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STUDY TO COMPARE THE EFFICACY OF PROSTAGLANDINS AND EXTRA AMNIOTIC BALLOON CATHETER METHODS FOR INDUCTION OF LABOUR.

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Conflicts of Interest: Nil

ABSTRACT:

Induction of labour is probably the most used obstetrical intervention, first described by the ancient Greek physician Hippocrates. Induction implies stimulation of contractions before the spontaneous onset of labour, with or without ruptured membranes. The purpose of induction of labour as compared to continuation is to end the pregnancy through vaginal delivery, in situations where pregnancy termination is expected to reduce risks to the mother or her baby. There are several different methods for cervical ripening, that can be categorized in mechanical (Foleycatheter) & pharmacological (prostaglandins). The aim of this study is to compare the efficacy of prostaglandins and extra amniotic balloon catheter for successful induction of labour. The comparative study was conducted in labour room of Patna Medical College Hospital, Dept of Obs & Gynae. All 100 pregnant women after 28 completed weeks of gestation were randomly allocated in two groups: Group A & Group B. GROUP A: induction with prostaglandins (PGE2 gel & misoprostol) GROUP B: induction with extra amniotic balloon of Foley's catheter. The data was presented as mean standard deviation (SD) or percentage. Student's unpaired t test and Chi square test were used to compare data between the two groups. In the present study, it was observed that the induction-labour interval and induction-delivery interval are less in extra amniotic balloon catheter group as compared to prostaglandins. There is no difference in caesarean section rate, neonatal mortality and morbidity when compared to prostaglandins. It can be a safe alternative to prostaglandins Also it can safely be used in patients where prostaglandins are contraindicated (previous caesarean section).

Key words: Prostaglandins, Balloon catheter, Induction of labour.

Introduction

Induction of labour is probably the most used obstetrical intervention, first described by the ancient Greek physician Hippocrates [1]. Induction implies stimulation of contractions before the spontaneous onset of labour, with or without ruptured membranes. Labour refers to the onset of effective uterine contractions leading to progressive effacement & dilatation of cervix resulting in expulsion of fetus followed by placenta & membranes. The purpose of induction of labour as compared to continuation is to end the pregnancy through vaginal delivery, in situations where pregnancy termination is expected to reduce risks to the mother or her baby. In the decision to induce labour or not, one has to find the right balance between benefits and possible harms of continuation of pregnancy. The two most important factors in that decision are the mother and her baby. Delivery before the due date is needed when the condition of the mother, the baby, or both, is severely compromised. Induction of labour increases the risks for neonatal and long-- term developmental complications, but could be justified if continuing pregnancy would jeopardize the baby through infection, asphyxia or intra uterine fetal demise (IUFD), depending on the clinical situation[2-8] . Similarly, from the maternal perspective, continuation of pregnancy could harm the mother in case of severe hypertension, infection or other

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pregnancy related complications.[9,10] Consequentially, induction of labour is an intervention that should only be performed when the benefits of ending pregnancy outweigh the risks of induction of labour, either from the perspective of the mother, the baby or both, or when the expected harm to one of them is less than the expected benefit for the other. It is of importance to distinguish between women with a ripe and unripe cervix. The Bishop score was developed in 1964 as a predictor of success for an elective induction in multiparous woman. There are several different methods for cervical ripening, that can be categorized in mechanical (Foleycatheter) & pharmacological (prostaglandins)

Prostaglandins not only play an important role in cervical ripening, but also have effect on uterine contractility [11]. The use of a balloon catheter as induction method was first described in 1862 by Tarnier. The mechanism of action is twofold. The first is mechanical, by direct dilatation through pressure on the cervix. Secondly, by releasing endogenous prostaglandins from the cervix[12,13]. The aim of this study is to compare the efficacy of prostaglandins and extra amniotic balloon catheter for successful induction of labour.

Material and Methods:

The study was conducted in labour room of Patna Medical College Hospital, Dept of Obs & Gynae.

Study subjects: 100 in both groups.

Study Duration: 2 yrs.

Study Design: Prospective Comparative study.

INCLUSION CRITERIA:

All pregnant women with gestational age >28 completed weeks with Bishop's score ≤4., requiring induction of labour. (Gestational age calculation was done by:

(i) LMP: Naegles' formula
(ii) Ultrasound (first trimester)

EXCLUSION CRITERIA

- Malpresentation
- Local infection: Vaginitis chorio-amnionitis, Genital herpes.
- Abnormal implanted placentas .
- Absent membranes.
- Classical caesarean scar.
- Previous 2 Caesarean section.

Before inducing, EDD was confirmed by taking into consideration:

- LMP,
- Regularity of menstrual cycles,
- Early Ultrasonogram scan.
- Then general examination and obstetric examination carried out.
- After ruling out low lying placenta by ultrasonogram, pelvic examination done and Bishop score calculated.
- It is a time – honored fact that Bishop Score is a sensitive indicator that
- Predicts successful induction of labour.

Table 1: Bishop scoring system:

Score	Dilation (cm)	Position of cervix	Effacement (%)	Station (-3 to +3)	Cervical Consistency
0	Closed	Posterior	0-30	-3	Firm
1	1-2	Mid position	40-50	-2	Medium
2	3-4	Anterior	60-70	-1,0	Soft
3	5-6	-	80	+1,+2	-

PROCEDURE

- All pregnant women after 28 completed weeks of gestation were randomly allocated in two groups: Group A & Group B.
- GROUP A :induction with prostaglandins(PGE2 gel & misoprostol)
- GROUP B: induction with extra amniotic balloon of Foley's catheter.
- Detailed history and examination was done.
- Pre & post induction Non stress test was done.

- Pre induction Bishop's score was assessed and improvement in Bishop's score was assessed every 6 hours.
- If there was any evidence of infection, it was treated accordingly.

DATA ANALYSIS

- The data was presented as mean standard deviation (SD) or percentage. Student's unpaired t 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:

Table 2: Distribution of Age

Age in Year	Group – A		Group – B		Total	p value
	Number	Percent	Number	Percent		
<20 yrs	5	5	5	5	10	
20-24	59	59	63	63	122	
25-29	28	28	25	25	53	
30-34	8	8	7	7	15	
Total	**100**	**100**	**100**	**100**	**200**	**>0.05[a]**
mean	**23.55 ± 3.46**		**23.5 ± 3.28**			**>0.05[a]**

[a] Chi-square test.

This table shows the distribution of patients for age in both regimens. Age ranged between 18-33 years in both group

Table 3: Indication for Induction

Induction	Group – A		Group – B		Total	P value
	Number	Percent	Number	Percent		
POST EDD	83	83	78	78	161	
HDP	10	10	10	10	20	
IUD	4	4	8	8	12	
OLIGO	3	3	4	4	7	
Total	**100**	**100**	**100**	**100**	**200**	**>0.05[a]**

[a]Chi-square test

This shows the distribution of the indication for induction.

Most common indication of induction is post datism(80.5%)

Table 4: Mean induction to active labour interval

	Group – A		Group – B		P value
	PRIMI	MULTI	PRIMI	MULTI	
ILI	8.41 ± 1.72	6.38 ± 1.17	6.08 ± 1.75	4.97 ± 0.96	<0.001[a]

[a] t-test.The mean induction active interval in primi with Extra amniotic balloon catheter was 6.08 hrs. The mean Induction to active labour interval in primi with PGs was 8.41hrs.

The mean Induction active labour interval in multiparous with Extra amniotic balloon catheter was 4.97 hrs. The mean Induction to active labour interval in multiparous with PGs was 6.38hrs.

Table 5: Induction delivery interval

Duration in Hours	Group – A				Group – B			
	Primi		Multi		Primi		Multi	
	No	%	No	%	No	%	No	%
6-12	26	49.4	24	70.6	40	63.5	36	97.3
12-24	40	60.6	10	29.4	23	36.5	1	2.7
Total	**66**	**100**	**34**	**100**	**63**	**100**	**37**	**100**

63.5% of Primi delivered within 12 hrs in the extra amniotic balloon catheter group compared to only 49.4% in the PGs group. 97.3% of Multi delivered within 12 hrs in extra amniotic balloon catheter group compared to 70.6% in the PGs group.

Table 6: Mean induction delivery interval

	Group – A		Group – B		P value
	PRIMI	MULTI	PRIMI	MULTI	
IDL	14.38 ± 3.44	12.28 ±2.15	10.89±2.61	9.43±1.73	<0.01[a]

[a] t-testThe mean Induction delivery interval in Primi with Extra amniotic balloon catheter was 10.89 hrs. The mean Induction to delivery interval in Primi with PGs was 14.38 hrs. The mean Induction to delivery interval in Multi with Extra amniotic balloon catheter was 9.43 hrs. The mean Induction to delivery interval in Multi with PGs was 12.28 hrs.

Table 7: Mode of Delivery Distribution

Mode of delivery	Group – A		Group – B		Total	P
	Number	Percent	Number	Percent		Value
Labour Natural	68	68	76	76	144	
LSCS	27	27	19	19	46	
Forceps/Vacuum	5	5	5	5	10	
Total	**100**	**100**	**100**	**100**	**200**	**>0.05[a]**

[a]Chi square test

76% of patients in extra amniotic balloon catheter delivered vaginally compared to only 68% in the PGs. LSCS were 27% in the PGs group whereas it was 19% in the extra amniotic balloon catheter.

Table 8: Maternal Outcome

	Group – A		Group - B		p value
	Number	%	Number	%	
Hyper Stimulation	6	33.3	-		
Post Partum Hemorrhage	8	44.4	8	61.5	>0.05[a]
Puerperal Pyrexia	4	22.2	5	38.5	>0.05[a]
Total	**18**	**100**	**13**	**100**	

[a] Chi-square test

No hyperstimulation was noted in extra amniotic balloon catheter whereas 6 had hyperstimulation in PGs group. PPH & Puerperal pyrexia were comparable in both the groups.

Discussion:

The study was conducted in dept of Obstetrics and Gynaecology, Patna medical college & hospital to compare the efficacy of extra amniotic balloon catheter and Prostaglandins for induction of labour. The study was carried out on 200 patients. 100 patients were induced with extra amniotic balloon catheter and 100 patients were induced with prostaglandins (PGE2 gel and

misoprost) Majority of the women in both groups belonged to 20-24years & were primigravida. Mean age of women Group A & Group B were 23.55±3.46 & 23.5±3.27 respectively. There was no significant difference between groups in age distribution. Similarly subjects in the study by & KARUNA KANTA DAS et al (2016) had the mean age of 24.14±4.18 & 23.08±4.06 years for prostaglandin gel & Foleys group. The mean age of subjects in prostaglandin & Foley group in the study of KHALDOUN KHAMAISEH et al(2010) was a little higher(26±6.3 & 26.1±5.5 years respectively).66% of patients in EABC group were primigravida compared to 63% in PG group. There was no significant difference between groups in gravida distribution. The study of of AUGUSTINE A. E. ORHUE (1994) & MANDANA MANSOUR et al (2013) had all primi patients. Majority (92.5%) of our patients induced were between 40-41 weeks for post-datism. Similarly post-datism was the most common causes for induction in the study of of AUGUSTINE A. E. ORHUE (1994), SAIMA QAMAR et al(2012) & KARUNA KANTA DAS et al(2016). In the present study, majority of the patients induced with EABC established active labour within 6 hrs whereas in PGs active labour was established in 6-12 hrs. Mean induction to active labour interval was significantly shorter in EABC group (5.52±1.30 vs 7.39±1.44).EABC was found to be more effective in causing cervical ripening than Prostagladins. Time to achieve contraction was found to be significantly shorter in Foleys group by AUGUSTINE A. E. ORHUE (2.22±1.35 vs 3.90±9.1) & MANDANA MANSOUR et al (457±178 min vs 609±238min). KARUNA KANTA DAS et al observed 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). However, the mean induction- delivery interval was comparable in both the groups. In our study, 67% patients induced with the EABC delivered within 12 hrs whereas only 6% delivered in PGs group. Mean induction to delivery interval was significantly shorter in EABC group (10.14±2.16 vs 13.32±2.8). Similarly, mean induction to delivery interval was found to be significantly shorter in the studies of AUGUSTINE A. E. ORHUE (11.10±4.61 vs17.91±5.43) & MANDANA MANSOUR et al (11.4±4.8 vs 18.9±6.4). KHALDOUN KHAMAISEH et al found longer induction-delivery in the Foley group than PGE2 (22.6±12.4 vs 21.4±11.6), but was not statistically significant.(p=0.31) 76% in EABC group & 68% in PG group delivered vaginally whereas 19% in EABC group &27% in the PGs group underwent cesaerean section.(p>0.05). Similarly, mode of delivery was found to be comparable in study of KHALDOUN KHAMAISEH et al, KARUNA KANTA DAS et al & AUGUSTINE A. E. ORHUE. Most common indication for LSCS in both groups was fetal distress (63.8%) followed by failed induction (19.2%) & cephalopelvic disproportion (8.5%). KHALDOUN KHAMAISEH et a(60% & 44% in both groups)l, KARUNA KANTA DAS et al(40%) & MANDANA MANSOUR et al(41% & 51% in both groups), all observed fetal distress being the most common indication for caesarean followed by failure to progress & failed induction. AUGUSTINE A. E. ORHUE observed cephalopelvic disproportion (10%) as most common indication for LSCS in PGE2 group as compared to fetal distress (6.7%) in Foleys group.6 patients had hyperstimulation in the PGs group. The patients were put in left lateral position. Oxygen was given by face mask & IV fluids were given. No hyperstimulation was seen in the extra amniotic balloon catheter group. Post partum hemorrhage & Puperal pyrexia were comparable in both the groups. There was no technical difficulty in Foley catheter insertion KARUNA KANTA DAS et al reported uterine hyperstimulation, maternal discomfort & PPH as maternal complications but no statistically significant difference between the two groups could be seen.In contrast, MANDANA MANSOUR et al reported 16% cases of chorioamnionitis in PGE2 group which was significantly higher than Foleys group(8.2%) & KHALDOUN KHAMAISEH et al(2010) observed more Uterine hyper stimulation in PGE2 group than Foley catheter 6 (3%) vs.1 (0.5%); P= 0.0013). In the present study mean APGAR at 1 min were 8.21±0.99 & 8.18±1.33 in PG & EABC group respectively. Mean APGAR at 5 min in both groups were 9±1 & 9.01±1.49.(p>0.05) .7.5% of neonates were admitted in NICU in EABC group & 12.5% in

the PGE2 gel group.($p>0.05$) for Birth asphyxia, meconium aspiration.This indicate that both methods are safe for neonates, and that no major differences are seen in neonates born to women delivered with each method. This supports similar reports from studies of KHALDOUN KHAMAISEH et al, MANDANA MANSOUR et al & SAIMA QAMAR et al (2012)

Conclusion:

Foley catheter balloon is an effective non-pharmacological method for cervical ripening. It has the advantage of simplicity, reversibility, low cost and lack of systemic or serious side effects. In the present study, we observed that the induction-labour interval and induction-delivery interval are less in extra amniotic balloon catheter group as compared to prostaglandins. Moreover there is no difference in caesarean section rate, neonatal mortality and morbidity when compared to prostaglandins. It can be a safe alternative to prostaglandins Also it can safely be used in patients where prostaglandins are contraindicated (previous caesarean section).

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