EVALUATE THE EFFICACY OF INSTILLATION OF INTRAVAGINAL PROSTAGLANDIN E2 GEL IN CERVICAL RIPENING: A COMPARATIVE STUDY.

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Abstract

Aim: to evaluate the efficacy of instillation of intravaginal prostaglandin E2 gel in cervical ripening.

Materials and methods: The present prospective comparative interventional study was conducted in the Department of Obstetrics and Gynecology, Nalanda Medical College and Hospital, Patna, Bihar. Total 60 patients were divided in to two groups. Group I (n=30): received two doses of 2 mg prostaglandin gel intravaginally, 6 hours apart, Group II (n=30): received single dose of 2 mg prostaglandin gel intravaginally. After administering the gel into the posterior fornix under aseptic conditions the woman was kept on the bed for 30 minutes and was observed for contractions, rupture of membranes, bleeding or fetal heart rate changes. The patients were also assessed to determine the modified Bishop score.

Results: Both the groups were comparable in demographic factors like age and period of gestation. The most common indication for induction was past dates followed by gestational hypertension and Oligohydramnios.

Conclusion: The study showed that intravaginal application of prostaglandin E2 is an effective, safe and acceptable method for induction of labor in women with unfavorable cervix and indications for induction.

Keywords: prostaglandin E2, labor, gestational hypertension, vaginal delivery, Bishop score

Introduction

Induction of labour has become an integral part of modern Obstetrics. It is indicated when the benefits to either the mother or fetus outweigh those of continuing the pregnancy.¹

Induction of labor should be simple, safe, effective and preferably non-invasive. The success of induction depends to a large extent on the consistency, compliance and configuration of the cervix.² The unripe cervix thus remains a well recognized impediment to the successful induction of labour.³

Induction of labour in an unripe cervix is associated with frequent maternal complications and leads to induction failure in up to 20-50% and associated with high rates of Caesarean delivery.⁴ 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 scenario of cervical ripening.

Local use of prostaglandin E2 (PGE2) by extra-amniotic, 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.⁵⁻⁷ Extra-amniotic use, besides being invasive is associated with increased risk of introducing infection.

The intravaginal application though less invasive and easy to use requires larger dose of the drug and hence associated with gastrointestinal side effects and uterine irritability. Besides its action is unpredictable and result often unsatisfactory.⁸ Hence the present study was conducted with the aim to evaluate the efficacy of instillation of intravaginal prostaglandin E2 gel in cervical ripening.

Materials and method

The present prospective comparative interventional study was conducted in the Department of Obstetrics and Gynecology, Nalanda Medical College and Hospital, Patna, Bihar

Inclusion criteria

- Age between 18-35 years
- Single pregnancy
- Period of gestation more than or equal to 28 weeks
- Bishop score of less than 5.

- Who give informed consent

Exclusion criteria

- Gestational age <28 weeks
- Parity >5
- History of allergy to the study drug
- Not willing to participate

Ethical approval and Informed consent

The study protocol was reviewed by the Ethical Committee of the Hospital and granted ethical clearance. After explaining the purpose and details of the study, a written informed consent was obtained.

Sample selection

The sample size was calculated using a prior type of power analysis by G* Power Software Version 3.0.1.0 (Franz Faul, Universitat Kiel, Germany). The minimum sample size was calculated, following these input conditions: power of 0.80 and $P \leq 0.05$ and sample size arrived were 24 participants in each group. The final sample achieved was 30 per group.

Grouping

Group I: received two doses of 2 mg prostaglandin gel intravaginally, 6 hours apart

Group II: received single dose of 2 mg prostaglandin gel intravaginally

Methodology

Before admission a comprehensive general physical examination, systemic and obstetric examination was conducted. After administering the gel into the posterior fornix under aseptic conditions the woman was kept on the bed for 30 minutes and was observed for contractions, rupture of membranes, bleeding or fetal heart rate changes. The patients were also assessed to determine the modified Bishop score.

Statistical analysis

The recorded data was compiled entered in a spreadsheet computer program (Microsoft Excel 2010) and then exported to data editor page of SPSS version 20 (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics included computation of percentages, means and standard deviations were calculated. Statistical test applied for the analysis was student t-test. Level of significance was set at $p \leq 0.05$.

Results

Table 1: Demographic and clinical profile

Variables	Groups	Mean	Std. Deviation	p-value
Age (Years)	I	25.20	3.48	0.532 (NS)
	II	25.57	3.52	
Gestational Age weeks	I	32.26	3.28	0.464 (NS)
	II	33.11	3.19	

Test applied: student t-test

Table 2: distribution of indications for induction

Indications	Group I N (%)	Group II N (%)
Past dates	11 (36.7%)	14 (46.7%)
Gestational hypertension	9 (30.0%)	8 (26.7%)
Oligohydramnios	3 (10.0%)	5 (16.7%)
IUGR	3 (10.0%)	1 (3.3%)
Pre-eclampsia	4 (13.3%)	2 (6.7%)

Table 3: comparison of mean induction delivery interval and contraction delivery interval

Variables	Groups	Mean	Std. Deviation	p-value
Induction delivery interval	I	12.89	3.78	0.001 (Sig)
	II	14.01	3.52	
Contraction delivery interval	I	11.76	3.91	0.001 (Sig)
	II	15.21	3.19	

Test applied: student t-test

Table 4: comparison of mean Bishop Score at different time intervals

Bishop Score	Groups	Mean	Std. Deviation	p-value
At 0 hr	I	1.19	0.48	0.632 (NS)
	II	2.01	0.72	
6 hr	I	4.78	1.28	0.564 (NS)
	II	4.97	1.19	
12 hr	I	10.91	2.11	0.001 (sig.)
	II	7.89	2.13	

Test applied: student t-test

Table 5: distribution of mode of delivery and rate of induction

Mode of Delivery	Group I N (%)	Group II N (%)
Vaginal	17 (56.7%)	14 (46.7%)
Caesarean	13 (43.3%)	16 (53.3%)
Induction rate		
Failed	1 (3.3%)	3 (10.0%)
Successful	29 (96.7)	27 (90.0%)

Discussion

A single application of PGE2 gel has been reported to be successful in 83% to 96% of cases. Successful use includes both spontaneous onset of labour and improvement in Bishop Score. However in about 5% to 25% of patients, a single application may not achieve spontaneous labour or cervical ripening. These patients may end as failed inductions if labour is induced with oxytocin as such. Several workers have attempted to use multiple instillations to overcome the problem of failure with single instillations.^{9,10} 9–12

The success of induction of labor was found to be directly proportional to the Bishop score at instillation. In a study done by Calder et al.⁷, the cervical score had improved

from a mean of 2.3 to 6.3 in 6 hours. The rate of improvement in Bishop score, in this study, was comparable to the results shown by Warke HS et al.¹¹

In our study success of induction refers to achieving vaginal delivery. In this study, 71.6% had vaginal delivery compared to study done by Warke HS et al.¹¹ which was 85.5%. The rate of failed induction was 10% in Group II. The largest reported study was conducted by Noah et al.¹² in 1986 and involved a multicentre trial under a single protocol in 16 centers in Africa where successful induction was achieved in 83%.

The induction delivery interval was shortened and fewer cesarean deliveries were performed (16%). Similarly, the success of induction in a study done by Calder et al.⁷ (1977) was 61% and 75% as per G. Jackson GM et al.¹³

The PGE2 gel has shown to shorten the induction delivery interval and thus results in less fetal and maternal morbidity and mortality. Various studies have shown considerable variation as far as induction delivery time is concerned ranging from 9 to 17.9 hours.^{12,14} In a study done by Jackson GM et al.¹³ this range was 13 to 20.2 hours.

Conclusion

The study showed that intravaginal application of prostaglandin E2 is an effective, safe and acceptable method for induction of labor in women with unfavorable cervix and indications for induction. It resulted in improved Bishop score, facilitates the process of induction, increased number of successful inductions, shortened application delivery interval and decreased cesarean delivery rate. Hence PGE2 gel can be recommended as a useful and potent method of induction of labor.

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