

TO COMPARE THE FETOMATERNAL OUTCOME OF ORAL MISOPROSTOL SOLUTION AND VAGINAL MISOPROSTOL TABLET FOR INDUCTION OF LABOUR AT TERM IN THE DEPARTMENT OF OBSTETRICS & GYNAECOLOGY, SMS MEDICAL COLLEGE, JAIPUR

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Abstract

Background: Induction of labour is a common intervention, required in situations where continuation of pregnancy may be lifethreatening for the mother and/or fetus. In industrialized countries, the induction rate ranges from 10-25%.

Methods: Randomized controlled trial was conducted at Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur.

Results: APGAR score at 1 min and 5 minutes was 6.64 and 6.84 in oral misoprostol and vaginal misoprostol group respectively, while at 5 minutes it is 6.7 oral group and 7 of vaginal misoprostol group. 34% of cases need NICU admission in Group-A (Oral misoprostol) and 14% in Group-B (Vaginal misoprostol) group. Meconium aspiration syndrome which is present 10% of patients in Group-A (Oral Misoprostol) while it is present in 6% of patients in Group-B (Vaginal misoprostol).

Conclusion: The lesser incidence of meconium-stained liquor and NICU admissions and fewer caesareans with better neonatal outcome in women induced with oral misoprostol outweigh its advantages over the vaginal misoprostol

Keywords: Misoprostol, Labor, Induction, Fetomaternal outcome.

Introduction

Induction of labour is a common intervention, required in situations where continuation of pregnancy may be lifethreatening for the mother and/or fetus.¹ In industrialized countries, the induction rate ranges from 10-25%.² Such inductions are frequently prolonged and unsuccessful, resulting in a higher cesarean delivery rate of 20%.^{3,4}

Several pharmacological agents are being used for labor induction, the commonest being oxytocin and prostaglandins. Oxytocin alone, especially in unfavorable cervix, frequently leads to induction failure and subsequent caesarean delivery.^{5,6} Although prostaglandin E2 (dinoprostone) has been in use since 1968 for labour induction and cervical ripening, the widespread use of this drug is limited because of its high cost and thermal instability leading to difficult storage. Moreover, oxytocin is still required in many cases after initial cervical ripening with Prostaglandin E2 (PGE2).⁷⁻⁹

Misoprostol is a synthetic prostaglandin E1 analogue. It was manufactured for the treatment of peptic ulcer disease.^{1,10} Though unlicensed by the Federal Drug Authority for this purpose,¹¹ Misoprostol is now increasingly and successfully being used for labour induction, with vaginal as well as oral routes.^{7,12,13} It is

economical, stable at room temperature, has easy handling and storage, rapid absorption and high potency.^{1,10} There is no evidence that oral misoprostol is inferior to the vaginal one and it has lower rates of uterine hyperstimulation because the total systemic bioavailability of orally administered misoprostol is three times lesser than that of vaginally administered misoprostol.¹³ In order to avoid uterine hyperstimulation, current suggestions are in favor of oral misoprostol given in small, frequent doses, titrated according to uterine response.¹⁴

Material & Methods

Place of study: Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur.

Duration of study: May 2018 to Aug 2019.

Type of study: Randomized controlled trial

Study Design: Prospective study

INCLUSION CRITERIA

- Primigravida
- Pregnancy at term
- Pregnancy with due date without labour pain
- Postdated pregnancy
- A live singleton foetus in cephalic presentation
- No history of uterine surgery
- Normal biophysical profile

Exclusion Criteria

Women with any medical problem:

- Coagulation disorders and thromboembolic disorders
- Abnormal placentation like placenta previa, abruptio placentae
- Uterine surgery like myoma
- Known hypersensitivity or contraindications to oral
- Patient's refusal to give consent
- Any antenatal medical complications
- A situation requiring LSCS

Statistical Analysis

Continuous variable was expressed as Mean and Standard deviation and compared by unpaired 't' test. Nominal / Categorical variables were summarized as Proportion and compared by chi-square test. p-value < 0.05 was taken as significant. Medcalc 16.4 version software was used for all statistical calculation

Observations

Table 1: Distribution of Patients According to Age Group

Age Group (in yrs)	Group-A		Group-B	
	No.	%	No.	%
21 - 25	34	68.00	20	40.00
26 - 30	10	20.00	18	36.00
31 - 35	6	12.00	12	24.00
Total	50	100.00	50	100.00

Above table shows that maximum number of patients in both the groups were in the age group of 21-25 years while the least number presented to the hospital belong to 31-35 years age group in both the study group

Table 2: Distribution of Patients According to the APGAR Score of Fetus Born

APGAR Score	Group-A		Group-B		p-value
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
1 min	6.64 ± 0.66	6.84 ± 0.47	6.84 ± 0.47	6.84 ± 0.47	0.085
5 min	6.70 ± 0.61	6.84 ± 0.47	6.84 ± 0.47	6.84 ± 0.47	0.203

This table shows APGAR score at 1 min and 5 minutes showing there is not much difference of values in both groups (Oral Misoprostol and Vaginal Misoprostol group)

Table 3: Distribution of Patients According to Birth Asphyxia After Misoprostol Use

Birth Asphyxia	Group-A		Group-B	
	No.	%	No.	%
Absent	43	86.00	47	94.00
Present	7	14.00	3	6.00
Total	50	100.00	50	100.00

$p = 0.318$ (NS)

Above table showed that the frequency of birth asphyxia was 14% and 6% in Group-A (Oral Misoprostol) and Group-B (Vaginal Misoprostol) respectively after misoprostol use.

Table 4: Distribution of Patients According to Need of Neonatal Resuscitation

Neonatal Resuscitation	Group-A		Group-B	
	No.	%	No.	%
Absent	48	96.00	48	96.00
Present	2	4.00	2	4.00
Total	50	100.00	50	100.00

$p = 1.000$ (NS)

Neonatal resuscitation was required in 4% in both Group-A (Oral Misoprostol) and Group-B (Vaginal Misoprostol) which shows there is no difference in both the group.

Table 5: Distribution of Patients According to NICU Admission

NICU Admission	Group-A		Group-B	
	No.	%	No.	%
Absent	33	66.00	43	86.00
Present	17	34.00	7	14.00
Total	50	100.00	50	100.00

$p = 0.034$ (NS)

Above table shows that 34% of cases need admission in Group-A (Oral Misoprostol) and 14% in Group-B (Vaginal Misoprostol).

Table 6: Distribution of Patients According to Meconium Aspiration Syndrome

Meconium Aspiration Syndrome	Group-A		Group-B	
	No.	%	No.	%
Absent	45	90.00	47	94.00
Present	5	10.00	3	6.00
Total	50	100.00	50	100.00

$p = 0.715$ (NS)

Above table shows presence of meconium aspiration syndrome which is present 10% of patients in Group-A (Oral Misoprostol) while it is present in 6% of patients in Group-B (Vaginal Misoprostol).

Table 7: Distribution of Patients According to Presence of Chorioamnionitis

Chorioamnionitis	Group-A		Group-B	
	No.	%	No.	%
Absent	48	96.00	49	98.00
Present	2	4.00	1	2.00
Total	50	100.00	50	100.00

$p = 1.000$ (NS)

Above table shows presence of chorioamnionitis 4% and 2% in Group-A (Oral Misoprostol) and Group-B (Vaginal Misoprostol) respectively.

Discussion

The present study was intended to compare the efficacy of oral misoprostol solution and vaginal misoprostol tablet for the induction of labor at term. The study was useful for the comparison of fetomaternal outcome after using oral misoprostol solution and vaginal misoprostol tablet.

In my study it was observed that APGAR score at 1 min and 5 minutes was 6.64 and 6.84 in oral misoprostol and vaginal misoprostol group respectively while.

While at 5 minutes it is 6.7 oral group and 7 of vaginal misoprostol group. In both the groups the results are not statistically significant ($p > 0.05$)

My study is comparable to study of Prameela et al (2018)¹⁵ where the APGAR score at 5 min 7/10 was seen in 7.7% in vaginal group as compared to 0% in oral group which was also statistically significant (0.004).

In a study of Syed S et al (2010)¹⁶ babies delivered were with a good APGAR score in 95% of cases both at 1 minutes and 5 minutes

In my study it was observed that 34% of cases need admission in Group-A (Oral misoprostol) and 14% in Group-B (Vaginal misoprostol) group. This study is comparable to study of Rasheed R et al (2007)¹⁷ where higher incidence of neonatal intensive care unit (NICU) admission in the vaginal group was mainly due to respiratory distress syndrome (RDS).

In a study of Prameela et al (2018)¹⁵ number of NICU admissions was also more in vaginal group compared to oral group.

In my study it was observed that meconium aspiration syndrome which is present 10% of patients in Group-A (Oral Misoprostol) while it is present in 6% of patients in Group-B (Vaginal misoprostol). However, 10.8% developed meconium aspiration syndrome.

Conclusion

The lesser incidence of meconium-stained liquor and NICU admissions and fewer caesareans with better neonatal

outcome in women induced with oral misoprostol outweighs its advantages over the vaginal misoprostol.

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