ORIGINAL
PROF-1629

INDUCTION OF LABOR

COMPARISON OF CERVICAL FOLEY'S CATHETER AND PROSTAGLANDIN E-2 AT TERM

DR. TAHIRA JABBAR
MBBS, FCPS (Gynaecology & Obstetrics)
Associate Professor,
Mohi-ud-Din-Islamic Medical College, Mirpur (AJ&K).

DR. FAIQA IMRAN
MBBS, FCPS (Gynaecology & Obstetrics)
Assistant Professor
Mohi-ud-Din-Islamic Medical College, Mirpur (AJ&K).

DR. SHAMAILA FAISAL
MBBS, FCPS (Gynaecology & Obstetrics)
Assistant Professor
Combined Military Hospital, Rawalpindi.

Dr. Robina Kauser
MBBS, MCPS, FCPS (Gynaecology & Obstetrics)
Assistant Professor
Mohi-ud-Din-Islamic Medical College, Mirpur (AJ&K).

ABSTRACT…background: Labor can be induced through a myriad of ways. The aim of this study was to compare the effectiveness of the intracervical Foley balloon catheter and intra vaginal 3 mg prostaglandin E2 tablet(s) in preinduction cervical ripening at term. **Methods:** Prospective analytic study of a cohort of 280 women selected through non probability sampling admitted in Obstetrics units, in two private hospitals one at Rawalpindi and the other at Mirpur (Azad Kashmir), from January 2009 to March 2010. All women were randomized to receive an intracervical Foley catheter or prostaglandin E2 tablets. The primary measured outcome was ripening of the cervix as measured with the Bishop score. **Results:** There were no differences in mean Bishop Scores between the prostaglandin and the Foley catheter groups. Bishop scores (mean ± S.D.) after ripening were 6.6±0.81 and 6.7±0.86 for the Foley catheter and prostaglandin groups, respectively (P=0.54). The prostaglandin group showed a statistically shorter induction to delivery time compared with the Foley catheter (16.5±2.2 and 20.51±3.89 h, respectively (P<0.01). Both the groups showed no statistically significant difference between the occurrences of spontaneous vaginal delivery. Labor was established in 72% cases of cervical Foley group. On the other hand induction occurred in 76% cases in prostaglandin group. There was no statistical difference between the need of oxytocin infusion for labor augmentation between the two groups and fetal distress was equally frequent in both the groups. **Conclusions:** Foley catheter was as effective as Prostaglandin E-2 at term for induction of labor with additional advantage of being cheaper, readily available and had no systemic side effects.

Key words: Prostaglandin E-2, Induction of labor. Intra cervical Foley catheter.

INTRODUCTION

Labor is accomplished with transformation in the biochemical connective tissue and with gradual effacement and dilatation of the uterine cervix on account of rhythmic uterine contractions of adequate frequency, force and extent[1]. Prolonged labor carries the increased risks of operative deliveries and maternal morbidities[2].

Induction of labor is an intervention intended to artificially start uterine contractions leading to progressive effacement and dilatation of the cervix and delivery of the fetus. It attempts to induce two interlinked components of labor, cervical ripening and uterine contractility. Cervical ripening is the conversion of rigid cervical sphincter associated with maintenance of pregnancy to a readily dilating structure that allows passage of the fetus with comparative ease[3,4]. Induction of labor is only performed upon specific indications. Labor is now considered as an intensive care situation and obstetrics emergencies can arise suddenly. For feto-maternal safety, active management is superior to expectant management and should be the routine management of choice[5].

A variety of techniques for induction of labor have been developed. Prostaglandins have been used for induction of labor since the 1960s. PGE2 increases successful vaginal delivery rates in 24 hours and cervical favorability with no increase in operative delivery rates[6]. Currently the most commonly used method is intra-cervical application of Prostaglandin E2[7]. However, systemic absorption of this agent is common resulting in nausea, vomiting and initiation of uterine contractions which may lead to uterine hyperactivity, especially in women with an unfavorable cervix and even placental abruption[8]. Depicting a woman with high likelihood for cervical ripening failure with prostaglandins will help selecting the most favorable technique for labor induction in such cases[9].

Cervical Foley has been used for induction of labor to ripen the cervix by mechanical means without causing hypertonic uterine contractions. It also stimulates the release of endogenous prostaglandins in the cervix[10]. Efficacy of Foley catheter to ripe the cervix may be objectively assessed through transvaginal ultra-

sonography and it helps predict the probability of success to induce labor in a woman who need preinduction ripening[11]. Such Mechanical methods are advantageous in terms of reversibility and reduced expenditure[12]. But Foley catheter is linked with a possibility of infections in larger studies. Thus, tremendous attention should be drawn towards carrying aseptic measures while inserting it to avoid maternal and probable neonatal infections[13].

Induction of labor in the presence of unripe cervix may result in many complications[14,15]. This study was conducted to determine the efficacy and role of cervical Foley catheter in ripening and dilatation of unfavorable cervix for induction of labor at term and to compare it with intra-vaginal application of Prostaglandins E-2, meanwhile comparing the cost effectiveness of two methods and any complications.

PATIENTS AND METHODS

This prospective randomized study was carried out at two private hospitals at Mirpur (AJ&K) and Rawalpindi. Between January 2009 to March 2010, 294 women at term who presented with unfavorable cervix indicating for labor induction were recruited for the study. Inclusion criteria to recruit the patients were singleton pregnancy, vertex presentation, intact membranes and normal fetal heart tracings. Patients with the history of previous caesarean section, ruptured membranes, any contraindications for vaginal birth, suspected cephalopelvic disproportion or unexplained antepartum hemorrhage were excluded.

A written consent was taken from all the patients. They were randomized to one of the 2 techniques, using a random number table. In the first group, 150 women were tried with PGE2 3 mg vaginal tablet, inserted in the posterior vaginal fornix. This was repeated at 6-hour intervals, if needed. For the second method, 144 women an attempt with a 20 size Foley catheter, introduced into cervix so as to go by the internal os via a sterile speculum method. Its balloon was filled with 50 ml distilled water and then it was tied to the inner side of the thigh to create a small traction.

All patients underwent general, systemic and pelvic examination and vital signs were recorded. Blood samples were drawn for complete blood count and cross-match. Fetal heart rate was monitored. Abdominal and cervical assessments were taken at 4–6 hour intervals to establish the start of labor and to gauge Bishop Score variations, except in some instances when it was indicated earlier. Amniotomy was carried out as soon as clinically possible.

The advancement of labor was watched every 2 hours. Friedman's criteria was used to identify labor abnormalities[16]. In such occurrences for these cases, labor was augmented by oxytocin infusion as according to the manual described by O'Driscoll and Meagher[17]. Intrapartum fetal heart rate was constantly monitored.

The primary outcome measures were the route of delivery and the time required from start of the induction to delivery. The secondary outcome measures were the change in Bishop Score, intrapartum complications or the requirement for oxytocin for labor augmentation.

Student t-test was used to compare the constant variables. Categorical variables were compared using the chi-squared or Fisher exact test. $P < 0.05$ was considered to designate a significant difference.

RESULTS

There were no significant differences in presenting characteristics between the 2 study groups (Table I) and both groups had similar indications for labor induction (Table II). Postdates and pre-eclampsia were the most frequent indications in both groups. The frequency of postdate pregnancies was significantly higher in the catheter group than the PGE2 group ($P = 0.028$).

As shown in Table III, the changes in Bishop score ware similar in the PGE2 group and the Foley catheter group (mean 6.6 ± SD 0.81 versus 6.7 ± 0.86) ($P = 0.54$). Similarly no statistically significant difference was found in the need of oxytocin for labor augmentation inn the catheter group (80.55%) and in the PGE2 group (76.66%) ($P = 0.083$).

Table-I. Presenting characteristics of women treated with Foley catheter or prostaglandin E-2(PGE2) vaginal tablet for induction labour

Characteristic	Catheter group (n=144)	PGE group (n=150)	P-value
Maternal age (years)	27.4±5.49	27.2±5.68	0.89
Gestational age (weeks)	39±1.89	39.5±1.7	0.25
Initial Bishop Score	2.66±1.42	2.6±1.34	0.86

Values are shown as mean (standard deviation)
n= number of patients

Table-II. Indications for induction of labor in women treated with Foley catheter or prostaglandin E2 (PGE2) vaginal tablet for induction of labor

Indication	Catheter group (n=144)		PGE2 group (n=150)		p-value
	No.	%	No.	%	
Post dates	58	40.27	47	31.33	0.11
Pre-eclampsia	41	28.47	48	32	0.51
Diabetes	16	11.11	24	32	0.22
Suspected IUGR	20	13.88	22	30	0.85
Suspected macrosomia	09	6.25	05	07	0.24

IUGR = Intra uterine growth restriction
n = number of patients

The time from initiation of the induction method to delivery was significantly shorter in the PGE2 group compared with the catheter group (16.5 ± 2.2 versus 20.51 ± 2.2 hours) (P < 0.01). Of women that were randomized to use PGE2, 61.33% delivered within 16 hours after initiation of induction compared with 41.66% of those randomized to use the Foley catheter. This was a statistically significant difference (P < 0.01). There were 42 women who delivered after 24 hours in the catheter group, compared with 10 women in the PGE2 group. This difference was highly statistically significant (P < 0.001).

There were no significant differences between the groups in intrapartum complications or in type of delivery (Table III). In addition, there were no statistically significant differences in fetal outcomes (Apgar scores at 5 minutes, birth weight, admissions to the neonatal intensive care unit or meconium aspiration) between the 2 groups (Table IV). No more than 2 × 3 mg PGE2 vaginal tablets were needed to achieve a clinically feasible cervix for amniotomy. No woman needed a blood transfusion. All women and their babies were discharged home in good condition.

DISCUSSION

This study reveals that both PGE2 and Foley catheter are safe when used for cervical ripening as well as labor induction at term. Both methods were effective in view of the induction to delivery interval and labor augmentation with oxytocin. The current study is in agreement with other reports regarding the use and safety of PGE2 vaginal tablets and Foley catheter for labor induction[18].

Induction of labor for planned delivery has become an established part of modern obstetrics. Many studies have been done on different methods of induction and comparison of these methods. Mechanical methods were the earliest techniques devised to ripen the cervix

Table-III. Labor and delivery outcomes of women treated with Foley catheter or prostaglandin E2 (PGE2) vaginal tablet for induction of labor

Outcome	Catheter group (n=144)		PGE2 group (n=150)		p-value
	No.	%	No.	%	
Bishop score after ripening Mean ± (SD)	6.6±0.81		6.7±0.86		0.64
Oxytocin required	116	80.55	115	76.66	0.42
Time from induction to delivery					
<16 hours	60	41.66	92	61.33	
16-24 hours	42	29.16	48	32	<0.001
>24 hours	42	29.16	10	6.66	
Mean ± SD	20.51±3.89		16.5 ± 2.2		<0.001
Intrapartum complications					
Fetal distress	28	19.44	22	14.66	0.28
Failure to progress	12	8.33	14	9.33	0.76
Delivery type					
Spontaneous vaginal	104	72.22	114	76	0.46
Forceps	06	04	04	3.66	0.48
Caesarean section	34	23.61	32	21.33	0.64

SD = Standard deviation
n = number of patients

Table-IV. Fetal outcomes of women treated with Foley catheter or prostaglandin E2 (PGE2) vaginal tablet for induction of labor

Outcome	Catheter group (n=144)		PGE2 group (n=150)		p-value
	No.	%	No.	%	
Mean ± SD birth weight (g)	3499±581		3457±532		0.76
Apgar score <6 at 5 min	08	5.55	7	4.7	0.73
Admission to NICU	12	8.33	10	6.7	0.59
Meconium present	25	17.33	30	20	0.56

NICU = neonatal intensive care unit *SD = Standard deviation* *N = Number of patients*

or to induce labor. Tools which were used include a range of variety of catheters and of laminaria tents, introduced into the cervical canal or into the extra-amniotic space. Mechanical methods were never completely discarded, but were replaced with by pharmacological ways during latest decades. Advantages of mechanical methods over pharmacological methods would be, less need of preservation, lesser expenditure and decreased side effects. Nevertheless, extraordinary consideration should be paid to contraindications (e.g. low-lying placenta), hazard of infection and maternal distress when putting in these tools[19].

In a review of a series of studies comparing mechanical methods with placebo/no treatment, only one study with 48 participants reported on vaginal delivery not achieved in 24 hours (69% with mechanical methods versus 77% with placebo/no treatment). The risk of caesarean section, reported in six studies including 416 women, was similar between groups. Comparing mechanical methods with vaginal PGE2, only one trial (109 women) reported on vaginal delivery not achieved in 24 hours. The use of mechanical method reduced the risk of hyper stimulation with fetal heart rate changes when compared with prostaglandins: vaginal PGE2, intracervical PGE2. There was no difference in the risk of caesarean section between mechanical methods and prostaglandins. Serious neonatal (three cases) and maternal morbidity (one case) were infrequently reported. When compared with oxytocin, use of mechanical methods reduced the risk of caesarean section. These results are similar whatever specific mechanical method was used, except with extra-amniotic infusion. When comparing extra-amniotic infusion with any prostaglandins, women were more likely to not achieve vaginal delivery within 24 hours; the risk of caesarean section was increased, without a reduction of the risk of hyper stimulation[19].

Currently one of the commonest methods is the intra vaginal application of prostaglandin E-2. There is convincing evidence that Prostaglandin E-2 is essential for the initiation and normal progress of labour[20]. Its low temperature storage requirement is itself a problem and experienced medical staff is mandatory for its use and storage.

Our analytic study showed that an inflated Foley Catheter placed in extra amniotic space is an effective method of ripening unfavorable cervix and there was no significant difference from Prostaglandin E-2, rather its results were better in many ways. It has a mechanical action of ripening away the fetal membranes from the lower uterine segment. This result in the release of lytic enzymes from lysosomes including phospholipase A, which acts on phospholipids to form arachidonic acids which in turn is converted into Prostaglandin E-2.

Observation made by Atad-et al from Israel revealed that double balloon Foley catheter was significantly better in improving the Bishop's score than Prostaglandin E-2 and Oxytocin[10]. Similarly Pennell and associates found that the single balloon catheter offers the best combination of safety and patient comfort had similar efficacy when compared with double balloon catheter and PGE2[21].

The main argument against the Foley Catheter was the risk of infection and accidental rupture of membranes. Maslovitz study of 1,083 women have shown that complications associated with trans-cervical ripening through Foley catheter with extra-amniotic saline infusion occurred in 7.6% and included acute febrile reaction, pain, vaginal bleeding and altered fetal presentation[22].

Heinemann noticed while reviewing randomized controlled trials that maternal infection rates were similar for patients who underwent ripening with extra amniotic saline solution infusion, Laminaria, or hygroscopic dilators. When compared with the use of pharmacologic agents alone, maternal and neonatal infectious morbidity came out to be high when mechanical agents were used for cervical ripening[23].

During our study aseptic precautions were carried out and policy of active management after expulsion of catheter was adopted. It was well tolerated by women in our study group. There were only two women in which accidental rupture of membranes occurred and both of them delivered after augmentation. This method is very cost effective in the third world and developing countries.

There lies a major risk of rupture of uterus whenever

labor is induced with prostaglandins which may be depicted when risk factors like multiparty, use of oxytocin and the condition of the cervix are taken into account. We did not come across any major complications in the present study. Comparison of intrapartum complications between groups showed no significant differences. Labor augmentation was carried out with oxytocin in 80.55% and 76.66% of the Foley and PGE2 groups, respectively. End result of labor and delivery matched up favorably well in both sets. This exhibits a comparable safety of both techniques that parallels the observations by others[24,25].

In the view of these findings, it can be deduced that cervical priming as well as labor induction at term is safe and efficient when using PGE2 tablets or Foley catheter, together with oxytocin infusion ,if required for labor augmentation, excluding any contraindications to induction. Prostaglandin E2 vaginal tablets is more efficacious to the intracervical Foley catheter in terms of shorter induction to delivery interval.

CONCLUSIONS

It is concluded that cervical Foley Catheter allows successful induction of labor as good as Prostaglandin E-2. However it has the additional advantage of being readily available, cost effective and a low frequency of systemic side effects.

REFERENCES

1. Norwitz ER, Robinson JN, Repke JT. **Labor and delivery.** In: Gabbe SG, Niebyl JR, Simpson JL, eds. Obstetrics: Normal and problem pregnancies. 3rd ed. New York: Churchill Livingstone; 2003.

2. Cheng YW, Hopkins LM, Caughey AB. **How long is too long: Does a prolonged second stage of labor in nulliparous women affect maternal and neonatal outcomes?.** Am J Obstet Gynecol. Sep 2004; 191(3):933-8.

3. ACOG. American College of Obstetricians and Gynecologists Practice Bulletin. **Dystocia and augmentation of labor. Clinical management guidelines for obstetricians-gynecologists.** No 49. American College of Obstetricians and Gynecologists: Washington, DC; December 2003.

4. Norwitz ER, Robinson JN, Repke JT. Labor and delivery. In: Gabbe SG, Niebyl JR, Simpson JL, eds. **Obstetrics: Normal and problem pregnancies.** 3rd ed. New York: Churchill Livingstone; 2003.

5. Prendiville WJ, Elbourne D, McDonald S. **Active versus expectant management in the third stage of labour.** Cochrane Database Syst Rev. 2000;CD000007.

6. Marsden W. **Misoprostol (Cytotec) for Labor Induction:** A Cautionary Tale, Editor's note, Midwifery Today, No. 49 - spring 1999.

7. Kelly AJ, Malik S, Smith L, Kavanagh J, Thomas J. **Vaginal prostaglandin (PGE2 and PGF2a) for induction of labour at term.** Cochrane Database Syst Rev. 2009 Oct 7 ;(4):CD003101.

8. Crane JM, Butler B, Young DC, Hannah ME. **Misoprostol compared with prostaglandin E2 for labour induction in women at term with intact membranes and unfavorable cervix: a systematic review.** BJOG. 2006 Dec; 113(12):1366-76.

9. Melamed N, Ben-Haroush A, Kremer S, Hod M, Yogev Y. **Failure of cervical ripening with prostaglandin-E2 can it be predicted?** J Matern Fetal Neonatal Med. 2009 Nov 9.

10. A Tad J. Hallak M, Auslendev R Porat- Packer, T Zafararti , D. Abranchovici H. **A randomized comparison of prostaglandin E2, oxytocin and the double balloon device in induction of labour.** Obstet Gynaecol 1996; 87: 223-7.

11. Cromi A, Ghezzi F, Tomera S, Scandroglio S, Colombo G, Bolis P. **Cervical ripening with a Foley catheter: the role of pre- and post ripening ultrasound examination of the cervix.** Am J Obstet Gynecol. 2007 Jan; 196(1):41.e1-7.

12. Syeda BM, Saba S, Ghazala M. Induction Of Labour, **A Randomized Trial comparing Prostaglandin E2 Pessary, Intracervical Foley Catheter and Extra Amniotic Saline Infusion.** J Surg Dec 2000; 19-20:12-8.

13. Salva S, Nadeem FZ, Afia Z, Rahat NQ. **Increased risk of cervical canal infections with Intracervical Foley Catheter.** J Coll Physicians Surg Pak Mar 2003; 13(3):146-9.

14. Sheiner E, Levy A, Feinstein U, et al. **Risk factors and outcome of failure to progress during the first stage of labor: a population-based study.** Acta Obstet Gynecol

Scand. Mar 2002; 81(3):222-6.

15. Sheiner E, Levy A, Feinstein U. **Obstetric risk factors for failure to progress in the first versus the second stage of labor.** J Matern Fetal Neonatal Med. Jun 2002; 11(6):409-13.

16. Friedman EA. **The labour curve.** Clinics in perinatology, 1981, 8(1):15–25.

17. O'Driscoll K, Meagher D. **Active management of labour.** The Dublin experience, 2nd ed. London, Bailli re Tindall, 1986.

18. Sobande AA, Al-Bar HM, Archibong EI. **A comparison of spontaneous labor with induced vaginal tablets prostaglandin E2 in grand multiparae.** Saudi medical journal, 2001, 22(8):698–701.

19. Boulvain M, Kelly A, Lohse C, Stan C, Irion O. **Mechanical methods for induction of labour.** Cochrane Database Syst Rev. 2001;(4):CD001233.

20. Millen Am. **Pattern of uterine activity after intra vaginal PGE2, preinduction cervical ripening.** British Journal of Obstet and Gynaecology 1991; 165:1006-1091.

21. Pennell CE, Henderson JJ, O'Neill MJ, McCleery S, Doherty DA, Dickinson JE. **Induction of labour in nulliparous women with an unfavourable cervix: a randomized controlled trial comparing double and single balloon catheters and PGE2 gel.** BJOG.2009 Oct;116(11):1443-52.

22. Maslovitz S, Lessing JB, Many A. **Complications of trans-cervical Foley catheter for labor induction among 1,083 women.** Arch Gynecol Obstet. 2010 Mar;281(3):473-7.

23. Heinemann J, Gillen G, Sanchez-Ramos L, Kaunitz AM. **Do mechanical methods of cervical ripening increase infectious morbidity? A systematic review.** Am J Obstet Gynecol. 2008 Aug;199(2):177-87; discussion 187-8.

24. Abou el-Leil LA, Nasrat AA, Fayed HM. **Prostaglandin E2 vaginal pessaries in the grandmultipara with an unripe cervix, a comparison of different parity groups.** International journal of gynaeco-logy and obstetrics, 1993, 40(2):119–22.

25. St Onge RD, Connors GT. **Preinduction cervical ripening: a comparison of intracervical prostaglandin E2 gel versus the Foley catheter.** American journal of obstetrics and gynecology, 1995, 172(2 Pt 1):687-90.

Article received on: 14/01/2010 Accepted for Publication: 03/01/2011 Received after proof reading: 16/05/2011

Correspondence Address:
Dr. Faiqa Imran
Assistant Professor Gynaecology & Obstetrics
Central Park Medical College, Lahore
Res: 126/F Askari 5, Gulberg III, Lahore
drfaiqa@yahoo.com

Article Citation:
Jabbar R, Faisal S, Imran F, Kauser R. Comparison of cervical Foley's catheter and prostaglandin E-2 for induction of labor at term. Professional Med J Apr-Jun 2011;18(2): 201-207.

PREVIOUS RELATED STUDIES

Maimoona Hafeez, Waseem Talib, Saadia Siddique. Induction of labour; comparison of efficacy of different methods.

Misbah Kausar Javaid, Samia Hassan, Tayyaba Tahira. Management preterm rupture of the membranes at term; induction of labour compared with expectant. Professional Med J Jun 2008; 15(2): 216-219.

Tayyiba Wasim, Saqib Siddiq. Comparison of prostaglandin E2 with misoprostol for induction of labour at term. Professional Med J Sep 2008; 15(3): 344-34.