Section: Obstetrics and Gynaecology

Original Research Article

COMPARISON OF TRANSCERVICAL FOLEY'S CATHETER WITH INTRACERVICAL PGE_2 FOR PREINDUCTION CERVICAL RIPENING IN WOMEN UNDERGOING TRIAL OF VAGINAL DELIVERY AFTER ONE LOWER SEGMENT CESAREAN SECTION

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Received : 18/02/2023
Received in revised form : 08/03/2023
Accepted : 30/03/2023

Keywords:
Preinduction Cervical Riping, Transcervical Foleys Catheter, Intracervical PGE2 Injection, Vaginal Birth, Caesarean Section.

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DOI: 10.47009/jamp.2023.5.3.354

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5(3); 1778-1784

Abstract

Introduction: Women who have had one lower segment caesarean section in the past are safe to choose vaginal birth after caesarean section (VBAC). For women undergoing VBAC, preinduction cervical ripening is frequently utilised to speed up labour induction. Transcervical Foley's catheter and intracervical prostaglandin E2 are two frequently employed techniques for preinduction cervical ripening. (PGE2). There is, however, little data comparing the efficiency and security of these two procedures in women undergoing VBAC. This study compares the efficacy and safety of intracervical PGE2 and transcervical Foley's catheter for preinduction cervical ripening in women undergoing VBAC. **Methods:** Women who have had one lower segment caesarean surgery in the past are participating in this prospective randomised controlled trial to test out vaginal birth. For preinduction cervical ripening, a total of 60 women will be enrolled and randomised to receive either a transcervical Foley's catheter or intracervical PGE2. The difference between the bishop score at 6 and 12 hours is the main indicator of success. The length of labor, the need for augmentation or intervention, and maternal and neonatal outcomes are examples of secondary outcome variables. **Results:** Preinduction cervical ripening for women undergoing VBAC can be accomplished with both a transcervical Foley's catheter and an intracervical PGE2 injection. However, the prostaglandin group performed more caesarean sections than the foleys group did, and neither group significantly increased the rate of caesarean sections. In comparison to prostaglandins, foleys cather carries a lower risk of uterine dehiscence and has fewer adverse effects. The research also discovered that women who got a transcervical Foley's catheter as opposed to an intracervical PGE2 injection have shorter labours. The two groups' maternal and newborn outcomes did not significantly differ from one another. **Conclusion:** The efficiency and safety of intracervical PGE2 and transcervical Foley's catheter for preinduction cervical ripening in women undergoing VBAC are being compared for the first time in this study, which is a randomised controlled experiment. The results of the study will be helpful in comparing the efficacy and safety of these two frequently used preinduction cervical ripening techniques in women who have had one prior lower segment caesarean section. The outcomes for women undergoing VBAC will be improved by this study's findings and clinical decision-making will be guided by its findings.

INTRODUCTION

Labor induction is the stimulation of regular uterine contractions before its spontaneous onset, using pharmacological or mechanical methods in order to generate progressive cervical dilation and subsequent delivery in women who are at least 20 weeks' gestation.[1] The consistency compliance and configuration of cervix decides the success of induction to a large extent.[2] Commonly used cervical scoring systems is the Bishop's score which takes into consideration five factors: dilatation, effacement, position, consistency of cervix, and station of the presenting part. A score less than 6 is labeled unfavorable therefore ripening of cervix is

used to increase the success rate of induction of labor.[3]

A woman with one previous transverse lower segment Caesarean section who undergo trial of labor after careful selection and ruling out contraindications, can also undergo induction of labor.

However, the potential increased risk of uterine rupture associated with any induction, and the potential decreased possibility of achieving VBAC (vaginal birth after cesarean), should be discussed with the patient.[4] Induced labor is less likely to result in VBAC than spontaneous labor.[4]

Prostaglandin E2 (PGE2) and the intra-cervical Foley catheter are both safe and effective procedures for ripening of cervix with unscarred uterus.[5] Ripening of cervix with PGE2 in a post-Cesarean section patient is still controversial. Several studies reported higher rates of uterine rupture with the use of PGE2[6], whereas others stated its safety.[7-9]

The use of intra-cervical Foley catheter insertion for induction of labor in a trial of VBAC has not been extensively studied. One recent study found it to be safe, with no demonstrated increase in uterine rupture rate.[6] Mechanical methods can be used without any pharmacological side effects.

Given the lack of data suggesting increased risk with transcervical catheters, such interventions are good option for induction of labor in women undergoing TOLAC (trial of labor after cesarean) with unfavourable cervix.[4] The aim of our study was to assess the effectiveness and safety of both PGE2 and the Foley catheter for the pre induction cervical ripening in a trial of VBAC.

MATERIALS AND METHODS

This prospective randomized controlled trial was carried out from January 2013 to December 2013 in the department of Obstetrics & Gynaecology, Maulana Azad Medical College & Lok Nayak hospital, a tertiary care teaching hospital.

The study population consisted of 60 patients fulfilling the **i**nclusion criteria of singleton pregnancy, gestation ≥37 weeks, with previous one lower segment cesarean section done >18 month back for non-recurrent indication with poor Bishop's score (≤6). Exclusion criteria were women with previous two LSCS, previous classical uterine scar, active infection of lower genital tract, known contraindications for administration of prostaglandins, impending eclampsia and patient not willing to participate in the study.

The primary outcome of the study was change in Bishop's score at 6 and 12 hours. Secondary outcomes included induction to delivery interval, mode of delivery, indication for operative delivery, number of patients requiring oxytocin (with total dose) in both the groups, incidence of adverse effects, uterine hyperstimulation, uterine scar dehiscence/rupture, FHR abnormality, staining of the amniotic fluid with meconium, neonatal outcomes in both groups.

In patients admitted in obstetric ward with previous one LSCS, demographic details, clinical details and relevant investigations were recorded. Detailed systemic and pelvic examination was done including cervical scoring by Bishop's score and pelvic assessment and any contraindication for vaginal delivery were ruled out. Women were selected carefully for trial of labor after cesarean (TOLAC). Women undergoing TOLAC in whom induction of labor was indicated, were recruited in the study. In patients meeting inclusion criteria written informed consent was obtained after proper counseling. To maintain power of study 90% with α error of 5%, minimum 12 women were needed in each group, on the basis of published data. We included 30 women in each group. All the 60 patients were randomized into two groups, using computer generated random number sequence for two arm study. Allocation concealment was done using opaque (serial numbered) sealed envelopes. 30 women randomized to group A underwent preinduction cervical ripening with Foley's catheter and in 30 who were randomized to group B, PGE_2 intracervical gel was used for preinduction cervical ripening.

Group A (n = 30)

A 16F Foley's catheter with a 30-mL balloon was inserted into the endocervical canal under direct visualization under all aseptic conditions. Foley's catheter was advanced into the endocervical canal, once past the internal os 30 mL saline was instilled into the balloon and the catheter was pulled back till the balloon hitched to the internal os and it was taped to internal thigh with slight traction so that constant pressure was maintained at the internal os. Patient kept in the labor ward with close monitoring of progress of labor and fetal heart monitoring with intermittent fetal auscultation. Pelvic examination was repeated to assess favorability of cervix and change in Bishop's score after 6 and 12 hours or earlier at the expulsion of the balloon if it extrudes on its own. If not expelled spontaneously it was removed at 12 hours.

Group B (n = 30)

Intracervical instillation of 0.5 mg of PGE_2 gel done, the tip of the catheter was kept below internal os. The patient was asked to remain in supine position for at least 15- 30 minutes to minimize leakage from the endocervical canal. Pelvic examination was repeated to assess favorability of cervix and change in Bishop's score after 6 hours and if Bishop's score was less than or equal to six, repeat pelvic examination and Bishop's scoring was done at 12 hours. Patient was kept in labor ward to monitor progress of labor and fetal heart rate by intermittent auscultation.

In both the groups, oxytocin and/or artificial rupture of membranes were used as further mode of induction after ripening of cervix or twelve hours of Foley's catheter insertion and PGE_2 instillation whichever was earlier, as per the hospital protocols. Oxytocin

ISSN (O): 2687-5365; ISSN (P): 2753-6556

was started @ 2mU/min and rate was doubled every one hourly according to uterine contractions upto maximum 32mU/min.

Uterine tachysystole (hyperstimulation) was defined as more than five contractions in 10 minutes, averaged over a 30-minute window.[12]Failure of preinduction cervical ripening (failure to progress) by Foley's catheter or PGE_2 gel was defined as Bishop's score less than or equal to six at twelve hours. Failed induction was taken as Bishop's score less than or equal to six at twenty-four hours, even after using oxytocin or ARM as further mode of induction.

Signs of uterine scar dehiscence/rupture were noted-maternal tachycardia and hypotension, sudden abnormal FHR, tenderness over uterine scar, unexplained vaginal bleeding, incoordinate uterine activity. Data collection was done in a predesigned proforma. Entire data was expressed by the descriptive statistics i.e. mean and standard deviation. For quantitative data, difference between means was measured by student's unpaired t test. For qualitative data, Chi square test was applied, wherever applicable. If P value was less than 0.05, the difference was considered to be statistically significant.

RESULTS

60 women participated in the study with 30 in each group. Both the groups were comparable in terms of demographic characteristics, indications of induction, preinduction Bishop's score, as shown in Table 1. The mean change at 6 hours in Group A was 1.30±1.29 while it was 1.51 ±.91 in Group B. This difference was not statistically significant. (p=0.15), using Mann Whitney U test.

The mean change of score from 0 to 12 hours was more in group A in which it was 4.07±1.97 as compared to 3.10± .83 in group B, which was statistically significant (p=0.021), using Student's t-test (Unpaired).

Table 1: Demographic and Baseline Characters of Cases

		Group A	Group B	P value
Age (years)		27.20 ±3.23	27.40 ±2.49	0.79 (NS)
Gestation age (weeks)		39.46±1.69	39.26±1.41	0.62 (NS)
Preinduction Bishop's score		3.10±.71	3.23±1.16	0.59 (NS)
Second gravida		17(57%)	20(67%)	0.42 (NS)
Multigravida (≥3)		13(43%)	10(33%)	0.36 (NS)
Indications	**Post term**	11(36.67%)	7(23.33%)	0.39 (NS)
	Hypertension	8(26.67%)	6(20%)	0.76 (NS)
	IUGR	3(10%)	2(6.67%)	0.64 (NS)
	↓Fetal movements	2(6.67%)	4(13.33%)	0.66 (NS)
	Oligohydroamnios	2(6.67%)	2(6.67%)	1.00 (NS)
	ICP	1(3.33%)	3(10%)	0.60 (NS)
	Others	3(10%)	6(20%)	0.46 (NS)

Table 2: Change in Bishop's Score At 6 And 12 Hours

Mean change in Bishop's score	Group A	Group B	Total
at 6 hours	1.30±1.29	1.51 ±.91	P=0.15 (NS)
at 12 hours	4.07±1.97	3.10± .83	P=0.021 **(S)**

Table 3: Secondary Outcomes

Outcome	Group A	Group B	P value
Induction to vaginal delivery interval(hours)	18.80±7.99	19.53±6.95	P=0.79 (NS)
Total oxytocin requirement(units)	9.24±3.61	10.67±3.97	P=0.20 (NS)
Mode of delivery LSCS	17(56.66%)	15(50%)	P=0.73 (NS)
Indication for caesarean section -			
Suspected scar dehiscence	2 (11.76%)	4 (26.66%)	P = 0.55(NS)
Failure to progress	4 (23.52%)	2 (13.33%)	
Failed induction	3 (17.64%)	3 (20%)	
Fetal distress	4 (23.52%)	5 (33.33%)	
Meconium-stained liquor	4 (23.52%)	1(6.66%)	

Table 4: Maternal Adverse Effects

EFFECTS	GROUP A	GROUP B	P value
Nausea	1(3.33%)	3(10%)	0.61 (NS)
Vomiting	0	2(6.66%)	0.49 (NS)
Headache	0	2(6.66%)	0.49(NS)
Discomfort	4(13.33%)	2(6.66%)	0.67(NS)
Tachycardia	2(6.66%)	4 (13.33%)	0.67(NS)

Table 5: Maternal Complications

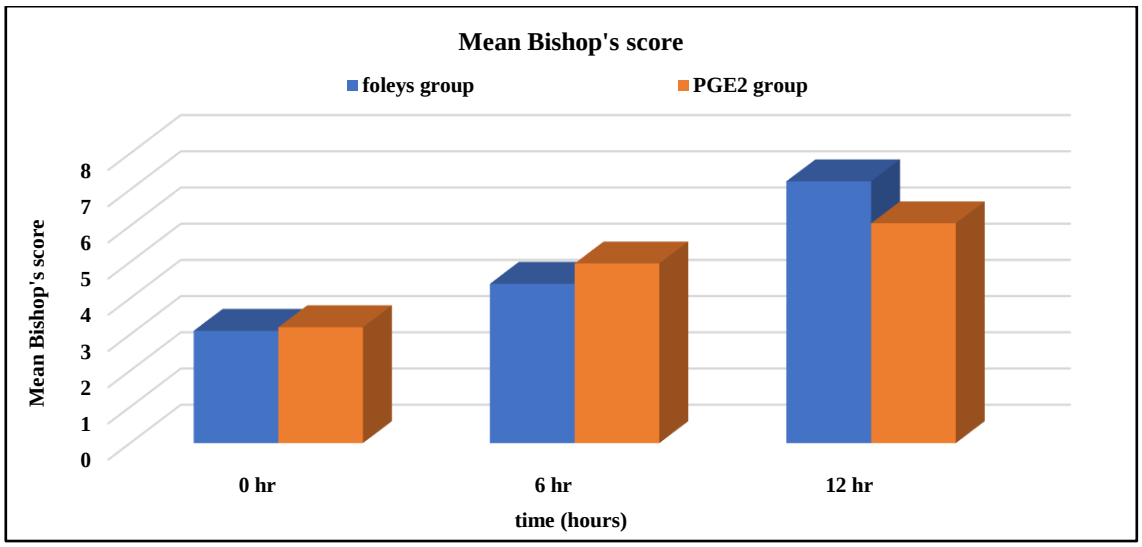
Complication	Group A N (%)	Group B N (%)	P value
Intrapartum pyrexia	1(3.33%)	3(10%)	0.61(NS)
Post-partum haemorrhage	1(3.33%)	2(6.66%)	1.00(NS)

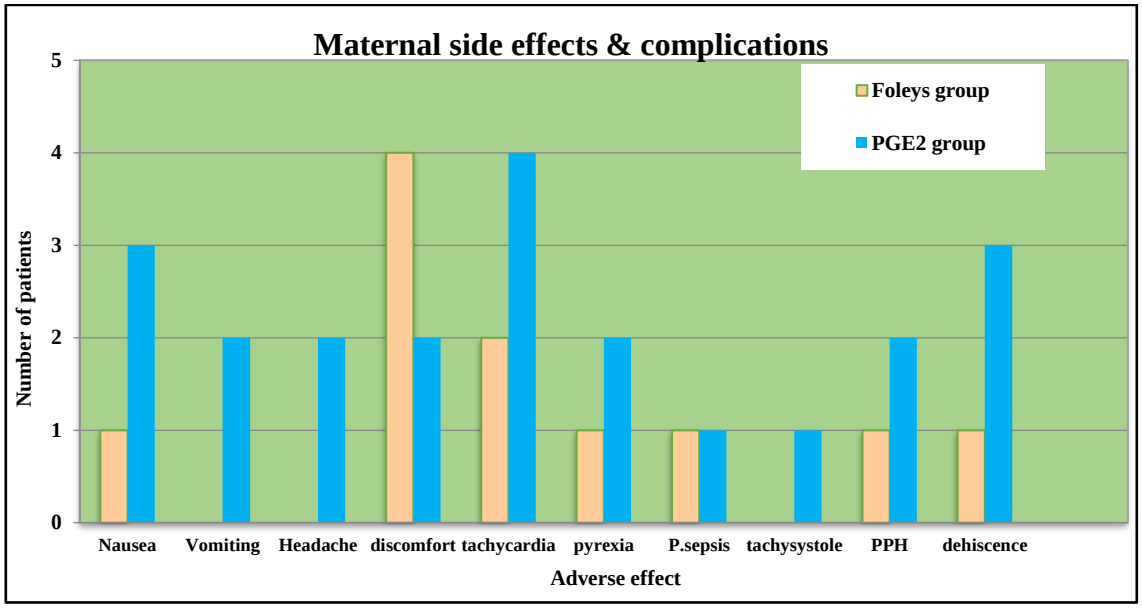
ISSN (O): 2687-5365; ISSN (P): 2753-6556

Puerperal sepsis	1(3.33%)	1(3.33%)	1.00(NS)
Uterine hyperstimulation (tachysystole)	0	2(6.66%)	0.49(NS)
Scar dehiscence	1(3.33%)	3(10%)	0.61(NS)

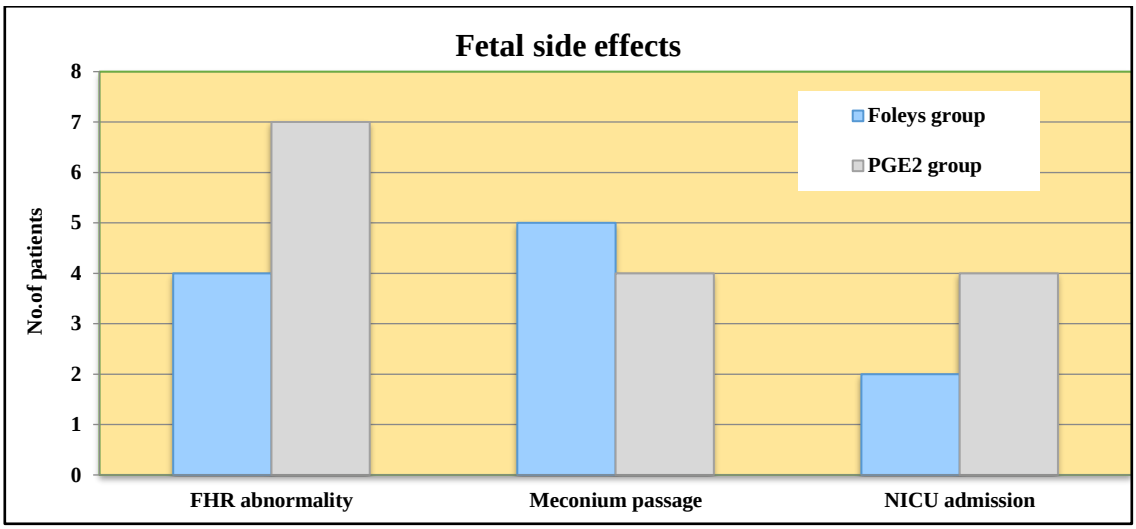
Table 6: Fetal Adverse Effects

Adverse effect	Group A	Group B	P value
FHR abnormality	4(13.33%)	7(23.33%)	0.50(NS)
Meconium passage	5(16.66%)	4(13.33%)	1.0(NS)
NICU admission	2(6.66%)	4(13.33%)	0.67(NS)
Mean apgar score at 5 minutes of birth	8.86±0.43	8.73±0.58	0.31(NS)





ISSN (O): 2687-5365; ISSN (P): 2753-6556



DISCUSSION

The present study was conducted on 60 term antenatal women with previous one LSCS due to non recurring indication with singleton pregnancy, in cephalic presentation who had to undergo induction of labor, and had an unfavorable Bishop's score (≤6) to compare the efficacy and safety of Foley's catheter balloon (mechanical) and PGE_2 gel (pharmacological) for cervical ripening before induction of labor. All the women meeting the inclusion criteria were randomly assigned to two groups, Foley's catheter (group A) and PGE_2 gel (group B). The age group, parity, and the period of gestation, indications for induction of labor, initial Bishop's score were comparable in both the groups as shown in table 1. The mean initial Bishop's score was 3.10±.71 in Group A and 3.23±1.16 in Group B. Both the groups irrespective of initial Bishop's score showed a substantial improvement of Bishop's score. At 6 hours in group A the mean Bishop's score increased to 4.4±1.45 while in group B the mean Bishop's score increased to 4.96±1.95 (P =0.41).

The mean change in score at 6 hours being 1.30±1.29 and 1.51 ±.91 in Group A and B respectively. This difference was not statistically significant (P=0.15). (Table-2) However, at 12 hour the mean Bishop's score was significantly more in Foley's catheter group as compared to PGE_2 group (P=0.043). At 12 hours the mean Bishop's score improved to 7.23±2.01 in group A and 6.07±2.06in group B. (Table-2) The mean change in Bishop's score at 12 hours being 4.07±1.97and 3.10± .83 in group A and B respectively (P value 0.021).

Niromanesh et al[10] found no differences in mean Bishop's scores between the prostaglandin and the Foley's catheter groups. Mean Bishop's scores after ripening were 6.6±0.80 and 6.7±0.86 for the Foley's catheter and prostaglandin groups, respectively (P=0.54). St Onge et al[11] and Dahiya et al[12] found Foley's catheter to as effective as PGE_2 gel in improving Bishop's score. Sciscione et al[13] and Prager et al[14] found Foley's catheter to be more effective than PGE_2 gel in their studies. This could be due to larger sample size in their studies to detect significant difference of efficacy in the two groups. The mechanism of the Foley's catheter is based on the presence of a mechanical traction acting continuously on the cervix and in addition it separates the chorion from the decidua releasing local prostaglandins. The mechanical factor and the indirect mechanism of release of prostaglandins takes time to exert its effect, that explains the comparable Bishop's score at 6 hours and significant difference in the two groups at 12 hours.

Secondary outcomes i.e. induction to delivery interval, vaginal delivery rate, need for oxytocin augmentation, indications of operative delivery were comparable in both groups (table 3).

The mean procedure to delivery interval in our study was18.80±7.99 hours in group A and 19.53±6.95 hours in group B. The difference was not statistically significant (P=0.79). The results were comparable to the study done by Deshmukh et al.[15]The induction to delivery interval was 15.32 ± 5.24 hours in Foley's group and 14.2 ± 5.14 hours in PGE_2 group (P = 0.291). The overall cesarean delivery rates in this study were similar in the two groups. It was 56.66 % in group A and 50 % in group B, the difference being not statistically significant. This do not agree with results reported in earlier retrospective cohort study done by Z. Ben-Aroya et al[16] and verifies the reliable efficacy of both the Foley's catheter and prostaglandin in preinduction cervical ripening. In their study a significant increase in the rates of repeated cesarean deliveries (49.1% vs. 35.2%, $p <$ 0.01) were observed in women in whom the Foley's catheter was used as compared to controls. No such changes were demonstrated in the PGE_2 group as compared to the controls.

When indications for cesarean sections were analyzed (Table 3) it was found that suspected scar dehiscence and fetal distress were higher in group A than group B (35.29% vs. 60%). This remarkable difference can probably be explained by the fact that prostaglandins increase myometrial contractions which at times causes uterine hyperstimulation

ISSN (O): 2687-5365; ISSN (P): 2753-6556

leading to fetal hypoxia. These pharmacological effects can be easily avoided by using mechanical methods like Foley's catheter. Similarly, Ravasia et al[6] in their study found that risk of uterine rupture was significantly increased in patients induced with PGE_2 gel as compared to Foley's catheter. Z. Ben-Aroya et al[16] also found non assuring fetal heart rate more in PGE_2 group (12.7%) compared to Foley's group (7.5%). Our study compared the side effects of the Foley's catheter and PGE_2 gel for preinduction cervical ripening (table 4,5). Local Discomfort was the main side effect experienced by women in the Foley's catheter group. Nausea, vomiting, headache, tachycardia was seen more in patients of group B although the difference was not statistically significant. Indicating the pharmacological side effect of prostaglandins which could be avoided using mechanical method like Foley's catheter.

Maternal complications noted were intrapartum pyrexia, PPH, puerperal sepsis, uterine tachysystole. None of the complications achieved a statistically significant difference between the two groups.

Scar dehiscence was noted intraoperatively in one patient in Foley's group and three patients in PGE_2 group. There is obvious difference in 2 groups. Uterine tachysystole can be a cause of dehiscence of the previous scar. Although very few studies have addressed the issue of scar dehiscence with use of Foleys's catheter, one recent study by Z.Ben-Aroya et al[16] reported zero incidence of uterine rupture with use of Foley's catheter. Similarly Ravasia et al[6] in their study found that risk of uterine rupture was significantly increased in patients induced with PGE_2 gel(2.9%) as compared to patients with spontaneous labor whereas such increased risk was not seen in Foley's catheter group(0.76%) compared to spontaneous labor group.

Fetal Adverse Effects (Table-6)

In the present study, 9 (30%) women in group A whereas 11 (36.66%) patients in group B showed signs of fetal distress in form of abnormal FHR pattern or meconium staining of liqour. This difference between the two groups although not statistically significant is probably due to induction of contractile activity of uterus by PGE_2 gel which at times can lead to tachysystole. 2(6.66%) neonates needed ICU admission in group A and 4 (13.33%) in group B (table -6). The mean apgar score was comparable in both the groups at 5 minutes as shown in table 6. St. Onge et al[5] found fetal distress in 23.5% of women in Foley's catheter group and 39.3% in PGE_2 group. Sciscione et al[17] observed non reassuring fetal heart rate pattern in 3.9% women in foley's catheter group and 5.6% in PGE_2 group. Thus, in agreement with other studies[12,18] all measures of fetal tolerance of the treatment, the Apgar score and frequency of admission to the neonatal intensive care unit, were same in two groups although incidence of fetal distress was more in the PGE_2 group in all the studies and the present study also.

The cost of cervical ripening by prostaglandin E_2 (Rs.380) is almost 6 times more in comparison to Foley's catheter (Rs.60). Prostaglandins are unstable and may lose their potency if they are not stored properly at low temperatures.

CONCLUSION

It can be concluded from the present study that Foley's catheter (mechanical) and prostaglandin E_2 gel (pharmacological) both are effective agents for preinduction cervical ripening in women with prior LSCS, which substantially improve the Bishop's score and increase the chances of successful labor induction. The mean change in Bishop's score at 6 hours was comparable in both groups. At 12 hours improvement in Bishop's score was significantly more in the foley's catheter group because of constant traction on cervix by Foley's catheter. There is no significant difference in their efficacy, induction to delivery interval, rate of cesarean section and perinatal outcome including mean APGAR score at 5 minute and NICU admission.

Foley's catheter did not increase the rate of cesarean section significantly and number of cesarean sections done for fetal distress was less than the prostaglandin group. Foley's catheter has fewer side effects and causes no uterine tachysystole so very strict monitoring of uterine contractions is not required during the ripening phase. Foley's catheter carries less risk of uterine scar dehiscence compared to prostaglandin. It also lacks the pharmacological side effects like vomiting and headache. Foley's catheter cause a six fold decrease in cost as compared to PGE_2 gel. Further PGE_2 cannot be used in patients with glaucoma, asthma or known hypersensitivity.

In developing countries where cost is an important limiting factor and very stringent conditions for storage of prostaglandins may not be available, Foley's catheter is a safe, effective, and relatively inexpensive means of performing preinduction cervical ripening in women with previous lower segment cesarean section with less incidence of fetal and maternal pharmacological side effects.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556

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ISSN (O): 2687-5365; ISSN (P): 2753-6556