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Dr. Vaishali Singh
Post Graduate Student (Presently
Senior Resident, Department of
Obstetrics & Gynecology, VMMC &
Safdarjung Hospital, New Delhi,
India

Dr. Paras Nath
Medical Officer, Hospital Siliguri,
Siliguri, West Bengal, India

Comparison of intracervical PGE2 gel and transcervical foley's catheter for preinduction cervical ripening

Dr. Vaishali Singh and Dr. Paras Nath

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Abstract

Introduction: Induction of labour is a common obstetric intervention, occurring in approximately 25% of term pregnancies in developing countries. Pharmacological and mechanical methods commonly used are prostaglandin preparations (PGE1 and PGE2) and various intracervical catheters (single or double balloon), respectively.

Material and Methods: Study was conducted in Siliguri District Hospital, Siliguri, Darjeeling, west Bengal. 100 antenatal woman admitted in obstetrics ward with pog more than 37 weeks were taken for study after applying inclusion and exclusion criteria. 50 were induced with cerviprime gel and 50 with intracervical foley catheter. Statistical analysis done.

Results: Mean interval between treatment initiation and delivery was not statistically significant, tachysystole was more common in group B women, rate of LSCS and NVD was similar in both groups.

Conclusion: It can be concluded from the present study that Foley's catheter {mechanical} and prostaglandin E2 gel [pharmacological] both are effective agents for preinduction cervical ripening which substantially improve the bishops score and increase the chances of successful labour induction. There is no significant difference in their efficacy, mode of delivery and perinatal outcome.

Keywords: PGE2 gel, transcervical foley's catheter, preinduction cervical ripening

Introduction

Induction of labour is a common obstetric intervention, occurring in approximately 25% of term pregnancies in developing countries. The increased caesarean delivery risk associated with induction is strongly influenced by the induction attempt duration, especially with an unfavorable cervix [5].

Common indications for induction of labour include postdated pregnancy, preeclampsia, and eclampsia, intrauterine fetal growth restriction, prelabour rupture of membranes, malformed foetuses, Rh-isoimmunisation, severe hydramnios, abruptio placenta, intrauterine fetal demise chorioamnionitis, oligohydramnios, maternal medical conditions like chronic nephritis, hypertension diabetes etc.

The contraindications to induction of labour include like previous myomectomy, previous uterine rupture, fetal transverse lie, placenta previa, vasa previa, invasive cervical cancer, active genital herpes, and previous classical or inverted T uterine incision [except in unusual circumstances such as extreme prematurity].

Pharmacological and mechanical methods commonly used are prostaglandin preparations (PGE1 and PGE2) and various intra cervical catheters (single or double balloon), respectively.

Cervical ripening refers to a process of preparing the cervix for induction of labor by promoting effacement and dilatation as measured by Modified Bishop's score.

Ripening of cervix may be achieved by mechanical techniques such as introduction of transcervical Foleys catheter [14, 15]. It can cause mechanical dilatation of cervix and stimulates endogenous release of prostaglandins by stripping the fetal membranes and release of lysosomes from decidual cells.

Material and Methods

The study was conducted in Siliguri District Hospital, Siliguri, Darjeeling, West Bengal, for a period of one year extending from January 2018 to December 2019. It was approved by ethical committee of the institution. All the cases fulfilling the inclusion and exclusion criteria and willingness to participate in the study were included in the study and they were divided into two groups. There were total 100 cases.

Corresponding Author:

Dr. Vaishali Singh
Post Graduate Student (Presently
Senior Resident, Department of
Obstetrics & Gynecology, VMMC &
Safdarjung Hospital, New Delhi,
India

Inclusion criteria

- Primigravida ≥ 37 weeks of gestation
- Singleton pregnancy
- Cephalic presentation
- Bishop's score ≤ 3
- Intact membranes
- Cases where conditions were fulfilled for vaginal delivery

Exclusion criteria

- Multiple pregnancy
- Malpresentation
- Absent membrane
- Antepartum haemorrhage
- Previous uterine scar
- Medical diseases, e.g. heart disease, renal disease.

Foley's catheter

An 18 size Foley's catheter (it comes in pre-sterilized pack using ethylene oxide) was introduced through cervix to extra-amniotic space using a sterile technique with the aid of a speculum and sponge holding forceps and 30 ml distilled water was instilled into the balloon. Then balloon is pulled up to the internal os.

Catheter was tapped with thigh. Prophylactic antibiotic was given.

Prostaglandin gel

PGE2 gel is available in the name of cervi-prime gel as a sterile preparation containing 0.5 mg of dinoprostone per 3 gm (2.5 ml) of gel in a prefilled syringe with a catheter for endocervical application. After exposing the cervix by speculum 0.5 mg of PGE2 was inserted intra-cervically from a loaded syringe and the patients were kept in lying down position at least 30 minutes for absorption of drugs.

Results

The study included 100 antenatal women attending in Siliguri District Hospital, Siliguri West Bengal, India from the period of January 2018 to December 2019, In Foley's catheter group, the mean interval between treatment initiation & delivery was 17 hrs. In PGE2 group mean interval between treatment initiation & delivery was 16 hrs. Difference of mean interval between treatment initiation & delivery between the two groups was not statistically significant ($p=0.4446$).

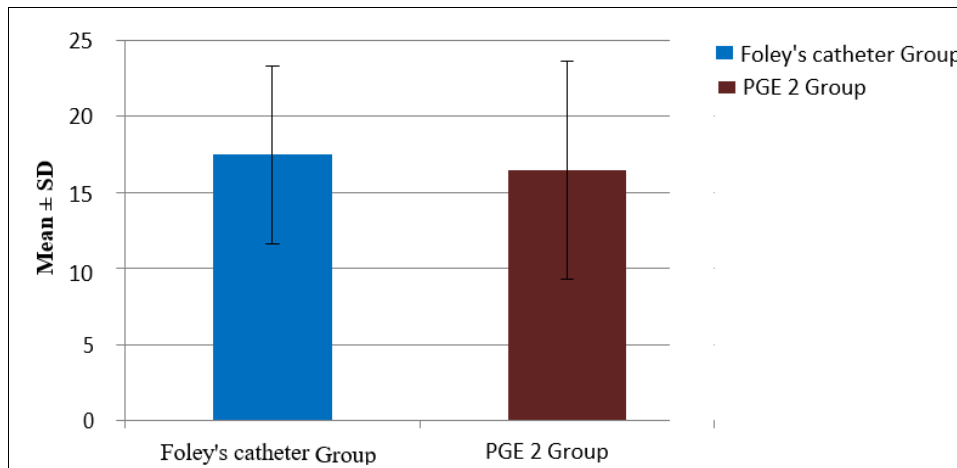


Fig 1: Mean Interval between treatment initiation and delivery (hours)

The indications were similar in the two groups, According to indication of induction, maximum number of patients 17(34.0%) were post-dated in both Foley's catheter and PGE2 group.

Association of indication of induction vs. group was not statistically significant ($p=0.5734$).

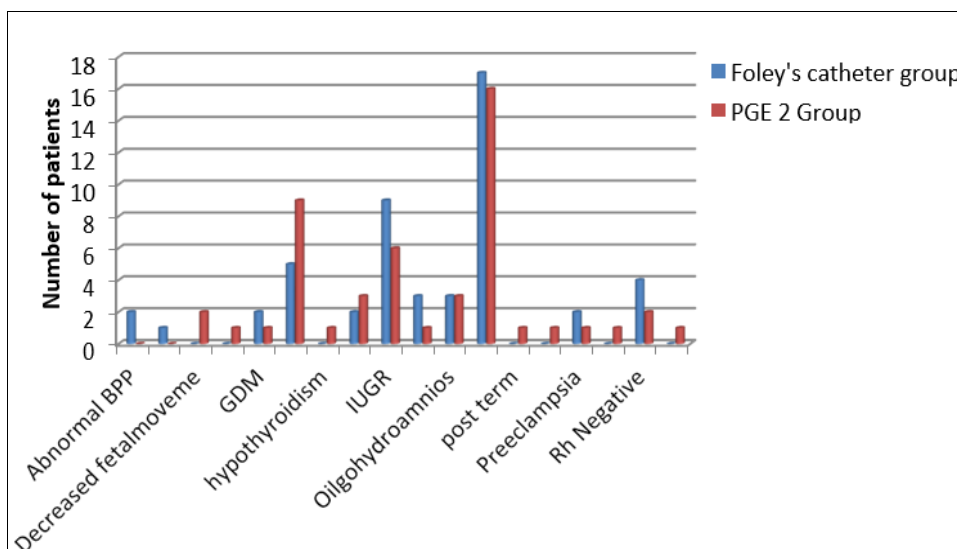


Fig 2: Indication of induction

Table 1: Maternal Complications

Maternal complications	Group A N (%)	Group B N (%)	Total	P-Value
No	46(92%)	43(86%)	89	0.65272
PPH	2(4%)	4(8%)	6	0.25014
Puerperal Sepsis	1(2%)	0(0%)	1	0.15854
Intrapartum Pyrexia	1(2%)	0(0%)	1	0.15854
Tachysystole	0(0%)	3(6%)	3	0.01428
Total	50	50	100	

Only four patients in Group A and seven patients in Group B developed some complications. Out of these, two patients in Group A and four patients in group B had PPH. One patient in Group A and no patient in Group B developed puerperal sepsis. One patient in Group A and no patient in Group B developed

intrapartum pyrexia. No patient in Group A and 3 patients in Group B developed tachysystole. Out of all these complications, only tachysystole achieved statistically significant difference (p value=0.01428)

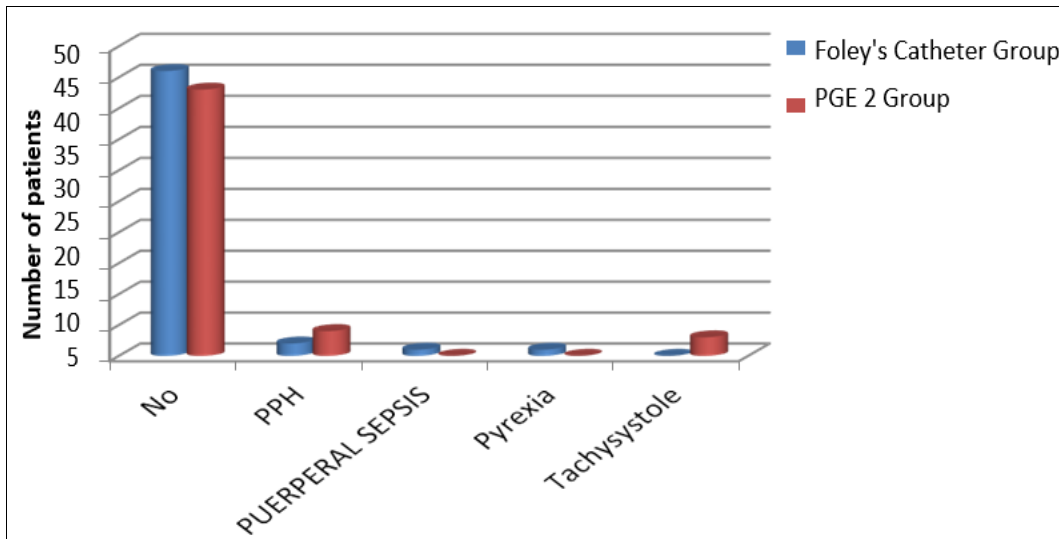


Fig 3: Maternal Complications

In Group A, 47(94.0%) patients had no fetal adverse effects. In Group B, 41(82.0%) had no fetal adverse effects. In group A, 2 patients had abnormal fetal heart rate whereas 5 patients in Group B had abnormal fetal heart rate. 1 patient in Group A had meconium passage whereas no patient in group B had meconium

passage. Presence of both MSL and abnormal fetal heart rate was present in 4 patients in Group B. Which was significantly higher compared to group B which had no patients with both MSL and abnormal FHR (p=0.00466).

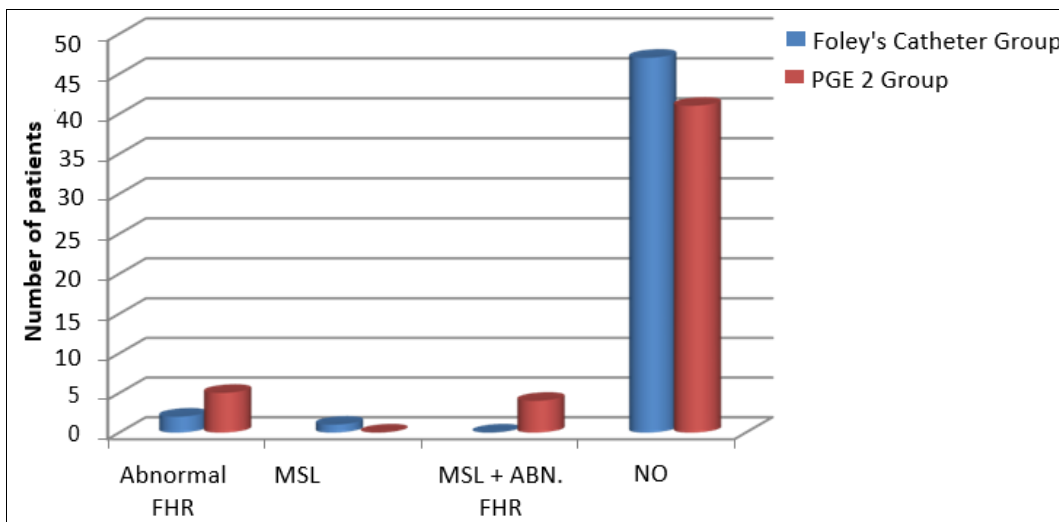


Fig 4: Fetal Adverse effects

In Group A, 39 patients had normal vaginal delivery, 3 patients were delivered by ventouse and 1 patient had forceps delivery. In Group B, 36 patients had normal vaginal delivery, 4 had

ventouse and 2 had forceps delivery. Rate of LSCS was 14% in Group A and 16% in Group B. The difference was not statistically significant. (p=0.3644).

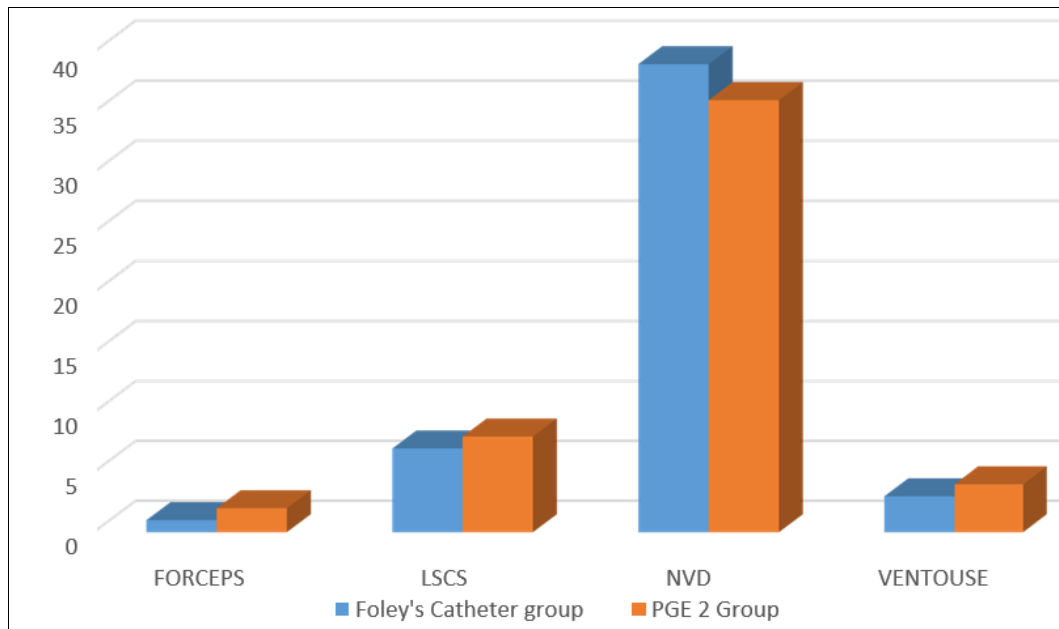


Fig 5: Mode of delivery

Discussion

The present study was conducted in Siliguri District Hospital, Siliguri, Darjeeling, West Bengal. 100 pregnant patients after 37 weeks gestation was randomly allocated into two groups:

Group A: Induction with extra amniotic Foley's catheter.

Group B: Induction with intracervical PGE2 gel.

We found that in Foley's catheter group, the mean age (Mean± S.D.) of patients was 25.2200 ± 4.4414 years. In PGE2 group, the mean age (Mean± S.D.) of patients was 24.5400 ± 3.7099 years. Thus age was matched in this study and difference of mean age in two was not statistically significant ($p=0.4081$).

We also found that difference of mean interval between treatment initiation & delivery between the two groups was not statistically significant ($p=0.4446$).

We found that in Foley's catheter group, 3 (6.0%) babies had NICU admission. In PGE2 group, 5(10.0%) patients had NICU admission. There was no statistically significant difference in NICU admission between the two groups ($p=0.4609$).

Alam A *et al.*, (2017) ^[41] found that apgar scores, birth weights and NICU admissions showed no significant difference between the two groups. This was comparable to our study. That study shows that both Foley's catheter and PGE2 gel are equally effective in pre induction cervical ripening.

We found that according to indication of induction, in Foley's catheter group, 17(34.0%) were postdated whereas in PGE2 group, 16(32.0%) had postdated. There was no difference between the two groups ($p=0.5734$).

We found that in Foley's catheter group, higher number of patients 46(92.0%) had no maternal complications. Similarly in PGE2 group, higher number of patients 43(86.0%) had no maternal complications. Among all the maternal complications like intrapartum pyrexia, tachysystole, PPH, puerperal sepsis, only tachysystole was significantly high in PGE2 group compared to foley's group($p=0.0148$)

Patabendige M *et al.*, (2017) ^[38] found that during induction of labour, 53(95%) reported mild or no discomfort. MBS of 6 or more was achieved in 36/56 (64%) Foley insertions. Twenty needed further intervention with prostaglandins. FC only group

had 5 caesarean sections and 31 vaginal deliveries and Foley/prostaglandin group had 7 caesarean sections and 13 vaginal deliveries.

In foley's catheter group, 2 out of 7 patients had undergone LSCS in view of failed induction, 2 due to fetal distress and 3 due to non-progress of labour. In PGE2 group, 2 out of 8 patients had undergone LSCS in view of failed induction and 6 due to fetal distress. This difference between the two groups was not statistically significant ($p=0.2236$).

Rabindranath dalui *et al.*, ^[32] found that extra amniotic Foley's catheter balloon is an effective, safe, simple, reversible, non-pharmacological mechanical method of preinduction cervical ripening.

Conclusion

It can be concluded from the present study that Foley's catheter {mechanical} and prostaglandin E2 gel [pharmacological] both are effective agents for preinduction cervical ripening which substantially improve the bishops score and increase the chances of successful labour induction. There is no significant difference in their efficacy, mode of delivery and perinatal outcome. The mean change in bishop's score at 6 hours was comparable in both groups. At 12 hours improvement in bishops score was significantly more in the Foley's catheter group. Induction of delivery interval was comparable in the two groups. Foley's catheter did not decrease the rate of caesarean section significantly but number of caesarean section done for fetal distress was less than the prostaglandin group but it was not statistically significant. Foleys catheter has fewer side effects and causes no uterine tachysystole so very strict monitoring of uterine contractions are not required during the ripening phase. It also lacks the pharmacological side effects like vomiting and headache. Foley's catheter causes a six fold decrease in cost as compared to PGE2 gel. Incidence of combination of meconium stained liquor and fetal distress was more in the prostaglandin group, however NICU admission rate and mean Apgar score at 5 min of birth was similar in both the groups. In developing countries where cost is an important limiting factor and very stringent conditions for storage of prostaglandins may not be available, Foley's catheter is a safe effective and relatively inexpensive means of performing preinduction cervical ripening.

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