A more liberal approach towards induction of labour in prolonged pregnancy does not result in an adverse labour outcome

Olav-Andre Klefstad[1], Inger Økland[1], Elsa Lindtjørn[1], Astrid B. Rygh[1], Kristine Kaada[1], Michael L. Hansen[1, 2] & Torbjørn M. Eggebø[1]

ABSTRACT

INTRODUCTION : Discussions among Norwegian obstetricians on how to handle prolonged pregnancies have been ongoing throughout the past decade. In 2011, the Norwegian Directorate of Health recommended a specialist care consultation one week after the estimated date of delivery, implying prompt induction of labour in women at risk. The aim of this study was to compare an expectant management with a more liberal approach towards induction of labour, and to assess how the women responded to these recommendations.

MATERIAL AND METHODS: A quality assurance study was performed at Stavanger University Hospital in women with a pregnancy length ≥ 290 days. A total of 480 women who delivered prior to the introduction of the new guidelines (control period) were compared with 493 women treated according to the new recommendations (study period).

RESULTS: A total of 421/493 (85%) women in the study period attended the consultation on day 290. Of these, 61% were recommended early induction of labour (within 24 hours) because their pregnancy was a risk pregnancy. Four percent of the women with risk factors awaited spontaneous labour until day 294, versus 20% of low-risk women. When comparing the two periods, we observed an increase in the frequency of induced labour from 38% to 65%, an insignificant elevation of Caesarean section rates from 11.5% to 13.8%, and no significant increase in other interventions or in adverse newborn outcomes.

CONCLUSION: A more liberal approach towards induction of labour one week after the estimated date of delivery did not lead to an adverse labour outcome.

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ORIGINAL ARTICLE

1) Department of Obstetrics and Gynaecology, Stavanger University Hospital, Stavanger, Norway
2) Copenhagen Cardiovascular Clinic, Copenhagen, Denmark

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According to the WHO, the estimated date of delivery (EDD) is on pregnancy day 280, calculated from the first day of the last menstrual period (LMP) [1]. However, Scandinavian studies have shown that the median pregnancy length is 282 or 283 days [2-4]. Pregnancies are considered post-term after 294 days, and reliable dating with ultrasound is a prerequisite for the diagnosis [5]. In some studies, an increased risk of perinatal mortality past term was described [6]. However, a Norwegian register study describe an improvement of perinatal mortality in recent years and no increased risk of post-term stillbirths in mothers < 40 years [7]. Still, the handling of the so-called prolonged pregnancies 7-14 days past EDD remains controversial. The risk of perinatal complications and mortality must be balanced against potential problems related to interventions. In retrospective registry studies, induction of labour has been associated with increased rates of Caesarean section (CS) [8]; however, prospective studies have not confirmed this finding [9]. In fact, a recently published meta-analysis concluded that induction of labour in women with intact membranes reduced the risk of CS [10].

Previously, a post-term consultation was recommended in Norway around day 294, and induction of labour was advised in pregnancies with an increased risk of intrauterine foetal growth restriction (IUGR), oligohydramnion, or a discrepancy of > 14 days between LMP-based and ultrasound-based EDD (recommendations from the Norwegian Society of Obstetrics and Gynaecology). Nevertheless, the practices varied widely among hospitals, which in July 2011 concerned the Norwegian Directorate of Health enough to recommend a consultation in specialist healthcare on day 290, also implying earlier induction of labour. Body mass index (BMI) > 25 kg/m^2 and maternal age > 35 years were added as risk factors, and more attention should be paid to maternal requests during the counselling. Induction of labour should start no later than day 294.

Out of concern that an earlier induction would lead to an increase in operative deliveries, some hospitals declined to adopt the new recommendations. At Stavanger University Hospital, we conducted a quality assurance study to assess the implications of the new guidelines, and to register how the expecting mothers responded to these recommendations.

MATERIAL AND METHODS

Stavanger University Hospital serves a population of approximately 320,000 people and is the only maternity unit in the region. The Delivery Ward followed the old guidelines until July 2011, and from August 2011 the

new recommendations from the Directorate of Health were implemented. We investigated the frequency of complicated pregnancies in women attending the recommended specialist care consultation at day 290 after the introduction of the new guidelines and registered how they responded to the new recommendations. All participants gave written informed consent. Furthermore, we compared obstetric parameters in two subgroups of women with a pregnancy length ≥ 290 days; those giving birth from November 2010 to June 2011 (control period) with those giving birth from August 2011 to March 2012 (study period). The new recommendations from the Directorate of Health were published in the local newspaper, and midwives and doctors in primary healthcare were informed directly through a coordinating physician before changes were implemented. The EDD was calculated at a second trimester ultrasound scan, and medical information from the deliveries were prospectively collected and recorded in the electronic obstetrical journal Imatis Natus.

At the 41-week consultation, all women were offered a clinical examination, a cardiotocography (CTG) and an ultrasound examination. Women with chronic illnesses, high-risk pregnancies, previous CS, non-reactive CTG, oligohydramnios (the deepest amniotic fluid pocket being < 20mm), or foetal growth restriction (estimated birth weight below the 10th percentile), were recommended induction of labour within 24 hours. Women with low-risk pregnancies were advised to await spontaneous labour until day 294, but maternal request for earlier induction was acknowledged. Information was given by a physician or a midwife according to standardised guidelines.

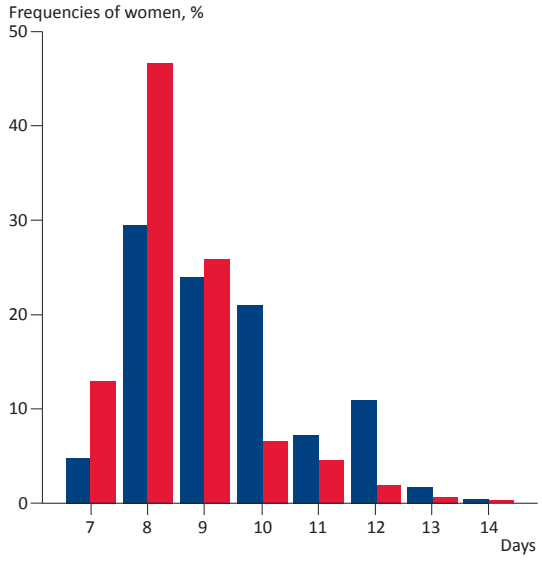
During 2009-2010, the overall frequency of CS in the department was 16% in women with induced labour versus 8% in women with spontaneous start of labour. We assumed a similar distribution of CS in this post-term population and that the frequency of labour induction would be around 50%. From a power analysis using alpha 0.05 and a power 0.8, around 500 women needed to be included in the study period to differentiate between CS rates in induced and spontaneous deliveries. Stavanger University Hospital has around 5000 deliveries per year, and we supposed that around 12% of the women would reach a pregnancy length of 290 days. Thus, we planned a study period of eight months, and used a similar eight-month period in 2010/11 as our control period.

Continuous variables were compared using the Mann-Whitney U test, and categorical variables using the χ^2 test. A p-value < 0.05 was considered significant. Data were analysed with the statistical software package IBM SPSS Statistics for Windows, v. 20.0 Armonk, NY: IBM Corp. The Regional Ethics Committee concluded that this was a quality assurance study (REK West 2012/485).

Trial registration: not relevant

FIGURE 1

Frequencies of women (y-axis) in the study period delivering from day seven to day 14 after their estimated day of delivery (x-axis). Risk group (n = 255, red columns) and low-risk group (n = 166, blue columns).



RESULTS

In all, 3,127 women delivered at the hospital in the control period, and 480 (15.4%) experienced a prolonged pregnancy lasting ≥ 290 days. During the study period, 3,158 women delivered, and 493 (15.6%) reached day 290, of whom 421 (85%) attended the consultation on day 290. Of these, 255/421 (61%) were recommended early induction of labour (within 24 hours) because of risk pregnancies; 145/255 due to a history of chronic illnesses or previous or actual pregnancy complications. 24/110 with uncomplicated pregnancies were ≥ 35 years old, and the pre-pregnant BMI was > 25 in 49 of the remaining 86 women. A total of 36 (8.5%) women had an estimated birth weight below the 10th percentile, 43 (10%) had oligohydramnious and 12 (2.9%) had an increased pulsatile index (> 2 standard deviations) in the umbilical artery. However, many of these women also had risk factors known before the examination. In 37 women, early induction was recommended only due to abnormal ultrasound findings. Early induction was planned in 82% of the women with risk factors. Four percent of the women with risk factors awaited spontaneous labour until day 294, versus 20% of the low-risk women. **Figure 1** illustrates the actual day of delivery in

the study population. The frequency of CS was 15.1% in women with induced labour and 9.0% in women with spontaneous start of labour (p = 0.11).

When comparing the two periods, we observed an increased frequency of labour induction from 38% to 65% (p < 0.01), and an insignificant elevation of CS rates from 11.5% to 13.8%. Maternal characteristics and labour outcomes are compared and presented in **Table 1**. We observed no cases of intrauterine foetal death in either of the periods.

TABLE 1

Characteristics of the study population

	Control period n = 480, % or median (range)	Study period n = 493, % or median (range)	p-value
Maternal characteristics			
Maternal age	29 (18-43)	30 (16-48)	0.07
Nulliparous women	44.1	46.3	0.53
Maternal age > 35 years	18.0	19.2	0.66
Pre-pregnancy BMI > 25	36.7	30.1	0.03
Pre-pregnancy BMI > 30	10.3	12.7	0.25
Characteristics related to induction			
Gestational age (days)	293 (290-299)	291 (290-297)	< 0.01
Induction	37.5	65.3	< 0.01
Bishop score	4.0 (1-10)	3.0 (0-12)	< 0.01
Use of misoprostol	23.5	49.7	< 0.01
Characteristics of the delivery			
Caesarean section	11.5	13.8	0.27
Operative vaginal delivery	20.8	22.7	0.48
Sphincter rupture	2.9	3.0	0.90
Estimated blood loss (ml)	300 (100-4,000)	300 (100-5,600)	0.95
Characteristics of the child			
Birth weight (g)	3,840 (2,615-5,800)	3,780 (2,655-5,180)	0.11
Birth weight < 10 percentile[a]	4.4	5.5	0.43
Birth weight < 2.5 percentile[a]	1.0	1.6	0.43
Apgar score 1 min	9 (2-10)	9 (2-10)	0.22
Apgar score 5 min	9 (4-10)	10 (3-10)	0.01
Apgar score 5 min < 7	1.0	1.4	0.59
pH in umbilical artery	7.22 (6.98-7.43)	7.23 (6.90-7.44)	0.20
Base deficit in umbilical artery	3 (–3 to 12)	3 (–3 to 14)	0.41

a) Birth weight < 10 percentile corresponds to < 3,150 gram, and birth weight < 2.5 percentile corresponds to < 2,900 g.

DISCUSSION

A total of 61% of the women attending the 290-day consultation were categorised as risk group patients. Among these, 82% accepted the advice of early induction of labour. Most of them had risk factors already acknowledged before the consultation. In the study period, we observed an increased rate of inductions of labour due to prolonged pregnancy and a lower median pregnancy length at delivery.. We also observed a small, but insignificant increase in the CS rate.

Perinatal morbidity and mortality and maternal morbidity increase beyond term [11]. The traditional assumption of an association between labour induction and complicated deliveries is based on registry studies comparing induced, i.e. typically high-risk, and spontaneous births. However, a retrospective study design does not reveal whether delivery interventions are due exclusively to the induction or rather to the pregnancy complications bringing about the induction. A prospective Danish study comparing induction week by week showed that elective induction in itself did not lead to an increased proportion of CS [12]. Heimstad et al conducted a randomised controlled trial of induction versus expectant management ekspektans management in pregnancy week 41 and found no increased use of CS or instrumental vaginal delivery [13]. They also found that women who were offered induction were more satisfied [14]. According to a Cochrane review, women should be given enough information to be able to choose between induction of labour and expectant management [15].

The median pregnancy length in our study population was, not unexpectedly, reduced from 293 to 291 days (p < 0.01), and more women had an unripe cervix at the start of induction (p < 0.01), thus needing ripening with prostaglandins. Misoprostol was used in women with a low Bishop score and no previous CS. All women were offered in-hospital surveillance during induction. We observed no adverse effects of misoprostol.

The new recommendations for handling post-term pregnancy emphasise the women's preferences. Some women with risk factors did not opt for early induction, while others with low-risk pregnancies opted for induction before day 294. This may explain why 18% of women with risk pregnancies were not induced impendingly, while 39% with low-risk pregnancies had an early induction.

Our study has limitations. Obviously, a randomised study design should be preferred; however, this would not be ethically acceptable because of the strict recommendations from the Directorate of Health that were in place when the study was planned. Therefore, a historical control group was chosen. The study was too small to assess changes in perinatal mortality. Previously, it has been shown that early induction may prevent one intrauterine foetal death among 500 women one week past EDD [16]. The counselling on day 290 was not a recommendation in Norway before July 2011; thus, we do not have results from ultrasound examinations in the control group. The maternal characteristics and the actual birth weights were similar in the two periods. We did not consider cost and resource consequences of routine changes, but another study has shown that elective birth induction is cost-effective [17].

We conclude that most women at risk followed the recommendations on early induction; furthermore, only

a minority of low-risk women wanted to await induction until day 294. A more liberal attitude towards induction of labour one week after the EDD resulted in an increased proportion of inductions, without important changes in labour outcomes. However, we cannot generalise because of the size of the study population.

CORRESPONDENCE: *Olav-Andre Klefstad*, Stavanger University Hospital, PO Box 8100, NO-4068 Stavanger, Norway. E-mail: klef@sus.no.

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