

A RANDOMISED CONTROLLED TRIAL COMPARING FOLEY'S CATHETER PLUS OXYTOCINE VERSUS VAGINAL MISOPROSTOL FOR LABOUR INDUCTION IN TERM PATIENTS

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Abstract

Introduction: In making the decision for an early delivery, the physician relies on clinical stability of the mother and fetus to decide between performing a Caesarean section and inducing labour for vaginal delivery. Labour induction in unfavourable cervix conditions is a difficult and lengthy procedure, for both mother and obstetrician. Many times it may fail and this outcome can be frustrating for both. The purpose of this study was to compare the effectiveness and safety of a 25-mcg vaginal tablet of misoprostol versus the Foley catheter in conjunction with intravenous oxytocin, for cervical ripening and labor induction in full-term and post-term pregnant women with an indication for immediate labor induction.

Methodology: It was a randomized controlled trial, hospital based, study at term gestation conducted at the Muslim Maternity and Zanana Hospital, Hyderabad (Telangana) during the period of May 2016 to May 2017. 126 pregnant women satisfying the inclusion and exclusion criteria of the study mentioned before were classified into two groups. Group A: receiving Misoprostol, n=63 and Group B: receiving Catheter plus oxytocin, n=63.

Results: In both groups, the most prevalent indication was prolonged pregnancy, followed by mild pre-eclampsia. The active phase to delivery interval in Group A (Misoprostol) was shorter compared to Group B (Foley's + oxytocin) and this difference is statistically significant ($p=0.011$). The overall duration of labour in the total group, categorised by the type of induction, did not show any significant differences. The rate of instrumental delivery was similar in both groups.

INTRODUCTION

Obstetricians face significant obstacles when it comes to achieving a vaginal delivery for women who need labour induction. Labour induction is typically carried out when the potential dangers associated with prolonging a pregnancy outweigh the advantages of giving birth. Indications for initiating labour include urgent situations like severe preeclampsia or ruptured membranes with chorioamnionitis. Other frequent medical and obstetric reasons for induction of labour include premature rupture of membranes, gestational hypertension, post-term pregnancy, low amniotic fluid levels, abnormal foetal condition, restricted foetal growth, chronic hypertension, and diabetes [1].

Undoubtedly, there is a strong correlation between cervical ripening and the likelihood of a successful vaginal delivery. Various techniques are employed for labour induction, although none of the existing treatments are devoid of associated medical hazards. Consequently, labour should only be induced when the potential dangers of allowing the pregnancy to progress beyond the risks of induction. Agents utilised for

induction should ideally replicate natural labour while avoiding excessive uterine contractions. The predominant techniques for inducing labour in cases where the cervix is unfavourable include the intravaginal use of misoprostol, the transcervical insertion of Foley's catheter, and the application of prostaglandin gel. However, when the cervix is ripe, oxytocin can be delivered intravenously.

A comparative analysis of misoprostol and Foley catheters has already been conducted. However, there is still uncertainty regarding the optimal option for cervical ripening and labour induction. Several researches demonstrated a preference for misoprostol [2-5], while others favoured the use of a Foley catheter [6-8]. Additionally, other investigations found a balance between the advantages and disadvantages of both methods [9-16].

The purpose of this study was to compare the effectiveness and safety of a 25-mcg vaginal tablet of misoprostol versus the Foley catheter in conjunction with intravenous oxytocin, for cervical ripening and labor induction in full-term and post-term

pregnant women with an indication for immediate labor induction.

MATERIAL AND METHODS

The study was conducted at the Tertiary care Hospital, A Prospective, randomized, open label, hospital based, comparative study at term gestation was carried out during the study period of 18 months

This prospective, Randomized, open label study comprising 126 women at term gestation admitted in the labour ward for term induction of labour with BISHOP SCORE <6, selected for the study. Induction of labour using vaginal misoprostol vs foley's catheter plus oxytocin was compared.

Primigravida and multiparous women with para ≤ 2 , with singleton pregnancy at 37-41 weeks of gestation with a single live fetus in vertex presentation admitted to labour rooms of hospital with unfavourable cervix and those requiring cervical ripening and induction of labour for the indications mentioned below were selected for the study. Inclusion criteria for our study included , Singleton pregnancy, Cephalic presentation, Live fetus, Intact membranes, Woman 37-41 weeks of gestation with reactive Cardio-Tocography ,Mild pre-eclampsia, Gestational Hypertension, Admission CTG reassuring, Bishop score ≤ 6 . Multiple pregnancies, Malpresentations, Placenta Praevia,.Scarred uterus, Severe Oligohydromnios (AFI ≤ 6) ,Severe Pre-eclamsia., Abnormal obstetric Doppler, Intra uterine Growth Restriction, Para>3, Uncontrolled Diabetes, Active genital herpes infection, Intrauterine Fetal demise and all obstetric contraindications for normal delivery were excluded from the study.

126 pregnant women satisfying the inclusion and exclusion criteria of the study mentioned before were classified to the two groups.

Group A : receiving Misoprostol, n=63, Group B: receiving Catheter plus oxytocin, n=63.

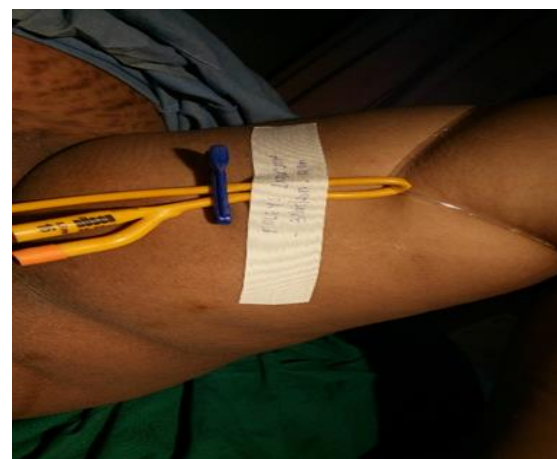
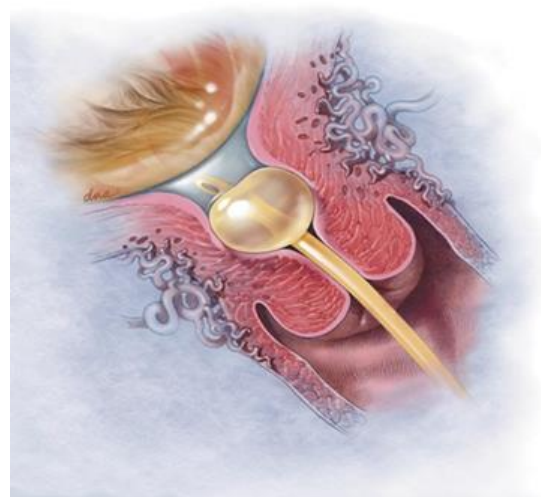
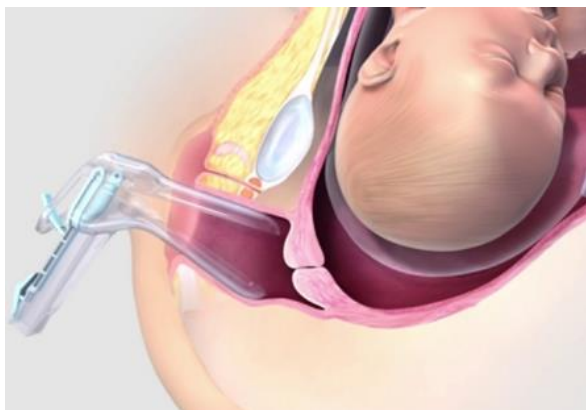


Fig. 1 Insertion of foley's catheter

RESULTS

The grounds for induction in the Misoprostol group are as follows: prolonged pregnancy (33.33%), preeclampsia (11%), oligohydramnios (11%), elective (15.87%), gestational diabetes mellitus (5%), gestational hypertension (3%), and Rh-negative pregnancy (2%).

In Foley's group treated with oxytocin, the indications for induction of labour include prolonged pregnancy (31.74%), mild pre-eclampsia (19.04%), oligohydramnios (15.87%), gestational diabetes mellitus (12.69%), elective induction (11.11%), gestational hypertension (3.17%), and Rh-negative pregnancy (6.37%). Therefore, in both groups, the most prevalent indication was prolonged pregnancy, followed by mild pre-eclampsia. The duration from 4 cm cervical dilatation to delivery in the Misoprostol Group (A) was 5.55 ± 2.21 hours, while in the Foley's + oxytocin group (Group) it was

6.80 ± 3.25 hours. The active phase to delivery interval in Group A (Misoprostol) was shorter compared to Group B (Foley's + oxytocin) and this difference is statistically significant ($p=0.011$). Therefore, the use of foley's catheter combined with oxytocin during induction is linked to a prolonged period of active labour. The average time it took for induction and delivery in the Misoprostol group (A) was 17.73± 3.0 hours, while in the Foley's + oxytocin group it was 16.44± 4.5 hours. $P = 0.053$, which is ($p>0.05$). Therefore, the result were not statistically significant. The overall duration of labour in the total group, categorised by the type of induction, did not show any significant differences. The caesarean delivery rate was 39.68% in the Misoprostol group, compared to 33.33% in the Foley's + oxytocin group. Consequently, the rate of caesarean section (LSCS) was slightly elevated in patients who were induced with Misoprostol, although this disparity does not have statistical significance. The probability is 0.43. The rate of spontaneous vaginal delivery was slightly higher in the group that received Foley's catheter plus oxytocin (55.55%) compared to the group that received Misoprostol (44.44%). The rate of instrumental delivery was similar in both groups.

Most common maternal complication in Foley's + oxytocin group was PROM (6.34 %) while in Misoprostol group ,it was Puerperial pyrexia (4.76 %).

Table 1. Comparison of Age of Subjects in Both the Groups

Age Group	Group A (N=63)	Percentage	Group B(N=63)	Percentage
20-24 years	35	55.50 %	36	57.14 %
25-30 years	27	42.80%	26	41.26
>30 years	1	1.50 %	1	1.50 %

Table 2. Comparison of Bishop's Score in the Both Groups

Bishop's Score	GROUP A (n=63)	GROUP B (n=63)
On Admission (T0)	3.41±0.66	3.95±0.70
Post Induction (T6)	6.41±1.17	7.66±1.04
Change	3± 0.8	3.71 ±0.77

Table 3. Indications for Induction

INDICATION	GROUP A (n=63)	Percentage	GROUP B (n=63)	Percentage
Prolonged Pregnancy	21	33.33 %	20	31.74 %
Gestational Hypertension	3	4.76 %	2	3.17 %
Mild Preeclampsia	11	17.46 %	12	19.04 %
Oligohydromnios	11	17.46 %	10	15.87 %
GDM	5	7.93 %	8	12.69 %
Rh Negative	2	3.17 %	4	6.37 %
Elective	10	15.87 %	7	11.11 %

Table 4. Foleys Insertion to Expulsion Time in Group B

Time	Group B (N=63)	Percentage
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0 – 6 Hrs	14	22.22 %
7-12 Hrs	49	77.77 %
>12 Hrs	0	0
Average Duration of Expulsion (Hrs)	8.36 hrs	

Table 5. Number of Doses of Misoprostol in Group A

Number Of Doses	Group A (N=63)	Percent
1	2	3 %
2	31	49. %
3	27	43 %
4	3	5 %

Table 6. Comparison of Induction to Active Phase Interval

Parameters	Group A (n=63)	Group B (n=63)
Range	9-18 Hrs	11-14Hrs
Mean (Hrs)+SD	12± 1.96	9.45± 1.9

Mean diff= 2.55. $t=7.41$, $df=124$, $P< 0.001$

Table 7. Comparison of Active Phase to Delivery Interval

Parameters	Group A (n=63)	Group B (n=63)
Range	2-12 Hrs	1-14 Hrs
Mean (Hrs)+SD	5.55 ±2.21	6.80±3.25

Mean Difference=1.3 , $t = 2.58$, $df = 120$, $P=0.011$

Table 8. Comparison of Induction to Delivery Interval in Both Groups

Parameters	Group A(n=63)	Group B(n=63)
Range	11-26 Hrs	7-28 Hrs
Mean(Hrs)+SD	17.73± 3.0	16.44± 4.5

Mean diff= 1.33. $t=1.95$, $df=124$, $P=0.053$

Table 9. Outcome of the Labour

Mode Of Delivery	Group A	Percentage	Group B	Percentage
Spontaneous vaginal delivery	28	44.44 %	35	55.55 %
Instrumental Delivery	10	15.87 %	7	11.11 %
LSCS	25	39.68 %	21	33.33 %

Chi Square = 1.655, $Df=2$, P value = 0.4371

Table 10. Comparison of CTG Changes in both groups

	Group A (N=63)	Percentage	Group B (N=63)	Percentage	P-Value
Reassuring	47	74.60 %	55	87.30 %	0.034
Non-Reassuring	7	11.11 %	5	7.93 %	0.27
Abnormal	9	14.28 %	3	4.76 %	0.034

Chi Square = 3.961, $Df=2$, P value = 0.138

Table 11. Comparison of Meconium Stained Liquor in Both Groups

	Group A	Percentage	Group B	Percentage
Thin MSL	13	20.63 %	10	15.87 %
Thick MSL	8	12.69 %	6	9.52 %

Chi Square = 0.003, Df=1, P value = 0.97

Table 12. Neonatal Variables

Variables	Group A (n=63)	Group B (n=63)	P-value
Mean birth weight(Kg)	3.07± 0.26	3.04± 0.35	0.58
1 min APGAR	6.34± 0.80	7.20± 1.09	0.001
5 min APGAR	8.44± 0.66	8.66± 0.89	0.11

Mean birth weight in Kgs Group-A is 3.07±0.26 kg

Mean birth weight in Kgs Group-B is 3.04±0.35 kg

P value is 0.58.The result is not significant at p>0.05.

Table 13. Neonatal Complications

Neonatal Variables	Group A (n=63)	Percentage	Group B (n=63)	Percentage
MAS	4	6.34 %	2	3.17 %
RDS	2	3.17 %	4	6.34%
Neonatal Resuscitation	2	3.17 %	2	3.17 %
Neonatal Jaundice	2	3.17 %	1	1.58 %
Blood sugar monitoring	3	4.76 %	1	1.58 %
NICU admission	13	20.63 %	10	15.87 %
Perinatal death	0	0 %	0	0 %

Table 14. Maternal Complications

Complications	Group A (n=63)	Percentage	Group B (n=63)	Percentage
APH	1	1.58 %	0	0 %
PPH	2	3.17 %	2	3.17 %
Cervical Tear	2	3.17 %	2	3.17 %
Puerperial Pyrexia	3	4.76 %	3	4.76 %
Blood Transfusion	1	1.58 %	0	0 %
PROM	1	1.58 %	4	6.34 %
Total	10	16 %	11	17 %

Chi square = 3.76, df= 5, p-value= 0.584 Result is not significant at P>0.05.

DISCUSSION

The findings of the present investigation demonstrated that administering a 25-µg vaginal tablet of misoprostol every 6 hours was superior to using a Foley catheter and oxytocin in achieving vaginal delivery during labour induction in pregnant women with an unripe cervix. This superiority was observed specifically at the 12 and 18-hour marks following the initiation of induction. The occurrence of negative effects on both the mother and the foetus was infrequent and showed no significant difference between the two groups.

Prior research has conducted a comparison between the utilisation of vaginal misoprostol and Foley catheter with oxytocin for the purpose of inducing labour. However, it is challenging to compare these investigations. Various dosages and time intervals have been employed, and the present investigation utilised a novel vaginal formulation of misoprostol. One advantage of the current study is that it demonstrates the effectiveness of a misoprostol tablet labelled for obstetric and vaginal use in cervical ripening and labour induction. This tablet performs similarly to other established methods, while avoiding the need for manipulation and the use of high dosage pills currently on the market.

The incidence of induction failure was nearly thrice higher in the Foley and oxytocin group compared to the misoprostol group, with 26 instances versus 9 cases, respectively. The failure rate in the misoprostol group was 7.6%, which aligns with the findings of another study.[17]

Furthermore, the duration from the initiation of labour induction to the birth through the vagina was notably shorter in the misoprostol group (with an average of 17 hours) compared to the Foley and oxytocin group (with an average of 20 hours). The aforementioned findings validate the prevailing inclination to regard misoprostol as the definitive benchmark for labour induction, particularly in cases where there are no contraindications for prostaglandin usage.

The Foley catheter is more efficacious as a cervical ripening agent than as a labour induction agent. This is why it is commonly associated to another technique for stimulating uterine contractions, typically oxytocin, as demonstrated in this study. The varying outcomes reported in the literature on the efficacy of oxytocin in labour induction using Foley catheter may be attributed to the storage conditions of the medication. Oxytocin stored in non-refrigerated conditions may decrease its shelf-life and, as a result, its effectiveness. [18-20]

The trial was conducted in a location with a tropical climate. In theory, there could be an additional explanation for why the combination of Foley catheter with oxytocin did not yield the same results as misoprostol. Uterine contractile anomalies and the passage of meconium were more prevalent in women who used misoprostol, as anticipated. The findings of these observations have been validated in other investigations. [7,14] Through a comprehensive analysis, it was found that the occurrence of hyperstimulation syndrome ranged from 0 to 7.2% when a 25 µg dose of misoprostol was administered. Additionally, the frequency of tachysystole was considerably lower in individuals who received 25 µg compared to those who received 50 µg of misoprostol.[21] The administration of misoprostol in this study did not result in increased occurrences of uterine contractile anomalies or meconium transit.

Although this experiment had a randomised design, it had certain shortcomings. Physicians and women were fully aware

of the labour induction method used, therefore it was not possible to blind them. As a result, there is a potential for biases when determining the failure of induction or recommending an other approach.

Caesarean section. Furthermore, it is important to highlight that the findings of this study are only applicable to women who do not have any previous uterine scarring, as they were not included in the research. Prudence is advised when administering misoprostol to women with a history of prior uterus operations.[22] Avoid regular use of misoprostol in such circumstances until more experience is gained and its safety is established. When faced with these situations, it is important to carefully evaluate the potential benefits of utilising a Foley catheter in conjunction with oxytocin.

Notwithstanding these constraints, the present study demonstrated that both misoprostol and the combination of Foley catheter and oxytocin are viable choices for cervical ripening and labour induction in situations where inducing labour is deemed necessary, although misoprostol exhibited slightly superior performance.

CONCLUSION

Our study indicates that intravaginal misoprostol is linked to a reduced time from induction to delivery compared to Foley's catheter. Additionally, it enhances the likelihood of vaginal delivery in cases where the cervix is not yet fully prepared at term. The use of a transcervical Foley catheter is linked to a reduced occurrence of uterine hyperstimulation. Therefore, the Foley catheter may be a viable option for individuals who are at risk of uterine rupture during labour.

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