Outpatient versus inpatient catheter balloon cervical ripening - a randomised trial

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BACKGROUND

- Induction of labour is a common obstetric intervention.
- Of the common cervical ripening agents, mechanical dilation with the balloon catheter is safer than pharmacological priming with prostaglandins as it does not cause uterine hyperstimulation (1).
- Currently, it is standard practice for women undergoing cervical ripening to be hospitalised from the time of balloon catheter insertion until after delivery.
- Recent studies have suggested that balloon catheter cervical ripening can be safely managed in the outpatient setting for low-risk pregnant women (2,3).
- However, there is limited evidence that outpatient cervical ripening provides a clear benefit to women presenting for labour induction with an unripe cervix.

OBJECTIVES

- To assess whether outpatient cervical ripening reduces the length of hospital stay compared to inpatient cervical priming
- To compare the birth outcomes between the two groups
- To inform future labour induction practices

METHODS

Design: Prospective randomised trial

Participants: Low-risk pregnant women requiring cervical ripening with the Cook® Cervical Ripening Balloon between 31 Oct 2018 and 31 July 2019 at The Women's at Sandringham

Randomisation: Allocation assignment with sequential opaque envelopes after balloon catheter placement

Ethics: Approved by the Royal Women's Hospital Human Research Ethics Committee (Project 18/17)

Statistical analysis: Descriptive statistics performed in Excel. GraphPad Prism 5.01 used for non-parametric comparisons (Mann-Whitney U) and contingency tables (Chi-squared).

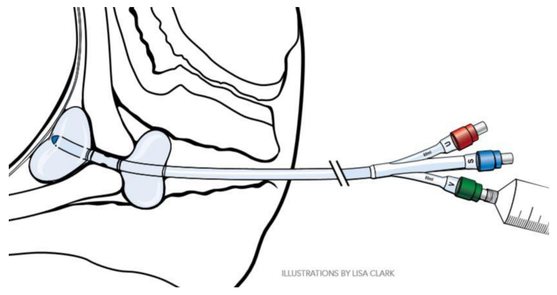

Figure 1: Cook® Cervical Ripening Balloon in situ

RESULTS

Maternal demographics

- 28 women were recruited: 12 outpatient, 16 inpatient.
- Indications for labour induction: post-dates > 41 weeks (53.6%), pregnancy-induced hypertension or preeclampsia (14.3%), gestational diabetes (14.3%), static fundal height or small for dates (7.1%), macrosomia (3.6%) and oligohydramnios (3.6%).

Characteristic (mean ± standard deviation)	Outpatient (n=12)	Inpatient (n=16)
Maternal age (years)	33.3 ± 3.7	34.4 ± 4.1
Gestational age at time of induction (days)	285 ± 7	282 ± 10
Driving distance from home to hospital (km)	11.8 ± 7.0	10.6 ± 3.8

Table 1: Maternal demographics

Labour and delivery outcomes

- Outpatient cervical ripening significantly reduced the pre-delivery inpatient time by an average of 8.3 hours (p=0.002).
- The average length of labour and hospital stay was also shorter for the outpatient group.

Outcomes (mean ± standard deviation)	Outpatient	Inpatient	p
Pre-delivery inpatient time (hours)^	17.8 ± 11.4	26.1 ± 6.2	0.002*
Total length of labour (hours)#	6.9 ± 3.5	8.6 ± 5.3	0.56
Duration of hospital stay (hours)^	64.8 ± 26.5	73.0 ± 23.9	0.50

^ n=12 outpatient and n=14 inpatient as 2 women had a delay in the continuation of their induction due to lack of beds
# n=10 outpatient and n=15 inpatient as 3 women had failed inductions
* p<0.05 was taken as statistically significant

Table 2: Labour and delivery outcomes

Maternal and neonatal outcomes

- The rate of instrumental vaginal delivery was significantly lower in the outpatient group compared to the inpatient group (0 vs 31.3%, p=0.05).
- The outpatient group also experienced a lower rate of birth complications, which included non-reassuring CTG, failure to progress, failed labour induction and postpartum haemorrhage (50% vs 75%, p=0.24).
- Most women required oxytocin (26/28, 93%). Two women in the inpatient group did not receive oxytocin due to precipitate labour and maternal choice.
- Neonatal outcomes were comparable between the two groups.

Maternal outcomes	Outpatient (n=12)	Inpatient (n=16)	p
Artificial rupture of membranes	11 (91.2%)	14 (87.5%)	1.00
Oxytocin required	12 (100%)	14 (87.5%)	0.49
Spontaneous vaginal delivery	8 (66.7%)	6 (37.5%)	0.25
Instrumental vaginal delivery	0 (0%)	5 (31.3%)	0.05*
Caesarean section	4 (33.3%)	5 (21.3%)	1.00
Birth complications	6 (50%)	12 (75%)	0.24
Postpartum haemorrhage	2 (16.7%)	5 (31.3%)	0.66
Postpartum fever	2 (16.7%)	2 (12.5%)	1.00
Neonatal outcomes			
Resuscitation required	2 (16.7%)	3 (18.8%)	1.00
Admission to special care nursery	1 (8.3%)	3 (18.8%)	0.61
Respiratory problems	1 (8.3%)	1 (6.3%)	1.00

* p<0.05 was taken as statistically significant

Table 3: Maternal and neonatal outcomes

CONCLUSIONS

- Outpatient catheter balloon cervical ripening has the potential to reduce the length of hospital stay and facilitate a better birth for the mother.
- Experience gained in this study is useful for the design of larger randomised trials, which are needed to further assess the benefit and acceptability of outpatient cervical ripening before definitive recommendations can be made.

REFERENCES

1. Jozwiak M, Oude Rengerink K, Benthem M, van Beek E, Dijksterhuis MG, de Graaf IM, et al. Foley catheter versus vaginal prostaglandin E2 gel for induction of labour at term (PROBAAT trial): an open-label, randomised controlled trial. Lancet. 2011;378(9809):2095-103.
2. Kruit H, Heikinheimo O, Ulander VM, Aitokallio-Tallberg A, Nupponen I, Paavonen J, et al. Foley catheter induction of labor as an outpatient procedure. Journal of perinatology: official journal of the California Perinatal Association. 2016;36(8):618-22.
3. Wilkinson C, Adelson P, Turnbull D. A comparison of inpatient with outpatient balloon catheter cervical ripening: a pilot randomized controlled trial. BMC pregnancy and childbirth. 2015;15:126.

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This trial is ongoing. Any queries can be directed to Vicky at vickychen677@hotmail.com