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A COMPARATIVE STUDY OF SAFETY & EFFICACY OF ORAL MISOPROSTOL VERSUS OXYTOCIN IN PREVENTION OF POSTPARTUM HAEMORRHAGE

Obstetrics & Gynaecology

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ABSTRACT

OBJECTIVE: To compare oral misoprostol with intramuscular oxytocin in prevention of postpartum haemorrhage in low risk vaginal birth in a tertiary care centre.
METHOD: In a prospective , open label controlled trial, 60 women were randomly allocated to 2 groups. Gr A – 10 units oxytocin i.m Gr B - 600µg misoprostol orally within 1 minute of delivery. The outcome measured was blood loss within 1 hour and 24hrs of delivery.
RESULTS: The mean blood loss in 1 hour post delivery was 151.14 ±12.40ml in Group A and 149.82±10.36 ml in Group B. The mean blood loss within 24hrs after delivery was 218.59 ±33.63 ml in Group A and 230.11±31.82 ml in Group B. There was no significant difference between the groups in terms of blood loss within1 hr and 24 hrs of delivery.
CONCLUSION: oral misoprostol 600µg is as effective as intramuscular oxytocin 10IU in the prevention of PPH in low risk vaginal delivery.

KEYWORDS

INTRODUCTION-

The aim of an obstetrician is a healthy mother and a healthy baby. The importance of obstetrics is reflected by the use of maternal and neonatal outcomes as an index of the quality of health and life among nations Maternal mortality is considered a key health indicator and the direct causes of maternal deaths are well known and largely preventable and treatable. Around 830 Women die from pregnancy or childbirth related complications all over the world everyday.(1) PPH accounts for a quarter of maternal deaths worldwide.PPH is a preventable cause of maternal morbidity and mortality. The commonest cause of PPH is **uterine atony** and is responsible for about 80% of PPH's.Therefore administration of uterotonic forms important part of active management of third stage of labour. There are various drugs and methods available for management of PPH. Drugs like oxytocin, ergot alkaloids, prostaglandins can be used for the management of third stage of labour. Oxytocin has been advocated by the WHO during the active management of third stage of labour.(2) Unfortunately access to oxytocin is still limited in many low resource settings due to need for cool storage, sterile equipment and administration by a skilled personnel. Oxytocin potency deteriorates when it is exposed to temperatures greater than 30˚C for prolonged periods of time. For this reason oxytocin should be distributed and stored along a cool chain which are not feasible in rural areas of resource poor countries like India. In recent years, Misoprostol, a synthetic analogue of prostaglandin E1 (PG E1), has been explored as an alternative for such settings. Prevention and treatment have depended primarily on injectable uterotonics. Misoprostol can be used as first-line therapy in the prevention and treatment of PPH where oxytocin is not available due to its proven ability to induce uterine contractions, low cost, stability at room temperature and ease of administration. Hence, the present study is being conducted to compare the efficacy and safety of oral misoprostol and intramuscular oxytocin in prevention of PPH which can helps us determine misoprostol as a suitable agent for management of the third stage of labour especially in resource poor settings.

MATERIALS AND METHODS

The study was conducted in the department of obsterics and gynecology at SMS medical college and hospital Jaipur, after ethical clearance from the institutional ethical committee.

Study Universe:
All patients admitted in labour room in Department of Obstetrics and Gynaecology, SMS Medical College Jaipur

Study Population:
All women undergoing normal delivery after applying inclusion and exclusion criteria

Type of Study:
A Prospective comparative interventional study.

Study Design:
Open label controlled trial

Place of Study:
Department of Obstetric and Gynecology, SMS Medical College and Hospital, Jaipur (Raj.)

Duration of Study:
From February 2019 onwards till August 2020.

SELECTION CRITERIA:
INCLUSION CRITERIA
Patients with singleton live pregnancy who delivered vaginally at term and who were willing to give consent for the study.

EXCLUSION CRITERIA
Cases with medical disorders like hypertensive disorders, previous uterine surgery, heart disease, coagulation disorders, respiratory disease, severe anaemia (Hb<7 gm), asthma, Diabetes
Malpresentation, malposition
Patients with polyhydramnios
Grand multipara
Ante partum haemorrhage
Instrumental delivery
Hypersensitivity or contraindication to prostaglandin use.

METHODOLOGY
After applying inclusion and exclusion criteria informed written consent was taken from the study population willing to participate and was recruited from Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur.

- Approval from institutional research, Review Board and Ethical Committee was taken.
- The study population was evaluated by history, clinical examination and relevant investigations.

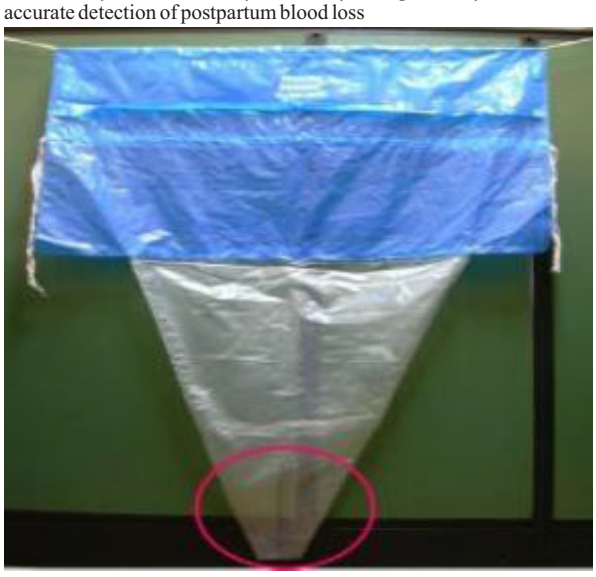
Women were randomly assigned with a 1:1 allocation using computer generated random numbers into one of two groups :
GROUP A(n=30):- 10 IU oxytocin i.m. just after delivery of the baby
GROUP B(n=30):- 600µg misoprostol tablet orally just after delivery of the baby

Comparison was made in terms of Quantitative assessment of blood loss within 1hr and 24hrs of delivery.

$$A = B + C$$

(Total amount of blood loss)
B. The amount of blood loss was measured by caliberated brass-v-drape.

It has a funnel shaped collection pouch which is caliberated, with a plastic sheet which is kept under the buttocks of the patient immediately after the delivery of the baby. It helps in early and most accurate detection of postpartum blood loss



C. Amount of blood loss due to soakage of gauze was done with the help of weighing machine.

$$\text{Measurement of blood loss (ml)} = \frac{\text{Weight of soaked gauze(gm) - weight of unsoaked gauze(gm)}}{1.06}$$

Density of blood =1060kg/m³
1ml of blood = 1.06gm of blood
Data thus collected was entered in excel sheet to prepare master- chart and was subjected to statistical analysis.

STATISTICALANALYSIS

Linear variables will be summarised as mean and standard deviation and will be compared by using unpaired t test.

Nominal / Categorical variables will be summarised as proportions and will be compared by using chi square test/fischer exact test
P-value <0.05 will be taken as significant.

RESULTS:

The mean age in Group A was 25.10 ± 2.04 and in Group B was 24.73 ± 2.21. There was no significant difference between the groups in terms of Age (Years) (p = 0.507). 56.7% of women belonged to rural area in Group A and 46.7% of women belonged to rural area in Group B hence there was no significant difference between the groups in terms of distribution of residence.There was no significant difference between the groups in terms of distribution of socioeconomic status.(p=0.708). There was no statistical difference between the incidence of confounding high risk factors of age, parity, booking status , religion, literacy. There was no significant difference between the various groups in terms of distribution of side effects. The mean blood loss in 1 hour post delivery was 151.14 ±12.40ml in Group A and 149.82±10.36 ml in Group B. There was no significant difference between the two groups in terms of blood loss within 1 hr. The mean blood loss within 24hrs after delivery was 218.59 ±33.63 ml in Group A and 230.11±31.82 ml in Group B. There was no significant difference between the groups in terms of blood loss within 24 hrs of delivery.

Table 1: comparison of the 2 groups in terms of blood loss in 1 hour (ml)

blood loss in 1 Hour (ml)	Group		t-test	
	Oxytocin	Misoprostol	T	p value
Mean (SD)	151.14(12.40)	149.82(10.36)	0.447	0.657
Median(IQR)	146.9(141.61-161.43)	149.56(141.66-156.07)		
Range	126.66-176.64	132.85 – 172.85		

Table 2: comparison of the 2 groups in terms of blood loss in 24hrs (ml)

Blood loss in 24 hrs (ml)	Group		t-test	
	Oxytocin	Misoprostol	T	p value
Mean (SD)	218.59(33.63)	230.11(31.82)	-1.364	0.178
Median (IQR)	211.02(199-235.54)	236.45(206.67-257.03)		
Range	165.42 - 298	158.52 - 295		

DISCUSSION-

In developing countries, like ours,PPH is a major cause of maternal death and arguably the most preventable. Attempts to reduce deaths from PPH have been complicated by the fact that many deaths occur in out-of-hospital settings or too quickly for the patient to be transferred to a health facility.Furthermore, prevention and treatment have depended primarily on injectable uterotonics, which are seldom available for births outside the health system. For these reasons, the use of misoprostol to prevent or treat PPH has attracted considerable attention. Administration of this drug on a wide scale at the community level to prevent and treat PPH is of major public health importance. . The mean blood loss in 1 hour post delivery was 151.14 ±12.40ml in Group A and 149.82±10.36 ml in Group B with p value 0.657. Similar results were observed in study done by **P Chaudhari et al(2012)(3)** they found mean blood loss was 153ml in misoprostol group and 146ml in oxytocin group with p = 0.36. Hence there was no significant statistical difference between the two groups. **Peter Wangwe et al (2009)(4)** found that mean estimated blood loss in the 1st hour was 160ml in misoprostol and 169ml in oxytocin group. The difference in their study was also not statistically significant. Although the blood loss was slightly higher than our study.In our study the mean blood loss within 24hrs after delivery was 218.59 ±33.63 ml in Group A and 230.11±31.82 ml in Group B with p value 0.178. Similar results were observed in a study done by **Savita Rani Singhal et al(2010)(5)** where mean blood loss was 260.35±97.45 ml in sublingual misoprostol group and 264.20±103.68 ml in 10IU i.m. oxytocin group. Almost similar results were observed by **Robert L Walley et al (2000)(6)**. They found that mean blood loss was 190ml in 400µg of oral misoprostol group and 187 ml in 10IU i.m. oxytocin group. Our results were consistence with study done by **Afolabi EO et al(2010)(7)** who observed that average blood loss was 155.6ml in 10IU I,m, oxytocin group and 153.20ml in 400µg oral misoprostol group. There was no significant difference between the two groups Thus, there was no statistical difference between the two groups in terms of blood loss. Hence it was observed in our study that oral misoprostol can be effectively used as a uterotonic.

CONCLUSION:

In the present study, it has been demonstrated that oral misoprostol 600µg appears to be as effective as intramuscular oxytocin 10IU in the active management of the third stage of labour. Oral misoprostol 600µg can be a miraculous drug at the level of peripheral health centres, home deliveries due to its ease and widely accepted route of administration with the feasibility of self administration, compliance, ease of availability, usefulness in busy obstetric settings, self limiting and less severe side effects, thermostability, shelf life, low cost, less need of skilled personnel.

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