ORIGINAL ARTICLE

TO COMPARE THE EFFECTS OF ORAL MISOPROSTOL ALONE AND IN COMBINATION WITH INTRACERVICAL FOLEY'S IN INDUCTION OF LABOR

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ABSTRACT

Background: Induction of labor (IOL) is an obstetric intervention designed,usedin 20-30% of all pregnancies. The aim of this study was to assess the efficacy of oral misoprostol alone versus oral misoprostol and Foley's catheter for IOL.

Methods: All pregnant women age ≥18 years requiring induction of labor for various reasons and with unfavorable cervixes admitted in Ziauddin University Hospital Karachi are included in the study. Women were induced in "Group A" with an intracervical Foley's catheter and tablet misoprostol 25 microgram given orally. In group B, women were given misoprostol 25 microgram tablets alone orally, subsequently every6 hourly for a maximum of four doses.

Results: Normal vaginal delivery was significantly higher in group A (n=62, 59.6%) than that of group B (n=42, 40.4%) patients. Caesarean section was found higher in group B (n=25, 83.3%) patients than that of group A patients (n=516.7%; p-value <0.001). Frequency of meconium was found in 3 (14.3%) patients in group A while 18 (85.7%) in group B (p-value <0.001.

Conclusion: The number of successful inductions within 24 hours was found better among women receiving oral misoprostol with intracervical Foley's. Moreover, spontaneous vaginal delivery was also found higher in women receiving oral misoprostol only.

KEYWORDS: Oral misoprostol, intracervical Foley, Induction of labor

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INTRODUCTION

Induction of labor (IOL) is an obstetric intervention designed to imitative commence the procedure of dilatation cervical, uterine contractions and ultimately delivering a child.[1-3] More than 22% of pregnant women underwent labor Induction[4, 5]. Some of the major conditions that call for an Induction of labor are, Hypertensive disorder, gestational diabetes (GDM), post-term pregnancy, less fetal movements of fetus and Prelabor rupture of membranes (PROM). IOL with an ominous and unripe cervix is linked with delayed labor than that of IOL with a favorable cervix. Additionally, there is a significant rise in the deliveries via instruments and caesarean sections. [6-10]

To make a favorable IOL in women with an unfavorable cervix it is commanding to achieve cervical ripening. Misoprostol(Prostaglandin E1) has been broadly considered as a component for IOL. Cochrane systematic reviews addressing the use of both orally administered and vaginally administered misoprostol[9-11] the conclusion of these reviews, that the misoprostol is a safe, competent, and effective Induction component. Orally administered misoprostol reduces degrees of uterine hyper stimulation and adverse fetal outcome that's why it

is preferred as compare to vaginally administered misoprostol.[9-11]

The British Royal College of Obstetricians and Gynecologists and the World Health Organization (WHO) suggested that the usage of misoprostol tablets as they are economical. [12-14]

Three trials meta-analysis results showed that the Foley's catheter has reduced the rate of hyper stimulation, leading to reduced 'asphyxia' and reduced the risk of the post-partum hemorrhage. Because of that the Trans cervical Foley catheter was recommended for IOL. It is gathered from the reports that the Foley catheter has, comparable rates of success to the IOL with misoprostol (vaginal and oral), and less uterine hyper stimulation (with and without fetal heart rate changes) and a caesarian section rate, associated with it. [15, 16]

The main apprehension of this study was to assess the magnitude of successful Inductions (within 24 hours). We are comparing the usage of misoprostol in conjunction with the use of a Foley's catheter, and misoprostol administered alone with no other drugs or device. So far, very few studies have been done comparing this combination with misoprostol. In addition, the total deliveries performed, type of delivery, the time duration of onset of labor, total time of Induction, and the required dosages of misoprostol.

METHODS

An experimental study was conducted in the Department of Gynecology and Obstetrics, Ziauddin University and Hospitals from 1st Aug 2017- 15th Feb 2018 after approval from the ethical review committee of Ziauddin University, Karachi.

A total of 134 (67 in each group) eligible pregnant women age ≥18 years and admitting in labor room for IOL for many indications and contesting to participate were included. Detailed history was taken from patients fulfilling the inclusion criteria after written informed consent. History regarding age, gravid, parity, and Gestational age, weight and indication for Induction was taken.

Before the starting the induction process, cervical ripeness was evaluated by digital examination of the cervix by the on call resident in the labor room. On the bases on dilatation, effacement, consistency, position and engagement the acquired Bishop score was noted. Fetal heart was checked by doing Cardiotocograph. Women with poor bishop (less than 6) were randomized subsequently (i.e. alternately) in two groups, group A and group B.

Group "A" goes through induction using a 25 microgram tablet misoprostol per orally and Trans cervical Foley catheter (size 18F with 30ml balloon). Four doses of Misoprostol were repeated 6 hourly. The Foley's catheter continued until active labor started, or the catheter fell out, or 24 hours have elapsed since insertion. Similarly, the tablet misoprostol was continued until active labor started or 4 doses of misoprostol completed. If the Foley catheter falls out within 24 h, the amniotic membrane was ruptured and/or oxytocin infusion started. If labor has not commenced after 24 hours of combined Foley's catheter and misoprostol induction is considered to be failed and further management was made by the clinical team on their choices (It could include the use of misoprostol, caesarean section, repeat Foley catheter, dinoprostone, or delay as deemed appropriate).

In group "B" women were induced using misoprostol 25 mcg tablets given orally every 6 hourly for a maximum of 4 doses or until active labor commences. If a woman fails to go in labor after a maximum of four doses the Induction is considered as failed. If women went into active labor artificial rupture of the membranes or oxytocin administration was carried out as per routine. Eligible women were allocated in a 1:1 ratio to Induction with a Foley catheter plus misoprostol or oral misoprostol alone.

RESULTS

In this study total 134 women were included. The mean age of the women in group A was 29.70 ±4.50 years while mean age of the patients in group B was 25.36 ±3.44 years. In group A, multigravida was found significantly higher (n=60, 61.2%) followed by primigravida (n=7, 19.4%). In group B, 29 (43.2%) patients were primigravida and 38 (56.7%) patients were multigravida (p-value <0.001).

The mean gestational age of the patients in group A was 39.52 ± 0.82 weeks while mean gestational age of the patients in group B was 39.22 ± 0.83 weeks. Indications of Induction of labor showed that post term pregnancy was significantly higher (n=49, 61.3%) in group A compared to group B (Table 1).

Table 1: Demographics and indication for induction in pregnant women.

	Group A *(n=67)*	Group B *(n=67)*	P value
Age in years (Mean±SD)	29.70±4.50	25.36±3.44	<0.001
Gravidity			
Primigravida	7 (19.4)	29 (43.2)	<0.001*
Multigravida	60 (61.2)	38 (56.7)	
Gestational age (in weeks)	39.52 ± 0.82	39.22 ± 0.83	0.787
Indication of induction of labor			
Post term pregnancy	49 (61.2)	31 (38.8)	0.011
Diabetes Mellitus	0 (0.0)	3 (100.0)	
Fetal growth restriction	2 (33.3)	4 (66.7)	
High Blood pressure	0 (0.0)	3 (100.0)	
Pre-eclampsia	2 (20.0)	8 (80.0)	
Others	14 (43.8)	18 (56.2)	

Group A: Oral Misoprostol with foley catheter
Group B: Only oral Misoprostol
(*)Fisher's exact test

Regarding failed induction, fetal distress, dystocia, hyper stimulation and tachysystole no significant difference was found among the two groups (Table 2).

Table 2: Outcome in labor and comparison of mode of Delivery in IOL patients

Outcome of labor	Group A n (%)	Group B n (%)	P value
Failed induction			
Yes	1 (14.3)	6 (85.7)	0.847*
No	4(17.4)	19(82.6)	
Dystocia			
Yes	1 (33.3)	2 (66.7)	0.257*
No	4(10.8)	33(89.2)	
Fetal Distress			
Yes	3 (15.0)	17 (85.0)	0.729*
No	2(20.0)	8(80.0)	
Placenta abruption			
Yes	0 (0.0)	0 (0.0)	-
No	5(16.7)	25(83.3)	
Tachysystole			
Yes	0 (0.0)	0 (0.0)	-
No	67 (50.0)	67 (50.0)	
Hyper stimulation syndrome			
Yes	0 (0.0)	0 (0.0)	-
No	67 (50.0)	67 (50.0)	
Mode of delivery			
Normal Vaginal Delivery	62 (59.6)	42 (40.4)	<0.001*
Caesarean Section	5 (16.7)	25 (83.3)	

Group A: Oral Misoprostol with Foley catheter
Group B: Only oral Misoprostol
(*)Fisher's exact test
(-) p value not computed

Significant difference was found in mode of delivery between two groups with more vaginal deliveries in women who were induced with intra cervical Foleys together with misoprostol (Table 3).

Table 3: Neonatal outcome in Group A and Group B

Neonatal outcomes	Group A n (%)	Group B n (%)	p-value
Meconium			
No	64 (56.6)	49 (43.4)	<0.001*
Yes	3 (14.3)	18 (85.7)	
Abnormal FHR patterns on CTG			
No	62 (57.9)	45 (42.1)	<0.001*
Yes	5 (18.5)	22 (81.5)	
Apgar score < 7			
No	65 (52.8)	58 (47.2)	0.027*
Yes	2 (18.2)	9 (81.8)	
Apgar score (Mean ± SD)			
at 1 min	7.22 ± 0.62	6.60 ± 0.89	0.002
at 5 min	8.72 ± 0.65	7.69 ± 1.0	<0.001
Neonatal infection			
No	63 (53.8)	54 (46.2)	0.018*
Yes	4 (23.5)	13 (76.5)	
Neonatal hospital stay > 3 days			
No	65 (52.8)	58 (47.2)	0.027*
Yes	2 (18.2)	9 (81.8)	

Group A: Oral Misoprostol with Foley catheter
Group B: Only oral Misoprostol
(*)Fisher's exact test

Induction to delivery interval was found higher in group B than that of group A (17.21 ± 6.4 vs. 10.31 ± 5.2, p-value 0.038). Similarly the total dose of misoprostol used was significantly higher in group B than that of group A (124.6 ± 39.3 vs. 101.5 ± 22.9 micrograms; p-value <0.001).

Table 3 shows the neonatal outcome in both groups with significant difference in the presence of meconium stained liqour, fetal distress, low Apgar score and prolonged hospital stay in Group B compared to Group A.

DISCUSSION

This study aim to assess the magnitude of successful inductions during a period of twenty-four hours among women receiving, oral misoprostol in conjunction with intracervical Foley's, and misoprostol orally administered on its own merit in IOL. Oral misoprostol was preferred to initiate IOL in this trial, as oral misoprostol is considered to be safe, useful and easier to manage the dose. [17, 18]

In this study, normal vaginal delivery was considerably higher in oral misoprostol with Foley's catheter group than that of patients with only oral misoprostol group. Cesarean section was found higher in only oral misoprostol group versus in oral misoprostol with Foley's catheter group. In a recent randomized controlled trial on the competence of orally administered misoprostol and Foley's catheter versus orally administered misoprostol alone to induce labor conducted by Hussain et al. [19] revealed that unsuccessful vaginal delivery within 24 hours was found higher in women with oral misoprostol and Foley's catheter than that of oral misoprostol alone. [19] Another recent study conducted by Morris et al. in 2017 on the secureness and potency of orally administered misoprostol in females undergoing induction of labor stated that oral misoprostol regimen to induce labor is safe, and logistically feasible. This study was conducted in a resource limited setting.[20]

In a trial comparing three methods, Foleys catheter with misoprostol, misoprostol alone and dinoprostone alone for labor induction the author found no advantage or benefit of Foleys catheter in successful labor induction.[21] Kehl et al[22] in a multicenter study also found no advantage of intracervical foleys on successful labor induction. The high incidence of successful induction resulting in normal vaginal delivery in misoprostol and intracervical group in our study compared to other could be due to difference in the parity between the two groups with more multigravidas in group in both groups.

In our study, total dosage of misoprostol used and induction to delivery interval was significantly greater in only orally administered misoprostol group than

that of orally administered misoprostol used along with Foley's catheter group. Similar finding was found in a randomized trial comparing two groups[23] and also reported by Hussain et al. [19]

In oral misoprostol with Foley's catheter group, fetal distress was found in three women while in only oral misoprostol group, fetal distress was found in seventeen women. There were none of the women with contraction abnormalities in both groups. Frequency of meconium was found considerably higher in only oral misoprostol group than that of women with oral misoprostol with Foley's catheter group. Abnormal fetal heart rate patterns on CTG were considerably higher in only oral misoprostol group than that of women with oral misoprostol with Foley's catheter group.

Apgar score less than seven was found significantly higher in only oral misoprostol group. Similar findings was observed by Hussain et al.19 study ,where majority of the neonates in the only misoprostol group had Apgar scores less than seven and were admitted to the NICU (neonatal intensive care unit).

CONCLUSION

The number of successful inductions within 24 hours was found better among women receiving oral misoprostol with intracervical Foley's. Moreover, normal vaginal delivery was also found higher in women receiving oral misoprostol with intracervical Foley's. Fewer complications were seen in group A than in group B. So we could say that induction of labor is more successful if intracervical Foleys catheter is used in combination with oral misoprostol.

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