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Safety and efficacy of vaginal misoprostol versus transcervical foley catheter and intravenous oxytocin for induction of labour

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Abstract

Introduction: A variety of drugs were used for induction of labour, but only oxytocin and prostaglandins have survived critical test of effectivity with a minimum of side effects for mother and child. The objective of this study is to compare efficacy and safety of vaginal misoprostol with transcervical Foley's catheter and intravenous oxytocin for induction of labour.

Methods: Eighty women at term gestation with the Bishops score < 4 with various indications for labour induction were randomly allocated to receive 25 microgram misoprostol vaginally 4 hourly (maximum 6 doses) or transcervical Foley's catheter with intravenous oxytocin (2mU/minute to a maximum of 32mU/minute). There were 40 women in each group.

Result: In the misoprotol group induction delivery interval was significantly less (5.50 versus 15.0 hours) and successful induction significantly higher (95% versus 75%) as compared to catheter/oxytocin group. There were more cases of hyperstimulation with misoprostol; however neonatal outcome was similar in both groups. There were more vaginal delivery and less caesarean section in misoprostol compared to Foley's catheter/oxytocin group.

Conclusion: Vaginal misoprostol is highly effective, safe to administer as an agent for induction of labour.

Key words: Vaginal misoprostol, intracervical catheter and oxytocin, induction of labour.

Introduction

In the past, a variety of drugs were used for induction of labour, but only oxytocin and prostaglandins have survived critical test of effectivity with a minimum of side effects for mother and child. [1] However, labour induction in the presence of an unfavorable cervix is associated with an increased likelihood of prolonged labour.[2] Due to this the use of cervical ripening agents prior to conventional methods of induction is now a standard practice.[2-5]

In developing countries such as Nigeria, conventionally cheap and feasible method used for pre induction cervical ripening is transcervical Foley's catheter. However in recent years, misoprostol, a synthetic prostaglandin E_1 analogue, originally developed as gastrocytoprotective agent, is being evaluated for term labour induction. Its advantages include effectiveness, low cost, stability at room temperature, and ease of administration. However the main concern with its use is excessive uterine response and studies had concentrated on finding the right dosage regimens that minimize this risk while maintaining efficacy [2,4,6,]

In this study the safety and efficacy of 25 microgram of vaginal misoprostol is compared with transcervical Foley's catheter and intravenous oxytocin for induction of labour.

Methods

This prospective randomized study was carried out at Victoria Specialist Hospital Ile-Ife and Ilesa Annexes between January 2003 to December 2006. Pregnant

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women who presented during this period with various indications for induction of labour with singleton fetus at term in cephalic presentation with intact membranes, Bishop score ≤4 and volunteering to participate in the trial were included in the study. Exclusion criteria include women with previous caesarean section, multiple pregnancy, sickle cell abnormality, bronchial asthma, heart disease or known hypersensitivity to prostaglandins. Only women who consented for the trial after counseling were recruited. The primary outcome measure is the induction-delivery interval. The secondary outcome measures include the percentage of successful induction, rate of caesarean section, and the neonatal outcome.

The sample size for the comparison of independent mean was used[7].

$$n = \frac{S^2 (-^1 A + Q -^1 B (Zx + Zp)^2}{Y^2}$$

S^2 = Pooled estimate of the common variance of the two samples.
QA = The proportion of the total sample in sample A.
QB = The proportion of the total sample in sample B.
Y = The difference detected between the means of two sample.

Using the computer system CPEA (computer programme for Epidemiologic Analysis) to calculate the sample size, it gave a minimum sample of 22 patients for each group. However, for this study, 40 patients were included in each group to make the result statistically significant. A total of 80 patients were recruited.

Women on misoprostal group received 25 microgram of misoprostol 4 hourly for a maximum of 6 doses. In the catheter/oxytocin group, a 16 F Foley's catheter was introduced just beyond the internal os and its ballon was inflated with 30ml of sterile water. Traction was applied by taping the distal end of the catheter to the medial aspect of thigh. This was done at 08.00 hours and the cervix was reassessed after 12hours and induction of labour commenced with simultaneous oxytocin and fore-water amniotomy. The initial dose of oxytocin (Syntocinon Cadila Health Care Ltd) is 2mU/minute and escalated by 2mU/minute every 30 minutes till the women went into established labour (three contractions in 10minutes each lasting 45-60 seconds) or the maximum dose of 32mU/minute was reached.

Throughout the induction, fetal heart rate was monitored by a fetoscope and Doppler machine and uterine contractions monitored manually.

The main measure of efficacy was successful induction. Secondary outcome measures were number of deliveries within 24 hours, mode of delivery, and total dose of inducing agents required for delivery. The measures of safety included the uterine tachysystole, uterine hypertonus, abnormal fetal heart reading, incidence of meconium passage and the neonatal outcome. Baseline data included maternal age, parity, gestational age, labour induction and preinduction cervical score.

Analysis was performed using statistical software SPSS version 11.5. Continuous variables were compared using the Fisher's Z test and discrete data with the χ^2 test. Level of significance was placed at $P<0.05$.

Results

Forty women received misoprostol and 40 received transcervical Foley's catheter and intravenous oxytocin. Maternal demographic characteristics and indications for induction were similar in the two groups (Table I).

There was successful induction in 38 of the 40 women who used misoprostol compared to 30 among 40 women who used Foley's catheter with intravenous oxytocin ($P = 0.03$). The mean induction delivery interval was

Table I. Demographic Characteristics and indications for labour induction

Variable	Misoprostol (n =40) mean± SD	Catheter / Oxytocin (n = 40) mean ± SD
Age (years)	26.1 (18-35)	26.2 (19-36)
Parity	1.12 (0-3)	1.3 (0-3)
Gestation (weeks)	38.25 (37-42)	38.15 (37-43)
Pre induction cervical score	3 (2-4)	4 (2-4)
Indication for induction	25 (62.5%)	26 (65%)
Post term pregnancy	10 (25%)	5 (12.5%)
Hypertension	10 (25%)	9 (22.5%)
Intrauterine growth retardation	5 (12.5%)	5 (12.5%)

significantly shorter in the misoprostol group (8.50 hours compared to 15 hours in Foley's catheter/ oxytocin group) P = 0.002. The mean dose of agent required for the induction was 75 microgram in misoprostol group and 30mU/minute of oxytocin. There were 4 cases of hypertimulation in misoprostol group and 2 cases with fetal distress compared to 3 cases with fetal distress in catheter/oxytocin group (Table 2).

Table 3 showed that more women achieved spontaneous vaginal delivery in misoprostol group (35) compared to 25 among catheter/oxytocin group (P = 0.02). There were however more women who had caesarean section in catheter/ oxytocin group compared to misoprostol group (10 versus 2). P = 0.03.

The neonatal Apgar Scores and birth weights were similar in both groups (Table 4). Table 5 shows the dose requirements till delivery. In the misoprostol group 2 women delivered with 25 microgram of misoprostol while 12 required up to 125 microgram to be delivered. In 4 (10%), a maximum dose of 150 microgram was administered and 2 (5%) of them had emergency caesarean section due to fetal distress. In the Foley's catheter/oxytocin group had 2 women delivered with the dose of 8-12mU/minute and with increasing dosage requirement more women delivered vaginally. However 4 out of the 10 women received up to 26-30mU/minute of oxytocin had emergency caesarean section while all the 6 women who received 30mU/minute of oxytocin had emergency caesarean section (Table 5).

Discussion

In this study, successful induction occurred in 95% of misoprostol group compared to 75% in catheter/ oxytocin group (p = 0.03). This is similar to the finding of other investigators.[2,8] The mean induction delivery interval for misoprostol group was 8.50 hours compared to 15 hours among catheter/oxytocin group (P = 0.002). This interval is shorter than that reported by other authors (11.58 hours versus 19.45 hours)[2]. Progress of labour was also rapid with misoprostol group as compared to that of oxytocin leading to greater number of women delivering within 24 hours (90% versus 70%). This is slightly higher than the finding of others who reported 88% of women delivery within 24 hours in misoprostol group compared to 72% in catheter/ oxytocin group[2]. Our finding is slightly lower than the findings by Calistan et al in which 91.3% delivered within 24 hours with sublingual misoprostol [9].

The main concern with misoprostol is the incidence of excessive uterine contraction, which appears to be dose related. Our study shows that the higher the dose of misoprostol the shorter is the induction-delivery interval, but higher is the incidence of uterine hyperstimulation. For instance hyperstimulation occurred in 10% of misoprostol group compared to none among catheter/oxytocin group.

Despite the relatively high incidence of hyperstimulation, it did not result in increase in caesarean section or poor Apgar scores. In short the neonatal outcome is better in the misoprostol group.

Table 2. Outcome of labour induction

Variable	Misoprostol	Catheter/Oxytocin	P value
Successful induction	38 (495%)	30 (75%)	0.03
Induction delivery interval in hours	8.50 (6.1-25.1)	15.0 (8.42-36.15)	0.002
Mean doses required range	75 microgram (50-150)	30ml/minute (8-36)	0.001
Hyperstimulation	4 (10%)	-	-
Fetal distress	2 (5%)	3 (7.5%)	-

Table 3. Mode of delivery

Variable mode of delivery	Misoprostol n =40	Catheter/Oxytocin n = 40	P value
Spontaneous vaginal delivery	35 (875%)	25 (62.5%)	0.02
Caesarean section	2 (5%)	16 (25%)	0.03
Vacuum	5 (12.5%)	5 (12.5%)	0.95
Cephopelvic	1 (2.5%)	2 (5%)	0.35
Fetal distress	2 (5%)	2 (5%)	0.65
Cervical dystocia	0	2 (5%)	0.35

Table 4. Neonatal outcome

	Misoprostol n =40mean ± SD	Catheter/Oxytocin =40mean ± SD	P value
Birth weight (kg) mean (range)	3.0 (2.4-3.6)	3.0 (2.5-3.7)	> 0.05
Apgar scores at 1 minute	7	7	> 0.05
Apgar scores at 5 minutes	9	9	> 0.05
Apgar scores <7 at 5 minutes	1 (2.5%)	2 (5%)	>0.05
Live births	39 (97.5%)	38 (95%)	>0.05
Still births	1 (2.5%)	2 (5%)	>0.05

Table 5. Dose requirement till delivery

Women entered (n = 40)			Women entered (n = 40)		
Dose of oxytocin (mu/minute)	Delivered Number	Not delivered Number	Dose of misoprostol (mcg)	Delivered Number	Not delivered Number
1-6	-	-	25	2 (5%)	-
8-12	2 (5%)	-	50	4 (10%)	-
14-18	4 (10%)	-	75	6 (15%)	-
20-24	8 (20%)	-	100	10 (25%)	-
26-30	10 (25%)	4 (10%)	125	12 (30%)	-
32	6 (15%)	6 (15%)	150	4 (10%)	2
Total	32	8		38	2

In conclusion, the use of vaginal misoprostol as a cervical ripening and labour inducing agent is highly effective and preferable to Foley's catheter/oxytocin regime. Since the use of misoprostol is inexpensive and less cumbersome to use and esthetically better compared to insertion of Foley's catheter and oxytocin infusions we recommend that its use should be encouraged and widespread.

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