

# Comparison of orally administered misoprostol and membrane sweeping for labor induction among women with singleton postdate pregnancies in South-South, Nigeria

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## Ethics Committee Approval

Ethical approval for the study were obtained from the institutional Ethical Review Committee of both hospitals. The reference numbers for the ethical approval of both hospitals are HREC/PAN/2022/003/0452 and CHW/ECC VOL 1/251 for Delta State Teaching Hospital, Oghara and Central Hospital, Warri, respectively. All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

## Conflict of Interest

No conflict of interest was declared by the authors.

## Financial Disclosure

The authors declared that this study has received no financial support.

## Published

2025 October 7

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## Abstract

**Background/Aim:** Postdate pregnancy is an indication for induction of labor to prevent post-term pregnancy with its associated complications. Labor induction processes require hospital admission, resulting in additional costs in managing patients. Therefore, safe and effective outpatient techniques that help reduce the need for inpatient induction of labor are beneficial. The aim of this study is to compare and evaluate the safety and effectiveness of two outpatient methods: a single 50 µg dose of oral misoprostol and membrane sweeping in preventing post-term pregnancy. It also examines the impact on reducing the need for hospital admission for labor induction in postdate singleton pregnancies across two tertiary hospitals in Delta State, Nigeria.

**Methods:** This two-center randomized controlled trial was conducted on women with uncomplicated postdate singleton pregnancies in an outpatient setting. A total of 157 participants were randomly assigned to one of two intervention groups: the oral misoprostol (OM) group or the membrane sweeping (MS) group. Participants in the OM group received a single 50 µg dose of oral misoprostol, while those in the MS group underwent a one-time membrane sweeping procedure at the antenatal clinic after 40 weeks of gestation.

**Results:** The participants' baseline sociodemographic and clinical characteristics were similar in both groups. This study found that the proportion of women that achieved spontaneous onset of labor in the OM group (92.1%) was more than in the MS group (85.3%), but this difference was not statistically significant ( $P=0.21$ ). This study showed that both 50 µg OM and MS are effective and safe methods for inducing labor on an outpatient basis in post-term pregnancies, with OM offering the benefits of a shorter latency period, decreased reliance for oxytocin augmentation in labor, and reduced overall labor duration ( $P<0.001$ ,  $P=0.003$  and  $P<0.001$ , respectively).

**Conclusion:** The study showed that both OM and MS are effective and safe outpatient agents in preventing post-term pregnancy, although the proportion of women achieving spontaneous onset of labor was greater in the OM group. The two outpatient induction methods were similar regarding neonatal outcomes and the need for Neonatal Intensive Care Unit (NICU) admission with no recorded maternal adverse effects. Both interventions demonstrated good safety profiles for outpatient care; however, a higher proportion of patients in the OM group reported a positive perception of the intervention compared to those in the MS group.

**Keywords:** oral misoprostol, membrane sweeping, outpatient basis, postdate pregnancies

## Introduction

One desired obstetric outcome is the prevention and management of prolonged gestation in order to circumvent the many associated complications. Post-term pregnancy is a high-risk pregnancy that is associated with maternal and perinatal morbidity and mortality [1]. It has been shown that women with otherwise uncomplicated pregnancies have increased risk of maternal and perinatal morbidity and mortality from the gestational age of 42 weeks and longer [2,3]. Fetal complications associated with post-term pregnancy include intrapartum asphyxia from progressive decline in placenta function, oligohydramnios and cord compression in labor, fetal macrosomia, shoulder dystocia, fetal dysmaturity syndrome and unexplained intrauterine fetal death. Maternal complications include anxiety, cephalopelvic disproportion, genital trauma associated with fetal macrosomia, as well as increased caesarean section rate. Neonatal complications are increased risk of birth trauma, meconium aspiration syndrome, and early neonatal seizures [2-4].

Postdate pregnancy occurs in 10-14% of pregnancies [3,4]. The incidence decreases as the accuracy of the dating criteria used increases. It is the most common indication for induction of labor in many centers in Nigeria and other developing countries [4-6].

The cause of postdate pregnancy is unknown. Predisposing factors include inaccurate dating; history of prolonged pregnancy; congenital fetal anomalies like congenital absence of fetal pituitary glands, anencephaly, and congenital fetal adrenal hypoplasia; placenta sulfatase deficiency; extra uterine pregnancy; family history; male fetuses; nulliparity; and obesity [2].

The management of a postdate pregnancy is either expected or an elective delivery of the baby. However, current evidence favors a policy of induction of labor after 41 weeks, as this has been associated with reduced incidence of perinatal mortality, meconium staining of the amniotic fluid, and caesarean section delivery compared with expected management, which has no observed increase in the risk of instrumental delivery, maternal analgesic requirements, or fetal heart rate abnormality [2,4,7,8].

Labor induction success is largely influenced by the readiness of the cervix. An unfavorable cervix requires ripening, which could be achieved with membrane sweeping or mechanical methods like laminaria tent, or extra-amniotic Foley's catheter placement. It could also be accomplished through pharmacological methods like prostaglandin E2 vaginal pessaries and gels, prostaglandin E1 analogue like misoprostol, and sometimes low dose oxytocin infusion [3].

Membrane sweeping is a procedure in which the fetal membranes are gently separated from the lower uterine segment using a circular motion of the examining fingers [9]. This technique is commonly performed to reduce the risk of post-term pregnancy and minimize the need for other induction methods, such as Foley's catheter insertion, misoprostol administration, or oxytocin infusion [10]. It is usually carried out after 40 weeks' gestation, and performed before 42 weeks of gestation. It has been found to stimulate the local release of prostaglandins F2a, the activity of phospholipase A2, the mechanical dilatation of the cervix, and the frequency of uterine contractions [11,12].

Misoprostol, a prostaglandin E1 analogue, is widely used for cervical ripening and labor induction. Its advantages include affordability, broad availability, and stability at room temperature.

Misoprostol can be administered through oral, vaginal, sublingual, or buccal routes. However, the sublingual and buccal routes are not currently recommended for labor induction due to limited supporting data [13]. Oral administration achieves peak plasma concentration more rapidly, typically within 30 minutes, whereas the vaginal route takes approximately one hour [14-16]. Cervical ripening and labor induction processes require inpatient care, resulting in additional costs in managing patients. Hence, any safe and effective interventions that helps in the reduction of the cost of management of patients are, therefore, beneficial. In a study conducted between April 2007 and March 2010 at Ladoke Akintola University of Technology Teaching Hospital, Osogbo, Nigeria, Adeniji et al. [17], reported that both 50 µg oral misoprostol and membrane sweeping administered on an outpatient basis, are safe and effective agents for inducing labor in uncomplicated postdate singleton pregnancies. The study showed that oral misoprostol has a shorter latency period advantage, reduced need for oxytocin augmentation in labor, and a shorter labor duration. Similar studies need to be conducted to document the validity of this finding and add to the body of knowledge.

Therefore, the aim of the study is to compare the efficacy and safety of the two outpatient techniques of single-dose 50 µg oral misoprostol and membrane sweeping in preventing post-term pregnancies and reducing the need for inpatient induction of labor in uncomplicated postdate singleton pregnancies.

## Materials and methods

This study was a randomized controlled trial of a single dose of 50 µg OM and MS in uncomplicated singleton postdate pregnancies. Participants recruited for the study had early ultrasound dating from 8 to 14 weeks of their pregnancy in addition to their last menstrual period, utilised for the determination of the expected delivery date.

The study was conducted between February 1, 2022 and December 31, 2022 at the department of Obstetrics and Gynaecology, Delta State University Teaching Hospital (DELSUTH), Oghara, and its affiliate, Central Hospital, Warri both in Delta State, South-South Nigeria. Patients with singleton and postdate pregnancies were recruited after providing informed consent.

Participants were randomly allocated into either of the two study arms (OM arm or MS arm) in a 1:1 ratio using a random permuted blocking technique with a block size of ten. For each block, ten computer generated three-digit random numbers were arranged on a spreadsheet with five rows and two columns. Each of the random numbers was cut into a piece of 5cm x 5cm paper, and sealed in an opaque brown envelope, which was identical for all the random numbers. If the random number picked by the participant matched the OM column, the participant was allocated to the OM study arm. If the random number matched the MS column, the participant was allocated to the MS study arm.

Ethical approval for the study was obtained from the institutional Ethical Review Committee of both hospitals. The reference numbers for the ethical approval of both hospitals are HREC/PAN/2022/003/0452 and CHW/ECC VOL 1/251 for Delta

State Teaching Hospital, Oghara and Central Hospital, Warri, respectively. Inclusion criteria included a parturient with a singleton live fetus, postdate pregnancy from 40 weeks and 1 day to 40 weeks and 9 days, intact fetal membranes, Bishop's score  $\leq 5$  and cephalic presentation. Patients excluded were those whose pregnancies were postdate pregnancies (of  $\geq 40$  weeks and 10 days), multiple pregnancies, grand multiparity, cephalopelvic disproportion, previous caesarean section or a uterine scar, fetal malpresentation, fetal distress, antepartum hemorrhage, premature rupture of the membranes and medical disorders.

### The Study Group

This study was a two-center randomized controlled trial of women with uncomplicated postdate singleton pregnancies. One hundred fifty-seven patients with singleton postdate pregnancies were randomized into two groups: The first group was the oral misoprostol (OM) group, while the second group was the membrane sweeping (MS) group. The OM group received a single oral dose of 50  $\mu\text{g}$  misoprostol on an outpatient basis, while the MS group underwent a one-time membrane sweeping procedure at the antenatal clinic. Cases where cervical access was not possible due to a non-yielding cervix were classified as "failed MS." In this study, spontaneous labor was defined as a participant's self-presentation to the labor ward with regular, painful uterine contractions occurring at least once every ten minutes. Failure to achieve spontaneous labor by 41 weeks and 3 days of gestation was classified as a prolonged pregnancy. Participants in this category were managed according to departmental protocols for cervical ripening and labor induction, which included intravaginal misoprostol and oxytocin titration, to facilitate delivery before 42 weeks of gestation or caesarean section as deemed appropriate.

The primary outcome measure was the proportion of women who achieved spontaneous onset of labor before 41 weeks and 3 days gestation. The secondary outcome measures were time interval from the initiation of intervention to the onset of labor (latency period), time interval from the onset of labor to delivery, route of delivery, need for oxytocin augmentation, and neonatal outcomes.

### Statistical analysis

Data entry and analysis were accomplished using the Statistical Package for Social Sciences (SPSS) version 26 (IBM® Inc, Il Chicago. USA). Analysis was by intention to treat (ITT).

The descriptive statistics of the study population were presented as frequency tables as illustrated below. Categorical variables were expressed as frequencies and percentages. Continuous variables that were normally distributed were expressed as mean (standard deviations), while non-normally distributed continuous variables were expressed as medians and interquartile range. Comparisons of participants' baseline characteristics and outcome measures between the two arms of the study were conducted using the chi square tests for categorical variables (with Fisher's exact test where applicable). Student's T test was used for continuous variables that were normally distributed, and the Mann Whitney U test was employed for continuous variables where normal distribution could not be assumed. The level of significance was set at 5%.

### Results

There were 205 patients who were assessed for eligibility for the study, from which 48 were excluded. Of the 48 patients excluded, 27 did not meet the inclusion criteria while 21 declined to participate in the study. The remaining 157 participants were randomized into 78 participants in the OM arm and 79 participants in the MS arm. Three participants were lost to follow-up, two in the OM arm and one in the MS arm. The intervention was discontinued in three participants in the MS arm due to a failed MS. All 157 randomized participants were finally analyzed.

Table 1 shows the baseline sociodemographic and clinical characteristics of the participants. The majority of the participants were within the age range, 25-29 years. However, there were no statistically significant difference in the mean age between the two study groups (30.78 [6.43] for the OM group and 31.01 [6.11] for the MS group). Most of the participants had post-primary education (69 [90.7%] and 71 [94.7%] for the OM group and MS group, respectively); and there was no statistically significant difference in the distribution of educational attainment between the groups.

The participants were also mostly in the Para 1-4 group {66 (86.8%) and 60 (80.0%) for the OM group and MS group, respectively}, and parity distribution between the OM group and the MS group were not statistically different ( $P=0.28$ ). Also, the difference between the mean gestational age in the two groups (40.22 [0.42] for the OM group and 40.23 [0.42] for the MS group) was not statistically significant ( $P=0.97$ ).

**Table 1:** Baseline demographic and clinical characteristics of participants

|                    |                 | OM-Group<br>(n = 76) |      | MS-Group<br>(n = 75) |      | Total<br>(n = 151) |      | $\chi^2/t$         | P-value |
|--------------------|-----------------|----------------------|------|----------------------|------|--------------------|------|--------------------|---------|
|                    |                 | n                    | %    | n                    | %    | n                  | %    |                    |         |
| Age group (years)  | <20 years       | 1                    | 1.3  | 2                    | 2.7  | 3                  | 2.0  | 2.686              | 0.748   |
|                    | 20-24 years     | 11                   | 14.5 | 10                   | 13.3 | 21                 | 13.9 |                    |         |
|                    | 25-29 years     | 26                   | 34.2 | 22                   | 29.3 | 48                 | 31.8 |                    |         |
|                    | 30-34 years     | 11                   | 14.5 | 17                   | 22.7 | 28                 | 18.5 |                    |         |
|                    | 35-39 years     | 19                   | 25.0 | 19                   | 25.3 | 38                 | 25.2 |                    |         |
|                    | $\geq 40$ years | 8                    | 10.5 | 5                    | 6.7  | 13                 | 8.6  |                    |         |
|                    | Mean (SD)       | 30.78 (6.43)         |      | 31.01 (6.11)         |      | 30.89 (6.25)       |      | -0.232             | 0.817   |
| Marital Status     | Single          | 5                    | 6.6  | 10                   | 13.3 | 15                 | 9.9  | 1.925 <sup>§</sup> | 0.185   |
|                    | Married         | 71                   | 93.4 | 65                   | 86.7 | 136                | 90.1 |                    |         |
| Level of Education | Primary         | 7                    | 9.2  | 4                    | 5.3  | 11                 | 7.3  | 0.859              | 0.651   |
|                    | Secondary       | 41                   | 53.9 | 43                   | 57.4 | 84                 | 55.6 |                    |         |
|                    | Tertiary        | 28                   | 36.8 | 28                   | 37.3 | 56                 | 37.1 |                    |         |
| Parity             | 0               | 10                   | 13.2 | 15                   | 20.0 | 25                 | 16.6 | 1.279 <sup>§</sup> | 0.281   |
|                    | 1 – 4           | 66                   | 86.8 | 60                   | 80.0 | 126                | 83.4 |                    |         |
|                    | Mean (SD)       | 1.83 (1.15)          |      | 1.49 (1.07)          |      | 1.66 (1.12)        |      | 1.859              | 0.065   |
| GA (weeks)         | Mean (SD)       | 40.22 (0.42)         |      | 40.23 (0.42)         |      | 40.23 (0.42)       |      | -0.044             | 0.965   |

Age Range: 16 – 44 years.  $\chi^2$  Chi Squared test, t: Independent sample t-test, §: Fischer's exact test

**Table 3:** Comparison of the agents of induction with regard to latency period

|                                |           | OM-Group<br>(n=70) |      | MS-Group<br>(n=64) |      | Total<br>(n=134) |      | $\chi^2/t$ | P-value |
|--------------------------------|-----------|--------------------|------|--------------------|------|------------------|------|------------|---------|
|                                |           | n                  | %    | n                  | %    | n                | %    |            |         |
| Latency Period (hours)         | < 12      | 35                 | 50.0 | 17                 | 26.6 | 52               | 38.8 | 18.313     | *<0.001 |
|                                | >12 – 24  | 32                 | 45.7 | 30                 | 46.9 | 62               | 46.3 |            |         |
|                                | >24 – 36  | 1                  | 1.4  | 15                 | 23.4 | 16               | 11.9 |            |         |
|                                | >36 – 48  | -                  | -    | -                  | -    | -                | -    |            |         |
|                                | >48       | 2                  | 2.9  | 2                  | 3.1  | 4                | 3.0  |            |         |
| Intervention to onset of Labor | Mean (SD) | 12.50 (8.59)       |      | 18.99 (10.02)      |      | 15.60 (9.82)     |      | -4.008     | *<0.001 |

 $\chi^2$ =Chi Squared test | t=Independent sample t-test**Table 4:** Comparison of events and outcomes of labor in the study groups

|                              |     | OM-Group<br>(n=70) |      | MS-Group<br>(n=64) |      | Total<br>(n=134) |      | $\chi^2$ | P-value |
|------------------------------|-----|--------------------|------|--------------------|------|------------------|------|----------|---------|
|                              |     | n                  | %    | n                  | %    | n                | %    |          |         |
| Need for Oxytocin<br>(n=136) | Yes | 14                 | 20.0 | 29                 | 45.3 | 43               | 32.1 | 9.830    | *0.003  |
|                              | No  | 56                 | 80.0 | 35                 | 54.7 | 91               | 67.9 |          |         |
| Mode of Delivery (n=136)     | VD  | 65                 | 92.9 | 54                 | 84.4 | 119              | 88.8 | 2.420    | 0.170   |
|                              | CS  | 5                  | 7.1  | 10                 | 15.6 | 15               | 11.2 |          |         |

VD: Vaginal Delivery, CS: Caesarean Section,  $\chi^2$  Chi Squared test**Table 5:** Comparison of labor duration in the study groups

|                           |           | OM-Group<br>(n=70) |      | MS-Group<br>(n=64) |      | Total<br>(n=134) |      | $\chi^2/t$ | P-value |
|---------------------------|-----------|--------------------|------|--------------------|------|------------------|------|------------|---------|
|                           |           | n                  | %    | n                  | %    | n                | %    |            |         |
| Duration of Labor (hours) | < 4       | -                  | -    | -                  | -    | -                | -    | 18.993     | *<0.001 |
|                           | >5 – 8    | 43                 | 61.4 | 19                 | 29.7 | 62               | 46.3 |            |         |
|                           | >9 – 12   | 22                 | 31.4 | 24                 | 37.5 | 46               | 34.3 |            |         |
|                           | >12       | 5                  | 7.1  | 21                 | 32.8 | 26               | 19.4 |            |         |
| Duration of Labor         | Mean (SD) | 7.74 (2.25)        |      | 9.97 (3.01)        |      | 8.80 (2.86)      |      | -4.824     | *<0.001 |
| Intervention to Delivery  | Mean (SD) | 20.24 (10.08)      |      | 28.92 (12.10)      |      | 24.39 (11.88)    |      | -4.489     | *<0.001 |

 $\chi^2$  Chi Squared test, t: Independent sample t-test**Table 6:** Neonatal outcomes in the study groups

|                                              |     | OM-Group    |      | MS-Group    |      | Total       |      | $\chi^2/t$         | P-value             |
|----------------------------------------------|-----|-------------|------|-------------|------|-------------|------|--------------------|---------------------|
|                                              |     | Mean (SD)   |      | Mean (SD)   |      | Mean (SD)   |      |                    |                     |
|                                              |     | n           | %    | n           | %    | n           | %    |                    |                     |
| Birth weight (kg)                            |     | 3.26 (0.30) |      | 3.19 (0.32) |      | 3.23 (0.31) |      | 1.294              | 0.198               |
| Mean (SD)                                    |     |             |      |             |      |             |      |                    |                     |
| APGAR score<br>(1 <sup>ST</sup> min) [n=141] | < 7 | 31          | 44.3 | 33          | 51.6 | 64          | 47.8 | 0.710              | 0.489 <sup>§</sup>  |
|                                              | ≥ 7 | 39          | 55.7 | 31          | 48.4 | 70          | 52.2 |                    |                     |
| Mean (SD)                                    |     | 6.86 (1.24) |      | 6.50 (1.35) |      | 6.68 (1.30) |      | 1.579              | 0.117               |
| APGAR score<br>(5 <sup>TH</sup> min) [n=141] | < 7 | 2           | 2.9  | 8           | 12.5 | 10          | 7.5  | 4.502              | *0.048 <sup>§</sup> |
|                                              | ≥ 7 | 68          | 97.1 | 56          | 87.5 | 124         | 92.5 |                    |                     |
| Mean (SD)                                    |     | 8.84 (1.12) |      | 8.42 (1.37) |      | 8.64 (1.26) |      | 1.924              | 0.057               |
|                                              |     |             |      |             |      |             |      |                    |                     |
| APGAR score (10 <sup>TH</sup> min)           |     | 9.86 (0.51) |      | 9.62 (0.79) |      | 9.74 (0.68) |      | 1.737              | 0.086               |
| Mean (SD)                                    |     |             |      |             |      |             |      |                    |                     |
| NICU Admission (n=141)                       | Yes | 4           | 5.7  | 10          | 15.6 | 14          | 10.4 | 3.510 <sup>§</sup> | 0.089               |
|                                              | No  | 66          | 94.3 | 54          | 84.4 | 120         | 89.6 |                    |                     |

NICU: Neonatal Intensive Care Unit,  $\chi^2$  Chi Squared test, t: Independent sample t-test, §: Fischer's exact test

Table 1 shows there was no statistically significant difference in the distribution of participants in each component between the two study groups.

Table 2 shows that the proportion of participants that achieved spontaneous onset of labor in the OM group (n=70; 92.1%) was more than in the MS group (n=64; 85.3%); however, there was no statistically significant difference (P=0.21).

**Table 2:** The Primary outcome measure which is the proportion of participants who had spontaneous labor

|                   |     | OM-Group<br>(n = 76) |      | MS-Group<br>(n = 75) |      | Total<br>(n = 151) |      | $\chi^2$           | P-value |
|-------------------|-----|----------------------|------|----------------------|------|--------------------|------|--------------------|---------|
|                   |     | n                    | %    | n                    | %    | n                  | %    |                    |         |
| Spontaneous Labor | Yes | 70                   | 92.1 | 64                   | 85.3 | 134                | 88.7 | 1.733 <sup>§</sup> | 0.209   |
|                   | No  | 6                    | 7.9  | 11                   | 14.7 | 17                 | 11.3 |                    |         |

 $\chi^2$  Chi Squared test

Table 3 shows that the mean of the latency period was shorter among participants in the OM group (12.50 [8.59] hours) than those in the MS group (18.99 [10.02] hours) and the difference was statistically significance (P<0.001).

Table 4 shows that more participants in the MS group (n=29; 45.3%) required oxytocin augmentation compared to those

in the OM group (n=14; 20.0%), and this was statistically significant (P=0.003). It was observed that more women in the OM group (n=65; 92.9%) had vaginal deliveries compared to participants in the MS group (n=54; 84.4%). However, this was not statistically significant (P=0.170).

Table 5 shows that the majority of the participants' duration of labor ranged from four to eight hours. However, the mean labor duration was significantly shorter among participants in the OM group (7.74 [2.25] hours) than those in the MS group (9.97 [3.01] hours); and the difference was statistically significant (P<0.001).

Table 6 shows that there were similarities in the neonatal outcomes in both the OM and MS groups, with more babies in the MS group (n=8; 12.5%) compared to the OM group (2; 2.9%) having moderate birth asphyxia at the fifth minute after birth. In addition, the neonates that were admitted in the Neonatal Intensive Care Unit in the MS group (n=10; 15.6%) were more than in the OM group (n=4; 5.2%); and there was no statistically difference (P=0.09).



## Discussion

This study compared the efficacy of two outpatient techniques of single-dose 50 µg oral misoprostol and membrane sweeping in preventing post-term pregnancies and reducing the need for hospital admission for induction of labor in postdate singleton pregnancies in two tertiary hospitals in Delta State, Nigeria. The findings of this study showed that the results of the comparison of the sociodemographic and clinical characteristics in both study groups were not statistically significant. This demonstrates that the randomization process was effective in ensuring that probable confounding variables were equally distributed in both groups and, therefore, unlikely to affect the results of the study.

The main objective of the study was to determine and compare the proportion of women who would achieve spontaneous onset of labor before 41 weeks and 3 days gestation in participants with postdate pregnancies who had single-dose 50 µg oral misoprostol and those who had membrane sweeping. The study revealed that the proportion of participants that achieved spontaneous onset of labor in the OM group (92.1%) was greater compared to the MS group (85.3%). However, the results showed no statistically significant difference between the two groups ( $P=0.209$ ).

This is in keeping with a study reported by Adeniji and Akintola et al. [17]. Their findings indicated that there was no statistical difference between the proportion of participants that achieved spontaneous onset of labor in both the OM and MS groups. Manipulation of the cervix during digital vaginal examination or membrane sweeping has been shown to trigger the onset of labor by stimulating the release of localized prostaglandins F2α, phospholipase A2, and cytokines from intrauterine tissues [32]. Additionally, misoprostol, a prostaglandin E1 (PGE1) analogue, undergoes rapid de-esterification into its active free acid metabolites, leading to a faster onset of action compared to the local prostaglandin production expected with membrane sweeping [33]. This difference may be attributed to the combined effect of the pre-recruitment digital vaginal examination used to assess the Bishop score ( $\leq 5$ ) prior to randomization and the administration of a single 50 µg oral dose of misoprostol in the OM group.

This study also demonstrated that both 50 µg OM and MS were effective for inducing labor on an outpatient basis in postdate pregnancies. However, the OM group demonstrated advantages, including a shorter latency period, reduced need for oxytocin augmentation, and a shorter duration of labor. Within 12 hours of intervention initiation, 44.9% of participants in the OM group reported being in labor, compared to 21.5% in the MS group. By 24 hours, the proportions increased to 85.9% and 59.5%, respectively. Orally administered misoprostol reaches its peak plasma concentration more rapidly than the vaginal route, achieving maximum levels within 30 minutes [14,15]. This also explained the combined effect of the endogenous locally released prostaglandins from the manipulation of the cervix during the pre-recruitment Bishop score assessment and the exogenous prostaglandins (OM) when compared with only endogenous prostaglandins from manipulation of the cervix and MS.

The study further revealed that more participants in the MS group, (45.3%), required additional need for oxytocin

augmentation when compared to participants in the OM group (20.0%) and this was statistically significant. This finding is in line with several studies that have demonstrated less need for oxytocin augmentation in patients who received misoprostol when compared to patients that had MS [17-19,21]. The duration of labor was significantly shorter in the OM group, in which 61.4% of those who had a vaginal delivery achieved it within eight hours, compared with 29.7% in the MS group, and this was statistically significant. These findings agreed with similar studies conducted by Adeniji and Akinola in Osogbo, Nigeria [17] and Kamal et al. in Cairo, Egypt [18]. Their reports showed that participants who received misoprostol had a shorter latency period, less oxytocin use for augmentation, and a shorter duration of labor.

In addition, this study showed that more participants in the OM group (92.9%) had vaginal deliveries compared to participants in the MS group (84.4%). This is in keeping with study done by Kamal et al. [18], but in contrast with the study done by Adeniji and Akinola [17], where the proportions of vaginal deliveries were similar in both the OM and MS groups. This finding is probably due to the difference in the methodology and the fact that their study utilized a smaller sample size, which may have introduced performance and detection bias.

Safety was defined in this study as any adverse effects that could jeopardize the life of the mother and or that of the fetus from the use of OM and MS. The reported maternal adverse effects of misoprostol, such as fever, diarrhea, vomiting, tachysystole, hyperstimulation, uterine rupture or postpartum hemorrhage were not observed in this study, possibly because of the single oral dose administered and a membrane sweeping. However, the neonatal outcomes in both OM and MS groups were similar, which agreed with studies done by Adeniji and Akintola [17] and Kamal et al. [18]. Furthermore, more babies in the MS group (12.5%) compared to OM group (2.9%) had moderate birth asphyxia at the fifth minute after birth. The birth asphyxia occurred in babies of relatively low birth weight and whose mothers had oxytocin augmentation of labor. There is documented evidence that low birth weight of neonates and oxytocin augmentation of labor contribute to the higher risk of perinatal asphyxia [34,35]. The neonates that were admitted in the Neonatal Intensive Care Unit in both groups were only monitored for observation and were discharged within 24 hours.

### Strength of the Study

One strength of the study is that it was a randomized controlled trial in which there was a randomized allocation of participants to the two study groups. This minimized selection bias and unequal allocation of confounders among the participants. In addition, it was a two-centre study enhancing the generalizability of the findings.

This research provided a high level of evidence on the performances of oral misoprostol and membrane sweeping as an outpatient technique in preventing post-term pregnancies in our environment, thereby enriching the growing body of knowledge and offering the women the best possible management.

### Limitations

This study also has limitations. It was not possible for either group in the study to be blinded to the participants. Nor was it possible for the investigator and the research assistants who were involved in data collection and analysis, as the interventions

in both groups were completely different. Nevertheless, the variables being measured were fairly objective, and the investigator and research assistants were as objective as possible.

### Conclusion

This study determined that the proportion of women that achieved spontaneous onset of labor in the OM group was greater compared to MS group, although there was no statistically significant difference. This study demonstrated that patients who received a single-dose oral misoprostol (OM) had a shorter latency period, reduced need for oxytocin augmentation, and a shorter duration of labor compared to those who underwent membrane sweeping (MS) on an outpatient basis. Both induction methods showed comparable neonatal outcomes, including the need for admission with no recorded maternal adverse effects.

### Recommendations

It is clear from the findings of this study that a greater proportion of participants achieved spontaneous onset of labor with a shorter latency period, reduced need for oxytocin augmentation and a reduced labor duration in participants given single-dose OM compared with MS on an outpatient basis. Therefore, it is recommended that OM can be used as an appropriate outpatient technique for labor induction in order to prevent post-term pregnancies and reduced the need for inpatient induction of labor in postdate pregnancies.

Furthermore, a larger multicenter study is recommended to further validate or refute the advantages of oral misoprostol observed in this study.

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