Women's experiences of outpatient induction of labour with double balloon catheter or prostaglandin pessary: A qualitative study.

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Abstract

Background: One quarter to one third of women experience induction of labour. Outpatient induction of labour may be safe and effective but women's views of this setting and of different methods of induction are sparse.

Aim: To explore women's experiences of outpatient induction of labour with either prostaglandin pessary or double balloon catheter.

Methods: Qualitative study using semi-structured, audio-recorded interviews with twenty-one women recruited to a feasibility trial of outpatient induction of labour. Transcripts were coded and analysed using a thematic framework approach.

Findings: Two key themes were identified. 'Ownership of induction of labour' concerned how women understood and experienced the induction of labour process and tried to maintain control of a procedure managed by medical professionals. Women felt unprepared for the steps in the process and for the time it would take. The balloon method was preferred as it was considered a gentler start to the process, although some women reported it was painful on insertion. 'Importance of place' reflected women's associations of the home with comfort, ease of support and distraction, and the hospital with safety yet also with discomfort and delays.

Discussion: This sample of women were keen to start induction without hormones. The randomised controlled trial design may have biased the sample towards women who wanted to experience the balloon method and outpatient setting where these were not usually offered, thus further cohort studies would be beneficial.

Conclusions: Women were positive about experiencing the early stages of induction of labour at home with the balloon catheter.

Keywords: Labor, induced; outpatients; birth setting; PGE2; balloon catheter; women's experiences.

Statement of significance

Problem	Rates of induction are increasing worldwide but little is known about women's experiences of and preferences for different methods or locations of induction.
What is already known	Experience of pain and satisfaction with prostaglandin pessary and with balloon catheter is mixed, with no clear 'best' method. Outpatient settings for induction of labour may be preferable to women but may introduce new anxieties.
What this paper adds	The outpatient setting worked well for the first stages of labour. Women valued both the comfort of home and the perceived safety of hospital, and preferred the balloon catheter in this sample.

1. Introduction

Rates of induction of labour (IOL) are rising internationally, and almost one third of women experienced IOL in the UK in 2016-2017 with differing rates of increase worldwide (1,2). Cervical ripening is the first stage of induction of labour, conducted using pharmacological methods first introduced as a routine process in the UK in the 1970s (3). More recently, there has been growing clinical and research interest in mechanical methods, and evidence on the benefits of mechanical versus pharmacological methods is mixed. The most recent Cochrane review suggests mechanical methods and prostaglandins do not differ in subsequent rates of caesarean section or in the proportion of overall deliveries taking longer than 24 hours after intervention (4). A meta-analysis of 96

randomised controlled trials (RCTs) concluded that prostaglandins were most effective at achieving vaginal birth within 24 hours but had the highest incidence of hyperstimulation, whilst the single balloon catheter had the lowest rate of hyperstimulation (5). However, a population-based study of over 7000 nulliparous women at term recently found that time to birth was significantly shorter after induction with balloon catheter than with prostaglandins, and there were no significant differences in adverse maternal or neonatal outcomes (6).

Compared with safety and efficacy, few studies report women's experiences of different methods of induction of labour. Research on women's experiences has largely been based on measures of satisfaction with IOL in general rather than with specific methods, with most surveys finding that women are largely less satisfied with IOL than with spontaneous labour (7,8). Considering experience of methods of cervical ripening, results are mixed and largely measure pain. Studies have shown more pain on insertion of the double balloon than single balloon or pessary (9); similar pain for double balloon and prostaglandin pessary on insertion (10); more pain from prostaglandin pessary than balloons once in situ (9,10); or no differences between methods of pain management or assessment of pain for oral misoprostol or combined oral misoprostol and double balloon groups (11).

A further factor contributing to women's experience of IOL concerns inpatient versus outpatient setttings. Cochrane reviews suggest that for low risk women, outpatient induction of labour is feasible and important adverse events are rare (12). Success of induction, rate of caesarean sections and neonatal admission rates are similar when the same method is given as inpatient or outpatient but evidence is sparse and the latest Cochrane review comparing inpatient with outpatient IOL (published 2013) included only 4 trials (13). Authors have suggested that outpatient induction of labour may be preferred by women because it enables a sense of control (14). A recent systematic review found only three qualitative studies of outpatient induction of labour published to date (reference removed for peer review), but the evidence suggests that some women prefer induction of labour at home because of the quiet and familiar environment, support from family members, not having to arrange childcare, and ability to mobilise, and freedom from constraints and unfamiliarity of hospital (15-17). However

it is also possible that women may be more anxious in the outpatient setting because of the uncertainties surrounding induction of labour, and practicalities with getting back to hospital (14).

There is also little research concerning the preferred method of outpatient cervical priming in induction of labour and most trials have used slow release dinoprostone pessaries (14). In a trial comparing inpatient prostaglandins with outpatient single balloon catheter, women in the outpatient group experienced significantly less discomfort and more sleep, but did not have a statistically significantly shorter total hospital stay (18). Meta-analytic results have indicated that oxytocin is needed for induction more often after mechanical methods than after misoprostol, indicating that mechanical methods ripen the cervix but do not cause contractions (19). This could be a feature supporting use of mechanical methods in the outpatient context as it may require less fetal monitoring (20).

Given the lack of evidence to suggest a best method or location of IOL, and the influence that women's experience of labour and birth can have on physical and mental health (21,22), it is important to explore in more depth women's experiences of IOL with a view to improving this experience (14). Our study directly addresses a call to focus on which methods of outpatient IOL women prefer (23) and advances the state of knowledge about IOL by considering women's experiences of two methods of IOL (prostaglandin pessary and double balloon catheter) both in the outpatient context.

We conducted a qualitative study nested within a randomised controlled trial of feasibility (RCTF) which took place at two hospitals in south east England. PROBIT-F (Prostaglandin Insert [Propess] Versus Trans-cervical Balloon Catheter for Outpatient Labour Induction: A Randomised Controlled Trial of Feasibility), had the primary aim of evaluating how many women with healthy pregnancies would be willing to enrol in an RCT comparing these two methods of IOL in an outpatient setting (under review, citation removed for peer review) . Secondary aims included: (i) examining in depth women's views on outpatient induction of labour and, (ii) understanding women's experiences and

preferences regarding the methods of induction of labour. Reported here are the findings related to these secondary aims.

2. Participant, ethics and methods

2.1 Design

A qualitative exploratory design, using semi-structured interviews, was chosen in which women could reflect on their IOL experience without constraints, as quantitative data cannot fully explore concepts of satisfaction with, and acceptability of, birth experiences.

2.2. Study participants

A total of 28 women completed the RCTF, 21 of whom took part in this qualitative study. Five women were not contactable by phone, one woman had returned to work full-time and did not feel able to take part, and one woman did not consent to be contacted after birth. A further two women who did not complete the trial as the balloon placement was unsuccessful were not contactable within the study period. Partners were also invited to take part in the interview, three of whom did so. Purposive sampling was planned but as numbers recruited to the RCTF were lower than expected, all women who took part in the RCTF were invited to interview. Women were eligible for inclusion in the RCTF if they were ≥ 37 weeks gestational age, with a single uncomplicated pregnancy and were booked for IOL, ≥ 18 years old, had sufficient English language skills to understand the information leaflet, and met local guidelines for outpatient cervical ripening. Women with parity ≥5, multiple pregnancy, with previous caesarean section or uterine scar, or complex medical or obstetric problems were excluded as were women who were contracting or who required analgesia. Following the clinical decision to induce labour, eligible women were informed about the study methods of induction and procedure orally and with an information leaflet by midwives at the obstetric departments of the two participating hospitals between October 2017 and March 2019. Discussions took place at women's 41 week appointment or postdates appointment at hospital one. At hospital two, women were informed of the study at their pre-induction clinic ultrasound scan between 39+0

and 41+2 weeks. The procedure at both hospitals involved being screened for eligibility, monitored for fetal wellbeing using cardiotocogram, receiving the intervention, further fetal/cardiotocogram monitoring, and then going home. Women returned to the hospital at onset of labour or the next morning (18-24 hours later), whichever was sooner. Admission was to the obstetric unit as hospital protocols did not allow admission to midwifery units after IOL. Women who agreed to participate in the trial were also asked for consent to be contacted after birth by a female qualitative researcher (initials removed for peer review) to take part in an interview. (Initials removed for peer review) is a research psychologist (PhD) with ten years' experience in qualitative interviewing, and has undertaken qualitative methods training. Women were contacted by (initials removed for peer review) by telephone at least four weeks after the birth, to allow women time to settle with their new baby. (Initials removed for peer review) explained her role as an academic researcher in the area of maternity care who was not involved with clinical care or employed by the National Health Service (NHS), to facilitate choice in deciding whether or not to take part in the interview, and openness during the interview process. The qualitative study was further explained and a time and location to interview was arranged if women wanted to take part. Four attempts were made to contact participants by telephone. The first author (initials removed for peer review) who conducted all interviews was not known to the trial participants, and clinical members of the research team before the study took place. Written consent was obtained for the qualitative interview before participation.

2.3 Ethics

Ethical approval was obtained from the NHS Health Research Authority East of England - Cambridgeshire and Hertfordshire Research Ethics Committee [Ref no. 17/EE/0295]. Participants provided separate written consent to (i) take part in the RCTF; and (ii) participate in the qualitative interview. All participants consented to the research findings being published in a peer-reviewed journal. The funder was not involved in the design of the study, the collection, analysis, and interpretation of data or in writing the manuscript.

2.4 Data collection

Most women (19/21) chose to be interviewed at home, with their baby (and partner in three cases), and two took part by telephone as they had moved out of area. An interview guide designed by two authors (initials removed for peer review) and reviewed by the third author, a midwife and academic (initials removed for peer review) facilitated semi-structured interviews (Additional file 1). Interviews took place between April 2018 and March 2019. Interviews were recorded and transcribed verbatim and rendered anonymous. Interview duration was from 18 to 52 minutes. (Initials removed for peer review) kept a reflexive diary to enable reflection on the interviews, on rapport with participants, and on assumptions born of professional and personal experience. Women were interviewed once; no repeat interviews took place. Transcripts were not returned to participants for correction.

2.5 Data analysis

An interpretivist approach with the intention of understanding women's lived experiences of IOL was adopted (24). Thematic framework analysis with an inductive/deductive approach was chosen as the method of analysis to allow for women's accounts to take the fore (25,26) whilst testing a previously published conceptual framework of experiences of IOL. The framework was generated through a process of qualitative systematic review and thematic synthesis. Findings from all available peer-reviewed studies of pregnant women's experiences of induction of labour in an outpatient or inpatient setting were analysed in three stages, generating descriptive codes, grouped codes and inductive analytical themes. Analytical themes comprised: 1) Making decisions about IOL; 2) Ownership of IOL; 3) Social needs, and 4) Importance of place (citation removed for peer review).

Data (interview transcripts) were imported into NVivo 11 software (QSR International, Melbourne, Australia). Thematic framework analysis involved three steps: 1) (Initials removed for peer review) coded transcripts line by line with codes from the previously developed framework if they were applicable, or with new descriptive codes generated according to meaning and content of the data; 2) Codes were then reviewed for fit with the framework and were either placed within existing themes or grouped to capture their meaning, into new themes. An adapted structure of super- and sub-ordinate codes was generated (see Table 2). Two further authors (initials removed for peer review) coded

separate subsamples of interviews, and coding was discussed and agreed upon, creating a final code book. (Initials removed for peer review) drafted a summary of findings agreed on by all authors; 3) Themes were revisited to check they work with all the data, e.g. to check there was enough evidence to support themes, to check if themes were too similar and should be collapsed, and to check for disconfirming evidence, and were revised accordingly. New themes did not arise in the final interviews therefore it is tentatively proposed that data saturation was reached. Participants were invited to provide feedback on findings at a patient and public involvement event. Two participants attended and four participants have helped to develop further research proposals. Standards for Reporting Qualitative Research (27) and Consolidated Criteria for Reporting Qualitative Studies (COREQ) guidelines (28) were adhered to when preparing this paper.

3. Findings

The median age of the 21 interviewees was 34 years (range 26-44). All except one were married or cohabiting. Nineteen women were White, one was Black and one was Asian. Seven women received the balloon catheter and 14 the prostaglandin pessary. See Table 1 for further participant and labour characteristics.

Two key analytical themes from the previously published framework of experience of IOL (citation removed for peer review) are reported. The first considers women's ownership of IOL, and three additional subthemes were added to the original framework: experience of method of IOL, further intervention, and experience of pain (the papers on which the framework was developed did not focus on these aspects in any detail). The second analytical theme considers the importance of place. A further sub-theme, transition between home and hospital, was added as women discussed the movement between home and hospital with some importance in their accounts of outpatient IOL. Themes and sub-themes are reported in Table 2.

3.1 Ownership of IOL

3.1.1 Understanding of the IOL process

There was variability in how much women knew, and what they expected, from the IOL process. For some women IOL was seen as 'the drip in your arm' (P07), a long and intense process that would be more painful than spontaneous labour. The cervical priming component of the IOL process - which this study had been designed to explore - was unfamiliar to several of the participants.

> *I just wasn't fully aware. I mean I knew, like I say, the final stage of induction, the final drip, very strong contractions, I knew that bit, but I didn't know anything else about it. (P07)*

> *I just thought "Oh, induction, I'm gonna end up with a drip, I'm gonna need an epidural" and I…and I didn't want any of that. (P11)*

Some women felt that they knew a limited amount about IOL. However, the earlier stages of IOL, the sequential steps that would be followed and the possible length of time of each stage were largely unknown to women. Ten women reported feeling surprised that contractions started immediately, or within a few hours of treatment, or that the entire labour and birth process was quick, having been told by healthcare professionals or friends and family that the process could take days.

> *And they…straight away [contractions] were every minute…they were…yeah, it happened really quick and I was like "is it meant to be this quick?" (P16)*

If the first treatment did not succeed in inducing contractions, women were largely unclear about what would happen next – some women expected their waters to be broken and were confused if another pessary or method of IOL was suggested.

> *I think that was mainly just unclear in the notes, what the follow-on process was if the…if the first induction didn't work, because yeah I just assumed I would go straight up to the next level. (P09)*

Women spent some time deliberating whether contractions had truly started, or whether low-level pain resulted from insertion of the balloon or pessary.

3.1.2 Choice and control in labour and birth

Women used a number of strategies to try to retain some control over the labour and birth process. A majority of women (17 out of 21) wanted a less medical approach to the start of labour and joining the trial was one way of realising this, as at least part of the process would be at home, and the possibility of having the balloon meant delaying pharmacological intervention. Further strategies included seeking information about the process, taking time to make decisions about interventions, having a hospital bag prepared and in the car, and setting up the labour room in a pre-defined way. However, some felt that there was no point in planning birth at all, because control was not in their hands, or felt disappointed if they had been encouraged to make a birth plan which then could not be met because of being induced.

> *I always felt a bit resentful when I was having the pessary put in. When I was just lying there thinking, like "I didn't really have a choice in any of that, so it's kind of pointless thinking so much about your dream situation, because that's just not how it works out." (P17)*

3.1.3 Experience of method of IOL

Views about the prostaglandin pessary prior to treatment were largely negative, with information from previous births, friends and family and /or the internet suggesting that it led to strong contractions without sufficient dilation, having an epidural, being put on the hormone drip, that it was painful to insert, and/or that it had no effect at all

> *Propess has got such a sort of heavy association with it…that having the balloon as an option was great. (P02, balloon)*

Only three women had heard of the balloon before. Once the participating women had been informed about the balloon through discussion with the midwife about the trial, they were positive about the method because it did not involve hormones and appeared to offer a more gentle first IOL intervention; many cited the chance to have the balloon as a key reason for taking part in the trial.

[The balloon] was less medicalised, I thought that just makes complete and utter sense, if it's just making your body do what it…it's just kind of giving it a push start, rather than, you know, kinda using medication. So, umm, I just wanted that. (P11, balloon)

All of the women interviewed described their physical experiences of induction as important. The physical experience started with the priming agent being inserted which could differ from the experience of it being in place. The majority of women who were induced with pessary reported that insertion was quick and not painful but mildly uncomfortable. Two women described insertion as 'scratchy' with one woman finding it painful and invasive enough to make her cry. Three women reported an extremely painful response to the pessary once in situ, which was recognised by its being removed early.

But it was…yeah, literally, back to back contractions and stuff, literally, straight from nothing to 110 percent, straight away. There was no, sort of, build up, it was just there. (P12, pessary)

For a further three women the pessary fell out, which two women perceived as being a sign that labour was progressing well because no further intervention took place at that time, but one woman considered that this stopped her labour as she then stopped having contractions.

Insertion of the balloon was reported as uncomfortable, but not painful, by four women, with it being compared to a cervical screening procedure, or to having a lot of pressure placed on the cervix. For three out of seven women, insertion of the balloon was a painful experience however. This pain continued for two women until they had the balloon removed 24 hours later, although one woman was able to sleep. Some women expressed surprise at how the balloons looked, not expecting them to be so large, or being unprepared for having the part of the device protruding from their vagina.

A further woman found insertion fine but once it was in place she considered the pain severe. For one woman who was contracting the balloon fell out at home, leaving her unsure what this meant and what she should do about it. The remaining women reported having the balloon removed painlessly and quickly back at the hospital.

When discussing what method of IOL they would opt for in the future five out of seven women who had the balloon (including two who found insertion painful) said they would use it again. The third woman who found insertion painful and then went on to have the pessary would choose the pessary in future. The woman for whom balloon insertion was not problematic but once placed was painful also would not use the balloon again. Largely, the balloon was perceived as a natural way to start the IOL process, and even when women wanted to be induced, the women in this study wanted to start with a non-pharmacological method that was perceived as more 'natural' and gentle.

> *I liked the idea of being induced, but in that way, rather than…going down the hormone route… Umm, and [the balloon] worked…you know, at the end of the day it worked in that it trig…it got everything going…And got it going naturally. (P18, balloon)*

> *I think I ended my labour feeling like I'd really experienced it, hadn't gone in…hadn't started it drugged up, hadn't gone in with an expectation of needing drugs, which I would've had with Propess. (P02, balloon)*

Contrastingly, no one randomised to the pessary definitely wanted to use that method again – all the women who had the pessary said they would either definitely try the balloon, or they would take the advice of medical professionals, about the current evidence on IOL methods. Women who perceived that the pessary had 'worked' still would have preferred to try the balloon in future labours.

3.1.4 Further intervention

Almost two thirds of women in each group needed further pharmacological intervention. Women largely saw this as inevitable, and remembered it as a long process to be endured; the details of which part of the process happened at which time took some concentration to recall. There was a sense that women judged their labour by how quickly they dilated. Long labours were recalled negatively, as if abnormal. A woman whose dilation was slow but consistent enough to not need further interventions considered it 'not good progress at all' (P01). Other reactions included feeling that the baby was never going to come, deciding not to have epidural anaesthesia to avoid further slowing, or asking for 'harder' intervention (P09).

I was like "it's never gonna happen, he's never gonna come out". You know, it's such a stupid thing but it just…it just felt like time stood still in that room, when I was like "I'm gonna be here forever"…'cause you've got no concept of time or anything like that. (P16)

I decided not to go for the epidural straight away, which I could have done, 'cause it can slow it down and I was like "well I'm bloody slow enough anyway." (P03)

Contractions that fluctuated from being strong, to very mild or to stopping altogether were frustrating for women, who considered that this was either because the pessary was taken out, or because of having to move location; from home to hospital or within the hospital. Concerning birth, 13 women had a spontaneous vaginal birth; this was largely reported as a positive experience. Five women (all in the pessary group) had a caesarean section. The build up to the operation was one of exhaustion, more waiting, or anxiety about the baby being OK, but the intervention itself was reported as highly professional with women knowing exactly what was going on.

3.1.5 Experience of pain management

One third of women started the IOL process not wanting to have epidural anaesthesia, because they were scared of needles, because of not being mobile, because they felt able to deal with the pain, or because of the effect it might have on slowing the labour. After being induced, over half had an epidural. The length that IOL took led to exhaustion for some women who reported that this was the reason they decided to have an epidural.

Before [the epidural] I just had no…I couldn't…I just…you know, when they ask you what your name and date of birth is before they give you drugs and I was just so blank tryna think what my date of birth was, and then after that I felt so much better, and I could feel my legs and everything and so then…that was my concern with having an epidural, but I was like "oh no I can feel my legs and I can move my legs and I'm pretty sure I can stand with…holding onto somebody, so this is fine." (P17)

Four women (all in the prostaglandin group) felt that the pain was unbearable as it changed very quickly from minimal to very intense and without breaks between contractions. Responses to having pain relief included feeling more able to actively participate in labour because the pain was reduced or gone altogether, or because of feeling more rested, and experiencing a change in mind set to feeling looked after rather than being alone. Almost half of women did not feel that they needed an epidural. Women in both groups used other pain relief options including Entonox and pethidine, or did not use pain relief:

> *There was quite a lot of discussion about "ooh, induction of labour, you always have a more painful labour", which was not my experience. I mean, I've got nothing to compare it to, but I did it with no drugs, so I wasn't like "this is horrific." (P19)*

3.2 Importance of place

A feeling that it would be advantageous to go home for part of labour, was a key reason why all women except one took part in the trial. Some women had a strong desire to go home and remain there as long as possible. Six women did not go home after receiving the IOL treatment, either because they changed their mind and did not want to, for example if they felt that their contractions were strong, or because they were recommended not to.

> *After a couple of hours, I started feeling some contractions, they said I was okay to go home, but the way the contractions were coming in, I thought "no, I'm not going home" (P10)*

Women retrospectively weighed up the pros and cons of being at home or in the hospital, considering whether it would be better to remain in the hospital if labour was going to be quick, or referring to events such as the cord being around the baby's neck, or the baby lying in a position that needed further intervention during birth, to justify why it had been useful to be in the hospital, although there was no suggestion in the trial information that women would not be in hospital at later stages of labour.

I wouldn't have been monitored in the same way [at home]. But at the beginning it was fine, so that wouldn't have been an issue, but…(P18)

3.2.1 Enduring the hospital

There was an overriding feeling that the hospital was a place to be endured. Women reflected that they wanted to spend as little time in hospital as possible. Having a private room was considered an advantage, but still less comfortable than home.

They did put me in my own room in the end because there was a room free. But, uhm, I much would've preferred to be at home, watching TV or just being able to do my own thing, rather than being stuck in an uncomfortable room…uncomfortable ward. (P01)

Lack of privacy, not being able to get in a comfortable position, an uncomfortable temperature, boredom, unfamiliarity, experiencing the hospital's routines rather than one's own, and concern for partners who could not sleep or get comfortable were all discussed as reasons for not wanting to be in the hospital. The most reported negative experiences of the hospital concerned waiting – either for healthcare professionals, for a space on a ward, or for the next stage in the IOL process. Women were understanding of the pressure that healthcare professionals were under and of how busy the hospital was, but were still left feeling frustrated that they had to wait or 'be assertive' (P15) in order to be seen, had to send their partner to find staff, were left 'hanging around' (P04), or were told they were better off at home, or would have to wait whilst emergencies were tended to.

I then waited sixteen hours, they took the pessary out and I waited for sixteen hours, waiting for a room, kept being told "oh, you're first on the priority list, we are busy but, like, you're the first to go over" and all of this, sixteen hours…then it had stopped, slowed down because I'd been waiting for 16 hours. (P15)

So I had to keep sending [partner] to go and find the midwives when my waters…waters then broke when I was on the maternity ward…(P13)

However, benefits to being in hospital later in labour were expressed. Even if a midwife was not a constant presence, there was a feeling of safety because staff were physically nearby.

> *The fact you've got a midwife there that you can chat to is handy. (P13)*

The belief that the hospital could facilitate a quicker or less painful birth, or allow women to rest after birth were cited as positive reasons for being there.

> *I think I felt that I wanted to just get things moving and that would happen in hospital. I don't know why, I thought going home, I'd just be bored and be just waiting and...you know, all that kinda stuff. (P09)*

Some women would leave the ward to walk 'to get movement going' (P04) and some were happy to send their partner home to rest and return later, although there was a feeling that one could not go too far because of the need to be monitored. Being attached to a machine was matter-of-factly reported by over half of the women who saw this as a normal part of the IOL process that provided some reassurance that their baby was not distressed, although it could be uncomfortable. Monitoring took place once women were admitted to the labour ward and therefore was the same for outpatient or inpatient if there were no concerns.

3.2.2 Keeping to established rhythms at home

Home was largely viewed as a better place to do the waiting that women associated with IOL. Reasons why home was preferable fell into three categories. Firstly, home was more comfortable. The possibilities of having a bath, wearing as few clothes as liked, getting into comfortable positions that may not be possible at hospital, lying in one's own bed, and eating chosen foods were all appealing.

> *So we ordered, like, an Indian curry and got it delivered, and had the T.V. on, like, was just sat in here on the, umm…on my bouncy ball, bouncing away. (P16)*

For others, being able to go home maintained some aspects of having a 'natural' birth. **S**econdly, distraction was a strategy employed to get through the first stages of IOL and this was easier at home.

Women could keep busy with their usual routines, including looking after older children, or could watch television, listen to music or audiobooks, go shopping or walk or do gardening. Thirdly, support was easier to coordinate at home. Partners (and sometimes women's mothers or sisters) could all be present at home, could rest better with more space, and could support older children and the mother in labour at the same time.

> *It was better for my son, 'cause I was able to have my sister here ready, just slipped off [to hospital] in the morning, I was actually not even in hospital one night. (P06).*

However there were perceived negatives to being at home. A number of women were concerned that the pessary or balloon might have become displaced, or did not know what to do with it if it came out, or were uncertain whether the pain they were experiencing was 'normal' although women were comfortable with calling the hospital to check.

3.2.3 Transition between home and hospital

Most women were not concerned about the time it would take to get from home to hospital, with most women having a journey time of up to twenty minutes. One woman had a 'worst case scenario' (P15) forty minute journey but still preferred to go home as she, and others, were aware that an ambulance could be called in an emergency. A few women felt that by going home after treatment they could have some sense of control in the transition between hospital and home, as there was a perception that they may be turned away if they arrived based on their own experience of pain. Time spent at home was variable. Of the 15 women who went home, three were there less than 6 hours and eight spent the 24 hours. Women were clear on, and reassured by, the process of calling the hospital if they felt they needed to, and on the subsequent return to hospital.

> *It was really nice to know and be reassured that I could go in and wouldn't be sort of sternly sent packing, you know? (P06)*

Some women found the return to hospital frustrating because, having been on their own clock, they then had to wait to park, to be seen or to get a room rather than wait on the ward, or they felt that staff they saw first did not know about the research they were taking part in.

4. Discussion.

We have added to the small qualitative research base of women's experience of IOL, by providing insights into IOL with the double balloon catheter, or prostaglandin pessary in an outpatient setting. Key findings include the under-preparedness that women felt around the process of IOL, the desire of many women in this sample to try the balloon catheter which was viewed as a gentler and more 'natural' introduction to IOL, and the desire to be at home for the first stage of IOL.

Understanding of IOL process

The results of our study corroborate a history of women feeling uninformed, or dissatisfied with information received about IOL, in the period before they were introduced to the trial (29,30). More recent qualitative research reports that women experiencing IOL as part of standard hospital protocol feel uninformed (31,32) but it is perhaps surprising that in an RCTF with its requisite stringent ethical approval processes and accompanying in-depth information for participants and staff training, that women still felt under-prepared for the IOL process. Few women in this study had questions about the RCT that they felt were not answered, and they considered that midwives were helpful and informative about the study. Rather, the issue was that before they were told about the trial women felt less informed about the IOL process generally, and were not able to ask questions about a process they had little knowledge of.

Knowledge and control of timings was important to women in both their expectations and experiences of IOL (33). It was perceived that IOL would take a long time, and this negative perception was subsequently compounded by experiences of delays and waiting related to health services. Timeliness of IOL is complex considering individual variation in women's pregnancies and births, and

differences within and between hospitals. Women in this study, and in other qualitative work expressed the belief that IOL takes a long time, and yet could still be surprised when labour was long, but equally when it was quick (31,32,34-36). Timeliness of the IOL process is one of the most reported negative aspect of IOL in surveys of women's experiences (37).

The unforeseen element of timing may demonstrate that women are genuinely not prepared for IOL, i.e. they do not have sufficient clear information about the possibilities of timings. To mitigate this possibility, clinician time, patience and empathy is likely to be needed. Written information is an important adjunct to a conversation with a healthcare provider, but research shows that it is unlikely that women will fully understand a procedure (and therefore be able to make an informed choice about it) unless a midwife explores it with them (38-40). This finding may also suggest that expecting birth to take a certain amount of time (i.e. having sufficient information and understanding it) does not make that birth satisfactory simply because it met expectations. Further research on the needs of women experiencing IOL would be useful, particularly on the determinants of a positive IOL experience (41); in other areas of maternity care it has been demonstrated that consistent support can make birth a more positive experience (42).

Another aspect of the IOL process that was not clear to women was the uncertainty about whether labour had started or whether immediate sensations following insertion of the pessary or balloon were due to its placement. Information should be given to women that makes clear how the feeling of contractions could be differentiated from effects of the treatment (or whether it is possible to tell the difference at all) and that describes possible scenarios with the pessary or balloon at home. Co-production of information with women who have experienced different methods of induction may help women to understand what to expect from the intervention. This knowledge gap also raises the issue of when women should be informed, or have a conversation, about induction of labour – at their post-dates appointment when they had first contact about the RCT is likely too late, and it may be that women need multiple discussions and written and verbal information about both the reasons for, and the process of IOL (40). Women may want to know about reasons for induction of labour earlier than their postdates appointment, to feel informed about making a decision. Information about the process

of induction may benefit women if it is conveyed at a later time, to ensure women are prepared at the point of induction. In a study where women were given a brochure about IOL in plain English as they arrived for the procedure, women were significantly more knowledgeable about the action and timing of the IOL treatment, side effects and time to birth than women who did not receive the brochure (43). The language used in verbal and written information is important: women in this study heard healthcare professionals say that the IOL process *could* take a few days, and based on this appeared to prepare for a longer rather than shorter labour. To provide a more balanced picture, women need to know that the labour may alternatively be quick.

Method of treatment

The results of our study suggest that women viewed the balloon as a gentler start to the IOL process which they were expecting to be long and painful. All women who had the pessary, and all but two who had the balloon wanted to try the balloon in the future. Although numbers were small in this study, almost half of women experienced the balloon as painful, on insertion and when in situ, but this would not discourage them from using it again in a subsequent labour, suggesting an acceptance of the pain and/or of the benefits of nonpharmacological methods of cervical priming. Previous research has shown similar results concerning pain related to the method, although clear comparison is difficult due to differences in pain measurement.

Our results are consistent with previous research indicating that balloon catheters are associated with some discomfort or pain on insertion. One study reported that 60% of women experienced discomfort or pain on insertion of the single balloon catheter (44), another that 70% found insertion ‘physically uncomfortable’ ((45) and 30% of women were ‘quite-’ or ‘very bothered’ by placement of the double-balloon in another (12). A RCT comparing single balloon, double-balloon and prostaglandin gel found that single balloon placement was significantly less painful than double balloon (10). Almost half the women who had the balloon in our study found it was still painful or uncomfortable when in place, and some research suggests that the single balloon is significantly less painful when in place than the double balloon which in turn is less painful than prostaglandin gel / pessary (10, 11). Kehl et al. (12)

found that 25% of women were still ‘quite-’ or ‘very bothered’ by the balloon once in place, and 51% in the study by Wilkinson et al (45) found wearing the balloon ‘physically uncomfortable’. However, in line with our findings, significantly more women who received the balloon in the study by Kehl et al. (12) were likely to recommend the method, than women who had a pharmacologic intervention (oral misoprostol in that case). In the study in Singapore (11) women were equally likely to recommend the prostaglandin pessary and the balloon. The difference between discomfort and pain is difficult to untangle and these mixed results may be due to pain and discomfort being conflated in the literature, when to women these may be different concepts with differing levels of acceptability (46). Furthermore, cultural and maternity systems differences may have a role to play in acceptance of labour pain, and of IOL methods (e.g.(47), thus further research is required to understand the acceptability, discomfort and pain associated with different methods of IOL in local contexts.

Importance of place

The distinction between the comfort of home and the safety and discomfort of the hospital that women reported corroborates the few qualitative studies of women’s experience of outpatient IOL. Limited quantitative evidence also suggests that outpatient IOL is preferred over inpatient IOL, increases satisfaction, and does not increase anxiety (48, 49). The availability of multiple sources of support at home, with space and privacy to rest and without the constraints of visiting times and availability of space for supporters to stay in the hospital, was universally appreciated (15,18,50). Additionally, being able to experience the initial stages of labour in the familiar and comfortable setting of their own home with its ready-made distractions was desired by the women in this study, in keeping with the proposition of the home as a therapeutic space for the cervical ripening stage of IOL (15). Women wanted to experience both the comforts of home, associated with spontaneous onset of labour, as well as the safety of hospital, defined by the provision of fetal monitoring and expertise of medical staff, and outpatient IOL appeared to provide both these aspects to women (15). None of the women in this study had wanted a home birth, but they had wanted to reduce time spent in the hospital, and for women matching these characteristics, outpatient IOL was a positive experience. One area deserving of further attention may be the transition back to the hospital for women

undergoing outpatient IOL. Research has indicated that admission to the hospital during labour can be problematic for women experiencing spontaneous labour. When women undergo IOL because they are told that there is a risk to their baby if they wait any longer, it may cause added frustration and anxiety if women then have to wait for a space in the ward or for further intervention when they return to the hospital (51).

Strengths and Limitations

The parent study used an RCT design, seen as the gold standard of evidence in healthcare interventions due to the theoretical reduction of selection bias. We interviewed a large proportion of the women who took part in the RCT, and as far as we are aware this is the first qualitative study of women's experiences of prostaglandin pessary or double balloon catheter in an outpatient setting. The parent study tested the feasibility of recruiting women indicated for IOL to an RCT design, which has implications for our qualitative results. In the NHS hospitals included in this study, recruitment was low. This suggests that the RCT design may not be optimal for IOL research. Other RCTs of IOL have experienced similar problems, indicating that women have preferences strong enough to prevent them from taking part (49). As the results demonstrated, women who participated in this trial largely did so for the possibility of trying the balloon instead of the prostaglandin pessary and / or to go home for the initial stages of IOL, which may bias these results in the direction of women reporting positively about the balloon because they preferred this to the prostaglandin pessary, and/or about going home because this was preferred to remaining in hospital. We were unable to contact two women for whom balloon catheter placement was not successful, which may further bias results in favour of the balloon. These women may be different from the general population. Furthermore, the finding that no women randomised to prostaglandin pessary would opt for this method as a first step in a subsequent IOL may be because these women had a preference for a method (balloon) that they did not receive. Therefore a patient-preference design or a cohort study may be beneficial in both recruitment rates and in reducing these biases. However our results do indicate that for women who would opt for the balloon and for the outpatient setting, given the choice, they were largely

experienced positively. A further limitation concerns the lack of ethnic diversity in women recruited to the trial and further research is needed to understand the experiences of non-white British women.

5. Conclusion

Women in this study felt under-prepared for IOL. For women who consider it advantageous to be at home for the cervical ripening stage of IOL, the outpatient setting worked well with the prostaglandin pessary and with the double balloon catheter. Insertion of the balloon catheter was considered painful by some, but the perceived benefits of starting IOL without hormones meant women favoured this method for future labours. Recruitment to the RCT was low and suggests that other study designs are required to further investigate experiences of outpatient IOL as the women who took part had an interest in having the balloon or going home. Women remain unprepared for the IOL process and changing this should be a priority for those involved in this common procedure.

List of abbreviations

IOL: induction of labour

RCT: randomised controlled trial

Additional files

Additional file 1 includes the topic guide for the semi-structured interviews (Additional file 1 Interview Topic Guide.pdf).

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Table 1. Participant characteristics

Participant	Site	Age	Relationship Status	Ethnicity	Parity	Treatment	Length At Home	Reason for return	Further Treatments	Epidural	Mode of birth	Time of treatment-Interview (weeks)
1	1	32	Married	White	1	Balloon	<6h	Labour	ARM + Oxytocin	Yes	SVD	14
2	1	30	Married	White	1	PGE2	0	-	ARM	No	SVD	13
3	1	44	Cohabiting	White	2	PGE2	24h	Agreed time	PGE2, ARM + Oxytocin	Yes	SVD	8
4	1	34	Cohabiting	White	1	PGE2	<18h	Labour	Oxytocin	Yes	C-section	7
5	1	35	Married	White	1	Balloon	24h	Agreed time	ARM + Oxytocin	No	SVD	7
6	1	37	Married	White	2	PGE2	24h	Agreed time	ARM	No	SVD	7
7	1	38	Married	White	2	Balloon	<12h	Labour	-	No	SVD	12
8	1	37	Married	White	2	PGE2	<18h	Labour	-	Yes	Instrumental	13
9	1	35	Married	White	1	Balloon	24h	Agreed time	PGE2	No	SVD	13
10	2	31	Single	Black	1	PGE2	0	-	ARM + Oxytocin	Yes	SVD	6
11	1	37	Married	White	3	Balloon	<6h	Labour	-	No	SVD	6
12	2	26	Cohabiting	White	1	PGE2	<12h	Labour	ARM + Oxytocin	Yes	C-section	13
13	1	33	Cohabiting	White	1	PGE2	0	-	-	No	C-Section	12
14	1	29	Married	Asian	2	PGE2	24h	Agreed time	ARM + Oxytocin	Yes	SVD	13

15	2	27	Married	White	1	PGE2	24h	Agreed time	Oxytocin	No	C-section (no labour)	11
16	2	32	Married	White	1	PGE2	24h	Labour	ARM + Oxytocin	Yes	C-section	13
17	1	32	Married	White	1	PGE2	0	NA	Oxytocin	Yes	SVD	8
18	1	39	Married	White	1	Balloon	0	NA	Oxytocin	Yes	SVD	14
19	1	38	Married	White	1	PGE2	<6h	Labour	-	No	SVD	8
20	1	39	Cohabiting	White	1	PGE2	24h	Agreed time	PGE2, ARM + Oxytocin	Yes	C-section	13
21	1	33	Married	White	1	Balloon	0	NA	ARM	Yes	Instrumental	11

ARM= Artificial rupture of membranes; Balloon = double balloon catheter; PGE2 = prostaglandin pessary; SVD = Spontaneous vaginal delivery

Table 2. Analytical themes and sub-themes.

Analytical themes and description	Sub-themes
1. Ownership of IOL	1.1 Understanding of the IOL process
How women understood and experienced the stages of the IOL process and tried to maintain control of a procedure which was managed by medical professionals	1.2 Choice and control in labour and birth 1.3 Experience of method of IOL* 1.4 Further intervention* 1.5 Experience of pain*
2. Importance of place	2.1 Enduring the hospital
Positive and negative views about the home and hospital setting	2.2 Keeping to established rhythms at home 2.3 Transition between home and hospital*

* Indicates sub-themes from the current study added to a previously published framework of induction of labour (citation removed for peer review).

Additional File 1.
Topic Guide for Postnatal Interviews

1. Experience of recruitment

What do you remember about being introduced to the trial?

What influenced your decision to take part?

Who was with you during the discussion about the research? What was their view?

What were your expectations of being involved in research compared with going in for labour as usual?

How did the location of the hospital and your journey here affect your decision, if at all?

Is there any information you now wish you had been given at the time?

2. Experience of being in a trial

What do you remember most about being in the trial?

Did you have any worries or questions about being involved?

If so, did you manage to talk to the research midwife about these?

Were any questions answered in a way you could understand?

How prepared did you feel for induction generally?

What would you say to other pregnant women about taking in a trial like this?

3. Experience of outpatient induction of labour

Please tell us the story of your experience of having your labour induced?

What was it like for you?

What did you feel about being able to go home while awaiting the start of active labour?

Did you have any worries?

If so, who did you talk to about these?

4. Acceptability of the different methods

What did you feel about having (as relevant to group) to help to start your labour?

Did you have any worries?

If so, who did you talk to about these?

If you were having another baby and needed to have your labour induced, what would you choose?

If a friend was offered an induction of labour, what would you say to them about the different options?

5. Other

Is there anything else you would like to tell us about being involved, or about your labour experience?

Author Agreement

The authors confirm that the article is their original work. The articles has not been previously published and is not under consideration for publication elsewhere. All authors have seen and approved the submitted manuscript. The authors abide by the copyright terms and conditions of Elsevier and the Australian College of Midwives.

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Conflict of interest

The authors declare that they have no competing interests.

Ethical statement

Ethical approval was obtained from the NHS Health Research Authority East of England - Cambridgeshire and Hertfordshire Research Ethics Committee [Ref no. 17/EE/0295] on 24th August 2017. Details of the trial are registered and publicly available here: https://clinicaltrials.gov/ct2/show/NCT03199820. All participants consented to the research findings being published in a peer-reviewed journal.

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Authors' contributions

Rose Coates: Methodology, Formal analysis, Investigation, Data curation, Writing – original draft, review and editing, Project administration. **Chris McCourt:** Conceptualization, Methodology, Formal analysis, Writing – review and editing, Supervision, Funding acquisition. **Georgina Cupples:** Formal analysis, Writing – review and editing, Project administration. **Mandie Scamell:** Formal analysis, Writing – review and editing. **Amarnath Bhide:** Writing – review and editing, Supervision, Funding acquisition.

Data Statement

The data that support the findings of this study are available on reasonable request from the corresponding author [RC]. The data are not publicly available due to them containing information that could compromise research participant privacy.