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COMPARATIVE STUDY IN A RURAL TERTIARY HOSPITAL IN MAHARASHTRA- BETWEEN FOLEY CATHETER AND DINOPROSTONE GEL FOR CERVICAL RIPENING AND INDUCTION OF LABOUR IN TERM PATIENTS WITH UNFAVOURABLE CERVIX(BISHOPS'S SCORE<4)

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ABSTRACT

BACKGROUND- Since ancient times, labour inducton is a well established obstetric concept. In the past few decades, rate of labour induction has increased dramatically. The primary objective of this study was to compare the efficacy of transcervical foley catheter with intracervical dinoprostone gel for cervical ripening and labour induction in term singleton pregnancies with unfavourable cervix.

METHODS- Term singleton pregnancies fulfilling inclusion criteria were randomized by chit box system to receive intracervical dinoprostone or transcervical foley catheter. Progress of labour was monitored with the help of partogram. Labour augmentation was done by oxytocin.

RESULTS- 110 patients in each group were enrolled. Group A was induced with transcervical Foley catheter and group B with dinoprostone gel. Baseline characteristics like maternal age, parity, gestational age were comparable in each group. There was a significant difference in the Bishop's score (<.0.05) at the end of 12 hours, Group B showing a greater improvement than A. A significant difference was also observed in the requirement of augmentation with Pitocin, 77.27% in foley group and 63.63% in dinoprostone group . Although, there was no significant difference observed in the mode of delivery (p>0.05) induction to delivery time interval (p>0.05) , maternal and neonatal morbidity between the groups.

CONCLUSION- To conclude, Though Dinoprostone is associated with rapid cervical ripening ,mean induction to delivery time interval and rate of vaginal deliveries were comparable among both the groups. Moreover, cost and safety profile of foley catheter makes it comparable or even superior to dinoprostone gel for cervical ripening and induction of labour, especially in developing countries.

KEYWORDS : Labour Induction, Cervical Ripening, Foley Catheter, Bishop's Score

INTRODUCTION-

Induction of labour is common obstetric procedure. It is defined as iatrogenic stimulation of uterine contractions to accomplish delivery prior to the onset of spontaneous labour aimed at delivery by vaginal route(1,2). In the present scenario, around 10-30% of obstetric patients undergo this procedure(1,2,3). Labour induction is indicated when benefits of termination to mother or/and fetus outweighs the risk associated with continuation of pregnancy(4). Common indications include posdatism, pre-eclampsia, oligohydramnios, gestational diabetes, IUGR(5,6). Undou btedly, cervical status assessed by Bishop's score, has a close relationship with successful labour induction and normal vaginal delivery. It is predicted that patients with a poor Bishop score will have an unacceptably high rate of induction failure(7).

Different methods available for cervical ripening and labour induction include oral/vaginal misoprostol, prostaglandin gel , intracervical foley's catheter etc. Pharmacological methods like misoprostol, mifepristone, dinoprostone gel has been extensively studied and are found to be effective agents for cervical ripening(8,9). PGE2 administered intravaginally or intracervically, improves Bishop Score and induction to delivery time when compared to those of untreated controls. The local application of PGE2 results in direct softening of the cervix by a number of different mechanisms (10,11). Uterine tachysystole and accompanying fetal distress is reported following administration of PGE2 in 1 to 5 percent of women (12).

Several studies has demonstrated that mechanical methods are equally effective for cervical ripening(13,14,15) & has been shown to shorten induction to delivery interval, decrease caesarean section rate and increase the rate of spontaneous vaginal delivery (16). Different catheter balloon volumes ranging from 30 - 80 ml. and even double balloon catheter have been studied for cervical ripening (15). The mechanical action of the Foley catheter strips the fetal membranes from the lower uterine segment and causes rupture of lysosomes in the decidual cells, part of which is phospholipase A. These lytic enzymes act on phospholipase to form arachidonic acid which is converted to prostaglandin, thereby improving the consistency and effacement of the cervix (17,18). The advantage of this method over the pharmacological preparation includes simplicity of preservation, lower cost and reduction of side effects.

Despite the availability of so many techniques, there is no method which is universally acclaimed as ideal for labour induction.

The objective of conducting this study is to compare a mechanical device with a pharmacological method for induction of labour with respect to improvement in the Bishop's score, induction to delivery time interval, mode of delivery, maternal and neonatal outcome.

METHODOLOGY-

This comparative prospective randomised study was conducted on 220 patients admitted in labour room for induction of labour between May 2019-October2019,in the department of Obstetrics and Gynaecology , Shri Vasantrao Medical college and hospital, Yavatmal. The study was approved by the Ethical committee of the institution. Patients with singleton live pregnancy with cephalic presentation at Term (>37 weeks) with intact membranes , unfavourable cervix(Bishop's score<4), no spontaneous contractions and adequate pelvis with any indication of induction were considered under inclusion criteria.

Patients with scarred uterus ,PROM ,active infection of cervix,

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vagina- e.g., Herpes etc ,APH , Cervical dilation>2.5 cm, presence of uterine contractions , Fetal distress/non reassuring fetal heart rate, malpresentation, contracted pelvis were excluded from the study. After taking a detailed history, thorough general & obstetric examination and calculation of pre-induction Bishop's score, eligible patients were explained about the methods of induction and consent was taken. Randomisation was done by chit box system and patients were divided into two groups, group A- induction with foley catheter and group B with intracervical dinoprostone gel.

Patients allotted to Group A were placed in lithotomy position, cusco's speculum was inserted and after visualization of cervix, vagina was cleaned with povidone iodine. Anterior lip of cervix was held with sponge holding forceps and under vision,16 Fr deflated catheter was inserted through the internal os and balloon inflated with 30ml normal saline. Catheter was strapped to the medial side of right thigh to maintain traction and was kept in place till spontaneous expulsion or removed at the end of 12 hours.

Patients allotted to Group B were placed in lithotomy position and dinoprostone gel was instilled intracervically. Reassessment was done every 6 hours and another dose was administered if there was no improvement in the Bishop's score, to a maximum of 3 doses.

Both groups were monitored with the help of partogram and labour augmentation was done by oxytocin. Oxytocin was started when patient had ≥6 cm dilatation and/or inadequate contractions(<3 contractions in 10 minutes, lasting for less than 40 sec). Patient with no improvement in Bishop's score at the end of 24 hours was labelled as failure. The following outcomes were studied and compared among the groups - improvement in the Bishop's score, need for augmentation of labour with oxytocin, induction to delivery time interval, mode of delivery, indication of LSCS, APGAR score and need of NICU admission.

Results were analysed statistically with chi square test and unpaired student T test. Differences with p-value<0.05 were considered statistically significant with the confidence limit of 95%.

RESULTS-

Among 220 patients, 110 were induced with foley catheter and 110 were induced with dinoprostone gel.

The mean age of cases studied in Group A and Group B was 29.10 ± 3.74 years and 28.61 ± 4.11 years respectively (Table 1).

The two groups were comparable with respect to gestational age(Table 3), parity(Table 2), indication for induction(Table 4) and pre-induction Bishop's score.

Table 1) Inter group comparison of mean maternal age-

	Group A		Group B		P Value
Age (in years)	MEAN	SD	MEAN	SD	
	29.10	3.74	28.61	4.11	0.530

Table 2) Inter group comparison of parity of cases -

	Group A(n=110)		Group B(n=110)	
Gravida	Number	Percentage	Number	Percentage
1st	76	69.09	74	67.20
2nd	22	20.00	28	25.45
3rd	12	10.9	4	3.63
4th	0	0	4	3.63

Table 3) Inter-group comparison of mean period of gestation-

	Group A (n=110)		Group B(n=110)	
	Mean	SD	Mean	SD
Period of gestation (in weeks)	38.4	1.03	38.2	0.92

Table4) Inter-group comparison of indication of induction-

	Group A (n=110)		Group B (n=110		P value
Indication	Number	percentage	Number	percentage	0.553
Postdatism	60	54.54	55	50.00	
GDM	08	7.27	10	9.09	
Pre eclampsia	30	27.27	25	22.72	
Oligohydramnios	08	7.27	12	10.9	
IUGR	04	3.63	08	7.27	

Table 5) Inter group comparison of improvement in Bishop's score-

Bishop's score (After 12 hours)	Group A (n=110)		Group B (n=110)		P value
	number	percentage	Number	percentage	0.001
5	25	22.72	12	10.90	
6	8	7.27	12	10.90	
7	32	29.09	16	14.54	
>8	45	40.90	70	63.63	

There was a significant difference in the Bishop's score (<.0.05) at the end of 12 hours, Group B showing a greater improvement than A(Table 5).

In group A,72 patients(65.45%) had normal vaginal delivery and 29 (26.36%) underwent LSCS whereas in group B, 78 patients(70.90%) had normal vaginal delivery and 27(24.54%) underwent LSCS. Overall, the difference in the mode of delivery was stastically insignificant(Table 6). Even the LSCS indications were comparable with Fetal distress being the most common indication of LSCS in both groups(Table 7).

Table 6) Inter-group comparison of Mode of delivery-

Mode of delivery	Group A(n=110)		Group B(n=110)		P value
	Number	Percentage	Number	Percentage	0.483
Normal	72	65.45	78	70.90	
LSCS	29	26.36	27	24.54	
Instrumental	09	81.81	05	45.45	

Table 7) Inter-group comparison of indication of LSCS

Indication Of LSCS	Group A(n=29)		Group B(n=27)		P value
	Number	percentage	Number	percentage	0.860
Fetal distress	18	62.08	15	55.55	
CPD	03	10.34	04	14.81	
Failure of induction	07	24.13	06	22.22	
DTA	01	3.44	02	7.40	

Induction to delivery time interval was similar in both groups, 20.23±9.82 hours in foley group and 20.28±9.39 in dinoprostone group (Table 8). A total of 85 patients(77.27%) in group A required Pitocin augmentation as compared to 70(63.63%) in group, difference being statistically significant (p value<0.05). This might be due to the mechanical dilatation which occurs with foley in the initial hours.

Maternal and neonatal outcomes were comparable in both the groups, as shown in Table 10 and 11.

Table 8) Inter-group Comparison of induction to delivery time interval-

Induction to time delivery interval (in hours)	Group A (n=110)	Group B (n=110)	P value

	Mean	SD	Mean	SD	
	20.23	9.82	20.28	9.39	0.975

Table 9) Inter-group comparison of requirement of Pitocin augmentation-

Oxytocin augmentation	Group A (n=110)		Group B (n=110)		P value
	number	percentage	Number	Percentage	
Required	85	77.27	70	63.63	0.027
Not required	25	22.72	40	36.36	

Table 10) Inter-group comparison of maternal compl ications-

complications	Group A (n=110)		Group B (n=110)		P value
	number	Percentage	Number	Percentage	
Nil	104	94.54	106	96.36	0.230
PPH	05	04.54	02	1.81	
APH	00	00.00	00	00.00	
Uterine Hyperstimulation	00	00.00	02	1.81	
Fever	01	0.90	00	00.00	

Table 11) Inter group comparison of NICU admissions-

NICU admission	Group A (n=110)		Group B (n=110)		P value
	number	Percentage	Number	Percentage	>0.05
Yes	10	77.27	08	63.63	
No	100	22.72	102	36.36	

DISCUSSION-

Mechanical methods were the first methods developed to ripen the cervix or induce labour. However, mechanical methods were never totally abandoned but extensively replaced by pharmacological methods in the last decades. Reintroduction of these methods for cervical ripening and induction of labor is now being considered due to their potential advantages of low cost, easy availability and fewer side effects.

This study was undertaken to compare the efficacy and safety of two commonly methods for induction of labour. Obstetric history including distribution of maternal age , parity, gestational age, indication for induction and pre-induction Bishop's score were comparable in Group A and B. These findings ruled out the possible bias in the study results.

In the present study, there was a significant difference in the Bishop's score (<.0.05) at the end of 12 hours, Group B showing a greater improvement than A. Similar findings were documented in studies conducted by Dahiya K. et al(19) ,St. Onge et al.(20) and Ezimokhai and Nwabinelli.(21). Another study conducted by Murthy et al(22) reported that the cervical ripening was achieved to a similar extent, with mean change in score being 7.2 in dinoprostone group and 6.8 in Foleys catheter group. The difference between these scores was not statistically significant.

In our study, mean duration of induction to delivery was comparable among the groups - 20.23±9.82 hours in foley group and 20.28 ± 9.39 in the dinoprostone group. This finding was consistent with study conducted by Dahiya et al(19),in which mean duration was 18.51 ± 8.52 in Foley catheter group and 18.21 ± 11.13 in prostaglandin group. Although studies by St Onge et al(20), Mathuriya et al(23) and Reshme et al (24)showed that induction to delivery time interval taken was more in the foley group than prostaglandin group.

In this study, there was no significant difference observed in the mode of delivery. Similar findings were documented in study conducted by Sciscione et al(25). Although studies by Murthy et al(22) and Mathuriya et al(23) reported higher number of vaginal deliveries in the dinoprostone group.

There was significant difference observed in the requirement of Pitocin augmentation, foley group requiring more than dinoprostone group; finding similar to study conducted by Reshme et al(24).

Two patients in the dinoprostone group had uterine hyperst imulation , finding similar to study done by Karunakanth Das et al(26). Overall, there was no significant difference with respect to maternal and neonatal morbidity between the groups, finding similar to Sciscione et al(25).

The current study support both the methods as effective and safe for cervical ripening and induction of labour. However, in specific situations ,eg trial of labour in previous cesearean birth and medical disorders like bronchial asthma, foley catheter is a safer option.

CONCLUSION-

To conclude, efficacy and safety of Foleys catheter as a cervical ripening agent is comparable to Dinoprostone gel. Simplicity of use, potential for reversibility, low cost, less chances of Uterine hyperstimulation are some of the added advantages offered by use of Foleys catheter , making it a desirable alternative for cervical ripening and induction of labour.

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