ORIGINAL ARTICLE

# Sublingual Misoprostol Prior to Caesarean Section-Randomized Controlled Trial

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Abstract

*Background:* ***Most severe maternal morbidities, including need for blood transfusions, extended hospital stays, and surgeries that may impair reproductive function, are caused by postpartum hemorrhage (PPH).***

*Aim and objectives:* ***To evaluate the effectiveness and safety of sublingual misoprostol prior to cesarean section (CS) in decreasing intraoperative blood loss and uterine atony at cesarean delivery.***

*Subjects and methods:* ***100 women who gave birth by caesarean section at the Obstetrics and Gynecology Department (Al-hussein) at Al-Azhar University Hospital participated in this randomized controlled clinical research, which ran from November 2023 to December 2024. There were two equal groups of patients.***

*Results:* ***Group I experienced a significantly lower blood loss (ml) at 1 hour, 4 hours, and 24 hours following delivery than Group II. 10.0% of the individuals in Group I required additional uterotonics, whereas 20.0% of the individuals in Group II required such assistance. Group I and Group II did not differ statistically significantly in terms of the requirement for blood transfusions, further uterotonics, or vaginal bleeding exceeding 1000 milliliters.***

*Conclusion:* ***Misoprostol administered sublingually may be a superior choice due to its quick absorption, extended duration of action, and highest overall bioavailability.***

*Keywords:* Sublingual misoprostol; Caesarean section

## 1. Introduction

More than 500 milliliters of expected blood loss during a vaginal delivery or more than 1000 milliliters of estimated blood loss during a cesarean delivery have historically been considered postpartum hemorrhage (PPH).[1]

In 2017, regardless of the delivery method, the American College of Obstetrics and Gynecology (ACOG) classified PPH as a cumulative blood loss of more than 1000 mL accompanied by hypovolemia symptoms within 24 hours of the birth process.[2]

Bleeding within the first 24 hours following delivery is known as primary postpartum hemorrhage, and bleeding between 24 hours and 12 weeks postpartum is known as secondary postpartum hemorrhage.[3]

Because of its powerful uterine impact, misoprostol, a PGE1 analogue, has been used to prevent and treat PPH; however, there is disagreement regarding the best dosage or method of administration.[4]

Misoprostol has been given orally or intrarectally in most studies at dosages between 400 and 1000 ug.[5]

Remarkably, misoprostol can be given rectally, vaginally, sublingually, buccally, orally, and sublingually. Rectal misoprostol is frequently used to prevent postpartum hemorrhage (PPH) after cesarean and spontaneous vaginal deliveries. When compared to the rectal route of administration, sublingual administration of misoprostol may be a preferable choice due to its quick absorption, extended duration of action, and highest overall bioavailability.[6]

In order to reduce intraoperative blood loss and uterine atony during cesarean delivery, this study sought to assess the safety and efficacy of sublingual misoprostol before CS.

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## 2. Patients and methods

From November 2023 to December 2024, 100 women who gave birth by caesarean section at the Obstetrics and Gynecology Department (Al-hussein) of Al-Azhar University Hospital participated in this randomized controlled clinical trial. Two groups of patients were formed: 50 women in Group I will receive 400 µg of misoprostol sublingually (two tablets of Misotac®, Sigma) five minutes before a uterine section. Fifty women in Group II (control) are given a sublingual placebo (2 pills) five minutes before a uterine section. Microcrystalline cellulose, sodium starch glycolate, hydrogenated castor oil, and hypromellose are all included in placebo pills. The size, color, shape, and packaging of these placebo tablets will be the same as those of Misotac® tablets.

Active management of the third stage of labor:

Routinely giving a preventative uterotonic medication right before, during, or right after the baby is born. The placenta is delivered via controlled cord traction with early cord clamping and cutting (i.e., prior to, concurrent with, or soon following the injection of an oxytocic, which is before cord pulsation stops).

In an effort to lower the risk of PPH and the blood loss linked to the third stage of labor, these therapies are regularly and proactively used. This package of actions has a wide range of potential modifications. A variety of uterotonic medications, including misoprostol, carbetocin, syntometrine (IM), ergometrine (IV or IM), oxytocin (intravenous or intramuscular), or combinations of these medications, can be employed.

Sample size calculation:

$$\text{Sample size} = \frac{\frac{z^2 \times p\,(1-p)}{e^2}}{1 + \left(\frac{z^2 \times p\,(1-p)}{e^2 N}\right)}$$

N represents the population size, e is the margin of error expressed as a decimal percentage, and z signifies the z-score. At a population size of 2,000,000 (number of births in Egypt in 2022), with a confidence level of 85%. Margin of error 5% = 100 cases.

Quantitative Measurement of Obstetric Blood Loss:

When the amniotic membranes are torn or the baby is born, the measurement of blood loss can begin. Prior to placenta delivery, vacuum and quantify all amniotic fluid in the collected canister. Take a reading from the suction canister and the drapes to see how much blood has been lost after the placenta has been delivered. The majority of the blood should now be identifiable. Keep track of the milliliters of blood loss and inform the staff. Make sure the scrub crew announces the start of irrigation before introducing fluid. Do not be surprised if the tissues absorb part of the regular saline. This is why the amount of fluid extracted from the abdomen by suction will not be exhaustive.

There are two options for collecting the irrigation fluid: either keep sucking into the same canister and measure the amount, or supply a separate suction line to collect the irrigation fluid into a different canister. Check the mass of any clots or objects that have been drenched with blood. Find the mass and multiply it by milliliters.

Total quantification of blood loss is determined at the end of the procedure by adding the weight-calculated volume of quantified blood to the volume of quantified blood in the suction canister. Lap pads wetted with regular saline don't contain much fluid, so keep that in mind. Once they're soaked in blood, use them as a dry lap pad to determine their weight.

Primary outcome:

Find out how many episodes of postpartum hemorrhage (PPH) occurred, how much blood was lost (500 ml or more) within one hour of enrollment, and whether misoprostol created any side effects.

Secondary outcome:

Neonatal complications include breathing problems, yellowing of the skin and eyes, low red blood cell count, respiratory distress, neonatal intensive care unit admission, blood transfusion, hemoglobin level less than 8g/dl one day after delivery, more uterotonics needed, and maternal mortality.

Method of randomization:

One kind of randomization is known as simple randomization, which relies on just one sequence of assignments. Assigning individuals to specific groups remains entirely random with this method. Tossing a coin is the simplest and most prevalent approach to randomly selecting an outcome. Each participant is assigned to one of two treatment groups—sublingual misoprostol or placebo control—based on the flip of the coin.

Inclusion criteria:

aternal age above 18years old, pregnant at term (37-40) weeks, elective planned cesarean section, and singleton pregnancy.

Exclusion criteria:

If a woman has any of the following risk factors, she is more likely to experience postpartum hemorrhage: low hemoglobin level (Hb<8%), multiple pregnancies, previous hemorrhage before delivery, polyhydramnios, labor that lasts more than twelve hours, a history of uterine rupture, two or more cesarean sections, or a history of serious diseases like heart disease, liver disease, renal disorders, or coagulopathy as well as conditions that make prostaglandin treatment inappropriate, such as a sensitivity to misoprostol or a history of severe bronchial

asthma.

Interventions:

All cases were subjected to the following before therapy: a detailed medical history, general physical examination, abdominal and vaginal examination, ultrasound examination by the 2–5MHz abdominal probe, and laboratory investigations.

Anesthesia:

Benefits of regional spinal anesthesia for caesarean sections include a lack of effect on uterine contractions, ease of administration and initiation of unconsciousness, decreased risk of systemic toxicity, and an increased density of the spinal anesthetic block.

Here is the measurement of blood loss:

Prenatal and postpartum visual assessment of blood loss has been the gold standard for obstetric blood loss measurement. Studies comparing visual estimating to quantitative measurement have shown that visual estimation tends to under- or overestimate the real blood loss depending on the amount. Researchers have looked at ways to make volume comparisons easier to visually estimate blood loss. Visual estimation accuracy has not been reliably improved by these technologies. Additionally, there seems to be no correlation between the age, specialty, or clinical experience of healthcare providers and ocular estimations of blood loss.

Advice on How to Measure Blood Loss After a Cesarean Section:

When the amniotic membranes are torn or the baby is born, the measurement of blood loss can begin.

Gather all amniotic fluid in the suction canister and measure it before the placenta is delivered.

Check the suction canister and drapes for signs of blood loss after the placenta is delivered. Nearly all of the blood has been found. Keep track of the milliliters of blood loss and inform the staff.

Get the scrub crew to agree on when to start irrigation before you add fluid. Bear in mind that the tissues absorbed a portion of the usual saline. Because of this, not all of the abdominal fluid was removed or recorded by suction.

If you want to measure how much irrigation fluid has been suctioned, you can either keep sucking into the same canister or use a second suction tube to transfer the fluid to a different container.

Weigh everything that has been touched with blood or has clots on it. To find the milliliters, you must first determine the weight. To get the entire amount of blood loss quantified at the end of the procedure, add the weight-based volume of quantified blood to the volume of quantified blood in the suction canister.

Lap pads wetted with regular saline don't contain much fluid, so keep that in mind. When they're completely soaked, put them through the same weighing process as a dry lap pad.

Ethical Consideration:

After receiving signed informed consents, the study protocol was authorized by the Local Ethics Committee.

Statistical Analysis:

Using SPSS (statistical software for the social sciences, version 20), the following analyses were performed on the data: Data presented quantitatively as mean, standard deviation, and range. Presentation of qualitative variables using numerical and percentage formats. A chi-square test will be employed to compare qualitative variables between groups. When one expects a value of 5 or less, Fisher's exact test is substituted for the chi-square test. When dealing with parametric data (SD<50% mean), the T-test will be employed for comparing quantitative variables. The odds ratio, risk differential, and relative risk. To measure the accuracy of the OR, the 95% CI is utilized.

## 3. Results

*Table 1. Demographic data of the studied patients.*

| | | NO.=100 |
|---|---|---|
| AGE(YEARS) | ≥30 | 53(53.0%) |
| | <30 | 47(47.0%) |
| | Mean±SD | 26.79±5.40 |
| | Range | 20.00-45.00 |
| GESTATIONAL AGE | Mean±SD | 37.70±1.21 |
| | Range | 37-41 |
| PARITY | Primipara | 23(23.0%) |
| | Multipara | 77(77.0%) |
| EMPLOYMENT STATUS | Unemployed | 80(80%) |
| | Employed | 20(20%) |
| EDUCATION | Primary | 34(34%) |
| | Secondary | 55(55.0%) |
| | Tertiary | 11(11%) |

The ages ranged between 20-45years (mean 26.79years), the Gestational age ranged between 37-41(mean 37.70), For the employment status there were 80(80%) women were unemployed, and 20(20.) women were employed, regarding the education there were 34(34%) women were primary, 55(55.0%) women were secondary and 11(11%) women were tertiary, (table 1).

*Table 2. Comparison between 2Groups regarding Antepartum HB, HTC (%).*

| ANTEPARTUM PCV (%) | GROUP-I | GROUP-II | TEST VALUE | P-VALUE | SIG. |
|---|---|---|---|---|---|
| ≥33 | 37(74.0%) | 38(76.0%) | -0.569• | 0.570 | NS |
| <33 | 13(26.0%) | 12(24.0%) | | | |
| MEAN±SD | 34.56±3.25 | 34.82±3.21 | | | |
| RANGE | 28-40 | 27-40 | | | |

*:Chi-square test, •:Independent t-test; P-value>0.05:Significant (S); P-value<0.05:Highly significant (HS)

The average antepartum HB, Htc(%) in Group-I were; 34.56±3.25, while average antepartum HB, Htc(%) in Group -II were 34.82±3.21, In Group I; 74.0% of them were antepartum HB, Htc(%) 33

and 26.0% were antepartum HB,Htc(%) <33, while the Group II; 76.0% of them were antepartum HB, Htc(%) ≥33 and 24.0% were antepartum HB, Htc(%)<33,(table 2; figure 1).

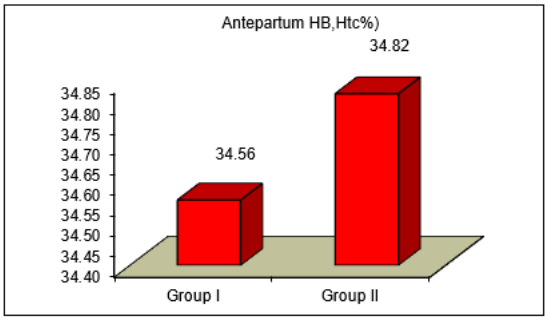


Figure 1. The variation in antepartum HB and Htc(%) between Groups I and II.

*Table 3. Comparison of the hours spent in the active phase of labor between the two groups.*

| DURATION OF ACTIVE PHASE OF LABOR(HOURS) | GROUP I | | GROUP II | | TEST VALUE | P-VALUE | SIG. |
|---|---|---|---|---|---|---|---|
| | No. | % | No. | % | | | |
| <3 | 2 | 4.0% | 3 | 6.0% | 1.154* | 0.562 | NS |
| 3-12 | 47 | 94.0% | 45 | 90.0% | | | |
| >12 | 1 | 2.0% | 2 | 4.0% | | | |

*: Chi-square test, •: Independent t-test; P-value>0.05: Non-significant (NS); P-value<0.05: Significant (S); P-value<0.01: Highly significant (HS).

In Group I, 94.0% of them had an active phase of labor duration (hours), with 4.0% having an active phase of labor duration (hours) <3. 6.0% of Group-II had an active phase of labor duration (hours) <3, and 90.0% had an active phase of labor duration (hours) >12. In contrast, 3-12 and 2.0% had an active phase of labor duration (hours) >12. The duration of the active phase of labor (hours) was 3.12% and 4.0% longer than 12, (table 3;figure 2).

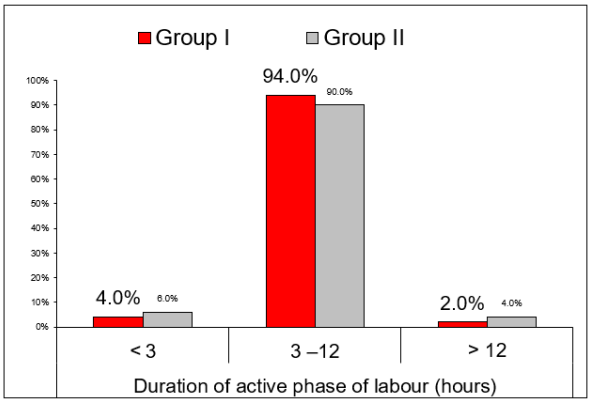


Figure 2. The distinction between Groups I and II with respect to the number of hours spent in the active phase of labor.

*Table 4. Comparison of blood loss between two groups.*

| PRIMARY OUT COME | GROUP-I | | GROUP-II | | TEST VALUE * | P-VALUE | SIG. |
|---|---|---|---|---|---|---|---|
| | No. | % | No. | % | | | |
| BLOOD LOSS ≥500 ML | 3 | 6.0 % | 8 | 16.0 % | 5.107 | 0.024 | S |
| ≥10% CHANGE IN HB, HTC. | 4 | 8.0 % | 1 0 | 20.0 % | 5.980 | 0.014 | S |
| NO OF CASES DEVELOPED PPH | 3 | 6.0 % | 8 | 16.0 % | 5.107 | 0.024 | S |

*: Chi-square test, •: Independent t-test; P-value>0.05: Non-significant (NS); P-value<0.05: Significant (S); P-value<0.01: Highly significant (HS)

In Group-I, 6.0% of them were blood loss ≥500ml and 8.0% were≥10% change in HB, Htc, while the Group-II; 16.0% of them were blood loss ≥500ml and 20.0% were≥10% change in HB, Htc,(table 4; figure 3).

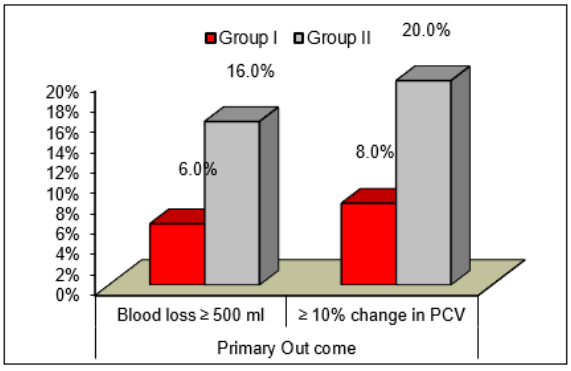


Figure 3. The variation in blood loss between Group I and Group II.

*Table 5. Comparison of the two groups' requirements for extra uterotonics, vaginal bleeding exceeding 1000 milliliters, and blood transfusions.*

| | GROUP I | | GROUP II | | TEST VALUE* | P-VALUE | SIG. |
|---|---|---|---|---|---|---|---|
| | No. | % | No. | % | | | |
| NEED FOR ADDITIONAL UTEROTONICS | 5 | 10.0% | 10 | 20.0% | 3.922 | 0.088 | NS |
| NEED FOR BLOOD TRANSFUSION | 1 | 2.0% | 2 | 4.0% | 0.687 | 0.407 | NS |

*: Chi-square test, •: Independent t-test; P-value>0.05: Non-significant (NS); P-value<0.05: Significant (S); P-value<0.01: Highly significant (HS).

In Group-I; 10.0% of them were Need for additional uterotonics, 2.0% were vaginal bleeding ≥1000ml and 2.0% were need for blood transfusion, while the Group-II; 20.0% of them were need for additional uterotonics, 2.0% were vaginal bleeding ≥1000ml and 4.0% were need for blood transfusion. The requirement for extra uterotonics, vaginal bleeding ≥1000 ml, and blood transfusions did not differ statistically significantly between Group I and Group II, (table 5; figure 4).

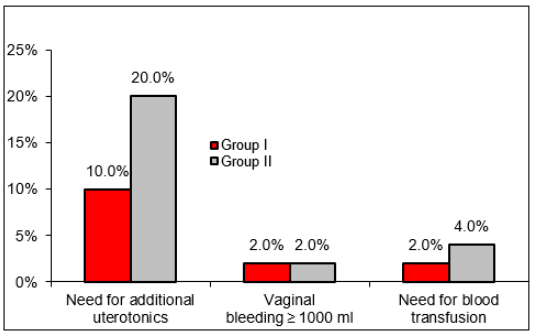


Figure 4. The distinction between Groups I and II with regard to the requirement for blood transfusions and extra uterotonics.

*Table 6. Comparison between 2 Groups regarding satisfaction of route of administration and side effects.*

| | | GROUP-I | | GROUP-II | | TEST VALUE* | P-VALUE | SIG. |
|---|---|---|---|---|---|---|---|---|
| | | No. | % | No. | % | | | |
| ACCEPTANCE OF ROUTE OF ADMINISTRATION | | | | | | – | – | – |
| SATISFIED | No | 6 | 12.0% | 14 | 28.0% | 8.000 | 0.005 | HS |
| | Yes | 44 | 88.0% | 36 | 72.0% | | | |
| UNPLEASANT EFFECTS | | | | | | – | – | – |
| SHIVERING | No | 21 | 42.0% | 42 | 84.0% | 37.838 | 0.000 | HS |
| | Yes | 29 | 58.0% | 8 | 16.0% | | | |
| HEADACHE | No | 49 | 98.0% | 49 | 98.0% | 0.000 | 1.000 | NS |
| | Yes | 1 | 2.0% | 1 | 2.0% | | | |
| DIARRHEA | No | 49 | 98.0% | 49 | 98.0% | 0.000 | 1.000 | NS |
| | Yes | 1 | 2.0% | 1 | 2.0% | | | |
| FEVER | No | 44 | 88.0% | 48 | 96.0% | 4.348 | 0.037 | S |
| | Yes | 6 | 12.0% | 2 | 4.0% | | | |
| PYREXIA | No | 45 | 90.0% | 49 | 98.0% | 5.674 | 0.017 | S |
| | Yes | 5 | 10.0% | 1 | 2.0% | | | |
| DEATH | No | 49 | 99.5% | 49 | 99.5% | 0.000 | 1.000 | NS |
| | Yes | 1 | 0.5% | 1 | 0.5% | | | |

*: Chi-square test, •: Independent t-test P-value>0.05: Non-significant (NS); P-value<0.05: Significant (S); P-value<0.01: Highly significant (HS).

In Group I; 88.0% of them were satisfied, 58.0% were shivering, 2.0% were headache, 2.0% were diarrhoea,12.0% were fever, 10.0% were pyrexia and 1.0% were death, while the Group-II; 72.0% of them were satisfied, 16.0% were shivering, 2.0% were headache, 2.0% were diarrhoea, 4.0% were fever, 0% were pyrexia and 1.0% were death. Regarding satisfaction and shivering, there was a statistically significant distinction between Group I and Group II. Group I and Group II also differed statistically significantly in terms of fever and pyrexia, but Group I and Group II did not differ statistically significantly in terms of headache, diarrhea, or death, (table 6; figure 5).

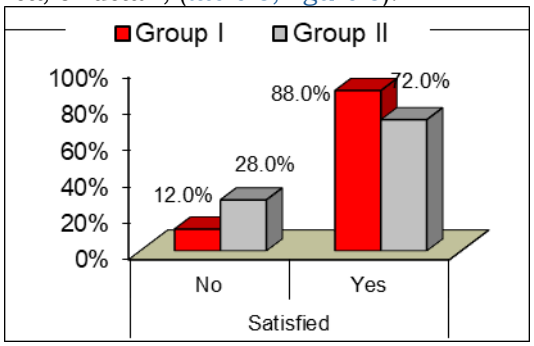


Figure 5. The difference between (Group-I and Group-II) regarding satisfied.

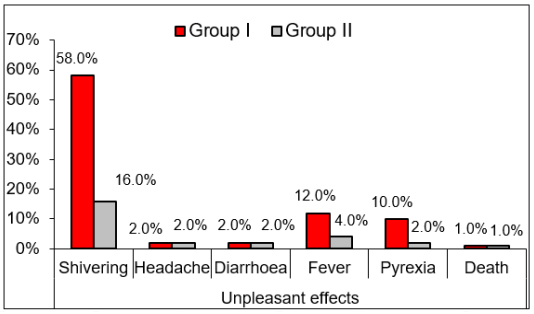


Figure 6. The distinction between Group I and Group II in terms of negative consequences.

## 4. Discussion

In the present study, in Group-I; 6.0% of them had blood loss ≥500ml while in the Group-II; 16.0% of them had blood loss ≥500ml.

In the current study, there was a statistically significant increase in Group-II compared to Group-I regarding blood loss ≥ 500ml and ≥10% change in HB% %, HTC.

In the current study, there was highly statistically significant decrease among Group-I than Group-II regarding Blood loss after delivery(ml) (1h, 4hr and 24h).

In this study, in Group-I; 10.0% of them needed for additional uterotonics, while in the Group-II; 20.0% of them needed for additional uterotonics. Concerning the requirement for extra uterotonics, vaginal bleeding of 1000 ml or more, and blood transfusion, no statistically significant distinction was found between Group I and Group II.

In this study, there was a notable disparity between Group I and Group II in terms of headache, diarrhea, and death; however, there was a statistically significant increase in Group I compared to Group II in terms of shivering and acceptance of administration route. Additionally, Group I had a higher incidence of fever and pyrexia than Group II.

Research agrees with the results of the current study:

An investigation into this matter was conducted in which 366 patients who were to undergo elective caesarean sections were assigned at random to either 400 µg of sublingual misoprostol (n=179) or a placebo pill (n=187) following intubation. Both groups had comparable newborn cardiovascular states and Apgar scores at 1 and 5 minutes.[7]

Consistent with previous research showing no significant difference in Apgar ratings at 1 and 5 minutes after cesarean birth among the three groups, these findings lend credence to the idea that misoprostol, when administered prior to surgery, has no negative effect on newborn outcomes.

Shivering and other adverse effects were more common in the Group given sublingual misoprostol than in the Group given oxytocin

(p<0.001).[8]

In a study by Sweed et al.,[9] Sublingual administration of misoprostol, as compared to rectal administration, considerably reduced the anticipated intraoperative hemorrhage following cesarean delivery, according to a study that evaluated the effect of an adjuvant of misoprostol and oxytocin.

The results of the study performed by Othman et al.,[8] determined that 20 units of oxytocin intravenously infusion was less efficacious than 400 µg of sublingual misoprostol. The research comprised 120 women who were going to have elective caesarean sections. In comparison to the oxytocin group, the misoprostol group had a considerably lower overall mean blood loss (490.75±159.90 mL vs. 601.08±299.49 mL; p=0.025).

The results of the study by Bellad et al.,[10] 652 pregnant women who were eligible for the study and gave their informed consent were given one of two treatments: conventional intramuscular (IM) oxytocin (10 IU) or 400 ug powdered sublingual misoprostol. Researchers found that compared to injectable oxytocin, sublingual misoprostol was more effective in preventing postpartum bleeding.

Researchers disagree with the results of the current study:

The studies of Dutta and Gupta[11] determined that, when comparing the effectiveness of oxytocin and sublingual/oral misoprostol in actively managing the third stage of labor with respect to projected blood loss, considering the various doses and routes of administration, the two drugs are comparable.

Research conducted by Vodouhe et al.,[12] By contrasting the use of 600µg of sublingual misoprostol with 20 units of intravenous oxytocin during umbilical cord ligation, it was found that neither Group experienced significantly different mean blood loss.

Gohar et al.,[5] was showed that a decreased estimated blood loss in the sublingual misoprostol group compared to the oxytocin group. Concerning postpartum bleeding, however, neither Group differs much from the other.

Ahmed[13] reduced blood loss during surgery when 20 units of oxytocin were injected shortly after delivery. The oxytocin group had a far greater rate of blood transfusions and extra uterine treatments compared to the misoprostol group.

All studies came in disagreement with our study due to:

Different methodology (inclusion and exclusion criteria); different dose, timing of misoprostol; comparison of misoprostol with other uterotonic, not with placebo.

Limitations of my study: Constrained time frame, underpowered data, insufficient number of studies conducted on the subject, and unavailability of relevant literature

### *4. Conclusion*

Because of its fast absorption, long half-life, and maximum overall bioavailability, sublingually giving misoprostol may be preferable.

## Disclosure

The authors have no financial interest to declare in relation to the content of this article.

## Authorship

All authors have a substantial contribution to the article

## Funding

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## Conflicts of interest

There are no conflicts of interest.

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