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Original Research Article

Induction of labour: a randomized controlled trial

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ABSTRACT

Background: Clinical trial between Foley's catheter and Dinoprostone gel for change in Bishop Score after 12 hours of labour induction, mode of delivery, maternofoetal outcome and cost effectiveness. Induction of labour is necessary if the woman does not get timely, adequate and appropriate labour pains. Bishop's score is used to assess cervical ripening. Hence, we note the change in Bishop Score after 12 hours of labour induction to assess the success rates, time taken for active labour and delivery, maternofoetal outcome and the cost effectiveness.
Methods: Block randomized controlled clinical trial between Foley's catheter and dinoprostone gel for a sample size of 76 in each group was done.
Results: In women administered dinoprostone gel, there was significant change in Bishop score with a mean score of 7. Shorter induction active labour interval and induction delivery interval proved it to be a faster inducing agent. No significant difference was noted in terms of mode of delivery. A higher rate of fetal distress was noted in Foley's group probably as a result of prolonged labour and need for further augmentation with oxytocin for a long duration.
Conclusions: In terms of cost of labour Dinoprostone gel though more expensive than the Foley's catheter, eventually proved to be equally economical for the patients considering the faster labour induction, considerable vaginal delivery rates and hence shorter stay in hospital.

Keywords: Dinoprostone gel, Foley's catheter, Induction delivery interval, Post induction, Preinduction

INTRODUCTION

Labour in obstetrics is strictly defined as uterine contractions that bring about demonstrable effacement and dilatation of the cervix. Induction of labour implies stimulation of contractions before the spontaneous onset of labour with or without ruptured membranes.[1]

The goal of obstetrics is a pregnancy that results in a healthy infant and healthy mother. To achieve this target, an ideal method for induction of labour should have efficacy and safety for both mother and fetus. The success of induced labour depends on the degree of ripening of the cervix, which can be best assessed objectively by cervical ripening score as developed by Bishop.[2]

Induction of labour is a standard obstetric approach in properly selected patients. Overall throughout the world up to 20 percent of women have labour induced by various methods. It is a method by which pregnancy is terminated artificially any time after 28th weeks of gestation for various indications. A long induction delivery interval inevitably leads to important complications such as fetal distress, maternal exhaustion, dehydration and sepsis. Perinatal morbidity and mortality increases when pregnancies are allowed to continue beyond term. Induction of labour should be simple, safe,

effective and preferably non-invasive. The success of induction depends to a large extent on the consistency, compliance and configuration of the cervix.[2] The unripe cervix thus remains a well-recognized impediment to the successful induction of labour.[3] A simple and efficient method of ripening of the cervix before induction is, therefore, clearly of use.[4] The main indications for medical induction of labour are pregnancy Induced hypertension (PIH), postdates, gestational diabetes mellitus (GDM), ante partum eclampsia (APE), intrauterine growth restriction (IUGR), intrauterine death (IUD) and other medical disorders in pregnancy.

Although systemic or local application of preinduction agents likes oxytocin and prostaglandins have gained widespread use in recent years, mechanical methods for cervical ripening are less popular mainly in fear of infection. The use of an extra amniotic catheter balloon inflated above the internal cervical os has been advocated as a safe, low-cost and non-pharmacological method of cervical ripening before induction of labour.[5]

Over the last two decades, prostaglandins have been used locally quite frequently for effective cervical ripening and intravaginal, intracervical and extra amniotic routes have all been attempted.[6] Studies state that prostaglandin E2 (PGE2) gel administered intracervically is particularly well suited for priming of an unripe cervix because it can have a combined contraction inducing and cervical ripening effect.[7]

Objectives of present study were to compare change in Bishop Score after 12 hours of labour induction by intracervical Foley's Catheter with that of intracervical Dinoprostone gel, to compare the time interval between induction of labour and active labour in the two groups, to compare the maternofoetal outcome following labour induction and to estimate the cost effectiveness between the two groups.

METHODS

The study was done at Bangalore Baptist Hospital for a period of one year from August 2012 to July 2013. Institutional ethical clearance was obtained before the start of the study. Written consent was taken from the participants after explaining the procedure. This was a randomized controlled clinical trial and sample size was 152 with 76 in each group. Block randomization, anonymity and concealment were done by picking choices in sealed envelopes in a box. On admission to labour room, patient was assessed by Modified Bishop's score. Patients were randomized into their respective groups A (Foley's catheter induction group) or B (PGE2 gel induction group) by the block randomization method. For those in group A, Foley's catheter-20G was introduced intracervically after visualising the cervix with Cusco's speculum and the bulb of catheter inflated with 40 ml normal saline. Modified Bishop's score was reassessed after 12 hours and noted for progress. Patients in Group B had PGE2 gel (0.5mg) instilled intracervically and reassessed after 6 hours. In case of Bishop's Score remaining less than 6, second gel ofPGE2 was instilled as above. If patient was getting good contractions with Bishop's score >5, no intervention was done and Bishop's score was reassessed after 6 hours and labour progress was monitored with a partograph.

Statistical analysis

Data obtained was coded and entered into an excel sheet. The comparison of pre-induction and post induction scores individually in each group was done by paired t test. The change in Bishop Score between the two groups was compared using Mann Whitney U test and within the group was compared using Wilcoxans signed rank test. P <0.05 was considered as statistically significant. SPSS Inc version 18.0 was used for statistical analysis.

RESULTS

In this study, subjects were in the age group of 21-25 years constituting 37.66 % and 46.67% respectively in the two groups. There was no statistically significant difference between the two groups in terms of age distribution. (X^2=4.0, p value=0.4). Majority of the patients were registered with distribution comparable between the two groups constituting 97.40% and 96.0% respectively (X^2=13.2 p=0.01). Most of the patients induced were primigravida in both the groups with a significant number of them in the Foley's group constituting 72.72% of the population (X^2=5.64 p value=0.10). Patients induced were 40 weeks and above constituting 67.53% and 49.33% respectively with no statistically significant difference. The indication for induction of labour was postdatism constituting 58.44% and 42.66% respectively. In 42 (54.54%) women only 1 Dinoprostone gel was used, 2gels were used in 30 (40 %) and 3 (4%) of Dinoprostone gel group population. Majority of the patients required augmentation with either pitocin or ARM or both in Foley's group constituting 83.11% of the population as opposed to only 66.67 % requiring either augmentation in Dinoprostone gel group respectively. This difference was found to be statistically significant (X^2=5.48 p=0.01).

In the 2 groups, most of the patients entered active labour after 12 hours. In the PGE2 group 20% of patients however entered active labour within 6 hours of induction as opposed to only 2.59% in the Foley group. A statistically significant difference was noted in the induction active labour interval between the 2 groups.

Majority of the patients delivered after 12 hours and within 24 hours in both the groups. Among the patients delivering within 12 hours majority were in the PGE2 gel group constituting 29.33% as opposed to 2.59% in Foley s group and the difference was found to be statistically significant.

Table 1: Demographic profile of the study subjects.

Demographic characters		Group F (n=77)	Group P (n=75)	P value
Age (years)	<20	10 (12.98)	7 (9.33)	0.313
	21-30	57 (74.02)	64 (85.33)	
	>31	10 (12.98)	4 (5.33)	
Registration of pregnancy	Yes	75 (97.40)	72 (96)	0.974
	No	02 (2.59)	3 (04)	
Number of times gravid	≤2	72 (93.50)	61 (81.33)	0.04
	>2	05 (6.49)	14 (18.66)	
Gestational age in weeks	37-40 wks	25 (32.46)	38 (50.66)	0.022
	>40 wks	52 (67.53)	37 (49.33)	
Indication for induction	Post dates	45 (5.44)	32 (42.66)	0.80
	IUGR	2 (2.59)	2 (2.66)	
	GDM	3 (3.89)	4 (5.33)	
	RH negative	0 (0)	2 (2.66)	
	Previous IUD	1 (1.29)	0 (0)	
	PIH	7 (9.09)	13 (17.33)	
	Oligohydraminos	6 (7.79)	7 (9.33)	
	Others (NRNST,elective)	13 (16.88)	15 (20)	

Fetal distress was the only complication noted in 25.97% and 13.33% in the Foley's and PGE2 group respectively. Majority of the patients delivered vaginally in both the groups constituting 53.24% and 69.33% respectively with 41.55% undergoing caesarean section in the Foley's group as compared to 28% in Dinoprostone gel group and the difference was not found to be significant (Chi sq=4.23 p=0.12). Major Indication for caesarean section in both the groups was foetal distress (Group A n=10, 12.98%) (Group B n=6,8.0%) followed by failure to progress (Group A n=7, 9.09%) (Group B n=5, 6.66%). Forceps delivery was observed in 4 (5.20%) women in group A and 2 (2.66%) women in group B.

Table 2: Pre-and post-induction bishop's score in the two groups.

Bishops Score	Group F Median (IQR)	Group P Median (IQR)	P value
Pre-Induction	3.0 (2.5-4.0)	6.0 (4.0- 7)	0.74
Post Induction	3.0 (2.0-4.0)	6.0 (4.0-13)	0.06
P value	P <0.001	P <0.001	

Table 3: Change in the bishop score between the two groups.

	Group F (N=77)	Group P (N=75)
Mean	5.96	7.69
SD	2.36	4.24

p=0.0022

In 25 (32.46%) and 17 (22.66 %) women additional PGE1 (25mcg) was used for induction of labour in both groups respectively.

Table 4: Comparison of time Interval between induction and active labour.

Time interval	F group (n=77)	P group (n=75)
<6 hours	2 (2.9)	15 (20.0)
6-12 hours	34 (44.15)	24 (32.0)
>12 hours	41 (53.24)	36 (48.0)

(X2 =12, p=0.003)

Table 5: Comparison of induction delivery interval in the two groups.

Duration in hours	Group F	Group P
<12	2 (2.59)	22 (29.33)
12-24	49 (63.3)	31 (41.33)
>24	26 (33.76)	22 (29.33)

X2=21.02, P<0.001

DISCUSSION

Labour is a complex process characterized by onset of effective uterine contractions leading to the progressive cervical dilatation and effacement of the cervix leading to expulsion of the fetus, placenta and the membranes. Pre-labour is characterised by both cervical ripening and myometrial excitement which finally culminate in labour. Understanding the physio-pharmacology of labour help clinicians to manage the process more efficiently and modify the process when required, by the use of pharmacological agents to stimulate or initiate labour.[8]

The aim of induction of labour is to achieve vaginal delivery well in advance of the natural timing of parturition. The aim of induction is an attempt to prematurely induce two interlinked components of labour mainly cervical ripening and uterine contraction. Hence the aim of induction is to pharmacologically intervene a

physiological process to mimic the natural process as closely as possible. The process by which the cervix becomes soft, compliant and partially dilated is termed cervical ripening. It is thought to be due to a combination of bio-chemical, endocrine, mechanical and inflammatory events.

During pregnancy, the cervix should remain firm and closed allowing the fetus to grow in utero until functional maturity is attained. During labour, it should soften and dilate, allowing the fetus to pass through the birth canal. This is one of the fundamental steps in the process of parturition. Braxton Hicks contractions have believed to a play a role in effacement of cervix. In the present study, patients in both the groups were found to be comparable with respect to age, ante natal care, gravidity, parity and gestational age at admission thereby eliminating majority of the confounding factors. Majority of the patients were induced for postdates.

The primary outcome measured was change in modified Bishop Score after 12 hours of labour induction. The results showed a statistically significant change in Bishop score in both the groups individually by paired t test (p=0.0001), however on comparison of both the groups by z test, Dinoprostone gel showed a clinically and statistically significant change in Bishop score proving to be better cervical ripening agent.

Present study showed a favorable outcome with PGE2 gel with respect to Bishop score whereas Azra et al and Krishna et al found no such difference.[9,10] Rabindranath et al obtained better results with Foley's catheter labour induction.[11] In a randomised prospective study on 200 patients by Deshmukh et al[12] the change in Bishop Score at the end of 6 hours was 5.56±1.89 and 5.49±1.82 with p value <0.001 for Foley's catheter and Dinoprostone group respectively, which was significant in itself but no difference was found between the 2 groups.

Krishna Dahiya et al conducted a randomised prospective study on 100 patients with 50 in each group comparing Foley's catheter to Dinoprostone gel for cervical ripening and noted the following. Both showed a significant change in Bishop Score with resulting p value<0.001, however no significant difference was noted between the 2 groups.[13] Sciscione et al conducted a prospective randomised study comparing Foley's catheter and PGE2 gel for cervical ripening on 77 and 72 patients respectively. They noted a significant change in Bishop Score in Foley's group after induction (p<0.001) and change in Bishop score (p -0.015) which was higher than the other group.[14]

Onge et al conducted a randomised prospective study with 30 and 36 patients allotted to PGE 2 and Foley's group respectively and their efficacy with respect to pre-induction cervical ripening compared. Both showed a significant change in Bishop Score (p<0.001) with no difference between the 2 groups noted. No significant difference was noted with respect to side effect profile, intrapartum complications and mode of delivery or C-section rate. The induction delivery interval was 16±1.7 hrs in Foley's group and 21.5±3.2 hrs(p-0.014) in PGE 2 group. No difference was noted in the Apgar, cord gases or birth weights. They concluded that no significant difference existed between the 2 groups.[15]

The induction active labour interval showed a significant number of patients (20%) in PGE2 group delivering within 6 hours of induction as compared to Foley's group (2.59%) with p=0.003, proving yet to be a faster cervical ripening agent. In a randomized study by Dewan et al among 35 patients in each group it was found that the induction to onset of labour pains between the two groups was not significantly different.

The induction delivery interval we found 29.33% in PGE2 delivering within 12 hours as compared to only 2.59% in Foley's group which was statistically significant (p=0.000) hence also proving to be a faster labour inducing agent. In earlier study done by Rabindranath et al however the population delivering within 12 hours was 10% in both groups and not found to be significant. In the study by Dalui et al the maximum number of women delivered between 12-24 hours in Foley's group and more than 24 hours in Dinoprostone group.

Onge et al in their study found the induction delivery interval was 16±1.7 hrs in Foley's group and 21.5±3.2 hrs (p-0.014) in PGE 2 group.[15] Sciscione et al found that total induction time was shorter in Foley's group 22.4 vs. 30.4 % (p<0.001). Patient charges were 31 % lower in Foley's group (p< 0.01).[14] In Foley's group there was a need for further augmentation with oxytocin or ARM or both as compared to Dinoprostone gel group which was found to be statistically significant. On comparing the outcome in terms of mode of delivery this study found a higher vaginal delivery rate and a lower C-section rate with Dinoprostone gel induction, however it was not found to be statistically significant.

The C-section rate was 14 % and 18.5 % which was not significant. Induction delivery interval was 15.32±5.24 and 14.2±5.14 with p-0.291. Hence it was concluded that both methods were equally effective. Krishna Dahiya et al found no difference between the 2 groups in terms of induction to delivery interval and mode of delivery.[13] Sciscione et al No difference between the 2 groups was noted in terms of mode of delivery, infant weight, rate of hyper stimulation, shoulder dystocia, patient discomfort, epidural use, oxytocin use or non-reassuring fetal heart pattern.[14]

The only complication noted was fetal distress in both the groups which constituted 25.97% and 13.33% in Foley's and Dinoprostone gel group respectively. In studies conducted by Rabindranath et al and Krishna et al an 8% rate of hyper tonicity was noted in Dinoprostone gel group. Dewanan et al found 14.3% increased rate of

nausea in Dinoprostone gel group. Krishna et al found 8% and 6% incidence of discomfort in Foley's and Dinoprostone group respectively. Rabindranath et al found <10% incidence of vaginal discharge, bleeding and pain in Foley's labour induction group, however no such incidence was recorded in our study. Deshmukh et al did not find any difference in side effects between the two groups. In the present study, no statistically significant difference was found in terms of total cost incurred to patients from labour induction from the time of admission to discharge**.** In fact, the mean cost obtained was higher for Foley's group. Hence cost as a factor did not prove to be advantageous for Foley's catheter as compared to Dinoprostone gel as a labour inducing agent even though the price of Foley's catheter was lesser than Dinoprostone gel on an absolute scale.

In the study by Dewan et al, Foley's catheter was a better agent for ripening the cervix as the success rate was 97%. This procedure may reduce the burden of costly and hazardous operative intervention, hospital stay and psychological adverse effect on the patients and family[3]. Krishna Dahiya et al found a highly statistically significant difference in terms of cost, with cost of Foley's catheter amounting to Rs. 60/- and Dinoprostone gel Rs 325/- with 54% requiring a second gel. Thus, they concluded that Foley's induction was a safe, effective, cheap mode of induction which can be used on an outpatient basis and was a superior method especially for developing countries.[13]

CONCLUSION

Dinoprostone gel is comparatively better than Foley's catheter for cervical ripening and labour induction. The faster induction process aids in reducing the rate of prolonged labour and its associated maternal and foetal complications.

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