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A randomised trial of two expectant managements of prelabour rupture of the membranes at 34 to 42 weeks

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Objective To compare obstetric and perinatal outcome between two different expectant managements in women with prelabour rupture of the membranes (PROM).

Design A randomised study.

Participants One thousand three hundred and eighty-five women with rupture of the membranes at 34 to 42 weeks without contractions.

Interventions Women without contractions 2 h after admission were randomised to early induction the following morning after PROM (early induction group) or induction two days later (late induction group). Women with contractions starting within 2 h after admission were included in the calculations as a short latency group. Digital examinations of the cervix were avoided until onset of active labour. Labour was induced with oxytocin in both groups if no spontaneous contractions occurred or if chorioamnionitis or fetal distress was detected.

Main outcome measures The frequency of spontaneous deliveries, operative deliveries, maternal and neonatal infections.

Results In nulliparous women, a higher rate of spontaneous deliveries was found in the late induction group (89%) compared with the early induction group (81%) ($P < 0.05$). The ventouse extraction rate was 7% and 14% respectively ($P < 0.05$). A low (2–4%) caesarean section rate was recorded and did not differ between the groups. Endometritis was detected in six women after delivery. Sixty-one children were treated with antibiotics, and no difference could be detected between the groups.

Conclusions A higher rate of spontaneous deliveries was found among nulliparous women with prolonged latency as compared with brief latency prior to induction. A protocol of no digital examination before labour was associated with infrequent maternal and fetal morbidity, regardless of latency.

INTRODUCTION

Prelabour rupture of the membranes (PROM) at term occurs in 5% to 10% of all pregnancies. Studies in the period 1960 to 1980 showed an increased risk of maternal and perinatal mortality when the time interval from rupture of the membranes until delivery was prolonged[1–3]. This fact was the main reason why a policy of immediate induction of labour after PROM was adopted. Other studies showed that expectant management resulted in a lower rate of caesarean sections without an increased risk of maternal or neonatal infections[4]. However, these studies were not prospectively and randomly designed and many of them included both preterm and term patients.

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Nine prospectively randomised trials have assessed the effects of early oxytocin stimulation on uterine contractions compared with expectant management for induction of labour in patients with PROM[5–13]. Quasi-randomisation was used in four of the studies[5–7,10] and a quasi-randomised study is in fact not random. Tamsen *et al.*[11] did not report their method of randomisation. Rydhström *et al.*[12] included 277 patients and their study showed a slightly increased rate of neonatal infections in the group that was conservatively managed. However, a digital examination was performed at admission to evaluate cervical dilatation, which might have influenced the outcome. In a carefully conducted study Grant *et al.*[13] demonstrated benefits for nulliparous women to await spontaneous contractions until the next morning compared with immediate induction. At

present, different opinions exist regarding the optimal latency period from PROM until induction.

The aim of this study was to evaluate risks and benefits for nulliparous and parous women with expectant periods up to 24 h and 72 h. The hypothesis tested was that there should be a higher frequency of spontaneous deliveries in the late induction group compared with the early induction group for nulliparous women. We expected to find differences in frequency of operative deliveries between nulliparous and parous women.

METHODS

Women with PROM between 34 and 42 gestational weeks were considered eligible for the study provided the following inclusion criteria were fulfilled:

1. Estimated gestational age 34 or more weeks based on an ultrasound examination before 20 weeks of gestation;
2. Normal pregnancy;
3. Singleton with the fetus in cephalic presentation;
4. Rupture of the membranes confirmed by a sterile speculum examination (no other tests for rupture of the membranes were used); and
5. A normal fetal heart rate (FHR) trace using an external ultrasound transducer.

The patient was not included in the study if there were any reasons for an immediate induction, e.g. patients with severe pre-eclampsia, bleeding, antibiotic therapy for Group B streptococcal colonisation, suspicion of intrauterine growth retardation (estimated fetal weight on ultrasound more than 25% below the normal weight) or chorio-amnionitis (maternal temperatures were $\geqslant 38$ °C on two occasions 1 h apart without evidence of any other sources of fever). A written informed consent was obtained from each patient and the study was approved by the Medical Ethics Committee, University of Göteborg.

Digital examinations were not allowed before the contractions started or labour was induced. Patients without contractions during the first 2 h after the speculum examination were randomly allocated either to induction within 24 h (early induction group) or to induction within 72 h (late induction group). The list of random numbers was generated by a computer. A sealed, opaque and sequentially numbered envelope containing the randomisation code was used for each patient. Women with contractions within 2 h after the speculum examination were also included in the calculations as a short latency group. For study purposes rupture of the membranes was said to occur when amniotic fluid was confirmed by a sterile speculum examination.

In the early induction group, the patients were observed in the antenatal ward awaiting contractions for up to 24 h. Body temperature was measured twice a day. A strict protocol was followed. Women in the early induction group were induced 2 h to 24 h after randomisation. If rupture of the membranes was diagnosed between midnight and 6:00 a.m. and no contractions had occurred by 8:00 a.m. the same day, induction was started with oxytocin. If rupture of the membranes was diagnosed between 6:00 a.m. and midnight and contractions were absent at 8:00 a.m. the next day, oxytocin was administered to induce labour. Five units of oxytocin were administered in 500 ml sodium chloride, and the *initial* dose of oxytocin was 2·5 i.u./min. The infusion rate was raised with 2·5 i.u./min every 30 min until satisfactory contractions occurred.

Women in the late induction group were observed at the antenatal ward awaiting contractions for up to 72 h. Women in the late induction group were induced 50 h to 72 h after randomisation. If rupture of the membranes was diagnosed between midnight and 6:00 a.m. and no contractions had occurred at 8:00 a.m. two days later, oxytocin was administered. On the other hand, if rupture of the membranes was diagnosed between 6:00 a.m. and midnight and no contractions were present by 8:00 a.m. three days later, such a patient received oxytocin at that time.

During the expectancy, a FHR trace and an analysis of C-reactive protein were performed each day. Body temperature was measured twice a day. In cases of an abnormal FHR, labour was induced. If chorioamnionitis was detected, the patient received antibiotics (Cefuroxim 1·5 g three times a day) and an oxytocin infusion was started. Chorioamnionitis was considered to be present if body temperatures were 38 °C or more on two occasions 1 h apart without evidence of any other sources of fever or if the C-reactive protein was elevated over 40 mg/l. All fetuses had a fetal scalp electrode adapted but no intrauterine pressure catheters were used. All women with spontaneous contractions starting within two hours after the sterile speculum examination were managed in the same way as the randomised groups.

The newborns were observed as other newborns (i.e. a paediatrician examined the infant on the day after delivery unaware of the woman's participation in the study). However, the paediatrician had the opportunity to get information from the

obstetrical record. No special protocol was used for diagnosing neonatal infections. It was thought that the use of such a protocol might lead to overdiagnosing of clinically unimportant conditions. The main parameters analysed and tested for differences between the groups were: frequency of spontaneous deliveries, operative deliveries, maternal and neonatal infections and Apgar score.

Analysis of variance was used to compare differences between the groups by Duncan's multiple range test or Tukey's studentised range test HSD. Proportions were compared by Fisher's exact test and adjustments (multiplication by three) of the *P*-values due to multiple comparisons were performed by Bonferroni's method. A *P*-value of less than 0·05, when appropriate adjusted by Bonferronis method, was considered statistically significant. SAS statistical software was used for analysis. Since the frequency of operative deliveries for women with PROM was unknown in our population, an independent consultant statistician performed an interim analysis of nulliparous women after 18 months. The frequency of operative deliveries was 19·6% in the early induction group and 11·5% in the late induction group. The sample size required to show a statistically significant difference in the operative delivery rate between nulliparous women in the groups with $\alpha = 0{\cdot}05$ and $\beta = 0{\cdot}20$ was 315 patients in each group.

RESULTS

Among the 27,502 deliveries from March 1989 to March 1993 a total of 1580 were eligible for the study and 1385 entered the trial. In total, 195 patients did not want to participate (i.e. 12% of all the eligible patients). After entering the trial, 502 were allocated to the early induction group and 510 to the late induction group, while 373 women had spontaneous contractions within 2 h after the speculum examination (short latency group). No differences regarding maternal age, gestational age, parity or birthweight were found, while, as expected, the time interval from PROM to onset of labour differed ($P < 0{\cdot}001$) between the three groups (Table 1). The women in the two randomised groups were distributed within the different gestational weeks according to Fig. 1. The women in the short latency group and late induction group who had the opportunity to await spontaneous contractions provided information about the time interval from rupture of the membranes to spontaneous labour. Twenty-six hours after PROM 80% had spontaneous contractions and after fifty hours 10% of the women were still awaiting contractions. The frequency of spontaneous deliveries differed between nulliparous and parous women ($P < 0{\cdot}001$) and for that reason they are presented separately.

Obstetrical outcome in nulliparous women

In the early induction group 38% of the women were induced because no contractions occurred during the latency period compared to 11% of the women in the late induction group ($P < 0{\cdot}001$). Two patients in the late induction group obtained oxytocin infusion because of chorioamnionitis and one woman due to an abnormal FHR trace. No difference was found in the duration of labour from established contractions until delivery between the three groups (Table 2). The use of oxytocin differed between the groups (Table 2). The rate of spontaneous deliveries was 89% in the late induction group compared with 81% in the early induction group ($P < 0{\cdot}05$). Ventouse extraction was more often used in the early induction group compared with the late induction group, 14% and 7%, respectively ($P < 0{\cdot}05$). In total 18 (6%) women in the early induction group were delivered by ventouse due to an abnormal fetal heart rate trace compared to 6 (2%) in the late induction group ($P < 0{\cdot}05$). Insufficient contrac-

Table 1. Characteristics of women with prelabour rupture of the membranes in the study. Results are mean (SD) or *n* [%] where appropriate. GA = gestational age; OL = onset of labour.

Outcomes	Early induction group ($n = 502$)	Late induction group ($n = 510$)	Short latency group ($n = 373$)
Maternal age (years)	28·1 (5·0)	27·6 (4·7)	27·8 (4·8)
GA (weeks)	38·9 (1·6)	38·8 (1·6)	39·1 (1·5)
GA 34–36 (weeks)	49 [10]	38 [8]	25 [7]
Birthweight (g)	3447 (490·9)	3444 (502·4)	3519 (477·5)
Nulliparous	317 [63]	323 [63]	229 [61]
Time PROM–OL (h)*	9·9 (7·1)	19·9 (20·1)	1·3 (0·7)
Spontaneous contractions*	310 [62]	454 [89]	373 [100]

* $P < 0{\cdot}001$ after correction by Bonferroni's method when appropriate.

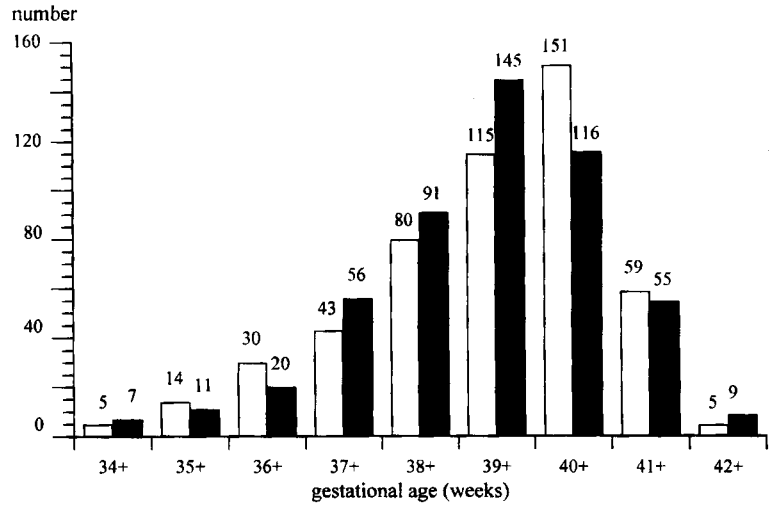

Fig. 1. Gestational age distribution among the participants in the study. □ = early induction group; ■ = late induction group.

Table 2. Outcome of the trial for nulliparous women in gestational weeks 34–42. Results are mean (SD) or *n* [%] where appropriate.

Outcomes	A Early induction group ($n = 317$)	B Late induction group ($n = 323$)	C Short latency group ($n = 229$)	Significance	Odds ratio (95% CI) A *vs* B
Established contractions to delivery (h)	8·0 (4·5)	8·4 (4·6)	7·9 (4·7)		
Oxytocin	240 [76]	216 [67]	126 [55]	A–B* A–C*** B–C*	1·54 (1·09–2·18)
Bishop score at onset of labour	6·2 (2·3)	7·0 (2·0)	6·4 (2·0)	A–B*** B–C**	
Spontaneous delivery	258 [81]	286 [89]	203 [89]	A–B*	0·57 (0·36–0·88)
Ventouse extraction	45 [14]	23 [7]	21 [9]	A–B*	2·16 (1·27–3·66)
Caesarean section	14 [4]	14 [4]	5 [2]		1·02 (0·48–2·18)

* $P < 0·05$; ** $P < 0·01$; *** $P < 0·001$ after correction by Bonferroni's method when appropriate.

Table 3. Analgesia used: nulliparous women. Results are *n* [%]. Key as for Table 2.

Outcomes	A	B	C	Significance	Odds ratio (95% CI) A *vs* B
Pethidine	9 [3]	16 [5]	19 [9]	A *vs* C*	0·56 (0·24–1·29)
Paracervical block	37 [12]	43 [13]	18 [8]		0·86 (0·54–1·38)
Epidural analgesia	69 [22]	61 [19]	45 [20]		1·20 (0·81–1·76)
None of above	210 [66]	212 [66]	157 [69]		1·03 (0·74–1·43)

* $P < 0·05$ after correction by Bonferronis method when appropriate.

tions in the second stage were the reasons for ventouse in 25 (8%) women in the early induction group compared with 16 (5%) women in the late induction group ($P > 0·05$). Two ventouses were performed in the early induction group and one in the late induction group, because of exhausted mothers. No differences in the caesarean section rates could be demonstrated between the two groups. The usage of analgesia was similar in both the early and late induction groups (Table 3). A group of special interest was that of the nulliparous women ($n = 32$) in the late induction group, in which spontaneous contractions did not occur before the time limit ran out. These women were induced and, when compared with nulliparous with spontaneous contractions in the late induction group, no differences in the mode of delivery could be detected. When the obstetrical outcome for nulliparous was analysed in relation to the Bishop Score at the start of delivery, only small differences

Table 4. Outcome of the trial for parous women on gestational weeks 34–42. Results are mean (SD) or *n* [%] where appropriate. OL = onset of labour.

Outcomes	D Early induction group ($n = 185$)	E Late induction group ($n = 187$)	F Short latency group ($n = 144$)	Significance	Odds ratio (95% CI) D *vs* E
Established contractions to delivery (h)	4·3 (2·7)	4·7 (3·3)	4·0 (2·9)	E–F*	
Oxytocin	109 [59]	70 [37]	34 [24]	D–E*** D–F*** E–F*	2·40 (1·58–3·64)
Bishop score at OL	6·6 (2·1)	7·2 (2·0)	6·9 (1·9)	D–E**	
Spontaneous delivery	176 [95]	179 [96]	138 [96]		0·87 (0·33–2·31)
Ventouse extraction	4 [2·2]	6 [3·2]	4 [2·8]		0·67 (0·19–2·40)
Caesarean section	5 [2·7]	2 [1·1]	2 [1·4]		2·57 (0·49–13·41)

* $P < 0·05$; ** $P < 0·01$; *** $P < 0·001$ after correction by Bonferroni's method when appropriate.

Table 5. Analgesia used: parous women. Results are *n* [%]. Key as for Table 4.

Outcomes	D	E	F	Significance	Odds ratio (95% CI) D *vs* E
Pethidine	3 [2]	4 [2]	0 [0]		0·75 (0·17–3·42)
Paracervical block	18 [10]	14 [8]	8 [6]		1·33 (0·64–2·76)
Epidural analgesia	14 [8]	16 [9]	3 [2]	E–F*	0·87 (0·41–1·85)
None of above	152 [82]	155 [83]	133 [92]	D–F*; E–F*	0·95 (0·56–1·62)

* $P < 0·05$ after correction by Bonferroni's method when appropriate.

could be detected between women with different scores. However, women with a Bishop Score of 1 or 2 ($n = 47$) had a caesarean section rate of 15% compared to all the other groups where the CS rate was 2–4% ($P < 0·01$).

Obstetrical outcome in parous women

The delivery started with spontaneous contractions in 61% of the women in the early induction group compared with 89% in the late induction group. In the early induction group in all 72 women were induced because no spontaneous contractions occurred during the latency period. Twenty-one women in the late induction group were induced, including one because of chorioamnionitis and one due to an abnormal FHR. In the short latency group a shorter period between established contractions and delivery compared with the late induction group was recorded (Table 4). No such differences were found between the early and the late induction groups. Spontaneous vaginal deliveries were achieved in 95% to 96% of the women (Table 4). One woman in the early induction group, three in the late induction group and none in the short latency group had a ventouse performed due to fetal distress. A delayed second stage was the reason for a ventouse in three women in the early induction group, two in the late induction group and four in the short latency group. One ventouse extraction was performed because of an exhausted mother in the late induction group. When the obstetrical outcome for parous women was analysed in relation to the Bishop score at the start of delivery, no differences could be detected. No differences between the early and the late induction groups regarding the use of analgesia were recorded (Table 5).

Maternal infections

Chorioamnionitis was diagnosed before labour in three patients in the late induction group. The diagnoses were made at 45 h, 46 h and 47 h after rupture of the membranes. All of them had an elevation in body temperature but no rise in CRP. Antibiotic therapy was given and the patients were induced by oxytocin administration. Chorioamnionitis during labour was diagnosed in two women in the early induction group, in four in the late induction group and in two in the short latency group. Two women in the early induction group and four in the late induction group developed an endometritis during the puerperal period. Four women in the early induction group, nine in the late induction group and two in the short latency group experienced chorioamnionitis and/or endometritis. The infectious morbidity

Table 6. Neonatal outcome. Results are mean (SD) or *n* [%] where appropriate. SCBU = Special care baby unit.

	G	H	I		
Outcomes	Early induction group ($n = 502$)	Late induction group ($n = 510$)	Short latency group ($n = 373$)	Significance	Odds ratio (95% CI) G *vs* H
Apgar score at 5 min < 7	6 [1·2]	6 [1·2]	1 [0·3]		1·01 (0·33–3·17)
Admission to SCBU	73 [15]	59 [12]	33 [9]	G–I*	1·29 (0·89–1·86)
Days at SCBU	4·4 (4·0)	5·1 (4·5)	5·5 (7·3)		
Antibiotics	24 [4·8]	23 [4·5]	14 [3·8]		1·06 (0·59–1·90)
Perinatal mortality	1†	0	0		

* $P < 0·05$ after correction by Bonferroni's method when appropriate.
† Lethal malformation.

was low in all groups and there was no statistically significant difference between the groups.

Neonatal outcome

No difference was detected in the number of children admitted to the special care baby unit (SCBU) between the early and the late induction groups (Table 6). There was only one perinatal death reported in the study population and the reason was a lethal malformation. A significant difference regarding SCBU admittance was detected among children born in gestational weeks 34 to 36 compared with weeks 37 to 42. The younger newborns were more often admitted to SCBU, 34% compared with 10% ($P < 0·001$), and the medium length of stay at SCBU also differed significantly, 7·4 days compared with 4·1 days. There were no differences in SCBU admission between the early induction group, the late induction group and the short latency group in the subgroup of babies born in gestational weeks 34 to 36.

DISCUSSION

A significantly higher proportion of nulliparous women delivered spontaneously if they were allowed to await contractions for up to 72 h compared with 24 h in the present study. The rate of ventouse extractions was higher in the early induction group but there were no differences in the caesarean section rate. The higher rate of ventouses in nulliparous women in the early induction group may be due to the lower Bishop score at the start of the delivery. They also required oxytocin more often, which could be one of the reasons for the higher frequency of ventouse for fetal distress in these women. The caesarean section rate differed between nulliparous and parous women with PROM and similar findings were reported in a study by Rydhström *et al.*[14]. In nulliparous women, Grant *et al.*[13] administered oxytocin immediately after PROM to one group and another group, conservatively managed, had to wait for spontaneous contractions until the next morning. Benefit in terms of a higher rate of spontaneous deliveries ($P = 0·02$) was found with the conservative policy. Grant *et al.*[13] raised the question of whether an expectancy period longer than 24 h could give additional benefits.

This trial showed benefits for the nulliparous women in terms of a higher frequency of spontaneous deliveries also when the latency period was extended up to 72 h. It is probable that some nulliparous women will consider it important to wait for spontaneous contractions and they should be informed that their chance to avoid an operative delivery will increase if the latency period is extended. These results imply that nulliparous women could be given the possibility to decide for themselves what policy to be used. The frequency of spontaneous deliveries did not differ among parous women independent of the length of the expectancy period. These findings indicate that nulliparous and parous women should be managed differently. For practical purposes, parous women can be induced the next morning after PROM without obvious drawbacks. Such a management may also have implications in terms of health economy.

The overall operative delivery rate was low in the present trial compared to others. In a study by Natale *et al.*[8], a caesarean section rate of 12·6% to 13·8% was found in a population of nulliparous and parous women. Grant *et al.*[13] reported caesarean section rates of 11·1% and 17·4% in their two groups and a forceps rate of 26·2% and 28·6%, respectively. Compared with the rate reported in this trial, their figures of operative deliveries were high. It is not easy to explain the substantial differences in the rates of operative deliveries between institutions. A number of different reasons, such as management of labour, organisation of the delivery wards, variable populations and perhaps also legislation could

be explanatory factors. Additional comparative studies are needed since it is obvious that the time of expectancy is not the only factor affecting the frequency of operative deliveries.

One of the most important questions in the management of PROM is whether a digital examination should be performed at admission or not. In our study, digital examinations were strictly avoided until the onset of labour. One of the reasons for including a vaginal examination before labour is to exclude a prolapsed cord. However, it is unlikely that such an obstetrical emergency is present if the FHR trace is normal. An FHR trace was conducted on all women at admission in this study. No obvious disadvantages could be elucidated to avoiding digital evaluation of the cervix before labour and these results are in accordance with those published by Gunn *et al.*[15] and Grant *et al.*[13]. Few randomised prospectively designed studies of PROM have had a protocol without digital examinations at admission. Wagner *et al.*[10] studied 182 nulliparous and parous women with PROM. One group was induced with oxytocin immediately and the other was induced 24 h after randomisation. They found that delayed induction was associated with an increase of neonatal infectious morbidity. However, it should be emphasised that women with infections in the group with delayed induction did not always adhere to the protocol (i.e. a digital examination had been performed at admission).

The incidence of chorioamnionitis prior to and during labour in our study (0·8%) is disparate from other studies. Duff *et al.*[6] found an incidence of 7·5%, but in their study a digital examination was done at admission. Wagner *et al.*[10] had no intra-amniotic infections at all, but a higher rate of postpartum endometritis than in our study (8·3% compared with 0·4%). The reason for the differences could be that our population had a low risk of infectious morbidity compared with the women in other studies. On the other hand, our hospital is a referral centre and our patients are a high risk population in relation to most other hospitals in Scandinavia. Almost 100% of pregnant women in Sweden are attending antenatal classes, including at least 12 checkups by a midwife. It should be emphasised that digital examinations are never performed at these visits.

Nulliparous women with PROM and an unripe cervix provide a difficult clinical problem. In this trial, a higher caesarean section rate was found only for nulliparous with a Bishop score of 1 or 2 at the start of labour compared with those with a higher Bishop score. Only 47 (6%) of the nulliparous women in the study population had a Bishop score of 1 or 2. In women with a very low Bishop score, the administration of prostaglandins may be a useful alternative to ripen the cervix[16]. However, since these patients are rare, their existence does not indicate that a routine digital examination should be performed at admission. For parous women there are probably no advantages in using prostaglandin and for 94% of our nulliparous women oxytocin was an effective drug for inducing labour. The remaining 6% may benefit from prostaglandins. We hope that the TERM PROM trial[17] will answer the question for this specific group. The TERM PROM trial is a multicentre study involving a lot of different centres in Canada, Denmark, Britain, Australia, Sweden and Israel. However, the conclusion from that trial may be confounded since the centres included have different caesarean section rates, managements of labour, oxytocin protocols and some examine the cervix at admission. An interesting subgroup to analyse in the TERM PROM study will be nulliparous women with a Bishop score of 1 or 2.

In conclusion, no obvious disadvantages were revealed if parous women were induced the morning after admission compared with 48 h later. An extended duration of the expectancy period in nulliparous women resulted in a higher rate of spontaneous deliveries. The difference was found only for ventouse extractions and not for the caesarean section rate. In our study population, in which digital examinations at admission were avoided, no difference in the incidence of infections between the groups was found, nor did the neonatal outcome differ between the groups.

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