Research Paper

Volume : 4 | Issue : 4 | April 2015 • ISSN No 2277 - 8179

Comparative Study of Intracervical PGE2 Gel With Extra Amniotic Foley's Catheter for Pre-Induction Cervical Ripening

Medical Science

KEYWORDS : Foley's catheter , cervical ripening, PGE2 gel

Dr.Savitha.T.S	Associate professor, Dept of OBG, KIMS Hospital and Research Centre , VV Puram, Bangalore , Karnataka , India.
Dr.kanmani T.R	Medical Social Worker, dept of OBG, KIMS Hospital and Research Centre , VV Puram, Bangalore , Karnataka , India.
Dr.Nirmala S	Professor, dept of OBG, KIMS Hospital and Research Centre , VV Puram, Bangalore , Karnataka , India.
Dr.P.Marimuthu	Addl Prof, Dept of Bio-statistics, NIMHANS, Hosur Main Road, Bangalore-11, India.

ABSTRACT

Background : The success of induction of labor depends on the cervical status at the time of induction.Objective: Is to compare the efficacy of extra amniotic Foley's catheter and intracervical PGE2 gel in cervical ripening for the successful induction of labor, maternal and fetal outcome. Study design: Randomized prospective study conducted in KIMS hospital between Jan 2012 to June 2013. 80 pregnant women attended labour ward for induction of labor are included. 40 patients received Dinoprostone gel and 40 patients received intracervical extra amniotic foley's catheter.Results: Both groups were comparable with respect to maternal age, parity, gestational age, indication for induction and initial bishop score. Both groups showed significant change in Bishop score after 12hours 7.21 and 7.81 for PGE2 gel and Foley's catheter respectively. There was no significant difference in the side effects between two groups. Cesarean sections were performed in 32.5 % in PGE2 group and 27.5 % in Foley's catheter group. The induction delivery interval was 16.96 ± 7 hrs in PGE2 group and 20.03 ±7.96 hrs in Foley's catheter group. APGAR score, birth weight and NICU admissions showed no differences between the two groups. Conclusion: The present study shows that both PGE2 gel and Foley's catheter are equally effective in preinduction cervical ripening.

Introduction:

The overall aim of obstetric practice is safe termination of pregnancy with a healthy baby and with minimal or no complications. Labor induction is the artificial initiation of uterine contractions prior to spontaneous onset leading to progressive effacement and dilatation of cervix. It is indicated where the benefits to either the mother or the fetus outweighs the benefits of continuing the pregnancy.

The success of labor depends on the cervical status at the time of induction.Cervical ripening refers to the process of preparing the cervix for induction of labor by promoting effacement and dilatation as measured by Bishop's score. To decrease the induction failure, cervical ripening is found to be the best method. Many pharmacological preparations are used like prostaglandins, (PGE1and PGE2) and oxytocin as the ripening agent. The prostaglandins mainly act through fibroblast activity and promote infiltration of leucocytes and macrophages in the cervical stroma. These cells are source of degraditive enzymes and change in extra cellular matrix associated with ripening. But systemic absorption can cause side effects like nausea, vomiting and uterine hyperactivity and fetal distress.

Foley's catheter is a mechanical method which strips the fetal membrane from lower uterine segment and causes the release of prostaglandins which improves effacement and consistency of the cervix. But Foley's catheter has not gained much popularity because of fear of infection. Therefore the study was undertaken.

Materials and Methods:

The prospective randomized study was conducted in the department of OBG KIMS hospital from June 2013 to November 2014. 80 pregnant women admitted for labor induction were selected for the study after a written and valid consent.

Inclusion criteria :

1. Primigravida
2. Singleton pregnancy
3. Cephalic presentation
4. ≥37 weeks of gestation
5. Bishop's score ≤4
6. Intact membranes
7. No previous scars on uterus

Exclusion criteria:

1. Multiple pregnancy
2. Malpresentation
3. Antepartum haemorrhage
4. Local infections –vaginitis
5. Medical disease like heart disease or renal disease.

Procedure:

The patients were randomly allocated in two groups. Group A and Group B.

Detailed history was collected regarding medical, surgical and obstetric. Vaginal examination was performed to rule out Cephalopelvicdisproportion and to assess Bishop Score. The ultra sound examination was conducted for gestational age, liquor volume, fetal maturity and well-being. Pre and post induction NST was taken.

Group A: PGE2 gel or Dinoprostone 0.5 mg was instilled intracervically. Patients were reassessed after 6 hours and if there was no improvement in Bishop score patient was subjected to another dose of Dinoprostone gel and again reassessed after 6 hours. Upto maximum of 3 doses of PGE2 gel within 24hours was used.

Group B: Under all aseptic precautions Foley's catheter no 16F was introduced through the cervix past the internal os and inflated with 30 ml of distilled water. The catheter was deflated and removed after 12 hours or earlier if membranes ruptured or patient went into active labour. Rescoring of bishop score was carried to note down the improvement in Bishop score.

If the contractions are not adequate in active phase of labour, oxytocin was started and if needed ARM was conducted to hasten the process of labour. Oxytocin augmentation was started if Bishop score was more than 6 in both groups. Women with no improvement in Bishop score at the end of 24 hours was considered as failure. Partogram was maintained throughout the labor. The primary outcome was change in Bishop score. The secondary outcome was the need for oxytocin augmentation, induction delivery interval, mode of delivery, maternal complications and neonatal outcome.

The data thus obtained was entered in an excel sheet and analyzed using Statistical Package for Social Services (Vs 18). The categorical variables were presented in the form of frequencies and percentages. The quantitative variables were analyzed using means and standard deviations. The Chi square test was used as a test of significance for categorical variables. A p value of less than 0.05 was considered as statistically significant.

Results:

Among 80 patients, 40 patients were selected for PGE2 gel (group A) and 40 patients (group B) for foley's catheter. The mean age of the patients was 24.2 ± 3.53 and 24.2 ± 3.8 and gestational ages in weeks were 39.6 ±14 and 40± 1.26 in group A and group B respectively as shown in Table-1. Indications for induction were mainly for postdatism and oligohydramnios in both group A and B.

Table 1 : Patient characteristics

Variable	Gr A (n=40)	Gr B (n=40)	p- value
Maternal age (mean±SD)	24.2±3.53	24.2±3.8	N.S
Gestational age (in weeks mean±SD)	39.60±1.4	40±1.26	NS

Table 2: Mean change in Bishop Score

Bishop Score	Group A	Group B	p-value
Mean score at 0 hour	2.37±0.73	2.7±0.71	NS
Mean score at 12 hour	7.20±3.50	7.81±2.94	NS
Mean change in bishop score	4.83±1.77	5.11±1.43	NS

Table 3: Outcome of both groups

Variables	Group A PGE2 gel N(%)	Group B Foley's group (%)	p-value
Oxytocin augmentation	35(87.5)	32(80.0)	NS
Mode of delivery FTVD Outlet forceps Vacuum delivery LSCS	 22(55) 2(5) 3(7.5) 13(32.5)	 28(70) 1(2.5) 0(0) 11(27.5)	NS
Induction delivery interval	16.96±7.0hours	20.03±7.96hours	NS

Table 4: Indication for cesarean section

Indication for LSCS	Group A n(%) 13(32.5)	Group B n(%) 11(27.5%)	P value
Fetal distress MSAF Non-progression of labour	4(10%) 1(2.5%) 8(20%)	6(15.0%) 1(2.5%) 4(10.0%)	NS

TABLE -5 Neonatal outcome

Variable	Group A	Group B	P value
Birth weight in kgs	2.94±0.3	2.88±0.4	NS
1 min APGAR 5 min APGAR NICU admission	7.14±0.224 8.80±0.345 4(10%)	6.82±0.834 8.43±0.241 9(22.5%)	NS

Oxytocin was started when Bishop Score was >6 in both the groups. A total of 5(12.5%) and 8(20%) women in group A and group B respectively did not receive any Oxytocin supplementation.

In group A: 11 patients received single dose of PGE2 gel and 14 patients received 2 doses of PGE2 gel and 15 patients received 3 doses of PGE2 gel. In group B no Foley's catheter was replaced.

Table-2 shows mean change in bishop score 0 hr and 12 hour. In group A mean change in bishop score was 4.83±1.77 and in group B 5.11±1.43. However there is no significant difference in the mean changes between two groups.

Oxytocin augmentation was required in 35 patients (87.5%) in group A and 32 patients (80%) in group B. In group A 27(67.5%) and in group B 29(72.5%) women delivered vaginally. In PGE2 gel group 13(32.5%) patients and in Foley's group 11(27.5%) patients underwent Cesarean section. There was no statistical significant difference was found with respect to route of delivery as shown in Table-3. Induction delivery interval (hour) in PGE2 gel was 16.96±7.0 and in Foley's group was 20.03±7.96. Tachysystole was observed in one patient with PGE2 gel and no one in the second group.

Incidence of meconium aspiration was almost similar in both the groups. The incidence of perinatal asphyxia with APGAR score ≤7 at 5 min were similar in both the groups as shown in table-4 and 5. Morbidity in both the groups was not significant.

Discussion:

The findings of our study shows both Foleys catheter and PGE2 gel are effective methods of cervical ripening. Prostaglandins like PGE2 are used extensively for cervical ripening. But these pharmacological agents are unstable at room temperature and not readily reversible if required like when there is a uterine hyperactivity or fetal distress. They are coupled with variable absorption, bronchospasm, and require continuous monitoring.

Embray and Mollison1 (1967) were the first to describe the use of Foleys catheter for cervical ripening. The Foleys catheter insertion is comparatively easier than other mechanical methods, reversible if needed, low cost and do not require continuous monitoring as uterine hyperactivity is less.

In our present study there was a significant change in bishop score at 0 and 12 hours and almost similar between the groups. The findings also conclude that either method doesn't have a statistical advantage over the other. There was no significant difference between prostaglandins and Foley's catheter in route of delivery and induction delivery interval. The usage of oxytocin 35(87.5%) in group A and 32(80%) in group B was in agreement with other studies. (3,4,5) The present study also revealed that there was no infection found with Foleys group.

Volume : 4 | Issue : 4 | April 2015 • ISSN No 2277 - 8179

Scissicone et al2 compared the two methods and showed that Foleys catheter group had a shorter induction delivery interval. Our present study findings incorporates the findings of St.Onge's and Connors(3,6) that foley's catheter and PGE2 gel found to be effective in improving the bishop score. Even the earlier study of Ezimokhai and Nwabinelli(4) and also recent study of Dahiya etal (6)and laddad et al (7)found that ripening effect of a Foleys catheter versus PGE2 gel were similar.

Conclusion: To conclude with, present study shows that intracervical prostaglandins and Foleys catheter appeared to be effective agents for cervical ripening and labor induction. Significantly Foleys catheter cost was lesser compared to PGE2 gel and thus appeared to be very useful in developing countries.

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