



Comparative Study of Intra Cervical Foley's Catheter versus Dinoprostone Gel for Cervical Ripening at Term.

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Citation this Article: Mohinee Dhaka, Rakhi Arya, Reena Pant, Krishna Priya Banerjee, "Comparative Study of Intra Cervical Foley's Catheter versus Dinoprostone Gel for Cervical Ripening at Term", *ijmsir*- January - 2020, Vol – 5, Issue -1, P. No. 28-33.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Aim-The success of labor induction depends on the cervical status at the time of induction. Objective- For effective cervical ripening both foley catheter and a dinoprostone gel are used. The aim of this study was to compare the efficacy and safety of the intracervical Foleys catheter and dinoprostone gel in cervical ripening for successful induction of labor.

Methods: It was a randomized controlled study conducted in the obstetrics department at SMS medical college, jaipur. 100 Women were enrolled with a bishops score <5 with various indication for induction of labour. They intracervical Foleys catheter insertion, and group B received Dinoprostone gel 0.5mg instilled intracervical. Maximum of 2 doses dinoprostone gel could be administered 6 hours apart. Primary efficacy parameter was change in Bishops score as compared to baseline.

Results: The groups were comparable with respect to maternal age, gestational age, indication of induction and initial Bishops score. Both the groups showed significant change in Bishops score at 12 hr, 8.02 ± 3.22

and 7.1 ± 4.48 in Foleys catheter and Dinoprostone gel, respectively. But p value was not statistically significant (0.242). The induction to delivery interval was 11.07 ± 4.82 hours in the foley's group and 9.99 ± 5.50 hours in PGE2 group (0.299). APGAR scores and NICU admissions showed no difference between the two groups.

Conclusion: This study shows that both Foleys catheter and Dinoprostone are equally effective in cervical ripening.

Keywords: Cervical ripening, Foleys catheter, dinoprostone gel.

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. The effect may last for long period and may 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

Chances of infection are no more than that of the usual hospital rate if strict aseptic precautions are observed. Also, Foleys is less costly than PGE₂ gel and has fewer side effect, reversible and easily available.⁵

Material and methods

It was a prospective, Randomized controlled study conducted in the department of Obstetrics & Gynaecology, SMS Medical College, Jaipur.

Total 100 women were enrolled, inclusion criteria were Primi gravid, singleton pregnancy, cephalic presentation

, gestational age >37wks who requiring induction of labour, Bishop's score <5, intact membranes, IUGR. Without Fetal compromise, women giving consent for participation in the study. Those with CPD and with previous uterine scar were excluded.

Women were thoroughly evaluated regarding complete history, detailed general and obstetrical examination. Gestational age was assessed by LMP or 1st trimester sonography. Detailed pelvic examination and Bishop's score was done. After getting informed and written consent, women were divided in two groups randomly. Foleys catheter was used in group A and PGE₂ gel in group B.

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 rupture. External electronic fetal heart rate monitoring was recorded before and for 20 minutes after Foley's catheter insertion.

In group (B)- Dinoprostone gel 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 20 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.

In women with Bishop's score >6 progress of labour was monitored using partograph. Induction-labour and induction-delivery interval, mode of delivery, APGAR score at 1 & 5 mins were noted. Women with no improvement in Bishop's score at the end of 24 hrs were considered as failure.

Statistical analysis: continuous variables were summarized as mean and SD while nominal variables as proportion. Parametric test was used for continuous variables and chi square test was used for nominal values. P values < 0.05 were taken as significant.

Results

In our study, Mean age in Group-A was 24.13 ± 2.16 yrs and in Group-B was 24.68 ± 2.37 yrs. Both groups were comparable (p-value > 0.05). 42 (84.00%) women were booked and 8 (16.00%) women were unbooked in Group-A. 36 (72.00%) women were booked and 14 (28.00%) women were unbooked in Group-B. Both group were comparable (p-value = 0.227). Most of cases were booked as the hospital is a tertiary care center. Mean gestational age of women was 38.1 ± 1.12 weeks in Group-A and 38.4 ± 1.23 weeks in Group-B which was not statistically significant (p-value < 0.084).

Table 1: Distribution of Cases According to Indications 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

Both the groups were comparable with regards to indications for induction of labour. (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). but 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), but 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).

Table 3 : Distribution of Cases According to Induction to Active Labour Interval

Active Labor Interval (in hrs)	Group-A	Group-B
Mean \pm SD	8.66 \pm 1.90	7.98 \pm 1.74

Induction to active labour interval was 8.66 hrs in Group-A as compared to 7.98 hrs in Group-B which was not statistically significant($p=0.080$).

Table 4: Distribution of Cases According to Induction to Delivery Time

Induction to Delivery Time (in hrs)	Group-A	Group-B
Mean \pm SD	11.07 \pm 4.82	9.99 \pm 5.50

The induction delivery interval in Group A was 11.07 \pm 4.82 hrs and 9.99 \pm 5.50 hrs in Group B. However, the difference was not statistically significant($p=0.299$)

Table 5: Distribution of Cases According to APGAR Score

APGAR Score	Group-A		Group-B		p-value
	Mean	SD	Mean	SD	
At 1 mint.	6.72	0.80	6.72	1.03	0.062
At 5 mint.	7.94	0.42	7.34	0.93	0.078

In our study, APGAR score at 1 minute in Group-A was 6.72 \pm 0.80 and in Group-B was 6.72 \pm 1.03. At 5 minute in Group-A was 7.94 \pm 0.42 and in Group-B was 7.34 \pm 0.93. The results were statistically insignificant($p\text{-value} > 0.05$).

Discussion

In this study no statistically significance was noted regarding to gestational age and indication for induction of labour in both the groups.

In this study, mean change in Bishop's score, in the Group-A as compared to Group-B, (2.26 \pm 0.83 vs 2.10 \pm .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 \pm .22 vs 7.14 \pm .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 \pm .92)

and in Group-B (7.342 \pm .31) there was statistically not significant. Similar observations was made by Perveena F et al (2016)⁶, they reported that mean pre-induction bishop's score (2.4 \pm 0.7) in Group-A & (2.5 \pm 0.8) in Group-B and post-induction bishop score (7.70. \pm 8) in Group-A & (7.6 \pm 0.8) in Group-B and improvement in Bishop's was 5.31 \pm .1 ($p < 0.001$) and 5.1 \pm 1.1 ($p < 0.001$), there was not significant. Kadam DA et al (2015)⁷ observations also in accordance with my study, that mean change in Bishop's score in Group-A was 5.27 \pm 2.28 and that of Group-B is 5.01 \pm 2.53, so the p-value was 0.600 means there was no significant difference between them. Also Laddad MM et al (2013)⁸ reported that mean change in Bishop's score in Group-A was 5.54 \pm 1.89 ($p < 0.0001$) and in Group-B it was 5.44 \pm 1.82 ($p < 0.001$). There was no significant difference between both groups.

Also in the study by Kanada AR et al (2019)⁹, 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 \pm 1.55 (< 0.0001) and PGE2 gel 5.14 \pm 1.60 (< 0.0001) which was highly significant.

In present study, induction to active labour interval was 8.66 hrs in Group-A as compared to 7.98 hrs in Group-B which was not statistically significant.

Similar observation was made by Garg R et al (2018)¹⁰ reported that the mean induction to active phase interval in both groups which was 5.8 \pm 0.80 hours in Group-A and 6.23 \pm 0.40 hours in Group-B, which was not significant. ($p > 0.1$).

In our study, the induction delivery interval in Group A was 11.07 \pm 4.82 hrs and 9.99 \pm 5.50 hrs in Group B. However, the difference was not statistically significant.

In similar study by Jha R et al (2017)¹¹ reported that induction-delivery interval showed no significant difference in the two groups. The mean I-D interval was 16.01 ± 5.5 hours and 16.3 ± 3.81 hrs in Group-A and Group B respectively. In a study conducted by Alam A et al (2016)¹² reported that induction-delivery interval showed no significant difference in the two groups. The mean induction-delivery interval was 16.01 ± 5.5 hours in Foley's group and 16.85 ± 3.81 hours in PGE₂ group.

In our study, APGAR score at 1 minute in Group-A was 6.72 ± 0.80 and in Group-B was 6.72 ± 1.03 . At 5 minute in Group-A was 7.94 ± 0.42 and in Group-B was 7.34 ± 0.93 . The results were statistically insignificant.(p-value > 0.05).

In a study conducted by Kanada AR et al (2019)⁹, incidence of perinatal asphyxia with APGAR score ≤ 7 at 5 minutes and meconium aspiration syndromes were similar in both the groups. However the morbidity in both the groups was not statistically significant. Murmu S et al (2018)¹³ reported that there was no significant difference in 1 and 5 minutes APGAR score between the two groups.

Conclusion

Our study showed that for cervical ripening there was no difference in efficacy between intracervical Foleys catheter and PGE₂ gel. Other factors like mean induction to active labour interval, mean induction to delivery interval and fetal maternal outcomes were similar in both the groups.

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