Original Article

Concurrent Use of Intracervical Foleys Catheter Plus Vaginal Misoprostol Versus Vaginal Misoprostol Alone for Induction of Labour

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Abstract

Objective: To compare frequency of mode of delivery and induction to delivery interval in women undergoing induction of labour with concurrent intracervical Foleys plus vaginal misoprostol versus vaginal misoprostol alone.

Methodology: It is a Randomized controlled trial conducted at MCH center,PIMS,Islamabad, Islamabad from 20th July 2016 to 19th January 2017. A total of 96 pregnant women of age group 18-35 years, with singleton cephalic fetus, were included and randomized into two groups: Group A (intracervical Foleys catheter plus vaginal misoprostol) & Group B (misoprostol alone), by using lottery method. In both cases, the mode of delivery and time taken from induction to delivery were recorded.

Results: Majority of the patients 68 (70.83%) were between 26 to 35 years of age,mean gestational age was 39.97 ± 0.85weeks Mean parity was 2.43 ± 1.22. There was a difference of 3.14 hours of induction to the delivery interval between the two groups which was statistically significant. Vaginal delivery was seen in 36 (75.0%) women in group A (intracervical Foleys catheter plus vaginal misoprostol) and in 26 (54.17%) women in group B (vaginal misoprostol alone) with p-value of 0.033

Conclusion: Concurrent use of Cervical Foleys and misoprostol is a simple, improved , cost-effective and safe regimen which results in higher vaginal deliveries rate and shorter induction to delivery time.

Keywords: mechanical methods, vaginal delivery, induction of labour.

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Introduction

Induction of labour (IOL) is the artificially initiating uterine contractions leading to progressive dilatation and effacement of the cervix for the purpose of achieving vaginal delivery. Labour is usually induced when the risks of continuing a pregnancy are more than the benefits of delivery. Labour is induced in about one-fifth of all maternities. The labour may be induced for maternal reasons (e.g., preeclampsia, cardiac or renal disease) or fetal reasons (e.g., intrauterine growth restriction) or a combination of maternal and fetal reasons (e.g., poorly controlled diabetes, preterm rupture of the membranes or post-term pregnancy).[2] Data from WHO global survey on maternal and perinatal health which included 373 healthcare

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facilities in 24 countries showed 9.6 % deliveries involved labour induction[3]

Ripening of the cervix may be done by both pharmacological and non-pharmacological (mechanical) methods. The pharmacological preparation includes the prostaglandins. Prostaglandin E2 analogue (or Dinoprostone) and Prostaglandin E1 analogue (misoprostol) are commonly employed. Prostaglandin E2 (or dinoprostone) requires refrigeration and is unstable at room. Prostaglandin E1 analogue, misoprostol is also in use for cervical ripening and induction of labour. Transcervical use of foley catheter for cervical ripening and induction of labour is one of the method for induction of labour. Embrey and Mollison first described using a transcervical Foley catheter for cervical ripening. Foley catheter appears to induce labour by direct mechanical dilatation of cervix as well as by stimulating an endogenous release of prostaglandin.[4]. Therefore, methods of cervical ripening that ripen the cervix in a short span of time have an important role in modern obstetrics[5]. Some randomized trials have compared the use of the Foley bulb, oxytocin, and misoprostol in different combinations for induction of labor. The results of these studies are conflicting with regard to induction to delivery time, success in achieving vaginal delivery, and labor complications.

There was no local study designed in Pakistan to compare the effectiveness of induction of labour with combination method (mechanical plus pharmacological) versus traditional pharmacological methods. There was a need for change of method of induction to increase vaginal delivery rate in our country to reduce the workload, morbidity and cost related to caesarian delivery. It is hypothesized that a synergistic combination of a mechanical agent (Foley catheter) with a pharmacological agent (intravaginal misoprostol) will result in higher number of vaginal deliveries compared to the use of misoprostol in isolation.

Methodology

This randomized control trial was conducted from July 20th, 2016 to Jan 19th 2017 at Maternal & Child Health Center, Pakistan Institute of Medical Sciences. After the approval of the institutional ethics committee, each consecutive patient who fulfilled eligibility criteria and consented to participate in the study was enrolled from outdoor and emergency department. Informed consent was taken from patients. Patients' detailed history and examination were done followed by relevant routine investigations. All study related information was collected on pre-designed proforma. A sample size of 96 was calculated. Sample size was calculated using WHO sample size calculator. Level of significance was set at 5%, power of test 80%,test value of populationrate of vaginal delivery for misoprostol 0.898[3] and test value of vaginal delivery in Cervical Folleys 0.65. [6] Patients were randomly allocated to groups,48 patients in each group by lottery method.

Patients in Group A were induced with intracervical Foleys catheter no. 16 concurrent with vaginal misoprostol by resident on call as per protocol of department. The Foley was inserted through the internal cervical Os under direct visualization with the sterile speculum, filled with 60 mL of normal saline, and then pulled gently against the internal Os. The catheter of the Foley bulb was taped to the patient's inner thigh under gentle traction. The dose of 50 microgram misoprostol tablet was placed in posterior vaginal fornix at the time of intracervical Foleys catheter insertion. Post Induction CTG was performed after one hour of induction procedure. Then reassessment was done for palpable uterine contractions and improvement in Bishop score after 6 hours. If bishop score was not more than 6 or palpable uterine contractions within 10 minute duration absent and fetal heart rate trace was reassuring then 50 microgram tab misoprostol was repeated and post induction CTG after 1 hour was done and reassessment was repeated after 6 hours. Foleys catheter was removed at 2nd reassessment after 12 hours irrespective of improvement in bishop score or palpable uterine contractions. However, 3rd dose of vaginal misoprostol was placed if required after reassessment after 12 hours. If the patient went into labour at any time since start of induction procedure further management of labour was done as per protocol of department. The Foley catheter was also removed if FHR were non-assuring mandating amniotomy, membranes ruptured.

Patients in Group B were induced by vaginal misoprostol 50 microgram only and was followed by 1-hour CTG and reassessment after 6 hours same as group A. vaginal misoprostol 50 microgram was repeated at 6 hrs and 12 hours of induction if no improvement in bishop score or palpable uterine contractions in the presence of reassuring fetal heart rate trace.

Emergency LSCS (EM LSCS) was performed at any time during induction to delivery interval if pathological fetal heart rate tracing seen on cardiotocograph or Meconium stained liquor noticed in case of spontaneous rupture of membranes or artificial rupture of membranes. EMLSCS for failed induction was done if patient did not go in labour after 3 doses of intravaginal misoprostol in

both groups. Mode of delivery was recorded. For patients undergoing Caesarean section, indication of caesarean delivery was recorded and for patients undergoing vaginal delivery, induction to delivery interval was recorded. Any maternal complications, APGAR score at birth and need of nursery/NICU admissions were also recorded.

Data was entered and analyzed using the SPSS version 11. For the qualitative variable: mode of delivery, Diabetes, hypertension, Oligohydramnios, pathological CTG, meconium staining and failed induction, frequency and percentage were calculated. Mean and standard deviation was calculated for age, parity, gestational age and induction to delivery interval. Effect modifiers like age, gestational age, parity, GDM, PIH and Oligohydramnios were controlled by stratification. Post stratification Chi-square test was applied to compare the mode of delivery in two groups. Independent sample t-test was used to compare induction to delivery interval between two groups. A p-value of ≤ 0.05 was considered statistically significant.

Results

Age range in this study was from 18 to 35 years with mean age of 27.92 ± 4.18years. The mean age of women in group A was 28.08 ± 4.08 years and in group B was 27.79 ± 4.34 years. Majority of the patients 68 (70.83%) were between 26 to 35 years of age as shown in Table I.

Gestational age was >38 weeks with mean gestational age of 39.97 ± 0.85weeks. Mean parity was 2.43 ± 1.22. Distribution of patients according to age, parity, PIH, GDM and oligohydramnios and post dates (> 41 weeks) in both groups is shown in Table I As far being post dates, in our unit patients are induced at 41 weeks if they don't deliver by then Vaginal delivery was seen in 36 (75.0%) women in group A (intracervical Foleys catheter plus vaginal misoprostol) and in 26 (54.17%) women in group B (vaginal misoprostol alone) with p-value of 0.033 (figure 1). In group A the indication for LSCS were pathological CTG in 3, Meconium stained liquor in 3, non progress of labour in 4 and failed induction in 2. In Group B the Indication of EMLSCS was pathological CTG in 4, meconium stained liquor in 5, non progress of labour in 2 and failed induction in 11 patients. Stratification of mode of delivery according to age of patients and gestational age, PIH, GDM & oligohydramnios is shown in Table II. More patients achieved vaginal delivery in group A than Group B, the effect was more marked in patients of low parity, Diabetes and oligohydromnios.

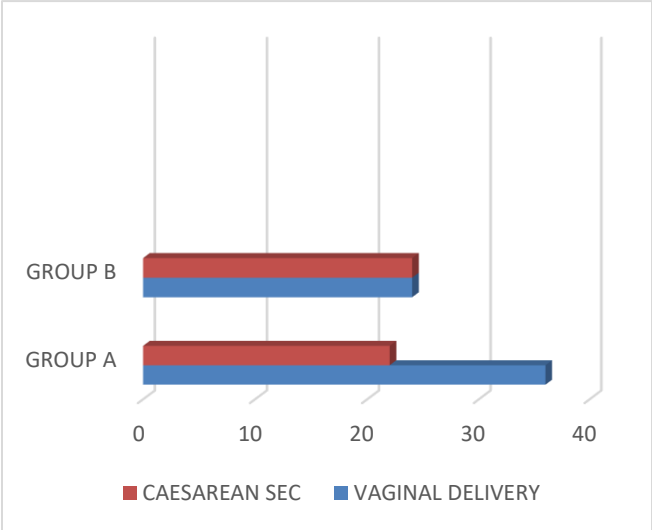

Table I: Distribution of Age, Gestational age, parity, PIH, GDM & Oligohydramnios for both groups (n=96)

variables		Group A		Group B		Total	
		No of patients N=48	Percentage %	No of patients N=48	Percentage %	No of Patients N=96	Percentage %
Age(years)	18-25	12	25.0	16	33.33	28	29.17
	26-35	36	75.0	32	66.67	68	70.83
Gestational Age (weeks)	38-40	37	33.33	29	27.08	29	30.21
	>40	11	66.67	19	72.92	67	69.79
Parity	≤ 2	23	47.92	21	43.75	44	45.83
	≥2	25	52.08	27	56.25	52	54.17
Co-Morbids	PIH	13	27.08	11	22.92	24	25.0
	DIABETES	14	29.17	12	25.0	26	27.08
	OLIGOHY-DROMNIOS	15	48.4	16	51.6	31	35.29
	>41 WEEKS	6	12.5	9	18.75	15	31.25

Table II: Stratification of mode of delivery according to Age, gestational age, Parity, PIH, GDM, Oligohydramnios						
VARIABLES		Group A (n=48) Mode of delivery		Group B (n=48) Mode of delivery		P-value
		Cesarean	Vaginal	Cesarean	Vaginal	
Age (years)	18-25(N=12)	02 (16.67%)	10 (83.33%)	06 (37.50%)	10 (62.50%)	0.227
	26-35 (N=36)	10 (27.78%)	26 (72.22%)	16 (50.0%)	16 (50.0%)	0.060
Gestational Age(weeks)	39-40 weeks (N=37)	02 (12.50%)	14 (87.50%)	04 (30.77%)	09 (69.23%)	0.227
	>40 weeks (N=11)	10 (31.25%)	22 (68.75%)	18 (51.43%)	17 (48.57%)	0.094
Parity	≤2 (N=23)	05 (21.74%)	18 (78.26%)	14 (66.67%)	07 (33.33%)	0.003
	>2 (N=25)	07 (28.0%)	18 (72.0%)	08 (29.63%)	19 (70.37%)	0.897
PIH (n=24)		05 (10.46%)	08 (16.66%)	06 (12.53%)	05 (10.46%)	0.459
GDM (n=26)		03 (06.26%)	11 (22.96%)	10 (20.83%)	06 (12.53%)	0.001
Oligohydromnois (n=31)		03 (06.26%)	11 (22.96%)	11 (22.96%)	09 (18.75%)	0.002
Gestational age ≥41 weeks (n=15)		01 (02.08%)	05 (10.46%)	03 (06.67%)	06 (12.53%)	0.52

Figure 1. Comparison of mode of delivery between two groups n=96, p=0.033

There was a difference of 3.14 hours of induction to delivery interval between the two groups which was statistically significant (see Figure 2). Regarding complications, 1 patient in group A had PPH and 2 patients in group B had PPH. The difference was not statistically significant. These patients were managed successfully with uterotonics there was no incidence of uterine hyper stimulation.

There were no stillbirths in either group. Four babies in Group A and 5 in Group B needed admission in nursery for observation.

There was no statistically significant difference in APGAR scores at 1 minute and at 5 minutes between the two groups

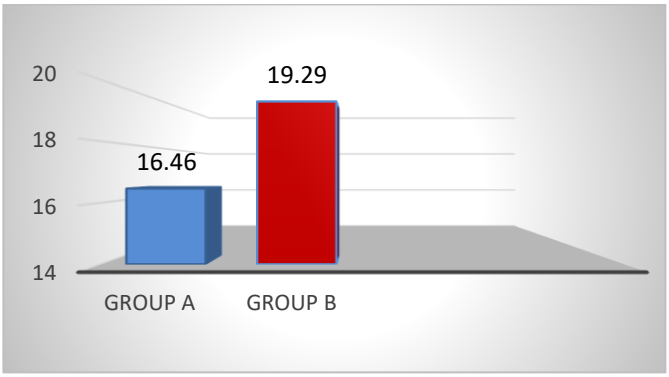

Figure 1: Comparison of induction to delivery interval in hours (P=0.001)

Discussion

Labour induction has been done using a number of methods. Vaginal delivery within a suitable time span cannot be achieved by Oxytocin when used for induction of labour in presence of low Bishop score. It increases risk of. Therefore, methods and agents that ripen the cervix in a short period of time play an important role in modern obstetrics.[7] There is no consensus as to what's the best and most proper method of cervical ripening and labor induction is in cases with an unripe cervix. Cervical foley catheter and vaginal misoprostol (prostaglandin E1) are used for labor induction and cervical ripening.[8-10] Research has suggested that mechanical methods have comparable clinical effectiveness to prostaglandins with no overall significant difference in Caesarean Section rates, vaginal delivery within 24 hours of induction, or need for oxytocin.[10] This study was conducted if combining cervical Folleys –a mechanical method with vaginal misoprostol will result in fewer cesarean sections and earlier vaginal delivery.

Few Studies have compared combined misoprostol and cervical Folleys with misoprostol using different routes and doses of misoprostol and different types with different filling pressures of Folleys ballon.[3,12,13] Lanka found no difference in induction to delivery time but some of their patients had lower gestational age and Bishop score than those in our study.[3] A study done in Germany[12] employed sequential use of Folleys and misoprostol while our study used concurrent misoprostol and Folleys and better results have been seen in concurrent versus sequential use.[13] A study conducted by Balducci et el using concurrent use of misoprostol and Folleys also did not find difference in Caesarean section rates and induction to delivery interval but this study had used lower misoprostol dose. [14] These aspects may explain shorter induction to delivery interval and higher chances of vaginal delivery seen in our study as compared to above reported studies.

Studies done by Kehl and Andes yielded results similar to ours.[15,16] A study done in India also reported increased chances of vaginal delivery and lower induction to the delivery interval as in our study.[17] We

used single balloon catheter The single balloon catheter produces mild mechanical expansion, stimulates endogenous prostaglandin secretion, promotes cervical dilatation, stimulates the release of oxytocins from local plexus of the cervix, helps in expansion of the cervix . It also boosts the synthesis of cervical tissue collagen and ripening. The single balloon catheter has also been seen to improve the comfort level of pregnant women, contribute to the active stage of labour thereby shortening the total stage of labor and decreasing the pain of delivery. [18] Adding misoprostol with cervical folleys has synergistic action, thereby explaining better efficacy of the combined method than single alone.[19]

In our study, lower maternal complications were seen than in other studies. This may be contributed to active management of the third stage of labour thereby reducing PPH incidence. Also, the clear SOPS for monitoring of Bishop Score and palpable contractions at each assessment before placing next dose of misoprostol may have contributed to nonoccurrence of hyperstimulation in either group.

The strength of the study is that no study has compared concurrent use of these two cost effective labour inducing agents with separate use of misoprostol. We also stratified results according to indications of inductions and variables that may have influenced an outcome.

The limitation is that due to the study design, the doctors and the patients could not have been blinded to the study. Secondarily use of oxytocin and instrumental deliveries were not studied.

Conclusion

This study concluded that induction of labour with intracervical Foleys catheter plus vaginal misoprostol leads to increased frequency of normal vaginal delivery as compared to vaginal misoprostol alone. So, it is recommended that combination method (mechanical plus pharmacological) should be used as first line therapy for induction of labour because it is simple, safe, better and more effective than misoprostol alone for induction of labour in order to reduce maternal morbidity.

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