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An Observational Study**

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**The Information Science  
Discussion Paper Series**

Number 98/06  
March 1998  
ISSN 1177-455X

## **University of Otago**

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## Induction of Labour for Post Term Pregnancy: An Observational Study

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**EDITORIAL COMMENT:** *We accepted this paper for publication because it discusses the important subject of prolonged pregnancy and whether induction of labour is associated with a significant change in the operative delivery rate and the perinatal mortality and morbidity rates. In many centres induction of labour is performed at 41 weeks' gestation in those patients who consent or wish this to be performed and indeed it is often the patient's motivation that determines the induction. Because of this practice the incidence of prolonged pregnancy which is defined as 42 weeks' gestation or beyond, has fallen from approximately 10-12% 30 years ago to about 2% in the 1990's. One of the senior reviewers of this paper provided the following statements which he considered should be kept in mind by readers of this paper. Although this is a carefully conducted study, the results and conclusions need to be interpreted with extreme caution. The words in the title 'an observational study' alert the reading audience to pitfalls which could result from systematic differences between the induction and 'control' groups which would necessarily be reflected in differences in outcomes which could then (erroneously) be attributed to the intervention. For example, women who declined the offer of induction of labour (who would therefore be 'controls') might also decline a recommendation for instrumental delivery which could then be misinterpreted to mean that induction of labour result in a 'higher' operative delivery rate compared to controls. A second caveat applies to the practice of multiple analyses of characteristics of 2 populations; 1 of 20 of such comparisons will result in  $p=0.05$  by chance alone. This point needs to be considered when interpreting findings reported here such as more married than unmarried women having induction of labour performed, or the conflicting finding of a decrease in the Caesarean section rate following induction for multiparas but an increase in nulliparas. These findings, and others, may be due to chance, and cannot in this observational study be viewed with the same confidence as findings derived from a randomized controlled trial.*

**Summary:** The aim of the study was to compare the 2 management protocols for postterm pregnancy; elective induction of labour at 42 weeks' gestation and continuing the pregnancy with fetal monitoring while awaiting spontaneous labour. A retrospective observational study compared a cohort of 360 pregnancies where labour was induced with 486 controls. All pregnancies were postterm (>294 days) by an early ultrasound scan. Induction of labour was achieved with either prostaglandin vaginal pessaries or gel or forewater rupture and Syntocinon infusion. The control group consisted of women with postterm pregnancies who were not induced routinely and who usually had twice weekly fetal assessment with cardiotocography and/or ultrasound. Women who had their labour induced differed from those who awaited spontaneous labour. Nulliparas (OR 1.54; 95% CI 1.24-1.83) and married women (OR 1.76; 95% CI 1.45-2.06) were more likely to have their labour induced. There was no association between the type of caregiver and induction of labour. Induction of labour was associated with a reduction in the incidence of normal vaginal delivery

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(OR 0.63, 95% CI 0.43-0.92) and an increased incidence of operative vaginal delivery (OR 1.46; 95% CI 1.34-2.01). There was no difference in the overall rate of Caesarean section. There was no difference in fetal or neonatal outcomes. Parity had a major influence on delivery outcomes from a policy of induction of labour. Nulliparas in the induced group had worse outcomes with only 43% achieving a normal vaginal delivery (OR 0.78, 95% CI 0.65-0.95). In contrast for multiparas, the induced group had better outcomes with less Caesarean sections (OR 0.88, 95% CI 0.81-0.96). This retrospective observational study of current clinical practice shows that induction of labour for postterm pregnancy appears to be favoured by nulliparous married women. It suggests that induction of labour may improve delivery outcomes for multigravas but has an adverse effect for nulliparas.

The aim of induction of labour is to reduce perinatal mortality and morbidity without increasing maternal morbidity. Postterm pregnancy, defined as a pregnancy of more than 42 weeks' gestation (>294 days)(1), is associated with increased perinatal mortality (2) and is the most common indication for induction of labour.

The debate continues as to whether induction of labour is beneficial for the postterm pregnancy in the absence of fetal compromise (3,4). This question has been addressed in the Cochrane Database of Systematic Reviews (CDSR). The 1995 edition, after a meta-analysis of 14 randomized controlled trials, concluded that for postterm pregnancy induction of labour reduced the risk of perinatal morbidity and slightly reduced the high likelihood of delivery by Caesarean section (5). This recommendation has been interpreted widely as implying that induction of labour is best practice. The 1997 version concluded that routine induction of labour has no effect on the incidence of Caesarean section (6).

The meta-analysis in CDSR (1997) after an analysis of approximately 6,000 pregnancies, showed a reduction in perinatal mortality (OR 0.2; 95% CI 0.06-0.70) and a reduction in the rate of Caesarean section (OR 0.87; 95% CI 0.77-0.99) following induction of labour. However from these data to avoid 1 perinatal death, more than 500 women must have an induction of labour. The data on the incidence of Caesarean section shows significant heterogeneity; 10 of the 12 trials showed no significant effect. A large recent randomized trial in 1994 by the National Institute and Child Health and Human Development Network showed a nonsignificant increase and concluded that either management scheme was acceptable (7).

Current practice audit questions the findings of CDSR and shows an increasing trend to induction of labour which has a significant effect on hospital workload.

An analysis of 4.5 years of current practice, with a rate of induction of 42.5%, is presented to determine which women and pregnancies are having an induction of labour and to determine the outcomes from current practice.

## MATERIALS AND METHODS

An observational cohort study was performed using maternity data prospectively collected on an electronic database. Every effort was made to ensure data accuracy. The data from all women delivering at National Women's Hospital in the 4.5-year period from January, 1992 to June, 1996 were perused to select women with a postterm pregnancy. Only women with an early ultrasound scan (less than 20 weeks' gestation) were selected. There were 36,025 women who delivered in this time period; 72% had an early ultrasound scan and of these 846 pregnancies were postterm.

A comparison was made between women who had labour induced for a postterm pregnancy (n=360) and those women who awaited spontaneous labour and acted as controls (n=486). analysis was by intention to treat. The induced group consisted of women with uncomplicated postterm pregnancies who were induced for postterm pregnancy as the sole indication. The control group consisted of women who elected to await spontaneous labour and included 19% (90 of 486) women whose pregnancy subsequently become complicated and required induction of labour (figure 1).

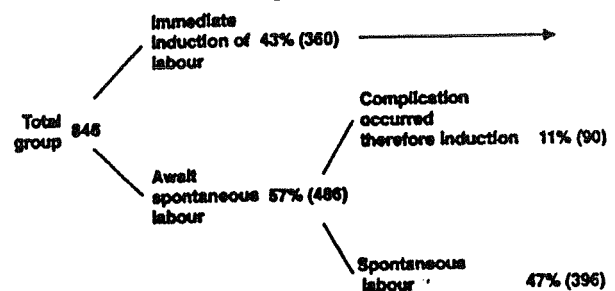


Figure 1. Management options for postterm pregnancy: Study design.

The method of induction of labour was similar between groups (table 1). Data were captured by midwifery staff after induction of labour in a separate section of the database from that used for augmentation of labour. Hence induction of labour by ARM and Syntocinon infusion was coded differently

Table 1. Methods of Induction of Labour

	Percentage of induced group (n = 360)	Percentage of Control group (n = 90)*
Prostaglandin alone	79.0	70.0
ARM alone	8.6	6.6
Syntocinon and ARM	12.4	23.4
	100	100

\*=18.5% (90 of 486) of the control group required induction of labour;

ARM = artificial rupture of membranes

from cases where Syntocinon was used later in the labour to enhance contractions.

The control group was monitored in the postterm period according to the instructions of the individual clinician. Recommended hospital practice was for a cardiotocography to be performed twice weekly and a liquor volume assessment weekly. The type of monitoring was not recorded.

Pregnancy characteristics studied included maternal age, ethnicity, parity, booking caregiver, smoking, educational background, marital status and past obstetric history. Outcome measures including method of delivery, pain relief in labour, postnatal stay (mother and baby), presence of meconium, fetal distress in labour, Apgar scores and neonatal unit admissions were analyzed.

#### Statistical method

Student's t test was used for analysis of continuous variables. chi squared test was used for categorical variables. Multivariate analysis was by stepwise logistic regression. an  $\alpha$ -level of 5% was used for all statistical tests. Analyses were performed using SAS 6.11 (SAS Institute Inc., Cary, North Carolina, USA).

## RESULTS

#### Pregnancy characteristics

In the 4.5 years of the study labour was induced for 42.5% (360 of 846) of the postterm population. This rate increased from 30% in 1992 to 53% in 1996.

Table 2. Characteristics of Women Whose Labour was Induced

	Percentage of total group	Rate of induction %	Odds ratio	95% CI
Overall	100	42.6		
Private booking	53	46.4	1.1	1.1-1.9
Consultant booking	11	40.9	0.9	0.6-1.4
GP booking	34	48.6	1.5	1.1-2.0
Midwife booking	8	44.9	1.1	0.7-1.8
Public booking	47	37.9	0.7	0.5-0.9
European	52	47.9	1.6	1.2-2.1
Maori	10	35.3	0.7	0.4-1.1
Polynesian	28	33.3	0.6	0.4-0.8
Nulliparous	51	47.9	1.6	1.2-2.1
Married	62	46.4	1.5	1.1-2.0
Poor history	4	36.4	0.8	0.4-1.6
Smoker	27	38.4	0.8	0.6-1.1
Reduced education	7	38.5	1.3	0.7-2.6

\*Significant results are shown in bold; GP = general practitioner

Women in the induced group differed from the control group who awaited spontaneous labour (table 2). European women, women booking for pregnancy care with their family practitioner (GP), private bookings, nulliparas and married women were more likely to have an induction of labour.

Marital status and parity remained significantly associated with the decision to induce labour after multivariate analysis (table 3). Factors analyzed which had no influence, included poor obstetric history, type of caregiver, ethnicity, smoking history and maternal age. Eight cases were deleted as there was a missing value for 1 variable; this left 355 women in the induced group and 483 in the control group for this analysis.

Table 3. Multivariate Analysis of Characteristics of Women with a Postterm Pregnancy Who Had an Induction of Labour

	Odds ratio	Parameter estimate	Confidence interval	p value
Nulliparas	1.54	0.43	1.24-1.83	0.004
Married	1.76	0.57	1.45-2.06	0.001

\*Other factors did not reach significance

All women in the induced group had delivered by 43 weeks and 2 days. In the control group 81% (394 of 486) delivered in the 42nd week, 11.5% (56 of 486) in the 43rd week and 3.7% (18 women; 0.02% of the total population) remained undelivered at the end of the 44th week of pregnancy.

#### Pregnancy outcome

Women in the induced group had more labour complications. There were no clinically significant differences in duration of labour (table 4). There was a difference in the time from onset of contractions to delivery. This subjective measurement relates to the induction of labour procedure. Women with spontaneous onset of labour tend to record the first contraction or 'tightening', while women induced with prostaglandins are told 'this is not a contraction only a prostaglandin pain'. There were no other significant differences in delivery timings.

Women in the induced group had increased usage of pain relief. There was no significant difference in the

Table 4. Duration of Labour in the 2 Groups in Hours (Mean  $\pm$  SE)\*

Time interval (hours)	Induced group (n = 278)	Control group (n = 375)	p value
Onset of contractions to delivery	8.2 $\pm$ 0.3	10.0 $\pm$ 0.4	0.01
Admission to labour ward to delivery	7.2 $\pm$ 0.4	6.9 $\pm$ 0.3	NS
Membrane rupture to delivery	6.9 $\pm$ 0.3	6.2 $\pm$ 0.4	NS

\*Women who had a Caesarean delivery have been excluded (19%); NS = not significant

usage of pethidine, on average 16%. However 54% (193 of 360) of women from the induced group had an epidural analgesia compared with 43% (208 of 486) of women from the control group ( $p < 0.002$ ). When subdivided by parity the difference remained but did not reach significance.

Women in the induced group also were more likely to require augmentation with oxytocin infusion for subsequent delay in labour; 39% (141 of 359) required augmentation compared with 28% (135 of 485) in the control group. When subdivided by parity the difference did not reach significance.

Induction of labour for postterm pregnancy was associated with a significant reduction in the incidence of normal delivery, an increase in the rate of operative vaginal delivery and no change in the overall incidence of Caesarean section (table 5). The reduction in the incidence of normal vaginal delivery was from 65.6% (319 of 486) for women in the control group to 58.6% (211 of 360) for those women in the induced group ( $p < 0.04$ ). This reduction in the number of normal vaginal deliveries was confined to nulliparas ( $p < 0.02$ ). There was no difference for multiparas. This is an adverse effect of induction of labour for nulliparas with 1 less normal vaginal delivery for every 14 women having an induction of labour (NNT=14; 95% CI 1-29).

Table 5. Delivery Method for Women with a Postterm Pregnancy: Induced and Control Groups

	Percentage of induced group (n = 360)	Percentage of Control group (n = 486)	Odds ratio	95% CI
Normal vaginal delivery	59.0	66.0	0.83	0.70-0.99
Operative vaginal delivery	19.0	12.0	1.10	1.03-1.15
Caesarean section	22.8	22.8	0.99	0.93-1.01
Caesarean section for failure to progress	72.0	59.0	1.50	1.00-2.20
Caesarean section for fetal distress	21.0	18.0	1.03	0.90-1.20

Significant results are shown in bold

The incidence of Caesarean section between groups was not significantly different (table 5). There was however a marked effect associated with parity. For multiparas induction of labour was associated with a significant reduction in the incidence of Caesarean section (from 21.8% in the control group to 11.1% in the induced group  $p < 0.006$ ; table 6). For nulliparas the difference was in the opposite direction but did not reach significance (induced group 31%, control group 24%; table 7). Seventy per cent of the Caesarean sections for nulliparas were for failure to progress. There was no difference between groups. Overall, failure to progress as an indication for Caesarean section was more common in the induced group (72%

Table 6. Multiparous Women: Delivery Outcomes

	Percentage of induced group (n = 153)	Percentage of Control group (n = 261)	Odds ratio	95% CI
Normal vaginal delivery	75	79	1.20	0.80-1.70
Operative vaginal delivery	10	3	1.10	1.01-1.13
Caesarean section	11	22	<b>0.88</b>	<b>0.81-0.96</b>

Significant results are shown in bold

Table 7. Nulliparous Women: Delivery Outcomes

	Percentage of induced group (n = 207)	Percentage of Control group (n = 225)	Odds ratio	95% CI
Normal vaginal delivery	43	55	<b>0.78</b>	<b>0.65-0.95</b>
Operative vaginal delivery	25	21	1.10	0.90-1.20
Caesarean section	31	24	1.10	0.98-1.24

Significant results are shown in bold

versus 59%); there was no difference in the incidence of Caesarean section for fetal distress.

There was a significant increase in the incidence of operative vaginal delivery for women who had an induced labour (table 5). This difference was confined to multiparas (NNT 19; 95% CI 1, 40; table 6). There was no effect on the incidence of operative vaginal delivery for nulliparas (table 7).

Rates of postpartum haemorrhage, manual removal, episiotomy and hospital readmission did not differ between groups.

The incidence of meconium staining was 15% (defined as moderate or thick meconium). The difference between groups did not reach significance. There was no significant difference in the incidence of fetal distress in labour between groups (defined as an alteration in the fetal heart rate outside the normal range in association with reduced variability and/or decelerations). Fetal and neonatal outcomes were generally good in both groups. There was only 1 perinatal death, a perinatal mortality rate of 1.2 per 1,000 births. This baby, a neonatal death, who died from multiple fetal abnormalities including a congenital heart defect and complications of meconium inhalation, was in the induced group. Eight per cent of the babies were admitted to the neonatal unit. There was no significant difference between groups. There was an increase in the incidence of low Apgar scores defined as 1-minute Apgar less than or equal to 6 in the induced labour group. This rate did not reach significance.

## DISCUSSION

Management of the postterm pregnancy remains controversial. The risks for a pregnancy which exceeds 42 weeks are well described, however the

question whether induction of labour improves outcome for these pregnancies is unclear. An alternative policy of twice weekly fetal surveillance can be employed until spontaneous onset of labour, reserving induction of labour for those pregnancies where there is evidence of fetal compromise (7).

In CDSR 1995 (5) the clear recommendation for management of postterm pregnancy was induction of labour at or before 42 weeks' gestation however the 1997 recommendation is less strong (6). This recommendation requires careful inspection. The data from CDSR (6) shows that more than 500 pregnancies require induction of labour to avoid 1 perinatal loss and that the effect of induction of labour on the incidence of Caesarean section is difficult to interpret with conflicting results from the 12 trials. The Canadian Study (8) has a major influence on the meta analysis (weight 64%) for the effect on the incidence of Caesarean section. This study was large ( $n=3,407$ ) but the method of induction of labour was different in the 2 groups, with vaginal prostaglandin gel being liberally used in the induced group (66% of whom were induced) and not being used for induction of labour in the control groups (32% of whom were induced). This introduces bias to the meta-analysis as it is well documented that induction of labour with prostaglandin preparations results in a lower Caesarean section rate when there is an unfavourable cervix (9). A clear recommendation to all women with a postterm pregnancy that induction of labour is the best policy may be an overinterpretation of the data. Audit of hospital practice shows that many women with a postterm pregnancy do not have an induction of labour and conversely many have their labour induced much earlier. Overall there are increasing rates of induction of labour but with the low incidence of perinatal mortality evidence of benefit from a policy of induction of labour is difficult to find.

This observational study was designed to determine the characteristics of the women who are being offered induction of labour and to compare outcomes from the 2 methods of management in current practice.

Previous studies have not addressed the characteristics of women offered induction of labour. It appears from this study that nulliparous, married women and possibly European women, are more likely to have their labour induced. This appears to be contrary to medical indications for induction of labour. One would expect that women who smoke, have a poor obstetric history or are older would be more likely to suffer complications of postterm pregnancy and therefore should be offered induction of labour.

It is possible that nulliparous married European women seek induction of labour for social convenience, but interestingly age was not a factor associated with induction of labour.

The overall effect of induction of labour was a reduced incidence of normal vaginal delivery (OR 0.83) and an increased incidence of operative vaginal delivery (OR 1.1), with no effect on the rate of Caesarean section.

Analysis of the data for nulliparas shows that women in the induced group had a significantly reduced incidence of normal vaginal delivery (OR 0.78) and no significant effect on the rate of operative vaginal delivery. There was no significant effect on the rate of Caesarean section although there were more Caesarean sections performed in the induced group (31% versus 24%), most for failure to progress in labour.

Multiparas in the induced group had significantly less Caesarean sections performed (OR 0.88) and more operative vaginal deliveries (OR 1.1) but there was no effect on the incidence of normal vaginal delivery.

Differing effects on the practice of induction of labour for nulliparas and multiparas is entirely plausible. The incidence of Caesarean section for postterm pregnancies is far higher for nulliparas. In CDSR (6) the incidence in the control group for nulliparas was 33% (533 of 1617) compared with 4.7% (44 of 944) for multiparas. Analysing the data in CDSR (6) by parity was only possible for 5 trials and is difficult to interpret due to the above mentioned differing methods of induction of labour and heterogeneity of results. In this study induction of labour appears to be beneficial for multiparas with a significantly reduced incidence of Caesarean section. However for nulliparas women the striking difference between groups was the reduction in normal vaginal deliveries for women who had their labour induced.

Studies of patient preference suggest that women, prefer induction of labour if their pregnancy exceeds 42 weeks (10), however they are dissatisfied if they require an interventional delivery (11).

The benefit of a reduction in perinatal mortality from a policy of induction of labour for postterm pregnancy is small. There appears to be evidence that for multiparas induction of labour is associated with improved delivery outcomes while for nulliparas induction of labour may reduce the rate of normal vaginal delivery. This question needs further study. In general the differences are so small that after appropriate unbiased explanation each individual women should be encouraged to make her own choice.

#### *Acknowledgements*

This project was supported by the National Women's Hospital Research Registrar Fund.

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