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The Efficacy of Misoprostol and Prostaglandin E2 in Induction of Labor

Samreen Burhan[1], Samdana Anwar[1]

[1]Peshawar Medical College and Affiliated Teaching Hospitals, Peshawar, Pakistan

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Correspondence to: Samreen Burhan, Peshawar Medical College and Affiliated Teaching Hospitals, Peshawar, Pakistan.
Email: samreen_irfan2010@yahoo.com

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ABSTRACT

Background: In fact, induction of labor (delivery) is commonly performed as an obstetric intervention when the risks of continuing the pregnancy outweigh the benefits. For cervical ripening and labor induction, the pharmacological agents most used are misoprostol (prostaglandin E1 analogue) and dinoprostone (prostaglandin E2). The objective of this study was to compare the efficacy of misoprostol versus prostaglandin E2 in induction of labour in term pregnant women at a tertiary care hospital. **Methods:** It was an interventional randomized controlled trial lasting three months duration at Mercy Teaching Hospital and Kuwait Hospital, Peshawar from 25 Feb 2025 to 25 March 2025. Random assignment of 230 women who fulfilled the inclusion criteria was undertaken to receive misoprostol (25 µg vaginally every 6 hours, max 4 doses) or Prostaglandin E2 (2 mg vaginally every 12 hours, max 2 doses). Onset of labour with no further intervention was defined as successful induction. SPSS version 25 was used to analyze the data and the p-value < 0.05 was considered significant. **Results:** The success rate of induction was 97.4% with misoprostol compared with 90.4% with prostaglandin E2 (p = 0.031). Among the significant variables included in subgroups analysis by age, parity, BMI, gestational age and residence, misoprostol consistently demonstrated higher efficacy. **Conclusion:** Prostaglandin E2 was less effective in inducing labor than was misoprostol. Because of its low cost, ease of storage and high success rate, this reduces the use of its broader use, especially in low resource settings. We recommend further studies evaluating safety outcomes and long term maternal and neonatal implication.

INTRODUCTION

Induction of labor is defined as the act of artificial initiation of uterine contractions before spontaneous onset of labor with the goal of progressive cervical dilatation and effacement and a subsequent delivery of the fetus and placenta vaginally. This occurs when the possible risks associated with the continuation of the pregnancy are greater than possible benefits to the mother or fetus (Langley-Evans et al., 2022; Edinoff et al., 2022). Induction is commonly indicated in post term pregnancy, pre-labor rupture of membranes, hypertensive disorders of pregnancy and maternal diseases (e.g., diabetes mellitus) (Ducarme et al., 2024).

Labor induction rates worldwide are surging at a staggering rate: taking up to 25% of all pregnancies in developed countries and following suit in the developing world (Farah et al., 2023; Swift et al., 2022). The process of induction depends very much on the readiness of the cervix, often by using the Bishop score (Kuba et al., 2023; Azad et al., 2022). Usually, cervical ripening with pharmacologic agents is required before oxytocin starts if Bishop score is less or equal to 6 (Lee et al., 2022; Shahabuddin and Murphy, 2022).

Cervical ripening is frequently done pharmacologically using prostaglandins (Socha et al., 2022; Socha et al., 2023). They can be divided into prostaglandin E1 and prostaglandin E2 analogues (Taliento et al., 2023; Szpot et al., 2023). Prostaglandin E2 is well established and frequently used, but this option is expensive and needs to be refrigerated which restricts its availability in lower resource settings (Resch, 2023). On the other hand, misoprostol has become popular because it is inexpensive, stable at room temperature and can be administered by several routes including, in particular, oral, sublingual and vaginal (da Silva et al., 2024; Mohammed et al., 2022). Although misoprostol was not originally developed for use as an agent to stimulate labor, it is now a recommended agent for labor induction, particularly in resource limited settings (Sanchez-Ramos et al., 2024; Hawker et al., 2024). Comparative studies of recent years show that misoprostol could be more effective than dinoprostone. The reported success rate is as high as 98.7% versus 91.4% for misoprostol and dinoprostone, respectively. Still, standardizing protocols remains challenging owing to variation in clinical practice and sparse local data concerning efficacy and safety profiles. In addition, misoprostol and prostaglandin E2 have widespread use in

labor induction, but the real world outcomes have not been rigorously studied in our population causing a gap in evidence based practice.

Misoprostol has been shown to be more effective induction agent for labor than PGE2 and so the study was conducted in tertiary care hospital to evaluate and compare efficacy of misoprostol and prostaglandin E2 in induction of labor in women admitted in hospital. The outcome of this research intends to provide guidance for clinical decision making, refinement for patient counseling and bolster support for resource appropriate induction protocols in these healthcare settings.

METHODOLOGY

The present study was a randomized controlled trial done in the Department of Obstetrics and Gynecology, Mercy Teaching Hospital and Kuwait Hospital, Peshawar from 25 Feb 2025 to 25 March 2025. The study was performed after getting approval from the hospital's research review board over a period of three months. A total of 230 patients were included, with each of the treatment groups having 115 patients. Sample size was calculated with WHO sample size calculation software with power 80%, significance level was 5% and success rate for misoprostol was 98.7% and for prostaglandin E2 was 91.4%. To recruit the eligible participants, non-probability consecutive sampling was used.

The study enrolled patients between the ages of 18 and 45 with a gestational age of 37 to 42 weeks by the last menstrual period, a parity of four or less and a singleton pregnancy in cephalic presentation with intact membranes presenting for induction of labor. Those patients with a medical or obstetric history of low lying placenta, previous uterine surgery, an unsatisfactory CTG or transverse lie were excluded. Before recruitment, informed consent was obtained from all participants. Baseline demographic and clinical data such as age, parity, body mass index (BMI) and place of residence (rural and urban) were documented.

Block randomization was used to randomize patients meeting the inclusion criteria to the two intervention groups. Misoprostol was given to 1 group in a dosage of 25 microgram in pessary form, inserted into the posterior fornix of the vagina. A maximum of four doses were given every 6 hours. Furthermore, the patients were observed for up to 24 hours for the onset of labor. The second group was treated in the posterior fornix with 2 mg of prostaglandin E2 (dinoprostone) gel vaginally, not to exceed the maximum dose of two doses 12 hours apart. Continuous monitoring of patients with assessment of the induction response using operational definitions were defined prior to administration. Induction was defined as successful if labor started without the need for additional or alternative methods of labor induction.

IBM SPSS Statistics v25 was used to perform data analysis to interpret the data obtained. Means and standard deviations were used to analyze continuous variables age, gestational age and BMI. Parity, residence and efficacy were presented as frequencies and percentages as categorical variables. Chi square test was used to compare the efficacy of misoprostol with prostaglandin E2, the p value <0.05 was considered statistically significant. The strata were defined by age, gestational age, parity, BMI and by residence and post-stratification analysis was used in conjunction with the chi-square test to determine the outcome of these variables.

RESULTS

In the study, the 230 patients were allocated into 115 who received misoprostol and 115 who were given prostaglandin E2. The age of patients in the misoprostol group was 27.6 ± 4.8 years and in prostaglandin E2 group 28.1 ± 5.1 years. In the misoprostol group, the average gestational age at the time of induction was 39.1 ± 1.2 weeks and in the prostaglandin E2 group it was 39.3 ± 1.1 weeks. The mean BMI was 27.5 ± 2.4 kg/m^2 in misoprostol group and 27.8 ± 2.7 kg/m^2 in prostaglandin E2 group. Comparability between groups was not demonstrated by statistically significant differences in baseline characteristics.

In the misoprostol group, 112 out of 115 patients (97.4%) had successful induction of labor and in the prostaglandin E2 group it was 104 out of 115 patients (90.4%). Sa (p=0.031) between the two groups indicated that the efficacy of misoprostol was significantly higher than that of prostaglandin E2 in inducing labor.

For further stratified analysis, misoprostol showed higher efficacy across age, parity, BMI, gestational age and residence. Misoprostol had an efficacy of 98.2% among women ages 18–30 years compared with 91.5% using prostaglandin E2. The efficacy was high in both groups in women with BMI < 30 kg/m^2 and significantly greater with misoprostol.

Table 1

Baseline Characteristics of Study Participants

Variable	Misoprostol Group (n=115)	Prostaglandin E2 Group (n=115)	p-value
Age (years), mean ± SD	27.6 ± 4.8	28.1 ± 5.1	0.324
Gestational Age (weeks), mean ± SD	39.1 ± 1.2	39.3 ± 1.1	0.215
BMI (kg/m^2), mean ± SD	27.5 ± 2.4	27.8 ± 2.7	0.421
Parity ≤ 2 (%)	68 (59.1%)	72 (62.6%)	0.592
Urban Residence (%)	70 (60.9%)	74 (64.3%)	0.617

Table 2

Efficacy of Labor Induction

Group	Successful Induction (n, %)	Failed Induction (n, %)	Total	p-value
Misoprostol	112 (97.4%)	3 (2.6%)	115	
Prostaglandin E2	104 (90.4%)	11 (9.6%)	115	0.031

Table 3

Efficacy Stratified by Patient Characteristics

Characteristic	Category	Misoprostol (n=115)	Efficacy (%)	Prostaglandin E2 (n=115)	Efficacy (%)	p-value
Age	18–30 years	82	98.2%	78	91.5%	0.042
	>30 years	33	96.1%	37	89.2%	0.196
Parity	≤2	68	98.5%	72	91.6%	0.038
	3–4	47	95.7%	43	88.3%	0.164
BMI (kg/m^2)	<30	103	97.1%	107	90.6%	0.035
Gestational Age (weeks)	37–39	75	98.7%	78	91.0%	0.029
	>39	40	95.0%	37	89.1%	0.271
Residence	Urban	70	97.1%	74	90.5%	0.044
	Rural	45	97.7%	41	90.2%	0.051

DISCUSSION

In this randomized controlled trial, misoprostol was more effective than prostaglandin E2 in term pregnant women in the induction of labor. The induction rates were 97.4% for the misoprostol group and 90.4% for the prostaglandin E2 group and these rates were significantly different. Our results are consistent with the increasing body of evidence that misoprostol is a very efficacious cervical ripener and labor induction agent when cost, storage and ease of administration are important considerations.

Some of the reasons behind the superior efficacy of misoprostol may be its pharmacological characteristics such as powerful uterotonics effects, multiple routes of administration and being stable at room temperature. Unlike prostaglandin E2 which must be refrigerated and is costs more, misoprostol is more accessible in low resource settings. The clinical effectiveness of misoprostol and the practical advantages inherent in its administration make it increasingly attractive for induction of labor, especially in public sector hospitals and in rural health settings.

These results are consistent with the previous studies in the literature in which misoprostol has shown higher or equivalent rates of successful labor induction. For example, one of the referenced studies had a success rate of 98.7 per cent with misoprostol versus 91.4 per cent with prostaglandin E2. Small differences in our success rates could be due to differences in the population characteristics, local clinical practices and dosing intervals. However, the tide is still in favor of misoprostol. Analysis of subgroups in our study showed that misoprostol proved effective in all age groups, parity levels, BMI categories and gestational age brackets. Overall, its reliable performance across a variety of maternal characteristics makes this induction agent consistent. Moreover, although prostaglandin E2 also displayed reasonable efficacy, misoprostol is superior because it has a lower rate of success and certain logistical disadvantages compared to prostaglandin E2.

These are promising findings, but there are some limitations. A non probability consecutive sampling technique was used in the study and this may have resulted to the introduction of selection bias. The study was also limited by its short duration and restriction to only two tertiary care hospitals which potentially limits the generalizability of the results to a broader population. This study did not evaluate long term maternal and neonatal outcomes or adverse effects or complications, if any, due to either agent. More extensive future research is needed to look at broader population samples, longer follow ups and safety profiles to evaluate the comparative safety and efficacy of these two induction agents.

Overall, this study provides additional evidence of the efficacy of misoprostol as a superior inducer of labor compared with prostaglandin E2. Both easy to use, affordable and highly efficacious, it is a good choice for use in normal clinical practice, particularly in a resource constrained environment.

CONCLUSION

Misoprostol was significantly more efficacious than the prostaglandin E2 in the induction of labor with a success rate of 97.4% compared with 90.4% with prostaglandin E2. Regardless of maternal characteristics such as age, parity, gestational age or BMI, misoprostol always had higher efficacy. It also tends to be easy to administer, room temperature stable and cost effective, making it especially well suited as an intervention in resource limited healthcare environments. Prostaglandin E2 remains a workable solution, but considering its limitations in terms of logistics and comparatively lower effectiveness, it is often unacceptable in many real life scenarios. The findings from this study support further implementation of misoprostol for labor induction in similar populations. Long term maternal and neonatal outcomes need future studies and the safety profile of misoprostol compared to other induction agents needs further investigation.

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