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ORIGINAL RESEARCH ARTICLE

Outpatient labor induction—Exploring future potential by assessing eligibility in a historical cohort

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Abstract

Introduction: Labor induction rates have increased over the last decades, and in many high-income countries, more than one in four labors are induced. Outpatient management of labor induction has been suggested in low-risk pregnancies to improve women's birth experiences while also promoting a more efficient use of healthcare resources. The primary aim of this paper was to assess the proportion of women in a historical cohort that would have been eligible for outpatient labor induction with oral misoprostol. Second, we wanted to report safety outcomes and assess efficacy outcomes for mothers and infants in pregnancies that met the criteria for outpatient care.

Material and methods: Criteria for outpatient labor induction with oral misoprostol were applied to a historical cohort of women with induction of labor at two Norwegian tertiary hospitals in the period January 1, through July 31, 2021. The criteria included low-risk women with an unscarred uterus expecting a healthy, singleton baby in cephalic position at term. The primary outcome was the proportion of women eligible for outpatient labor induction. Secondary outcomes included reasons for ineligibility and, for eligible women, safety and efficacy outcomes.

Results: Overall, 29.7% of the 1320 women who underwent labor induction in a singleton term pregnancy met the criteria for outpatient labor induction. We identified two serious adverse events that potentially could have occurred outside the hospital if the women had received outpatient care. The mean duration from initiation of labor induction to administration of the last misoprostol was 22.4 h. One in 14 multiparous women gave birth within 3 h after the last misoprostol dose.

Conclusions: In this historical cohort, three in ten women met the criteria for outpatient management of labor induction with oral misoprostol. Serious adverse events were rare. The average time span from the initiation of labor induction to the last misoprostol was nearly 24 h. This suggests a potential for low-risk women with an induced labor to spend a substantial period of time at home before labor onset.

Abbreviations: BMI, body mass index; IOL, induction of labor; LINO, the labor induction inpatient and outpatient project; TGCS, the Ten Groups Classification System.

However, larger studies testing or evaluating labor induction with oral misoprostol as an outpatient procedure are needed to draw conclusions.

KEYWORDS
birth, induction of labor, maternity care, misoprostol, obstetrics, outpatient labor induction

1 | INTRODUCTION

The rates of induction of labor (IOL) have increased over the last decades, and in many high-income countries, more than one in four labors are induced.[1–3] In Norway, IOL rates have increased from 11.5% in 2002 to 29.1% in 2022.[4] This increase leads to several challenges for both women and providers of maternity care. For women, IOL is associated with a negative labor experience,[5–7] and for providers, the higher proportion of IOL increases the need for maternity staff and other resources.[3,8]

In several countries, women are offered IOL as outpatients if their pregnancy is classified as low risk.[9–14] Outpatient management of IOL is associated with better maternal satisfaction and might reduce the use of maternity care resources.[8–10,15,16] In Norway, national guidelines recommend a sequential IOL method, with Foley catheter as the initial method followed by low-dose misoprostol, administered either vaginally or orally.[17] Although women receive outpatient care during Foley catheter treatment, they are admitted to hospital during the misoprostol phase.[17] As misoprostol is prescribed to the majority of women with IOL,[18] a substantial number of women are hospitalized during the IOL process.

Recently, two papers have published data on outpatient IOL with orally administered low-dose misoprostol.[13,14] Hence, we wanted to assess the potential and feasibility of including oral misoprostol in the outpatient procedure in Norway. We applied criteria for outpatient IOL with oral misoprostol to a historical cohort of women with IOL at two Norwegian tertiary hospitals where misoprostol was administered orally. The primary aim was to assess the proportion of women eligible for outpatient IOL. The secondary aim was to report safety outcomes and assess efficacy of the IOL processes of the eligible pregnancies.

Key Message

Three in ten women were considered eligible for outpatient labor induction using oral misoprostol. Few severe adverse events were identified. This suggests potential benefits in adopting oral misoprostol for outpatient labor induction in low-risk women. Larger studies are needed.

2 | MATERIAL AND METHODS

This historical cohort study reports results from the first study in the Labor Induction Inpatient and Outpatient (LINO) project (ClinicalTrials.gov Identifier: NCT04746248). Data for the current study were collected from the electronic obstetric records at two tertiary maternity units in Norway with 1750 and 6900 annual births, respectively. We included all women with induced labor from January 1, through July 31, 2021, with a singleton live fetus beyond 37^{+0} weeks of gestation.

To this cohort, we applied the LINO project criteria for outpatient management of IOL, see details in Figure 1. The criteria were developed through a pragmatic approach in close collaboration with obstetricians and midwives at the two participating maternity units. The criteria were based on national guideline recommendations, applying local procedures to ensure that the criteria were in line with current clinical practice.[17,19] In short, women eligible for outpatient IOL had low-risk pregnancies with an unscarred uterus expecting a term, singleton healthy baby in cephalic position. In the Ten Groups Classification System (TGCS), this corresponds to groups 2a and 4a.[20] In addition, to be eligible for outpatient IOL, a woman had to be induced using Foley catheter and/or oral misoprostol.

The IOL procedure at the participating units during the study period was sequential.[19] Women with an unripe cervix had a Foley catheter for 24 h before treatment with misoprostol until labor onset, up to a maximum of 48 h. Unripe cervix was defined as Bishop score <8 for nulliparous and <6 for multiparous women. Misoprostol was administered orally in doses of 25 μg every 2 h or 50 μg every 4 h until the woman experienced regular, painful contractions, with a maximum dose of 200 μg/24 h. At one of the sites, women self-administered the misoprostol, whereas midwives administered the tablets at the other sites. After the misoprostol treatment, or sooner in cases of a favorable cervix, artificial rupture of membranes was performed, followed by oxytocin infusion. The choice of IOL method was made after an overall individual assessment by the attending obstetrician. Hence, misoprostol was sometimes preferred as the initial IOL method even with an unripe cervix, although Foley catheter was recommended as initial method according to the hospital's procedure. The IOL procedure was occasionally altered because of provider issues. A clinical examination, including maternal vital signs, cervical assessment, and cardiotocography was performed before the Foley catheter insertion and before the first misoprostol administration. Subsequently, the cardiotocography and cervical assessment were repeated every 6 h or sooner if indicated or upon labor onset. A pregnancy was defined as post-term at 42^{+0} weeks, or at 41^{+3} weeks if the woman's pregestational body mass index (BMI) was ≥35 kg/m^2 or maternal age was ≥39 years. In cases of prelabor

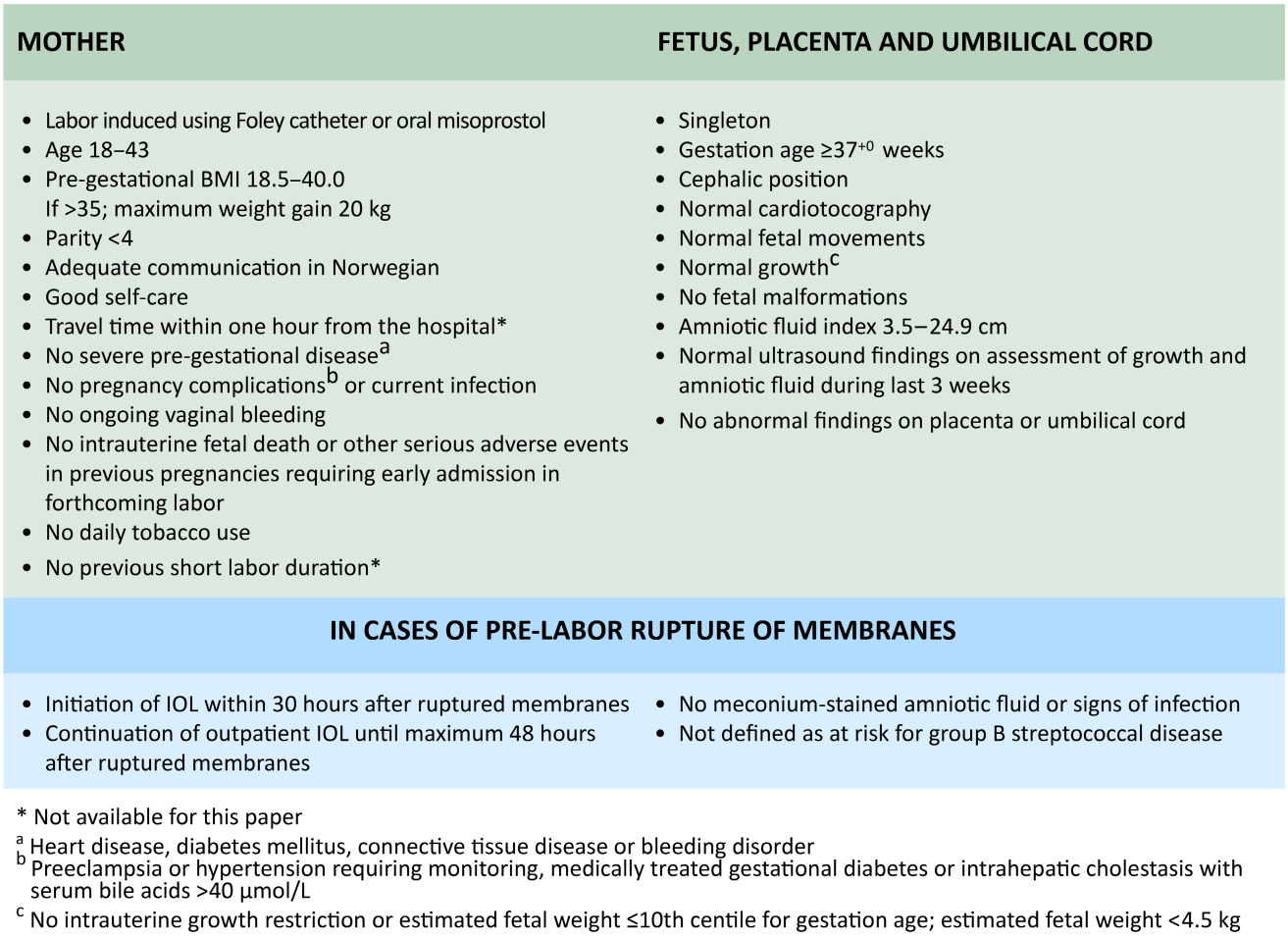

FIGURE 1 Eligibility criteria for outpatient labor induction in the LINO project.

rupture of membranes, labor was induced after 24–48 h, or earlier in cases of meconium-stained amniotic fluid or suspected infection. The partograph was typically started when the woman requested assistance in managing her contractions, whether it was in early labor, at the onset of active labor, or later, if the woman did not report her contractions. In this study, the start of the partograph was considered the most appropriate time-point to serve as a surrogate for time of arrival at the hospital if a woman had started with contractions as an outpatient.

Background characteristics included parity, maternal age at delivery, pregestational maternal BMI, gestational age at delivery, and indication for IOL. The primary outcome of the study was the proportion of women eligible for outpatient IOL according to the LINO project criteria. For women not eligible for outpatient IOL, secondary outcomes included reasons for ineligibility. For women eligible for outpatient IOL, secondary outcomes included main indication for IOL, Bishop score before IOL, IOL methods, mode of delivery including indications for cesarean section, and estimated blood loss. Secondary maternal outcomes also included serious adverse events defined as immediate cesarean sections, uterine rupture, placental abruption, and postpartum hemorrhage (≥1000 mL). Neonatal serious adverse outcomes included shoulder dystocia, Apgar score <7 after 5 min and umbilical artery pH <7. Further, we wanted to report serious adverse events that could have occurred outside the hospital if the women had been induced as outpatients. Hence, serious adverse events happening before or within the first hour after the start of the partograph were investigated in detail. In addition, we assessed the following time-to-event outcomes: time from initiation of IOL to administration of the last misoprostol, hours from insertion of Foley catheter to first misoprostol and to delivery, hours from first misoprostol to last misoprostol and to delivery, hours from last misoprostol to delivery, and the number of women giving birth within 24 h after initiation of IOL. Furthermore, the number of women giving birth within 3 h after the last misoprostol dose was examined. Moreover, subgroup analyses were conducted for women induced because of prelabor rupture of membranes, and for the cohort excluding women with prelabor rupture of membranes.

2.1 | Statistical analyses

Cases were categorized into three groups according to the TGCS: "TGCS group 2a" was nulliparous women with a term singleton

cephalic fetus, "TGCS group 4a" was multiparous women with a term singleton cephalic fetus without previous cesarean section, and "Other TGCS groups" included TGCS group 5 consisting of multiparous women with uterine scar and single cephalic term fetus and TGCS groups 6 and 7 including nulli- and multiparous women with single fetus in breech position.[20] Results are presented as numbers and percentages, mean ± standard deviation or median. Between-group comparisons were carried out using Student's *t* test or Mann–Whitney *U* test, as appropriate. Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 29 (IBM Corp., Armonk, NY, USA).

3 | RESULTS

An overview of the study sample is given in Figure 2 and maternal characteristics are presented in Table 1. Of the included women, 717 (54.3%) were nulliparous, 437 (33.1%) had given birth once, and 166 (12.7%) had given birth more than once. Mean maternal age at delivery was 32.8 ± 4.6 years, mean pregestational BMI was 25.0 ± 5.0 kg/m^2, and mean gestation at delivery was 280.7 ± 10.6 days.

Of the women with IOL, 392 (29.7%) were assessed as eligible for outpatient IOL with misoprostol; 237 (33.1%) of the nulliparous women and 155 (25.7%) of the multiparous women. Reasons for ineligibility are listed in Table 2.

The most common reason for not being eligible for outpatient IOL was maternal pregnancy complications followed by fetal growth restriction, reduced fetal resources, not speaking Norwegian, and previous cesarean section.

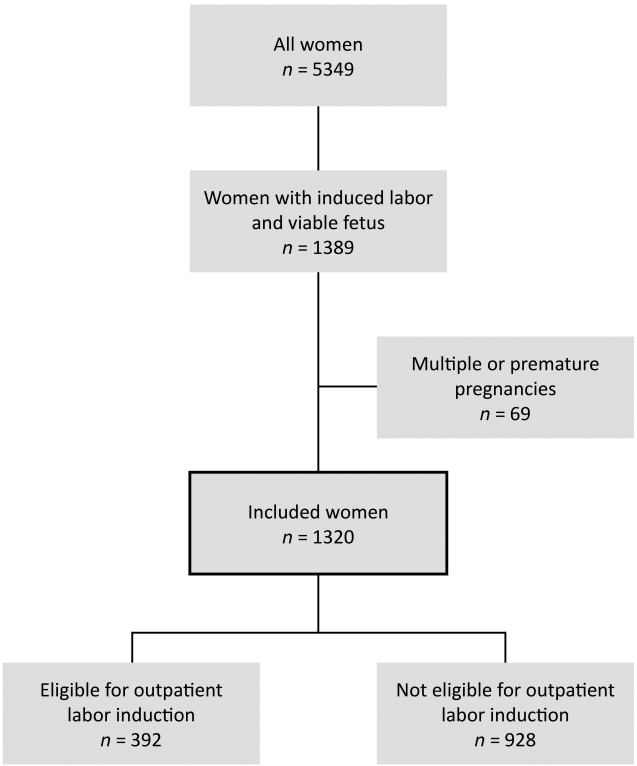

FIGURE 2 Flow chart of included women and women eligible for outpatient labor induction.

The majority of women with hypertension or intrahepatic cholestasis were assessed as ineligible for outpatient IOL because of the severity of the condition or additional risk factors. Among the 91 women with hypertension, only 10 were eligible for outpatient IOL. Similarly, out of the 44 women with intrahepatic cholestasis, only 6 were assessed as eligible. For further details, see Appendix S1.

Among women eligible for outpatient IOL, the main indications for IOL were post-term pregnancy, prelabor rupture of membranes, maternal request, and fetus large for gestational age (Figure 3). The IOL processes and labor outcomes are presented in Table 3.

In the group of women eligible for outpatient IOL, a total of 276 (70.4%) were induced with Foley catheter, of whom 207 (75.0%) were subsequently given misoprostol. Out of the 323 women induced with misoprostol, 207 (64.1%) had a Foley catheter before the misoprostol treatment. A vast majority of the women using misoprostol, 81.1%, needed eight tablets or fewer to induce labor, with a mean of 5.8 ± 4.3 tablets.

Among women induced with Foley catheter as the initial IOL method, the mean Bishop score was significantly lower compared with if the IOL process was initiated with misoprostol (Bishop scores 2.2 ± 1.3 vs 4.5 ± 1.7, $p \leq 0.001$). In the group of 116 women who initiated the IOL with misoprostol, 32 (27.6%) received only one dose of the medication.

A serious adverse event occurred in four deliveries before or within the first hour after the partograph was started. If outpatient care had been provided, two of these could potentially have happened outside the hospital. The first was an immediate cesarean section for placental abruption in a nulliparous pregnancy following spontaneous rupture of membranes. In the second case, a multiparous woman had a postpartum hemorrhage of 1000 mL as the result of a retained placenta after a short labor. For more details, see Table S1. There were no cases of uterine rupture, shoulder dystocia, or umbilical cord artery pH <7.0 in deliveries with a partograph shorter than 1 h.

With regard to time-to-event outcomes, the mean duration from initiation of IOL to administration of the last misoprostol was 22.4 ± 18.9 h. Median durations of the stages in the IOL process for each TGCS group are shown in Figure 4.

When comparing nulliparous and multiparous women, median time from initiation of IOL to administration of the last misoprostol was not significantly different ($p = 0.135$ in the group with Foley catheter as the initial IOL method, see Figure 4A, and $p = 0.097$ in the group with misoprostol as initial method, see Figure 4B). However, the time from administration of the last misoprostol to delivery was significantly shorter among multiparous women ($p \leq 0.001$ for both of the initial IOL methods, see Figure 4A,B). One in every 14 multiparous women gave birth less than 3 h after taking the last misoprostol, compared with one in every 100 nulliparous women. Additional efficacy outcomes are presented in Table 4.

In subgroup analyses of women with prelabor rupture of membranes, the rate of cesarean section was 6.5% and the mean time

TABLE 1 Background characteristics for all women with induced labor and term singleton pregnancy January–July 2021.

	All $N=1320$		TGCS group 2a $n=687$		TGCS group 4a $n=462$		Other TGCS groups $n=171$	
Characteristics	***n***	**%**	***n***	**%**	***n***	**%**	***n***	**%**
Parity								
Nulliparous	717	54.3	687	100	n/a	n/a	30	17.5
Multiparous	603	45.7	n/a	n/a	462	100	141	82.5
Maternal age (years)								
<30	293	22.2	201	29.3	62	13.4	30	17.5
30–38	817	61.9	405	59.0	303	65.6	109	63.7
≥39	210	15.9	81	11.8	97	21.0	32	18.7
Pregestational BMI (kg/m^2), $n=1299$								
≤18.4	32	2.5	22	3.3	9	2.0	1	0.6
18.5–24.9	732	56.4	410	60.7	227	50.1	95	55.9
25.0–29.9	333	25.6	154	22.8	132	29.1	47	27.6
30.0–34.9	132	10.2	56	8.3	54	11.9	22	12.9
35.0–39.9	48	3.7	22	3.3	22	4.9	4	2.4
≥40.0	22	1.7	12	1.8	9	2.0	1	0.6
Gestational age (weeks^{days})								
37^{0-6}	113	8.6	59	8.6	40	8.7	14	8.2
38^{0-6}	244	18.5	102	14.8	100	21.6	42	24.6
39^{0-6}	259	19.6	126	18.3	90	19.5	43	25.1
40^{0-6}	217	16.4	114	16.6	80	17.3	23	13.5
41^{0-6}	284	21.5	152	22.1	101	21.9	31	18.1
$\geq 42^{0}$	203	15.4	134	19.5	51	11.0	18	10.5
Main indication for labor induction[a]								
Post-term pregnancy[b]	264	20.0	156	22.7	87	18.8	21	12.3
Prelabor rupture of membranes[c]	222	16.8	139	20.2	59	12.8	24	14.0
IUGR or SGA	123	9.3	75	10.9	33	7.1	15	8.8
Large-for-gestational-age	104	7.9	37	5.4	45	9.7	22	12.9
Diabetes, medically treated[d]	91	6.9	41	6.0	37	8.0	13	7.6
Maternal request	90	6.8	16	2.3	56	12.1	18	10.5
Oligohydramnios	85	6.4	47	6.8	24	5.2	14	8.2
Preeclampsia	79	6.0	53	7.7	21	4.5	5	2.9
Hypertension	72	5.5	41	6.0	18	3.9	13	7.6
Other maternal indications[e]	113	8.6	50	7.3	49	10.6	14	8.2
Other fetal indications[f]	77	5.8	32	4.7	33	7.1	12	7.0

Abbreviations: BMI, body mass index; IUGR, intrauterine growth restriction; SGA, small for gestational age; TGCS, the Ten Groups Classification System.

[a]As defined by the attending clinician, guided by local procedures.

[b]Post-term pregnancy: ≥ 42^{+0} weeks of gestation or ≥ 41^{+3} weeks of gestation if pregestational BMI ≥35 kg/m^2 or maternal age ≥39 years.

[c]Induced 24–48 h after membrane rupture or earlier in cases of meconium-stained amniotic fluid or suspected infection.

[d]Including pre-existing and gestational diabetes mellitus.

[e]Including intrahepatic cholestasis, not medically treated gestational diabetes mellitus, obstetric history, chronic disease, severe psychiatric illness.

[f]Including polyhydramnios, reduced fetal movements, non-reassuring cardiotocography.

from initiation of IOL to administration of the last misoprostol was 8.2 ± 9.5 h. Details of the subgroup analyses of women with prelabor rupture of membranes, as well as of the cohort excluding this group, are shown in Table S2 and Figure S1.

4 | DISCUSSION

In this study, we found that three in ten women with an induced labor and a singleton term pregnancy met the criteria for outpatient

TABLE 2 Reasons for not being eligible for outpatient labor induction with misoprostol.[a]

	All $N = 928$		TGCS group 2a $n = 450$		TGCS group 4a $n = 307$		Other TGCS groups $n = 171$	
Reason for ineligibility	***n***	**%**	***n***	**%**	***n***	**%**	***n***	**%**
Any maternal pregnancy complication[a]	258	27.8	148	32.9	77	25.1	33	19.3
GDM, medically treated	92	9.9	38	8.4	39	12.7	15	8.8
Preeclampsia	89	9.6	63	14.0	21	6.8	5	2.9
Hypertension requiring monitoring	67	7.2	43	9.6	13	4.2	11	6.4
Severe ICP	22	2.4	12	2.7	7	2.3	3	1.8
Other	2	0.2	0	0.0	2	0.7	0	0.0
Abnormal fetal growth								
IUGR or SGA[b]	194	20.9	120	26.7	51	16.6	23	13.5
Large for gestational age, >4.5 kg	6	0.6	2	0.4	4	1.3	0	0.0
Other reduced fetal resources[c]	146	15.7	83	18.4	45	14.7	18	10.5
Non-Norwegian speakers	134	14.4	71	15.8	41	13.4	22	12.9
No Norwegian or English	64	6.9	31	6.9	26	8.5	7	4.1
Previous cesarean section	125	13.5	n/a	n/a	n/a	n/a	125	73.1
Obstetric history[d]	68	7.3	15	3.3	42	13.7	11	6.4
Chronic maternal disease[e]	59	6.4	37	8.2	16	5.2	6	3.5
Breech position	47	5.1	n/a	n/a	n/a	n/a	47	27.5
Abnormal amniotic fluid								
Oligohydramnios	43	4.6	22	4.9	18	5.9	3	1.8
Polyhydramnios	27	2.9	10	2.2	14	4.6	3	1.8
Meconium-stained amniotic fluid	39	4.2	29	6.4	6	2.0	4	2.3
Pregestational BMI								
$<18.5\,kg/m^2$	32	3.4	22	4.9	9	2.9	1	0.6
$\geq 40.0\,kg/m^2$ or $\geq 35\,kg/m^2$ and weight gain in pregnancy >20 kg	30	3.2	17	3.8	12	3.9	1	0.6
Poor self-care	20	2.2	13	2.9	7	2.3	0	0.0
Parity ≥4	13	1.4	n/a	n/a	10	3.3	3	1.8
Need for prophylactic GBS treatment	11	1.2	6	1.3	4	1.3	1	0.6
Suspected infection	10	1.1	8	1.8	2	0.7	0	0.0
Tobacco use	8	0.9	4	0.9	3	1.0	1	0.6
IOL methods only applicable in hospital	17	1.8	6	1.3	11	3.6	0	0.0

Abbreviations: BMI, body mass index; GBS, Group B Streptococcus; GDM, gestational diabetes mellitus; ICP, intrahepatic cholestasis of pregnancy; IOL, induction of labor; IUGR, intrauterine growth restriction; SGA, small for gestational age; TGCS, the Ten Groups Classification System.

[a]Some women met more than one criterion for not being eligible.

[b]Intrauterine growth restriction or estimated ≤10th centile weight for gestational age.

[c]Reduced fetal movements, non-reassuring cardiotocography, fetal anomalies, or abnormal findings at the placenta or umbilical cord.

[d]Previous intrauterine fetal death, placental abruption or short labor duration, uterine abnormalities or scarred adnexa or uterus other than cesarean section.

[e]Including diabetes mellitus, bleeding disorders, heart disease, severe psychiatric illnesses.

IOL with oral misoprostol. The most common reasons for ineligibility were maternal pregnancy complications and reduced fetal resources. Among women eligible for outpatient IOL, the most common indications for IOL were post-term pregnancy, prelabor ruptures of membranes, maternal request and a fetus large for gestational age. We identified two serious adverse events that potentially could have occurred outside the hospital if the women had received outpatient IOL care.

The proportion of women eligible for outpatient IOL in our study is significantly lower than the findings from a Danish study of outpatient IOL with oral misoprostol. In that study, 71.9% of the women with IOL received outpatient care. Other studies on outpatient IOL

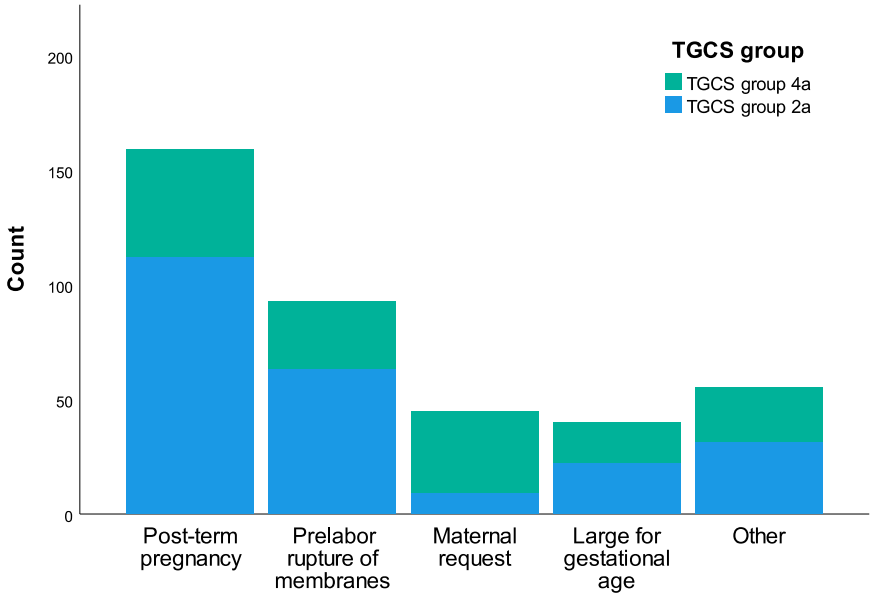

FIGURE 3 Main indication for induction of labor among women eligible for outpatient labor induction. "Other" includes hypertension not requiring monitoring, oligohydramnios with amniotic fluid index <3.5 cm, mild intrahepatic cholestasis, not medically treated gestational diabetes mellitus.

using other IOL methods report proportions of eligible women ranging from 8.3% to 53.0%.[21–23] Although eligibility criteria for outpatient IOL are not described in detail in all the papers, the published criteria seem comparable to the LINO study criteria, with some differences regarding women with hypertension, preeclampsia, diabetes, and small-for-gestational-age fetuses. However, the described differences do not explain the whole difference.

We identified two serious adverse events that potentially could have happened outside the hospital if the women had been induced as outpatients. The first event was a placental abruption occurring when the membranes ruptured spontaneously before onset of labor. Placental abruption is associated with uterine cavity decompression, such as spontaneous or artificial membrane rupture.[24] To the best of our knowledge, IOL has not been identified as an independent risk factor for placental abruption, although several indications for inducing labor, such as hypertensive disorders and polyhydramnios, are known risk factors.[25] In this case, no risk factors for placental abruption were identified in the woman's medical record. For the second serious adverse event, a multiparous woman had an estimated postpartum blood loss of 1000 mL after a quick labor. There was no information in the medical record indicating when the woman first felt the contractions. Hence, she may have arrived at the hospital well before giving birth if she had an outpatient IOL. No conclusion regarding safety can be made based on these findings, given the design and size of this study. However, the low numbers of serious adverse events are in line with findings from systematic reviews on outpatient IOL in low-risk pregnancies, where no increased risk of adverse maternal or neonatal outcomes was found, compared with inpatient management.[9–12] Most studies on outpatient IOL use Foley catheters, although low-dose oral misoprostol is considered to be a safe IOL method, with fewer cesarean sections and a comparable risk of other complications compared with Foley catheter.[26] In the two published papers on outpatient IOL using oral misoprostol, few adverse events were seen, but the studies were underpowered for safety outcomes.[13,14]

We were unable to make a precise estimation of the potential outpatient-time, because of the design of the study. However, the mean time from initiation of IOL to administration of the last misoprostol was 22.4 h. Hence, there is a potential for women to stay at home for a substantial number of hours, which could benefit both women and maternity care providers. As the time from initiation of the IOL to the last misoprostol dose was comparable between nulliparous and multiparous women, both groups might benefit from an outpatient IOL. However, it is worth noting that among multiparous women, one in every 14 women gave birth within 3 h after the last misoprostol dose, compared with one in every 100 nulliparous women. Hence, multiparous women should be advised to have a low threshold to return to the hospital at the onset of contractions, especially if they have a history of short labor. The shorter IOL duration among women using misoprostol as the initial IOL method compared with women with Foley catheter is probably because of a ripe cervix, as indicated by the significantly higher Bishop scores.

We did not identify any increased risk of adverse outcomes among the group of women induced because of prelabor rupture of membranes. However, it is worth noting that the mean duration from initiation of IOL to administration of the last misoprostol was relatively short at 8.2 h. This should be taken into consideration when assessing the potential benefits of recommending outpatient IOL for these women.

A strength of this study is that the LINO project criteria for outpatient IOL were decided in close collaboration with the maternity care providers and are in line with clinical practice. They are also comparable to the criteria in two other Nordic studies investigating outpatient IOL with oral misoprostol.[27,28] Hence, these criteria are likely to be relevant in other settings. The study population and the maternity care system are also comparable to the other Nordic

TABLE 3 Labor induction process and labor outcomes among women eligible for outpatient labor induction.

	All $N=392$		TGCS group 2a $n=237$		TGCS group 4a $n=155$	
	n	%	*n*	%	*n*	%
Bishop score before IOL, $n=386$						
≤3	262	67.9	167	71.4	95	62.5
4–5	95	24.6	50	21.4	45	29.6
≥6	29	7.5	17	7.3	12	7.9
Labor induction methods						
Foley catheter, no misoprostol	69	17.6	42	17.7	27	17.4
Misoprostol, no Foley catheter	116	29.6	68	28.7	48	31.0
Foley catheter followed by misoprostol	207	52.8	127	53.6	80	51.6
Oral misoprostol—number of tablets, $n=323$[a]						
1–8 tablets	262	81.1	151	77.4	111	86.7
9–16 tablets	59	18.3	42	21.5	17	13.3
>16 tablets	2	0.6	2	1.0	0	0.0
Artificial rupture of membranes	114	29.1	66	27.8	48	31.0
Oxytocin	56	14.3	45	19.0	11	7.1
Other[b]	23	5.9	20	8.4	3	1.9
Mode of delivery						
No instrumental vaginal delivery	292	74.5	148	62.4	144	92.9
Cesarean section	52	13.3	45	19.0	7	4.5
Immediate	6	1.5	3	1.3	3	1.9
<20 min	18	4.6	15	6.3	3	1.9
>20 min	28	7.1	27	11.4	1	0.6
Instrumental vaginal delivery	48	12.2	44	18.6	4	2.6
Main indication for cesarean section[c]						
Prolonged labor	22	42.3	20	44.4	2	28.6
Fetal distress	15	28.8	12	26.7	3	42.9
Failed labor induction	8	15.4	8	17.8	0	0.0
Other	7	13.5	5	11.1	2	28.6
Postpartum hemorrhage						
<500 mL	213	54.3	105	44.3	108	69.7
500–1000 mL	125	31.9	90	38.0	35	22.6
>1000 mL	54	13.8	42	17.7	12	7.7
Serious adverse events						
Uterine rupture	0	0.0	0	0.0	0	0.0
Placental abruption	1	0.3	1	0.4	0	0.0
Shoulder dystocia	5	1.3	4	1.7	1	0.6
Apgar score <7 after 5 min	7	1.8	7	3.0	0	0.0
pH in umbilical artery <7.0	2	0.5	2	0.8	0	0.0

Abbreviation: IOL, induction of labor; TGCS, the Ten Groups Classification System.

[a]With or without previous Foley catheter.

[b]Dinoprostone vaginal insert or a second treatment with Foley catheter.

[c]As defined by the attending obstetrician.

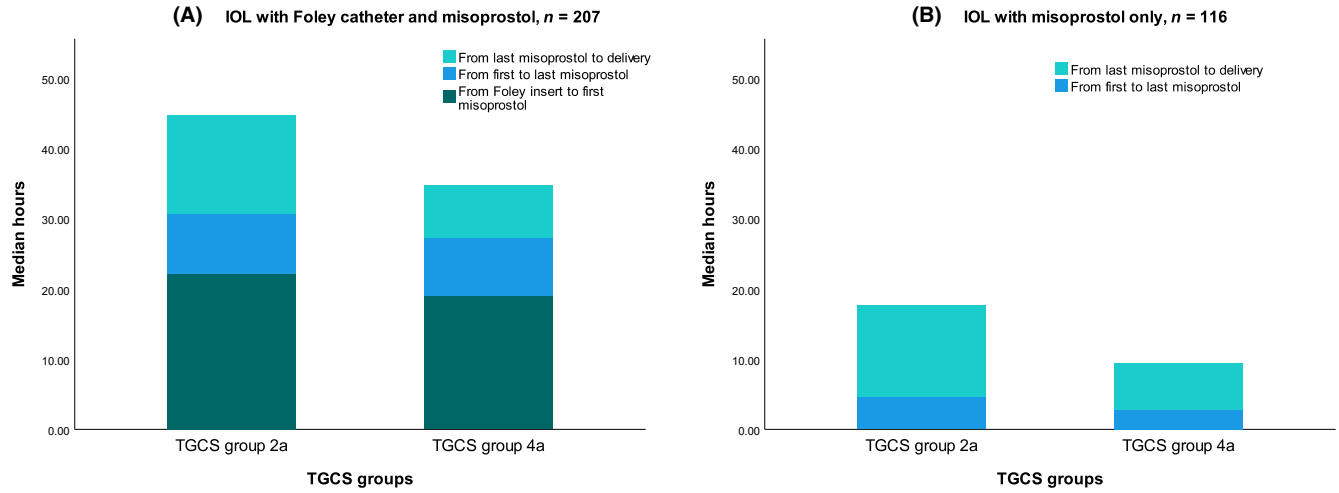

FIGURE 4 Stacked bar of median hours of the stages in the labor induction processes. (A) Induction of labor with Foley catheter and misoprostol, (B) Induction of labor with misoprostol without Foley catheter. TGCS group 2a, nulliparous with a term singleton cephalic fetus; TGCS group 4a, multiparous with a term singleton cephalic fetus without previous cesarean section.

TABLE 4 Mean time-to-event outcomes in women with induction of labor (IOL) using Foley catheter vs misoprostol as initial labor induction method.

	All	Foley catheter as initial IOL method	Misoprostol as initial IOL method
From initiation of IOL to delivery (hours), mean ± SD	32.9 ± 21.4	39.1 ± 21.1	18.0 ± 13.3
From Foley insert to last misoprostol (hours), mean ± SD	30.9 ± 16.9	30.9 ± 16.9	n/a
From first misoprostol to last misoprostol (hours), mean ± SD	10.6 ± 11.9	12.5 ± 12.1	7.1 ± 10.8
Vaginal delivery within 24 h, *n* (%)	148 (37.8)	58 (21.0)	90 (77.6)

countries. Hence, our findings are likely to be valid for regions and countries with similar maternity care systems.

The design of this study has some limitations. There will always be a distinction between eligibility assessed from medical records and eligibility in a clinical setting. Some variables important for the suitability of outpatient management were missing, such as travel distances, duration of previous labor(s), and whether the woman was experiencing any contractions. Furthermore, we assessed every criterion separately, while a combination of factors could have led to different conclusions. Furthermore, some of the criteria depend on subjective assessments and will probably vary between both women, maternity care providers, and maternity units. In addition, as all women in this study were inpatients during the misoprostol treatment, we are unable to determine whether their outcomes would have differed in an outpatient setting. Preventing adverse outcomes largely relies on the woman's self-reporting, and we do not know whether being an outpatient would increase or decrease the threshold for contacting healthcare personnel. Nevertheless, women in this study underwent more frequent observations than they would in an outpatient setting, which may have contributed to the low number of adverse events. Furthermore, the assessments of when to discontinue misoprostol administration in the presence of mild or irregular contractions might vary between inpatient and outpatient settings. Finally, but of great importance, a considerable limitation in this study is that the women's voices were not a part of the study. Although early hospitalization before onset of active labor could be a barrier for a positive labor experience for some women, other women consider the hospital to be a place of safety.[5]

5 | CONCLUSION

In this historical cohort study, we found that three in ten women with a term singleton pregnancy and induced labor could have been eligible for outpatient management with oral misoprostol. In the eligible group, serious adverse events before or in early labor were rare. On average, women in this group used nearly 24 h from initiation of IOL to administration of the last misoprostol. However, multiparous women should be advised to have a low threshold for returning to the hospital, as one in 14 multiparous women gave birth within 3 h after taking the last misoprostol. Nevertheless, our findings indicate a potential for including oral misoprostol to the outpatient IOL procedure in Norway. However, larger studies testing or evaluating outpatient IOL with oral misoprostol are needed to draw conclusions regarding the safety, efficacy, feasibility, and acceptability. Women's experiences should be an essential part of this research.

AUTHOR CONTRIBUTIONS

Conceptualization and methodology: Kjersti Engen Marsdal, Ingvil Krarup Sørbye, Stine Bernitz, Kristine Ask, Ranveig Elise Tulluan Sve, and Mirjam Lukasse. Data collection and analyses: Kjersti Engen Marsdal, Kristine Ask and Ranveig Elise Tulluan Sve. Writing of the manuscript: Kjersti Engen Marsdal. Substantial editing and discussion of the manuscript: Kjersti Engen Marsdal, Ingvil Krarup Sørbye, Stine Bernitz, and Mirjam Lukasse. All the authors have read and approved the final version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

All authors confirm that there are no conflicts of interest.

ETHICS STATEMENT

The study was approved by the Data Protection Officers at Vestre Viken Hospital Trust on December 17, 2020, reference 20/10740-1 and at Oslo University Hospital on January 6, 2021, reference 21/00074. Written informed consent was waived as data were collected anonymously as part of routine clinical care.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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