International Journal of Clinical Obstetrics and Gynaecology

ISSN (P): 2522-6614
ISSN (E): 2522-6622

www.gynaecologyjournal.com
2020; 4(6): 139-142
Received: 08-08-2020
Accepted: 22-09-2020

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Comparison of efficacy of different modes of induction in predicting the outcome of labour: A randomized controlled trial

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DOI: https://doi.org/10.33545/gynae.2020.v4.i6c.744

Abstract
Aim: To Compare the efficacy of PGE2 gel (Prostaglandin E2 gel), oral misoprostol and combination group (Foleys bulb + oral misoprostol) in predicting the outcome of induction of labour.
Materials and Methods: This prospective randomized controlled trial included 300 women requiring induction of labour. A total of 101 women were randomly allocated to PGE2 gel group, 99 women to oral misoprostol group, 100 women allocated to the combination group using computer generated allocation sequence. The primary outcomes which was analysed in the study were time interval between induction and active phase of labour and time interval between induction and delivery.
Results: The mean time interval between induction and active phase of labour was shorter with combination group compared to the prostaglandin E2 group & oral misoprostol group (8hrs vs 11hrs vs 13hrs, p value 0.004). The combination group and the prostaglandin E2 had almost the same shorter time interval between induction and delivery (17hrs vs 17hrs vs 20hrs, p value 0.104). No significant difference was observed with regard to maternal and neonatal outcomes.
Conclusion: In our study, the combination group achieved shorter time interval between induction and active phase of labour, while combination group and PGE2 gel group had almost similar time interval between induction and delivery and also higher number of vaginal deliveries compared to oral misoprostol group without increasing labour complications.

Keywords: Efficacy, induction of labour, PGE2 gel, misoprostol, foleys bulb

Introduction
Induction of labour is a common obstetric procedure involving complex set of interventions with numerous choices and challenges for clinicians and mothers [1]. Most common indication for labour induction is post term pregnancy which helps in reducing the perinatal deaths [2, 3]. Other indications include premature rupture of membranes, termination of high-risk pregnancies, potential fetal compromise like fetal growth restriction, non-reassuring fetal surveillance, maternal medical conditions, chorioamnionitis, abruptio placentae and intrauterine fetal demise. Inductions are also done for social reasons without obstetric or medical indications [4, 6].
Successful inductions result in vaginal delivery but sometimes fails leading to increased risk of operative vaginal deliveries, Caesarean sections mostly due to hyperstimulation and abnormal fetal heat rate patterns. Women should be assessed properly regarding indications and contraindications for induction. Other factors include assessment of pelvis, bishop score, fetal size, membrane status and presentation [7, 9]. The favorability of cervix plays an important role for successful labour induction. Discussion with the patient regarding indication for induction and its risk factors must be documented. The rate of induction varies according to ethnicity [10]. There are few well designed studies describing different methods of induction.
Our study was designed to review the different modes of induction, its indication and the outcome of induced labour and the significance of it in the routine obstetric practice.

Materials and Methods
The present study was a randomized controlled trial carried out in the department of Obstetrics & gynaecology, Joseph hospitals, Chennai, from June 2019 to January 2020 with 300 study population after obtaining approval from the Institutional Ethical committee. Informed consent was taken from all cases included in the study. Study was also registered under Clinical trial act (CTRI/2019/06/019614)

Inclusion Criteria
Gestational age after 37weeks irrespective of parity
Singleton, cephalic presentation
Intact membranes
Unfavourable cervix (Bishops score <6)
Reassuring cardiotocography

Exclusion Criteria
Fetal malpresentation
Rupture of membranes
Multifetal gestation
Non reassuring fetal heart rate changes
Fetal growth restriction (defined as estimated fetal weight less than 10th percentile for gestational age)
Fetal demise
Previous cesarean delivery or other uterine surgery (myomectomy, cornual wedge resection)
Anomalous fetus

Primary outcomes
Time interval between induction and active phase of labour
Time interval between induction and delivery.

Secondary outcomes
Dosage of Prostaglandins, Mode of delivery, Hyperstimulation (defined as greater than five uterine contractions in 5minutes with fetal heart rate decelerations), Postpartum haemorrhage (defined as estimated blood loss greater than 500ml for vaginal delivery or greater than 1000ml for caesarean delivery), Chorioamnionitis and Neonatal outcomes.

In Group I (PGE2 gel) women received 0.5mg of Dinoprostone gel intracervically from the prefilled syringe, maximum of 3 doses, 6hrs apart after exposing the cervix by cuscos speculum and the patients were allowed to lie down for at least 30minutes.

In Group II (Oral misoprostol) women received 25mcg oral misoprostol every 4 hours, up to maximum of 4 doses. Once the cervix becomes favourable (Bishops score ≥6) or the patient enters into active labour, drug was discontinued. Further management of labour was with expectant management or amniotomy or augmentation of labour with intravenous oxytocin.

In Group III (combination group) women received oral misoprostol 25mcg every 4hours, maximum of 4 doses. In addition, a 20F Foleys bulb was inserted into the internal os by direct visualization with the aid of a sterile speculum and bulb was inflated with 50ml distilled water. Foleys catheter was pulled with gentle traction and was taped to patients medial aspect of the thigh. After Foleys bulb expelled, further management of labour carried on with amniotomy or intravenous oxytocin.

In all the three groups, patients who had unfavourable cervix (BS<6) even after completion of maximum doses, were started on intravenous oxytocin at 2milliunits/min increasing by 2milliunits every 20minutes until regular contractions occurs. In all the patients cardiotocography was used for fetal heart rate monitoring and uterine contractions assessed clinically. In our study, failed induction was labelled to patients whose bishop score was less than 6 even after 12hrs of intravenous oxytocin administration in the latent phase of labour.

The details of all the patients which included demographic characteristics, medical and antenatal history, course of labour, indication for labor induction and outcome were collected. The collected data were analyzed with IBM.SPSS statistics software 23.0version. To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean and standard deviation were used for continuous variables. To find the significant difference in the multivariate analysis the one way ANOVA with Tukey's Post-Hoc test was used. To find the significance in categorical data, Chi-Square test was used. In both the above statistical tools the probability value, 0.05 is considered as significant level.

Results
A total of 300 women were enrolled in the study from June 2019 to January 2020 [Fig 1]. Of these, 101 were assigned to PGE2 gel group, 99 assigned to oral misoprostol group and 100 to the combination group.

The three groups were comparable with regard to baseline characteristics including indication for induction of labour [Table 1]. Most of the study population were term nulliparous women. The most common indication for induction of labour was postdated pregnancy. The mean Bishop's score was similar in the three groups (3[range 1-6]).

The primary outcome were mean time interval from induction to active phase of labour was 8 hours in the combination group, 11 hours in PGE2 gel group and 13hours in the oral misoprostol group, which was statistically significant (p <0.004) irrespective of parity in all the three groups. The mean time interval from induction to delivery was 17hours in both Group I & III (PGE2 group & combination group), whereas 20 hours in the oral misoprostol group. This was not statistically significant (p <0.104) [Table 2].

The proportion of women who achieved vaginal delivery were 69% in Group I, 63% in Group III while its 52% in Group II which was not statistically significant (p 0.084). Caesarean section rate also was more in Group II constituting 18% compared to other two groups [Table 2].

Most of the patients in Group I needed only single dose for induction. The mean number of oral misoprostol doses used for induction in the combination group (Group III) were lower compared to oral misoprostol group (Group II) [Table 3]. In patients who had failed induction with one method of induction, we used other method of induction in order to increase the rate of vaginal delivery and its outcome is mentioned and the comparison was statistically significant (p <0.002) [Table 4] There were no differences in oxytocin augmentation or epidural analgesia use.

The incidence of secondary outcomes were not significantly different in three groups. [Table 5].

Table 1: Demographics & Patient Characteristics:

Characteristics	Group I (n-101)	Group II (n-99)	Group III (n-100)
Parity - G1	70 (69.3%)	76 (76.8%)	77 (77%)
G2	31 (30.7%)	23 (23.2%)	23 (23%)
GA - <40weeks	62 (61%)	53 (53%)	67 (67%)
>40weeks	39 (39%)	46 (47%)	33 (33%)
Bishop score	3 (1-6)	3 (1-6)	3 (1-6)
Indication for Induction			
Postdated	39 (39%)	46 (46%)	33 (33%)
Social reason	17 (17%)	22 (22%)	23 (23%)
Decreased FM	7 (7%)	5 (5%)	5 (5%)
Gestational DM	16 (16%)	10 (10%)	12 (12%)
PIH	11 (11%)	8 (8%)	14 (14%)
Big baby	5 (5%)	3 (3%)	5 (5%)
Prolonged latent phase	6 (6%)	4 (4%)	6 (6%)
Bad Obstetric History	-	1 (1%)	1 (1%)
Cholestasis	-	-	1 (1%)

Table 2: Comparison of outcome of Primary outcome

Parameters	Group I (n-101)	Group II (n-99)	Group III (n-100)	p Value
Time to enter into active phase	11±3hrs	13±4hrs	8±2hrs	0.004
Induction to delivery time	17±5hrs	20±6hrs	17±4hrs	0.104
Mode of Delivery				
Spontaneous Vaginal Delivery	70 (69%)	51 (51.5%)	63 (63%)	0.084
Instrumental Delivery	23 (22.8%)	30 (30.3%)	26 (26%)	
Caesarean Section	8 (7.9%)	18 (18%)	11 (11%)	

Table 3: Comparison of outcomes of Secondary outcomes:

Parameters	Group I (n-101)	Group II (n-99)	Group III (n-100)	p Value
No. of doses	1 (1-3)	4 (1-4)	2 (1-4)	0.0005
Oxytocin acceleration	42(42%)	55 (55%)	54 (54%)	0.095
Epidural Analgesia	23 (23%)	33 (33%)	34 (34%)	0.150
Fetal weight	3 (2.9-3.5)	3 (2.8-3.3)	3 (2.9-3.7)	0.279
Indication for C. Section				0.872
Failed induction	1 (12%)	8 (44%)	1 (9%)	
Fetal distress	2 (25%)	3 (17%)	3 (27%)	
Non progress of labour	2 (25%)	6 (33%)	5(45%)	
Big baby	2 (25%)	1 (6%)	2 (18%)	
Obstructed labour	1 (12%)			

Table 4: Second method of induction

Initial method	2nd method used	Outcome	p Value
Group I (PGE2 gel)	Foleys -1	ID-1	0.002
Group II (Oral Misoprostol)	Foleys -8	ND-3, LSCS-4, ID-1	
Group III (Foleys + Oral Misoprostol)	PGE2 gel -1	LSCS-1	

Table 5: Maternal & neonatal complications:

Parameters	Group I (n-101)	Group II (n-99)	Group III (n-100)	p Value
Maternal complications				
PPH	5 (5%)	7 (7.1%)	1 (1%)	
Chorioamnionitis	1 1%)	-	2 (2%)	
CPT	1 (1%)	1 (1%)	-	
Neonatal Complications				
Hyperstimulation	3 (3%)	8 (8%)	5(5%)	
Meconium stained liquor	7 (7%)	8(8%)	6 (6%)	
Shoulder Dystocia	2 (2%)	1 (1%)	2 (2%)	
Neonatal death	-	-	-	

Discussion

In our study, we found that the time to enter into active phase with the combination group was only 8hrs while it was 11hrs with the Prostaglandin E2 gel group & 13hrs with only Oral Misoprostol group. The difference in induction to delivery time was 3±4hrs with Prostaglandin E2 gel & the combination group compared to the Oral Misoprostol group. No differences were observed in labour complications or adverse maternal & neonatal outcomes. Our study was similar to study done by Gayathri Mathuriya *et al*. who concluded that prostaglandin E2 gel has shorter time interval between induction and delivery [11].

The total number of doses required for inducing delivery decreases when an additional method of induction is used. This leads to decreased incidence of complications like hyperstimulation and low apgar at birth. In our study, maximum number of patients in group I needed only single dose for ripening.

A large systematic review and network meta analysis comparing the use of Foley's catheter, oral misoprostol and dinoprostone gel for cervical ripening in the induction of labour done by W Chen *et al*. concluded that no method of labour demonstrated overall superiority [12].

This study is a prospective randomized controlled trial involving both nulliparous and multiparous using three different induction agents. There were very few randomized controlled study comparing the efficacy of Foleys and oral Misoprostol with Prostaglandin E2 gel in the literature. Mei-Dan *et al*. in his study proved that Foleys balloon is more cost effective than the double balloon catheter [13].

While inducing labour, the major areas of concern are patient acceptability and cost effectiveness and also shorter interval time from induction to delivery [14]. Our study has taken all these factors into consideration. A very few analysis evaluating combined approach have been published. The only disadvantage of prostaglandin E2 gel is, it is cost expensive and needs refrigeration. While misoprostol is considered cheaper, stored at room temperature and Foleys bulb is inexpensive, readily available in all situations [15]. Bishop score plays a major role and mode of induction can be decided depending on the resource settings.

Conclusion

The results of our randomized trial showed that the time interval from induction to enter into active phase is shorter with combination group. While the time interval from induction to delivery and the percentage of vaginal deliveries are almost the

same with Prostaglandin E2 gel and the combination group. Hence in low resource settings, combination of mechanical and pharmacological method would also suffice the ease of monitoring & delivery with shorter interval since Prostaglandin E2 gel is cost expensive and needs refrigeration. These results suggest that combination of induction agents may be used to achieve safe and timely delivery in the presence of an unfavourable cervix. Although not directly evaluated in the study, decreased time interval from induction to delivery by 3-4hours would be significant for patients, health care providers and hospitals. Hence further studies should be of sufficient power to assess significant labour complications and adverse maternal and neonatal complications.

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