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Induction and age

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Randomized trial of labor induction in women 35 years of age or older
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Reviewed by Gemma McKenzie

Context and aims of the study
The rate of caesarean section is 38% among nulliparous women (first time mums) in the UK who are 35 years of age or older and 50% among those who are 40 years of age or older.[1] Further, there are higher rates of obstetrical intervention among older women than among younger ones.[1] The study was designed to see whether induction of labour at 39 weeks' gestation for first time mothers aged 35 years or over, would reduce the rate of caesarean section deliveries.

Methodology
The study was a randomised controlled trial, which took place within 38 NHS hospitals and one Primary Care Trust.

Women eligible to take part in the study were those who:

- Were nulliparous (first time mums)
- Would be 35 or over on their expected due date
- Had a singleton, live fetus in the cephalic (head down) position.

Even if a woman satisfied these criteria, she was excluded if:

- Her baby had a known congenital abnormality that would lead to neonatal death
- There were any indications that she may have problems in labour, such as evidence of fetal compromise
- There were any indications that she may have problems with a vaginal delivery, such as placenta previa
- She was to have expectant management, for example due to gestational diabetes
- She had had a previous myomectomy (removal of fibroids from the womb)
- She did not have an ultrasound examination before 22 weeks' gestation

- She had undergone IVF with a donor egg.

The number of women who took part in the study was 619. Participants were randomly assigned either to undertake an induction of labour between 39 weeks 0 days and 39 weeks 6 days, or to undergo expectant management. Expectant management would mean that the mother would wait for spontaneous labour, unless a situation arose that would require either an induction or caesarean section. If a mother in the expectant management group went beyond 41 weeks and 0 days (at least seven days past her due date), she could undergo an induction if she wished. The researchers then captured data regarding the medical outcomes of the births and compared this data between the two groups.

The participants also filled out a Childbirth Experience Questionnaire (CEQ), which was sent to them one month after the birth. The questionnaire has 22 questions and a copy can be found at: ctsu4.nottingham.ac.uk/ts0918/docs/ Childbirth_Experience_Questionnaire_CEQ.pdf.
The contents comprise questions such as:

- I felt strong during birth
- I was tired during labour and birth
- I felt happy during labour and birth
- Some of my memories from childbirth make me feel depressed
- I felt that I handled the situation well.

Women then responded with ticking either agree, mostly agree, mostly disagree or totally disagree.

The purpose of this questionnaire was to see whether induction of labour at 39 weeks or expectant management had an impact on women's birthing experience, and to then compare the results between the two groups.

Results
The study did not conclude that inducing first time mums aged over 35 at 39 weeks' gestation would prevent stillbirths.

The researchers were clear in their conclusion that:
'Our trial did not address whether induction of labour at 39 weeks of gestation can prevent stillbirths'.
They conceded that to explore this issue would require '*an extremely large*' study.

There was no significant difference between the induction group and the expectant management group with respect to the frequency of caesarean sections.

The rate of assisted vaginal deliveries (such as use of forceps or ventouse) was higher in the induction group than in the expectant-management group, but that rate was not statistically significant.

Inducing first time mums aged over 35 at 39 weeks' gestation had no reported short-term effects on mother or baby in comparison with women who had expectant management.

The researchers were clear in stating that they analysed short-term effects only, that is that they did not look at any physical, mental, emotional or psychological long-term effects to either mother or baby. The researchers conceded that there were a number of
observational studies that have suggested a possible association between early births at 37-39 weeks' gestation and subtle long-term effects on children's development and educational attainment, when compared with births between 40-41 weeks' gestation.

The short-term physical effects centred on the period during birth and immediately after, such as whether a mother haemorrhaged or the baby required oxygen.

In comparison to the women who were induced at 39 weeks and the women who had expectant management, there were no significant reported differences with the satisfaction they felt regarding their birth experiences.

AIMS comments
As highlighted above, the study does not prove that inducing women who are aged over 35 can prevent stillbirth. This was not the aim of the project and as highlighted by the researchers, to explore this issue would require an extremely large study. Further, any conclusions that the researchers can draw are not generalisable to all women aged over 35, as the study only focused on first time mums who had 'low-risk' pregnancies and who gave birth in a hospital.

Although there was no significant difference between the induction group and the expectant management group with regards to the number of caesarean sections and assisted deliveries, the figures in both groups suggest highly medicalised births. The following bullet points outline and explore the relevant figures:

- 304 women were induced between 39 weeks 0 days and 39 weeks 6 days (the induction group).
- Out of those 304 women 98 (32%) ended up with caesarean sections.
- Four of the 98 women who had caesarean sections had also had an attempted assisted vaginal delivery with the use of instruments.
- 115 (38%) of the 304 women had assisted vaginal deliveries.

This means that 213 (70%) of the women who were in the induction group ended up with either assisted deliveries or with a caesarean section.

- 314 women had expectant management.
- 103 (33%) of those ended up with caesarean sections.
- Seven of the 103 women who had caesarean sections had also had an attempted assisted delivery with the use of instruments.
- 104 (33%) of the expectant management group ended up with assisted vaginal deliveries.

This means that 207 (66%) of the expectant management group ended up with either assisted deliveries

or with a caesarean section.

It is also crucial to remember that within the expectant management group, 154 (49%) of the women still had their labours started with a medical induction. In total, from the figures it appears that out of 314 women in the expectant management group, 178 (57%) of the women had their labours induced or acellerated.

Due to the frequent use of induction in the control group (the expectant management participants), the study is therefore very narrow. Consequently, it is not a comparison of the outcome of inducing a woman at 39 weeks, with the outcome of leaving her to continue her pregnancy until she goes into spontaneous labour, as over half of the expectant management group were induced anyway. Further, given that induction featured heavily in both groups, it is perhaps unsurprising that there were very few medical differences in the outcomes between the induction and the expectant management groups.

What becomes clear in this study, is that the reason these births were so highly medicalised needs further exploration. Were there such high levels of assisted deliveries and caesarean sections because first time mums aged over 35 labour and birth 'badly'? There is research suggesting that women over 35 are at higher risk of various obstetric problems in comparison with women under 35, but that is not the same as saying that women over 35 have a high risk of experiencing those problems. Nor is it the same as saying there are high rates of these problems with women over 35. This is highlighted in the following point made by the researchers:

'The risks of perinatal death, hypertensive disease, gestational diabetes mellitus, placenta previa, and placental abruption are higher among women 35 years of age or older than among younger women.[2]

Bearing this point in mind, and taking a wider view of the study, it is unclear whether the factortriggering such high rates of assisted deliveries and caesarean sections is the age of the woman, the frequent use of induction, or the perception that older women labour and birth 'badly', and the consequences of that, such as more restrictive birthing environments and limited birth choices. As a result, the study is only useful in the sense that it concludes that there are no differences in short term outcomes between first time mums aged over 35 who are induced at 39 weeks, and first time mums over 35 who follow the usual obstetric pathway. In both scenarios, the outcome is very high rates of assisted deliveries and caesarean sections. But the crucial, underlying reasons as to why that is so, do not form part of the study and are therefore not explored. Further, the role of induction of labour in these high rates of assisted deliveries and caesarean sections – regardless of when it happens – is also not considered, but is something that needs to be researched.

There are also relevant issues regarding the researchers' conclusions about women's satisfaction levels and their birthing experiences. First, it is certainly arguable that a questionnaire may not be the ideal way to capture the complexity and depth of information required to fully understand how a woman feels about her baby's birth. Information captured numerically is very limiting when trying to learn about another person's experiences. Second, undertaking the questionnaire only a month after birth may be

somewhat premature. In AIMS' experience, it is not uncommon for women to develop symptoms of birth trauma months or years later, and in particular, during subsequent pregnancies. Third, not all of the women who took part in the study completed the questionnaire. Seventeen percent did not return it. Finally, even without all of these limitations, the CEQ does not give any information about women's satisfaction with their births over the long-term, which would be particularly relevant if they gained a different insight or perspective after having more than one birth.

Conclusion

Regardless of what the media or the maternity services may suggest, this study is very narrow in its conclusions and does not apply to all pregnant women aged over 35. Further, it does not provide any insight into the prevention of stillbirth. What the study can conclude however, is that for a low risk first time mother aged over 35, who births in hospital after an induction at 39 weeks, there are no differences in short term medical outcomes for her or her baby, in comparison to the same type of woman who is not induced at that point in time. There are several other conclusions that can also be drawn. The first is that first time mums aged over 35, birthing in the hospital environment, even when labelled 'low risk' are likely to experience high rates of instrumental and surgical deliveries. The crucial question as to why this is so, however, remains unanswered. Looking at the control group (the expectant management participants), we can also conclude that first-time low risk mums aged over 35, birthing in the hospital environment, also experience high rates of induction. Again, the reason that this is so, needs to be explored more fully. Third, given the high rates of induction and the frequent instrumental and surgical deliveries, it is crucial to discover whether one is causing the other, or whether the determining factor in all of these assisted deliveries and caesarean sections is age.

Finally, a questionnaire is a very limited tool to gather information on women's birthing experiences. What is particularly concerning is its focus on the short term, and the lack of insight into how a woman may feel much later on, once she has digested her experience and is no longer consumed by the needs of a newborn. What would be particularly useful is follow up research on the long-term physical, mental, emotional and psychological effects between the two groups in the study, and additionally whether there were any differences between the women who were induced – regardless of when – and those who were not. Such research would provide greater clarity and context to the present study.

AIMS experience of the 35/39 study

Since the publication of this study, we have had many women contact us via our helpline to ask for advice regarding induction of labour for women aged over 35 and its use to prevent stillbirth. Although the study itself is usually not cited, it appears that there may be some pressure on women aged over 35 to be induced based on a misinterpretation of the 35/39 study. There is some indication that this pressure is coming from midwives and other health care professionals.

The confusion surrounding the study may come from the website[3] the researchers used to explain, promote and recruit for their project. It states:
'Starting labour a week early might prevent a small number of stillbirths, but it might also lead to longer labours and possibly more Caesarean births. To find out, we need to compare these two different ways of managing women.'

This very confusing paragraph suggests that the researchers are in some way looking at preventing stillbirth with their study. The reality is that the study was far too small to be able to explore this subject. As Sara Wickham points out in her blog post,[4] this may be because the researchers could not recruit enough women who were willing to undergo induction of labour at 39 weeks. Even the researchers concede that 86% of the women eligible to participate in the study, declined to get involved.

Consequently, regardless of what the researchers hoped to achieve, the necessary number of women required to explore whether inducing first time mums aged over 35 at 39 weeks decreased the stillbirth rate, did not materialise. It is therefore wrong for anyone to suggest that this study is evidence that women aged over 35 should be induced in order to limit their risk of having a stillborn baby. That was not the outcome of the study, and the researchers were not in a position to explore that issue.

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