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Sublingual Misoprostol- A Safe Alternative to Intramuscular Oxytocin for Active Management of Third Stage of Labour.

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Abstract:-
OBJECTIVE*:- To study and compare the effects between tablet Misoprostol (600µg) sublingual and Injection Oxytocin (10IU) intramuscular in active management of 3rd stage of labour.*
MATERIALS AND METHODS*:- A prospective study was carried out in department of obstetrics and gynaecology at NMCH Patna (BIHAR),The study was carried on 200 women undergoing vaginal delivery who were randomized into two groups of 100 women each. GROUP A received 600mcg misoprostol sublingually immediately after delivery and clamping of cord while GROUP B received 10IU intramuscular oxytocin immediately after delivery of baby. Both groups were studied for amount of blood loss, duration of 3rd stage, drop in haemoglobin post delivery, incidence of PPH and side effects of drugs. The blood loss was measured by collecting the blood and clots in kelly'□s pad after delivery. Haemoglobin estimation was done at the time of admission and 48 hours after delivery. At the end of the study, the data was analysed by using t-test and chi-square test.*
RESULT*:- Mean age was 22.98 years and 22.41 year in group A and B respectively. There was no statistically significant difference in the duration of third stage of labour and mean fall in haemoglobin level in the two groups (p>0.05). The mean blood loss was 75.35±3.50ml in misoprostol group compared to 90.3±6.79ml in oxytocin in group and the difference was not statistically significant.*
CONCLUSION *:-It is concluded from the present study that sublingual misoprostol is an efficacious and safe alternative intramuscular oxytocin in the active management of 3rd stage of labour.*
Keywords*: Misoprostol, oxytocin, Third stage of labour*

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I. Introduction

Postpartum haemorrhage is one of the leading causes of maternal death worldwide; it occurs in about 10.5% of births and accounts for over 130,000 maternal deaths anually.[1] Primary postpartum haemorrhage (PPH) is the most common form of major obstetric haemorrhage. The traditional definition of primary PPH is the loss of 500 ml or more of blood from the genital tract within 24 hours of the birth of a baby.[2] PPH can be minor (500–1000 ml) or major (more than 1000 ml). Major can be further subdivided into moderate (1001–2000 ml) and severe (more than 2000 ml). In women with lower body mass (e.g. less than 60 kg), a lower level of blood loss may be clinically significant.[3] Secondary PPH is defined as abnormal or excessive bleeding from the birth canal between 24 hours and 12 weeks postnatally.[4] Active management of the third stage of labour is highly effective in preventing postpartum haemorrhage among facility-based deliveries. It is more effective than physiological management of preventing blood loss, severe postpartum haemorrhage (>500 ml) and prolonged third stage of labour.[5] International Federation of Gynecologists and Obstetricians (FIGO), the International Confederation of Midwives (ICM), as well as by WHO recommend routine use of active management of labour for all vaginal singleton births in health facilities.[6,7] Cord clamping is excluded based on research indicating that delayed clamping benefits preterm (and probably term) infants.[8] Use oxytocin as it is associated with fewer side effects than oxytocin plus ergometrine.[9] In the country like india, where most of the deliveries are conducted by dai at home, active management with injectable like oxytocin becomes really difficult and sublingual administration of misoprostol is an easy option as temperature maintenance is not required with no risk of injection related diseases.

AIMS AND OBJECTIVES:
To study and compare the effects between tablet Misoprostol (600µg) sublingual and Injection Oxytocin (10IU) intramuscular in active management of 3rd stage of labour.

II. Material And Methods

A prospective randomized controlled trial study was conducted from January 2018 to December 2019 at the labour room in the Department of Obstetrics and Gynaecology, NALANDA MEDICAL COLLEGE AND HOSPITAL, PATNA ,200 women with above 28 weeks of gestation , undergoing spontaneous onset of labour and spontaneous vaginal delivery without any complicating factors were included in the study. Exclusion criteria Chorioamnionitis, Previous caesarean section, Coagulation abnormality, Severe anaemia in pregnancy with Hb less than 6gm and Cardiac diseases. Once a patient had been identified as being eligible they were approached for participation. After admission and informed consent, history regarding the demographic profile and obstrtric care was taken from each women and purpose of study was explained. Maternal blood sample was taken for determination of haemoglobin level, and women were monitored for delivery as per protocol. Women were allocated to randomization in two groups. Group A received 600µg Misoprostol sublingually immediately after delivery and clamping of the cord while Group B received 10U intramuscular oxytocin immediately after delivery of baby. Background information related to age, gravida, para & pre delivery vital signs were collected. Deliveries were conducted in the lithotomy or dorsal position, and allocated drug was administered immediately after the delivery of the baby. Controlled cord traction was done immediately after the delivery of the baby (without waiting for the signs of placental separation) by Brandt Andrew's method in both the groups. After delivery of baby- kelly´s pad were placed below the perineum and amount of blood loss was calculated using the formula used by Gai, *et al.*[10] In the intervention phase, all AMTSL procedures were encouraged but the uterotonic agent used prophylactically was misoprostol 600µg(sublingually) and oxytocin 10IU(intramuscular). The duration of placenta separation and expulsion was noted from watch. If the placenta was not delivered within 30 minutes of the delivery of the baby, a diagnosis of retained placenta was made and it was removed manually. All placentas were examined to rule out retained bits of placenta and membranes. Side effects such as nausea, vomiting, diarrhoea, shivering, and pyrexia were recorded. On appearance of signs of excessive blood loss, other uterotonics such as methylergometrine/ carboprost were given immediately in both the cases. Episiotomy wounds, tears if present were immediately repaired. Once the hemostasis was ensured and the uterus sufficiently contracted, the women were shifted from the labour table and monitored in the labour room for two hours following delivery. At the end of 2 hours the women were asked about the side effects attributable to the drug and this was recorded if present. The amount of blood loss was estimated at the end of the delivery of placenta and any additional loss was verified before transferring the patient to the ward after 2 hours of observation in the labour room. When the women were hemodynamically stable, the uterus well contracted and no significant vaginal bleeding, they were transferred to the maternity ward. The level of hemoglobin was measured 48 hours postpartum from the maternity ward. The women were followed up till discharge. Comparison of difference in hemoglobin levels in both the groups was maintained.

OUTCOME MEASURES

The primary outcome measures were the amount of blood loss during delivery and the occurrence of PPH defined as blood loss >500ml, determined by documenting vitals signs and observing bleeding per vaginum. Safety of the drugs was assessed by drugs adverse effects like nausea, vomiting, shivering, fever which was inquired and noted one hour post delivery.

III. Results

The results are shown in tables 1 to 3. During study period of one year, 200 women were eligible for randomization by convenient sampling. Out of the study population, 100 women received 600µg Misoprostol sublingually and 100 received 10U intramuscular oxytocin for AMTSL. None of the women withdrew from study. The demographic characteristics like age of women and parity were comparable in both drug group (Table 1)

Table 1: Demographic characteristics

Variables	Group A (n=100)	Group B (n=100)	P- value
Age (years) (Mean+SD)	22.98±3.11	22.41±3.87	0.642 (p>0.05)
Parity(=n) (%) Nulliparous Multiparous(p>1)	46% 54%	44% 56%	NS

The duration of third stage of labour, amount of blood loss, need of additional oxytocin and fall in haemoglobin, were compared in TABLE 2, the additional use of oxytocin were needed in 11% in group A and 8% in group B. There was no case of retained placenta, laparotomy and hysterectomy.

Table 2. Distribution of patients according stage of labour, blood loss, additional oxytocin and fall in Hb%.

Parameter	**Group -A**	**Group-B**	**P- value**
Duration of 3rd stage in minutes (Mean±SD)	4.37±2.4	4.13±1.9	0.177(p>0.05)
Blood loss (ml) (Mean±SD)	75.35±3.50	90.3±6.79	0.201(p>0.05)
Fall in Hb (Mean±SD)	0.7±0.72	0.57±0.38	0.615(p>0.05)
Additional oxytocin(n)	11%	8%	0.197(p>0.05)

It was observed that side effects like nausea, vomiting, shivering and fever was more commonly observed in misoprostol group as compared to oxytocin group($p<0.05$) (Table 3) Table3.Distribution of patients according to side effects

Side effects	Group A n (%)	Group B n (%)
Nausea	04 (4%)	02 (2%)
vomiting	02 (2%)	01 (1%)
Diarrhoea	15 (15%)	00
Fever	50 (50%)	00
Shivering	70 (70%)	02 (2%)

IV. Discussion

The third stage of labour is a crucial period where negligence can turn a previously uneventful pregnancy into a disaster. The role of uterotonics is to stimulate myometrial contraction, the major factor reducing the third stage bleeding. Misoprostol has been found to be effective in prevention and treatment of PPH. Various routes of administration have been tried for misoprostol like oral, vaginal, rectal and sublingual. Sublingual route avoids the first pass effect through the liver and can also be given in patients where oral administration is not possible.

In present study the mean age (Mean±S.D) of the group A was 22.98 ±3.11 years with range 17-35 years and the median age was 22.5 years. The mean age (Mean±S.D) of the group B was 22.41 ±3.87 years with range 17-35 years and the median age was 22.0 years. Chi-square (χ^2) test showed that there is no significant difference between age groups . t-test showed that there is no significant difference between the mean age of the two groups. Thus the subjects of the two groups were age matched. In present study the majority of cases were Multiparous, 54% patients in group A and 56% patients in group B. 46% patients in group A and 44% patients in group B were Nulliparous. There was no significant difference in the parity distribution of patients between the two groups. Chi-square (χ^2) test showed that there was no significant difference between group A and Group B.. In present study the duration of 3rd stage of labour (minutes) (Mean±S.D) in group A was 4.37 ± 2.4 minutes and the duration of 3rd stage of labour (minutes) (Mean±S.D) in group B was 4.13± 1.9 minutes.t-test showed that there was no significant difference between this two groups. Magann *et al.*, 2008 stated that the mean length of the third stage of labour was 6 minutes, and the 97 percentile was 30 minutes. The amount of time from neonatal delivery to placental delivery is important because there is a direct relationship between the time interval and the risk of significant maternal morbidity. [11] In the present study the mean blood loss during the third stage of labour in group A was 75.35 ± 3.50 ml and the blood loss in group B was 90.3 ±6.79ml. t-test showed that there was no significant difference between the two groups (t=1.21771; p. Value = 0.201). p. Value is not significant Gunjan singh *et al.*[12] in a study in 2009 showed that Patients who received 600 µg of misoprostol had the lowest blood loss (96.05±21.1 mL), and oxytocin (154.7±45.7 mL). In the present study 11% patients in group A (misoprostol 600mcg) who needed additional oxytocin to prevent PPH. Whereas in group B (10U oxytocin) 8% patients required additional oxytocin to control PPH . The p. value is 0.197 (P>0.05) . There was no significant difference between the two groups. The need of additional uterotonics was highest with misoprostol as compared to oxytocin drugs used in the study by Gohil [13] with p = 0.037 and 0.009, respectively. In the present study shows that mean change in hemoglobin level (Pre + post) in the group A receiving misoprostol 600µcg sublingual was 0.7 ±0.72 (Mean±S.D) and group B receving oxytocin 10IU intramuscularly was 0.57 ±0.38 (Mean±S.D). Chi-square (χ^2) test showed that there was no significant difference between group A and Group B (p=0.615). J.T Gohil *et al.*[14] in a study showed that there was no significant difference in the pre-delivery and the post-delivery hemoglobin concentration amongst the groups with p = 0.061. In the present study Group who received misoprostol 600mcg sublingual was associated with

the side effects of nausea in 4%, vomiting 2% shivering in 70%, diarrhoea in 15%, rise of temperature (≥37.5°C)in 50%. The group which received oxytocin 10unit IM presented with side effects of nausea in 2% , vomiting 1%, shivering in 2%, fever in 0% diarrhoea in 0%. As regards side effects, misoprostol was associated with shivering and pyrexia in significantly high number of patients as compared to the other drugs used in the study by Gohil [15] while nausea, vomiting and headache were more associated with oxytocin.

V. Conclusion

Sublingual misoprostol is an efficacious and safe alternative intramuscular oxytocin in the active management of third stage of labour especially in developing countries, both at tertiary and community level. Although side effects are comparatively more in misoprostol group than oxytocin but they are not life threatening and it settled with time without any treatment.

So, it is worthy to use sublingual misoprostol as an alternative to oxytocin.

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