Aswan University Medical Journal, volume 5 / No.3/ September 2025 (118-125) Online ISSN: **2735-3117**

ORIGINAL ARTICLE

Comparative Study of Induction of Labour at term by Misoprostol Vaginal Insert versus Dinoprostone Vaginal Insert

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ABSTRACT

Keyword: Induction of Labour, Misoprostol Vaginal Insert, Dinoprostone Vaginal Insert, Outcome

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Background: Inducing labor risks inefficient contractions (fetal hypoxia) or excessive activity (uterine rupture), often from induction agents. **Objectives:** Compare 25µg vaginal misoprostol vs. 3mg dinoprostone for term labor induction. **Methodology:** Compare 25µg vaginal misoprostol vs. 3mg dinoprostone for term labor induction. **Results:** Regarding delivery outcomes in two groups, Vaginal delivery: 80% success (A) vs. 88% (B). **CS rates**: 20% (A; 2 for failed induction, 3 for bradycardia) vs. 12% (B). **Time to deliver**: Dinoprostone faster (327 vs. 613 min; *p<0.05*). **Safety**: Comparable side effects (*p>0.05*). **Neonatal outcomes**: mean APGAR 8 (both groups); NICU admissions: 2 per group **Conclusion:** According to the results of our study, Dinoprostone gives less time and can beused safely in induction of labour.

INTRODUCTION

An essential component of obstetric practice is labor induction. It is mostly used in modern obstetrics when carrying a pregnancy to term could endanger the mother, the fetus, or both **(**1**).**

Traditionally, oxytocin infusion has been used to induce labor; however, multiple investigations have demonstrated that this method does not produce equally satisfying outcomes in cases of unfavorable cervical anatomy **(2)**.

The principal concerns related to labor induction are ineffective contractions and excessive uterine activity, which may lead to fetal hypoxia and increase the risk of complications **(3)**.

oxytocin was synthesized in the 1950s, and since then, the treatment of labor induction has been frequently employed to facilitate delivery by stimulating uterine contractions before spontaneous labor begins (**4)**.

Prostaglandins are frequently employed to induce labor in women who have a postdate pregnancy or a problematic pregnancy with conditions such as preeclampsia, diabetes mellitus, intrauterine fetal growth retardation, or fetal distress **(5)**.

An analogue of prostaglandin E1, misoprostol is approved for use in the management and prevention of peptic ulcers.For obstetric indications of inducing labor and abortion, it is commonly utilized. By

binding specifically to EP-2/EP-3 prostaglandin receptors, it functions as an efficient myometrial stimulant in the uterus of a pregnant woman **(6)**.

The US Food and Drug Administration has approved dinoprostone (prostaglandin E2) vaginal inserts for cervical ripening in women who are full term. These inserts have historically been used for cervical priming. Dinoprostone is costly, must be refrigerated, inserted into the cervix, and many patients need extra oxytocin augmentation during labor induction **(7).**

The objective of the research was to evaluate the effectiveness and safety of two methods for inducing labor at term: 25µg vaginal misoprostol and 3mg dinoprostone vaginal insertion.

PATIENTS AND METHODS

This was a randomized controlled, single blind trail conducted on 50 patients who were candidates for labor induction at term. The low-risk patients with unfavorable cervices before induction of labor were targeted at Obstetrics & Gynaecolog department, Aswan University Hospital, Egypt from march 2023 to september 2023.

Inclusion criteria: Age less than 35 years, gestational age ≥ 36weeks, Singleton pregnancy, multigravida (Para1, 2, 3), A reactive cardiotocographic trace with a Bishop score of five or lower prior to the onset of labor.

Exclusion criteria: Individuals experiencing active labor, symptoms and signs indicative of chorioamnionitis, signs of fetal distress, such as the presence of other maternal or fetal factors that contraindicate induction of labor, and meconium or a non-reassuring cardiotocographic trace. Premature rupture of the membranes 24 hours or more prior to the commencement of treatment, if the gestational age is under 36 weeks. Severe preeclampsia and a body mass index above 50.

Methods

The following were administered to the eligible subjects included in this investigation:

Full history involving: Personal, obstetric, menstrual, past, family history and history of present pregnancy**, Clinical examination including:** General examination: Vital signs, heart, chest, and lower limb examination and anthropometric evaluation included weight in kilograms (Kg) and height in centimeters (cm), **abdominal examination:** in order to evaluate the fundal level, the location and orientation of the foetus, the anticipated weight of the foetus, the foetal heart rate, and the existence of scars from prior operations such as myomectomy or cesarean sections and **vaginal examination:** in order to evaluate the cervical position, dilatation, consistency, length, and head station (using a modified version of Bishop's score, in addition to checking the state of the membranes, pelvic capacity, positioning, and presentation).

Investigations

Laboratory investigations: 5 millimeters was drawn from each patient once and blood grouping and Rh typing, CBC, urine analysis, screening of diabetes mellitus were done, **Abdominal ultrasound:** Following the transvaginal sonography (TVS) examination, a digital vaginal exam was carried out to evaluate the cervical consistency, effacement, dilation, position, and station of the presenting part. The Burnett modification was used to compute the bishop score, which was subsequently used to confirm the gestational age, fetal number, viability, presentation, position, estimated fetal weight, and grade of placental maturity **(8)** and **CTG:** Evaluation through the implementation of fetal heart rate tracing.

Enrollment & Allocation of the patients

A computer-generated random schedule was employed to designate individuals to one of the two study groups: Group (A): all patients received 25µg misoprostol inserted in the posterior

vaginal fornix by the physician in the delivery suite (given every 4hrs for a maximum of 3 doses or until active labor started) **(9)** and **Group (B):** The physician in the delivery suite inserted 3mg dinoprostone into the posterior vaginal fornix of all patients at a 6-hour interval, with a maximum of two doses or until active labor commenced **(9)**. The progression of labor was monitored. The duration of the active phase of labor and the time until delivery was recorded. Assignments were concealed by placing them in opaque, sealed envelopes that were consecutively numbered and drawn in a specific order. Before the designated treatment administration, the envelope was opened. The intervention was known to the physician, while the mothers were unaware of the preparation they received. Treatment allocation was not subject to modification. Mothers withdrew from the study after they requested an alternative treatment.

Follow up

Cardiotocography (CTG) was conducted after 120 minutes of each dose to confirm fetal wellbeing and assess uterine contractions. Patients were examined abdominally and vaginally at 4 hours intervals in the misoprostol group and at 6 hours intervals in the dinoprostone group. The next dose was administered if no uterine contractions or unfavorable cervices were found. Active labor or reaching the maximum dose of the medicine caused the dosage to be stopped. When patients' membranes were still intact when they entered the active phase of labor, they were given an AROM. Examining the vagina every four hours during active labor allowed for the evaluation of cervical dilatation, effacement, state of liquor, head station, and moulding, among other outcomes. The use of electrocardiotocography or Sonicade for continuous fetal monitoring was performed as prescribed. The women were observed using a digital adaptation of the World Health Organization partograph, which incorporates an alert line to indicate the anticipated cervical dilatation and an action line to be drawn four hours later. In the initial stage of labor, when the action line was passed, labor dystocia was detected. During the second stage of labor, labor dystocia was identified when either the latent period or the ejection phase extended more than an hour.

Outcome measures

The primary outcome measure: The interval from medication insertion to delivery, also known as the induction to delivery interval. **While secondary outcomes include Maternal outcomes:** Mode of delivery, uterine hyperstimulation, rate of occurrence of nausea &vomiting and **Pyrexia:** Defined as maternal temperature of ≥ 38C. **Fetal outcomes:** Admissions to the NICU and Apgar scores at 1-5 minutes.

Ethical Consideration

Confidentiality: All participants in this investigation were guaranteed confidentiality to the greatest extent possible. The study participants will not be identified in any report or publication that is as a result of the data collected in this research. **Research statement:** This study raised questions of ethics, both in terms of substance and methodology. All patients were informed of the study's goals, procedures, and potential dangers before they were allowed to participate. In order to participate in this study, participants must acknowledge that it is an investigational study, that there are risks and benefits associated with it, that they can withdraw from it at any time without compromising their right to adequate healthcare at the study site, that they will be able to reach someone with questions about the study, and that their participation is voluntary and informed. **Informed consent:** In the same way as her other records, the participant's signed informed consent form was a permanent component of the research records.

RESULTS

Table (1): Comparison between studied cases according to Demographic data

	Group A (n = 25)		**Group B (n = 25)**		**p-value**
Age (years)					
Range.	20 – 35		23 – 35		0.642
Mean ± SD.	28 ± 4.64		28.4 ± 3.33		
BMI					
Range.	23.7 – 31.7		23.9 – 31.8		0.642
Mean ± SD.	27.47 ± 2.49		28.05 ± 2.56		
Parity	No.	%	No.	%	
1	16	64.0	12	48.0	0.290
2	7	28.0	8	32.0	
3	0	0	3	12.0	
4	1	4.0	2	8.0	
5	1	4.0	0	0.0	
Previous abortion	No.	%	No.	%	
No	23	92.0	23	92.0	1.0
Yes	2	8.0	2	8.0	
Gestational age					
Range.	36 – 42		36 – 42		0.156
Mean ± SD.	38.8 ± 2.14		39.64 ± 1.98		
Bishop score					
Range.	1 – 4		1 – 4		0.070
Mean ± SD.	2.64 ± 1.19		2.04 ± 1.1		

The mean age was 28 years old ± 4.64, and the mean BMI was 27.47 ±2.49, all study subjects were multi para with mean gestational age of 39 weeks. (Table 1)

Table (2): Comparison between examined cases in accordance with Delivery outcomes

	Group A(n = 25)		**Group B(n = 25)**		**p-value**
	No.	%	No.	%	p
Vaginal delivery	20	80.0	22	88.0	0.157
Cesarean section:	5	20%	3	12%	0.157
Failure of induction	2	8%	2	8%	
Emergency CS due tofetal bradycardia	3	12%	1	4%	

Induction to labortime (min)					
Range.	549 – 677		250 – 447		0.003*
Mean ± SD.	613 ± 63.25		327 ± 37.14		
Labor duration(min)					
Range.	205 – 410		211 – 520		0.076
Mean ± SD.	263.24 ± 83.81		358.6 ± 127.46		
Oxytocin use	7	28.0	11	44.0	0.239
Tachysystole	10	40.0	3	12.0	0.024*
Tocolysis use	5	20.0	1	4.0	0.612

Regarding delivery outcomes in two groups, In Group A, 20 cases of successful vaginal delivery were reported, with 5 cases requiring CS. Two cases were due to induction failure and three to severe fetal bradycardia. The mean induction time was 613 minutes. In Group B, 22 cases had successful vaginal delivery, with 3 cases requiring CS. The mean induction time was 327 minutes. (Table 2)

Table (3): Comparison between examined cases in accordance with maternal complications

	Group A(n = 25)		**Group B(n = 25)**		**p**
Side effects	No.	%	No.	%	
excessive vomiting	14	56.0	15	60.0	0.772
Diarrhea	6	24.0	9	36.0	0.355
epigastria pain	14	56.0	10	40.0	0.258
Pyrexia	7	28.0	8	32.0	0.758
Delivery complications					
uterine ruptureOASIS*	0	0%	0	0%	0
Post partum hemorrhage	1	4%	1	4%	0.286
	6	24%	5	20%	0.733

* OASIS: Obstetrical anal sphincter injuries

Regarding maternal complication of study subjects, it showed vomiting was about 56% in group A and 60% in group B, also the cases with pyrexia where 7 in the first group and 8 cases in the second group, and regarding the delivery complication, there was no case of uterine rupture, only one case of OASIS in each group, also, there was 6 cases had postpartum hemorrhage in group A and 5 cases in group B, there was no significant variance between two groups concerning Side effects and delivery complications p>0.05. (Table 3)

Table (4): Comparison between examined cases in accordance with fetal outcomes

	Group A(n = 25)		**Group B(n = 25)**		**P-value**
Complications	No.	%	No.	%	P
Apgar score 5					
Range.	6 – 10		6 – 10		0.449
Mean ± SD.	8.4 ± 1.19		8.12 ± 1.39		
NICU admissions	2	8.0	2	8.0	1.0

Regarding fetal complications among the study subjects, in Group A and Group B the mean APGAR score was 8 while 2 neonates in each group required early NICU admission. There was no significant variance regarding Apgar score 5 and NICU admissions p= 0.449, 1.0 respectively. (Table 4)

DISCUSSION

The medical practice of inducing labor is an essential component of obstetrics. It is most commonly attempted in contemporary obstetrics when continuing the pregnancy could be harmful to either the mother or the fetus or both. Oxytocin infusions have been the standard method for inducing labor for many years, however a large number of studies have demonstrated that this method is unable to provide similarly satisfying results in women who have an unfavorable cervix **(10)**.

In terms of the demographic data collected from the study subjects, such as their age, gestational age, parity, BMI, physical examination, modified Bishop's score, and laboratory examinations, no significant distinction was found among the groups. The findings were comparable to those of **Maggi et al.,** who assessed the efficacy of a vaginal insert containing 200 μg of misoprostol against a vaginal insert containing ten milligrams of dinoprostone in facilitating labor induction in women with an unfavorable cervix. Participating in the trial were 220 women; 109 (49.5%) were given MVI and 111 (50.5%) were given DVI. The research displays demographic information as well as baseline characteristics. There was little difference between the two groups with regard to maternal age, BMI, method of conception, and Bishop score **(10)**.

In this study, **Ayaz et al.** aimed to evaluate the safety and effectiveness of two methods for elective induction of labor in women who had never given birth before: intravaginal misoprostol and dinoprostone. Among the 120 participants in the study, 78 (or 65%) were younger than 25 years old, while the remaining 30 were older than 25 years old. Both Groups had similar mean ages; Group A was 23 and Group B was 25. After the insertion of a single dose, 18 (30%) subjects in Group A experienced active labor, while only eight (14%) in Group B went into labor **(11)**.

In accordance with **Sire et al.,** there was no significant variance between the two groups in terms of instrumental deliveries. Cesarean delivery was significantly more prevalent in the misoprostol group ($p = 0.005$) due to abnormal fetal heart rate **(12)**.

Consistent with this investigation, there were statistically significant variations between the groups with regard to of tachysystole and induction to labor time. Our results contradict those of **Maggi et al.,** who reported no difference in the probability of surgical vaginal delivery; rather, they observed that women induced with MVI had a higher likelihood of vaginal birth compared to those induced with DVI (88% vs 74%, P = 0.007). The MVI group exhibited a significantly shorter median interval from drug administration to the onset of labor and from drug administration to delivery in comparison to the DVI group **(10)**.

Misoprostol had a significantly reduced median duration between induction and labor onset in contrast to dinoprostone (855 min vs 1740 min; P < 0.001), which is in line with the findings of **Wing et al (13)**.

Misoprostol and dinoprostone vaginal inserts were tested for inducing labor with intact membranes in a recent research by **Mlodawski et al.** Consistent with our findings, they also found that vaginal misoprostol increased the incidence of cesarean section (OR 2.71 95% CI 1.63-4.47). While misoprostol has been the subject of numerous research in recent years, very few have examined PROM as an individual case **(14)**.

Kerr et al. performed a review encompassing thirteen randomized trials that compared low-dose oral misoprostol with vaginally administered dinoprostone. The findings indicate that oral misoprostol is associated with a reduced incidence of cesarean sections compared to vaginal dinoprostone (RR 0.84, 95% CI 0.78–0.90; 13 trials, 9676 women; evidence of moderate uncertainty). However, it was found that most trials included women with both intact and ruptured membranes, complicating the conduct of meaningful analyses. Furthermore, the analysis revealed a significant imbalance among the subgroups **(15)**.

Wang et al. reported that neonatal outcomes 5, there was not a significant distinction in neonatal Apgar ratings of seven or higher at the intervals of one, five, and ten minutes. In addition, there was not a significant variation in the rates of meconium-stained fluid or neonates admitted to the NICU. Vaginal dinoprostone was associated with a significantly higher frequency of non-reassuring fetal heart rates than OMS (p = 0.04) **(16)**.

CONCLUSION

According to the results of our study, Dinoprostone gives less time and can be used safely in induction of labour

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