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Induction of labour versus expectant management at term by subgroups of maternal age: an individual patient data meta-analysis*,**



Kate F. Walker a,*, Gemma Malin b, Philippa Wilson a, Jim G. Thornton a

- ^a Maternity Department, Nottingham City Hospital, Nottingham University Hospitals NHS Trust, Nottingham NG5 1PB, UK
- ^b Maternity Department, Queen's Medical Centre, Nottingham University Hospitals NHS Trust, Nottingham NG7 2UH, UK

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ABSTRACT

Background: British women are delaying childbirth. Women aged 35 years or over have a higher risk of perinatal death. There is a linear relationship between maternal age and delivery by emergency caesarean in nulliparous women. Many obstetricians induce older women at term attempting to improve perinatal outcomes, others are reluctant for fear of increasing caesarean rates. A recent systematic review of induction of labour versus expectant management in women at term, found induction was associated with a reduction in caesareans (OR 0.83, 95% CI 0.76–0.92).

Objectives: To identify whether induction of labour changes the risk of caesarean section in women aged 35 years or over.

Study design: Search strategy: Available data sets from RCTs included in the Wood et al. systematic review (31 trials) and suitable RCTs published since week 23, 2012.

Selection criteria: Studies were included if they were randomised controlled trials comparing induction of labour with expectant management at term with intact membranes with a singleton or multiple pregnancy in a cephalic presentation.

Data collection and analysis: A quantitative meta-analysis of individual patient data (IPD) using a random-effects model to calculate odds ratios.

Results: In total 2675 women (five studies) were included in the meta-analysis and 2526 women (four studies) were included in the IPD meta-analysis. There was no statistically significant increase in caesarean section rates seen in either analysis.

Conclusions: Induction of labour in women of advanced maternal age has no statistically significant effect on caesarean section rates.

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Introduction

The average age at childbirth in the UK is increasing, and more women are giving birth aged 35 years or over [1]. The overall caesarean rate for nulliparous women less than 35, 35–39 and \geq 40 years old is 21%, 38% and 50% respectively [2]. The caesarean rate for nulliparous women in labour (both spontaneous and induced) at term excluding breech presentation is 22.8% among women 35–39 years of age and 27.4% among women aged 40 years or older (Smith et al., unpublished data, Scottish maternities 2004–2008).

In nulliparous women, the relationship between maternal age and delivery by emergency caesarean is linear [3] which suggests a biological effect of advancing maternal age on labour performance, rather than simply obstetrician or maternal preference.

Women aged 35 years or over are also at higher risk of antepartum and intrapartum stillbirths and neonatal deaths [4]. Stillbirth is especially important to this group, because they are relatively less likely to have future pregnancies. Induction at, or before, the due date may be beneficial because the gestational age of delivery associated with the lowest cumulative risk of perinatal death is 38 weeks [5]. It is recognised by obstetricians that women aged 35 years or over reach the 41–42 week stillbirth risk at which induction is currently offered to all women [6] at earlier gestational ages [7], but it is a commonly held belief amongst obstetricians, midwives and the general public that induction of labour at term increases the chance of an emergency caesarean section. This belief

 $[\]mbox{\ ^*}$ Submitted on behalf of the 'Sub-group analysis of the Wood Systematic Review study group'. A full list of members of the group is given in Appendix 1.

^{**} Study conducted in Nottingham, UK.

^{*} Corresponding author. Tel.: +44 0115 823 1893. E-mail address: katefwalker@doctors.org.uk (K.F. Walker).

was fuelled by observational studies comparing women who were induced versus women who laboured spontaneously demonstrating an increased risk of caesarean associated with induction of labour [8–10]. The limitation of these observational studies was that women who were induced were compared with women who laboured spontaneously. A more appropriate comparison adopted by Stock et al. was where women who were induced were compared with women who were managed expectantly (continuation of pregnancy until either spontaneous labour or need for either delivery by caesarean section or induction of labour arises) [11]. Using this comparison induction of labour did not increase the risk of caesarean section.

In 2013, Wood et al. published a systematic review of randomised controlled trials of induction of labour versus expectant management in women with intact membranes at term and found that a policy of induction of labour was associated with a 17% reduction in the risk of caesarean section (OR 0.83, 95% CI 0.76–0.92) [12]. What is not certain is whether this holds true for women of advanced maternal age (AMA) who have an increased age related risk of emergency caesarean section.

Many obstetricians already induce older pregnant women at term (39% women aged 40–44, 58% women aged over 45), and many others believe that induction would improve perinatal outcomes but are reluctant to offer it for fear of increasing caesarean rates [13]. However, it is equally plausible that induction might reduce caesarean section in which case an effective intervention is being under implemented.

The Wood et al. systematic review found a reduction in the risk of caesarean section associated with a policy of induction of labour at term for women with intact membranes [12], a subgroup analysis of this systematic review will be undertaken to investigate whether this is true for women aged 35 years or over given the linear relationship between maternal age and delivery by emergency caesarean.

Materials and methods

A protocol driven systematic review with individual patient data (IPD) meta-analysis of induction of labour versus expectant management at term for women with intact membranes by subgroups of maternal age was performed. The review was performed in accordance with published guidance [14]. The protocol is given in Appendix 2. The review is registered with Prospero (CRD42014009452) at http://www.crd.york.ac.uk/PROSPERO.

Literature search

Available data sets from RCTs comparing induction of labour with expectant management in women with intact membranes included in the Wood et al. systematic review (31 trials) and suitable RCTs published since week 23, 2012. The search strategy adopted by Wood et al. and described in detail by the authors [12] was replicated by Dr P Wilson (PW) from week 23, 2012 until 1st June 2014 to identify new randomised trials published. Abstracts were obtained for all citations and were independently reviewed by PW and KW. Full texts were obtained for all relevant articles.

Study selection

Specific and prospectively defined inclusion criteria were used to determine which studies were suitable for inclusion in the meta-analysis. All studies were required to have participants randomly assigned to either induction of labour or expectant management. Induction of labour was performed using a variety of methods: amniotomy and oxytocin (early trials); cervical ripening (with prostaglandins or mechanical methods) and amniotomy and

oxytocin (more recent trials); prostaglandins only (early trials). All studies were required to have participants between 37 and 42 weeks gestation with intact membranes with a singleton or multiple pregnancy with a cephalic presentation (singleton or of the presenting twin). Each study was required to include the outcomes of caesarean section and perinatal death (excluding deaths due to fetal congenital abnormality). All studies were graded as high or low quality based on three indicators as in the Wood Systematic Review: adequate randomisation and allocation concealment; limited losses to follow up (<20%) and intention-to-treat analysis.

Data acquisition and extraction

Anonymised datasets were requested and transferred securely for analysis. The data were sorted according to maternal age and managed in Microsoft Excel. A Collaborator's Agreement was signed by each Chief Investigator of the individual participating randomised controlled trials and the Chief Investigator of this study to guarantee: their willingness to participate and option to withdraw at any time during the course of the study; confidentiality of individual trial results and the policy for publication.

Data analysis

A quantitative meta-analysis of IPD using a random-effects model was performed using Stata Version 11, to calculate odds ratios and their 95% confidence intervals (CI). Odds ratios were chosen as the summary statistic for consistency with the Wood systematic review. The analysis was performed using the 'metan' command [15]. The outcomes for caesarean section and perinatal death, comparing induction with expectant management by maternal age, were calculated. All authors were asked to supply their full dataset from the primary study. If available a subgroup analysis by maternal age <35, 35–37, 38–40, >40 was planned. Where full datasets were not available, authors were asked to provide data by maternal age <35 and ≥35 years.

Due to the expected presence of clinical and statistical heterogeneity between studies, a random effects model was used throughout to account for this. The random effects model synthesizes the log OR estimates for each test and weights each study by the inverse of the study's variance plus between-study variance. We plotted summary OR data in forest plots and assessed the between-study heterogeneity in each analysis by estimating tau-squared [16] (an estimate of the between-study variance) with its corresponding *P*-value.

Results

The literature search identified 10 citations not previously included in the Wood Systematic Review. Abstracts for those citations were read by PW and KW. Full articles were retrieved for 2 abstracts. Full articles were reviewed by PW and KW. One trial was excluded as it had a quasi-experimental study design with no randomisation [17]. One trial was excluded as it was an induction method RCT with no expectant management arm for comparison [18]. A study flow diagram for the updated literature search is shown in Fig. 1.

All 31 authors from the Wood Systematic Review were contacted by email, post or phone. Six authors agreed to collaborate. Five authors provided data for inclusion in the meta-analysis (Table 1). Four studies were rated as high quality, one study (Boulvain) did not have sufficient available from the abstract or from the authors on request to allow assessment of quality.

Four authors provided full datasets with relevant variables (Koopmans, Boulvain, Boers and Van den Hove) and one author provided study outcomes by maternal age <35 years and ≥35

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