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COMPARISON OF PRE AND POST INDUCTION BISHOPS SCORE IMPROVEMENT IN INTRACERVICAL FOLEY'S CATHETER AND PGE2 GEL

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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 <5with various indication for induction of labour. They intracervical Foleys catheter insertion and group B received Dinoprostone gel 0.5mg instilleted 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, gestation age, indication of induction and initial Bishop's score. Both the groups showed significant change in the Bishop's score at 12 hr,8.02 $\pm$ 3.22 and 7.1 $\pm$ 4.48 in Foleys catheter and Dinoprostone gel, respectively, But p value was not statistically significant(0.242).

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

Introduction

Induction of labor is a common procedure in obstetrics. It is usually performed when risk of continuing a pregnancy is more than benefit of delivery. Cervical ripening has got a close relationship with the success rate of delivery[1]. Cervical ripening refers to a process of preparing the cervix for induction of labor by promoting effacement and dilatation as measured by Bishop's score[2]. Induction of labour should be safe, simple and effective. The success of induction depends upon the consistency, compliance and configuration of cervix. 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.[3]

Pharmacologic agents(PGE2 Gel) are unstable and may have less potency if they are not stored properly. Their effects are not readily reversible.[4]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.[5] 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.[4] Mechanical stretching of cervix also augments production of hyaluronic acid, which may enhance cervical swelling and softening.

Material and methods

It was a prospective, Randamized 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 ,bishops 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 ruptures. 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:continous 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 Age

Age Group (in yrs)	Group-A		Group-B	
	No.	%	No.	%
<20	3	6.00	2	4.00
21 – 25	33	66.00	32	64.00
26 – 30	11	22.00	12	24.00
31 – 35	2	4.00	3	6.00
>35	1	2.00	1	2.00
Total	**50**	**100.00**	**50**	**100.00**
Mean ± SD	**24.13 ± 2.16**		**24.68 ± 2.37**	

p = 0.154

In our study, in Group-A, out of 50 cases, 33 (66.00%) were 21-25 yrs age group, 11 (22.00%) cases were 26- 30 yrs age group, 2 (4.00%) cases were 31- 35 yrs age group, 3(6.00%) cases were <20 yrs age group, 1 (2.00%) cases were >35 yrs age group. In our study, out of 50 cases, 32 (64.00%) were 21-25 yrs age group, 12 (24.00%) cases were 26-30 yrs age group, 3 (6.00%) cases were 31- 35 yrs age group, 2 (4.00%) cases were <20 yrs age group, 1 (2.00%) cases were >35 yrs age group in

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 Need for Augmentation

Need for Augmentation	Group-A (n=50)		Group-B (n=50)	
	No.	%	No.	%
ARM	3	6.00	4	8.00
Oxytocin	7	14.00	7	14.00
Oxytocin + ARM	11	22.00	9	18.00

p-value = 0.642

In our study, the need for oxytocin augmentation was 7 (14.00%) women in both groups. 3 (6.00%) women required ARM in Group-A & 4 (8.00%) women required ARM in Group-B. 11 (22.00%) cases in Group-A & 9 (18.00%) cases in Group-B required oxytocin + ARM for augmentation.

29 (58.00%) cases in Group-A & 30 (60.00%) cases in Group-B went into spontaneous labour which did not require augmentation. There was not statistically significant difference in the need for augmentation of labor in both the groups.

Table 4: Distribution of Cases According to Mode of Delivery

Mode of Delivery	Group-A		Group-B	
	No.	%	No.	%
LSCS	12	24.00	13	26.00
Normal Delivery	38	76.00	37	74.00
Total	50	100.00	50	100.00

p-value = 0.99

The need for operative intervention was also not statistically significant in both the groups. Cesarean section was done in 12 (24.00%) cases in Group-A and 13 (26.00%) cases in Group-B. Normal deliveries were done in 38 (76.00%) cases in Group-A and 37 (74.00%) cases in Group-B. There was no association of increased rate of cesarean section with the Foley's catheter and PGE2 gel use.

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 ± 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)[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 ± 1.55 (<0.0001) and PGE2 gel 5.14 ± 1.60 (<0.0001) which was highly significant.

In our study, the need for oxytocin augmentation was 7 (14.00%) women in both groups. 3 (6.00%) women required ARM in Group-A & 4 (8.00%) women required ARM in Group-B. 11 (22.00%) cases in Group-A & 9 (18.00%) cases in Group-B required oxytocin + ARM for augmentation. 29 (58.00%) cases in Group-A & 30 (60.00%) cases in Group-B went into spontaneous labour which did not require augmentation. Similar observation was made by Kanada AR et al (2019)[9] ,Murmu S et al (2018)[10] , reported that in Group-1 8.6% women required ARM, 37.1% women required oxytocin augmentayion, whereas in Group-2, need for augmentation of labour by ARM was in 10%, oxytocin infusion in 40% and both ARM + oxytocin in 20% women.

The need for operative intervention was also not statistically significant in both the groups. Cesarean section was done in 12 (24.00%) cases in Group-A and 13 (26.00%) cases in Group-B.Similar to our Alam A et al (2016)[11], reported the need for operative intervention (LSCS) was not significant in both the groups. LSCS was done in 21% in Group-A and 19% in Group-B.

Conclusion

Our study showed that for cervical ripening there was no difference in efficacy between intracervical Foleys catheter and PGE_2 gel. Other factors like Augmentation of labour, mode of delivery and feto maternal outcomes were similar in both the groups.

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