

Double-Balloon Device for 6 Compared With 12 Hours for Cervical Ripening

A RANDOMIZED CONTROLLED TRIAL

HYPOTHESIS: double-balloon device for 6 vs. 12 hours will result in a shorter time to delivery without affecting cesarean delivery rate.

INCLUSION: Any Indication for labor induction at ≥ 37 weeks, **singletons, cephalic**, Bishop score ≤ 5

EXCLUSION: History of cesarean delivery, ruptured membranes, contraindications to vaginal delivery

PROCEDURE: Usual insertion, **80ml** in each balloon. Removing after **6 or 12 hours** as randomized or by rupture of the membranes. After removal artificial rupture of membranes and start with **oxytocin** infusion

I° OUTCOME →

II° OUTCOME →

	Nulliparous (n=101)			Parous (n=96)		
	6h (n=48)	12h (n=53)	P-value	6h (n=49)	12h (n=47)	P-value
Insertion-to-delivery-time (h)	25.6	31.4	0.04	18.0	22.6	<0.01
Total Balloon Time (h)	6.3	11.3	<0.01	6.2	10.0	<0.01
Bishop at removal	5.7	5.3	0.29	5.3	5.6	0.22
Δ Bishop	3.3	3.1	0.43	2.8	2.9	0.82
Removal-to-delivery-time	19.4	20.1	0.89	11.8	13.2	0.52
Total Pitocin time	15.4	14.3	0.42	8.7	9.6	0.88
C-section rate (%)	9 (19)	16 (30)	0.18	1 (2)	4 (9)	0.20
Intrapartum Fever	2 (4)	8 (15)	0.09	0 (0)	2 (4)	0.24
PPH	0 (0)	2 (4)	0.49	2 (4)	0 (0)	0.49
5min APGAR <7	1 (2)	6 (11)	0.12	0 (0)	1 (2)	0.4

- Insertion-to-delivery interval is **significantly shorter** after 6-hours for both nulliparous and parous women
- **Bishop score change** and **cesarean delivery rate** were **similar** between groups regardless of parity
- In the combined cohort, **12h** was associated with **higher rates of maternal intrapartum fever** (2% vs 10%, P=.02)