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A COMPARATIVE STUDY OF ORAL, RECTAL AND INTRAMUSCULAR ADMINISTRATION OF MISOPROSTOL FOR THE PROPHYLAXIS OF POST-PARTUM HEMORRHAGE

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KEYWORDS :

INTRODUCTION

Post-partum hemorrhage (PPH) remains a challenge for anaesthetists and obstetricians.[1] Worldwide, hemorrhage remains a major cause of maternal death—it is estimated that between one-quarter and a half of preventable maternal deaths are secondary to hemorrhage.[2,3]As much as 600 ml (more than a quarter) of blood flows through the placenta each minute in a full-term pregnancy. The severe bleeding that occurs after birth is the largest direct cause of maternal deaths. Globally, nearly one quarter of all maternal deaths are associated with PPH, and in most low-income countries it is the main cause of maternal mortality. Failure of the uterus to contract (uterine atony) adequately after childbirth is the most common cause of postpartum hemorrhage. In the absence of timely and appropriate action, a woman could die within a few hours. In the developed world, PPH is a largely preventable and manageable condition. In developing countries, mortality from PPH remains high. All women who carry a pregnancy beyond 20 weeks' gestation are at risk for PPH and its sequelae. Treatment is delayed by failure to recognize PPH. The physiological changes of normal pregnancy mask the clinical presentation of hypovolemia.

The visual estimation of blood loss at the time of delivery is notoriously inaccurate. Blood may be contaminated with amniotic fluid; bleeding may occur vaginally or via a surgical wound; blood loss can take place over hours or days; may be concealed internally (e.g. placental abruption), or be hidden under drapes or on the floor. Blood collected via suction, the weighing of surgical swabs, and a careful search for concealed blood loss on the floor or under the operating drapes must be included in the estimation of blood loss, especially in suspected major hemorrhage. However, any clinical evidence of maternal cardiovascular compromise may represent significant blood loss irrespective of estimates.

PPH protocols are mandatory on all obstetric units. Initial resuscitation requires prompt, effective teamwork maintained by regular, multidisciplinary 'skills and drills' training. The team should include input from obstetrics, hematology, and anaesthesia at consultant level. There must be a system in place that ensures efficient access to blood products and robust channels of communication with portering and laboratory staff.[4,5]

The best preventive strategy for PPH is active management of the third stage of labor which includes uterine massage, controlled cord traction and administration of uterotonics. Amongst the various uterotonics used, ICM (International Confederation of Midwives) and FIGO (International Federation of Gynecology and Obstetrics) have committed themselves to making increased access to misoprostol for the management of PPH particularly in low-resource settings where intravenous oxytocin remains largely unavailable or not feasible. In the absence of personnel to offer active management of third stage of labor, it is recommended that the trained health worker should offer misoprostol 600 mcg orally immediately after the birth of the baby. The recommended dose does not change according to the woman's weight.[6]

Side-effects of misoprostol

Shivering, chills and/or fever are all commonly associated with misoprostol. The shivering is self-regulating and even if high temperatures occur, they are transient and settle with reassurance and symptomatic treatment. Gastro-intestinal effects include transient diarrhea, nausea and vomiting but are rare. Small amounts of misoprostol or its active metabolite may appear in breast milk, however, no adverse effects on nursing infants have been reported[7]

METHODS

This prospective comparative study was conducted in the post-graduate department of obstetrics and gynecology, GMC, Srinagar from December 2018 to January 2019. A randomized comparative trial was conducted in which 150 low risk pregnant women (primigravida or multigravida) who underwent normal vaginal delivery were included. The study subjects were divided into three groups with 50 subjects in each group. The three groups were given oral misoprostol(600 mcg), rectal misoprostol(600 mcg) and intramuscular misoprostol(125 mcg) respectively. The hemoglobin concentration was measured in all the subjects at the time of admission.

INCLUSION CRITERIA

1. Age 25-35 years
2. Singleton pregnancy
3. Cephalic presentation
4. Primigravida or multigravida
5. Normal vaginal delivery
6. Gestational age $\geq$ 28 weeks

EXCLUSION CRITERIA

1. Age > 35years.
2. Caesarean delivery.
3. Pregnancy with risk factors for PPH (multiple gestation, hydramnios, prolonged and augmented labour, placenta praevia, placental abruption, adherent placenta, retained placenta, macrosomia, instrumental delivery, uterine fibroids, chorioamnionitis, general anaesthesia).
4. Thrombophilias.
5. Pregnancy with medical disorders- diabetes mellitus, hypertension, asthma, anemia, cardiac disorders.
6. Preeclampsia and eclampsia.
7. Pyrexia in labor.
8. Previous history of PPH.

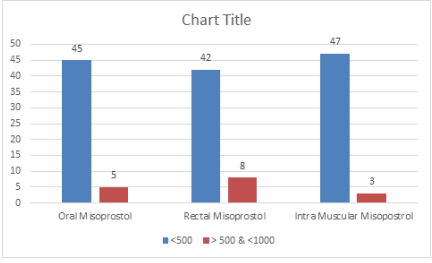
Randomized administration of oral misoprostol, rectal misoprostol and intramuscular misoprostol was done at the time of delivery of anterior shoulder. The placenta was delivered by controlled cord traction. The placenta was carefully examined for completeness. Immediately after the delivery, linen soiled with amniotic fluid was removed, a disposable plastic bag was placed under the patient and a sterile pan was applied against the patient's buttocks to collect all blood until 1 hour after delivery. The episiotomy, if given, was stitched in layers. The blood in the bed pan along with blood stained sanitary pads and blood contained in plastic bags were weighed (gm). The known dry weight of these items was subtracted to give the approximate volume of blood in ml (1ml = 1.05gm approximately). Vitals of the patient were carefully monitored including half hourly pulse rate charting and BP charting. Maternal hemoglobin concentration was measured again 24 hours after delivery. The outcome was measured in terms of:

A. Amount of blood loss during delivery (ml) [during third stage of labor].
B. Postpartum drop in maternal hemoglobin (g/dl).
C. Side effects of misoprostol.

OBSERVATIONS AND RESULTS

Table 1. AMOUNT OF BLOOD LOSS DURING DELIVERY (ml)

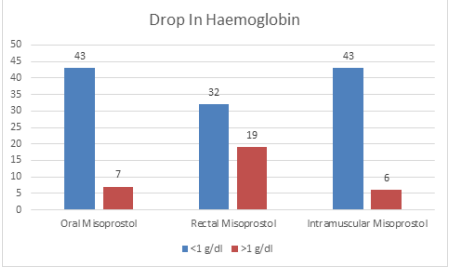
Blood Loss (ml)	Oral Misoprostol	Rectal Misoprostol	Intra Muscular Misopostrol	Total
<500	45	42	47	134
> 500 & <1000	5	8	3	16



Out of 150 subjects included in the study, 50 subjects were present in each group. Amongst 150 subjects, about 134 (89.3%) subjects had blood loss <500 ml during delivery amongst which 45 (90%) subjects belonged to oral misoprostol group, 42 (84%) belonged to rectal misoprostol group and 47 (94%) belonged to intramuscular misoprostol group. The remaining 16 subjects had blood loss > 500 ml but < 1000 ml amongst which 5 (11%) subjects belonged to oral misoprostol group, 8 (16%) belonged to rectal misoprostol group and only 3 (6%) belonged to intramuscular misoprostol group.

TABLE 2. DROP IN HEMOGLOBIN (Hb g/dl) AFTER DELIVERY.

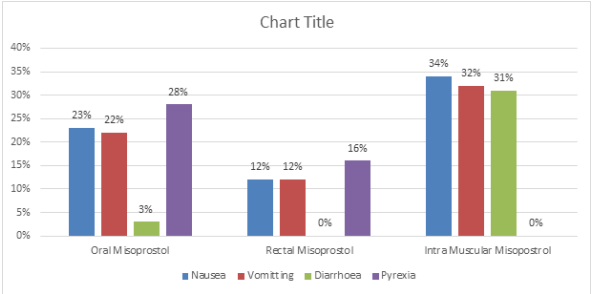
Hb Drop (g/dl)	Oral Misoprostol	Rectal Misoprostol	Intramuscular Misoprostol	Total
<1 g/dl	43	32	43	118
>1 g/dl	7	19	6	32



Of the 150 subjects, 118 subjects (78.6%) had postpartum Hemoglobin drop of <1g/dl. The maximum number of cases with a drop in Hemoglobin concentration < 1g/dl was observed in the oral and intramuscular misoprostol group [43 (86%) subjects each] as compared to the rectal group [32 (64%) subjects]. The remaining 32 (21.3%) subjects had a significant Hemoglobin drop of > 1g/dl. The maximum number of subjects with a significant Hemoglobin drop of > 1 g/dl was found in the rectal misoprostol group 19 (59.3%) and least in the intramuscular group 6 (18.7%).

TABLE 3. DISTRIBUTION OF SIDE-EFFECTS

Side Effects	Oral Misoprostol	Rectal Misoprostol	Intra Muscular Misopostrol	Total
Nausea	23%	12%	34%	23.00%
Vomitting	22%	12%	32%	22%
Diarrhoea	3%	0%	31%	11%
Pyrexia	28%	16%	0%	20%



Out of 150 subjects, 34(22.6%) subjects had nausea with maximum incidence in the intramuscular misoprostol group (34%) and least in rectal group (12%).

A total of 33(22%) subjects had vomiting with maximum incidence in intramuscular group (32%) and least incidence (12%) in rectal group.

A total of 17(11.3%) subjects had diarrhea with maximum incidence in intramuscular group (31%) and no case reported in rectal group.

None of the cases in intramuscular misoprostol group had pyrexia with highest number of cases in oral group (28%) as compared to rectal group (16%).

DISCUSSION

Post-partum hemorrhage (PPH) is the most important direct cause of maternal mortality in low resource countries, and one of the most preventable. As the most common cause for PPH is the failure of the uterus to contract adequately (atonic uterus), a key aspect in prevention of PPH is uterotonic therapy. The role of uterotonics is to stimulate myometrial contraction, the major factor reducing the third stage bleeding. The most widely used agent is injectable oxytocin. However, it requires parenteral administration, and, therefore, skills to give injections as well as sterile equipment; and refrigeration. For this reason, misoprostol, an E1 prostaglandin analogue, has attracted considerable attention as an alternative to oxytocin for the prevention of PPH in resource poor settings. Misoprostol is effective, simple to administer, and presents none of the logistical difficulties associated with use of oxytocin[8,9].

Misoprostol has been consistently shown to reduce the need for postnatal blood transfusion , transfer to a health facility and surgical interventions. Doses of under 600 µg have also been studied in an attempt to reduce the incidence of shivering and fever[10].

CONCLUSION

The third stage of labor is a crucial period where negligence can turn a previously uneventful pregnancy into a disaster. An intramuscular administration of misoprostol given prophylactically immediately after delivery of baby and cord clamping is found to be a highly effective and acceptable in active management of third stage of labor. Intramuscular misoprostol has the advantage in terms of decreased blood loss leading to decreased requirement of blood transfusion after delivery thereby decreasing maternal morbidity and mortality. However, the incidence of side-effects of this drug remain mostly attributed to its intramuscular route of administration.

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