Original Article

Obst & Gynae

Comparison of Efficacy of Cervical Foleys Catheter and Prostaglandin E2 for Induction of Labour

1. Kulsoom Bhatti 2.Tehmina Mahar 3. Rubina Hafeez

1. Asstt. Prof. 2. Senior Registrar 3. Registrar, Dept. of Obstetrics and Gynaecology,
Ghulam Muhammad Mahar Medical College Hospital Sukkur

ABSTRACT

Introduction: Labor and subsequent termination of pregnancy in presence of unfavorable cervix requires cervical ripening in order to reduce complication and to diminish the rate caesarean sections as well as the duration of labor. There are a number of agents used for cervical ripening. Two commonly used agents are transcervical Foleys catheter and prostaglandin E2 vaginal pessary.

Objective: To determine and compare the effects of inflated transcervical Foleys catheter and prostaglandin E2 vaginal tablet on pre-induction ripening of cervix.

Study Design: A prospective quasi-experimental study.

Place and Duration of Study: This study was conducted at the Department of Obstetrics and Gynaecology, Ghulam Muhammad Mahar Medical College Hospital Sukkur from 1st July 2011 to 30th June 2012.

Patients and Methods: A total 100 women were selected through non-probability sampling with a gestational age between 28-41 weeks and unfavorable cervix, requiring induction of labor were allocated in two groups. All women were received an intracervical Foleys catheter or prostaglandin E2 tablets. The outcome variables including the change in cervical Bishop Score, beginning of uterine contractions and complications during and after labor were assessed. Student's t test and chi-square were used for the analysis of data.

Results: There were no differences in mean Bishop Score changes between the Foleys catheter and prostaglandin group. Bishop Score after ripening were 6.6±61 and 6.7±0.86 for Foleys catheter and prostaglandin E2 group (P=0.64). The prostaglandin group showed a statistically shorter induction to delivery time 15.0±7.7 compared with Foleys catheter 20.81±5.8 and (P=<0.01). Both group showed there was no significant difference in occurrence of labor. Vaginal delivery occurred in 74% in Foleys group while 78% in prostaglandin group. There were needed more oxytocin for labor augmentation in Foleys group as compared to prostaglandin group.

Conclusion: Foleys catheter was found effective as prostaglandin E2 for induction of labor additional benefits like cheaper, readily available, no need of extensive monitoring and lower chance of tachycystole and other systemic side effects.

Key Words: Foleys catheter, Prostaglandin E2, Bishop Score, Cervical ripening.

INTRODUCTION

Labor is accomplished with transformation in the biochemical connective tissue and with gradual effacement and dilation 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] for the patient with an unfavorable cervix number of cervical ripening agents are available. These include mechanical dilation and prostaglandin E2 administration. Mechanical dilation was first described with laminaria, more recently; the use of a transcervical balloon catheter (Foleys catheter) has also been used successfully.[3] The Foleys catheter is inserted in order to act primarily as a cervical ripening agent, with the capacity to modify the cervical status, and may have limited effect on uterine contractions. Regarding prostaglandin administration, PGE2 given vaginally or intracervically has been shown to be an effective ripening agent.[4] A Cochrane review in 2001 comparing all forms of mechanical dilation with all prostaglandins concluded that there is insufficient evidence to assess the effectiveness of mechanical methods, compared with prostaglandins in women with unripe cervices. The use of these methods as compared with the use of prostaglandins was associated with fewer episodes of excessive uterine contractions, without modifications of the risks of caesarean section.[5] 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.[6]

Cervical ripening with Foleys catheter are advantageous in term of reversibility and reduced expenditure.[7] But Foleys 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.[8]

Induction of labor in the presence of unripe cervix may result in many complications.[9]The purpose of this study was to determine the efficacy and role of intracervical Foleys catheter in ripening and dilatation of unfavorable cervix with intra-vaginal prostaglandin E2 tablet in term of compare the induction to delivery time and also complication rates of two methods.

PATIENTS AND METHODS

This is a quasi-experimental study was conducted at the department of Obstetrics and Gynaecology Ghulam Muhammad Mahar Medical College Hospital Sukkur during one year period between 1st July 2011 to 30th June 2012, 100 women with a gestational age between 28-41 weeks and unfavorable cervix requiring induction of labor, were randomly allocated in two groups.

Inclusion criteria were singleton pregnancy, vertex presentation with intact membranes. Subjects with history of previous 2 caesarean section, ruptured membranes, any other contraindications for vaginal birth or unexplained antepartum hemorrhage were excluded from the study.

An informed written consent was obtained from all the patients.

For each woman, a digital pelvic examination was performed to determine the Bishop Score of cervix. They were randomized to one of the 2 techniques; one group of 50 women received prostaglandin E2 vaginal tablet containing 3mg dino-prostone inserted in the posterior fornix and repeated after 4-6 hours if needed. For the other group of 50 women a Gauge 20 size Foleys catheter introduced in to the cervix under aseptic conditions and its balloon was inflated with 50 ml normal saline and then it was tied to the inner side of the thigh to create traction. Patient was put on broad spectrum antibiotic, fetal heart rate was monitored. Abdominal and cervical assessment was taken at 4-6 hour intervals to assess the Bishop score and start of labor, Amniotomy was carried out as soon as clinically possible.

The primary study outcome measures were the changes in cervical Bishop Score, induction to delivery interval, route of delivery. The secondary outcome measures were the intrapartum complications, neonatal outcomes included APGAR score at 1 and 5 minutes and NNICU admission.

Student's t-test was used to compare the constant variables, and chi-square test was used for categorical data. Statistical tests with $p<0.05$ were considered significant.

RESULTS

There were no significant differences between the two study groups, (Table: I) showed the demographic characteristics of participants.

Table No. I: Characteristics of study population

Variables	Foleys catheter (n=50)	Prosta-glandin E2 (n=50)	P- value
Mean maternal age	28.1±7	27±5.1	0.85
Gestational age wks	28-41	28-41	0.25
Parity	1-5	0-5	-
Initial Bishop Score	2.66±1.42	2.6±1.34	0.86
Bishop Score after Ripening of cervix	6.6±0.61	6.7±0.86	0.64
Mean induction to delivery interval	20.8±5.8	15.0±7.7	<0.01

Regarding indications for labor induction as shown in (Table: 2) postdates and pre-eclampsia were the most frequent indications in both groups. The frequency of postdate pregnancies were higher in PGE2 group than Foleys catheter group (P=0.040).

Table No.2: Indications for induction of labor

Indication	Foleys catheter (n=50)	Prostaglandin E2(n=50)	P-value
Postdates	33 (66%)	35 (70%)	0.040
Pre-eclampsia	07 (14%	05 (10%)	0.43
Intrauterine fetal Death	06 (12%)	07 (14%)	0.25
Suspected macrosomia	04 (08%)	03 (06%)	0.25

As shown in (Table: 3) regarding need of oxytocin for labor augmentation, in 86% of cases oxytocin required in Foleys group as compared to 80% in PGE2 group (P=0.42), so there was no significant difference in oxytocin requirement in both groups. Induction to delivery time varied from 8 to 36 hours and was significantly shorter in the PGE2 group (15.0±7.7) compared with the Foleys catheter group (20.8±5.8) and P-value <0.01.

Table No.3: Mode of delivery

Variables	Foleys catheter (n=50)	PGE2 group (n=50)	P=value
Oxytocin required	43=86%	40=80%	0.42
Spontaneous vag:delivery	37=74%	39=78%	0.46
Instrumental vag:delivery	03=06%	02=04%	0.48
Caesarean section	10=20%	09=18%	0.64

Regarding mode of delivery more women were delivered vaginaly in PGE2 group as compared to Foleys catheter group (39=78% versus 37=74%) and

(P=0.46) and there were no significant difference in caesarean section rate in both groups.

There were no significant differences between the groups in intrapartum complications as shown in (Table: 4). Minor complications observed included nausea and vomiting in 2 cases, headache and hot flushes in one case of PGE2 group.

There was no case of tachysystole seen in catheter group as compared to two cases were seen in PGE2 group.

Table No.4: Maternal and fetal complications

Maternal complications	Foleys group	PGE2 group	P-value
Failed induction	02=04%	01=02%	0.01
Pyrexia	02=04%	02=04%	0.80
Tachysystole	--	02=04%	--
Retained placenta	01=02%	01=02%	0.01
Fetal complications			
Fetal distress	03=06%	03=06%	0.01
Apgar score<7 at 1min:	07=14%	08=16%	0.10
Admission to NNICU	10=20%	12=24%	0.45

In addition there were no statistically significant differences in fetal out comes (Apgar score at one minute, meconum aspiration or admission to NNICU) between the both groups.

None of women needed a blood transfusion in both groups.

DISCUSSION

This study reveals that both PGE2 and Foleys catheter are safe when used for cervical ripening as well for labor induction. Prostaglandin E2 and transcervical Foleys catheter is both considered appropriate induction agent by ACOG,[10] 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 Foleys catheter for labor induction.[11]

Induction of labor for planed delivery has become an established part of modern obstetrics. Many studies have been done on different methods of induction and comparison of these methods. Advantages of mechanical methods over pharmacological methods would be, less need of preservation, lesser expenditure and less side effects, Nevertheless extraordinary consideration should be paid to contraindications such as low lying placenta, hazard of infection and maternal distress when putting of these tools.[5]

Onge in 1995, found no difference between the efficacy of intra-cervical Foleys catheter and prostaglandin E2 vaginal tablet, and also their side effects.[12]In our study also no significant difference were seen in both groups.

Currently one of the commonest methods is the intravaginal PGE2. There is convincing evidence that prostaglandin E2 is essential for the initiation and normal progress of labor, [13] its low temperature storage requirement is itself a problem and experienced medical staff is mandatory for its use and monitoring.

Our experimental study showed that an inflated Foleys catheter placed in extra amniotic space is an effective method of ripening unfavorable cervix and there was no significant difference from PGE2. Foleys catheter has a mechanical action of ripening away the fetal membranes from the lower segment. This causes the released of lytic enzymes from the lysosomes including phospholipase A, which acts on phospholipids to form arachidonic acids which in turn converted in to PGE2.

Observation was made by Pennell and associate found that the single balloon catheter offers the best combination of safety and patients comfort had similar efficacy when compared with double balloon catheter and PGE2.[14]

The main argument against the Foleys catheter was the risk of infection and accidental rupture of membranes.

Heinemann study of 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.[15] In our study aseptic precautions were carried out and policy of active management after expulsion of catheter was adopted. In this study only one woman in which accidental rupture of membrane occurred and she was delivered after augmentation of labor.

This method is very cost effective in the developing countries in the low resource set up.

Comparison of intrapartum complications between groups showed no significant differences, labor augmentation was carried out with oxytocin in 86% and 80% of Foleys and PGE2 groups. End result of labor and delivery matched up favorably well in both sets. Safety of both techniques were parallel that observed by others.[16, 17]

CONCLUSION

Foleys catheter was found effective as prostaglandin E2 for induction of labor additional benefits like cheaper, readily available, no need of extensive monitoring and lower chance of tachycystole and other systemic side effects.

REFERENCES

1. Norwitz ER, Robin JN, Repke JT. Labor and delivery. In: Gabbe SG, Niebyl, Simpson JL, editors. Obstetrics: Normal and problem

pregnancies. 3rd ed. New York: Churchill Living stone; 2003.
2. Cheng YW, Hopkins LM, Caughey AB. How long is too long: Does a prolonged second stage of labor nuliparous women affect maternal and neonatal outcomes? Am J Obstet Gynecol 2004; 191(3): 933-8.
3. Gelber S, Sciscone A. Mechanical methods of cervical ripening and labor induction. Clin Obstet Gynecol 2005; 49: 642-57.
4. Kelly AJ, Kavanagh J, Thomas J. Vaginal prostaglandin (PGE2 and PGF2α) for induction of labor at term. Cochrane Database systemic Rev 2003; 4: CD 003101.
5. Boulvain M, Kelly A, Lohse C, Stan C, Irion O. Mechanical methods for induction of labor. Cochrane Data Base Syst Rev 2001; CD 001233.
6. Prendiville WJ, Elbourne D, Mcdonalds. Active versus expectant management in the third stage of labor. Cochrane Database Syst Rev 2000; CD 000007.
7. Syeda BM, Saba S, Ghazala M. Induction of labor, A randomized trial comparing prostaglandin E2 pessary, intracervical Foleys catheter and extra amniotic saline infusion. J Surg 2000; 19-20: 12-8.
8. Salva S, Nadeem FZ, Afia Z, Rahat NQ. Increased risk of cervical canal infection with intracervical Foleys catheter. J Coll Physcians Surg Pak 2003; 13(3) 146-9.
9. Sheer 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 E 2002; 81(3): 222-6.
10. ACOG Practice Bulletin Number 107. Induction of labor Washington DC: American College of Obatetricians and Gynaecologist 2009.
11. Sobande AA, AL-Bar HM, Archibong EL. A comparison of spontaneous labor with Induced vaginal tablets PGE2 in grand multipara. Saudi Med J 2001; 22(8):698-701.
12. St Onge RD, Conners GT: Pre-induction cervical ripening: a comparison of Intracervical PGE2 tablet versus the Foleys catheter. Am J Obstet Gynecol 1995; 172(2pt1): 687-90.
13. Millen AM. Pattern of uterine activity after intravaginal PGE2, Pre induction cervical Ripening. Birtish J Obstet and Gynecol 1991; 165: 1006-1091.
14. Pennell CE, Henderson JJ, O, Neill MJ, Mc Cleevy S, Doherty DA, Dickinson JE. Induction of labor in nulliparous women with an unfavorable cervix: a randomized Controlled trial comparing double and single balloon catheters and PGE2 gel. BJOG. 2009 Oct;116 (11): 1443-52.
15. Heinemann J, Gillen G, Sanche Z, Ramos L, Kaunitz AM. Do mechanical methods of cervical ripening increases infectious morbidity? A Systemic review. Am J Obstet Gynecol 2008; 199(2): 177-87; discussion 187-8.
16. St Onge RD, Connors GT. Pre-induction cervical ripening: a comparison of intracervical Prostaglandin E2 gels versus the Foleys catheter. Am J Obstetrics and Gynecol 1995;172 (2pt,1): 687-90.
17. Abou el-Lell LA, Nasrat AA, Fayed HM. Prostaglandin E2 vaginal passaries in the grand multipara with an unripe cervix, a comparison of different parity groups. Int J Gynecol and Obstetrics 1993; 40(2): 119-22.

Address for Corresponding Author:
Dr. Kulsoom Bhatti
Asstt. Prof. Obs. & Gynae,
Ghulam Muhammad Mahar Medical College,
Sukkur.
Cell # 03083234318
Email Add: bhattikulsoom@ymail.com