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Original Article

RECTAL MISOPROSTOL VERSUS INTRAVENOUS SYNTOMETRINE IN ACTIVE MANAGEMENT OF THIRD STAGE OF LABOUR IN LOW RISK WOMEN

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ABSTRACT

Objectives: To compare the efficacy of rectal 400 micrograms Misoprostol and intravenous syntometrine (5 units of Oxytocin + 0.2mg erogmetrine) in active management of third stage of labour for prevention of primary postpartum haemorrhage in low risk women.
Study Design: Comparative cross-sectional study.
Setting: Department of Obstetrics and Gynaecology, Unit-V, Lyari General Hospital, Dow University of Health Sciences, Karachi.
Duration: Six months after approval of synopsis from10th January, 2011 to 10th July, 2011.
Sample size: One hundred low risk pregnant women divided in two groups. Consists 50 patients in rectal misoprostol Group-A and group-B consists of 50 patients intravenous syntometrine.
Methods: Informed consent was taken before inclusion of subjects into the study. A total one hundred low risk pregnant women divided in two groups. Group-A 50 patients in rectal misoprostol and 50 patients of intravenous syntometrine in group-B.
Results: Overall demographic data in the both groups was similar. Average age of the pregnant woman was observed 26.4±4 Years (Ranging 19-35). The average age in group A was 26.02±4.03 years while in group B was observed 26.68±3.95 years. The average gravida was 2.09±0.91 in group A and 2.11±0.94 in group B. There was significant difference in side effects between groups in which nausea found more in group-A (40% versus 20%, P=0.029), vomiting observed more in group-A than group-B (36% versus 16%, P=0.023). There was significant difference in shivering between two groups, more in group-A than group-B (P=0.009). Blood pressure after delivery was significantly raised in group-B than group-A (P=0.001). Blood loss in both groups was measured. Postpartum haemorrhage was found in 3 patients in group A and only 1 patient in group B. Data revealed insignificant difference between the frequencies of the patients with PPH (Chi-Square =1.05, df=1, p=0.31). Haemoglobin concentration more than 10% was significantly high in group B than group A.
Conclusion: Rectal misoprostol is of equivalent efficacy to parental syntometrine in the active management of third stage of labour with lesser side effects.

Keywords: Misoprostol, Oxytocin, Third stage, Active management.

INTRODUCTION

Labour is a clinical diagnosis defined as the initiation and perpetuation of uterine contraction with goal of producing cervical effacement and dilatation.[1] Thirdstage of labour is defined as the duration from the birth of the baby until the complete expulsion of placenta and membrane. The third stage of labour can be managed actively or expectantly. In physiologic “expectant” management oxytocic drugs are not used, placenta

is delivered by gravity and maternal efforts and cord is clamped after delivery of placenta.

The third stage of labour usually last between 5 and 10 minutes. Active management decreases the duration of third stage of labour hence results in an average 40% decrease in the incidence of primary postpartum haemorrhage.[2] Primary postpartum haemorrhage is defined as the excessive bleeding from the genital tract following the delivery of the baby. It is a serious obstetrical emergency and is an important cause of maternal morbidity and mortality, not only in the developing countries but also in the developed countries.[3] Active management of third stage of labour is superior to expectant management which results in significantly reduced risk of maternal blood loss and primary postpartum haemorrhage.[4] Blood loss greater than 500ml is the most commonly accepted definition of PPH and the definition most commonly used in the randomized controlled trial. Primary PPH is defined as excessive blood loss within 24 hours after child birth and single, most important cause of maternal death worldwide,[5] commonly caused by uterine atony, which accounts for 75% - 90% of cases.[6] So in modern world third stage of labour is managed actively for early delivery of placenta and have reduced the risk of PPH, anaemia and morbidity in puerperium.[7]

The two most commonly used oxytocic agents for the third stage of labour are oxytocin and erogmetrine. On reviewing the literature, it is found that syntometrine (5IU oxygocin and 0.5mg erogmetrine), is more efficaous than oxytocin alone (at a dose of upto 10IU) in reducing, postpartum blood loss, but at the expense of adverse effects like vomiting and hypertension.[8]

These drugs have disadvantages, for being used by parental route, which may preclude its use due to the increased cost of syringes, the trained personnel required and the risk of transmitting blood born viral infections e.g. hepatitis B, C and HIV.[9] WHO has considered the problem and several other approaches have been investigated such as sucking and nipple stimulation, oral erogmetrine but not found effective.[10]

Misoprostol has been widely used for obstetric and gynaecological indications, such as induction of abortion and of labour.[11] It is inexpensive, easily stored at room temperature and has few systemic side effects. It is rapidly absorbed orally per-rectally and vaginally.

MATERIAL AND METHODS

Setting: Department of Obstetrics and Gynaecology Unit-V, Lyari General Hospital, Dow Medical University of Heath Sciences, Karachi.

Duration: 10th January, 2011 to 10th July, 2011.

Study design: Comparative cross-sectional study.

Sample size: One hundred low risk pregnant women divided in two groups. Consists 50 patients in rectal misoprostol Group-A and group-B consists of 50 patients intravenous syntometrine.

Sampling technique: Non-probability convenience sampling.

SAMPLE SELECTION:

Inclusion criteria:

- Booked and non-booked.
- Second, 3rd and 4th gravidae.
- Singleton pregnancy.
- Patient with cephalic presentation.
- Spontaneous vertex delivery.

Exclusion criteria:

- All grandmultiparae (parity five or above).
- Patient with medical complication along with pregnancy.
- Patient with genital tract lacerations and tears were excluded after drug administration.
- Patients who are predisposed to postpartum haemorrhage.
  - APH (Antepartum haemorrhage)
  - Multiple pregnancies.
  - Macrosomic babies (weight >4 kgs).
  - Polyhydroamnios.
  - Instrumental delivery.
  - Cephalopelvic disproportion (CPD).
- Previous caesarean section.
- Patient who receive blood transmission during labour.
- Patient with haemoglobin 8 grams and less were excluded from study.

Data analysis:

Statistical analysis was performed using SPSS version-10. Frequency and percentage were computed for categorical variables like need for blood transfusion and side effect of syntometrine and misoprostol groups. Mean and standard deviation was computed for continuous variables age, gestational age, parity, blood pressures, plus, prenatal and postnatal hemoglobin, blood loss after delivery for both group. Independent sample t test was applied to compare men difference between groups for age, gestational age, parity, blood pressures, plus, prenatal and postnatal hemoglobin, blood loss after delivery. Chi-Square test or fisher's exact test were used to compare haemoglobin concentration, PPH, side effect and need

Table-1

DESCRIPTIVE STATISTICS OF STUDY VARIABLES

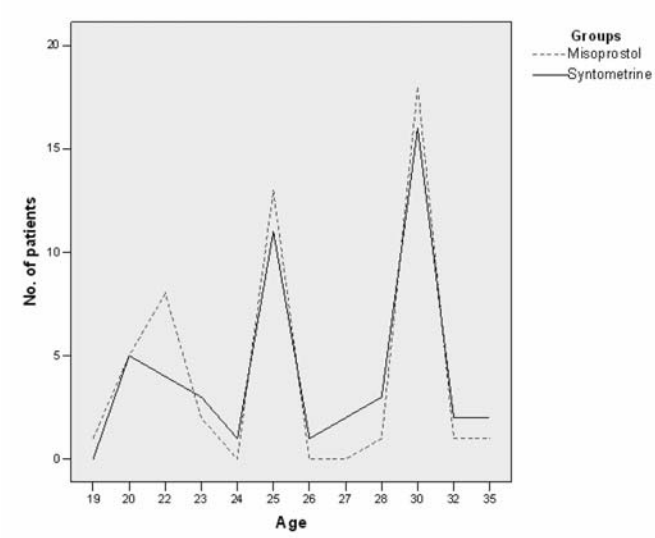
(n= 100)

Variables	Mean ±SD	95%CI	Median(IQR)	Min-Max
AGE (Years)	26.4±4	25.6-27.1	25(7)	19-35
Gestational Age (Weeks)	38.7±1.1	38.5-38.9	39(1.0)	37-42
Parity	1.7±0.8	1.5-1.8	2(1.0)	0-3
Systolic Blood Pressure (mmHg)	115±6.6	113.7-116.3	120(10)	100-130
Diastolic Blood Pressure (mmHg)	72.8±7.3	71.4-74.2	70(10)	60-90
Pulse (per minutes)	84±4.4	83.1-84.9	82(6)	75-92

Figure-1

AGE COMPARISON BETWEEN GROUPS

(n=100)



for blood transfusion between two groups (syntometrine and misoprostol). Pd"0.05 was considered level of significant.

RESULTS

The study carried out on 100 patients divided in two groups Group A (misoprostol), and group-B (syntocinon), containing 50 patients each, was analyzed in to two hypothetical phases regarding comparison of proportion of the patients with postpartum haemorrhage and side effect of drug. Study variables are mentioned in Table 1 and age in Figure 1.

Overall demographic data in the both groups was similar. Average age of the pregnant woman was observed 26.4±4 Years (Ranging 19-35). Distribution of age is presented in figure-4. The average age in group A was 26.02±4.03 years while in group B was observed 26.68±3.95 years. The average gravida was 2.09±0.91 in group A and 2.11±0.94 in group B. Average gestational age, parity, pulse, systolic and diastolic blood pressure according to groups is presented in table-2. Significant difference of mean was not found in these characteristics (independent sample t test; P> 0.05).

In group A, 50% women were nullipara and single parous, 50% women were multiparous, whereas, in group B, 48% were nulli and single parous and 52% were multiparous as shown in table-3.

Blood loss in both groups was measured. Postpartum hemorrhage was found in 3 patients in group A and only one patient in group B. Data revealed insignificant difference between the frequencies

Table-2

COMPARISON OF VARIABLES BETWEEN GROUPS

Variables	Misoprostoln= 50	Syntometrinen= 50	P-values
AGE (Years)	26.02±4.03	26.68±3.95	0.41
Gestational Age (Weeks)	38.66±1.07	38.78±1.07	0.91
Gravida	2.09±0.91	2.11±0.94	0.51
Parity	1.66±0.79	1.64±0.89	0.23
Systolic Blood Pressure (mmHg)	115.8±7.02	114.20±6.09	0.58
Diastolic Blood Pressure (mmHg)	73.2±6.5	72.40±7.99	0.23
Pulse (per minutes)	83.48±3.8	84.52±4.8	0.57

Independent sample t test applied for mean comparison between groups.

Table-3

FREQUENCY DISTRIBUTION OF PARITY IN TWO GROUPS

(n=100)

Parity	Misoprostol	Syntometrine
Nullipara (0)	01(2%)	04(8%)
Single Para	24(48%)	20(40%)
Multi Para	25(50%)	26(52%)
TOTAL	**50**	**50**

Table-4

HEMOGLOBIN LEVEL BEFORE DELIVERY

(n=100)

Haemoglobin	Misoprostol	Syntometrine
>12 %	0(0%)	3(6%)
10-12 %	37(74%)	33(66%)
8-9 %	13(26%)	14(28%)
TOTAL	**50**	**50**

Chi-Square=3.27, df=2, P=0.195 (Not Significant)

of the patients with PPH (Chi-Square =1.05 df=1, p=0.31). Haemoglobin concentration after delivery is presented in table-4. Proportion difference was significant between groups in hemoglobin. Haemoglobin concentration more than 10% was significantly high in group B than group A.

DISCUSSION

The routine prophylactic administration of an uterotonic agent is an integral part in the active management of the 3rd stage of labour. In our study, we used rectal misoprostol as a prophylactic uterotonic agent in 3rd stage of labour management and compared it with uterotonic oxytocin and ergometrine, which is used since decades.

Despite of marked improvement in the management of postpartum haemorrhage; it remained significant contributor to maternal morbidity and mortality. It accounts for 28% of maternal death in developing countries.[12]

There was discussion at the initial stages of trial as to whether a rectal medication can cause refusal to participate in the study. This is because women think that rectal route is an invasive method than injection. Women usually accept injections as a part of obstetric care. In our study misoprostol was administered per rectally because it is associated with fewer side effects, can be administered easily while attending delivery and can also be given by traditional birth attendant (Dai), who were not familiar with injections and also be given to nauseated mothers. Compare to vaginal route, it allows drug absorption without being expelled by postpartum delivery of placenta. Practical advantage of rectal route includes assessment of the anal sphincter. It can be used in women in whom intravenous access is limited i.e. home birth or if it is desirable to limit intravenous fluid and hold blood loss to minimum i.e. cardiac patients.

Different investigators had compared the effect of two utertotonic agents and found no significant difference in estimated blood loss or change in antepartum to postpartum haemoglobin concentration. These findings are comparable to our findings. In our study there was no statistically significant difference between two groups in frequency of PPH which is 3% in misoprostol group and 1% in syntometrin group (P=0.31), diagnosed by estimation of blood loss and by measured of pre and post-delivery Hb% concentration. This clinical trial shows that 400µg rectally administered misoprostol is as effective as parentral conventional uterotonic in prevention of excessive blood loss in the 3rd stage of labour. Gerstanfeld TS,[13] gave 200µg misoprostol rectally and his results showed significant difference in additional uterotonic agents required in misoprostol group, but in our study 3 of 50 subjects in group-A and 1 of 50 subjects in group-B needed at least one additional agent to control bleeding after vaginal delivery because uterine contraction were considered inadequate. Out of these 4 women, all subjects received 40IU oxytocin infusion.

There was significant difference in complain of nausea (P=0.029) and vomiting (OP=0.023) in both groups in our trial and it was more common in misoprostol group. Similar results were found in study by Lumbiganon P study,[14] but the incidence were extremely low and difference between the groups was not statistically significant.There is progressive improvement in the management of postpartum haemorrhage globally, and more studies are required to established state-of-art care.[15,16]

CONCLUSION

In light of this research study it is concluded that rectally administered misoprostol is a good substitute to syntometrine for prophylaxis of PPH.

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