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A COMPARATIVE STUDY OF 25 MICROGRAMS VERSUS 50 MICROGRAMS OF INTRAVAGINAL MISOPROSTOL FOR CERVICAL RIPENING AND INDUCTION OF LABOUR (IOL)

Obstetrics & Gynaecology

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ABSTRACT

Background- Misoprostol is a safe drug and increasing the dose needed to be tried for decreasing Induction- delivery- interval (IDI). Objectives- To compare 25µG versus 50µG of intravaginal Misoprostol for cervical ripening and induction of labor (IOL). Methods- A prospective observational comparative study was done in the Department of Obstetrics & Gynecology of a tertiary institute of northern India from January 2018 to June 2019. One hundred pregnant women with Bishop's Score <6 for induction of labour were randomized : Group A (50 Odd No.) Tab.25µG Misoprostol pervaginum and Group B (50 Even No.) Tab.50µG Misoprostol pervaginum. In both groups, a thorough history, physical and obstetrical examination including Bishop's score was done. The same dose was repeated 4 hourly with monitoring the progress of labor and FHS. Number of doses required, induction-delivery- interval, need for oxytocin augmentation, mode of delivery, complications and fetal outcome were recorded. Statistical Analysis: by using chi-square, one sample t-test between percents, and McNemar test on Epi Info 7.2.31.Results- Both groups were comparable for all the outcome variables. (P>0.05.) However significantly greater number of women delivered with only one dose of 50µG versus 25µG i.e., 40% versus 20% (P=0.008). Also, more women delivered in <12 hours with 50µG (41.86%) than 25µG (22.73%) Misoprostol pervaginum (P=0.016). Furthermore, more women delivered in <12 hours and with only a single dose of 50µG (41.86%) than 25µG(22.73%) Misoprostol pervaginum (P=0.016). Conclusions- 50µG is more effective than 25µG Misoprostol pervaginum in all women for induction of labor especially significantly more where delivery needs to be expedited like HDP as significantly more women delivered in <12 hours (P=0.016)with single dose only(P=0.008).

KEYWORDS

Misoprostol, Induction of Labor (IOL), Induction-delivery-interval (IDI) , Pervaginum, Intrapartum complications

INTRODUCTION

Reduction in maternal and infant mortality is included in the Sustainable Development Goals of India [1]. As per the SRS statistical report 2018, perinatal mortality rate is alarming- 22 / 1000 live births. Labor induction is progressively becoming one of the most common obstetric interventions in these women. The prevalence of induction is up to 22% in India [2].

Induction must be carried out only when necessary and not as a routine elective procedure [1]. Approximately 50% of all women undergoing labour induction have an unfavourable cervix, or low Bishop score, which requires ripening. One of the advantages of prostaglandins over mechanical methods is that prostaglandins help not only to ripen the cervix, but to stimulate myometrial contractility also.

The recommendations from the American College of Obstetricians and Gynecologists (ACOG) in 2009 and the International Federation of Gynecology and Obstetrics (FIGO) 2013 are for an initial dose of 25 micrograms of vaginal Misoprostol for labour induction to reduce complications [3,4]. Misoprostol is a synthetic PGE1 analogue, that is in use worldwide for both cervical ripening and induction of labour. It is inexpensive, stable at room temperature, and available in more than 80 countries [4]. Misoprostol is approved by Drug Controller General of India (DCGI) on 8/12/2006 for 25 µG, 100µG and 200µG for cervical ripening, prevention of post-partum hemorrhage and first trimester of abortion with mifepristone with higher strength approval of 50µG for same approved indications on 26/08/2008 [5]. Misoprostol is a good alternative in a low-resource setting, as it is comparatively inexpensive, simpler to administer, and does not require refrigeration for storage [6]. Misoprostol is a safe and well-tolerated drug [7].

The optimal dose of Misoprostol for the induction of labour is uncertain. Despite the recommendations, many obstetricians in the USA and other countries continue to employ 50 micrograms vaginal dose. This ongoing use of the 50-micrograms dose of Misoprostol may reflect published reports suggesting that 50 micrograms dosing works faster, resulting in a decreased interval to vaginal delivery, more deliveries within 24 hours, and lesser need for oxytocin augmentation. The comparative safety of 25- and 50-microgram doses has been uncertain, however, with conflicting published results as to the incidence of adverse outcomes with the two doses.There is a perilous uncertainty about the effect of induction. Determining the effect of elective induction of labor on maternal and neonatal outcomes is of utmost importance. This may be advantageous in all women for Induction of Labour especially significantly more where delivery needs to be expedited like HDP as women need to be delivered in <12 hours. As no single method of labor induction is ideal, the search continues.

Objectives

To compare the safety and efficacy of 25 µG with 50 µG of intravaginal Misoprostol for cervical ripening and (IOL).

To study feto-maternal outcomes in two different dosage groups e.g., Number of doses required, induction-delivery- interval, need for oxytocin augmentation, mode of delivery, intrapartum complications, MAS (Meconium Aspiration Syndrome), NICU admission, need of resuscitation and severe birth asphyxia.

MATERIAL AND METHODS

This was a prospective observational comparative study conducted in the Department of Obstetrics and Gynecology of a tertiary care institute of northern India from January 2018 to June 2019. Ethical clearance from IEC was taken. One hundred women with indication for (IOL)were enrolled in the study after fulfilling the inclusion and exclusion criteria. Counselling was done and written informed consent was taken. Randomization was done by allotting alternate number to women: Group A- Odd number, Group B- Even number. As per predesigned proforma history, general physical examination and systemic examination was done to exclude any maternal disease. Period of gestation was ascertained by date of LMP and/or earliest ultrasound. Obstetrical examination, Bishop's score and for pelvic assessment done. The patient was given the drug as per assigned Group And protocol. WHO Partogram was maintained for monitoring the progress of labor and fetal well-being. Maternal and fetal outcome variables were noted. Failure of induction was defined when the women did not deliver within 24 hours of induction or caesarean was done due to any maternal or fetal indication.

The drug is not approved by Drug Controller General of India for live fetus as per GCPR guidelines 2018.

Group A (Comparator Group) - Misoprostol 25µG every 4 hourly intra vaginal tablets until progress to active labor.

Group B (Intervention Group) - Misoprostol 50µG every 4 hourly intravaginal tablets until progress to active labor.

Inclusion criteria

All women with

- Age: 18 -35 Years

- Gestation age of 37-41 weeks or more
- Bishop's Score less than 6
- Singleton pregnancy
- Cephalic presentation
- Intact membranes (to r/o chorioamnionitis)
- Parity less than 5
- Reactive NST (non-stress test
- Woman's willingness

Exclusion criteria

- Abnormal fetal heart patterns (by Fetal Doppler)
- Malpresentation,
- Suspected cephalopelvic disproportion
- Placenta previa
- Abruptio placentae.
- Previous uterine surgery
- Any contraindication to receiving prostaglandins e.g., h/o cardiac disease, glaucoma.
- Previous attempts of labor induction in present pregnancy
- Active herpes simplex virus infection
- Parity more than 4
- Pyrexia 1000 F
- Prior serious adverse event related to prostaglandins administered by any route for any indication.
- Woman's unwillingness

Technique for intravaginal application of Misoprostol tablets

- Tablet Misoprostol was kept intravaginally in the posterior vaginal fornix (as per suitable dose), without the use of any gel / lubricant (gel may prevent the tablet from dissolving).
- The patient was kept in a recumbent position for 30 minutes.
- Fetal heart rate and uterine activity was monitored continuously for at least three hours after Misoprostol application before the patient was allowed to be ambulated.
- The drug was repeated every 4 hours till regular adequate uterine contractions were achieved.
- Females with inadequate contraction or no uterine contraction were augmented using oxytocin (after four doses of Misoprostol or earlier if inadequate contraction).
- When oxytocin (Pitocin) augmentation was required, a minimum interval of three hours as recommended after the last Misoprostol dose was followed.

Software Epi Info 7.2.31 was used for chi-square, one sample test between percent's and McNemar test. P value <0.05 was taken significant. P>0.05 - non-significant.

RESULTS

The mean age Group in Group A was 24.30±3.03 years and in Group B was 24.78±3.59 years. The maximum number of patients in both the groups were in age Group of 20-24 years and there was no significant difference in the two groups (P=0.4419) NS (Table 1).

There were 58% nullipara and 42% multipara in Group A as compared to 66% nullipara and 34% multigravidas in Group B. Majority of subjects were primigravidae in both groups (P=0.6229) NS (Table1).

The mean gestational age was 39.25±1.75 weeks in Group A and 39.49±1.84 weeks in Group B. It was evident that the subjects in both the Groups were almost equally distributed as far as period of gestation was concerned (P=0.6334) NS (Table 1).

Table 1 Distribution Of Patients According To Age, Parity And Period Of Gestation

Age Group (In years)	Group A (25µG)		Group B (50µG)	
	No. of Patients	%Age	No. of Patients	%Age
20-24	30	60%	31	62%
25-29	17	34%	13	26%
30-34	3	6%	4	8%
>35	0	0%	2	2%
Total	50	100	50	100
Mean±SD	24.30±3.03		24.78±3.59	
Chi-square	3.742			
P Value	0.4419			
Significance	NS			
Parity	Group A (25µG)		Group B (50µG)	
	No. of Patients	%Age	No. of Patients	%Age
0	29	58%	33	66%
1	12	24%	9	18%
2	6	12%	7	14%
3	3	06%	1	2%
Total	50	100	50	100
Mean±SD	0.66±0.91		0.52±0.81	
Chi-square	1.7636			
P Value	0.6229			
Significance	NS			
Period of Gestation (In weeks)	Group A (25µG)		Group B (50µG)	
	No. of Patients	%Age	No. of Patients	%Age
37-38	21	42%	16	32%
39-40	17	34%	17	34%
41-42	4	8%	7	14%
>42	8	16%	10	20%
Total	50	100	50	100
Mean±SD	39.25±1.75		39.49±1.84	
Chi-square	1.716			
P Value	0.6334			
Significance	NS			

Group A had 10% cases with Bishop's Score 2 at the start of (IOL). Bishop's score 3, 4 and 5 was observed in 38%, 44% and 8% of cases respectively in Group A whereas Group B had 16% of the cases with Bishop's Score 2 at the start of (IOL) and Bishop's score 3, 4 and 5 was observed in 46% and 32% and 6% of cases, respectively. Mean Bishop's Score in Group A was 3.50±0.62 and in Group B was 3.28±0.65 (P=0.5392) NS ((Table 2).

Preeclampsia and eclampsia were the most common indications in Group A and as well as Group B i.e., 58% and 54% respectively. Other indications were deranged color doppler, fetal growth restriction, gestational diabetes mellitus, intrahepatic cholestasis of pregnancy and oligohydramnios. Both Groups were comparable (Table 2).

Table 2 Distribution Of Patients According To Bishop's Score, Indications For IOL

Bishop's Score	Group A (25µG)		Group B (50µG)	
	No. of Patients	%Age	No. of Patients	%Age
2	5	10%	8	16%
3	19	38%	23	46%
4	22	44%	16	32%
5	4	8%	3	6%
Total	50	100	50	100
Mean±SD	3.50±0.62		3.28±0.65	
Chi-square	2.1635			
P Value	0.5392			
Significance	NS			
Indications for IOL	Group A (25µG)		Group B (50µG)	
	No. of Patients	%Age	No. of Patients	%Age
Antepartum Eclampsia	7	14%	6	12%
Preeclampsia with Non-severe Features	13	26%	14	28%
Preeclampsia with Severe Features	9	18%	7	14%
Post-Term/Post-Mature	8	16%	10	20%
Deranged Color Doppler	1	2%	3	6%
Fetal Growth Restriction	5	10%	4	8%
Gestational Diabetes Mellitus	1	2%	2	4%
Intrahepatic Cholestasis of Pregnancy	4	8%	3	6%
Oligohydramnios	2	4%	1	2%
Total	50	100	50	100

Only one dose was required by 10 (20%) in Group A and 20 (40%) in Group B which is statistically highly significant (P =0.008) HS. But 80% in Group A and 60% in Group B required 2 or more doses which was statistically not significant. The mean of Group A was 2.20±0.88 doses which was slightly higher than 1.96±0.98 doses of Group B (Table 3).

In Group A, among 50 women who were induced 84% women had vaginal delivery while 12% underwent caesarean section due to different indications and 4% had instrumental delivery. In Group B, vaginal delivery occurred in 80% cases and 14% landed up in caesarean section and 6% patients required instrumental intervention (P=0.8497) NS (Table 3).

In Group A 22.73% and in Group B 41.86% delivered in <12 hours and 61.36 in Group A and 48.84% in Group B delivered between 12 to <24 hours; 15.91% in Group A and 9.30% in Group B took >24 hours to deliver. The mean (IDI) in Group A was 15.17±5.10 hours while in Group B it was 14.43±6.14 hours (P=0.542) NS. Although the mean time from induction to delivery in both the groups was not significant, the number of women taking <12 hours to deliver was significantly more in Group B (P=0.016) HS (Table 3).

Table 3 Distribution Of Patients According To Number Of Doses Of Misoprostol, Mode Of Delivery And Induction-delivery-interval

No. of Doses	Group A (25µG)		Group B (50µG)		P Value*
	No. of Patients	%Age	No. of Patients	%Age	
1	10	20%	20	40%	**0.008**
2	25	50%	17	34%	0.079
3	10	20%	8	16%	0.505
4	5	10%	5	10%	>0.05
Total	50	100	50	100	
Mean±SD	2.20±0.88		1.96±0.98		
Mode of Delivery	Group A (25µG)		Group B (50µG)		
	No. of Patients	%Age	No. of Patients	%Age	
Vaginal Delivery	42	84%	40	80%	
Instrumental Delivery	2	4%	3	6%	
C Section	6	12%	7	14%	
Total	50	100	50	100	
Chi-square	0.3257				
P Value	0.8497				
Significance	NS				
Induction Delivery Interval (In hours) (n=87)	Group A (25µG) (n=44)		Group B(50µG) (n=43)		P Value*
	No. of Patients	%Age	No. of Patients	%Age	
<12	10	22.73	18	41.86	**0.016**
12 to <24	27	61.36	21	48.84	0.232
>24	7	15.91	4	9.30	0.187
Total	44	100	43	100	
Mean±SD	15.17±5.10		14.43±6.14		0.542

*One sample t-test between precents

The total number of induced patients requiring C section was 6 (12%) in Group A and 7 (14%) in Group B. Out of women requiring C section after induction 33.33% in Group A and 57.14% in Group B had C section due to fetal distress (P=0.369) NS. C section was done for non-progress of labor in 50% in Group A and 28.57% in Group B induced cases (P=0.386) NS (Table 4).

In Group A 8% patients and in Group B 16% patients had intrapartum complications. Tachysystole had almost similar incidence in both the groups (8% in Group A and 10% in Group B) whereas no PPH and no perineal tear was observed in Group A and in Group B 2% patients had PPH and 4% had perineal tear. (P=0.3679) NS (Table 4)

Table 4 Distribution Of Patients According To Need Of Oxytocin Augmentation, Indication For Caesarean And Intrapartum Complications

Oxytocin Augmentation	Group A (25µG)		Group B (50µG)		P Value
	No. of Patients	%Age	No. of Patients	%Age	
Required	13	26%	9	18%	
Not Required	37	74%	41	82%	
Total	50	100	50	100	
Chi-square	0.9324				
P Value	0.334				
Significance	NS				
Indication for Caesarean (n=13)	Group A(25µG) (n=6)		Group B(50µG) (n=7)		P Value*
	No. of Patients	%Age	No. of Patients	%Age	
Fetal Distress	2	33.33%	4	57.14%	0.369
Non Progress of Labor	3	50.00%	2	28.57%	0.386
Other	1	16.67%	1	14.29%	0.879
Intrapartum Complications	Group A (25µG)		Group B (50µG)		P Value
	No. of Patients	%Age	No. of Patients	%Age	
Perineal Tear	0	0%	2	4%	
Post-Partum Hemorrhage	0	0%	1	2%	
Tachysystole	4	8%	5	10%	
Chi-square	2.0000				
P Value	0.3679				
Significance	NS				

*One sample t-test between percents

The incidence of MAS, NICU admission, need of resuscitation and severe birth asphyxia was 4%, 4%, 2%, and 4% in Group A and 8%, 8%, 6%, 6% in Group B respectively which was slightly higher in Group B. Also, one baby was still born in Group B in an eclamptic mother who had refused for Caesarean section. However, (P=0.9489) NS (Table 5).

One minute APGAR score <7 was observed in 2% in Group A and 10% in Group B (P=0.092) NS

APGAR score at 5 minute was comparable in both Groups, APGAR <7 was present in 2% in Group A and 4% in Group B (P=0.557) NS (Table 5).

Table 5 Distribution Of Patients According To Fetal Outcome And APGAR Score

Fetal Outcome		Group A(25µG)		Group B(50µG)		P Value
		No. of Patients	%Age	No. of Patients	%Age	
Meconium Aspiration Syndrome		2	4%	4	8%	
NICU Required		2	4 %	4	8%	
Resuscitation		1	2%	3	6%	
Severe Birth Asphyxia		2	4%	3	6%	
Still Birth		0	0%	1	2%	
Chi-square		0.7194				
P Value		0.9489				
Significance		NS				
	APGAR Score	Group A (25µG)		Group B (50µG)		P Value
		No. of Patients	%Age	No. of Patients	%Age	
1 min	<7	1	2%	5	10%	0.092
	>7	49	98%	45	90%	
5 min	<7	1	2%	2	4%	0.557
	>7	49	98%	48	96%	

DISCUSSION

The comparative safety of 25 and 50 microgram of Misoprostol doses has been uncertain, however, with conflicting published results as to the incidence of adverse outcomes with the two doses. Comparison with various studies published in literature is given as follows (Table 6).

The mean age was 24.30±3.30 years in Group A (25µG) and 24.78±3.56 years in Group B (50µG) in the present study which was comparable to that of other studies by [8,9,11,12].

The present study showed 58% women were nullipara and 42% multipara in Group A, whereas 66% were nullipara and 34% where multipara in Group B. Results were comparable with other studies [8,9,11,12].

A similar study on post-term pregnancies with mean gestational age of 41.14 weeks and 41.28 weeks in 25µG and 50µG Group, respectively [8]. In the present study the mean gestational age in Group A was 39.23±1.72 weeks and in Group B was 39.47 ±1.81 weeks, similar with the other studies [11,12].

Table 6: Comparison With Various Studies BORDRERS AROUND EACH STUDY/SHADING

Author and Year of Study		Meydanli et al [8] (2003)		Bharathi et al [9] (2013)		Azubuike et al [10] (2015)		Adebayo et al [11] (2017)		Aggarwal et al [12](2018)		Present Study (2019-20)	
		Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
Mean Age Years= yrs.		27.7± 5.4	26.4± 4.8	(21 to 25) 58%	(21 to 25) 48%	-		29.28± 4.71	29.39± 4.00	25.28± 4.71	25.39± 4.00	24.30± 3.30	24.78± 3.56
Parity Nullipara=N Multipara=M		N66% M33%	N58% M41%	N76% M24%	N56% M44%	-		N47.8% M52.2%	N45.7% M54.3%	N40% M60%	N44% M56%	N58% M42%	N66% M34%
Period of Gestation Days=d Weeks= wks		288± 1.5d 41.143 wks.	289±2d 41.285wks	-	-	-	-	40±1.92wks	39.54±4.50wks	39.54±1.92wks	39.27±4.5 wks	39.23±1.72wks	39.47±1.81wks
Score		2.3±0.67	2.1±0.7	-	-	-	-	3.84± 0.97	3.88±1.06	3.14±0.97	3.12±1.06	3.50± 0.62	3.28± 0.65
Induction Delivery Interval Hours=hrs.		-	-	14.5hrs	9.45hrs	-	-	13.8± 5.9hrs	14.0± 5.7hrs	13.8±5.89	14.0± 5.7	15.17±5.10	14.43±6.14
No. of Doses		2.8±0.7	1.1±0.3			2.12 ± 0.9	1.76± 0.97					2.20± 0.88	1.96± 0.98
Oxytocin Augmentation		6.70%	11.60%	40%	32%	55%	45%	20.60%	17.40%	20%	16%	26%	18%
Mode of Delivery	NVD	81.60%	78.30%	72%	50%	72.09%	72.09%	80.40%	76.10%	80%	82%	84%	80%
	Instrumental Delivery	3.30%	5%	12%	12%	2.32%	2.32%	6.50%	11.90%	4%	4%	4%	6%
	C-section	18.30%	22.60%	16%	38%	10.95%	25.58%	13.10%	10.90%	16%	14%	12%	14%
Intrapartum Complications	Techy	6.70%	14.90%	-	-	5%	12.20%	2.20%	1.63%	2.20%	8%	8%	10%
	PPH	-	-	-	-	-	-	-	2.20%	-	4%	0%	2%
	Perineal Tears	-	-	-	-	-	-	-	2.20%	-	4%	0%	4%
Neonatal Complications	Meconium Aspiration Syndrome (MAS)	-	-	-	-	2.50%	-	-	-	-	-	4%	8%
	Required NICU	3.30%	3.30%	6%	12%	5%	18.60%	5.40%	3.30%	4%	4%	4%	8%
	Resuscitation	-	-	-	-	-	4.60%	-	-	-	-	2%	6%
	Severe Birth Asphyxia	-	-	-	-	2.50%	4.60%	-	-	-	-	4%	6%
APGAR Score	1min< 7	-	-	-	-	7.50%	18.60%	7.60%	7.60%	8%	8%	2%	10%
	5min< 7	-	-	-	-	2.50%	9.30%	5.40%	2.20%	4%	2%	2%	4%

In the present study the mean Bishop's Score in Group A was 3.50±0.62 and in Group B it was 3.28± 0.65 which was comparable to a study in which mean Bishop's Score was 3.84± 0.97 and 3.88±1.06 in Group A and B, respectively [11]and in which the mean Score was 3.14 ± 0.97 in Group A and 3.12 ±1.06 in Group B [12]. While mean Bishop's Score of 2.3. ±0.67 in Group A and 2.1±0.7 in Group B was reported by another study [8] which may be because the study was conducted on different regional Group of women.

In the present study the main indication for (IOL)in Group A and Group B was hypertensive disorders of pregnancy i.e., 58% and 54% respectively. Post term pregnancy was second important indication constituting 16% women in Group A and 20% in Group B. While in other studies post term was main indication for (IOL) [11,12]. Intrauterine fetal death, fetal growth restriction and oligohydramnios, gestational diabetes mellitus were the other indications in our and these studies [11,12].

In the present study, the mean Induction-delivery-interval (IDI) in Group A was 15.17±5.10 hours while in Group B it was 14.43±6.14 hours. The present study is consistent with others who also found (IDI) almost equal in Group A and Group B i.e., 13.8 ± 5.9 hours and 14.0 ±

5.7 hours [11] and 13.8± 5.89 hours and 14.0± 5.7 hours [12]. except for Bharathi et al [9] who reported shorter (IDI) with 50µG Misoprostol (14.5 and 9.5 hours).

The mean number of doses of Misoprostol required was 2.8±0.7 in Group A and 1.1±0.3 in Group B [8] and 2.12±0.9 in Group A and 1.76±0.97 in Group B [10] like the present study i.e., 2.20 ±0.88 doses in Group A and 1.96 ±0.98 doses in Group B.

The present study shows that 26% in Group A and 18% in Group B required oxytocin augmentation. Other studies did not vary much i.e., 20.6% and 20% in Group A and 17.4% and 16% in Group B, respectively [11,12]. Meydanli et al [8] (2003) showed a lower rate of oxytocin requirement 6.7% in Group A and 11.6% in Group B. While a higher rate of oxytocin augmentation in both Groups was reported by other studies (40% and 55% in Group A and 32% and 45% in Group B respectively) [9,10].

The present study shows that 84% women had vaginal delivery, 12% had C section and 4% had instrumental delivery in Group A and 80% had vaginal delivery, 14% had C section and 6% patients had instrumental intervention in Group B. There was no difference in overall caesarean delivery rates reported by most authors [8,11,12]. Other studies reported a higher rate of Caesarean section in Group B than in Group A (16% and 38%) and (25.58% and 10.95%) [9,10]. Incidence of instrumental delivery was also 12% in each group in study done by Bharathi et al (2013) [9] which is higher from that of our and all other mentioned studies [8,10-12].

With respect to incidence of tachysystole (hyperstimulation syndrome) in Group A and Group B 8% and 10%, there was no significant difference observed in our study, although other studies have demonstrated increased incidence of uterine contraction abnormalities in the 50µG Group than 25µG Group i.e., 6.7% and 14.9% ,5.0 % and 12.2 % ,2.2 % and 1.63 % and 2.2% and 8.0 % respectively [8,10,12] except for one study that reported comparatively lower rate i.e., 2.2 % and 1.63% in Group A and Group B [11].

Incidence of hemorrhage was more in Group B than Group A in our study i.e., 0 % and 2 %, comparable to others i.e., 0% and 2.2% and 0% and 4% [11,12].

Perineal tears were more in Group B than Group A in our study i.e., 0% and4%, comparable to others i.e., 0%,2.2%. And 0% and 4% [11,12]. No PPH and no perineal tear reported in both groups by two studies [8,10].

In present study neonates required NICU care 4% and 8% in Group A and Group B which was comparable with many other studies i.e., 3.3 % and3.3 %, 5.4 % and 3.3%, 4 % and 4% [8,11,12]. But was lesser as compared to 6% and12% and 5% and 18.6% respectively by other studies [9,10].

MAS was 4 % and 8% in Group A and Group B in our study which was higher than 2.5% and 0% by Azubuike et al [10] and many studies did not report any case in both the groups [8,9,11,12].

Neonatal resuscitation was required in 2 % and 6 % in Group A and Group B in present study, 0% and 4.6 % in another study [10] and many studies did not report any case in both the groups. [8,9,11,12].

Severe birth asphyxia was 4% and 6% in Group A and Group B in present study ,2.5 % and 4.6% in another study [10] while many studies did not report any case in both the groups. [8,9,11,12].

The present study shows Apgar Score <7 as 2%,10% at 1minute and 2%,4% at 5 minutes in Group A and Group B respectively, comparable with other studies i.e., 7.6%,7.6% and 5.4%,2.2% [11] and 8%,8% and 4%, 2% [12]. Azubuike et al [10] had showed higher incidence of Apgar <7 at 1 minute as 7.50%, 18.60% and at 5 minute as 2.5%,9.3% in Group A, Group B, respectively.

Limitation of study: Inadequate sample size as less no of women were willing to participate in the study, more so as GCPR guidelines 2018 has clearly mentioned that Misoprostol is not yet approved for induction of labor for a live fetus by Drug Controller General of India. There is a perilous uncertainty about the effect of induction. As no single method of labor induction is ideal, the search needs to be continued.

CONCLUSION

The present study compared efficacy and safety of 25µG Misoprostol versus 50µG Misoprostol intravaginally for cervical ripening and (IOL). Both 25µG and 50µG Misoprostol were almost equally effective and well tolerated for cervical ripening and Induction of Labour. Both groups were comparable for all the outcome variables. (P>0.05.) However, greater number of women delivered with only one dose of 50µG versus 25µG i.e., 40% versus 20%, highly significant (P=0.008). Also, more women delivered in <12 hours with 50µG (41.86%) than 25µG (22.73%) Misoprostol pervaginum (P=0.016). Furthermore, more women delivered in <12 hours and with only a single dose of 50µG (41.86%) than 25µG (22.73%) Misoprostol pervaginum (P=0.016). This may be beneficial in all women for Induction of Labour especially significantly more where delivery needs to be expedited like HDP as significantly more women delivered in <12 hours (P=0.016) with single dose only(P=0.008). The caesarean section rate, safety profile as well as the neonatal outcome in two groups was almost similar.

"Compliance with Ethical Standards" :

Conflict of Interest: The authors declare that they have no conflict of interest

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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