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**Original Research Article**

# Efficacy and safety of oral misoprostol solution compared to sublingual misoprostol for induction of labor at term pregnancy

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## ABSTRACT

**Background:** Induction of labor (IOL) is the artificial stimulation of uterine contractions at term to achieve vaginal delivery. This study aimed to compare the efficacy and safety of 25 µg oral versus sublingual misoprostol for labor induction at term pregnancy. The aim of the study was to compare the efficacy and safety of oral misoprostol solution versus sublingual misoprostol for induction of labor in term pregnancies.
**Methods:** This randomized controlled trial was conducted at the Department of Obstetrics and Gynecology, Institute of Child and Mother Health (ICMH), Matuail, Dhaka, Bangladesh, from July 2023 to June 2024, including 66 term pregnant women with a singleton cephalic fetus and unfavorable cervix (Bishop score <6). Participants were randomized to oral misoprostol solution (Group A, n=33) or sublingual misoprostol (Group B, n=33), with labor progress, maternal, and neonatal outcomes monitored. Data were analyzed using SPSS v26, with P<0.05 considered significant.
**Results:** Among 66 term women (33 oral, 33 sublingual), most were 20-30 years, housewives, with normal BMI and primigravida. Indications and gestational age were similar. Oral group required higher misoprostol doses (3.6±1.1 vs. 3±1.9, p=0.010), but labor times, oxytocin use, Bishop score improvement, delivery mode (vaginal 72.7% vs. 75.8%), neonatal outcomes, and adverse effects were comparable. Success rates were 84.8% vs. 90.9%.
**Conclusions:** Both oral and sublingual misoprostol are similarly effective for labor induction, with oral misoprostol showing a slightly safer profile.

**Keywords:** Efficacy, Induction, Labor, Misoprostol, Safety

## INTRODUCTION

Induction of labor (IOL) is an artificial stimulation of uterine contractions at 28 or more weeks of gestation but before the spontaneous onset of labor to achieve vaginal delivery.[1] Elective induction is commonly described as the induction of labor at term, without an evident clinical necessity, with the aim of enhancing maternal and perinatal outcomes.[2] In full-term pregnancy, IOL involves the use of medications and various techniques to initiate labor for childbirth. This approach is frequently employed in obstetrics to manage high-risk pregnancies when the onset of natural labor does not occur spontaneously.[3]

Induction of labor is indicated when the risk of continuing the pregnancy, for the mother or the fetus, exceeds the risk associated with induction of labor and delivery.[4] Urgent reasons for induction include conditions such as preeclampsia at ≥37 weeks, chorioamnionitis, unresponsive serious pregnancy-related illnesses, suspected fetal compromise, and premature rupture of membranes (PROM) with maternal group B streptococcal colonization. Contraindications for induction include previous uterine rupture, structural deformities of the pelvis, and abnormal fetal presentation. Despite induction, some women may not go into labor.[5] Induction increases the risk of caesarean section, instrumental vaginal delivery, chorioamnionitis, umbilical cord prolapse, and uterine rupture in both scarred and unscarred uteri.

The rates of labor induction have shown a consistent increase, with an estimated average occurrence of one in every four term births in high-income countries, with comparable rates in low- and middle-income countries (LMICs).[6] Labor induction rates vary widely between countries and even among obstetric units in the same geographic region.[7] In 2019, IOL was used in around 20% of women giving birth in Europe and 29.4% in the USA, while Sri Lanka reported the highest rate in Asia at 35.5%.[8,7] A study in India reported an incidence of 20.36%.[9] Maternal age, parity, body mass index (BMI), pre-existing medical conditions, and Bishop score affect IOL success. The likelihood of caesarean section after induction increases with advanced maternal age (>35 years), obesity (BMI >40 kg/m²), large fetal size (EFW >4 kg), and diabetes mellitus.[10] A Bishop score <6 is considered unfavorable and associated with poor outcomes, while a score of 8 is favorable and associated with higher rates of vaginal delivery after induction.[11]

The choice of induction method pharmacological, mechanical, or a combination may determine success or failure. Factors influencing method choice include cervical and membrane status, parity, and patient and provider preference.[1,12] Cervical ripening, a method of IOL, can be achieved mechanically (e.g., balloon catheters) or pharmacologically (e.g., prostaglandins).[5] Prostaglandins are endogenous uterine hormones that relax the cervix and increase contraction frequency and intensity. Dinoprostone (prostaglandin E2) can be administered vaginally but is unstable at room temperature and expensive.

Misoprostol, a prostaglandin E1 analogue originally developed for treating stomach ulcers, is cheap, heat-stable, and has a long shelf-life.[13] It is also used to prevent or treat postpartum hemorrhage, a major cause of maternal morbidity and mortality, by inducing uterine contractions. Misoprostol has been used for labor induction or cervical ripening since the mid-1980s, though optimal dosage and administration routes are not fully established.[14] It can be administered orally, sublingually, buccally, or vaginally, with usual doses of 25-50 µg sublingually every 4-6 hours if contractions are absent or insufficient.[15] Complications may include tachysystole, hypertonus, uterine hyperstimulation, and uterine rupture.[16]

Previous studies have evaluated sublingual, vaginal, or oral misoprostol for labor induction and postpartum bleeding prevention, but results are sometimes conflicting. Bartusevicius et al reported that 50 µg sublingual misoprostol every 4 hours had similar efficacy to 25 µg vaginal misoprostol for term labor induction.[17] Sheir et al observed that 50 µg sublingual misoprostol had higher maternal and perinatal safety compared to vaginal misoprostol, including lower caesarean rates due to fetal distress and fewer hyperstimulation events.[18] In contrast, Handal-Orefice et al found oral misoprostol was associated with increased cesarean rates and longer time to vaginal delivery versus vaginal misoprostol.[19] Siwatch et al reported that low-dose 25 µg misoprostol was effective and safe via both sublingual and oral routes.[20]

Considering these findings, this study aims to compare the efficacy and safety of 25 µg oral misoprostol solution with sublingual misoprostol for labor induction at term pregnancy. This study aimed to compare the efficacy and safety of oral misoprostol solution versus sublingual misoprostol for induction of labor in term pregnancies.

## METHODS

This randomized controlled trial was conducted at the Department of Obstetrics and Gynecology, Institute of Child and Mother Health (ICMH), Matuail, Dhaka, Bangladesh, from July 2023 to June 2024. A total of 66 term pregnant women with a singleton cephalic fetus and an unfavorable cervix (modified Bishop score <6) were enrolled and randomly assigned to two groups: Group A (n=33) received oral misoprostol solution, and Group B (n=33) received sublingual misoprostol.

### *Inclusion criteria*

Eligible participants were women aged 18–40 years with a clinical indication for induction of labor. All participants had a singleton pregnancy with a cephalic presentation at a gestational age between 37 and 42 weeks, a modified Bishop score of less than 6, and a gravidity of 1–3. Written informed consent was obtained from all participants prior to enrollment.

### *Exclusion criteria*

Women were excluded if they had multiple pregnancies or any contraindication to labor or vaginal delivery, including cephalopelvic disproportion, malpresentation, fetal compromise, prior uterine surgery, or antepartum hemorrhage. Additional exclusion criteria included active genital infection, severe maternal medical conditions such as uncontrolled epilepsy, glaucoma, asthma, or cardiovascular, renal, or hepatic disease, and known hypersensitivity to misoprostol or other prostaglandins.

Oral misoprostol solution was prepared by dissolving a 200 µg tablet in 200 mL of water (1 µg/ml), with Group A receiving 25 mL misoprostol orally every 2 hours (up to six doses) and Group B receiving 25 µg sublingual misoprostol tablet every 2 hours (up to six doses). Uterine contractions were monitored every 30 minutes, and cervical dilation every 4 hours. Administration was discontinued upon regular contractions (every 3-5 min, ≥60 s), cervical dilation ≥5 cm, membrane rupture, uterine tachysystole, or non-reassuring fetal heart rate. Oxytocin augmentation was applied as indicated. Induction was considered unsuccessful if adequate contractions and a Bishop score ≥6 were not achieved within 24 hours, and caesarean delivery was offered.

Demographic data, obstetric history, BMI, indication for induction, time to active labor, induction-to-delivery interval, mode of delivery, maternal adverse effects (hyperstimulation, tachysystole, fever, nausea/vomiting, diarrhea), and neonatal outcomes (APGAR scores, birth weight, NICU admission) were recorded using a semi-structured checklist. Primary outcomes included time to active labor, induction-to-delivery interval, mode of delivery, and need for oxytocin, while secondary outcomes included maternal and neonatal adverse effects. Ethical approval was obtained from the Institutional Review Board of ICMH, Dhaka, and written informed consent was obtained from all participants. Data were analyzed using SPSS version 26; continuous variables were expressed as mean±SD and compared using Student's t-test, while categorical variables were presented as frequencies and percentages and compared using the Chi-square test, with $P<0.05$ considered statistically significant.

## RESULTS

The majority of patients in Group A and Group B were aged between 20 and 30 years, comprising 69.6% and 60.6% of each group, respectively, with mean ages of 23.8±4.4 years and 25.3±8.7 years. Additionally, 72.7% of participants in both groups reported a monthly family income between 10,000 and 20,000 BDT. In Group A, 57.6% of the participants, and in Group B, 60.6% of the participants had an educational status below HSC. The majority in both groups were housewives (93.9% vs. 91%) (Table 1 and 2).

**Table 1: Distribution of patients according to socio-demographic factors (n=66).**

| Socio-demographic variables | | Group A (n=33), N (%) | Group B (n=33), N (%) | P value |
|---|---|---|---|---|
| **Age group (years)** | <20 | 5 (15.2) | 6 (18.2) | 0.769 |
| | 20 to 30 years | 23 (69.6) | 20 (60.6) | |
| | Above 30 years | 5 (15.2) | 7 (21.2) | |
| | Mean±SD | 23.8±4.4 | 25.3±8.7 | 0.376 |
| **Educational status** | Below HSC | 19 (57.6) | 20 (60.6) | 1.000 |
| | HSC and above | 14 (42.4) | 13 (39.4) | |
| **Occupation** | Housewife | 31 (93.9) | 30 (91) | 1.000 |
| | Working women | 2 (6.1) | 3 (9) | |
| **Monthly family income (BDT)** | <10000 | 5 (15.2) | 7 (21.1) | 0.663 |
| | 10000 to 20000 | 24 (72.7) | 24 (72.7) | |
| | >20000 | 4 (12.1) | 2 (6.2) | |

**Table 2: Distribution of patients according to obstetric history (n=66).**

| Obstetric variables | | Group A (n=33), N (%) | Group B (n=33), N (%) | P value |
|---|---|---|---|---|
| **Gestational age (weeks)** | 37 to 39 weeks | 19 (57.6) | 20 (60.6) | 1.000 |
| | 40 to 42 weeks | 14 (42.4) | 13 (39.4) | |
| **Parity** | Primigravida | 15 (45.5) | 16 (48.5) | 0.685 |
| | 2nd Gravida | 11 (33.3) | 8 (24.2) | |
| | 3rd Gravida | 7 (21.2) | 9 (27.3) | |

In terms of parity, 45.5% of patients in Group A were primigravida, 33.3% were second gravida, and 21.2% were third gravida; in Group B, these figures were 48.5%, 24.2%, and 27.3%, respectively. Regarding gestational age, 57.6% of Group A participants were between 37 and 39 weeks, while 42.4% were between 40 and 42 weeks. In Group B, 60.6% were between 37 and 39 weeks, and 39.4% were between 40 and 42 weeks. There was no statistically significant difference between the two groups regarding obstetric history (Table 2).

In both Group A and Group B, the majority of patients had a normal BMI (63.6% vs. 54.5%). The mean BMI was 24±3.7 kg/m² in Group A and 25.2±2.8 kg/m² in Group B. The difference between the groups was not statistically significant (Table 3).

In Group A, the indications for induction of labor were gestational diabetes mellitus (12.1%), gestational hypertension (15.2%), preeclampsia (9.1%), obstetric cholestasis (3%), premature rupture of membranes (27.3%), postdated pregnancy (18.2%), oligohydramnios (12.1%), and intrauterine growth restriction (3%). In Group B, the corresponding indications were gestational diabetes mellitus (9.1%), gestational hypertension (12.1%), preeclampsia (12.1%), premature rupture of membranes (30.3%), postdated pregnancy (21.2%), and oligohydramnios (9.1%). There was no significant difference in the indications for induction between the two groups (Table 4).

**Table 3: Distribution of participants according to BMI (n=66).**

| BMI (kg/m²) | Group A (n=33), N (%) | Group B (n=33), N (%) | P value |
|---|---|---|---|
| **Normal** | 21 (63.6) | 18 (54.5) | 0.157 |
| **Overweight** | 9 (27.3) | 15 (45.5) | |
| **Obese** | 2 (6.1) | 0 (0.0) | |
| **Underweight** | 1 (3.0) | 0 (0.0) | |
| **Mean±SD** | 24±3.7 | 25.2±2.8 | 0.168 |

**Table 4: Distribution patients according to indication for induction of labor (n=66).**

| Indication | Group A (n=33), N (%) | Group B (n=33), N (%) | P value |
|---|---|---|---|
| **IUGR** | 1 (3.0) | 2 (6.1) | 1.000 |
| **Gestational diabetes mellitus** | 4 (12.1) | 3 (9.1) | 1.000 |
| **Gestational hypertension** | 5 (15.2) | 4 (12.1) | 1.000 |
| **Preeclampsia** | 3 (9.1) | 4 (12.1) | 1.000 |
| **Obstetric cholestasis** | 1 (3.0) | 0 (0.0) | 1.000 |
| **Premature rupture of membranes** | 9 (27.3) | 10 (30.3) | 1.000 |
| **Postdated pregnancy** | 6 (18.2) | 7 (21.2) | 1.000 |
| **Oligohydramnios** | 4 (12.1) | 3 (9.1) | 1.000 |

In both groups, the need for oxytocin, time to initiate active labor, and induction-to-delivery interval were statistically similar. However, the total dose of misoprostol administered was significantly higher in Group A compared to Group B (Table 5).

The mean Bishop Score at initial assessment was 1±1.3 in both Group A and Group B. After four hours of the first dose, the mean Bishop Score increased to 3.8±1.1 in Group A and 4.4±1.1 in Group B, a statistically significant difference. At 8 hours, the mean Bishop Score was 8.8±0.8 in Group A and 9.4±1.3 in Group B, which was also statistically significant (Table 6).

The success rate of misoprostol induction was 84.8% in Group A and 90.9% in Group B, and the difference was not statistically significant (p = 0.708).

**Table 5: Distribution of patients according to effectiveness of misoprostol (n=66).**

| Number of dose requirement | Group A (n=33), N (%) | Group B (n=33), N (%) | P value |
|---|---|---|---|
| **1** | 0 (0.0) | 3 (9.1) | 0.154 |
| **2** | 5 (15.1) | 6 (18.2) | |
| **3** | 9 (27.3) | 14 (42.4) | |
| **4** | 14 (42.4) | 9 (27.3) | |
| **5** | 3 (9.1) | 1 (3.0) | |
| **6** | 2 (6.1) | 0 (0.0) | |
| **Mean±SD** | 3.6±1.1 | 3±1.9 | 0.010 |
| **Need of oxytocin** | 25 (75.8) | 23 (69.7) | 0.783 |
| **Time to initiate active labor (hour)** | 5.5±1.6 | 5.3±2.2 | 0.702 |
| **Induction to delivery interval (hour)** | 11.4±1.8 | 11.3±1.9 | 0.894 |

**Table 6: Distribution of participants according to Bishop score (n=66).**

| Bishop Score | Group A (n=33) | Group B (n=33) | P value |
|---|---|---|---|
| **0 hour** | 1±1.3 | 1±1.3 | 0.924 |
| **4 hours** | 3.8±1.1 | 4.4±1.1 | 0.014 |
| **8 hours** | 8.8±0.8 | 9.4±1.3 | 0.035 |

**Table 7: Distribution of patients according to success rate of misoprostol induction (n=66).**

| Outcome | Group A (n=33), N (%) | Group B (n=33), N (%) | P value |
|---|---|---|---|
| **Successful** | 28 (84.8) | 30 (90.9) | 0.708 |
| **Not successful** | 5 (15.2) | 3 (9.1) | |

In both Group A and Group B, the majority of women had vaginal deliveries (72.7% vs. 75.8%). The difference was not statistically significant (Table 8).

**Table 8: Distribution of participants according to mode of delivery (n=66).**

| Mode of delivery | Group A (n=33), N (%) | Group B (n=33), N (%) | P value |
|---|---|---|---|
| **Vaginal delivery** | 24 (72.7) | 25 (75.8) | 1.000 |
| **Caesarean delivery** | 9 (27.3) | 8 (24.2) | |

Mean birth weight (3±1 kg vs. 2.9±1 kg), APGAR score at 1 minute (7±0.7 vs. 7.1±0.8), APGAR score at 5 minutes

(8.6±0.5 vs. 8.7±0.5), NICU admission (6.1% vs. 9%), and presence of meconium in amniotic fluid (24.2% vs. 18.2%) were statistically similar between Group A and Group B (Table 9).

Nausea/vomiting (3% vs. 6.1%), pyrexia (3% vs. 12.2%), headache (0% vs. 3%), and tachysystole (3% vs. 3%) were observed in both groups, with no statistically significant differences. Overall, Group B exhibited slightly higher rates of adverse effects than Group A (Table 10).

**Table 9: Distribution of participants according to fetal outcome (n=66).**

| Fetal outcome | Group A (n=33) | Group B (n=33) | P value |
|---|---|---|---|
| **Birth weight (kg), Mean±SD** | 3±1 | 2.9±1 | 0.668 |
| **APGAR score at 1 min, Mean±SD** | 7±0.7 | 7.1±0.8 | 0.855 |
| **APGAR score at 5 min, Mean±SD** | 8.6±0.5 | 8.7±0.5 | 0.641 |
| **Admission to NICU (N, %)** | 2 (6.1) | 3 (9.0) | 1.000 |
| **Meconium in amniotic fluid (N, %)** | 8 (24.2) | 6 (18.2) | 0.764 |

**Table 10: Distribution of participants according to maternal adverse effects (n=66).**

| Adverse effect | Group A (n=33), N (%) | Group B (n=33), N (%) | P value |
|---|---|---|---|
| **Nausea/vomiting** | 1 (3.0) | 2 (6.1) | 1.000 |
| **Pyrexia** | 1 (3.0) | 4 (12.2) | 0.355 |
| **Headache** | 0 (0.0) | 1 (3.0) | 1.000 |
| **Tachysystole** | 1 (3.0) | 1 (3.0) | 1.000 |

## DISCUSSION

With a rising prevalence, induction of labor (IOL) has become one of the most common obstetrical procedures. Misoprostol, a prostaglandin E1 analog, is widely used as a primary method for labor induction. Although multiple studies have demonstrated its efficacy, further research is needed to determine the optimal dose and route of administration. The present study aimed to evaluate the efficacy and safety of oral misoprostol solution compared to sublingual misoprostol for induction of labor in term pregnancies. A total of 66 women were included, with 33 women receiving oral misoprostol solution (Group A) and 33 women receiving sublingual misoprostol (Group B).

In both groups, the majority of participants were aged 20-30 years (69.6% vs. 60.6%), with mean ages of 23.8±4.4 years and 25.3±8.7 years, respectively. There was no statistically significant difference between groups. Previous studies have reported similar findings; for example, Datta et al, observed mean ages of 27.1±3.8 years and 27.2±4.4 years in the oral and sublingual groups, respectively (p=0.9385).[21] Similarly, Shetty et al, reported mean ages of 28.7 years and 27.6 years in the oral solution and sublingual groups, which were not significantly different (p=0.21).[22] Monthly family income, occupation, and educational status were also comparable between groups, consistent with findings from Amini et al.[23] Labor induction is more common in women aged 20-34 years, as this age range represents the majority of pregnant women, and practices may vary based on maternal health, medical guidelines, and provider recommendations.

The majority of participants in both groups had normal BMIs (63.6% vs. 54.5%). Regarding parity, 45.5% of women in Group A were primigravida, 33.3% second gravida, and 21.2% third gravida; in Group B, these proportions were 48.5%, 24.2%, and 27.3%, respectively. Parity, BMI, and baseline Bishop scores were statistically similar between groups, consistent with findings reported by Amini et al and Shetty et al.[24,22] Induction of labor is more common among first-time mothers due to increased prenatal monitoring, higher risk of complications such as prolonged pregnancy and preeclampsia, longer labor durations, and the likelihood of elective induction for convenience or anxiety reduction.

Gestational age and indication for induction were also statistically similar between groups, with the majority of participants between 37 and 39 weeks of gestation (57.6% vs. 60.6%). This finding aligns with previous studies (Ahmad et al; Shetty et al; Datta et al; Amini et al. [22,20,21,23] Labor induction is most commonly performed around 39-41 weeks to ensure fetal maturity and minimize post-term risks, while induction between 37-39 weeks is primarily performed for medical indications to safeguard maternal or fetal health.

In the present study, time to initiate active labor (5.5±1.6 hours vs. 5.3±2.2 hours) and induction-to-vaginal-delivery interval (11.4±1.8 hours vs. 11.3±1.9 hours) were comparable between groups. Mode of delivery and oxytocin augmentation were also statistically similar. A previous study by Parimkayala et al reported shorter induction-to-delivery intervals in the sublingual group, with 46.7% of women requiring oxytocin compared to 75% in the oral group, but no significant difference in vaginal delivery rates.[26] In the current study, the mean dose of misoprostol was significantly higher in Group A (3.6±1.1) than in Group B (3±1.9). Ahmad et al similarly reported that the sublingual group required fewer doses for successful induction (1.4 vs. 2.1) and had shorter induction-to-delivery intervals (16.81±8.08 hours vs. 21.06±9.22 hours, p<0.05).[25] Datta et al and Amini et al also found lower oxytocin requirements and shorter induction intervals with sublingual administration.[21,24]

Baseline mean Bishop Scores were 1±1.3 in both groups. After four hours of the first dose, scores increased to 3.8±1.1 in Group A and 4.4±1.1 in Group B, a statistically significant difference. At 8 hours, the scores were 8.8±0.8 and 9.4±1.3, respectively, again showing a significant difference. Both groups demonstrated improvement over time, but Group B consistently had higher Bishop scores. Datta et al similarly reported faster Bishop score progression in the sublingual group (4.68±2.34 vs. 3.52±2.14 at 4 hours; 11.39±2.06 vs. 10.48±2.59 at 8 hours, $p<0.05$).[21] Ahmad et al also found greater Bishop score improvement in the sublingual group.[25]

The overall success rate of misoprostol induction was 84.8% in Group A and 91% in Group B, slightly higher in the sublingual group. Adverse effects were slightly higher in the sublingual group than in the oral group but not statistically significant. Minimal adverse effects were observed in both groups, including nausea/vomiting (3% vs. 6.1%), pyrexia (3% vs. 12.2%), headache (0% vs. 3%), and tachysystole (3% vs. 3%). Neonatal outcomes including birth weight, APGAR scores at 1 and 5 minutes, NICU admission, and meconium-stained amniotic fluid were similar between groups.

Previous studies suggest that both oral and sublingual misoprostol are safe and effective for labor induction, though sublingual administration may achieve higher bioavailability and faster cervical ripening (Shetty et al; Siwatch et al; Datta et al; Amini et al).[22,20,21,23] The current study indicates that while both routes are effective with minimal adverse effects, oral misoprostol may be preferable when minimizing adverse effects is a priority.

This study had several limitations. First, all samples were collected from a single study site, which may limit the generalizability of the findings. Second, the sample size was relatively small, potentially reducing the statistical power to detect differences between groups. Third, long-term follow-up of participants was not conducted, precluding assessment of longer-term maternal or neonatal outcomes. Finally, the 25 µg dose of misoprostol was not available, which limited comparison with lower-dose regimens commonly used in clinical practice.

## CONCLUSION

This study demonstrated that both oral misoprostol solution and sublingual misoprostol were similarly effective for labor induction, with comparable outcomes in time to initiate active labor, induction-to-delivery interval, delivery mode, and oxytocin use. Although the sublingual group showed a slightly higher success rate (91% vs. 84.8%) and faster Bishop score improvement, the differences were not statistically significant. Adverse effects were minimal in both groups, with slightly higher incidences of nausea, vomiting, and pyrexia in the sublingual group, but these differences were also not significant. Neonatal outcomes, including birth weight, APGAR scores, and NICU admissions, were comparable across both groups. The study suggests that while sublingual misoprostol may have a slight efficacy advantage, oral misoprostol offers a more favorable safety profile with fewer adverse effects.

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