A Comparison between Single Dose of 50 μg Oral Misoprostol and 25 μg Vaginal Misoprostol for Labor Induction

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Objective: *To compare the efficacy and safety of a single dose of 50 μg oral misoprostol with 25 μg vaginal misoprostol for labor induction.*

Material and Method: *This study was a randomized, double-blind controlled trial conducting in pregnant women admitted at delivery room, Department of Obstetrics and Gynecology, Bangkok Metropolitan Administration Medical College and Vajira Hospital between March 2002 and January 2005. All 146 pregnancies at ≥ 37 weeks' gestation who had indication for labor induction with unfavorable cervix were randomly divided into a group of single dose of 50 μg misoprostol orally or 25 μg misoprostol vaginally. Initial and six hours after misoprostol administration, Bishop scores were evaluated. Requirement of oxytocin augmentation, complication due to uterine hypertonus, incidence of vaginal delivery, Apgar score at 1 and 5 minutes, and number of neonate admitted at neonatal intensive care unit (NICU) were recorded.*

Results: *The baseline characteristics and median initial Bishop scores were comparable in both groups. At 6 hours after misoprostol administration the median cervical changes of women who received oral or vaginal misoprostol were statistically significant different, 3 and 4, respectively. The median time interval to vaginal delivery of women who received oral misoprostol was significantly longer than of those who had vaginal drug, 16.9 and 11.8 hours respectively. Comparable neonatal outcomes were found in both groups in terms of assigned Apgar score at 1 and 5 minutes.*

Conclusion: *A single dose of 25 μg vaginal misoprostol appears to be more effective than 50 μg oral dose in improving Bishop scores and decreasing the time to vaginal delivery in women with unfavorable cervix without severe adverse effects.*

Keywords: *Labor induction, Cervical ripening, Single dose misoprostol, Oral, Vaginal*

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In general, labor induction is indicated when the benefits of delivery outweigh the risks of pregnancy continuation, such as any events leading to compromised maternal and/or fetal health. Oxytocin is a drug which is commonly used for labor induction. However, its use in pregnant women with unriped cervix appears to have high failure rate with an increase rate of cesarean section[1]. Prostaglandin compounds have recently been introduced for cervical ripening and labor induction. Prostaglandin E_2 is the first compound used for this purpose and is usually administered vaginal route[2]. Misoprostol, a prostaglandin E_1 synthetic analog, is another prostaglandin compound used in this clinical setting and can be used either by oral or vaginal route. Many studies reported the efficacy of misoprostol in ripening cervix and inducing labor in women with low Bishop scores.[2-7]

One clinical trial comparing 3 doses of 200 μg oral misoprostol or 50 μg vaginal misoprostol showed similar effectiveness of the two regimens but uterine tachysystole and hyperstimulation ocurred more commonly in the oral group than in the vaginal group (38.7%

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vs 20.0% and 44.1% vs 21.2% respectively)[8]. These side effects of oral misoprostol was lessened by using the drug at lower dose. This was reported in one study that the lower doses oral misoprostol at 50 μg still had similar efficacy as vaginal drug with comparable incidence of uterine tachysystole, 9% and 7.3% respectively[9]. However, most of these studies used multiple drug dosages which led to inconvenience to the physician and the women being treated.

The objectives of this study were to compare the efficacy of single low dose in both oral and vaginal drug; 50 μg oral misoprostol and 25 μg vaginal misoprostol. The requirement of oxytocin augmentation after misoprostol administration and any adverse effects were also studied.

Material and Method

We conducted a randomized double-blind controlled trial in the delivery room, Department of Obstetrics and Gynecology, Bangkok Metropolitan Administration Medical College and Vajira Hospital during March 1, 2002 and January 31, 2005. The protocol was approved by the Institutional Ethics Committee before the start of the study. Written informed consent was obtained from each woman before entering into the study.

All women who sought for antenatal care at BMA Medical College and Vajira Hospital during the study period and were indicated for labor induction were invited to enter into the study. Inclusion criteria were (1) singleton gestation in a cephalic presentation, (2) reassuring fetal heart rate (FHR) pattern, (3) unfavorable cervix (was defined as Bishop score of ≤ 6)[10] (4) gestational age ≥ 41 weeks without labor pain or $\geq$ 37 weeks with indications for labor induction such as hypertension, oligohydramnios, IUGR, and gestational diabetes mellitus, (5) intact amniotic membranes and (6) absence of uterine contraction observed in a 20 minute interval. Exclusion criteria included (1) estimated fetal weight of > 4,000 g or evidence of cephalopelvic disproportion, (2) parity of ≥ 6, (3) previous cesarean delivery or history of uterine incision, (4) any contraindication to vaginal delivery such as placenta previa, vasa previa and active genital herpes simplex infection, (5) evidence of chorioamnionitis as determined by maternal temperature $\geq$ 100.4ºF and the presence of either uterine tenderness or, foul-smelling amniotic fluid, or both, (6) any contraindication for prostaglandin use eg. history of glaucoma or preexisting cardiac disease.

Consenting candidates were reassessed in the next early morning (6 AM, day 1) for uterine contraction and reassuring fetal heart rate (FHR) pattern with external fetal monitoring and external tocodynamometry used for a 20-minute period. The women who had reassuring (FHR) pattern and absence of uterine contraction underwent digital cervical examination by a resident or attending staff in charge to determine their Bishop score. Of those women who obtained Bishop score ≤ 6 were randomized to receive either oral or vaginal misoprostol. The misoprostol 25 μg tablet was prepared by dividing the 200 μg tablet to one-eight by using electrical weight balance. Vitamin B6 placebo was prepared by dividing the vitamin B6 100 mg tablet into 25 μg tablet. Each of the two drugs appeared similar in appearances. The randomization was stratified by block of four and was performed by the resident or the attending staff. The uninvolved staff prepared the opaque envelope which contained two packs labeled "vaginal medication" (either 1 vitamin B6 placebo or 1 misoprostol [Cytotec®; Searle, Chicago, IL]; and "oral medication", either 2 vitamin B6 placebo or 2 misoprostol). Hence, each envelope contained 1 pack of oral placebo and 1 pack of vaginal misoprostol or 1 pack of vaginal placebo and 1 pack of oral misoprostol. Regardless of any regimen assigned, each woman received a single dose of 2 oral tablets with 30 ml of water and a single dose of 1 vaginal tablet placed in the posterior fornix of the vagina. The study women, nurses, residents, attending staff and investigators were unaware of the block randomization and group assignment until data analysis was completed.

Continuous external fetal monitoring and external tocodynamometry [Ohaus-model AP210S] were used in all women. Nonreassuring fetal heart rate patterns were defined as the presence of either fetal tachycardia or bradycardia, late decelerations, repetitive variable deceleration, prolong deceleration, and decrease beat to beat variability.

Evaluation of uterine activity monitoring was performed to assess the frequency and duration of contraction. Excess uterine activity consisted of uterine tachysystole or hypertonus. Uterine tachysystole was defined as at least 6 contractions in 10 minutes for 2 consecutive 10-minute periods; hypertonus was defined as a single contraction that lasted longer than 2 minutes. Uterine hyperstimulation was defined as tachysystole or hypertonus associated with nonreassuring fetal heart rate pattern. This condition was treated with one or all of the actions: cessation of any oxytocin infusion, maternal lateral positioning, intravenous fluid blousing and oxygen supplementa-

tion. A 0.25 mg dose of terbutaline was administered intravenously or subcutaneously if contraction caused either hyperstimulation or woman discomfort.

Depending on the treatment allocation, 50 μg of misoprostol was given orally or 25 μg of misoprostol was given vaginally. After the primary evaluation at the start, the next evaluation of Bishop score and uterine contraction were performed at six hours after misoprostol administration, if uterine contraction was not adequate (was defined as < 3 contraction in a 10-minute period of observation), failure to progress to the active phase of the first stage of labor (was defined as failure to achieve a cervical dilatation of ≥ 4 cm)[10], or after spontaneous rupture of membranes during misoprostol administration, oxytocin was administered via infusion pump. The infusion was initiated with a dose of 2 mU/min, with incremental increase of 1-2 mU/min every 15-30 minutes to a maximum of 40 mU/min. Women who required oxytocin infusion and failed to progress to the active phase of the first stage of labor after misoprostol administration 12 hours, oxytocin infusion was halted for a period of 12 hours and restarting of oxytocin augmentation in the next morning (6AM, day 2). The artificial membrane rupture was performed at the discretion of the residents and attending staff.

The primary outcomes were the time interval from misoprostol administration to delivery and the number of women required oxytocin augmentation for labor.

The secondary outcomes were failed induction, mode of delivery, the incidence of peripartum maternal complications: uterine tachysystole, hypertonus, hyperstimulation, excessive bleeding, chorioamnionitis. The neonatal outcomes were also studied, including 1 and 5 minute Apgar scores, need for resuscitation (positive pressure ventilation, intubation, or chest compressions), and admissions to the neonatal intensive care unit (NICU).

Statistical analyses were analyzed using SPSS 11.5 (SPSS, Chicago, IL). Demographic data were reported in numbers or percentages and mean with standard deviation or median with range. Student's t test (two tailed analysis) was used for normally distributed continuous variable, whereas Mann-Whitney U test was used for those that was not normally distributed. The categorical data were compared by Chi-square or Fisher's exact test as appropriate. Statistical significance was assigned to P value of < 0.05.

Results

A total of 146 women were enrolled in the study, 73 (50%) received oral misoprostol and 73 (50%) received vaginal misoprostol. Table 1 shows clinical characteristics of the women of the two groups. Only gestational age showed statistical significance but no clinical significance (41.0 versus 41.3 weeks).

Indications for labor induction were not significantly different between the two groups (Table 2). The majority of indications were estimated gestational age greater than 41 weeks. The other indications were oligohydramnios (amniotic index of < 5 cm), postterm pregnancy (estimated gestational age > 42 weeks), chronic hypertension, and gestational diabetes mellitus.

The initial median Bishop scores prior to misoprostol administration of the two groups were not statistically significant different. A significantly greater median Bishop score change, assessed at 6 hours after misoprostol administration, was observed in the vaginal group than the oral group, 4 versus 3 (p=0.01). Less number of women in the vaginal group required oxytocin augmentation than those in the oral group (29/73 [39.7%] versus 41/73 [56.2%], p=0.047). The median time interval from initiation of labor induction to vaginal delivery of the women in the vaginal group was approximately 5 hour sooner than the median time of the oral group (p=0.01). When we factored the women according to the use of oxytocin, the time interval to delivery of women who had oral drug was longer than those who had vaginal drug, 28.1 hours versus 12.6 hours respectively. This 16 hours difference appeared to be clinical significant, however this did not reach statistical significance (p=0.09) (Table 3).

Table 4 depicts modes of delivery and indications for cesarean section. No difference in numbers of vaginal and cesarean section deliveries between the two groups was found. The numbers of operative vaginal deliveries between the two groups were not significant different. Five women of oral group compared to only one woman of vaginal group underwent operative vaginal deliveries. The indications for cesarean section were either fetal distress or induction failure (was defined as failure to achieve a cervical dilatation of ≥ 4 cm after oxytocin augmentation on day 2) and arrest disorder of labor. Emergency cesarean section delivery were performed in seven women; three in the oral group and four in the vaginal group. All were due to fetal distress. Oxytocin was administered in 4/7 women (two from each oral and vaginal group). Three out of these four women had oxytocin 24 hours after misoprostol and one had it at 6 hour after. The interval from oxytocin infusion to fetal distress ranged from 1.5-7.5 hours.

Table 1. Baseline characteristics of oral versus vaginal misoprostol administration groups (N=146,73 in each group)

Characteristics	Oral (n=73)	Vaginal (n=73)	P-value
Age (year): mean (SD)	25.6 (5.7)	25.3 (5.8)	0.61*
BMI (kg/m^2): mean (SD)	28.3 (3.6)	28.6 (4.4)	0.73*
Parity			
Nulliparous [n, (%)]	45.0 (61.6)	44.0 (60.3)	0.87**
Multiparous [n, (%)]	28.0 (38.4)	29.0 (39.7)	
Gestational age (week) : mean (SD)	41.3 (0.4)	41.0 (1.0)	0.02*

*Unpaired t test, **Chi square test

Table 2. Primary indications for induction of oral versus vaginal misoprostol administration groups (N=146,73 in each group)

Characteristic	Oral n=73 (%)	Vaginal n=73 (%)	P-value
Gestational age > 42 weeks	6 (8.2)	5 (7.5)	0.12##
Gestational age >41–42 weeks	64 (87.7)	55 (75.2)	
Oligohydramnios	3 (4.1)	9 (12.2)	
Preeclampsia	0 (0)	2 (2.7)	
Chronic hypertension	0 (0)	1 (1.3)	
Gestational diabetes mellitus	0 (0)	1 (1.3)	

Fisher's exact test

Table 3. Bishop score and time to vaginal delivery of oral versus vaginal misoprostol administration groups (N=146,73 in each group)

Outcome	Oral (n=73)	Vaginal (n=73)	P-value
Initial Bishop score : median (range)	3 (0-6)	3 (0-6)	0.07*
Bishop score change at 6 hours after misoprostol administration : median (range)	3 (0-9)	4 (0-11)	0.01*#
Required oxytocin augmentation (%)	41 (56.2)	29 (39.7)	0.047**#
Time interval from induction to vaginal delivery (hour) : median (range)	16.9 (7.5-61.3) n=50	11.8 (4.0-46.7) n=55	0.01*#
Time interval induction to vaginal delivery without oxytocin augmentation (hour) : median (range)	12.3 (8.1-56.5) n=25	11.5 (4.0-41.4) n=40	0.32*
Time interval from induction to vaginal delivery with oxytocin augmentation (hour) : median (range)	28.1 (7.5-61.3) n=25	12.6 (9.1-46.7) n=15	0.09*

*Mann-Whitney U test, **Chi square test
#Statistical significance

Table 4. Mode of delivery and indication for cesarean section of oral versus vaginal misoprostol administration groups (N=146,73 in each group)

Mode / indication	Oral n (%)	Vaginal n (%)	P-value
Vaginal route	50/73 (68.5)	55/73 (75.3)	0.36**[a]
Spontaneous vaginal delivery	45 (61.6)	54 (73.9)	0.10**[b]
Vacuum extraction	4 (5.5)	1 (1.4)	
Forceps extraction	1 (1.4)	0 (0)	
Cesarean section	23/73 (31.5)	18/73 (24.7)	
Fetal distress	3 (4.1)	4 (5.5)	1.00[# #]
Failure of induction / augmentation	8 (11)	6 (8.2)	0.57**
Arrest disorders of labor	12 (16.4)	8 (11)	0.34**

[# #] Fisher's exact test **Chi square test

[a]: compare between vaginal route and cesarean section

[b]: compare between spontaneous vaginal delivery and operative vaginal deliveries (vacuum extraction and forceps extraction)

Table 5. Intrapartum complications of oral versus vaginal misoprostol administration groups (N=146,73 in each group)

Complications	Oral n (%)	Vaginal n (%)	P-value
Tachysystole	0 (0)	1 (1.4)	0.32[# #]
Hypertonus	0 (0)	0 (0)	1.00[##]
Hyperstimulation	0 (0)	2 (2.7)	0.15[# #]
Postpartum hemorrhage	0 (0)	1 (1.4)	0.32[# #]

[# #] Fisher's exact test

Table 6. Neonatal outcomes of oral versus vaginal misoprostol administration groups (N=146,73 in each group)

Variable oral	Oral (n=73)	Vaginal (n=73)	P-value
Median birth weight (gram) (range)	3300 (2270-4320)	3200 (2500-4300)	0.15*
Median Apgar score at 1 min (range)	9 (5-10)	9 (5-10)	0.96*
Median Apgar score at 5 min (range)	10 (8-10)	10 (9-10)	0.31*
Neonatal resuscitation			
No (%)	72 (98.6)	72 (98.6)	1.00[##]
Yes (%)	1 (1.4)	1 (1.4)	

* Mann-Whitney U test, [##] Fisher's exact test

Table 5 illustrates intrapartum complications. No differences were observed in number of women who experienced uterine tachysystole, hyperstimulation and postpartum hemorrhage (was defined as blood loss > 500 ml in vaginal delivery and > 1000 ml in cesarean section delivery). No uterine hypertonus was observed in either group. Only three women in vaginal group developed abnormal uterine contractile patterns while no such event occurred in the oral group. However, the difference did not reach statistical significance. Two women developed hyperstimulation; one at 5.5 hours after vaginal misoprostol and another at 1.5 hour after oxytocin. The first woman resolved with intravenous terbutaline. While the other one, together with another woman who had tachysystole which developed 3.5 hours after oxytocin did not response to terbutaline treatment and underwent cesarean section delivery for fetal distress.

Table 6 illustrates neonatal outcome data. No differences were observed in median birth weight between the two groups. The median 5 and 10 minutes Apgar scores were comparable in both groups, and the number of neonatal resuscitation were similar. No cases of neonatal admission to neonatal intensive care unit

were required in either group.

Discussion

Oxytocin is a common and widely used agent for induction of labor. However, many disadvantages are observed. The efficacy is limited in women with unriped cervices. Administration requires intravenous infusion with continuous monitoring of fetal heart rate and uterine contractions. Misoprostol, a prostaglandin E_1 synthetic analog, is another drug used for both cervical ripening and induction of labor. Its efficacy is well documented. Its more convenience in administration is one advantage over the conventional oxytocin. This renders an increasing use of the drug for labor induction.

Our study used a single dose of oral misoprostol and at lower dose at 50 μg in order to reduce the incidence of uterine tachysystole or hyperstimulation which had been demonstrated in other reports from higher drug dosages.

The results of this study showed that vaginally administered misoprostol was more effective than orally administered misoprostol for cervical ripening and labor induction. A single dose of vaginal misoprostol administration promotes more effective uterine contraction and cervical ripening than oral misoprostol administration, as determined by better Bishop scores change. The efficacy was also demonstrated by the lesser time interval to vaginal delivery in vaginal misoprostol group than the oral group. These results were consistent with the results of Bennett et al[11]. The authors reported longer time interval from induction to vaginal delivery, 4 hours longer in orally treated women (1072 ± 593 minutes vs 846 ± 385 minutes, p=0.004). However, in contrast to our study, they found similar efficacy between the two groups. The better efficacy of the vaginal drug in our study might be explained by the pharmacokinetics of the drug that the mean plasma concentration of the vaginal drug, although elevated more slowly, but persisted longer and at higher concentration than the oral drug.[12] Hence, only single dose of vaginal route might be suffice that its efficacy was not different from the multiple drug doses even at lower dosages than the oral drug.

The better efficacy of the vaginal drug administration over the oral drug was also evidenced as significantly lesser number of women requiring oxytocin use, 39.7% versus 56.2% in the vaginal and oral group respectively. This was consistent with the result from the study of Wing et al. who used the same drug doses of both oral and vaginal as in our study. Approximately 60% of their women in the vaginal group required oxytocin while 75% in the oral group did (p=0.01)[13].

We did not find any significant difference in mode of delivery between the two groups. This was concordant to the study of Wing et al. who, although found that the women in the vaginal group had lower rate of cesarean section delivery than that of the oral group, the difference was not statistically significant[13].

Our study confirmed that lower dose of the drug had lesser uterine activity complications. We rarely found any major complications relevant to the drug used. Hyperstimulation was observed within 6 hours after misoprostol administration in one woman (1.4%). Of noted, two women (2.7%) who oxytocin were used developed hyperstimulation in one woman (1.4%) and tachysystole in one woman (1.4%). This might be a special precaution for the use of misoprostol in combination with oxytocin. The fetus from these women developed some degree of fetal distress but all were recovered to maternal resuscitation with intravenous fluid and oxygen administration. Only one (1.4%) newborn in each group required resuscitation at birth.

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เปรียบเทียบการใช้ยามัยโสพรอสทอลครั้งเดียว ชนิดรับประทานขนาด 50 ไมโครกรัมกับยามัยโสพรอสทอลชนิดสอดทางช่องคลอดขนาด 25 ไมโครกรัม ในการชักนำการคลอด

ริต้า ไพศาลตันติวงศ์, มยุรี เกตุการณ์

วัตถุประสงค์: *เปรียบเทียบประสิทธิภาพและความปลอดภัยของการใช้ยามัยโสพรอสทอลครั้งเดียวชนิดรับประทานขนาด 50 ไมโครกรัมกับยามัยโสพรอสทอลชนิดสอดทางช่องคลอดขนาด 25 ไมโครกรัม ในการชักนำการคลอด*

วัสดุและวิธีการ: *การศึกษานี้เป็น randomized double-blind controlled trial ในสตรีตั้งครรภ์ที่รับไว้ในห้องคลอด ภาควิชาสูติศาสตร์-นรีเวชวิทยา วิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาล ระหว่าง มีนาคม พ.ศ. 2545 ถึง มกราคม พ.ศ. 2548 สตรีทั้งหมด 146 ราย มีอายุครรภ์ตั้งแต่ 37 สัปดาห์ขึ้นไป มีข้อบ่งชี้ในการชักนำการคลอด ได้รับการสุ่มแบ่งเป็นกลุ่มที่ได้รับยามัยโสพรอสทอลขนาด 50 ไมโครกรัมรับประทาน หรือกลุ่มที่ได้รับยาขนาด 25 ไมโครกรัมโดยการสอดทางช่องคลอด บันทึก Bishop score ก่อนและ 6 ชั่วโมงหลังให้ยา การให้ยา oxytocin เสริม ภาวะแทรกซ้อนเนื่องจากการหดรัดตัวของมดลูกมาก อัตราการคลอดทางช่องคลอด Apgar score ที่ 1 และ 5 นาที และทารกที่ต้องรับไว้ใน NICU*

ผลการศึกษา: *สตรีทั้ง 2 กลุ่มไม่มีความแตกต่างกันของข้อมูลพื้นฐานทั่วไปและ Bishop score ก่อนได้รับยา Bishop score ที่เปลี่ยนไปที่ 6 ชั่วโมงหลังได้รับยาระหว่างกลุ่มที่ได้รับยารับประทาน และสอดยาทางช่องคลอดพบว่าแตกต่างกันอย่างมีนัยสำคัญทางสถิติ, คะแนน 3 และ 4 ตามลำดับ ระยะเวลาการคลอดทางช่องคลอดของกลุ่มที่ได้รับยารับประทานยาวกว่ากลุ่มที่ได้ยาสอดทางช่องคลอดอย่างมีนัยสำคัญทางสถิติ คือ 18.5 และ 12.3 ชั่วโมงตามลำดับ คะแนน Apgar ที่ 1 และ 5 นาที ของทารกจากสตรีทั้ง 2 กลุ่มใกล้เคียงกัน*

สรุป: *การใช้ยามัยโสพรอสทอลขนาด 25 ไมโครกรัม ครั้งเดียวสอดทางช่องคลอดมีประสิทธิภาพมากกว่าการใช้ยามัยโสพรอสทอล ขนาด 50 ไมโครกรัมรับประทานในการเพิ่มคะแนน Bishop และลดระยะเวลาการคลอดทางช่องคลอดในรายที่ปากมดลูกไม่พร้อม โดยไม่เกิดผลข้างเคียงรุนแรง*