Original Article

Fetomaternal Outcomes in Induction of Labour with Intracervical Foley's Catheter Alone Versus Induction with Foley's Catheter Plus Single Dose Dinoprostone

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Abstract

Background: Combining a transcervical Foley catheter with dinoprostone may accelerate cervical ripening, but the added pharmacological stimulus could alter maternal and neonatal safety. This study compared prespecified fetomaternal outcomes after induction with a Foley catheter alone and after induction with a Foley catheter plus a single dose of dinoprostone. **Material and Methods:** This prospective observational comparison included 100 primigravid women at 37 weeks of gestation or later with singleton, cephalic pregnancies, intact membranes, a reactive fetal heart-rate trace, and an unfavourable cervix. Fifty women received an intracervical Foley catheter and 50 received the catheter with 0.5 mg intracervical dinoprostone gel. Maternal outcomes were postpartum haemorrhage, puerperal sepsis, intrapartum pyrexia, and uterine tachysystole. Fetal distress, 5-minute Apgar score, and neonatal intensive care unit admission were assessed. Binary outcomes were reanalysed with Fisher's exact test, risk ratios, risk differences, and 95% confidence intervals. **Results:** Postpartum haemorrhage occurred in 2 of 50 women after Foley catheter alone and 3 of 50 after the combined method (risk ratio 1.50, 95% confidence interval 0.26 to 8.60). Puerperal sepsis, intrapartum pyrexia, and tachysystole each occurred in 1 of 50 versus 2 of 50 women. Fetal distress occurred in 3 of 50 versus 5 of 50 pregnancies (risk ratio 1.67, 95% confidence interval 0.42 to 6.60), and neonatal intensive care admission occurred in 4 of 50 versus 5 of 50 newborns (risk ratio 1.25, 95% confidence interval 0.36 to 4.38). Mean 5-minute Apgar scores were 8.94 (standard deviation 1.08) and 9.28 (standard deviation 0.97), respectively; the mean difference was 0.34 (95% confidence interval -0.07 to 0.75). No comparison reached statistical significance. **Conclusion:** A Foley catheter combined with one dose of dinoprostone did not produce a statistically demonstrable increase in the recorded maternal or neonatal adverse outcomes. The low event counts and wide confidence intervals do not establish equivalence or exclude clinically important differences. Larger, adequately powered studies with standardised safety definitions are required.

Keywords: Labour induction, cervical ripening, Foley catheter, dinoprostone, maternal safety, neonatal outcome.

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Introduction

Induction of labour is undertaken when the expected maternal or fetal benefit of ending pregnancy exceeds the risk of continued gestation. When the cervix is unfavourable, the first clinical decision is how to achieve ripening without creating avoidable uterine hyperactivity, infection, fetal compromise, or neonatal morbidity. International guidance recognises both pharmacological preparations and balloon catheters as valid approaches, while emphasising appropriate selection, monitoring, and readiness to manage complications.[1-3]

A transcervical Foley catheter applies pressure at the internal cervical os and promotes local endogenous prostaglandin release. Dinoprostone, a prostaglandin E2 preparation, remodels cervical collagen and can initiate uterine activity. Their concurrent use is biologically plausible because the mechanical component can dilate the cervix while a single pharmacological dose supports ripening. Randomised studies have reported faster progress with some combined protocols, particularly among nulliparous women, although estimates vary with dinoprostone formulation, balloon volume, parity, and oxytocin policy.[4-6]

The same mechanism that could improve efficiency also creates a safety question. Dinoprostone may increase contraction frequency, and excessive uterine activity can accompany fetal heart-rate abnormalities. A catheter that remains across the cervix may provide a route for ascending organisms, although

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trials comparing balloon and pharmacological methods have reported inconsistent differences in intrapartum and postpartum infection. Contemporary randomised evidence indicates that maternal infection and uterine hyperstimulation may move in opposite directions depending on the induction method, while composite neonatal outcomes often remain similar.[7,8,9]

Safety assessment therefore requires more than a single endpoint. Postpartum haemorrhage may reflect prolonged or augmented labour, operative birth, or uterine atony. Pyrexia and puerperal sepsis capture different stages of infectious morbidity. Tachysystole measures excessive uterine activity, whereas fetal distress reflects the fetal response recorded during labour. Five-minute Apgar score and neonatal intensive care unit admission provide complementary information after birth, although neither endpoint alone identifies a causal pathway. Standardised fetal monitoring terminology and careful interpretation of Apgar scores are essential when these events are compared.[10,11]

Most induction trials are designed around time to delivery or vaginal birth and are not powered for uncommon adverse events. This produces a recurrent interpretive problem: a non-significant p value may reflect low information rather than comparable safety. Reporting the absolute event difference, relative risk, and confidence interval helps distinguish an observed absence of evidence from evidence of no important difference. The need is particularly relevant in single-centre studies, where rare outcomes may occur only once or twice in each group.

The present analysis uses a prospective cohort of 100 primigravid women who underwent cervical ripening with an intracervical Foley catheter alone or with a Foley catheter plus one dose of dinoprostone. This study addresses the prespecified maternal, fetal, and neonatal outcome.

The primary objective was to compare postpartum haemorrhage, puerperal sepsis, intrapartum pyrexia, and uterine tachysystole between the two induction groups. The secondary objective was to compare fetal distress, 5-minute Apgar score, and neonatal intensive care unit admission. Because the original sample size was calculated for induction efficiency rather than rare adverse events, the analysis was framed as an exploratory safety comparison and emphasised estimation with confidence intervals.

Materials and Methods

Study design and setting: This was a prospective observational comparison conducted in the labour room of the Department of Obstetrics and Gynaecology at Kalpana Chawla Government Medical College, Karnal, Haryana, India, over approximately one year. The study enrolled 100 antenatal women, with 50 women in each induction group. The report follows the principles of the Strengthening the Reporting of Observational Studies in Epidemiology statement.[12]

Participants: Eligible participants were primigravid women at 37 completed weeks of gestation or later with a live singleton fetus in cephalic presentation, intact membranes, a reactive fetal heart-rate trace, and a modified Bishop score of 6 or lower. Gestational age was established from the last menstrual period when cycles were regular and was checked against first-trimester ultrasonography. Induction was undertaken for accepted obstetric indications, including post-term pregnancy, hypertensive disease, oligohydramnios, fetal growth restriction, congenital fetal conditions compatible with labour, and other documented indications.

Exclusion criteria were multiple pregnancy, non-cephalic presentation, ruptured membranes before induction, active genital infection, placenta praevia or antepartum haemorrhage, significant cardiac or renal disease, suspected cephalopelvic disproportion or contracted pelvis, polyhydramnios, sepsis, a non-reassuring fetal heart-rate trace before induction, and refusal to participate. These criteria selected a term, nulliparous population in whom either study method could be used without a recognised contraindication.

Induction protocols: For the Foley-alone group, the participant was placed in lithotomy position after counselling and consent. Under aseptic precautions, a speculum was introduced and the anterior cervical lip was held with sponge-holding forceps. A Foley catheter was advanced through the endocervical canal into the extra-amniotic space. The balloon was filled with 30 to 40 mL of distilled water, and the catheter was gently retracted until the balloon rested against the internal os.

For the combined group, the same catheter procedure was accompanied by one intracervical application of dinoprostone gel containing 0.5 mg prostaglandin E2 in 2.5 mL. The gel was placed below the internal os to reduce the risk of membrane injury, and the woman remained recumbent for 30 minutes. The use of a single dose distinguished the protocol from regimens that repeat prostaglandin administration during ripening. Studies of concurrent Foley and dinoprostone preparations have used related strategies, but differences in formulation and timing limit direct equivalence across trials.[4-6]

Maternal vital signs, uterine activity, and fetal heart rate were observed after induction. Cervical assessment was repeated at 12 hours or earlier if the catheter was expelled. Oxytocin was started when spontaneous labour did not begin, according to the unit protocol, and labour was followed with a partograph.

Outcome measures: The maternal safety outcomes were postpartum haemorrhage, puerperal sepsis, intrapartum pyrexia, and uterine tachysystole. Each was recorded prospectively on the study proforma from clinical observations and case records. The outcome categories were not treated as mutually exclusive; one participant could contribute to more than one complication. A composite maternal endpoint was therefore not calculated because participant-level overlap between complications was unavailable.

Fetal distress was recorded when the treating team diagnosed intrapartum fetal compromise on the basis of fetal monitoring and clinical assessment. Uterine tachysystole was interpreted in the clinical context of excessive contraction frequency; contemporary fetal monitoring terminology defines tachysystole by more than five contractions in 10 minutes averaged over 30 minutes.[10] The study proforma did not include a central adjudication process, cord blood gas measurement, or a graded classification of fetal heart-rate abnormalities.

Neonatal outcomes were the 5-minute Apgar score and admission to the neonatal intensive care unit. Apgar scores were

analysed both as the reported mean with standard deviation and as their full ordinal distribution. A score below 7 at 5 minutes was also described because it is a commonly reported threshold, while recognising that an Apgar score is a standardised description of neonatal condition and response to resuscitation rather than a diagnosis of intrapartum asphyxia.[11] The indication and duration of neonatal intensive care admission were not available for stratified analysis.

Statistical analysis: Categorical outcomes are presented as counts and percentages using 50 women or newborns per group as the denominator. Because several expected cell counts were below five, two-sided Fisher's exact tests were used instead of relying on asymptotic chi-square tests. The effect measure was the risk ratio for the Foley-plus-dinoprostone group relative to the Foley-alone group, with a 95% confidence interval calculated on the logarithmic scale. Absolute risk differences with Wald 95% confidence intervals are also reported. A Haldane-Anscombe correction was used only when a zero cell prevented estimation.

The difference in mean 5-minute Apgar score was assessed from the reported group means, standard deviations, and sample sizes with Welch's two-sample t method. Statistical tests were two sided, and p values below 0.05 were considered statistically significant. No adjustment was made for multiple comparisons because the analysis was exploratory; the confidence intervals and the consistency of outcome patterns were given greater interpretive weight than isolated p values. Reanalysis was performed with Python 3.12 and SciPy 1.17.

Ethical considerations: The Institutional Ethics Committee of Kalpana Chawla Government Medical College approved the study. All participants or their legally authorised representatives provided written informed consent. The study procedures were incorporated into monitored labour-room care, and confidentiality was maintained throughout data collection and analysis.

Results

Study cohort and completeness: The analysis included 100 women and their newborns: 50 underwent induction with an intracervical Foley catheter alone and 50 underwent induction with the Foley catheter plus one dose of dinoprostone. The safety outcome tables contained observations for all 100 mother-newborn pairs.

Maternal outcomes: Maternal complications were uncommon in both groups. Postpartum haemorrhage was recorded in 2 women (4%) after Foley catheter alone and in 3 women (6%) after Foley catheter plus dinoprostone. The absolute difference was 2 percentage points (95% confidence interval -6.5 to 10.5), and the relative risk was 1.50 (95% confidence interval 0.26 to 8.60). Fisher's exact p value was 1.000.

Puerperal sepsis, intrapartum pyrexia, and uterine tachysystole each occurred in 1 of 50 women (2%) in the Foley-alone group and 2 of 50 women (4%) in the combined group. For each endpoint, the risk difference was 2 percentage points (95% confidence interval -4.7 to 8.7), the relative risk was 2.00 (95% confidence interval 0.19 to 21.36), and Fisher's exact p value was 1.000. The wide intervals reflect the small number of events and are compatible with both lower and substantially higher risk. [Table 1] presents the complete maternal estimates.

Table 1: Maternal adverse outcomes after labour induction

Outcome	Foley alone n/N (%)	Foley plus dinoprostone n/N (%)	Risk difference percentage points (95% CI)	Risk ratio (95% CI)	Fisher p
Postpartum haemorrhage	2/50 (4)	3/50 (6)	2.0 (-6.5 to 10.5)	1.50 (0.26 to 8.60)	1.000
Puerperal sepsis	1/50 (2)	2/50 (4)	2.0 (-4.7 to 8.7)	2.00 (0.19 to 21.36)	1.000
Intrapartum pyrexia	1/50 (2)	2/50 (4)	2.0 (-4.7 to 8.7)	2.00 (0.19 to 21.36)	1.000
Uterine tachysystole	1/50 (2)	2/50 (4)	2.0 (-4.7 to 8.7)	2.00 (0.19 to 21.36)	1.000

CI, confidence interval. Risk ratios and risk differences compare Foley plus dinoprostone with Foley alone. Events may overlap within participants, so a composite maternal event rate was not calculated.

Fetal and neonatal outcomes: Fetal distress was documented in 3 pregnancies (6%) in the Foley-alone group and 5 pregnancies (10%) in the combined group. The corresponding risk difference was 4 percentage points (95% confidence interval -6.6 to 14.6), and the relative risk was 1.67 (95% confidence interval 0.42 to 6.60; Fisher's exact p=0.715). The remaining 47 and 45 pregnancies, respectively, had no recorded fetal distress.

Neonatal intensive care was required for 4 newborns (8%) after Foley catheter alone and 5 newborns (10%) after the combined method. The risk difference was 2 percentage points (95% confidence interval -9.2 to 13.2), and the relative risk was 1.25 (95% confidence interval 0.36 to 4.38; Fisher's exact p=1.000). The available data did not specify whether admission was prompted by respiratory transition, infection evaluation, hypoglycaemia, observation after fetal heart-rate abnormalities, or another indication.

Table 2: Fetal and neonatal outcomes

Outcome	Foley alone	Foley plus dinoprostone	Effect estimate (95% CI)	p value
Fetal distress	3/50 (6%)	5/50 (10%)	RR 1.67 (0.42 to 6.60)	0.715
NICU admission	4/50 (8%)	5/50 (10%)	RR 1.25 (0.36 to 4.38)	1.000
5-minute Apgar score below 7	0/50 (0%)	1/50 (2%)	RR 3.00 (0.13 to 71.93)*	1.000
Mean 5-minute Apgar score	8.94 (SD 1.08)	9.28 (SD 0.97)	MD 0.34 (-0.07 to 0.75)	0.100

CI, confidence interval; MD, mean difference; NICU, neonatal intensive care unit; RR, risk ratio; SD, standard deviation. *Haldane-Anscombe correction used because one cell contained zero events.

Five minute Apgar score: The mean 5-minute Apgar score was 8.94 (standard deviation 1.08) in the Foley-alone group and 9.28 (standard deviation 0.97) in the combined group. The mean difference was 0.34 points in favour of the combined method (95% confidence interval -0.07 to 0.75; p=0.100). Forty women (80%) in the Foley-alone group and 41 women (82%) in the combined group had a 5-minute score of 9 or 10. One newborn in the combined group had a score of 6; no newborn in the Foley-alone group had a score below 7. The full distribution is shown in [Table 3].

Table 3: Distribution of 5-minute Apgar scores

Apgar score	Foley alone n (%)	Foley plus dinoprostone n (%)	Total n (%)
6	0 (0)	1 (2)	1 (1)
7	7 (14)	2 (4)	9 (9)
8	9 (18)	6 (12)	15 (15)
9	14 (28)	14 (28)	28 (28)
10	20 (40)	27 (54)	47 (47)
Total	50 (100)	50 (100)	100 (100)

Values are counts with column percentages in parentheses.

Interpretation of tabulated outcomes: The event counts in [Table 1 and 2] are low. The relative risks therefore have broad confidence intervals and should not be read as precise estimates of harm. Table 3 shows that the difference in mean Apgar score was driven mainly by a larger number of scores of 10 in the combined group; clinically low scores remained uncommon.

Precision of the safety estimates: None of the recorded comparisons reached the conventional threshold for statistical significance. The point estimates for the rare binary outcomes were numerically above 1.0 for the combined group, but every confidence interval crossed the null and extended across a clinically broad range. Figure 1 displays this imprecision on a logarithmic scale. The data therefore identify no clear safety signal in this cohort, but they do not establish that the two methods have equivalent risks.

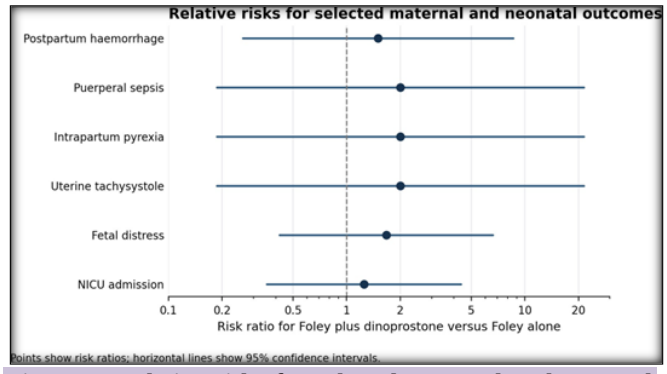


Figure 1: Relative risks for selected maternal and neonatal outcomes

Risk ratios compare Foley catheter plus dinoprostone with Foley catheter alone. Values to the right of 1 indicate a higher observed event rate in the combined group. All confidence intervals cross 1 and remain wide because the outcomes were uncommon.

Discussion

In this prospective comparison of 100 term primigravid women, recorded maternal adverse events were rare after both induction protocols. Postpartum haemorrhage occurred in 4% and 6% of women, while puerperal sepsis, intrapartum pyrexia, and tachysystole occurred in 2% and 4%. Fetal distress occurred in 6% and 10%, and neonatal intensive care admission occurred in 8% and 10%. Mean 5-minute Apgar scores were high in both groups. These observations did not show a statistically demonstrable difference between Foley catheter alone and Foley catheter plus a single dose of dinoprostone.

The central interpretive finding is the limited precision of the estimates. For example, the relative risk for tachysystole was 2.00, but its 95% confidence interval ranged from 0.19 to 21.36 because only three events occurred. A p value of 1.000 in that setting does not mean identical safety. It indicates that the observed distribution is readily compatible with chance under the null hypothesis. The same caution applies to postpartum haemorrhage, infection, fetal distress, and neonatal intensive care admission.

Maternal safety: Postpartum haemorrhage was infrequent and differed by one case between groups. The study was not designed to separate uterine atony from traumatic, retained-placenta, or operative causes, and it did not provide quantified blood loss. Any causal explanation would therefore exceed the available evidence. Randomised comparisons of Foley and dinoprostone have generally treated postpartum haemorrhage as a secondary safety endpoint and have not consistently identified a difference, although protocols and populations vary substantially.[7,9,13]

The infection outcomes deserve separate consideration. A balloon catheter is a foreign body positioned across the cervix, whereas dinoprostone can shorten the time required for ripening in some protocols. These competing mechanisms could influence infection in either direction. The present cohort recorded one versus two cases of puerperal sepsis and one versus two cases of intrapartum pyrexia. Large contemporary randomised data comparing dinoprostone with Foley alone found more suspected intrapartum and postpartum infection with Foley, but more hyperstimulation with fetal heart-rate changes after dinoprostone.[7] That trial compared single methods and cannot be directly translated to concurrent use, yet it illustrates why infection and uterine activity should be examined together rather than collapsed into one safety label.

Tachysystole occurred in one woman after Foley alone and two after the combined method. The direction is biologically plausible because the combined protocol adds an exogenous uterotonic prostaglandin stimulus. At the same time, the absolute difference was only two percentage points, and no severe consequence can be attributed to those events from the available

aggregate data. Trials using controlled-release dinoprostone have reported protocol-dependent rates of tachysystole, and some have found lower excessive uterine activity with balloon methods.[8,14,15] Continuous surveillance after prostaglandin administration remains important even when only one dose is used.

Fetal and neonatal outcomes: Fetal distress was numerically more frequent in the combined group, but the eight total events provided little precision. Fetal heart-rate abnormalities can arise from uterine tachysystole, placental insufficiency, cord compression, meconium, or baseline maternal and fetal conditions. The study did not provide the tracing category, duration, relation to contractions, or cord gas values, so the endpoint should be understood as a clinically recorded intrapartum diagnosis rather than a pathophysiologically adjudicated event.

The neonatal findings were reassuring at a descriptive level. Most newborns had a 5-minute Apgar score of 9 or 10, the group mean scores were close, and only one score below 7 was recorded. Neonatal intensive care admission differed by one newborn. Randomised trials of Foley and dinoprostone, including studies in nulliparous women and pregnancies with an unfavourable cervix, have likewise reported broadly similar Apgar and admission outcomes, although individual trials were seldom powered for rare neonatal morbidity.[9,16-19]

Apgar score and intensive care admission should not be treated as interchangeable. Apgar score describes neonatal condition at a defined time and is influenced by gestational maturity, medications, resuscitation, infection, and congenital factors. Intensive care admission also depends on local thresholds and bed availability. The concordance of high mean Apgar scores and low admission rates in both groups supports the absence of an obvious neonatal safety signal, but neither outcome rules out transient acidemia or less visible morbidity.[11]

Comparison with combined method studies: The protocol is most directly comparable with the randomised study by Chowdhary and colleagues, which combined a Foley catheter with a single 0.5 mg dose of intracervical dinoprostone gel. That study reported improved ripening and a shorter induction-to-delivery interval without an evident increase in caesarean birth or adverse neonatal outcomes.[4] A pilot trial by Edwards and colleagues used a controlled-release dinoprostone insert with Foley and found a shorter time to vaginal birth among nulliparous women, while the result differed in parous participants.[5] Vallikkannu and colleagues also found efficiency benefits in term nulliparas when a controlled-release insert was used concurrently with Foley.[6] These studies support the biological rationale for combination treatment but do not settle the safety question. Dinoprostone gel, tablets, and controlled-release inserts differ in dose delivery and the ability to remove the preparation. Balloon volume, traction, time in situ, timing of amniotomy, and oxytocin protocols also influence uterine activity and infection exposure. A finding from one combination regimen should therefore not be generalised to all concurrent mechanical-pharmacological strategies.

Other randomised studies have compared single-balloon or double-balloon catheters with dinoprostone rather than using them together. Their results show that safety patterns depend on the population and protocol. Trials in prolonged pregnancy, nulliparous women, oligohydramnios, and women with a previous caesarean birth have not yielded one universally superior method across maternal and neonatal outcomes.[13-20] This heterogeneity supports local protocol evaluation and standardised adverse-event reporting.

Clinical implications: For women resembling this cohort, the combined single-dose protocol may be considered without evidence from this study of a large immediate increase in recorded fetomaternal complications. That statement should remain narrow. The data do not justify declaring the combined method equally safe, nor do they support relaxing fetal surveillance after dinoprostone. Clinicians should continue to confirm eligibility, document baseline fetal well-being, monitor uterine activity and fetal heart rate, and remove or withhold agents when excessive contractions or fetal compromise occur in accordance with institutional guidance.[1,2,3,10]

Absolute risks are useful for counselling. In this sample, adding dinoprostone corresponded to observed increases of two percentage points for each recorded maternal complication, four percentage points for fetal distress, and two percentage points for neonatal intensive care admission. These are sample estimates, not expected treatment effects. Their confidence intervals include reductions as well as increases, so they should be presented as uncertain rather than as fixed excess risks.

Strengths: The study collected maternal, intrapartum, and neonatal outcomes prospectively within one clinical unit. Equal group sizes simplified direct comparison, and restriction to term primigravid women reduced variation from parity and prematurity. The present report avoids duplicating efficacy tables and instead provides new risk ratios, absolute differences, exact tests, and confidence intervals for the safety outcomes. It also preserves the full Apgar distribution rather than reporting only a mean.

Limitations: Small sample size and non-randomized nature of study are limitations of present study. Further research with randomized trials is required to validate the findings of the current study.

Conclusion

In this prospective cohort, maternal complications, fetal distress, low 5-minute Apgar score, and neonatal intensive care admission were uncommon after cervical ripening with either an intracervical Foley catheter alone or a Foley catheter combined with one dose of dinoprostone. No outcome showed a statistically demonstrable between-group difference. Because event counts were small and confidence intervals were wide, the findings indicate an absence of a clear safety signal rather than proof of equal safety. The combined regimen should continue to be used with standard maternal and fetal monitoring, and its uncommon adverse effects should be evaluated in larger, well-defined multicentre studies.

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Conflicts of interest

There are no conflicts of interest.

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