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Original Research Article

A comparison of buccal versus vaginal misoprostol for induction of labour at term to correlate maternal and foetal outcome

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ABSTRACT

Background: Induction of labour with prostaglandins offers the advantage of promoting cervical ripening with stimulation of myometrial contractility. The use of prostaglandin preparations with or without oxytocin infusion, widely recognized and accepted as a standard method of labour induction, has been shown to reduce induction time and the risk of failed induction.
Methods: The present study was a prospective observational study undertaken in the obstetrics and gynaecology department of Adesh Medical College and Hospital, Kurushetra, Haryana, India from 01 June 2023 to 30 November 2023. Total 100 patents were randomly allocated to either group A (n=50) who receive 25 µg misoprostol buccally four hourly upto maximum of four doses, group B (n=50) who receive 25 µg misoprostol vaginally four hourly upto maximum of four doses. Various parameters noted were time interval from induction to vaginally delivery, mode of delivery, maternal adverse effect, and neonatal outcome.
Results: The mean induction delivery interval in group I was 14.17 hours and 12.9 hours in group II. The mean number of doses in group I was 1.58±0.36 and 1.26±0.28 in group II. The mode of delivery in group I (buccal) patients was full-term vaginal delivery (FTVD) in 33 of patients, instrumental (forceps) 2 of patients and lower segment caesarean section (LSCS) in 15 of patients. While as in group II (vaginal) patients 35 of patients had FTVD, 1 had instrumental (forceps) and 14 had LSCS. The results of present study were indicated that participants who were treated with buccal misoprostol were suffering from gastrointestinal experiences and tachysystole which was the result of misoprostol dosage.
Conclusions: Misoprostol in either buccal or vaginal route has proven to be equally effective for inducing labour in women at term pregnancy. This study found that the women who are treated with buccal misoprostol are suffering from gastrointestinal experiences more than vaginal misoprostol. However, easy intake is observed if the drug is administered buccally outweighs its advantages over the vaginal misoprostol.

Keywords: Induced labor, Misoprostol, Pre-induction cervical ripening, Apgar score

INTRODUCTION

Induction of labour is needed when the pregnancy continuation is associated with higher risks than the benefits of delivery.[1] Labour induction near term is required in 10-20% of women.[2] The methods which are commonly available for the purpose of induction, are non-pharmacological and pharmacological use of drugs like oxytocin, and prostaglandins. The use of prostaglandin preparations with or without oxytocin infusion, widely recognized and accepted as a standard method of labour induction, has been shown to reduce induction time and the risk of failed induction.[3] Misoprostol can be administered by various routes that include oral, buccal, sublingual and vaginally.[4] In 1992, misoprostol was first reported for the termination of a pregnancy with a live fetus.[5]

The goal of successful induction of labour is to: achieve a vaginal delivery to avert an anticipated adverse outcome associated with continuation of pregnancy; bring about the

adequate uterine activity sufficient for cervical changes and foetal descent without causing uterine hyperstimulation or foetal compromise; the infant should be delivered in a good condition within an acceptable time frame and with minimum maternal discomfort or side-effects; and induction process should allow a natural birthing experience which is as safe as possible and maximize maternal satisfaction.[2] Induction of labour with prostaglandins offers the advantage of promoting cervical ripening with stimulation of myometrial contractility. Misoprostol (zytotec) a synthetic prostaglandin E1 (PGE1) analogue, has the advantage of being inexpensive, easy to store and stable at room temperature.

Aim and objectives

Aims and objectives of the study were to compare 25 mcg of buccal misoprostol versus 25 µg of intravaginal misoprostol for induction of labour at term to correlate maternal and foetal outcomes.

METHODS

The present study was undertaken in the obstetrics and gynaecology department of Adesh Medical College and Hospital, Kurushetra, Haryana, India from 01 June 2023 to 30 November 2023. The study was planned after obtaining clearance from the institutional ethics committee.

Selection of cases

The methods were explained to the pregnant women who underwent medical and obstetric indication of labour and only those who volunteered were finally selected for the study. Prior to interview, informed consents were taken from every respondent. Patients who met the selection criteria were explained about the advantages and disadvantages of the procedures. Among them, those who provided their informed consents were interviewed and recruited in the study.

Inclusion criteria

Patients with singleton pregnancy with live foetus, cephalic presentation, gestational age >37 weeks, and Bishop score <5 were included.

Exclusion criteria

Patients with previous uterine surgery, parity >3, antepartum haemorrhage, and any contraindication to normal vaginal delivery such as cephalopelvic disproportion, severe oligohydraminos, and intrauterine growth restriction (IUGR).

Methods of administration

The patients were randomly assigned to one of the two groups of route of administration.

Group I (buccal misoprostol) included 50 women. One tablet of 25 µg misoprostol was given orally 66 and dose was repeated every four hours for a maximum of four doses.

Group-II (vaginal misoprostol) included 50 women. One tablet of 25 µg misoprostol was placed in vagina. The dose was repeated every four hours for a maximum of four doses.

The doses were repeated till effective uterine contractions (more than 3 contractions in 10 minutes), cervical dilatations of 3 centimetres and Bishop's score of 8 were achieved. Patients were monitored for uterine contractions and foetal heart rate during this period.

Per vaginal examination was done at four hours and eight hours following drug administration or earlier, if the patient complained of draining per vagina or labour pains.

Oxytocin infusion was started in active phase of labour, in the absence of adequate uterine contractions, 6 hours after the last dose of drug was given.

Maternal pulse rate, blood pressure and foetal heart rate were monitored every 30 minutes from the time of induction.

Process of labour was assessed through partogram by noting the strength and duration of uterine contractions, descent of presenting part, dilatation and effacement of cervix.

The outcome measures are: time interval from induction to vaginally delivery, mode of delivery, maternal adverse effect, and neonatal outcome.

Statistical analysis

It was done in computer using statistical package for the social sciences (SPSS) 17 version. Descriptive statistics (mean, standard deviation), and other suitable statistical tests ('t' test, Chi-square test) is applied as per applicability. The statistical significance of the difference between two groups were based on p value. A p value of <0.05 was considered to be statistically significant.

RESULTS

Table 1 shows the gravida-wise distribution of pregnant women. The number of patients who were primigravida was 33 in group II and it was 32 in group I. The number of patients who were multipara was 17 in vaginal group II and it was 18 in buccal group I. Shows the statistically not significant association between parity and route of administration of drug p=0.47 (p value >0.05).

Table 2 shows that the mean age of patients was 25.48±8.77 years in group I and 26.03±8.99 years in the group II (p value=0.63). The mean period of gestation was

38.06±10.23 weeks in group I and 38.16±11.01 weeks in the group II (p value=0.72). The mean Bishop was 3.21±1.10 in group I and 3.66±1.46 in the group II (p value=0.32).

Table 1: Parity of subjects (n=50).

Parity	Group I (buccal)		Group II (vaginal)	
	N	%	N	%
Primi	32	64	33	66
Multi	18	36	17	34
Total	50	100	50	100

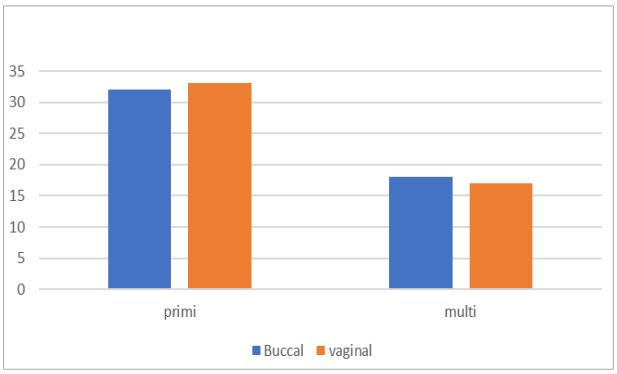

Figure 1: Parity of subjects.

Table 2: Demographic characteristics of subjects.

Parameters	Group I (buccal)	Group II (vaginal)	P value
Maternal age in years	25.48±8.77	26.03±8.99	0.63
Period of 6 gestation in weeks	38.06±10.23	38.16±11.01	0.72
Pre-induction Bishop scores	3.21±1.10	3.66±1.46	0.32

Table 3 shows that the mean induction delivery interval in group I was 14.17 hours and 12.9 hours in group II with p value is more than 0.05 which is statistically insignificant.

Table 3: Number of doses required for successful outcome, induction–delivery interval.

Parameters	Group I (n=50)	Group II (n=50)	P value
Mean no. of doses	1.58±0.36	1.26±0.28	>0.05
Induction to delivery interval	14.17±4.00	12.9±2.91	>0.05

Table 4 shows that the mode of delivery in group I (buccal) patients was FTVD in 33 of patients, instrumental l (forceps) 2 of patients and LSCS in 15 of patients. While as in group II (vaginal) patients 35 of patients had FTVD, 1 had instrumental (forceps) and 14 had LSCS (p value=0.201).

Table 4: Comparison based on mode of delivery (n=50).

Mode of delivery	Group I (buccal)		Group II (vaginal)		P value
	N	%	N	%	
Normal	33	66	35	70	0.201
Instrumental (forceps)	2	4	1	2	
LSCS	15	30	14	28	
Total	50	100	50	100	

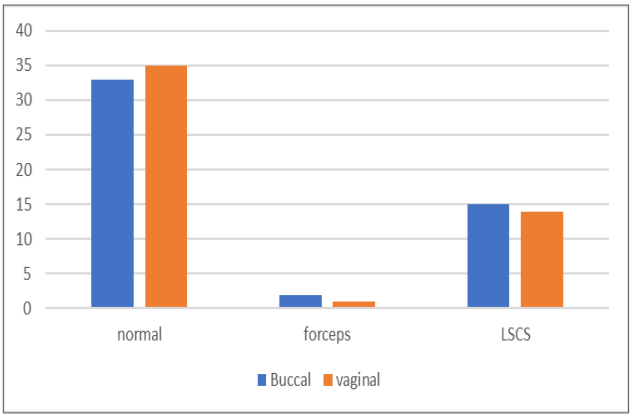

Figure 2: Comparison based on mode of delivery.

Table 5 shows that in group I patients 10 of mothers had nausea, 8 had vomiting, 3 had tacysystole, 2 had meconium-stained liquor (MSL) and 2 had postpartum haemorrhage (PPH), while as in group II patients 4 of mothers had nausea, 3 had vomiting, 1 had tacysystole, 1 had meconium-stained liquor (MSL) and 3 had postpartum haemorrhage (PPH), The p value was statistically insignificant.

Table 5: Maternal complication.

Complications	Group I (buccal)		Group II (vaginal)	
	N	%	N	%
Nausea	10	20	4	8
Vomiting	8	16	3	6
Tacysystole	3	6	1	2
MSL	2	2	1	2
PPH	2	4	3	6

Table 6 shows that in group I the mean Apgar score at 1 minute was 6.10±0.86 and in group II it was 7.01±1.17 with p value of 0.245. The mean APGAR score at 5 minutes in group I was 7.05±1.61 and in group II it was 7.41±0.77 with p value of 0.109 (statistically insignificant).

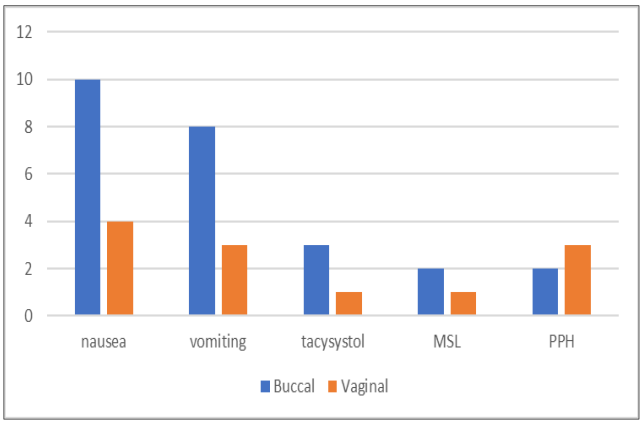

Figure 3: Maternal complications.

Table 6: Neonatal outcomes.

Variables	Group I MD±SD (n=50)	Group II MD±SD (n=50)	P value
APGAR at 1 min.	6.10±0.86	7.01±1.17	0.245
APGAR at 5 min.	7.05±1.61	7.41±0.77	0.109
NICU admission	5 (10%)	4 (4%)	0.091

DISCUSSION

Misoprostol is safe for the induction of labor and has gained popularity as an IOL agent in recent years since it was developed.[6] The present study was conducted in the obstetrics and gynaecology department of Adesh Medical College and Hospital, Kurukshetra, Haryana from 01 June 2023 to 30 November 2023.

The number of patients who were primigravida was 33 in group II and it was 32 in group I. The number of patients who were multipara was 17 in vaginal group II and it was 18 in buccal group I. Shows the statistically not significant association between parity and route of administration of drug p=0.47 (p value >0.05).

The mean induction delivery interval in group I was 14.17 hours and 12.9 hours in group II with p value more than 0.05 which is statistically insignificant. Vaginal group had a shorter induction to delivery interval of 12.9 hours as compared to 14.17 hours in buccal group. But there was no significant difference between the two. The results of the present study done on buccal versus vaginal misprostol were comparable with those of the following studies (Table 6). Results of Redling et al also shows that there was time to delivery was significantly shorter in the vaginal group with a higher rate of vaginal deliveries within the first 24 hours.[7]

The mean number of doses in group I was 1.58±0.36 and 1.26±0.28 in group II with p value more than 0.05 which is statistically insignificant.

The mode of delivery in group I (buccal) patients was FTVD in 33 of patients, instrumental (forceps) 2 of patients and LSCS in 15 of patients. While as in group II (vaginal) patients 35 of patients had FTVD, 1 had instrumental (forceps) and 14 had LSCS (p value=0.201) (statistically insignificant). Handal-Orefice et al investigated that the frequency of cesarean delivery was higher in the oral than the vaginal misoprostol group (32% versus 21%; p=0.04).[8]

In group I patients 10 of mothers had nausea, 8 had vomiting, 3 had tacysystole, 2 had meconium stained liquor (MSL) and 2 had postpartum haemorrhage (PPH), while as in group II patients 4 of mothers had nausea, 3 had vomiting, 1 had tacysystole, 1 had MSL and 3 had postpartum haemorrhage (PPH). The p value was statistically insignificant. The results of present study indicated that participants who were treated with buccal misoprostol were suffering from gastrointestinal experiences and tachysystole which was the result of misoprostol dosage. Carlan et al investigated that the effect of buccal and vaginal misoprostol on the induction of labor.[9] Their findings show that 63% of the vaginal group compares to 67% of the buccal group reached vaginal delivery in 24 hours. Tachysystole for the buccal group was 38% which was greater than 19% in the vaginal group. Zahran et al show 13.8% of meconium excretion results for the sublingual group and 16.3% for the vaginal group.[10]

In group I, the mean Apgar score at 1 minute was 6.10±0.86 and in group II it was 7.01±1.17 with p value of 0.245. The mean APGAR score at 5 minutes in group I was 7.05±1.61 and in group II it was 7.41±0.77 with p value of 0.109 (statistically insignificant). In group I, 5 out of 50 babies had neonatal intensive care unit (NICU) admission while as in group II, 4 out of 50 babies had NICU admission. The p value was 0.091 (statistically insignificant). Kreft et al neonatal outcomes were similar except for significantly more frequent infant referral to neonatal intensive care in the >1P group receiving the 50 µg regimen (11% versus 4%).[11]

Table 6: Comparison between the studies.

Study	Present study	Akbari et al[12] (2024)	Dadashaliha et al[13] (2021)	Redling et al[7] (2019)	Komala et al[2] (2013)
Mean induction delivery interval	Group I (buccal) was 12.9 hours and 14.17 hours in group II (vaginal)	Time of reaching delivery in less than 24 hours was 89% for the buccal group, and 83% for the vaginal group.	Time to delivery hours in sublingual group was 8.4±0.92 hours and 9.2±1.5 in vaginal group.	Time to delivery hours in oral group was 37.68 hours and 15.91 hours in vaginal group.	Induction delivery interval in oral group was 12.9 hours and 14.04 hours in vaginal group.

Continued.

Study	Present study	Akbari et al[12] (2024)	Dadashaliha et al[13] (2021)	Redling et al[7] (2019)	Komala et al[2] (2013)
Mean number of doses	Group I was 1.58±0.36 and 1.26±0.28 in group II.	Buccal group was 1.14±0.425 and 1.14±0.355 in vaginal group.	Single dose of misoprostol n (%) 63% women were needed in sublingual and 28% in vaginal group.	-	

CONCLUSION

Misoprostol in either buccal or vaginal route has proven to be equally effective for inducing labour in women at term pregnancy. This study found that the women who are treated with buccal misoprostol are suffering from gastrointestinal experiences more than vaginal misoprostol. However, easy intake is observed if the drug is administered buccally outweighs its advantages over the vaginal misoprostol.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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