

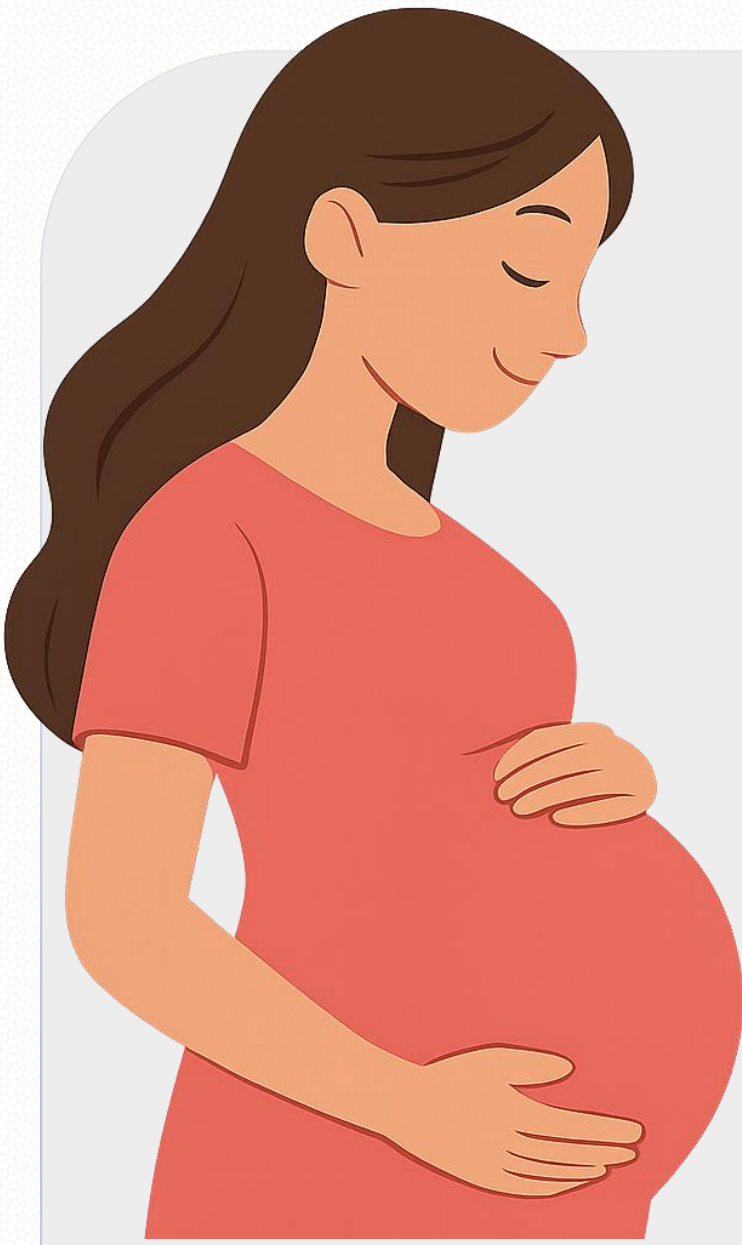


Mifepristone Versus Transcervical Foley Catheter for Pre-induction Cervical Ripening – Randomised Controlled Trial

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OBJECTIVE

- Induction of labour (IOL) at term and late-term is the most commonly performed procedure worldwide, with an incidence of 25%. It is indicated either for maternal or foetal indications. The success of IOL depends on the degree of ripening of the cervix.
- The aim of the study was to determine and compare the **EFFICACY** i.e., change in Bishop score and the **SAFETY** of oral Mifepristone with transcervical Foley catheter in women with singleton term and late term pregnancy undergoing pre-induction cervical ripening.

STUDY DESIGN

Open-label | Randomized Controlled | Non-inferiority Trail

METHODOLOGY

All women planned for IOL from December 2021 to April 2023 at a tertiary care centre in South India, fulfilling the eligibility criteria, were recruited. The participants were equally randomized into two groups:

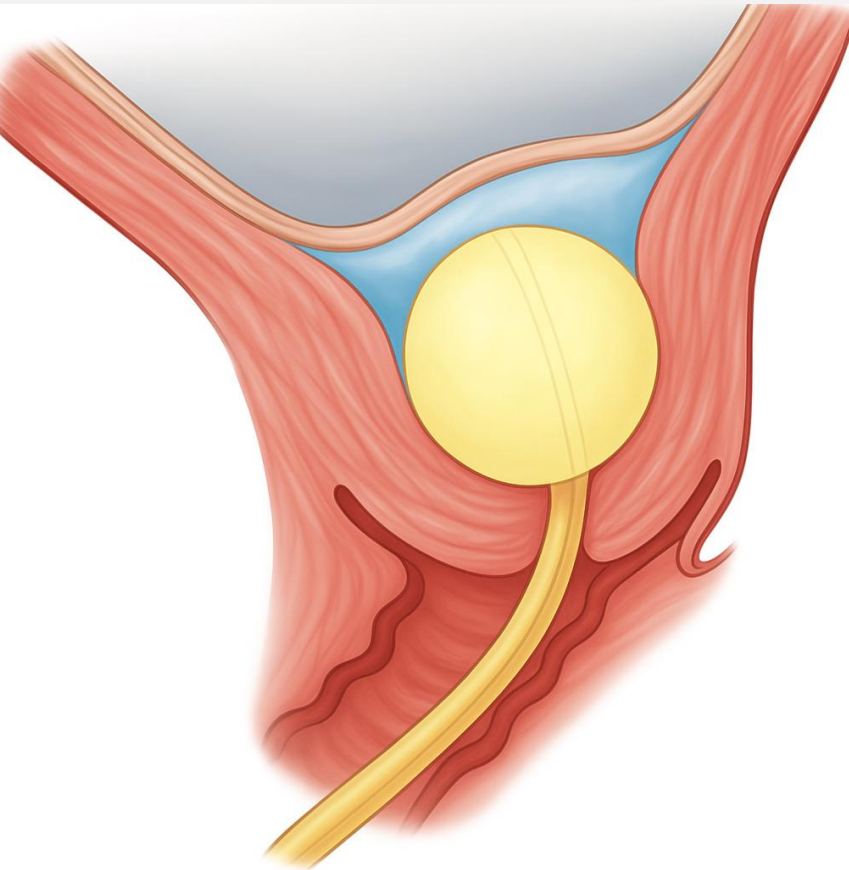
Group A (n=133)

Single Oral Mifepristone 400mg



Group B (n=133)

Transcervical Foley for 24 hours.



Inclusion Criteria:

- Age > 18 years
- Period of gestation 39^w to 42 weeks
- Single live foetus with cephalic presentation with reactive Non stress test
- Bishop score ≤ 6
- Intact membranes
- Unscarred uterus
- Planned for IOL

Exclusion Criteria:

- Absolute contraindications for vaginal delivery
- Patients requiring imminent delivery
- Evidence of chorioamnionitis
- Participants with known contraindications to Mifepristone

Statistical Analysis:

Using STATA Software, Intention-To-Treat (ITT) and Per Protocol analysis (PPA) were performed; $p < 0.05$ considered significant

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Primary Outcome

Change in Bishop's score at 24 and 48 hours of intervention

Secondary Outcomes

Maternal

Need for additional ripening/induction/augmentation agents | Ripening to delivery interval (in hours) | Maternal infection | I.C.U. admission | Side-effects of the ripening method

Perinatal

Respiratory support | NICU admission | Neonatal infection | Death (intrapartum/ neonatal)

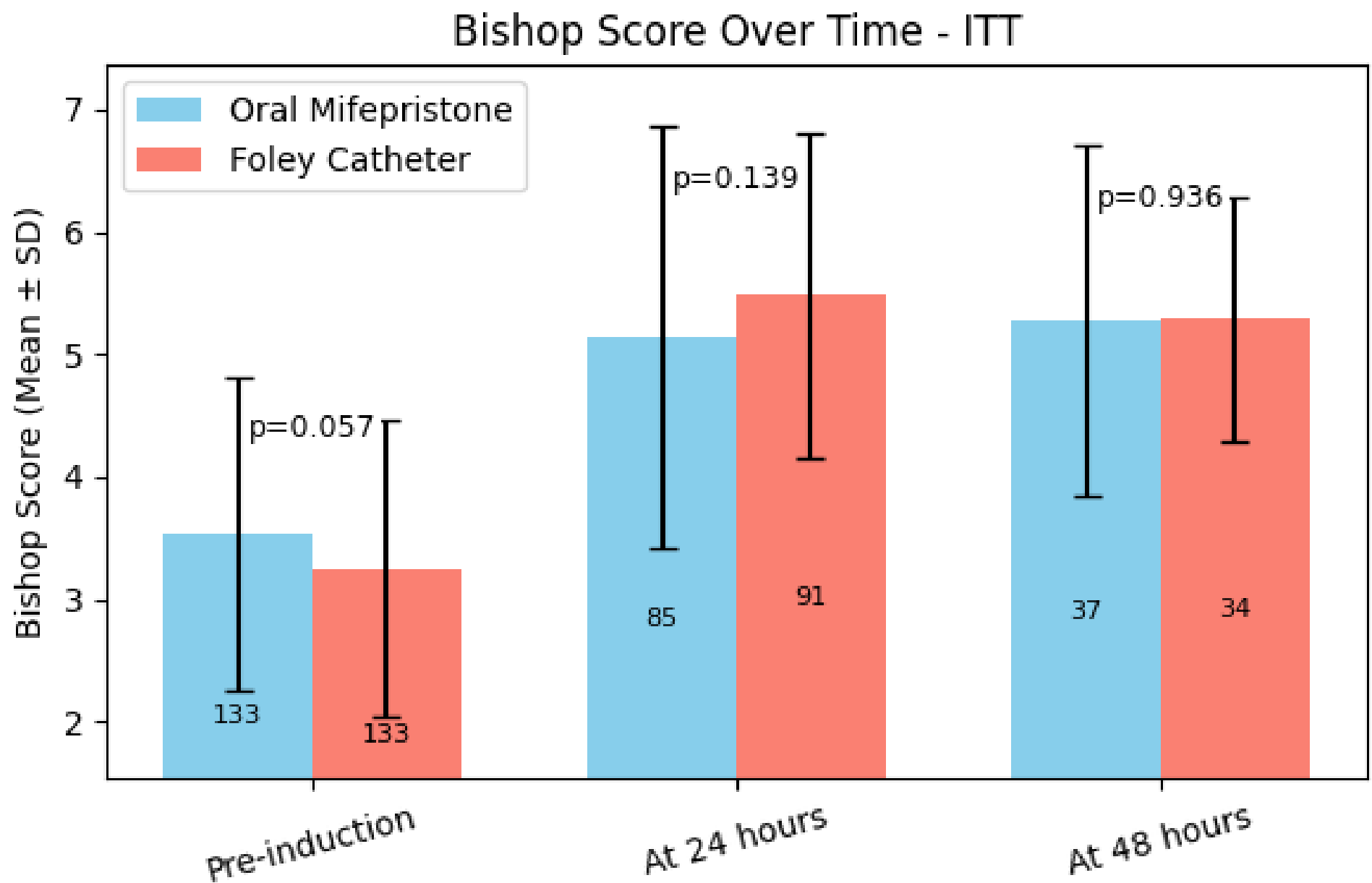
CONCLUSION

- Mifepristone (400mg) demonstrated comparable efficacy to trans-cervical Foley catheter for pre-induction cervical ripening in singleton term and late-term pregnancies.
- While it significantly increased the need for additional ripening agents, it reduced the need for induction agents and Oxytocin.
- Two-thirds of women delivered within 48 hours, with Mifepristone showing a shorter ripening-to-delivery interval.
- Mifepristone was associated with complications like uterine hyperstimulation and antepartum hemorrhage, but the overall safety profiles of both methods were comparable.

RESULTS

Baseline Characteristics

Age, BMI, Parity, gestational age, pre-induction Bishop score, Indication for IOL, and coexisting medical conditions were comparable between both the groups.



	Mifepristone (n=133)	Foley (n=133)	p-value
Ripening to Delivery interval (hours)	43.90 ± 29.84	46.22 ± 27.93	0.514
Vaginal Delivery	104 (78.2%)	114 (85.7%)	0.329
LSCS	29 (21.8%)	19 (14.3%)	
Need for additional agents:			
▪ Ripening	13 (9.8%)	6 (4.5%)	0.089
▪ Induction	19 (14.5%)	28 (21%)	0.383
▪ Augmentation	52 (39.1%)	61 (45.9%)	0.264

