Outpatient induction of labour with prostaglandins: Safety, effectiveness and women’s views

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## Abstract

*Background* Nearly 28% of women underwent induction of labour in England in 2015-16. Women frequently report delays and poor experiences, and the process can put additional pressure on to busy labour wards. Outpatient induction of labour (OPIOL) enables women to return home to await the onset of contractions.

*Aim* This literature review aims to explore the current research evidence base about OPIOL using prostaglandins and to identify gaps in the evidence base. Outcomes will be compared with those induced as inpatients.

*Method* An electronic search was conducted to identify relevant quantitative and qualitative studies using keywords’. Once the final studies had been identified, a narrative synthesis of the findings was conducted.

*Findings* Adverse outcomes were rare but the studies were not sufficiently powered to detect significant differences between outpatients and inpatients. There were some differences in cost and effectiveness between the included studies which may be explained by disparities in study design, participant characteristics and operational issues. Time avoided in hospital by outpatients ranged from 7.5 hours to 11.76 hours. Satisfaction was generally higher with OPIOL although some women expressed apprehension about being at home.

*Conclusion* While OPIOL with prostaglandins is acceptable to women, it is not clear whether there are significant differences in safety and effectiveness outcomes due to the low frequency of adverse perinatal events as well as methodological and quality issues of the included studies. There is a need for further UK research to compare outcomes, maternal experiences and cost effectiveness of OPIOL.

*Key words*: Outpatient induction of labour, prostaglandin, dinoprostone, Propess, Prostin

## Introduction

Induction of labour is a procedure which is offered to women when it is considered that giving birth is of greater benefit to the mother or baby than remaining pregnant (Thomas et al. 2014). Labour may be induced by pharmacological, mechanical and surgical means (NCCWCH 2008). These methods are used to stimulate maternal production of prostaglandins to ripen the cervix so that it starts to soften and dilate, stimulating uterine contractions. Recent data shows 27.9% of women underwent induction in England in 2015-16 for fetal or maternal reasons, prolonged rupture of membranes or post-maturity (NHS Digital 2016). However, women frequently report poor experiences, lack of information and autonomy, poor support and long delays (Reid et al. 2011; Murtagh and Folan 2014; O'Dwyer et al. 2015) and the process can increase workload on busy labour wards (NCCWCH 2008; Kelly et al. 2013; Carroll et al. 2016).

In response to these issues and facilitated by the development of modified-release preparations of prostaglandins, outpatient induction of labour (OPIOL) has become a viable and attractive option. In a recent survey of 164 UK trusts by Sharp et al. (2016), around 18% had introduced outpatient management, or were planning to do so. All units offered outpatient management to women with post-dates pregnancies, and 72% also offered this option to women with locally-defined low-risk, term pregnancies.

Despite the introduction of OPIOL, there has been little research into its safety, efficacy and acceptability to women (NCCWCH 2008). This is significant because while prostaglandin preparations are the most commonly used pharmacological options to induce labour and are recommended by national guidance, one of the possible side effects is hyperstimulation of the uterus which can cause changes in the fetal heart rate pattern, uterine rupture and fetal hypoxia (NCCWCH 2008). Despite the overall incidence of such harm being very low, some clinicians remain concerned about the use of prostaglandins in an outpatient setting (Henry et al. 2013) and how women should be monitored once they go home (Rauf and Alfirevic 2011; Sharp et al. 2016). Such uncertainty may indeed impact clinicians’ attitudes, vigilance and decision-making (Grobman 2015).

Mechanical methods of cervical ripening such as balloon catheters are an alternative to vaginal prostaglandins as women are less likely to experience hyperstimulation with changes in fetal heart rate pattern (RR 0.17 95% CI 0.05 to 0.63; 3 studies 794 women)(Jozwiak et al. 2012). While there is a tendency for vaginal birth not to be achieved within 24 hours when balloon catheters are used compared to vaginal prostaglandins this is not statistically different (50.2% versus 36.7%; RR 1.97 95% CI 0.43 to 8.95; 2 studies 477 women)(Jozwiak et al. 2012). Furthermore, the likelihood caesarean section and instrumental birth is not significantly different (Jozwiak M et al. 2012). However, there is an ongoing debate about whether use of foley catheters increases the risk of intrapartum infection with a reported rate of 11.3 per cent (Gommers et al. 2017) although comparison with vaginal prostaglandins suggest differences in observed rates are not statistically significant (Jozwiak et al. 2012; McMaster et al. 2015).

This review aims to explore, describe and critically analyse the current research evidence base about OPIOL using prostaglandins and to identify gaps in the evidence base. The population of interest are women at low risk of complications with prolonged pregnancies and how their outcomes compare with women induced as inpatients.

## Method

A literature review was conducted in September 2016 to identify relevant research about OPIOL. Using population, intervention, comparison, outcome (PICO) framework, search criteria were identified and refined using an iterative pearl-growing technique (Bettany-Saltikov and McSherry 2016; Booth et al. 2016) (Table 1, Box 1).

#### Table 1: Population, intervention, comparison, outcome (PICO) framework

|  |  |  |
| --- | --- | --- |
|  | Inclusion criteria | Exclusion criteria |
| Participants | Women at low risk of complication | Women at high risk of complication |
| Intervention | OPIOL using dinoprostone | OPIOL with balloon catheter, misoprostol |
| Comparison | Inpatient induction of labour using dinoprostone | Comparison with placebo |
| Outcomes of interest | Women’s experiences/satisfaction  Vaginal birth not achieved within 24 hours  Use of oxytocin  Duration of hospital stay  Time avoided in hospital  Induction to labour interval  Induction to birth interval  Uptake of epidural analgesia  Mode of birth  Uterine hyperstimulation  Meconium stained liquor  Apgar score  Cord pH  Neonatal unit admission  Serious maternal complication (e.g. placental abruption, uterine rupture, postpartum haemorrhage)  Maternal death  Serious neonatal complication (e.g. seizures, hypoxic ishaemic encephalopathy)  Perinatal death  Cost | Experiences and satisfaction of staff caring for women |
| Type of study | Primary research i.e. randomised controlled trials/experimental studies, cohort studies (prospective or retrospective), questionnaires, qualitative studies | Systematic reviews |

#### Box 1: Keywords used to search electronic databases

|  |
| --- |
| Dinoprostone  Prostaglandin  PGE2  Propess  Outpatient  Ambulatory  Home  Induc\* labo\*r  Cervical priming  Cervical ripening |

Electronic databases CINAHL, Embase, Medline, Scopus and Web of Science were searched using the keywords and relevant subject headings. To avoid publication bias, a grey literature search was also conducted (Booth et al. 2016). Data was then imported into a bibliographic database, which was used to remove duplicate records. Abstracts were retrieved to establish whether studies met the pre-defined inclusion criteria.

Full papers were then retrieved for further evaluation and quality assessment. Reference and citation searching was also undertaken to identify further relevant studies (Centre for Reviews and Dissemination 2009; Booth et al. 2016). Search alerts were created to ensure relevant articles published between September 2016 and July 2017 were retrieved for review (Figure 1).

Studies were included if they were randomised controlled trials, cohort studies, questionnaires or qualitative studies which compared OPIOL using dinoprostone with inpatient management. Studies using misoprostol were excluded due to the increased likelihood of hyperstimulation, even with controlled-release formulations (NCCWCH 2008; Wing et al. 2013) and the required frequency of low-dose oral administration which makes it unsuitable for outpatient management (Alfirevic 2014).

Once the final papers had been identified, data was extracted into a standardised template and tabulated to facilitate comparison and quality assessment was undertaken (Programme 2013). Due to the heterogeneity of the included studies, a narrative synthesis of the findings was conducted (Arai et al. 2007; Booth et al. 2016). The following key dimensions were considered: safety, clinical and cost effectiveness as well as the experiences of women of outpatient induction of labour. These correspond with the fundamental elements of care quality described by Lord Darzi in *High Quality Care for All* (Darzi 2008; Department of Health 2008).

#### Figure 1: PRISMA flow diagram of study search selection process (Booth et al. 2016)



## Results

#### Summary

A total of eleven studies met the inclusion criteria (Table 2). Only one of the studies was conducted in the UK (Stock et al 2014).

Table 2: Included studies comparing OPIOL and inpatient management using prostaglandins

|  |  |  |
| --- | --- | --- |
| Author | Location | Type of intervention |
| Adelson et al. (2013) | Adelaide, Australia | Part of Outpatient Priming for Induction of Labour (OPRA) randomised controlled trial study using vaginal dinoprostone gel. Cost analysis based on duration of stay, time avoided in hospital for outpatient group, professional care given and birth outcomes. |
| Awartani et al. (1999) | Saskatoon, Canada | A prospective non-randomised study using vaginal dinoprostone gel. Compared birth outcomes, duration of hospital stay and maternal satisfaction. |
| Biem et al. (2003) | Saskatoon, Canada | A randomised controlled trial using a vaginal controlled release dinoprostone pessary. Compared birth outcomes, duration of hospital stay, time avoided in hospital for outpatient group and maternal satisfaction. |
| Cundiff et al. (2017) | Vancouver, Canada | A retrospective cohort analysis using vaginal controlled release dinoprostone pessary. Compared birth outcomes. |
| Farmer et al. (1996) | Oklahoma, USA | A prospective cohort analysis, compared with a historic inpatient cohort using intracervical dinoprostone gel. Compared birth outcomes, duration of stay, maternal satisfaction and cost. |
| Howard et al. (2014) | Adelaide, Australia | Part of OPRA randomised controlled trial using vaginal dinoprostone gel. OPRA participants and other pregnant volunteers approached to take part. A discrete choice experiment to determine preferences around setting for IOL. |
| Oster et al. (2011) | Adelaide, Australia | Part of OPRA randomised controlled trial using vaginal dinoprostone gel. Semi-structured interviews with 16 participants and thematic analysis to explore women’s preferences and experiences of outpatient and inpatient management. |
| Salvador et al. (2009) | Vancouver, Canada | A retrospective cohort study using a vaginal controlled-release dinoprostone pessary. Compared birth outcomes. |
| Stock et al. (2014) | Edinburgh, United Kingdom | A retrospective cohort study using vaginal dinoprostone gel. Compared birth outcomes, time to birth interval and time avoided in hospital for outpatient group. |
| Turnbull et al. (2013) | Adelaide, Australia | Part of OPRA randomised controlled trial using vaginal dinoprostol gel. Questionnaire to determine satisfaction and experiences of care. |
| Wilkinson et al. (2015) | Adelaide, Australia | OPRA randomised controlled trial using vaginal dinoprostone gel. Compared birth outcomes. |

### Safety

#### Adverse events

Seven of the eleven studies reported on outcomes relating to maternal and neonatal safety (Farmer et al. 1996; Awartani et al. 1999; Biem et al. 2003; Salvador et al. 2009; Stock et al. 2014; Wilkinson et al. 2015; Cundiff et al. 2017). Serious outcomes were rare and the studies were underpowered to detect whether there were significant differences in severe perinatal morbidity and mortality between outpatient and inpatient groups. Wilkinson et al. (2015) reported 3 cases of hypoxic ischaemic encephalopathy (HIE) amongst 215 women who underwent OPIOL and 2 amongst 210 women managed as inpatients. There was also one perinatal death in a case which involved a woman randomised to OPIOL who subsequently laboured spontaneously. Stock et al. (2014) reported three adverse neonatal outcomes amongst the 907 women who underwent OPIOL including one neonatal death, one case of HIE and one case with meconium aspiration leading to infant death at 3 months of age. Biem et al. (2003) reported one case of meconium aspiration, a uterine rupture resulting in hysterectomy and a hysterectomy for postpartum haemorrhage amongst 150 women managed as inpatients. No other serious adverse events were reported by the other studies suggesting adverse events were either rare or poorly reported (Alfirevic et al. 2016).

No significant differences were found between OPIOL and inpatient management in terms of admission to neonatal unit and the incidence of low Apgar at 5 minutes of age, which ranged between 0 (Awartani et al. 1999) to 3.3% (Wilkinson et al. 2015). Differences in neonatal unit admission criteria, outcome definition and post-operative practices around neonatal care made comparison of this outcome difficult and admission rates ranged between 0.5% (Wilkinson et al. 2015) and 18% (Awartani et al. 1999).

#### Hyperstimulation

A variety of definitions of hyperstimulation were noted in the included studies making it hard to make comparisons. These included hypertonus lasting more than two minutes, tachysystole of more than five contractions in 10 minutes, as well as the presence or absence of fetal distress. For instance, Biem et al. (2003) distinguished between hyperstimulation and ‘*true hyperstimulation*’ (pg. 27) which was defined as the presence of fetal distress in addition to hypertonus or tachysystole. Conversely, Awartani et al. (1999) did not make this distinction. Stock et al. (2014) adopted a different nomenclature – tachysystole alone, tachysystole requiring tocolysis and tachysystole with fetal heart rate changes indicating emergency delivery.

The incidence of hyperstimulation ranged from 2.1% (Stock et al. 2014) to 10% (Biem et al. 2003) and no significant differences were found between outpatients and inpatient management except in the study by Salvador et al. (2009). This is because women with increased uterine activity or abnormal fetal heart patterns detected during sixty minutes of post-administration observation and fetal monitoring were not discharged home and were included in the inpatient group for data analysis. It is possible this contributed to the increased likelihood of caesarean section for this group (OR 1.50, 95% CI 1.14 to 1.98; p=0.004).

### Effectiveness

#### Duration of labour and hospital stay

A variety of different measures were used making comparison difficult. These included induction to labour and induction to birth interval (Awartani et al. 1999; Biem et al. 2003), length of labour (Wilkinson et al. 2015), duration of stay (Farmer et al. 1996; Awartani et al. 1999; Biem et al. 2003; Wilkinson et al. 2015), and vaginal birth within 24 hours (Biem et al. 2003; Salvador et al. 2009; Stock et al. 2014; Wilkinson et al. 2015; Cundiff et al. 2017). Time avoided in hospital by outpatients would perhaps be a more informative outcome measure and was reported by Adelson et al. (2013), Biem et al. (2003) and Stock et al. (2014). The average time avoided in hospital ranged between 7.5 and 11.76 hours although the studies by Adelson and Stock were not explicit about how this was calculated. Biem et al. (2003) extrapolated the time avoided in hospital from the time of dinoprostone administration to the time of readmission to hospital, correcting for the one-hour initial and mid-point assessments 12 hours later, if done.

#### Oxytocin augmentation

Awartani et al. (1999) and Salvador et al. (2009) found outpatients were significantly more likely to require augmentation. This may reflect the small sample size in the former study and selection bias in the latter as women experiencing uterine hyperstimulation were moved to the inpatient cohort and were less likely to require augmentation (Nelson et al. 2015). Similarly, Cundiff et al. (2017) found outpatients were significantly more likely to require augmentation although the authors concede this was likely to be due to differences between the comparison groups with outpatients having a less favourable physiological starting point. In contrast, the randomised controlled trials by Biem et al. (2003) and Wilkinson et al. (2015) and the selection of matching controls from a historic patient cohort by Farmer et al. (1996) make their finding of no significant difference in oxytocin requirement more reliable.

#### Mode of birth

Seven of the studies reported on spontaneous vaginal birth and/or instrumental birth and found no difference between outpatients and inpatients (Farmer et al. 1996; Awartani et al. 1999; Biem et al. 2003; Salvador et al. 2009; Stock et al. 2014; Wilkinson et al. 2015; Cundiff et al. 2017). However, as already stated, Salvador et al. found caesarean section was significantly more likely for inpatients, conceivably associated with selection bias (Nelson et al. 2015). Cundiff et al. (2017) made the same observation, and again this is likely to have been due to selection bias, with women being more likely to be managed as inpatients if they were being induced for pre-labour rupture of membranes which can be associated with higher rates of complications in labour than a post-dates pregnancy alone (Bond et al. 2017).

#### Cost

Two of the included studies consider differences in cost between outpatient and inpatient management (Farmer et al. 1996; Adelson et al. 2013) and neither of these studies were conducted in the UK making application of the findings to the NHS difficult. Overall hospital stay was not significantly shorter when comparing nulliparous women managed as outpatients and inpatients (Farmer et al. 1996) and there were additional operational costs associated with triaging women on readmission (Adelson et al. 2013). This suggests that while OPIOL seems an attractive proposition to free up bed space in the short-term, that overall sending women home may not be associated with significant benefits in terms of cost savings and bed occupancy.

### Women’s views

#### Preferred environment for IOL

Satisfaction scores were generally higher amongst outpatient participants. Awartani et al. (1999) conducted telephone interviews after discharge and found 96% of women were satisfied with OPIOL management versus 56% of inpatients (p<0.0001). Similarly, Turnbull et al. (2013) and Howard et al. (2014) found outpatients gave positive responses overall although they were not approached until seven weeks after birth which may have introduced recall bias (Rattray and Jones 2007). Likewise, Biem et al. (2003) found satisfaction was higher for outpatients in the first 12 hours of the induction process (p=0.002).

Women’s responses were not exclusively positive. Turnbull et al. (2013) state that nearly a third of women (45 out of 143) agreed or strongly agreed with the statement ‘*I was worried about how long I should wait at home*’. While Turnbull et al. (2013) state most women were not concerned about this issue, to negate the views of 31.5% of respondents is a potential source of bias.

#### Themes of comfort and safety

Oster et al. (2011) was the only study to conduct semi-structured interviews in their research. They used purposive sampling amongst Outpatient Priming for Induction of Labour (OPRA) participants to select sixteen women from different demographic backgrounds in order to obtain diverse insights into experiences of inpatient and OPIOL (Hunt and Lathlean 2015). The interviews were conducted between seven weeks and four months after the birth which may have introduced recall bias. Appropriate methods were used to achieve data saturation and identify themes (Lathlean 2015).

The authors made good use of excerpts to contrast the lights, machines and discomfort of a sterile hospital environment versus the comfort, freedom, calming familiarity and social intimacy of being at home surrounded by family and loved ones. One of the women found being in hospital more relaxing, however, as she knew she did not have to worry about childcare commitments. The inclusion of disconfirming evidence enhances the credibility of this study (Polit and Beck 2006).

Participants were also concerned about safety and some expressed apprehension or fear of being at home. Access to medical professionals and fear of the unknown or an unexpected emergency were also highlighted.

#### Mediating factors

Demographic factors, travel time and anticipated number of trips per induction influenced preferences for induction setting (Oster et al. 2011; Howard et al. 2014). Participants were willing to make an extra 1.42 trips to hospital with a total travel time no more than 30.6 minutes per trip to have OPIOL. Older, college or university-educated women in their first pregnancy were more likely to prefer outpatient management whereas women who had previously received obstetric led care or were from non-English backgrounds preferred inpatient management.

#### Contact with the staff during the induction period

It was not clear how best to monitor or provide reassurance to women during the induction process. Oster et al. (2011) stated some women were reassured by having telephone support available if they needed it. This suggests further research is needed into how best to communicate with women while they are undergoing OPIOL and whether this is helpful in terms of ongoing risk assessment.

## Discussion

This review has highlighted a dearth of research comparing outpatient and inpatient management of IOL using dinoprostone. Out of eleven retrieved studies, only Stock et al. (2014), who used dinoprostone gel, conducted their research in the UK.

While all the studies cited the inclusion of women with uncomplicated, healthy pregnancies, the risk status and indications for induction were mixed which makes comparison difficult and undermines reliability (Booth et al. 2016). This makes it challenging to generalise the findings to healthy, nulliparous women being induced to avoid prolonged pregnancy alone. Studies carried out as part of the OPRA trial in Australia initially included women with diet-controlled diabetes or a BMI of 35kg/m2 or above (Oster et al. 2011; Adelson et al. 2013; Turnbull et al. 2013; Howard et al. 2014; Wilkinson et al. 2015). Similarly, Cundiff et al. (2017) included participants with pre-labour rupture of membranes, Salvador et al. (2009) included participants with hypertension, ‘*fetal issues*’, gestational diabetes and ‘*maternal illness*’, Farmer et al. (1996) included women with hypertension, diabetes, rhesus isoimmunisation and fetal growth restriction and Biem et al. (2003) included women with hypertension and growth restriction. Awartani et al. (1999) included women with suspected fetal macrosomia and other indications for IOL which were not explicitly stated.

The only UK-based study (Stock et al. 2014) also used a definition of ‘*uncomplicated*’ pregnancy and it may be reasonable to assume women with hypertension, diabetes, growth restriction and other conditions were excluded in line with national definitions and UK practice (National Collaborating Centre for Women’s and Children’s Health 2008).

The findings suggest OPIOL is acceptable to women although there are tensions between the comfort of being at home versus anxiety, uncertainty, and concerns about safety outside hospital. These findings reflect other studies excluded from the review on the basis of having no inpatient comparison group (Neale et al. 2002; O'Brien et al. 2011; O'Brien et al. 2013; Okunoye et al. 2015; Dhavliker et al. 2016). This suggests women have unmet support needs when undergoing OPIOL.

A UK cost comparison between inpatient and outpatient settings was entirely absent from this review which is a significant finding. Alfirevic et al. (2016) also note the lack of UK evaluation of resource use and direct and indirect costs associated with IOL in overall.

## Strengths and limitations

Firstly, rigorous methods were used to conduct a comprehensive literature search and to document it clearly. This ensures transparency and replicability (Centre for Reviews and Dissemination 2009; Booth et al. 2016). Another strength of this review was that it used a narrative synthesis approach to integrate quantitative and qualitative research findings.

However, despite this approach the search may not have been exhaustive. Another potential limitation is the absence of non-English language studies. These were excluded for pragmatic reasons but represent another source of bias (Harden et al. 2006).

## Conclusions and recommendations

This review has demonstrated that while OPIOL is acceptable to most women, there is uncertainty and apprehension for some. It is not clear from the evidence whether there are significant differences in safety and effectiveness outcomes due to methodological approaches and quality issues already mentioned. Furthermore, due to the low frequency of adverse perinatal events, it is difficult to provide unequivocal evidence about the safety of OPIOL as studies would have to be much larger to be sufficiently powered to detect differences in rare outcomes (Kelly et al. 2013; Grobman 2015). As the number of women being induced continues to increase, further research is needed to identify appropriate management strategies and the acceptability of these to women.

## Key points

* Studies about OPIOL using prostaglandins are heterogenous in terms of participants’ risk status and methodological approach making comparison difficult.
* Time avoided in hospital ranged between 7.5 and 11.76 hours.
* Women liked the comfort and familiarity of being at home. Others were reassured by remaining in hospital and having health professionals nearby.
* Where reported, poor outcomes were rare.

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