Original Article

Compare the Sublingual and Per Rectal Routes of Misoprostol Administration in Third Stage of Labor in Terms of Average Blood Loss

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ABSTRACT

Objective: To compare the sublingual and per rectal routes of misoprostol administration in third stage of labor in terms of average blood loss.

Study Design: Randomized controlled trial study.

Place and Duration of Study: This study was conducted at the in Obstetrics and Gynaecology Department, District Headquarter Hospital, Gujranwala during 23-6-2018 to 24-12-2018.

Materials and Methods: 100 patients were selected form the outpatient/ emergency department of District Headquarter Hospital, Gujranwala. The patients were divided in two groups A and B via lottery method. After the delivery of the baby the group A patients received 400 micro grams of misoprostol sublingually while the group B patients received the same amount of misoprostol via rectal route as suppository. Immediately after cord clamping and division, a kidney dish was firmly placed against perineum to collect the blood.

Results: Mean age of women in this study was 31.61±5.2 in Group-A and 29.94±4.54 years in Group-B. Mean amount of blood loss in Group-A and in Group-B was significantly higher in Group-B women i.e. Group-A: 313.14 vs. Group-B: 412.90, p-value=0.000.

Conclusion: Sublingual route of misoprostol administration in third stage of labor in terms of average blood loss was more effective as compared to per rectal route.

Key Words: Sublingual, Per Rectal, Misoprostol, Administration, Third stage, Labor, Blood loss

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INTRODUCTION

The third stage of labor is the shortest of all three stages of labor. It refers to the period between the delivery of newborn until the complete delivery of placenta and attached membranes.[1] The main complication of the third stage of labor is the postpartum hemorrhage (PPH). Most of the complications in third stage of labor occur in the low risk women and therefore most of the institutions have specific strategies to deal with unexpected outcomes.[2]

The World Health Organization estimates that 25% of the total maternal deaths are due to the PPH.[3]

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The women with PPH have long hospital stay and have more chance to develop the iron deficiency anemia and delay in initiation of breastfeeding. All these factors reflect the requirement of effective and simple measures to prevent the incidence of PPH.[4] The administration of uterotonic agents, early cord clamping and controlled cord traction can be useful to prevent PPH.[5]

There are many uterotonic agents available and each has its own limitations and drawbacks i.e. oxytocin has reduced potency in suboptimal environment and similarly methylergometrine is unstable at high temperatures. Nowadays, misoprostol is used globally and an active uterotonic agent as it is stable at room temperature and is inexpensive.[6,7]

The routes of the misoprostol can be oral, sublingual (SL) per-rectal (PR) or per vaginal. In 2017, Sreelatha, S., et al. conducted a study in which the average blood loss during the third stage of labor was 305.20 ± 102.04 ml for sublingual route of misoprostol while for the rectal route it was 398.20 ± 119.28 ml (p value <0.001).[8]

Rationale: The purpose of my study is to add in existing body of knowledge as misoprostol can be used by various routes. No studies have been carried out to date in Pakistan to establish the best route of

misoprostol for the active management of 3rd stage of labor. In my study, I want to compare the sublingual and parenteral routes of misoprostol in terms of blood loss in DHQ teaching hospital Gujranwala. These results will help us to reduce the incidence of PPH, which in turn reduce the hospital stay, hospital costs and maternal mortality.

MATERIALS AND METHODS

This Randomized controlled trial was conducted in Obstetrics and Gynaecology Department, District Headquarter Hospital, Gujranwala during 23-6-2018 to 24-12-2018.

Sample Size

Sample size of 100 cases (50 in each group) is calculated with 80% power of test, 95% confidence interval and taking mean blood loss in third stage of labor as 305.20±102.04 ml[8]in SL group versus 398.20±119.28 ml[8]in PR group.The data was collected through non-probability consecutive sampling technique.

Inclusion Criteria

1. Patients having normal vaginal delivery
2. Singleton pregnancy assessed via ultrasound
3. Full term pregnancyassessed via ultrasound
4. Age range between 20 to 40 years

Exclusion Criteria

1. Hemoglobin < 8 g/dl
2. Patients with multiple pregnancies i.e. parity ≥ 4
3. Patients with malpresentations, uterine fibroids assessed via ultrasound
4. Patients with bleeding diathesis i.e. prothrombin time >20 seconds
5. Patients who have taken NSAIDS in last 07 days
6. Immuno compromised patients including corticosteroid therapy.
7. Patients with gestational diabetes mellitus
8. Previous history of any chemotherapy or radiotherapy, any history of repeated infections.
9. Patients with severe hepatic, renal, CVS dysfunction

Data Collection Procedure: After permission from the concerned authorities and ethical committee and after fulfilling the inclusion / exclusion criteria 100 patients were selected form the Obstetrics and Gynaecology outpatient/ emergency department of District Headquarter Hospital, Gujranwala. Hospital registration numbers and informed consent was taken from all patients.

The patients were divided in two groups A and B via lottery method. After the delivery of the baby the group A patients received 400 micro grams of misoprostol sublingually while the group B patients received the same amount of misoprostol via rectal route as suppository.

Immediately after cord clamping and division, a kidney dish was firmly placed against perineum to collect the blood. The placenta was delivered via controlled cord traction method. The blood collected in kidney dish was measured in milliliters and was recorded on the specially designed Performa attached as annexure A.

Data Analysis: Data was analyzed using SPSS version 22. The variables to be analyzed was quantitative data like age, BMI, parity and blood loss in third stage of labor. Mean and standard deviation was calculated for quantitative data. Both groups were compared in terms of average blood loss during third stage by independent sample t test.

RESULTS

Mean age of women in this study was 31.61±5.2 in Group-A and 29.94±4.54 years in Group-B. In both groups minimum and maximum age was 23 and 40 years. In Group-A 22(44%) women's BMI was normal, 15(305) were overweight and 13(26%) were obese, while in Group-B 17(34%) women BMI was normal, 17(34%) were overweight and 16(32%) were obese.

Table No.1: Age of women in study Groups

	Group-A	Group-B
n	**50**	**50**
Mean	31.62	29.94
Standard Deviation	5.20	4.546
Minimum	23	23
Maximum	40	40

Parity status of women in both treatment groups can be seen in table-3 in detail. Mean amount of blood loss in Group-A and in Group-B was significantly higher in Group-B women. i.e. Group-A: 313.14 vs. Group-B: 412.90, p-value=0.000. Women in age group 23-30 years (Group-A: 315.70±64.26 vs. Group-B: 412.36± 59.19) and 36-40 years (Group-A: 283.85±47.75 vs. Group-B: 439.66±66.43) had significantly higher blood loss in Group-B as compared to Group-A women.

Table No.2: Parity of women in study Groups

	Group-A	Group-B	Total
1	27(54%)	15(30%)	**42**
2	8(16%)	23(46%)	**31**
3	15(30%)	12(24%)	**27**
Total	**50**	**50**	**100**

Table No.3: Amount of blood loss in study Groups

	Group-A	Group-B
N	**50**	**50**
Mean	313.14	412.90
Standard Deviation	59.85	63.59
Minimum	220	287
Maximum	415	515
p-value	0.000	

Women with normal BMI (Group-A: 322.18 vs. Group-B: 394.17), overweight (Group-A: 304.53 vs. Group-B: 435.41) as well as obese women (Group-A: 307.76 vs. Group-B: 408.87) had significantly higher blood loss in Group-B as compared to Group-A. Women with parity status 1,2 and 3 had significantly higher blood loss in Group-B as compared to Group-A.

Table No.4: Amount of blood loss in study Groups in relation to age of women

Age	Group-A	Group-B	p-value
23-30	315.70±64.26	412.36±59.19	**0.000**
31-35	352.00±39.94	402.57±72.68	**0.071**
36-40	283.85±47.75	439.66±66.43	**0.000**

Table No.5: Amount of blood loss in study Groups in relation to BMI of women

BMI	Group-A	Group-B	p-value
Normal	322.18±61.89	394.17±54.04	0.001
Overweight	304.53±58.03	435.41±69.43	0.000
Obese	307.76±60.98	408.87±62.96	0.000

DISCUSSION

There are numerous advantages with regard to the administration of Misoprostol, as it can be administered through various routes, orally, rectally, sublingually or by the vaginal route[9]. Moreover, it is commonly used in developing nations, as it is inexpensive, easy to store, and stable at room temperature. Earlier studies have successfully established the prophylactic use of misoprostol for the reduction of blood loss after delivery, when compared with the conventional uterotonics[10].

Although it can be used by various routes, no studies have been carried to date, to establish the best route of misoprostol administration for the active management of the third stage of labor[11]. Even as previous researches have established the superiority of conventional uterotonics to misoprostol, they have also recommended the use of misoprostol during the non-availability of these conventional uterotonics as well as during unsafe circumstances[12].

The effectiveness of Misoprostol in reducing blood loss and preventing PPH has been proved by various studies[13]. But the most effective route has not been established yet. Most of randomized trials studied oral and rectal routes,[13] one systematic review, and another meta-analysis suggested sublingual misoprostol to be the most promising route[14].

In this study SL and PR routes of misoprostol administration was compared. Findings of this study showed that patients who were in Group-B among them mean blood loss was significantly higher as compared to Group-A patient's blood loss. Group-A: 313.14 vs. Group-B: 412.90, p-value=0.000

Findings of this study is consistent with the findings reported by Sreelatha, S., et al who showed minimal blood loss with sublingual group as compared to rectal route[15-18].

CONCLUSION

Results of this study conclude that sublingual route of misoprostol administration in third stage of labor in terms of average blood loss was more effective as compared to per rectal route.

Author's Contribution:

Concept & Design of Study:	Maryam Naeem
Drafting:	Memona Latif, Faiza Nawaz
Data Analysis:	Munazza Latif, Sana Aftab
Revisiting Critically:	Maryam Naeem, Memona Latif
Final Approval of version:	Maryam Naeem

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