

Subject Area:

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Stripping of membranes versus vaginal misoprostol in induction of labor

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Abstract

Background

The objective of this study was to evaluate the safety and efficacy of membrane stripping and vaginal misoprostol in the induction of labor in low-risk patients at term pregnancy (38–40 gestational weeks).

Aim

This study was done to compare the efficacy and safety of the two techniques for cervical ripening/labor induction by stripping of membranes and low-dose vaginal misoprostol on the outcome of labor induction in singleton pregnancies between 38 and 40 weeks.

Patients and methods

This prospective study was conducted for 9 months. The study included 100 women divided randomly into two groups: group I ($n = 50$) in which stripping of membranes was performed and group II ($n = 50$) which received intravaginal misoprostol. In group I, stripping of membranes was performed to be repeated after 48 h then followed up within 72 h of the first visit. In group II, patients received 25 μg vaginal misoprostol tablets every 6 h with a maximum of four doses after admission for follow-up of fetal well-being and observations of the route of delivery and indication of cesarean section. Time interval from the start of induction to the delivery time and need for oxytocin augmentation and labor complications were observed. Outcome data as fetal weight, Apgar scores at 1 and 5 min, and need for admission to neonatal ICU were recorded.

Results

Stripping of membranes is as effective as vaginal misoprostol, but the induction-delivery interval was significantly lower in misoprostol. There were no statistically significant differences between the two groups in the results of neonatal outcome.

Conclusion

Both methods were effective and safe in the induction of labor; however, misoprostol needs hospital admission, with no increases in the risk of neonatal outcome and minimal adverse effects.

Keywords: Induction-delivery interval, prolonged gestation, stripping of membranes, vaginal misoprostol

INTRODUCTION

Induction of labor is one of the most common procedures in obstetrics, and it is carried out in ~20% of pregnancies [1,2]. The method of induction must achieve quick onset of labor, lower incidence of failure, not increase in perinatal morbidity, and also prevent an increase in section (CS) or instrumental delivery rate [3].

Both mechanical and biochemical means are used for cervical ripening and induction of labor [4]. Mechanical methods include membrane stripping or sweeping and amniotomy,

whereas biochemical means include prostaglandin, oxytocin, and laminaria [2]. The success of induction depends mostly on the consistency, configuration of the cervix, and compliance of the patient [5].

Gestational hypertension, preeclampsia, eclampsia, gestational diabetes, post-term pregnancy, and fetal growth retardation are medical conditions, which need induction of labor [6].

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Stripping or sweeping of membranes is defined as the digital separation of the chorioamniotic membranes from the lower uterine segment. It leads to an increase in prostaglandin metabolites in maternal circulation and local prostaglandin production [7,8].

The reported adverse effects of membranes stripping are mild bleeding, increase maternal discomfort, and irregular uterine contractions [9].

Misoprostol, a PGE1 analog, is used as a medical agent for cervical ripening. It can be used either intravaginally or orally and has an excellent half-life (30–60 min) [10]. The vaginal route reaches a peak after 1–2 h and declines slowly [11].

Aim

The aim of the study is to explore the comparative efficacy and safety of the two techniques for cervical ripening/labor induction, that is, stripping of the membrane (mechanical method) and low-dose vaginal misoprostol (pharmaceutical method) on the outcome.

PATIENTS AND METHODS

This prospective study was conducted at El-Mataria Teaching hospital for 9 months between January 2018 and September 2018.

Before initiation of the study, approval was obtained from a convened institutional review board at El-Mataria Teaching Hospital. Informed consent was taken from each patient. The patients residing very near to the hospital only were selected to avoid further complications.

All recruited patients had an early ultrasound for dating of their pregnancy, which was correlated with the expected date of delivery according to the first day of last menstrual period, which was calculated by Naegele's rule to exclude wrong dates.

Inclusion criteria

The following were the inclusion criteria:

- (1) Primigravida, second, and third gravid women
- (2) Bishop's score less than or equal to 6
- (3) Intact fetal membranes
- (4) Single live fetus
- (5) Term 38–40 weeks
- (6) Vertex presentation
- (7) Estimated fetal weight of less than or equal to 3500 g.

Exclusion criteria

The following were the exclusion criteria:

- (1) Grand multipara
- (2) Bishop's score more than 6
- (3) Premature rupture of the membranes
- (4) Dead fetus
- (5) Multiple pregnancies
- (6) Post-term pregnancies of more than 40 weeks of gestation
- (7) Fetal malpresentation
- (8) Estimated fetal weight more than 3500 g
- (9) Antepartum hemorrhage

- (10) Previous CS or a uterine scar
- (11) Nonreactive nonstress test, or any suspicious sign of fetal distress
- (12) Any contraindications for vaginal delivery such as cephalopelvic disproportion and placenta previa.

The study included 100 women divided randomly into two groups: group I ($n = 50$) in which stripping of membranes was performed and group II ($n = 50$) which received intravaginal misoprostol.

In group I, stripping of membranes was performed by separation of the lower membranes as much as possible from its cervical attachment in outpatient department to be repeated after 48 h if labor did not start then follow-up within 72 h of the first visit. Patients with unyielding cervixes preventing access into the cervical canal were excluded from this group.

In group II, women were admitted and received 25 µg vaginal misoprostol tablet every 6 h with a maximum of four doses as recommended by FIGO 2017 after admission for follow-up of fetal well-being.

All patients in both groups who did not go into spontaneous labor within 3 days were categorized as 'failed labor induction,' and they become reassessed by nonstress test, reassured and managed according to our departmental protocol of cervical ripening and labor induction to ensure delivery before 42 weeks of gestation.

To eliminate bias, attending obstetricians in the labor ward were blinded to the labor-inducing agents used in the study groups.

Observations were noted as follows:

- (1) Age, parity, gestational age, indication for labor induction, estimated fetal weight, and Bishop score
- (2) Number of stripping and total doses of misoprostol
- (3) Route of delivery and indication of CS
- (4) Time interval from the start of induction to delivery time
- (5) Need for oxytocin augmentation
- (6) Labor complications
- (7) Fetal weight, Apgar scores at 1 and 5 min, and need for neonatal ICU (NICU) admission.

Statistical analysis

Statistical analysis was done using the statistical package for the social sciences (SPSS software version 25; SPSS Inc., Chicago, Illinois, USA). The methods used for statistical analysis were as follows:

Descriptive statistics

Mean, SD, and range were used for parametric numerical data, whereas the median was used for nonparametric numerical data. SD is the ideal measure of variability and is usually expressed as plus and minus values to follow the arithmetic mean of the sample.

Analytical statistics

- (1) Student's *t*-test was used to assess the statistical significance of the difference between the two study group means (values of quantitative data)

- (2) Mann–Whitney test (*U*-test) was used to assess the statistical significance of the difference of a nonparametric variable between the two study groups
- (3) χ^2 -test was used to examine the relationship between two qualitative variables
- (4) Level of significance was set as follows:
 - (a) *P* value more than 0.05: nonsignificant
 - (b) *P* less than 0.05: significant
 - (c) *P* less than 0.001: highly significant.

RESULTS

Tables 1 and 2 revealed a nonstatistically significant difference in mean age, gestational age, Bishop score, and percentage of parity in group I when compared with group II (*P* > 0.05).

Table 3 revealed that group I has a nonstatistically significant difference in indications of induction of labor in comparison with group II (*P* > 0.05).

Table 4 revealed that the number of stripping of membranes was not significantly different in cases delivered vaginally when compared with cases delivered by CS.

Table 5 revealed that dose of vaginal misoprostol was not significantly different in cases delivered vaginally when compared with cases delivered by CS.

Table 6 and Fig. 1 revealed that group I has no statistically significant difference in need of oxytocin and mode of delivery of labor compared with group II (*P* > 0.05).

Table 7 revealed that group II has high significantly shorter induction-delivery interval in comparison with group I (*P* < 0.001).

Table 8 and Fig. 2 revealed that there is no statistically significant difference in indication of CS in group I when compared with group II.

Tables 9 and 10 revealed that outcomes (fetal weight, Apgar score at 1 and 5 min, and admission to NICU) of group I were nonstatistically significantly different when compared with group II (*P* > 0.05)

Adverse effects of group I included 6 (12%) cases of premature rupture of membranes and one case of antepartum hemorrhage, whereas adverse effects of group II included four (8%) cases of hypertonicity of the uterus, three (6%)

Table 1: Demographic data of study groups (I and II) regarding age, gestational age, and Bishop score

	Groups		Chi-square	P	Significance
	I	II			
Age					
Range	19-32	19-33	1.109	0.270	NS
Mean±SD	24.82±3.37	24.09±3.99			
Gestational age					
Range	38-40	38-40	0.876	0.383	NS
Mean±SD	39.52±0.67	39.64±0.69			
Bishop score					
Range	1-6	1-6	1004.500	0.085	NS
Median (interquartile range)	3.00 (2.00-4.00)	4.00 (2.75-5.00)			

Table 2: Comparison between groups I and II regarding parity

	Groups		χ^2	P	Significance
	I	II			
Parity					
Primigravida	21 (42.0)	30 (60.0)	3.241	0.072	NS
Multipara	29 (58.0)	20 (40.0)			

Table 3: Comparison between groups I and II regarding indications of induction of labor

	Groups [n (%)]		χ^2	P	Significance
	I	II			
Indications of induction					
GDM	19 (38.0)	14 (28.0)	7.67	0.104	NS
PIH	5 (10.0)	13 (26.0)			
Mild PET	8 (16.0)	6 (12.0)			
Social	18 (36.0)	17 (34.0)			

GDM, gestational diabetes mellitus; PET, preeclampsia toxemia; PIH, pregnancy-induced hypertension.

Table 4: Number of stripping of membranes in relation to mode of delivery

	Stripping of membranes [n (%)]		χ^2	P	Significance
	1	2			
Mode of delivery			0.709	0.400	NS
Vaginal delivery	20 (87.0)	21 (77.8)			
Cesarean section	3 (13.0)	6 (22.2)			

Table 5: Dose of misoprostol (μg) in relation to mode of delivery

	The dose of misoprostol [n (%)] (μg)				χ^2	P	Significance
	25	50	75	100			
Mode of delivery					1.402	0.705	NS
Vaginal delivery	3 (50)	14 (70)	5 (62.2)	12 (75)			
Cesarean section	3 (50)	6 (30)	3 (37.5)	4 (25)			

Table 6: Comparison between groups I and II regarding the need for oxytocin and mode of delivery

	Groups [n (%)]		χ^2	P	Significance
	I	II			
Need for oxytocin					
No	21 (42.0)	26 (52.0)	1.004	0.316	NS
Yes	29 (58.0)	24 (48.0)			
Mode of delivery					
Vaginal delivery	41 (82.0)	34 (68.0)	2.613	0.106	NS
Cesarean section	9 (18.0)	16 (32.0)			

Table 7: Comparison between groups I and II regarding induction-delivery interval (h)

	Groups		Chi-square	P	Significance
	I	II			
Induction delivery (h)					
Range	8-72	3-34	230.00	<0.001	HS
Median (interquartile range)	52.00 (35.25-66.25)	17.00 (10.00-23.00)			

Table 8: Comparison between groups I and II regarding the indication of cesarean section

	Groups		χ^2	P	Significance
	I	II			
Indications of cesarean section					
Failed induction	2 (22.2)	3 (18.8)	0.080	0.961	NS
Failed progress	3 (33.3)	5 (31.3)			
Fetal distress	4 (44.4)	8 (50.0)			

cases of vomiting, two (4%) cases of diarrhea, and one case complaining of fever.

DISCUSSION

We performed a randomized controlled trial to evaluate methods of induction of labor, by either membranes stripping or intravaginal misoprostol (25–100 μg) in pregnant women between 38 and 40 weeks of gestation who were routinely monitored.

There was only one study done to compare membranes stripping and misoprostol on the induction of labor. Adeniji and Akinola [12] compared membrane stripping and oral misoprostol (50 μg) in outpatient women.

Our study classified the women randomly after an interview about each method and precautions. Women preferred stripping as they could go home after it, whereas cases that received misoprostol were admitted to hospital according to FIGO

Table 9: Comparison between groups I and II regarding fetal weight (g) and Apgar score at 1 and 5 min

	Groups		Chi-square	P-value	Significance
	I	II			
Fetal weight (g)					
Range	2800-3500	2900-3500	0.0854	0.932	NS
Mean±SD	3167.0±182.27	3164.0±168.74			
Apgar score 1					
Range	3-8	3-9	1008.000	0.085	NS
Median (interquartile range)	7.00 (6.00-8.00)	8.00 (7.00-9.00)			
Apgar score 5					
Range	6-9	7-9	1234.50	0.895	NS
Median (interquartile range)	9.00 (8.00-9.00)	9.00 (8.00-9.00)			

Table 10: Comparison between groups I and II regarding neonatal ICU

	Groups [n (%)]		χ ²	P	Significance
	I	II			
Neonatal ICU					
No	45 (90.0)	46 (92.0)	0.122	0.727	NS
Yes	5 (10.0)	4 (8.0)			

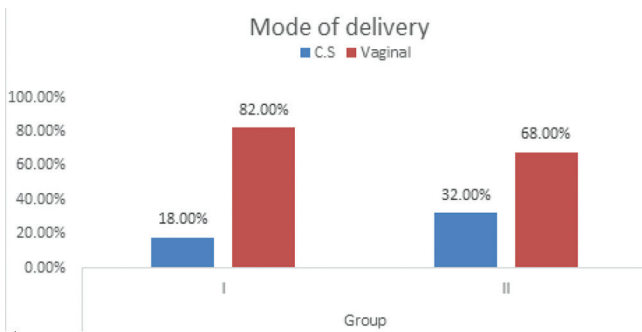


Figure 1: Comparison between groups I and II regarding the mode of delivery. CS, cesarean section.

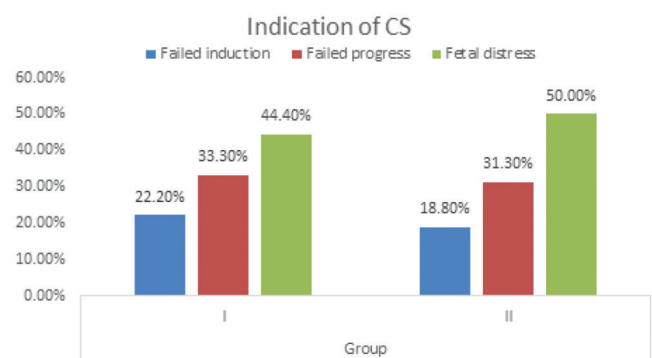


Figure 2: Comparison between groups I and II regarding the indication of cesarean section (CS).

2017, which recommends admission in cases of induction of labor via misoprostol.

This is in contrast to Adeniji and Akinola [12] who found that more women who received oral misoprostol felt positive about the intervention in comparison with women in the membrane stripping group.

Our study showed that there was an increase in cases delivered vaginally in group I (82%) versus group II (68%), but this difference was nonsignificant. In contrast, cases delivered by CS were more in group II (32%) compared with group I (18%).

Cases that received oxytocin for augmentation in group I were more than those in group II, but the difference was nonsignificant. Induction-delivery interval was shorter in group II (17 h) compared with group I (52 h), and this difference was statistically highly significant.

This agrees with Adeniji and Akinola [12] who demonstrated that patients who received 50 µg oral misoprostol had a shorter

latent period, less oxytocin use for augmentation, and shorter duration of labor.

In this study, failed induction and failed progress were more in group I in comparison with group II, whereas fetal distress was more in group II, but this difference was nonsignificant.

Our study demonstrated a nonsignificant difference in neonatal outcome results and admission to the NICU in both groups I and II.

This also agrees with Adeniji and Akinola [12] who found similar results for neonatal outcomes and need for admission to NICU.

Our study documented that both methods had minimal adverse effects.

Other studies done on misoprostol compared vaginal with oral route.

Hissane *et al.* [13] suggested that sublingual administration of misoprostol 50 µg was neither more effective nor safer than the same dose administered vaginally.

In contrast, Jadai Swamy and Hangaraga [3] concluded that both sublingual and vaginal routes of administration of misoprostol were effective, but the sublingual route had a short induction-delivery period. Less number of doses were needed in than sublingual versus pervaginal group, and less minor and no major adverse effects were reported in both groups [3].

Levine *et al.* [14] compared four induction methods: misoprostol alone, Foley's catheter alone, misoprostol–cervical Foley's catheter concurrently, and Foley's catheter–oxytocin concurrently. They found that combination methods achieved a faster median time (twice the chance) to delivery than either single agent alone.

CONCLUSION

Both stripping membranes and vaginal misoprostol were effective and safe in the induction of labor. However, misoprostol needs hospital admission. Both methods were not associated with increased risk of neonatal outcome. Method of induction must vary individually according to woman's request and the possibility for admission.

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Conflicts of interest

There are no conflicts of interest.

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