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Original Research Paper

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"COMPARISON OF USE OF IV OXYTOCIN INFUSION WITH AND WITHOUT SUBLINGUAL MISOPROSTOL FOR POSTPARTUM HEMORRHAGE PREVENTION IN LOWER SEGMENT CAESARIAN SECTION"

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ABSTRACT **Background:** Postpartum hemorrhage (PPH) is a major cause of maternal mortality. The current study is to compare the efficacy of oxytocin with and without sublingual misoprostol for PPH prevention in lower segment caesarian section. **Methods:** It was a prospective study conducted in MGM Medical College, Navi Mumbai including all Female patients with singleton pregnancy for a period of 2 years of total 100 cases. **Results:** All deliveries conducted during the study it was observed mean reduction of 1.41 g/dl in hemoglobin level in Oxytocin with sublingual misoprostol group, and 1.93 g/dl in hemoglobin level in Oxytocin without sublingual misoprostol. The decline was significantly greater in Oxytocin without sublingual misoprostol group. The side effects noted was that shivering among 16% subjects in Oxytocin with misoprostol group, which is greater as compared to Oxytocin without misoprostol group (4%). **Conclusions:** The decline in hemoglobin level was significantly greater in Oxytocin without sublingual misoprostol group as compared to with sublingual misoprostol group. It can be concluded that sublingual misoprostol with oxytocin is more effective than oxytocin alone in the prevention of PPH in the developing countries.

KEYWORDS : Postpartum Hemorrhage, Misoprostol , Oxytocin.

INTRODUCTION

Postpartum hemorrhage (PPH) is a major cause of maternal mortality, especially in under resourced countries, accounting for nearly one quarter of all maternal deaths worldwide. The most common cause of PPH is the failure of the uterus to contract adequately, which is responsible for approximately 70% of primary PPHs. With the increasing incidence of caesarean section, PPH may become more common, because the average blood loss during caesarean section is twice that during vaginal delivery.

Postpartum hemorrhage following a cesarean delivery has been defined as blood loss over 1000 ml. Recent studies have estimated that the prevalence of postpartum hemorrhage after cesarean delivery ranges from 0.6% to 6.4% (median, 3%), although the frequency depends on the criteria used to define this condition and the method used to calculate blood loss.

According to WHO, oxytocin is the uterotonic drug of reference.But oxytocin presents logistic constraints related to its conservation for it always requires being kept refrigerated. Misoprostol is an uterotonic drug which has a long shelf life and does not require refrigeration; it is therefore suitable for underprivileged context. It may be used without risk in women with hypertensive disorders.

Misoprostol, as a prostaglandin E1 (PGE1) analogue, not only has strong uterotonic activity through selectively binding E–series prostanoid receptors (Ep2/Ep3), but is also relatively inexpensive and is stable at room temperature, unlike other prostaglandins. It is well absorbed when administered by oral, buccal, sublingual, vaginal or rectal routes. As a consequence of these properties, this agent has attracted great interest as an effective alternative for PPH prevention and management in resource poor countries.

We undertook to perform a prospective randomized test in order the efficacy of oxytocin with and without misoprostol (400 μg) by sublingual route in PPH prevention. The primary endpoint is reduction of perioperative blood losses objectively assessed based on drop in hematocrit.

AIM AND OBJECTIVES

To compare the efficacy of oxytocin with and without sublingual misoprostol for PPH prevention in lower segment caesarian section.

MATERIAL AND METHODS

Study Design:
A Hospital based prospective Observational study

Study Area:
Department of gynecology and obstetrics unit, MGM hospital, Kalamboli, Navi Mumbai.

Study Duration: 2 years

Source Of Data:
Female patients with ongoing singleton pregnancy, in which a cesarean section with loco-regional anesthesia was performed

Sampling Technique And Sample Size:
Consecutive type of nonprobability sampling was used for selection of study subjects. A total of 100 patients fulfilling the eligibility criteria were included in the study after taking prior informed consent. Institutional ethics committee permission was taken prior to study

Inclusion Criteria:
Singleton pregnancy, Age > 18 years, giving informed consent

Exclusion Criteria:
Anemia with Hemoglobin level <8 g/dl Placenta previa ,Abruptio Placentae , Intra-uterine ,Fetal Death(IUFD), HELLP Syndrome, Bleeding disorders, History of postpartum hemorrhage, History of uterine rupture, History of 2 or more cesarean sections.

Methodology
This study was carried out in Tertiary care hospital. Women were assigned randomly into group A and group B. Group A received 20 IU of oxytocin (10 IU used for IM injection and 10 IU diluted into 500 ml of Ringer's lactate solution to be used in 30

minutes) . Group B received 20 IU pitocin in the same manner with 400 μg misoprostol (2 tablets of misoprostol 200 μg each) sublingually after umbilical cord clamping. Randomization was done by random table generated online. An interviewer coordinated data collected on the case proforma. The primary endpoint in our study was drop in hemoglobin levels (difference between preoperative hemoglobin level and the one measured 48 hours after the cesarean section). Total blood loss could not be estimated due to variable amounts of liquor mixing with blood in each patient. Secondary endpoints included occurrence of adverse effects associated with administration of misoprostol or oxytocin, temperature was measured using mercury thermometer 60 minutes (min) and 90 min after administration of the study treatment. Fever was defined by a temperature higher or equal to 38°C. The data was collected by healthcare providers involved in the study after administration of uterotonic drug.

Statistical Analysis

A standard case record proforma was used to capture demographic information, clinical history, clinical examination findings, and investigation reports. MS Excel worksheets were used to enter the data. For frequency analysis, the data was displayed in the form of tables and charts. The data was analyzed using SPSS version 22 software, and appropriate statistical tests were used. A statistically significant P-value was defined as less than 0.05.

RESULTS

Age Distribution

In this study the age distribution is evaluated among the study subjects. We observed that maximum of the study subjects belonged to the age group of 21 to 30 years (50% and 46% in either groups), followed by 31 to 40 years (26% and 36% respectively). The study subjects were comparable in either study groups with respect to age distribution. (The chi-square statistic being 1.0798. The p-value is 0.582808)

Age distribution	Oxytocin with sublingual misoprostol		Oxytocin without sublingual misoprostol	
	Number of subjects	Percentage	Number of subjects	Percentage
Less than 20 years	11	22	9	18
21 to 30 years	25	50	23	46
31 to 40 years	13	26	18	36
More than 40 years	1	2	0	0
Total	50	100	50	100
Significance	The chi-square statistic is 1.0798. The p-value is insignificant -0.5828			

ANC Registration

In the current study the ANC registration status among the study subjects was evaluated. We observed that majority of the study subjects were booked (registered) (58% and 64% in either study groups respectively), while 42% and 36% study subjects were unbooked. The difference was not found to be statistically significant. (The chi-square statistic is 0.3783. The p-value is .538509)

ANC registration	Oxytocin with sublingual misoprostol		Oxytocin without sublingual misoprostol	
	Number of subjects	Percentage	Number of subjects	Percentage
Booked	29	58	32	64
Unbooked	21	42	18	36
Total	50	100	50	100
Significance	The chi-square statistic is 0.3783. The p-value is .538509			

Parity

In the current study the Parity among the study subjects was evaluated. It was observed that majority of the study subjects were multigravida (62% and 58% in either groups), while 38% and 42% subjects were primigravida. The difference was not found to be statistically significant. (The chi-square statistic is 0.1667)

Parity	Oxytocin with sublingual misoprostol		Oxytocin without sublingual misoprostol	
	Number of subjects	Percentage	Number of subjects	Percentage
Multigravida	31	62	29	58
primigravida	19	38	21	42
Total	50	100	50	100
Significance	The chi-square statistic is 0.1667. The p-value is .683091			

Gestational Age

In the current study we assessed the Gestational age among the study subjects. It was observed that majority of the subjects had gestational age greater than 36 weeks (54% and 58% in either groups resp.), followed by 33 to 35 weeks (28% and 30% in either groups respectively). The difference was analyzed using chi-square test, and found to be non-significant. (The chi-square statistic is 0.425. The p-value is .935032)

Gestational age	Oxytocin with sublingual misoprostol		Oxytocin without sublingual misoprostol	
	Number of subjects	Percentage	Number of subjects	Percentage
Less than 28 weeks	2	4	1	2
28 to 32 weeks	7	14	5	10
33 to 35 weeks	14	28	15	30
More than 36 weeks	27	54	29	58
Total	50	100	50	100
Significance	The chi-square statistic is 0.425. The p-value is .935032			

Body Mass Index

The Body mass index among the study subjects was assessed. We observed that majority of the study subjects had BMI within the range of normal BMI (52% and 46%), followed by overweight (60% and 38% in either groups respectively.)

Body mass index	Oxytocin with sublingual misoprostol		Oxytocin without sublingual misoprostol	
	Number of subjects	Percentage	Number of subjects	Percentage
Underweight	2	4	4	8
Normal BMI	26	52	23	46
Overweight	20	40	19	38
Obese	2	4	3	6
Morbid obese	0	0	1	2
Total	50	100	50	100

Decline in hemoglobin levels Post-LSCS (after 48 hours)

In the present study we evaluated the mean reduction in hemoglobin levels. We observed mean reduction of 1.41 g/dl in Oxytocin with sublingual misoprostol group, and 1.93 g/dl in Oxytocin without sublingual misoprostol. The decline was significantly greater in Oxytocin without sublingual misoprostol group.

Study groups	Mean Hb Before	Mean Hb After	Mean decline
Oxytocin with sublingual misoprostol	10.15	8.74	1.41
Oxytocin without sublingual misoprostol	10.71	8.77	1.93
Significance	P value: <0.0001		

Side Effects

The side effects among the study subjects were assessed in the study. It was observed that shivering among 16% subjects in Oxytocin with misoprostol group, which is greater as compared to Oxytocin without misoprostol group (4%). Fever was also noted among 2% subjects in Oxytocin with misoprostol group.

Side effects	Oxytocin with misoprostol		Oxytocin without misoprostol	
	Number of subjects	Percentage	Number of subjects	Percentage
Shivering	8	16	2	4
Fever	1	2	0	0

DISCUSSION

Age Distribution

We evaluated the age distribution among the study subjects in the present study. It was observed that majority of the study subjects belonged to the age group of 21 to 30 years (50% and 46% in either groups), followed by 31 to 40 years (26% and 36% respectively). The study subjects were comparable in either study groups with respect to age distribution. (The chi-square statistic is 1.0798. The p-value is .582808).

ANC Registration

In the current study we evaluated the ANC registration status among the study subjects. We observed that majority of the study subjects were booked (registered) (58% and 64% in either study groups respectively), while 42% and 36% study subjects were unbooked. The difference was not found to be statistically significant. (The chi-square statistic is 0.3783. The p-value is .538509). In the study conducted by Bijoy Kumar Dutta, study groups were comparable with respect to their age distribution and ANC registration status (44.5% and 45.5% booked in either group).

Parity

In the current study we assessed the Parity among the study subjects. We observed that majority of the study subjects were multigravida (62% and 58% in either groups), while 38% and 42% subjects were primigravida. The difference was not found to be statistically significant. (The chi-square statistic is 0.1667. The p-value is .683091). However in the study conducted by Bijoy Kumar Dutta, majority of the subjects were primigravida (64% and 69% in either group).

Gestational Age

In the current study we assessed the Gestational age among the study subjects. We observed that majority of the study subjects had gestational age more than 36 weeks (54% and 58% in either groups respectively), followed by 33 to 35 weeks (28% and 30% in either groups respectively). The difference was analyzed using chi-square test, and found to be non-significant. (The chi-square statistic is 0.425. The p-value is .935032).

Body Mass Index

In the current study we assessed the Body mass index among the study subjects. We observed that majority of the study subjects had BMI within the range of normal BMI (52% and 46%), followed by overweight (60% and 38% in either groups respectively).

Decline In Hemoglobin Levels Post-operative (after 48 Hours)

In the present study we evaluated the mean reduction in hemoglobin levels. We observed mean reduction of 1.41 g/dl in Oxytocin with sublingual misoprostol group, and 1.93 g/dl in Oxytocin without sublingual misoprostol. The decline was significantly greater in Oxytocin without sublingual misoprostol group. MB Bellad et al in their study observed that 9.7% and 45.6% of women experienced a hemoglobin decline of >10% after receiving misoprostol and oxytocin, respectively ($P \leq 0.001$).

Side Effects

In the current study we assessed the side effects among the study subjects. We observed shivering among 16% subjects in Oxytocin with misoprostol group, which is greater as compared to Oxytocin without misoprostol group (4%).Fever also noted among 2% subjects in Oxytocin with misoprostol group. Picklu Chaudhuri et al in their study observed that Shivering and pyrexia were encountered more often in the misoprostol than in the oxytocin group (shivering: 19%versus 0.8%, $P<0.001$, relative risk [RR] 0.86, 95% confidence interval [CI] 0.82-0.90; pyrexia: 2.3% versus 0%, $P=0.03$, RR 0.97, 95% CI 0.95-0.99)

CONCLUSIONS

The present study concludes that:

1. The decline in hemoglobin level was significantly greater in Oxytocin without
   sublingual misoprostol group as compared to with sublingual misoprostol group.
2. We observed shivering and pyrexia more among Oxytocin with misoprostol group,
   as compared to Oxytocin without misoprostol group.
3. It can be concluded that sublingual misoprostol with oxytocin is more effective
   than oxytocin alone in the prevention of PPH in the developing countries. It is safe,
   Affordable, cost-effective and easy to administer by Traditional Birth Attendants
   (TBAs) and Community Health Workers (CHWs) in the rural communities.

Declarations

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Conflict of interest: None declared
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