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Induction of Labor Using Vaginal Misoprostol Alone or Combined with Intracervical Foley Catheter

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ABSTRACT

Background: Induction of labor is a common intervention in obstetric practice, which is a procedure used to stimulate uterine contractions during pregnancy to accomplish delivery prior to the onset of spontaneous labor.

Objective: The aim of the present study was to select the best method for induction of labor.

Patients and methods: This study was conducted on 72 pregnant women for induction of labor in Maternity Hospital, Faculty of Medicine, Zagazig University Hospitals. Pregnant women were divided into: group (A): 36 patients who underwent induction of labor by intra-vaginal misoprostol and group (B): 36 patients who underwent induction of labor by intravaginal misoprostol combined with intracervical Foley catheter. All patients were subjected to full history taking, proper examination. Primary and secondary outcomes were estimated for all the studied patients.

Results: Between the studied groups, there was statistically non-significant difference regarding parity, gestational age or birth weight. There was statistically significant difference between the studied groups regarding number of misoprostol doses, induction of active stage and induction of delivery time, occurrence of complications and occurrence of dystocia, tachysystole and vomiting.

Conclusion: This comparative study showed that the use of Foley's with vaginal misoprostol results in a shorter induction to delivery time compared with vaginal misoprostol alone.

Keywords: Foley Catheter, Labor Induction, Misoprostol.

INTRODUCTION

Induction of labor is a common intervention in obstetric practice, which is a procedure used to stimulate uterine contractions during pregnancy to accomplish delivery prior to the onset of spontaneous labor [(1)]. Successful labor induction leads to a vaginal birth. A health care provider might recommend labor induction for various reasons, primarily when there's concern for a mother's health or a baby's health as labor induction carries various risks, including infection and the need for a Cesarean section. Sometimes the benefits of labor induction outweigh the risks [(2)].

Prostaglandins are frequently used for labor induction in pregnant women. The presence of cervical immaturity indicates the use of prostaglandin compounds, frequently followed by oxytocin infusion, prostaglandins are received orally or applied locally to the cervix or the vagina, to promote both cervical ripening and myometrial contractility [(3)]. Various prostaglandins preparations including misoprostol vaginal tablets, dinoprostone vaginal gel and vaginal insert are commercially available to be used in labor induction. Misoprostol is a synthetic prostaglandin El analogue and has been reported to be a considerably safe and efficacious cervical ripener. It's inexpensive, easy to administer, stable at room temperature, does not require refrigeration [(4)]. In spite of different doses and routes of administration (sublingual, oral, vaginal), ideal dosage and mode of administration still remain to be controversial. Potential complications such as uterine rupture, tachysystole and uterine hyperstimulation should be emphasized with respect to adverse maternal-neonatal outcome [(5)].

The use of Foley's catheter as a mechanical method for labor induction has been recommended in many developing countries. The reports from different countries have mentioned excellent results with the use of Foley's catheter either alone or in combination with prostaglandins [(6)]. Although the exact mode of action of Foley's catheter is not fully understood. Yet it has been postulated that the catheter stimulates various unspecified regions of the uterus, elevates its excitability and causes regular uterine contractions [(7)]. Therefore, the aim of the present study was to select the best method for induction of labor.

PATIENTS AND METHODS

This study was conducted on 72 pregnant women for induction of labor in Maternity Hospital, Faculty of Medicine, Zagazig University Hospitals. This study was conducted in the period from October 2020 to April 2021.

Inclusion Criteria:

Pregnant woman with valid indication for induction of labor. Gestational age ≥ 37 weeks (calculated from reliable menstrual dates and/or late first trimester or early second trimester ultrasound). Age: 18-40 years old. Vertex presentation with intact fetal membranes. Normal fetal non-stress test. Modified Bishop Score ≤ 5. Cervical dilation less than or equal to 2cm.

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Exclusion criteria:

Any contraindication for vaginal delivery (e.g. placenta previa, accrete … etc.). Any contraindication for induction of labor (e.g. fetal malpresentation, prior uterine surgery). Active labor (continuous contractions more than 3 times in 10 minutes at onset of induction of labor (IOL). Antepartum hemorrhage.

Patients fulfilling inclusion criteria were randomly assigned into 2 groups: Group (A):

36 patients underwent induction of labor by intravaginal misoprostol, and **Group (B):** 36 patients underwent induction of labor by intravaginal misoprostol combined with intracervical Foley catheter.

Methodology:

All pregnant women was assessed by the following: Thorough history taking: with particular emphasis on gestational age, history of prior surgery, history of prior medical disorders or drug allergy, history of any problems in the current pregnancy. General examination with particular emphasis on blood pressure and urine dipstick to detect preeclampsia, pulse to exclude hemodynamic instability. Abdominal examination; fundal level, fetal position and fetal heart rate to ensure single intrauterine pregnancy. Pelvic examination to ensure adequate pelvis, fetal presentation and to assess cervical condition.

Ultrasound imaging to confirm presenting part, assess placental site, fetal biometry and liquor. Non Stress Test must be reassuring to exclude fetal compromise and any contraindications for induction of labor. Laboratory investigations such as; CBC, PT, PTT, INR, liver and kidney function tests.

Intervention:

Group A: Misoprostol group (36 women); participants received 25 µg misoprostol in the form of Vagiprost® in the posterior vaginal fornix for maximum five doses four hours apart. If a satisfactory Bishop score of 8 or uterine contractions weren't reached after the last dose (fifth) by 4 hours, this was considered as a failure of induction of labor**.**

Group B:

Transcervical Foley catheter in combination with vaginal misoprostol group (36 women); participants received misoprostol by the same dose and method used in group 1.

Transcervical Foley catheter was passed using aseptic techniques in the hospital labor ward. If the Bishop score was less than 8 or uterine contractions weren't reached after the last dose (fifth) by 4 hours, this was considered as failure of induction of labor**.**

Wait 48 hour from start of induction if failure of induction and reassurance the patient and other method of induction was tried.

Outcomes:

1. Primary outcomes: for time interval from starting induction of labor till delivery.
2. Secondary outcomes: for number of misoprostol doses, Time interval from starting induction of labor till reach active stage of labor, Mode of delivery, Maternal side effects; pyrexia, nausea and vomiting and Secondary outcomes related to maternal morbidity.

Ethical approval:

The study was approved by the Ethical Committee of Zagazig Faculty of Medicine. An informed consent was obtained from all patients in this research. Every patient received an explanation for the purpose of the study. All given data were used for the current medical research only. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

Data were analyzed using the software SPSS (Statistical Package for the Social Sciences) version 20. Quantitative variables were described using their means and standard deviations. Categorical variables were described using their absolute frequencies and percentage and were compared using chi square test or Fisher exact test when appropriate. Kolmogorov-Smirnov (distribution-type) and Levene (homogeneity of variances) tests were used to verify assumptions for use in parametric tests. To compare quantitative continuous data between two groups, independent sample t test was used. The level statistical significance was set at $P<0.05$. $P\leq0.001$ was considered as statistically highly significant.

RESULTS

The present study showed that regarding parity there was statistically non-significant difference between the studied groups (Table 1).

Table (1): Comparison between the studied groups regarding obstetric history

Parameter	Groups		p
	Misoprostol only group	Combined misoprostol and Foley catheter group	
	N=36 (%)	N=36 (%)	
Parity:			
PG	2 (5.6)	3 (8.3)	
P1	8 (22.2)	9 (25)	0.678
P2	18 (50)	16 (44.4)	
P3	8 (22.2)	8 (22.2)	

There was statistically non-significant difference between the studied groups regarding gestational age or birth weight (Table 2).

Table (2): Comparison between the studied groups regarding fetal data

Parameter	Groups		P
	Misoprostol only group	Combined misoprostol and Foley cathete group	
	N=36 (%)	N=36 (%)	
Birth Weight (kg): Mean ± SD	3.19 ± 0.11	3.25 ± 0.16	0.073
Gestational age (w): Mean ± SD	38.0 ± 0.76	37.86 ± 0.87	0.471

There was statistically significant difference between the studied groups regarding number of misoprostol doses (higher in group received misoprostol alone) (Table 3).

Table (3): Comparison between the studied groups regarding misoprostol doses

Parameter	Groups		p
	Misoprostol only group	Combined misoprostol and Foley catheter group	
	N=36 (%)	N=36 (%)	
Number of misoprostol doses: Mean ± SD	2.61 ± 0.49	1.44 ± 0.5	<0.001**

**: Statistically highly significant

There was statistically significant difference between the studied groups regarding induction of active stage and induction of delivery time (both were higher in misoprostol only group) (Figures 1 and 2).

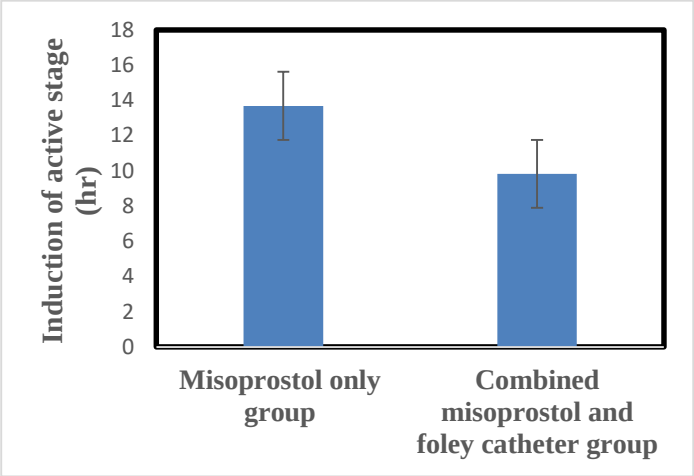

Figure (1): Simple bar chart showing comparison between the studied groups regarding induction of active stage

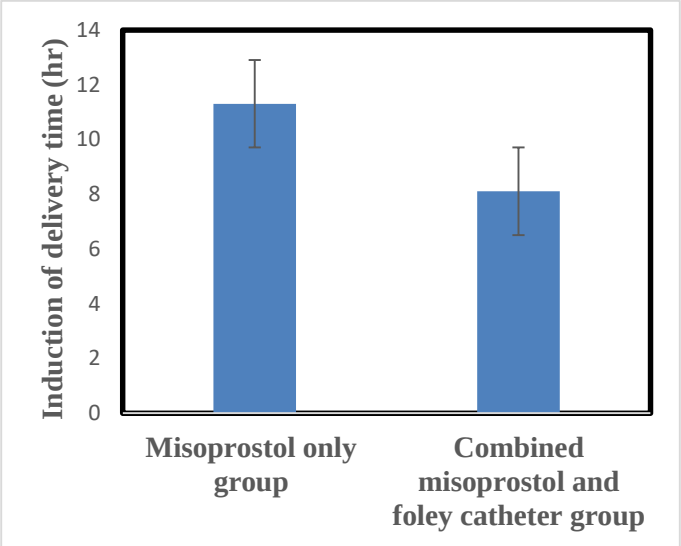

Figure (2): Simple bar chart showing comparison between the studied groups regarding induction of delivery

Concerning postnatal complications: there was statistically significant difference between the studied groups regarding occurrence of complications. There was statistically significant difference between the studied groups regarding occurrence of dystocia, tachysystole and vomiting (all were significantly higher in misoprostol group only). There was statistically non-significant difference between the studied groups regarding occurrence of failed induction, fever, hypertonus, hyperstimulation, persistent non-reassuring fetal heart rate (FHR) (Table 4).

Table (4): Comparison between the studied groups regarding mode of delivery

Complications	Groups		p
	Misoprostol only group	Combined misoprostol and Foley catheter group	
	N=36 (%)	N=36 (%)	
No	4 (11.1)	15 (41.7)	0.003*
Dystocia	6 (16.7)	1 (2.8)	0.107
Failed induction	2 (5.6)	0 (0)	0.493
Fever	3 (8.3)	4 (11.1)	1
Hyperstimulation	3 (8.3)	3 (8.3)	1
Hypertonus	4 (11.1)	4 (11.1)	1
Persistent non-reassuring FHR	1 (2.8)	3 (8.3)	0.614
Tachysystole	10 (27.8)	6 (16.7)	0.256
Vomiting	3 (8.3)	0 (0)	0.239*

*: Statistically significant

DISCUSSION

Induction of labor is indicated in medical, obstetric and fetal conditions in which prolongation of pregnancy, would jeopardize maternal and fetal wellbeing and in which no contraindication to amniotomy, and use of oxytocin and prostaglandins [8]. Misoprostol, artifcial prostaglandin analogue, is a drug used for cervical softening and labor stimulation by a variety of routes including oral, buccal, sublingual and vaginal routes [9].

The use of Foley's catheter as a mechanical method for labor induction has been recommended in many developing countries. The reports from different countries have mentioned excellent results with the use of Foley's catheter either alone or in combination with prostaglandins [6].

The aim of this study is to evaluate the efficiency and the outcomes of using vaginal misoprostol alone versus the combination of vaginal misoprostol and intracervical Foley catheter in induction of labor.

Regarding mode of delivery in this study, there was statistically non-significant difference between the studied groups (eight patients [22.2%] within misoprostol group versus six patients within combined group [16.7%]) were delivered Cesarean section. On other hand as regard vaginal delivery there were 28 [77.8%] within misoprostol group versus 26 patients within combined group [83.3%]. **Siwatch *et al.*** [10] in his research study the rate of vaginal delivery in misoprostol group was 84% and in Foley's plus misoprostol group was 86%. The rate of lower segment Cesarean section was 16% in misoprostol group and 14% in Foley's plus misoprostol group. The calculated p value was statistically insignificant.

Many other studies also show no much difference and statistically insignificant in rate of vaginal delivery compared both groups. **Hussein *et al.*** [11] compared 50 ug misoprostol vaginal alone versus 50 ug misoprostol vaginal and intracervical Foley catheter, their results came in agreement with this study regarding mode of delivery, as the majority of women in both groups delivered vaginally

Regarding the number of doses given in either groups, the current study shows in misoprostol group 2-3 versus 1-2 doses in the combined group, that means the dose requirement for misoprostol in the misoprostol group was reported to be more as compared to the combined group. The number of misoprostol doses in another comparable study carried by **Hussein *et al.*** [11] about of the subject who used vaginal misoprostol and of those who received misoprostol vaginally plus intracervical Foley catheter 3 versus one dose only in both groups respectively

The results of the present study show that the rate of success (i.e. the mean induction to delivery interval) was significantly shorter in Foley's catheter plus vaginal misoprostol group than misoprostol alone group. There was statistically significant difference between the studied groups regarding induction of active stage and induction of delivery time (both were higher in misoprostol only group 9 – 17 hours versus 6-14 hours). In **Hussein *et al.*** [12] study nulliparous women of combination group had lower induction to active phase of interval than misoprostol group (p=0.003). This showed that the combination of Foley's bulb and vaginal misoprostol results in early start of active phase of labour in nulliparous women. It was 7.45±4.68 hours in parous women of combination group and 6.70±3.85 hours in misoprostol group; difference was statistically insignificant (p=0.680). Induction to delivery interval was 11.76±5.89 hours in combination group and 14.54±7.32 hours in misoprostol group with difference of 2.78 hours and the difference was statistically significant.

There was statistically non-significant difference between the studied groups regarding occurrence of failed induction, fever, hypertonus, hyperstimulation, persistent non-reassuring FHR. The occurrence of uterine contraction abnormalities was similar in both groups in contrast with a study by **Carbonell *et al.*** [13].

Thus, our study suggests that the combination of Foley's with vaginal misoprostrol may be useful to achieve timely and safe delivery in the presence of unripe cervix with no increased maternal and fetal complications.

CONCLUSION

We can conclude that the use of Foley's with vaginal misoprostrol results in a shorter induction to delivery time compared with vaginal misoprostol alone.

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Conflict of Interest: Nil.

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