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# Has perinatal outcome improved after introduction of a guideline in favour of routine induction and increased surveillance prior to 42 weeks of gestation?

## A cross-sectional population-based registry study

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## ABSTRACT

**Objective:** To investigate whether new national guidelines of routine induction of labour and increased surveillance in low risk pregnancies at 41<sup>+2-5</sup> weeks of gestation as an alternative to expectant management until 42<sup>+0</sup> weeks of gestation has improved perinatal outcome.

**Methods:** A questionnaire-based study regarding local induction practices among all Danish delivery units and a cross-sectional population-based registry study based on data from the Danish Medical Birth Registry (DMBR) in the years 2009–2012.

**Outcome measures:** Primary outcomes were frequencies of induced labour and perinatal mortality; secondary outcomes were indicators of perinatal morbidity and instrumental delivery rates.

**Results:** The questionnaire data showed that 22 of the 24 Danish delivery units complied with the new guidelines in 2012. The study population retrieved from the DMBR included 36,845 low-risk pregnancies at or beyond 41<sup>+2</sup> weeks of gestation. The number of labour inductions within the study population had doubled after implementation of the new guideline. The increased proportion of induced labour did not appear to influence perinatal morbidity or instrumental delivery rates. Perinatal mortality remained steady in the years 2009, 2010 and 2011 whereas a reduction of 60 % was seen in 2012. However, this change was not statistically significant ( $P = 0.10$ ).

**Conclusion:** This population-based study with a high reported adherence to the new national guideline found no changes in instrumental deliveries or perinatal outcomes after implementation of earlier routine induction of labour and increased surveillance in low risk pregnancies.

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## Introduction

It is well-documented that prolonged pregnancy increases the risk of adverse foetal and maternal outcomes, including risk of

## Contributors' statement

Sanne Lausen Wolff: conceptualized and designed the study was actively involved in data collection and made the analyses. Drafted the initial manuscript revised suggestions for the manuscript and submitted the approved manuscript.

Iben Lorentzen, Agnete Pers Kaltoft, Heidi Schmidt, and Monique Mensink Jeppesen: were actively involved in conceptualizing the study and revised suggestions for the manuscript.

Rikke Damkjær Maimburg: Dr Maimburg financially supported the data collection and reviewed and revised the manuscript.

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perinatal death [1–3]. Management of post-date pregnancies is continuously debated since existing literature has failed to determine the ideal gestational age for routine induction of labour [2,4–7]. Labour is induced when the benefits of delivery outweigh the risks of continuing the pregnancy; the appropriate time to intervene in post-date, low-risk pregnancies however remains unknown. Randomized controlled trials have suggested that induction of labour may reduce perinatal mortality, but they lack statistical power; observational studies are challenged by methodological limitations. Some studies of routine labour induction have used women in spontaneous labour as a control group [8–10]. This is not a realistic comparison since the actual choice is between induction of labour and expectant management, which means that women undergoing expectant management may go into spontaneous labour, but some will alternatively develop gestational risk factors that independently require induction of labour. A number of systematic reviews have been conducted assessing the ideal management of

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pregnancy beyond term [2–5]. Though methodologically well-conducted, reviews have failed to determine when labour preferably should be induced post-term. Wennerholm et al. stated that existing literature was insufficient for meta-analysis [3].

In Denmark, elective induction of labour has traditionally been recommended at gestational week 42<sup>+0</sup>. The Danish Society of Obstetrics and Gynecology (DSOG) revised their national guidelines in 2011 recommending antenatal surveillance of the mother and foetus twice a week in pregnancies from 41<sup>+3</sup> weeks of gestation and routine induction of labour between 41<sup>+2</sup> and 41<sup>+5</sup> weeks of gestation [11]. A recently published observational study investigated the changes in perinatal outcomes in children born at or beyond term during a thirteen-year period in Denmark. The study found that perinatal outcome appeared to have improved following implementation of more progressive induction policy [12]. However, during this period of time, numerous clinical changes were made. For instance, maternal risk factors such as diabetes, BMI  $\geq 35$  or age  $\geq 40$  are now considered indications for early induction of labour in Denmark. Determining whether earlier induction of labour and increased surveillance guidelines have improved outcome in low risk pregnancies would require a study regarding a shorter period of time as well as exclusion of risk factors to prevent confounding effects from other changes in clinical practice.

A more progressive induction policy involves a considerable increase in the number of labour inductions, possibly leading to alternative risk factors for mother and child such as increased rates of instrumental delivery or risk of foetal distress due to uterine hyperstimulation [13,14]; an evaluation of selected maternal and neonatal outcomes before and after the DSOG guideline change is warranted to determine whether changes have improved the clinical practice in low-risk post-date pregnancies in Denmark.

## Objective

The aim of this study was to investigate whether a policy of routine induction of labour and increased surveillance in low-risk pregnancies between 41<sup>+2</sup> and 41<sup>+5</sup> weeks of gestation as an alternative to expectant management until 42<sup>+0</sup> weeks of gestation has influenced perinatal and maternal outcomes.

## Methods

An electronic study-specific questionnaire was developed and forwarded by email to the heads of midwifery at the 24 delivery units in Denmark. The questionnaire included questions regarding local details of present and previous post-date labour induction policies. If a delivery unit reported that the local guideline had been changed within the study period, the date of implementation was requested. Additionally, we asked whether routine post-date surveillance of the mother and foetus had been changed within the study period; if so the participants were asked to specify the content of the antenatal surveillance before and after modification as well as the date of implementation.

We conducted a cross-sectional population-based registry study based on data from the Danish Medical Birth Registry (DMBR) [15], which contains information on all births in Denmark. Gestational age in Denmark was determined according to routine ultrasonography between 11<sup>+3</sup> and 13<sup>+6</sup> weeks of gestation for more than 90% of the pregnancies [16].

Information about in vitro fertilization (IVF) was obtained from the Danish National In Vitro Fertilization Register (DNIVFR) [17], and additional diagnoses regarding maternal diabetes and neonatal aspiration of meconium were obtained from the Danish National Patient Registry (DNPR), containing information on all somatic and acute hospital contacts since 1977 [18]. In Denmark, every citizen is assigned with a unique civil registration number. This number

**Table 1**

Maternal characteristics and mode of delivery in low-risk<sup>a</sup> pregnancies exceeding 41<sup>+2</sup> gestational weeks in 2010 and 2012.

|   | 2010 (ref.) |          | 2012 |          |
|---|-------------|----------|------|----------|
|   | n           | (%)      | n    | (%)      |
| Low-risk pregnancies at GA <sup>b</sup> $\geq 41 + 2$ | 9713        | (100.00) | 8545 | (100.00) |
| Primiparae  | 4660        | (48.52)  | 4247 | (49.90)  |
| Multiparae  | 4945        | (51.48)  | 4264 | (50.10)  |
| Body Mass Index $\geq 25$ kg/m <sup>2</sup>           | 3070        | (32.84)  | 2782 | (33.17)  |
| Age $\geq 35$ years                                   | 1751        | (18.03)  | 1480 | (17.32)  |
| <b>Labour onset</b>                                   |             |          |      |          |
| Induction of labour                                   | 2548        | (26.23)  | 4441 | (51.97)  |
| Elective caesarean section                            | 81          | (0.83)   | 92   | (1.08)   |
| <b>Delivery</b>                                       |             |          |      |          |
| Acute caesarean section                               | 1377        | (14.18)  | 1128 | (13.20)  |
| Vacuum extraction                                     | 979         | (10.08)  | 807  | (9.44)   |

<sup>a</sup> Low-risk meaning that pregnancies complicated by preeclampsia, hypertension, diabetes, multiple pregnancy, BMI  $\geq 35$ , maternal age  $\geq 40$  years or IVF-pregnancy were excluded.

<sup>b</sup> Gestational age.

enables accurate linkage of information across different national registries. Civil registration numbers for mothers and children respectively were used to merge registry data in this study.

The primary outcomes of this study were frequencies of labour inductions and perinatal mortality (defined as the sum of intra uterine foetal death at  $\geq 22$  weeks of gestation and death during the first seven days postpartum). Secondary outcomes included rates of acute caesarean sections, vacuum extractions, Apgar Score  $< 7$  at 5 minutes postpartum, umbilical artery blood pH  $< 7.1$ , foetal scalp blood pH testing, admissions to neonatal intensive care units, aspiration of meconium and infant birth weight  $> 4500$  g.

## Statistical analyses

Descriptive analyses were conducted to show the total number of deliveries as well as the mode of delivery and maternal characteristics in the study period. We mainly compared the years 2010 (the last year before the guideline revision) and 2012 (the year the majority of delivery units had implemented the guidelines), see Table 1.

Incidences of both primary and secondary outcomes were measured as prevalence proportion ratios per year, and the years 2010 and 2012 were compared using logistic regression to estimate odds ratios (OR) and 95% confidence intervals (CI). Results were considered statistically significant when a two-sided p-value was less than 5%.

To determine whether findings were likely to be a result of the changed management of pregnancies that exceeded 41<sup>+2</sup> weeks of gestation, we repeated the analyses on deliveries within week 40. Tendencies that were found both in weeks 40 and at  $\geq 41 + 2$  were considered to be attributable to other changes in clinical practice such as changed routines of monitoring foetal well being or intervention procedures such as augmentation of labour.

Multiple logistic regression analyses were used to adjust for possible confounders (maternal age, maternal BMI, and parity). This analysis was additionally performed with supplementary correction for the use of augmentation in labour (data not shown).

Data management and statistical analyses were performed using STATA Statistical Software, Version 11 (STATA-corp, college station, TX, USA, 2006).

## Results

### Questionnaire data

The electronic questionnaires were completed by all 24 Danish delivery units; the results revealed that during 2011 and 2012 a total

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