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Outpatient cervical ripening: discomfort/pain during speculum and Foley catheter insertion

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ABSTRACT

Objective: To examine discomfort/pain associated with the Foley catheter insertion process and explore factors affecting discomfort/pain.
Design: This cohort study conducted in the context of larger randomised clinical trial comparing silicone and latex Foley catheters.
Setting: A tertiary hospital in Western Sydney.
Participants: Outpatient pregnant women (eligible participants in the main study).
Interventions: We asked about the discomfort/pain expectations and experience during the digital vaginal examination and insertion of the speculum, insertion of the Foley catheter and while the catheter was *in situ*.
Measurements: We used visual analog scale and a purposefully designed questionnaire to measure outcomes.
Findings: We found digital vaginal examination and speculum insertion (mean pain score = 4.6–4.7/10) to be significantly more uncomfortable than Foley catheter insertion (mean pain score = 3/10), while having the catheter *in situ* for a median of 14 h was mid-way in discomfort (mean pain score = 3.7/10). Only 12–13% of women experienced no discomfort during digital vaginal examination and speculum insertion, while about 40% experienced no discomfort during Foley catheter insertion. We identified no factors that influenced the experience of discomfort during speculum insertion. However, being overseas-born (odds ratio = 1.91, 95% = 1.10, 3.33) and experiencing discomfort during the speculum insertion (odds ratio = 8.15, 95% = 3.19, 20.79) increased the chance of discomfort on catheter insertion. Women's discomfort was not influenced by inserter designation or experience.
Key conclusions: Digital vaginal examination and speculum insertion were moderately uncomfortable while insertion of a Foley catheter and having the catheter *in situ* for several hours were less uncomfortable procedures.
Implications for practice: Only 8% of insertions were rated as difficult by staff while 70% were rated easy. This, together with the fact that the inserter's level of experience had no influence on women's discomfort, are reassuring for midwives who wish to teach and learn this common procedure.

Introduction

Induction of labour is performed in about 25% of pregnancies in high-resource countries (Martin et al., 2017; Australian Institute of Health and Welfare, 2016). If the cervix is unfavourable for labour (defined by a Bishop score < 7 based on the length, dilatation, position and consistency of uterine cervix together with fetal station in the pelvis), a method to 'ripen' the cervix prior to induction is needed. The available options are synthetic prostaglandins (vaginal or oral) to soften and open the cervix (Cunningham et al., 2014), or mechanical devices inserted into the cervix such as a Foley catheters (made from silicone or latex materials) which stimulate the production of natural prostaglandins and also apply direct pressure onto the cervix to assist in cervical ripening (Durie et al., 2015). These options appear to have similar efficacy. However, a Foley catheter causes less uterine hyperstimulation and fetal heart rate changes (Vaknin et al., 2010; Jozwiak et al., 2012;

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American College of Obstetricians and Gynecologists, 2009). It is therefore more suitable for outpatient use where the woman goes home with the catheter in situ and returns for the formal induction the following morning rather than being admitted to hospital overnight.

Foley catheters are usually inserted under vision via a vaginal speculum. The vaginal speculum is a medical tool used by health care professionals to access and visualize the vaginal canal and cervix. The current design of a typical speculum was updated in 1870 by Thomas Graves and has since only been slightly modified. In general, each speculum is comprised of two blades (the posterior usually slightly longer) with a hinged joint that can be opened and locked into position to allow hands-free visualization of and access to the vagina (Taylor et al., 2017). After fixing the speculum inside the vagina, the catheter is fed into the external cervical os, up the cervical canal and beyond the internal cervical os with the catheter balloon inflated when it is above the internal cervical os (Prager et al., 2008; Jozwiak et al., 2011; Pennell et al., 2009). In this location it abuts the amniotic membranes and fetal head.

A large body of research exists on Foley catheter cervical ripening, including many randomised trials, but almost all of it has focused on labour, birth and newborn outcomes, with little attention given to women's experience of the procedure (Jozwiak et al., 2011; Diederen et al., 2018). While the routine cervical screening speculum examination undergone by non-pregnant women is widely-recognised as uncomfortable (Gungorduk et al., 2015; Asiedu et al., 2017; Bakker et al., 2017) especially in the popular media (Beli, 2018), little attention has been given to the speculum discomfort of late-pregnancy women or the additional discomfort associated with Foley catheter insertion. A few Foley catheter studies (Sciscione et al., 2001; Gadel Rab et al., 2015; Pennell et al., 2009; Policiano et al., 2017) have briefly mentioned that mild discomfort may be experienced. Other papers (Jonsson et al., 2011; Diederen et al., 2018) have described more significant discomfort in some women with one study (Maslovitz et al., 2010) reporting pain necessitating removal of the catheter in almost 2% of women. We have been unable to locate any studies that have explored factors which influence a woman's experience of discomfort or pain during this procedure aside from a very small study which looked at speculum versus digital insertion in women with a Bishop score of at least 3 (Jonsson et al., 2011).

The growing use of Foley balloon catheters for cervical ripening necessitates a more detailed investigation of the late-pregnancy woman's experience of this procedure. The aim of this study, therefore, is to examine the level of discomfort/pain associated with both speculum insertion and Foley catheter insertion in term pregnant women undergoing outpatient cervical ripening and to explore factors that may influence their discomfort/pain.

Methods

Design and setting

This prospective cohort study was part of a randomised clinical trial comparing the rate of accidental rupture of the (amniotic) membranes (acROM) and other outcomes for latex versus silicone single-balloon Foley catheters conducted between May 2015 and July 2017 in an outpatient setting at our Hospital, which is a large, low-middle income multiethnic tertiary service in Sydney, Australia. In the current paper, the study question was the pain and discomfort experienced by pregnant women during and after the Foley catheter insertion.

Ethical approval

Our study protocol was approved by the Western Sydney Human Research Ethics Committee prior to commencement.

Study size

The sample size was calculated for the parent study. In the absence of published data and from our limited experience, we estimated a likely 2% acROM rate with the stiffer silicone catheter and 0.5% rate with the more flexible latex catheter. Based on this estimate, using an alpha of 0.05 and a power of 80%, a sample size of 870 participants in each group was needed. Because of the uncertainty surrounding this estimate, the study protocol allowed independent data/safety monitoring committee review after every 100 participants with the stopping point determined as a very significant difference in the primary outcome ($p \leq 0.001$) between the cohorts. The study did conclude early, after the recruitment of 534 women, as the primary study question had been answered at that level of significance (McGee et al., 2018).

Participants

Eligible pregnant women who required Foley catheter cervical ripening before induction of labour were recruited after assessment of Bishop score and a normal pre-induction cardiotocograph (CTG). Inclusion criteria were as follows: (a) aged $\geq$16 years; (b) intact amniotic membranes; (c) placenta not closer than 2 cm from internal os; (d) absence of undiagnosed vaginal bleeding; (e) reassuring pre- ripening CTG; (f) Bishop score < 7; and (g) gestational age $\geq$ 36 weeks at the time of intervention.

Exclusion criteria were (a) prior use of prostaglandin gel or Foley catheter for ripening in the current pregnancy; (b) active or purulent infection of the lower genital tract; (c) lethal congenital anomaly or fetal demise; (d) allergy to latex; (e) unable to speak English

Variables

Variables of interest included demographic characteristics (parity, age, country of birth and BMI), clinical characteristics (indication for Foley insertion, gestational age, bishop score before and after the intervention), women's self-reported knowledge of the procedure and expectation and experience of discomfort or pain during the initial digital vaginal, insertion of speculum insertion and Foley catheter, as well as clinicians rating of difficulty of Foley insertion.

Intervention

All women booked for outpatient Foley catheter cervical ripening underwent a digital vaginal examination at presentation to confirm the Bishop score was still <7. After this assessment, the insertion of the speculum and Foley catheter took place with the woman in dorsal lithotomy position. A lubricated metal Graves vaginal speculum was inserted to provide sufficient visualization of the external cervical os to permit catheter insertion. The cervix was not cleaned with antiseptic solution. An 18F Foley catheter was then introduced as described earlier, the balloon inflated with 30 mL sterile water and the catheter taped under light tension to the inner thigh. A post-insertion, 60-minute CTG was then performed. If the CTG result was normal, there were no regular uterine contractions, bleeding was minimal, and there were no maternal or fetal indications for hospital admission, the woman was discharged home according to hospital protocol. She was advised to return the following morning for formal induction of labour