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Measuring women's experience of induction of labor using prostaglandin vaginal gel

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ABSTRACT

Objective: To describe and examine the EXIT (EXperiences of Induction Tool), and report on the experience of women undergoing PGE2 vaginal gel IOL, who were participants in a randomized controlled trial comparing early amniotomy with repeat-PGE2.

Study design: Following an evening dose of PGE2 vaginal gel, 245 women with live singleton term pregnancies were randomized to amniotomy or repeat-PGE2. Women's experience of IOL was a secondary outcome measure, assessed using the self-report EXIT administered by phone at 7–9 days post-partum. The 10-item EXIT assessed women's experiences in multiple domains using a 5-point agreement scale. Principal components analysis with orthogonal varimax rotation was undertaken to examine the scale structure. Internal consistency, face, content, construct and discriminant validity were also assessed.

Results: The final 3-component solution comprised 8 of the 10 EXIT items, explained 76.1% of the variance and had a good fit to model ($p < 0.001$). The three resulting components were representative of women's experience of the time taken to give birth, discomfort with IOL, and subsequent contractions. The items loading to each component showed good internal consistency for *time taken to give birth* ($\alpha = 0.88$), *discomfort with IOL* ($\alpha = 0.78$), and *experience of subsequent contractions* ($\alpha = 0.87$). Women in the repeat-PGE2 group reported a less favorable experience with the time taken to give birth (mean (SD): 3.5 (1.4) vs 3.9 (1.2); $p = 0.04$) and more *discomfort with IOL* (2.9 (1.1) vs 2.5 (1.0); $p = 0.04$) compared to women in the amniotomy group. At the individual item level, women in the amniotomy group responded more positive about the time taken to have their baby (median (IQR): 4 (3–5) vs 3 (2–5); $p < 0.01$); and less negative to the question about the number of vaginal examinations (2 (1–3) vs 2 (1–4); $p = 0.05$).

Conclusions: The EXIT shows promise as an instrument for assessing women's experience of IOL. Women undergoing PGE2 vaginal gel IOL reports a more positive experience with an early amniotomy rather than with repeat-PGE2.

Introduction

The 21 st century healthcare consumer expects excellent clinical outcomes [1]. In maternity care, more than any other area of healthcare, the psychological and emotional experience of the healthcare encounter has risen to be one of the most important factors that consumers use to judge the quality of their care [2,3]. This underpins the imperative to explore women's preferences and experiences during pregnancy, labor and birth, and for including them in decisions regarding their care.

Women's experiences have been described in various trials comparing different IOL methods and protocols [4–10]. Although more than 25% of women now undergo induction of labor (IOL) [11–14], there are surprisingly few published studies addressing women's perceptions of the IOL experience, and the findings from retrospective and prospective studies are inconsistent. Furthermore, among these trials no consistent instrument was used to measure women's experience. Given the multidimensional nature of satisfaction, [15] it has been challenging to develop meaningful

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and robust measures of healthcare experience [16]. Very few validated measures exist [17] and in particular, no validated patient experience measures exist for women undergoing IOL.

This paper reports women's experiences of IOL at term from a randomized controlled trial comparing amniotomy with repeat prostaglandin (PGE2) [18]. In the absence of a validated metric, a patient experience tool – the EXperience of Induction Tool (EXIT) – was developed de novo for this trial. This paper describes and examines the EXIT, and reports the experiences of women undergoing PGE2 vaginal gel IOL who received an amniotomy or repeat PGE2.

Materials and methods

A randomized controlled trial comparing two protocols of PGE2 vaginal gel IOL was undertaken between March 2010 and August 2013. The methods are described in detail elsewhere [18]. In summary, all women with live singleton pregnancies at or beyond 37 + 0 weeks gestation, booked for IOL using PGE2 vaginal gel (Prostin E2; Pfizer Australia, West Ryde, NSW, Australia) and with a Modified Bishop's score <7, were considered eligible for inclusion in the study. Following an initial evening dose of intravaginal PGE2 gel (2 mg for nulliparous, 1 mg for multiparas), women were randomized the following morning into either the amniotomy group or repeat-PGE2 group. Women in the amniotomy group underwent artificial rupture of membranes (ARM) regardless of Modified Bishop's score, and only received a further 1 mg dose if an experienced clinician deemed that performing and ARM was not technically possible. Women randomized to the repeat-PGE2 group received further doses of 1 mg PGE2 to a maximum of 3 doses, until the Modified Bishop's score was ≥7 when an ARM was performed. In both groups, an oxytocin infusion was commenced as soon as the membranes were ruptured. The trial protocol was registered (ACTRN:12613000370707) and ethics approval was granted from the Mater Health Services Human Research Ethics Committee (Ref 1315M).

The primary outcome of the trial was the time from commencement of IOL until birth. Women's experience of IOL was a secondary outcome measure and was assessed using the EXIT. The EXIT was administered by phone at 7–9 days post-partum by a research midwife who was not involved in the woman's intrapartum or postpartum care and who was blinded to the woman's treatment allocation. For non-English speaking women, the tool was administered with the assistance of a phone interpreter. An attempt was made to call women on 3 separate occasions before concluding that the data were unobtainable.

The EXIT was developed de novo by three psychologist-researchers (RT, YM, SP) with expertise in patient-reported measurement. Following a review of the existing literature on women's experience of IOL and consultation with women, 10 items were developed to capture meaningful aspects of women's experience of IOL. Items were then refined through collaborative review with four clinician-researchers (one nurse, one midwife, two obstetricians). The final 10-item scale included five reverse-scored items. In addition, 3 single-item measures (global satisfaction with the birth experience, likelihood of choosing the same method of IOL again, and likelihood of recommending the method of IOL to a friend or relative; see Table 1) were administered alongside the EXIT to enable the assessment of concurrent validity. Women were also invited to respond to four process evaluation items comprising two quantitative items (perceived adequate preparation for induction and perceived necessity of medical procedures), and two qualitative items (exploring women's experience of IOL, and their views on ways to improve the experience of other women undergoing IOL). Responses to all quantitative items were recorded on a 5-point Likert scale either from 1 ('strongly disagree') to 5 ('strongly agree') or from 1 ('definitely not') to 5 ('definitely'). Responses to the qualitative questions were coded as "positive" or negative" and example statements are presented for illustrative purposes.

Face and content validity from the perspective of subject matter experts was assessed by seeking feedback on the EXIT and additional items from a group of 8 senior obstetricians and midwives, and also from a team of 4 research midwives who are actively involved in clinical trials and administration of written surveys. Pre-planned analyses included principal components analysis with orthogonal varimax rotation, to examine the structure of the 10-item EXIT. Reliability was tested using the Cronbach's alpha coefficient of internal consistency of the included items. Internal convergent validity was tested by Pearson's correlations between respondents' mean responses (to the included items) and their articulated likelihood of choosing the same method of IOL again and recommending the method of IOL to a friend or relative (items 14 and 15 in Table 1).

The Students *t*-test (normal distribution) and Mann Whitney *U* test (normal distribution) were used for analysis of continuous variables. All analyses were performed using StataSE 10.1

Table 1
EXIT (EXperiences of Induction Tool) Items.

EXIT Original 10-item scale	1. I was happy with how long it took for my labor to start after I first had the vaginal gel
	2. I was happy with how long it took for my baby to be born after I first had the vaginal gel
	1. I was unhappy about the number of internal vaginal examinations I had
	2. Being induced was painful
	3. I could move around as freely as I wanted to after being induced
	4. Having my waters broken (membranes ruptured) was unpleasant
	5. I experienced unpleasant side effects after being induced
	6. The frequency of my contractions was manageable
	7. The intensity of my contractions was manageable
	10. I was unhappy with the procedures that followed being induced
Global satisfaction	11. Overall, I was happy with my birth experience
Process evaluation items	12. Looking back, do you feel you were adequately prepared for being induced?
	13. Looking back, do you feel that everything that happened during your birth was necessary?
	Free Text 1: Lastly, is there anything else about your experience of being induced or having your baby that you'd like to share?
	Free Text 2: And can you suggest any ways to improve women's experiences of being induced?
Assess validity of 10-item scale	14. Given your experience, would you choose to be induced in this way again?
	15. Would you recommend being induced in this way to a friend or relative?