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Original Research Article

A PROSPECTIVE COMPARATIVE STUDY OF INDUCTION OF LABOUR WITH FOLEY CATHETER AND DINOPROSTONE GEL IN POST-DATED PREGNANCY AND ITS OUTCOME IN A TERTIARY CARE HOSPITAL

Faahima Rhismiya[1], Poorana Devi V[2]

[1]Consultant, Department of Obstetrics & Gynaecology, Mehta hospital, Chetpet, Chennai, Tamil Nadu, India
[2]Assistant professor, Department of Obstetrics and Gynaecology, Government Villupuram medical College

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Corresponding Author:
Dr. Poorana Devi V,
Email: drpoorana@gmail.com

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Abstract

Background: Post-dated pregnancies increase maternal and foetal risks, such as higher rates of induced labour, caesarean section, macrosomia, and shoulder dystocia, making induction more necessary. This study aimed to compare the success of Foley catheters and prostaglandin E2 (PGE2) in females presenting with post-dated pregnancy. **Materials and Methods:** This prospective interventional study included 100 patients who crossed the EDD + 2 days at the Government Villupuram Medical College, Mundiyampallam for one year. Patient details were collected and dating scans and bedside ultrasonography were performed. Patients were randomly assigned to two groups: Foley catheter insertion group, and PGE2 gel group. The induction rates, delivery modes, and neonatal outcomes have also been documented. **Result:** No significant differences were observed in age (p=0.93), mode of delivery (p=0.73), and gravida status (p=0.86) between the groups. The mean Apgar score at 1 min was significantly higher in the Foley group (7.5) than in the dinoprostone group (5.5) (p=0.04). Both groups had 12 patients with oxytocin and AROM in induction augmentation. Uterine tachysystole occurred in 4 patients in the dinoprostone group and none in the Foley group with a significant difference (p=0.04). Intrapartum PPH was reported in two patients in the dinoprostone group and in none in the Foley group (p=0.15). Intrapartum pyrexia was observed in 3 Foley group patients and none in the dinoprostone group (p=0.07). **Conclusion:** Both Foley catheters and dinoprostone gels increased spontaneous vaginal delivery rates and reduced caesarean deliveries, with no reported maternal or neonatal deaths. However, further studies are required to assess their efficacy.

INTRODUCTION

The desired goal of delivering a healthy baby with a healthy mother is only attained after careful planning of antenatal care and delivery. Pregnancy beyond 40 completed weeks or 280 days has an impact on maternal and perinatal outcomes for any delivery. Post-dated pregnancy carries specific hazards to both the mother and foetus. While mothers are faced with problems like increased incidences of induced labour, instrumental delivery, and a lower (uterine) segment caesarean section (LSCS) with associated morbidities, foetuses are faced with morbidities ranging from macrosomia to shoulder dystocia.[1] As there is foetal and maternal risk associated with post-dated pregnancy, the need for induction is greater with post-dated pregnancy.[2]

Induction of labour is a method of artificially stimulating the uterus to initiate labour. It is typically carried out by administering prostaglandins or oxytocin to pregnant women, or by rupturing the amniotic membranes.[3] The need for "induction of labour" arises because the advantages of delivery outweigh those of continuing to carry the pregnancy. Hence, to achieve this goal, the induction of labour procedures needs to be carefully evaluated for indication, choice of method, and skilful execution.[4] As obstetric techniques have developed rapidly and the range of obstetric services has expanded, there has been much discussion and deliberation about the rise in obstetric interventions and warranted concern has been expressed regarding the alarming increase in caesarean deliveries almost everywhere in the world.[5]

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It has been noticed in routine as well as through literature that PGE2 is a more effective method for induction of labour and has benefits in terms of early spontaneous delivery without compromising the health of the foetus and mother.[6] But we have also observed that there is controversy in the results of previously conducted studies, and the studies mentioned above were conducted on small sample sizes. So, a study intends to find a more suitable and beneficial method of induction of labour and conduct this study on a larger sample size to make this study more reliable.[7]

Aim

This study aimed to compare the success rates of Foley catheters and dinoprostone in females presenting with post-dated pregnancy.

MATERIALS AND METHODS

This prospective interventional study included 100 patients who crossed the estimated due date + 2 days in the Department of Obstetrics and Gynaecology at the Government Villupuram Medical College, Mundiyampallam for one year. This study was approved by the Institutional Ethics Committee before initiation, and informed consent was obtained from all patients.

Inclusion Criteria

Patients with sure dates, antenatal women who had regular menstrual cycles and did not conceive during lactational amenorrhea, antenatal women who crossed the expected date of delivery (EDD) +5 days confirmed by dating scan, singleton pregnancy, cephalic presentation, unscarred uterus, and intact membranes were included in this study.

Exclusion Criteria

Antenatal women before their EDD and gestational age after EDD + 5 days, who conceived during lactational amenorrhea, who had a history of previous LSCS, malpresentation, APH, CPD, foetal distress, PROM, diabetes, PIH, anaemia, foetal anomalies, macrosomia, and multiple pregnancies were excluded from this study.

Methods

A total 100 patients were randomly assigned to two equal groups using the lottery method. Patients in Foley group (n=50) underwent Foley catheter insertion using specific techniques and monitoring. Dinoprostone group (n=50) was administered PGE2 gel with subsequent assessments.

All patient details were systematically recorded; physical, systemic, and abdominal examinations were performed. EDD was confirmed through a dating scan, ensuring regular menstrual cycles and bedside ultrasonography was performed on admission to check for oligohydramnios. Continuous foetal monitoring was performed using cardiotocography (CTG) to identify any signs of foetal distress. Following aseptic precautions, the vaginal examination was performed after confirming intact membranes.

In Foleys group, a speculum examination was performed, and an 18F standard latex Foley catheter was inserted using an aseptic technique above the internal cervical os and inflated with 50 ml of sterile water. The catheter was taped to the inner thigh with slight traction and the lumen was occluded. The position and traction of the balloon were checked once or twice every hour, and the catheter remained in place until the balloon was expelled spontaneously.

In the Dinoprostone group, the PGE2 gel was applied. they received an initial 0.5 mg dose per vaginum (PV) which was inserted intracervically. Post-insertion CTG was performed for at least 30 minutes. All the patients were monitored clinically for the progress of labour and foetal well-being. Partograms were maintained for all cases. Reassessment was performed using the bishop score after 6 h in Group B. PGE2 gel was reapplied if the bishop score was < 6. After 12 h, if the bishop score was < 6, they were considered to have failed induction, and if the CTG was found to be non-reactive, they were considered for LSCS. Induction rate, mode of delivery including instrumental and vacuum delivery, operative interference, and intrapartum haemorrhage were monitored. Maternal morbidities such as uterine hyperstimulation with or without abnormalities in foetal heart rate, atonic postpartum haemorrhage, 3rd-degree perineal tear and complete perineal tear were noted and analysed. Foetal outcomes such as low Apgar score, meconium aspiration syndrome, NICU admission, macrosomia and shoulder dystocia were also noted, tabulated and analysed.

Statistical Analysis

Data are presented as mean, standard deviation, frequency, and percentage. Continuous variables were compared using an independent-sample t-test. Categorical variables were compared using Pearson's chi-square test. Significance was defined as $P < 0.05$, using a two-tailed test. Data analysis was performed using IBM-SPSS version 21.0 (IBM-SPSS Science Inc., Chicago, IL).

RESULTS

The mean age for the Foley group is 28.09±6.3 years, and the Dinoprostone group is 27.63±8.4 years. There were no significant differences in age (p=0.93), mode of delivery (p=0.73), and gravida (p=0.86) between the groups [Table 1].

At 1 min, the good group had a mean Apgar score of 7.5, whereas the admitted group had a lower score of 5.5. At 5 min, the good group showed further improvement, with a mean score of 8.5, compared to 6.5 in the admitted group, which showed a significant difference (p=0.04) [Table 2].

Under induction augmentation, oxytocin was used in 32 patients in Foley's group, and ARM was performed in six patients. In the dinoprostone group, oxytocin was used in 28 patients and ARM was

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performed in 10 patients. Both groups had 12 patients with oxytocin and AROM. Regarding the levels of NICU, in Foley's group, level I had 7 patients and level II had 5 patients. In the dinoprostone group, level I had 10 patients and level II had 3 patients [Table 3].

In the Foley group, 37 neonates had good outcomes and 13 were admitted. In the Dinoprostone group had 38 neonates with good outcomes and 12 were admitted. There was no significant difference in the neonatal outcomes between the two groups (p=0.72) [Table 4].

Uterine tachysystole was observed in four patients in the dinoprostone group and none of the patients in the Foley group, with a significant difference (p=0.04). In the dinoprostone group, intrapartum postpartum haemorrhage occurred in 2 patients, and none of the patients had it in the Foley group. Additionally, intrapartum pyrexia was noted in none of the dinoprostone patients compared to three in the Foley group. There were no significant differences in intrapartum PPH (p=0.15) and intrapartum pyrexia (p=0.07) between the groups [Table 5].

Table 1: Demographic details, mode of delivery and gravida between groups

		Foleys groups	Dinoprostone groups	P value
Age (in mean)		**28.09±6.3**	**27.63±8.4**	**0.93**
Mode of delivery	Forceps	0	3	0.73
	Labour natural	30	37	
	Vacuum	7	2	
	LSCS	8	13	
Gravida	Primi	38	36	0.86
	Multipara	12	14	

Table 2: Comparison of mean Apgar score among neonates

		Mean		P value
		Good	Admitted	
Apgar score	1 min	7.5	5.5	0.04
	5 min	8.5	6.5	

Table 3: Induction augmentation and level of NICU admission postpartum among study patients

		Foleys group	Dinoprostone group
Induction augmentation	Oxytocin	32	28
	Artificial rupture of membranes	6	10
	Oxytocin and AROM	12	12
Level of NICU	I	7	10
	II	5	3

Table 4: Neonatal outcomes

		Good	Admitted	P value
Neonatal outcomes	Foleys	37	13	0.72
	Dinoprostone	38	12	

Table 5: Maternal outcomes

Maternal outcome		Dinoprostone	Foleys	P value
Uterine tachysystole	Yes	4	0	0.04
	No	46	50	
Intrapartum PPH	Yes	2	0	0.15
	No	48	50	
Intrapartum pyrexia	Yes	0	3	0.07
	No	50	47	

DISCUSSION

In the present study, we compared the efficacy and safety of dinoprostone intracervical gel with those of Foley's catheter for induction of labour in post-dated pregnancies. Two groups of 50 patients each were recruited for this study, which met all inclusion criteria. Although several studies have been conducted to compare induction methods and identify the safest and most effective induction of labour methods, no consensus has been reached. The factors that need to be considered when selecting an ideal cervical ripening method include surgical delivery rates (C-section), induction to delivery interval, maternal complications, and neonatal outcomes. Many of these outcomes can be used as indicators of the effectiveness of induction methods. Efficacy and safety are equally significant factors when selecting a method for IOL implantation and cervical ripening. Therefore, an ideal agent provides a balance between the two factors, with minimal side effects for the parturient and the neonate.

In our study, the mean age of the patients in the dinoprostone gel group was 27.63±6.3 years and, that in Foley's group was 28.09±8.4 years. In the study conducted by Mathuriya et. al., the mean age of the subjects in the gel group was 23.5 years and in Foley's group was 24.2 years.[8]

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In our study, 72% and 76% of the patients were primigravida in the dinoprostone and Foley groups respectively. In the study conducted by Dahiya et. al., 56% of patients in the gel group and 62% in the Foley group were primigravidas.[9]

In our study, the rates of normal vaginal delivery were slightly higher in the Foley's group (60%) as compared with the rates in the gel group (74%). In a study conducted by Pennell et al., the rate of vaginal delivery was comparable between the gel group (38%) and the Foley group (41%).1[10]However, in the study by Mathuriya et. al., the rate of normal delivery was slightly higher for the gel group (87%) versus that for the Foley group (73%).[8]

In our study, the rates of C-sections were not comparable between the two groups (26% vs. 16%), which is in line with the data reported by Jha et al. Out of 80 patients with previous caesarean section, 52 (65%) patients had a repeat caesarean section.[11] However, a study by Dahiya et. al. showed slightly higher rates of C-sections in the gel group 9 while Mathuriya et. al. demonstrated higher rates for C-sections in the Foley's group.[8]

In our study, most neonates (74% in the gel group vs. 76% in Foley's group) did not have any complications requiring admission to the neonatal nursery (Level I) or special care unit (Level II). The rates of neonatal admission to the NICU were comparable between the two groups (24% in gel vs. 26% in Foley's). 77% were level I admissions, and 23% were level II admissions. In the Dinoprostone group, 58% were level I admissions and 42% were level II admissions. No neonatal deaths occurred during this period. In the study by Mathuriya et. al., 13.3% of the neonates required admission to NICU (Level I or II) with slightly more admissions in the Foley's group (16% vs 10.7%) due to birth trauma, asphyxia, respiratory difficulties, and jaundice requiring phototherapy.[8]

CONCLUSION

Both Foley and dinoprostone gels were associated with higher rates of spontaneous vaginal delivery and were equally efficacious in induction. There was a significant reduction in caesarean deliveries in both groups. No neonatal or maternal deaths occurred in either group. Further studies should be conducted in the future to determine their efficacy.

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