International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Kaur K et al. Int J Reprod Contracept Obstet Gynecol. 2021 May;10(5):1802-1808
www.ijrcog.org
pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20211417

Original Research Article

Intra-cervical foley's catheter or PGE2 gel for induction of labour: which one is better: a prospective study

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Received: 20 March 2021
Revised: 05 April 2021
Accepted: 06 April 2021

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ABSTRACT

Background: Labour is clinically defined as the initiation and perpetuation of uterine contraction with goal of producing progressive cervical effacement and dilatation. The Foley's catheter is an effective alternative to prostaglandins for cervical ripening/labour induction. Study was done to compare the efficacy of intracervical Foley's catheter and PGE2 gel as a cervical ripening agent and to study maternal and fetal outcome in terms of mode of delivery and Apgar score.
Methods: This randomized controlled study was conducted in Obstetrics and Gynaecology department, Government Medical College, Patiala. 200 women with indication for induction of labour were enrolled in the study to investigate the efficacy and fetomaternal outcome of induction of labour with intracervical Foley's catheter comparing with PGE2 gel.
Results: The mean age in group A was 24.41±3.37 and in group B was 24.24±3.17 years. The 95% women were induced successfully in group A and 97% were successfully induced in group B. Preeclampsia and postdatism were the most common indications for induction in both groups. The mean induction delivery interval in group A was 15.20±4.53 hours and in group B was 15.86±4.79 hours. 4.21% cases required NICU admission in group A while in group B, it was 5.15% cases.
Conclusions: Our study concludes that there is no difference in efficacy between intracervical Foley's catheter and intracervical PGE2 gel for induction of labour and both methods are complementary to each other.

Keywords: Labour, Foley's catheter, PGE2 gel, Vaginal delivery, Caesarean

INTRODUCTION

Normal labour is the presence of regular uterine contractions that results in effacement and dilatation of cervix with voluntary bearing down efforts leading to expulsion of the products of conception per vaginum.[1]

Labour is clinically defined as the initiation and perpetuation of uterine contraction with goal of producing progressive cervical effacement and dilatation. Induction of labour refers to the process whereby uterine contractions (>3 in 10 mins each lasting for 30-45 seconds), cervical softening and effacement are initiated by medical or surgical means before the onset of spontaneous labour. 50% of inductions in Asian facilities are elective, highest being in Sri Lanka (77.2%). This is followed by Thailand (44.6%), Japan (41.0%), India (32.1%) and China (20.4%), lowest rate of induction of labour is in African countries, Nigerian being having lowest rate of 1.4%. The rate of elective inductions are increasing nowadays. According to ACOG, one fifth of all pregnancies are terminated with various methods of induction.[2]

Low bishop scores are associated with increased risk of cesarean delivery. Other factors that increase the risk of

cesarean section after induction include nulliparity, obesity, maternal age greater than 30 years, fetal macrosomia, use of epidural anesthesia, use of magnesium sulfate, and chorioamnionitis.

Success of induced labour depends upon the degree of ripening of cervix which can be assessed by various scoring systems and the most commonly used method is Bishop scoring which includes cervical dilatation, length of cervix, consistency of cervix, position of cervix and station of presenting part. The total score is 13 and favourable score is 6-13.[8] It was modified in 1982 and effacement was considered by cervical length in centimeters instead of percentage.

The various methods of methods of induction of labour are: mechanical, surgical, pharmacological and combined methods.

Transcervical Foley's Catheter

It is a mechanical method and its effect on cervical ripening was first described by Embrey and Mollison in 1967. The Mechanical action of Foley's Catheter strips the foetal membranes from the lower uterine segment which causes release of phospholipase A2, prostaglandins, and cytokines which are associated with cervical dilatation.[9]

The ACOG (2009) guidelines recommend the Foley's catheter as a sensible and effective alternative to prostaglandins for cervical ripening/labour induction (grade A recommendation). Its use is mentioned as an option for outpatient induction.

According to WHO, recommendations (2011) balloon catheters are recommended for labour induction and are approximately as efficient as vaginal prostaglandins (PGE2, misoprostol).

The combination of balloon catheter and oxytocin is recommended as an alternative when prostaglandins (including misoprostol) are not available or are contraindicated. The balloon catheter is also mentioned as an option for labour induction after previous caesarean section.[12]

The surgical method of induction includes stripping of membranes and fore water amniotomy (Artificial rupture of membranes). The pharmacological methods are prostaglandins, mifepristone, oxytocin and relaxin.

The mechanical devices result only in cervical dilatation and the PG agents both soften and efface the cervix but the combination of the two methods may result in a greater degree of cervix ripening and successful labour induction.

The aim and objective of the study was to compare the efficacy of intracervical Foley's Catheter and PGE2 gel as a cervical ripening agent, to study maternal and fetal outcome in terms of mode of delivery and Apgar score.

METHODS

The present randomized controlled study was conducted in Department of Obstetrics and Gynaecology, Government Medical College, Rajindra Hospital Patiala from January 2017 to 2018. 200 women with indication for induction of labour were enrolled in the study after fulfilling the inclusion and exclusion criteria. The proper counselling was done and written informed consent was taken. It was carried out to investigate the safety, efficacy and fetomaternal outcome of induction of labour with intacervical Foley's Catheter comparing with the commonly used agent PGE2 gel. Patients admitted to labour room for induction of labour were enrolled for study. After written and informed consent, 200 women were assigned randomly into 2 groups fulfilling the inclusion and exclusion criteria after proper counselling and clinical assessment. Particulars of the patient and detailed history as per proforma was recorded. A thorough general physical examination and systemic examination was done to exclude any maternal disease. Obstetrical examination and vaginal examination was done to assign Bishop's score and for pelvic assessment.

GROUP A-100 patients were inserted intracervical Foley's catheter. Under aseptic precaution 16 F foley's catheter was introduced beyond the internal OS and its balloon was inflated with 30-60 ml sterile water. Traction was applied by taping the distal end of the catheter with medial aspect of the thigh. Catheter was checked for its position and traction at 4-6 hours interval. Intracervical catheter was removed after 24 hours if it doesn't get expelled.

GROUP B-100 patients were given 0.5 mg PGE2 gel under fully aseptic conditions. PGE2 Gel was inserted intracervically while patient in lithotomy position and patient was told to lie down for 30 min. Assessment of bishop's score was done, dose was repeated if required when patient was reassessed after 12 hours and again at 24 hours.

Inclusion criteria

Gestation age of 37 weeks or more, bishop <6, singleton pregnancy, cephalic presentation, intact membranes, primigravida/multigravida and women's willingness.

Exclusion criteria

Previous uterine surgery, antepartum hemorrhage, allergy to prostaglandins, CPD and woman's unwillingness.

Statistical analysis

The collected data was compiled and analysed statistically statistical analysis was performed using Chi square statistics and compared. IBM Software Excel and statistical Package for Social Sciences (SPSS) version 22 was used.

RESULTS

The maximum number of subjects were in age group of 21-25 years in both the study groups. The mean age in group A was 24.41±3.37 and in group B was 24.24±3.17 years. The p value was 0.714 which was statistically not significant (Table 1). 72% patients were primigravida and 28% were multigravida in group A and 58% patients were primigravida and 42% were multigravida in group B. The p value was 0.492 which was not significant (Table 1). According to the modified kuppuswamy scale, majority of the patients were from lower socioeconomic status, (54%) in group A and 48% in group B. Its p value was 0.177 which was again not significant (Table 1). The mean gestation age was 39.39±1.73 weeks in group A and it was 39.62±1.74 in group B. The subject in both the groups were almost equally distributed and p value was 0.356 which was not significant (Table 1). Preeclampsia was the most common indication for induction of labour in group A (40%) while postdatism was most common in group B (33%). Second most common indication was postdated pregnancy in group A in 29% cases and in group B, it was preeclampsia (32%) (Table 2).

Table 1: Maternal characteristics.

Characteristics	Group A		Group B		P value
Age (years)	**Patients**	**%**	**Patients**	**%**	
16-20	7	7	15	15	
21-25	63	63	54	54	0.714
26-30	24	24	27	27	Not significant
31-35	6	6	4	4	(NS)
Mean±SD	24.41±3.37		24.24±3.17		
Parity					
Primigravida	72	72	58%	58	0.492
Multigravida	28	28	42	42	NS
Socioeconomic status					
Lower	54	54	48	48	0.177
Middle	44	44	45	45	NS
Higher	2	2	7	7	

Table 2: Indication for induction of labour.

Indication for induction	Group A		Group B	
	Patients	**%**	**Patients**	**%**
Antepartum eclampsia	8	8	11	11
Congenital anomaly	1	1	4	4
Derranged colour doppler	4	4	3	3
Fetal growth restriction	5	5	6	6
Gestational diabetes mellitus	2	2	1	1
Intrahepatic Cholestasis of Pregnancy	1	1	0	0
Intrauterine-fetal death	4	4	6	6
Oligohydraminos	5	5	4	4
Post datism	29	29	33	33
Pre-eclampsia	40	40	32	32
Polyhydramnios	1	1	0	0

The 95% women were induced successfully in group A and 97% were successfully induced in group B. 5% women in group A and 3% in group B had failed induction and all of them underwent caesarean section. The p value was 0.46 and it was statistically not significant (Table 3). Among 95 women who had successful induction, 84.21% had vaginal delivery while 15.79% underwent caesarean section due to fetal distress, meconium stained liquor or no-progress of labour. In group B, vaginal delivery occurred in 79.38% cases and 20.62% landed up caesarean section despite good uterine contractions due to fetal distress or meconium stained liquor or non-progress of labour. The p value was 0.486 which was not significant (Table 3). In group A, about 28.42% of subjects delivered in less than 12 hours and in group B, 26.80% delivered in less than 12 hours. The mean induction delivery interval in group A was 15.20±4.53 hours and 15.86±4.79 hours. The p value was 0.352 and it was statistically not significant (Table 3). The most common indication for LSCS in both the groups was fetal distress (40%). The other common indication for caesarean section was 26.6% and 35% in both the groups respectively due to meconium stained liquor (Table 4). Hypertonicity was observed in 2.04% of cases in group A and in 6.06% in group B. Postpartum

haemorrhage, shivering, nausea, vomiting and infections are some of the other less common complications encountered. (Table 4). 6.32% of the neonates in group A faced fetal distress and in group B, it was 8.25%. 4.21% of the newborn in group A had neonatal jaundice whereas in group B, it was 3.09%. Almost 2% newborns in both the groups had meconium aspiration syndrome. 4.21% cases required NICU admission in group A while in group B, it was 5.15% cases. The p-value was 0.238 and it was statistically not significant (Table 5). APGAR <7 at 1 minute was 5.2% in group A and 7.2% in group B and p-value was 0.576 which was not significant. The APGAR <7 at 5 minutes in group A was 2.1% and in 3.09% in group B. Its p-value was 0.676 and it was statistically not significant (Table5).

Table 3: Results of induction.

Characteristics	Group A		Group B		P value
Results	**Patients**	**%**	**Patients**	**%**	
Successful induction	95	95	97	97	0.46 NS
Failed induction	5	5	3	3%	
Mode of delivery					
Vaginal delivery	80	84.21	77	79.38	0.496 NS
Caesarean section	15	15.79	20	20.62	
Induction delivery interval (time in hours)					
6-12	27	28.42	26	26.80	0.352 NS
>12-18	36	37.89	31	31.96	
18-24	32	33.68	40	41.24	
Mean induction delivery time	15.20±4.53		15.86±4.79		

Table 4: Indication for caesarean section and maternal side effects.

Indication for caesarean	Group A		Group B	
	Patients	**%**	**Patients**	**%**
Meconium stained labour	4	26.6	7	35
Non progress of labour	3	20	5	25
Severe preeclampsia with HELLP	2	13.33	0	0
Fetal distress	6	40	8	40
Side effects				
Hypertonic uterus	2	2.04	6	6.06
Nausea	3	3.06	5	5.05
Postpartum haemorrhage	1	1.02	2	2.02
Infection	2	2.04	1	1.01
Fever, shivering	2	2.04	2	2.04
Vomiting	3	3.06	6	6.06

Table 5: Neonatal complications and Apgar score.

Neonatal complications	Group A (n=95)		Group B (n=97)		P value
	Patients	**%**	**Patients**	**%**	
Foetal distress	6	6.32	8	8.25	0.238 NS
Neonatal jaundice	4	4.21	3	3.09	
Meconium aspiration	2	2.11	2	2.06	
NICU Admission	4	4.21	5	5.15	
Apgar score at 1 min					0.576 NS
<7	5	5.2	7	7.2	
>7	90	94.7	90	92.7	
Apgar score at 5 min					0.676 NS
<7	2	2.1	3	3.09	
>7	93	97.8	95	97.9	

DISCUSSION

Induction of labour with unfavourable cervix results in prolonged labour and increased rate of caesarean section. With time various methods of induction have come into practice. Each method has certain advantages and disadvantages inherent to it. It was found that in our study the mean of bishop's score in group A was 3.13±0.87 and in group B was 3.36±0.91 which was comparable to the study by Dr. V Revathi in which the mean bishop score was 2.60±1.55 in group A and 2.86±1.57 in group B (Table 6).

Table 6: Comparison of bishop's score at start of induction.

Author name and year of study	Group A	Group B
Revathi et al[9]	2.60±1.55	2.86±1.57
Alam et al[7]	1.91±0.70	1.90±0.77
Murmu et al[4]	1.74±0.27	1.48±0.82
Present study	3.13±0.87	3.36±0.91

The main indication for induction of labour in Group A was Preeclampsia in 40% women and post-dated pregnancy in 29% which was also the main factor in other studies and the main indications for induction in Group B were Preeclampsia in 32% and post-dated pregnancy in 33% which were comparable with studies conducted by Anjumam Alam and Deshmukh V.L. (Table 7). The mean induction delivery interval in Group A was 15.20±4.53 hours while in Group B was 15.86±4.79 hours. This shows that the induction delivery interval was equal in subjects who were induced with intracervical catheter and PGE2 gel.

The present study is consistent with studies done by Sunita Murmu and Deshmukh and various other studies also found this interval almost equal in both groups (Table 8).

The incidence of vaginal delivery in present study was 84.21% and caesarean study was 15.79% in Group A which was comparable with study done by Laddad, i.e., 82.5% and 17.5% respectively, by Dharmavijaya, it was 86% and 14% and by Sunita Murmu, it was 84.31% and 15.7% respectively (Table 9).

The NICU admissions in the groups A and B were less (4.21% and 5.15%) respectively as compared to other studies. Complications in both the groups such as fetal distress and meconium aspiration syndrome were almost equal as the studies conducted by Manisha Laddad, Dharmavijaya and Deshmukh (Table 10).

The fetal outcome with apgar score <7 at 1 minute was comparable to various studies which was 10% in the study conducted by Dharmavijaya, 7.1% by Sunita Murmu and 5.2% in present study in group A. It was comparable to various studies in group B, which was 11% in study by Dharmavijaya, 8.6% by Sunita Murmu and 7.2% in our study. The fetal outcome with Apgar score <7 at 5 minutes was 1% in study conducted by Revathi in group A which was same as in our study (2.1%). It was 7.5% in study by Deshmukh and 7% by Anjuman Alam which were different from the present study. The outcome with Apgar score <7 at 5 min in the present study in group B was 3.09% while it was 8% in the studies conducted by Deshmukh and Anjuman Alam. Limitation of the study was ours is a Government institute, PGE2 gel is sometimes not available freely due to limited supply.

So, this difficulty was faced while inducing the patients and it was bought by voluntary contribution to complete the study.

Table 7: Comparison of indication for induction of labour.

	Group A			Group B		
Indication	**Present study (%)**	**Deshmukh et al[13] (%)**	**Alam et al[7](%)**	**Present study (%)**	**Deshmukh et al[13] (%)**	**Alam et al[7](%)**
Pre-clampsia	40	27.14	40	32	36.5	37
Postdatism	29	29.5	32	33	31	30
Intrauterine fetal death	4	6.5	6	6	8.5	7
Fetal growth restriction	55	5	6	4	5.5	7
Oligohydramnios	5	5	3	6	0.5	4
Polyhydramnios	1	-	-	-	-	-
Antepartum eclampsia	8	-	-	11	-	-
Others	8	17	13	8	17	15

Table 8: comparison of induction delivery interval of subjects in various studies.

Name of author of study	Group A (hours)	Group B (hours)
Deshmukh et al[13]	15.32±5.24	14.2±5.14
Dharmavijaya et al[10]	15.32±5.24	14.2±5.14

Continued.

Name of author of study	Group A (hours)	Group B (hours)
Jha et al[11]	16.01±5.50	16.85±3.81
Alam et al[7]	16.01±5.50	16.85±3.81
Murmu et al[4]	12.2	15.47
Present study	15.20±4.53	15.86±4.79

Table 9: comparison of mode of delivery in subjects of group A in various studies.

Name of Author of study	Vaginal delivery (%)	Caesarean section (%)
Laddad et al[16]	82.5	17.5
Dharmavijaya et al[10]	86	14
Murmu et al[4]	84.31	15.7
Present study	84.21	15.79

Table 10: Comparison of neonatal complications in various studies.

Name of author and year of study	Group A				Group B			
	Fetal distress (%)	Neonatal jaundice (%)	Meconium aspiration syndrome (%)	NICU admission (%)	Fetal distress (%)	Neonatal jaundice (%)	Meconium aspiration syndrome (%)	NICU admission (%)
Deshmukh et al[13]	8.5	-	4.5	18.5	10.5	-	5.5	21
Laddad et al[16]	9	-	4	19	10.5	-	5	21.5
Dharmavijaya et al[10]	8.5	-	4.5	18.5	10.5	-	5.5	21
Present study	6.23	4.21	2.11	4.21	8.25	3.09	2.06	5.15

CONCLUSION

Our study concludes that there is no difference in efficacy between intracervical Foley's catheter and intracervical PGE2 gel for induction of labour. Also, other factors like induction delivery interval, maternal and neonatal outcomes were similar in both the groups. Both methods are complementary to each other

ACKNOWLEDGMENTS

It gives me immense pleasure to express my deepest sense of gratitude to my respected seniors and colleagues Dr. Khushpreet Kaur and Dr. Balwinder Kaur in carrying out this project. I am highly thankful for the guidance and encouragement given to me and appreciate the efforts put by my juniors for collecting the data and helping me in writing down this manuscript.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kaur K, Kaur B, Kaur N, Kaur G Intra-cervical Foley's catheter or PGE2 gel for induction of labour: which one is better- a prospective study. Int J Reprod Contracept Obstet Gynecol 2021;10:1802-8.