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TO COMPARE THE EFFICACY OF INTRA CERVICAL FOLEY'S CATHETER WITH INTRA CERVICAL DINOPROSTONE GEL IN CERVICAL RIPENING FOR THE SUCCESSFUL INDUCTION OF LABOR

Dr Mamta Choudhary[1], Dr Dharmpal Godara[2]

[1]MBBS, MS, Department of Obstetrics & Gynaecology, Govt. S.K. Medical College, Sikar (Rajasthan)
[2]MBBS, MS, Department of General surgery, Govt. S.K. Medical College, Sikar (Rajasthan)

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Corresponding author: Dr Dharmpal Godara
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Abstract

Background: This study compared the efficacy and safety of the intracervical Foley catheter and dinoprostone insert for cervical ripening to achieve successful labor induction.

Methods: This was a randomized controlled study conducted. Group A received Dinoprostone cervical gel 0.5mg instilled in the cervical canal. Maximum of three doses (1.5mg dinoprostone) could be administered 6 hours apart. Patients randomized to group B were subjected to Foleys catheter insertion. Primary efficacy parameter was change in Bishops score as compared to baseline.

Conclusion: Our study showed that for pre induction cervical ripening there was no difference in efficacy between intracervical Foleys catheter and PGE_2 gel.

Keywords: Foleys catheter, Induction of labour, Prostaglandins

Introduction

Labor induction has become more widespread in most countries during the past decade, with 20% to 30% of all deliveries worldwide involving induced labor. Successful labor induction depends on the cervical status at the time of induction. It is predicted that patients with a poor Bishop score will have an unacceptably high rate of induction failure. However, a variety of methods, including mechanical and pharmacologic methods, are available for cervical ripening.[1]

The administration of intra cervical prostaglandins (PGE2, PGF2) produce cervical change in pregnant women and become the standard method of ripening and induction of labour. These pharmacologic agents are however unstable and may have less potency if they are not stored properly. Their effects are not readily reversible.[2]Systemic absorption of prostaglandins agent is possible and may result in nausea, vomiting, diarrhoea and initiation of uterine contraction. The effect may last for long period and lead to uterine hypertonicity, placental abruption and uterine rupture.[3]

Intracervical Foleys catheter induction produces a mechanical distension of lower uterine segment, stripping the fetal membranes from decidua leads to activation of lysosomes and phospholipase –A, leading to formation of arachidonic acid which is later converted to PGs.[2] Mechanical stretching of cervix also augments production of hyaluronic acid, which may enhance cervical swelling and softening. Another potential mechanism enhancing cervical softening is the stimulation of inflammatory cytokine secretion, such as interleukins and MMPs. In addition, myometrial stretching increases expression of cyclooxygenase-2(COX-2) and Production of prostaglandins.[4]

Use of Foleys catheter is associated with reduced induction delivery interval, decreased caesarean rate, increased rate of spontaneous vaginal delivery. Chances of infection are no more than that of the usual hospital rate if strict aseptic precautions are observed. Also, Foleys is less costly then PGE2 and has fewer side effect, reversibile and easy available.[5]

Material and Methods

Type of Study: Randomized Control Study in Term Pregnant women.

Study Design: Prospective Study

Inclusion Criteria

- Primi gravida
- Gestational age >37wks who requiring induction of labour
- Cephalic presentation
- Bishops score <5
- Intact membranes
- IUGR Without Fetal compromise
- Singleton pregnancy

- Women giving consent for participation in the study

Exclusion Criteria

- Cephalopelvic disproportion
- Pregnancy with previous uterine scar.

In Study Group (A) - Intra cervical Foley's catheter No.18 was introduced through the endocervix under direct visualization into the extra amniotic space, using aseptic technique and balloon was inflated with 30 ml of normal saline and was retracted so that it rests on the internal os. The catheter was strapped to inner thigh after applying slight traction. Prophylactic antibiotic was given. Mobilization was encouraged. The Bishop's score was reassessed on spontaneous expulsion, in absence of spontaneous expulsion, the catheter was deflated, removed and the cervix reassessed after 12 hours or earlier if membranes ruptures. External electronic fetal heart rate monitoring was recorded before and for 40 minutes after Foley's catheter insertion.

Control Group (B)- Dinoprostone gel dose of 0.5 mg per 3 gm in 2.5 ml prefilled syringe after exposing the cervix with speculum, was introduced into the endocervix just below the level of the internal os using aseptic precaution and woman was kept in lying down position for atleast 30 minutes for absorption of drug. Prophylactic antibiotic was given. External electronic fetal heart rate monitoring was recorded before and for 40 minutes after each Dinoprostone gel insertion. The woman was reassessed after 6 hours and if there was no improvement in Bishop's score, she was subjected to a second dose of Dinoprostone gel, and the Bishop's score was reassessed after 6 hours.

Statistical Analysis

All data thus collected was entered in excel sheet and was subjected for statistical analysis. Quantitative data was summarised as mean and SD whereas qualitative data as percentage. Significant difference in means was analyse by using unpaired student's t test and difference in proportion was analysed by using Chi-square' test. P-value < 0.05 was taken as significant.

Results

Table 1: Distribution of Cases According to Indication for Induction of Labour

Indication for Induction of Labour	Group-A		Group-B	
	No.	%	No.	%
IUGR	2	4.00	3	6.00
Postdate	15	30.00	22	44.00
Oligohydramnios	4	8.00	3	6.00
Hypertension	10	20.00	8	16.00
ICP	2	4.00	2	4.00
Due Date	17	34.00	12	24.00
Total	50	100.00	50	100.00

p-value = 0.0638

In our study, in Group-A 15 (30.00%) women and in Group-A 22 (44.00%) women were post dated. IUGR was present in 2 (4.00%) women in Group-A & 3 (6.00%) in Group-B. Oligohydramnios was present in 4 (8.00%) women in Group-A & 3 (6.00%) in Group-B. Hypertension was present in 10 (20.00%) women in Group-A & 8 (16.00%) in Group-B. ICP was present in 2 (4.00%) women in Group-A & Group-B. 17 (34.00%) women in Group-A & 12 (24.00%) in Group-B were admitted on due date. Both the groups were comparable (p-value < 0.0638).

Table 2: *Distribution of Cases According to Change in Bishop's Score*

Bishop's Score	Group-A (n=50)		Group-B (n=50)		p-value
	Mean	SD	Mean	SD	
Mean Pre-induction	2.26	0.83	2.1	0.79	0.538
Mean Post-induction	8.02	3.22	7.1	4.48	0.242
Mean Incremental Changes	6.56	1.92	7.34	2.31	0.06

In our study, mean pre-induction Bishop's score was a little higher in Group-A as compared to Group-B, (2.26 ± 0.83 vs 2.1 ± 0.79). The difference between them was statistically insignificant (p-value = 0.538). Mean post-induction Bishop's score was higher in Group-A as compared to Group-B (8.02 ± 3.22 vs 7.1 ± 4.48). The difference between them was statistically insignificant (p-value = 0.242). Mean incremental change in the Bishop's score in Group-A was (6.56 ± 1.92) and in Group-B was (7.34 ± 2.31) which was statistically not significant (p-value = 0.06).

Discussion

In our study, Group-A, 15 (30.00%) women were post date and in Group-B 22 (44.00%) women were post date. IUGR was present in 2 (4.00%) women in Group-A & 3 (6.00%) in Group-B. Oligohydramnios was present in 4 (8.00%) women in Group-A & 3 (6.00%) in Group-B. Hypertension was present in 10 (20.00%) women in Group-A & 8 (16.00%) in Group-B. ICP was present in 2 (4.00%) women in Group-A & Group-B. Due date was present in 17 (34.00%) women in Group-A & 12 (24.00%) in Group-B. Similar to our study Kanada AR et al (2019)[6] reported most common indication for induction of labour was pregnancy induced hypertension and postdatism. The most common indication for induction of labour in a study done by Rao SC et al (2019)[7] was IUGR, oligohydramnios / postdatism. Murmu S et al (2018)[8] reported the most common indication for induction of labour was PIH, others were postdated pregnancy, FGR, decrease fetal movement, oligohydramnios.

In our study, mean change in Bishop's score, in the Group-A as compared to Group-B, (2.26 ± 0.83 vs 2.10 ±.79) the difference between them was statistically Insignificant at preinduction Bishop's score. Mean change in Bishop's score, higher in the Group-A as compared to Group-B, (8.023 ± .22 vs 7.14 ± .48) the difference between them was statistically Insignificant at post induction Bishop's score. Mean incremental change in the Bishop's score, in Group-A (6.561 ± .92) and in Group-B (7.342 ± .31) there was statistically not significant. Similar observations was made by Perveena F et al (2016)[9], they reported that mean pre-induction bishop's score (2.4 ± 0.7) in Group-A & (2.5 ± 0.8) in Group-B and post-induction bishop score (7.70. ± 8) in Group-A & (7.6± 0.8) in Group-B and improvement in Bishop's was 5.31 ± .1 ($p<0.001$) and 5.1 ± 1.1 ($p<0.001$), there was not significant. Kadam DA et al (2015)[10] observations also in accordance with my study, that mean change in Bishop's score in Group-A was 5.27 ± 2.28 and that of Group-B is 5.01 ± 2.53, so the p-value was 0.600 means there was no significant difference between them. Also Laddad MM et al (2013)[11] reported that mean change in Bishop's score in Group-A was 5.54 ± 1.89 ($p < 0.0001$) and in Group-B it was 5.44 ± 1.82 ($p < 0.001$). There was no significant difference between both groups.

Also in the study by Kanada AR et al (2019)[6], they reported that both Foley's catheter and PGE2 gel were equally effective in pre-induction cervical ripening. The mean change in Bishops score in Foley's catheter was 5.10 ± 1.55 (<0.0001) and PGE2 gel 5.14 ± 1.60 (<0.0001) which was highly significant.

In Group-B, 12 (24.00%) cases needed double application and in 38 (76.00%) cases there were single application of gel. In Group-A spontaneous expulsion of Foley's catheter occurred in 13 (26%) women and in 37 (74%) expulsion occurred at 12 hours. In the study conducted by Rao SC et al (2019)[7] most of the women in Group-B received two dinoprostone gel doses (55%). In Group-A patients the mean foley's catheter expulsion time was 8.66 ± 2.7 hours. Garg R et al (2018)[12] study reported that second of dose of PGE2 gel was required 70.00% in Group-B 70.00% and 20.00% in Group-A.

Conclusion

Our study showed that for pre induction cervical ripening there was no difference in efficacy between intracervical Foleys catheter and PGE_2 gel.

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