Original Article

DOI: 10.7860/JCDR/2012/5003.2689

The Transcervical Foley Catheter Versus the Vaginal Prostaglandin E_2 Gel in the Induction of Labour in a Previous One Caesarean Section – A Clinical Study

Obstetrics and Gynaecology Section

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ABSTRACT

Objective: To compare the effectiveness and the safety of the transcervical Foley catheter and the prostaglandin E_2 (PGE_2) gel for the induction of labour in women with a previous one caesarean section with an unfavourable cervix at term.

Method: This study was conducted in the Department of Obstetrics and Gynaecology, J.N. Medical College, Aligarh, (U.P),India. Seventy women with singleton pregnancies at term, with previous one lower segment caesarean sections with a cephalic presentation and a Bishop's score of ≤ 6, who required induction at term were included in the study. Group A had 35 women in whom the transcervical Foley catheter was inserted and Group B included 35 women in whom the PGE_2 gel was inserted vaginally for the induction of labour.

The Bishop's score after 12 hours of induction, the oxytocin requirement, the induction to delivery interval, the mode of delivery, the maternal complications and the neonatal outcome were compared.

Results: The Foley catheter and the PGE_2 gel had a comparable effect on the Bishop's score after 12 hours and the induction to the delivery interval was slightly shorter with the Foley catheter (18.15 hours) as compared to 21.06 hours with the PGE_2 gel. There was no case of uterine rupture or scar dehiscence.

Conclusion: In this study, both the modes of induction in women with previous one caesarean sections were safe, simple and effective. The main advantages of the cervical ripening with the Foley catheter over the Prostaglandin E_2 gel are the low cost, reversibility and the lower risk of systemic and serious side effects like uterine hyperstimulation and rupture, as well as it induces a significant ripening and dilatation of the cervix and a shorter induction to the delivery interval. So, the cervical ripening effect of the Foley catheter is as good as that of the Prostaglandin E_2 gel in women with previous one caesarean sections.

Key Words: Foley catheter, PGE_2 (Prostaglandin E2) gel, Bishop's score, TOL – Trial Of Labour, VBAC –Vaginal Birth After Caesarean section

INTRODUCTION

The induction of labour is common in the obstetric practice and it is aimed at, to deliver a healthy baby and to maintain the health of the mother. In the absence of a ripe or a favourable cervix, a successful vaginal birth is less likely. The cervix is considered to be unfavourable if the Bishop's score is less than 6 and if the cervical ripening is indicated prior to the artificial rupture of the membranes and the production of oxytocin, to reduce the incidence of a failed induction and a caesarean delivery.

Various techniques have been used to ripen the unfavourable cervices, which include pharmacological and non-pharmacological (mechanical) methods. The pharmacological methods include prostaglandins (PGE_1, PGE_2), oxytocin, oestrogens, mifepristone, etc. The non-pharmacological methods include a transcervical Foley catheter, bougies, hygroscopic laminaria tents and forewater amniotomy. The externally administered prostaglandins are effective at the cervical ripening and they hasten the delivery, but they increase the risk of the uterine hyperstimulation and produce foetal heart rate changes [1].

The mechanical methods stimulate the endogenous prostaglandin production, thus ripening the cervix. Embrey and Mollison first described the use of a transcervical Foley catheter for the cervical ripening [2]. Obed and Adewele documented its effectiveness in increasing the Bishop's score in women with Unripe cervix [3].

Nowadays, VBAC has been actively promoted for reducing the rising caesarean delivery rates. The effectiveness and the safety of the induction or augmentation in women with a previous one lower segment caesarean section, who were undergoing the Trial of Labour (TOL), is being studied. With the induction of labour in a previous caesarean section, the uterine rupture can be a serious event that can threaten the life and the neurological status of the baby and result in significant uterine bleeding which will require a hysterectomy. So, a cautious attempt may be taken in inducing labour in the women with a previous one caesarean section. The aim of this study was to compare the effectiveness and the safety of the transcervical Foley catheter and the Prostaglandin E_2 (PGE_2) gel in the induction of labour in the women with a previous one caesarean section with an unfavourable cervix at term.

MATERIALS AND METHODS

This study was conducted in the Department of Obstetrics and Gynaecology, J.N. Medical College, A.M.U, Aligarh, India. Seventy cases of a previous one lower segment caesarean section were selected for the study, depending on the modes of induction which were carried out in them. The cases who had a gestational age of

≥ 37 weeks, those who had singleton pregnancies with a previous one caesarean section with a cephalic presentation, those who had a reassuring foetal status and those with a Bishop's score of ≤ 6 were included. The exclusion criteria were ruptured membranes, intrauterine foetal death, twin pregnancy, polyhydramnios, placenta previa and any contraindication for the labour induction. A written informed consent was taken from all the cases who were under study. The indications for the cervical ripening and the induction of labour were pregnancy induced hypertension, post term pregnancies, oligohydramnios, intrauterine growth restrictions, diabetes mellitus and foetal congenital anomalies.

In group A, - Foley catheter No. 16 F was used to ripen the cervix in 35 cases. Under aseptic conditions, with the patients lying in the lithotomy position, the cervix was assessed on a Bishop's scoring scale. A 16 French Foley catheter with a 30ml balloon was inserted into the endocervical canal, beyond the internal os and the balloon was inflated with 30ml of sterile water.

The catheter was strapped to the thigh with gentle traction. The catheter was checked for its position and the traction at 4-6 hours intervals. The catheter was either removed at 12 hours or it was expelled spontaneously and it was checked whether the modified Bishop's score had improved or a whether a spontaneous rupture of the membranes had occurred. The Artificial Rupture of the Membranes (ARM) was followed by the starting with an intravenous oxytocin infusion of 2.5 units of oxytocin in 500ml of 5% dextrose at 10 drops/minute. The dose was increased at 10 drops/minute interval upto a maximum of 60 drops/ minute, or till the desired uterine contractions were achieved.

In group B, - 0.5mg Dinoprostone PGE_2 gel was used in 35 cases .Under aseptic conditions, the PGE_2 gel in a pre-loaded syringe, was inserted into the posterior fornix. The next dose was repeated at 12 hours if the Bishop's score was ≤ 6. ARM was followed by the starting with of an oxytocin infusion when the Bishop's score had improved. There was a gap of at least 6 hours between the last dose of the PGE_2 gel and ARM with the oxytocin infusion.

To evaluate the success of the cervical ripening, the primary outcome measures which were undertaken were:

1. Cervical score improvement: In Group A – The difference between the initial cervical examination and the examination at expulsion/ removal of the Foley catheter. In Group B – The difference between the initial cervical examination and after 12 hours after giving the last dose of the PGE_2 gel.

2. The mode of the delivery

3. Induction: the delivery interval

The secondary outcome measures were a neonatal APGAR score at 5 minutes and any intrapartum complications like uterine tachysystole (6 contractions in 10 minutes, in two consecutive 10 minute periods), uterine hypertonicity (contractions lasting longer than 3 minutes), uterine rupture and sepsis. The intermittent foetal heart rate monitoring was done at 30 minutes and the modified WHO partograph was followed up for the labour management.

RESULTS

In our study, the effectiveness and the outcome of the Foley catheter (Group A) and the PGE_2 gel (Group B) were compared for the induction of labour in women with a previous one lower segment caesarean section. In [Table/Fig-1], the maternal profile has been compared. There was no significant difference in the maternal age, the gestational age or the parity of the cases.

The primary outcomes of both the methods of induction have been summarized in [Table/Fig-2]. There was a significant improvement in the Bishop's score with both the Foley catheter and the PGE_2 gel after 12 hours.

6 (17.14%) cases in Group A and 9 (25.71%) cases in Group B needed only ARM for the augmentation of labour, while 29 (82.86%) cases in Group A and 26(74.29%) cases in Group B required both ARM and oxytocin for the labour augmentation. The mean induction to the delivery interval was shorter with the Foley catheter (18.15 hours) as compared to the 21.06 hours with the PGE_2 gel.

Out of 25 vaginal deliveries which were done with the use of the Foley catheter, 21 (Group -A) women delivered within 24 hours, while 4 delivered between 24 -48 hours of the induction and they had a slow progress. With the use of the PGE_2 gel 13 (Group B) women delivered in 24 hours and 8 women delivered after 24 hours, but within 48 hours of the induction.

The mode of the delivery and the indication of the caesarean section have been summarized in [Table/Fig-3]. Out of the 35 cases in the Foley catheter group, 25 (71.43%) delivered vaginally and 10 (28.57%) delivered by caesarean section, while in the PGE_2 gel group, 21 (60%) had vaginal deliveries and 14 (40%) had repeat caesarean sections. The most common cause of the caesarean

Parameters	Group –A (N =35) Foley catheter	Group – B (N=35) PGE2 Gel
Mean maternal age (range 20 -40 years)	25.09	26.12
Mean Gestation age (37 - 42 weeks)	39.24	38.89
Mean Parity (2 - 5)	3.09	3.2
Indications for induction		
Postmaturity	8	7
IUGR	9	5
Preeclampsia	9	11
Congenital malformations	2	3
Others	7	9

[Table/Fig-1]: Maternal Demographic Profile

Parameters	Group A Foley Catheter (N = 35)	Group B PGE_2 Gel (N =35)
Mean Bishop's score at start of induction	2.80	2.95
Mean Bishop's score after 12 hours of induction	7.45	6.59
Augmentation required		
ARM	6	9
ARM + Oxytocin	29	26
Mean induction delivery interval (hours)	18.15	21.06
Failed induction	2	4
Women delivered		
Within 24 hours of start of induction	21	13
Between 24-48 hours of induction	4	8

[Table/Fig-2]: Induction Outcome in two Groups

Parameters	Group – A Foley Catheter (N = 35)	Group –B PGE_2 gel (N =35)
Mode of delivery		
Spontaneous vaginal delivery	25 (71.43 %)	21 (60%)
Caesarean section	10 (28.57%)	14 (40%)
Indications for Caesarean section		
Failed induction	2	4
Fetal distress	5	6
Nonprogress of labour	2	2
Scar tenderness	1	2

[Table/Fig-3]: Mode Of Delivery in two Groups

Parameters	Group – A Foley Catheter (N = 35)	Group –B PGE_2 gel (N =35)
Uterine tachysystole	0	3
Uterine hypertonicity	0	1
Uterine rupture	0	0
PPH	5	8
Puerperal pyrexia	2	1

[Table/Fig-4]: Maternal Complications

Parameters	Group – A Foley Catheter (N = 35)	Group –B PGE_2 gel (N =35)
APGAR score at 5 minutes		
4-6	4	5
7-8	10	13
9-10	21	17
Baby weight (kg)		
≤2.5	6	3
2.6 -3.0	17	18
3.1 -3.5	8	11
≥3.6	4	3

[Table/Fig-5]: Neonatal Outcome

section was foetal distress. Induction failed in 2(5.71%) cases in the Foley group and in 4(11.43%) cases in the PGE_2 gel group.

The maternal complications have been summarized in [Table/Fig -4]. There is no case of uterine rupture or scar dehiscence. Uterine hypertonicity and tachysystole were seen in the cases which were induced by using the PGE_2 gel. Few cases had mild atonic PPH which was unrelated to mode of induction. The neonatal outcome [Table/Fig-5] had no significant difference in either of the 2 groups.

DISCUSSION

The rising rate of caesarean sections is posing a problem to the obstetricians , as they are reluctant in giving the Trial of Labour to the women with a previous one caesarean section, as there is a risk of a uterine rupture which can pose a threat to the mother and the foetus and a possibility of a subsequent litigation. The policy of VBAC is a contribution towards bringing down the caesarean section rate and reducing the maternal morbidity and mortality. The Trial of Labour (TOL) is a relatively safe procedure, but it is not risk free and it should be attempted with caution.

Approximately about 15% labours are induced. The preinduction cervical ripening is associated with the success of the induction in women with unfavourable cervix [4]. Labour 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 PGE_1, PGE_2, oxytocin, oestrogens, mifepristone, etc. and non-pharmacological (mechanical) methods like Foleycatheter, laminaria, amniotomy, etc.

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.

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 [5]. But Foleycatheter 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 [6].

In our study, Foley catheter and the PGE_2 gel produced similar effects in the ripening of the cervix in women with a previous one lower segment caesarean section. The main advantage of the Foley catheter is that the mean induction to the delivery interval is shorter, the vaginal delivery rate (VBAC) is more and that no case of uterine hypertonicity or tachysystole is noted, as compared to the PGE_2 gel, as well as its storage is easy and its cost is low.

A study which was conducted on the VBAC induction by D. Ravasiax et al., 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 PGE_2 exposure during the TOL was associated with more than a 6 fold increase in the uterine ruptures as compared to that in the spontaneous labour [7].

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 [8].

According to an open label randomized control trial which was done by the PROBAAT study group, in women with unfavourable cervices at term, the induction of labour with a Foley catheter was similar to the induction of labour with the Prostaglandin E_2 gel, with fewer maternal and neonatal side effects.

The results of this trial tended to favour the Foley catheter use over the prostaglandin use, as the process mimicked the physiology of the labour onset more closely, resulting in a less likelihood of hyperstimulation, foetal heart rate abnormalities and postpartum haemorrhage.

These factors gain increasing significance in situations of foetal compromise or when a uterine rupture was a risk. Also, a catheter initiated induction could be preferable, when the monitoring is less accessible or when the storage and the cost issues of the prostaglandins are important [9].

CONCLUSIONS

In this study, both the modes of induction in the women with a previous one caesarean section were safe, simple and effective. The main advantages of the cervical ripening with the Foley catheter over the prostaglandin E_2 gel are the low costs, reversibility and a lower risk of systemic and serious side effects like uterine hyperstimulation and rupture, as well as it induces a significant ripening and dilatation of the cervix and it produces a shorter induction to the delivery interval. So, the cervical ripening effect of the Foley catheter is as good as that of the prostaglandin E_2 gel in women with a previous one caesarean section.

REFERENCES

[1] Kelly AJ, Malik S, Smith L, Kavanagh J, Thomas J. Vaginal prostaglandin (PGE2 and PGF2α) for induction of labour at term. *Cochrane database Syst Rev.* 2009;4:CD 003101.

[2] Embrey, Mollison BG. The unfavourable cervix and induction of labour using a cervical balloon. *BJOG.* 1967;74:44.

[3] Obed JY, Adewole IF. The unfavourable cervix : Improving the Bishop score with the Foley catheter. *West Afr J Med.* 1994;13(4):209-12.

[4] Chung JH, et al. A prospective randomized controlled trial that compared misoprostol, Foley catheter and combination misoprostol–Foley catheter for labour induction. *Am J Obstet Gynecol*.2003;189 (4):1031 -35.

[5] Syeda BM, Saba S, Ghazala M. Induction of labour, A Randomised Trial Comparing Prostaglandin E2, Pessary, Intracervical Foley Catheter and Extra-amniotic saline infusion. *J Surg.* Dec. 2000;19-20:12-18.

[6] Salva S, Nadeem FZ, Alfia Z, Rahat NQ. Increased risk of cervical canal infections with intracervical Foley catheter. *J Coll Physicians Surg Pak*. Mar. 2003; 13(3):146-49.

[7] Ravasiax D, Woodx S, Pollard J. Uterine rupture during induced trials of labour in women with a previous cesarean delivery. *American Journal of Obstetrics and Gynaecology*. Jan. 2000; in two parts, part 2, 182 (1).

[8] Landan MB, Hauth JC, Leveno KJ, Spong CY, Leindecker S, Varner MW, et al. Maternal and perinatal outcomes associated with trial of labour after prior cesarean delivery. *New England Journal of Medicine*.2004;351(25):2581-89.

[9] Jozwiak M, Oude Rengerink K, Benthem M, van Beck E et al: PROBAAT study Group. Foley catheter versus vaginal Prostaglandin E2 gel for induction of labour at term (PROBAAT Trial) ;an open label, randomized contolled trial. *Lancet.* 2011. Dec 17;378(9809):2095-103.

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FINANCIAL OR OTHER COMPETING INTERESTS:

None.

Date of Submission: **Aug 31, 2012**
Date of Peer Review: **Sep 28, 2012**
Date of Acceptance: **Nov 21, 2012**
Date of Publishing: **Jan 01, 2013**