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Induction of labour with foley catheter is better alternative to misoprostol

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Abstract
AIM- The aim of this study was to compare the efficacy of induction of labour with Foley balloon inflation to 60ml with sublingual misoprostol. MATERIALS AND METHODS -This randomised controlled trial (n= 320) was performed on women with singleton pregnancy with cephalic presentation and unfavourable cervix admitted in RG Kar Medical College during the period of July 2011 to June 2012. In Foley group, labour was induced by placing No. 20 transcervical Foley catheter and inflating the balloon to 60 ml along with intravenous oxytocin. In Misoprostol group, sublingual misoprostol was used, 25 mcg every 4 hours to a maximum of 5 doses until adequate uterine contractions. Intravenous oxytocin was administered in patients with protraction or arrest disorders. RESULTS -The two groups were similar in demographic characteristics, indication for induction, pre-induction Bishop score, maternal and fetal complications. Time from induction to delivery was significantly shorter in Foley catheter group compared to misoprostol group(15.19+2.83 vs 16.16+3.35 hr, $p<0.05$). Mean post induction Bishop Score at 6 hours and 12 hours was significantly higher in Foley catheter group compared to misoprostol group (5.98+1.46 vs 4.95+1.33 and 8.45+1.5 vs 7.12+1.6, $p<0.05$). CONCLUSION - labour induction with Foley catheter is a safe and effective method of with less induction to delivery time. It avoids the side effects of misoprostol like nausea, vomiting, diarrhoea, fever shivering as well as uterine complications like tachysystole, rupture, and fetal death. CLINICAL SIGNIFICANCE –Induction of labour by Transcervical foley is a better alternative to misoprostol and should me more widely used.

Keywords: Induction of labour, foley, misoprostol, bishop score, mean time to induction

Introduction
Labour must be induced artificially when benefits of termination of pregnancy outweighs those of continuing pregnancy. Currently a quarter of all pregnant women in industrialized countries undergo artificial induction of labour [1]. For induction of labour two different approaches are used, which are often used in combination. The first one being cervical ripening with or without stimulating uterine contractions and the second one being uterine contractions leading to cervical effacement and dilatation [2].
Methods of cervical ripening constitute administration of synthetic prostaglandin E1 (PGE1) and prostaglandin E2(PGE2). Although prostaglandins are one of the most common methods of induction of labour, it has several side effects like nausea, vomiting, diarrhoea, shivering, fever, uterine hypertonus, tachysystole, hyperstimulation and meconium stained liquor. Rarely it may also cause uterine rupture [3]. Mechanical method like transcervical Foley catheter is one of the oldest methods with minimal complication. Along with mechanical dilation it also stimulates release of endogenous prostaglandins from fetal membranes [4]. The aim of our Randomised controlled study was to compare induction of labour with 60 ml Foley balloon inflation and 25 mcg sublingual misoprostol and its effect on maternal and fetal outcomes.

Materials and methods
The study was designed as a prospective comparative randomised controlled study on 320 primigravida with singleton pregnancy (gestational age >/= 36 weeks) with cephalic presentation and unfavourable cervix (Bishops Score <6) requiring induction of labour for maternal or fetal indications. Exclusion criteria being multiple gestation, rupture of membranes, non cephalic presentation, multiparous mother or with prior caesarean delivery. The study protocol was cleared with local institutional ethics committee. Informed consent was obtained from all patients. The patients were randomised into two groups the Foley catheter group, the

misoprostol group, having 160 women in each group.

Patients in Foley group were treated with No. 20 Foley catheter which was placed trans-cervically either by digital or speculum method and the balloon was inflated by 60 ml normal saline. Intravenous oxytocin was started after 60 minutes @ 1-2 mUnits/ min and was gradually increased by 1-2 mUnits/min every 30 minutes, if needed. Eventual expulsion of Foley balloon was noted. Patients in misoprostol group were treated with 25 mcg sublingual misoprostol every 4 hours to a maximum of 5 doses until adequate uterine activity was achieved i.e; >/= 3 contractions in 10 minutes. In active phase of labour, intravenous oxytocin was administered in protraction or arrest disorder after ruling out fetal distress or overt fetopelvic disproportion. Progress of labour was monitored by partograph in all patients. The maternal and fetal outcomes in both the groups were compared.

Result and analysis

Data was analysed by SPSS software [IBM Inc.] $p<0.05$ was taken to be statistically significant. Patients were comparable age-group wise. [Table 1] Indication for induction of labour [Table 2], Pre-induction BISHOP scoring [Table 3], uterine contractions [Table 5] were similar in both the groups. Bishops score at 6 hours and 12 hours post induction was statistically higher in Foley group compared to misoprostol group (5.98+1.46 vs 4.95 +1.33 cm and 8.45+1.5 vs 7.12 +1.6 cm, $p< 0.05$) [Table 3]. The mean induction to delivery time was significantly shorter in Foley group A compared to Misoprostol group and this was found to be clinically significant. (15.19+2.83 vs 16.16+ 3.35 hr, $p< 0.05$) [Table 4]. Maternal and neonatal complications were also similar in both the groups. [Table 6]

Discussion

Induction of labour is indicated when risk due to continuation of pregnancy outweighs that of termination of pregnancy [1]. Induction with use of prostaglandins is widely accepted as a standard method. Sublingual route was used assuming that it has higher efficacy than vaginal route [5]. It also avoids the first pass effects of gastrointestinal and hepatic systems [6]. while uterine hyperstimulation rates may be the same as vaginal misoprostol [7]. Foley catheter in our study was used due to its cost effectiveness, reversibility and minimal side effects. Risk of perinatal infection is also negligible [8].

Misoprostol and transcervical Foley catheter are considered appropriate inducing agents by ACOG [9]. Despite the data supporting its use, there is still controversy regarding misoprostol as an inducing agent as it can cause uterine rupture maternal [10]. and fetal morbidity or mortality [11]. Although in our opinion, misoprostol when used correctly remains an appropriate agent for labour induction. For those who do not want to use misoprostol, the results from our study must be reassuring that the use of transcervical Foley catheter has less induction to delivery interval with no increase in uterine hypertonicity. Maternal complication like post partum haemorrhage was seen in both the groups and were controlled by medical management. Neonatal morbidity was due to HIE 1 and 2, meconium aspiration and NICU admission was seen in few babies and was comparable in both the groups. These babies were admitted in NICU for some duration and got treated and were discharged. There was no neonatal mortality till the babies were in hospital.

Conclusion

The results of our randomized trial show that labour induction with Foley catheter is a safe and effective method with less induction to delivery time. It avoids the side effects of misoprostol like nausea, vomiting, diarrhoea, fever, shivering as well as uterine complications like tachysystole, rupture (specially in women who had previous caesarean section), and fetal death.

Given the proven feasibility of using Foley catheter and the same being readily available, cost effective and with low frequency of systemic side effects, we believe that application of transcervical foley catheter is a better alternative to using misoprostol and should be used more widely and frequently.

Acknowledgement

This study was approved and reviewed by institutional ethics committee and have been performed in accordance with the ethical standards described in an appropriate version of the 1964 Declaration of Helsinki, as revised in 2013 The authors did not receive any material or financial help during this study.

Table 1: Comparison of age groups

Age	Foley group	Misoprostol group	
18-21 years	61(38.2%)	65(40.7%)	p =0.881
22-28 years	92(57.5%)	89(55.6%)	
>28 years	7(4.3%)	6(3.7%)	

Table 2: Indication for induction of labour

Indication of Induction	Foley group	Misoprostol group	
IUGR	18 (11.3%)	15(9.3%)	p =0.751
GDM	8 (5%)	10(6.2%)	
PIH	22(13.7%)	17(10.6%)	
Post-dated	59(36.8%)	56(35.2%)	
PROM	53(33.2%)	62(38.7%)	
Grand total	160(100%)	160(100%)	

Table 3: Pre and post induction Bishop Score comparison

BISHOP score	Foley Group	Misoprostol group	
Pre-induction	3.40 ± 1.25	3.20 ± 1.22	p = 0.14
6 hr post-induction	5.98 ± 1.46	4.95 ± 1.33	p <0.0001
12 hr post-induction	8.45 ± 1.5	7.12 ± 1.6	p <.0001

Table 4: Comparison of induction to delivery interval

Induction –Delivery Interval	Foley group	Misoprostol group	
Mean(hours)	15.19	16.16	p = 0.005
SD	2.83	3.35	

Table 5: Comparison of uterine contraction

Uterine contraction	Foley group	Misoprostol group	
Adequate	108 (67.6%)	123(76.8%)	p = 0.08
Inadequate	49(30.6%)	32(20.1%)	
Hypertonic	3(1.8%)	5(3.1%)	

Table 6: Maternal and neonatal complications

Complications		Foley group	Misoprostol group
Maternal	Uterine rupture	0	0
	PPH	8	7
	CPT	0	1
	Maternal death	0	0
Neonatal	HIE 1	10	11
	HIE 2	2	2
	Convulsion	2	1
	Meconium Aspiration	4	5
	Hypoglycemia	0	1
	NICU admission	3	4

References

1. Marconi AM. Recent advances in the induction of labor. F1000Res. 2019; 8:F1000. Faculty Rev-1829. Published 2019 Oct 30.
2. Hofmeyr GJ, Alfirevic Z, Kelly AJ, *et al.* Methods for cervical ripening and labour induction in late pregnancy: Generic protocol. Cochrane Database Syst Rev. 2009; 116:562
3. Allen R, O'Brien BM. Uses of misoprostol in obstetrics and gynecology. Rev Obstet Gynecol. 2009; 2(3):159-168.
4. Gommers JSM, Diederen M, Wilkinson C, *et al*. Risk of maternal, fetal and neonatal complications associated with the use of the transcervical balloon catheter in induction of labour: A systematic review. Eur J Obstet Gynecol Reprod Biol. 2017; 218:73-84.
5. Alfirevic Z, Keeney E, Dowswell T, *et al*. Labour induction with prostaglandins: a systematic review and network meta-analysis. BMJ. 2015; 350:h217. 10.1136/bmj.h217
6. Amini M, Reis M, Wide-Swensson D. A Relative Bioavailability Study of Two Misoprostol Formulations Following a Single Oral or Sublingual Administration. Front Pharmacol. 2020; 11:50.
7. Alfirevic Z, Aflaifel N, Weeks A. Oral misoprostol for induction of labour. Cochrane Database of Systematic Reviews. 2014; 6:CD001338.
8. Cromi A, Ghezzi F, Tomera S, Uccella S, Lischetti B, Bolis PF. Cervical ripening with the Foley catheter. Int J Gynaecol Obstet. 2007; 97(2):105-109. doi:10.1016/j.ijgo.2006.10.014
9. ACOG Committee on Practice Bulletins -- Obstetrics. ACOG Practice Bulletin No. 107: Induction of labor. Obstet Gynecol. 2009; 114(2 Pt 1):386-397.
10. Melanie M. Plaut, Martin L. Schwartz, Suzanne L. Lubarsky MD. Uterine rupture associated with the use of misoprostol in the gravid patient with a previous cesarean section. AJOG. 1999; 180(6):P1535-1542.
11. Heimstad R, Romundstad PR, Eik-Nes SH, Salvesen KA. Outcomes of pregnancy beyond 37 weeks of gestation. Obstet Gynecol. 2006; 108(3 Pt 1):500-508.