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RESEARCH ARTICLE

MATERNAL OUTCOMES OF USING DINOPROSTONE GEL AND DINOPROSTONE INSERT FOR INDUCTION OF LABORAT TERM PREGNANCY: A COMPARATIVE STUDY

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ABSTRACT

Introduction: Induction of labor is defined as the process of artificially stimulating the uterus to start labor. Aims and Objectives: The study was done to compare the maternal outcomes of using dinoprostone gel and dinoprostone insert for induction of labor. **Material and Methods:** A hospital-based prospective comparative study was conducted in the Department of Obstetrics and Gynecology, SMS Medical College, Jaipur from April 2018 to November 2018. 100 pregnant women at term attending the antenatal clinic were enrolled and were divided into two groups, Group-A (intracervical gel) and B (vaginal insert) comprising 50 women in each group. The primary outcome in terms of mode of delivery, the number of women delivering vaginally, and time interval from induction to delivery were measured. **Results:** In Group-A, a total of 35 (70.00%) women had a vaginal delivery and 15 (30.00%) had a cesarean section. In Group-B, a total of 38 (76.00%) women had a vaginal delivery and 12 (24.00%) women had cesarean section According to parity, greater number of primipara women delivered vaginally in insert group. Similarly, a greater number of multipara delivered with insert. In the present study, 35.30% primiparas and 18.75% multiparas had a caesarean section in the gel group, whereas 33.33% primiparas and 5.89% multiparas had a cesarean delivery in the insert group. In primipara women, the time interval from induction to vaginal delivery was shorter (18.18 ± 2.11 hours) in the insert group as compared to gel (19.2 ± 2.06 hours). Similar results were seen in multiparas (gel, 14.3 ± 3.12 hours vs. insert, 13.26 ± 1.14 hours). **Conclusion:** In terms of successful vaginal delivery, dinoprostone vaginal insert is similar to intracervical gel in efficacy.

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INTRODUCTION

Induction of labor is defined as the process of artificially stimulating the uterus to start labor.[1]WHO recommends induction to be performed with a clear medical indication which generally includes gestational age of 41 completed weeks or more, prelabour rupture of amniotic membranes, hypertensive disorders, maternal medical complications, and other complications (World Health Organization, 2011). In India, the rate of elective induction of labor is 32.1%.[2] According to WHO guidelines, prostaglandins should be the first-line drugs for IOL (World Health Organization, 2011). Common prostaglandins used are dinoprostone (PGE2) and misoprostol (PGE1). Dinoprostone comes in two formulations which are. Dinoprostone gel (3 g gel/0.5 mg Dinoprostone) - intra-cervical, but not above the internal os. The application can be repeated after 6-8 hrs, not to exceed 3 doses in 24 hrs.

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Dinoprostone vaginal pessary (10 mg embedded in a mesh) - placed transversely in the posterior fornix of the vagina for 24 hrs. Dinoprostone insert was introduced in 1995 worldwide.[3] Since then, numerous studies have been done at various international levels and this novel Dinoprostone preparation has been put to judicial use in many countries for more than 2 decades. However, in India, it was licensed for use in June 2016.[4] It has been utilized since then at many health care facilities. Still a lot of institutes favor use of traditional Dinoprostone gel for induction of labor.

Rationale for Development: The dinoprostone vaginal pessary was developed to provide a continuous, controlled release of a low-dose dinoprostone in an easy-to-use formulation. It eliminates the risk of 'dose dumping', which has been associated with an increased likelihood of adverse events. The presence of a retrieval system also means that the pessary can be rapidly and easily removed, immediately eliminating the source of dinoprostone. In this study we compared the maternal outcomes of using dinoprostone gel and dinoprostone insert for induction of labor in term pregnancy.

MATERIAL AND METHODS

A hospital based prospective comparative study was conducted in the Department of Obstetrics and Gynecology, SMS Medical College, Jaipur from April 2018 to November 2018. 100 pregnant women were enrolled and divided into two groups, Group-A and B, each comprising of 50 women. Group-A was intracervical gel and Group-B was vaginal pessary. All singleton pregnancies, at term, with cephalic presentation and giving consent were included. Women with a scarred uterus, allergy to the drug or an inadequate pelvis were excluded from study. Informed written consent was taken. In gel group, we originally enrolled a total of 128 pregnant women. Out of 128, 78 women (60.90 %) went into active labor after first gel insertion and all those women were excluded from study. The remaining 50 women who were eligible for second gel insertion were studied thereafter. After second gel, reassessment was done after 6 hrs. In the insert group, insert removal was done when women achieved active labor or after 12 hours of induction, whichever was earlier.

In both groups, after 12 hours, if the cervical dilatation was less than 4 cm, we waited for another 12 hours along with monitoring of the fetal heart. Augmentation with oxytocin was given if uterine contractions were present but inadequate for the progression of labor. Labor monitoring was done as per WHO guidelines. Data collection and statistical analysis were done. Continuous variables were summarized as mean and standard deviation and were analyzed by using unpaired T-test. Nominal/ categorical variables were summarized as proportions and were analyzed by using chi-square/Fischer exact test. A P-value of less than 0.05 was taken as significant.

RESULTS

In our study, percentage of primipara was 68.00% in Group-A and 66.00% in Group-B. The difference was statistically insignificant (p = 0.99). In Group-A, a total of 35 (70.00%) women had vaginal delivery and 15 (30.00%) had caesarean section. In Group-B, total 38 (76.00%) women had vaginal delivery and 12 (24.00%) women had caesarean section. The difference was not statistically significant (p=0.652). Parity wise, in Group-A, 64.70% primiparas and 81.25% multiparas had vaginal delivery and in Group-B, 66.67% primiparas and 94.11% multipara patients had vaginal delivery. The difference was statistically insignificant. In present study, induction to delivery time difference between gel and insert in relation to parity was found to be statistically significant (p = 0.001). In primipara women time interval from induction to vaginal delivery was shorter (18.18 ± 2.11 hours) in insert group as compared to gel (19.2 ± 2.06 hours). Similar results were seen in multiparas (gel, 14.3 ± 3.12 hours vs. insert, 13.26 ± 1.14 hours). In present study, 35.30% primiparas and 18.75% multiparas had caesarean section in gel group, whereas 33.33% primiparas and 5.89% multiparas had caesarean delivery in insert group. This difference was not statistically significant. In our study, fetal distress was the most common indication of LSCS in both groups. The causes of fetal distress in gel group included meconium stained liquor (4), fetal tachycardia (2) and late decelerations (2). For insert group, fetal tachycardia was most common in 3 out of 5 cases. Meconium stained liquor was seen in 2 cases. With respect to parity, rate of fetal distress was higher in primipara in both groups (5 vs. 3 in gel and 4 vs. 1 in pessary).

Complications like postpartum hemorrhage and tachysystole were more common in multipara women as compared to primipara women. The incidence of tachysystole was higher with gel as compared to insert.

DISCUSSION

The process of induction of labor requires a careful assessment of the indication, appropriate choice of the method and skillful procedure to attain the final goal of obstetrics. In our study, number of primiparas were higher in both gel and insert groups because primipara women commonly require induction of labor as compared to multipara women. In Group-A, 35 (70.00%) women had vaginal delivery and 15 (30.00%) had caesarean section. In Group-B, 38 (76.00%) women had vaginal delivery and 12 (24.00%) women had caesarean section. The difference was not statistically significant (p=0.652).Mazumdar ND *et al* (2018)[5] found statistically significant difference in vaginal delivery with more women delivering in pessary group. According to parity, greater number of both primipara and multipara women delivered vaginally in insert group. Insignificant difference was seen between mode of delivery and parity. These differences in primiparas, although were insignificant, but still give us an insight that primipara women were more benefited with pessary insertion. A primipara cervix is firm, closed and longer as compared to multipara cervix. Placement of prostaglandins very near to the cervix helps in better ripening. A closed firm cervix may pose challenge for intracervical gel instillation.

In our study, both primiparas and multiparas had shorter duration of labor in insert group.Basu A *et al* (2012)[6] noted that the mean time from induction to delivery showed a significant difference, with women receiving gel delivering earlier than those having insert (p = 0.018).Mazumdar ND *et al* (2018)[5] in their study also found similar results. In present study, 35.30% primiparas and 18.75% multiparas had caesarean section in gel group, whereas 33.33% primiparas and 5.89% multiparas had caesarean delivery in insert group. This difference was not statistically significant.Facchinetti F *et al* (2007)[7], Triglia MT *et al* (2010)[8], Zeng X *et al* (2015)[9]and Garg S *et al* (2018)[4] all reported that no significant differences appeared for cesarean section in both groups. In both groups, fetal distress was the most common indication for cesarean section. Fetal distress was more often seen in primipara women as compared to multipara women in both groups.Incidence of fetal distress was higher with intracervical gel as compared to vaginal pessary.

A probable explanation for this finding could be that intracervical gel instillation causes whole drug to be placed inside the cervix like ‘dose dumping’. This may cause the gel to ascend upwards into the uterus. Also, insertion requires proper skill. During insertion of intracervical gel, it may accidentally be instilled above internal os and inside uterus. Insertion of prostaglandins inside uterus is associated with increased incidence of meconium stained liquor and tachysystole. However this mishap can be prevented with vaginal insert.

Table 1. Obstetric History Wise Distribution

Obstetric history	Group-A (Gel Group)		Group-B (Insert Group)	
	No.	%	No.	%
Primipara	34	68.00	33	66.00
Multipara	16	32.00	17	34.00

Table 2. Mode of Delivery Wise Distribution

Mode of Delivery	Group-A {n=50} (Gel Group)		Group-B {n=50} (Insert Group)	
	No.	%	No.	%
Normal Vaginal Delivery	35	70.00	38	76.00
LSCS	15	30.00	12	24.00
Total	50	100.00	50	100.00

p = 0.652

Table 3. Mode of Delivery in Relation to Parity

Mode of Delivery	Group-A {n=50} (Gel Group)				Group-B {n=50} (Insert Group)				p-value
	Primipara {n=34}		Multipara {n=16}		Primipara {n=33}		Multipara {n=17}		
	No.	%	No.	%	No.	%	No.	%	
Normal Vaginal Delivery	22	64.70	13	81.25	22	66.67	16	94.11	0.848
LSCS	12	35.30	3	18.75	11	33.33	1	5.89	0.762

Table 4. Average duration of induction to delivery in relation to parity

Parity	Group-A (Gel Group)		Group-B (Insert Group)	
	Average Duration (in hours)			
	Mean	SD	Mean	SD
Primipara	19.2	2.06	18.18	2.11
Multipara	14.3	3.12	13.26	1.14
p-value	0.001		0.001	

Table 5. Indications of Caesarean Section

Indications of Caesarean Section	Group-A {n=50} (Gel Group)		Group-B {n=50} (Insert Group)	
	No.	%	No.	%
Fetal Distress	8	16.00	5	10.00
Failed Induction	6	12.00	3	6.00
NPOL	1	2.00	1	2.00
CDMR	0	0.00	3	6.00

The vaginal insert releases drug at controlled rate of 0.3 mg/ hour which ensures that dinoprostone is slowly and uniformly distributed to the cervix. It has less chance of ascending upwards. Insertion of pessary is less invasive and rather easier as compared to gel. Whereas a gel cannot be retrieved back once inserted, a vaginal pessary can be removed as soon as one suspects tachysytole or fetal distress. Ashwal E *et al* (2014)[10] reported that the rates of cesarean section due to non-reassuring fetal heart rate (NRFHR) were similar in both groups. Similar results were seen in study by Garg *et al*. (2018). The incidence of failure of induction was higher with gel group. This may be because once the patient is mobile, intracervical gel can get dislodged from its site of action. It may be also because of washing out of gel with liquor in cases of leaking. This was not seen with vaginal pessary as the pessary being solid material stays where it is placed in spite of patient's mobility and liquor drainage. Kumari *et al*. (2018) and Mazumdar *et al*. (2018) found statistically insignificant difference in number of failed induction in both the groups. The duration of action of pessary is 24 hours whereas gel needs to be repeated 6 hourly. Thus we can wait up to 24 hours after single pessary insertion which saves the patient from repetitive vaginal examination. This also decreases chances of infection along with being less painful to the patient.

Complications like postpartum hemorrhage and tachysystole were more common in multipara women as compared to primipara women. The incidence of tachysystole was higher with gel as compared to insert. Ashwal *et al*. (2014) and Kumari *et al*. (2018) found that vaginal insert was associated with an increased rate of tachysystole as compared to gel.

Conclusion

To conclude, in terms of success and failure, vaginal inserts releasing dinoprostone are not different from intracervical gel. However, there are some advantages to insert over conventional gel preparation. These include fewer doses required to achieve ripening and induction, less invasiveness and pain to women along with a decreased number of vaginal examinations. Also, it is easy to administer and remove allowing greater dose control and reduced risk of adverse effects.

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