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A COMPARATIVE STUDY OF INDUCTION TIME TO DELIVERY INTERVAL OF ORAL VERSUS VAGINAL 25µg MISOPROSTOL FOR CERVICAL RIPENING AND INDUCTION OF LABOUR IN PRELABOUR RUPTURE OF MEMBRANES

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ABSTRACT
The objective of the study is to compare the induction time to delivery interval of Oral versus Vaginal 25µg Misoprostol for Cervical Ripening and Induction of Labour in Prelabour Rupture of Membranes. Equivalent doses of orally and vaginally administrated misoprostol in induction of labour in Primigravida at 37-42 weeks of gestation with vertex presentation with prelabour rupture of membranes. 100 patients divided in oral, 50 cases (mean gestational age group 37 weeks 2 days) and vaginal group, 50 cases (mean gestational age group 38 weeks 3 days) received Tab. 25 µg of misoprostol every 4 hourly either orally or digitally administered in the posterior fomix in the vaginal group. Maximum up-to 6 doses in both groups. Primary outcome of the study was induction delivery interval in oral group 22.90 hours and in vaginal group 17.38 hours. The mean BISHOP score for oral and vaginal group was 4.6 and 5.7 respectively after 8 hours of administration of misoprostol. Vaginal group requires less oxytocin augmentation for delivery. APGAR score at I minute in oral group was 7.56 and for vagina group was
7.48. NICU admissions are statistically not significant. The mean induction delivery interval was significantly shorter in vaginal group, the cause of which could be longer duration action, no first pass metabolism and direct action of vaginal misoprostol on uterus on cervix. In oral group failed induction was observed in 6% cases, whereas in vaginal group, no induction failure was observed. Vaginal misoprostol is more effective than oral misoprostol for induction oflabour.
Keywords: Primigravida, misoprostol, oxytocin

I. INTRODUCTION

Induced labour is one in which pregnancy is terminated artificially, any time after fetal viability is attained, by a method that aims to secure vaginal delivery.[57] The state of the cervix is almost always related to the success of labour induction, duration and likelihood of vaginal delivery. [1]

The primary condition that must be fulfilled to interfere with the this natural process is when the benefits of terminating pregnancy for the mother and her unborn fetus or both clearly outweighs the potential harms.

The ideal inducing method should be safe for the mother and the fetus, inexpensive, easy, simple to use and reversible. The induction of labour has two components cervical ripening and stimulation of uterine contraction.

To achieve dilatation of cervix and delivery of the fetus, it is well recognized that the success of induction of labour which ultimately aims at achieving the vaginal delivery depends to a great extent on the favourability of cervix or its rediness to go into labour. [2, 3]

Misoprostol is a synthetic prostaglandin E1 analogue used originally for the prevention and treatment of peptic ulcer caused by the prolonged use of NSAIDs. Its use as a cervical ripener and labor inducer is upcoming and being tried enthusiastically by obstetricians worldwide. With time it has crossed the legal hurdles in Western as well as developing countries including India. It has advantage of being cheap, stable at room temperature and easy to be administered by various routes i.e. vaginal, oral, sublingual or rectal. Absorption by oral route is erratic, at the same time it is more rapid than vaginally administered misoprostol reaching peak serum concentration within 30 minutes compared to one hour with vaginal route. Oral misoprostol elimination rapidly (2-3 h) than vaginal ($\geq$ 4h)[3]

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To be successful, induction of labour must fulfill three criteria. First it should result in labour namely adequate uterine contractions and progressive dilatation of cervix. Second this labour should result in vaginal delivery, as there is little purpose in bringing about labour as a mere preparation for caesarean section. Third, in variable pregnancies, these aims must be achieved with a minimum discomfort and risk to both mother and fetus[2].

The success of induction of labour primarily depends on the status of cervix at the time of induction. A prepared/ripe cervix has far better chance of successful induction of labour than an unripe cervix. [2, 3, 4]

A successful induction of labour leads to vaginal delivery of the infant in a good condition, in an acceptable time frame and with minimum maternal discomfort or side effects [5,6.]

There are various methods of induction of labour falling in two broad categories: non - pharmacological and pharmacological. The aim of the obstetrician should be to select the ideal method of induction which is safe, reliable, cheap, easily applicable, readily available, and which results in good maternal and foetal outcome.(7)

Investigations have predominantly focused on the dosing and timing of administration with intra vaginal application. There are . few clinical studies on the use of orally administered misoprostol for induction of labour. In view of the above, this comparative study is undertaken to evaluate the safety and efficacy of oral and vaginal routes of administration of misoprostol for induction of labour.

Prostaglandins as pharmacological agents have always fascinated the obstetrician for induction of labour as well as cervical ripening agent. Recently, Prostaglandin E1 (Misoprostol) tablets as an inducing agent of labour by various routes e.g. vaginal, oral etc have received huge attention. As it is cheap, easily available, has long half life and easily administrable, it is fast gaining popularity.

The objective of the present study A Comparative Study of Induction time to delivery interval of Oral versus Vaginal 25µg Misoprostol for Cervical Ripening and Induction of Labour in Prelabour Rupture of Membranes

INCLUSION CRITERIA:
Primi gravida at 37-42 weeks of gestation with Vertex Presenation with Prelabor Rupture of Membranes.

EXCLUSION CRITERIA:
1. Multigravida
2. Multiple pregnancy
3. Pregnancy with medical disorder like heart disease, DM etc.
4. Pregnancy with other conditions like placenta praevia, abruptio placentae, IUGR, Polyhydramnios, Oligohydramnios, CPD etc.
5. Case with Contraindications of prostaglandins.
6. Pregnancies with malpresentation and malposition.

The cases were divided into two groups of 50 each to receive misoprostol 25µg 4 hourly either by intravaginal or oral route.

In all patients, the cervical status was assessed by using modified Bishop Score to induction.

ORIGINAL BISHOP SCORE

	0	1	2	3
Dilatation	0	1-2	3-4	>4
Length of Cervix (in cm)	>4 cm	3-4 cm	1-2 cm	<1 cm
Station in cm	-3	-2	-1,0	+1, +2
Consistency	Firm	Average	Soft	-
Position	Posterior	Mid	Anterior	-

Repeat Bishop Scores were assessed prior to each dose. Dosage was repeated every 4 hourly until an adequate contraction pattern set in (establishment of 3 uterine contractions in a period of 10 minutes) or once the cervical dilatation reaches 4cms, maximum up-to 6 doses. After

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induction, the patients were monitored for signs of labour, when labour ensured, they were closely monitored for maternal vital signs, progress of labour and fetal heart rate, which was monitored by intermittent auscultation in majority of cases.

Maximum allowable doses were 6 i.e., 25µg 4 hourly by oral or vaginal route. If labour did not ensure even after 4 hours following last dose, it was considered as failed induction and other methods of induction like oxytocin, dinoprostone gel was tried.

Following parameters were recorded number of doses, and the interval between induction to onset of uterine contraction, induction - delivery interval, mode of delivery, maternal and neonatal complications and adverse effects of the drug like fever, diarrhea, nausea and others.

Tachysystole was defined as more than 5 uterine contractions per 10 minutes without fetal heart changes for 2 consecutive 10 minute periods.

Hyperstimulation was defined as exaggerated uterine response (tachysystole or prolonged uterine contraction of >90 seconds) accompanied by FHR deceleration or tachycardia.

Indication for Induction:

Primigravida at 37-42 weeks of gestation with vertex presentation with prelabour rupture of membranes.

Incidence:

The incidence of prelabour rupture of membranes in primi at term is 9.6%.

Table-1: showing incidence of PROM cases

	Number	**Percentage**
Total no. of deliveries	**15918**	**9.6%**
Total no of PROM cases	**1528**	

Demographic profile:

In our study, 44% cases were booked and 56% were unbooked, there is no statistically significance difference observed between booking and unbooking status. Maximum number of cases (69%) seen in the age group of 21-30 years and 62% cases seen from the rural area and 38% from urban area.

Table-2: showing Demographic profile of women

Parameter		**NUMBER**			**Percentage**
Age in years	20 or below	30	Oral	16	30%
			Vaginal	14	
	21-30	59	Oral	32	59%
			Vaginal	28	
	31-40	11	Oral	5	11%
			Vaginal	6	
Residence (Social status)	Rural	62	Oral	32	62%
			Vaginal	30	
	Urban	38	Oral	15	38%
			Vaginal	23	
Booking status	Booked	81	Oral	40	81%
			Vaginal	41	
	Unbooked	19	Oral	10	19%
			Vaginal	9	

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Gestational age:

In vaginal group, maximum gestational week for induction of labour was 40 weeks, 4 days, Minimum gestational week for induction of labour was 38 weeks, 2 days and mean gestational week for induction of labour was 38 weeks, 3 days.

In oral group, maximum gestational week for induction of labour was 40 weeks, 6 days. Minimum gestational week for induction of labour was 37 weeks, 2 days and mean gestational week for induction of labour was 38 weeks, 2 days

Tabl-3: showing gestational age

	No. of Patients	Mean Gestational Week	Min	Max	'F' Value	'p' value
Oral	50	38 w 3 days	37 w 2 days	40 w 6 days	0.992	<0.0001
Vaginal	50	38 w 2 days	38w 2 days	40 w 4 days		

Number of dose of drug required for delivery:

In the present study, minimum number of dose required was 1 in 4% of cases. Maximum number of dose required was 5 in 10% of cases and 48% required 3 doses in oral group.

Minimum number of dose required was 1 in 28% of cases. Maximum number of dose required was 4 in 6% of cases and 48% required 2 doses in vaginal group.

Table 4: Showing number of doses of drug required for delivery

Dose	Number of Dose					Total
	1	2	3	4	5	
Oral	2	10	24	9	5	50
	4.0%	20.0%	48.0%	18.0%	10.0%	100.0%
Vaginal	14	24	9	3	0	50
	28.0%	48.0%	18.0%	6.0%	0	100.0%

Chi-square value	df	'p' value
	29.5834	<0.001

Bishop Score:

Bishop score, which is one of the important determinants for induction of labour was measured: First at the time of dose administration, next after 8 hours and then before every repeat dose.

For Vaginal group, the mean pre-induction score was 3.14 and mean bishop score was 5.70 after 8 hours. Minimum pre-induction Bishop Score was 1 and maximum was 7 are observed.

In oral group, the mean pre-induction score was 2.82. Mean bishop score was 4.60 after 8 hours. Minimum pre-induction Bishop score was 1 and maximum was 5 are seen.

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Table 5: Response to Drug in terms of Bishop Score

		N	Mean	SD	Min.	Max.	't' value	'p' value
Pre Induction Bishop	Oral	50	4.3	0.966	1	5	1.368	0.245
	Vaginal	50	3.3	1.326	1	5		
8 Hours Bishop Score	Oral	50	4.6	1.0	2	6	10.276	0.002
	Vaginal	50	5.7	1.744	3	7		

Augmentation with Oxytocin

In our present study, 30 cases (60%) required augmentation in oral group.

For Vaginal Group, 16 cases (32%) required augmentation with Oxytocin and Rest 34 cases (68%) did not require any augmentation in vaginal group.

Table 6: Showing requirement of augmentation with oxytocin

Dose	Augmentation with Oxytocin		Total
	Yes	No	
Oral	30	20	50
	60.0%	40.0%	100.0%
Vaginal	16	34	50
	32.0%	68.0%	100.0%

Chi-sq value	df	'p'
7.890	1	0.005

Induction to Delivery Interval

In oral group, mean induction to vaginal delivery interval was 22.90 hours. Minimum induction to vaginal delivery interval was 10 hours and maximum induction to vaginal delivery interval was 28 hours when observed.

In vaginal group, mean induction to vaginal delivery interval was 17.38 hours, minimum induction to vaginal delivery interval was 8 hours and maximum induction to vaginal delivery interval was 26 hours.

Table 7: Showing induction to delivery interval

N		Mean Induction to delivery Interval (Hrs.)	SD	Min.	Max.	't' value	'p' value
Oral	50	22.90	4.062	10	28	42.603	<0.001
Vaginal	50	17.38	4.389	8	26		

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Failed Induction

The incidence of failed induction was 6% (3cases), reported in oral group only in the present study.

Table 8: Showing failed induction

Dose	Failed Induction		Total
	Yes	No	
Oral	3	47	50
	6.0%	94.0%	100.0%
Vaginal	0	50	50
	.0%	100.0%	100.0%
	3	97	100
Chi-Square Value	3.0% 97.0%	100.0%	
		Df	'p' value
		1	.079

Mode of delivery

For oral group, 68% (34 cases) proceeded for normal delivery. 12% (6 cases) required LSCS intervention and 4% (2 cases) required forceps application for delivery and 16% (8 cases) required vacuum application for delivery.

For vaginal group, 76% (38 cases) proceeded for normal delivery. 8% (cases) required LSCS intervention and 2% (1 case) required forceps application for delivery, 14% (7 cases) required vacuum application for delivery.

Table 9: Mode of Delivery after Induction

Dose	Mode of Delivery				Total
	Normal	Caesarean Section	Forceps	Vacuum	
Oral	34	6	2	8	50
	68.0%	12.0%	4.0%	16.0%	100.0%
Vaginal	38	4	1	7	50
	76.0%	8.0%	2.0%	14.0%	100.0%

Chi-Square Value	DF	'p' value
1.022	3	0.796

Liquor Characteristic

For Oral group, 80% (40 cases) exhibited clear liquor, 12% (6 cases) exhibited thin MSAF and 8% (4 cases) exhibited thick MSAF.

For Vaginal group, 76% (38 cases) exhibited clear liquor, 16% (8 cases) exhibited thin MSAF and 8% (4 cases) exhibited thick MSAF

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Table 10: Showing characteristic of liquor

Dose	Liquor			Total
	Clear	Thin MSAF	Thick MSAF	
Oral	40	6	4	50
	80.0%	12.0%	8.0%	100.0%
Vaginal	38	8	4	50
	76.0%	16.0%	8.0%	100.0%

Chi-Square Value	Df	'p' value
0.337	2	0.845

Maternal Complication

In our study, 90% (45 cases) encountered no maternal complication, 6% (3 cases) mothers developed diarrhea, 2% (1 case) mothers developed fever, No case of tachysystole and 2% (1 case) of mothers experienced uterine hyperstimulation in oral group.

For Vaginal group, 88% (44 cases) encountered no maternal complication, there is no case of diarrhea, 4% (2 cases) mothers developed fever, 4% (2 cases) mothers experienced tachysystole and 4% (2 cases) of mothers experienced uterine hyperstimulation

Table 11: Showing maternal complication

			Maternal Complication			
Route	Diarrhea	Fever	Tachy Systole	Uterine Hyperstimulation	No Complication	Total
Oral	3 6.0%	1 2.0%	0 .0%	1 2.0%	45 90.0%	50 100.0%
Vaginal	0 .0%	2 4.0%	2 4.0%	2 4.0%	44 88.0%	50 100.0%

Chi-Square Value	Df	'p' value
5.678	4	0.255

APGAR score:

APGAR score of the neonate was recorded at 1 minute and 5 minutes after birth for Oral Group, in our study minimum 1 minute APGAR score was 4/10 which proceeded to be 6/10 after 5 minutes, maximum 1 minute APGAR score was 8/10 which proceeded to be 9/10 after 5 minutes, mean 1 minute score was 7.56, mean 5 minutes score was 8.70 8 neonates (16% cases) had APGAR score < 6 at 1 minute and 1 neonate (2% cases) had APGAR score 6 at 5 minutes seen in oral group.

In vaginal group, minimum 1 minute APGAR score was 5/10 which proceeded to be 7/10 after 5 minutes, maximum 1 minute APGAR score was 8/10 which proceeded to be 9/10 after 5

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minutes, mean 1 minute score was 7.48, mean 5 minutes score was 8.74, 10 neonates (20% cases) had APGAR score < 6 at 1 minute and none of the neonates had APGAR < 6 at 5 minutes

Table 12: Showing APGAR score at 1 and 5 minutes

		N	Mean	SD	Minimum	Maximum	'F' value	'p' value
APGAR at 1 min	Oral	50	7.56	1.013	4	8	0.159	0.691
	Vaginal	50	7.48	.995	5	8		
APGAR at 5 min	Oral	50	8.70	.735	6	9	0.081	0.776
	Vaginal	50	8.74	.664	7	9		

Neonatal Complications

There are 8% (4 cases) of neonates required NICU admission due to neonatal complication. Out of the 4 NICU admissions 3 were admitted for Respiratory Distress. Syndrome (RDS) and 1 case for thick meconium stained liquor in oral group.

For vaginal group, 10% (5 cases) of neonates required NICU admission due to neonatal complication. Out of the 5 NICU admissions- 2 were admitted for Respiratory Distress, 1 case for Low Birth Weight, 1 case for thick meconium and 1 case was kept for observation (TSB Monitoring).

Table 13: Showing neonatal complications

Dose	**Neonatal Complication**		**Total**
	NICU Admission	No Complication	
Oral	4	46	50
	8.0%	92.0%	100.0%
Vaginal	5	45	50
	10.0%	90.0%	100.0%

Chi-Square Value	**Df**	**'p' value**
0.122 1	4	0.727

NICU Admission:

In the present study, 4 nos. of cases (8%) developed neonatal complications. Of these, 3 required NICU admission for respiratory distress and 1 for meconium stained condition in oral group.

In vaginal, 5 nos. of cases (10%) neonate admitted in NICU. Of these 2 nos. of cases (4%) cases were admitted due to respiratory distress, 1 because of low birth weight, 1 had meconium aspiration syndrome and 1 was kept for observation.

Table 14: Showing indication for NICU admission

	Complication Reason (Neonatal)				
	Respiratory distress	LBW	Observation	Meconium	Total
Oral	3	0	0	1	4
	75.0%	.0%	.0%	25.0%	100.0%

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Vaginal	2	1	1	1	5
	40.0%	20.0%	20.0%	20%	100.0%
Total	5	1	1	2	9
	55.6%	11.1%	11.1%	22.2%	100.0%

Indications for Emergency LSCS

In our study, 12% (6 cases) required emergency LSCS, Of the 6 cases, 1 case was taken for LSCS due to Deep Transverse Arrest (DTA), 3 cases were taken for LSCS due to Failed Induction, 1 case was taken for LSCS due to Direct Occipito Posterior Position and 1 case was taken for LSCS due to Thick Meconium Stained Liquor in oral group.

For vaginal group, 4 cases (8%) required emergency LSCS. Out of the 4 cases 1 case was taken for LSCS due to Deep Transverse Arrest (DTA), 1 case was taken for LSCS due to Thick Meconium Stained Amniotic Fluid (MSAF) and 2 cases were taken for LSCS for Uterine Hyper Stimulation (UHS).

Table 15: Showing indication for emergency LSCS

Dose	**DTA**	**Failed Induction**	**Remark**			**Total**
			Direct OP	Thick MSAF	UHS	
Oral	1	3	1	1	0	6
	16.7%	50.0%	16.7%	16.7%	.0%	100.0%
Vaginal	1	0	0	1	2	4
	25.0%	0.0%	0.0%	25%	50.0%	100.0%

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II. DISCUSSION

Response to Drug in terms of Bishop Score

Before induction of labour, cervical scoring was done by Bishop's score and for both the groups, next cervical scoring was done after 8 hours. Beforeadministrating next dose of misoprostol, PV examination was done. If the patient had already gone into active labour, further misoprostol administration was withheld.

Mean pre-induction bishop score for Oral group was 2.82 ± 1.466. For vaginal group, the mean value was 3.14 ± 1.262 which was statistically insignificant (p = 2.45). After 8 hours, the bishop score for oral group had a mean of 4.6 ± 1.714 and for vaginal group, the mean was 5.7 ± 1.717, which was statistically significant (p = 0.002). It indicates that the improvement in cervical score was significantly more in vaginal group as compared to the oral group after the first dose.

Number of Doses of Drug Required for Delivery

Majority of cases in the oral group needed 3 doses for induction of labour. Only two cases delivered after 1 dose. In vaginal group, majority required only two doses for induction of labour whereas 14 cases delivered after 1 dose of Misoprostol.

This result is consistent with the study done by Shetty Ashalatha[121], March 2001, where for oral group, 48.9% of cases required more than 1 dose for induction and in vaginal group, only 22.2% required more than 1 dose for induction. Also, the study by Kwon et al, 2001[(8)] showed similar results since mean number of doses required was more in the oral group as compared to the vaginal group.[9,10]

This is mostly because pharmacokinetics is different in oral vs. vaginal administration of Misoprostol. For oral administration, the onset of action is 8 mins. The time taken to reach the maximum concentration (Tmax) is 30 mins and duration of action is 2 hours. For vaginal administration, the onset of action is 20 mins, Tmax is 70 mins and duration of action is 4 hours. It is clear by the pharmacokinetics[11,] vaginal Misoprostol remains effective for longer time and hence lesser dosage is required for induction of labour.[11.12]

Requirement of Augmentation with Oxytocin

In the present study, it was found that 30(60%) cases in oral group and 16 (32%) cases in vaginal group required augmentation with Oxytocin. The difference was statistically significant (p = 0.005) indicating that oral administration of Misoprostol for induction of

labour requires additional methods of labour augmentation, such as Oxytocin drips.

The findings of this study are consistent with the previous studies, as shown in the table below. In all the previous studies shown below, more cases in oral group required augmentation with Oxytocin as compared to vaginal group for delivery[13,14]

Induction to Vaginal Delivery Interval

The induction to delivery interval is one of the primary outcomes of the present study. In Oral group, the mean interval was 22.90 hours and the same in vaginal group was 17.38 hours. The difference is statistically significant ($p < 0.001$), indicating that vaginal route of administration leads to lesser induction to delivery interval as compared to the oral route. Also, in vaginal group, the maximum induction to delivery interval was 24 hours, i.e. all the cases delivered within 24 hours of induction of labour. The same measure was 28 hours in the oral group.

This finding corroborates the pharmacokinetics of oral and vaginal route of administration of Misoprostol since vaginal route has longer duration of action than oral route. It can also be explained on the basis of greater Oxytotic effect of Misoprostol on uterus via vaginal route due to direct access to myometrium via cervical canal. [14 15]

The total systemic bio-availability of vaginally administered Misoprostol is 3 times greater than that of oral Misoprostol.[16 17]

Findings of the present study coincide with the earlier ones outlined in the table below. In all the studies, including the present one, the Induction Delivery Interval (IDI) in oral group was longer than that of vaginal group.

Failed Induction

In the present study, 3 cases (6%) in oral group failed to proceed to active labour, while there was no failure of induction in the vaginal group, though the difference was statistically insignificant ($p = 0.079$). More cases of induction failure in oral group could be attributed to:

- More 1st pass metabolism of oral Misoprostol
- Less bio-availability of the drug
- Less direct access to uterine myometrium in case of oral administration

In three cases, even after 6 doses of Misoprostol orally, there was minimal improvement in Bishop's score even after 24 hours of induction. Hence, these cases were declared as failure of induction and were taken for emergency LSCS. However, the perinatal outcome of all the three cases was good.

Most of the comparative studies of different routes of administration have not reported failed induction as a separate outcome of interest. Those who have reported it have shown oral groups to have more failure to induction.

Mode of Delivery after Induction

In the oral group, 34 cases (68%) proceeded for unassisted vaginal delivery. Another 10 cases required assistance in terms of vacuum and forceps. Of these, 8 (16%) required vacuum extraction and remaining 2(4%) required Forceps delivery.

In vaginal group, 38 (76%) cases proceeded to unassisted vaginal delivery and 8 (16%) cases required assistance in terms of vacuum and forceps.

Majority of the assisted vaginal deliveries were meant to cut short the second stage of labour as these cases had meconium stained liquor.

Indication for Emergency LSCS

In oral group, a total of 6 cases (12%) required emergency LSCS. Failed induction was the main reason for LSCS in oral group (3 cases, 6%), one each for failure of progress of labour, DTA and DOP. The case where DTA was the reason for LSCS, the neonate had to be admitted to NICU for respiratory distress (birth wt 3.2 kg). Another case required LSCS because of thick meconium with Fetal Heart Rate (FHR) variability. The neonate had to be admitted to NICU for respiratory distress.

In vaginal group, a total of 4 cases required emergency LSCS. Of these, 2 cases required LSCS for Uterine Hyperstimulation (UHS). Both the cases had meconium stained liquor and one of the neonates had to be admitted to NICU for respiratory distress. There was a failure of progress of labour because of DeepTransverse Arrest (DTA) in one case, hence it was taken for LSCS. Another case required LSCS due to thick Meconium Stained Amniotic Fluid (MSAF) and Fetal Heart Rate (FHR) variability.

The difference in requirement of LSCS in two groups is not statistically significant.

Previous studies have shown similar trend. Detailed breakup of reasons for emergency LSCS could not be obtained from previous studies.[17,18]

Characteristic of Liquor

In the present study, in oral group, 80% of the cases had clear liquor. Of the remaining 10 cases (20%), 6 (12%) had thin Meconium Stained Amniotic Fluid (MSAF) and 4 (8%) had thick

Meconium Stained Amniotic Fluid (MSAF).

In the vaginal group, 76% (38 cases) had clear liquor. Of the remaining 12, 8 cases (16%) had thin MSAF and remaining 4 cases (8%) had thick Meconium Stained Amniotic Fluid (MSAF).

Thin Meconium Stained Amniotic Fluid (MSAF) had no adverse effect on any of the neonates in both the groups. In vaginal group, neonatal outcome was good in case of thin Meconium Stained Amniotic Fluid (MSAF). One case of thin MSAF was associated with uterine hyperstimulation which was taken for Caesarean Section. Another one case which was taken for Caesarean Section for Deep Transverse Arrest (DTA). Other two cases of thin MSAF were associated with tachysystole and fever, but it had no adverse effect on the mother or neonate.

In Oral group, all the 6 cases of thin MSAF had good neonatal outcome. All such cases delivered vaginally in which 3 required vacuum delivery and the rest 3 delivered spontaneously. One case of thin MSAF was associated with fever and another case with uterine hyper stimulation.

Out of 4 thick MSAF cases in oral group, 3 neonates required NICU admission. Two cases were taken for LSCS, out of which, 1 case was failure of progress of labour due to DTA. Rest two had assisted vaginal delivery with forceps and vacuum.

Common side effects of Misoprostol for induction of labour are nausea, vomiting, watery diarrhea, uterine cramps, uterine hyperstimulation, fever, tachycardia and chest pain. [39]

In Oral group, a total of 5 (10%) cases developed some kind of maternal complication. Of these 5 cases, 3 developed diarrhea, 1 pyrexia and 1 case witnessed uterine hyperstimulation.

In vaginal group, maternal complication developed in 6 (12%) cases. Of these 6 cases, 2 developed pyrexia, 2 tachysystole and 2 witnessed uterine hyperstimulation.

More incidence of diarrhea in oral group can be attributed to more GI absorption of the drug in oral group. Also, since vaginal administration directly targets the uterus, more incidences of UHS and tachysystole was observed in vaginal group. However, this finding was found to be statistically insignificant (p = 0.225).There is a higher trend of maternal complication in vaginal route, which concerns the safety of this route as compared to oral group.

Data available with the previous studies show no statistically significant differences in maternal outcome between oral and vaginal groups. However, there is a higher trend of maternal complication in vaginal group. Present study also indicates the same pattern and is consistent with previous studies.

APGAR score at 5 minutes:

In oral group, only 1 case resulted in APGAR score < 6 at 5 minutes and the vaginal group did not have any such case. These differences were statistically insignificant (p = 0.315).

The lone case in oral group was a forceps assisted vaginal delivery and the baby was admitted to NICU for respiratory distress. The birth weight of the neonate was 2.7 kg.

Previous studies in conjunction with the present one show that there is no significant difference in neonatal outcome in terms of APGAR score between oral and vaginal administration.

Neonatal Outcome in terms of NICU admissions

In the present study, 4 cases (8%) developed neonatal complications. Of these,

3 required NICU admission for respiratory distress and 1 for meconium stained condition.

In vaginal, 10% (5 cases) neonates had to be admitted to NICU. Of these 2 (4%) cases were admitted due to respiratory distress, 1 because of low birth weight, 1 had meconium aspiration syndrome and 1 was kept for observation for TSB Monitoring.

In previous studies NICU admissions were more because of associated comorbid condition of the neonate. There were no significant differences in NICU admission for oral and vaginal group.

The present study is the analysis of 100 cases of primi at 37-42 weeks of gestation with vertex presentation single tone pregnancy with PROM admitted and treated in the department of Obstetrics and Gynaecology, Gauhati Medical College and Hospital, Guwahati, Assam. The study covered tenure of one year from the period 1st June, 2016 to 31st May, 2017.

The maternal and fetal outcome of 100 cases of Primigravida at 37-42 weeks of gestation with Vertex Presenation with Pre-labor Rupture of Membranes Observed and analysed. Two routes of administration of Misoprostol (Vaginal and Oral) were compared in this study with respect to safety, efficacy, maternal and foetal outcome.

The criteria for evaluation of maternal outcome considered were - induction to delivery interval, need of Oxytocin augmentation, mode of delivery, failure of induction of labour and maternal complications.

Liquor characteristics and number of NICU admissions were observed to evaluate foetal

outcome.

The incidence of prelabour rupture of membranes cases is 9.6%. In our study, 44% cases were booked and 56% were unbooked, there is no statistically significance difference observed between booking and unbooking status. Maximum number of cases (69%) seen in the age group of 21-30 years, 62% cases seen from the rural area and 38% from urban area.In the present study for oral group; 48% of cases required 3 doses of tab. misoprostol 25 µg for delivery and in vaginal group 48% of cases required 2 doses of tab. misoprostol 25 µg. for spontaneous delivery.The mean pre-induction bishop score were 3.14 in the vaginal group and 2.82 in the oral group and the mean bishop score is 5.7 after 8 hours of induction in vaginal group and 4.6 in oral group are observed.

In the present study 32% of cases required augmentation with oxytocin in vaginal group and 68% cases did not required augmentation.60% cases required augmentation with oxytocin in oral group. 40% cases did not require any augmentation.

1) The mean induction delivery interval was 17.38 hours in vaginal group and 22.90 hours in oral group were observed. The minimum induction to spontaneous delivery was 10 hours in oral group and 8 hours in the vaginal group.
2) There was no failure of induction in vaginal group of patients whereas 6% of cases in the oral group of induction failure but the result was not statistically significant (p=0.079).
3) The majority of cases (76%) delivered spontaneously and 8% of cases required LSCS in the vaginal group. 68% of cases delivered spontaneously in oral group. 12% of cases required LSCS in oral group.
4) In Oral group, 80% exhibited clear liquor, 12% exhibited thin MSAF and 8% exhibited thick MSAF. In Vaginal group, 76% exhibited clear liquor16% exhibited thin MSAF and 8% exhibited thick MSAF were observed.
5) In the present study 90% encountered no maternal complication in oral group, 6% mothers developed diarrhea, 2% developed fever and 2% of mothers experienced uterine hyperstimulation. In Vaginal group, 88% encountered no maternal complication, 4% mothers developed fever, 4% experienced tachysystole, and 4% experienced uterine hyperstimulation.

6) In Oral Group:

- Minimium 1 minute APGAR score was 4/10 which proceeded to be 6/10 after 5 minutes
- Maximum 1 minute APGAR score was 8/10 which proceeded to be 9/10 after 5 minutes
- Mean 1 minute score was 7.56
- Mean 5 minutes score was 8.70
- 8 neonates (16% cases) had APGAR score < 6 at 1 minute
- 1 neonate (2% cases) had APGAR score 6 at 5 minutes For Vaginal Group:
- Minimium 1 minute apgar score was 5/10 which proceeded to be 7/10 after 5 minutes
- Maximum 1 minute apgar score was 8/10 which proceeded to be 9/10 after 5 minutes
- Mean 1 minute score was 7.48
- Mean 5 minutes score was 8.74
- 10 neonates (20% cases) had APGAR score < 6 at 1 minute

7) 8% (4 cases) of neonates required NICU admission due to neonatal complication.

Out of the 4 NICU admissions, 3 were admitted for Respiratory Distress, Syndrome (RDS) and 1 case for Thick Meconium stained liquor in oral group.
In Vaginal Group, 10% of neonates required NICU admission due to neonatal complication
Out of the 5 NICU admissions

- 2 were admitted for Respiratory Distress
- 1 case for Low Birth Weight
- 1 case for Thick Meconium
- 1 case was kept for observation (TSB Monitoring)

8) In Oral Group, 12% required emergency LSCS, 1 case was taken for LSCS due to Deep Transverse Arrest (DTA), 3 cases were taken for LSCS due to Failed Induction, 1 case was taken for LSCS due to Direct Occipitto Posterior Position and 1 case was taken for LSCS due to Thick Meconium Stained Liquor. In Vaginal Group, 8% required emergency LSCS. Out of the (4 cases) 8%, 1 case was taken for LSCS due to Deep Transverse Arrest (DTA), 1 case was taken for LSCS due to Thick Meconium Stained Amniotic Fluid (MSAF), and 2 cases were taken for LSCS for Uterine Hyper Stimulation (UHS)[19,20]

III. CONCLUSION

Tablet Misoprostol is stable at room temperature and does not require refrigeration. It is easy to administer and easy to monitor and much more effective for labour induction specially in cases of prelabour rupture of membrane as compared to other labour inducing agents like oxytocin.The oral misoprostol had shorter duration of action, longer induction delivery interval, more

number of doses is required for induction, more first pass metabolism of oral misoprostol, less direct access to uterine myometrium and less systemic bioavailability.The vaginal misoprostol has better efficacy as compared to oral misoprostol as it is absorbed locally and it could be attributed to the direct access to myometrium via cervical canal, the total systemic bioavailability of vaginally administered misoprostol is three times greater than the oral misoprostol.From the present study it can be concluded that the induction to delivery interval in vaginal misoprostol is more effective in comparison to oral misoprostol for induction of labour when administered in similar dosage of 25µg. The vaginal route requires lesser dosage, the induction delivery interval and the incidence of failed induction is also less in this group. With respect to the neonatal outcome no significant statistical difference was noted in either of the groups..

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