Induction of labour in a pandemic

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Induction of labour in a pandemic

A rapid analytic scoping review

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Key points

- A shift towards earlier inductions may lead to 15%-20% more inductions (Rydahl E et al 2019). This higher induction rate puts a strain on the maternity service and is likely to result in longer periods of hospitalisation for women and their companions. At present recommendations in the UK are for IOL to be offered to women with uncomplicated pregnancies who go beyond 41 weeks. It is critical that women know that when induction of labour (IOL) is offered, that it is an offer and not an expectation. Women should be helped to make an informed choice about IOL, and should are informed about the benefits and risks of induction of labour and expectant management, and the differences that the Covid 19 pandemic will make. Based on observational studies, induced labour is usually more painful, and women should be informed that the provision of epidurals may be restricted during the Covid 19 outbreak.

- Over a three-month covid-19 outbreak period, continuing with a *management policy for reduced fetal movements* based on the AFFIRM/Saving Babies Lives type protocol could increase bed occupancy/exposure time for an average Trust with 4000 births a year by approximately 300 maternal hours in labour, 60 maternal days postnatal, and 60 neonatal days postnatal. These hours of exposure would increase again if birth companion and postnatal visitors are factored in. This would affect 50 individual labouring woman/birth companions, along with attending staff, and 30 postnatal women and their babies (and visitors if allowed), also along with attending staff. There would be no change in the stillbirth/perinatal death rate, when compared to an alternative policy of expectant management, though 5 less babies would be born small for gestational age.

- *Outpatient cervical ripening* may reduce the length of time women spend in hospital associated with IOL although there is currently a lack of evidence to confirm this assumption. Outpatient cervical ripening does not eliminate the need for hospital admission during IOL. While there is as yet, insufficient evidence to confirm that it is as safe as hospital cervical ripening, few adverse effects have been reported. There is some evidence that outpatient cervical ripening may increase women's satisfaction and sense of control. Midwives must ensure that women know when and how to call a midwife for advice and support if needed and that they have a clear plan for returning to hospital.

- The following sections from the RCM Midwifery Guidance* for Induction of Labour have particular resonance at a time when women have additional concerns due to the pandemic. These include the need for information and high quality communication about available options (*Improving women's experiences of induction of labour*); the impact that induction may have on other options including choice of place of birth *(Supporting women to make decisions about induction of labour)* and the limited evidence related to what is often referred to as 'home induction' *(Returning Home following cervical priming).*

* RCM Blue Top Midwifery Guidance (No 2). Midwifery Care for Induction of Labour, Sept 2019. www.RCM.org.uk

Question 1: At what gestation do the risks of expectant management versus induction for post-dates outweigh the risks of being in hospital for an extended length of time during a covid-19 epidemic in terms of both clinical and psychological outcomes in the short and longer term.

Overview

- The key principles for quality maternity care must be applied in relation to labour induction
- Women should be informed about the risks and benefits of induction of labour for them and their baby, and that being induced is likely to increase their stay on labour wards
- Women must be informed if (due to the covid-19 pandemic) birth companions will not be not allowed to stay with them during the induction process, until they are in active labour
- The choices women make about having their labour induced or not must be respected
- Review of optimising maternity in the time of the Covid 19 Pandemic will give a useful background to this topic (Renfrew et al 2020)

Given the conflicting evidence and the absence of updated national guidelines the question cannot be answered with any certainty. NICE guidelines (2008) recommend that all women should be offered information about risks associated with pregnancies that last more than 42 weeks and be told their options. Women should be offered induction of labour between 41 and 42 weeks to avoid risks of prolonged pregnancy.

Recently rates of IOL in the UK have increased in many services, in part in response to recent trial evidence that has not yet been reviewed for inclusion in systematic reviews, and has not been included in clinical guidelines. This includes an important variation in previously common practice, IOL before 41 weeks gestation. Clinical guidelines should be reviewed continually as new evidence emerges, to ensure the most up to date advice is given to women, and best practice is offered.

Recent systematic reviews are used here, to understand the potential benefits and harms of induction of labour when compared to waiting for labour to start spontaneously, or expectant management. These should be considered in the context of pressure put on services by the Covid-19 pandemic, and the potential risks of infection to women, their babies, and staff, arising from induction of labour when compared with waiting for labour to start.

The principle of giving women information about the potential benefits and risks of IOL compared with waiting for labour to start spontaneously is fundamental and should be observed especially in the time of a pandemic when women are likely to be particularly anxious about their care. This information should be given sensitively, so that it is understood, and without invoking further anxiety and fear. Decision aids should be used.

Here the following are considered:

- Current guidance and the benefits and risks to mother and baby of induction of labour compared with waiting for spontaneous labour. The need to inform women fully and obtain informed consent.
- The impact on the service that may be operating at or above capacity in a pandemic
- The need to reduce time spent in hospital for the mother and baby to reduce risks of infection

- The infection risk to staff of certain procedures (for example care in labour, assisted birth and caesarean section).
- The availability of pain relief in particular epidural

What do recent systematic reviews tell us about potential benefits and risks of induction of labour at term?

The Cochrane Review (2018) on induction of labour for improving outcomes for woman at or beyond 42 weeks gestation, to see if induction of labour at term (usually after 41 weeks gestation) could reduce risks of for babies, included only low risk pregnancies. It was concluded that a policy of labour induction at or beyond term compared with expectant management is associated with fewer perinatal deaths and fewer caesarean sections but more operative vaginal births. NICU admissions were lower and fewer babies had low Apgar scores with induction. It is stated that no important differences were seen for most of the other maternal and infant outcomes. The absolute risk of perinatal death is small. Only two trials reported on maternal satisfaction and no trials have yet reported on maternal anxiety or depression, or breast feeding. The authors conclude that the optimal timing of offering induction of labour to women at or beyond term warrants further investigation.

WHO recommendations for Induction of labour (2018) comments that IOL is not risk free and many women find it to be uncomfortable. The guidelines were produced with a view to promoting and to improving maternal outcomes worldwide, and to promoting the best-known practices in labour and childbirth. The review is based on updated Cochrane reviews. Much of the evidence is graded as weak and it is noted there are considerable gaps in knowledge.

The review included general principles that included:

Induction of labour should be performed only when there is a clear indication for it and the expected benefits outweigh its potential harms.

Induction of labour should be performed with caution since the procedure carries the risk of uterine hyperstimulation and rupture and fetal distress.

WHO advised IOL is not recommended in women with an uncomplicated pregnancy of less than 41 weeks.

Rydhal E, Eriksen L, Juhl M (2019) Effects of induction of labour prior to post term in low risk pregnancies, identified, assessed and synthesized the best available evidence on the effects of induction prior to post term on the mother and fetus. Maternal and fetal outcomes after routine labor induction in low risk pregnancies at 41+0 to 41+6 gestational weeks were compared to routine induction at 42+0 to 42+6 gestational weeks (post term). The authors concluded that induction prior to post term was associated with few beneficial outcomes and several adverse outcomes that draw attention to possible iatrogenic effects.

There was an emphasis in this study on producing evidence of high quality, and in particular the use of stricter inclusion criteria. Consequently, the number of studies included is small, and the study is not therefore powered to draw conclusions on perinatal mortality. However, a detailed account is given of many of the deaths included in the study.

Much of the emphasis of studies of IOL in comparison with expectant management is focussed on perinatal death, and reduction of c/s. This study found an increase in C/S in association with IOl, and a number of potential harms to the mother. There is no indication in the evidence of long-term effects on the baby, for example cerebral palsy or HIE. A proxy measure of pH <7.10 is used in this study.

Results do not support widespread use of routine induction prior to post term 41+0-6 gestational weeks.

The most recently reported RCT (Wennerholm et al 2019) performed to evaluate if induction of labour at 41 weeks improves perinatal and maternal outcomes in women with low risk pregnancy compared with expectant management and induction of labour at 42 weeks, was stopped early owing to a significantly higher rate of perinatal mortality in the expectant management group. The proportion of c/s and instrumental delivery, or any other major maternal mortality did not differ between the groups. While commenting that the results should be interpreted cautiously the authors recommend IOL should be offered to women no later than 41 weeks gestation. Of interest the deaths seem to have been mainly in the first-time mothers' group. The effect of parity on perinatal mortality rates should be considered further.

In response to this report the RCOG (2019) comments

"the findings of this Swedish trial are in line with what is already known – that pregnancies that continue to, or pass, 41 weeks are usually safe and straightforward, but there is a small yet significant increase in stillbirth risk.

"Current UK guidance recommends that induction of labour should be offered to women with uncomplicated pregnancies who go beyond 41 weeks to avoid the risks of prolonged pregnancy, including stillbirth. We support the continual review of clinical guidelines as new evidence emerges to ensure best practice.

"A woman's individual needs and preferences should always be taken into account and they must have the opportunity to make informed decisions in partnership with their healthcare professionals."

Study	Some risks and benefits	Implications
Cochrane review 2018	Induction compared with expectant management associated with fewer deaths of babies and fewer c/s, but more assisted births. The chances of babies dying are small. No difference perineal trauma, bleeding after birth, trauma to babies.	Although the chances of babies dying are small, it may help to offer women appropriate counselling to make an informed choice between induction of labour for pregnancies at, or later than, term - or waiting for labour to start and/or waiting before inducing labour. The best time to offer induction of labour to women at or beyond term is not yet clear and warrants further investigation. The risk profiles of women as well as their values and preferences could also be considered.

WHO 2018	Uterine hyperstimulation and rupture and fetal distress, bleeding and c/s	IOL should only be performed when there is a clear medical indication and the expected benefits outweigh harms. IOL is recommended for woman who are known with certainty to have reached 41 weeks. Induction of labour is not recommended in women with an uncomplicated pregnancy at gestational age less than 41 weeks.
Rydahl E et al (2019)	IOL at 41=0-6 gestational weeks associated with increased risk of c/s, c/s due to failure to progress, chorioamnionitis, labor dystocia, precipitate labor, uterine rupture	Lacked statistical power to draw conclusions on perinatal death, no differences postpartum haemorrhage, shoulder dystocia, meconium aspiration, 5-minute Apgar score less 7, or admission to NICU. Policy of awaiting spontaneous onset of labor until 42+0-0 gestational weeks showed approximately 70% went into spontaneous labor. Results do not support widespread use of routine induction prior to post term 41+0-6 gestational weeks

Table: Key findings and implications

Implications

Current guidance and benefits and risks

Women should be offered IOL by 41 weeks. Benefits and risks of induction of labour compared to expectant management, including potential maternal risks, as well as any limitations in the evidence should be explained. Risks should be explained in absolute numbers, or absolute risks, using decision aids that include visual representation of numbers (dots graphics). Lack of evidence on the experience of IOL should be explained.

The impact on the service that may be operating at or above capacity in a pandemic

Rhydal et al (2019) comment that with earlier IOl rates will rise by 15%-20%. Not only may this detract from the care of other women, in pregnancy, labour and after birth, but if women consent to IOl and are then kept waiting, this adds considerably to anxiety. Estimations of the level of women having induction of labour, so that they might be properly supported without compromising care to other women is important particularly with the pressures and uncertainty of pandemic conditions. There must be a response and escalation plan for when service needs change unexpectedly. Careful collaboration and agreement should be sought between clinical and management staff and interdisciplinary teams. Teams should talk.

The need to reduce time spent in hospital for the mother and baby to reduce risks of infection

There is no clear evidence on time spent in hospital when women have labour induced. However, given what we know from experience of the time spent waiting for labour to start, this is a factor that should be explained to women. Time in hospital is a potential risk for infection and should be taken into account in weighing up benefits and harms. See information on out of hospital induction.

The infection risk to staff of certain procedures (for example care in labour, assisted birth and caesarean section).

While all women require intensive support and monitoring in labour the monitoring required with IOL is of a different nature and may make it more difficult to distance physically from the woman. IOL is associated with a higher risk of assisted birth, requiring closer proximity. Evidence on the effect of IOL on c/s rates is mixed. Some indicate a reduced c/s rate, some no difference, and some an increase. A policy of IOL should not be based on the aim of reducing c/s. Rather other evidence based approaches should be used (WHO 2018).

The availability of pain relief in particular epidural

Again, there is conflicting evidence from systematic reviews on the use of analgesia with IOL. However, observational data indicates that the pain of labour is greater with induction and women are more likely to require epidural. Women should be informed that in case of reduced anaesthetist presence epidural may not be available or immediately available.

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Question 2: What is the impact of the current policy on reduced fetal movements?

Overview

This section assumes that, if induction is being undertaken for decreased fetal movements, this will be done in hospital, without outpatient cervical ripening, as the assumptions underlying the rationale for induction in this case are that the fetus is at immediate and high risk, which implies the need for close monitoring, and rapid response if there is evidence of further fetal compromise.

The main evidence comes from the AFFIRM trial (Norman et al 2018). The trial was designed and powered to test a package of interventions, including raising maternal awareness of reduced FMs, CTG (ideally computerised) and ultrasound scans (with umbilical artery doppler if possible, and with assessment of fetal growth and liquor volume), and expediated birth, depending on gestation and clinical findings.

The trial found that this package **did not decrease still birth at or beyond 24 weeks gestation** (4.06/1000 vs 4.40/1000) **or perinatal death, at any gestation (overall** . It **increased the risk of induction of labour** (40.7% vs 35.9%) and **increased the risk of CS** (28.4% vs 25,5%). It **decreased the percentage of babies born small for gestational age** (1.5% versus 2.0%) but not of any need for resuscitation, or of admissions to neonatal unit.

The results of a recent multicentred trial conducted in Sweden based on increasing maternal awareness of reduced fetal movements found no improvement in apgar scores (the main outcome). As for AFFIRM, there was a reduction in the incidence of small for gestational age babies in this trial. There was also a small decrease in caesarean section rates for the intervention group (19% vs 20%) (Akselsson et al 2020).

A recent observational study of six London hospitals found no association between reduced fetal movements and a range of adverse outcomes, but did find an increased rate of induction (56% versus 31.9%). This study found no increase in the incidence of SGA (Bhatia et al 2019)

Even though the AFFIRM trial did not find a benefit for this intervention, the package of interventions used in AFFIRM remains the recommended approach in the current Saving Babies Lives care bundle, along with a recommendation to minimise the use of induction of labour for women presenting with decreased fetal movements at under 39 weeks gestation (NHS England 2019)

Implications

In the recent Bhatia et al study in six London hospitals, on average 22.6% of women presented with at least one episode of reduced fetal movements (range 14.9-32.5%)[1]

For an average unit of 4000 births, this equates to 904 women per year (226 within the expected covid three month peak period)

Based on the AFFIRM results, continuing with the current strategy for reduced fetal movements over the three month covid-19 period:

1. Will not change the numbers of stillbirths or neonatal deaths over this period

[1] The UK rate for sites in the AFFIRM trial is not reported in the AFFIRM results paper, so the Bhatia et al rates are used for the calculations in this paper

2. Will reduce the number of small babies born from 20 to 15
3. Will not change the number of babies admitted to NICU
4. Will increase the number of inductions from 359 to 407
5. Will increase the number of caesarean sections from 255 to 284

There do not appear to be data on length of time in labour wards comparing women who are induced with those in spontaneous labour. However, in the recent ARRIVE trial (Grobman 2018), the difference was, on average, 20 hours vs 14 hours (6 hours absolute difference). There was a small difference in the postnatal period in favour of the induction group, reported in percentage of women against postnatal days (for example, 82.1% versus 80% staying in for less than 2 days). The actual difference in days is not given, so this has not been possible to factor in for this analysis.

The current NHS site states that average length of stay following CS is around 3 or 4 days, compared with an average of 1 or 2 days for a vaginal birth (https://www.nhs.uk/conditions/caesarean-section/). For the table below, this difference is assumed to be 2 days.

Impact per 1000 births	***Stillbirth/ perinatal death***	***Small for gestational age neonates***	***Induction of labour***	***Caesarean section***	***Neonatal admissions***	***Length of stay, total extra hours (in labour, mother +/- birth companion)***	***Total length of stay, days (postnatal mother +/- birth companion)***	***Length of stay, days (neonate)***
IoL for reduced FMs (based on the AFFIRM trial package/Saving Babies Lives)	0	5 less	50 more	30 more	No difference	50 x 6 more 300 (600 with birth companion)	2 x 30 more =60 days (mother) (plus extra visitor hours)	2 x 30 more =60 days

Conclusion

This model suggests that the increased occupancy/exposure time for an average Trust with 4000 births a year related to women/babies over a three month period, associated with an AFFIRM-type policy for reduced fetal movements, would be approximately 300 maternal hours in labour, 60 maternal days postnatal, and 60 neonatal days postnatal. These hours of exposure would increase if birth companion and postnatal visitors are factored in. This would affect 50 individual labouring woman/birth companions, along with attending staff, and 30 postnatal women and their babies (and visitors if allowed), also along with attending staff

There would be no change in the stillbirth/perinatal death rate, when compared to a policy of expectant management, though 5 less babies would be born small for gestational age.

It is not clear what the cross-infection rate is in hospital at the moment. When this is clear, the implications, if any, of this extra exposure time (for women, babies, birth companions and staff) can be modelled.

Times for extra hours of people in hospital in labour double when birth companions are included. **However, not allowing birth companions will probably increase length of labour/ rates of interventions/ demand for epidurals/ length of postnatal stay.**

What are the alternatives?

Given that sites randomised to the control condition during the AFFIRM trial did not have higher rates of stillbirth or perinatal death, but did have lower rates of induction and CS, the practices in those sites might be worth considering. This would risk a small increase in small for gestational age babies, with no increase in the need for resuscitation or neonatal unit admission, and would limit the other risks of longer hospital stays and increased intervention for a much larger number of women, babies, birth companions, and staff.

The AFFIRM trial report does not specify what these 'watchful waiting' policies were.

It is therefore recommended that Trusts are asked to provide their protocols for reduced fetal movement prior to the AFFIRM trial as a basis for a minimal safe induction policy for reduced fetal movements during the covid-19 crisis.

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Question 3: What are the risks and benefits of outpatient cervical ripening?

Overview

There is as yet insufficient evidence to confirm that outpatient cervical ripening (often referred to as home cervical ripening) is as safe as hospital based cervical ripening. Studies have found few adverse effects and suggest it is feasible but these are underpowered to make clear recommendations (Kelly, Alfirevic , Ghosh , 2013; Vogel et al, 2017). A current NIHR funded research study addresses these issues (Stock et al, 2020)

Outpatient cervical ripening may have benefits over hospital cervical ripening during the pandemic. It may reduce the time spent in hospital associated with IOL and this is desirable in reducing workload and opportunity for virus exposure. However there is currently insufficient evidence to confirm this anticipated benefit (Adelson et al, 2013; Stock et al 2012). Outpatient cervical ripening does not eliminate the need for hospital admission, electronic fetal monitoring will be required immediately following the procedure and while cervical ripening may initiate labour onset, generally artificial rupture of membranes and intravenous infusion of oxytocin are required. These are both inpatient procedures (discussed above).

Outpatient cervical ripening may reduce separation of women from their families and there is some evidence that it increases women's satisfaction and sense of control (Coates et al, 2018; Evans et al 2019). Midwives must ensure that women know when and how to call a midwife for advice and support if needed and that they have a clear plan for returning to hospital (RCM, 2019).

Prostaglandin pessaries are currently the most commonly used method for outpatient cervical ripening in the UK and recommended by NICE (2008). Use of balloon catheter have also been shown

to be effective and may reduce the incidence of uterine hyperstimulation compared to prostaglandins (Jozwiak et al, 2011). However, they may be less acceptable to women (Ten Eikelder et al, 2017). Oral misoprostol has high rates of uterine hyperstimulation (Wing et al, 2013), and is not used outwith hospitals in the UK. Osmotic dilators (an alternative mechanical method) are under evaluation in hospitals (SOLVE trial; ISRCTN20131893) but have not yet been shown to be effective or established in UK practice.

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