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A COMPARATIVE STUDY BETWEEN SUBLINGUAL MISOPROSTOL 600 mcg TO CONVENTIONAL OXYTOCIN 1O IU INTRAMUSCULAR IN ACTIVE MANAGEMENT OF THIRD STAGE OF LABOR

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ABSTRACT Post-Partum Hemorrhage is the most important cause of maternal mortality and morbidity PPH is defined as blood loss of more than 500 ml from genital tract at vaginal delivery, 1000 ml at Cesarean Section or 1500 ml at Cesarean Hysterectomy. A prospective, randomized, comparative study was conducted over duration of 6 months at Narayana Multispeciality Hospital, Jaipur,Rajasthan at in-patient department .A total of 100 term singleton pregnant female were included in study.Patient with risk pregnancy,such as preeclampsia,antepartum haemorrhage,multifetal gestation,previous LSCS pregnancy were excluded from study.Total patient were randomly allocated in two groups.Group 1 received Tab misoprostol 600 mcg sublingually at the time of cord clamping.Group 2 received injection oxytocin 10 IU intramuscular at the time of cord clamping. Objective of this study were to compare the amount of blood loss in third stage of labor, to compare the difference in hemoglobin at the time of admission and 24 hrs post delivery and to compare the adverse effects of both the uterotonics. Study results were that Misoprostol is as effective as oxytocin in active management of third stage of labor. We observed that the estimated blood loss during third and fourth stage of labour, postpartum drop in hemoglobin were comparable in both the groups.Misoprostol was associated with higher incidence of shivering but no other serious adverse effects occurred as compared with oxytocin.This study concluded that Sublingual misoprostol is as effective as oxytocin in active management of third stage of labor and can be used safely in vaginal deliveries for prevention of PPH, specially in non-institutional deliveries and in places of low resource settings

KEYWORDS :

INTRODUCTION

Postpartum hemorrhage is the leading cause of maternal death worldwide with an estimated mortality rate of 140,000 per year or 1 maternal death every 4 mins[1].Atonicity is the most common cause**(2).** PPH is defined as blood loss of more than 500 ml from genital tract at vaginal delivery, 1000 ml at Cesarean Section or 1500 ml at Cesarean Hysterectomy. It is classified as primary or secondary. Primary PPH occurs within the first 24 hours of delivery and secondary PPH occurs between 24 hours and 6 – 12 weeks of postpartum[3]**.**

Active management of third stage of labor consists of intervention designed to speed the delivery of placenta by increasing uterine contraction and to prevent PPH**.**[4]The usual components are:

- Giving a uterotonic drug within one minute of birth of newborn
- Clamping and cutting the umbilical cord soon after birth
- Applying controlled cord traction to deliver placenta.

oxytocin is found to be effective in reducing the risk of PPH by 50**%.(5,6)**It has also been advocated by the WHO during the active management of third stages of labor**(7**). But oxytocin need storage at low temperature and a skilled person to administer drug by I.M. or I.V. route,which is not feasible in rural areas or poor resources regions due to non availability of sterile needles, syringes or refrigerating equipment's.

Misoprostol, a Prostaglandin E1 analogue, was first introduced as an anti-inflammatory drug for peptic ulcer disease. Later on, it gained popularity as an effective modality for medical evacuation of uterus in spontaneous miscarriages, therapeutic termination of first and second trimester pregnancies, cervical ripening agent for induction of labor. As per Cochrane review Misoprostol oral or sublingual at a dose of 600mcg shows promising result when compared to Placebo in reducing blood loss after delivery**(8)** It is stable at room temperature, inexpensive and rapidly absorbed into circulation after sublingual administration and can be self-administered.

Highest peak concentration are achieved with oral and sublingual administration then in vaginal or rectal administration**(9**). Pyrexia is more common when the dose exceed 600mcg**(10)**.

Hence the purpose of study was to compare efficacy and safety of sublingual misoprostol in active management of third stage of labor with currently used intramuscular injection oxytocin

MATERIALS AND METHOD

A prospective, randomised, comparative study was carried out at Narayana Multispeciality Hospital, Jaipur at in-patient department. A total of 100 Term singleton pregnant females having completed 37 weeks of pregnancy in labour admitting in Antenatal care ward selected for study.

1.INCLUSION CRITERIA

a. Term singleton pregnant females admitted for delivery.

2.EXCLUSION CRITERIA

a. Patients at increased risk of PPH like anaemia, pre-eclampsia, antepartum haemorrhage (abruption and placenta previa).
b. Women with multifetal gestation, pre-term labor, polyhydramnios, chorioamnionitis, history of post partum haemorrhage, lower segment caesarean delivery in previous pregnancy, coagulation disorders.
c. Patients who have contraindications to use of prostaglandins like HELLP syndrome and hypersensitivity reaction.

Patients were randomly divided in two groups:

- Group 1 - Received Tab. Misoprostol 600mcg sublingually at the time of cord clamping.
- Group 2 - Received Inj. Oxytocin 10 IU IM at the time of cord clamping
- .Hemoglobin were measured at the time of admission to the labor room.
- Sterile pads, mops and drapes that were to be used after cord clamping were weighed.
- At the time of cord clamping, initial uterotonic (misoprostol or oxytocin) was given to the patient according to the group to which she was allotted.
- After cord clamping, used liquor soaked drapes were replaced by sterile pre-weighed drapes.
- Signs of placental separation (lengthening of cord, gush of blood and straightening of uterine fundus) were noted and placenta was delivered by controlled cord traction.
- A sterile preweighted pad is given to the patient for the next one hour
- Strict record of her vitals was kept and bleeding per vaginum and uterine contractility was noted every 15 min for first hour and every 30 min for the next hour.
- Any heavy bleeding was recorded within 24 hrs of delivery.

Estimation of blood loss :All soaked drapes and pads will be weighed on a weighing scale which will be then substracted from the initial weight of drypads.A 100 gm increase in weight was considered to be equivalent to 100 ml blood loss (assuming specific gravity of blood equivalent to 1gm/ml).This had given us estimated blood loss in millilitres.

Hemoglobin values was measured 24 hrs after delivary.Since 500 ml blood loss signifies a drop of 1 gm of Hemoglobin.So in our study difference in pre and post-delivery Hemoglobin was estimated to calculate blood loss in millilitres.

Side effects of these uterotonic agents' i.e nausea, vomiting, fever, shivering Diarrhoea, etc were noted.

The quantitative variables in both the groups were expressed as mean± SD and compared using unpaired t-test. The qualitative variables were expressed as percentages and compared using Chi–square test. A p value 0.05 was considered statistically significant. Statistical Package for Social Sciences (SPSS) Software version 18.0 was used for statistical analysis.

RESULTS

1. Estimated blood loss(ml)

Table 1 - Comparison of Mean ± SD of Estimated Blood loss (ml) in two groups

	Group	N	Mean	Std. Deviation	Std. Error Mean	t-value	p-value
Blood loss 3rd Stage	Misoprostol	50	101.10	57.87	8.18	0.238	0.813
	Oxytocin	50	99.36	61.49	8.70		
Blood loss 4th Stage	Misoprostol	50	54.54	35.72	5.05	1.124	0.264
	Oxytocin	50	48.16	22.16	3.13		
Total (3rd + 4th stage)	Misoprostol	50	155.64	75.82	10.72	0.655	0.514
	Oxytocin	50	147.52	69.33	9.80		

Table 1 show that difference in mean of estimated blood loss during third stage, fourth stage and total blood loss in both the groups was not statistically significant.

2. Comparison of Drop in Hemoglobin(gm/dl) In two groups

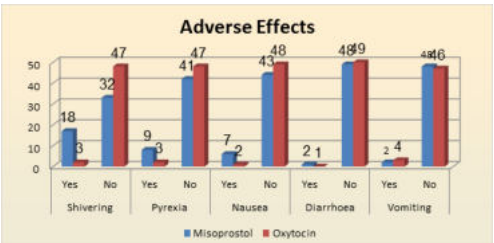
Table 2 – Comparison of Mean ± SD of Haemoglobin At the Time of Admission, 24hrs After Delivery and Drop in Hemoglobin (gm/dl) In two groups

	Group	N	Mean	Std. Deviation	Std. Error Mean	t-value	p-value
Hemoglobin Pre(gm/dl)	Misoprostol	50	11.66	1.09	0.15	1.441	0.153
	Oxytocin	50	11.35	0.96	0.14		
Hemoglobin Post(gm/dl)	Misoprostol	50	11.31	1.11	0.16	1.405	0.163
	Oxytocin	50	11.02	0.94	0.13		
Hemoglobin Diff(gm/dl)	Misoprostol	50	0.35	0.18	0.03	0.244	0.808
	Oxytocin	50	0.33	0.14	0.02		

(Where haemoglobin pre is the haemoglobin at the time of admission, haemoglobin post is the haemoglobin 24hrs after delivery, and haemoglobin diff is the drop in haemoglobin.)

Table 2 show that the difference in mean of hemoglobin at the time of admission in labour room, hemoglobin 24hrs after delivery and drop in haemoglobin in two groups was not statistically significant.

3.Adverse effects



Graph 3- Frequency Distribution of Various Adverse Effects experienced by women in two groups

Graph 3 shows that in this study, shivering and pyrexia were the two most common adverse effects which were experienced by the patients. Shivering was more common in misoprostol group than in oxytocin group (the difference was statistically significant p< 0.001). Other adverse effects like pyrexia and nausea were also more common in misoprostol group but the difference was statistically insignificant.

DISCUSSION

Active management of third stage of labor have significantly reduced the incidence of PPH. The role of uterotonics is to stimulate myometrial contraction, the major factor in reducing the third stage bleeding. The aim of the present study was to evaluate the role of misoprostol in active management of the third stage of labour and to compare it with oxytocin.

The two groups were comparable on the basis of age of women, gravidity, socio economic status, hemoglobin at the time of admission. The difference between these factors in two groups was not statistically significant.

Majority of the patients in this study were between the age group of 26-30 years in both the groups (62% in misoprostol group and 60% in the oxytocin group). 39% of the total women were primigravidas and 37% were gravid 2.

In our study we found that total estimated blood loss during third stage of labour was not statistically significant in misoprostol group and oxytocin group. In our study difference between drop in hemoglobin in misoprostol group and oxytocin group was statistically insignificant. The drop in hemoglobin correlated well with the estimated blood loss.. In the present study, shivering was experienced by more in misoprostol group and then women in oxytocin group. The difference was statistically significant The difference in occurrence of other adverse effects like pyrexia, diarrhoea, nausea and vomiting in the two groups was statistically insignificant**.**

CONCLUSION

Misoprostol is an effective uterotonic agent when administered sublingually allows the uterus to contract within few minutes. It is stable at room temperature, inexpensive and rapidly absorbed into circulation after sublingual administration.Though associated with higher incidence of shivering, sublingual misoprostol can be used as an alternative to oxytocin as shivering can be easily managed especially in poor resource settings where skilled birth attendants and sterile needles, syringes or refrigerating equipment's are not available. Therefore Misoprostol can be used as a effective and safe uterotonic in place of oxytocin especially at centers of poor delivery settings.

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