THE USE OF MISOPROSTOL FOR THE INDUCTION OF LABOUR IN A PRIVATE GENERAL HOSPITAL IN GHANA

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Abstract

Introduction: Misoprostol has been successfully used for the induction of labour especially in patients with an unripe cervix. Few studies done in Africa to document its use have been done in teaching hospitals in Nigeria, Ghana and South Africa. This study was therefore undertaken to assess the use of Misoprostol in a typical private primary care hospital setting in Ghana.

Methods: Delivery records of one hundred and thirty three (133) consecutive women admitted to the Maternity unit for induction of labour for medical or obstetric reasons, who successfully delivered vaginally, were reviewed and data extracted from patient records for univariate analysis.

Results: The mean maternal age was 29.18 years (SD: 4.83) with 46.6% of them being nullipara. Gestational age at induction was between 38 to 41 weeks. The insertion of Misoprostol-to-delivery time lasted for a mean of 13.80 (SD 7.85) hours with a range of 1.67 to 40.75. 50.4% delivered with perineal injury and a majority of these (65.67%) occurred in the nulliparous patients. The mean Apgar score at 1 minute was 7.02 [SD 2.52] whilst that for 5 minutes was 8.31[SD 2.79]. The difference was however statistically significant ($p < 0.000$).

Conclusion: Due to the high incidence of perineal injury in nulliparous patients in this study (65.67%), there should be an evaluation of the delivery techniques of the midwives in the hospital especially on using timely episiotomies to reduce these injuries. Misoprostol induction is however recommended for use in primary care.

Key Words: Misoprostol, Induction, Labour, Ghana, Vaginal, Private, Hospital.

Introduction

Misoprostol (methyl II, 16-dihydroxy-16methyl-9-oxoprost-13E-en-oate), a synthetic prostaglandin E1 analogue, is a gastric cyto-protective agent marketed for use in the prevention and treatment of peptic ulcer disease caused by non-steroidal anti-inflammatory drugs.[1] Even though Misoprostol is not approved by the US Food and Drug Administration for use during pregnancy,[2] it has been successfully used for labour induction, especially in patients with an unripe cervix. It was first used to induce labour with a live fetus in 1991.[3] A number of trials have shown that Misoprostol is an effective agent for cervical ripening and labor induction.[4,5,6] Published meta-analyses have stated that women who received Misoprostol for labour induction had a higher rate of vaginal delivery within 24 hours of induction and a lower Caesarean rate than women in whom labour was induced by other methods.[7,8] The drug is inexpensive, easily stored at room temperature, rapidly absorbed after oral and vaginal administration, and has few systemic adverse effects.[9,10] Being an analogue and not a native prostaglandin confers higher potency and longer duration of action because it is less readily destroyed by metabolizing enzymes.[11]

In a recent Cochrane systematic review of Misoprostol use in induction of labour in 2006, its high efficacy and reasonable safety profile were confirmed. Oral and vaginal routes were considered equally effective. The reviewers, however, found lack of dose ranging studies and recommended that till this is achieved the dose should not exceed 50micrograms.[12] However, there has been continuing concern that Misoprostol may be associated with uterine hyperstimulation and tachystole,[13,14] and that, particularly in women with a prior caesarean delivery; this may be associated with uterine rupture and fetal death.[15,16] A case of disseminated intravascular coagulation has been reported after Misoprostol use in Nigeria.[17]

Induction of labor is a common obstetric procedure employed in response to a broad range of conditions in which prompt delivery may be perceived to reduce the risk of maternal or neonatal morbidity and mortality. It accounts for around 20% of all deliveries in the United Kingdom, Canada, and in the United States.[18,19,20] In 1990, data compiled by the National Center for Health Statistics showed the rate of induction of labor to be 9.5%. By 2005, the frequency of labor induction more than doubled to 22.3%.[21] Much lower rates (<10%) are reported in Africa.[22]

Few studies have been done in Africa to document the use of Misoprostol. Most have been done in teaching hospitals in Nigeria,[23,24] and South Africa. In

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Ghana, one study done and published in 2002 was also conducted in a teaching hospital.[25]

This study was therefore undertaken to assess the use of Misoprostol in a typical private primary care hospital setting in Ghana.

Materials and Methods

The study was conducted at the Narh Bita Hospital in Tema, Ghana. It was the first hospital to be accredited in Ghana for the training of Family Medicine residents. Narh Bita Hospital has a maternity unit and an efficiently run antenatal service with specialists and residents of Family Medicine, Medical officers and Nurse/Midwives. All operative delivery anaesthesia is handled by nurse anaesthetists. The use of Misoprostol was introduced into the hospital in the year 2000. A new records system was introduced in 2006 and this provided the data for the study. Narh Bita Hospital is an 80-bedded private hospital with a maternity wing which has 15 beds. Average number of deliveries per month is 95. Of these deliveries, 27.4% (n=26) will deliver via Cesarean section whilst 10.5% (n=10) will be induced with misoprostol. On the average, 20% of inductions fail. It is a private general practice healthcare facility, which has no facilities for electronic fetal monitoring, intrauterine pressure monitoring, scalp electrodes or fetal blood pH for assessment of the fetus.

Delivery records of one hundred and thirty three (133) consecutive women admitted to the Maternity unit from January 2006 to December 2008 for induction of labour for medical or obstetric reasons, who successfully delivered vaginally, were reviewed and data extracted for univariate analysis.

Patients were admitted on the evening before the induction after being selected by any of the doctors at the outpatient antenatal service. At 04:00hrs on the day of induction, a quarter of a tablet of 200mcg of Misoprostol was inserted into the posterior fornix by the midwife on night duty. Immediately after the insertion, the following patient baseline vital signs were recorded – Blood pressure, Radial pulse, axillary temperature. The initial fetal heart rate was also recorded using either the Fetal Doppler (Nicolet Imex Elite Model # 200) or the Pinard stethoscope. The Misoprostol insertion was repeated six hourly till patient was in active labour. Active labour was defined as the presence of two to three contractions in ten minutes, each lasting greater than thirty seconds or the os uteri being at least three centimeters dilated with 80% effacement. The patients were observed for Hyperstimulation (four or more contractions in a ten minute period), Tachystole (six contractions in ten minutes for two consecutive ten minute periods) and Hypertonus (single contraction lasting longer than two minutes). The liquor was also observed for meconium staining. Details of the duration of the delivery, number of doses of Misoprostol used, duration of the third stage, state of the perineum, Apgar score at 1 and 5 minutes; measurements of the fetus (weight, length, head circumference) and post delivery blood pressure and temperature were extracted. Data on the mothers – age, parity, gestational age at induction, pre-delivery temperature and blood pressure – were also recorded.

Exclusion Criteria

Any patient who did not have established labour six hours after the sixth dose of Misoprostol was diagnosed as failed induction and excluded from the study. Thirty five (35) women were induced with misoprostol but were not included in the study. Thirty (30) of them failed to establish labour after the full dose of cytotec and were delivered successfully via caesarean section. Two (2) patients who were induced for intrauterine fetal death, and whose induction failed by the criteria of this study, delivered vaginally after administration of intravenous oxytocin. One patient who failed induction was referred to another facility on request. The authors gathered that this last patient had some financial difficulties when it was suggested that cesarean delivery was indicated. Two (2) patients requested for caesarean delivery after insertion of the first dose of misoprostol. This was carried out successfully in both cases.

The data was first extracted into Excel spreadsheet, cleaned and then transported into SpSS version 16 for analysis.

Results

One hundred and thirty three delivery records which satisfied the inclusion criteria were reviewed (Table 1). The mean maternal age was 29.18 years (SD: 4.83) with a range from 18 to 41 years. Primigravida consisted of 46.6%, single multipara was 24.8%, and those with three children were 5.3%. The gestational age at induction was between 38 weeks to 41 weeks. The mean values for pre-induction temperature, systolic blood pressure and diastolic blood pressure were 36.40C [SD 0.55], 122.7mmHg [SD 16.57] and 77.4mmHg [SD 11.17] respectively. Similar figures for post induction were 37.20C [SD 0.64], 124.1mmHg [SD 15.52] and 78mmHg [SD 11.00]. The difference noticed between pre-delivery and post-delivery systolic blood pressure (an increase of 1.4mmHg) was not statistically significant (p=0.398); and the difference in diastolic pressure before and after delivery (a rise of 0.6mmHg) was also not statistically significant (p=0.374). The number of 50mcg tablets of Misoprostol used per induction ranged from 1 to 6 with mean and mean of 2.41 [SD 1.14]. Two patients needed 5 and 6 doses each to achieve labour. Third stage duration was between 5 to 30 minutes with a median of 5 minutes and a mean of 11.55 [SD 28.29] minutes. The insertion of misoprostol-to-delivery time lasted for a mean of 13.80 [SD 7.85] hours with a range of 1.67 to 40.75hours. Sixty-six (49.6%) delivered without perineal injury. Perineal injuries consisted of tears (20.3% n=27) and episiotomies (30.1% n=40).

Table 1: Summary of nominal data

Variable	Mean	Mode	Median	Standard Deviation	Range
Age (in years)	29.18	28.00	28	4.830	18 – 41
Parity	1.02	1.00	0	1.206	0 – 4
Temperature on Admission (^{0}C)	36.438	36.400	36.0	0.5543	35.0 – 38.6
Pre-Delivery Systolic Blood Pressure (in mmHg)	122.71	120.00	110	16.566	80 – 180
Pre-Delivery Diastolic Blood Pressure (in mmHg)	77.44	80.00	80	11.174	50 – 120
Post Delivery Systolic Blood Pressure (in mmHg)	124.12	120.00	120	15.523	90 – 180
Post Delivery Diastolic Blood Pressure (in mmHg)	78.01	80.00	80	11.009	50 – 120
Duration of Labour (in hours)	14.2744	12.7500	13.08	8.78488	1.67 – 56.3
Dose of Misoprostol Used	2.41	2.00	2	1.142	1 – 6
Duration of Third Stage (in minutes)	11.55	5.00	5	28.290	2 – 240
Birth Weight Of Babies (in kg)	3.311	3.220	3.0	0.5222	1.6 – 4.6
Length of Baby (in cm)	50.54	51.00	50	3.507	40 – 58
Head circumference of Babies (in cm)	34.76	35.00	36	1.763	29 – 39
Apgar Score At 1 Minute	7.02	8.00	8	2.517	0 – 10
Apgar Score At 5 Minutes	8.31	9.00	9	2.794	0 – 10

A majority of these (46.6% n=62) occurred in the nulliparous patients and this difference noted was statistically significant ($p < 0.00001$). One patient (0.8%) had hyperstimulation whilst two (1.6%) had tachystole. Both were managed with an intravenous infusion of Normal saline and had successful vaginal delivery. Only one patient (0.8%) had precipitate labour (less than two hours) and she was a 24year old primip who also sustained a tear. The mean duration of the third stage was 11.55mins [SD 28.29] with a range of 2 minutes to four (4) hours. There was no incidence of primary postpartum haemorrhage. The mean Apgar score at 1 minute was 7.02 [SD 2.52] whilst that for 5 minutes was 8.31[SD 2.79]. The difference was however statistically significant ($p < 0.0001$) (Table 2). One patient (0.8%) had a five minute Apgar score of 5. There were 81 (60.9%) male and 52 (39.1%) female babies. The babies delivered had a mean birth weight of 3.31kg [SD 0.52]; a mean length of 50.54cm [SD 3.51]; and a mean head circumference of 34.76cm [SD 1.76].

Discussion

The results show that the mean induction-to-delivery interval of 13.08 (SD: 7.85) hours after six-hourly intra-vaginal insertion compares favourably with studies done in Pakistan (13.50hrs),[26] Nigeria (13.08hrs in Kano and 12.1hrs in Zaria24). It was however longer than 9.73 (SD: 4.32) hrs recorded in Madiuguri, Nigeria[23]; and 10.2 (SD: 3.8) hours in Accra, Ghana. The induction-to-delivery interval of 13.08 hours was however significantly shorter than 15.73 (SD: 2.54) hours recorded in similar study in Bosnia.[27] These countries also have poorly-resourced primary care healthcare facilities. This means that a majority of patients delivered within 24 hours of

Table 2: Tests of Significance among various variables

#	Variable	χ^2	df	p value
1	Parity of patient and state of perineum after delivery	30.15	8	0.000
2	Parity of patient and pre-delivery diastolic blood pressure	52.65	28	0.003
3	Parity of patient and post-delivery diastolic blood pressure	43.223	28	0.33
4	Age of patient and post-delivery systolic blood pressure	2.2442	198	0.014
5	Dose of cytotec and duration of labour	6.277	565	0.034
6	Parity and age of patient	1.176	88	0.019
7	Age of patient and weight of baby	6.252	550	0.014
8	Age of patient and length of baby	4.697	374	0.001
9	Age of patient and head circumference of baby	2.995	220	0.000
10	Apgar at 1 minute and Apgar at 5 minutes	4.075	42	0.000
11	Baby weight and Apgar at 1 minute	2.263	175	0.005

induction. All these studies recorded low complication rates and excellent fetal outcomes. The finding that pre-delivery and post-delivery measurements of temperature and blood pressures were not statistically different further adds credence to the safety profile of misoprostol use in the induction of labour. We also noticed a sharp rise in the diastolic blood pressure as parity increased from two to three both before and after delivery (Table 2). This difference was found to be statistically significant (p=0.003 and 0.033 before and after delivery respectively). Interestingly, the pressure dropped after this in patients with a parity of four. This observation is useful in the management of patients who undergo induction of labour since the diastolic blood pressure appears to be more sensitive than the systolic blood pressure in predicting prognosis and outcomes. The dose of 50µg every four hours to a maximum of six worked well in almost all the patients and is recommended as an alternative dose regimen for the induction of labour using misoprostol. The dose of cytotec was significantly related to the duration of labour (p=0.034). The duration of the third stage was a respectable average of 11.55±28.29mins which compares favourably with other studies (10.66 ± 7.41; 7.9±3.4mins)[28,29] with no incidence of primary postpartum haemorrhage. Finally, babies delivered had good Apgar scores at one and five minutes again testifying to the safety in misoprostol use for induction of labour. There was improvement in Apgar scores from 1-minute to 5-minutes in the babies delivered and this difference was statistically significant (p=0.000).

There is enough empirical evidence from across the world that Misoprostol use in induction of labour is cheap, easier to handle and transport, less invasive and safe. Its storage does not require refrigeration. Significantly, most of these studies have been conducted in teaching hospitals with obstetricians being the principal investigators. Misoprostol use, however, is most suited for poorly resourced primary care settings – lack of medical equipment, skilled manpower and patient ability to pay. Unfortunately, its use in these settings has not been reported in Ghana. In this study, a setting of such nature was selected to determine the real usage of Misoprostol.

It was also noted that there was reduction in the rate of perineal tears and need for episiotomies as parity increased. This difference was statistically significant (p<0.00001). This means that misoprostol use in nullipara should be closely monitored with timely episiotomies to reduce these injuries.

This study needs to be replicated in similar settings to strengthen the findings and help shape policy for the management of misoprostol induction labour in Ghana.

Conclusion

With a low incidence of complications of labour recorded and healthy foetal outcomes, misoprostol induction is recommended for primary care.

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