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ORIGINAL ARTICLE

Comparative Study of Efficacy and Safety of Oral Versus Vaginal Misoprostol for Induction or Labour

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Abstract
Objective To compare the efficacy of oral with vaginal misoprostol for induction of labour.
Design A randomized trial.
Setting Tertiary care hospital.
Participants Two hundred women requiring induction of labour.
Methods Group A received oral misoprostol 50 mcg 6 hourly maximum 4 doses to 100 patients and Group B received vaginal misoprostol 50 mcg 6 hourly maximum 4 doses to 100 patients. When the patient entered active stage of labour i.e. clinically adequate constractions of 3/10 min of >40 s duration, and cervical dilatation of with 4 cm, further doses of misoprostol were not administered. Statistical analysis was done using chi-square test and *t* test.
Result Both groups were comparable with respect to maternal age, gestational age, indication of induction and initial modified Bishops score Mean number of dosage required for successful induction were significantly less in vaginal group than oral group (in oral groups A were $2.73 + 0.58$, and in vaginal Group B $2.26 + 0.52$, P value < 0.0001 highly significant). The induction delivery interval was significantly less in vaginal group than oral group (Group A $15.24 + 3.47$ h Group B $12.74 + 2.60$ h, $P < 0.0001$ highly significant). Oxytocin augmentation required was less in vaginal group. 26 caesarean sections were performed in oral group and 17 caesarean sections were done in vaginal group (P value 0.06 NS). APGAR score, birth weight, NICU admissions showed no difference between the two groups.
Conclusion This study shows that vaginal route of administration of misoprostol is preferable to oral route for induction of labour when used in equivalent dosage of 50 mcg 6 hourly.

Keywords Induction of labour · Misoprostol vaginal route · Induction delivery interval

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Introduction

Induction of labour is the artificial initiation of labour before its spontaneous onset for the purpose of delivery of the fetoplacental unit using mechanical or pharmacologic methods [1]. The success of labour induction depends on the cervical status at the time of induction.

It is generally predicted that the patients with a poor Bishop's score ≤3 have unacceptably higher rates of failure of induction [2].

The new synthetic prostaglandian E1 analogue 'Misoprostol' licenced primarily for the prevention and treatment of non steroidal anti-inflammatory drug induced ulcers of gastrointestional tract, is a promising agent for labour induction [3–5]. Misoprostol is conveniently administered

through the oral, sublingual, buccal, vaginal and rectal routes [6]. It is inexpensive, easily stored at room temperature and has few systemic side effects.

The purpose of this study was to compare the efficacy and safety of oral versus vaginal misoprostol for induction of labour in the equivalent dosage of 50 mcg 6 hourly. The induction delivery interval, maternal and fetal outcome and need for augmentation of labour in these two groups were also compared.

Materials and Methods

The study was conducted at GMCH, Aurangabad in the Department of obstetrics and Gynaecology from July 2010 to Dec 2011. Ethical committee approval was taken and in July 2010. The study population ($n = 200$) was a mixture of high and low risk population. Patients at term with various indications for induction of labour were included in the study after a written, valid consent.

Inclusion Criteria

1. Primigravida
2. Gestational age 34–42 weeks
3. Singleton viable pregnancy
4. Bishop's score ≤ 5
5. Cephalic presentation
6. Clinically adequate pelvis
7. Reactive non stress test.

Exclusion Criteria

1. Known hypersensitivity or any contraindication to the use of prostaglandins.
2. Any antenatal complication necessitating emergency caesarean section.
3. Patients refusal to give consent.

The patients were randomly allocated to either Group A, ($n = 100$) who received oral tablet misoprostol 50 mcg 6 hourly for maximum four doses or Group B, ($n = 100$) who received vaginal tablet misoprostol 50 mcg 6 hourly for maximum four doses.

The Modified Bishop's score was determined. Each patient was questioned in detail and examined thoroughly. Last menstrual period was ascertained and correlated clinically.

Demographic profile, gestational age, number of doses required, induction–delivery interval, mode of delivery and feto maternal outcome was noted.

Patient was considered to be in active labour if she had painful uterine contractions of 3/10 min of >40 s duration. Amniotomy was done at cervical dilatation of 4 cm and further doses of misoprostol withheld. Patient was started oxytocin augmentation if she had no progress of labour for 2 h on WHO partograph. Those patients who had contractions <3/10 min of <40 s duration were considered to be not in active labour. These patients were administered further doses of misoprostol according to the protocol.

Failure of induction was declared if patient failed to go in active phase of labour within 24 h of induction.

Student's t test and chi-square test were used to statistically compare the two groups. Differences with a P value of <0.05 were considered statistically significant with the confidence limit of 95 % (Power of test 80 %).

Result

Group A and Group B had 100 randomised patients each. Both the groups were comparable with respect to the maternal age, gestational age, indication for induction and pre-induction modified Bishop's score (Tables 1, 2).

Mean pre induction Bishop's score in oral group was 3.09 ± 0.692 and in vaginal group was 3.17 ± 0.721.

Discussion

The results of this study show that vaginal route of administration of misoprostol is preferable to oral route when used in equivalent dosage.

The mean number of dosage of misoprostol required for successful labour induction was 2.73 ± 0.58 in the oral group and 2.26 ± 0.52 in vaginal group (P value < 0.0001, highly significant) (Table 2). Similar were observations of Rozina Rasheed et al., Wing DA et al. and Janice S. Kwon et al. where dosage requirement was less in vaginal group than oral group [7].

Mean induction delivery interval for successful outcome was 15.24 ± 3.47 h in oral group and 1.74 ± 2.60 h in oral group and 12.74 ± 2.60 h in vaginal group. The mean induction delivery interval was significantly less in vaginal group ($P < 0.0001$, highly significant). Similar observations were observed by Rozina Rasheed et al., Wing DA et al. and Janice S. Kwon et al. where induction delivery interval was less in vaginal group than oral group [8–10].

In oral group 26 patients required LSCS of which 19 were due to fetal distress and one due to impending eclampsia. These can not be attributed to failure of drug. Three patients in Group A had LSCS due to non progress of labour due to unforeseen cephalopelvic disproportion. Only three patients in oral group had undergone LSCS due to failed induction.

Table 1 Demographic Profile

Sr. No.	Variable	Group A $n = 100$	Group B $n = 100$	P
1.	Maternal age in years	21.64 ± 2.342	21.36 ± 2.048	0.1152 NS
2.	Gestational age in weeks	39.44 ± 1.902	39.52 ± 1.8785	0.765 NS
3.	Mean pre induction M. Bishops score	3.09 ± 0.6921	3.17 ± 0.7218	0.42 NS

Sr. No.	Indication of induction	Group A $n = 100$	Group B $n = 100$	P value
1.	Prolonged pregnancy	37	40	NS
2.	P1H	10	13	NS
3.	Prom	9	4	NS
4.	Other	44	43	NS

No statistically significant difference was demonstrated between the two groups

Table 2 Number of doses required for successful outcome, mode of delivery, induction–delivery interval

Sr. No.	Variable	Group A $n = 100$	Group B $n = 100$	P value
1.	Mean number of doses for successful outcome	2,73 ± 0.58	2.26 ± 0.52	0.0001 Highly significant
2.	Induction delivery interval in hours	15,24 ± 3.47 h	12.74 ± 2.60 h	<0.0001 Highly Significant
3.	Spontaneous vaginal delivery	68	73	
4.	Instrumental deliveries	6	10	
5.	LSCS	26	17	
	Total	100	100	

Table 3 Need for Oxytocin augmentation

Sr. No.	Oxytocin augmentation	Group A	Group B	Total
1.	Required	19	11	30
2.	No required	81	89	170
	Total	100	100	200

Table 4 Maternal side effects of drugs

Sr. No.	Side effect parameter	Group A ($n = 100$)	Group B ($n = 100$)	Total
1.	Nausea	2	2	4
2.	Vomiting	3	2	5
3.	Dizziness	1	0	1
4.	Headache	1	0	1
5.	Fever	6	3	9
6.	Tachysystole	5	2	7
7.	Hypertonus	3	1	4
8.	Uterine hyperstimulation	1	2	3
	Total	22	12	34

Table 5 Neonatal outcome

Sr. No.	Variable	Group A ($n = 100$)	Group B ($n = 100$)
1.	MSAF	6	11
2.	MAS	3	4
3.	LSCS	26	17
4.	Imin APGAR <7	30	28
5.	5 min APGAR <7	9	19
6.	NICU admission	30	28
7.	Neonatal death	0	1

In vaginal group, out of 17 LSCS, 14 patients required LSCS for fetal distress which cannot be attributed to failure of drug, three patients had non progress of labour due to unforeseen cephalopelvic disproportion. None of the patients in vaginal group had LSCS for failed induction.

In oral group ten patients required maximum dose (4 doses). Out of these five patients delivered vaginally. No significant side effect seen. All five babies had APGAR score <7. The five patients who required LSCS, indications were

1. Failed induction-3 cases
2. Fetal distress-1 case
3. Failure to progress-1 case

Of this five patients one had nausea, one had dizziness and one had vomittings. But the side effects were not severe enough to stop the drug. All babies had APGAR >7.

In vaginal group four patients required maximum dose (4 doses). Out of these two patients delivered vaginally. No significant side effects. All babies APGAR was >7.

Out of four patients, two required LSCS for fetal distress. No significant side effect. APGAR score of both babies >7.

19 % of patients required oxytocin augmentation in oral group and 11 % in vaginal group. [Chi sq. 0, 93, $P - 0.06$ NS] (Table 3). Oxytocin augmentation was more in patients with poor bishops score (Table 4) side effects of misoprostol in both groups were not significant. However fever and tachysystole were the most commonly seen side effects.

Fetal outcome data showed no significant difference between two groups with respect to birth weights (Group A 2,820 ± 377 g, Group B 2730 ± 447 g $t = 1.53$, $P = 0.12$ Not significant) (Table 5). MAS (6 % in Group A and 11 % in Group B), 1 min APGAR score <7 (30 in Group A, 28 in Group B), NICU admissions (30 in Group A, 28 in Group B).

Thus present study shows that the fetal outcome results were also comparable in both the groups.

Conclusion

In conclusion, this study shows that for induction of labour, vaginal misoprostol is preferable to oral misoprostol when used in equivalent dosage of 50 mcg.

In vaginal route of administration compared to oral route, the number of dosage required is less, induction delivery interval is less, less incidence of failed induction, less requirement of oxytocin augmentation and less maternal side effects of drug.

Neonatal outcome is comparable in both groups.

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