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RESEARCH ARTICLE

A COMPARITIVE STUDY OF EFFECTIVENESS OF 400µgm OF SUBLINGUAL MISOPROSTAL VS 0.2Mg OF I.V METHYERGOMETRINE IN THIRD STAGE BLEEDING

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ABSTRACT

The third stage of labor is the most crucial stage of labor as in it lurks more unheralded treachery than in the first two stages combined. It carries with it the potential dangers like postpartum hemorrhages, retention of placenta, shock, pulmonary embolism and uterine inversion. 200 cases of vaginal deliveries conducted in Government General Hospital, Kakinada, were studied from November 2013 to October 2014. The current study is aimed at determining the efficacy of 400micrograms of misoprostol (PGE1) when given sublingually at the birth of anterior shoulder, in comparison with 200 micrograms (0.2mg) of intravenous methyl ergometrine, in the active management of third stage of labor, in reducing the third stage of blood loss and in reducing the risk of atonic postpartum hemorrhage. The patients were divided in two groups, 100 for each treatment regimen, misoprostol group and methyl ergometrine group. In all the groups majority of the patients both primis and second gravidas were in 21-25 years age groups Majority of the primis and secondgravidas were in 39-40 weeks gestational age. The mean duration of 3rd stage in misoprostol group was 3.52±1.11 mins.and in methyl ergometrine group was 6.58±213min.P value0.001.whic is statistically significant. The mean total third stage blood loss which includes the blood loss at delivery and the blood loss up to 1hr of postpartum period was 86.85cc in the misoprostol group and that in the methylergometrine group was 161.63cc. Misoprostol can be routinely used instead of methylergometrine for more effective management of third stage of labor. As misoprostol was easier to administer and safe, it is an acceptable alternative available other uterotonincs which are in use for the third stage of labor and management of PPH.

INTRODUCTION

Postpartum hemorrhage still remains a dreaded complication in modern obstetrics and accounts for about 27.6%of maternal death in India where maternal deaths contribute to1% of total deaths, 2.5% of all female deaths and 12.5% of all deaths in females between 15 and 44years.Therefore, minimizing the third stage blood loss becomes an essential measure to reduce the maternal morbidity and mortality (Debalina Datta and Pratyay Pratim Datta, 2013). Although risk factors may increase a woman's chances of developing post-partum hemorrhage, 2/3rd of the cases of PPH occur without any predisposing factor hence all pregnant women remain at a risk of developing PPH. Globally about11% of women having live births have severed PPH, amounting to 14 million women a year. The major burden of this is borne by women in underdeveloped and developing countries. The incidence of PPH is 3-6% of all normal deliveries. The incidence is higher in operative deliveries, especially when conducted under general anesthesia.

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The incidence is 3.9% in vaginal deliveries and 6.4% in cesarean deliveries. Uterine atony is the most common cause of PPH. Active management of the third stage of labor (AMSTL) was recommended by WHO for the prevention of PPH due to uterine atony in facility births (WHO, 2009).

MATERIALS AND METHODS

200 cases of vaginal deliveries conducted in Government General Hospital, Kakinada, were studiedfrom November 2012 to October 2014.The patients were divided in two groups, 100 for each treatment regimen, misoprostol group and methyl ergometrine group.

Misoprostol Group

This group includes 100 patients (50primi+50second gravida) who had vaginal delivery to whom 400 micrograms of misoprostol, PGE1 was given sublingually after delivery of anterior shoulder of baby.

Methylergometrine Group

This group includes 100 patients (50primi+50second gravida) who had vaginal delivery, to whom 200 micrograms (0.2gm)

of methyl ergometrine was given intravenously after the delivery after the delivery of the anterior shoulder of baby, followed by10 units of oxytocin was given as a drip in 500 ml of 5% dextrose, intravenously.

Case Selection

All patients were randomly selected irrespective of their weight. At the time of admission patient's age, parity gestational age, booking status and investigations such as hemoglobinlevel, blood grouping and typing, urinealbumin, sugar and microscopic, HIV and HBS AG status were noted. The medical history was properly elicited. Patients were randomly allocated into two treatment groups, misoprostol group and methyl ergometrine group. Woman had normal vaginal delivery with or without episiotomy (primi and second gravida) was enrolled.

Materials Used

1. Misoprostol tablet 200µg/100µg (ziotec/Misoprost).
2. Inj. Methyl ergometrine (Methergine0.2mg ampoule.
3.2CC Syringe with needle (disposable).
4. Disposable post- partumhemorrhage bag.
5. Weighing machine.
6. Stop watch.

Inclusion Criteria

- Patients with vaginal delivery
- Primi and second gravida
- Gestational age>37 weeks
- Singleton pregnancy
- Cephalic presentation-LOA/LOT
- With a live fetus
- Spontaneous onset of labor and patients in active labor
- Mild anemia complicating pregnancy
- Previous H/O PPH
- Previous caesarean delivery-VBAC

Exclusion Criteria

- Teenage
- Grand multipara
- Polyhydraminos
- Hypertensive disorders
- PROM/Chorioamnionitis
- Diabetes complicating pregnancy
- Hepatic disease
- Renal disease
- Intra uterine death of fetus

Table No.1. Age Distrubution

Sl.no.	Age range(yrs)	Misoprostol group				Methylergometrine group			
		Primis 50		Second 50		Primis 50		Second 50	
		No	%	No	%	No	%	No	%
1.	20	26	52	20	40	24	48	16	32
2	21-25	22	44	27	54	23	46	33	66
3	26-30	2	4	3	6	3	6	1	2
Mean age		21.4		21.9		21.7		21.84	
Totalmean age		21.8 yrs				21.7 yrs			

Table No.2. Distribution of risk factors

Sl.no.	Risk factors	Misoprostol group		Methylergometrine group	
		No	%	No	%
1	Anaemia	9	9	8	8
2	Post dates	22	22	12	12
3	Previous lscs vbac	2	3	2	2
4	Previous h/o	1	1	1	1
	Total	35	35%	23	23%

Table No.3. Duration of Labour

Sl.no.	Avg.duration of labour	Misoprostol group		Methylergometrine group	
		Primis	Second	Primis	Second
1	First stage(hrs)	13.04±2.44	8.30±2.51	11.40±3.05	7.07±3.03
2	Second stage(min)	29±10.1	20±11.13	24.1±12.30	17.58±11.24
3	Total(hrs)	13.3	8.5	12.04	8.24
4	Mean(hrs)	11.3		10.12	

Table No. 4. Duration of third stage (min)

Sl.no.	Duration of third stage(min)	Misoprostol group		Methylergometrine group		P value
		No	%	No	%	
1	<3	18	18	6	6	
2	3-6	74	74	21	21	
3	6-10	8	8	68	68	
4	>10	-	-	5	5	
	Total	100	100%	100	100%	0.001

Table No.5. Mean Duration Of Third Stage

Sl.no	Avg.duration of labour	Misoprostol group		Methylergometrine group		P value
		Primis	Second	Primis	Second	
1	Third stage(min)	3.57±1.16	3.48±1.07	6.5±2.3	6.57±3.03	
2	Group mean (min)	3.52±1.11		6.58±213		0.001

Table No.6. Third Stage Mean Blood Loss

Sl.no	Mean blood loss(cc)	Misoprostol group		Methylergometrine group	
		Primis	Second	Primis	Second
1	Immediate(cc)	8.48±72.9	67.6±55.9	146.9±115.5	137.4±109.9
2	After 1 hour(cc)	13.8±14.8	7.6±4.4	19.0±11.01	20.3±17.6

Table No.7. Totalthird Stage Blood Loss

Sl.no	Mean blood loss(cc)	Misoprostol group		Methylergometrine group		P value
		Primis	Second	Primis	Second	
1	Total	98.5±82.3	75.2±58.01	165.9±119.2	157.3±118.24	
2	Group mean	86.85		161.63		0.001

Patients with traumatic PPH due to cervical tears etc. were excluding from the study.

Observations

All the observations were recorded and comparison was done between both the groups with the various studies available, on the safety and efficacy of Misoprostol and Methyl ergometrine.

- Interval between injection of the drug and expulsion of the placenta.
- Duration of 3rd stage of labor.
- Amount of blood loss.
- Side effects of drugs.
- Need for any additional oxytocic.
- Maternal complications.
- Third stage complications.

RESULTS

Total number of 200 cases were randomly recruited into the study 100 for each treatment regimen and the results were compared and discussed here. Table no.1 The age of the patients ranged between 20-30 years. In all the groups majority of the patients both primis and second gravid as were in 21-25 years age groups. The mean in the misoprostol group was 21.18 years and that in the methyl ergometrine group was 21.7 years. The parity in both groups was 50 primis and 50 second gravidas. Majority of the primis and second gravidas were in 39-40 weeks gestational age group in both the groups. The mean gestation age in the misoprostol group was 40 weeks and that in the methyl ergometrine group was 39.5 weeks. The high risk factors like anaemia, previous history of PPH were almost equally distributed in both the groups. The distribution of other risk factors were also not significantly different in both the groups. The average duration of the 1st and 2nd stages was similar in both the groups. The mean duration of labor in misoprostol group was 11.31 hours and was in methyl ergometrine group was 10.12hrs. The duration of third stage in misoprostol group was between 3min and 6min.The duration of third stage in methyl ergometrine group was between 6min and 10 mins.18% of patients in misoprostol group and6%of patients in methyl ergometrine group had duration below 3min.5% of patients in methyl ergometrine group had duration more than 10 MINS. Two patients had retention of placenta in methyl ergometrine group, which was removed manually. The mean duration of 3rd stage in misoprostol group was 3.52±1.11 mins.and in methyl ergometrine group was 6.58±213min.P value0.001.whic is statistically significant. The mean blood loss in third stage of labor immediately at delivery was significantly decreased in misoprostol group. It was 76.2cc when compared to 142.15cc I the methyl ergometrine group. The mean total third stage blood loss which includes the blood loss at delivery and the blood loss up to 1hr of postpartum period was 86.85cc in the misoprostol group and that in the methylergometrine group was 161.63cc.

Misoprostol caused pyrexia in 8% and shivering in16% of the patients and methyl ergometrine caused a mild rise in B.P.in 3%of the patients and retained placenta in 2% of patients. The gastrointestinal side effects like nausea and vomiting occurred in 3% of patients in the methylergometrine group. Other side effects did not occur in misoprostol group in the study.

DISCUSSION

In our study duration of third stage of labor was 3.52±1.11minutes similar to results observed by Surbek et al. (Surbek *et al.,* 1999) and Ng et al[(4)]who used oral misoprostol and syntometrine in third stage of labor. However, longer duration was observed by Devi *et al.* (Devi *et al.,* 1988) and Bhattacharya *et al.* (Bhattacharya *et al.,* 1988) while using methyl ergometrine maleate 0.2 mg intravenously. Hoj *et al.* in 2005 (Hoj *et al.,* 2005) comparing 600 µg sublingual misoprostol with placebo, observed that mean blood loss is 10.5% less in misoprostol group than in the control group. In all the groups majority of the pateints, both primis and second gravidas were in 21-25 years age groups. The high risk factors like anaemia, previous history of PPH**,** were almost equally distributed in both the groups. The distribution of others risk factors were also not significantly different in both the groups. The distribution of third stage in misoprostol group was between 3min to 6min. The duration of third stage in methyl ergometrine group was between 6 min to 10 mins. 18% of

patients in misoprostol group and6%of patients in methyl ergometrine group had duration below 3min.5% of patients in methyl ergometrine group had duration more than 10 mins which was similar in other studies . (Ameetpatki *et al.,* 1993; Arulkumaran *et al.,* ?) The mean duration of 3rd stage in misoprostol group was 3.52±1.11 mins.and in methyl ergometrine group was 6.58±213min. P value 0.001. Which is statistically significant.

The mean blood loss in third stage of labor immediately at delivery was significantly decreased in misoprostol group. It was 76.2cc when compared to 142.15cc I the methyl ergometrine group. The mean total third stage blood loss which includes the blood loss at delivery and the blood loss up to 1hr of postpartum period was 86.85cc in the misoprostol group and that in the methylergometrine group was 161.63cc, similar to other studies (Priyabhinde *et al.,* 1993; Walraven *et al.*, 2005) Misoprostol caused pyrexia in 8% and shivering in16% of the patients and methyl ergometrine caused a mild rise in B.P.in 3%of the patients and retained placenta in 2% of patients and the gastrointestinal side effects like nausea and vomiting occurred in 3% of patients in the methylergometrine group which are known side effects (Katzung's, ?). Other side effects did not occur in misoprostol group in the study.

The present study compared the duration of the third stage of labor, blood loss, and adverse effects of three oxytocic regimes. The sublingual route of administration of misoprostol was chosen in the present study because of better pharmacokinetics compared with oral or vaginal routes. Sublingual tablets were easy to administer and well accepted by women also reported by Gohil *et al.* (Gohil and Tripathi, 2011). Oral misoprostol has been found to have comparable results to standard parenteral oxytocics in reducing PPH (Tang *et al.,* 2002). However, conflicting results showing that misoprostol is less effective than traditional uterotonics have also been published (El-Refaey *et al.,* 2000). A recent Cochrane meta-analysis concluded that misoprostol is better than a placebo but less effective than conventional parenteral oxytocics during active management of third stage of labor (Mousa *et al.,* 2014). According to WHO recommendations (Mathai *et al.,* 2007) for prevention of PPH ''active management of third stage of labor'' should include administration of an uterotonic action soon after birth of the baby, delays cord clamping, and delivery of the placenta by controlled cord traction, followed by uterine massage. Adequate storage and parenteral administration of an oxytocic by a trained health worker is not feasible in many developing countries including India. Misoprostol offers distinct advantages because it is stable at room temperature, affordable, and easy to administer.

Conclusion

Misoprostol can be routinely used instead of methylergometrine for more effective management of third stage of labor. As misoprostol was easier to administer and safe, it is an acceptable alternative available other uterotonincs which are in use for the third stage of labor and management of PPH. Misoprostol is strongly recommended for prophylactic support in cases where postpartum hemorrhage is anticipated like anemia complicating pregnancy, big bay, multigravida, polyhydramnios etc. Misoprostol can be used in bronchial asthma patients for whom other PGs are contraindicated. The side effects caused due to misoprostol are very minimal, transient and reversible due to small dose. The routine use of misoprostol should be made mandatory for improving women's health in developing countries as per WHO recommendations.

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