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Original Research Article

## Elective induction of labour at 39 weeks in low-risk nulliparous women versus expectant management: a pilot randomized control trial

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### ABSTRACT

**Background:** Elective induction of labor (EIOl) is a debated topic, but recent evidence suggests potential benefits. The ARRIVE trial found that e IOL at 39<sup>0</sup>/7 to 39<sup>4</sup>/7 weeks in low-risk nulliparous women significantly reduced cesarean delivery rates (18.6% vs. 22.2%) and composite perinatal morbidity (4.3% vs. 5.4%).<sup>3</sup> This aligns with other studies showing that continuing pregnancy beyond 39 weeks increases maternal/fetal risks. Given that race/ethnicity influences pregnancy duration and outcomes, the current research gap is the lack of specific data on e IOL at 39 weeks in the Indian population

**Methods:** This open-label randomized trial at RIMS, Ranchi (March 2021-October 2022) compared EIOl to Expectant Management (EM) in 60 low-risk nulliparous Indian women (n=30 per group), with the primary outcome being the rate of cesarean delivery. Participants were randomized at 38 weeks and the e IOL group was induced between 39 and 39<sup>5</sup>/7 weeks using dinoprostone/oxytocin.

**Results:** The present randomized, open-label trial conducted on low-risk nulliparous Indian women compared EIOl at 39 weeks with expectant management (EM), analyzing 27 participants in each final group. The primary finding demonstrated that e IOL significantly reduced the Cesarean Delivery rate (37% vs. 66.7% in EM, p=0.038) and led to a shorter postpartum hospital stay. While baseline characteristics were comparable, the EM group developed more complications (e.g., preeclampsia, non-reassuring FHR) leading to higher intervention rates. Although secondary neonatal outcomes (e.g., perinatal death, NICU admission) showed a favorable trend for e IOL, these differences were not statistically significant.

**Conclusions:** This pilot RCT in India found that EIOl at 39 weeks significantly reduced the cesarean delivery rate (33.3% vs. 60% in expectant management, p=0.038), suggesting one CS is avoided per four inductions. EIOl was safe, showing no increase in adverse maternal outcomes (PPH, infection) and even shorter hospital stays, while maintaining positive neonatal outcomes. The study supports EIOl as a safe, effective strategy to lower CS rates in low-resource settings.

**Keywords:** Cesarean delivery, Induction of labor, Maternal infection, NICU admission, PPH

### INTRODUCTION

Labor induction is necessary for specific maternal and fetal conditions (e.g., preeclampsia, term PROM). However, EIOl is debated. Optimal timing is critical, as both preterm birth (leading cause of neonatal mortality) and post-term pregnancy increase maternal and fetal morbidity

as well as mortality. ACOG advises considering e IOL between 41<sup>0</sup>/7 weeks and 41<sup>6</sup>/7 weeks and recommending it after 42<sup>0</sup>/7 weeks, while avoiding it before 39 weeks. FOGSI recommends EIOl only after 39 weeks. Perinatal mortality rates are lowest at 39 weeks. Continuing pregnancy beyond 39 weeks increases risks of placental insufficiency, preeclampsia, macrosomia, higher cesarean rates and increased morbidity/mortality.<sup>1</sup> Prior

observational studies suggested elective induction did not reduce adverse outcomes, but they were often flawed. Caughey et al systematic review found that induction at <41 weeks had no significant difference in cesarean rates, but expectant management 41 weeks was associated with increased cesarean rates (OR 1.22; 95% CI 1.07-1.39).<sup>2</sup> Stock et al, large cohort study of 1.27 million Scottish women found e IOL resulted in decreased perinatal mortality and a minimal increase in cesarean rates (9.3% vs. 8.4%).<sup>3</sup>

The ARRIVE randomized low-risk nulliparous women to EIOL at 39/7 to 39+7 weeks or expectant management.<sup>4</sup> The EIOL group showed significantly better outcomes.

Lower composite perinatal morbidity: 4.3% vs. 5.4% (RR 0.80). Lower cesarean delivery rates: 18.6% vs. 22.2% (RR 0.84). Lower hypertension rates: 9.1% vs. 14.1% (RR 0.64).

A subsequent meta-analysis confirmed that e IOL at 39 weeks significantly lowered the risk of cesarean delivery, maternal peripartum infections and perinatal adverse outcomes

There are currently no studies on Eiol at 39 weeks in the Indian population, which is relevant as factors like race and ethnicity (e.g., Asian, African Americans) are accepted to affect pregnancy duration.<sup>5</sup> A study of Indian women found the median gestation at spontaneous labor was 39 weeks. Other Indian studies show higher rates of cesarean and intrapartum complications after 41 weeks. The present study is planned to compare e IOL with expectant management in low-risk nulliparous Indian women to evaluate its impact on cesarean rates and neonatal outcomes.<sup>6</sup>

The objectives of the study are to determine the effect of Eiol) on caesarean delivery rates in low-risk nulliparous women compared to expectant management, while evaluating associated risks of maternal hypertensive disorders and adverse perinatal outcomes, including mortality and severe neonatal morbidity.

## METHODS

This was an open-labelled, randomised, parallel group trial conducted at the Department of Obstetrics & Gynaecology, RIMS, Ranchi, from March 2021 to October 2022. The trial was registered under CTRI (CTRI/2021/10/037487). Simple randomisation was used to allocate participants into two equal groups, with the allocation sequence generated by a computer and concealed using opaque sealed envelopes.

### *Study population and enrolment*

The study focused on low-risk nulliparous women aged 18 to 30 years. Low risk was defined as the absence of conditions requiring delivery before 41 weeks. Key

inclusion criteria were a singleton, vertex pregnancy with a reliable gestational age between 39 weeks and 39 weeks + 5 days and consent for elective induction. The detailed exclusion criteria included conditions like malpresentation, prior deliveries, contraindications to labor, established labor, fetal issues (demise, FGR, oligohydramnios) and certain maternal medical conditions or complications (e.g., placenta previa, HIV, major medical illness). Participants were screened for eligibility between 37 weeks and 38 weeks 5 days of gestation.

### *Sample size and management strategies*

The calculated sample size for the study was 86 (43 per group), based on assumptions including an Alpha of 0.05 and a Power of 0.80. However, the final sample size was reduced to 60 participants (30 in each group), randomizing participants at 38 weeks of gestation, citing difficulties in enrolment due to the COVID-19 pandemic. The two arms were the Eiol group and the EM group. Women in the e IOL group were scheduled for induction between 39 weeks and 39 weeks + 5 days. The EM group continued routine care and was asked to forgo elective delivery before 40 weeks 1 day but not beyond 42 weeks. The induction protocol involved cervical priming with dinoprostone gel 0.5mg intracervically (up to 3 doses), followed by oxytocin stimulation if needed, guided by the Bishop score.

### *Data analysis and trial outcome measures*

Data was entered into Microsoft Excel and analysed using JAMOVI. Both quantitative data (expressed as mean, median and standard deviation) and qualitative data (expressed as rates, proportions and percentages) were analysed using the central limit theorem. The Chi-square test was used for categorical variables and the t-test was used for continuous variables, assuming data were normally distributed. Both intentions to treat (ITT) and per protocol (PP) analyses were conducted. The primary maternal outcome was the number of participants with caesarean delivery.

Secondary maternal outcomes included PPH, non-elective hysterectomy/surgical interventions, maternal infection, hypertensive disorders and operative vaginal delivery/perineal tears. Secondary Neonatal Outcomes included perinatal deaths, APGAR score <7 at 5 minutes, meconium aspiration, infection/seizure, shoulder dystocia/birth trauma and a comparison of birth weight. Follow-up for both mother and neonate lasted until hospital discharge.

## RESULTS

Per-protocol delivery in the induction group was defined as electively induced labor from 39 weeks to 39 weeks+4 days or medically indicated delivery on or before 39 weeks because of a new medical condition that has developed. Per-protocol delivery in the expectant management group

was defined as spontaneous labor or induction from 40 weeks to 41 weeks +6 days or medically indicated delivery on or before 41 weeks +6 days

### Screening and recruitment

A total of 77 pregnant women were screened for eligibility at 37 weeks 0 day to 38 weeks 5 days. Out of these 60 women who met the eligibility criteria were randomized in two arms in a 1:1 ratio. Out of 30 women randomized in the induction arm (EIOL), three withdrew consent and only 27 were analyzed. In the expectant arm, two were lost to follow up and one woman opted for delivery at another place. Therefore, 27 women in each arm were included in final analysis.

### Maternal characteristics analysis in trial

The baseline demographic characteristics were comparable between the two study arms. The mean age of women in the Induction arm was  $24.62 \pm 3.31$  years, which was similar to that in the expectant arm at  $25.00 \pm 2.89$  years. Similarly, the mean BMI did not differ significantly between the groups, with the EIOL group recording  $21.94 \pm 1.44$  kg/m<sup>2</sup> and the expectant group recording  $22.78 \pm 1.49$  kg/m<sup>2</sup>.

Regarding other baseline factors, the majority of study participants belonged to the Hindu religion and the women of different religions were distributed almost equally in both the Induction and Expectant arms. Furthermore, a high proportion of women in both groups presented with an unfavourable cervix, as indicated by a modified Bishop's score of less than 5 at the time of admission. Specifically, 70% in the expectant management group and 73% in the EIOL group had a modified Bishop's score of  $< 5$ . No significant difference was noted in the modified Bishop's score distribution between the two groups upon admission, confirming a balanced baseline risk for induction failure.

### Findings of pregnant women at the time of admission

In the induction EIOL group one woman developed preeclampsia at 38 weeks 4 days for which induction was done whereas the rest 26 induction was for study. In the expectant group 17 (63% of women presented with spontaneous labor mostly early labor, 4 (14.8%) came with ruptured membranes, 5 (18.5%) presented with hypertensive disorders of pregnancy and 1 (3.7%) of women developed oligohydramnios. Induction for ruptured membranes and hypertension were most frequently observed in the expectant group than in the induction group.

### Primary outcome

Table 1 shows that caesarean delivery rate in two groups as per protocol analysis. In the induction group (EIOL) caesarean rate was 37% compared to 66.7% in expectant

management group. The relative risk was 42% lower in induction group than expectant group. RR, 0.52; 95%CI 0.289 to 0.971; p value 0.038. Table 2 shows the caesarean rate in two groups as per intention to treat analysis. The cesarean rate in induction group (EIOL) was 33.3% whereas in expectant group was 60%. The relative reduction in caesarean rate using this protocol was 43%. (RR, 0.57; 95%CI 0.32 to 1.005; p value 0.038). Thus, there was 43% reduction in caesarean delivery rate. Absolute risk reduction in caesarean rate was 26.7% in EIOL group. This translates to NNT of 3.6. Thus, our data shows that one caesarean delivery may be avoided by every four deliveries among low-risk nulliparous women who plan to undergo elective induction of labour at 39 weeks.

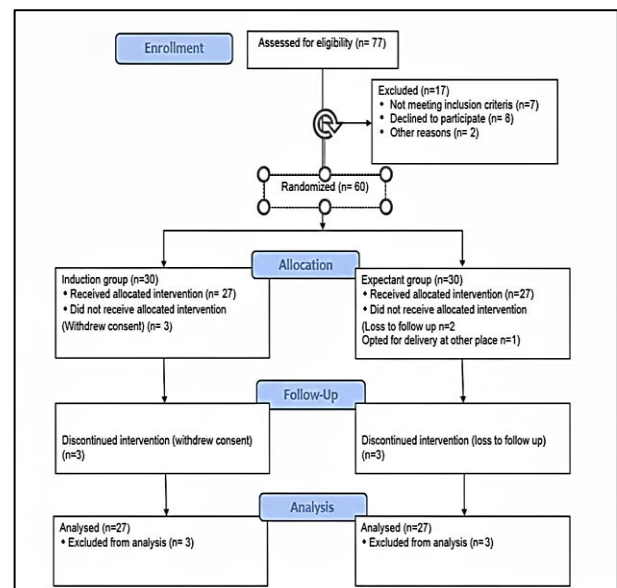


Figure 1: Eligibility, randomization, allocation, follow-up, analysis.

### Secondary maternal outcome

#### Indication of caesarean section

Failed induction was defined by the lack of regular uterine contractions (every 3 min) after completing cervical ripening (PGE2 gel 3 times) and 12-24 hours of oxytocin post-rupture. Non-reassuring FHR included Category II/III abnormalities (decelerations, tachy/bradycardia). Oligohydramnios was defined as vertical pocket  $< 2$  and AFI  $< 5$ . In terms of outcomes, one expectant woman with oligohydramnios developed fetal distress after induction. In the Intervention arm had nine Cesarean sections (7 for failed induction, 2 for FHR/meconium issues), while the Expectant arm had 14 (1 for failed induction, 9 for non-reassuring FHR and 4 for fetal distress/meconium).

#### HDP (gestational hypertension/ preeclampsia)

Out of 27, four women in the expectant group developed preeclampsia and one developed gestational hypertension

whereas, one woman in the induction group (EIOL) developed preeclampsia. On applying the chi-square hypothesis, we get a p value of 0.192 and RR 0.308(95CI:0.05-1.88).

**PPH**

Out of 27 women in the expectant management group, four developed PPH, of which three was atonic and one was traumatic. One woman in intervention (EIOL) group developed atonic PPH. There was no significant difference in the occurrence of PPH in both groups.

**Instrumental vaginal delivery**

One woman in expectant group required forceps assisted vaginal delivery compared to none in elective induction group.

**Maternal infection**

Four women 14.8% in expectant group developed wound infection compared to one (3.7%) in induction group. The (RR 0.88;95%CI:0.74 to 1.05, p value 0.159).

**Duration of postpartum hospital stay**

Postpartum hospital stay duration was more in the expectant management group compared to the induction. RR, 0.52; 95% CI: 0.289 to 0.971; p value 0.029. The difference in the postpartum stay was statistically significant.

**Outcome of newborns**

*Birth weight*

The average weight of a newborn in EIOL group was 2.81±0.321 and that in the expectant arm was 2.90±0.289. On comparing the data, we get a p-value of 0.252. There was no significant difference in the mean birth weight of newborns between the two groups.

*Meconium aspiration syndrome in neonates*

The proportion of MAS in the expectant group was four out of 27 deliveries whereas in the induction group (EIOL) was one out of 27 deliveries. There was no significant difference in the outcome of both groups.

*Perinatal death*

Out of 27 neonates, two in the expectant group had perinatal death, no such outcome was observed in the induction (EIOL) group. RR, 0.93; 95% CI 0.83 to 1.03, p value 0.15.

*Neonatal intensive care unit admission*

Four neonates in the expectant group were admitted to NICU (Neonatal Intensive Care Unit) whereas one neonate in the induction group required NICU admission.

*APGAR score*

There was no significant difference between the 1-minute APGAR score of newborns in both arms.

**Table 1: Caesarean delivery rate A: Per protocol.**

		Intervention		RR (95% CI)	*P value
		Expectant group	Induction group		
<b>Mode of delivery</b>	Vaginal delivery	9 (33.3%)	17 (63%)	1 (ref)	0.029
	Caesarean delivery	18 (66.7%)	10 (37%)	0.52 (0.29-0.97)	
<b>Total</b>		27	27		

\*statistically significant.

**Table 2: Caesarean delivery rate B: Intention to treat analysis.**

		Intervention		RR (95% CI)	*P value
		Expectant group	Induction group		
<b>Mode of delivery</b>	Vaginal delivery	12 (40%)	20 (66.7%)	1 (ref)	0.038
	Caesarean delivery	18 (60%)	10 (33.3%)	0.57 (0.32-1.00)	
<b>Total</b>		27	27		

\*statistically significant.

**Table 3: Comparing occurrence of PPH.**

		Intervention		RR (95% CI)	*P value
		Expectant	Induction		
<b>PPH</b>	No	23 (85.2%)	26 (96.3%)	1 (ref)	0.15
	Yes	4 (14.8%)	1 (3.7%)	0.88 (0.74-1.05)	
<b>Total</b>		27	27		

\*statistically significant.

**Table 4: Occurrence of instrumental vaginal delivery.**

		Intervention		RR (95% CI)	*P value
		Expectant	Induction		
Instrumental vaginal delivery	No	7 (87.5%)	19 (100%)	1 (ref)	Not computed
	Yes	1 (12.5%)	0 (0.00%)	Not computed	
<b>Total</b>		8 (100%)	19 (100%)		

\*statistically significant.

**Table 5: Occurrence of maternal infection.**

		Intervention		RR (95% CI)	*P value
		Expectant	Intervention		
Maternal infection	No	23 (85.2%)	26 (96.3%)	1 (ref)	0.159
	Yes	4 (14.8%)	1 (3.7%)	0.88 (0.74-1.05)	
<b>Total</b>		27	27		

\*statistically significant.

**Table 6: Duration of postpartum hospital stay.**

		Intervention		RR (95% CI)	*P value
		Expectant	Induction		
Duration of hospital stay	≤2 days	9 (33.3%)	17 (63%)	1 (ref)	0.029
	> 2 days	18 (66.7%)	10 (37%)	0.52(0.29-0.97)	
<b>Total</b>		27 (100%)	27		

\*statistically significant.

**Table 7: Occurrence of perinatal death.**

		Intervention		RR (95% CI)	*P value
		Expectant	Induction		
Perinatal death	No	25 (92.6%)	27 (100%)	1 (ref)	0.15
	Yes	2 (7.4%)	0 (0.00%)	0.93 (0.83-1.03)	
<b>Total</b>		27	27		

\*statistically significant.

**Table 8: Number of NICU admission.**

		Intervention		RR (95% CI)	*P value
		Expectant	Induction		
NICU admission	No	25 (92.6%)	27 (100%)	1 (ref)	0.15
	Yes	4 (7.4%)	1 (0.0%)	0.88 (0.74-1.05)	
<b>Total</b>		27 (100%)	27 (100%)		

\*statistically significant.

**Table 9: Comparison of APGAR score in both groups.**

		Intervention		*P value
		Expectant	Induction	
APGAR score	>7	22 (81.5%)	26 (96.3%)	0.192
	≤<7	5 (18.5%)	1 (3.7%)	
<b>Total</b>		27 (50.0%)	27 (50.0%)	

\*statistically significant.

## DISCUSSION

The study aimed to evaluate whether EIOL at 39 weeks increases the caesarean delivery rate and other adverse maternal and neonatal outcomes in low-risk nulliparous women, comparing it to EM. The decision regarding the timing of delivery depends on balancing maternal and perinatal risks. The context is that perinatal mortality is

lowest at 39 weeks as neonatal risks from prematurity fade and stillbirth rates increase. A randomized trial's primary maternal outcome, the caesarean delivery rate, was significantly lower in the induction group, showing a relative risk reduction of 43% (RR, 0.57, 95% CI 0.32 to 1.00; p value 0.03).<sup>1</sup> This aligns with Caughey et al.'s meta-analysis, which reported expectant management was associated with a higher odds ratio (OR) of caesarean



delivery than EIOL (OR, 1.22: 95% CI, 1.07 to 1.39); absolute risk difference, 1.9 percentage points (95%CI, 0.2 to 3.7 percentage points)).<sup>7</sup> The ARRIVE trial, a large RCT, also observed a lower caesarean rate in the induction group (18.6%) versus the expectant group (22.2%).<sup>5</sup> Baseline maternal characteristics were similar regarding mean age (EIOL 24.62±3.31 years, EM 25.0±2.89 years) and mean BMI (EIOL 21.94±1.44 Kg/m<sup>2</sup>, EM 22.78±1.49 Kg/m<sup>2</sup>). Grobman et al reported a high proportion of women in their study belonged to the white race (91% in EIOL, 93% in EM).<sup>3</sup>

Grobman et al also noted a significantly lower incidence of hypertension in the induction group (9.1%) compared to the expectant group (14.1%).<sup>3</sup> Regarding other outcomes, Grobman et al observed a risk reduction of 34% for perinatal death in the induction group (RR, 0.66, 95% CI 0.12 to 3.33, p value 0.049) and a shorter postpartum hospital stay for the EIOL group.<sup>3</sup> A meta-analysis found the risk of peripartum infection was lower in the induction group (2.8%) compared to the expectant group (5.2%).<sup>6</sup> The risk for the meconium aspiration syndrome did not differ between the groups in Caughey et al's meta-analysis, nor did the odds of operative vaginal delivery.<sup>7</sup>

Indications for the caesarean deliveries were not significantly different between the spontaneous labor group and the induction group, with failure to progress being the most common indication.<sup>8</sup> Vrouenraets, Francis et al observed a caesarean delivery rate of 12% in the spontaneous labor group, whereas it was 23.8% in women whose labor was electively induced.<sup>9</sup> In contrast to the current study, The mean age of women was higher in the study by Souter et al (29.8 years and 29.3 years in the EIOL and EM group).<sup>9</sup>

Keulen et al observed 3 (0.3%) neonates in the induction group versus 8 (0.9%) in the expectant management group who were admitted to a NICU.<sup>10</sup> Keulen et al also found that 11 (1.2%) infants in the induction group and 23 (2.6%) in the expectant management group had an Apgar score <7 at five minutes (RR 0.48, 95% CI 0.23 to 0.98).<sup>10</sup> Middleton P, et al, reported no clear difference in rates of postpartum haemorrhage between induction and expectant management groups (RR, 1.09, 95% CI 0.92 to 1.30).<sup>11</sup> Middleton et al reported that infants born to mothers in the induction group had lower birthweights than those born to mothers in the expectant management group (mean difference of -69.43 g, 95% CI -96.83 to -42.02).<sup>11</sup> Middleton et al reported four perinatal deaths in the induction group compared with 25 perinatal deaths in the expectant management group.<sup>11</sup> Middleton et al observed a 23% relative reduction in the risk of meconium aspiration syndrome in the induction groups compared with the expectant management groups.<sup>11</sup> Middleton et al observed more babies in the induction group had APGAR scores less than 7 at the time of birth compared to the neonates in the expectant group (RR, 0.70, 95% CI: 0.50 to 0.98).<sup>11</sup> Middleton P, et al, also reported that the rate of operative vaginal birth was higher in the labor induction groups

compared with expectant management (RR 1.07, 95% CI 0.99 to 1.16).<sup>11</sup>

Beigh et al reported that the percentage of patients delivered by caesarean section was 31% in the induction group and 23% in the expectant management group.<sup>12</sup> Beigh et al reported that atonic PPH was seen in 6% of cases and traumatic in 1% of cases in the induction group.<sup>12</sup> Wagner et al conducted an observational cohort study and noticed a lower caesarean delivery rate of 2.4% in the induction group compared to 4.6% in the expectant management group (OR: 0.70, 95% CI: 0.53 to 0.92).<sup>13</sup>

Sauter et al reported that at 39 weeks gestation, the caesarean rate in electively induced nulliparous women was 14.7% vs 23.2% in expectantly treated nulliparous women.<sup>14</sup> Miller et al observed mean BMI of women in the induction group was 30.1 Kg/m<sup>2</sup>±5.3 Kg/m<sup>2</sup> whereas in the expectant arm was 28.8 Kg/m<sup>2</sup>±4.4 Kg/m<sup>2</sup>.<sup>15</sup>

Miller et al analyzed that 38/79 (44%) of women in the expectant group came in spontaneous labor compared with 2/82 (2%) in the induction group.<sup>15</sup> Miller et al, reported that the caesarean rate in the induction of labor group was 30.5% (25/82) compared with 17.7% (14/79) in the expectant management group.<sup>15</sup> Begum et al conducted a retrospective cohort study and reported no significant difference in the mode of delivery in expectant management and EIOL group, observing a caesarean rate of 46.8% in the induction group and 51% in the expectant group.<sup>16</sup> Begum et al also reported no significant difference in the mean birth weight of neonates in the expectant management group (3±0.41) compared to the induction group (2.9±0.34).<sup>16</sup>

The optimal timing for delivery involves balancing maternal and perinatal risks, with the lowest perinatal mortality rate typically observed at 39 weeks gestation. A randomized trial investigated the effect of EIOL at 39 weeks on the caesarean delivery rate and other adverse outcomes. The study reported that the EIOL group had a significantly lower caesarean rate (33.3%) compared to the expectant management group (60%), showing a 42% lower relative risk in the induction group (RR, 0.52: 95% CI 0.289 to 0.971, p=0.038). This reduction was also reflected in the intention-to-treat analysis (RR, 0.57: 95% CI 0.32 to 1.00; p value 0.038) and the induction group also had a shorter postpartum hospital stay. The study acknowledges that its small sample size may limit its power to detect infrequent outcomes.

These findings align with the results of the ARRIVE trial, a large multicentric randomized controlled trial, which also observed a lower caesarean rate in the induction group (18.6%) compared to the expectant group (22.2%). Similarly, the study by Grobman et al reported a significantly lower incidence of hypertension (9.1% versus 14.1%) and a shorter postpartum hospital stay in the induction group, despite similar median BMI and unfavourable Bishop's scores between groups.

Furthermore, Grobman et al noted a 34% risk reduction in perinatal death in the induction group (RR, 0.66, 95% CI: 0.12 to 3.33, p value 0.049). Consistent with the current study, Keulen et al also observed fewer adverse neonatal outcomes in the induction group, including lower rates of NICU admissions and Apgar scores <7 at five minutes.

However, the current study's findings contrast with some other literature. For example, Vrouenraets, Francis et al reported a significantly higher caesarean delivery rate in the electively induced group (23.8%) compared to the spontaneous labour group (12%).<sup>9</sup> Similarly, Beigh et al from India found a higher caesarean section rate in the induction group (31%) versus the expectant group (23%). Middleton et al reported a higher rate of operative vaginal birth in the labor induction groups (RR 1.07, 95% CI 0.99 to 1.16) and a higher rate of babies with APGAR scores less than 7 in the induction group, contrary to the current study.

Conversely, the current findings are supported by the meta-analysis by Caughey et al which observed that expectant management was associated with a higher odds ratio of caesarean delivery (OR, 1.22 (95% CI, 1.07 to 1.39)) across nine randomized controlled trials, though they found no difference in meconium aspiration syndrome or operative vaginal delivery. Other supportive data comes from Wagner et al and Sauter et al who also reported lower caesarean rates in the induction groups. The current study's demographic data (mean age) and non-significant difference in mean birth weight were concurrent with Begum et al who also reported no significant difference in the mode of delivery between their induction and expectant groups.

### **Limitations**

The primary limitations are the small sample size of the pilot trial (n=27 per arm), which severely reduced statistical power for confirming safety or harm in secondary outcomes like perinatal mortality. The open-label design introduced a high risk of performance bias (physician intervention), potentially exaggerating the difference in caesarean rates. Generalizability is limited, as the study focused only on low-risk nulliparous women in a single, low-resource Indian setting, restricting the applicability to other populations or clinical environments. Crucially, the trial did not adequately assess the systemic burden or cost implications of routine elective induction on already strained labour ward resources.

### **CONCLUSION**

This pilot randomized controlled trial, conducted on low-risk nulliparous women in a low-resource setting in India, compared the outcomes of EIOL at 39 weeks with expectant management up to 41 weeks. The primary finding was a significant reduction in the caesarean delivery rate in the induction group (33.3% in the EIOL group vs. 60% in the expectant group, a 43% relative

reduction, p=0.038). This suggests that one caesarean delivery may be avoided for every four elective inductions. Furthermore, the induction group did not show an increase in adverse maternal outcomes, such as PPH, hypertensive disorders or infection and even showed a shorter postpartum hospital stay. Neonatal outcomes, including perinatal mortality, meconium aspiration syndrome (MAS) and NICU admission, were also not negatively affected by EIOL, consistent with findings from larger trials like the ARRIVE study.

The study concludes that offering EIOL at 39 weeks to low-risk nulliparous women appears to be a safe and effective strategy for lowering the caesarean birth rate, even in low-resource environments. While the evidence supports improved maternal and perinatal outcomes, the routine application of EIOL at the population level in low-resource settings is challenging due to the potential added cost and burden on strained labour wards and staff. However, EIOL remains a beneficial and safe alternative for women who actively opt for the intervention for personal reasons or in remote settings where consistent term follow-up is difficult. Further, larger trials are needed to fully assess the clinical and economic impact of this intervention in similar settings.

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*Ethical approval: The study was approved by the Institutional Ethics Committee*

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