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Original Research Article

Comparing Effectiveness of Transcervical Foley Catheter Versus Intracervical Dinoprostone Gel for Induction of Labour

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Abstract: The present study was aimed at comparing the efficacy and safety of transcervical foley catheter versus intracervical prostaglandin E2 gel for labour induction by recording the difference in the Bishop's score as well as noting the maternal and neonatal outcome. This prospective study was conducted on 100 pregnant women in the Department of Obstetrics & Gynaecology, Gauhati medical college, Guwahati, Assam between June 2015 and May 2016. The participants were randomly allocated in two groups. Group A consisted of 50 patients who were given induction of labour with transcervical Foley catheter and Group B consisted of 50 patients who were given induction with prostaglandin E2 gel. Difference in preinduction and postinduction Bishop's score was noted. Other outcomes noted were mode of delivery, induction-delivery time, maternal and fetal complications. The study groups were comparable with respect to age, gestational age, parity and religion. The change is Bishop's score was highly significant in both the groups ($p<0.001$). However, the mean preinduction, postinduction and change in Bishop's score was comparable in both the groups. The mean induction- active labour time and requirement of labour augmentation was significantly higher in catheter group. However, the mean induction- delivery interval was comparable in both the groups. There were 2 cases of uterine hyperstimulation in gel group. Both the methods were equally efficacious in causing cervical ripening. Therefore, Foley catheter can be used as a safer and cheaper alternative to prostaglandin E2 gel for labour induction.
Keywords: Induction of labour, Foley catheter, Dinoprostone gel, Bishop's score

INTRODUCTION

The process of spontaneous labour is preceded by various changes in both mother and fetus, which should be given every chance to operate on its own. Induction of labour (IOL) should be offered only when it is believed that the outcome for the mother or baby or both, is better served by delivery than by continuing the pregnancy [1]. In many pregnancies, when IOL is offered cervix may not be in ripened state. Failure of cervix to ripen prior to onset of uterine contraction leads to poor outcome in terms of successful vaginal delivery. It can even lead to fetal compromise. The rate of successful induction is more with a ripe cervix, while the risk of caesarean delivery is found to be high in cases with unfavorable cervix and poor Bishop's score [2, 3]. Cervical ripening is achieved through either pharmacological agents or mechanical methods by increasing the local concentration of hormones that bring changes responsible for this process [4].

Mechanical methods include various types of bougies, catheters or laminaria tents, introduced into the cervical canal or into the extra-amniotic space [5]. These methods act by dilating cervix both mechanically by stretching the cervix as well as by releasing prostaglandins locally. While currently accepted mechanical method is insertion of Foley catheter extra-amniotically [6]. WHO has recommended Balloon catheter as an acceptable method of IOL [7]. There was no evidence of increased infection for either mother or baby with Foley catheter use [8, 9]. Also the low cost makes it particularly useful in limited resource settings like developing countries. Pharmacological agents include prostaglandins and oxytocin used for IOL.

Prostaglandins act by various mechanisms. They sensitize uterus to oxytocin and also help in cervical ripening. They cause softening of the cervix by alteration in the extracellular ground substance of the cervix. This occurs by increasing the activity of collagenase enzyme. However, they can sometimes result in uterine hyperstimulation due to hypertonic uterine contractions which can lead to fetal distress [10]. This becomes a potential drawback in using synthetic prostaglandins. Recent studies have shown that IOL with Foley catheter induces cervical ripening without inducing uterine contractions. This significantly reduces the rate of uterine hyperstimulation [11, 12].

The present study was conducted to compare mechanical methods and pharmacological methods for IOL. Each method has different sets of benefits and adverse reactions and none of the available option is superior.

MATERIALS AND METHODS

All women of age ≥ 18 years and Gestational age ≥ 37 weeks coming to the Department of Obstetrics & Gynaecology, with a medical or obstetric indication for labour induction and an unfavourable cervical Bishop's score ≤ 5 were eligible for the study. Patients with known hypersensitivity to prostaglandins and latex, previous caesarean delivery or a history of uterine surgery, previous attempted IOL for this pregnancy, placenta previa, undiagnosed vaginal bleeding, preeclampsia, eclampsia, fetal anomaly, fetal demise, maternal heart disease, active genital herpes infection, premature rupture of membranes and suspected chorioamnionitis were excluded from the study. 100 pregnant women with the inclusion criteria were selected randomly and equally distributed in two groups. In Group A, IOL was given with 16 Fr Foley Catheter and in Group B, Prostaglandin E2 (Dinoprostone) gel was given.

Procedure

Foley catheter group (Group A)

After asking the patient to urinate, she was asked to lie in lithotomy position. Under all aseptic conditions, a vaginal examination was performed to assess the preinduction Bishop's score. Then, Sim's speculum was inserted to visualize the cervix and to clean it with povidone iodine solution. The anterior lip of cervix was held with sponge holding forceps, following which a sterile prepacked 16 Fr Foley catheter was inserted into the endocervical canal with the help of a sterile artery forceps. The catheter was inserted beyond the internal OS and balloon was then inflated with 30ml of sterile water. The catheter was then pulled back so that the balloon got hitched back against the internal OS. The outside portion of catheter was strapped to the medial aspect of upper thigh in such a way that a gentle traction was maintained. Patient was observed for the initial 15 min for any leakage of amniotic fluid or water from the catheter causing deflation of the balloon. The catheter was checked for its position and the traction at 4-6 hours interval. Fetal heart rate monitoring was performed hourly and uterine activity was noted. The catheter was either removed after 12 hours or got expelled spontaneously. On expulsion of catheter a digital examination was performed and Bishop score was reassessed. The change in Bishop's score was noted.

Prostaglandin E2 gel group (Group B)

The patients of this group also underwent aseptic speculum examination and preinduction Bishop scoring. Dinoprostone or PGE2 gel was applied intracervically for induction. It comes as a translucent gel containing 0.5mg Dinoprostone per 3.0g in a specially designed ready to use disposable syringe. The syringe comprises of three components, the catheter, plunger and the barrel. Using a speculum, the cervix was cleaned of excess mucus and the entire contents of the syringe were administered into the cervical canal just below the level of internal os using the catheter. Following application, the patient was instructed to remain recumbent for atleast 30 minutes. Fetal heart rate and uterine activity were monitored. After 12 hours of giving gel, a repeat digital examination was performed and a repeat Bishop's score was assigned.

Depending upon the change in Bishop score, women were either given oxytocin or misoprostol for labour augmentation. Misoprostol was used in cases with lower Bishop's score change, while Oxytocin was used in patients with higher Bishop's score change. The oxytocin infusion was started following the Artificial rupture of the membranes (ARM). The oxytocin infusion consisted of 2.5 units of oxytocin in 500ml of Ringer lactate at 10 drops/minute. The dose was increased at 10 drops/minute interval upto a maximum of 60 drops/minute, or till the desired uterine contractions (three contractions every 10 minutes lasting for 40 seconds) were achieved. Standardized intrapartum treatment guidelines were used for all the patients.

The data was presented as mean ± standard deviation (SD) or percentage. Student's unpaired *t* test, Mann Whitney test and Chi square test were used to compare data between the two groups. P value <0.05 was considered to be statistically significant.

RESULTS AND OBSERVATIONS

The population demographics of both the groups were comparable. Mean age of the patients in the study group was 23.63± 4.123 S.D. years, ranging from 18 years to 36 years. Majority of women belong to Hindu religion and rural background in both the groups. The women had comparable

frequency of antenatal check ups in both the group. Mean Gestational age (in days) was 280.91 ± 10.01 S.D. ,ranging from 259 to 299. The mean parity of the study group was 0.39 ± 0.71 S.D., ranging from 0 to 4. Majority of cases were given labour induction due to postdated pregnancy and gestational hypertension. Other minor indication included Gestational Diabetes mellitus, Rh negative pregnancy, oligohydramnios, etc.

Table 1: Patient demographic data

Parameters		Group A	Group B	P value
Age		23.08 ± 4.06 S.D.	24.14 ± 4.18 S.D.	>0.05
Parity		0.3 ± 0.71 S.D.	0.48 ± 0.71 S.D.	>0.05
Gestational age		280.9 ± 10.16 S.D.	280.92 ± 9.95 S.D.	>0.05
Religion (%)	Hindu	35	29	>0.05
	Islam	15	21	>0.05
Number of antenatal checkups	0	10	11	>0.05
	<4	33	31	>0.05
	>4	7	8	>0.05

Table 2: Indications for IOL

Indication for induction (%)	Group A	Group B	P value
Postdated	29	27	>0.05
Hypertensive disorder	22	29	>0.05
Diabetes mellitus	2	1	>0.05
Rh negative	5	1	>0.05
IUGR	9	5	>0.05
Oligohydramnios	3	2	>0.05

The mean initial and final Bishop's score was comparable in both the groups. The mean Bishop's score change over 12 hours in the Group A and Group B were 4.6 ± 2.14 S.D. and 4.37 ± 2.36 S.D. respectively, having a non significant *p* value of 0.8414. There was a highly significant change between pre-induction and post-induction Bishop's score (p value< 0.0001).

Table 3: Initial and Final Bishop's score and the difference between the two

Bishop's score	Group A	Group B	P value
Mean initial Bishop's score	3.58 ± 0.95 S.D.	3.76 ± 0.96 S.D.	>0.05
Mean final Bishop's score	8.16 ± 2.04 S.D.	7.91 ± 2.71 S.D.	>0.05
Bishop's score rise	4.6 ± 2.14 S.D.	4.37 ± 2.36 S.D.	>0.05

In Group A, 25 cases (50%) experienced spontaneous balloon expulsion within 12 hours. While in other 50% cases, Foley was taken out after 12 hours. The mean balloon expulsion time was 10.42±2.24 hours. 13 cases delivered before completion of 12 hours by vaginal delivery, of which 4 cases were in Group A and 9 were in Group B (*p* value=0.13).

Out of total 100 cases, 46% cases required augmentation with either oxytocin or misoprostol and 54% cases did not require augmentation, which has a significant *p* value of 0.0273. Out of total 46 cases who required augmentation, 29 were in Group A and 17 in Group B (*p* value=0.01). Among the 54 cases who did not require augmentation, 21 were in Group A and 33 in Group B (*p* value= 0.01).

Table 4: Labour augmentation requirement

Augmentation status	Group A	Group B	Total	*p* value
Required	29	17	46	0.0273
Not required	21	33	54	
Total	50	50	100	

The mean duration from induction to active labour (in hours) in Group A and in Group B are 14.08 ± 4.802 S.D. and 11.92 ± 4.66 S.D. respectively, which has a significant *p* value of 0.0355. The mean duration from induction to delivery (in hours) in Group A and in Group B are 19.08 ± 6.48 S.D. and 17.27 ± 6.19 S.D. respectively, with a non significant p value of 0.22.

In both the groups, majority of cases delivered vaginally (68% in Group A and 62% in Group B). The mode of delivery was divided into spontaneous vaginal delivery (65%), assisted vaginal delivery (8%) and LSCS (27%) which was comparable in both the groups (*p* value= 0.7133). The major indication for LSCS was fetal distress (48%) followed by induction failure (26%) and prolonged labour (18%). The distribution of cases was comparable in both the groups (*p* value >0.05).

There were 9 maternal complications, number being fewer in Group A but not statistically significant (*p* value >0.05). 4 were Antepartum which included uterine hyperstimulation and maternal discomfort, both of them in Group B. 5 were postpartum, in which 2 cases of PPH and 1 case of pyrexia were in Group B and 2 cases of wound infection were in Group A. There was no case of uterine rupture. There were 20 cases in which neonatal complications were seen, 9 were in Group A and 11 were in Group B. Out of the 20 cases, the commonest was Neonatal Hyperbilirubinemia (60%). There was no case of maternal and neonatal mortality in the study.

Table 5: Delivery outcome

Delivery outcome	Group A	Group B	P value
Spontaneous vaginal delivery (%)	34	31	>0.05
LSCS (%)	13	14	>0.05
Assisted vaginal delivery (%)	3	5	>0.05
Induction-delivery time (hours)	19.08 ± 6.48 S.D	17.27 ± 6.19 S.D.	>0.05

DISCUSSION

The age, parity and gestational age were comparable in both the groups in the present study. Jozwiak M *et al* had comparable mean ages of 30.9 and 30.6 years in both the groups [11]. Dalui R *et al* had similar patient demographics as the present study, Primigravida being 64% in catheter group and 78% in gel group [13]. Prager M *et al*, Henry A *et al* and Pennell CE *et al* had reported similar characteristics as the present study with the mean gestational age of 39-40 weeks [12, 14, 15].

Majority of cases were booked pregnancies, but the number of antenatal check ups were inadequate. Only fifteen percent women had more than 4 checkups. This may be explained by the reduced awareness in the rural population who constituted the major part of the study group. Seventy-seven percent women constituted the rural population in this study group. Available literature did not show the evaluation of subjects based on these characteristics. There was one study by Henry A *et al* which discussed about the type of antenatal care either by physician or midwifery clinic. However, there was no mention about the number of antenatal visits [15].

The most common indications for IOL in this study were postdated pregnancy and gestational hypertension. In a review by Pennell CE *et al* and Jozwiak M *et al*, most cases were primigravida who were induced for similar indication i.e. postdated pregnancy and gestational hypertension [11, 12]. In a review by Dalui R *et al*, the most common indication for labour induction was pregnancy induced hypertension recorded as 44% in catheter group and 46% in gel group. While postdated pregnancy was quite low noted as six and eight percent respectively [13].

In the present study, there was a highly significant change in Bishop's score before and after induction in both the groups (p value <0.0001). However, mean preinduction and postinduction Bishop score as well as change in the score was statistically insignificant between the two groups. The findings of studies by Ezimokhai M *et al* and St Onge RD *et al* were in agreement with the above results [16, 17]. Similarly, Niromanesh S *et al* found statistically similar mean final Bishop's score in both groups (p value= 0.54). However they recorded statistically significant difference in duration to cervical ripening (3.4±2.1 hours in catheter group versus 6.5±3.2 hours, p value= 0.001) [18].

Dalui R et al had similar initial Bishop's score but the change in score was significantly higher in catheter group (5.32±1.47) as compared to gel group (2.64±0.93) with p value <0.001 [13]. Similarly, Sciscione AC reported significantly greater change in Bishop's score in catheter group (3.5 versus 2.7, p value= 0.01) along with a shorter induction time of 22.4 hours versus 30.4 hours in the gel group (p value <0.001) [19].

Women required significantly higher rate of labour augmentation in the foley catheter group than gel group (58% versus 34%, p value= 0.01). Available literature revealed studies with similar finding of increased requirement of oxytocin in catheter group versus gel group such as Jozwiak M *et al* (86% versus 59%,p<0.0001), Al-Taani MI *et al*, Cromi A *et al* (81.8% versus 51.8%,p<0.05), Henry *et al* (88% versus 59%, p<0.001) and Vaknin Z (p=0.0002) *et al*. [11, 15, 20, 21]. The additional requirement of oxytocin in Foley catheter group could be explained because of inability to generate simultaneous painful uterine contractions as seen with the use of locally applied prostaglandins [21]. While only one study was found that exhibited comparable use of oxytocin for augmentation in both the groups conducted by Sciscione A *et al* [19].

In the present study, the mean duration from induction to active labour was significantly higher in the catheter group (14.08 ± 4.802 hours versus 11.92 ± 4.66 hours, p= 0.035). The mean duration from induction to vaginal delivery is 19.08 ± 6.48 hours in Foley catheter group and 17.27 ± 6.19 hours in gel group, which was statistically non significant (p value= 0.22). Noor N *et al* recorded statistically similar induction to active labour time, but significantly longer induction-delivery time in catheter group than gel group (p < 0.01) [22]. Henry A *et al* stated that PGE2 gel is faster than foley catheter in induction as they recorded higher number of patients delivering within 12 hours of admission (53% in gel group versus 28% in catheter group, p value= 0.01). However total inpatient stay was statistically insignificant (p value=0.26) [15]. Similarly Jozwiak M *et al* recorded significant difference in delivery time (29 hours in catheter group versus 18 hours in gel group, p value <0.0001) [11]. In contrast to previous studies, St Onge RD *et al* reported significantly shorter induction to delivery duration in the Foley group compared to PGE2 gel group (16 ±1.7 hours versus 21.5 ± 3.2 hours, p value =0.014) [17].

Sixty-eight percent cases in Foley catheter group and sixty-two percent in gel group delivered vaginally (p value= 0.52). The rate of caesarean delivery as well as operative vaginal delivery was also comparable in both the groups. Twenty-seven percent cases delivered by caesarean section, while eight percent underwent operative vaginal delivery. The most common indication for caesarean delivery was fetal distress in 40% cases, followed by induction failure and non progress of labour in 25.9% and 18.5%, respectively. Findings of Jozwiak M *et al* were in accordance with those of present study. Majority of cases in their study had vaginal delivery (66% in catheter group versus 67% in gel group). Similarly, the rate of caesarean delivery in both groups were comparable (p value= 0.38). However, their major indication for caesarean section was failure of progress of labour in first stage which was significantly more in the catheter group than gel group (p value= 0.02). This was followed by fetal distress which was comparable in both the groups [11].

Maternal and fetal outcome was similar in both the cases. Two cases in the gel group developed hypertonic contractions and experienced discomfort due to pain in the present study. These cases were delivered by emergency caesarean section because of fetal bradycardia. Sciscione A et al reported comparable outcomes in terms of maternal side effects [19]. Jozwiak M *et al* reported cases of uterine hyperstimulation and uterine rupture following dinoprostone gel use. However, the difference between two groups was statistically insignificant [23].

In our hospital setting, Foley catheter was found to be consuming lesser cost as compared to Dinoprostone gel. In addition, the gel requires refrigeration for its storage. Sciscione A *et al* supported this advantage of Foley catheter over dinoprostone gel [19].

CONCLUSION

Both the methods were equally efficacious in causing cervical ripening. Therefore, Foley catheter can be used as a safer and cheaper alternative to prostaglandin E2 gel for labour induction.

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