Original article

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Comparative Study of Transcervical Foley Catheter Versus 50 μg Intravaginal Misoprostol for Induction of Labor

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Abstract

Objectives

To determine and compare the efficacy and safety of transcervical foley catheter and 50μg intravaginal misoprostol for induction of labor after 37 completed weeks of gestation and to determine the maternal and fetal outcome. *Materials and Methods:* This was a prospective study conducted from March 2014 to August 2015 in R.L Jalappa Hospital and Research centre, Tamaka, Kolar. A total of 200 cases were included in the study. Each group was alternatively induced with transcervical foley catheter and 50μg of intravaginal misoprostol. The two groups were comparable with respect to maternal age, parity, gestational age and pre induction modified bishop score. Post induction bishop score after 6hours, induction delivery interval, mode of delivery, maternal and fetal outcomes were recorded. The collected data was analyzed using student 't' test and chi square test. *Results*: The groups were comparable with respect to maternal age, parity, gestational age and pre induction modified bishop score. The mean induction to active stage was significantly less in misoprostol group (7.46±4.82hrs) when compared to foley catheter group (9.7±4.47hrs) with p=0.01**. Mean induction to delivery interval was less in misoprostol group (14.59±5.57) when compared to foley catheter group (15.67±4.91) with p value of 0.005**. The requirement of oxytocin augmentation was significantly more in foley catheter group with p<0.001**.

The cesarean section rate was high in foley catheter group (40%) when compared to misoprostol group (29%) with p=0.223 which was not statistically significant. Apgar scores, birth weight, neonatal intensive care unit admissions and maternal side effects showed no difference between two groups. *Conclusion:* Misoprostol as a method of induction of labor intravaginally in dosage of 50μg is more efficacious than transcervical foley catheter in terms of shorter induction delivery interval and less oxytocin augmentation.

Maternal and perinatal outcomes were similar in both the methods of induction confirming the safety of both methods.

Keywords: Foley Catheter; Induction of Labor; Misoprostol.

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Introduction

Induction of labor at term is defined as artificial initiation of uterine contractions for termination of pregnancy after 37 completed weeks of gestation either due to maternal, fetal or combined indications by any method aimed at initiation of labor to delivery. For majority of women labor starts spontaneously and results in vaginal delivery at or near term [1].

Induction of labor is indicated when the benefits of delivery to mother and fetus outweigh the potential risks of continuing the pregnancy [2]. Labor is commonly induced in response to a number of fetal and maternal situations, including post term pregnancy, preeclampsia and rupture of the

membranes without the onset of spontaneous contraction. Induction rates between 10% and 25% are common in industrialized countries. The induction of labor is aimed at, to deliver a healthy baby and to maintain the health of the mother [3].

Over the last two decades, there has been an abrupt increase in the labor induction rate, from 9.5% in 1990 to 21.2% in 2004 [4]. The use of foley catheter for induction of labor was first described in 1967 [5]. Currently, Foley catheter balloon is the most commonly used mechanical device for cervical ripening and labor induction, which acts not only as a mechanical dilator of the cervix but also a stimulator of endogenous prostaglandins release from the fetal membranes [6].

In the latter half of 20th century, the biological roles of prostaglandins in labor process have been studied [7]. Prostaglandin E analogue (PGE1) misoprostol is a new promising agent for labor induction. Initially it was approved for treatment of gastric ulcers but later it has been evaluated for induction of labor since 1992 [8].

Various studies have compared transcervical foley catheter with intravaginal misoprostol for induction of labor. Although existing evidence suggests that both foley catheter and misoprostol are appropriate for induction of labor at term, further large prospective trials are required to define an optimal and safe method. In this regard, the objective of this study is to compare the efficacy of transcervical foley catheter with intravaginal misoprostol for induction of labor.

Aims and Objectives

1. To determine efficacy and safety of transcervical Foley catheter in induction of labor
2. To determine efficacy and safety of intravaginal Misprostol in induction of labor
3. To compare maternal and fetal outcomes between the two groups

Materials and Methods

Total of 200 patients who required induction of labour for any medical or obstetric indication, admitted to RL Jalappa Hospital and Research Centre, Tamaka, Kolar during March 2014 to July 2015.

Inclusion Criteria

- Gestational age of 37weeks or more
- A single live fetus with cephalic presentation
- Intact membranes
- Modified bishop score of 5 or less

Exclusion Criteria

- Antepartum hemorrhage
- Previous cesarean section
- Gravida ≥5
- Any contraindication to vaginal delivery
- Allergy to prostaglandins

Written informed consent was obtained for each woman before participation.

Method of Collection of Data

It was a prospective study conducted in the Department of Obstetrics and Gynecology attached to Sri Devaraj Urs Medical College, Tamaka, Kolar from March 2014 to July 2015

Total 200 cases meeting inclusion criteria were divided into two groups- Group A (100 cases foley catheter) and Group B (100 cases intravaginal misoprostol) alternatively. The two groups were comparable with respect to maternal age, parity, gestational age and pre induction modified bishop score.

A complete history including maternal age, parity, gestational age were noted. Abdominal examination was done to know the presentation, uterine tone and fetal heart rate. Per vaginal examination was done to know the modified bishop score and to rule out cephalopelvic disproportion. Cardiotocograph (CTG) and obstetric scan were done to all patients to ascertain the fetal well being. An informed written consent was taken prior to induction.

Group A cases were placed in the lithotomy position, a cusco's speculum was inserted and cervix was visualized and cleaned with povidone iodine. The anterior lip of cervix was grasped with a ring forceps and a 16F foley catheter with 30ml balloon was inserted into the endocervical canal under direct vision. Once past the internal os, the balloon was filled with 30ml of distilled water and catheter strapped to the inner thigh to maintain traction. The catheter was checked for extrusion of balloon from the cervix every 6 hours by vaginal examination. The catheter was remained in place until the balloon was expelled spontaneously or removed at the end of 12 hours of insertion. Oxytocin infusion was initiated in those patients with inadequate uterine contractions after the expulsion or removal of catheter.Women

enrolled in group B, misoprostol 50µg tablet was placed intravaginally in the posterior fornix and the dose was repeated every 6 hours, till patient gets adequate uterine contractions (3 contractions in 10min) or cervical dilatation of >3cm or maximum of 6 doses. If they do not respond to above protocol, they will be considered failed induction and further PGE2 or oxytocin was used for delivery. All women underwent cardiotocography 20minutes after administration of misoprostol. In both groups, progress of labor was monitored by partogram in active stage of labor. Labor was augmented with oxytocin if required.

Statistical Analysis

Student 't' test has been used to find the significance of study parameters on continuous scale between two groups on metric parameters. Chi- square/ Fisher exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables.

Results

Both the groups were comparable with respect to the maternal age, gestation age, indication for induction, and pre-induction bishop's score (Table 1).

No statistically significant difference was demonstrated between the two groups.

Table 1: Comparison of maternal demographic characteristics in two groups

Maternal demographic characteristics	Group A (Foley) (n=100)	Group B (Misoprostol) (n=100)
Age in years	23.83±2.45	24.00±2.75
Nullipara	73(73.0%)	76(76.0%)
Multipara	27(24.0%)	24(24.0%)
Gestational Age	39.92±0.89	39.95±0.86
Pre induction modified bishop score mean±SD)	3.18±0.65	3.18±0.64

Table 2: Post induction bishop score after 6 hours

Post induction bishop score after 6 hours	Group A (Foley) (N=100)		Group B (Misoprostol) (N=100)	
	No	%	No	%
6	69	69.0	61	61.0
7	29	29.0	35	35.0
8	2	2.0	4	4.0

The mean post induction bishop score after 6hours in group A was 6.27±0.51 and in group B was 6.32±0.66 with p value of 0.435 , which was statistically not significant

Table 3: Induction to active stage interval in vaginally delivered cases

Induction to active stage(hours)	Group A (Foley) (n=60)		Group B (Misoprostol) (n=71)	
	No	%	No	%
≤8	27	45	48	67.6
9 - 16	25	41.6	21	29.5
≥17	8	13.3	2	2.8
Mean ±SD	9.7±4.47		7.46±4.82	
Inference	Mean induction to active stage interval was significantly less in Group B (7.46hrs) when compared to Group A (9.70hrs) with P=0.01**			

** Strongly significant

Table 4: Induction to delivery interval in vaginally delivered cases

Induction to delivery interval (hours)	Group A (Foley) (n=60)		Group B (Misoprosotl) (n=71)	
	No	%	No	%
≤12	12	20.0	44	62.0
13-24	40	66.7	25	35.2
25-36	8	13.3	2	2.8
Mean± SD	15.67±4.91		14.59±5.57	
Inference	Mean induction delivery interval is significantly less in Group B when compared to Group A with p= 0.005**			

** Strongly significant

Table 5: Requirement of oxytocin augmentation

Oxytocin augmentation	Group A (Foley) (n=60)		Group B (Misoprostol) (n=71)	
	No	%	No	%
Required	57	95%	22	30.9%
Not required	3	5%	49	69%
Inference	Requirement of Oxytocin augmentation is significantly more in Group A with P<0.001**			

** Strongly significant

Table 6: Mode of delivery

Mode of Delivery	Group A (Foley) (N=100)		Group B (Misoprostol) (N=100)	
	No	%	No	%
Vaginal Delivery	57	57.0	66	66.0
Assisted vaginal delivery	3	3	5	5
Cesarean section	40	40	29	29

Table 7: Maternal adverse effects

Maternal Adverse effects	Group A (Foley) (n=100)		Group B Misoprostol) (n=100)		P value
	No	%	No	%	
Fever and chills	1	1.0	2	2.0	1.000
Postpartum hemorrhage	1	1.0	3	3.0	0.621
Cervical tear	0	0.0	1	1.0	1.000
Nausea and Vomiting	0	0.0	1	1.0	1.000

Table 8: Fetal outcome

Fetal outcome	Group A (Foley) (n=100)		Group B (Misoprostol) (n=100)		P value
	No	%	No	%	
Birth weight(kgs)					
<2.5	2	2	2	2	0.786
2.5-3.5	96	96	95	95	
>3.5	2	2	3	3	
1 minute Apgar <7	6	6.0	5	5.0	0.756
5minute Apgar<7	3	3.0	2	2.0	0.651
Meconium stained liquor	20	20.0	30	30.0	0.102
Neonatal resuscitation	25	25.0	30	30.0	0.428
NICU admission required	11	11.0	16	16.0	0.301

In group B 67.6% (48/71) went into active stage of labour within 8hours of induction where as in group A only 45% (45/60) went into active labour within 8hours.

The mean induction to active stage was significantly less in group B (7.46±4.82hrs) when compared to group A (9.7±4.47hrs) with p=0.01**.

44 cases (62%) delivered within 12 hours of induction in group B when compared to only 12 cases (20%) in group A, with p value 0.001** .

Mean induction delivery interval was less in group B (14.59±5.57) when compared to group A (15.67±4.91) with p value of 0.005**.

In group A, 57 cases (95%) required oxytocin augmentation whereas only 22 cases (30.9%) required oxytocin in group B. Thus the requirement of oxytocin augmentation was significantly more in group A with p<0.001**.

In group A, 60% delivered vaginally whereas in group B 71% delivered vaginally.

Assisted vaginal delivery was 3% in group A and 5% in group B.

The cesarean section rate was high in group A (40%) when compared to group B (29%) with p=0.223 which was not statistically significant.

Maternal minor adverse effects (nausea, vomiting) were 1 in group B when compared to no case in group A. Fever and chills were 2% and 1% among group B and group A respectively with p value of 1.000. Postpartum hemorrhage was 1% and 3% among group A and B respectively with p=0.621.1 case of cervical tear was noted in group B and no case

was noted in group A.

Table 8 shows that 1 min and 5 min Apgar score were similar in both the groups. The neonatal birth weights were also comparable in both the groups. 11% of babies in Group A and 16% of babies in Group B got admitted in the neonatal intensive care unit (NICU). However, the morbidity in both the groups were not statistically significant.

Discussion

Induction of labor is indicated for termination of pregnancy at term for various medical, obstetric and other conditions. The main concerns with induction of labor are prolonged labour, failed induction, and excessive uterine activity which may cause fetal distress. These problems may lead to increased risk of cesarean section [9]. This study compares the efficacy and safety of transcervical foley catheter versus intravaginal misoprostol for induction of labor.

In the present study maternal age, parity and gestational age were similar in both the groups. Indications for induction of labor were statistically similar between both the groups, the most common being postdated pregnancy in both the groups.

In present study, the mean post-induction bishop score after 6 hours in foley group was 6.27±0.51 hour and in misoprostol group was 6.32±0.66 hour which was statistically not significant with p value of 0.435. The mean induction to active stage interval was significantly less in misoprostol group (7.46±4.82 hrs) when compared to foley catheter group (9.7±4.47hrs) with p= 0.01**.

In the present series, 62% (44/71) of patients delivered vaginally within 12 hours of induction in misoprostol group compared to only 20% (12/60) in foley group with p= 0.001** which was consistent with study by Jani P S where 57.3% patients delivered within 6 hours in misoprostol group , whereas only 8% delivered in foley's catheter with p< 0.001 [10].

In the present study, the mean induction to delivery interval was significantly shorter (14.59±5.57hrs) in misoprostol group when compared to (15.67±4.91hrs) foley catheter group with p= 0.005** which was comparable to study by Owolabi et al who concluded that induction to delivery interval was significantly shorter in the misoprostol group than in foley group with 8.7±2.4 hour and 11.9±2.7 hour respectively [11]. The shorter induction delivery interval in misoprostol group could be explained on the basis of greater oxytocic effect on uterus via vaginal route due to direct access to myometrium by cervical canal [6]. Kharel S (2010) in his study found that the induction to delivery interval in the misoprostol group was 1293.72 ± 881.35 minutes compared with 1505.10 ± 736.36 minutes in the catheter group which was not statistically significant (P value 0.19) [12].

Oxytocin augmentation was required more in foley group (95%) as compared to misoprostol group (30.9% ; p value< 0.001**) which is comparable to the study done by Kharel S et al [12]. This is in contrast to study conducted by Fareed P in 2015 who found that 67% of women in foley catheter group required augmentation as compared to 61% in misoprostol. There was no significant difference in the need for augmentation of labor in both the groups [13].

In the present study, 60% delivered vaginally in foley catheter group and 71% delivered vaginally in misoprostol group. Cesarean section was more common among foley group 40% when compared to 29% in misoprostol group. This was statistically not significant with p value of 0.223

In the present study, 86.2% underwent cesarean section for fetal distress among misoprostol group compared to 90% among foley group with p value of 0.236.

Maternal minor adverse effects (nausea, vomiting, fever) were more in misoprostol group (7 cases) when compared to foley group (2 cases) but did not reach statistical significance (p=1.000). In present study, the incidence of postpartum hemorrhage was 1% in group A and 3 % in group B. In our study, there were no cases of abnormal uterine contractions in both the group which was comparable to a study by Kharel S [12].

In our study there was no incidence of infection in foley catheter group. This was consistent with study by Kharel S [12].

In the present study, meconium stained liquor was seen in 30% of cases in misoprostol group compared to 20% in foley group which was not statistically significant with p= 0.102. Jani P S in his study found meconium passage occurred more in misoprostol group (28%) than in foley catheter group (18%) which was not statistically significant [10].

1 minute Apgar score <7 was 6% in group A and when compared to 5% in group B which was not statistically significant. Neonatal resuscitation was 25% in group A and 30% in group B which was not statistically significant. NICU admission was 11% in group A and 16% in group B. Neonatal outcomes were similar in both the groups.

Conclusion

Fifty µg Misoprostol intravaginally as a method of induction of labor is more efficacious than Transcervical Foley catheter in terms of shorter

induction delivery interval and less oxytocin augmentation. Maternal and perinatal outcomes were similar in both methods of induction confirming the safety of both methods.

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