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A randomised control study: Sublingual misoprostol versus intramuscular oxytocin in the active mangement of third stage of labour

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Abstract

Purpose: To compare the outcome of sublingual misoprostol versus intramuscular oxytocin in the active management of third stage of labour.

Methods: This randomized control study included 332 cases who fulfilling selection criteria, the study cases comprised of those women in the third stage of labour after vaginal delivery. Patients were randomly allocated into two groups, group A (166 cases) receive 400µg sublingual Misoprostol tablet and group B (166 cases) receive 10 IU intramuscular oxytocin after delivery of baby, before cord clamping. The main outcome measures estimation of amount of blood loss in 1st one hour of labour, next 23 hours and total blood loss upto 24 hours.

Results: There Mean blood loss during third stage of labour.was not statistically significant in groupA, recieve 400 µg sublingual Misoprostol tablet and groupB, receive 10 IU intramuscular oxytocin after delivery (p>.05).

Conclusion: The sublingual misoprostol 400 mcg appers to be as effective as intramuscular oxytocin 10 IU in the active management of third stage of labour.

Keywords: Misoprostol, oxytocin, postpartum, haemorrhage, blood loss, labour

Introduction

Postpartum period is a time of relief and joy for all involved but there are potential danger links for mother during this period. Among three stages of labor, mortality and morbidity mostly occur in the third stage of labor (As a result of PPH).[1] Postpartum heamorrhage is an important cause of maternal mortality, accounting for nearly one quarter of all maternal deaths worldwide. Atonicity is the most common cause.[2] Postpartum heamorrhage is defined as any amount of bleeding from or into the genital tract following birth of the baby upto the end of the puerperium, which adversely affects the general condition of the patient evidenced by rise in pulse rate and falling blood pressure is called postpartum hemorrhage.[3]PPH has also been defined as either a 10% change in the haematocrit between admission and postpartum period or a need for blood transfusion.[4]

Postpartum heamorrhage is defined as blood loss of > 500 ml after vaginal delivery or a loss > 1000 ml after caesarean delivery and > 1500 ml after caesarean hysterectomy.[5]
Etiology of postpartum heamorrhage–[6]

a. Atonic PPH (80 to 85%)
b. Traumatic PPH (20%)
c. Retained product of conception
d. Combination of traumatic and atonic causes.
e. Blood coagulation disorders

Heamorrhage remain the leading cause of maternal mortality, accounting for approximately 25% of deaths.[7]
Third stage of labour_it begins after explusion of fetus and ends with explusion of placenta and membranes (after birth).Its average duration is about 15 minutes in both primigravida and multipara. The duration is however reduced to 5 minutes by active management of third stage of labour, which includes controlled cord traction, uterine fundal massage and administration of pharmacological uterotonic. These includes oxytocin, ergometrine, and prostaglandins. [1,5,8]
It has now been accepted that in order to decrease the incidence of PPH and its morbidity various measures are needed to be accepted. Use of uterotonics play an important role in management of atonic PPH.
Uterotonics,helps in preventing or stopping excessive blood loss from an atonic uterus during caesarean section.[9]
Misoprostol is used in obstetrics and gynaecology,for induction of labour, cervical ripening before surgical procedures, and the treatment of postpartum haemorrhage. Misoprostol's advantages over other synthetic prostaglandin analoges are its low cost, long half life, heat stability, and worldwide availability.[10]
Oxytocin is a short amino-acid polypeptide hormone used to stimulate uterine contractions.[11] Although oxytocin is the gold standard drug for prevention and treatment ofpph, It requires cold storage,sterile equipments and trained personale.[12]

Aim and objectives

To compare the outcome of sublingual misoprostol versus intramuscular oxytocin in the active management of third stage of labour.

Material and methods

This Prospective hospital based randomized control study was conducted in Department of Obstetrics &Gynaecology, SMS Medical College, Jaipur (Rajasthan) from January 2016 to February 2017.
The study cases comprised of those women in the third stage of labour after vaginal delivery, 332cases who fulfilling selection criteria was included in the study. Exclusion criteria included women with any risk factor of postpartum heamorrhage i.e. Instrumental delivery, Cervical tear, Anemia, Antepartum Heamorrhage, Poly-Hydramanios, Pregnancy induced hypertension, Multiple pregnancy, Bronchial asthma, Diabetes mellitus, Previous caeserian section, Fibroid uterus, Heart disease, Liver disease, Renal disorders , Coagulation abnormalities. Patients were randomly allocated into two groups, groupA (166 cases) recieve 400 µg sublingual Misoprostol tablet and groupB (166 cases) receive 10 IU intramuscular oxytocin after delivery of baby, before cord clamping. The main outcome measures estimation of amount of blood loss in 1st one hour of labour, next 23 hours and total blood loss upto 24 hours.
The amount of blood loss was measured by a calibrated plastic blood collection drape. Estimation of amount of blood loss in episiotomy of vaginal delivery was also done using soakage gauge from episiotomy site with the help of weighing machine.

All the data collected was analyzed. Statistical analysis was performed using chi-square test for qualitative data and student t test was used for quantitative data.

Results

This study was conducted in the department of obstetric and gynaecology, SMS Medical College Jaipur (Rajasthan) from January 2016 to February 2017.

Table 1: Distribution of cases according to blood loss in 1st hour.

Blood loss (in ml)	Group A		Group B	
	No.	%	No.	%
51 – 100	25	15.06	21	12.65
101 – 150	94	56.62	86	51.81
151 – 200	35	21.08	42	25.30
201 – 250	7	4.21	11	6.63
251 – 300	3	1.80	4	2.41
>300	2	1.20	2	1.20
Total	**166**	**100.00**	**166**	**100.00**

Mean blood loss in first hour.

Blood loss (in ml)	Mean ± S.D.		P value	Significance
	Group A	Group B		
In 1 hr	136.05 ± 40.42	146.03 ± 45.80	>.05	NS

Table 2: Distribution of cases according to blood loss in next 23 hours.

Blood loss (in ml)	Misoprostol		Oxytocin	
	No.	%	No.	%
≤ 50	6	3.61	7	4.21
51 – 100	153	92.16	148	89.16
101 – 150	6	3.61	6	3.61
151 – 200	1	0.60	5	3.01
Total	**166**	**100.00**	**166**	**100.00**

Mean blood loss in next 23 hours.

Blood loss (in ml)	Mean ± S.D.		P value	Significance
	Group A	Group B		
Next 23 hrs.	74.46 ± 14.89	78.15 ± 24.02	>0.05	NS

Table 3: Distribution of cases according to blood loss upto 24 hours.

Blood loss (in ml)	Group A		Group B	
	No.	%	No.	%
101 – 150	6	3.61	2	1.20
151 – 200	65	39.15	62	37.35
201 – 250	72	43.37	61	36.75
251 – 300	17	10.24	29	17.46
>300	6	3.61	12	7.23
Total	**166**	**100.00**	**166**	**100.00**

Mean blood loss upto 24 hours.

Blood loss (in ml)	Mean ± S.D.		P value	Significance
	Group A	Group B		
First 24 hours	210.15 ± 44.95	223.65 ± 55.58	>0.05	NS

Table 4: Mean blood loss according to gravida.

Gravida	Group A	Group B	P value	Significance
Primigravida	197.86 ± 41.52	201.70 ± 40.44	>0.05	NS
Second gravida	208.70 ± 32.31	220.37 ± 40.74	>0.05	NS
≥ Third gravida	231.64 ± 56.07	269.37 ± 71.59	>0.05	NS

The study cases comprised of those women in the third stage of labour after vaginal delivery, 332 cases who fulfilling selection criteria was included in the study.

Table 1 shows the mean blood loss in 1st hour in ml was136.05 ± 40.42 in Group A and 146.03 ± 45.80 in Group B. This difference was not statistically significant.(p>.05) Table 2 shows the mean blood loss in next 23 hours was 74.46 ± 14.89 ml in Group A and78.15 ± 24.02 ml in Group B . But it was not statistically significant.(p>.05). Table 3 shows mean blood loss up to 24 hours in group A and group B was 210.15 ± 44.95 ml and 223.65 ± 55.58 ml respectively but the difference was not statistically significant.(p>.05). Table 4 shows Amount of blood loss increase with increased with increase in gravida. Difference among both groups was not statistically significant.(p>.05)

Discussion

This study demonstrated that sublingual misoprostol 400 mcg appearsto be as effective as intramuscular oxytocin 10 IU in the active management of third stage of labour. Mean blood loss in 1sthour was 136.05 ± 40.42 in Group A and 146.03 ± 45.80 in Group B. This difference was not statistically significant.(p>.05) Our finding also were consistent with Peter Wangwe et al (2009) study which reported that the mean blood loss was equal in both the misoprostol and oxytocin group respectively.[13] The mean blood loss in next 23 hours was 74.46 ± 14.89 ml in Group A and78.15 ± 24.02 ml in Group B . But it was not statistically significant.(p>.05). The mean blood loss up to 24 hours in group A and group B was 210.15 ± 44.95 ml and 223.65 ± 55.58 ml respectively but the difference was not statistically significant.(p>.05).) Our finding also were consistent with Gohil JT et al (2011) study[14], Afolabi EO et al (2010) study which reported that sublingual misoprostol 400 mcg appears to be as effective as intramuscular oxytocin 10 IU in the active management of third stage of labour.[1]Savita Rani Singhal et al (2010) study which reported that the mean blood loss was equal in both the misoprostol and oxytocin group respectively.(p>.05)[15] and Robert L Wallay et al (2000) study which reported thatoral misoprostol appearsto be as effective as intramuscular oxytocin in minimizing blood loss in third stage of labour[16].

Conclusion

Based on the data found in our study We observed thatsublingual misoprostol 400 mcg appearsto be as effective as intramuscular oxytocin 10 IU in the active management of third stage of labour. Sublingual misoprostol 400 mcg can be a miraculous drug at the level of peripheral health centers due to its simplicity in use regarding route of administration, thermostability, shelf life of years, low cost and less need for a trained staff. It also avoid

first pass effect and achieve highest peak concentration.

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