

# Misoprostol: An Effective Agent for Cervical Ripening and Labor Induction: A 2-Year Review in a Tertiary Center

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## Abstract

**Background:** Misoprostol a PGE<sub>1</sub> analogue has increasingly been used for cervical ripening in preparation for induction of labour with variable outcome for both mother and baby. **Objectives:** To determine the effectiveness of Misoprostol in cervical ripening and labour outcome in Aminu Kano Teaching Hospital Kano. **Study Design:** A study of all patients who had cervical ripening for induction of labour using Misoprostol at AKTH Kano, Nigeria, between 1st Jan 2012-31st Dec 2013. **Socio-demographic data** of these patients including number of doses inserted before ripening is achieved, duration, course and outcome of labour were documented. **Result:** Four hundred and two women were admitted for cervical ripening. 365 women met the inclusion criteria out of the 358 folders retrieved, giving a retrieval rate of 98%. Despite this six folders did not contain enough information for the study and were excluded leaving us with a sample size of 352. They had a successful cervical ripening with an average of 2 insertions. Spontaneous onset of labour without further intervention was observed in 266 women (75.5%). However, 86 women (24.5%) were induced with oxytocin following cervical ripening. The mean duration of labour among those that had spontaneous onset of labour following Misoprostol insertion was 9.8 hours. 96% of the patients had vaginal delivery while 4% had Caesarean section. **Conclusion:** Misoprostol was associated with favorable outcome following cervical ripening with a low caesarean section rate.

## Keywords

Misoprostol, Cervical Ripening, Outcome, AKTH

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## 1. Introduction

The aim of induction of labour is to achieve vaginal delivery, however it presents a challenge to an obstetrician when the cervix is unfavorable. There are various methods for achieving cervical ripening, these include mechanical dilator (intra cervical Foley's balloon Catheter) pharmaceutical agent (PGE<sub>1</sub>, PGE<sub>2</sub>) when the cervix is deemed unfavorable [1] [2].

Misoprostol is increasingly being used for cervical ripening, as it often results in spontaneous onset of labour [3] [4], and may replace the traditional Foley's catheter/oxytocin protocol [3] [4]. It is a stable synthetic 15 deoxy 16 methyl analogue of naturally occurring PGE<sub>1</sub> which was originally introduced as a therapy for gastric ulcer but now widely found to be useful in reproductive health [5]-[7]. It is inexpensive, easy to store and stable at room temperature gradually becoming the optimal choice for cervical ripening especially in low resource setting like ours [8].

Misoprostol is a cheap drug with easy mode of storage, administration, and may thus be more convenient for use [9] [10]. It is available in tablet form and has a shelf life of several years if kept at room temperature and in aluminum blister pack to prevent contact with air. There has been several publication on the use of Misoprostol for cervical ripening and subsequent induction of labour across Nigeria [10]-[12].

However, there is paucity of such data from our center. This study was conducted to determine the efficacy of misoprostol in cervical ripening and document its effect on duration and outcome of labour.

## 2. Objective

To determine the effectiveness of Misoprostol in cervical ripening and its effectiveness on labour.

## 3. Materials and Methods

This is a retrospective study carried out in the Department of Obstetrics and Gynaecology at Aminu Kano Teaching Hospital, Kano State. Records of patients who had cervical ripening using Misoprostol from 1st Jan 2012-31st Dec 2013 and babies admitted to SCBU were retrieved and analyzed. The information extracted include age, parity, indication for induction of labour, number of doses of Misoprostol inserted, whether or not spontaneous labour ensued, additional oxytocin use for induction, length of active phase of labour, mode of delivery as well as maternal and fetal outcome.

The exclusion criteria were multiple gestation, delivery before 37 weeks gestational age, non-cephalic presentation, intra uterine fetal demise, oligohydraminous, placenta praevia and known lethal congenital abnormality. The beginning of first stage of labour was defined as onset of painful, palpable, regular uterine contraction occurring at least 1 in 10 minute period lasting 30 minutes. All inductions were performed as in-patient following clear indication. A detailed history and examination was done. During examination the pre-induction Bishop score was assessed. A score less than 6 was described as "unripe cervix" and greater than 6 was described as "ripened cervix". Afterward the following investigations were done: Full blood count/packed cell volume, Grouping and cross match, ultrasound scan and cardiotocography. The patients was reviewed to rule out any contraindication to vaginal delivery. After review, the patients were counselled and at 12:00 midnight 50 µg of misoprostol was inserted into the posterior vagina fornix of patients with unripe cervix by the Registrar on-call every six hours until the ripening is achieved to a maximum of 4 doses.

The primary outcomes of measure was mode of delivery (spontaneous vagina delivery operative vagina delivery and Caesarean section). Specific maternal outcome measure include incidence of perineal laceration, post-partum haemorrhage, and uterine rupture. The neonatal outcome were 1 minute APGAR score, occurrence of birth trauma and admission to SCBU. The data were analyzed using frequencies and percentages. Chi square test was used to test for significance difference between qualitative variables. A P-value of <0.005 was taken as significant.

## 4. Results

During the period of study, 482 patients were admitted for cervical ripening, 365 patients met the inclusion criteria but 358 folders were retrieved, giving folder retrieval rate of 98%. Out of 358 folders retrieved, six of this did not contain enough information needed for the study. Thus the sample size for this study was 352. These were subjected to analysis.

Two hundred and twenty seven (64.4%) were multipara while one hundred and twenty five (35.6%) were primigravida as shown in **Table 1**. The commonest indication for admission was postdate pregnancy accounting for 42.9% of cases as in **Table 2**. The average number of doses that were inserted to achieve cervical ripening was two as shown in **Table 3, Table 4**. Two hundred and sixty six (75.5%) went into spontaneous labour while 24.5% had to be induced with oxytocin. The mean cervical ripening delivery interval among those that had spontaneous labour was  $9.8 \pm 1.4$  hours. Ninety six percent of patients had vagina delivery while 4% had caesarean section delivery.

Fetal ( $P < 0.001$ ) and Maternal ( $P < 0.001$ ) complications were significantly more among those with duration of cervical ripening greater than 12 hours. Post-partum haemorrhage was the commonest maternal complication and uterine rupture was the least accounting for 0.6% of cases. The commonest neonatal complication was birth Asphyxia. There was no maternal morbidity or fresh still birth during the period under review as shown in **Tables 5-9**.

## 5. Discussion

In this study all patients had successful cervical ripening with Misoprostol. The average age of patient was 26 years with teenagers constituting 5%. Primigravidae accounted for 35.6% while grand multipara constituted 1.2% as shown in **Table 1**. The fewer number of grandmultipara may have been due to non-presentation for hospital services on account of successful outcome of their previous pregnancies. They also constitute the group

**Table 1.** Socio-demographic data.

| Age      | Frequency | %    |
|----------|-----------|------|
| <19      | 18        | 5.0  |
| 20 - 29  | 229       | 65.2 |
| 30 - 39  | 82        | 23.3 |
| >40      | 23        | 6.5  |
| Total    | 352       | 100  |
| Parity   | Frequency | %    |
| 0        | 125       | 35.6 |
| 1 - 4    | 223       | 63.2 |
| $\geq 5$ | 4         | 1.2  |
| Total    | 352       | 100  |

**Table 2.** Indications for admission.

| Indications                        | Frequency | %    |
|------------------------------------|-----------|------|
| Postdate pregnancy                 | 151       | 42.9 |
| Hypertensive disorder in pregnancy | 125       | 35.6 |
| PROM                               | 40        | 11.2 |
| Previous unexplained stillbirth    | 10        | 2.8  |
| GDM                                | 9         | 2.5  |
| Polyhydraminos                     | 7         | 2.0  |
| IUGR                               | 6         | 1.8  |
| Others                             | 4         | 1.2  |
| Total                              | 352       | 100  |

**Table 3.** Mean bishop score per parity before cervical ripening.

| Parity | Mean Bishop Score |
|--------|-------------------|
| 0      | 2.5 ± 0.6         |
| 1 - 4  | 4.6 ± 1.7         |
| ≥5     | 5.3 ± 0.2         |

**Table 4.** Number of misoprostol insertion.

| Number | Frequency | %    |
|--------|-----------|------|
| 1      | 46        | 13.1 |
| 2      | 248       | 70.5 |
| 3      | 44        | 12.2 |
| 4      | 14        | 4.2  |
| Total  | 352       | 100  |

**Table 5.** Duration of cervical ripening.

| Duration (hours) | Frequency | %    |
|------------------|-----------|------|
| 0 - 6            | 46        | 13.1 |
| 7 - 12           | 248       | 70.5 |
| 13 - 18          | 44        | 12.2 |
| 19 - 24          | 14        | 4.2  |
| Total            | 352       | 100  |

**Table 6.** Mode of induction of labour.

| Mode        | Frequency | %    |
|-------------|-----------|------|
| Spontaneous | 266       | 75.5 |
| Oxytocin    | 86        | 24.5 |
| Total       | 352       | 100  |

**Table 7.** Mode of delivery.

| Mode                      | Frequency | %    |
|---------------------------|-----------|------|
| SVD                       | 332       | 94.2 |
| Operative vagina delivery | 6         | 1.8  |
| Caesarean section         | 14        | 4.0  |
| Total                     | 352       | 100  |

**Table 8.** Comparison between duration of cervical ripening and fetomaternal complication.

| Duration (hours) | Maternal     | Fetal        |
|------------------|--------------|--------------|
| <12              | 4            | 4            |
| >12              | 13           | 18           |
| Total            | 1722         |              |
| Test             | Fisher exact | Fisher exact |
|                  | = 0.000      | = 0.000      |
| P-value          | <0.001       | <0.001       |

**Table 9.** Complications.

| Complications      | Frequency | %    |
|--------------------|-----------|------|
| Maternal           |           |      |
| Hyperstimulation   | 3         | 0.9  |
| Maternal PPH       | 8         | 2.3  |
| Perineal Tear      | 4         | 1.1  |
| Ruptured uterus    | 20.6      |      |
| Maternal death     | 0         | 0    |
| Fetal              |           |      |
| Fetal distress     | 2         | 0.6  |
| Birth Asphyxia     | 12        | 3.4  |
| Fetal birth trauma | 5         | 1.4  |
| NNS                | 3         | 0.9  |
| Fresh still birth  | 0         | 0    |
| Total              | 39        | 11.2 |

of patient that may have had contraindication for the use of Misoprostol.

Majority of the patient 78.5% were admitted for induction of labour due to postdate pregnancy and hypertension disorder of pregnancy in keeping with previous observation [2] [13] [14]. Two hundred and ninety four patients constituting 83.6% achieved cervical ripening with a maximum of two insertions as shown in **Table 4**. This suggests that in well selected patients, misoprostol could be a fast and reliable option to achieve cervical ripening.

The mean induction delivery interval of  $9.8 \pm 1.4$  hours was comparable to the  $8.7 \pm 2$  hours reported from Ife and 9.3 hours reported from Sokoto [14] and Ghana [15]. It is however lower than  $13 \pm 5$  hours and higher than 7.1 hours (SD  $\pm 3.3$ ) in the studies by Onafowokan *et al.* [9] and Tabowei [13] respectively. The reason for higher value compared to the study by Onafowokan *et al.* may be due to proportion of high multipara during this study, in the years under review.

Two hundred and sixty-six patients (75.5%) had spontaneous labour after cervical ripening, while eighty-six patient (24.5%) were induced with oxytocin following cervical ripening. Ekele *et al.*, kwawukume and Ayertey reported similar findings [11] [15]. This may be due to dual effects of misoprostol for cervical ripening and induction of labour.

The vaginal delivery success rate was 96% was comparable with the previous work reported by Onafowokan *et al.* [9] and Ekele *et al.* [2] The 4% of patient who had caesarean section were those that had 4 insertions of Misoprostol, this was similar to findings from Ibadan [16].

There was also an observed increase in maternal morbidity, and a composite neonatal complication with a longer cervical ripening delivery interval especially among those who had multiple doses of Misoprostol and induction with oxytocin. Two uterine rupture were recorded during the years of review and was among those that had multiple insertions of Misoprostol and additional induction of labour with oxytocin. This might be due to synergetic effects of multiple doses on gravid uterus and inaccurate dosing when dividing 200 microgram into four pieces.

## 6. Conclusion

Misoprostol was found to be safe and effective for cervical ripening with significant proportion of patients progressing into spontaneous labour thereafter. Care must however be exercised when the dose of insertion is greater than two as most of the unpleasant outcome are recorded with a dose insertion of three or more. Thus there is need for proper assessment and patient selection if complications are to be avoided.

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