Do Cervical Ripening Balloons Increase the Risk of Preterm Birth in a Subsequent Pregnancy?

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Introduction

Induction of labour (IOL) is the most frequently performed obstetric intervention world wide. The use of mechanical methods of cervical ripening are increasing due to the reduced risk of hyper stimulation with fetal heart rate changes and a comparable caesarean section risk.[1] It remains unclear whether the ripening action is due to mechanical pressure or release of prostaglandins. In the setting of dilation and evacuation of the uterus during the first or second trimester, the cervix is dilated over minutes. Although subsequent pregnancy outcomes are generally positive, this procedure has been associated with cervical incompetence and preterm birth [2]. It is plausible that using a single or double balloon catheter could similarly disrupt the cervical stroma, impacting its integrity and strength. [2—8] Few studies have explored the relationship between mechanical methods of cervical ripening and preterm birth in subsequent pregnancies. Two studies have compared a Foley catheter with prostaglandin (PGE2)and report no difference in the rate of preterm birth in a subsequent pregnancy. Given the paucity of data, especially for double balloon catheters, this study aims to report on the risk of preterm birth in the next pregnancy, amongst women who have been induced using a Cook cervical ripening balloon in their index pregnancy

Objectives

To explore if prim parous women who underwent a balloon IOL in their index pregnancy have higher rates of preterm birth in subsequent pregnancies compared to those who underwent IOL with PGE2.

Methods

A retrospective cohort study was performed. A cohort of primiparous women induced using a balloon catheter who went on to have a second birth at Mater Mothers Hospital were matched 1:2 to a cohort induced using PGE2. The groups were matched with respect to age, inter-pregnancy interval, smoking status, indication for induction and BMI. Women with additional risk factors for preterm birth (history of excisional cervical biopsy, uterine abnormalities and multiple pregnancies) were excluded.

The baseline characteristics of the matched groups were compared to ensure similarity between the groups. The primary outcome measure and secondary outcomes measures were compared for the groups who underwent balloon catheter vs pharmacological ripening in the index pregnancy. Categorical data was analysed using the Chi squared test and continuous data using a Student-t test or Mann-Whitney U for normal and non normal distributed data respectively. Comparisons were deemed statistically significant at the 0.05 level.

Results

Table 1: Baseline characteristics

	Balloon N=88	PGE2 N=176	P value
Demographics	N (%)	N (%)	
Maternal age (years)			
<18	4(4.55)	2(1.14)	
18-35	72(81.82)	158 (89.77)	0.102[a]
>35	12 (13.64)	16(9.09)	
Ethnicity	-		
Caucasian	50 (56.82)	107(60.80)	
ATSI	6(6.82)	2(1.14)	0.040[a]
Other	32 (36.36)	67(38.07)	
IOL indication			
Prolonged Pregnancy	24(27.27)	51(28.98)	
Fetal/Maternal	51 (57.95)	104(59.09)	0.802[a]
Other	13(14.77)	21(11.93)	
Smoking status			
Smoker	4(4.55)	6(3.61)	0.648[a]
Non smoker	84(95.45)	170 (96.59)	
Inter-pregnancy interval			
<12 months	26(29.55)	62(35.23)	0.356[a]
>12 months	62(70.45)	114(64.77)	
	Mean (Std. Dev)	Mean (Std.Dev)	
Maternal age (years)	28.62 (5.95)	28.91 (4.77)	0.6697[b]
BMI (kg/m^2)	26.82 (6.59)	26.54 (6.03)	0.7249[b]

[a] using Chi squared [b] using student ttest

Table 2: Primary and Secondary Outcomes

Primary Outcome			
	Balloon N (%)	PGE2 N (%)	P value
Preterm birth < 37 weeks	0 (0)	4 (2.34)	0.148[a]
Secondary Outcomes			
Mode of delivery			0.825[a]
Vaginal delivery	29 (32.95)	56 (32.75)	
Caesarean section	55(62.5)	104 (60.82)	
Instrumental delivery	5 (4.55)	11 (6.43)	
Gestation at next delivery (weeks) *Median (25%, 75%)*	39.2(38.4-40.2)	39.3 (38.4-40.24)	0.5538[c]
Duration of labour (mins) *Mean (Std. Dev)*	161.5 (172.15)	154.90.4 (173.02)	0.3851[b]

[a] using Chi squared, [b] using student ttest, [c] using Mann-Whitney U

The results of this study show there is no increased rate of preterm birth in subsequent pregnancies when induced with a balloon compared to PGE2. Whilst groups were not matched evenly for age and inter-pregnancy interval (both associated with higher rates of preterm birth), groups with larger numbers of these characteristics actually had lower rates of preterm birth. The only statistically significant difference between groups was with regards to ethnicity. Rates of preterm birth are higher amongst Indigenous women however the balloon group had three times the number of ATSI women compared to the PGE2 group and still had no increase in the preterm birth rate.

Conclusion

Balloon IOL remains a safe alternative to PGE2 with lower rates of uterine hyper stimulation. Although a theoretical risk of cervical weakness exists due to mechanical damage to cervical stroma, this has not been supported by limited research to date.

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