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A Comparative Study of Safety & Efficacy of Foley's Induction with Prostaglandin E2 Gel Induction

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ABSTRACT: ***Background:*** To compare maternal and fetal outcome with intracervical foley's catheter and intracervical PGE2 gel on pre-induction cervical ripening for induction of labor. ***Methods:*** A Prospective Longitudinal study was carried out in antenatal cases beyond 37 weeks at tertiary care hospital, maharashtra. Pertinent data was collected and analyzed. ***Results:*** 50% patients were induced with PGE2 Gel (Group 1) and 50% patients were induced with Foley's catheter (Group 2). The mean time interval between time of induction and delivery was 14.63±3.42 hours in Group 1 and 15.73±2.20 hours in Group 2. 52 (69.4%) patients in Group 1 had Full Term Normal Delivery (FTND) while 21 (28%) had Lower Segment Caesarean Section (LSCS). 73 (97.4%) patients in Group 2 had FTND while 1 (1.3%) patient had LSCS. The preinduction and postinduction bishops score between the groups was (3.53±0.84 vs. 3.44±0.74) and (6.91±1.24 vs. 7.33±0.83) respectively. ***Conclusion:*** Induction with foley's catheter has significant improvement in Bishop's score and shorter induction delivery interval as compared to PGE2 gel. Foleys catheter is advantageous as it lacks specific storage condition. It could be considered a cost effective alternative for pre induction cervical ripening.

Keywords: Induction of labor, Foley's catheter, PGE2 gel, Bishop's score, Maternal and fetal outcome.

RESEARCH PAPER

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INTRODUCTION

The aim of induction is to perform a safe vaginal delivery. Induction is a challenge to the clinician; mother & fetus must be selected & supervised carefully. Labor induction is a frequently used method in the management of high-risk pregnancy. At present, both medical and mechanical methods have been applied for cervical ripening in women with an unfavorable cervix.

As the oldest methods to induce labor, mechanical methods were developed to promote cervical ripening and the onset of labor by dilating the cervix. Hygroscopic and osmotic dilators are effective, but they might be associated with an increase in maternal infection and are seldom used in the term labor induction. Currently, Foley catheter balloon is the most commonly used mechanical device for labor induction, which acts not only as a mechanical dilator of the cervix but also a stimulator of endogenous prostaglandins release from the fetal membranes.

Oral and parenteral routes of administration of prostaglandins are associated with unacceptably higher rates of gastrointestinal side effects (25-55%). Local applications of Prostaglandin E2 (PGE2) gel in the form of intracervical gel are associated with fewer side effects.

Prostaglandin E2 intracervical gel contains 5mg Dinoprostone & when applied locally it induces collagen break down, dispersion, fluid absorption by stromal tissues & effective cervical ripening for induction of labor. In some cases early uterine activity may start as well. But it is relatively expensive & requires refrigeration.

OBJECTIVES

1. To compare the safety of labor induction with intracervical foley's catheter and intracervical PGE2 gel in pre-induction cervical ripening.
2. To evaluate and compare the efficacy between intracervical foley's catheter and intracervical PGE2 Gel in labor induction

3. To find out and compare maternal and fetal outcome between the two groups.

MATERIAL AND METHODS

A Prospective Longitudinal study will be carried out in the Department of Obstetrics and Gynecology of Rural Medical College, Loni. All antenatal patients, beyond 37 weeks of gestation who will be induced for poor progress of labor in the Department of Obstetrics and Gynecology of Pravara Rural Hospital (PRH, Loni) will be included as study subjects. Women who will be not willing to participate in the study will be excluded. Pertinent data will be collected using a pre-validated and pre-tested study tool, from all study subjects, during a study period of October 2018 to September 2020.

Inclusion Criteria

- Completed 37 weeks of Pregnancy induced with PGE2 gel or Foley's catheter
- Singleton pregnancy with vertex presentation
- Cervix Bishop's Score <6
- No Contraindication to vaginal delivery

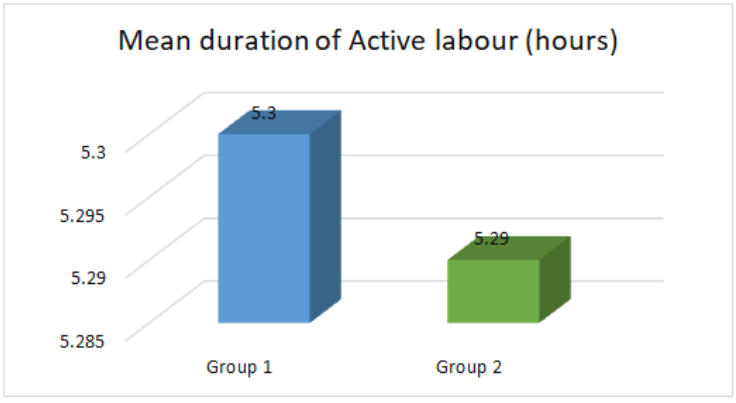
Exclusion Criteria

- Multiple pregnancy
- Placenta previa
- Premature rupture of membranes.
- CPD
- Previous LSCS or Major uterine surgery
- Fetal Distress
- Medical conditions like Asthma, Hypertension and Glaucoma

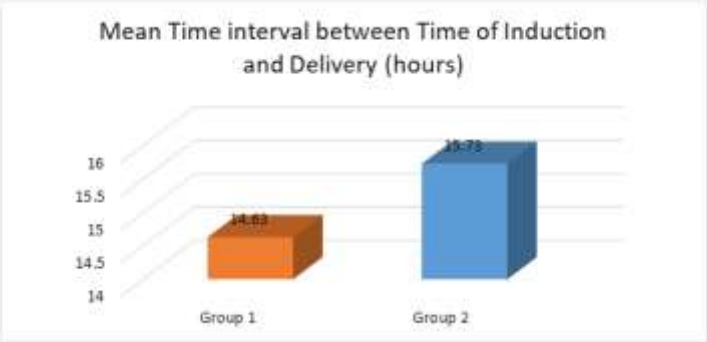
RESULTS

Out of total 150 patients in the study period of 2 years from 75 patients were induced with PGE2 Gel (Group 1) and 75 patients were induced with Foley's catheter (Group 2). The mean duration of active labour was 5.30±1.75 hours and 5.29±1.31 hours in Group 1 and Group 2 respectively. The mean time interval between time of induction and delivery was 14.63±3.42 hours in Group 1 and 15.73±2.20 hours in Group 2. 52 (69.4%) patients in Group 1 had Full Term Normal Delivery (FTND) while 21 (28%) and 2 (2.6%) patients had Lower Segment Caesarean Section (LSCS) and Ventouse delivery respectively. 73 (97.4%) patients in Group 2 had FTND while 1 (1.3%) patient each had LSCS and Ventouse delivery. The most common indication of LSCS in Group 1 was fetal distress (42.9%) followed by failure of induction (38.1%), non Progress of labor (14.3%) and fetal distress with thick MSL (4.7%). The pre-induction Bishop Score was comparable between the groups (3.53±0.84 vs. 3.44±0.74; p>0.05) while the post-induction Bishop Score was significantly lower in Group 1 compared to Group 2 (6.91±1.24 vs. 7.33±0.83). 2 (2.7%) and 1 (1.3%) neonate in Group 1 and Group 2 respectively required NICU admission.

Indication	Group 1		Group 2	
	N	%	N	%
Post dates	60	80%	60	80%
PROM	6	8%	3	4%
PIH	5	6.70%	8	10.70%
Oligohydramnios	4	5.30%	4	5.30%



Bishop Score	Group 1		Group 2		p Value
	Mean	SD	Mean	SD	
Pre-induction	3.53	0.84	3.44	0.74	>0.05
Post-induction	6.91	1.24	7.33	0.83	**<0.05**



Maternal Complications	Group 1		Group 2		p Value
	N	%	N	%	
MSL	4	5.30%	3	4%	>0.05
Infection	2	2.60%	3	4%	

Mode of Delivery	Group 1		Group 2	
	N	%	N	%
FTND	52	69.40%	73	97.40%
LSCS	21	28%	1	1.30%
Ventouse	2	2.60%	1	1.30%
Total	75	100%	75	100%

DISCUSSION

It was observed in the present study that the mean gestational age between the groups (39.71±0.89 weeks vs. 39.33±0.30 weeks; p>0.05). Similar findings were seen in study done by Malakar A *et al*., [1] With mean gestational age in group A was 39.87 ± 0.8 weeks and in group B was 39.66 ± 0.99 weeks. This is also comparable to the Murmu S *et al*., [2] study which found mean gestational age was 38.4±1.82 weeks in group 1 and 37.9±1.64 weeks in group 2.

It was observed in our study that 5.3% patients in Group 1 had oligohydramnios while 4% patients had PIH, 1.3% patient each had polyhydramnios, pre eclampsia and UV prolapse. 1.3% patient in Group 2 had BOH. This is consistent with the studies of Malakar A *et al*., [1] and Murmu S *et al*., [2]. Murmu S *et al*., [2] study observed commonest indication for induction in Foley's and PGE2 gel group was pregnancy induced hypertension which constituted 38.6% in group 1 and 37.1% in group 2. Other indications for induction of labor were post-dated pregnancy, FGR, decreased fetal movement, oligohydramnios etc. Malakar A *et al*., [1] randomised comparative analysis found various indications for induction were post-dated pregnancy, term preeclampsia, intrauterine growth restriction, less foetal movement and Rh-negative pregnancy.

In the present study, the mean duration of active labour was 5.30±1.75 hours and 5.29±1.31 hours in Group 1 and Group 2 respectively. The mean time interval between time of induction and delivery was significantly lesser in Group 1 compared to Group 2 (14.63±3.42 hours vs. 15.73±2.20 hours; p<0.05). This is in concordance to the study of Malakar A *et al*., [1] where the induction-delivery interval in group A was 28.58 ± 7.54 hours and in group B it was 24.37 ±9.34 hours. This is comparable to the study of Murthy BK *et al*., [3] where Induction delivery interval was almost similar in the two groups (11.6 vs 11.1 in dinoprostone and Foleys catheter group respectively). Murmu S *et al*., [2] prospective randomized comparative study observed induction to delivery interval was significantly lower for group 1 as compared to group 2.

In our study, 69.4% patients in Group 1 had Full Term Normal Delivery (FTND) while 28% and 2.6% patients had Lower Segment Caesarean Section (LSCS) and Ventouse delivery respectively. 97.4% patients in Group 2 had FTND while 1.3% patient each had LSCS and Ventouse delivery. Malakar A *et al*., [1] and Murmu S *et al*., [2] noted similar observations in their studies. Malakar A *et al*., [1] randomised comparative analysis observed that in groupA, 82% delivered vaginally and 7 out of these required instrument application (14%). In group B, 64% delivered vaginally and 6% of them were assisted by instrument application.

Murmu S *et al*., [2] prospective randomized comparative study found rate of vaginal delivery was 80% and 78.6% in group 1 and group 2 respectively.

It was observed in the present study that the rate of LSCS in Group 1 was 28% and in group 2 was 1.3%. This finding was consistent with the study of Malakar A *et al*., [1].

Malakar A *et al*., [1] analysis reported caesarean delivery rate in group A was 18 % and in group B it was 36. In the present study, the pre-induction Bishop Score was comparable between the groups (3.53±0.84 vs. 3.44±0.74; p>0.05) while the post-induction Bishop Score was significantly lower in Group 1 compared to Group 2 6.91±1.24 vs. 7.33±0.83; p<0.05). This is similar to the study of Malakar A *et al*., [1] where mean Bishop Scores at the onset of the study in group A and B were 2.28 ± 0.67 and 2.48 ± 0.5 respectively. This is also comparable to the study of Murthy BK *et al*., [3] where both groups achieved post induction Bishops score as (7.2 vs 6.81). Murmu S *et al*., [2] study observed Mean pre- induction and post-induction Bishop's score were 2.47±0.65 and 8.9±1.45 in group A whereas in group B they were 2.38±0.78 and 8.22±1.60 respectively. It was observed in our study that the mean APGAR Score at 1 min was 7.01 ± 0.12 and 7.03 ± 0.16 in Group 1 and Group 2 respectively. The mean APGAR Score at 5 mins was 8.04 ± 0.20 and 8.01 ± 0.12 in Group 1 and Group 2 respectively. 2.7% and 1.3% neonate in Group 1 and Group 2 respectively required NICU admission. This is comparable to the studies of Murmu S *et al*., [2]. Murmu S *et al*., [2] prospective randomized comparative study reported no significant difference in 1 and 5 minutes APGAR score between the two groups. Incidence of NICU admission was 1.4% in group1 and 5.7% in group2

CONCLUSION

Both PGE2 gel and intra-cervical Foley's catheter are effective methods for pre-induction cervical ripening. However, with Foley's catheter there was significant improvement in Bishop's score and shorter induction delivery interval as compared to PGE2 gel. Foley catheter for cervical ripening is a far cheaper option to PGE2 in term of medicinal/device cost.

Because of low cost and easy storage, it is suitable for low resources settings with limited monitoring facilities. It also has the advantage of simplicity, reversibility and lack of systemic as well as serious side effects.

Foleys catheter is advantageous in terms of lack of specific storage conditions and cost of treatment, it could be considered a cost effective alternative for pre induction cervical ripening.

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