A RANDOMIZED COMPARISION OF FOLEY CATHETER INSERTION VERSUS PROSTAGLANDIN E_2 VAGINAL PESSARY FOR INDUCTION OF LABOUR IN POST DATE PREGNANCY

Nadia Arif, Mamoona Mushtaq*

Combined Military Hospital Multan. * Military Hospital Rawalpindi

ABSTRACT

Objective: To see the safety and efficacy of cervical Foley catheter insertion in post date pregnancy, for induction of labour, as compared to prostaglandin E_2 vaginal pessary.

Study Design: A comparative, cohort study.

Place and Duration: The study was conducted in the department of obst / Gynae MH Rawalpindi from Sep 2003 to Sep 2004.

Patients and Methods: There were hundred subjects in each group including both primigravidas and multigravdas upto para 3 with singleton pregnancy, postdates 6-10 days, age 20-30 years, Bishop score 3-6 with adequate pelvis. Sampling technique was convenient, non probability

Results: In primigravidas improvement in Bishop Score after 06 hours was similar in both Group A {Foley catheter} (32 %) and Group B {Prostin E_2} (30 %). While in multigravidas improvement in Bishop Score was more in foley catheter in Group A (36 %) as compared to Group B (24%). The induction delivery interval was 12 hours in 69% cases of Group A and 67% cases of Group B ($p<.001$). In Group A 80% patients were delivered by spontaneous vaginal delivery, 9% were delivered by lower segment ceasarian section (LSCS). Where as in Group B 76% patients were delivered by spontaneous vaginal delivery, 11% were delivered by lower segment ceasarian section (LSCS). There were 4 cases of non progress of labour, 4 cases of fetal distress, 2 cases of meconium aspiration and 1 case of uterine hyperfunction in Group A. However there were 5 cases of fetal distress, 3 cases of meconium aspiration, 3 cases of uterine hyperfunction and 1 case of uterine rupture in Group B.

Conclusion: A good cervical preparation was achieved with Foley catheter by mechanical effect of the distended balloon and by release of endogenous PGE_2 comparable to extra amniotic PGE_2. The readily available Foley catheter was inexpensive and there were no maternal systemic side effects.

Keywords: Prostin E_2, Foley Catheter, Induction of Labour

INTRODUCTION

Labour induction is the initiation of uterine contractions prior to their spontaneous onset, leading to cervical dilatation, effacement and delivery of the baby [1]. Post term pregnancy may be defined as a gestation of any length beyond 40 weeks [1]. The purpose of induction is to achieve benefit to the health of the mother and/or the baby, greater then if the pregnancy continues. There is good evidence that induction of labour should be offered routinely to all women whose pregnancies continue beyond 41 weeks gestation [2, 3]. Induction during this period is associated with beneficial outcome in terms of reduced caesarian section rate, reduced operative vaginal delivery, reduced chance of fetal distress, meconium staining, macrosomia, and reduced risk of fetal and neonatal death [4-6].

Prolonged pregnancy appears to be more common in primigravidae and women with previous prolonged gestations [7]. Hypertension or preeclampsia, diabetes, abruptio placentae and intrauterine growth restriction are factors that increase the risk of adverse perinatal outcome in post term pregnancy [8, 9]. Even in the absence of known risk factors, prolonged pregnancy is associated with an increased incidence of meconium staining of the amniotic fluid and an increased risk of macrosomia, with associated dystocia and brachial plexus injury [6, 10]. It has also been associated with intrapartum fetal hypoxia, which may result in fetal acidosis, neonatal

Correspondence: Maj Nadia Arif, Gynaecologist, Combined Military Hospital Multan
Email: salman_arif@hotmail.com
Received: 09 April 2008; Accepted: 25 Feb 2009

seizures and intra partum stillbirth or neonatal death [11-14].

Methods presently used for induction of labour include those that rely on mechanical stimulation to promote cervical effacement, dilatation and uterine contractility, those that employ pharmacological agents [8, 9] to modify cervical form and those that stimulate uterine contractions to establish labour [1, 15].

Labour that is induced with a favourable cervix usually involves amniotomy – with or without oxytocin – if the presenting part is low and well applied to the cervix. Otherwise oxytocin or prostaglandins are used to bring the presenting part down, or the obstetrician – gynaecologist may consider a controlled artificial amniotomy. In the presence of an unripe cervix, induction should include prostaglandins [8, 9] for cervical ripening, sweeping of the membranes [16], oxytocin or mechanical ripening with a foley catheter [13, 14, 17]. The safety of oral or vaginal misoprostol in inducing labour for prolonged pregnancies has been established [7].

The primary mechanism of cervical ripening by Foley catheter is through Prostaglandin release from decidual separation rather than by its mechanical effects [18].

PATIENTS AND METHODS

All patients were admitted through Gynae OPD with all basic investigations within normal limits and bishop scoring done. On admission, an admission cardiotocography (CTG) was done. All patients were selected alternatively for Foley Catheter (Group A) and tablet Prostin E_2 (3mg) (Group B). In group A a Foley catheter was inserted in the cervix using aseptic technique at night. The balloon was filled with 40cc of distilled water. Patients were reassessed after 6 hrs. If the Foley catheter was expelled then artificial rupture of membranes was done but if the bishop has not improved then re-induction with Foley catheter was done on the next night. One tablet of Prostin E_2 (3mg) was placed in posterior fornix of vagina at 0400 hrs in the morning in group B and reassessed after 6 hrs. If no progress was seen then a second tablet was placed after 6 hrs. Artificial rupture of membranes was done at 4.0cm dilatation followed by syntocinon infusion. Fetal heart sounds were auscultated throughout the procedure. The denominators assessed were induction-delivery interval, artificial rupture of membrane (ARM) -Delivery interval, improvement of Bishop Score, mode of delivery, instrumental deliveries, fetal distress, Apgar score of babies, neonatal sepsis, chorioamnionitis and puerperal sepsis.

Statistical Analysis

Data analysis was done by SPSS software. Chi Square was used to test the hypothesis. A 'P' value of <0.05 was taken as significant, relevant descriptive statistics were reported, and calculation made by using 'SPSS'.

RESULTS

Out of 200 women, 100 women were subjected to Foley catheter insertion (Group A) and 100 women were subjected to insertion of prostin E_2 (Group B) .Indication for induction was post date pregnancy in both groups. In primigravidas improvement in Bishop Score after 06 hours was similar in both Group A (32 %) and Group B (30 %). While in multigravidas improvement in Bishop Score was more in foley catheter in Group A (36 %) as compared to Group B (24 %) (Table-1).

The analysis of mean duration of labour showed that there was no statistically significant difference between these two groups. The ARM delivery interval was 2-4 hours in 69% cases of Group A (p>0 .005) and 67% cases of Group B while it was 4-6 hours in 36% cases of Group A and 33% cases of Group B. The induction delivery interval was 12 hours in 69% cases of Group A and 67% cases of Group B (p<0.001) (Fig. 1).

In Group A 80% patients were delivered by spontaneous vaginal delivery, 9% were delivered by LSCS, forceps were applied in 6% and vacuum in 5% of cases. Where as in Group B 76% patients were delivered by spontaneous vaginal delivery, 11% were delivered by LSCS; forceps were applied in 7% and vacuum in 6% of cases (Fig 2 & 3). There were 4 cases of non progress of labour, 4 cases of fetal distress, 2 cases of meconium aspiration and 1 case of

uterine hyperfunction in Group A. However there were 5 cases of fetal distress, 3 cases of meconium aspiration, 3 cases of uterine hyperfunction and 1 case of uterine rupture in Group B (Table-2).

Two babies had an apgar score of 4/10 at the end of 1 min while another two had 7/10 at the end of 5min in Group B where as all babies in Group A had an apgar score of 9/10.There was no increased frequency of neonatal sepsis, chorioamnionitis or puerperal sepsis in any of my patients. There was no accidental rupture of membranes while introducing foley catheter. There was no perinatal mortality/morbidity however there was 1 case of uterine rupture.

Table 1: Bishop scoring scale and change in bishop score

Parity	Method of Cervical Ripening	Total No.	Bishop Score After 6 Hrs	
			6-9	10-13
Primi	Foley's catheter	52	20 (38.5%)	32 (61.54%)
	PGE2	52	22 (42.3%)	30 (57.7%)
Multi	Foley's catheter	48	12 (25%)	36 (75%)
	PGE2	48	24 (50%)	24 (50%)

Table 2: Frequency of side effects in group a and group B

	Side effects	Frequency	%
Foley (group A)	Nausea	Nil	Nil
	Vomiting	Nil	Nil
	Diarrhoea	Nil	Nil
	Accidental rupture of membranes	Nil	Nil
	Chorio amniotis	Nil	Nil
	Hypertonicity	01	1%
Prostin (Group B)	Nausea	15	15%
	Vomiting	08	8%
	Diarrhoea	03	3%
	Accidental rupture of membranes	Nil	Nil
	Chorio amniotis	Nil	Nil
	Hypertonicity	03	3%

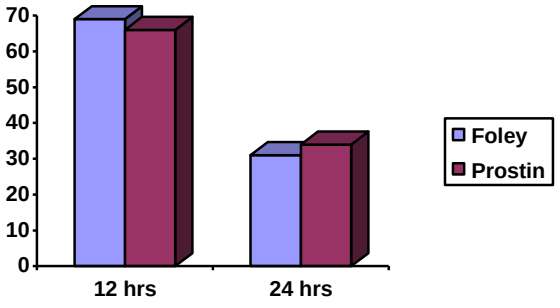

Fig. 1: Induction delivery interval in group a and group b patients

DISCUSSION

Cervical ripening is a normal preclude to the onset of myometrial contractions; it is important to choose a method which will ripen the cervix and have a successful outcome of planned induction of labour [19].

In this study of 200 patients, I have found that average mean duration of labour for both groups were almost similar and there was no statistical significant difference between the two groups.

In a randomised study by M. Ezimokhai and JN Nwabinelli7 for induction of labour, comparative study was done between Foley catheter and dinoprostone (5mg) gel. The improvements in cervical score and outcome of induction of labour were similar in both groups. Similar outcome is seen in our study.

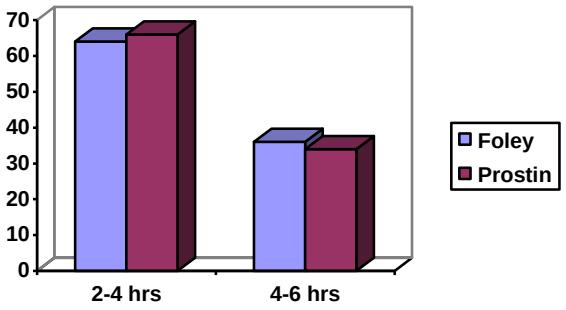

Fig. 2: Arm delivery interval in group a and group b patients

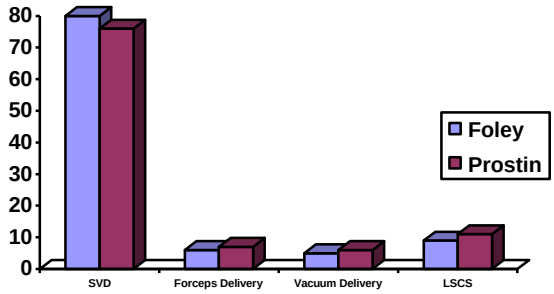

Fig. 3: Mode of delivery in group a and group b patients

The main argument against the use of Foley catheter has been a risk of introduction of infection with accidental rupture of fetal membranes. In my study aseptic precautions were carried out and the policy of active management after expulsion of the foley was adapted so none of the women had antepartum, intrapartum or post partum pyrexia. Foley catheter acts as a mechanical dilator and improves dilatation rather than effacement of the cervix, whereas PGE_2 acts by softening and increasing the effacement of the cervix rather than dilatation. For successful induction with Foley catheter immediate amniotomy followed by titrated oxytocin drip is needed as the cervix tends to close down after removal of Foley catheter.

PGE_2 pessary is expensive, twice as much as the price of a Foley catheter, also it has to be stored in the refrigerator below 2^0C temperature and as seen in our study the side effects of PGE_2 like nausea, vomiting, diarrhoea are quite frequent, whereas they are absent in Foley catheter group.

Further, cases of uterine hyper tonicity and fetal bradycardia have been reported following use of prostaglandins [20] and this necessitates monitoring of the fetus even in the preinduction cervical ripening phase.

Schreyer and Colleagues [20] in 1987 studied the change in Bishop's score between Foley catheter and intravaginal prostaglandin gel and found that 13% had hypertonic contraction as compared to my study where it was only 2%.

Sciscione and colleagues [15] compared the efficacy of intracervical prostaglandin E_2 gel with insertion of a Foley bulb for efficacy in preinduction cervical ripening the out come was comparable to our study.

Ranka et al also compared foley catheter with dinoprostone gel for preinduction cervical ripening. In their study, both foley and PGE_2 gel have been equally effective in primi gravidas in achieving cervical ripening and improving Bishop's score and promoting changes resembling physiological events of ripening and labour, however in cases of multigravidas, Foley catheter have been superior (75%) as compared to PGE_2 (50%) [21].

In today's expensive world, Foley catheter which is half the price of PGE_2 vaginal pessary is definitely a safer and cheaper alternative. Foley catheter can also be used in cases of bronchial asthma, increased intra ocular pressure and previous LSCS [22] foley catheter thus provides a better alternative.

A study was carried out in the Department of Obstetrics and Gynaecology, Jinnah postgraduate medical centre on 146 patients. The methods used were PGE_2 vaginal pessary, syntocinon infusion, extra amniotic Foley catheter and ARM followed by syntocinon infusions. Common indications were post maturity and hypertensive disorders of pregnancy. Induction of labour was successful in 80% of patients with prostin E_2 vaginal pessary being the most effective method [18].

Ghazzi F et al [23] evaluated the efficacy of intra vaginal prostaglandin E_2 gel in comparison with that of a Foley catheter for cervical ripening and induction of labour. It was concluded that the Foley catheter is a valid alternative to prostaglandin E_2 gel for pre induction cervical ripening and it is associated with a lower caesarian section rate in multiparous woman. Similar results were obtained by Thomas [24] in 1986.

Based on the findings of my present study, we agree that the PGE_2 is effective method for induction of labour, but at the same time foley catheter is effective, very simple, cost effective and convenient method. In a way it is better for the developing countries like our. Similar studies have been done in Nigeria, Egypt, and India where foley catheter proved to be more effective as compared to PGE_2. The results of my study are consistent with these studies, as discussed earlier. So the foley catheter can be adapted as separate method of induction parallel to PGE_2 in the Military Hospitals. It can be used for induction of labour safely and effectively at a particular Bishop score.

Thus foley catheter from our study has proved to be equally effective for preinduction ripening of cervix in primigravidas and

superior to PGE_2 in multigravidas. Thus Foley catheter is definitely safer, better and cheaper alternative to PGE_2 gel and it is definitely recommended where prostaglandins are contraindicated.

CONCLUSION

It is concluded that good cervical preparation is achieved with Foley catheter by the mechanical effect of distended balloon and by release of endogenous PGE_2 as compared to the extra amniotic PGE_2. The readily available and inexpensive Foley catheter allows successful induction and reduces the induction delivery interval almost the same as with PGE_2. But its additional benefit is that there are no maternal systemic side effects and many other risk which can affect mother and fetus in case of prolonged labour as well as it is cost effective as compared to the PGE_2.

REFERENCES

1. Mackenzie I Z. Labour induction including pregnancy termination for fetal anomaly. In : James D K, Steer P J, Weiner C P, Gonik B. High risk pregnancy: management options. 2nd ed. London: Harcourt Publishers 1999: 079- 1101.
2. ACOG Practice Patterns. Management of post term pregnancy. Int J Gynaecol Obstet 1997; 60:86-91.
3. Alfirenic Z, Walkenshaw SA. Management of post term pregnancy: to induce or not? Br J Hosp Med 1994; 52: 218-21.
4. Rogers MS. Induction and augmentation of labour. In: Chamberlain G, Steer PJ Turnbull's Obstetrics.3rd ed. London: Harcourt Publishers, 2001: 563-79.
5. Moore L, Martin JN Jr. prolonged Pregnancy. In: Danforth's Obstetrics and gynaecology. 9th ed. London: Lippincott Williams and Wilkins; 2003, 219-23.
6. Grant JM. Induction of labour confers benefits in prolonged pregnancy. Br J Obstet Gynaecol. 1994; 111: 99-102
7. Sciscione A, Nguyen L, Manley, Pollock M, Maas B, Colmorgen G. A randomised comparison of trans-cervical foley catheter to intra vaginal misoprostol for pre induction cervical ripening. Obstet Gynecol 2001; 97: 603-7.
8. Anwar S, Shami N, Akbar N, Asif S. Induction of labour by prostaglandin E2 vaginal tablets in patients with previous caesarean section. J coll Physicians Surg Pak 2002; 12: 208-11.
9. Nuzhat PK, Rakhshanda R, Zahida D. Induction of labour with prostaglandin E2 vaginal tablet in women with pre-labour rupture of membranes (PROM) at or near term with unfavourable cervix. Pak J Obstet Gynacol 1998; 11: 78-81.
10. Rosen MC, bickinson JC. Management of post term pregnancy. N Engl J Med. 1992; 326; 1628-1629.
11. Ingemarsson I, Kallen K. Still births and rate of neonatal deaths in 76, 761 post term pregnancies in Sweden, 1982-1991: 1 register study.
12. Amjad T. Termination of Pregnancy witrh fetal death in second trimester; Foley catheter verses extra amniotic Prostaglandins. J Coll Physican Surg Pak 1999; 9: 403-5.
13. Sherman DJ, Frenkel E, Toubin J, Arieli S, Caspi E, Bukovsky I. Ripening of the unfavourable cervix with extra-amniotic catheter balloon: clinical experience and review. Obstet Gynacol Surv 1996; 51: 621-7.
14. Mazhar SB, Sarwar S, Mahmud G. Induction of labour, a randomised trial comparing PGE2 pessary, intra cervical Foley catheter and extra amniotic saline infusion. J Surg (PIMS) 2000; 19-20: 12-8.
15. Sciscione A. McCullough H, Manley J, Shlossman P, Pollock M, Colmorgen G. A prospective, randomised comparison of Foley catheter insertion verses intra cervical Prostaglandin E2 gel for pre induction cervical ripening. Am J Obstet Gynecol 1999; 180: 55-9.
16. Berghella V, Rogers RA, Lescale K. Stipping of membranes as a safe method to reduce prolonged pregnancies. Obstet Gynaecol. 1996; 87: 927-31.
17. Atad J, Hallak M, Vid Y, Auslender R and Abramo VH. Ripening and dilatation of the unfavourable cervix for inductin of labour by double balloon device experience with 250 cases B.J Obstet Gynaecol 1997; 104: 29-32.
18. Sherman DJ, Frenkel E, Toubin J, Arieli S, Caspi E, Bubovsky I. Ripening of the unfavourable cervix with estra amniotic catheter balloon. Obstet Gynaecol Surv 1996; 51: 621-7
19. Hayat TK. Induction of labour in unripped cervix an experience with 153 patients. J Coll Physicians Surg Pak 1997; 7: 5: 205-8.
20. Schreyer P, Sherman and Colleagues. Obstet and Gynecol 1989; 73: 938.
21. Ranka PR , Gupta AS , Parulekar SV . Pre induction cervical ripening, an easier and safer alternative. Indian Med Assoc .1998; 96: 297-308.
22. Hacket GA, Reginald P, Paintem BD. Comparison of the foley catheter and dinoprostone pessary for cervical preparation for second trimestu obocation. Br J Obstet Gynaecol 1989: 96: 1432-4.
23. Ghazzi F, Massino F, Raio L, Naeo E, Bvalesteric D, Bolis P. Extra amniotic foley catheter and prostaglandin E2 gel for cervical ripening at term gestation. Eur J Obstet Gynaecol 2001, 97: 183-7.
24. Thomas IL, Chenoweth JN, Trone GN, Jhonson IR. Preparations for induction of labour of the unfavourable cervix with foley catheter compared with vaginal prostaglandin. Aust NZJ Obstet Gynaecol 1986; 26: 30-5.