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Original Research Article

Is mifepristone better than dinoprostone gel for induction of labor at term? Feto-maternal outcome in tertiary referral hospital

K. Sowmya Krishna*, Janaki Vellanki

Department of Obstetrics and Gynecology, Gandhi Medical College and Hospital, Secunderabad, Telanagana, India

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***Correspondence:**
Dr. K. Sowmya Krishna,
E-mail: sowmyakrishna1990@gmail.com

ABSTRACT

Background: The global increase in labor inductions has resulted in corresponding rise in failed inductions, instrumental deliveries and c-section rates significantly contributing to feto-maternal morbidity and mortality indicating critical need for better induction methods ensuring safer outcomes with minimal complications. This study compares 200mg oral mifepristone with 0.5mg intracervical dinoprostone gel for labor induction in latent phase at term gestation, focusing on safety, efficiency, complications and feto-maternal outcomes.
Methods: This was a prospective, randomized comparative study conducted at Gandhi Hospital, a tertiary healthcare teaching institute, from April to June 2024 admitted for safe confinement after 37 completed weeks of gestation in OBG department, divided into Group A and B (75 each) receiving 200mg oral mifepristone and 0.5mg intracervical dinoprostone gel respectively.
Results: The induction delivery interval was significantly shorter in Group B compared to Group A. However, the rate of successful induction of labor (IOL) or vaginal delivery was higher in Group A. Group B had higher rate of interventional deliveries including vacuum, forceps delivery or LSCS, with more maternal complications & NICU admissions.
Conclusions: It concludes that mifepristone is a better drug reducing the need for additional prostaglandins or other induction methods and has modest effect on cervical ripening for labor induction at term with lesser complications despite longer induction delivery interval compared to dinoprostone. Therefore, mifepristone is a safe, efficient and cost-effective drug offering easy patient compliance and application.

Keywords: Cervical dilatation, Cost effective, Dinoprostone gel, Mifepristone, Term gestation, Safety and efficacy

INTRODUCTION

The incidence of labor induction has been steadily increasing over recent decades in both developed and developing countries. It involves artificially initiating uterine contractions during the latent phase of labor when they are inadequate resulting in the progressive effacement and dilation of cervix, facilitating vaginal delivery.[1,2] Induction is advised when its benefits to the mother and fetus outweighs the risk of continuing the pregnancy, as it can lower the chances of unnecessary cesarean sections.[3] Various methods are employed for labor induction, but an ideal agent should be safe, easy to use, and acceptable to the patient.[4,5] Recent studies highlight mifepristone as a promising drug for late-pregnancy labor induction due to its anti-progestin properties.[6]

Mifepristone (RU-486), a synthetic steroid hormone analogue, has both anti-progesterone and anti-glucocorticoid effects. It acts centrally and peripherally.[7] As a 19-nor steroid, it binds more strongly to progesterone receptors than progesterone itself, blocking its cellular action. With rapid absorption and a long half-life of 25-30 hours, mifepristone selectively antagonizes progesterone receptors at low doses. It stimulates endogenous prostaglandin release and increases uterine sensitivity to

prostaglandins, aiding labor progression even at term.[8] At higher doses, it blocks cortisol by acting on glucocorticoid receptors, affecting the hypothalamic-pituitary-adrenal axis, raising circulatory cortisol levels thereby managing hyperglycemia in some patients. Mifepristone's affinity is greater for glucocorticoid 2 receptor than glucocorticoid 1.[7]

Dinoprostone is a synthetic analog of naturally occuring prostaglandin (PGE2) used to induce labor. Applied locally, it aids cervical ripening and delivery. Until recently, it was commonly used, but other methods are now being explored to reduce complications and improve outcomes. Successful labor induction depends on the state of the cervix, assessed through Bishop score.[9]

Induction poses challenges in pregnant women with an unfavorable cervix, especially when they haven't undergone cervical ripening phase before labor. Dinoprostone gel was traditionally used for term patients, while mifepristone was employed for mid and early pregnancy termination, pre-abortion cervical dilation, or labor induction in cases of intrauterine death (IUD).[2] Recent studies suggest Mifepristone is potential for labor induction in term pregnancies with live fetuses, though research remains limited.

The purpose of this study was to compare the efficacy of Oral Mifepristone and intra-cervical Dinoprostone gel for cervical priming at term induction with unfavorable cervices and find out whether it is suitable and effective labor inducing agent. It evaluates cervical score changes, induction-to-delivery interval, delivery mode, maternal complications and fetal outcomes via Apgar scores, NICU admissions, and the overall safety and efficacy of these drugs.[10]

METHODS

This prospective randomized comparative study was conducted from April to June 2024 over a three-month period at Gandhi Hospital, Hyderabad, Telangana, a tertiary referral and teaching institute. The study included 150 term patients undergoing induction and delivery in the Obstetrics and Gynecology department.

Participants were divided into two groups of 75 each. Group A received 200 mg oral mifepristone, while Group B received 0.5 mg dinoprostone gel administered intra-cervically. The pre-induction Bishop score was assessed, and post-induction scores were evaluated after 24-48 hours or at labor onset. If cervical dilation and effacement remained inadequate or uterine contractions were insufficient, a repeat dose was administered. Oxytocin augmentation was initiated after 5 cm cervical dilatation if progress was unsatisfactory, along with artificial rupture of membranes when necessary.[1] Maternal side effects, induction-to-delivery intervals, mode of delivery, fetal distress/complications, Apgar scores at 1 and 5 minutes, and need for NICU admission were recorded

Patients must provide consent for the study and meet specific inclusion criteria. Eligible participants include those with term gestation (37 completed weeks to 40 weeks), aged 18 to 40 years. The study is limited to singleton pregnancies with cephalic presentation in latent phase of labour, with bishop score less than 6, with estimated fetal weight between 2 to 4 kg. Participants must either have previous history of NVD or an adequate pelvis for a trial of labor. They should not have any comorbidities/medical conditions nor contraindicated for mifepristone (e.g., chronic adrenal failure, concurrent long-term corticosteroid therapy, hemorrhagic disorders) and dinoprostone gel (e.g., asthma or glaucoma).

Patients with a history of instrumental delivery, previous LSCS, or uterine surgery, and those with multiple pregnancies, grand multipara (≥4), malpresentation, cephalopelvic disproportion, contraindicated to vaginal delivery, antepartum hemorrhage, or patients with significant maternal cardiac, renal, or hepatic complications, hypersensitivity to mifepristone or prostaglandins, adrenal insufficiency, severe pre-eclampsia/eclampsia, active genital herpes or other unidentified medical conditions, PROM, or symptoms of chorioamnionitis, severe oligohydramnios, non-reassuring FHR patterns, IUFD, IUGR and EFW <2kg or >4kg are all excluded.

Statistical analysis

Data was entered in Microsoft Excel as a master chart and analyzed using descriptive statistics, group comparison, and mean and standard deviation were calculated using T-test and chi-square test, with p value <0.05 as significant.

RESULTS

In our study baseline demographic data like Age, parity, stage of labor (latent phase), period of gestation, indication for induction of labor and pre and post Bishop scores were all considered and participants were divided randomly into 2 groups, Group A (mifepristone 200 mg oral, single dose) & Group B (dinoprostone gel 0.5 mg intracervically, repeated as necessary). This study assessed the efficacy of mifepristone as a labor-inducing agent on term patients compared to dinoprostone gel, fetal and neonatal wellbeing along with maternal morbidity and mortality.

Table 1: Patient age.

Age (in years)	Count (%)
≤20	14 (9)
20- 24	84 (56)
25-29	43 (29)
30-34	7 (5)
≥ 35	2 (1)
Total	150

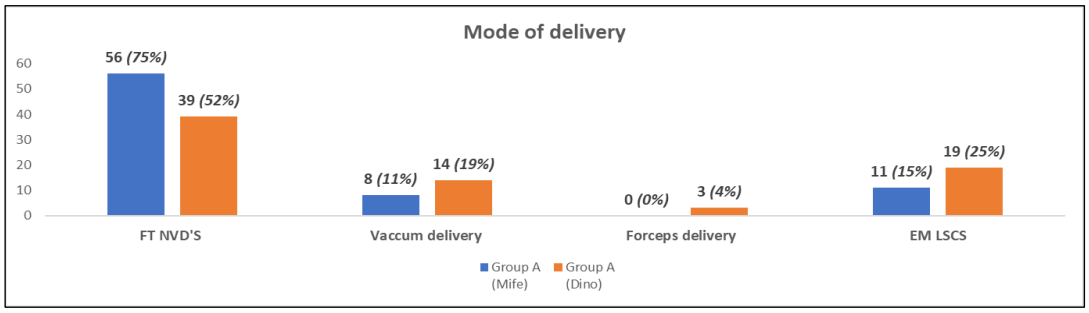

Figure 1: Mode of delivery.

Table 2: Parity index.

Parity	Count (%)
Primigravida	78 (52)
Multigravida	72 (48)
Total	150

Table 3: Bishop score.

		Count (%)	Group A (mife) mean±SD	Count (%)	Group B (Dino) mean±SD	P value
Pre-induction Bishop score (not significant)	≤ 3	27 (36)	2.96±0.19	39 (52)	2.77±0.43	0.0352
	>3	48 (64)	4.46±0.77	36 (48)	4.64±0.87	0.3189
	Total	75	3.92±0.95	75	3.66±1.15	0.1333
Post induction ≥ 6 Bishop score (significant)	≤24 hrs	35 (47)	8.8±1.66	27 (36)	6.33±0.74	<0.0001
	24 to 48 hrs	19 (25)	10.31±1.43	14 (19)	8.22±0.97	<0.0001
	After 48 hrs	8 (11)	10.75±1.035	1 (1%)	8±0	-
	Total	62 (83)		42 (56)		

Table 4: Induction delivery interval.

Duration in hours		Count (%)	Group A (mife) mean±SD	Count (%)	Group B (Dino) mean±SD	P value
Induction delivery interval	24 hrs	37 (49)	16.46±4.49	33 (44%)	13.79±4.64	0.0171
	24 - 48 hrs	23 (31)	37.92±6.72	34 (45%)	33.69±6.07	0.0166
	> 48 hrs	15 (20)	62.52±10.02	8 (11%)	65.62±14.77	0.5555
Overall induction delivery interval			32.25±19.04		28.3±17.28	0.1854

Table 5: Failed induction.

Total failed induction cases [post induction bishop score ≤5 after 24 hours]	Count (%)	Group A (mife) mean±SD	Count (%)	Group B (Dino) mean±SD	P value
Failed induction	6 (8)	4.83±0.41	13 (17)	3.76±0.44	0.0001

Table 6: Maternal complications.

Maternal complications	Group A (mife) (%)	Group B (Dino) (%)	Chi square value	P value
Vomiting/nausea	3 (4)	10 (13)	4.35	0.0370
Uterine abruption	1(1)	1 (1)	0.01	0.9242
Uterine hyperstimulation	0 (0)	1 (1)	1.14	0.2866
PPH	0 (0)	1 (1)	1.14	0.2866
No side effects	71 (95)	62 (83)	5.37	0.0204
Total	4 (5)	13 (17)		

Table 7: Fetal complication.

Fetal complication	Group A (mife) (%)	Group B (Dino) (%)	Chi square value	P value
Respiratory distress	4 (5)	12 (16)	4.89	0.0568
Meconium aspiration	2 (3)	5 (7)	1.77	0.2455
Cord prolapse	0	0	-	-
Total	6 (8)	17 (23)	6.21	0.0127

Table 8: Apgar scores.

		Count (%)	Group A (mife) mean±SD	Count (%)	Group B (Dino) mean±SD
Apgar score <7	1 min	2 (3)	6±0	12 (16)	5.58±0.52
	5 min	0	0±0	3	5.66±0.57

Table 9: NICU.

	Group A (%)	Group B (%)
NICU	3 (4)	17 (23)

DISCUSSION

In our study, the mean pre-induction Bishop score (Table 3) was 3.92±0.95 in Group A and 3.66±1.15 in Group B, with no significant difference. This was consistent with studies by Sandhya et al and Sailatha et al, while findings from Yelikar et al, Gupta et al, Pal and Khaula et al and Desh mukh et al differed but however their values were not statistically significant.[6,11-15]

Post-induction (Table 3), overall 83% of Group A (i.e 8.8±1.66) achieved a Bishop score ≥6 compared to 56% of Group B (6.33±0.74), indicating significantly better outcome in Group A. Sah and padhye et al, Neilson et al, Athawale et al, Priyanka et al, Gupta et al, Gaikwad et al, Yelikar et al, Pathak et al were all similar to our study and they were statistically significant.[4,10,13,14,16,18,21] Wing et al, Baev et al, were also similar to our study but their studies were not statistically significant.[20,22] But Sandhya et al, Sailatha et al, Pal & Khaula, compared mifepretone with dino prostone gel and found that patients induced with dino prostone group had more favorable Bishop score.[11,12,15] This differed from our study, however it was not statistically significant.

The induction-to-delivery interval (Table 4), was marginally longer in Group A (32.25±19.04 hours) compared to Group B (28.3±17.28 hours). This difference was not statistically significant and aligns with findings of Neilson et al and Athawale et al whereas Sandhya et al, Gupta et al, Gaikwad et al, Sailatha et al, Deshmukh et al, and Pathak et al were also similar to our study but statistically significant.[4,6,8,11,12,14-16,18] Baev et al had similar induction delivery interval in both groups, However Sah et al and Yelikar et al studies had significantly more induction delivery interval with dinoprostone group, which differed from our study.[10,13,20]

Failed induction (Table 5), was significantly more frequent in Group B (17%) compared to Group A (8%). It was the leading cause of LSCS in both groups with higher rate in Group B (25%) compared to Group A (15%), while vaginal deliveries were more common in Group A (86%) than Group B (75%) aligning with prior research by Neilson et al, Athawale et al, Priyanka et al, Gupta et al, Wing et al, Gaikwad et al, Sailatha et al, Yelikar et al and Pathak et al which were statistically significant.[4,8,12,14,22] Sandhya et al, Sah et al, Deshmukh et al, Pal & Khaula et al also showed similar results in their study but it was statistically not significant.[6,10,11,15] Baev et al found same number of failed induction rate in both groups.[20]

Instrumental deliveries (Figure 1: Mode of delivery) were also more frequent in Group B (23%) compared to Group A (11%) as observed in similar studies by Neilson et al, Athawale et al, Sailatha et al and Pal & Khaula et al.[8,12,15,17] Maternal complications (Table 6) were three times higher in Group B (17%) compared to Group A (5%), with uterine hyperstimulation seen only in Group B (1.33%), while uterine abruption occurred equally in both groups. This was statistically significant and consistent with studies of Sandhya et al, Deshmukh et al, Yelikar et al and Pathak et al, Athawale et al, Gaikwad et al, Sailatha et al were also similar to our study but statistically not significant.[4,8,6,11-13,18] Sah et al, Gupta et al, Baev et al, Pal & Khaula et al showed statistically significant number of maternal complications in their study in both the groups.[10,14,15,20]

Fetal complications (Table 7), including fetal distress, were significantly more frequent in Group B (23%) compared to Group A (8%). Apgar scores <7 (Table 8) at 1 minute and 5 minutes were more frequent in Group B, with 12 and 3 cases, respectively, compared to 2 and 0 in Group A. NICU admissions (Table 9) were also higher in Group B (23%) versus Group A (4%). Athawale et al and Gupta et al were similar to our study.[8,14] Sandhya et al, Wing et al, Gaikwad et al, Yelikar et al, Deshmukh et al, Pathak et al were also similar to our study but they were statistically not significant.[4,6,11,13,18,22] Sah et al, Neilson et al, Sailatha et al, Baev et al compared both mifeprestone and dinoprosotne gel and found same number of fetal

complications in both groups, though it was not significant.[10,12,16,19]

All the above studies support this study findings, indicating that mifepristone is a more effective and safer induction agent even at term gestation compared to dinoprostone gel.

Limited follow-up duration may fail to capture long-term maternal or neonatal outcomes. As Not much of studies were under taken, this study highlights the need for involving more personnel, extending the duration, and ensuring long-term follow-up with patients. Additionally, future research should include larger populations and consider diverse factors, such as maternal medical conditions and there by conducting more comprehensive studies which would provide valuable insights into the outcomes of labor induction using these drugs, profound maternal and neonatal outcomes ultimately benefiting society on a broader scale.

CONCLUSION

In conclusion, mifepristone proved to be a superior cervical ripening agent compared to the routinely used intracervical dinoprostone gel. It required less intervention and improved labor induction outcomes in term pregnancies with comparatively better efficacy. Although the induction-to-delivery interval was slightly longer with mifepristone, the rate of successful vaginal delivery was more with better neonatal outcomes. Mifepristone offers additional advantages such as ease of oral administration, storage stability at room temperature, and allowing patients to remain ambulatory. In contrast, dinoprostone gel requires refrigeration, medical personnel for administration, and strict aseptic techniques. Mifepristone caused no significant maternal complications, uterine contraction issues, or excess blood loss. Thus, oral mifepristone (200 mg) is a safe, cost-effective, and patient-friendly alternative to dinoprostone gel (0.5 mg).

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REFERENCES

1. Cunnigham FG, Leveno KJ, Bloom SL, Spong CY, Dashe JS, Hoffman BL, Casey BM, Jeanne S. Sheffeld William Obstetrics. 24th ed. McGraw-Hill, New York, Chapter 37; 2014:668-671.
2. Hiralal K. DC Dutta's text book of Obstetrics. 8th ed. Chapter 16, Chapter 35. Jaypee Brothers Medical Publishers;2018:203,601.
3. Cunnigham FG, Leveno KJ, Bloom SL, Hauth JC, Williams LC. Williams Obstetrics. 22nd ed. McGraw Hill Professional; 2005:536.
4. Pathak A, Singh S, Singh S, Kumar R, Tyagi A. Comparative study to evaluate the efficacy and safety of oral Mifepristone versus intracervical Dinoprostone gel for induction of labour and their effects on fetomaternal outcome. Int J Reprod Contracept Obstet Gynecol. 2019;8(7):2678-82.
5. Speroff, L. and Fritz, M. The clinical gynecologic endocrinology and infertility. 7th ed. Lippincott Williams & Wilkins, Philadelphia; 2005.
6. Deshmukh K, Patange RP. Comparative study between mifepristone and dinoprostone gel for cervical ripening and induction of labour. Int J Heal Sci. 2022;(I):4067-77.
7. Autry Blake M, Wadhwa Roopma. Mifepristone. In: StatPearls. Treasure Island (FL): StatPearls Publishing; 2024.
8. Athawale R, Acharya N, Samal S, Hariharan C. Effect of Mifepristone in cervical ripening for induction of labour. Int J Reprod Contracept Obstet Gynecol. 2013;2(1):35-8.
9. American college of obstetricians and gyneacologists. Induction of labor. Practice bulletin no. 10. Washington, D.C.: ACOG; 1999.
10. Sah MK, Padhye SM. Mifepristone versus intracervical prostaglandin E2 gel for cervical ripening in primigravid patients at term. Int J Reprod Contracept Obstet Gynecol. 2018;7(3):824-8.
11. Kumari S, Solanki V, Singh U, Mehrotra S. Comparative study of mifepristone with dinoprostone gel in induction of labor in full-term pregnancy: an open-label randomized controlled trial. J South Asian Feder Obs Gynae. 2021;13(3):98-102.
12. Sailatha R, Famida AM, Chellaiyan VG, Vijayalakshmi K, Sathiya S, Renuka S.. Mifepristone: an alternate to dinoprostone in induction of labour. Int J Reprod Contracept Obstet Gynecol. 2017;6(5):1880-4.
13. Yelikar K, Deshpande S, Deshpande R, Lone D. Safety and efficacy of oral mifepristone in preinduction cervical ripening and induction of labor in prolonged pregnancy. J Obstet Gynaecol of India. 2015;65(4):221-5.
14. Gupta A, Verma A, Madan I, Kashyap M. Efficacy and safety of oral mifepristone for cervical priming and induction of labor in term pregnancy. Int J Reprod Contracept Obstet Gynecol. 2018 Jul 1;7(7):2766.
15. Pal R, Khalua T. Comparative analysis of safety, efficacy and fetomaternal outcome in term live pregnancy for induction of labour with oral mifepristone and intracervical dinoprostone gel. IOSR J Dent Med Sci. 2018;17(4):77-81.
16. Hapangama D, James P Neilson. Mifepristone for induction of labour. Cochrane Database Syst Rev. 2009;2009(3):CD002865.
17. Hapangama D, Neilson JP. Mifepristone for induction of labour. Cochrane Database Syst Rev 2000;2000(4):CD002865.
18. Gaikwad V, Mittal B, Puri M. Comparative analysis of safety, efficacy and fetomaternal outcome of Induction of labor with mifepristone versus intracervical dinoprostone gel. Res J Pharm Biol Chem Sci. 2014;5(2):611.

19. Baev O, Karapetian A, Babich D, Sukhikh G. Comparison of outpatient with inpatient mifepristone usage for cervical ripening: A randomised controlled trial. Euro J Obstetr Gynecol Reproduct Biol: X. 2023;18:100198.
20. Baev OR, Rumyantseva VP, Tysyachnyu OV. Outcomes of mifepristone usage for cervical ripening and induction of labour in full-term pregnancy. Randomized controlled trial. Eur J Obstet Gynecol Reprod Biol. 2017;217:144-9.
21. Priyanka, Shetty SS. The effect of mifepristone in induction of labour at term. MedPulse Int J Gynaecol. 2021;17(2): 32-5.
22. Wing DA, Guberman C, Fassett M. A randomized comparison of oral mifepristone to intravenous oxytocin for labour induction in women with prelabour rupture of membranes beyond 36 weeks gestation. Am J Obstet Gynecol. 200;192(2):445-51.

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