Original article :

Study of Comparative Evaluation of Vaginal and Oral Doses of Misoprostol for Labour Induction

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Abstract

Background: Induction of labour is the artificial initiation of labour before its spontaneous onset to deliver the feto-placental unit. The frequency of induction varies by location and institution. Hence; the present study was conducted for comparing vaginal and oral doses of misoprostol for labour induction.

Materials & Methods: A total of 200 pregnant females were enrolled in the present study. All the subjects were randomly divided into two study groups as follows: Group A: Subjects given oral dose of Misoprostol, and Group B: Subjects given vaginal Misoprostol. When uterine activity suggested the onset of labour, vaginal assessment was performed and the women would be sent to the labour ward. Failed induction of labour was defined as vaginal delivery not achieved within 24 hours of initiating induction of labour. All the results were recorded in Microsoft excel sheet and was subjected to statistical analysis using SPSS software.

Results: Mean age of the patients of group A and group B was 31.5 years and 30.9 years respectively. Induction to vaginal delivery interval was similar in both the study groups. While comparing the cervical ripening variables among the two study groups, non-significant results were obtained. Also, while comparing the neonatal outcome among the two study groups, non-significant results were obtained.

Conclusion: Oral misoprostol is equally effective as its vaginal route in induction of labor.

Keywords: Vaginal, Misoprostol, Labour induction.

INTRODUCTION

Induction of labour is the artificial initiation of labour before its spontaneous onset to deliver the feto-placental unit. The frequency of induction varies by location and institution. The rate of induction in western subcontinent has increased steadily from 12.9% in 1991–1992 to 19.7% in 1999–2000. The rate reached a high of 23.7% in 2001–2002, decreased slightly to 21.8% in 2004–2005, and has since remained steady. The 2010 BC Perinatal Health Registry reveals a similar trend and rate, with post-term pregnancies (> 41 +0 weeks) representing 34%, the largest group, of the total inductions in BC. When undertaken for appropriate reasons, and by appropriate methods, induction is useful and benefits both mothers and newborns. The goal of induction is to achieve a successful vaginal delivery that is as natural as possible. The objectives of this guideline are to summarize the indications for induction, review current methods of cervical ripening and labour induction, and evaluate the safety and effectiveness of agents and methods used in cervical ripening and labour induction.[1- 3]

There are few absolute indications for inducing labour, and priorities vary with the obstetrician. Post-maturity (when the pregnancy extends well beyond the expected delivery date) still heads the list, followed by suspected fetal growth retardation and maternal hypertension. Social factors—such as the woman's own wishes—play a larger part these days. In a meta-analysis of 10 randomized controlled trials comparing induction at 41-42 weeks with conservative treatment, Crowley showed the increased risk of perinatal deaths associated with prolonged pregnancy. The risk is reduced by induction at 41 weeks (Cochrane Collaboration). A non-medical indication for induction is the woman's own wishes. Many mothers exceeding their expected delivery date by a week consider that their pregnancy has gone far enough and ask for induction. Roberts and Young found that about 70% of women expressed the wish to be induced after 41 weeks. Provided that the cervix is ripe, many obstetricians would agree with this choice and use a non-invasive method—for example, prostaglandins.[4- 6] A single study was found comparing induction of labour with misoprostol to oxytocin in women of advanced maternal age (≥ 35) with an unfavourable cervix (Bishop < 6). The results were consistent with other studies showing the benefit of PG over oxytocin in an unripe cervix.[7]

Hence; the present study was conducted for comparing vaginal and oral doses of misoprostol for labour induction.

MATERIALS & METHODS

The present study was conducted comparing vaginal and oral doses of misoprostol for labour induction. A total of 200 pregnant females were enrolled in the present study. All the subjects were randomly divided into two study groups as follows:

Group A: Subjects given oral dose of Misoprostol, and

Group B: Subjects given vaginal Misoprostol

Inclusion criteria were those whose age were between 25–38 years, multigravida and gestational age between forty to forty-two weeks. Vital signs and a check of the abdomen were part of the thorough history and general physical examination. A fetal cardiotocographic tracing was carried out to verify the health of the fetus. Comprehensive blood and urine examinations, blood grouping, and Rh factor testing were all part of the baseline studies. Bishop's score was determined before administering any preparation, and if it was less than six, the patient was scheduled for labor induction. When uterine activity suggested the onset of labour, vaginal assessment was performed, and the women would be sent to the labour ward. Failed induction of labour was defined as vaginal delivery not achieved within 24 hours of initiating induction of labour. All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software. Chi-square test and student t test was used for evaluation of level of significance.

RESULTS

The mean age of the patients of group A and group B was 31.5 years and 30.9 years respectively. Induction to vaginal delivery interval was similar in both the study groups. While comparing the cervical ripening variables among the two study groups, non-significant results were obtained. Also, while comparing the neonatal outcome among the two study groups, non-significant results were obtained.

Table 1: Obstetrical outcome

Variable		Group A	Group B	p-value
Induction to vaginal delivery interval detail	**Less than 12 hours**	53	55	0.21
	12 to 24 hours	36	35	
Mode of delivery	**C-Section**	11	10	0.51
	Vaginal delivery	89	90	

Table 2: Complications of Cervical ripening

Variables	Group A	Group B	p-value
Urine hyper stimulation	10	12	0.49
Uterine tachysystole	21	18	0.61
Allergic reaction	6	3	0.88
Nausea/Vomiting	5	6	0.34

Table 3: Neonatal outcome

Variable		Group A	Group B	p-value
Birth weight (gram)		3021.2	2977.8	0.125
Peri-natal		1	2	0.642
Ambo ventilation		13	9	0.821
APGAR < 7	**1 min**	6	5	0.449
	5 min	8	6	0.797

DISCUSSION

The incidence of labour induction has increased over the last decade. Labour induction may be indicated by medical or obstetrical complications of pregnancy or may be requested or chosen for non-medical or social reasons. When a woman and her care provider decide that labor induction is desired, they must next choose a method of induction. Several factors may influence the choice of method for induction of labour including cervical and membrane status, parity, and patient and provider preference.[8] Hence; the present study was conducted for comparing Vaginal and Oral Doses of Misoprostol for Labour Induction.

Mean age of the patients of group A and group B was 31.5 years and 30.9 years respectively.

Induction to vaginal delivery interval was similar in both the study groups. While comparing the cervical ripening variables among the two study groups, non-significant results were obtained. Also, while comparing the neonatal outcome among the two study groups, non-significant results were obtained. Previous research carried on mifepristone for induction of labour combining 10 trials included 1108 women. The authors found that mifepristone was superior to placebo in achieving a favourable cervical score or initiating labour within 48 hours (4 studies, 293 women, 75/152 versus 27/171; RR 2.41, 95% CI 1.70 to3.42, NNT = 4). Compared to placebo, mifepristone reduced the risk for caesarean section (9 trials, 1043 women, 163/ 661 versus 113/ 382; RR

0.74, 95% CI 0.60 to 0.92; NNT = 14), but increased the risk for instrumental vaginal delivery (7 trials, 814 women, 139/540 versus 47/274; RR 1.43, 95% CI 1.04 to1.96; NNH = 14). Compared to placebo, mifepristone increased the likelihood of FHR abnormalities (5 trials, 721 women, 101/493 versus 35/228; RR 1.60, 95% CI 1.12 to 2.29; NNH = 11) but did not adversely affect neonatal outcomes.[9] Zieman M et al compared the pharmacokinetics of vaginal and oral administration of the prostaglandin E1 analogue, misoprostol. All 20 subjects completed the study. The maximum mean (+/- standard deviation [SD]) of misoprostol acid differed significantly between the oral and vaginal groups (277 +/- 124 compared with 165 +/d- 86 pg/mL, respectively; P = .03, analysis of variance), as did the mean +/- SD time to peak levels (34 +/- 17 compared with 80 +/- 27 minutes, respectively; P < .001) and areas under the misoprostol concentration versus time curve (mean +/- SD) up to 4 hours (n = 20,273.3 +/- 110.0 compared with 503.3 +/- 296.7 pg.hour/mL, respectively; P = .033) and up to 6 hours (n = 10, 300.0 +/- 103.3 compared with 956.7 +/- 541.7 pg.hour/mL, respectively; P = .029). The extent of absorption was highly variable among subjects in each group. There are significant differences in the pharmacokinetics of misoprostol administered by vaginal and oral routes that may explain the difference observed in clinical efficacy.[10] Wing DA et al compared the effect of vaginal administration of misoprostol (Cytotec) with that of dinoprostone (Cervidil) on cervical ripening and labor induction. Two hundred patients with indications for induction of labor and unfavorable cervical examinations were randomly assigned to receive vaginally administered misoprostol (prostaglandin E1) or the dinoprostone (prostaglandin E2) vaginal insert. There was a significantly lower prevalence of tachysystole (six or more uterine contractions in a 10-minute window for two consecutive 10-minute periods) in the misoprostol group (7.1%) than in the dinoprostone group (18.4%) (relative risk 0.52, 95% confidence interval 0.31 to 0.89, p = 0.02). There were no significant differences in frequency of uterine hyperstimulation or hypertonus. Abnormal fetal heart rate tracings were found in 23 (23.2%) of misoprostol-treated patients and 35 (35.7%) of dinoprostone-treated patients (relative risk 0.73, 95% confidence interval 0.52 to 1.01, p = 0.0546). Vaginally administered misoprostol is as effective as dinoprostone for cervical ripening and the induction of labor.[11] Windrim R et al evaluated the effectiveness, safety, and gastrointestinal tolerance of misoprostol taken orally for induction of labor, against established protocol, with the interval from induction to vaginal birth as the primary outcome measure. Two hundred seventy-five women who presented with indication for induction of labor were assigned randomly to receive either 50 micrograms of misoprostol orally every 4 hours as needed or treatment according to our established protocol (physician-chosen combinations of intracervical or vaginal prostaglandins every 4-6 hours, artificial rupture of membranes, and oxytocin infusion). The mean time (+/-standard deviation) to vaginal birth with oral misoprostol was 926 +/- 521 minutes versus 909 +/- 585 minutes with the established protocol, a nonsignificant difference. There were no clinically or statistically significant differences in maternal secondary outcome measures (cesarean rate, frequency of epidural use, perineal trauma, or manual removal of the placenta). There was no difference in frequency of maternal gastrointestinal side effects. Neonatal outcomes, including cord blood acid-base analysis, were not different. Oral misoprostol may be a new option for labor induction.[12]

CONCLUSION

Oral misoprostol is equally effective as its vaginal route in induction of labor.

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