The RCT was carried out between September 2002 and December 2005 in 4 primary health center areas of Belgaum District, Karnataka State, India, serving 43 villages with a total population of 100 000. Within these villages, more than half of the deliveries occurred at home or in rudimentary health facilities (subcenters), conducted by auxiliary nurse midwives (ANMs) who practice expectant management of the third stage of labor without a physician in attendance (ie, delivery without preventive uterotonics, routine fundal massage, or cord traction). The participating ANMs were responsible for screening and recruiting study participants, obtaining informed consent, providing the intervention, measuring blood loss, following the participants and their newborns for 6 weeks postpartum, and collecting study data. A single oral dose of 600 µg misoprostol (3 tablets) or placebo (3 tablets identical in appearance) was administered to 1620 women (812 misoprostol and 808 placebo) after delivery of the baby and within 5 minutes of clamping and cutting the umbilical cord. Following the intervention, women were monitored by the ANM for at least 2 hours, according to usual standard of care, to determine blood loss and possible need for transfer to a higher-level facility.

The primary outcome of the RCT, postpartum hemorrhage, was determined using a calibrated blood collection drape with a plastic receptacle developed for study use. The drape was placed under the buttocks of the woman after delivery of the newborn [13]. Blood loss was assessed for up to 2 hours after delivery. Further details of the study design can be found in previous publications [6, 9].

The study (identifier NCT00097123: www.ClinicalTrials.gov) was approved by Institutional Review Boards at the University of Missouri-Kansas City; the collaborating Indian site,

Jawaharlal Nehru Medical College, Belgaum, Karnataka, India; the National Institutes of Health; the Indian Council of Medical Research; and RTI International, the data coordinating center.

Pregnant women residing in the study villages and anticipating an uncomplicated spontaneous vaginal delivery at home or in a subcenter were eligible for inclusion and were screened at or beyond 28 weeks of gestation. Participants deemed to be high risk, and not appropriate for home or subcenter births by Ministry of Health guidelines, were excluded from the trial based on the following criteria: previous or planned cesarean delivery; hemoglobin levels below 8 g/dL; antepartum bleeding; hypertension in the current pregnancy; multiple pregnancy; history of pregnancy complications including ante/postpartum hemorrhage, retained placenta, and acute inversion of the uterus. Women with a past or current history of other high-risk conditions such as diabetes, heart disease, seizures, placenta previa, or breech delivery were similarly excluded, as were women with a history of bronchial asthma because of a known contraindication to misoprostol. Women who were transferred to a higher level of care during early labor were not randomized and are not part of the current analysis. Therefore, the sample included only women evaluated during prenatal care and early labor and assessed to be at low risk for PPH.

For purposes of this analysis, women who experienced acute PPH (≥ 500 mL blood loss) were compared with women who did not (< 500 mL). Comparisons within each treatment group for maternal, sociodemographic, and perinatal characteristics were performed and tested for statistical significance using χ^2 analysis. For dichotomous variables with an expected value of less than 5 in one or more cells, Fisher exact test was used; and t tests were used to compare continuous variables. Next, 3-way classification of observations by possible risk factor, PPH, and treatment group was tested for independence using χ^2 for the categorical variables and ANOVA for continuous variables. Finally, logistic regression models were developed for: (1) maternal/sociodemographic, and (2) maternal/sociodemographic and perinatal variables, to assess the inter-relationships between these factors. These models were fitted for maternal and demographic factors and then for maternal, demographic, and perinatal factors. We were interested in identifying the contribution, if any, of each set of factors to PPH. Each model was developed separately for each treatment group, and then for all observations, controlling for treatment. A significance level of $P=0.05$ was used for all significance testing. All analyses were performed using SPSS version 15.0. (SPSS, Chicago, IL, USA).

3. Results

A total of 1620 women were randomized to receive either misoprostol ($n=812$) or placebo ($n=808$). Blood loss data were missing for one woman; the following analyses are based on 1619 observations. Acute PPH occurred in 9.2% ($n=149$) of all women in the study. The rate of PPH among women receiving misoprostol was 6.4% ($n=52$) compared with a placebo rate of 12% ($n=97$). These results have been previously reported [9].

For purposes of this analysis, we compared those women who sustained an acute PPH ($n=149$) with those who did not ($n=1470$), regardless of treatment group. There were no significant differences between the 2 groups in maternal and sociodemographic characteristics, including age, religion, education, marital status, interpregnancy interval, or parity (Table 1).

In the misoprostol group, there were no statistically significant perinatal variables when comparing PPH and no PPH groups. The placebo group did show some significant differences in perinatal characteristics. For women with PPH in the placebo group, prenatal

hemoglobin levels were lower ($P=0.048$); they were less likely to have reported recent compliance with iron supplementation ($P=0.015$); and they were also more likely to have had fewer than 4 prenatal visits ($P=0.001$). These women were also more likely to have experienced a perineal tear ($P=0.048$), to have had significantly larger newborns ($P<0.001$), and to have had an undelivered placenta ($P=0.039$). However, for each of these factors, when the misoprostol and placebo groups are compared by whether they experienced acute PPH or not, there are no significant differences between the groups except for hemoglobin level ($P=0.027$). This suggests that treatment group assignment did not alter the relationship between these factors and PPH (Table 1).

Table 2 provides the results of multivariate logistic modeling. In model 1 (maternal and sociodemographic variables), controlling for treatment, the only variable found to be significant was treatment. As expected, women in the misoprostol group had a significantly lower risk for acute PPH ($P<0.001$).

In model 2 (Table 2) that included maternal, sociodemographic, and perinatal factors, results varied somewhat by treatment group. For the misoprostol group, significant variables included having fewer than 4 prenatal visits ($P=0.025$) and perineal tear ($P=0.043$). For the placebo group, significant variables included birth weight ($P=0.001$), fewer than 4 prenatal visits ($P=0.001$) and perineal tear ($P=0.032$). In the model that included all observations, clinical variables found to be significantly associated with an increased risk for acute PPH were higher birth weight ($P=0.003$), lack of iron supplementation ($P=0.037$), fewer than 4 prenatal visits ($P<0.001$), perineal tear ($P=0.003$), and treatment group assignment ($P<0.001$). No maternal or sociodemographic factors were significant.

4. Discussion

This study compared within a population of low-risk women, women who experienced acute PPH with those who did not. In this population in Southern India there were no maternal or sociodemographic factors and few perinatal factors associated with acute PPH. The women in this study were homogeneous with respect to marital status, age, and education.

Misoprostol use, as previously reported, was found to be strongly associated with a reduction of acute PPH. Factors that may be potentially useful for assessing risk for acute PPH were unsupplemented iron status and fewer than 4 prenatal visits. Although reported iron supplementation was not related to an increase in prenatal hemoglobin levels in our analysis, this may be due to the timing of the hemoglobin assessment, which occurred at the time of enrollment in the study and ranged between 28 weeks and delivery [14]. Women who received iron supplementation were more likely to have enrolled in prenatal care prior to 16 weeks of gestation than women who did not receive supplementation.

Three prenatal visits is the number recommended in India by the Ministry of Health; in this sample 54% of women received 3 visits and had a rate of PPH almost as high as those with 2 visits. Women who enrolled for prenatal care before 16 weeks of gestation had one more prenatal visit compared with those enrolled at 16 weeks or later. Our findings suggest that the recommended number of visits should be increased to 4 and women should begin care earlier than 16 weeks. Future studies are required to determine whether the associations noted in this analysis are confirmed and if increased visits do in fact reduce the risk for PPH. The World Health Organization recommends all women have at least 4 visits with a skilled attendant to address key components of prenatal care, beginning early in the first trimester [15].

Several factors that differentiated women with and without PPH may not be useful for referral purposes. Birth weight and multiple gestations, which are poorly correlated with

prenatal physical exam findings, are not generally estimated prenatally by minimally trained birth attendants and ultrasounds are not usually available. Potential for sustaining a perineal tear or having an undelivered placenta are not known in advance of delivery, and thus are not useful for referral purposes.

Nevertheless, these findings may have implications for women delivering in low-resource settings as uterine atony has been reported, in hospital-based studies, to be associated with 90% of PPH. However, home deliveries attended by minimally-skilled health providers may also be associated with increased perineal lacerations and retained placental tissue, neither of which appears to be amenable to the uterotonic properties of misoprostol.

Our finding that the relationship between perineal laceration and PPH did not vary by treatment group suggests that the main benefit of misoprostol is its uterotonic effect and that the drug is likely to have little or no effect on reducing acute PPH from other causes. This suggests that further reduction in PPH will require skill building for birth attendants as well as analysis of the relationship between such training and a possible reduction in lacerations, retained placental tissue, and acute PPH.

An important finding of this analysis is that in a population of low-risk women who have been screened there are still women who unexpectedly experience acute PPH. In rural areas of India where expectant management of labor is practiced, a PPH rate of approximately 12% can be anticipated [9]. This high prevalence further emphasizes the need for primary preventive efforts through the provision of an easy to use, stable uterotonic agent such as misoprostol, or possibly the Uniject form of oxytocin [3, 7, 9, 13, 16–18]. Research suggests that within rural health settings, oral misoprostol can effectively be integrated into local practice and can significantly reduce the incidence of PPH and the need for emergency patient transfer and emergency obstetric care (blood transfusion and surgical intervention) [9, 10].

Although oral misoprostol in particular holds great promise for prevention of PPH caused by atony, it will not completely eliminate it, and is unlikely to be useful for women who sustain a perineal laceration. Therefore, other elements of postpartum care are also essential to address the delays that contribute to PPH morbidity and mortality [19]. When uterotonics prove ineffective in the face of excessive postpartum blood loss, early and accurate diagnosis is critical, suggesting the need for a calibrated blood collection device which can alert the birth attendant to a possible emergency situation [20]. Also, given that the average interval from onset of PPH to death is only 2 hours, availability of reliable emergency transportation to a higher-level facility is critical [21]. A lack of reliable roads, fuel, communication, and the ability to maintain vehicles all contribute to transportation challenges [22, 23]. Underserved rural areas should also consider the use of the nonpneumatic antishock garment which holds promise for stabilizing women with excessive blood loss while awaiting transfer [24]. All of these components, along with an ongoing skill-building training program for birth attendants, should be included in the development of any program to comprehensively address morbidity and mortality associated with acute PPH in low-resource settings.

No single intervention can eliminate the excess mortality and morbidity of PPH; only a multifaceted approach to acute PPH prevention and management can maximize the impact on saving women's lives [25].

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Table 1

Maternal, sociodemographic, and perinatal variables

Risk Factor	Misoprostol (n=811)				Placebo (n=808)			Overall P [†]
	Estimated blood loss mL N (column %)	500	Estimated blood loss < 500 mL N (column %)	P*	Estimated blood loss mL N (column %)	500	Estimated blood loss < 500 mL N (column %)	
Total	52		759		97		711	
<i>Maternal/Sociodemographic</i>								
Age (mean, SD)	24.0 (3.3)		23.2 (3.3)	0.111	23.2 (2.9)		23.2 (3.2)	0.914
Married	52 (100.0)		757 (99.7)	1.000	96 (99.0)		710 (99.9)	0.226
Religion								
Hindu	39 (75.0)		539 (71.0)	0.318	67 (69.1)		487 (68.5)	0.278
Muslim	7 (13.5)		76 (10.0)		15 (15.5)		78 (11.0)	
Other	6 (11.5)		144 (19.0)		15 (15.5)		146 (20.5)	
Education								
Literate	35 (67.3)		475 (62.6)	0.491	65 (67.0)		446 (62.7)	0.409
Parity								
Nulliparous	11 (21.2)		236 (31.1)	0.185	25 (25.8)		200 (28.1)	0.728
Parity 1–2	32 (61.5)		440 (58.0)		63 (64.9)		433 (60.9)	
Parity 3+	9 (17.3)		83 (10.9)		9 (9.3)		78 (11.0)	
Interpregnancy interval 2 yrs	22 (42.3)		269 (35.4)	0.323	44 (45.4)		275 (38.7)	0.209
<i>Perinatal</i>								
Hemoglobin (mean, SD)	9.8 (0.9)		9.6 (0.9)	0.205	9.5 (1.1)		9.6 (0.9)	0.048 ⁺
Iron taken within 2 months of delivery	21 (40.4)		397 (52.3)	0.096	40 (41.2)		387 (54.4)	0.015 ⁺
Prenatal visits < 4 visits	40 (76.9)		500 (65.9)	0.092	78 (80.4)		456 (64.1)	0.001 ⁺
Perineal Tear	8 (15.4)		71 (9.4)	0.184	16 (16.5)		68 (9.6)	0.048 ⁺
Preterm delivery	10 (19.2)		162 (21.3)	0.715	17 (17.5)		164 (23.1)	0.208
Undelivered placenta	0 (0.0)		1 (0.1)	1.0	2 (2.1)		1 (0.1)	0.039 ⁺
Birth weight (mean, SD)	2859 (371)		2777 (374)	0.127	2937 (426)		2778 (384)	<0.001 ⁺
Duration of labor (mean, SD)	8.0 (5.2)		8.0 (5.4)	0.958	7.1 (4.0)		8.0 (5.3)	0.081

* P-values determined using χ^2 or Fisher exact test when expected cell count < 5 for categorical variables and t-test for continuous variables

[†] P-values determined using χ^2 for categorical variables and interaction term resulting from two-way ANOVA for continuous variables

⁺Significant at 0.05

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Table 2

Multivariate model of risk for acute postpartum hemorrhage.

Variables	Misoprostol group		Placebo group		All observations	
	Odds Ratio (95% CI)	P	Odds Ratio (95% CI)	P	Odds Ratio (95% CI)	P
<i>Model 1: Maternal/Sociodemographic variables</i>						
Age	1.031 (0.915, 1.161)	0.620	1.023 (0.922, 1.135)	0.669	1.028 (0.951, 1.112)	0.490
Religion						
Hindu	1.652 (0.674, 4.051)	0.272	1.288 (0.707, 2.346)	0.409	1.389 (0.845, 2.282)	0.195
Muslim	2.086 (0.665, 6.540)	0.207	1.809 (0.834, 3.923)	0.133	1.856 (0.980, 3.514)	0.058
Other	(ref)		(ref)		(ref)	
Literate	1.274 (.679, 2.393)	0.451	1.165 (0.724, 1.873)	0.530	1.199 (0.822, 1.750)	0.346
Parity						
0	0.520 (0.131, 2.061)	0.352	1.486 (0.457, 4.835)	0.510	0.981 (0.403, 2.387)	0.967
1-2	0.701 (0.282, 1.741)	0.444	1.379 (0.606, 3.139)	0.444	1.035 (0.565, 1.896)	0.912
3+	(ref)		(ref)		(ref)	
Interpregnancy interval 2 yrs	1.113 (0.579, 2.141)	0.748	1.325 (0.797, 2.205)	0.278	1.234 (0.826, 1.843)	0.304
Treatment	-		-		0.504 (0.354, 0.718)	<0.001*
<i>Model 2: Maternal/Sociodemographic and perinatal variables</i>						
Age	1.025 (0.907, 1.158)	0.694	1.013 (0.908, 1.130)	0.821	1.019 (0.939, 1.105)	0.650
Religion						
Hindu	1.533 (0.609, 3.857)	0.364	1.143 (0.611, 2.135)	0.676	1.265 (0.759, 2.108)	0.367
Muslim	1.707 (0.525, 5.549)	0.374	1.607 (0.703, 3.673)	0.260	1.667 (0.856, 3.249)	0.133
Other	(ref)		(ref)		(ref)	
Literate	1.141 (0.597, 2.181)	0.690	1.045 (0.633, 1.726)	0.863	1.103 (0.746, 1.631)	0.622
Parity						
0	.271 (0.062, 1.186)	0.083	1.805 (0.496, 6.568)	0.370	.846 (0.324, 2.205)	0.732
1-2	.566 (0.221, 1.450)	0.236	1.458 (0.617, 3.446)	0.390	.995 (0.533, 1.860)	0.988
3+	(ref)		(ref)		(ref)	
Interpregnancy interval 2 yrs	1.086 (0.553, 2.134)	0.811	1.279 (0.756, 2.165)	0.360	1.154 (0.766, 1.740)	0.493
Hemoglobin	1.360 (0.962, 1.922)	0.082	.773 (0.596, 1.002)	0.052	.933 (0.761, 1.144)	0.506
Iron supplementation	0.647 (0.357, 1.174)	0.152	.713 (0.451, 1.126)	0.146	.683 (0.476, .978)	0.037*

Variables	Misoprostol group		Placebo group		All observations	
	Odds Ratio (95% CI)	P	Odds Ratio (95% CI)	P	Odds Ratio (95% CI)	P
< 4 prenatal visits	2.202 (1.102, 4.402)	0.025 *	2.436 (1.407, 4.218)	0.001 *	2.297 (1.498, 3.520)	<0.001 *
Perineal tear	2.492 (1.028, 6.040)	0.043 *	2.105 (1.066, 4.154)	0.032 *	2.222 (1.303, 3.787)	0.003 *
Preterm delivery	1.014 (0.481, 2.141)	0.970	.690 (0.388, 1.227)	0.206	.770 (0.490, 1.210)	0.257
Birth weight	1.032 (0.954, 1.116)	0.432	1.106 (1.043, 1.173)	0.001 *	1.074 (1.025, 1.124)	0.003 *
Duration of labor	1.022 (0.966, 1.082)	0.446	.958 (0.906, 1.014)	0.139	.987 (0.947, 1.028)	0.520
Treatment	-		-		.500 (0.349, 0.716)	<0.001 *

* Significant at 0.05.