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Role of intracervical foley's catheter as pre-induction cervical ripening agent in reducing rate of primary caesarean section

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Abstract
Induction of labour may be required for various maternal or foetal reasons at times in the presence of poor Bishop's scoring. Cervical ripening is beneficial in these situations.
A randomised comparative analysis was carried out using intracervical Foleys catheter instillation followed by a single dose of dinoprostone gel if required in one group and only dinoprostone gel for ripening in other group. Maternal and neonatal complications, mode of delivery and induction-delivery interval were assessed. We found a higher vaginal delivery rate of 82% in the first group in comparison to 64% in the other group. The difference was statistically significant (p=0.0426). Though a longer induction-delivery interval was observed in the first group, the maternal and foetal outcomes were similar. Intracervical Foley's catheter instillation when used for cervical ripening in unfavourable cervices, either alone or sequentially with dinoprostone gel can significantly reduce the Primary Caesarean section rate without compromising maternal and neonatal safety.

Keywords: Cervical ripening, bishop's score, intracervical foleys instillation, dinoprostone gel, induction

Introduction
Induction of labour can be defined as the artificial initiation of uterine contractions before its natural onset, with the purpose of delivery of the feto placental unit. It is indicated in conditions with obstetric or medical problems where the benefit of expeditious delivery outweighs the risk of continuing pregnancy. The common indications are post-term pregnancy, gestational hypertension, preeclampsia, maternal diabetes mellitus, foetal compromise and for logistic reasons [1]. The method of induction must be both safe and effective.
Modified Bishops Score system is most commonly used for cervical assessment prior to induction [2]. Cervix is considered unfavourable if the score is less than 6. There is an increased risk of caesarean section associated with induction of labour in unfavourable cervix. Cervical ripening refers to a process of preparing the cervix for induction of labour by promoting effacement and dilatation and may have a role in reducing the incidence of failed induction and caesarean delivery [3-4].
Ripening of cervix may be achieved by mechanical techniques such as introduction of intracervical Foley's catheter. It causes mechanical dilatation of cervix and stimulates endogenous release of prostaglandins by stripping the foetal membranes and release of lysosomes from decidua cells [5-6-7]. Local application of dinoprostone causes connective tissue softening, cervical effacement and uterine activity [5].
Foleys catheter is cheaper than dinoprostone gel and is easily preserved at room temperature unlike dinoprostone gel which requires preservation at a temp of 2-8 ºC. Also, use of dinoprostone gel requires caution in some conditions like asthma, glaucoma, epilepsy, compromised cardiac, hepatic or renal function [8].
The institute of our study, Andaman and Nicobar Islands Institute of Medical Sciences, being the only referral centre in the whole of Andaman & Nicobar Islands, has a higher Caesarean section rate, nearly 34% in 2017. Our study aimed to evaluate the possible role of intracervical Foley's instillation as a safe and effective method of cervical ripening in women with an unripe cervix and its role in reducing the rate of caesarean section without compromising maternal and foetal outcome.

Materials and Method

This study was conducted in the Department of Obstetrics and Gynaecology, Andaman & Nicobar Islands Institute of Medical Sciences (ANIIMS) over a duration of six months from October 2018 to March 2019. 100 patients admitted in the labour ward for induction due to various indications like preeclampsia, diabetes, post-dated pregnancy, intrauterine growth restriction were selected for the study. The inclusion & exclusion criteria are as below.

Inclusion criteria

a. Singleton pregnancy
b. Term pregnancy
c. Cephalic presentation
d. Parity < 3
e. Bishop score ≤ 3

Exclusion criteria

a. Malpresentation
b. Rupture of Membrane
c. Post Caesarean pregnancy
d. Polyhydramnios
e. Heart disease
f. Imminent eclampsia
g. Placenta praevia
h. Any condition precluding vaginal delivery

This was a randomised prospective study begun after obtaining the institutional ethics committee permission. Of the 100 women, every alternate woman was assigned into group A or group B. Detailed history, general physical, systemic and obstetric examination including per-vaginum examination for assessment of Bishop Score and routine antenatal investigations were carried out. A written informed consent was taken before the procedure.

Under all aseptic precautions, Foley's catheter no. 16F was inserted intra-civically in group A. The balloon of this catheter was inflated with 50 ml normal saline and Foley's catheter pulled so that the bulb rests on the internal os. The catheter was strapped to the thigh and allowed to self-expel or removed after 12 hours or earlier if membranes ruptured. After removal, Bishop's Score was assessed, if > 6, oxytocin was started. If ≤ 5 one dose of dinoprostone gel was given in the posterior fornix.

In group B, dinoprostone gel i.e. 0.5 mg in 3 gm. base was introduced. Patient was re-assessed after six hours and if there was no improvement in Bishop Score, patient was subjected to another dose of dinoprostone gel up to maximum three doses. Oxytocin augmentation was started if Bishop's score was more than six.

Both groups received prophylactic antibiotic i.e. single dose of Injection Ampicillin. Parto gram was maintained during labour. Failure of induction was declared if no regular uterine contractions commenced (One every 3 minutes) after one cycle of cervical ripening and 12-18 hours of oxytocin administration after rupture of membranes.

The primary outcome measures were Caesarean section rate, neonatal outcome, and maternal complications including intra partum or postpartum fever. The secondary outcome measure was the induction delivery interval. A comparative analysis between the two groups was done with regard to these measures. The data was analysed statistically by unpaired t-test & Chi-square test using SPSS software. Statistical significance was set at $p<0.05$ with the confidence interval of 95% (power of test 80%).

Results

In our study, the two groups were similar in age and parity. Most patients were in the age group of 18-25 yrs. The mean age in Group A and B were 24.56 ± 4.18 and 25.32 ± 4.16 years respectively. There were 37 nulliparous patients in group A and 34 in group B (Table 1).

Table 1: Age and parity distribution

Parameters		Group A Foleys n (%)	Group B Dino prostone n (%)	P value
Age Group (Years)	< 18 years	2 (4%)	0 (0%)	Chi-square = 2.667, p=.446, not significant
	18-25 years	28 (56%)	28 (56%)	
	26-30 years	18 (36%)	18 (36%)	
	>30 years	2 (4%)	4 (8%)	
	Total	50	50	
	Mean ± SD	24.56 ± 4.18	25.32 ± 4.16	P=0.3644, Not significant
Parity	Nulliparous	37 (74%)	34 (68%)	Chi-square = .437, p=.509, not significant
	Multiparous	13 (26%)	16 (32%)	
	Total	50	50	

Table 2: Parameters at induction of labour

Parameters		Group A Foleys n (%)	Group B Dino prostone n (%)	P value
Gestational Age		39.87 ± 0.8	39.66 ± 0.99	P=0.9304, Not significant
Pre Ripening Bishop		2.28 ± 0.67	2.48 ± 0.5	P=0.0939, Not significant
Indication	Post dated	30 (60%)	26 (52%)	Chi-square = 1.270, p=.530, not significant
	PIH	11 (22%)	16 (32%)	
	Others	9 (18%)	8 (16%)	

The two groups were comparable in terms of gestational age. Mean gestational age in group A was 39.87 ± 0.8 weeks and in group B was 39.66 ± 0.99 weeks. 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. The various indications for induction were post-dated pregnancy, term preeclampsia, intrauterine growth restriction, less foetal movement and Rh-negative pregnancy. (Table 2).

Table 3: Mode of delivery and induction delivery interval

Mode Of Delivery	Group A Foleys n (%)	Group B Dinoprostone n (%)	P value
Normal vaginal delivery	34 (68%)	29 (58%)	Chi-square = 5.397, p=.145, not significant
Ventouse delivery	4 (8%)	1 (2%)	
Forceps delivery	3 (6%)	2 (4%)	
Total vaginal delivery (Normal + Instrumental)	41 (82%)	32 (64%)	P=0.0426, significant at 5% level
Induction Delivery Interval (hours) Mean ± SD	28.58 ± 7.54	24.37 ± 9.34	P = 0.0365 significant at 5%level
Caesarean section	9 (18%)	18 (36%)	P=0.0426, significant at 5% level

Of the 50 patients of Group A, less than half (n=22, 44%) required a single dose of dinoprostone gel after removal or expulsion of intracervical Foley's for continuing induction, the others needed artificial rupture of membranes and oxytocin augmentation. 41 women (82%) delivered vaginally and 7 out of these required instrument application (14%). In group B, artificial rupture of membranes and oxytocin augmentation was used for all the 50 women after the last dose of dinoprostone gel. 32 out of 50 (64%) delivered vaginally and 3 (6%) of them were assisted by instrument application. The difference in the total vaginal delivery rate in the two groups was found to be statistically significant (p=0.0426).

The women in the group that received Foley's (group A) required approximately 4 hours more than the other group to achieve vaginal delivery. The induction-delivery interval in group A was 28.58 ± 7.54 hours and in group B it was 24.37 ± 9.34 hours with p=0.0365 making it statistically significant.

The caesarean delivery rate in group A was 18 % and in group B it was 36%. This difference was statistically significant (p=0.0426) showing that women in the Foleys group needed less caesarean delivery compared to the other group. (Table 3).

Table 4: Maternal complications

Maternal parameters	Group A foleys n (%)	Group B dinoprostone n (%)	P value
Intrapartum/ Postpartum fever	3(6%)	5(10%)	P >.05, Not Significant
Hyperstimulation	2(4%)	3(6%)	P >.05, Not Significant
Vomiting	4(8%)	7(14%)	P >.05, Not Significant
Diarrhoea	1(2%)	2(4%)	P >.05, Not Significant
Total	10 (20%)	17 (34%)	P >.05, Not Significant

There was no significant difference in maternal morbidity or complications in the two groups in spite of having a longer induction delivery interval in group A. Maternal parameters like fever, hypers timulation, vomiting and diarrhoea for both the groups are shown in table 4.

Table 5: Neonatal Outcome

Neonatal Parameters	Group A Foleys	Group B Dinoprostone	P value
Birth wt (kg) Mean ± SD	2.9 ± 0.48	2.94 ± 0.4	P= 0.6518, Not significant
APGAR 1 min Mean ± SD	6.8 ± 0.45	6.7± 0.56	P=0.3274, Not significant
APGAR 5 min Mean ± SD	8.8 ± 0.63	8.7 ± 0.32	P=0.3194, not significant
Early neonatal sepsisn (%)	1 (2%)	2(4%)	P >.05, Not Significant
Meconium aspiration syndrome n (%)	2 (4%)	1(2%)	P >.05, Not Significant
Respiratory distressn (%)	2(4%)	2(4%)	P >.05, Not Significant
NICU admissionn (%)	13 (26%)	14(28%)	p>0.05, not significant
Total complications	18 (36%)	19 (38%)	p>0.05, not significant

Neonates in both the groups had comparable outcomes. Mean baby weight in group A was 2.9 ± 0.48 kg and 2.94 ± 0.4 kg in group B respectively. Early onset neonatal sepsis and need for NICU admission were not higher in the Foleys group. Neonatal parameters like APGAR Scores at 1 and 5 minutes, meconium aspiration Syndrome, respiratory distress are shown in table 5.

Discussion

In modern obstetrics, more than 22% of pregnant women undergo labour induction [1]. A cross-sectional population based analysis by Davey *et al* found the Caesarean delivery rate following labour induction to be 26.5% whereas it was 12.5% in women with spontaneous onset of labour [9]. Though Caesarean delivery may be lifesaving in various circumstances for the mother, the baby or both, the rapid increase in Caesarean rate over the last many years without a concomitant decrease in maternal, foetal morbidity or mortality raises a serious concern whether the caesarean section is overused [10]. As observed in the Obstetric Care Consensus 2014 by the American College of Obstetrician and Gynaecologists and the Society for Maternal and Foetal medicine, contemporary labour may be slower than previously thought. Prolonged latent phase (more than 20 hours in primigravida or more than 14 hours in multigravida) should not be an indication for caesarean section. Hence caesarean deliveries for failed induction of labour can be avoided by allowing longer duration of the latent phase (up to 24 hours or longer) and administering oxytocin for at least 12-18 hours after membrane rupture before deeming induction a failure if maternal and foetal status allow [10].

According to WHO, the ideal rate for Caesarean delivery should be 10-15% [11]. As supported by the obstetric Care Consensus on Safe Prevention of the Primary Caesarean, use of cervical ripening agents such as misoprostol, dinoprostone, Prostaglandin E2 gel, Foleys catheter, laminaria tent reduce the rate of Caesarean rate. In our study we have sequentially used Foleys catheter intra cervically and dinoprostone gel in an attempt to achieve cervical ripening in cervices with poor Bishops followed by initiation of uterine contractions.

Studies by various contemporary authors who have compared use of Foleys catheter versus Dinoprostone gel as ripening agent

were reviewed and found that the induction- delivery intervals were in the range of 10-19 hours in the first group and 11-16 hours in the second group [12-13-14-15-16-17-18]. A comparative analysis is given in Table 6.

Table 6: Comparative analysis of Induction Delivery Intervals

Author	Induction delivery interval in foleys group mean (hours)	Induction delivery interval in dinoprostone group mean (hours)
Present Study	28.58 ± 7.54	24.37 ± 9.34
Dileep P. Javadekar *et al*.	13.6 ± 16.9	11.08 ± 5.6
Penagaluru Radha *et al*.	10.2	12.7
Anjuman Alam *et al*.	16.01 ± 5.50	16.85 ± 3.81
Raheela Baloch *et al*.	19.45	11.58
Krishna Dahiya *et al*.	18.51 ± 8.52	18.21 ± 11.13
Mumtaj M *et al*.	16.48	14.66

In our study, induction-delivery interval in group A was 28.58 ± 7.54 hours and in group B it was 24.37 ± 9.34 hours. Possible reasons for longer induction delivery in our study could be sequential use of intracervical foleys catheter and dinoprostone in Group A and overall acceptance of a longer latent phase, allowing for 12- 18 hrs. Use of oxytocin augmentation after artificial rupture of membranes before deeming the induction a failure when maternal and foetal parameters were reassuring.

The need for Caesarean delivery was found to be lesser, 18% in group A compared to 36% in group B, the difference being statistically significant (*P* 0.0426). These findings were consistent with those of other authors, like Penagaluru Radha *et al* showing 18 % for Foleys group and 32 % for Dinoprostone group [13]. Mumtaj M *et al* showed that 11.5% of para-1 patients of Foleys Group whereas 40.9% of the para-1 patients of PGE2 Group delivered by caesarean section [18].

On comparison of the two groups regarding maternal complications like fever, hypers timulation, diarrhoea and vomiting no statistically significant differences were found. These finding were consistent with those of Dileep P *et al* and Penagaluru Radha *et al* but contrary to the findings of Gayatri Mathuriya *et al*, where Dinoprostone group had significantly more minor complications [12-13-16]. Neonatal outcome did not differ significantly in our study between the two groups, similar to the studies by Anjuman *et al*. and Krishna *et al.* [14-17] a study by Penagaluru Radha *et al* showed more NICU admission in Dinoprostone group [13].

Conclusion

For most low risk pregnancies, compared to vaginal delivery, caesarean delivery appears to pose greater risk of maternal mortality and morbidity as well as long term risks associated with subsequent pregnancies. In this context, intracervical foleys catheter may aid to lower the caesarean delivery rate. Though sequential usage may increase the overall induction delivery interval, it does not appear to increase the incidence of neonatal sepsis, admission to the neonatal unit or the incidence of puerperal or intra partum fever. Moreover, Foleys catheter is less costly, can be preserved in room temperature and can be used in conditions where Dinoprostone gel is not advised. By using Foleys catheter as the initial ripening agent, we can also decrease the total usage of dinoprostone gel.

Hence in women in whom induction of labour is deemed necessary in the presence of poor Bishops score, intracervical Foley's catheter may be used as a ripening agent alone or sequentially with other agents like dinoprostone gel to achieve a higher vaginal delivery rate without hampering maternal of neonatal safety.

Conflict of interest: The authors declare that they have no conflict of interest.

Informed consent was obtained from individual participants included in the study

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Ethical approval: The study was approved by the Institutional Ethics Committee, ANIIMS

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