OUTCOMES IN ELECTIVE INDUCTION OF LABOUR WITH 50 µG INTRAVAGINAL MISOPROSTOL IN POSTDATE SINGLETON LIVE PREGNANCY AT KORLE-BU TEACHING HOSPITAL

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Abstract

***Background*:** Induction of labour is indicated when the risk associated with expectant management of labour is higher. The most common indication for labour induction is postdate pregnancy and induction for this indication has been shown to reduce perinatal death. Misoprostol is the most commonly used drug for labour induction at the Korle-Bu Teaching, the leading national referral centre in Ghana.

Method: To assess the outcomes in Elective Induction of Labour using 50 µg of intravaginal misoprostol in postdate singleton live pregnancies at Korle-Bu Teaching Hospital. This was a prospective cohort study carried out to measure the rates of vaginal deliveries and factors affecting vaginal deliveries during labour induction. One hundred and sixteen pregnant women of at least 41 weeks gestation.

Women were included and followed up from the first insertion of misoprostol to delivery.

Results: Eighty-six patients (74.1%) had vaginal delivery and 30 (25.9%) were delivered by caesarean section. Among those who delivered vaginally, 77 (89.5%) delivered within 24 hours. There was a significant association between mode of delivery and Bishop Score (P=0.002). The highest Apgar score at the first minute was 7 in 55 babies (47.4%) and the lowest was 3 in 2 babies (1.7%).

Conclusions: The high rate of vaginal delivery and absence of induction related perinatal mortality confirmed the effectiveness and safety of misoprostol in postdate singleton live pregnancy at Korle-Bu Teaching Hospital

Key Words: Misoprostol; Labour induction; Postdate, Intravaginal.

Introduction

Induction of labour (IOL) has become a common practice for the Obstetrician today. Over the past several decades, the incidence of labour induction for shortening the duration of pregnancy has continued to rise. Labour induction is indicated when the risk associated with expectant management of labour is higher. In developed countries, the proportion of infants delivered at term following induction of labour can be as high as one in four deliveries[1]. Rates of labour induction are increasing in developing countries as well. This rate varies from 9.5%-33.7% of all pregnancies annually[2]. In Canada, the rate has increased from 12.9 in 1992 to 21.8% in 2005 and in the USA, it has increased from 9.5 in 1990 to 22.1% in 2005. [3,4]. In African countries, although it is low, it is also on the rise, reaching 11.6% in some regions.

The most common indication for labour induction is postdate pregnancy, defined as a pregnancy lasting more than 294 days, or 42 completed weeks after the first day of the last menstrual period. However, some physicians believe that the term should be used for the more global group of patients for whom reliable dating criteria may not be available[5]. Induction for this indication has been shown to reduce the likelihood of perinatal death because these pregnancies have been shown to have an association with the increase of perinatal mortality, morbidity, and operative delivery[6]. For labour induction, the most commonly used drug is misoprostol. Its high efficacy and reasonable safety profile have been confirmed in several studies[7, 8, 9] and it has remained a common drug used since 2001. This drug is inexpensive, easily stored at room temperature and rapidly absorbed after oral or vaginal administration. Misoprostol is used with many protocols according to hospital policies and the most commonly used is intravaginal misoprostol of 50µg which is seen to be effective.

Induction of labour with misoprostol has successful results in vaginal delivery but sometimes fails with potential risks of increased rate of operative vaginal delivery, caesarean birth, excessive uterine activity, abnormal foetal heart rate patterns, uterine rupture and maternal water intoxication among other complications[7,8]. Therefore, it is important to know maternal and foetal outcomes during induction of labour with misoprostol for postdate pregnancy. The main aim of this study is to assess outcomes of delivery (rate of vaginal delivery, maternal, foetal and neonatal

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complications) after induction in postdate live singleton pregnancy with 50ug intravaginal misoprostol at the Korle-Bu Teaching Hospital (KBTH), the main referral teaching hospital in Ghana.

Subjects and methods

This was a prospective cohort study of 116 postdate pregnancies to measure the rates of vaginal deliveries and factors affecting vaginal deliveries during induction of labour between 1st May and 30th June 2015 at the Department of Obstetrics and Gynaecology KBTH.

Elective induction of labour was decided by the team on duty according to the gestational age by last menstrual period or early ultrasonography. After all examinations to rule out current contraindications, the patient's cervical scoring was done according to the Bishop score which was deemed unfavourable if the score was less than 6. The Patient was then admitted to the ward for labour induction with misoprostol. In the morning of induction of labour (duty day), the patient was counselled about labour induction and reassessed to check for any further cervical changes before starting. Thus, a quarter of 200 µg misoprostol was inserted into the posterior fornix every four hours until the patient went into active labour, which was defined as having three contractions in ten minutes with each lasting longer than thirty seconds or the cervix was four centimetres dilated. The patient was reviewed each time before inserting the next 50 µg if it was necessary until a maximum of 200 µg was inserted. At least 6 hours after the last dose of misoprostol, if the cervix is considered favourable, oxytocin drip was then set up, and patient monitored at the labour ward for uterine contractions (number and duration), foetal heart rate, liquor colour, and cervical dilation and recorded on the partograph. In the advent of abnormal occurrence including vaginal bleeding, foetal distress, uterine hyper-stimulation, patient was sent to theatre for emergency caesarean section.

To recruit participants, the investigators went to the labour ward every morning to check the labour induction list for the following day. Once patients were identified, introduction and invitation for participation in the study were made. Translators were made available to assist those who did not understand English to ensure consistency and therefore validity. Induction was set up on the appointed day of labour induction and the questionnaire was filled up after written informed consent or verbal informed consent. Information which could not be obtained on direct questioning was taken from patient's folder.

The study had three sections. The first section collected demographic information using multiple choice and fill-in-the blank questions. The second section comprised of multiple choice questions regarding participant's pregnancy parameters and section three was about labour and delivery settings, infant parameters and complications.

Comparison of numerical variables was carried out using the Student t-test for independent samples.

For comparison of categorical data, the Chi^2 test and Fisher exact were carried out. All statistical calculations were carried out using Epi Info 7.1.5. P values less than 0.05 was considered statistically significant.

Results

A total of 176 patients had induction of labour during the study period. Out of these, 122 (65.90%) cases were on account of postdate (their estimated or actual gestational age was more than 41 weeks). Six patients were excluded because they had initial Bishop Scores greater than 6. One hundred and sixteen cases were therefore included in the study (Fig. 1).

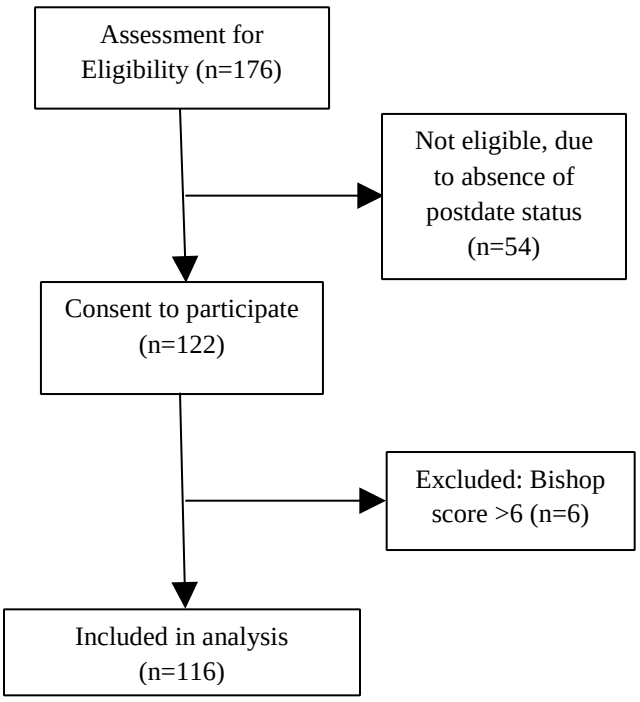

Fig. 1 Flow chart of study participants.

The mean age of the women was 29 years (SD 5.5), most 78 (67.24%) were married, more than half 65 (56.03%) had only primary level of education, 24 (20.69%) had tertiary level education and they were all from varied occupations with traders forming the largest group (43.11%) (Table I).

Of the 116 women, 27 (23.3%) were pregnant for the first time (primigravida) and 89 (76.7%) pregnant before (multigravida). However, 45 (38.8%) were delivering for the first time (nulliparous). The mean gravidity was 3.0 (SD1.8) and parity was 1.8 (SD 1.3). Most of the women, 96 (82.8%), had attended antenatal

Table 1. Social-Demographic Characteristics

Variables	Frequency (N)	Percentage (%)
Age:		
Mean age	29 (SD 5.5)	
<20	5	4.31
20-24	16	13.80
25-29	40	34.50
30-45	38	32.75
35-39	14	12.06
≥40	3	2.58
Total	116	100
Marital status:		
Single	26	22.41
Cohabiting	12	10.35
Married	78	67.24
Total	116	100
Education:		
None	12	10.35
primary	65	56.03
Secondary	15	12.93
Tertiary	24	20.69
Total	116	100
Occupation:		
Traders	50	43.11
Artisans	33	28.46
Service	6	5.17
Finance	5	4.3
Secretaries	5	4.32
Student	4	3.45
Health	3	2.58
Pastor	1	0.86
Others	9	7.75
Total	116	100

N: Number, %: Percentage, ≥: equal to or more than

clinic in other hospitals, and were referred to Korle-Bu Teaching Hospital on account of having gone past estimated 40 weeks or 280 days). The mean gestational age was 41 weeks 1 day with standard deviation of 2.5 days. Fourteen (12.1%) women were induced at 42 weeks gestation or beyond, the greater majority being induced after 41 but before 42 completed weeks of gestation. Although 97 (83.6%) could not remember the date of the last menstrual period, only 67 (57.8%) had an early ultrasound scan done before 14 weeks of gestation (Table 2).

The Bishop score of five was recorded in 51 (44.0%), four in 30 (25.9%), three in 20 (17.2%), two in 7 (0.6%) and one in 2 (1.72%) women. Only one dose of misoprostol (Cytotec) was sufficient to lead to the onset of labour in 67 (57.8%) patients and only 2 onset of labour in 67 (57.8%) patients and only 2 (1.7%) women had up to four doses inserted (Table 3).

Table 2: Pregnancy Parameters

Variables	Frequency (N)	Percentage (%)
Gravidity:		
Primigavida	27	23.27
2-4	65	56.03
≥5	24	20.70
Total	116	100
Parity:		
Nulliparous:	45	38.80
2-4	70	60.34
≥5	1	0.86
Total	116	100
Gestational age:		
41w-41w6d	102	87.93
≥42w	14	12.07
Total	116	100
LMP known:		
Yes	19	16.38
No	97	83.62
Total	116	100
Early Scan (7-14 weeks):		
Yes	67	57.76
No	49	42.24
Total	116	100
Antenatal Clinic Attendance:		
Yes	96	82.76
No	20	17.24
Total	116	100

LMP: Last menstrual period

Table 3: Induction Parameters

Variables	Frequency (n)	Percentage (%)
Number of doses:		
1	67	57.76
2	33	28.45
3	14	12.07
4	2	1.72
Total	116	100
Time between first dose and vaginal delivery:		
Within 12H	51	59.30
12H-24H	26	30.23
24H-48H	7	8.14
≥48H	2	2.33
Total	86	74

H: Hour

The mean interval between the first dose inserted and the second was 6.88 hours in 49 patients, between the second dose and third was 8.09 hours and between third dose and fourth was 8.5 hours (Table 4).

Table 4: Time Characteristic during Induction

Variables	Frequency (N)	Mean (hours)	Standard Deviation (SD)
Mean time(hours) between doses:			
1st -2nd	49	6.88	2.67
2nd -3rd	16	8.09	4.70
3rd -4th	2	8.50	2.12
Time between induction to delivery			
VD	86	12.72	10.63
CS	30	22.49	13.56

VD: Vaginal Delivery, CS: Cesarean section

One hundred and ten patients went into active labour in a mean of 9.82 (SD 12.1) hours after the first dose was inserted. There was no significant association between Bishop score and number of doses of Cytotec used. However, women with lower Bishop scores were more likely to require oxytocin augmentation. This was done in 26 (22.41%) patients. The oxytocin infusion rates in two patients were not recorded. The highest rate of oxytocin infusion was 34.0 (SD 13.8) drop/min (correlation coefficient = -0.12) but not significant (p=0.17).

For obstetric outcomes, 86 (74.13%) patients had vaginal delivery and 30 (25.87%) were delivered by caesarean section (Table 5).

Table 5: Effect of Parity, Gestational Age and Bishop's Score on Mode of Delivery

Variables	Mode of Delivery		P-Value/ Or/Ci
	VD	CS	
Parity:			
nulliparous	30 (66.67)	15 (33.33)	0.19*/0.53/ [0.23 1.24]
Multiparous	56 (78.87)	15 (21.13)	
Gestational Age:			
41W-41W6D	77 (75.49)	25 (25.51)	0.27**/1.71 / [0.52-5.58]
42W and more	9 (64.29)	5 (35.71)	
Bishop Score:			
1-3	15 (51.72)	14 (48.28)	0.002*/0.24 / [0.09-0.59]
4-5	71 (81.61)	16 (18.39)	

Among those who delivered vaginally, 77 (89.53%) delivered within 24 hours. Episiotomy was performed in 20 (23.73%) patients while 29 (33.73%) had first degree perineal tears. Indications for Caesarean Section were Cephalo-pelvic-disproportion in 14 (46.67%), foetal distress in 13 (43.33%) and failed induction (no cervical response to induction) in 3 (10%) cases. There was no statistically significant difference between parity and gestational age and mode of delivery but there was a significant association between mode of delivery and Bishop Score (P=0.002). The higher the Bishop score, the greater the likelihood of the women having vaginal delivery. The mean blood loss was 224.50 (SD 158.0) ml. for those delivered vaginally and 428.00 (SD 160.0) ml. for those delivered by CS. The most common complications were abnormal foetal heart rate and meconium staining of the liquor, 42.86% and 38.10% respectively. One case of PPH was reported, hysterectomy with conservation of both ovaries was done on account of uterine atony.

The highest Apgar score at the first minute was 7 in 55 (47.41%) babies (Table 6). The lowest was 3 in 2 babies. At 5 minutes, 110 (94.82%) babies had Apgar score of 7 or more the mean weight of babies was 3,113.79 g and male babies were 50.86%. Five babies were referred to Neonatal intensive care unit (NICU) on account of severe asphyxia (2 neonates), Meconium stained liquor (2 neonates) and offensive liquor (1 neonate) but all were discharged in satisfactory conditions.

Table 6: Neonatal Outcomes

Parameters	Frequency (N)	Percentage (%)
Apgar score 1 minute:		
≤6	30	25.86
≥7	86	74.14
Apgar score 5 minute:		
≤6	6	5.17
≥7	110	94.82
Infants sex:		
Male	59	50.86
Female	57	49.82
Birth weight (g):		
<2000	1	0.87
2000-2500	8	6.89
2500-3000	44	37.93
3000-3500	48	41.38
≥4000	15	12.93

Discussion

In our study, the proportion of postdate as indication for induction of labour was 65.90% and this result is similar to the study of GIRIJA in India (Manipal) (69.8%)[9] but higher than the results of OUEDRAOGO in Burkina, JESPER FRIIZE in Denmark and FREMY in France (32.4%, 34.6%, 40% respectively)[11,12,13]. On the other hand, it remains lower

than those found in Africa, especially in Nigeria and in Ghana[1, 14, 15]. This may be due to errors in estimation of gestational age, as most women did not remember their last menstrual periods and some did not have first trimester ultrasound scan.

The need to augment labour with oxytocin infusion occurred in 22.41% of subjects. This rate was lower than those found in the Cochrane review (39.07%), as well as in a study in Nigeria (41.86%)[16,17]. However, this result was higher than those reported in Pakistan and in another region in Nigeria, 12% and 16.4% respectively[18,19].

It is generally agreed that the success of induction of labour is vaginal delivery and that caesarean section after induction can be considered a failure of induction. In this study, the success rate of vaginal delivery (74.13%) was independent of parity and gestational age but correlated with the Bishop score. However, induction success rate of 82% was reported in the same Ghanaian hospital in 2002[15], and in another teaching hospital in Nigeria[14]. The difference might be linked to the fact that their study was not selective in terms of gestational age. Our finding is still lower than that found in Pakistan (84%) where a study was done in post-term pregnancy[11]. This difference could be due to the fact that the study participants were fewer (78 patients). Our finding is similar to that described in Burkina (80%), River state in Nigeria, (79.7%), Saudi Arabia (77%), Morroco (76%) and in Moniaya, Nigeria (77.7%)[11,14,20,21,22]. All these studies show that with the same dosage of misoprostol, the success rate may be different. About 90% of vaginal delivery occurred within 24 hours in this study. Similar results were found by other authors in their studies[18,22] confirming the effectiveness of misoprostol in induction of labour.

The caesarean section rate of 25.87% is comparable to that found in Nigeria (22.3%)[22] but is higher than others in literature (13%-15%) and other studies (10.8%, 8.3%,11.1%)[18,19,23]. The commonest indication for caesarean section was cephalo-pelvic disproportion (CPD) followed by feotal distress as reported by other studies[18,23,24]. The mean birth weight was 3113g with extremes of 1900 and 3900; this means that the macrosomia could not be responsible for the CPD.

The overall mean-time from induction to vaginal delivery was 12.72±10.63 hours and was similar to the findings of other studies in Nigeria (12.0±3.6) and Ghana (13.8±7.9),)[22, 25], On the other hand, our findings are slightly higher than the 10.2 hours found in an earlier study in Ghana[15]. This difference might be due to the mean longer intervals between doses in our study. That could affect how quickly contractions were established making labour progress more slowly. The finding in this study is however, lower than what has been reported in other studies[7, 26].

Oxytocin was required for augmentation in 22.41%. This result was lower than what was recorded in Port Harcourt, Nigeria (41.9%) but higher than those recorded in Pakistan (12%) and in Ibadan, Nigeria (15.9%)[, 17,18,19]. This difference might be explained by the variation in protocols. In our study there was a strict observance of at least 6 hour intervals between last dose of misoprostol and start of Oxytocin infusion. The need for augmentation was significantly associated with the Bishop Score. It is not very clear why lower Bishop Scores were not associated with higher number of doses of Cytotec but were associated with an increased likelihood of the need for oxytocin augmentation.

There were three (2.60%) cases of failed induction, no progress in cervical changes and or foetal distress which was similar to the finding in a previous study in Ghana (4%)[15], but lower than in Morocco (13.12%) and in India (20%)[21, 24] and higher than the finding of 0.9% in Pakistan[18]. There was no case of hyper-stimulation recorded in our study. This was similar to that found in Nigeria[19] but different from the findings in Pakistan, in India and in Egypt (Cairo) where they found various proportions of hyper-stimulation (1.81%, 5.8%, and 16% respectively)[18,24,27]. The absence of hyper-stimulation in our study may be due to the fact that the mean interval between the doses of misoprostol was longer than the conventional time between doses, which is 6 hours.

Despite studies linking misoprostol use to the high incidence of uterine rupture, especially the dose of 50µg, there was none observed in this study. This is similar to the findings in India and Germany (Berlin)[24,28]. Others have, however, reported instances of uterine rupture with 50µg of misoprostol, a case each in the Ghana and Gabon studies[15,23.] The absence of uterine rupture (a dreaded complication from misoprostol administration) could be explained by the absence of tachysystole during monitoring with CTG and hyper stimulation, and that women with scarred uterus were excluded from this study.

Twenty per cent of patients had complications in our study, the most common were meconium stained liquor and abnormal foetal heart rate. Such complications are reported in literature and in many studies in Africa than in Asia but with variables rates; in Pakistan (4.01%, 40%) in India (23.64%, 11.82%) and in Egypt (10%, 22%) [18,24,27].

Five babies were admitted to NICU with favourable outcomes. Six babies (5%) had Apgar score of less than 7 at 5 minutes, which is similar to reports in literature compared to placebo and others studies in Africa and Asia. In our study, no case of fresh stillbirth was recorded while in others studies, some cases were recorded [18].

Conclusion

Postdate pregnancy is the commonest indication for induction of labour and intravaginal Misoprostol remains the drug of choice for IOL in our teaching hospital for postdate pregnancy when the cervix is unfavourable. It has an increased rate of vaginal delivery within 24 hours and neither parity nor gestational age is

associated with success of induction. However, Bishop Score is associated with the success of vaginal delivery; the higher the Bishop Score, the more likely is vaginal delivery, as a higher Bishop score signifies readiness of the cervix for labour. Foetal distress and cephalo-pelvic disproportion are the main indications for the caesarean sections. The neonatal outcomes after the IOL were generally acceptable, confirming the effectiveness and the reasonable safety of misoprostol used in induction of labour in postdate singleton live pregnancy at Korle-Bu Teaching Hospital

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