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LABOR INDUCTION WITH COMBINED LOW DOSE VAGINAL MISOPROSTOL WITH FOLEY CATHETER VS VAGINAL MISOPROSTOL IN POSTDATE NULLIPAROUS WOMEN- A RANDOMIZED STUDY

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ABSTRACT **Objective-** To compare the effect of IOL in nulliparous postdate pregnant women with misoprostol with and without foley catheter (30cc) on induction to delivery interval. **Materials and Methods-** This was randomized case control study done on 200 nulliparous low risk women which was done over a period of 1 year from January 2019 to January 2020. **Results-** The demographic characteristic of the women were comparable in both of the study groups. The induction to delivery interval (min) in group 1 was 878.1±169.5 (mean±SD) and in group 2 was 1088.1±224.4 (mean±SD) ($p < 0.001$). The time to active labor (min) in group 1 was 501.0±137.8 (mean±SD) and in group 2 was 675.4±210.6 (mean±SD) ($p< 0.001$). Duration of labor in group 1 was 454.6±102 (mean±SD) and in group 2 was 493.2±122.2 (mean±SD) which was highly statistically significant ($p<0.001$). Oxytocin augmentation was required in 5 women in group 1 and 17 women in group 2 ($p= 0.013$). Bishop score significantly improved in combination group ($p<0.01$). Lesser number of doses of misoprostol required in combination group ($p<0.001$). No significant difference with respect to mode of delivery and also in neonatal outcomes in both of the study groups.

KEYWORDS : Induction Misoprostol Foley catheter

INTRODUCTION

Induction of labor implies stimulation of contractions before the spontaneous onset of labor, with or without ruptured membranes. It is one of the most commonly performed interventions in the obstetrics. It is often indicated when the risks of continuing pregnancy outweigh the benefits to the mother and fetus. The aim of the procedure is to achieve cervical ripening and stimulate uterine contractions before beginning of labor and it is performed due to obstetric or fetal indications.[1] Postdate pregnancy, which has been known to be the most common indication of induction, has an average frequency of 10%[2] and occurs when pregnancy exceeds 40 weeks of gestation beyond which pregnancy is advised to terminate because of possible detioration of placental function. About 15 % of all gravid women with unfavorable bishop score may need cervical ripening.[3] Although there are several techniques and agents to assist in cervical ripening for IOL, but the best agent or method remains uncertain. Induction of labor can be achieved by chemical (for example prostaglandins and oxytocin), mechanical (transcervical foley catheter, amniotomy and laminaria tents) or both. Fore water amniotomy and oxytocin titration are the most common established methods of induction of labor. Cervical ripening is attempted first mainly by the use of prostaglandins or by mechanical methods such as transcervical foley catheter. Misoprostol- a synthetic prostaglandin E1 analogue frequently used for IOL worldwide, mainly because of its low cost and easy storage. It is recommended by the American College of Obstetricians and Gynecologists, Royal College of Obstetricians and Gynecologists, as well as the International Federation of Gynecology and Obstetrics (FIGO) and the WHO.[4,5] Its use can result in shorter induction to delivery interval and reduced requirements for oxytocin. However, uterine contractile abnormalities, uterine rupture, meconium passage and fetal heart abnormalities are possible complications of its use. Foley catheter is the most common mechanical method and one of the oldest method. It has several potential advantages over pharmacologic methods. They are relatively inexpensive, easy to store, and easy to remove when necessary, lacks systemic side effects, reversible with reduced risk of uterine hyper stimulation.[6] The WHO guidelines for IOL recommend foley as one of the first line methods for IOL (moderate quality evidence, strong recommendation).[7] Both the methods are supported by ACOG due to their high safety profile and comparative effectiveness.[8] Thus, although the best agent and method for induction of labor remains uncertain, it is biologically plausible that a combination of a mechanical methods and chemical agent may have a synergistic effect, resulting in a greater degree of cervical ripening and shorter induction-to-delivery interval. Hence this study was planned to compare the concurrent use of vaginal misoprostol with and without foley catheter for IOL in postdate nulliparous women.

Aims and Objective

To compare the effect of IOL in nulliparous postdate pregnant women with misoprostol with and without TCFC (30cc) on induction to delivery interval. The outcome was measured in terms of induction to delivery interval, time to active labor, need for oxytocin augmentation, hyperstimulation, number of women delivered vaginally within 24 hours and APGAR score of the neonates.

MATERIALS AND METHOD

This study was conducted on nulliparous women admitted for IOL in labor room of Department of Obstetrics and Gynecology, Dr. Rajendra Prasad Government Medical College Kangra at Tanda (Himachal Pradesh)- a tertiary care institute in sub himalayan region of India.

Study Design

This was randomized case control trial which was done over a period of 1 year from January 2019 to January 2020. It was performed after taking permission of the ethical committee of the Dr. Rajendra Prasad Government Medical College.
(Registration no. ECR/866/Rajendra/Inst/HP/2013/108 dated 10.1.2019)

Inclusion Criteria

1. Age group 18 to 35 yrs.
2. Nulliparous pregnant women with period of gestation (POG) more than or equals to 40 weeks.
3. Intact membrane.

Sample Size

The sample size was estimated a priori based on primary outcome. We calculated that to achieve 80% power to detect a difference of 180 minutes between the mean induction to delivery interval of the two groups, minimum 188 women had to be randomized in to 2 groups (94 women in each group) using a two-sided t test and accepting an error of 0.05. We took a sample size of 100 women in each group.

Data Collection

A proforma was filled in every case including detailed history, age, gravida status, gestational age, menstrual history, past, family and personal history were all recorded. General physical examination was done in every case as well as complete obstetric examination. Routine investigations including USG was performed. Fetal well being was assessed by the help of NST and BPP, if required.

Definitions Used

Fetal distress: non reassuring or abnormal cardiotocography (CTG) readings.
Hyperstimulation: presence of >5 contractions in 10 minutes or a contraction exceeding 2 minutes with FHR abnormalities.
Postpartum hemorrhage: any amount of blood loss causing signs or symptoms of hypovolemia.
CTG abnormalities: abnormal CTG patterns as per the American College of Obstetricians and Gynecologists guidelines.
Meconium-stained liquor (MSL): dark green or pea soup amniotic

fluid that is thick, tenacious, and contains lumps of meconium.

Chorioamnionitis- It is defined clinically whenever temperature more than100.4°F persisting more than 1hour or any fever ≥101°F during labor or in puerperium with associated 2 or more clinical features-

1. Maternal or fetal tachycardia
2. Foul discharge per vaginum
3. Uterine tenderness
4. Maternal leukocytosis

Methodology

After satisfying inclusion and exclusion criteria. Informed consent was taken by all the participants in the study. Randomization was done through a computer-generated assignment that used simple randomization with one to-one allocation for each arm of the study. The allocation was concealed by placement in sequentially numbered, opaque, sealed envelopes that was drawn in a consecutive order. A total number of 200 women were randomized either of the two groups.

Group 1- They received misoprostol 25 micrograms which was inserted per vaginally and Foley catheter was simultaneously inserted through internal os with the use of sterile speculum. It was inflated with 30 ml normal saline and taped to inner side of thigh with under traction so that balloon could exert pressure on the cervical os. Bishop score assessment and administration of misoprostol was done every 4 hours up to maximum of 5 doses if bishop score was <6. It was removed if there was spontaneous leakage per vaginum and if it did not expelled within 12 hours of IOL. In case of expulsion of FC, bishop score was assessed. If the bishop score was more than 6, misoprostol was discontinued and further management was at the discretion of the labor room team.

Group 2- They received misoprostol 25 mcg vaginally which was repeated every 4 hours maximum up to 5 doses. Misoprostol was discontinued once the bishop score more than equals to 6, in presence of uterine contractions, MSL and fetal distress.

In both of the groups, once the cervix became favorable (bishop score greater than 6) or if the patient was in active labor, misoprostol was discontinued and further management was at the discretion of labor room team and this included expectant management, artificial rupture of membrane or oxytocin infusion. Oxytocin was initiated in all patients 6 hours after last misoprostol dose in those patients who did not had 3 regular contractions lasting for about 45 seconds in 10 minutes. It was started as an infusion beginning at 4mIU per minute in an escalating pattern with a maximum dose of 42mIU/min until adequate contractions are established. Continuous fetal heart rate monitoring and uterine contraction monitoring were performed in all women. WHO partograph was employed for monitoring the progress of labor in all the women participated in the study. A close watch was kept over meconium stained liquor, fetal distress and hyperstimulation was duly recorded. If there was no improvement of bishop score even after administration of maximum doses of misoprostol, administration of misoprostol was discontinued and further management was on discretion of senior consultant of labor room.

Statistical Analysis

It was performed by SPSS 19 software for windows using parametric and non-parametric tests when appropriate. p value <0.05 was deemed statistically significant.

OBSERVATIONS AND RESULTS

From January 2019 to January 2020, 230 women were assessed for eligibility, out of which 200 women were allocated to the study. (Figure 1) They were randomized in to two groups. No women were excluded from analysis from both of the groups. (Figure 1)

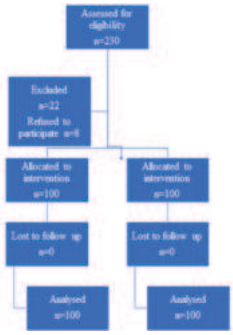

Figure 1: Flowchart Of The Participants

Demographic Characteristics

The demographic characteristic between both of the group was comparable. The age (years) of women in group 1 was 26.0±1.5 (mean±SD) and in group 2, it was 26.1±1.3 (mean±SD) which was statistically insignificant (p=0.765). The BMI (Kg/m2) of women in group 1 was 28.0±1.1 (mean±SD) and in group 2, it was 27.9±1.1 (mean±SD) which was statistically insignificant (p=0.511). In group 1, 85 had no previous one abortion and 15 had one previous abortion. In group 2, 82 had no previous one abortion and 18 had previous one abortion which was statistically in significant (p=0.568). The POG (days) in group 1 was 283.4±1.5 (mean±SD) and in group 2, it was 283.6±1.6. (mean±SD) which was statistically insignificant(p=0.262). In group 1, the bishop score (n) at admission was 3 [median (IQR; 2-3)] and in group 2, it was 3 [median (IQR;3-4)] which was statistically insignificant(p=0.192). (TABLE 1)

Table 1 Demographic Characteristics

Characteristics	Group 1 (n=100)	Group 2 (n=100)	p value
Age (years)#	26.0±1.5	26.1±1.3	0.765
BMI (Kg/m2) #	28.0±1.1	27.9±1.1	0.511
Parity$ 1.No previous abortion	85	82	0.568
2. Previous one abortion	15	18	
POG (days)#	283.4±1.5	283.6±1.6	0.262
Bishop score at admission*	3 [2.-3]	3 [3-4]	0.192

#Data expressed as mean±SD; #Independent t-test. $Data expressed as frequency. *Data expressed as median [IQR], Mann-Whitney test.

Labor Characteristics

In group 1, the doses of misoprostol required was 2 [median (IQR;2-3)] and in group 2, it was 3.5 [median (IQR;3-4)] which was statistically significant(p<0.001). The bishop score (n) at 4 hours of women in group 1 was 4 [median (IQR; 3-5)] and in group 2 it was 3 [median (IQR; 3-.4)]. The bishop score at 8 hours of women in group 1 was 8 [median (IQR; 5-8)] and in group 2, it was 3.5 [median (IQR; 3-8)]. The bishop score at 12 hours of women in group 1 was 8 [median (IQR: 8-12)] and in group 2, it was 5 [median (IQR; 5-10.5)]. There was statistically significant difference with respect to bishop score at 4, 8 and 12 hours (p<0.01). The time to active labor (min) of women in group 1 was 501.0±137.8 (mean±SD) and in group 2, it was 675.4±210.6 (mean±SD) which was statistically significant (p < 0.0001). In group 1, the duration of labor (min) was 454.6.±102 (mean±SD) and in group 2, it was 493.2±122.2 (mean±SD) which was statistically significant (p=0.017). In group 1, 5 women required augmentation of labor with oxytocin and in group 2, 17 women required oxytocin augmentation which was statistically significant. (p=0.013) (TABLE 2)

Table 2 Labor Characteristics

Characteristics	Group 1 (n=100)	Group 2 (n=100)	P value
Doses of misoprostol required*	2 [2- 3]	3.5 [3-4]	<0.001
Bishop score* 4-hours 8-hours 12-hours	4 [3-5] 8 [5-8] 8[8-12]	3[3-4] 3.5 [3-8] 5 [5- 10.5]	<0.01 <0.01 <0.01
Time to active labor (mins)#	501.0±137.8	675.4±210.6	<0.001
Duration of labor (min) #	454.6±102.7	493.2±122.2	0.017
Oxytocin use in women (n)$	5	17	0.013

#Data expressed as mean±SD; #Independent t-test. $Data expressed as frequency. *Data expressed as median [IQR], Mann-Whitney test.

Maternal Outcomes

In group 1, the time taken from IOL to delivery (min) was 878.1±169.5 (mean±SD) and in group 2, it was 1088.1±224.4 (mean±SD) which was statistically significant (p<0.001). In group 1, 83 had normal vaginal delivery whereas 4 and 13 women had operative vaginal

delivery and cesarean section respectively. In group 2, 82 women had normal vaginal delivery whereas 3 and 15 had operative vaginal delivery and cesarean section respectively which was not statistically significant (p=0.86). In group 2, one had serious maternal morbidity. She had acute fetal distress during second stage for which operative vaginal delivery was conducted. She delivered an alive term male child, cried immediately after birth. She had severe traumatic postpartum hemorrhage with shock, underwent repair in OT and was transfused 6 units of blood products. Post-operative period was uneventful. No women in either of the groups had chorioamnionitis. The most common indication of LSCS was MSL with fetal distress in both of the groups (7% in group 1 and 9% in group 2).(TABLE 3)

Table 3 Maternal Outcomes

Characteristics	Group 1 (n=100)	Group 2 (n=100)	P value
Induction to delivery interval(min)#	878.1±169.5	1088.1±224.4	<0.001
Mode of delivery (n)$ 1.Vaginal deliveries	83	82	0.86
2.Operative vaginal delivery	4	3	
3. LSCS	13	15	

#Data expressed as mean±SD; #Independent t-test $Data expressed as frequency

Neonatal Outcomes

In group 1, the APGAR score at 1 minute after birth was 8 [median (IQR 7- 8)] and in group 2, it was 7 [median (IQR 7- 8)]. In group 1, the APGAR score at 5 minutes after birth was 9 [median (IQR 9- 9)] and in group 2, it was 9 [median (IQR 8.-9)]. Out of 200 births, 6 were admitted in NICU. In group 1, 4 were admitted in NICU and in group 2, 2 neonates were admitted in NICU which was not statistically significant. One neonate in group 1 had perinatal morbidity. Operative vaginal delivery was conducted in view of acute fetal distress and baby did not cried immediately after birth. APGAR score was 5 at 1 minute and 7 at 5 minutes. Baby was admitted in NICU and further diagnosed with hypoxic ischemic encephalopathy grade 1. Later on, he developed neonatal sepsis and baby was discharged after 4 weeks. (TABLE 4)

Table 4 Neonatal Outcomes

Characteristics	Group 1 (n=100)	Group 2 (n=100)	P value
APGAR at 1-min *	8 [7-8]	7 [7-8]	0.426
APGAR at 5-min *	9 [9- 9]	9 [8-9]	0.067
NICU admissions (n)$	4	2	0.678

$Data expressed as frequency
*Data expressed as median [IQR], Mann-Whitney test

DISCUSSION

The study did not had significant difference with respect to demographic profile of women enrolled in study. As per our observations, simultaneous use of vaginal misoprostol with foley catheter resulted in significantly shorter induction to delivery interval. Also, there was statistically significant shorter time to active labor, duration of labor and lesser use of oxytocin compared to vaginal misoprostol alone without any concomitant increase in maternal complications such as chorioamnionitis, hyperstimulation, PPH and fetal complications such as fetal distress, low APGAR score at 1 min and 5 min and NICU admissions. The outcomes of this study are as follows-

Women in combination group (group 1) had statistically significant shorter induction to delivery interval by 210 minutes(3.5hours) than misoprostol alone group (group 2) (p<0.001). In study conducted by Priyadarshini et al[9], induction to delivery was found to be statistically significantly shorter by 5.3 hours. Similarly, Ugwu et al[10] found that induction to delivery interval was shorter in combined group by 3 hours which was statistically significant. Foley catheter causes mechanical dilatation of cervix due to direct pressure effect of inflated balloon on it. This causes endogenous release of prostaglandin from the cervix. Simultaneous use of foley and vaginal misoprostol cause synergistic effect leading to increased levels of prostaglandins which leads to greater degree of cervical ripening and effective uterine contractions, thereby reducing the interval.

This also explains that women in combination group had statistically significant improvement in bishop score at 4, 8 and 12 hours after induction (p<0.01). These observations are concordant with the study conducted by Priyadarshini et al[9], Ugwu et al[10] (p<0.01) in which, the synchronous use of foley catheter and misoprostol was significantly effective than the other methods in achieving a favorable cervix within 12 hours. The clinical significance of the shorter cervical ripening time obtained with the synchronous use could be considered in clinical situations where there is need to hasten vaginal delivery in the presence of an unfavorable cervix. Again, the complications associated duration of use of the foley alone or that due to the use of high dose misoprostol (50µg) alone are almost completely eliminated. Additionally, the shorter ripening duration which translated significantly to a shorter induction to delivery interval.

However, Lanka et al[11] did not reported statistically significant difference in induction to delivery interval in combination group(p=0.46). Further, they did not found any significant improvement in bishop score. Chung et al[12] and Kashanian et al[13] too have similar observations in their respective studies. In our study, the assessment of the cervical status, together with the administration of misoprostol was done 4-hourly, whereas in study by Chung et al[12], cervical status assessment and administration of misoprostol was done every 3 hours. This might have affected their study outcome, considering that the pharmacokinetic profile of misoprostol has shown that the half-life is 4-6 hours. It follows therefore that any misoprostol administration shorter than 4-hourly intervals may not produce the desired effect. Furthermore, while this study recruited only postdate women. In these studies, both term and pre-term subjects. This might have also contributed to the differences in results obtained.

In our study, women in combination group took statistically significantly lesser time to achieve active labor in comparison to misoprostol only group by 3 hours (180 minutes) (p<0.001). By combining two methods, we achieved favorable cervix and effective uterine contractions in a shorter duration in the combination group without increased side effects of both the methods. This might have led significantly shorter time to achieve active labor. Similar observation were made by Priyadarshini et al[9], in which women in combination group had went in to active labor after induction significantly earlier as compared with women induced with misoprostol by 5.6 hours. (p<0.0001). Aduloju[14] et al found that IOL with foley and intravaginal misoprostol results in lesser time time to achieve active labor after induction by 2.5 hours. This can be explained by the above observations that that more number of women achieved favorable bishop score within 12 hours in whom IOL was done with combined use of foley and misoprostol. However, our results are not in agreement with Chung et al[12] and Kashanian et [13]. After expulsion or removal of foley, if there were no uterine contractions, oxytocin was used for initiating uterine contractions. We used vaginal misoprostol for maximum five doses in absence of uterine contractions following expulsion of foley, which might have led to achieve active labor in a significantly shorter time.

In combination group, significantly lesser number of women required oxytocin for augmentation of labor compared to misoprostol group (p=0.013). Our results are consistent with Aduloju et al[14] who reported oxytocin requirement in labor was significantly lower in the foley and misoprostol group. This is because the use of foley or misoprostol is capable of stimulating endogenous release of oxytocin. Therefore, combining these two agents will ultimately results in less oxytocin requirement in labor than using either agent alone. However, no difference was observed by Chung et al[12] and Lanka et al[11] with respect to oxytocin requirement. They had preterm gestations too in their study. As the oxytocin receptors increases with gestational age, therefore use of oxytocin might have led to suboptimal action.

Chorioamnionitis is an acute inflammation of the membranes and chorion of the placenta typically due to ascending polymicrobial bacterial infection. Placement of foley catheter acts as foreign body thereby cause increased risk of ascending infections. In our study, none of the women in either of the study group had chorioamnionitis. Chung et al[12] found that 20.9 % women induced with foley and misoprostol and 6.1% women induced with misoprostol only had chorioamnionitis. (p = .07). This difference may be due to the fact that

in this study, vaginal examination was done every 3 hours and maximum 6 doses of misoprostol was administered. This caused increased risk of ascending infection, which was potentially attributable to multiple vaginal examinations for misoprostol administration in the presence of foley catheter.

We observed that there was no statistically significant difference among the study groups with respect to the mode of delivery (p=0.659) and this is concordant with the observations made by Aduloju et al[14], Priyadarshini et al[9] and Ande et al[15]. There was no statistically significant difference with respect to indication of LSCS in both of the study group. However, majority of women had LSCS for acute fetal distress. This is implicated with the use of misoprostol. It causes uterine contractile abnormalities such as tachysystole and uterine hyperstimulation. This leads to meconium stained liquor and fetal heart changes. No statistically significant difference was observed in the outcomes of neonates of both of the study groups with respect to birth weight, sex, NICU admissions, APGAR score at 1 minutes and 5 minutes.

Strength Of Study

This prospective clinical trial adequately powered to assess the induction to delivery interval and other secondary variables in women induced with foley catheter (30 cc) and misoprostol 25 mcg vs. misoprostol 25 mcg alone. We had additional benefit by conducting successful vaginal deliveries within 24 hours without any undue increasing the complications and avoided added cost to the subjects enrolled in study as foley catheter, misoprostol 25 mcg and oxytocin is widely available in our labor ward. This benefit is particularly relevant for low resource settings in developing countries like India where conducting deliveries while keeping the safety of both mother and fetus in hands of the treating obstetricians and optimal utilization of limited health resources is of paramount importance. Since misoprostol is increasingly utilized in contemporary obstetric practice for IOL with insufficient evidence regulating its use for this indication, this study provides relevant data to inform decision making.

Limitations Of Study

Despite the randomized design of this trial, it was not possible to mask the attending obstetrician or the women on the method of induction assigned, which may have potential for bias by the care providers.

CONCLUSION

We concluded from our study that with the simultaneous use of foley catheter and vaginal misoprostol for IOL in nulliparous postdate pregnant women contributed significantly to reduction of induction to delivery interval, time to active labor, duration of labor, oxytocin augmentation, doses of misoprostol and significant improvement in bishop score at 4, 8 and 12 hours without any concomitant adverse maternal and fetal effects. Hence, we recommend the simultaneous use of foley catheter and vaginal misoprostol for routine induction in labor ward.

Ethical Consideration

The study was conducted after getting approval of the institutional ethics committee. Enrollment was done only after taking informed written consent. There was no drug trial or human/animal experiment involved. Investigators were aware of 'Declaration of Helsinki (modified 2000). These were followed in letter and spirit.

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The authors don't have any relevant financial information to disclose.

Conflict Of Interest

None

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