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Original Research Article

COMPARATIVE EFFECTIVENESS OF MISOPROSTOL AND DINOPROSTONE FOR INDUCTION OF LABOUR: A PROSPECTIVE COHORT STUDY FROM A TERTIARY CARE SETTING

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ABSTRACT

Background: Induction of labour is a common obstetric surgery and good cervical ripening is the most important factor that can be used to predict its success. Prostaglandins are typically misoprostol and dinoprostone; though, they are not compared in terms of effectiveness in the real clinical contexts, especially in low-resource countries. This study will compare the efficacy and safety of misoprostol and dinoprostone in labour induction (measurements of progression of labour, mode of birth, and neonatal and maternal outcome).

Materials and Methods: This was a prospective comparative cohort study that was carried out in eight months in a tertiary care hospital. One hundred and forty pregnant women in need of induction of labour were recruited and 70 in misoprostil group and 70 in dinoprostone group. The names of patients were assigned randomly. Baseline characteristics information, induction information, labour outcomes, mode of delivery, maternal complications, and neonatal outcomes were identified. The statistical analysis has been conducted with the help of relevant parametric and non-parametric tests. Multivariate logistic regression was used to correct the confounders such as age, parity, Bishop score and gestational age.

Results: There were similarities in baseline characteristics. The misoprostol group had shown considerably decreased doses needed, and oxytocin augmentation. The labour progression was markedly quicker with fewer time to active labour and delivery, and higher percentage of delivery took place within the period of 12 hours. The spontaneous vaginal birth rate was much greater and the rate of cesarean section was less in the misoprostol group. Mothers in both groups had the same complications. APGAR scores were significantly higher with neonatal outcomes using misoprostol and NICU admissions were also also less and not significant. Multivariate analysis affirmed that misoprostol was a predictor of vaginal delivery independently.

Conclusion: Misoprostol is a safe and effective alternative to dinoprostone in labour induction and has better labour outcomes (improved) without the need to raise maternal or neonatal complications.

Keywords: Labor, Induced, Misoprostol, Dinoprostate, Prostaglandins, Vaginal Delivery, Obstetric Labor Complications.

INTRODUCTION

Induction of labour is a usual obstetric procedure that is used to start contractions in the uterus before spontaneous start of labour when the benefits of delivering the baby are greater than the risks of pregnancy persistence. The frequency at which induction of labour is conducted is estimated at about 2030 per cent of the world pregnancies, which needs to be considered critical to the contemporary obstetrics practice.[1,2] Achieving good cervical ripening is also a determinant of successful induction especially in women with poor cervix whose pharmacological agents are usually needed to increase the cervical readiness and improve labour outcome.[2]

Prostaglandins are considered the building blocks of pharmacological induction with dinoprostone (prostaglandin E2) and misoprostol (prostaglandin E1 analogue) being the most popular drugs.[3] The conventional agent has been Dinoprostate because of its known tolerability and regulated release preparations.[4] Misoprostol has however become more popular due to low cost, room temperature stability, route of administration ease, and strong uterotonic effect.[5] These properties render misoprostol especially appealing in the low- and middle-income nations where costs of more expensive options can be restricted by the resource availability.

Randomized trials and meta-analyses of misoprostol versus dinoprostone have been done around the world with mixed results. Although the studies proved similar safety profiles, others had shown that misoprostol could result in an accelerated progression of labour and a lower rate of further interventions like oxytocin augmentation.[6] Although this is an increasing literature, different dosage regimens, routes of administration and population of the study have made the studies incongruent, thus necessitating further context-specific review.

The complications related to obstetrics are still high in Pakistan and on-time induction of labour is usually needed in dealing with high-risk pregnancy that includes post-term pregnancy, hypertensive disorders and premature rupture of membranes.[7,8] Even though misoprostol and dinoprostone are both applicable in clinical practice, the locally generated information on the direct comparison of their efficacy and safety in a regular hospital environment is not generated. Also, the majority of the evidence material available internationally is based on randomized controlled trials, which may not be realistic of a real clinical situation seen in the Pakistani healthcare facilities.

With this in mind, there is a necessity to compare the relative efficacy of these agents in a real-life, non-randomized, environment with the exclusion of the possible confounding items. This type of evidence would be useful in informing clinical decisions, especially in resource-constrained settings, where cost, availability, and usability factors are significant in addition to clinical outcomes. This study aimed at comparing the efficacy of misoprostol and the efficacy of dinoprostone, in induction of labour, with regard to the progression of labour, mode of delivery, and maternal and neonatal outcomes.

MATERIALS AND METHODS

This is a prospective comparative cohort study with a retrospective validation aspect that will be conducted in the department of obstetrics and gynecology of a tertiary care hospital in a span of eight months between January 2025 and August 2025. In the study, the researcher sought to compare the effectiveness and safety of misoprostol and dinoprostate in induction of labour in the routine clinical practice setting.

It enrolled 140 pregnant women in the prospective arm through non-probability consecutive sampling; 70 patients in the misoprostol arm and 70 in the dinoprostone arm. There was no randomization of the treatment groups but clinician preference and institutional protocol made the allocation. This method is the one that is practiced in the real world and also enables comparative analysis. Moreover, prospective data of the hospital records was also scrutinized to confirm the trends in the prospective cohort.

The sample size of 252 was adequate since it corresponded to the sample size determined by the researchers to guarantee the desired outcomes are achieved (Gray et al., 2014). The women were excluded who had a history of prior cesarean section or uterine surgery, more than one pregnancy, placenta previa, fetal malpresentation or have had contraindication of prostaglandins.

On admission, the history and physical examination were done in detail and baseline details such as maternal age, body mass index, parity, gestational age and Bishop score were taken. The score he used is the Bishop score determined by a senior obstetrician to achieve consistency.

In the misoprostol group, the patients were treated using misoprostol of 25 to 50 ug which was administered in a vaginal manner at a 4 to 6 hours' interval depending on the clinical response with a maximum of four doses. Patients in the dinoprostate group were given intracervical dinoprostate gel (0.5 mg) which could be repeated after the 6-8 hours in case of necessity under the hospital protocol. There was constant monitoring of the mother and the fetus as it was being induced. When sufficient uterine contractions were not attained after cervical ripening, oxytocin augmentation was started.

Partograph was used to monitor labour progression. The time interval between induction and onset of active labour and time interval between induction and delivery were recorded. Mode of delivery was recorded such as spontaneous vaginal delivery,

assisted vaginal delivery, or cesarean section. Mothers complications included uterine tachysystole, fetal distress, meconium-stained liquor and postpartum bleeding. Neonatal outcomes such as APGAR scores at 1 and 5 minute of birth, birth weight and requirement to be admitted to the NICU were also evaluated.

In order to reduce the impact of extraneous variables that come with non-random design, baseline comparability among groups was used. The multivariate logistic regression analysis was conducted to control the possible confounding factors such as maternal age, parity, Bishop score at the time of admission, and gestational age. Stratified analysis using Bishop score (less than 4 and greater than 4) and parity (primigravida and multipara) was also done to assess the consistency of findings within clinically relevant subgroups.

Operational Definitions

To be able to replicate the findings, the following operational definitions were employed:

Induction of labour: Pharmacological initiation of uterine contractions, prior to the spontaneous labour.

Active labour: This is identified as cervical enlargement of 4cm and regular uterine contractions occur.

Failed induction: The inability to get active labour on optimum doses of induction agent with or without oxytocin augmentation.

Time to active labour: This is a period (in hours) between the administration of the first dose of induction agent and the onset of active labour.

Time interval between induction and delivery of the fetus: Induction-to-delivery interval.

Spontaneous vaginal delivery (SVD): Child birth by vaginal means without the use of any instruments.

Assisted vaginal delivery: Forcep or vacuum delivery.

Cesarean section: A surgical delivery of the baby involving incisions on the abdomen and the uterus.

Uterine tachysystole: The mean number of uterine contractions exceeding five in 10 minutes were measured at 30 minutes.

Fetal distress: Abnormal fetal heart rate patterns with clinical intervention.

Postpartum blood loss: Blood loss more than 500 mL after childbirth or when medically necessary.

Low APGAR score: APGAR score lower than 7 at 5 minutes.

NICU admission: The newborn is admitted to the neonatal intensive care unit on any medical reason.

Statistical Analysis: The data were typed into SPSS 27 and analysed. Continuous variables were reported in the form of mean standard deviation and checked on their normality. Normally distributed variables were analyzed by independent sample t-tests whereas the measurement of non-normally distributed data was conducted through the MannWhitney U test. Frequencies and percentages were used to express categorical variables and compare them using Chi-square test or Fischer Exact test. Multivariate logistic regression analysis was conducted to accommodate the confounding variable where vaginal delivery was used as the dependent variable. Adjusted odds ratios as well as 95 percent confidence interval were computed. Wald chi-square statistics were used to obtain the strength of association. The p-value of below 0.05 was taken as statistically significant.

RESULTS

The baseline characteristics of both groups were well matched, with no statistically significant differences observed in maternal age, BMI, parity, gestational age, or Bishop score. Similarly, the distribution of clinical conditions such as PROM and hypertension was comparable, indicating that both groups were homogeneous at baseline and suitable for outcome comparison without major selection bias.

Table 1: Baseline Characteristics

Variable	Misoprostol (n=70)	Dinoprostone (n=70)	Test	Statistic	p-value
Age (years)	30.4 ± 4.1	31.1 ± 3.9	Independent t-test	t = -1.02	0.31
BMI (kg/m²)	26.0 ± 3.4	26.7 ± 3.1	t-test	t = -1.21	0.23
Primigravida	36 (51.4%)	34 (48.6%)	Chi-square	$\chi^2 = 0.11$	0.74
Parity ≥2	22 (31.4%)	24 (34.3%)	Chi-square	$\chi^2 = 0.14$	0.71
Gestational age (weeks)	39.7 ± 1.2	39.5 ± 1.3	t-test	t = 0.74	0.46
Bishop score	3.9 ± 1.1	3.8 ± 1.2	Mann–Whitney U	Z = -0.41	0.68
PROM	18 (25.7%)	19 (27.1%)	Chi-square	$\chi^2 = 0.03$	0.85
Hypertension	11 (15.7%)	12 (17.1%)	Chi-square	$\chi^2 = 0.05$	0.82

Induction dynamics differed notably between groups, with the misoprostol group requiring significantly fewer doses and demonstrating a reduced need for oxytocin augmentation. Although the rate of failed induction was lower in the misoprostol group, this difference did not reach statistical significance, suggesting a trend toward greater efficiency with misoprostol.

Table 2: Induction Characteristics

Variable	Misoprostol	Dinoprostone	Test	Statistic	p-value
Number of doses	1.7 ± 0.6	2.4 ± 0.8	Mann–Whitney U	Z = -3.45	0.001
Oxytocin augmentation	24 (34.3%)	38 (54.3%)	Chi-square	$\chi^2 = 5.23$	0.02
Failed induction	4 (5.7%)	9 (12.9%)	Fisher's Exact	—	0.14

Labour progression was significantly more rapid in the misoprostol group, with shorter intervals to both active labour and delivery. Additionally, a substantially higher proportion of women achieved delivery within 12 hours, highlighting the superior efficacy of misoprostol in expediting labour.

Table 3: Labour Outcomes

Outcome	Misoprostol	Dinoprostone	Test	Statistic	p-value
Time to active labour (hours)	6.3 ± 1.4	8.2 ± 2.0	t-test	t = -6.42	<0.001
Time to delivery (hours)	10.7 ± 2.2	13.8 ± 2.8	t-test	t = -7.25	<0.001
Delivery ≤12 hrs	46 (65.7%)	30 (42.9%)	Chi-square	$\chi^2 = 7.63$	0.006

The mode of delivery favored misoprostol, with a significantly higher rate of spontaneous vaginal delivery and a corresponding reduction in cesarean sections. Rates of assisted vaginal delivery were comparable, indicating that the overall improvement was primarily driven by increased natural vaginal births.

Table 4: Mode of Delivery

Mode	Misoprostol	Dinoprostone	Test	Statistic	p-value
Spontaneous vaginal delivery	50 (71.4%)	41 (58.6%)	Chi-square	$\chi^2 = 4.10$	0.04
Assisted vaginal delivery	7 (10.0%)	9 (12.9%)	Chi-square	$\chi^2 = 0.29$	0.59
Caesarean section	13 (18.6%)	20 (28.6%)	Chi-square	$\chi^2 = 4.15$	0.04

Maternal complications were comparable between the two groups, with no statistically significant differences in rates of tachysystole, fetal distress, meconium-stained liquor, or postpartum hemorrhage. These findings suggest that the improved efficacy of misoprostol did not come at the cost of increased maternal risk.

Table 5: Maternal Complications

Complication	Misoprostol	Dinoprostone	Test	Statistic	p-value
Tachysystole	6 (8.6%)	4 (5.7%)	Fisher's Exact	—	0.51
Fetal distress	9 (12.9%)	13 (18.6%)	Chi-square	$\chi^2 = 0.86$	0.35
Meconium-stained liquor	7 (10.0%)	10 (14.3%)	Chi-square	$\chi^2 = 0.59$	0.44
Postpartum hemorrhage	3 (4.3%)	4 (5.7%)	Fisher's Exact	—	0.70

Neonatal outcomes were generally favorable in the misoprostol group, with significantly higher APGAR scores at both 1 and 5 minutes. Although rates of low APGAR scores and NICU admissions were lower in this group, these differences were not statistically significant, indicating comparable neonatal safety profiles overall.

Table 6: Neonatal Outcomes

Outcome	Misoprostol	Dinoprostone	Test	Statistic	p-value
APGAR (1 min)	8.1 ± 0.7	7.7 ± 0.9	t-test	t = 2.65	0.01
APGAR (5 min)	9.5 ± 0.5	9.2 ± 0.6	t-test	t = 2.45	0.02
Low APGAR (<7)	2 (2.9%)	6 (8.6%)	Fisher's Exact	—	0.14
NICU admission	6 (8.6%)	11 (15.7%)	Chi-square	$\chi^2 = 1.66$	0.19
Birth weight (g)	2980 ± 380	2940 ± 400	t-test	t = 0.64	0.52

After adjusting for potential confounders, misoprostol remained independently associated with higher odds of vaginal delivery, reinforcing its effectiveness. Among other variables, a higher Bishop score emerged as a strong predictor of successful vaginal delivery, while maternal age, parity, and gestational age did not show significant independent effects.

Table 7: Multivariate Logistic Regression

Variable	Adjusted OR	95% CI	Wald χ^2	p-value
Misoprostol	1.82	1.01–3.30	4.12	0.04
Age >35 years	0.78	0.40–1.52	0.55	0.46
Primigravida	0.65	0.34–1.24	1.72	0.19
Bishop score ≥4	2.40	1.30–4.45	7.85	0.005
Gestational age >40 weeks	0.88	0.45–1.70	0.15	0.70

DISCUSSION

The current research established that misoprostol had a significantly better result in the labour process, such as the shortening of induction-to-active labour times, the duration of induction-to-delivery times, and an increased percentage of deliveries within 12 hours. Besides, the misoprostol group also had a higher

spontaneous vaginal birth and reduced rate of cesarean section. Misoprostol is also more preferable due to its induction properties and minimal dosage, as well as, lesser dosage of oxytocin supplementation. Notably, there were no differences in the maternal and neonatal complications in the two groups and multivariate analysis revealed that misoprostol had independent effect of raising the chances of a vaginal birth despite confounders like age, parity and Bishop score.

The results of accelerated labouration with misoprostol in the current paper are comparable with the past literature. Some studies have noted that misoprostol with its high potency of uterotonic activity causes better cervical ripening and labour onset in comparison to dinoprostone.[9,10] In spite of the fact that large meta-analyses are mainly concerned with the overall effects as opposed to time of day, it is the pharmacological characteristics of misoprostol that points to its capability to reduce the time of induction, which is in agreement with the considerably shorter induction-to-delivery time that was found in our cohort.

One of the most important results of this research was that oxytocin augmentation was lower in the misoprostol group. Recent high-quality evidence is a strong indication of this. A meta-analysis released in 2024 indicated that misoprostol was a significant aid to the need of oxytocin relative to dinoprostone (RR = 0.83, p = 0.02), which is intrinsically effective in prompting uterine contractions.[10] On the same note, the second large meta-analysis on more than 10,000 patients validated the finding, that misoprostol is linked with greater success rate of induction and fewer additional augmentation techniques.[11] These findings are almost similar to the decrease in oxytocin use that was exhibited in our research which supports the strength of our findings.

In terms of mode of delivery, the current research showed that the rate of spontaneous vaginal birth, and a low rate of cesarean section was greater in the misoprostol group. Although the existence of a statistically significant difference in cesarean rates between misoprostol and dinoprostone has been reported as none in some previous meta-analyses,[12] several reporting studies have indicated the tendency to achieve better results of vaginal birth with misoprostol. The variation could be attributed to the variation in study design, population characteristics, and dosing regimens. In practice, in any cohort environment as we have in the real world, where treatment allocation is a mirror of clinical practice, misoprostol efficiency can be more directly related to better delivery outcomes.

Notably, there were no significant differences in maternal safety outcomes in this study as there were no complications related to tachysystole, fetal distress, or postpartum bleeding that were found. This agrees with the fact that there is some evidence in terms of systematic reviews that show that the two agents have similar safety profiles. A massive meta-analysis of 39 randomized trials showed no significant differences in important maternal outcomes in tachysystole and postpartum hemorrhage between misoprostol and dinoprostone.[12] As much as there are studies that propose a slightly increased uterine hyperstimulation rate with misoprostol, the differences usually have dose dependence and can be addressed in a clinical manner.[13]

The safety of misoprostol as shown in the current study by neonatal outcomes also have better APGAR scores and no more adverse neonatal events like NICU admission. These results are in line with available evidence that indicates that there are no significant differences in neonatal outcomes of the two agents. Several meta-analyses have shown that misoprostol and dinoprostone showed similar rates of low APGAR scores, NICU admission, and neonatal morbidity.[10,12] This implies that the enhanced effectiveness of misoprostol does not affect the safety of the neonatal care.

The multivariate analysis of the present study enhances the validity of the results by proving that misoprostol was an independent predictor of vaginal birth even after controlling one of the most important confounders. This is especially significant taking into consideration the non-randomized design. The strong independent predictor status of the role of Bishop score is also adequately maintained in the literature since cervical favorability is a vital determinant of successful induction. This study combines both real and statistically manipulated data to offer evidence that is both clinically relevant and methodologically sound in proving that misoprostol is an effective and safe alternative to dinoprostone in routine obstetric practice.

Strengths and Limitations

The strengths of this study are that it has a prospective design, equal sample size, and the extensive assessment of maternal and neonatal outcomes. The fact that multivariate analysis was conducted to correct the effects of confounding factors makes the findings more valid, whereas the fact that the study was conducted in a real clinical environment makes it more generalizable especially to resource-constrained settings. The study is however limited by its non-random nature, thus could cause residual confounding even after statistical correction. Also, being a single-center study, the results might not be entirely applicable to other populations and healthcare settings. The sample size used, though sufficient in primary outcomes, might be inadequate to identify rare adverse events.

CONCLUSION

Compared to dinoprostone, misoprostol has a better effect in terms of a faster progression of labour, a decreased incidence of other interventions and a higher probability of spontaneous vaginal delivery without affecting the safety of the maternal or neonatal outcome. Such results justify the application

of misoprostol as a highly effective and convenient induction of labour agent, especially in a place where cost and accessibility do matter. It is suggested to conduct further large-scale and multicenter studies that would allow confirming these findings and developing a better evidence base.

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