International Journal of Clinical Medicine, 2026, 17(11), 359-367
https://www.scirp.org/journal/ijcm
ISSN Online: 2158-2882
ISSN Print: 2158-284X

Oral Misoprostol for Labor Induction: Body Mass Index Matters

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How to cite this paper: Day, B., Dangott, S., Lamichhane, R., Yoost, J., Mitchell, B. and Cottrell, J. (2026) Oral Misoprostol for Labor Induction: Body Mass Index Matters. *International Journal of Clinical Medicine*, **17**, 359-367.
https://doi.org/10.4236/ijcm.2026.1711025

Received: September 26, 2026
Accepted: November 15, 2026
Published: November 18, 2026

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Abstract

Objective: Induction of labor can be undertaken with a variety of agents, and optimizing delivery in the obese gravida is of clinical interest. The purpose of this study was to evaluate oral misoprostol dosing on time to delivery and mode of delivery based on Body Mass Index (BMI) in a patient population with a high prevalence of obesity. **Methods:** This was a retrospective chart review among subjects who underwent induction of labor at 37 weeks or greater during January 2018 through December 2020 and oral misoprostol was the starting induction medication. Data abstraction included BMI on admission, time of initial misoprostol dose, number of total misoprostol doses, use of other induction agents, time of delivery and mode of delivery. The primary outcomes were time from initial misoprostol dose to delivery, total number of misoprostol doses, and mode of delivery stratified by BMI. **Results:** 344 patients met inclusion criteria with mean BMI of 35.5 kg/m^2. No patients were in the underweight BMI classification (<18.5 kg/m^2), and only 16 patients (4.7%) were in normal range (18.5 - 24.9 kg/m^2). Univariate analysis demonstrated that BMI, subsequent use of dinoprostone, and subsequent use of Foley bulb mechanical dilation were all significantly associated with increasing time to delivery ($p < 0.05$). Using multiple linear regression and controlling for age, number of prior deliveries, number of misoprostol doses, dinoprostone use, Foley bulb use, and delivery mode, BMI was found to be a significant risk factor for an increased time to delivery. For every unit increase in BMI ≥ 30 kg/m^2, the time to delivery increased by 9.4 minutes. **Conclusion:** In gravidas undergoing induction of labor with oral misoprostol, increasing BMI was correlated with a longer time to delivery, increased doses of oral misoprostol, and higher rate of cesarean delivery. Patients with obesity should be counseled on

how BMI may impact their induction process and their ultimate mode of delivery.

Keywords

Misoprostol, Obesity, Labor, Induction, Cesarean Delivery, Dinoprostone, Foley Bulb, Body Mass Index (BMI)

1. Introduction

Obesity is a well-known risk factor for failed induction of labor [1] [2]. According to 2022 United States Center for Disease Control data, 41% of the state of West Virginia residents are obese (Body Mass Index > 30 kg/m^2), which is the highest rate in the United States [3]. Given this extremely high rate of obesity in our population, and the increasing rates of obesity in the United States, determining the most efficacious method for induction of labor is paramount [4].

There are several means of labor induction, including usage of the medications misoprostol or dinoprostone and mechanical mechanisms such as a Foley balloon catheter. Misoprostol is a synthetic prostaglandin E1 analog that ripens the cervix by degrading cervical collagen and augments labor by increasing myometrial contractions. While off-label for induction of labor, misoprostol can be given orally or vaginally in doses of 25 micrograms (mcg) or 50 mcg [5]. Dinoprostone, a prostaglandin E2 analog, is another commonly used cervical ripening agent available in a gel or vaginal insert preparation [6]. Induction of labor via a Foley balloon catheter is accomplished by placing the catheter through the cervix to provide internal pressure on the cervix, which triggers release of endogenous prostaglandins.

Given the clinical importance in optimizing induction of labor in the obese gravida, the aim of this study was to evaluate oral misoprostol dosing on time of delivery and mode of delivery based on Body Mass Index (BMI).

2. Methodology

This study was a retrospective cohort study at a single academic institution. Subjects were included if they underwent induction of labor at a gestational age of 37 weeks or more during the time of January 2018 through December 2020 and oral misoprostol was given as a starting induction agent. Subjects were excluded for gestations less than 37 weeks, use of a starting agent other than misoprostol for labor induction, spontaneous labor, multifetal gestations, lethal fetal anomalies, intrauterine fetal demise, or missing required data points during abstraction. Subjects who received induction agents other than misoprostol were included provided oral misoprostol was the first agent used during their admission for induction of labor.

The institutional protocol for induction of labor with misoprostol is to admin-

ister an initial loading dose of 50 mcg orally. After four hours, an additional four doses of 25 mcg of oral misoprostol could be given every four hours for a total of up to five doses. The decision to proceed with additional doses is based on individual physician preference.

Subject medical record data abstraction included BMI on admission, time of initial misoprostol dose, number of total misoprostol doses administered, time of delivery, mode of delivery, gravity and parity, and any other induction agents used after misoprostol. The primary outcomes were time from initial oral misoprostol dose to delivery, total number of oral misoprostol doses, and mode of delivery stratified by BMI.

The descriptive summaries were presented as mean for the continuous variables and frequency (percent) for the categorical variables. We performed univariate analysis—two-sample t-test, correlation test, and multiple regression analyses to estimate the effects of several factors on time to delivery. Also, pairwise comparisons were performed to analyze the effect of weight on time to delivery with Tukey's familywise error rate adjustment.

All statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC). The results were considered statistically significant when the p-values were less than 0.05. The study was performed in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Marshall University (1682811-6).

3. Results

There were 2635 deliveries during the study period and 344 patients met inclusion criteria. The mean subject age was 26.7 years with a range from 16 to 41 (Table 1). The mean BMI at time of delivery was 35.5 kg/m^2 with a range of 21 kg/m^2 to 71 kg/m^2. No patients were in the underweight BMI classification (<18.5 kg/m^2), and only 16 patients (4.7%) were in normal range (18.5 - 24.9 kg/m^2). The remaining BMI classifications from overweight to class III obesity were relatively evenly split (Table 1). When grouped by presence of obesity, 245 subjects (71.2%) were obese with a BMI ≥ 30 kg/m^2. Most subjects had not had a prior delivery, with 71.8% being nulliparous.

Cervical ripening agents used following oral misoprostol included vaginal dinoprostone and Foley balloon mechanical dilation. There were 134 subjects (39%) who had a Foley balloon placed following oral misoprostol, and only 8 subjects (2.3%) who received dinoprostone. Per inclusion criteria, all subjects in this study received oral misoprostol as their starting induction agent. With increasing BMI classification (Table 2), a greater number of doses of misoprostol were given ($p = 0.021$).

The overall Cesarean Delivery (CD) rate was 23.5%. When subjects were excluded that underwent CD for fetal indications, such as abruption or non-reassuring fetal status, the CD rate decreased to 19.1%. The latter rate reflects subjects undergoing CD for failed induction, failure to progress in labor or arrest of descent.

Among these subjects with failed inductions, the CD rate increased with increasing BMI class from 0% in normal weight patients to 32.9% for class III obesity (Table 2, $p \leq 0.001$). Of the 19 cesarean deliveries performed for fetal indications such as non-reassuring fetal status, none were among normal-weight BMI patients. Six (31.5%) were among overweight subjects (BMI 25 - 29 kg/m^2), 9 (47.4%) were among subjects with BMI 3 - 35 kg/m^2, and 4 (21.1%) were among subjects with BMI > 40 kg/m^2.

Body mass index, subsequent use of dinoprostone, and subsequent use of Foley bulb mechanical dilation (Table 3) were all significantly associated with increasing time to delivery ($p < 0.05$), while number of prior deliveries was negatively correlated with time to delivery ($p < 0.05$). Using multiple linear regression and controlling for age, number of prior deliveries, number of misoprostol, dinoprostone use, Foley bulb use, and delivery mode, it was found that higher BMI was associated with an increased time to delivery. For every unit increase in BMI ≥ 30 kg/m^2, the time to delivery increased by 9.4 minutes (Table 4).

Compared to individuals whose BMI was less than 30, individuals with BMI ≥ 30 had a significantly longer time to delivery. In average, women with a BMI ≥ 30 took 157 minutes longer to deliver.

Similarly, subgroup analysis of mean time to delivery by dichotomized groups of non-obese vs obese (BMI < 30 kg/m^2 vs BMI ≥ 30 kg/m^2) demonstrated prolonged mean time to delivery in the subjects with obesity. Subjects with BMI ≥ 30 kg/m^2 had significantly higher delivery time among those who delivered vaginally, used Foley bulb, or had no prior delivery compared to their counterparts (Table 5).

Table 1. Descriptive data, medication used for labor induction and mode of delivery among 344 subjects (n (%) unless otherwise noted).

Age		Range 16 - 41 26.7 (SD 5.7)
BMI		Range 21 - 71 35.5 (SD 8.3)
BMI Class	18 - 24 kg/m^2 (Normal)	16 (4.7)
	25 - 29 kg/m^2 (Overweight)	83 (24.1)
	30 - 34 kg/m^2 (Class I Obesity)	93 (27.0)
	35 - 39 kg/m^2 (Class II Obesity)	64 (18.6)
	>40 kg/m^2 (Class III Obesity)	88 (25.6)
BMI Study Category	<30 kg/m^2	99 (28.8)
	≥30 kg/m^2	245 (71.2)
Prior Deliveries	One or More	97 (28.2)
	No Prior Delivery	247 (71.8)

Continued

Number of Misoprostol Doses	1	66 (19.2)
	2	87 (25.3)
	3	77 (22.4)
	4	67 (19.5)
	5	47 (13.7)
Vaginal Dinoprostone	Yes	8 (2.3)
	No	336 (97.7)
Foley Bulb	Yes	134 (39)
	No	210 (61)
Delivery Mode	Vaginal	263 (76.5)
	Cesarean Delivery	81 (23.5)
Delivery Mode Excluding Fetal Indications	Vaginal	263 (80.9)
	Cesarean Delivery	62 (19.1)

SD: Standard Deviation.

Table 2. Omnibus ANOVA of misoprostol use and cesarean delivery rate among BMI groups.

BMI Category (n)	Misoprostol (mean, SE)	p-value*	Cesarean Delivery** n (%)	p-value*
18 - 24 (16)	2.19 (0.26)		0 (0)	
25 - 29 (83)	2.57 (0.14)		6 (7.8)	
30 - 34 (93)	2.82 (0.13)	0.021	14 (16.3)	<0.001
35 - 39 (64)	3.08 (0.17)		14 (22.6)	
>40 (88)	3.03 (0.13)		28 (32.9)	

*Between groups; **Excluding fetal indications. SE: Standard Error of mean.

Table 3. Univariate analysis evaluating time to delivery among individual variables.

		Mean Time to Delivery in Minutes (SE)	p-value
BMI Category	BMI < 30 kg/m^2	1453.0 (62.5)	<0.001
	BMI ≥ 30 kg/m^2	1720.6 (42.0)	
Vaginal Dinoprostone	Yes	2460.6 (307.4)	<0.001
	No	1624.2 (35)	
Foley Bulb	Yes	1821.2 (62.6)	<0.001
	No	1530.3 (40.4)	
Prior Deliveries	No Prior	1716.9 (41.3)	<0.001
	One or More	1457.0 (65.8)	

SE: Standard Error of mean.

Table 4. Multiple linear regression of time to delivery in minutes based on BMI, controlling for age, number of prior deliveries, number of misoprostol, dinoprostone use, Foley bulb use and delivery mode.

	Estimate in Minutes	p-value
Per 1-Unit Increase in BMI ≥ 30 kg/m^2	9.4	0.025
BMI Category		
BMI < 30 kg/m^2	Reference Group	0.04
BMI ≥ 30 kg/m^2	157.4 Minutes	

Table 5. Subgroup analysis of mean time to delivery by BMI categories.

Variable	Time to Delivery in Minutes (SE)		Time to Delivery in Hours, Minutes		p-value
	<30 kg/m²	≥30 kg/m²	<30 kg/m²	≥30 kg/m²	
Delivery Mode					
Cesarean	1432 (223.2)	1825 (78)	23 h 52 min	30 h 25 min	0.056
Vaginal	1456.2 (64.1)	1680.5 (49.6)	24 h 16 min	28 h	0.008
Excluding Fetal Indications					
Cesarean	1937 (276)	1938.4 (80.3)	32 h 17 min	32 h 18 min	0.996
Vaginal	1456.2 (64.1)	1680.5 (49.6)	24 h 9 min	28 h	0.007
Foley Bulb					
Yes	1528.2 (129)	1916.9 (69.3)	25 h 28 min	31 h 56 min	0.007
No	1415.4 (68.3)	1582.9 (49.4)	23 h 35 min	26 h 22 min	0.054
Prior Delivery					
None	1482.7 (73.4)	1807.7 (48.1)	24 h 42 min	30 h 7 min	<0.001
One or More	1384.8 (119.3)	1489.3 (79.1)	23 h 4 min	24 h 49 min	0.466

SE: Standard Error of mean.

4. Discussion

Among subjects undergoing induction of labor with oral misoprostol, increasing BMI was correlated with a longer time to delivery, increased doses of oral misoprostol, and higher rate of CD. Subjects with BMI > 30 kg/m² had statistically longer times to delivery, especially among nulliparous subjects and those who delivered vaginally. The use of other cervical ripening agents, such as vaginal dinoprostone and Foley balloon mechanical dilation, was also correlated with increased time to delivery. This is not surprising, as per institutional protocol these agents are typically not implemented until maximum dosing of misoprostol is utilized. Multiparity decreased time to delivery, although most subjects were nulliparous.

These findings agree with what has been previously published evaluating the impact of obesity on duration of labor and failed induction. However, prior studies looking at obesity and labor induction are limited by the number of patients with obesity. One study evaluated only vaginal misoprostol in doses of 25 mcg and had few subjects with BMI > 30 kg/m² compared to other classifications [7]. Furthermore, in a Cochrane Review of oral misoprostol, many of the analyzed studies did not include BMI as a data metric [8]. In studies comparing oral misoprostol and vaginal dinoprostone, mean BMIs were reported as 25.3 kg/m² vs 26.1 kg/m² [9], while another study reported only 37% of the cohort had a BMI > 30 kg/m² [10]. In contrast, a recent study focusing on perinatal outcomes at our institution demonstrated that among 858 patients, 55% of the subjects had a BMI > 30 kg/m² and 29% had a BMI > 40 kg/m² [11].

Previous studies have demonstrated increased dose requirements of vaginal misoprostol with increasing BMI [7] [12]. Norman *et al.* concluded that obesity (BMI > 30 kg/m²) was associated with longer labor duration and prolonged first

stage of labor among both nulliparous and multiparous women [13]. However, this is the first study to specifically demonstrate the increased dose requirement of oral misoprostol with increasing BMI.

While oral misoprostol has been demonstrated to be a more effective ripening agent compared to vaginal dinoprostone or vaginal misoprostol, these studies primarily focused on subjects with normal BMIs [9] [10]. Pharmacokinetically, oral misoprostol achieves greater peak plasma concentration and has a shorter duration to maximum concentration than vaginal misoprostol [14]. Studies have also shown that the extent of misoprostol absorption is highly variable among subjects with both vaginal and oral administration [15]. Robust pharmacokinetic studies are needed to elucidate the effect of body mass index on absorption of oral misoprostol.

This study is limited by the retrospective design, and importantly, the data were limited by the low number of normal-weight subjects in our population to use as a control group. The robustness of comparison between BMI groups was limited given that our study population heavily skewed toward obese patients. Our study also did not examine confounders such as induction indication, exact gestational age at induction, cervical status, or comorbid maternal conditions. Finally, given the nature of induction of labor, balancing institutional norms and individualized patient care, there is clinical heterogeneity in induction agents after the initial dose of misoprostol due to physician discretion.

Strengths of this study include a large sample size at a single institution, with all deliveries from a single practice group in an area with a high prevalence of obesity. As a tertiary academic medical center, we also benefit from continuous coverage of labor and delivery by highly qualified physicians and trainees, and we believe this contributes to our cesarean delivery rate of 23.5% for this study.

As we continue to understand how obesity impacts labor, future studies could explore ways to improve efficacy and success of cervical ripening in this population. Comparisons of increased drug dosage, decreased drug intervals, and comparing routes of administration among subjects with significant obesity could be further explored. Future cost analysis could also factor in labor duration and hospital stay for induction, along with medication costs.

5. Conclusion

Our data demonstrate that BMI positively correlates with increased oral misoprostol doses, time to delivery, and rate of cesarean delivery. Patients with obesity should be counseled on how this may impact their induction process and their ultimate mode of delivery.

Ethics Approval and Consent to Participate

The requirement for informed consent was waived by the committee due to the retrospective, non-interventional nature of the study and the anonymity of the patient data.

Consent for Publication

All authors consent to publication.

Funding

No funding of any source is reported.

Availability of Data and Materials

All data supporting the findings of this study are available upon reasonable request.

Acknowledgements

We acknowledge the Translational Sciences Core of COBRE/ACCORD, Clinical, and Translational Sciences Department, Joan C. Edwards School of Medicine, Marshall University for analytics support.

Author Contributions

BD: Conceptualization, Methodology, Investigation, Writing—Original Draft. SD: Methodology, Investigation. RL: Formal Analysis, Writing—Original Draft. JY: Conceptualization, Methodology, Investigation, Writing—Review & Editing, Supervision. BM: Conceptualization, Methodology, Writing—Review & Editing. JC: Writing—Review & Editing, Supervision. All authors reviewed the manuscript.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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