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Women's experiences of induction of labour with misoprostol tablets compared with vaginal insert

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ABSTRACT

INTRODUCTION. The aim of this study was to compare nulliparous women's experiences with induction of labour using two different regimens of misoprostol.

METHODS. We adapted a validated questionnaire regarding experience with induced labour. In two different hospitals, 123 women undergoing medical induction of labour completed a questionnaire after delivery. An independent-samples T-test was used for comparison of parametric continuous variables and Pearson's χ^2 test was used for categorical data. The two groups differed regarding BMI and pregnancy complications. No adjusted estimates were calculated.

RESULTS. Women induced with oral misoprostol experienced more painful induction of labour (p = 0.019) and described feeling that their length of stay at hospital was excessive (p = 0.028). Overall, the experience of giving birth after induction of labour was reported as "good" among 87.8% of women induced with oral misoprostol compared with 72.7% of the women induced with a slow-release misoprostol vaginal insert (p = 0.039).

CONCLUSION. In two departments characterized by several differences, including whether vaginal or oral misoprostol was used, induction with oral misoprostol in an out-patient setting was associated with a better experience of labour than induction with a slow-release misoprostol vaginal insert.

FUNDING. Region Zealand Health Scientific Research Foundation supported the study financially.

TRIAL REGISTRATION. The study was registered with clinicaltrials.gov ID: NCT02693587 on 26 February 2016 and with EudraCT number 2020–000366-42 on 23 January 2020 (retrospectively registered).

In Denmark, 24% of deliveries are induced, with a 27% prevalence among nulliparous women [1]. Hence, it is of great importance to offer a regimen of induction that is safe and cost efficient and that also provides the best possible experience for the parents.

In a recent study, we compared women induced with oral misoprostol to slow-release vaginal insert [2] finding that induction with vaginal misoprostol led to faster deliveries and an increased risk of tachysystole but with

similar perinatal outcomes and incidence of Caesarean or instrumental vaginal delivery. Low-dose oral misoprostol appeared to be safe but was associated with an increased use of secondary methods of induction and a non-significant trend towards more intrapartum fever than vaginal misoprostol.

Most studies have evaluated safety and efficacy in relation to induction [3], but recently more attention has been dedicated to women's experiences of induction of labour, suggesting that women's experience should be an important factor in the decision-making process [4].

The aim of this study was to compare two populations of nulliparous women with unripe cervices regarding experiences of induction of labour and who gave birth after induction with oral misoprostol and slow-release vaginal insert.

METHODS

All nulliparous women with planned vaginal delivery and medical induction of labour were evaluated. The inclusion criteria were term, singleton pregnancies with cephalic presentation.

The exclusion criteria were previous uterine scar, suspicion of foetal growth restriction and prelabour rupture of membranes. Furthermore, the women needed to be able to complete the questionnaire in Danish language.

This was a prospective cohort study conducted in two different obstetric departments in the region of Zealand from November 2015 to November 2017 with telephone follow-up until May 2018.

The demographic population of women in the two departments who answered the questionnaire differed regarding BMI and pregnancy-related medical conditions (**Table 1**). Women with gestational diabetes mellitus (GDM) were referred to one of the departments [2].

TABLE 1 Characteristics of questionnaire responders and non-responders to the questionnaire.

	Responders (N_r = 123)		Non-responders (N_n = 165)	
Characteristic	**oral misoprostol (n = 57)**	**vaginal misoprostol (n = 66)**	**oral misoprostol (n = 115)**	**vaginal misoprostol (n = 50)**
Maternal age, mean (± SD), yrs	28.2 (± 5)	28.5 (± 5.6)	27.2 (± 5.1)	26.9 (± 4.7)
BMI, mean (± SD), kg/m2	30.5 (± 8.3)[a]	27.6 (± 6.9)	29,1 (± 7,4)[b]	28 (± 7.6)[c]
Caesarean section, n (%)	16 (28.1)	23 (34.8)	79 (68.7)	36 (72)
Maternal educational level, n (%)			-	-
< 10 yrs	6 (10.7)[d]	6 (9.1)		
10-15 yrs	26 (46.4)	35 (53.0)		
> 15 yrs	24 (42.9)	25 (37.9)		
Cigarette use, n (%)	7 (12.3)	10 (15.2)	18 (15.7)	9 (18.0)
Pre-existing medical conditions, n (%)	7 (12.3)	7 (10.62)	15 (13.0)	5 (10.0)
Pre-existing psychiatric conditions, n (%)	3 (5.26)	5 (7.56)	11 (9.6)	5 (10.0)
Pregnancy-related medical conditions, n (%)	22 (38.6)	17 (25.8)	69 (60.0)	14 (28.0)
GDM	2 (9.1)	1 (5.9%)	27 (39.1)	-
Pre-eclampsia	6 (27.2)	11 (64.7)	16 (23.2)	5 (35.7)
Hypertension	2 (9.1)	2 (11.8)	7 (10.4)	-
Intrahepatic cholestasis	1 (4.5)	1 (5.9)	4 (5.8)	2 (14.3)
Others	11 (50)[e]	2 (11.8)	15 (21.7)[f]	7 (50)
Indication for induction, n (%)	57 (100)	66 (100)	115 (100)	50 (100)
Medical/obstetrical	44 (77.2)	45 (68.2)	91 (79.1)	31 (62.0)
Post-dates	13 (22.80)	21 (31.8)	24 (20.9)	19 (38.0)
Other	-	-	-	-
Bishop Score[i], mean (± SD), points	4.18 (± 1.770)[d]	3.26 (± 1.572)	4.40 (± 2.262)[g]	3.16 (± 1.405)[c]
Gestational age at delivery, mean (± SD), wks + days	40 + 6 (± 1 + 4)	40 + 6 (± 1 + 3)	40 + 5 (± 1 + 2)	40 + 4 (± 1 + 4)
Birthweight, mean (± SD), g	3,706 (± 528)[h]	3,697 (± 526)	3,619 (± 532)	3,556 (± 485)
Epidural, n (%)	44 (77.2)	32 (48.5)	90 (78.3)	20 (40)
Post-partum haemorrhage n (%)				
500-1,000 ml	10 (17.5)	9 (13.6)	16 (13.9)	8 (16.0)
> 1,000 ml	4 (7.0)	7 (10.6)	14 (12.2)	2 (4.0)
Time from induction to delivery, mean (± SD), min.	3,107.89 (± 1,363.10)	1,420.27 (± 824.65)	2,925.39 (± 1,584.18)	1,683.22 (± 1,128.13)
≤ 24 h, n (%)	8 (14)	39 (59.1)	15 (13)	27 (54)
> 24 h, n (%)	49 (86)	27 (40.9)	100 (87)	23 (46)
≤ 48 h, n (%)	22 (38.6)	61 (92.4)	67 (58.3)	43 (86)
> 48 h, n (%)	35 (61.4)	5 (7.6)	48 (41.7)	7 (14)

GDM = gestational diabetes mellitus; SD = standard deviation.
a) Data on n = 44.
b) Data on n = 106.
c) Data on n = 49.
d) Data on n = 56.
e) Including 5 with GDM + other diagnosis.
f) Including 3 with GDM + other diagnosis.
g) Data on n = 113.
h) Data on n = 25.
i) ≤ 5 points: not prepared for labour; 6-7 points: induction may or may not be successful; ≥ 8: labour is likely to begin soon.

One department (Næstved) used 25 µg oral tablets of misoprostol every two hours with a maximum of eight administrations per day. Treatment was discontinued when the woman was in active labour or after two days. Women were examined in the out-patient clinic prior to induction, and as a minimum daily.

The other department (Holbæk) used a 200 µg slow-release vaginal misoprostol insert. The vaginal insert was removable and released misoprostol at a controlled rate for up to 24 hours. The treatment was discontinued when the woman was in active labour, after 24 hours or if tachysystole occurred in combination with cardiotocography (CTG) changes. Membranes were ruptured artificially without delay when the cervical conditions were found to be favourable based on the midwife's assessment.

The women induced with oral misoprostol were offered an out-patient setting unless a medical indication existed for admitting the woman to the obstetric department. They were told to contact the hospital when regular contractions started or if they had any other symptoms or questions. The women who were induced with vaginal misoprostol slow-release insert were hospitalised from the beginning of induction.

All participating women completed a questionnaire after delivery. Women who did not complete the questionnaire before leaving the hospital were contacted by telephone a total of three times within the following few months and invited to participate.

The main outcomes were the women's experiences and satisfaction with the method used for induction. Secondary outcomes included pain perception and experienced length of hospital stay.

The questionnaire was based on items in the Wijma Delivery Expectancy/Experience Questionnaire, which was previously validated [5, 6]. We elaborated 17 questions regarding the woman's moods and experiences of labour induction with most answers being provided on a scale ranging from one to five. The women were also asked about their overall satisfaction with labour induction and asked to provide some additional background data (Supplementary material https://ugeskriftet.dk/files/a04220232_-_supplementary.pdf). All questionnaires were anonymous and all women provided written or oral informed consent for collection of data for this study [2].

The study was conducted in accordance with the guidelines of the Declaration of Helsinki and approved by the Regional Ethics Committee (no. 50213), the Regional Medicines Agency and the Danish Data Protection Agency (REG-81-2015) on September 25; 2015.

The statistical analyses were performed with SPSS Statistics. Normally distributed continuous data were reported as mean (± standard deviation). Percentage calculation was based on the number of available observations. For the analysis of the questions, we combined the answers; "strongly agree" and "agree", "disagree agree" and "strongly disagree", as well as "very satisfied/very good" and "satisfied/good" and "dissatisfied/bad" and "very dissatisfied/very bad". We used an independent-samples T-test comparison of parametric continuous variables and Pearson's χ^2 test was used for categorical data.

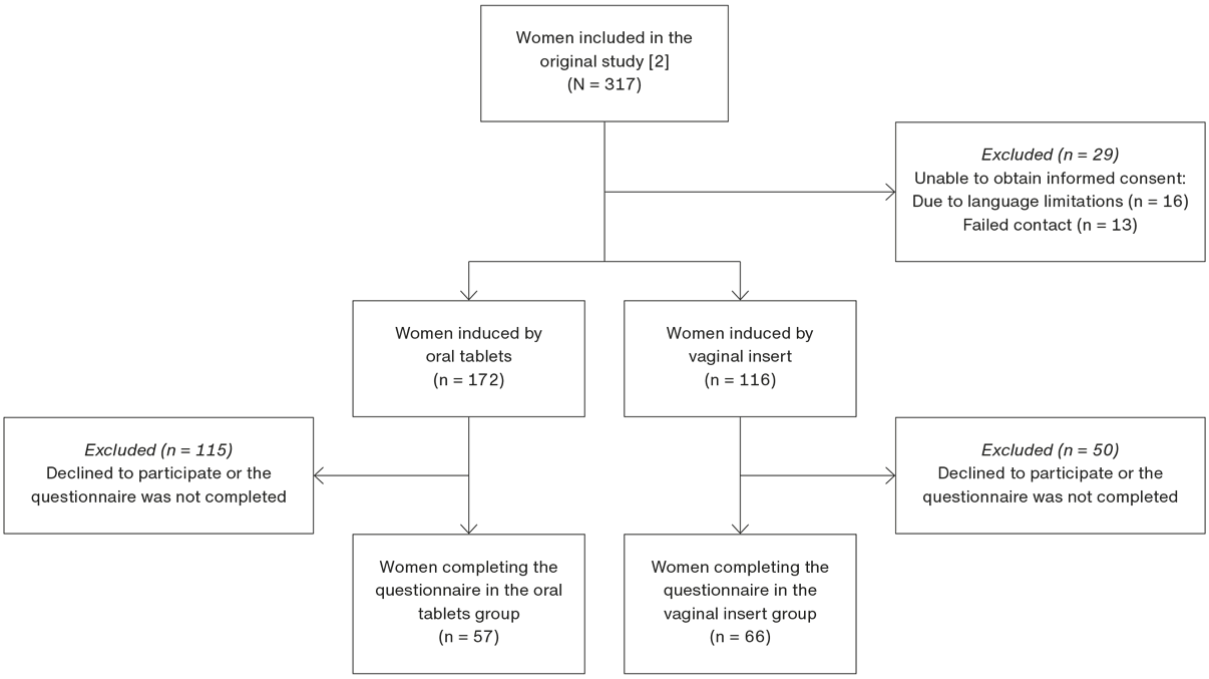
We planned to include 420 women [2], but the sample size was not reached due to a smaller number of eligible women than expected during the data collection period. The period could not be expanded since the permission for one of the medications expired and a major change in electronic patient records was introduced at the hospitals.

Trial registration: The study was registered at clinicaltrials.gov ID: NCT02693587 on February 26; 2016 and on EudraCT number 2020–000366-42 on January 23; 2020 (retrospectively) registered.

RESULTS

A total of 288 women in the cohort were eligible for the study and 123 completed the questionnaire, of whom 57 were allocated to oral misoprostol and 66 to slow-release vaginal insert (**Figure 1**). Baseline demographics of responders in the oral misoprostol and slow-release vaginal misoprostol groups differed on several parameters, including GDM, BMI, Bishop Score and use of epidural anaesthesia. More women induced with slow-release vaginal insert delivered within 24 hours. A total of 61.4% of women induced with oral misoprostol spent more than 48 hours from induction to labour compared with 7.6% of the slow-release vaginal insert group (Table 1).

FIGURE 1 Flow chart of the women in the study.



Clinical characteristics between responders and non-responders of the questionnaire were similar, except for the distribution of GDM and the time from induction to delivery, with more women with GDM being found in the non-responder group induced by oral misoprostol (Table 1). Furthermore, time from induction to delivery differed between the responder and non-responder group with more women in the responder group delivering within 24 hours. During the study period, women with GDM were referred to one department (Næstved) only. Characteristics of the two groups excluding women with GDM are presented in **Table 2**.

TABLE 2 Characteristics of questionnaire responders and non-responders, excluding women with gestational diabetes.

Characteristic	Responders	Non-responders
Method of induction		
Oral excluding GDM, n	55	88
Maternal age, mean (± SD), yrs	28 (± 5)	27 (± 5)
BMI, mean (± SD), kg/m²	30.7 (± 8.4)	28.6 (± 7.4)
Caesarean section, n (%)	15 (27.3)	26 (29.5)
Maternal educational level, n (%)		-
< 10 yrs	6 (10.9)	
10-15 yrs	25 (45.5)	
> 15 yrs	23 (41.8)[a]	
Cigarette use, n (%)	6 (10.9)	14 (15.9)
Pre-existing medical conditions, n (%)	7 (12.7)	12 (13.6)
Pre-existing psychiatric conditions, n (%)	3 (5.9)[b]	9 (10.8)[c]
Pregnancy-related medical conditions, n (%)	20 (36.4)	42 (47.7)
Pre-eclampsia	6 (30)	16 (38.1)
Hypertension	2 (10)	7 (16.7)
Intrahepatic cholestasis	1 (5)	4 (9.5)
Others	11 (55)	15 (35.7)
Indication for induction, n (%)	55	88
Medical/obstetrical	42 (76.4)	65 (73.9)
Post-dates	13 (23.6)	23 (26.1)
Bishop Score[h], mean (± SD), points	4.1 (± 1.8)[d]	4.5 (± 2.3)[e]
Gestational age at delivery, mean (± SD), wks + days	41 + 0 (± 1 + 3)	40 + 6 (± 1 + 3)
Birthweight, mean (± SD), g	3,720 (± 534.5)[f]	3,580 (± 541.3)[g]
Post-partum haemorrhage, n (%)		
500-1,000 ml	10 (18.2)	11 (12.5)
> 1,000 ml	4 (7.3)	8 (9.1)
Time from induction to delivery, n (%)		
≤ 24 h	7 (12.7)	14 (15.9)
> 24 h	48 (87.3)	74 (84.1)
≤ 48 h	21 (38.2)	56 (63.6)
> 48 h	34 (61.8)	32 (36.4)

GDM = gestational diabetes mellitus; SD = standard deviation.
a) Data on n = 54.
b) Data on n = 51.
c) Data on n = 83.
d) Data on n = 54.
e) Data on n = 86.
f) Data on n = 24.
g) Data on n = 45.
h) ≤ 5 points: not prepared for labour; 6-7 points: induction may or may not be successful; ≥ 8: labour is likely to begin soon.

In the comparison of the oral misoprostol group and slow-release vaginal insert group, we found no significant differences regarding the women's emotions during induction, overall evaluation of the induction of labour or feelings about the labour being induced (**Table 3**).

TABLE 3 The women's experience with labour induction.

Question Answer	Oral misoprostol, n (%) (N_r = 57)	Vaginal misoprostol, n (%) (N_t = 66)	p value
How did you experience the length of your hospital stay during induction?			0.028
Acceptable	2 (3.5)	5 (7.6)	
Too short	36 (63.2)	52 (78.8)	
Too long	19 (33.3)	9 (13.6)	
How did you experience the number of midwife examinations during induction and labour?			0.165
Acceptable	1[a] (1.8)	3 (4.5)	
Too few	50 (89.3)	51 (77.3)	
Too many	5 (8.9)	12 (18.2)	
"I felt I could handle the pain during induction"			0.019
Agree	5 (8.8)	19 (28.8)	
Neither nor	12 (21.1)	12 (18.2)	
Disagree	40 (70.2)	35 (53)	
"I felt helpless during induction"			
Agree	31 (54.4)	39 (59.1)	
Neither nor	18 (31.6)	12 (18.2)	
Disagree	8 (14.0)	15 (22.7)	
"I felt positive during induction"			0.226
Agree	10 (17.5)	20 (30.3)	
Neither nor	13 (22.8)	15 (22.7)	
Disagree	34 (59.6)	31 (47.0)	
"I felt I would never come out of it"			0.386
Agree	32 (56.1)	29 (43.9)	
Neither nor	9 (15.8)	12 (18.2)	
Disagree	16 (28.1)	25 (37.9)	
"I felt I could handle it during induction"			0.554
Agree	11 (19.3)	17 (25.8)	
Neither nor	13 (22.8)	17 (25.8)	
Disagree	33 (57.9)	32 (48.5)	
"I felt I no longer wanted to participate during induction"			0.335
Agree	35 (61.4)	35 (53.0)	
Neither nor	9 (15.8)	8 (12.1)	
Disagree	13 (22.8)	23 (34.8)	
"I felt happy during induction"			0.219
Agree	8 (14.0)	17 (25.)	
Neither nor	13 (22.8)	16 (24.2)	
Disagree	36 (63.2)	33 (50.0)	
"I felt like giving up during induction"			0.889
Agree	31 (54.4)	38 (57.6)	
Neither nor	10 (17.5)	12 (18.2)	
Disagree	16 (28.1)	16 (24.2)	
"I felt induction took a really long time"			0.213
Agree	15 (26.3)	27 (40.9)	
Neither nor	8 (14.0)	9 (13.6)	
Disagree	34 (59.6)	30 (45.5)	
"I felt calm during induction"			0.593
Agree	12 (21.1)	16 (24.2)	
Neither nor	20 (35.1)	27 (40.9)	
Disagree	25 (43.9)	23 (34.8)	
Compared with other women giving birth, how did you experience your labour induction process?			0.810
Good	33 (57.9)	36 (54.5)	
Average	16 (28.1)	22 (33.3)	
Bad	8 (14.0)	8 (12.1)	
How do you evaluate your labour induction?			0.498
Easier	39[a] (69.6)	40 (60.6)	
Average	7 (12.5)	13 (19.7)	
Harder	10 (17.9)	13 (19.7)	

To be continued >

TABLE 3 (continued) The women's experience with labour induction.

Question Answer	Oral misoprostol, n (%) (N_r = 57)	Vaginal misoprostol, n (%) (N_t = 66)	p value
Did you feel safe during induction?			0.645
Safe	50 (87.7)	56 (84.8)	
Unsafe	7 (12.3)	10 (15.2)	
How was your overall experience of giving birth?			0.039
Good	50 (87.7)	48 (72.7)	
Bad	7 (12.3)	18 (27.3)	
How did you experience your pregnancy?			0.720
Good	47 (82.5)	56 (84.8)	
Bad	10 (17.5)	10 (15.2)	
How satisfied are you that your labour was induced?			0.550
Satisfied	47 (82.5)	57 (86.4)	
Unsatisfied	10 (17.5)	9 (13.6)	

a) Data on n = 56.

We found a non-significant trend towards women being induced with slow-release vaginal insert more often reporting dissatisfaction with the duration of induction of labour with 40.9% versus 26.3% of the dissatisfied women being induced with oral misoprostol.

Significantly more women induced with oral misoprostol reported time spent at the hospital during induction and labour as "not acceptable" or "too long". Also, they more often reported that they could not handle the pain during induction of labour (Table 3).

Although time from induction to birth was experienced as longer and more painful by women who were induced with oral misoprostol, the overall experience of giving birth after induction was significantly more positive in this group than among women induced with slow-release vaginal insert (Table 3).

DISCUSSION

Comparing the overall experience of birth in two departments which differed in several respects, we found that that the overall birth experience was more positive in the department in which oral misoprostol was used for induction than in the department where slow-release vaginal insert was used.

To our knowledge, this is the first study comparing women's experiences with induction of labour with oral misoprostol or slow-release misoprostol vaginal insert. The present study is not without limitations. When we initiated this study, no validated questionnaires existed on women's experiences of induction of labour.

The Wijma Delivery Expectancy/Experience Questionnaire is the most frequently used instrument for measurement of expectations and fear of childbirth. We designed the questionnaire for the present study based on the themes raised by Wijma et al. [5]. However, it is a limitation that the adapted questionnaire was not validated.

Another limitation is that the women were asked about their experience of the whole procedure after giving birth, and not specifically about their experience with induction. The questionnaire did not include questions on preferences of induction of labour in future pregnancies – nor questions on expectations, worries about the baby or the availability and quality of care received before and during labour, which previous reports have shown are relevant domains for women's overall labour experience [7, 8].

A recent review concluded that women's experiences with induced labour may likely be improved by adopting a communicative and patient-centred approach [4].

This study was also subject to methodological limitations as it was neither randomised nor blinded and because it was set in two different hospitals. During the study period, all women with GDM were referred to one of the departments. Apart from GDM several differences characterised the two populations of responders, including BMI and pregnancy-related medical conditions. No adjusted estimates were calculated.

Unfortunately, the desired number of women included in this study was not reached due to logistical challenges resulting in a weaker statistical power than foreseen.

Another limitation was the difference in in- versus out-patient regimen for induction, where the women's experience may reflect their opportunity to leave the hospital more than the method as such. Knowledge of women's preferences in this aspect is limited [9]. Use of oral misoprostol in an outpatient setting may potentially be more comparable to spontaneous initiation of labour where women usually spend the time during the latent phase outside hospital. However, it is also possible that some women may be more anxious in the outpatient setting because of the uncertainties surrounding induction of labour and practicalities.

One final limitation is the response rate achieved in the two groups. More women in the slow-release vaginal insert group (53%) than in the oral group (46%) participated. Although no difference in demographic characteristics between responders and non-responders was found except for faster deliveries (within 24 hours) in the responding group, the difference in response rate of the groups may result in a potential risk of biased results. One obvious reason herefore may be that these women were not informed about the study prior to induction; and when they received the questionnaire immediately after delivery, they were more likely to forget or opt out of completing the questionnaire as they had just become mothers.

Previous studies investigating women's experiences with induction achieved a response rate of 55.1% [10] and 70% [11]; the latter study informed orally and in writing about the study at least one day before admission.

In the present study, we found that time from induction to delivery had no impact on women's birth experience or their experience with induction of labour when comparing women delivering within 24 hours with women with more than 48 hours after induction.

It seems plausible that the risk of secondary interventions increases with the time interval between initiation of induction and delivery, thereby creating more contact moments with the attending midwife, leading to a higher satisfaction with the induction.

The relative risk of hyperstimulation increased with the use of slow-release vaginal insert, as demonstrated in our recent study and reported in other studies [2, 12, 13]. Hyperstimulation may possibly affect the lalbour experience, which supports our finding that the vaginal insert group had a more negative experience of labour.

A clinical trial on oral versus vaginal misoprostol found no difference in the average interval from the first dose of misoprostol to delivery. Even so, 14% of the women in the vaginal group versus 7.5% in the oral group were dissatisfied with the use of misoprostol [14].

Other studies found no difference in labour experience or time from induction to delivery between vaginal and oral misoprostol [15].

Research on women's experiences with a fast versus a slow delivery is sparse. Neither a fast nor a slow delivery seems to make a difference to the experience of giving birth; nor does it seem to be important for the women's overall experience of labour and satisfaction with the procedure. Induced women might be less satisfied in general because the experience of the time of induction is not in line with the women's expectations. Experiences differ among pregnant women. What is important for one woman may be less important for another. Clinical factors such as gestational age, BMI, parity, indication for induction and ripening of the cervix

may be factors to consider when designing individual induction regimens.

CONCLUSION

In two departments, which were different in several respects, including whether vaginal or oral misoprostol was used, the experience with induction of labour in nulliparous women using oral misoprostol or vaginal inserts was comparable. Even though no adjusted estimates were calculated, we found that the labour experience was overall better among women induced with oral misoprostol in an out-patient setting. The duration from induction of labour to delivery does not seem important to birth experience.

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