COMPARISON OF DINOPROSTONE WITH TRANSCERVICAL BALLOON CATHETER FOR LABOUR INDUCTION

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ABSTRACT

Objective: To compare transcervical balloon catheter with dinoprostone in terms of frequency of cesarean section.

Study Design: Randomized controlled trial.

Place and Duration of Study: Department of Obstetrics and Gynaecology, Combined Military Hospital Peshawar, from 1st Nov 2011to 30th Jun 2012.

Methodology: A total of 800 patients were selected who underwent labour induction. They were randomly divided into group 'A' and 'B' with 400 patients in each group. Patients in group 'A' were induced using Dinoprostone 3mg placed in posterior vaginal fornix and repeated after 6 hours if labour did not establish. In group 'B'Foley catheter (26fr) was placed within the cervical canal and inflated with 60 ml of sterile water for labour induction. Patients who underwent caesarean section in both the study groups were then recorded. Induction to delivery interval was also noted in both the study groups.

Results: Mean age of sample was 27.78 ± 4.507. In Group A out of 400 Patients 102 (25.5%) while in Group B 91 (22.7%) underwent cesarean section (p=0.826).

Conclusion: There is no difference in the rate of caesarean section when using Prostaglandin E2 (Dinoprostone) or the Balloon Catheter (Foley Catheter) for induction of labour.

Keywords: Dinoprostone, Induction of Labour, Transcervical Balloon Catheter.

INTRODUCTION

Induction of labour is a common practice in obstetrics. About 30%[1] of the pregnancies requiring induction of labour may be induced for both fetal as well as maternal reasons; among them are, postterm pregnancy, pre-eclampsia and rupture of membranes without onset of spontaneous contractions within 24 hours[2]. The success of this procedure is mainly dependant on the state of cervix at the time of commencement and good results expected with soft and effaced cervices[2]. Similarly failed inductions landing in cesarean section are expected in closed and firm cervix that is difficult to distend[3]. Many methods have been used for cervical ripening[4], common being biochemical and mechanical agents. Among biochemical agents synthetic Prostaglandin E2 (dinoprostone) is used which initiates physiological cervical ripening and also increases the sensitivity of the myometrium to oxytocin. Although Prostaglandin E2 decreases the risk of cesarean section, but still there is a concern about fourfold increase in uterine hyperstimulation, which causes fetal heart rate changes[1].

Mechanical ripening methods apply pressure on the internal os. Lower uterine segment when over stretched causes localized release of prostaglandins. The advantage of using balloon catheter as mechanical agent is that it is easy to insert, cost effective and there is no increased risk of perinatal infection[5,6].

The purpose of this study was to help establish the role of balloon catheter for successful labour induction in our setup. The results of this study will help clinicians in better understanding the benefits of cheap and safe balloon catheter, over newer more costly drugs available for labour induction.

PATIENTS AND METHODS

This randomized controlled trial was conducted in Combined Military Hospital Peshawar from 1st Nov 2011 to 30th Jun 2012. Patients having gestational age 37-41weeks with Bishop Score 4-6 were included in the

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study. Patients having pre-eclampsia, diabetes and absence of spontaneous contractions at 41 week were also included in the study group. Patients having contraindications to foley catheter e.g. premature rupture of membranes, contraindications for the administration of prostaglandins and for vaginal delivery, a previous caesarean section or other form of uterine surgery, breech presentation, signs of infection and/or the necessity for immediate delivery as indicated by, for example, pathological cardiotocography and bishop score less than 4 were not included. Surgical procedure consent was taken from all the patients who participated in the study. Patient's name, age, address and hospital registration numbers were recorded. Relevant general physical examination and systemic examination was then performed. Baseline laboratory investigations including Blood Complete Picture, Cross-match, Hepatitis screening was done in all cases.All the women had cardiotocography 30 minutes prior to and 45 minutes after administration of the medication or implantation of the catheter.During labour, monitoring was done through fetal heart auscultation and external CTG intermittently. The patients were divided into two groups by random allocation based on computer generated table of random numbers. Rate of caesarean section were recorded in both the groups.

Data was analyzed using SPSS version 17. Mean and Standard deviation(SD) were calculated for age and induction to delivery time. Frequency and percentages were calculated for qualitative variables like mode of delivery. Chi square test was used to compare qualitative variables between the groups while independent sample's t-test was applied for comparison of quantitative variables. A *p* value of less than <0.05 was taken as significant.

RESULTS

A total of 800 patients were included in the study. Each group was composed of 400 patients. Average age in Group A was 27.87 years (SD=4.676) while in Group B it was 27.68 years (SD=4.335), (*p*=0.190). The average Gestational age in Group A was 40.43 weeks (SD=1.255) and in Group B it was 40.48 weeks (SD=1.203), (*p*=0.262)

The mean induction to delivery interval for the total patients in study was 12.71 hours (SD=3.130). In Group A it was 13.15 hours (SD=2.927) while in Group B it was 12.28 hours (SD=3.267), (*p*=0.110).The comparison of caesarean section rate in dinoprostone and foley catheter group is illustrated in table-1.

The main indications for induction were absence of spontaneous contractions at 41 week (81.3%), pre-eclampsia (7.5%), oligohydramnios (2.6%), diabetes (4.5%) and others e.g. maternal request, decrease fetal movements and cholestasis of pregnancy.

DISCUSSION

Labour is achieved by transformation of connective tissue component and with gradual dilatation and effacement of the cervix. There are also rhythmic uterine contractions which are of an adequate force and extent. Induction of labour is basically an active intervention intended to start uterine contractions resulting in progressive effacement and dilatation of the cervix and ultimately delivery of the fetus. Induction generally speaking has two major components, cervical ripening and uterine contractility. Cervical ripening means the conversion of rigid cervical sphincter which was associated with maintenance of pregnancy

Table-1: Comparison of caesarean section rates among the study groups.

Caesarean section	Dinoprostone Vs Foley catheter		Total n (%)	*p*-value
	Group A n (%)	Group B n (%)		
Yes	102(25.5)	91 (22.7)	193 (24.2)	0.826
No	298 (74.5)	309 (77.3)	607 (75.8)	

to a dilated structure for the passage of the fetus.

Over the years many techniques for induction of labour have been developed. Prostaglandins for labour induction have been used since 1960. PGE2 use increases the likelihood of vaginal delivery rates in 24 hours without any increase in operative delivery rates. Currently the commonest method used for labour induction is intra-cervical application of Prostaglandin E2[7]. However there is a debate about their safety as they can cause nausea, vomiting and uterine hyperstimulation[8].

Cervical foley catheter has been used for labour induction. It induces cervical ripening by mechanical means without causing hypertonic uterine contractions. In addition to mechanical effect, it also stimulates the release of endogenous prostaglandins in the cervix[9]. The main advantages of mechanical methods are their cost effectiveness. Transcervical catheter insertion are associated with infection, that is why tremendous attention should be drawn towards carrying aseptic measures while using them to avoid maternal as well as neonatal infections[10].

Induction of labour is an established part of obstetrics these days. Many studies have been conducted on different methods of induction of labour. Mechanical methods were among the first techniques devised to induce labour. In recent times there is a trend shift towards the newer pharmacological methods for labour induction.

There are many studies conducted to determine any benefit for newer pharmacological agents over the previously employed mechanical method of labour induction. One such study was conducted by Onge in 1995. He conducted his study in a maternity care center in Canada. Rate of caesarean section in his study was 17.6% with foley while 25% in prostaglandin E2 group[11].

In 2001, Ghezzi conducted a similar study comparing multiparous and nulliparous women. The results of the study were more in favour of foley catheter[12]. In 2006, Saleem conducted a study with a sample size of 226. He also included misoprostol in his study groups. The results of his study depicted no benefit of any of the methods over the other[13].

In 2009 a study was published in BJOG, it also compared double balloon catheter as well. Besides measuring rate of caesarean section, it also measured other parameters like pain, hyperstimulation and induction to delivery time. In this study the rate of caesarean section was 36% with balloon catheter while it was 37% with PGE2[14].

During recent years a study was conducted in Groene Hart Hospital, Gouda, Netherlands in 2011, in which foley catheter was compared with prostaglandin E2 for labour induction at term. It was the first time when a large sample size of 824 was taken for the study purpose. Results of this study showed that the rate of caesarean section was 23% in foley catheter while 20% in prostaglandin group[15].

Present study was conducted in Combined Military Hospital, Peshawar. It is a tertiary care hospital with a huge turnover of patients. A total of 800 patients were included in study. Out of them, 400 patients were placed in group A in which dinoprostone was used while 400 patients in group B were induced with the help of foley catheter.

Table-2: Main indications for induction of labour among the study groups.

Main Indications for induction	Dinoprostone Vs Foley catheter		*p*-value
	Group A n (%)	Group B n (%)	
Absence of spontaneous contractions at 41week	323 (80.75)	328 (82)	0.206
Pre-eclampsia	31(7.75)	29 (7.25)	0.072
Diabetes	19 (4.75)	17 (4.25)	0.116
Oligohydramnios	12 (3)	9 (2.25)	0.440
Others	15 (3.75)	17 (4.25)	0.130

The mean age of the study sample was 27.78years. There was also no major difference in both the study groups as well (27.87 and 27.68). The mean induction to delivery time in the study sample was 12.71 hours. In group A in it was 13.15 hours, while in foley catheter group it was 12.28 hrs. It is obvious that there is no advantage in terms of induction to delivery time.While one study published in BJOG in 2008 showed slight advantage of foley catheter[16].

Out of 800 patients 193 (24.2%) underwent caesarean section. In Group A(Dinoprostone) 102 (25.5%) had caesarean. This was almost comparable with Foley catheter group 91 (22.7%). Thus, using foley catheter for labour induction will not increase the rate of caesarean section or the induction to delivery interval. The average cost of foley catheter 26fr is about 210 Rupees while a single tablet of dinoprostone costs about 425 Rupees. Hence the benefit of using foley catheter is its cost effectiveness.This relatively cheaper option will help reduce the cost when considering a hospital where turnover of the patients is large. Having said so, still there are newer pharmacological agents coming up with claims of even better results than prostaglandin E2[16].

CONCLUSION

Balloon catheter is safe and an effective method for labour induction. It has been used for many years and enjoys a good safety profile. Dinoprostone is also equally effective and safe but is a costly method for induction. Therefore in our setups Foley catheter may be recommended as a first choice for induction of labour.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

AUTHORS CONTRIBUTION

Mamoona Iqbal, Humaira Tariq, substantial, Humaira Chaudhry, conception, analysis, discussion and conclusion.

REFERENCES

1. Pennell C, Henderson J, O'Neill M, McCleery S, Doherty D, Dickinson J. Induction of labour in nulliparous women with an unfavourable cervix: a randomised controlled trial comparing double and single balloon catheters and PGE2 gel. BJOG. 2009; 116: 1443–52.
2. Prager M, Eneroth-Grimfors E, Edlund M, Marions L. A randomised controlled trial of intravaginal dinoprostone, intravaginal misoprostol and transcervical balloon catheter for Labour induction. BJOG 2008; 115: 1443–50.
3. Vahratian A, Zhang J, Troendle JF, Sciscione AC, Hoffman MK. Labour progression and risk of caesarean delivery in electively induced nulliparas. Obstet Gynecol 2005; 105: 698–704.
4. Moleti CA. Trends and controversies in labour induction. MCN Am J Matern Child Nurs. 2009; 34: 40-7.
5. Cromi A, Ghezzi F, Tomera S, Uccella S, Lischetti B, Bolis PF. Cervical ripening with the Foley catheter.Int J Gynecol Obstet. 2007;97:105–9.
6. Patro-Małysza J, Marciniak B, Leszczyńska-Gorzelak B, Bartosiewicz J, Oleszczuk J. Effectiveness of intracervical catheter as a Labour preinduction method. Ginekol Pol. 2010 ; 31-6.
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 ;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; 113(12): 1366-76.
9. 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.
10. Salva S, Nadeem FZ, Afia Z, Rahat NQ. Increased risk of cervical canal infections with Intracervical Foley Catheter. J Coll Physicians Surg Pak 2003; 13(3): 146-9.
11. St Onge RD, Connors GT. Preinduction cervical ripening: a comparison of intracervical prostaglandin E2 gel versus the Foley catheter. Am J Obstet Gynecol. 1995; 172 (2 Pt 1): 687-90.
12. Ghezzi F, Massimo F, Raio L, Di Naro E, Balestreri D, Bolis P. Extra-amniotic Foley catheter and prostaglandin E(2) gel for cervical ripening at term gestation. Eur J Obstet Gynecol Reprod Biol. 2001; 97(2): 183-7.
13. Saleem S. Efficacy of dinoprostone, intracervical foleys and misoprostol in Labour induction. J Coll Physicians Surg Pak. 2006; 16(4): 276-9.
14. Pennell CE, Henderson JJ, O'Neill MJ, McChlery S. Induction of labour in nulliparous women with an unfavourable cervix: a randomised controlled trial comparing double and single balloon catheters and PGE2 gel. BJOG. 2009; 116(11): 1443-52.
15. Jozwiak M, Oude Rengerink K, Benthem M, Foley catheter versus vaginal prostaglandin E2 gel for induction of labour at term (PROBAAT trial): an open-label, randomised controlled trial. Lancet. 2011; 378(9809): 2095-103.
16. Prager M, Eneroth-Grimfors E, Edlund M, Marions L. A randomised controlled trial of intravaginal dinoprostone, intravaginal misoprostol and transcervical balloon catheter for labour induction. BJOG. 2008; 115(11): 1443-50.