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Original Research Article

Comparative study of dinoprostone vaginal pessary versus PGE2 gel in labour induction: a randomised controlled study

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ABSTRACT

Background: Induction of labour is a method of prematurely or artificially stimulating the onset of labour prior to onset of spontaneous labour. Different preparations of prostaglandin are available differing in their effectiveness, side effects, and price. But the most commonly used agent for induction of labour is the shorter acting PGE2 gel. However recently the longer acting PGE2 vaginal pessary has become available. The aim of this study is to compare the efficacy of PGE2 vaginal pessary versus intracervical PGE2 gel in induction of labour.
Methods: A total of 170 antenatal patients were included in the study with 85 each group. Group A was given one dose of PGE2 vaginal pessary and group B was given PGE2 gel which was repeated for maximum of 3 doses at 6 hours interval. Patients were examined for cervical ripening, uterine contractions, fetal heart monitoring and complications. Augmentation, labour duration, type of delivery, complications were all noted for both groups.
Results: The 56.47% in pessary group and 40% in gel group did not need augmentation which was statistically significant (p=0.029). There was no difference in the mode of delivery between two groups.
Conclusions: In my study, comparing PGE2 gel with PGE2 vaginal pessary, there was no significant difference between them in efficacy and complication. The only significant difference noted in my study was reduced need for augmentation of labour in pessary than PGE2 gel.

Keywords: Induction, PGE2 gel, PGE2 vaginal pessary

INTRODUCTION

Induction of labour is a method of prematurely or artificially stimulating the onset of labour prior to onset of spontaneous labour. Induction of labour consists of preinduction cervical ripening and acceleration of uterine contractions. Labour is often induced in term pregnancies due to various fetal-maternal conditions using different methods and drug formulations.[1] In developing countries up to 25% of all term deliveries at term now involve induction of labour.[2]

Three criteria must be satisfied for induction to be successful. First the mother should have adequate uterine contractions and progressive dilatation of cervix. Secondly there should be minimum risk to mother and baby. Thirdly induction should end in vaginal delivery.

There are various methods to induce labour. Commonly used agents for induction are prostaglandin E2 (Dinoprostone), prostaglandin E1, Foley's catheter, laminaria, dilapan, oxytocin and artificial rupture of membranes.[2] Prostaglandins remain preferred method for cervical ripening and labour induction.

Prostaglandins play a crucial role in cervical ripening by increasing inflammatory mediators in cervix and inducing cervix remodelling. It acts on the cervical collagen

structure and causes degradation of collagen by peptidases and proteases with increase in glycosaminoglycans and water content of the cellular matrix, which makes the collagen fibres loose and separated. It is used when Bishop's score is <six.[7]

Different preparations of prostaglandin are available differing in their effectiveness, side effects, and price.[3,4] But the most commonly used agent for induction of labour is the shorter acting PGE2 gel. However recently the longer acting PGE2 vaginal pessary has become available.

PGE2 gel is available as 0.5 mg of dinoprostone in 2.5 ml syringe. It is placed intra-cervically. Dose is repeated every 6 hours for a maximum of 3 doses.

PGE2 vaginal delivery system (Propess) has controlled release hydrophilic matrix containing 10 mg of dinoprostone. It is a thin, flat, rectangular polymeric wafer within a white mesh polyester sac with long tail. It releases drug at a rate of 0.3 mg/hour for 24 hrs.

The advantage of longer acting pessary is single application, easy administration, easy removal when required need for fewer vaginal examinations, thus reducing the risk of ascending infections and reducing maternal anxiety related to induction of labour.[5,6]

Aim

Aim of the study was to compare the efficacy of PGE2 vaginal pessary versus intracervical PGE2 gel in induction of labour.

METHODS

Study design

The study design was of randomised controlled study.

Place of study

The study carried out at Department of Obstetrics and Gynaecology, Vijaya Hospital, Chennai. The study conducted from February 2019 to April 2020.

Inclusion criteria

Inclusion criteria included-term patient, nullipara, singleton pregnancy, cephalic presentation, clinically adequate pelvis, Bishops score of 6 or <6, intact fetal membranes, reactive fetal heart rate pattern, hypertensive disorders of pregnancy, gestational diabetes mellitus, Rh -ve pregnancy.

Exclusion criteria

Patients with Maternal-Multipara, previous LSCS, H/O antepartum haemorrhage, hypersentivity to PGE2, H/O upper segment scar, previous traumatic or difficult delivery, suspected cephalopelvic disproportion, cervical carcinoma, genital infection. Fetal-Malpresentation, cord prolapse, non-reassuring fetal heart pattern, IUGR, placenta previa, vasaprevia, unexplained vaginal bleedings were excluded from the study.

Sample size

Sample size included-170 with 85 in each group.

Procedure

Those women who fulfil the inclusion criteria were subjected to study. Consent was taken from participants in the study. Those women were randomly allocated in two groups. Group A was given PGE2 vaginal pessary and group B was given PGE2 gel.

After per vaginal examination, Bishop scoring was done. Group A was given one dose of PGE2 vaginal pessary taken out from the freezer, and inserted horizontally in the posterior fornix. It acts for a period of 24 hours. Patient was kept in recumbent position for 30 minutes after insertion. Patient was examined for uterine contractions, fetal heart rate and complications.

Pessary was removed after 24 hours of insertion or if patient entered into active labour, spontaneous rupture of membranes, uterine hyperstimulation, uterine tachysystole or fetal distress.

Group B was given PGE2 gel which was repeated for maximum of 3 doses at 6 hours interval. Patients were examined for cervical ripening, uterine contractions, fetal heart monitoring and complications. Augmentation, labour duration, type of delivery, complications were all noted for both groups.

Ethical considerations

The study abides by the rules of the ethical committee. No intervention causing harm to patient mentally, physically or financially is being done.

This study is conducted at Vijaya Hospital, Chennai.

Women with inclusion criteria were selected after explaining in detail about study design, written consent and detailed history was taken.

Those women who fulfilled the inclusion criteria were included in the study. These women were randomly allocated to 2 groups. Group A was given PGE2 vaginal pessary and group B was given PGE2 gel. PGE2 gel was repeated for maximum of 3 doses at 6 hrs interval.

Statistical analysis

Statistical analysis is going to be done by the statistical software STATA 11.0.

Continuous variables will be representing as 'mean (SD)' and categorical variables are representing as 'frequency (percentage)'. Chi square test or Fisher's exact test will be used to assess differences in categorical data. Student unpaired T test/ Mann Whitney U test will be used for differences in means of two independent data. P<0.05 will be considered significant.

RESULTS

Induction of labour is a common obstetric intervention. Failed induction results in cesarean section. Judicious use, selection of patients, timing of induction and method of induction plays a crucial role. In my study the rate of induction was around 42%.

Table 1: Baseline characteristics of patients in PGE2 vaginal pessary and PGE2 gel groups.

Characteristics	PGE2 vaginal pessary	PGE2 gel	P value
Age (years)			
20-35	81	83	0.405
>35	4	2	
Gestational age (weeks)			
37-40	58	61	0.615
>40	27	24	
Modified bishop score (mean)	3	3	0.984

Most patients where between 20-35 years in both groups. There was not much difference in number of term and post-dated patients in both groups. Mean Bishop's score was same in both groups.

Table 2: Indication for induction of labour.

Indications	PGE2 vaginal pessary	PGE2 gel
Due date	32	29
Post date	22	22
Gestational hypertension	11	10
Gestational diabetes mellitus	15	16
Rh -ve	0	1
Oligohydraminos	3	6
Obstetric cholestasis	2	1
Total	85	85

The most common indication for induction in my study was due date and postdate (59.4%). The other common indications for induction were gestational diabetes mellitus (21.76%) and gestational hypertension (9.41%).

The need for augmentation of labour was less for propess than PGE2 gel (statistically significant p=0.029). Mean induction to delivery interval in propess was 19.2 hours, whereas in PGE2 gel was 18.6 hours. Thus, patient induced with PGE2 gel delivered earlier than propess (statistically insignificant). There was no difference in the mode of delivery between two groups. Vaginal delivery was 53% in propess and 54% in gel. LSCS was done in 47% in propess, 46% in gel. LSCS due to failed induction -40% in gel group, 48.7% in pessary group. Tachysystole and hyperstimulation were more common in propess than PGE2gel. There was not much difference in the Apgar score between the two groups. Fetal complications were less in my study.

Table 3: Maternal and fetal outcome following induction of labour.

Variables	PGE2 vaginal pessary	PGE2 gel	P value
Labour augmentation	37	51	0.029 (significant)
Induction to delivery (hours)			
<12	18	18	0.155
12-24	45	34	
>24	22	33	
Vaginal delivery	40	40	0.984
Instrumental delivery	5	6	0.984
LSCS	40	30	0.984
Maternal complications	14	5	0.181
NICU Admissions	2	4	0.406

DISCUSSION

The induction of labour has continued to increase over past few decades.[8] In developed countries, number of deliveries following induction is as high as one in four deliveries.[9] According to the global survey conducted by world health organisation (WHO) in 3,00,000 antenatal mothers over 24 countries, about 9.6% were delivered by induction of labour. The result of the survey showed lower rates of induction in African countries compared with Asian and South American countries.[10]

Induction of labour is a method of prematurely or artificially stimulating the onset of labour prior to onset of spontaneous labour. Labour is often induced in term pregnancies due to various fetal- maternal conditions using different methods and drug formulations.[1]

Proper selection of patients and timing of induction are most important for successful induction and avoiding complications as induction of labour causes more strain than spontaneous labour to mother and fetus. There is

various risk for induction like caesarean delivery, postpartum haemorrhage, chorioamnionitis and uterine scar rupture.[11]

The rate of induction of labour various by institution and location. In our institution incidence of induction is around 42%. The most common indication for induction in my study was due date and post-date which accounts to 59.4%. Other common indications were gestational diabetes mellitus (21.76%) and gestational hypertension (9.41%).

Augmentation was done by amniotomy and oxytocin. The need for augmentation of labour was more for patients given PGE2 gel than pessary. In pessary group, 56.47% did not need augmentation whereas in PGE2 group, only 40% did not need augmentation which was statistically significant (p=0.029). The mean induction to delivery interval in PGE2 gel was 18.6 hrs whereas in pessary group was 19.2 hours irrespective of mode of delivery. Thus, in my study group patient induced with gel delivered earlier than pessary group though it statistically insignificant.

Successful vaginal delivery including instrumental delivery was similar in pessary (54.1%) and PGE2 gel (52.9%) groups. Similarly, LSCS rate was same in both groups. The most common cause of LSCS in both groups were failed induction. It accounts for 40% in gel group, 48.7% in pessary group. But the difference was statistically insignificant. Other causes of LSCS in both groups were fetal distress, arrest of descent, meconium-stained liquor and non-progression of labour. None of them were statistically significant.

There were not much maternal complications in both gel and pessary group. The complications noted were tachysystole, hyperstimulation and post-partum haemorrhage. Though in my study pessary had higher rate of tachysystole and hyperstimulation when compared with gel, it was statistically insignificant. The rate of postpartum haemorrhage was equal in both groups. Hyperstimulation was not an indication for LSCS in any patient. Hyperstimulation and tachysystole settled within half an hour after removing pessary. Use of tocolytics for hyperstimulation was required only for one patient. The fetal complications noted in my study were asymptomatic hypoglycaemia, perinatal depression, meconium aspiration syndrome and hyponatremic dehydration. There was no significant difference in fetal complications between two groups.

Limitations

Sample size is small. Multigravida were not included in the study.

CONCLUSION

In my study, comparing gel with process, there was no significant difference between them in efficacy and complications. The only significant difference noted in my study was reduced need for augmentation of labour in PGE2 vaginal pessary than PGE2 gel. PGE2 vaginal pessary is easy to administer and there is no need for intervention for 24 hrs unless otherwise indicated. In properly selected cases both prostaglandin gel and vaginal pessary are significantly effective in induction of labour. Induction of labour is associated with increased rate of caesarean delivery.

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

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