



Journal Homepage: -www.journalijar.com
**INTERNATIONAL JOURNAL OF
 ADVANCED RESEARCH (IJAR)**

Article DOI:10.21474/IJAR01/8779
 DOI URL: <http://dx.doi.org/10.21474/IJAR01/8779>



RESEARCH ARTICLE

COMPARISON OF EFFICACY AND SAFETY OF INTRACERVICAL FOLEY'S CATHETER BALLOON WITH INTRACERVICAL PROSTAGLANDIN E2 GEL (DINOPROSTONE) FOR INDUCTION OF LABOUR.

Dr. Hemlata and Dr. Godawari Joshi.

Department of obstetrics and gynaecology, government medical college & dr. S. T. G. H. Haldwani.

Manuscript Info

Manuscript History

Received: 20 January 2019

Final Accepted: 22 February 2019

Published: March 2019

Key words:-

Green's function, Fick's Law, Thermal diffusivity, Thermal conductivity.

Abstract

Introduction: Induction of labour is an intervention after 28 weeks of gestation, intended to artificially initiate uterine contractions resulting in the progressive effacement and dilatation of the cervix and ending in vaginal delivery. Sometimes because of medical or obstetric complications of pregnancy, cervical ripening and induction of labour is often required. Induction of labour is indicated when the benefits to either the mother or fetus outweigh those of continuing the pregnancy [1].

Aim Of The Study: To compare efficacy and safety of intracervical Foley's balloon catheter with intracervical prostaglandin E2 gel (dinoprostone) for induction of labour.

Objectives: To compare cervical ripening, induction-delivery interval, mode of delivery, maternal complications and fetal outcome by two methods.

Materials And Methods: Prospective randomized controlled study. **SAMPLE SIZE-** Each group 50, determined by statistical analysis. Successful induction considered if the patient entered the active phase of labour/ bishop score 6.

Result: In present study, both groups were comparable in age distribution. In both the groups, most of the study subjects were between the age group of 18-25 years (76% in pgE2 v/s 70% in Foley's catheter group). Mean age in PGE2 gel group was 23.20 ± 3.03 years while Mean age in Intra-Cervical Foley's Catheter group was 23.92 ± 3.11 years. Mean gestational age in PGE2 gel group was 39.12 ± 1.33 weeks compared to 39.06 ± 1.18 weeks in Intra-Cervical Foley's Catheter group. At start of induction mean Bishop score was 1.62 ± 1.10 in PGE2 gel group while it was 1.58 ± 1.01 in Intra-Cervical Foley's Catheter group. Deshmukh V et al also reported similar pre-induction mean Bishop score (1.48 ± 0.67 in Foley's Catheter group v/s 1.59 ± 0.59 in pgE2 gel group). In our study, post-induction mean Bishop score at 6 hours was 6.56 ± 2.13 in PGE2 gel group while it was 4.70 ± 2.21 in Intra-Cervical Foley's Catheter group. Mean change in Bishop score between 0 to 6 hours was significantly higher in pgE2 gel group (4.94 ± 1.78) compare to Foley's catheter group (3.12 ± 1.78). The rate of LSCS in pgE2 gel group was 10% and 32% in Foley's catheter group respectively. The induction delivery interval showed

significantly higher time in intracervical Foley's catheter groups. The mean induction delivery interval was 13.80 ± 3.83 hrs in Foley's group and 9.65 ± 2.13 hrs in PGE₂ group. In our study, common maternal complication observed were Intrapartum pyrexia (1 case in pgE2 gel group and 8 cases in Foley's catheter group) and puerperal pyrexia (1 case in pgE2 gel group and 4 cases in Foley's catheter group). 1 case of hyperstimulation was also seen in pgE₂ gel group. Apart from that we have not seen any other complication in mothers. The present study shows that the fetal outcome results were also comparable in both the groups.

Conclusion: The results of this trial tended to favor the prostaglandins use over Foley catheter use. The main advantage of the PGE₂ gel is that early ripening of cervix, lesser caesarean rate and infection rate as compared to the Foley's catheter while disadvantage is higher chances of uterine hypertonicity or tachysystole. but Foley's catheter mimicked the physiology of the labour onset more closely, resulting in a less likelihood of hyperstimulation, fetal heart rate abnormalities and postpartum hemorrhage.

Now, there is recent trend of reintroducing the mechanical methods like the Foley catheter, as there is an availability of sterile devices, controlling one of the principal contraindications- infection. Such mechanical methods are advantageous in terms of their reversibility and the reduced expenditure. But Foley's catheter has been linked with a possibility of infections in some larger studies. Thus, tremendous attention should be drawn towards carrying out aseptic measures while it is being inserted, to avoid maternal and probable neonatal infections.

Copy Right, IJAR, 2019,. All rights reserved.

..... Introduction:-

Induction of labour is an intervention after 28 weeks of gestation, intended to artificially initiate uterine contractions resulting in the progressive effacement and dilatation of the cervix and ending in vaginal delivery. The incidence of induction varies widely from 5-30%. The goal of Obstetric is a pregnancy that results in a healthy infant and a healthy mother. For majority of women, labour starts spontaneously and results in vaginal delivery at or near term. Sometimes because of medical or obstetric complications of pregnancy, cervical ripening and induction of labour is often required. Induction of labour is indicated when the benefits to either the mother or fetus outweigh those of continuing the pregnancy [1]. Common indications for labour induction include preeclampsia, premature rupture of membranes, chorioamnionitis, intrauterine growth retardation, isoimmunization, maternal medical problems, fetal demise, postdated pregnancy and oligohydramnios. The chief contraindications to labour induction are placenta previa, transverse lie, prolapsed umbilical cord, active genital herpes infection, and pelvic structural deformities; Cephalopelvic disproportion. 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].

Therefore, cervical ripening or preparedness for induction should be assessed before a regimen is selected. Many methods have been devised to ripen the cervix and this process has been described as preinduction cervical ripening. Pharmacologic agents available for cervical ripening and labour induction include prostaglandins, misoprostol, mifepristone and relaxin. Local application of Prostaglandin E₂ (PGE₂ or Dinoprostone) has been in use for cervical ripening since late 1960s. 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 [4,5]. Uterine tachysystole and accompanying fetal distress is reported following administration of PGE₂ in 1 to 5 percent of women [6].

The use of a cervical catheter also appears to be effective for cervical ripening & has been shown to shorten induction to delivery interval, decrease caesarean section rate and increase the rate of spontaneous vaginal delivery [7]. Different catheter balloon volumes ranging from 30 - 80ml and even double balloon catheter have been studied

for cervical ripening [8]. The mechanical action of the Foley catheter, strips the fetal membranes from the lower uterine segment and causes release 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 [9,10]. Failed inductions leading to caesarean section are expected in closed and firm cervix that is difficult to distend[11]. The advantage of this method over the pharmacological preparation includes simplicity of preservation, lower cost and reduction of side effects.

This study was planned to compare the efficacy and safety of 30 ml Intracervical Foley catheter balloon with that of intracervical Dinoprostone gel for cervical ripening for induction of labour at term.

Inclusion Criteria-

1. Pregnant nulliparous women
2. Singleton fetus in cephalic presentation
3. Bishop score <4
4. Intact membranes
5. Patient giving consent

Exclusion Criteria-

1. Any active or purulent infection of lower genital tract
2. Spontaneous labour at start of planned induction
3. Abnormal CTG at start of induction
4. Scarred uterus such as previous caesarean section
5. Malpresentation in labour
6. Cephalopelvic disproportion
7. Severe asthma
8. Tumors occupying the pelvis
9. Major degree placenta previa
10. Carcinoma cervix
11. Active herpes, HIV infection
12. Patient not willing to participate in study

History taking from the patient included the last menstrual period, menstrual cycle regularity, past obstetric and medical history. Clinical general examination of the patient done. Obstetric examination done. After correlating the history, clinical findings and previous ultrasound findings, according to the indication, patient selection for induction is done. After selecting the patients for study, their Bishop score assessed. Major degrees of cephalopelvic disproportion ruled out.

Method Of Application

Intracervical Foley's Catheter

Patient was placed in 'lithotomy position', perineum and vagina cleansed with betadine solution. No.16 foley's catheter was introduced into the endocervix by direct visualization or blindly by locating the cervix with the examining fingers and guiding the catheter over the hand and fingers through the endocervix and into the potential space between the amniotic membrane and lower uterine segment. The balloon reservoir was inflated with 30ml of distilled water. The balloon was strapped to the inner aspect of one thigh with slight tension. Monitoring done using partograph. Bishop score reassessed after six hours and 12 hours. Foley's balloon catheter removed after 12 hours if there is no expulsion. Method considered failure if labour doesn't start after 3 doses. All patients received prophylactic antibiotics.

Prostaglandin E2gel instillation

PGE2 gel – Cerviprime gel which contains 0.5 mg of PGE2 gel present in prefilled syringe was used. Monitoring of fetal heart rate and uterine activity continuously. Gel introduced into the cervix as follows-Patient in lithotomy position, perineum and vagina cleaned with betadine. Dinoprostone gel inserted using pre-filled syringe into the endocervix just below the level of the internal os, care taken not to injure the membranes. Patient to remain recumbent for 30 minutes after the procedure. Bishop score assessed after six hours after the procedure. Gel repeated 6 hrly upto a maximum of three doses unless the bishop score is >6 or regular painful uterine contractions <5 minutes have commenced.

Partogram was used to monitor the progress of labour.

Successful induction considered if the patient entered the active phase of labour/ bishop score 6.

Discussion:-

The present study entitled “To compare safety and efficacy of intracervical Foley’s catheter Ballon with intracervical prostaglandin gel E2 (Dinoprostone) for induction of labour” was a prospective hospital-based study conducted in nulliparous pregnant women with unfavorable cervix over 37 weeks of gestational age. The main objective of study was to compare cervical ripening, induction-delivery interval, fetal outcome and mode of delivery between both methods. 50 patients in each group were recruited and followed till neonatal outcome.

Approximately about 15% labours are induced. The pre-induction cervical ripening is associated with the success of the induction in women with unfavorable cervix¹⁰³. Labor induction in an unfavorable cervix is a different and a lengthy procedure and it is tiring for both the mother and the Obstetrician. The different methods which are used for cervical ripening are pharmacological methods like oxytocin, estrogens, mifepristone, PGE1, PGE2, etc. and non-pharmacological (mechanical) methods like Foley’s catheter, laminaria, amniotomy, etc¹⁰³.

When the labour onset occurs physiologically, the cervix ripens before the myometrial contractions start. The intracervical placement of the Foley catheter induces the cervical ripening without inducing any uterine contractions, while the prostaglandins affect the cervical ripening and the uterine contractions simultaneously.

In present study, both groups were comparable in age distribution. In both the groups, most of the study subjects were between the age group of 18-25 years (76% in pgE2 v/s 70% in Foley’s catheter group). Mean age in PGE2 gel group was 23.20 ± 3.03 years while Mean age in Intra-Cervical Foley’s Catheter group was 23.92 ± 3.11 years.

Ziyauddin F et al¹⁰⁴ also compared the effectiveness and the safety of the transcervical Foley catheter and the prostaglandin E2 (PGE2) gel for the induction of labor in 70 women with a previous one caesarean section, in J.N. Medical College, Aligarh, (U.P), India. Mean age in their study was 25.09 years in Foley’s catheter group while 26.12 in PGE2 gel group. Similar age distribution was reported by another study from India by Rajeswari A et al¹⁰⁵. In contrast to our study little higher maternal age was reported by Masood et al¹⁰⁶ who conducted a prospective quasi-randomised clinical trial which included 90 term pregnant women who were randomly assigned to receive intracervical foley catheter, dinoprostone 3 mg tablets or misoprostol 25µg tablets vaginally to compare the efficacy, safety and acceptability for induction of labor in women with previous one caesarean section at term. In this study, mean age in Intra-Cervical Foley’s Catheter group was 27.56 ± 4.07 years while in PGE2gel group it was 27.53 ± 3.89 years. It might be due to the fact that they have selected all women with one previous cesarean section.

Similar maternal age was reported by Deshmukh V et al¹⁰⁷ who reported mean age in Foley’s catheter group as 22.27 ± 2.97 years while in Ziyauddin F et al it was 22.00 ± 2.79 years. This study was conducted at GMCH, Aurangabad from July 2005 to January 2008 to compare the efficacy of intra-cervical Foley’s catheter with PGE2 gel for pre-induction cervical ripening and it included 200 participants in each group.

In our study, mean gestational age in PGE2 gel group was 39.12 ± 1.33 weeks compared to 39.06 ± 1.18 weeks in Intra-Cervical Foley’s Catheter group. Similar to our study, Ziyauddin F et al reported mean gestational age as 39.24 weeks in Foley’s catheter group and 38.89 weeks in pgE2 gel group. Mean gestational age in study by Masood et al reported as 39.8 ± 1.03 weeks in Foley’s catheter and 39.5 ± 0.77 weeks in PGE2 gel group which is also comparable to our study. Study by Rajeswari A et al also reported similar gestational weeks distribution.

Pre-induction Bishop score:

In present study, at start of induction mean Bishop score was 1.62 ± 1.10 in PGE2 gel group while it was 1.58 ± 1.01 in Intra-Cervical Foley’s Catheter group. Deshmukh V et al also reported similar pre-induction mean Bishop score (1.48 ± 0.67 in Foley’s Catheter group v/s 1.59 ± 0.59 in pgE2 gel group).

In contrast to our study Ziyauddin F et al reported mean bishop score at start of induction as 2.80 in Foley’s catheter group and 2.95 pgE2 gel group. The difference may be due to the fact because in our study we have taken study subjects with Bishop score ≤ 4 at start of induction while in study by Ziyauddin F et al, they included study subjects with Bishop score ≤ 6 at start of induction so higher values were obtained.

Post induction Bishop score:

In our study, post-induction mean Bishop score at 6 hours was 6.56 ± 2.13 in PGE2 gel group while it was 4.70 ± 2.21 in Intra-Cervical Foley's Catheter group. It was significantly higher in pgE2 gel group compare to Foley's catheter group.

Deshmukh V et al reported post-induction mean Bishop score at 6 hours as 7.04 ± 1.72 in Foley's Catheter group v/s 7.08 ± 1.87 in pgE2 gel group. Author reported no significant difference between both group at post induction.

Post-induction mean Bishop score at 12 hours in our study was 6.0 in PGE2 gel group while it was 7.58 ± 3.11 in Intra-Cervical Foley's Catheter group but at 12 hours this difference was statistically non-significant. Similar to our study, Ziyaaddin F et al reported mean bishop score at post induction at 12 hours as 7.45 in Foley's catheter group and 6.95 in pgE2 gel group.

Change in Bishop score:

In present study, mean change in Bishop score between 0 to 6 hours was significantly higher in pgE2 gel group (4.94 ± 1.78) compare to Foley's catheter group (3.12 ± 1.78). In study by Deshmukh V et al mean change in Bishop score between 0 to 6 hours was comparable and no significant difference was observed between both group (5.56 ± 1.89 in Foley's Catheter group v/s 5.49 ± 1.82 in pgE2 gel group).

Similar findings were reported by Fareed P et al who compared the efficacy of intracervical Foleys catheter and intracervical PGE2 gel in preinduction cervical ripening in Srinagar from Mar 2011- Mar 2013 in 200 patients. In this study improvement in the bishop's score in Group A was 5.3 ± 1.1) and in Group B it was 5.1 ± 1.1 ; however no significant difference in the mean changes was observed.

Caesarean section rate and indications:

In present study, the rate of LSCS in pgE2 gel group was 10% and 32% in Foley's catheter group respectively. The most common indication for LSCS in both the group was fetal distress. Foley's catheter group had 16 cases for fetal distress and pgE2 gel Group had 4 cases of fetal distress. The rate of LSCS in our study is agreeable. There was significant association of increased rate of cesarean section with the Foley's catheter usage. Similar findings were observed by Kadam DA et al who reported that cesarean section rate for Foleys group was 26.08 % and that for PGE2 group was 0% and this difference was statistically significant. Study by Rajeswari A et al reported similar caesarean section rate in both group (21% in Foley's group v/s 19% in pgE2 gel group). Similar to our study, most common indication in their study was also fetal distress. Group F had 9 cases for FD and Group P had 11 cases of fetal distress. Rate of cesarean section reported in study by Deshmukh V et al was 14% in Foley's group and 18.5% in pgE2 gel Group. In this study, cases of fetal distress were 8.5% in Foley's group and 10.5% in pgE2 gel group. Alam A et al also reported higher cesarean section rate in both groups (21% in Foley's group and 19% in pgE2 gel group). Author reported that LSCS was done for fetal distress in Foley's group for 9 cases and in pgE2 gel group for 11 cases. The other indications for LSCS being failure to progress (6 and 5 respectively and failure of induction (3 and 1 respectively).

Mean Induction-delivery interval:

The induction delivery interval showed significantly higher time in intracervical Foley's catheter groups. The mean induction delivery interval was 13.80 ± 3.83 hrs in Foley's group and 9.65 ± 2.13 hrs in PGE2 group. In contrary to the findings, Rajeswari A et al reported mean induction delivery interval as 16.01 ± 5.5 hrs in Foley's group and 16.85 ± 3.81 hrs in PGE2 group. Higher mean I-D interval was also reported by Deshmukh V et al (15.32 hrs in Foley's group and 14.2 hrs in PGE2 group) and Masood A et al (19.93 hrs in Foley's group and 20.10 hrs in PGE2 group).

In the study done by Marta Jozwiak et al, they found that induction to delivery duration in PGE2 group was significantly less as compared to Foleys group, P value was 0.0001. But in the study done by Azra Naseem et al they found that the induction to delivery duration was significantly less in Foleys group as compared to PGE2 group with P value 0.008.

Maternal complications:

In our study, common maternal complication observed were Intrapartum pyrexia (1 case in pgE2 gel group and 8 cases in Foley's catheter group) and puerperal pyrexia (1 case in pgE2 gel group and 4 cases in Foley's catheter group). 1 case of hyperstimulation was also seen in pgE2 gel group. Apart from that we have not seen any other

complication in mothers. Ziyauddin F et al also reported also reported 1 case of uterine hypertonicity and 1 case of puerperal pyrexia in pgE2 gel group while 2 cases of puerperal pyrexia were seen in Foley's group but in contrary to our study, 13 cases of PPH were also reported by author (5 in Foley's group and 8 in pgE2 gel group). Rajeswari A et al did not found any case of infection but side effects associated with pgE2 gel like uterine hypertonicity and tachysystole were reported in 4 & 2 cases respectively.

Fetal outcome:

Fetal outcome data showed no significant difference between Foley's catheter Group and pgE2 gel Group with respect to NICU admission rate (6 and 6 respectively). Thus, the present study shows that the fetal outcome results were also comparable in both the groups. Compare to our study, NICU admission rate was very high in study by Deshmukh V et al (18.5% in Foley's group v/s 20.5% in pgE2 gel group) but no significant difference was reported. Similar to present study, Rajeswari A et al also reported lesser NICU admission rate (12% in Foley's group v/s 5% in pgE2 gel group) and both groups were found to be comparable. 5 Cases in Foley's group and 4 cases in pgE2 gel group were admitted to NICU in study by Masood A et al.

In our study, PGE2 gel produced better effects compare to Foley's catheter in the ripening of the cervix in women at 6 hrs but both were comparable at 12 hrs. The main advantage of the PGE2 gel is that early ripening of cervix, lesser caesarean rate and infection rate as compared to the Foley's catheter while disadvantage is higher chances of uterine hypertonicity or tachysystole.

Ravasia DJ et al conducted a study on the VBAC induction and showed that the Foley catheter induction was associated with a lowest rupture rate in the induced TOL group and that it was comparable to the results in the spontaneous TOL group. The PGE2 exposure during the TOL was associated with more than a 6fold increase in the uterine ruptures as compared to that in the spontaneous labour.

In the large NICHD study, the use of the prostaglandin-based medications to induce labour was associated with a nonsignificant increase in the risk of the uterine rupture as compared to the mechanical methods of induction of labour (such as the use of a Foley catheter). In this study, the risk of the uterine rupture was 140/10,000 inductions with the use of prostaglandins as compared to the 89/10,000 inductions with the use of a Foley catheter to dilate the cervix.

According to an open label randomized control trial which was done by the PROBAAT study group, in women with unfavorable cervixes at term, the induction of labour with a Foley catheter was similar to the induction of labor with the Prostaglandin E2 gel, with fewer maternal and neonatal side effects.

Result:-

CHARACTERSTIC	Intracervical PGE2 gel group	Intracervical Foley catheter group	P value
1. Mean age	23.20±3.03	23.92±3.11	0.49
2. Cases according gravida	G1 84% G2 12% G3 4%	G1 86% G2 8% G3 6%	0.73
3. Cases according to gestational age (in weeks)	37-37wk+6d 38-38wk+6d 39-39wk+6d 40-40wk+6d 41-41wk+6d	37-37wk+6d 14% 38-38wk+6d 18% 39-39wk+6d 26% 40-40wk+6d 30% 41-41wk+6d 11%	0.74

	42wks	24wks 1%	
0 12%	0	14%	0.95
1 42%	1	40%	
2 24%	2	20%	
3 20%	3	22%	
4 2%	4	4%	
4. Bishop score at 0 hour			
5. Bishop score at 6 hours	≤5 6-10 >10	26.0% 72.0% 2.0%	<0.01
6. Bishop score at 12 hours	≤5 6-10 >10 *52 patients delivered before 12 hours	≤5 0.0 6-10 100.0 >10 0.0	0.03
7. Change in Bishop score between 0 to 6 hours	0-2 3-5 >5	0-2 10.0 3-5 56.0 >5 34.0	<.01
8. Change in Bishop score between 6 to 12 hours	0-2 3-5 >5	0-2 0.0 3-5 100.0 >5 0.0	0.02
9. Mean Bishop score	Bishop score at 0 hours Bishop score at 6 hours Bishop score at 12 hours Change in Bishop score between 0 to 6 hours Change in Bishop score between 6 to 12 hours	1.58 1.62 4.70 6.56 7.58 6.00 3.56 4.94 3.56 3.20	0.91 <0.01 0.54 <0.01 0.82
10. Mode of delivery	LSCS Vaginal delivery	32.0 10.0 68.0 90.0	0.01

11. Indication of LSCS	Fetal distress Meconium stained liquor	100.0% 80.0% 0.0% 20.0%	0.23
12. Induction to active labor interval	<6 hours 6-12 hours >12 hours	<6 hours 88.0 6-12 hours 12.0 >12 hours 0.0	<0.01
13. Induction to delivery interval	6-12 hours >12 hours	6-12 hours 92.0 >12 hours 8.0	<0.01
14. Interval between Induction to active labor and delivery	Interval between Induction to active labor (In hours) Interval between Induction to delivery (in hours)	Mean-active labor 6.55 Mean-delivery 3.15 13.80 9.65	<0.01 <0.01
15. Maternal complications	Hyperstimulation PPH Intra partum pyrexia Puerperal pyrexia Wound sepsis	0.0 2.0 0.0 0.0 16.0 2.0 8.0 2.0 0.0 0.0	0.98 - 0.03 0.36 -
16. NICU admission	Yes No	12.0 12.0 88.0 88.0	-

Data entry and statistical analysis:

The collected data were transformed into variables, coded and entered in Microsoft Excel. Data were analyzed and statistically evaluated using SPSS-PC-19 version.

Quantitative data was expressed in mean, standard deviation and difference between two comparable groups were tested by student 't' test or Mann Whitney 'U' test while qualitative data were expressed in percentage. Difference between the proportions were tested by chi square test. 'P' value less than 0.05 was considered statistically significant.

Result:-

In present study, both groups were comparable in age distribution. In both the groups, most of the study subjects were between the age group of 18-25 years (76% in pGE2 v/s 70% in Foley's catheter group). Mean age in PGE2 gel group was 23.20 ± 3.03 years while Mean age in Intra-Cervical Foley's Catheter group was 23.92 ± 3.11 years. Mean gestational age in PGE2 gel group was 39.12 ± 1.33 weeks compared to 39.06 ± 1.18 weeks in Intra-Cervical Foley's Catheter group. At start of induction mean Bishop score was 1.62 ± 1.10 in PGE2 gel group while it was 1.58 ± 1.01 in Intra-Cervical Foley's Catheter group. Deshmukh V et al also reported similar pre-induction mean Bishop score (1.48 ± 0.67 in Foley's Catheter group v/s 1.59 ± 0.59 in pGE2 gel group). In our study, post-induction mean Bishop score at 6 hours was 6.56 ± 2.13 in PGE2 gel group while it was 4.70 ± 2.21 in Intra-Cervical Foley's Catheter group.

Mean change in Bishop score between 0 to 6 hours was significantly higher in pgE2 gel group (4.94 ± 1.78) compared to Foley's catheter group (3.12 ± 1.78). The rate of LSCS in pgE2 gel group was 10% and 32% in Foley's catheter group respectively. The induction delivery interval showed significantly higher time in intracervical Foley's catheter groups. The mean induction delivery interval was 13.80 ± 3.83 hrs in Foley's group and 9.65 ± 2.13 hrs in PGE2 group. In our study, common maternal complication observed were Intrapartum pyrexia (1 case in pgE2 gel group and 8 cases in Foley's catheter group) and puerperal pyrexia (1 case in pgE2 gel group and 4 cases in Foley's catheter group). 1 case of hyperstimulation was also seen in pgE2 gel group. Apart from that we have not seen any other complication in mothers. The present study shows that the fetal outcome results were also comparable in both the groups.

Summary And Conclusion:-

The results of this trial tended to favor the prostaglandins use over Foley catheter use but further more study needed for this as the process of Foley's catheter mimicked the physiology of the labour onset more closely, resulting in a less likelihood of hyperstimulation, fetal heart rate abnormalities and postpartum hemorrhage.

Now, there is recent trend of reintroducing the mechanical methods like the Foley catheter, as there is an availability of sterile devices, controlling one of the principal contraindications- infection. Such mechanical methods are advantageous in terms of their reversibility and the reduced expenditure. But Foley's catheter has been linked with a possibility of infections in some larger studies. Thus, tremendous attention should be drawn towards carrying out aseptic measures while it is being inserted, to avoid maternal and probable neonatal infections.

References:-

1. B. A. Brindley and R. J. Sokol, "Induction and Augmentation of Labor. Basis and Methods for Current Practice," *Obstetrical & Gynecological Survey*, Vol. 43, No. 12, 1988, pp. 730-743. doi:10.1097/00006254-198812000-00004 [Citation Time(s):1]
2. K. F. Trofetter, "Cervical Ripening," *Clinical Obstetrics and Gynecology*, Vol. 35, No. 3, 1992, pp. 476-486. doi:10.1097/00003081-199209000-00007 [Citation Time(s):1]
3. J. E. Stempel, R. P. Prins and S. Dean, "Preinduction Cervical Ripening: A Randomized Prospective Comparison of the Efficacy and Safety of Intravaginal and Intracervical Prostaglandin E₂ Gel," *American Journal of Obstetrics & Gynecology*, Vol. 176, No. 6, 1997, pp. 1305-1312. doi:10.1016/S0002-9378(97)70350-8 [Citation Time(s):1]
4. N. Uldbjerg, G. Ekman and A. Malmstrom, "Ripening of the Human Uterine Cervix Related to Changes in Glycosaminoglycans and Collagenolytic Activity," *American Journal of Obstetrics & Gynecology*, Vol. 147, No. 6, 1983, pp. 662-666.
5. K. F. Trofetter, D. Bowers, R. N. Standby, A. Gall and A. P. Killam, "Preinduction Cervical Ripening with Prostaglandin E₂ Gel," *American Journal of Obstetrics & Gynecology*, Vol. 153, No. 3, 1985, pp. 268-271.
6. R. P. Prins, R. N. Bolton and C. Mark, "Cervical Ripening with Intravaginal Prostaglandin E₂ Gel," *Obstetrics & Gynecology*, Vol. 63, 1984, pp. 697-702. [Citation Time(s):1]
7. C. James, A. Peedicayil and L. Seshardi, "Use of the Foley Catheter as a Cervical Ripening Agent Prior to Induction of Labor," *International Journal of Gynecology & Obstetrics*, Vol. 47, No. 3, 1994, pp. 229-232. doi:10.1016/0020-7292(94)90566-5 [Citation Time(s):1]
8. D. A. Guinn, A. R. Goepfert, M. Christine, J. Owen and J. C. Hauth, "Extra-Amniotic Saline, Infusion and Intracervical Dinoprostone Gel for Cervical Ripening," *Obstetrics & Gynecology*, Vol. 182, 2000, pp. 1039-1044. [Citation Time(s):1]
9. D. J. Sherman, E. Frenkel, J. Tovbin, S. Arieli, E. Caspi and I. Bukovsky, "Ripening of the Unfavorable Cervix with Extra-Amniotic Catheter Balloon: Clinical Experience and Review," *Obstetrical & Gynecological Survey*, Vol. 51, No. 10, 1996, pp. 621-627. doi:10.1097/00006254-199610000-00022
10. F. Arias, "Pharmacology of Oxytocin and Prostaglandins," *Clinical Obstetrics and Gynecology*, Vol. 43, No. 3, 2000, pp. 455-468. doi:10.1097/00003081-200009000-00006.