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Original research article

INDUCTION OF LABOUR WITH SUBLINGUAL MISOPROSTOL COMPARED TO VAGINAL DINOPROSTONE IN TERMS OF NEONATAL OUTCOME IN WOMEN WITH PROLONGED PREGNANCY

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Abstract: *Labor induction in postdate pregnancies can impact neonatal outcomes, including Apgar scores and the need for NICU care. Various induction agents, such as sublingual misoprostol and vaginal dinoprostone, offer differing efficacies. This study aims to compare the neonatal outcomes of these two agents to determine the more effective option for labor induction in postdate pregnancies.* ***Objective:*** *To compare neonatal outcomes, specifically Apgar scores <7 at 1 minute and NICU admissions within the first 24 hours, between neonates born to postdate women induced with sublingual misoprostol versus vaginal dinoprostone.* ***Methods:*** *This randomized controlled trial was conducted in the Department of Obstetrics and Gynecology, Unit 1, Holy Family Hospital, Rawalpindi, from January 2024 to July 2024. After Institutional Research Forum approval, 200 women meeting the selection criteria were randomized via the lottery method into two groups. Group I received 25 mcg of sublingual misoprostol every 4 hours up to 4 doses, and Group II received 3 mg vaginal dinoprostone every 6 hours up to 2 doses. Neonatal Apgar scores were recorded at delivery, and NICU admissions were monitored within 24 hours. Data were documented on structured proforma and analyzed using SPSS.* ***Results:*** *The mean maternal age in Group I was 27.17±4.71 years and in Group II 28.33±4.25 years. Both groups had comparable gestational ages (41.60±0.49 vs. 41.68±0.46 weeks) and parity (1.64±0.79 vs. 2.05±0.83). Group I neonates had higher mean Apgar scores at 1 minute (7.25±2.08) compared to Group II (6.62±2.07), with significant group differences (p=0.04). NICU admissions were required in 30% of neonates, with 48.8% needing NICU care, and fewer admissions in Group I (p=0.04). NICU care showed a significant association with maternal age over 28 years (p=0.000) and nulliparous status (p=0.007) but was not significantly different for those under 28 years or multiparous.* ***Conclusion:*** *Sublingual misoprostol demonstrated superior efficacy to vaginal dinoprostone in labor induction for prolonged pregnancies, with improved neonatal outcomes, including higher Apgar scores and fewer NICU admissions. Age and parity influenced outcomes, highlighting sublingual misoprostol as an effective choice for better neonatal health.*

Keywords: Prolonged Pregnancy, Sublingual Misoprostol, Vaginal Dinoprostone, Apgar score.

Introduction

Labor induction is a common intervention for managing prolonged pregnancies, where gestation exceeds 40 weeks. Labor induction involves artificially stimulating the uterus to start labor.(1, 2) This process accounts for approximately 25% of deliveries at term.(3) Cervical ripening, which prepares the cervix for labor, is a crucial step in facilitating delivery.(4) Prostaglandins are the agents responsible for both cervical ripening and inducing uterine contractions.(5, 6) Typically, a normal vaginal delivery occurs between 37 and 42 weeks of pregnancy.(7) Effective induction methods are crucial for optimizing both maternal and neonatal outcomes. Sublingual misoprostol and vaginal dinoprostone are two widely used agents for this purpose.(8) Misoprostol, a prostaglandin E1 analogue, is known for its efficacy in cervical ripening and labor induction, offering advantages such as ease of administration and cost-effectiveness.(9) Dinoprostone, a prostaglandin E2 analogue, is traditionally used for its controlled release and well-documented safety profile.(10) Despite the extensive use of these agents, their comparative effectiveness in terms of neonatal outcomes, such as APGAR scores and the need for NICU admissions, remains a subject of ongoing research. This study aims to compare the efficacy and safety of sublingual misoprostol versus vaginal dinoprostone in inducing labor in women with prolonged pregnancies, focusing on their impact on neonatal health outcomes. By evaluating these two induction methods, the study seeks to provide insights into the optimal choice for improving neonatal well-being and guiding clinical practice. Thus the objective of the study was to compare the neonatal outcomes in terms of frequency of Apgar scores <7 at 1 minute and need for NICU care in 1st 24 hours between neonates born to postdate women induced with sublingual misoprostol, with those induced with vaginal dinoprostone.

Methodology

The study was a randomized controlled trial conducted in the Obstetrics and Gynaecology Unit-I of Holy Family Hospital, Rawalpindi, over six months from January 2024 to July 2024. A total of 260 participants were included, with 130 women in each group, determined based on neonatal outcomes using the WHO sample size calculator. The calculations considered a 95% confidence level and 80% power. For APGAR scores below 7, expected populations were set at 0.126 and 0.04, requiring 130 participants per group. Similarly, for NICU admissions, anticipated

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populations of 0.2539 and 0.1219 suggested a requirement of 110 participants per group. To ensure adequate statistical power, a higher sample size was selected.

Eligible participants were gravid women with a singleton, cephalic pregnancy at or beyond 41 completed weeks of gestation, with reactive pre-induction cardiotocography (CTG), intact membranes, and a normal detailed anomaly scan. Exclusions were women with any diagnosed medical disorder, pre-induction fetal distress, intrauterine growth restriction (IUGR), or any known allergy to prostaglandins. Additionally, women with prior caesarean sections, myomectomy, uterine surgery, or contraindications to spontaneous vaginal delivery, and those with parity above three were excluded.

After approval from the Institutional Research Forum of Rawalpindi Medical College, participants meeting the criteria were provided detailed information regarding the study's purpose and procedures, followed by written informed consent. Randomization was achieved through the lottery method, assigning participants into two study groups to receive either misoprostol or dinoprostone for labour induction. The misoprostol group received 25 mcg sublingually at four-hour intervals, with a maximum of four doses. The dinoprostone group was administered 3 mg in the posterior fornix of the vagina at six-hour intervals, up to a maximum of two doses. Neonatal outcomes were assessed at delivery, specifically APGAR scores and NICU admission requirements. Data were systematically recorded on a structured proforma, and SPSS Version 25 was used for statistical analysis.

Results

In this study, the maternal age in Group I was 27.17±4.71 years, while in Group II it was 28.33±4.25 years. The gestational age was similar between the groups, with Group I at 41.60±0.49 weeks and Group II at 41.68±0.46 weeks. The average parity was 1.64±0.79 in Group I and 2.05±0.83 in Group II. The Apgar score at 1 minute was higher in Group I, with a mean score of 7.25±2.08, compared to 6.62±2.07 in Group II. The gender distribution of neonates showed that 51.2% were male (133) and 48.8% were female (127). Regarding APGAR scores at 1 minute, 30% of neonates (78) had a score of less than 7, while 70% (182) had a score greater than 7. Additionally, 48.8% of neonates (78) required NICU admission. In comparing the APGAR scores between Group I and Group II, a significant difference was found with a p-value of 0.04; specifically, 31 neonates in Group I had an APGAR score of less than 7, while 47 in Group II had a score below 7. Conversely, 99 neonates in Group I scored above 7, compared to 83 in Group II. Additionally, the need for NICU care also showed a significant difference (p-value = 0.04), with 31 neonates in Group I requiring NICU care compared to 47 in Group II, while 99 neonates in Group I did not need NICU care, versus 83 in Group II. In the stratification by age, the need for NICU care was not significantly different among women under 28 years old, with 26 in Group I and 16 in Group II requiring NICU care (p-value = 0.333). However, for women over 28 years old, a significant difference was observed, with 5 in Group I and 31 in Group II needing NICU care (p-value = 0.000). Regarding parity, the need for NICU care was significantly higher in nullipara women, with 31 in Group I and 41 in Group II (p-value = 0.007). In contrast, the need for NICU care among multipara women was not significantly different, with 0 in Group I and 6 in Group II (p-value = 0.083).

Table 1: Comparison of Maternal and Neonatal Characteristics between Group I and Group II

Variables	Groups	
	Group I	Group II
Age (Year)	27.17±4.71	28.33±4.25
Gestational age	41.60±0.49	41.68±0.46
Parity	1.64±0.79	2.05±0.83
APGAR Score	7.25±2.08	6.62±2.07

Table 2: Distribution of Neonatal Gender, APGAR Scores, and NICU Admission (n= 260)

Variables	Frequency(%)
Gender of Neonates	
Male	133(51.2%)
Female	127(48.8%)
APGAR Score at 1 minute	
< 7	78(30%)
>7	182(70%)
NICU Admission	78(48.8%)

Table 3: Comparison of Need for NICU care and Apgar score in both groups (n= 260)

	Groups		P-Value
	Group I	Group II	
APGAR Score			
<7	31	47	0.04
>7	99	83	
Need for NICU care			
Yes	31	47	0.04
No	99	83	

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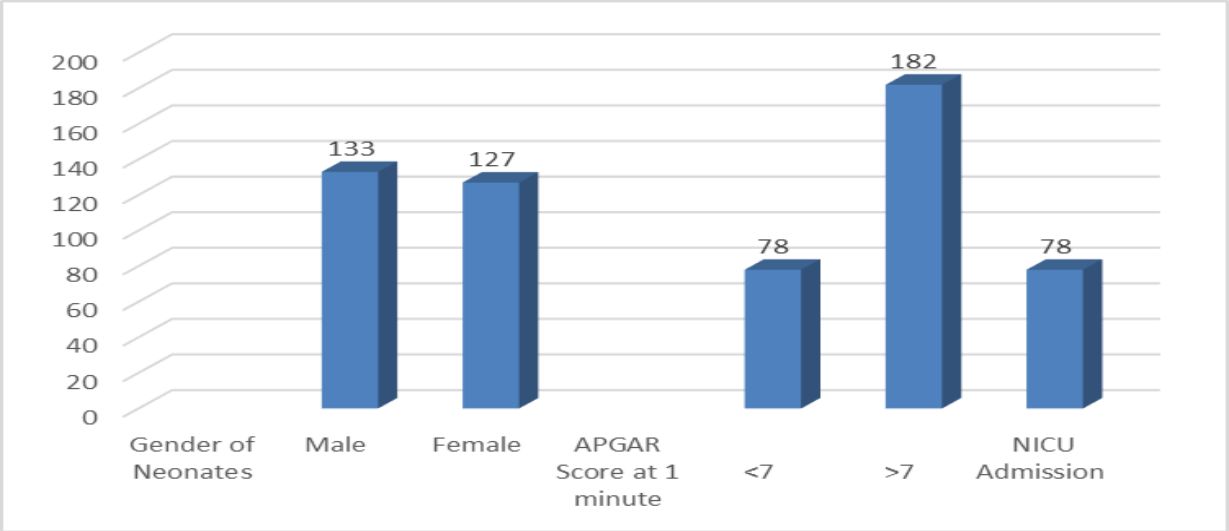

Fig 1: Demographic and characteristics

Table 4: Stratification of Need for NICU care concerning Age and parity (n= 260)

		Groups		P-Value
		Group I	Group II	
Age	**Need for NICU care**			
<28 years	yes	26	16	0.333
	No	38	36	
>28 years	yes	5	31	0.000
	No	61	47	
Parity				
Nullipara	yes	31	41	0.007
	No	73	42	
Multipara	yes	0	6	0.083
	No	26	41	

Discussion

This study aimed to compare neonatal outcomes, specifically the incidence of APGAR scores below 7 at 1 minute and the need for NICU care within the first 24 hours, between newborns delivered to post-term women induced with sublingual misoprostol and those induced with vaginal dinoprostone. To achieve this, a randomized controlled trial was conducted in the Obstetrics and Gynaecology Unit-I at Holy Family Hospital, Rawalpindi. A total of 260 cases were selected through non-probability consecutive sampling, based on predetermined inclusion and exclusion criteria.

Existing literature indicates that there is no significant difference in the average time from induction to delivery between the two groups (14.32±0.13 hours in Group I vs. 14.92±0.18 hours in Group II, p=0.75), as well as in the mode of delivery, indications for cesarean section, and perinatal outcomes. However, a significant difference was noted in the requirement for oxytocin augmentation, with 32% in Group I and 68% in Group II (p=0.005). Low-dose vaginal misoprostol was found to be equally effective and safe as dinoprostone gel for cervical ripening and labor induction at term.(11) In our study, the mean APGAR score ± standard deviation was 7.25 ± 2.08 in the misoprostol group, compared to 6.62 ± 2.07 in the dinoprostone group.

Our research found that 51.2% of the neonates were male and 48.8% were female. An APGAR score below 7 was observed in 30% of cases, while 70% had scores above 7. Additionally, 30% of the neonates required NICU care, whereas 70% did not. In the misoprostol group, 23.84% of neonates had APGAR scores below 7, compared to 36.15% in the dinoprostone group, with significantly better outcomes for misoprostol (p-value = 0.000). In a previous study, 16 neonates in the misoprostol group required NICU admission, compared to 5 in the dinoprostone group. Four neonatal deaths were reported in the misoprostol group, while two occurred in the dinoprostone group. Moreover, 44.4% of patients in the misoprostol group had meconium-stained liquor, compared to 34% in the dinoprostone group. Dinoprostone was found to be more effective in pregnancies at or beyond 41 weeks, although misoprostol showed comparable outcomes but is not the first-choice drug.(12)

Our study's chi-square analysis revealed a significant association between study groups and the need for NICU care (p-value = 0.042). Among women under 28 years old, there was no significant association between study groups and NICU care (p-value = 0.333), while in women over 28, a significant association was found (p-value = 0.000). A significant relationship between study groups and NICU care was also observed across different parity groups, with p-values of 0.007 and 0.083, respectively. Previous research highlighted that although misoprostol was more effective, the incidence of uterine hyperstimulation was significantly higher with the misoprostol protocol compared to

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dinoprostone. Nonetheless, NICU admissions and APGAR scores at 1 and 5 minutes were similar between the groups, with misoprostol being more efficient for labor induction.(13) In another study, women in the misoprostol group reported higher pain levels between induction and administration of analgesia, although this difference did not reach statistical significance. Vaginal misoprostol was found to be a more effective induction agent than 1 mg dinoprostone vaginal gel, with no adverse effects on delivery mode or fetal outcomes. The increased pain associated with misoprostol must be balanced against its shorter induction time and reduced need for intravenous oxytocin augmentation.(14)

Conclusion

This study concludes that sublingual misoprostol is more effective than vaginal dinoprostone for labor induction in women with prolonged pregnancy, as evidenced by significantly better neonatal outcomes. The misoprostol group had a lower frequency of APGAR scores below 7 and fewer neonates requiring NICU care compared to the dinoprostone group. Effect modifiers, such as age and parity, influenced outcomes, with notable exceptions for women under 28 years of age. Overall, misoprostol offers a favorable alternative to dinoprostone for cervical ripening and labor induction, contributing to improved neonatal well-being.

Declarations

Data Availability statement
All data generated or analyzed during the study are included in the manuscript.
Ethics approval and consent to participate.
Approved by the department concerned. (IRBEC-HFHISB-02/23)
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Conflict of interest

The authors declared an absence of conflict of interest.

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References

1. Recommendations W. Induction of labour at or beyond term. Geneva: World Health Organization. 2018.
2. Summers L. Methods of cervical ripening and labor induction. Journal of Nurse-Midwifery. 1997;42(2):71-85.
3. Deepika T, Nagabushan H, Manohar R. A comparative study between sublingual misoprostol (PGE1) versus intracervical dinoprostone Gel (PGE2) in the induction of labor:-A prospective observational study. Journal of Pharmacology and Pharmacotherapeutics. 2019;10(4):132-7.
4. Kurian MJ, Rao B, Rao A, Shameem V. Effect of vaginal pH on efficacy of dinoprostone gel for labour induction. International Journal of Reproduction, Contraception, Obstetrics and Gynecology. 2016;5(4):1196-202.
5. Sahu RR, Sonawane A. A prospective study of sublingual misoprostol (PGE1) versus intracervical dinoprostone (PGE2) followed by sublingual misoprostol (PGE1) for induction of labour in singleton full term pregnancy. Indian Journal of Obstetrics and Gynecology Research. 2016;3(4):307-13.
6. Pierce S, Bakker R, Myers DA, Edwards RK. Clinical insights for cervical ripening and labor induction using prostaglandins. American Journal of Perinatology Reports. 2018;8(04):e307-e14.
7. Spong CY. Defining "term" pregnancy: recommendations from the Defining "Term" Pregnancy Workgroup. Jama. 2013;309(23):2445-6.
8. Faucett A, Daniels K, Lee H, El-Sayed Y, Blumenfeld Y. Oral misoprostol versus vaginal dinoprostone for labor induction in nulliparous women at term. Journal of Perinatology. 2014;34(2):95-9.
9. Arage MW. Labor Induction. New Aspects in Cesarean Sections: IntechOpen; 2023.
10. Lokugamage AU. The use of misoprostol for labour and delivery: University of London, University College London (United Kingdom); 2004.
11. Madaan M, Agrawal S, Puri M, Nigam A, Kaur H, Trivedi SS. Is low dose vaginal misoprostol better than dinoprostone gel for induction of labor: a randomized controlled trial. Journal of clinical and diagnostic research: JCDR. 2014;8(9):OC31.
12. Shafiq AA, Shuja S, Imran F, Kishwar N, Liaquat N. Comparison of misoprostol with dinoprostone for induction of labor in postdated pregnancy. Journal of Surgery Pakistan (International). 2014;19(1):1-5.
13. Liu A, Lv J, Hu Y, Lang J, Ma L, Chen W. Efficacy and safety of intravaginal misoprostol versus intracervical dinoprostone for labor induction at term: A systematic review and meta-analysis. Journal of Obstetrics and Gynaecology Research. 2014;40(4):897-906.
14. Danielian P, Porter B, Ferri N, Summers J, Templeton A. Misoprostol for induction of labour at term: a more effective agent than dinoprostone vaginal gel. BJOG: An International Journal of Obstetrics & Gynaecology. 1999;106(8):793-7.

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