Cervical ripening at home or in hospital during induction of labour: the CHOICE prospective cohort study, process evaluation and economic analysis

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language which may offend some readers.

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Scientific summary

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Scientific summary

Background

Around one in three pregnant women in the UK undergo induction of labour (IOL). The first step often involves cervical ripening (opening and shortening the cervix). Cervical ripening may be undertaken using either balloon catheters or administration of prostaglandin. Cervical ripening at home may reduce hospital stay during IOL and may be more acceptable to women than in-hospital cervical ripening. It is unclear whether it may increase risks to the unborn baby due to less monitoring of their well-being during the IOL process and whether it is acceptable to women and partners. It is also unclear whether home cervical ripening is cost-effective.

Objective

To assess whether it is safe, effective, cost-effective and acceptable to service users and providers to carry out home cervical ripening during IOL, the research questions asked were:

Is home cervical ripening within an acceptable margin of in-hospital cervical ripening for safety, cost and acceptability outcomes?
Is a strategy of home cervical ripening using a balloon as safe as in-hospital cervical ripening using prostaglandin for the primary outcome of neonatal unit (NINU) admission within 48 hours of birth for 48 hours or more?
Is home cervical ripening as acceptable to service-users and health professionals as in-hospital cervical ripening?
Are NHS and service user costs of home cervical ripening using a balloon comparable to costs of in-hospital cervical ripening using prostaglandin?

Methods

This project incorporated a prospective multicentre observational cohort study using real-world data from hospital electronic health records, a survey of service users and nested case studies involving interviews and focus groups, evaluating process and service user and provider experiences, and a health economic analysis.

The original design was a comparison of home versus in-hospital cervical ripening using a non-inferiority design to determine whether home cervical ripening is within an acceptable margin (+ 4%) of in-hospital cervical ripening for the safety outcome of NNU admission, whether it is more acceptable to women and whether it is cost-effective. As insufficient home cervical ripening cases were identified at the pilot analysis stage, the statistical analysis was modified to a simple logistic regression on the primary outcome (NNU admission within 48 hours for 48 hours or more), unadjusted and adjusted by potential confounders. This was done because the limited sample size of the primary exposure variable (home vs. hospital) did not have enough power to answer the non-inferiority question as proposed. This had a knock-on effect on the other aspects of the project as well.

Observational cohort

A total of 26 maternity units in the UK contributed data to the observational cohort study, of whom 8 offered balloon home cervical ripening and 18 offered only in-hospital cervical ripening using prostaglandin. The sample included geographically and socially diverse populations. All units used the

BadgerNet Maternity Notes (System C, Stratford-upon-Avon, UK) information system to record routine maternity care information.

Deidentified data on all eligible women having IOL was extracted from the BadgerNet system using existing data fields. Data were securely transferred to the University of Edinburgh.

Data were analysed using SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA). We used mixed-effects logistic regression for the comparison of NNU admission within 48 hours to control for treatment indication bias, with hospital/trust as a random effect. Further outcomes were reported descriptively as medians and interquartile ranges, proportions and percentages.

Process evaluation

A process evaluation was undertaken to identify contextual influences on implementation of cervical ripening protocols and outcomes and assess the acceptability of home cervical ripening and the experiences of women and their birth partners, professionals and other key stakeholders.

The process evaluation comprised an online postnatal survey, five case study sites and qualitative interviews and focus groups with service users and staff. Overall, 309 women returned completed surveys. In the case study sites, interviews were undertaken with women (n = 43), partners (n = 17) and health professionals (n = 48) and four focus groups were conducted with health professionals (n = 28).

Because the COVID-19 pandemic occurred during the study period, which had wide-reaching effects on maternity care, an additional survey of healthcare professionals at all UK NHS trusts and boards was conducted to determine whether aspects of practice and policy around IOL had altered in response to the pandemic. In total, surveys were returned from 92 of the UK NHS trusts and boards offering maternity services across the UK.

Survey data were reported using descriptive statistics and qualitative data were analysed using a thematic framework. The original design involved audio recording of a sample of consultations where IOL is discussed to assess women's involvement in the decision-making processes (analysed using the OPTION scale); however, COVID-19-related restrictions precluded this element.

Health economic analysis

An economic analysis was undertaken from the perspective of the NHS and Personal Social Services using a decision tree model, populated with data from the CHOICE study. Resource use data were combined with unit costs to calculate the within study cost for each strategy and outcomes were reported in terms of incremental cost per NNU admission avoided. A secondary analysis considered the patient perspective, including costs incurred by women and their families relating to IOL, gathered from the qCHOICE survey responses.

Data sources

- Electronic patient records from 26 study sites (extracted via the BadgerNet maternity records data system): observational cohort study; economic analysis.
- Qualitative interviews and focus groups: process evaluation.
- Postnatal survey: process evaluation; economic analysis.
- Published literature: economic analysis.

Results

Observational cohort study

The unanticipated context of the CHOICE study was an NHS under pressure to manage high IOL rates (range 31–49%) and long delays throughout the IOL process during the COVID-19 pandemic. Home

cervical ripening using balloon was performed in women for a wide array of indications (low to moderate risk groups) and from 37 weeks of gestation.

The main analysis population consisted of 17,350 women with singleton pregnancies having IOL at 37 weeks or later, of whom 515 underwent home cervical ripening using balloon, 4332 underwent in-hospital cervical ripening with prostaglandin in hospitals that only offered in-hospital cervical ripening, and 7397 women underwent in-hospital cervical ripening with prostaglandin in a hospital that also offered home cervical ripening.

Compared with in-hospital cervical ripening with prostaglandin, the rate of NNU admission within 48 hours of birth for 48 hours or more following home cervical ripening with balloon was not increased. The event rate for this primary outcome was expected to be 6% for the in-hospital group. The rate was much lower than expected in both arms (3.1% after home cervical ripening vs. 4.8% after in-hospital cervical ripening) and there was no statistically significant difference between groups before or after adjusting for potential confounding variables. However, the odds ratio of 0.75 has a wide 95% confidence interval (CI) of 0.35 to 1.64 (0.81; 95% CI 0.36 to 1.81 in the adjusted analysis) signalling substantial uncertainty in this finding.

Process evaluation

Eligibility criteria for those offered the option of home cervical ripening varied between sites. Care was often planned around capacity rather than in line with guidance/policy. Of 230 survey respondents who underwent to in-hospital cervical ripening, the mean stay prior to transfer to labour ward was 31.5 hours (range 0–260 hours). Women reported physically and emotionally unsafe situations caused by these delays.

Impact of COVID-19

Of responding sites, 23% reported a change in the method used for cervical ripening and 28% reported a change in criteria for offering home cervical ripening. Only 7% and 6%, respectively, reported changes in the professionals undertaking cervical ripening or the approach for post-dates IOL. The majority of respondents stated that there was no change (61%) or that more women (28%) were discharged home after cervical ripening. There was little consistency in policy changes during the pandemic – one study site expanded home cervical ripening eligibility while another completely suspended it.

Acceptability to service users

While attitudes towards home cervical ripening were positive, the experiences of those who actually went home were mixed. The positive experiences were most often associated with being in the comfort of one's own environment. Safety appeared to be the biggest concern for those who said they would not want to return home for cervical ripening. Crucially, women and birth partners wanted the choice to go home or stay in hospital and lack of choice was evident both in survey responses and in case study site interviews.

Women who had home cervical ripening were more likely to choose that option again (64%) and recommend it to others (61%) than those who stayed in hospital (55%, 54%). Women who had a balloon catheter inserted reported more discomfort than those who had a prostaglandin pessary or osmotic dilator, although ability to cope with discomfort was similar across all cervical ripening methods. Attentive care and access to pain relief were important to women and birth partners.

Acceptability to clinicians and health professionals

Attitudes were generally positive, and many healthcare professionals perceived mechanical methods to be the safest for home cervical ripening. Home cervical ripening was often seen as a potential solution to workload and capacity issues, but several professionals highlighted that it was not necessarily straightforward and that there could be unintended consequences for workload, including the management of re-admissions.

Information
Half of survey respondents did not feel they had enough information about what to expect during IOL, and over half (57%) felt that they had either had no choice or no alternative when deciding to have IOL.

Psychological correlates
Forty-one survey respondents described their experience of IOL as difficult or traumatic. Some maternity professionals also reported moral distress in relation to the process.

Factors mediating experience:
The principal factors mediating experience of IOL were support from healthcare professionals, the presence of birth partners, information provision and having choice, privacy and having their own space, and delays. In the survey, the most important factor in a positive experience was support from kind, caring staff and feeling safe.

Barriers and enablers of adoption
Staff shortages was one of the key barriers to adoption of home cervical ripening. Delays during IOL were linked to unit capacity, staffing and workload. Enablers included cross-boundary collaboration, cross-trust/board knowledge sharing, consistent training and professional confidence.

Health economic analysis
The economic model found that home cervical ripening with balloon led to cost savings of £993 (−£1198, −£783) per woman, with no difference in NNU admissions avoided (mean 0.005; 95% CI −0.05 to 0.013). At willingness-to-pay thresholds above £3000, there is an 82% probability that home cervical ripening with balloon is the optimal option and in economic terms would be considered the dominant strategy compared with in-hospital cervical ripening with prostaglandin.

Probabilistic sensitivity analysis indicates little uncertainty regarding the cost savings, however there was uncertainty regarding the impact on NNU admission. Any potential increase in NNU admissions between arms would be negligible.

The cost savings in the home cervical ripening group are driven primarily by reduced time in an antenatal ward for the home cervical ripening group, with an average of 476 minutes (7.9 hours) compared with 2243 minutes (37.4 hours) in the in-hospital group. The resource use and cost data also indicate some of the 'hidden' or displaced costs of the home cervical ripening option, with an increased number and duration of phone calls from women and their partners to the hospital compared with those in the in-hospital group.

Economic analysis of 'spill over' costs found that the average transport cost was higher among the mothers who had hospital cervical ripening (£23.10) than mothers who had home cervical ripening (£18.74). The total patient perspective cost was higher in the hospital arm (£954) compared with the home arm (£665), which was predominantly driven by the opportunity cost of partners'/other caregivers' time supporting the mother either at home or in hospital 'away from other activities'.

Conclusions

The CHOICE study provided multiple perspectives on the difference between home cervical ripening with balloon and in-hospital cervical ripening with prostaglandin during IOL, within a context of high IOL rates and multiple delays in the process. Home cervical ripening with balloon appears both safe and cost-effective when compared with in-hospital cervical ripening with prostaglandin for a range of indications, although safety conclusions are uncertain. Acceptance of home cervical ripening depends upon high-quality informed decision-making and consistent support for women throughout the IOL process, a reality that was often lacking in the study participants' experience.

Future research should focus on:

- Further exploration and implementation of system features that lead to positive experiences of home cervical ripening.
- Measuring rare but important safety outcomes of home cervical ripening.

Practice implications of the CHOICE findings are that units should consider the practicalities of offering genuine choice around setting for IOL and ensure adequate staffing and support for women throughout their IOL experience regardless of setting for cervical ripening. Unless women feel supported to choose between home and in-hospital settings, and they have sufficient information to allow realistic expectations of the IOL process, women will not have positive birth experiences.

Study registration

Current Controlled Trials ISRCTN32652461.

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