

# International Journal of Clinical Obstetrics and Gynaecology

ISSN (P): 2522-6614  
ISSN (E): 2522-6622  
© Gynaecology Journal  
[www.gynaecologyjournal.com](http://www.gynaecologyjournal.com)  
2024; 8(1): 28-32  
Received: 21-11-2023  
Accepted: 23-12-2023

**Dr. Payal Lalchandbhai Chhatani**  
Department of obstetrics and  
Gynaecology, GMERS Medical  
College and General Hospital,  
Gotri, Vadodara, Gujarat, India

**Dr. Dipa Pitre**  
Associate Professor, Department of  
obstetrics and Gynaecology, Gmers  
Medical College and General  
Hospital, Gotri, Vadodara,  
Gujarat, India

## Comparison of 25 microgram of sublingual misoprostol with 25 micrograms of vaginal misoprostol for induction of labour at term

**Dr. Payal Lalchandbhai Chhatani and Dr. Dipa Pitre**

**DOI:** <https://doi.org/10.33545/gynae.2024.v8.i1a.1413>

### Abstract

**Background:** This study was undertaken to compare the efficacy and safety of 25 microgram of misoprostol by vaginal and sublingual route for labour induction in term pregnancy.

**Method:** A prospective randomized comparative clinical study to compare the effects of low dose misoprostol with vaginal and sublingual misoprostol administration for induction of labour at term, study was done at labour room of GMERS Medical College and general hospital, Gotri, Vadodara from September 2020 to September 2022. Total 150 patients of Term pregnancy requiring induction of labour for various indications were selected, divided into two groups by random allocation, half were given vaginal and half were given sublingual 25 microgram misoprostol every 4 hourly for maximum of 5 doses. Main outcome measures were induction to delivery interval, number of doses of misoprostol, mode of delivery, meconium stained liquor, incidence of uterine tachysystole and hypertonus.

**Results:** On comparing both groups in the sublingual group shorter induction to delivery interval ( $P=0.0035$ ), a smaller number of doses of misoprostol ( $P=0.0445$ ) and less number of per vaginal examination ( $P=0.0130$ ). Less number of oxytocin augmentation ( $P=0.6994$ ) were found compared to vaginal group, more number of patient delivered vaginally in sublingual group ( $P=0.1808$ ), but statistically not significant. There was no significant difference in the age group and gestational age, Bishop score, indication for induction of labour, Drug side effects like diarrhea vomiting, uterine hypertonus and meconium stained liquor among the groups in the study.

**Conclusion:** Misoprostol was effective in induction of labor when administered by either sublingual or vaginal route. Sublingual route had significantly less induction to delivery time interval and less doses were required and convenient to the patient as less pervaginal examinations are required. Sublingual route seems to have better efficacy than vaginal route.

**Keywords:** Induction of labour, misoprostol, sublingual route and vaginal route, at term induction of labour

### Introduction

Induction of labour can be defined as an intervention intended to artificially initiate uterine contractions resulting in progressive effacement and dilatation of cervix <sup>[1]</sup>. Induction of labour includes natural, mechanical, surgical and pharmacological methods. Misoprostol is a synthetic analogue of prostaglandin E1 and is less expensive, more stable and easier to store. It has been used for cervical ripening and can be administered in various routes including sublingual, vaginal and oral. Vaginal administration of misoprostol is a common route of practice for labour induction, but due to risk of side effects like uterine hyperstimulation syndrome, as well as having the inconvenience of vaginal administration <sup>[2]</sup>. To avoid this undesirable effect and inconvenience of vaginal administration other routes like oral and sublingual was sought. Only few studies have been reported in the literature of misoprostol given sublingually for labor induction. Hence this study was designed to compare the efficacy and safety of sublingual versus vaginal misoprostol for labor induction.

### Aim

The objectives of this study were to determine the efficacy and safety of 25 microgram of sublingual misoprostol compared with 25 microgram of vaginal misoprostol for the induction of labour, in women with a live, term fetus and an unripe cervix and to evaluate maternal outcomes after sublingual and vaginal routes of administration.

**Corresponding Author:**  
**Dr. Payal Lalchandbhai Chhatani**  
Department of obstetrics and  
Gynaecology, GMERS Medical  
College and General Hospital,  
Gotri, Vadodara, Gujarat, India

## Materials and Methods

**Study Setting:** labour room in the in the Department of obstetrics and gynecology GMERS Medical College and General Hospital, Gotri, Vadodara.

**Study Design:** A prospective randomized comparative clinical study to compare the effects of low dose sublingual misoprostol with vaginal misoprostol administration for induction of labour at term.

**Sample Size:** 150 patients

**Duration of study:** September 2020 – September 2022

### Inclusion criteria

Live singleton pregnancy at a gestational age of 37 completed weeks or more with a medical or obstetric indication for induction including:

Gestational age  $\geq$  41 weeks [PD],

Prelabour rupture of membrane [PROM],

Preeclampsia without severe features

Gestational diabetes mellitus [GDM]

- Both nulliparous and multiparous women
- A cephalic presentation
- An unfavorable cervix (Bishop's score less than or equal to 6)
- A reassuring fetal heart tracing

### Exclusion Criteria

- Multiple gestations
- Malpresentation (presentation other than cephalic)
- Previous uterine surgery including cesarean surgery.
- Known contraindications to the use of prostaglandins (e.g.

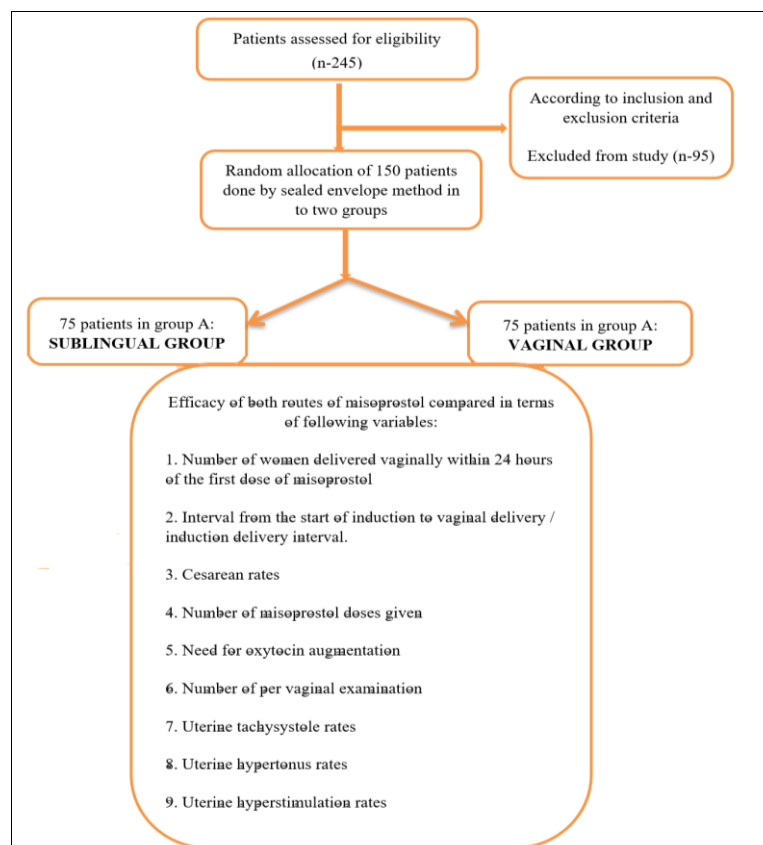
Asthma)

- Grand-multiparity (more than 5)
- Need for immediate delivery.
- Chorioamnionitis or hyperthermia  $> 38^{\circ}\text{C}$
- Active vaginal bleeding
- Ultrasonically estimated oligohydramnios, polyhydramnios, suspicion of fetal malformation, macrosomia or growth restriction.

**Method of randomization:** Randomization was done by Simple randomization technique. Patients were randomly allocated the route of misoprostol for induction of labour by sealed envelope method. 150 envelopes were made, 75 out of them mentioning sublingual route and rest of them mentioning vaginal route. Each patient was asked to choose one envelope and accordingly the route was allocated to that patient. Hence 75 patients received the sublingual route and 75 received the vaginal route.

In this study Antenatal patients between 18-38 years of age with Term pregnancy requiring induction of labour for various indications were admitted in Labour room. 75 Number of patients were allocated for 25 microgram sublingual misoprostol administration every 4 hourly for maximum of 5 doses and other 75 Number of patients were allocated for 25 microgram vaginal misoprostol administration every 4 hourly for maximum of 5 doses. If patient had at least three regular contraction in 10 minutes, enters active phase of labour then subsequent dose of misoprostol was withheld. As soon as fetal head engagement and cervical dilation permitted, amniotomy was performed, followed by oxytocin augmentation if needed but not earlier than 4 hours after the last misoprostol dose. Continuous fetal cardiotocography was used throughout the study. In all the patients maternal outcome were measured in terms of variables as mentioned below.

## Methodology



### Data management and statistical analysis

- Data was collected over two year of period in a predesigned Performa and entered in a Microsoft excel sheet.
- Statistical analysis was done using Microsoft excel version 2011 and Med Calc software. P-value taken by MedCalc 12.5.
- Results were presented by calculating the means between the groups and were compared using Comparison t test and other variables were analyzed using chi square test. And the  $P < 0.05$  was considered statistically significant.

Sr. No.	Maternal outcomes	Group A: Sublingual	Group B: Vaginal	
1	Induction to delivery interval	8.84 ±4.53 hours	11.76±5.42 hours	P=0.0035
2	Vaginal delivery	81.33%	70.67%	P=0.1808
3	Cesarean section	18.67%	29.33%	
4	Number of doses of misoprostol	1.64±0.67	2.11±0.97	P=0.0445
5	Number of pervaginal examination	2.59±1.2	3±1.39	P=0.0130
6	Need of oxytocin augmentation	21.33%	25.33%	P=0.6994
7	Uterine tachysystole	14.67%	2.67%	P=0.0247
9	Uterine hypertonus	6.67%	4.00%	P=0.7163
10	Uterine hyperstimulation	1.33%	0.00%	P=1.000
11	Drug side effects	18.67%	10.67%	P=0.2485
12	Meconium stained liquor	28.00%	22.67%	P=0.5733

Incidence of uterine tachysystole was more in sublingual route compared to vaginal route and was statistically significant. Drug side effects like diarrhea vomiting, uterine hypertonus and meconium stained liquor were more in sublingual group compared to vaginal route but was not statistically significant. There was no significant difference in the age group and gestational age, Bishop score, indication for induction of labour, among the groups in the study.

### Discussions

In this study 150 patients were selected according to inclusion and exclusion criteria, was divided in two groups by random allocation with sealed envelope method. None of the women from either group withdrew from the study.

There was no significant difference in the age group and gestational age in both the group. Mean age of sublingual group A was (25.71±4.40) and mean gestational age was (38.91±1.54), in Vaginal group B mean maternal age is (25.45±3.70) and mean gestational age was (38.96±1.61).

There was no significant difference between Bishop score, indication for induction of labour, oxytocin induction among the groups in the study.

### Induction to delivery interval

In this study the results showed that in sublingual group A significantly shorter duration of induction to delivery interval, less doses of misoprostol and less number of per vaginal examination compared to vaginal misoprostol. Mean induction delivery interval in sublingual group A was (8.84±4.53) shorter compared to vaginal group B was (11.76±5.42).

Bartusevicius A., *et al.* [3] in his study of Sublingual compared with vaginal misoprostol for labour induction at term: a randomized controlled trial found that the induction to vaginal delivery time was significantly shorter in the sublingual group (15.0±3.7 hours) compared with the vaginal group (16.7 ± 4.1 hours,  $P= 0.03$ ).

Elhassan, E. M., A. M. Nasr, and I. Adam. [4] In his study Sublingual route compared with oral route and vaginal route of misoprostol for labor induction found that the induction to vaginal delivery time was significantly shorter in the sublingual group (13.26±3.7 hours) compared with the vaginal group

### Results

On comparing sublingual and vaginal route of misoprostol for induction of labour it was found that There was statistically significant difference in the induction to delivery interval, which was shorter in the sublingual group, less number of doses of misoprostol and less number of per vaginal examination were required in sublingual group. Less number of patient required oxytocin augmentation in sublingual group compared to vaginal group, more number of patient delivered vaginally in sublingual group, but statistically not significant difference.

(15.10 ± 4.78 hours,  $P= 0.03$ ).

Caliskan *et al.* [5] in his study Misoprostol 50 µg sublingually versus vaginally for labor induction at term: a randomized study found the mean induction delivery interval in sublingual group was (11.8±7 hrs) and (12.4±6 hrs) in vaginal group. \_

### Number of doses of misoprostol

In this study in sublingual group A mean number of doses required was (1.64±0.67) was less compared to vaginal group B that was (2.11±0.97) and statistically significant.

Vanathi [6] in his study Comparison of 25 microgram of sublingual misoprostol with 25 micrograms of vaginal misoprostol for induction of labour at term found that sublingual group A mean number of doses required was (1.85±1.02) was less compared to vaginal group B that was (2.3±1.2).

El Kattan EA [7] in his study of Sublingual 50 microgram versus 50 micrograms of vaginal misoprostol for induction of labor in term primigravidas: a randomized study found that the mean number of misoprostol doses used in the sublingual group was lower than that needed in the vaginal group (2.2±1.1 vs. 2.48±1.08, respectively,  $P=0.373$ ).

### Mode of delivery

In this study results 75 patients were taken in each subgroups, in sublingual group A 61(81.33%) was delivered vaginally and 14(18.67%) were taken for LSCS, in vaginal group B 53(70.67%) were delivered vaginally, 22(29.33%) were taken for LSCS.

Madhu J [2] in her study of Comparison of sublingual versus vaginal routes of misoprostol in induction of labor found that the rate of LSCS in sublingual group was 12% and in per vaginal group it was 14%.

Souza ASR [8], in his study of Comparison of sublingual versus vaginal misoprostol for the induction of labour: a systematic review found that there was no statically significant difference among the groups regarding vaginal delivery.

Feitosa FEL, [9] in her study Sublingual vs. vaginal misoprostol for induction of labor found that Vaginal delivery rates were 57% in the sublingual group and 69% in the vaginal group (RR, 0.8; 95% CI, 0.6–1.1), statistically not significant.

El Kattan EA [7] in his study of Sublingual 50 microgram versus

50 microgram of vaginal misoprostol for induction of labor in term primigravidas: A randomized study found that in the sublingual group (76%) achieved vaginal delivery within 24 hours compared with those in the vaginal group (72%); however, this difference was statistically not significant ( $P=0.747$ ).

#### Number of per vaginal examination

In this study had significant reduction in number of pelvic examinations before delivery. Patient would be comfortable when number of pelvic examinations was reduced. In this study in sublingual group A 54.17% patients required 1-2 pervaginal examination, 40% required 3-4 pervaginal examination, in vaginal group B 36% patients required 1-2 pervaginal examination, 45.33% required 3-4 pervaginal examination.

Nassar *et al.* [10] had studied on patient satisfaction criteria and they had concluded that sublingual misoprostol was satisfactory route of administration than vaginal route. This route of administration may reduce the chance of infection particularly in PROM cases because of less number of vaginal examinations required. On considering these facts and observation of this study shows significant decrease in number of per vaginal examination sublingual route may be a satisfactory route of administering misoprostol.

#### Oxytocin augmentation

In this study in sublingual group A 21.33%, in vaginal group B 25.33% needed oxytocin augmentation needed.

Madhu J [2] in her study found that requirement of Oxytocin augmentation was 30% with sublingual Misoprostol and 40% with per vaginal Misoprostol.

Tayyba A, Mehreen N. [11] in her study Comparison between Sublingual and Vaginal Misoprostol for Labor Induction at Term found that there was same number of patients required oxytocin augmentation in both sublingual and vaginal group that was 49%.

In contrast study by Nassar *et al.*, [10] 81.1% cases in sublingual group needed augmentation.

#### Side effects

In this study 14.67% patient developed uterine tachysystole in sublingual group A, and only 2.67% in vaginal group B with  $P$  value of 0.0247 which is statistically significant. 6.67% patients developed uterine hypertonus in sublingual group A, and 4% in vaginal group B. Only 1 patient developed uterine hyperstimulation syndrome in sublingual group A. Drug side effects like nausea, vomiting 18.67% developed in sublingual group A, and 10.67% in vaginal group B.

Ayati S [12] in her study Vaginal Versus Sublingual Misoprostol for Labor Induction at Term and Post Term, 2.2% patient developed uterine tachysystole in sublingual group, and 2.0% in vaginal group. 11% patients developed drug side effects in sublingual group, and 5.0% in vaginal group.

Siwatch S [13] in his study Sublingual vs Vaginal Misoprostol for Labor Induction found that in sublingual group 0.01% case of each hypertonus and hyperstimulation, in vaginal group 0.01% case of hypertonus, tachysystole and hyperstimulation, which is statically non-significant. 3.0% patients developed drug side effects in sublingual group, and 2.0% in vaginal group.

#### Meconium stained liquor

In this study 28% patient had meconium stained liquor in in sublingual group A, and only 22.67% in vaginal group B with  $P$  value of 0.5733 which is statistically not significant.

Jahromi BN [14] in his study Sublingual versus vaginal misoprostol for the induction of labor at term found that

Meconium-stained amniotic fluid was seen in 12% women in the sublingual group and 4% in the vaginal group ( $P=0.03$ ).

In contrast Fisher *et al.*, [15] in his study Oral versus vaginal misoprostol for induction of labor: a double-blind randomized controlled trial found more MSL found in vaginal group (7.8%) then in sublingual group (1.6%).

#### Conclusion

25 micrograms of Misoprostol is effective in induction of labor both with sublingual and vaginal routes. Furthermore sublingual routes poses some advantages like convenient to administer and might be more suitable than vaginal form due to less number of per vaginal examination and also Sublingual route was significantly less induction to delivery interval and less Number of doses required compared to vaginal group. Only few patients had minor side effects in both groups. Uterine tachysystole were seen more in sublingual route. No other major side effects were reported. Sublingual route seems to have better efficacy than vaginal Misoprostol, seems to be acceptable to patients and is an option to be considered to induce labour at term.

#### Acknowledgement

A journey is easier when you travel together. This study is the major part of my long Journey in pursuing my Post Graduation in Obstetrics and gynecology. There are some people who made this journey easier with words of encouragement and support. It is a pleasant aspect that I have now the opportunity to express my gratitude for all of them.

As I look back after finishing this study and realize that at no stage in the progression of this work have I felt so happy and relieved as now, when I have settled down to acknowledge the unending blessings of health and strength that Almighty God has showered on me to be able to finish this study.

The protagonist of this study is my respected teacher and mentor DR Dipa Pitre, Associate professor, dept. of OBGY, GMERS medical college, Gotri, Vadodara. I am very grateful to have teacher like her who is powerhouse of energy and positivity, whose interest, and motivation, and constant supervision ever helping nature made it possible for me to complete this work.

A very special thanks to my seniors cum friends Dr. Shweta and Dr. Asmita for always guiding me through this journey and making it easier for me. I am heartily thankful to my parents Mr. Lalchandbhai Chhatani and Mrs. Vidhya Chhatani my grandmother Mrs. Ishwari Chhatani my loving sisters Heena and Mamta and my dear brother Mayur and the coolest Jiju Sunny without whom I would not have been where I am today. The unconditional love and unshakable faith, which they have bestowed upon me is important to acknowledge but impossible to be expressed in words, deeds or thoughts.

I would also like to gratefully acknowledge my best friend cum fiance Dr. Sandip Balar for being the constant support of my life and being an inspiration for me.

My patients, who readily agreed to be a part of this study, I thank you all.

Above all I am grateful to the Almighty God, only by virtue of his grace and blessings I am able to stand to this occasion in life.

DR. Payal Lalchandbhai Chhatani

#### Conflict of Interest

Not available

#### Financial Support

Not available

**References**

1. Ryan R, McCarthy F. Induction of labour. *Obstet Gynaecol Reprod Med.* 2016;26(10):304–10.
2. Madhu J, Hangaraga US. Comparison of sublingual versus vaginal routes of misoprostol in induction of labor. *Int J Reprod Contracept Obstet Gynecol.* 2017;6(7):3062–7.
3. Bartusevicius A, Barcaite E, Krikstolaitis R, Gintautas V, Nadisauskiene R. Sublingual compared with vaginal misoprostol for labour induction at term: A randomised controlled trial. *BJOG Int. J Obstet. Gynaecol.* 2006;113(12):1431–7.
4. Elhassan EM, Nasr AM, Adam I. Sublingual compared with oral and vaginal misoprostol for labor induction. *Int. J Gynecol Obstet.* 2007;97(2):153–4.
5. Caliskan E, Bodur H, Ozeren S, Corakci A, Ozkan S, Yucesoy I. Misoprostol 50 µg sublingually versus vaginally for labor induction at term: A randomized study. *Gynecol Obstet Invest.* 2005;59(3):155–61.
6. Vanathi N. Comparison of 25 microgram of sublingual misoprostol with 25 microgram of vaginal misoprostol for induction of labour at term [PhD Thesis]. KAP Viswanathan Government Medical College, Tiruchirappalli; c2011.
7. El Kattan EA, Abdel Moety GA, AbdElRazek AA. Sublingual versus vaginal misoprostol for induction of labor in term primigravidas: A randomized study. *J Evid-Based Women's Health J Soc.* 2013 Aug;3(3):111–4.
8. Souza ASR, Amorim MMR, Feitosa FEL. Comparison of sublingual versus vaginal misoprostol for the induction of labour: a systematic review. *BJOG Int J Obstet Gynaecol.* 2008;115(11):1340–1349.
9. Feitosa FEL, Sampaio ZS, Alencar Jr CA, Amorim MMR, Passini Jr R. Sublingual vs. vaginal misoprostol for induction of labor. *Int J Gynecol Obstet.* 2006;94(2):91–5.
10. Nassar AH, Awwad J, Khalil AM, Abu-Musa A, Mehio G, Usta IM. A randomised comparison of patient satisfaction with vaginal and sublingual misoprostol for induction of labour at term. *BJOG Int J Obstet Gynaecol.* 2007;114(10):1215–1221.
11. Tayyba A, Mehreen N. Comparison between Sublingual and Vaginal Misoprostol for Labor Induction at Term. *PJMHS.* 2013;7(4):1038–41.
12. Ayati S, Vahidroodsari F, Farshidi F, Shahabian M, Afzal Aghae M. Vaginal Versus Sublingual Misoprostol for Labor Induction at Term and Post Term: a Randomized Prospective Study. *Iran J Pharm Res IJPR.* 2014;13(1):299–304.
13. Siwatch S, Kalra J, Bagga R, Jain V. Sublingual vs Vaginal Misoprostol for Labor Induction. *J Postgrad Med.* :6.
14. Jahromi BN, Poorgholam F, Yousefi G, Salarian L. Sublingual versus vaginal misoprostol for the induction of labor at term: a randomized, triple-blind, placebo-controlled clinical trial. *Iran J Med Sci.* 2016;41(2):79.
15. Fisher SA, Mackenzie VP, Davies GA. Oral versus vaginal misoprostol for induction of labor: A double-blind randomized controlled trial. *Am. J Obstet Gynecol.* 2001;185(4):906–10.

**Creative Commons (CC) License**

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International (CC BY-NC-SA 4.0) License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

**How to Cite This Article**

Chhatani PL, Pitre D. Comparison of 25 microgram of sublingual misoprostol with 25 micrograms of vaginal misoprostol for induction of labour at term. *International Journal of Clinical Obstetrics and Gynaecology.* 2024;8(1):28-32.