ORIGINAL ARTICLE

Comparison of 25 and 50 microgram of misoprostol for induction of labour in nulliparous women with postdate pregnancy in Port Harcourt

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Abstract

Background: Induction of labor for postdate pregnancy using misoprostol is one of the most common interventions in pregnancy. However, the optimal dose of misoprostol is yet to be determined with previous reports utilizing different dosages.

Objective: The main objective of this study was to compare the effectiveness and safety of 25 μg versus 50 μg of intravaginal misoprostol for induction of labor in nulliparous women with postdate pregnancy.

Methodology: This was a prospective study in which 88 nulliparous women with postdate pregnancy were randomly selected to receive either 25 μg or 50 μg of misoprostol for induction of labor. Student's *t*-test and Chi-square test were used to compare proportions.

Results: There was no significant difference between the two groups with regard to the induction-vaginal delivery interval between the two doses. The proportion of women delivering vaginally with a single dose of misoprostol (11/40 vs. 23/43, $P = 0.01$) and vomiting were significantly greater in the 50 μg group. However, there was no significant difference between both groups in terms of the need for augmentation of labor, caesarean section, tachysystole and hyperstimulation syndrome.

Conclusion: Intravaginal administration of 25 μg of misoprostol appears to be as effective, but safer than 50 μg for induction of labor in nulliparous women with postdate pregnancy.

Key words: Induction of labor, misoprostol, Port Harcourt, postdate pregnancy

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Introduction

Postdate pregnancy presents one of the commonest management dilemmas that confront any practicing obstetrician. Most obstetric units routinely offer induction of labor between 41 and 42 weeks of gestation to minimize the adverse perinatal risks associated with postdate pregnancy.

In general, induction of labor is indicated when the benefit of delivery to the mother or fetus outweighs the potential risks of continuing the pregnancy.[1] Postdate pregnancy is the commonest indication for induction of labor accounting for more than 46.8% of such reported interventions.[1] At the University of Port Harcourt Teaching Hospital (UPTH) postdate constitutes about 13% of total deliveries, while, in Sokoto and Maiduguri, it accounted for 3% and 6.6% of the deliveries, respectively.[1-3]

Misoprostol (15-deoxy-16-hydroxy-16-methyl prostaglandin E_1) a synthetic prostaglandin E_1 analogue is the most widely used agent for induction of labor.[4,5] It was first developed for the prevention and treatment of peptic ulcers because of its gastric acid antisecretory properties and its various mucosal protective effect. Its cervical softening

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and uterotonic effects on the female genital tract were considered as side-effects rather than therapeutic benefits when misoprostol was first introduced.[6] In comparison with other prostaglandin analogs, misoprostol has the advantages of being cheap, widely available, stable at room temperature and having relatively few side-effects which include nausea, vomiting, diarrhea, fever, tachysystole, hyperstimulation and risk of uterine rupture.[4-8]

Misoprostol can be administered through several routes, but the vaginal route has been shown to be the most effective.[9,10] In contrast to the oral route, the plasma concentration increases gradually after vaginal administration, reaching its maximum level after 70-80 min before slowly declining with detectable drug levels still present after 6 h.[5,9] Although vaginal absorption has been shown to be slower and the peak concentrations lower than that for the other routes, the serum level of misoprostol is sustained at that low level for a longer period. In fact, at the end of 6 h the serum level of misoprostol after vaginal administration is higher than those of the sublingual and oral routes.[5] Therefore, the effect of misoprostol may still be present for longer than 6 h after a single dose, though the threshold serum level for clinical action is unknown.[5] At present, there is no consensus yet to the optimum dose, frequency and routes of administration of misoprostol for induction of labor. Dosages ranging from 25 μg every 2 h to 100 μg as a single dose have been used. The currently observed practice at the UPTH is that some obstetricians use 50 μg of misoprostol for induction of labor in nulliparous women and 25 μg in multiparous women, while others adhere to the ACOG recommendation of using 25 μg irrespective of parity.[11] There is, therefore, the need to compare the different dosing regimen in our parturient with similar indication in order to eliminate bias in determining the dose that is most efficient and safe and to standardize our practice.

Methodology

This study was carried out at the UPTH from September 2011 to May 2012. Ethical approval for the conduct of the study was obtained from the Ethics Committee of the hospital. The study subjects were drawn from the antenatal clinic, antenatal ward and labor ward of the hospital. Patients confirmed to have postdate pregnancy and met the eligibility criteria were recruited to take part in the study following informed consent. The participants had an obstetric scan done to estimate fetal weight and to exclude any contraindication to vaginal delivery before being enrolled into the study. A single blind randomization technique was used to randomly select participants for the study using the table of random numbers to receive either 25 μg or 50 μg of misoprostol (Cytotec®; Pharmacia Ltd., UK). Each participant's group was recorded in her case file and the proforma that was designed for each participant. After confirmation of Bishop's score to be less than 6, the chosen dose of misoprostol was passed into the posterior fornix of the vagina under aseptic conditions. Repeat doses of misoprostol were passed every 6 h for a maximum of 4 doses. The decision for the insertion of subsequent doses of misoprostol is determined by assessing for uterine contractions and fetal heart rate (FHR) pattern. Further doses of misoprostol are withheld at the onset of labor (one or more palpable uterine contractions in 10 min). At the onset of labor, the patient is transferred to the labor ward and her labor is monitored on a partogram accordingly. The time at which the doses of misoprostol were passed and the time at onset of labor were recorded in the patient's proforma. Artificial rupture of fetal membrane was performed in active phase of labor at a cervical dilatation of 4 cm if not contraindicated. Patients who subsequently had arrest of dilatation (no change in cervical dilatation >2 h) in the absence of cephalopelvic disproportion at least 6 h after the last dose of misoprostol tablet received 10 IU of oxytocin (Synpitan®, Deva, TR) in 1 L of infusion for augmentation of labor escalated according to the departmental protocol.

The rate of cesarean section, vaginal delivery occurring within 24 h of administration of the first dose of misoprostol, interval between beginning of induction and delivery, need for oxytocin augmentation, fetal and neonatal morbidities were determined. Hyperstimulation syndrome defined as tachysystole (six contractions in two consecutive 10 min periods) or uterine hypertonus/hypersystole (i.e. a single contraction lasting longer than 2 min) with abnormalities in the FHR using the cardiotocogram was also documented.[12] Babies with APGAR score of <7 at the 1st min were regarded as asphyxiated (birth asphyxia) and birth asphyxia is classified as mild if the score is 6, moderate for a score of 4 and 5 while a score of 3 or less is severe birth asphyxia. Babies whose APGAR scores were ≤6 at the 5th min following resuscitation were admitted into the special care baby unit (SCBU) for further evaluation and treatment and also those who develop serious complications such as meconium aspiration, neonatal encephalopathy and hyperbilirubinaemia.

Exclusion criteria

Women with Bishop's score >6, noncephalic presentation, prelabor rupture of membranes, oligohydramnios, para 1 and above, unsure gestational age, intrauterine growth restriction, obstetric complications such as diabetes mellitus and hypertension, previously scared uterus following procedures such as myomectomy, macrosomic babies and those with any contraindications to vaginal delivery were excluded from the study.

Calculation of sample size

The sample size was calculated using the formula for comparison of two means (sample size of each group).[13]

$$n = \frac{(u + v)^2 \left(SD_1^2 + SD_2^2\right)}{(\mu 1 - \mu 2)^2}$$

Where n is the required minimum sample size, u is the one-sided percentage point of the normal distribution corresponding to 100% minus the power, and with power of 90%, u is therefore 1.28, v is the percentage point of the normal distribution corresponding to the required (two-sided) significance level (which is 0.05) and equals 1.96. Standard deviation (SD_1), from the previous study of 50 μg group = 2.9[8] while SD_2, from the study of 25 μg group = 8.48[14] and μ1−μ2 is the expected difference between the means and equals 4.6.

$$n=\frac{(1.28+1.96)^2\times(2.92+8.48)}{(4.6)^2}=40$$

Drop out of approximately 10% (of 40) =4. Therefore, 44 women were randomly selected to receive 25 μg of misoprostol, while 44 women were also randomly selected to receive 50 μg of misoprostol. Data entry and analysis were performed using the Epi Info version 6.04d (CDC, Atlanta, Georgia, USA) statistical software. Chi-square test and Student's *t*-test was used to test for significance at $P < 0.05$ as appropriate.

Results

The mean age of women in the 25 μg group was 29.4 ± 3.12, while the mean age in the 50 μg group was 27.0 ± 5.07. The mean Bishop score at the initial assessment was 2.95 ± 1.08 and 2.55 ± 0.82 in the 25 μg and 50 μg groups respectively and there was no significant difference ($t = 1.91$, $P = 0.05$). Four women in the 25 μg group and one in the 50 μg group were excluded from the study due to violations in the study protocol.

Thirty-two women (80.0%) in the 25 μg group and 32 women (74.4%) in the 50 μg group were delivered vaginally. Twenty-three women (57.5%) in the 25 μg and 26 women (60.5%) in the 50 μg were delivered vaginally within 24 h of induction ($P = 0.783$). Women in the 50 μg group were not more likely to deliver vaginally within 12 h of labor induction with vaginal misoprostol when compared with the 25 μg group (10/43 vs. 6/40, $P = 0.500$). The proportion of women delivering vaginally with one dose of vaginal misoprostol was significantly greater in the 50 μg group (23/43 vs. 11/40, $P = 0.01$). However, the mean number of misoprostol doses applied was not different in both groups (2.12 ± 0.94 vs. 1.77 ± 0.97, $P = 0.09$). Similarly the number of women delivered vaginally within 12-24 h and more than 24 h of induction in the 25 μg group (42.5% and 22.5%) and 50 μg group (37.2% and 16.27%) were not significantly different ($P > 0.05$) [Table 1]. Eight (20.0%) women in 25 μg and 11 (25.58%) in the 50 μg group had failed induction of labor with vaginal misoprostol. Two women (5.0%) in the 25 μg group

Table 1: Neonatal complications

Complications	25 μg (*n*=40)	50 μg (*n*=43)	Relative risk value	*P*
Admitted in SCBU	2 (5.0)	8 (18.6)	0.38	0.05
Severe birth asphyxia	1 (2.5)	2 (4.6)	0.65	0.542
Meconium aspiration syndrome	1 (2.5)	2 (4.65)	0.68	0.527
Hyperbilirubinemia	1 (2.5)	2 (4.65)	0.68	0.527
Neonatal encephalopathy	0 (0.0)	1 (2.3)	Not derivable	0.518
Neonatal death	0 (0.0)	1 (2.3)	Not derivable	0.518
APGAR scores<7 (1-min)	3 (7.50)	8 (18.60)	2.22	0.136
APGAR scores<7 (5 min)	1 (2.5)	4 (9.3)	0.71	0.41

SCBU=Special care baby unit

Table 2: Clinical outcomes

Outcome	25 μg (*n*=40)	50 μg (*n*=43)	*t*-test	*P*
Induction vaginal delivery interval (min±SD)	1103.656±447.654	1017.500±654.848	0.616	0.5410
Doses of misoprostol applied (*n*±SD)	2.125±0.939	1.767±0.972	051.7	0.091
			χ^2	*P*
Vaginal delivery <12 h	6	10	0.45	0.500
Vaginal delivery 12–24 h	17	15	0.51	0.476
Vaginal delivery >24 h	9	7	0.19	0.660
Mode of delivery				
Spontaneous vaginal delivery (*n*)	31	31	0.12	0.733
Caesarean delivery (*n*)	8	11	0.37	0.55
Instrumental vaginal delivery (*n*)	1	1	Not derivable	0.7
Caesarean delivery for FHR abnormalities	2	3	0.01	0.934
Vaginal delivery after 1 dose (*n*)	11	23	5.79	0.01
Number of needed more than 1 dose of misoprostol				
2 doses	16	10	2.7	0.10
3 doses	9	7	0.52	0.47
4 doses	4	3	0.01	0.92
Oxytocin augmentation	22	18	0.96	0.328
Birth weight (g)	3297.50±425.01	3460.465±528.763	1.539	0.127

SD=Standard deviation; FHR=Fetal heart rate

Table 3: Maternal complications

Complications	25 μg (*n*=40) (%)	50 μg (*n*=43) (%)	χ^2	*P*
Tachysystole	1 (2.5)	3 (7.5)	0.26	0.6079
Hypertonus	0 (0.0)	0 (0.0)	Not derivable	Not derivable
Hyperstimulation syndrome	1 (2.5)	2 (4.7)	0.00	0.949
Nausea	2 (5.0)	6 (14.0)	1.02	0.156
Vomiting	1 (2.5)	9 (20.9)	5.02	0.01
Fever	1 (2.5)	2 (4.7)	0.00	0.527
Shivering	1 (2.5)	2 (4.7)	0.00	0.527
Diarrhea	1 (2.5)	0 (0.0)	0.00	0.481

and three women (7.0%) in the 50 μg group required emergency cesarean delivery for FHR abnormalities during the induction process ($P = 0.9$). There was no significant difference noted in the overall incidence of cesarean deliveries or the incidence of vacuum deliveries [Table 2]. There was no significant difference between the two groups with regard to the interval from the first dose of misoprostol to vaginal delivery (1103 ± 448 min in the 25 μg group vs. 1017 ± 655 min in the 50 μg group, $P = 0.54$). There was also no significant difference noted between the two groups in the number of women requiring oxytocin augmentation (22 (55%) in the 25 μg group vs. 18 (41.9%) in the 50 μg group) [Table 2].

There was no significant difference noted between the two groups in the incidence of tachysystole, hyperstimulation syndrome or the tocolytic use [Table 3]. Similarly, there was no difference between the two groups in drug adverse effects such as nausea, shivering, fever and diarrhea. However, there was a significant number of women in 50 μg group with vomiting compared to 25 μg group (1 (2.5%) vs. 9 (20.9%), $P = 0.01$) Table 3. There was no case of uterine rupture in the two groups within the study period.

Statistically, there was no significant difference in the neonatal outcomes [Table 1]. The mean birth weight, the incidence of birth asphyxia, and the number of infants admitted to the SCBU were similar in the two groups. However, one baby in the 50 μg group had early neonatal death from neonatal encephalopathy.

Discussion

The results of this study indicate that 25 μg of intravaginal misoprostol every 6 h is as effective as 50 μg for labor induction in postdate pregnancy. The proportion of women that were delivered vaginally within 12 h of induction were greater in the 50 μg group, whereas greater number of women in the 25 μg group delivered within 12-24 h and in more than 24 h; though this was not significant. This is in contrast to findings by El-Sherbiny *et al*. and Meydanli *et al*. whose findings showed that significantly more women in the 50 μg group were delivered vaginally within 12 h of induction, while significantly more women in the 25 μg group delivered vaginally within 12-24 h of induction.[14,15] The significant difference not observed in our findings could be attributed to smaller sample size. According to some studies, the mean interval from induction to vaginal delivery was significantly shorter in the 50 μg group compared with those that received the 25 μg dose.[14,16-18] However, in a randomized controlled trial comparing effectiveness of 25 μg versus 50 μg of intravaginal misoprostol every 4 h for induction of labor, it was reported that induction-delivery interval was not significantly different between the two groups (685 ± 201 min in 25 μg group vs. 625 ± 177 min in 50 μg group).[15] Similarly, in another randomized clinical trial by Rahman *et al*. comparing 50 μg of misoprostol administered orally and 25 μg of misoprotol administered vaginally every 4 h did not show any significant difference in the induction-delivery interval between both groups (21.22 h in the oral group and 20.15 h in the vaginal group).[19] The corresponding intervals were found to be 1103.656 ± 447.654 min, and 1017.500 ± 654.848 min, respectively in our study. This is consistent with other findings as well.[12,20,21] However, the longer duration in induction-delivery interval observed in our study could be attributed to discontinuation of dose administration at onset of uterine contraction in contrast to administration until adequate uterine contractions were observed at the six-hourly frequency. Moreover, the duration of labor whether spontaneous or induce has been found to be shorter in multiparous women compared to nulliparous women used in this study.[22,23] Although the 50 μg dose was associated with significant proportion of women delivering after a single dose in this study, we were unable to demonstrate a significant difference in delivery within 24 h and need for oxytocin augmentation unlike in other studies.[15,16,20] These discrepancies in our study from other studies can be explained by the lack of significant difference in the initial Bishop score of the study groups (2.950 ± 1.085 in the 25 μg vs. 2.558 ± 0.825 in 50 μg group, $P = 0.05$) and clinical heterogeneity associated with the previous studies especially as further dose administration of misoprostol was withheld at onset of uterine contraction in our study.

Our findings are consistent with those of Sanchez-Ramos, Nigam and Meydanli *et al*. who reported no dose-related difference with regard to the rates of cesarean and operative vaginal deliveries, the proportion of women requiring caesarean deliveries for FHR abnormalities, abnormal APGAR scores and admissions to the SCBU[15,21] This is in contrast with findings from Gupta *et al*., who reported higher incidence of APGAR score <7 at 1-min and admission to neonatal intensive care unit.[24]

With respect to incidences of tachysystole and hyperstimulation syndrome in the two treatment group, though there were fewer cases reported our findings are consistent with similar studies in other centers that showed no statistically significant

difference in the two groups.[12,15,16] However, Eroglu *et al*. and Loto *et al*. both reported higher incidence of tachysystole in the 50 μg group than in the 25 μg group, but no difference was observed in the incidence of hyperstimulation syndrome.[18,25] Ding *et al*. on the other hand, in a similar study in nulliparous women, reported a higher incidence of hyperstimulation in 50 μg group, but no difference in tachysystole.[20] Studies from different literatures have proven that frequency of administration, rather than dose, could be a significant factor in causes of these complications.[7,26] They stated that the incidences of tachysystole and hyperstimulation syndrome are related to dose interval.[7,26] Therefore, the six-hourly dose interval of administration used in our study could have accounted for fewer incidences of these complications. The less frequent dosing interval caused fewer complications with resultant longer induction-delivery interval. It has been noted that the effect of misoprostol administered vaginally still lingers for longer than 6 h after a single dose.[5] Thus, multiple dosing at four hourly interval may have a synergic effect with resultant complications. Gastrointestinal side-effects, especially vomiting was significantly more in the 50 μg group, which is consistent with findings from other studies.[24] Despite studies linking misoprostol use to the high incidence of uterine rupture, there was none observed in this study similar to the findings by Kreft *et al*.[17] The absence of uterine rupture; a dreaded complication from misoprostol administration could still be explained by low incidences of tachysystole and hyperstimulation, as well as prompt intervention at onset of these complications and the fact that only nulliparous women were used in the study and those with scared uterus were excluded.

In order to compare the efficacy and safety of two dosing regimen of intravaginal misoprostol in a selected population, only one indication (postdate pregnancy) for induction of labor was slated in our study. This was to avoid potential heterogeneity associated with varying indications. I acknowledge the potential for bias because the study design did not require blinding of the investigator.

Conclusion

The 25 μg of intravaginal misoprostol administered six-hourly appears to be as effective but safer than 50 μg for induction of labor in nulliparous women with postdate pregnancy. The use of 50 μg misoprostol may be recommended when there is a need to expedite vaginal delivery.

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