

5-2019

Comparison of Single-Balloon with Double-Balloon Transcervical Catheters Used for Cervical Ripening and the Incidence of Altered Fetal Presentation

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Henry Ford Hospital

Medical Education Research Forum

May 3rd, 2019

Objective

To determine whether double-balloon transcervical catheters used for cervical ripening during labor induction are associated with an increased incidence of altered fetal presentation in comparison with single-balloon transcervical catheters.

Balloon Catheters

Single-balloon catheter

- Foley catheter



Double-balloon catheter

- Cook Cervical Ripening Balloon



Altered Fetal Presentation

Cephalic to any non-cephalic presentation (malpresentation).

Breech vaginal delivery and cesarean delivery are associated with increased morbidity and mortality compared to cephalic vaginal delivery.



Source: F. Gary Cunningham, Kenneth J. Leveno, Steven L. Boker, Catherine Y. Spong, and S. Dale
Barber, L. Hoffman, Eric M. Casper, Andrea S. Cluett, Wilkie Chamberlain, with Gillian
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Methods

Retrospective study

Women received either Foley catheter or Cook catheter for cervical ripening

August 2013 and December 2017

Single healthcare system (4 different hospitals)

1,378 women total

Foley catheter (n = 776)

Cook catheter (n = 603).

Reviewed: Maternal age and BMI, gestational age, amniotic fluid index, neonatal birth weight, fetal presentation, and mode of delivery.

Methods

Categorical data were summarized as counts and percentages.

Numerical/continuous data were summarized as means with corresponding standard deviations.

Between-group mean differences were compared by calculating t-tests for independent measures.

Categorical data were compared using the chi-square test for association or Fisher's exact test.

A p-value <0.05 (two-tail) was considered statistically significant.

Microsoft Excel was used for data entry.

Minitab Statistical Software (State College, PA) or Langsrud online calculator (<http://www.langsrud.com/fisher.htm>) were used for analyses.

Data

	Cook	Foley	P-value
N	776	603	
Age	27.4 +/- 6.1	27.6 +/- 5.4	0.54
BMI	30.1 +/- 8.6	28.4 +/- 7.6	0.002
AFI (cm)	11.7 +/- 5.2	9.9 +/- 5.5	0.016
Birth weight (g)	3208.4 +/- 508.7	3311.1 +/- 470.1	<0.001
Gestational age (weeks)	39.55	39.38	0.021
Altered presentation	4	2	0.41

Results

Altered presentations:

2 of 776 patients who received a Foley catheter (0.26%)

4 of 603 patients who received a Cook catheter (0.66%)

Between-group difference was not statistically significant ($p = 0.41$).

Patients who received a Cook catheter tended to have a higher BMI ($p = 0.002$), higher AFI ($p = 0.016$), lower neonatal birth weight ($p = <0.001$), and later gestational age ($p = 0.021$).

Discussion

Statistical overpowering?

Women with higher BMI tended to receive a Cook catheter.

**Easier placement of Cook catheters in obese patients with assistance of provided stylet?

Women with lower AFI tended to receive a Foley catheter rather than Cook catheter.

**Greater likelihood of ruptured amniotic membranes in the Foley catheter group?

**Manufacturer of Cook catheters discourages use in setting of ruptured membranes due to lack of including these women in studies.

Women with smaller fetuses tended to receive a Cook catheter rather than Foley catheter.

**Not due to gestational age

Women at earlier gestational ages tended to receive a Foley catheter (39.38 weeks) versus Cook catheter (39.55 weeks).

Conclusion

When compared to the single-balloon transcervical catheter, the double-balloon catheter does not seem to be associated with an increased risk of altering fetal presentation during cervical ripening.

Acknowledgements

A special thank you to:

Gregory Goyert, MD (Henry Ford Health System, Detroit, MI)

Richard Jarski, PhD, PA (School of Health Sciences Oakland University)

Henry Ford Hospital Biostatistics Department

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