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Misoprostol for labor induction: an alternative to dinoprostone? A retrospective observational study

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Abstract

Background Misoprostol and dinoprostone are established agents for labor induction. Since the introduction of standardized dosing regimens of misoprostol, few studies have evaluated its clinical use. The primary objective was to assess the implementation of a misoprostol-based induction protocol and its safety and effectiveness in routine obstetric care. Secondary objectives included comparing induction-to-delivery time between misoprostol and dinoprostone, evaluating the induction-to-labor interval, need for a second method, and obstetric/neonatal outcomes.

Methods We conducted a retrospective observational study from September 2021 to December 2024. Inclusion criteria were singleton term pregnancies undergoing labor induction with either misoprostol (Group 1) or dinoprostone (Group 2) and a Bishop score < 7.

Results 528 patients were included in Group 1 and 345 in Group 2. A robust double analysis was applied to balance age, gestational age, Bishop score, and parity, aiming to mitigate the potential influence of baseline differences between the groups. No significant differences were observed in induction-to-delivery time ($p = 0.710$) or time to active labor ($p = 0.652$). However, Group 1 showed a significantly higher vaginal delivery rate (OR = 1.38; 95% CI: 1.10–1.73; $p = 0.004$) and a lower risk of postpartum hemorrhage (OR = 0.58; 95% CI: 0.46–0.73; $p < 0.001$).

Conclusions The standardized oral misoprostol protocol proved safe and effective for labor induction in patients with an unfavorable cervix. Compared with vaginal dinoprostone, misoprostol showed similar neonatal outcomes and maternal advantages, including higher vaginal delivery rates and reduced postpartum hemorrhage, supporting its use in routine obstetric practice.

Keywords Induction of labor, Misoprostol, Dinoprostone, Labor, Cesarean section, Postpartum hemorrhage, Vaginal delivery

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Background

Dinoprostone is a synthetic analogue of prostaglandin E2 (PGE2). In Italy, the two most commonly used formulations are the 10 mg controlled-release vaginal insert (Propess 10 mg, 0.3 mg/h) and the intravaginal gel (Prepidil 1–2 mg). Dinoprostone primarily modifies cervical consistency, promoting dilation and effacement, and indirectly enhances myometrial responsiveness to oxytocin, facilitating uterine contractions [1]. Its use is recommended in the management of an unfavorable cervix [2]. A recent review highlighted several advantages of dinoprostone pessary for labor induction: it can be removed in cases of tachysystole or uterine hypertonus, often resolving these complications, and its controlled-release mechanism may allow a more gradual cervical ripening and labor onset [1]. The use of intravaginal dinoprostone gel markedly declined after the July 2021 note from the Italian Medicines Agency (AIFA), issued in response to a European Medicines Agency communication recommending greater caution and restricting its clinical use [3]. However, not all international societies adopted these limitations, leading to divergent practices [4, 5].

Misoprostol is a synthetic analogue of prostaglandin E1 (PGE1) initially developed with the purpose of preventing gastric ulcers [6]. While its effects on the female reproductive tract were initially considered incidental, misoprostol has become a cornerstone in obstetrical and gynecological practice in the last decade. Its favorable safety profile, minimal side effects, and room-temperature stability support its widespread use [7]. In labor induction, misoprostol facilitates cervical ripening and stimulates uterine contractions [8]. Both oral and vaginal administration routes have demonstrated efficacy in initiating labor and achieving delivery [7]. Alfirevic [9] highlighted that oral misoprostol is comparable to vaginal misoprostol and dinoprostone and, is associated with fewer low Apgar scores and postpartum hemorrhages than vaginal dinoprostone. When compared with oxytocin, oral misoprostol was associated with a significant reduction in cesarean rate but a significant increase of tachysystole [10]. These findings have solidified misoprostol's inclusion in labor induction guidelines [4, 11, 12] and its designation as an essential medicine by the World Health Organization [13]. In Italy, the landscape of labor induction practices underwent a significant shift in February 2021 when AIFA approved oral misoprostol for term labor induction, making it reimbursable by the National Health Service (https://www.aifa.gov.it/legge-648-96). The recommended protocol involved diluting a 200 mcg tablet to achieve a 25 mcg dose, administered every two hours, up to a maximum of 200 mcg/24 hours. However, this dilution method presented practical challenges, notably the difficulty in ensuring accurate dosing due to inconsistent tablet dissolution. To address these limitations, 25 mcg tablets were introduced commercially in May 2021, simplifying administration and minimizing potential dosage errors. Subsequently, these pre-dosed tablets were recommended in the Italian guidelines of induction of labour [14]. The introduction of this formulation represents a relevant advancement in clinical practice, as it allows, for the first time, the administration of a precise and standardized dose guaranteed by the manufacturer. This constitutes a substantial improvement compared with previous approaches, in which misoprostol tablets were dissolved in water, potentially resulting in variability in the administered dose.

In several Centers, including our own, the use of misoprostol in solution was therefore avoided due to concerns regarding dose accuracy and reproducibility. The availability of a tablet with a fixed dosage has contributed to enhancing the safety profile of the drug, thereby supporting its more consistent and reliable use in routine clinical practice. In this context, we designed the present study to evaluate the implementation of a labor induction protocol based on misoprostol and to assess its safety and effectiveness in routine obstetric care.

Methods

This retrospective observational study was conducted from September 1, 2021, to December 31, 2024, at *Ospedale della Misericordia*, Udine. Data was collected through a review of patient medical records and available hospital computer system data.

The inclusion criteria were singleton term pregnancies (≥ 37 weeks of gestation) undergoing labor induction during the study period with oral misoprostol – 25 mcg or 50 mcg tablets - (Group 1) or dinoprostone – 1 or 2 mg in gel or 10 mg pessary – (Group 2) and a Bishop score < 7. The exclusion criteria included the inability to retrieve the patient's medical record or the patient's refusal to continue with induction. The selection of the induction agent was based on individual patient clinical and anamnestic characteristics as determined by the attending obstetrician and so based on operator preference. Since its approval by AIFA and its marketing in predosed tablets, oral misoprostol has become the preferred first-line agent for most inductions due to its efficacy and cost-effectiveness. However, in certain clinical situations (e.g., specific cervical ripening requirements, contraindications to oral administration), vaginal dinoprostone was utilized. The protocol for misoprostol administration specifies two possible dosing regimens: 25 mcg tablets administered every 2 hoursup to a maximum of 8 tablets within 24 h (maximum 200mcg/24 hours); or 50 mcg every 4 h, with a maximum of 4 tablets administered within 24 h (maximum 200mcg/24 hours). Drug administration should be avoided in the presence of uterine contractions or onset of labor. As for dinoprostone, we have

two options: 10 mg vaginal pessary, placed near the cervix for up to 24 h, or as a 1–2 mg gel, administered every 6 h up to a maximum of 6 mg.

According to the hospital protocol, all patients undergoing labor induction are admitted to the obstetrics ward for maternal and fetal monitoring. Prior to the initiation of labor induction, all women underwent a non-stress test (NST) of approximately 30 minutes' duration or until predefined adequacy criteria were met. FHR monitoring was performed as follows: 45 min after the first misoprostol dose, 30 min after subsequent doses, continuous monitoring after dinoprostone gel, and intermittent monitoring every two hours after dinoprostone pessary placement.

The primary objective was to assess the safety profile of misoprostol when used according to the proposed induction protocol, with particular attention to maternal and fetal outcomes, in comparison with an established induction protocol based on dinoprostone.

Secondary objectives included evaluating the effectiveness of misoprostol versus dinoprostone in terms of time from induction initiation to delivery, time to labor onset, need for additional induction methods, mode of delivery, incidence of postpartum hemorrhage, and neonatal outcomes, including 5-minute Apgar scores, umbilical artery pH, and NICU admission.

Finally, we decided to evaluate the safety profile of misoprostol also in specific high-risk subgroups of our population, particularly women with PROM and those with gestational diabetes.

Table 1 Patients characteristics

Characteristic	Misoprostol $N=528^1$	Dinoprostone $N=345^1$	p-value[2]
Maternal age (years)	33.0 (29.0, 37.0)	34.0 (30.0, 38.0)	0.027
Reason for induction			
Post-term pregnancy	74 (14%)	42 (12%)	
PROM	145 (27%)	87 (25%)	
GDM	133 (25%)	91 (26%)	
Cholestasis	22 (4.2%)	18 (5.2%)	
Thrombophilia	33 (6.2%)	19 (5.5%)	
Polyhydramnios	21 (4.0%)	12 (3.5%)	
Oligohydramnios	26 (4.9%)	7 (2.0%)	
HDP	20 (3.8%)	12 (3.5%)	
Parity			0.003
P0	302 (57%)	229 (66%)	
P1	157 (30%)	92 (27%)	
P2+	69 (13%)	24 (7%)	
GA (days)	278 (8)	276 (8)	0.001
Bishop t0	2.31 (1.25)	2.00 (1.21)	0.001

PROM Premature Rupture of Membranes, *GDM* Gestational Diabetes Mellitus, *FGR* fetal Growth restriction, *HDP* Hypertensive Disorders of Pregnancy, *GE* Gestational Age, *P0* nulliparous, *P1* pregnant of second baby, *P2+* given birth to more than one baby, *t0* time zero

All patients who were followed or hospitalized at our institution signed a consent form allowing access to their medical records and the use of their data for scientific research purposes. The collected data was entered into an Excel spreadsheet accessible only to the study promoter and collaborators, all bound by confidentiality obligations and data protection regulations in accordance with current standards. The study was approved by the Institutional Review Board on November 20, 2023 (IRB Protocol No. 240/2023). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Statistical methods

Categorical variables were expressed by frequency and percentage, while continuous variables were expressed by median and interquartile range. Categorical variables were compared using the chi-squared test or Fisher's exact test, while quantitative variables were compared using the t test or Mann-Whitney U test, as appropriate. The effects of the method of induction on vaginal spontaneous delivery, post-partum hemorrhage, induction duration and time induction - active labor were assessed using a doubly robust analytical approach. Specifically, an exposure model (inverse probability weighting, IPW) was combined with outcome models: logistic regression for binary outcomes (vaginal spontaneous delivery and postpartum hemorrhage case) and a robust linear regression for continuous outcomes (induction duration and time induction - active labor). IPW was employed to balance differences in covariates between the two groups of induction. Standardized mean differences (SMDs) were calculated to discriminate unbalanced variables. The covariates included in the adjustment were maternal age, gestational age, parity and Bishop score at baseline. Statistical significance was accepted for $p<0.05$. All analyses were performed using Rstudio.

Results

A total of 873 patients were included in the study, with 528 in Group 1 and 345 in Group 2. In Group 1, the majority of patients underwent labor induction with misoprostol at a dose of 50 mcg (88%), while 12% received a tablet of 25 mcg. Regarding dinoprostone, 90.5% of patients were induced with the pessary (10 mg), while the remaining 9.5% received the vaginal gel (1 mg or 2 mg). In Table 1 the characteristics of patients included in the two groups are reported. A preliminary analysis highlighted some differences between the two groups. Maternal age at delivery was 33 years in Group 1 and 34 years in Group 2 ($p=0.027$), while gestational age differed by two days, though still statistically significant ($p=0.001$). Parity also varied between the groups, with a higher proportion of nulliparous women in Group 2 ($p=0.003$). Additionally,

the Bishop score at time 0 was lower in Group 2 compared to the misoprostol group. The primary indications for labor induction were comparable between the two groups, with the most common reasons being premature rupture of membranes (PROM), gestational diabetes, and post-term pregnancy.

Table 2 reports the number of patients in each group who required an alternative method to continue the induction process, with a higher incidence observed in Group 2.

A preliminary analysis revealed that the time from induction initiation to delivery was significantly shorter in Group 1 compared to Group 2 as reported in Table 3. No differences were observed for the other time-related variables assessed. Furthermore, the rate of spontaneous vaginal deliveries was higher in Group 1 than in Group 2, despite similar fetal outcomes. Finally, postpartum hemorrhage occurred more frequently in Group 2 than in Group 1.

To mitigate the potential influence of baseline differences between the two groups on induction time and maternal-fetal outcomes, a secondary analysis was performed. Specifically, a robust double analysis was applied to balance age, gestational age in days, Bishop score at t0, and parity (Fig. 1). The results of this secondary analysis indicated that there were no differences between the two groups in terms of induction duration and time from induction to active labor (Table 4). However, Group 1 showed a significantly higher likelihood of vaginal delivery compared to Group 2. Furthermore Group 1 was associated with a significantly lower risk for post-partum hemorrhage (Table 4).

We subsequently conducted a supplementary analysis to assess the efficacy of these two induction methods in at-risk populations, specifically focusing on the two categories most prevalent in our cohort: women with premature rupture of membranes and those with gestational diabetes. The corresponding data are presented in the tables provided as supplementary material (Tables 5 and 6). No statistically significant differences were observed between the two groups with respect to induction duration, mode of delivery, or maternal and neonatal complications.

Table 2 Number of induction methods used

Characteristic	Misoprostol *N* = 528	Dinoprostone *N* = 345	*p*-value
N° of induction methods			0.001
1	255 (48%)	158 (46%)	
2	178 (34%)	99 (29%)	
3	79 (15%)	60 (17%)	
4	15 (2.8%)	20 (5.8%)	
5	1 (0.2%)	9 (2.6%)	

Table 3 Maternal and fetal outcomes

Characteristic	Misoprostol *N* = 528	Prostaglandine *N* = 345	*p*-value
Induction duration (min)	1,322 (817, 2,249)	1,583 (867, 2,666)	0.031
Active labor (min)	152 (80, 290)	145 (70, 280)	0.365
Second stage of labour (min)	45 (21, 90)	47 (20, 95)	0.828
Time induction - active labor (min)	980 (575, 1,830)	1,205 (594, 2,070)	0.240
Vaginal Spontaneous Delivery (VSD)	410 (78%)	239 (69%)	0.006
Vaginal Operative Delivery (VOD)	52 (9.7%)	49 (14%)	0.039
Caesarean Section	67 (13%)	57 (17%)	0.113
Caesarean Section for CTG alteration	32/67 (48%)	23/57 (40%)	0.408
Operative delivery (CS or VOD) for CTG alteration	54/112 (48%)	47/92 (51%)	0.683
Apgar 5'	9.00 (9.00, 9.00)	9.00 (9.00, 9.00)	0.749
Apgar 5' ≥ 7	516 (98%)	339 (99%)	0.496
Umbilical artery pH	7.27 (7.22, 7.33)	7.27 (7.22, 7.32)	0.791
Weight (gr)	3,474 (3,160, 3,760)	3,345 (3,110, 3,625)	0.001
NICU admission	11 (2.1%)	7 (2.0%)	0.956
Post-partum hemorrhage	92 (17%)	93 (27%)	0.001

Discussion

In the present study, we primarily focused on evaluating the safety profile of the recently introduced misoprostol formulation for labor induction in patients with unfavorable cervix (Bishop score < 7), administered according to a standardized induction protocol, in comparison with an established protocol based on vaginal dinoprostone. Our findings suggest that this new formulation of misoprostol is characterized by a reassuring safety profile, with maternal and fetal outcomes comparable to those observed with dinoprostone. This observation is particularly relevant in light of previous concerns related to dose variability and safety associated with non-standardized preparations of misoprostol.

Within this context, the analysis of secondary outcomes provides additional insights into the clinical performance of the protocol. We found no significant difference between the two methods in terms of induction-to-delivery interval, indicating comparable overall effectiveness. Notably, the use of oral misoprostol was associated with a higher rate of vaginal delivery and a lower incidence of postpartum hemorrhage compared to vaginal dinoprostone, suggesting potential clinical advantages. Furthermore, neonatal outcomes were similar between groups, further supporting the safety of the protocol.

Dinoprostone and misoprostol are well-documented in the literature for their effectiveness in labor induction. Their mechanism of action involves binding to smooth muscle cells in the decidua, triggering uterine

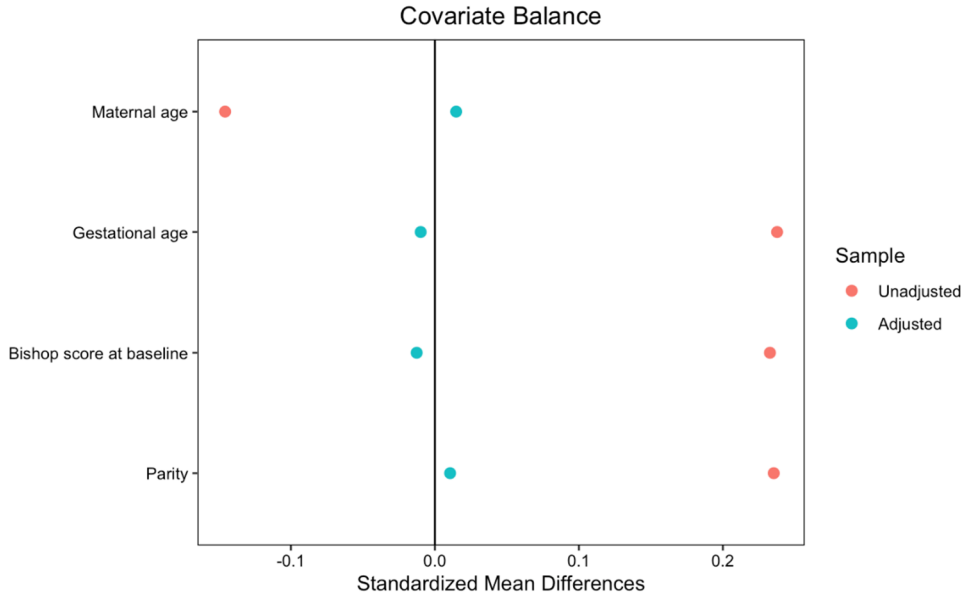

Fig. 1 SMDs of unbalanced covariates before and after IPW application

Table 4 Doubly robust estimation of the effect of Misoprostol vs. Dinoprostone on delivery outcomes

Outcome	Effect estimate (95% CI)	*p*-value
Time induction - active labor (min)		
Misoprostol vs. Dinoprostone	ß: 29.64 (-99.44, 158.72)	0.652
Induction duration (min)		
Misoprostol vs. Dinoprostone	ß: -28.59 (-179.48,122.30)	0.710
Vaginal Operative Delivery		
Misoprostol vs. Dinoprostone	OR: 1.38 (1.10,1.73)	**0.004**
Post-partum hemorrhage		
Misoprostol vs. Dinoprostone	OR: 0.58 (0.46,0.73)	**<0.001**

OR odds ratio estimated with logistic regression, *ß* beta regression estimated with robust linear regression

contractions. These contractions facilitate cervical ripening by promoting collagen degradation in the connective tissue of the cervical stroma. Notably, PGE1 induces a greater increase in uterine contractility compared to PGE2 [15]. In the literature, there are conflicting data regarding the duration of induction when comparing oral misoprostol versus vaginal dinoprostone. In fact, some authors have shown that dinoprostone is superior to misoprostol in terms of reducing the time between the start of induction and delivery [16], while other studies report the opposite [17–20]. Moreover, some authors find no difference between the two methods as highlighted in Alfirevic's Cochrane review [9]. In our case, we align with the latter, as no statistically significant differences were observed in terms of time. However, aside from differences in the time from induction to delivery, what clearly emerges from our study is a notable advantage of misoprostol in terms of increasing vaginal delivery rates. This finding accords with prior meta-analyses indicating a higher likelihood of vaginal birth with oral misoprostol compared to vaginal dinoprostone [9, 16, 18, 19]. The observed advantage may derive from the more stable and gradual absorption of oral misoprostol, resulting in a more physiological uterine contractility pattern and reduced need for additional interventions. This interpretation is supported by pharmacokinetic differences: oral misoprostol reaches peak plasma concentrations within 12–60 min and declines within 120 min, whereas vaginal dinoprostone exhibits a plasma half-life of approximately 2.5–5.0 min [15].

The significantly lower incidence of postpartum hemorrhage in the misoprostol group is another key finding of our retrospective study. The underlying mechanism is not entirely clear. However, misoprostol is usually used as a treatment for postpartum hemorrhage due to its well-known uterotonic properties, which contribute to effective uterine contractions, thereby reducing the risk of atony-related hemorrhage [21]. Interestingly, it appears that this reduction in postpartum hemorrhage risk is more strongly associated with the oral formulation rather than the vaginal formulation [9]. In our study, this difference remained statistically significant even after adjusting for confounding factors to ensure greater homogeneity between the two groups. Nevertheless, not all studies have yielded consistent results regarding a protective effect on PPH of misoprostol versus dinoprostone. For instance, in a 2023 systematic review and meta-analysis of 39 randomized controlled trials, Taliento et al. [22] found no statistically significant difference in PPH rates between th two agents, with consistent results across subgroups by route of administration. More granular evidence from a 2024 individual participant data meta-analysis of eight trials including 4,180 women suggested that

low-dose vaginal misoprostol was associated with lower composite adverse maternal outcomes than vaginal dinoprostone, a composite that included severe PPH (≥ 1000 mL), ICU admission, maternal infection, uterine rupture, and maternal death [23]. Likewise, an updated 2024 meta-analysis confirmed comparable efficacy and perinatal safety, with significantly lower composite adverse maternal outcomes in the vaginal misoprostol group than in the vaginal dinoprostone group [24]. Interestingly, in a cochrane review [9], oral misoprostol was associated with a lower risk of postpartum hemorrhage than vaginal misoprostol (RR 0.57, 95% CI 0.34–0.95). These findings suggest that while overall PPH rates may not differ substantially, misoprostol could confer an advantage for more severe maternal outcomes in selected settings. However, heterogeneity in dose regimens, routes of administration, obstetric populations, and definitions of maternal outcomes limits firm conclusions. Further prospective studies and randomized trials are needed to clarify whether the apparent protective effect of misoprostol is genuine, whether it depends on route or dosing strategy, and whether it is mediated by uterine priming, reduced oxytocin augmentation, or other mechanisms.

Focusing instead on neonatal outcomes in our study, no significant differences were observed between the two groups in terms of Apgar scores, umbilical cord pH, or NICU admission. Previous systematic reviews have also reported no significant differences [17–19, 22], and this is certainly an important finding, as it highlights that both agents have a favorable safety profile.

Our study further indicates that this induction protocol can be safely applied to at-risk patients, such as women admitted for PROM or gestational diabetes. A sub-analysis in these two groups did not reveal any differences in induction duration, mode of delivery, or maternal and neonatal outcomes.

Labor induction is frequently perceived unfavorably by pregnant women, reflecting both a preference for a physiological birth and concerns regarding its potential duration. Accordingly, patient experience and satisfaction with prostaglandin-induced cervical ripening appear to vary with the method employed, as observed by Lepelletier et al. [20]. In their recent study, oral misoprostol was associated with higher levels of patient satisfaction and reduced discomfort. Beyond clinical outcomes, patient preferences and comfort should be considered integral to the decision-making process regarding induction methods.

Taken together, these findings support the use of the new misoprostol formulation within a standardized induction protocol, highlighting its favorable safety profile and reinforcing its role as a reliable option in routine obstetric practice. From a clinical perspective, the adoption of this protocol may contribute to improving the standardization of care, enhancing safety, and optimizing obstetric outcomes, thereby supporting its broader implementation in contemporary labor induction strategies.Although there is no difference between the two agents in terms of induction-to-delivery time, the finding that misoprostol is associated with a higher rate of vaginal delivery and a lower risk of postpartum hemorrhage is particularly relevant, especially considering that postpartum hemorrhage remains the leading cause of maternal mortality worldwide.

Many previous studies have compared misoprostol and dinoprostone without using the new tablet formulation, which is likely easier to administer and allows for more precise dosing. Further research using this formulation is clearly needed, and ideally, future studies should include randomized controlled trials to provide more robust and reliable evidence.

Strengths and Limitations

Strengths of our study include the large sample size, enhancing statistical power and reliability, and the single-center design, which ensured uniform clinical management through a consistent labor induction protocol. Moreover, the statistical analysis allowed robust comparisons between groups with initial differences, strengthening result validity and minimizing potential confounding. The main limitation of this study is its retrospective design, which is inherently less robust than a prospective randomized controlled trial and subject to potential biases, including selection bias and unmeasured confounding, limiting causal inference.

Conclusions

The newly introduced oral misoprostol formulation, administered within a standardized induction protocol, is safe and effective for patients with an unfavorable cervix. Compared with vaginal dinoprostone, it demonstrates comparable neonatal outcomes and potential maternal benefits, including higher vaginal delivery rates and lower postpartum hemorrhage. These findings support its adoption in routine practice, offering a reliable, standardized, and safer approach to labor induction, with implications for guideline development.

Abbreviations

AIFA	Italian medicines agency
FHR	Fetal heart rate
IPW	Inverse probability weighting
IRB	Institutional review board
NICU	Neonatal intensive cure unit
PGE1	Prostaglandin E1
PGE2	Prostaglandin E2
PROM	Premature rupture of membranes
SMDs	Standardized mean differences

Supplementary Information

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Supplementary Material 1.

Authors' contributions

A.S., E.R., L.D and G.V conceptualization and methodology. M.C., G.B., P.P. and A.S data curation. M.D.M. and G.V. formal analysis. A.S., E.R., M.C. and G.B. writing original draft. L.D. and G.V. writing review & editing, supervision. All authors have read and approved the final version of the manuscript and agree with its submission.

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Data availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request and are stored in an Excel file."

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board of University of Udine on November 20, 2023 (IRB Protocol No. 240/2023). The study was conducted in accordance with the principles of the Declaration of Helsinki. The IRB considered informed consent not applicable because of the retrospective nature of the study, and because the study results have no significant personalized impact on the individuals involved.

Consent for publication

All patients admitted to our clinic sign a consent form allowing access to their medical records and the potential use of their data for scientific publications. All identifying information has been removed to ensure complete anonymity.

Competing interests

The authors declare no competing interests.

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