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Original Research Article

A comparative study of single versus repeat instillation of intravaginal prostaglandin E2 gel for induction of labour

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ABSTRACT

Background: The aim of induction was to achieve successful vaginal delivery where continuation of pregnancy is not desirable. Unfavourable cervix is one of the main causes of failed induction. Introduction of intravaginal prostaglandins E2 has revolutionised the method of cervical ripening. More than one dose of prostaglandin E2 (PGE2) gel may be necessary to facilitate cervical ripening and increase the chances of vaginal delivery.
Methods: This retrospective study was done to find the efficacy of repeat instillation of intravaginal PGE2 gel and to compare the maternal and fetal outcome between the single instillation group and repeat instillation group. The women who went into labour or achieved cervical ripening with a single instillation of PGE2 gel forms Group A. Those who required repeat instillation of PGE2 gel forms Group B. Both groups were compared for specific parameters.
Results: Primigravidas required repeat instillation. Postdated pregnancy was the most common indication for induction of labour. 45.2% of primis required only single dose and 54.8% required repeat dose. About two third (77.8%) of multipara required only one dose and a third of multipara needed repeat dose. In Group A 90.7% had vaginal delivery, 9.3% had Caesarean section. Group B 95.7% had vaginal delivery and 4.3% had Caesarean section.
Conclusions: Prostaglandins PGE2 (0.5 mg) gel is recommended to be used intravaginally. We applied 2 doses of intravaginal PGE2, 24 hours apart and no complications like uterine hyperstimulation was seen. There is no increased fetal risk with repeat instillation of intravaginal PGE2 gel.

Keywords: Prostaglandin E2, Induction, Vaginal delivery, Single versus repeat instillation, Intravaginal

INTRODUCTION

Induction of labour is now an integral part of modern Obstetrics. The aim of induction was to achieve successful vaginal delivery where either continuation of pregnancy endangers the life or wellbeing of the mother or the fetus or the pregnancy has achieved term and still spontaneous labour has not occurred. The infant should be born in good condition with less trauma within acceptable time frame and with least maternal complications. It is not possible to achieve 100% success when labour is induced. Several factors influence the outcome. Unfavourable cervix is one of the main causes of failed induction. In order to overcome this, cervix should be ripened. The physical and biochemical changes in the uterine cervix resulting in its softening and dilatation are recognized as cervical ripening. It is well recognized that induction of labour is more successful when attempted with a well ripened cervix.

Induction of labour in an unripecervix is associated with frequent maternal complications and leads to induction

failure in upto 20-50% and associated with high rates of Caesarean delivery.[1] Even when vaginal delivery is achieved these patients often have prolonged labour, with high incidence of instrumental delivery and fetal asphyxia.

In an attempt to ripen the cervix various pharmacological and physical agents have been evaluated such as breast stimulation, amniotomy, oxytocin infusion, estrogen gel, mechanical and electrical devices and local and systemic Prostaglandins. Introduction of Prostaglandins has revolutionised the method of cervical ripening. Several published studies have reported significant improvement in Bishop score, higher numberof vaginal deliveries, shorter duration of labour and fewer caesarean deliveries without adversely affecting the neonatal outcome.[2,3]

Local use of prostaglandin E2 (PGE2) by extraamniotic, intravaginal and intracervical route has been found to be effective in priming the cervix and inducing labour in patients at term with poor Bishop score.[1] The recommended routes of application of prostaglandins (PGE2) are intracervical and intravaginal as these have been reported to be most advantageous in terms of increased efficacy and diminished side effects.[4,5] A single dose PGE2 of 0.5 mg has been found to be superior to placebo in ripening the cervix.[4,5]

Various authors have reported success rates of vaginal delivery ranging from 83% to 90% after induction using PGE2 gel.[6] Extra-amniotic use, besides being invasive is associated with increased risk of introducing infection. The intracervical application requires larger dose of the drug and hence associated with gastrointestinal side effects and uterine irritability.[7] The intracervical use has adverse side effects.

According to literature, intracervical application requires larger dose than intravaginal dose and thus associated with side effects. Intracervical application has draw backs. The patient has to be in lithotomy position, necessitates using of instruments to visualize the cervix and there is risk of accidental placement of the gel into extraamniotic space. Intravaginal application is easy and causes less discomfort to the patient.Intravaginal instillation is as effective as intracervical application.

Objective of the present study was to evaluate the efficacy of single instillation vs repeat instillation of intravaginal PGE2 gel in cervical ripening, to compare the maternal and fetal outcome between patients who had single instillation and repeat instillation, to study the adverse effects, if any of repeat instillation of intravaginal prostaglandin E2gel.

METHODS

It is a retrospective study. This study was conducted in the Department of Obstetrics and Gynaecology, SMT NHL Medical College, Ahmedabad. Sixty patients, who had induction of labour were included in this study after applying the following inclusion and exclusion criteria.

Inclusion criteria were singleton pregnancy, vertex presentation, gestational age greater than or equal to 34 completed weeks. Bishop score less than or equal to 6.

The exclusion criteria were bishop score >6, previous uterine scar, non-vertex presentation, medical conditions like glaucoma or asthma, antepartum haemorrhage.

Procedure

An informed consent was taken. All the patients were administered. 0.5 mg prostaglandin gel intravaginally. The commercially available gel in a prefilled syringe (cerviprime) that contains 0.5mg of PGE2was used for all the patients. The gel was administered into the posterior fornix of vagina under aseptic conditions and the woman was kept on the bed supine for 4 hours and was observed for contractions, rupture of membranes, bleeding or fetal heart rate changes.

After 24 hours, if the patient had not gone into labour, a reassessment of the cervical status was done. If the Bishop score was less than 6, another instillation of intravaginal gel was done.Iflabour did not occur spontaneously after repeat instillation and Bishop score was 6 or more, oxytocin induction/augmentation was done if necessary. If bishop score was still less than 6 after waiting for 4 hours after repeat instillation cesarian section was done. The patients who went into labour or achieved cervical ripening with a single instillation of PGE2 gel forms Group A. Those who required repeat instillation of PGE2 gel forms Group B. Initial Bishop Score, change in score with repeat instillation of prostaglandin gel, mode of delivery, side effects of prostaglandin and maternal and fetal complications were noted. The details obtained were used to compare between the groups A and B. Appropriate statistical tests were used to determine the efficacy of instillation of intra vaginal PGE2 gel. We used Modified Bishop score.

Table 1: Modified Bishop score-13.

Score	0	1	2	3
Dilatation (cervical)	Closed	1-2	3-4	5
Length (cervix)	>4	3-4	1-2	0
Consistency (cervix)	Firm	Medium	Soft	-
Position (cervix)	Post	Mid	Ant	-
Station (head)	-3	-2	-1,0	+1,+2

RESULTS

Out of 60 cases studied, there were 32 women who had single instillation and 28 women had repeat dose instilled (Table 2, 3). The majority of the women in both the

groups were between 18-27 years of age (Table 2). The mean age of the patients in the both groups was not significantly different from each other. There was no statistically significant differences in pattern of distribution of patients based on age group. Primis were 44 and multiparous were 16.

Out of 44 primigravida women, 45% (20) had single instillation and 55% (24) had multiple instillation (Table 3). It was observed that there were significantly more primi gravid patients in Group B compared to group A. Out of 16 multiparous patients 12 patients (75%) required single instillation compared to 45% primi parous patients. Among multiparous women 12 (75%) required single instillation compared to 4 (25%) which is statistically significant (Table 3).

The period of gestation was similar in both the groups. About 75% of patients in both the groups were between 38 and 42 weeks (Table 4). The most common indication for induction of labour in both the groups was post-dated pregnancy followed by pregnancy induced hypertension (Table 5). No of intravaginal PGE2 instillations: Among Primis, 45% had one dose. 75% of multipara had single instillation which is statistically significant compared to Primis and rest of the multiparous women equally had two doses.

The initial bishop score and the mean change in bishop score was analysed after single and repeat instillation of cerviprime gel. Among 60 patients, patients who went into spontaneous labour and c section in both groups were noted. In Group A 61% of women received Oxytocin augmentation and in Group B 76% had Oxytocin. Fetal distress, cephalopelvic disproportion and non-progression of labour were the indications for caesarean section.

Table 2: Age distribution.

Age group in years	Group A (Single instillation)	Group B (Repeat instillation
< 20	9 (28.1%)	7 (25%)
21 -25	19 (59.3%)	18 (65.2%)
26 - 30	4 (12.6%)	3 (9.8%)

Age distribution shows there is no significant change in single and repeat instillation group.

Table 3: Gravida.

Gravida	Group A	Group B	Total
	Single instillation	Repeat instilation	
Primi	20 (62.5%)	24 (85%)	44 (73%)
Multipara	12 (37.5%)	4 (15%)	16 (17%)
Total	32	28	60

This table signifies that most primi patient needs repeat instillation as compared to multipara patients.

Table 4: Gestational age.

Gestational age in weeks	Group A (Single instillation)	Group B (Multiple instillation)
34- 36	2 (6.75%)	2 (7.2%)
37-39	10 (22.25%)	5 (17.8%)
40-42	20 (71%)	21 (75%)

Post datism in the most common indication of induction of labour.

Table 5: Indications.

Indications	Group A (Single instillation)	Group B (Multiple instillation)
Post date	20 (62.5%)	21 (75%)
Pregnancy induced hypertension	4 (12.5%)	2 (7.14%)
Prom	6 (18.75%)	4 (14.28%)
Oligohydroamnios	2 (6.25%)	1 (3.57%)
Total	32	28

Table 6: Type of delivery.

Type of delivery	Single instillation	Repeat instillation	Total
Spontaneous delivery	25	24	49
Primi	5	20	25
Multi	20	4	24
C- section	7	4	
Primi	5	3	8
Multi	2	1	3

Majority of primipatients required repeat instillation as compared to multipara patient.most primi patient in induced group required c section compared to multi para.

Table 7: Causes of caesarean section.

Cause of c section	Single instillation	Repeat instillation
Fetal distress	2	2
Obstructed labour	1	1
Npol+induction failure	1	4
Total	4	7

Most common cause of c section in both groups is non progress of labor.

After repeat instillation of PGE_2 24 hours apart we waited for 6 hours if bishop didn't improve and spontaneous labour did not start we took emergency c section of the patient for non progress of labour+ induction failure.

Note: repeat instillation is done after 24 hours of first instillation and time duration of repeat instillation group is counted after repeat instillation of PGE_2 gel.

Table 8: Time duration in spontaneous delivery in both the groups.

Time duration	Single instillation		Repeat instillation	
Time	**Primi**	**Multi**	**Primi**	**Multi**
<6 hours	0	5	4	1
6 to 12 hours	1	10	11	3
12 to 18 hours	3	4	4	0
18 to 24 hours	1	1	1	0
Total	5	20	20	4

DISCUSSION

Intravaginal instillation of PGE2 gel has been accepted as a useful method of cervical ripening for induction of labour.[4,5] A single application of PGE2 gel has been reported to be successful in 83% to 96% of cases.[1] Successful outcome includes both spontaneous onset of labour and improvement in Bishop score.[6] Amongst primi patients 85% primis required repeat instillation. In 45% of total patients, a single application had not achieved spontaneous labour or cervical ripening and so repeat instillalation was done in them. Several institutes have attempted to use multiple instillations to overcome the problem of failure with single instillations.[8-11]

However in our study most multipara (50%) delivered within 12 hours of single instillation and most primis required repeat instillation and among them most primis delivered within 12 hours of repeat instillation.

Sasikala et al found that using 0.5 mg of PGE2 single dose intravaginally as a safe method of cervical ripening prior to induction of labor. Prolonged pregnancy was the commonest indication for induction in our study 68%, Bhatla et al, had prolonged pregnancy in 36.25% and Mainprize et al in 40%, Norchi et al in their series had only 10% of induction for prolonged pregnancy.[8-11] In our study most of our patients either had spontaneous labour or achieved a ripe cervix within 2 instillations of PGE2 gel.

18% patient were taken for emergency c section with most common indication being non progress of labour and induction failure. No changes were seen in fetal distress after single and repeat instillation. No difference is seen in c section for obstructed labour in both the groups.

CONCLUSION

In the present study PGE2 0.5mg gel is used intravaginally and found to be effective in cerical ripening and spontaneous labour. Among all 89% patients delivered spontaneously and only 11% required emergency c section. Most primi patients (85%) required repeat instillation. Most multipara delivered within 12 hours of single instillation and most primis delivered within 12 hours of repeat instillation. There is no increased fetal risk or uterine hyperstimulation with repeat instillation and beneficial if used in appropriately.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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