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Original Research Article

Comparison of dinoprostone slow-release vaginal insert with intracervical Foley catheter in cervical ripening for induction of labour: a prospective observational study

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ABSTRACT

Background: Cervical ripening prior to induction of labour is crucial as unfavorable cervix with poor Bishop's score can lead to caesarean section. Two most widely used methods are vaginal dinoprostone and intracervical Foley catheter. Studies conducted worldwide to determine the efficacy and safety of these methods provided no consensus regarding superiority. Thereby, the present study aims to compare the efficacy of these two methods for successful cervical ripening during induction of labour.
Methods: In this prospective observational study, all antenatal women admitted for induction of labour satisfying the inclusion criteria were enrolled. Women in group A were induced with dinoprostone slow-release vaginal insert and those in group B with intracervical Foley catheter. Sample size was 72 in each group. Both the groups were followed till delivery and assessed for improvement in Bishop's score, induction to active phase duration, induction to delivery time, use of other agents, mode of delivery, incidence of hyperstimulation and neonatal outcomes.
Results: Induction to active phase duration and to delivery time was statistically shorter in dinoprostone slow-release vaginal insert group than intracervical Foley group. Improvement in Bishop's score, mode of delivery and indication for LSCS were not statistically significant. Uterine hyperstimulation was significantly higher in Dinoprostone insert group. Neonatal outcomes were similar.
Conclusions: Dinoprostone slow-release vaginal insert resulted in better Bishop's score during re assessment, reduced need for second agent, shorter induction to active phase and to delivery time when compared with intracervical Foley catheter and so can be used effectively for successful cervical ripening.

Keywords: Dinoprostone, Foley, Induction, Labour

INTRODUCTION

Induction of labour is defined as artificial stimulation of uterine contractions before the onset of spontaneous labour.[1] This is indicated when the risks of continuing the pregnancy exceeds the risks associated with induction of labour.[2-4] Though achieving a successful vaginal delivery is the goal, failure leading to caesarean section results due to unfavourable cervix with poor Bishop's score at the onset.[5,6]

Various methods are available for cervical ripening which include mechanical, pharmacological, surgical, and non-pharmacological methods. Mechanical methods include intracervical Foley catheter and laminaria tents.[7,8] Pharmacological methods include dinoprostone slow-release vaginal insert, dinoprostone cervical gel, misoprostol and mifepristone. Surgical methods include amniotomy and sweeping of membranes. Nonpharmacological methods such as herbal, acupuncture, castor oil, sexual intercourse and hot baths

are not recommended these days.[8] Pharmacological methods are the preferred agents for induction of labour worldwide.[8-10]

Two most widely used methods are vaginal dinoprostone and intracervical Foley catheter and studies have been conducted worldwide to determine the efficacy and safety of these methods with no consensus regarding superiority of either method. Dinoprostone vaginal inserts are associated with the complication of uterine hyperstimulation but can easily be removed whenever needed making its usage easier and superior.[11,12] Hence this study is conducted to compare the efficacy of these two methods in ripening of cervix for induction of labour.

METHODS

This prospective observational study was conducted in a tertiary care hospital, in Pondicherry, from January 2020 to July 2021, after obtaining institutional human ethics committee approval. Inclusion criteria were primigravida at 37-42 weeks of gestation with single live foetus in cephalic presentation with Bishop's score ≤3 with intact membranes requiring labour induction. Exclusion criteria were previous uterine scar, abnormally implanted placenta, malpresentation and contracted pelvis. They were divided into two groups of 72 subjects each, group A: Women induced with dinoprostone slow-release vaginal insert and group B: Women induced with intracervical Foley catheter. Bishop's score was assessed in both the groups before inducing with the proposed agent.

Dinoprostone vaginal insert was placed in the posterior fornix of vagina and removed after 24 hours or removed immediately in case of uterine hyperstimulation or leaking per vaginum. Uterine hyperstimulation was defined as more than 5 contractions in 10 minutes or a single contraction lasting longer than 2 minutes associated with fetal distress. In group B, a 22 F Foley catheter was guided into the cervical canal by direct visualization using speculum or blindly by locating the cervix with the examining fingers through the endocervix. The balloon was inflated with 60 ml of normal saline, and it was taped to the thigh with traction. Patients were reassessed after 24 hours or before that in case of expulsion or leaking per vaginum.

During reassessment of both the groups, if the cervix was unfavorable (Bishop score <6) other agents such as prostaglandin E1, prostaglandin E2 or oxytocin was used. If the cervix was favorable (Bishop score ≥6) amniotomy or oxytocin augmentation was done. Using partogram, maternal vitals, fetal heart rate, uterine contractions and progress of labour were recorded.

Both the groups were followed till delivery and the following parameters were assessed: improvement in Bishop's score, use of other agents, mode of delivery, induction to active phase duration, induction to delivery time, maternal complications such as uterine hyperstimulation, meconium-stained liquor and postpartum hemorrhage and neonatal outcome: birth weight, APGAR score and NICU admission.

Data analysis was carried out in SPSS software version 17.0. Qualitative variables were presented as frequency and percentages and quantitative variables as mean (standard deviation) or median (range) depending upon the distribution of data. Qualitative variables between the two groups were compared using Chi square test and quantitative variables by independent t-test or Mann Whitney test depending on the normality of the quantitative data. A p value of less than 0.05 was considered as statistically significant.

RESULTS

The two groups were comparable as per age, demographic status, BMI and gestational age. The median (IQR) Bishop's score of the patients in dinoprostone group was 3 (1-5) and in Foley catheter group, it was 2 (1-3). Mean (SD) improvement in Bishop's score in dinoprostone group was 3.1 (2.3) and 2.3 (1.4) in Foley catheter group which was higher in dinoprostone group though not statistically significant (p=0.09) (Table 1). 60% of patients in Foley catheter group required other agents for induction and only 26% of the patients in dinoprostone group required the same which was statistically significantly (p<0.001) (Table 2).

Table 1: Comparison of improvement in Bishop's score between groups.

Groups	N	Median	IQR	P
Dinoprostone insert	72	3	1-5	0.09
Foley catheter	72	2	1-3	

Mann Whitney U test, p=0.09 (Not significant).

Table 2: Use of other agents.

Use of other agents	Dinoprostone		Foley catheter	
	N	%	N	%
No	53	73.6	29	40.3
Yes	19	26.4	43	59.7
Total	72	100	72	100

Chi square p<0.001 (Significant).

The median (IQR) induction to active phase duration in dinoprostone group was 16 hours (9-26) and in Foley catheter group, it was 22.45 hours (17-27.3). Mean (SD) induction to active phase duration was 18.5 hours (10.8) in dinoprostone group and 22.1 hours (18.6) in Foley catheter group which was significantly shorter in the former (p=0.03) (Table 3). Mean (SD) induction to delivery time was 21 hours (11.3) in dinoprostone group and 26.3 hours (10.4) in Foley catheter group which was significantly shorter in the former group (p=0.004) (Table 4). Mode of delivery and indication for LSCS were similar in both the

groups. The 6% of the patients in dinoprostone group had uterine hyperstimulation whereas there was no such complication in the Foley catheter group which was significant statistically (p=0.04). The 9.7% of the patients in dinoprostone group had PPH and 4.2% in Foley catheter group had this complication which was comparable. Regarding the neonatal outcome, birth weights, meconium staining of liquor, APGAR scores and NICU admissions were comparable in the two groups.

Table 3: Comparison of induction to active phase duration between groups.

Groups	N	Median (hr. min)	IQR
Dinoprostone	49	16.0	9-26
Foley catheter	56	22.45	17-27.30

Mann Whitney U test, p=0.03 (Significant).

Table 4: Comparison of induction to delivery time between groups.

Groups	N	Median (hr. min)	IQR
Dinoprostone	72	21.8	11.8-27.50
Foley catheter	72	26.15	19.4-32.30

Mann Whitney U test, p=0.004 (Significant).

DISCUSSION

To the best of our knowledge, this is one of the few studies in India to compare the efficacy of using dinoprostone slow-release vaginal insert and intracervical Foley catheter in achieving successful cervical ripening for induction of labour.

Regarding improvement of Bishop's score, a meta-analysis of 6 RCTs conducted by Wang et al showed improvement in Bishop's score was significantly greater in patients who received dinoprostone insert when compared with Foley group (MD-0.89, 95% CI-1.12 to -0.67, p<0.01).[11] On the contrary, a retrospective comparison of PGE2 vaginal insert and Foley catheter for outpatient cervical ripening done by Blair et al had significantly higher Bishop's score during re assessment in Foley group when compared with dinoprostone group.[13] However, in studies conducted by Wang et al, Du et al and Cromi et al there was no significant difference in improvement in Bishop score between the groups.[14-16] In the present study reassessment Bishop's score was higher in dinoprostone vaginal insert group than Foley group though it was not statistically significant (p=0.09).

A significant reduction in induction to active phase duration in the group that was given dinoprostone as compared to the Foley catheter group was observed in the present study (p=0.03) which is similar to a prospective study conducted by Du et al in China where induction to active phase interval was shorter in dinoprostone group than Foley group (10.63 hours vs 16 hours, p=0.028).[15] Cromi et al did a RCT and showed a similar result, induction to active phase duration of 15.2 hours vs 21.3 hours in PGE2 vaginal insert and Foley group respectively.[17] On the contrary, in a prospective randomized study conducted by Suffecool et al, induction to active phase duration was shorter in Foley group when compared with dinoprostone group (12.3±3.7 hours vs 19.1±8 hours, p=0.0001).[18] This result was also showed by Cromi et al in Italy. Foley group achieved active phase in shorter duration (15.6 hours) than PGE2 vaginal insert group (16.6 hours).[16]

In their study, Du et al showed induction to delivery time was shorter in dinoprostone group than Foley group (12.96 hours vs 18.44 hours, p=0.22).1[5] Similarly, a meta-analysis conducted by Wang et al showed that time from induction to delivery was significantly shorter in dinoprostone vaginal insert group (MD 5.73 hours, 95% CI 1.26-10.20, p=0.01) than Foley group.[11] Cromi et al reported the same result favouring dinoprostone vaginal insert for induction of labour (ID time: 18.417 hours vs 25.517 hours).[17] These results were similar to the present study where a significantly shorter interval was observed in the dinoprostone insert group (p=0.004).

On the contrary Manly et al reported a significantly shorter induction to delivery time in Foley group compared with controlled release prostaglandin group (16.2 hours vs 27 hours) (p<0.001).[19] A similar observation was found in RCT conducted by Prager et al where induction to delivery time was shorter in Foley group compared with intravaginal dinorpostone group (12.9 hours vs 17.3 hours, p<0.00001).[20] Similar results were obtained by Suffecool et al and Edwards et al favouring Foley catheter for induction of labour.[18,21]

In the present study 59.7% women in Foley group required second cervical ripening agent and only 26.4% of the women in dinoprostone group required this, which implies dinoprostone is more effective in cervical ripening (p<0.001). Similarly in a randomized study by Cromi et al, 87 patients (65.9%) in dinoprostone insert group and 60 patients (45.1%) in Foley group went into active labour without additional intervention.[17] In a RCT by Cromi et al in Italy, 56 patients (54.4%) in dinoprostone group entered active labour without additional intervention compared with 35 patients (33.3%) in Foley group (p=0.003).[16] Wang et al also reported other agents requirement was less frequent when dinorpstone insert was used (RR 0.07, 95% CI 0.03-0.19, p<0.01).[11] On the contrary Manly et al did a retrospective comparative analysis of women induced with Foley and prostaglandins and showed women in Foley group were more than 10 times less likely to require a second cervical ripening agent compared with women in PGE2 controlled release group (1.1% vs 8.4%, p=0.018).[19]

Regarding complications, the present study showed significantly higher occurrence of hyperstimulation with dinoprostone vaginal insert (p=0.04). Similarly, 25.8% patients induced with vaginal dinoprostone developed

hyperstimulation and none of the patients in Foley group had this complication in the study by Suffecool et al.[18] Another similar study by Wang et al showed incidence of uterine hyperstimulation was significantly higher in dinoprostone group when compared with Foley group, 16.9% of dinoprostone group and only 4.5% of Foley group developed uterine hyperstimulation with p=0.04. (OR 0.08, 95% CI 0.01-0.69) and also the rate of non-reassuring fetal heart rate status was significantly lower in Foley group (p=0.01).[14] However a systematic review and meta-analysis conducted by Zhu et al showed no difference in the incidence of hyperstimulation between Foley and dinoprostone vaginal insert group.[5]

Regarding neonatal outcome, the present study did not have any statistically significant differences between the groups as per APGAR scores at one and five minutes. This is similar to the results obtained by Suffecool and Blair et al, Du et al also reported comparable rates of meconium staining of liquor in the two groups.[13,15,18] In the present study 3 babies (4.2%) in dinoprostone and 4 babies (5.6%) in Foley group out of 72 in each group required NICU admission, which was not statistically significant between both the groups (p=0.6). This implies our study had good neonatal outcome in both the groups. This was similar to systematic review conducted by Jozwiak et al with 4% (n=4/107) vs 7% (n=8/119) in Foley and dinoprostone group (RR 0.56, 95% CI 0.17-1.79).[6]

CONCLUSION

Dinoprostone slow-release vaginal insert resulted in better Bishop's score during re assessment, reduced need for 2nd agent, shorter induction to active phase and induction to delivery time when compared with intracervical Foley catheter and so can be used effectively for successful cervical ripening during labour induction.

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