International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 13, No. 11, November 2024 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_13.11.2024.140

Original Research

A Comparative Study of Vaginal Dinoprostone Insert with Intracervical Dinoprostone Gel for Cervical Ripening and Induction of Labor in Nulliparous Women with Unfavorable Cervix

Ekta Thadani[1], Sweety Nuwal[2], Renu Thadani[3], Chetan M. Savani[4]

[1]Assistant Professor, Department of Obstetrics and Gynecology, K. M. Medical College, Mathura, Uttar Pradesh, India.
[2]Consultant, Department of Obstetrics and Gynecology, Opera Hospital and Research Centre, Kota, Rajasthan, India.
[3]Consultant, Gynaecologist, MM Hariom Trust Hospital,Gandhidham, Gujarat, India.
[4]Associate Professor, Department of Surgery, School of Medical Sciences, Sri Satya Sai University of Technology and Medical Sciences, Sehore, Madhya Pradesh, India.

Corresponding Author:
Dr. Chetan M. Savani,
Associate Professor, Department of Surgery, School of Medical Sciences, Sri Satya Sai University of Technology and Medical Sciences, Sehore, Madhya Pradesh, India.
Email: dr.chetansavani@gmail.com

Received Date:05October2024 Accepted Date: 14November2024

Abstract

Background: The ideal agent to induce labor must effectively convert an unfavourable cervix to one receptive to delivery but also needs to be safe, easy to administer and acceptable to the patient. Prostaglandins have a central role in the physiological events of cervical ripening and parturition and have been widely used for induction of labor.**Aim:** To compare the efficacy of dinoprostone gel with dinoprostone insert for induction of labor in nulliparous women with unfavorable cervix in terms of Mode of delivery (vaginal versus caesarean), Induction delivery interval & Fetomaternal outcome.**Materials and Methods:** The study was carried out in the department of Obstetrics and Gynaecology at a tertiary care hospital in western India was conducted between October 2017-Jan 2019 on pregnant patients with >37 weeks of gestation after applying inclusion and exclusion criteria.**Results:** The study group consists of 260 subjects from urban, rural settings and different socioeconomic classes. In present study, out of total number (260) of participants, 92 (35.38%) participants had to undergo cesarean section. Out of which, 44 (33.85%) belonged to gel group while 48 (36.92%) participants belonged to insert group. This difference was not statistically significant (p=0.697). In present study, maximum number of participants (158 out of 260) delivered between 12-24 hours in both the groups. Among 158 participants, 66 (50.77%) participants of gel group while 92 (70.77%) participants of insert group delivered within 12-24 hours which was statistically significant (p <0.001). The mean induction to delivery interval was 18.07 + 7.10 hours in gel group and 15.31 + 5.44 hours in insert group which was statistically significant (p<0.001>). In present study, total of 55 (21.15%) neonates from mothers of both groups had complications, 22 (16.92%) were from insert group while 33 (25.38%) were from gel group. The difference was not statistically significant (p= 0.129). In present study, maternal complications occurred in 21(16.15%) participants of gel group and 3 (2.31%) participants of insert group which was significant statistically (p<0.001).**Conclusion:** The familiarity of the induction of labor and cervical ripening is slowly rising in every setting from rural to well equipped urban hospitals. The result from the present study suggests that slow release intravaginal dinoprostone insert may be effective and safe for cervical ripening and labor induction and may have several indications and advantages in obstetric care. The main disadvantage of insert is it high costs which prohibits the wider usage across the developing Indian continent.

Keywords: Induction of Labor, Intracervical Dinoprostone Gel, Dinoprostone Insert.

DOI: 10.69605/ijlbpr_13.11.2024.140

Introduction

Labor induction is a widely used practice for the delivery of babies at term, employed in up to 25% of deliveries in developed countries[1]. It is applied for intentional initiation of labor before spontaneous onset, for the purpose of delivery of the fetoplacental unit[2]. Induction of labor is indicated when the risk of continuing pregnancy exceeds the risk associated with induced labor and delivery for the mother or the fetus[3].Successful labor induction varies widely depending upon several factors, including characteristics of population being induced such as age, parity, race, body mass index (BMI), gestational age, neonatal weight and management of the induction[4].Cervical ripeness is typically assessed using the modified Bishop's scoring system, in which a score is generally based on the dilation, length of the cervix, station, position and consistency of the cervix[5]. A Bishop score of < 6 is generally considered to indicate an unfavourable or unripe cervix[2,3].

The relationship between a low Bishop score and a failed induction, prolonged labor, and a high cesarean birth rate was first described prior to the widespread use of cervical ripening agents[6] but has persisted even after the introduction of these agents[7]. The ideal agent to induce labor must effectively convert an unfavourable cervix to one receptive to delivery but also needs to be safe, easy to administer and acceptable to the patient[8]. The causes of failure are mostly failed induction, nonprogress of labor, fetal distress, undiagnosed cephalopelvic disproportion (CPD), meconium stained liquor, and prolonged latent phase[9]. Cervical ripening is governed by prostaglandins, naturally occurring hormone like compounds that are found throughout the body[10]. Many different methods (pharmacological and mechanical) have been used for induction of labor and ripening of the cervix, but preferred method for cervical ripening and labor induction is prostaglandins[11]. Prostaglandins have a central role in the physiological events of cervical ripening and parturition and have been widely used for induction of labor. In parturition, it acts through a number of different mechanisms to stimulate cervical remodeling, as well as other processes such as uterine contractions[12].

Dinoprostone, (11α,15S-dihydroxy-9-oxo-prosta-5Z,13E-dien-1-oic acid) only prostaglandin approved by the US Food and Drug Administration for cervical ripening in labor induction, is one of the synthetic prostaglandins (PGE_2) with a half life of approximately 2.5-5 minutes in tissue[13], most commonly used to achieve cervical ripening and labor induction, and can be administered as tablets, suppositories, gel (vaginal and intracervical) or as a controlled release intravaginal pessary[1,2]. It has been shown to increase the rate of vaginal delivery within 24hour and is generally given when the cervix has a Bishop's score of $\leq$ 6. There have been several meta-analysis and systematic reviews evaluating the use of PGE2 and suggesting that it is effective for cervical ripening and labor induction, without distinguishing between dinoprostone insert and gel. The slow release PGE2 vaginal insert achieved cervical ripening and subsequent delivery over a shorter time period[14]. Conversely, another study declared PGE2 gel was superior for the induction of labor[15]. Thus our objective was chiefly to evaluate the sustained release preparation of dinoprostone as a removable pessary (Propess, Ferring Pharmaceuticals, Malmo, Sweden) for cervical ripening and to compare it with our current method of induction requiring 6-hourly insertion of short acting dinoprostone gel (Prostin E2, Upjohn, UK) in terms of initiating labor, the duration of labor, delivery outcome and neonatal outcome in women with an unfavourable cervix and intact membranes.

Aims & Objectives

To compare the efficacy of dinoprostone gel with dinoprostone insert for induction of labor in nulliparous women with unfavorable cervix in terms of:

i) Mode of delivery (vaginal versus cesarean).
ii) Induction –delivery interval.
iii) Fetomaternal outcome in both gel and insert groups.

Materials And Methods

The study was carried out in the department of Obstetrics and Gynaecology at SDMH, Jaipur.

Inclusion Criteria:

i) Patient giving consent for induction of labor.
ii) Singleton pregnancy.
iii) Nulliparous woman.
iv) Gestational age > 37 weeks.
v) Bishop's score < 4.

Exclusion Criteria:

i) History of previous uterine surgery.
ii) Any contraindication to normal vaginal delivery (suspected CPD, placenta previa, non-cephalic presentation).
iii) Hypersensitivity to prostaglandins.
iv) Any chronic medical illness (cardiac disease, pelvic tumor).
v) Rupture of membranes.

Information regarding all the eligible candidates was obtained with respect to maternal age, gestational age, BMI, birth weight, pre- induction Bishop's score, vital parameters, investigations,

DOI: 10.69605/ijlbpr_13.11.2024.140

cause of induction and amniotic fluid index (AFI) and candidates were divided into two groups. Total of 260 subjects were recruited in present study, 130 in each group (insert and gel). They were enrolled to take part in the study after written informed consent and after taking into consideration of the inclusion and exclusion criteriae. They were followed till the discharge of mother and baby from the hospital and feto- maternal outcome of these patients were compared across the study group.

Dinoprostone intracervical gel was inserted in one group and vaginal insert in another group. In the labor room, the women underwent general examination and obstetrical examination (per abdomen, per speculum and per vaginal) scheduled for labor induction after due informed consent and Bishop scoring (<= 4) and were allocated to group (gel or insert). Labor monitoring was done according to the new FIGO consensus guidelines on intrapartum fetal monitoring.

After delivery, maternal outcome in terms of postpartum haemorrhage, blood transfusion and length of hospital stay while fetal oucome in terms of APGAR score (1min and 5min), weight, sepsis, neonatal intensive care unit (NICU) admission and length of hospital stay was assessed.

Continuous variables were summarized as mean and standard deviation (SD) while nominal/categorical variables as proportions (%). Unpaired t-test was used for continuous variables whereas Chi-square test/Fisher's exact test was used for nominal/categorical variables. Ordinal variables were expressed as median and range and were analyzed by using MANNWHITNEY U TEST. p value< 0.05 was taken as significant. MEDCALC 16.4 version software was used for all statistical calculations.

Observation & Results

The present study was conducted on pregnant women, A total of 260 participants were included in the study. The following observations were made. Majority of study subjects, 58.85%, were in the age group 25-30 years in both groups (gel59.23% and insert 58.46%), the difference being statistically insignificant.

The mean induction-delivery interval was 18.07 $\pm$ 7.10 hours in gel group and 15.31 $\pm$ 5.44 hours in insert group which was statistically significant ($p<0.001$).

Table 1: Distribution of Study Group According to Age.

Age (years)	Group				Total	
	Gel		Insert			
	No.	%	No.	%	No.	%
20-24	25	19.23	26	20.00	51	19.62
25-30	77	59.23	76	58.46	153	58.85
≥30	28	21.54	28	21.54	56	21.54
Total	130	100.00	130	100.00	260	100.00

Chi-square = 0.026 with 2 degrees of freedom; P = 0.987.

Table 2: Distribution of Study Groups According to Mode of Delivery.

Mode of delivery	Group				Total	
	Gel		Insert			
	No.	%	No.	%	No.	%
Cesarean section (CS)	44	33.85	48	36.92	92	35.38
Vaginal Delivery (VD)	86	66.15	82	63.08	168	64.62
Total	130	100.00	130	100.00	260	100.00

Chi-square = 0.151 with 1 degree of freedom; P = 0.697

Table 3: Characteristics of Both Group According to Induction-delivery Interval.

Parameters	Group	N	Mean	SD	Median	Min.	Max.	'p' Value*
Induction-delivery interval (hours)	**Gel**	130	18.07	7.10	18	5	30	<0.001
	Insert	130	15.31	5.44	14	5	26	

Unpaired 't'test.

DOI: 10.69605/ijlbpr_13.11.2024.140

Table 4: Distribution of Study Group According to Fetal Outcome.

Fetal complications	Group				Total		'p' value
	Gel		Insert				
	No.	%	No.	%	No.	%	
Hypoglycemia	14	10.77	4	3.08	18	6.92	0.028
Meconium Aspiration Syndrome	3	2.31	4	3.08	7	2.69	1.000
Pathological Jaundice	6	4.62	2	1.54	8	3.08	0.281
RDS	5	3.85	5	3.85	10	3.85	0.747
Sepsis	1	0.77	0	0.00	1	0.38	1.000
TTN	2	1.54	4	3.08	6	2.31	0.680
Total	33	25.38	22	16.92	55	21.15	0.129

*****Chi-square test.

Table 5: Distribution of Study Group According to Maternal Outcome.

Maternal complications	Group				Total		"p" value
	Gel		Insert				
	No.	%	No.	%	No.	%	
Forceps Delivery	8	6.15	1	0.77	9	3.46	0.042
Uterine Hyper stimulation	7	5.38	1	0.77	8	3.08	0.073
PPH	4	3.08	1	0.77	5	1.92	0.366
Cervical Tear	3	2.31	0	0.00	3	1.15	0.245
Blood transfusion	2	1.54	0	0.00	2	0.77	0.478
Bilateral Uterine Artery Ligation	1	0.77	0	0.00	1	0.38	1.000
Total	21	16.15	3	2.31	24	9.23	<0.001

*Chi –square test.

Discussion

This study was conducted from October 2017 to January 2019. Pregnant women >37 weeks of gestation fulfilling the inclusion and exclusion criteria were included in the study. The Bishop's score of pregnant women after detailed history and examination was assessed and after explaining about mode of induction with dinoprostone vaginal insert or with dinoprostone intracervical gel, they were induced with either of the above mentioned methods. According to consent given, they were divided into gel and insert group. The mode of delivery and fetomaternal outcome in both groups were assessed.

In present study, mean age of participants was 27.14 ± 3.15 years in gel group while 27.14 ± 3.08 years in insert group which was not statistically significant(p=0.987). In this study, 66.15 % participants of gel group and 63.08% participants of insert group delivered vaginally (p >0.05).16 (12.31%) participants of gel group while 17 (13.08%) participants of insert group had failed induction as the most common reason of CS. The mean induction to delivery interval was 18.07 $\pm$ 7.10 hours in gel group and 15.31 $\pm$ 5.44 hours in insert group which was statistically significant (p<0.001).

In our study, 33 (25.38 %) neonates of gel group developed complications as compared to 22 (16.92 %) neonates of insert group (p=0.129). 14 (10.77%) neonates of gel group and 4 (3.08%) neonates of insert group developed hypoglycemia which was statistically significant (p=0.028).In present study, 21 (16.15%) participants of gel group developed abnormal maternal outcome as compared to 3 (2.31%) participants of insert group, the difference being significant statistically (p<0.001).7 (5.38%) participants of gel group and 1 (0.77%) participant of insert group had uterine hyperstimulation (p=0.073). 8 (6.15%) participant of gel group and 1 (0.77%) participant of insert group had instrumental (forceps) delivery which was significant statistically (p>0.05). 4 (3.08%) participant of gel group and 1 (0.77%) participant of insert group had PPH (p=0.36). Considering mode of delivery and neonatal outcome, both the insert group and gel group showed similar results while there was less number of PV examinations, shorter hospital stay, short induction-delivery interval, less need of augmentation, significant change in Bishop's score and better maternal outcome with insert group.

Conclusion

In the present study, both the dinoprostone insert and gel were efficient in achieving cervical ripening and successful vaginal delivery in nulliparous women and shortening the length of labor.Further studies with larger sample sizes are needed to

DOI: 10.69605/ijlbpr_13.11.2024.140

evaluate the real safety of these prostaglandins. After all, mode of delivery often depends on other events that present later in labor, such as CPD or fetal distress, thus confounding any possible causative association between choice of induction procedure and mode of delivery.

The main disadvantage of insert is it high costs which prohibits the wider usage across the developing Indian continent. In view of these findings, the low Bishop's score should be considered as an indication to prefer the slow release dinoprostone insert for promoting cervical ripening in patients at term, since it reduces pain and discomfort with less number of vaginal examinations, shorter induction-delivery interval and shorter hospital stay, thereby improving the physical and emotional wellbeing of the parturient.

References

1. World Health Organization. WHO recommendations for induction of labor. Vol 1. Geneva, Switzerland: WHO; 2011.http;//who.int. Accessed 31 July 2018.
2. American College of Obstetricians and Gynaecologists. Induction of labor. ACOG Practice Bulletin N.107. Obstet Gynecol 2009; 114:386-97.
3. Leduc D, Biringer A, Lee L et al. SOGC clinical practice guideline: induction of labor. J Obstet Gynaecol Can.2013; 35(9):840-57.
4. Pevzner L, Rayburn WF, Rumney P, et al. Factors predicting successful labor induction with dinoprostone and misoprostol vaginal inserts. Obstet Gynecol. 2009; 114(2 pt 1) :261-67.
5. Burnett JE Jr. Preinduction scoring: an objective approach to induction of labor. Obstet Gynecol. 1966; 28 (4) 479-83.
6. Talaulikar VS, Arulkumaran S. Failed induction of labor: Strategies to improve the success rates. Obstet Gynecol Surv 2011; 666:717-28.
7. Xenakis EM, Piper JM, Conway DL, Langer O. Induction of labor in the nineties: conquering the unfavourable cervix. Obstet Gynecol 1997; 90:235-9.
8. Filosomi F, Torricelli F, Voltolini M, et al: Efficacy and safety of slow release dinoprostone insert for induction of labor: Correlation with parity. J Chinese Clin Med 2010; 5:1-6.
9. Lawani OL, Onyebuchi AK, Iyoke CA, Okafo CN, Ajah LO. Obstetric outcome and significance of labor induction in a health resource poor setting. Obstet Gynecol Int 2014.
10. Bakker R, Pierce S, Myers D. The role of prostaglandins E_1 and E_2, dinoprostone, and misoprostol in cervical ripening and the induction of labor: a mechanistic approach. Arch Gynecol Obstet. 2017; 296(2):167-79.
11. Pitale DL. Effectiveness of dinoprostone vaginal pessary in induction of labor at term. Int J Reprod Contracept Obstet Gynecol. 2017; 6(12):5528-31.
12. Shirley M. Drugs. 2018 Oct; 78(15):1615-24.
13. Cervidil® prescribing information. Ferring pharmaceuticals Inc, Parsippany, NJ; February 2016.
14. Ashwal E, Hiersch L, Melamed N, Manor Y, Wiznitzer A, Hod M, Yogev Y. Pre-induction cervical ripening: comparing between two vaginal preparations of dinoprostone in women with an unfavourable cervix. J Matern Fetal Neonatal Med. 2014; 27:1874-79.
15. Taher SE, Inder JW, Soltan SA, et al. Prostaglandin E_2 vaginal gel or tablets for the induction of labor at term: a randomised controlled trial. BJOG 2011; 118:719-25.