



The Labour Progression Study (LaPS): Duration of labour following Zhang's guideline and the WHO partograph – A cluster randomised trial

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ABSTRACT

Objective: To investigate labour duration in different phases of labour when adhering to Zhang's guideline for labour progression compared with the WHO partograph.

Design: A secondary analysis of a cluster randomised controlled trial.

Setting: Fourteen Norwegian birth care units, each with more than 500 deliveries per year constituted the clusters.

Participants: A total of 7277 nulliparous women with singleton foetus in a cephalic presentation and spontaneous onset of labour at term were included.

Intervention: Seven clusters were randomised to the intervention group that adhered to Zhang's guideline ($n = 3972$) and seven to the control group that adhered to the WHO partograph ($n = 3305$) for labour progression.

Measurements: The duration of labour from the first registration of cervical dilatation (≥ 4 cm) to the delivery of the baby and the duration of the first and second stages of labour; the time-to-event analysis was used to compare the duration of labour between the two groups after adjusting for baseline covariates.

Findings: The adjusted median duration of labour was 7.0 h in the Zhang group, compared with 6.2 h in the WHO group; the median difference was 0.84 h with 95% confidence interval [CI] (0.2–1.5). The adjusted median duration of the first stage was 5.6 h in the Zhang group compared with 4.9 h in the WHO group; the median difference was 0.66 h with 95% CI (0.1–1.2). The corresponding adjusted median duration of the second stage was 88 and 77 min; the median difference was 0.18 h with 95% CI (0.1–0.3).

Key Conclusions: : The women who adhered to Zhang's guideline had longer overall duration and duration of the first and second stages of labour than women who adhered to the WHO partograph.

Implications for practice: : Understanding the variations in the duration of labour is of great importance, and the results offer useful insights into the different labour progression guidelines, which can inform clinical practice.

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Introduction

Traditionally, the progress of labour is measured by cervical dilatation; however, the expected progression varies between countries and according to guidelines. There is no standardised definition of labour duration and the onset of labour, nor is there a consensus as to which guideline is best suited for clinical use (Abalos et al., 2018; Caughey, 2015; Hanley et al., 2016; Souza et al., 2018; Vahratian et al., 2006).

The first stage of labour is often divided into two phases; latent and active. The active phase is conventionally defined as the interval when the cervix is effaced and dilated from four centimetres to full dilatation. Similarly, the second stage is divided into the latent and active phases. In the latent (descending) phase, the baby's head is descending towards the pelvic floor and, in the active (expulsion) phase, the mother is actively pushing the baby out (NICE guidelines, 2014; World Health Organization, 2000).

The clinical expectations of cervical dilatation amongst nulliparous women have been influenced by the work of Friedman from the mid-1950s (Friedman, 1954). Accordingly, Philpott and Castle (1972a, 1972b) developed guidelines for assessing labour progression, which became part of the partograph prompted by the World Health Organization (WHO) since 1994 (World Health Organization, 1994). However, with an increased use of obstetric interventions during labour, increasing maternal body mass index (BMI) and childbearing age, questions were raised whether the progress of active labour, according to the WHO partograph, was still relevant to women today (Souza et al., 2018; Zhang et al., 2010b, 2002). In the early 2000, (Zhang et al., 2002) presented a labour curve with a hyperbolic shape based on data from 1329 low-risk women. The findings were confirmed in a large cohort with 27 170 nulliparous women in 2010 (Zhang et al., 2010a). They found that labour progresses more slowly than previously thought and that cervical dilatation accelerate as labour advances.

However, the applicability of stages, phases and time limits in labour is challenging, mainly because of variations in defining the onset of labour and transition of phases and stages (Abalos et al., 2018; Hanley et al., 2016). Thus, understanding the normal variations of duration of labour is of great importance and should be the basis for identifying the actual slow progress of labour, which requires interventions (Neal et al., 2010, 2015; Souza et al., 2018; Zhang et al., 2010b, 2002), mainly because the slow progress of labour (labour dystocia) is a common indication of interventions in labour. The purpose of this paper is to investigate labour duration from a cervical dilatation of 4 cm to delivery when adhering to Zhang's guideline for labour progression compared with the WHO partograph.

Methods

Design, participants and procedure

This is a secondary analysis of the Labour Progression Study (LaPS), a cluster randomised controlled trial undertaken in Norway, with the aim to evaluate the effects of two different guidelines for labour progression. The study protocol was published in 2017 (Bernitz et al., 2017), and detailed methodological considerations and results for the primary outcome have been published elsewhere (Bernitz et al., 2019). The trial was registered at www.clinicaltrials.org (NCT02221427) prior to the inclusion of clusters and participants.

Participating clusters and individuals

Intrapartum care in Norway takes place in governmental institutions and is free of charge. Midwives are present at all births and

responsible for women with low-risk labours and assist with all spontaneous deliveries. Obstetricians are involved in care for high-risk women and called upon if medical assistance is needed during labour. Approximately 60 000 babies are born annually in 46 birth institutions, 24 of which have more than 500 deliveries per year. The birth care is organised at three different levels: Level 1 consists of obstetric units as well as neonatal intensive care unit in large hospitals, which have obstetricians, paediatricians and anaesthesiologists available 24 h a day. Level 2 consists of obstetric units within hospitals with obstetricians and anaesthesiologists on call, and Level 3 consists of midwife-led units, both alongside and free-standing. In case of complications or change in risk status at Level 3, the woman is transferred to a reference hospital of Level 1 or 2. This study was conducted at Levels 1 and 2 with more than 500 births annually. To create a representative selection of obstetric units in Norway, all geographic health regions were included. The management at the obstetric units were contacted by a LaPS study group member. Units with the ability to adhere to the protocol were considered eligible. To secure a thorough implementation of the trial, the management at all participating obstetric units signed a cooperation agreement committing to adhere to the protocol. Fourteen birth care units participated in the trial, of which seven were randomised to the intervention group and seven to the control group. The sites were randomly allocated to the two treatments using the randomization.com webpage (Dallal, 2008). The randomization was stratified by annual number of deliveries and proportion of intrapartum caesarean sections (ICS), provided from the national birth registry. Nulliparous women with a singleton term foetus with cephalic presentation and spontaneous onset of labour in gestational age of 37 weeks or more, denoted as Group 1 in the Ten Group Classification System (TGCS) (Robson et al., 2015), and who understood Norwegian were eligible for participation. The birth care units adhered to the allocated guideline for all TGCS Group 1 women. The eligible women who provided their informed consent were included in the analyses. The estimation of gestational age was based on a second trimester ultrasound scan.

Procedures

Prior to the onset of the trial, the staff at all sites received identical information about the LaPS study. This information was also printed on flyers and distributed at the information meetings. After randomisation, information according to the trial arms and how to use the allocated guidelines was distributed to the staff at new meetings. Written information about the trial and the guidelines was also printed on posters and made visible and available for midwives and obstetricians at all times. The women received written information regarding the study on flyers at the second trimester ultrasound scan or upon admission in the labour ward. During this time, the women were also asked by a midwife to sign an informed consent. No women consent after delivery and only eligible women who provided an informed consent were included in the analysis.

Each birth care unit provided a local coordinator who was responsible for the recruitment and inclusion of the participants and recording the required data. For the intervention group who adhered to Zhang's guideline for labour progression (Supplementary Material, SAP), labour dystocia was diagnosed if the cervical dilatation did not meet the expected progression from one centimetre to the next according to the 95th percentile. Labour dystocia in the second stage was diagnosed if the descending phase lasted longer than one hour and 45 min or two and a half hours for women with epidural analgesia (EDA), or if the expulsion phase lasted longer than 60 min. For the control group who adhered to WHO partograph for labour progression (Supplementary Material, SAP), labour dystocia was diagnosed if cervical dilatation was slower than 1 cm

per hour, assessed after four hours. Labour dystocia in the second stage was diagnosed if the descending phase lasted longer than one hour or two hours for women with EDA, or if the expulsion phase lasted longer than 60 min. If labour dystocia was diagnosed, the guideline according to augmentation with amniotomy and synthetic oxytocin infusion was followed as a common routine at all birth care units in Norway (Norwegian Medical Association, 2014). The women in the LaPS study were monitored from a cervical dilatation of 4 cm or more and regular contractions. During the whole study period, all the birth care units were closely followed up by a member of the LaPS research group to assist and motivate them. The clinical outcomes were registered in a web-based Case Report Form (web-CRF), designed by the Unit of Applied Clinical Research at the Norwegian University of Science and Technology to ensure consistent recording of information. The system is transparent, so that all corrections can be traced with dates and signatures. The local coordinators had access only to their own part of the CRF and were responsible for assuring that all data entered were de-identified, complete, and accurate.

Outcomes of the current study

The main outcome of this paper was the duration of labour, defined as the time from the first registration of a cervical dilatation of 4 cm or more to the delivery of the baby. Other outcomes included the duration of the first stage (from 4 to 10 cm of cervical dilatation) and the duration of the second stage (from 10 cm of cervical dilatation to delivery). In addition, the descriptive statistics on cervical dilatation from one integer centimetre to the next for the two study groups are presented.

Statistical analysis

The sample size calculation was based on ICS endpoint, described and presented elsewhere (Bernitz et al., 2019). A Statistical Analysis Plan (SAP) for this study was written and approved, pre-specifying all the analyses prior to group comparison analysis, with the purpose of avoiding result-driven analyses (Supplementary Material, SAP). Simple frequencies and proportions were used to describe the characteristics of the birth care units and the participating women.

The outcome duration of labour, duration of the first stage and the duration of the second stage were time-to-event variables and were analysed using a mixed Weibull regression model with cluster as a random intercept and treatment as fixed effect (Stedman et al., 2012). The analyses are presented in adjusted estimated group-specific marginal median times and adjusted study group differences. In addition, the accelerated delivery time factor is presented, used to quantify how slow or fast the birth time progress was for women in the Zhang group compared with the women in the WHO group. In the model, we adjusted for stratification variables (the annual ICS rates and number of deliveries) and for predefined covariates, considered to be potential risk factors for ICS on an individual level (maternal age, BMI, civil status and educational level as well as birth weight and neonatal head circumference), in addition we adjusted for the first registration of cervical dilatation. Kaplan-Meier curves were included for descriptive purposes (Supplementary Material, Figure S1-3). Both EDA and augmentation with synthetic oxytocin are difficult to investigate, because slow progress is a potential indication of these interventions. Neither augmentation with synthetic oxytocin nor EDA were included in the analyses, because they were started after the onset of labour and, therefore, were considered mediators rather than confounders (Hernan et al., 2002).

For the outcome duration of labour, delivery was defined as the event of interest. The duration of labour, from the first par-

tograph registration (≥ 4 cm) to delivery, either vaginally or by ICS, was registered for all the participating women; there were no unobserved event in this analysis, hence no censoring. The event of interest for the outcome duration of the first stage was cervical dilatation of 10 cm; thus, women with ICS in the first stage were right censored at the time of ICS. Delivery was the event for the outcome duration of the second stage, and women with ICS in the first stage of labour were left censored at the time of ICS. The missing covariate data were imputed using stochastic linear regression single imputation. The time intervals for cervical dilatation by centimetre are presented descriptively. The missing intermediate dilatation values were imputed using linear interpolation. The missing values due to ICS were not imputed. The women with less than two recordings of cervical dilatation were excluded (see further clarifications in the appended SAP). The time-to-event analyses were analysed in Stata v15 (StataCorp. 2015. Stata Statistical Software: Release 15.1. College Station, TX, USA). The duration of progression from one integer centimetre to the next was analysed in R, version 3.5.0.

Results

Fourteen birth care units throughout Norway took part in this study. Between December 1, 2014 and January 31, 2017, 7277 of 11 615 eligible women were included—3972 and 3305 women in the Zhang and WHO groups, respectively (Fig. 1). The baseline characteristics of the two study groups are described in Table 1. No data were missing for the covariates included in the analyses except for BMI (0.3%) and civil status (0.8%). The characteristics of the women who were not included are presented in the Supplementary Material (Table S1).

Duration of labour from 4 cm to delivery

The unadjusted median duration of labour was 6.6 h (Percentile [P] 5th, 95th: 1.4, 16.0) in the Zhang group and 6.1 h (P5th, 95th: 1.3, 13.8) in the WHO group (Table 2). After 3.6 and 10.5 h in active labour, respectively 75% and 25% of the women in the Zhang group had not delivered as compared with 3.4 and 9.5 h for the women in the WHO group. Figure S1 shows the unadjusted Kaplan-Meier plots for women adhering to Zhang's guideline and WHO partograph. The adjusted median duration was 7.0 h in the Zhang group and 6.2 h in the WHO group, with a corresponding adjusted median difference of 0.84 h (95% CI 0.2–1.5). The adjusted accelerated delivery time factor for duration of labour was 1.14 (95% CI 1.0–1.2) (Table 2). There were no missing data for this outcome.

Duration of first stage from 4 to 10 cm

The unadjusted median duration of the first stage was 5.0 h (P5th, 95th: 0.5, 15.0) in the Zhang group and 4.5 h (P5th, 95th: 0.5, 12.5) in the WHO group (Table 2). After 2.5 and 8.5 h in the first stage of labour, respectively 75% and 25% of the women in the Zhang group had not reached 10 cm of cervical dilatation as compared with 2.0 and 8.0 h for the women in the WHO group. Figure S2 shows the unadjusted Kaplan-Meier plots for women adhering to Zhang's guideline and WHO partograph. The adjusted median duration was 5.6 h in the Zhang group and 4.9 h in the WHO group, with a corresponding adjusted median difference of 0.66 h (95% CI 0.1–1.2). The adjusted accelerated delivery time factor for duration of the first stage was 1.13 (95% CI 1.0–1.3) (Table 2).

Duration of the second stage from 10 cm to delivery

The unadjusted median duration of the second stage was 76 min (P5th, 95th: 17, 242) in the Zhang group and 75 min

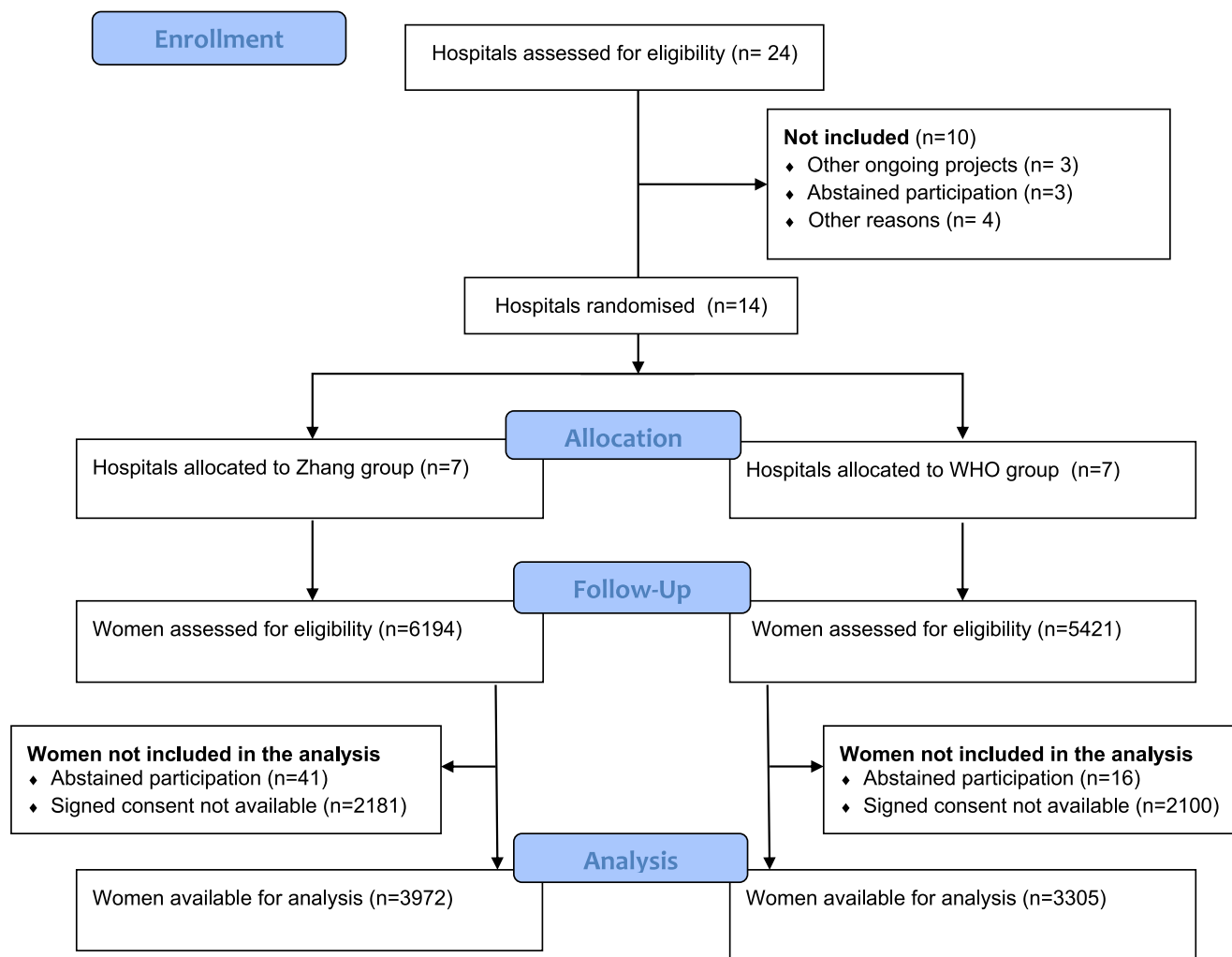


Fig. 1. Flowchart of hospitals and participants.

(P5th, 95th: 16, 204) in the WHO group (Table 2). After 40 and 142 min in the second stage, respectively 75% and 25% of the women in the Zhang group had not delivered as compared with 40 and 127 min for the women in the WHO group. Figure S3 shows the unadjusted Kaplan-Meier plots for women adhering to Zhang's guideline and WHO partograph. The adjusted median duration was 88 min in the Zhang group and 77 min in the WHO group, with a corresponding adjusted median difference of 0.18 h (95% CI, 0.1–0.3). The adjusted accelerated delivery time factor for the duration of the second stage was 1.14 (95% CI, 1.1–1.2) (Table 2).

Duration from one integer centimetre to the next

Table 3 shows the duration required to advance from one integer centimetre of cervical dilatation to the next among the TGCS Group 1 women in the two study groups. The observed median duration from one integer centimetre to the next differed between the two study groups; however, the differences were reduced as labour advanced and from 8 cm of cervical dilatation, the time intervals were equal for women who delivered vaginally.

Discussion

Main findings

Our study found that women who adhered to Zhang's guideline for labour progression had longer overall duration of labour, duration of first and second stages compared with women adhering to the WHO partograph. The differences were statistically significant, although no significant differences were found in maternal or neonatal clinical outcomes, published elsewhere (Bernitz et al., 2019). The results contribute to clarify the duration of different phases of labour when adhering to different guidelines both first and second stages, based on data from a contemporary clinical setting. In 2018, WHO announced a knowledge gap in labour progression (World Health Organization, 2018), and our randomised trial makes an important contribution to the challenge by presenting the duration of different phases of labour.

Strengths and limitations

This study was well planned and offered a thoroughly implemented trial with a sufficiently power. The included variables had few missing values and were tripled checked for errors. Despite the robust design, there are some possible limitations. Due to unavailable consent, 4338 women were not included in the study, which may be explained by periods of high workload in the birth care

Table 1
Characteristics of included hospitals ($n = 14$) and participants ($n = 7277$).

	Zhang group Participants ($n = 3972$)	WHO group Participants ($n = 3305$)
Hospital characteristics		
Deliveries per year		
<3000, 6 hospitals in each group, n (%)	2688 (36.9)	2233 (30.7)
≥3000, 1 hospital in each group, n (%)	1284 (17.6)	1072 (14.7)
Characteristics related to the mother		
Maternal age in year at delivery, mean (SD)	28.4 (4.6)	28.5 (4.5)
Civil status (cohabitant or married), n (%)	3741/3946** (94.8)	3137/3271** (95.9)
Higher education >12 years, n (%)	2412 (60.7)	2017 (61.0)
Smoking during first trimester, n (%)	230/3963** (5.8)	210/3247** (6.5)
Pre-pregnant body mass index [†] , mean (SD)	23.6/3966** (4.3)	23.8/3287** (4.3)
Gestational age at onset of active labour (days), mean (SD)	281 (7.0)	281 (8.0)
Characteristics related to labour		
Cervical dilatation at first registration, n (%)		
4 cm	1954 (49.2)	1642 (49.7)
5 cm	1006 (25.3)	841 (25.4)
6 cm	403 (10.1)	338 (10.2)
7 cm	222 (5.6)	178 (5.4)
8 cm	167 (4.2)	118 (3.6)
9 cm	106 (2.7)	99 (3.0)
10 cm	114 (2.9)	89 (2.7)
Amniotomy, n (%)	1396 (35.1)	1223 (37.0)
Oxytocin augmentation, n (%)	1658 (41.7)	1561 (47.2)
Epidural analgesia, n (%)	1913 (48.2)	1653 (50.0)
Labour dystocia, n (%)	1882 (47.4)	1512 (45.7)
Mode of delivery		
Operative vaginal, n (%)	839 (21.1)	581 (17.6)
Caesarean section, n (%)	271 (6.8)	196 (5.9)
Characteristics related to the newborn		
Birth weight (gram), mean (SD)	3528 (427)	3518 (414)
Head circumference (cm), mean (SD)	35.0 (1.4)	35.0 (1.4)

** Total numbers are presented due to missing values.

† The body-mass index is the weight in kilograms divided by the square of the height in metres.

Table 2
Duration of stages and phases and in active labour.

	Zhang group $n = 3972$ Unadjusted median (5th, 95th percentile)	Adjusted estimated median (95% CI)	WHO group $n = 3305$ Unadjusted median (5th, 95th percentile)	Adjusted estimated median (95% CI)	Accelerated delivery time factor (95% CI)	Adjusted median difference (95% CI)	p-value
Duration of labour (≥4 cm to delivery) [†] (hours)	6.6 (1.4, 16.0)	7.0 (6.5–7.5)	6.1 (1.3, 13.8)	6.2 (5.7–6.6)	1.14 (1.0–1.2)	0.84 (0.2–1.5)	0.008
Duration of 1st stage (4 cm to 10 cm) ^{†,*} (hours)	5.0 (0.5, 15.0)	5.6 (5.2–6.0)	4.5 (0.5, 12.5)	4.9 (4.5–5.4)	1.13 (1.0–1.3)	0.66 (0.1–1.2)	0.023
Duration of 2nd stage (10 cm to delivery) [‡] (min)	76 (17, 242)	88 (83.2–92.7)	75 (16, 204)	77 (72.4–81.4)	1.14 (1.1–1.2)	0.18 (0.1–0.3)	0.000

CI: Confidence interval.

Analysed with Weibull regression, adjusted for annual ICS rates and number of deliveries, maternal age, body-mass index, civil status, educational level, cervical dilatation at first registration and birthweight and head circumference of the neonate.

† Full Analysis Set (FAS)

* Censoring; ICS.

‡ Women with ICS in the first stage of labour were left censored at the time of ICS and not included in the analysis.

Table 3
Comparison of duration of labour in hours for Robson group 1*.

Cervical dilatation (cm)	Zhang's guideline $N = 3588$	WHO partograph $N = 3021$	Zhang's guideline $N = 269$	WHO partograph $N = 194$
	Delivered vaginally		Delivered by ICS	
4 cm to 5 cm	1.5 (6.0)	1.0 (4.5)	2.2 (8.4)	1.9 (8.4)
5 cm to 6 cm	1.0 (3.9)	0.9 (3.5)	1.9 (7.9)	1.4 (6.6)
6 cm to 7 cm	0.8 (3.0)	0.7 (3.5)	1.4 (6.5)	1.1 (6.5)
7 cm to 8 cm	0.6 (2.9)	0.5 (3.0)	0.9 (5.4)	0.9 (5.4)
8 cm to 9 cm	0.5 (2.5)	0.5 (2.5)	1.2 (7.0)	0.9 (5.2)
9 cm to 10 cm	0.5 (3.0)	0.5 (3.0)	1.4 (6.0)	1.5 (5.0)

Data are hours, median (95th percentile).

*Numbers are restricted to women with at least two cervical dilatation measurements during labour.

units. To assess the risk of selection bias, the baseline characteristics of the non-participating women were registered. We found differences between the participating and non-participating women in the proportions of those aged ≥ 35 , those who were cohabiting/married, those who had attended higher education and those with low BMI.

The LaPS cover large geographic areas in Norway, which allows the results to be generalised to a larger population in Norway. Owing to the fact that LaPS included all the participating women and did not exclude women in labours with adverse neonatal and maternal outcomes, the results can be generalised to a population of TGCS Group 1 (Robson et al., 2015). However, it is important to note that this is a single country trial (i.e. in Norway), where the ICS rate is considered low. It is a known challenge in labour progression studies that participants are admitted to the labour ward with different cervical dilatation status and, therefore, contribute unequally to the duration of labour (Vahratian et al., 2006), hence our adjustments for this in the analyses. Another challenge is that vaginal examinations were performed upon indication and no continuous observations were recorded; consequently, the exact time when the cervix reached a full centimetre of dilation was impossible to record.

Interpretation

The ways to assess labour progression and define labour dystocia remain unclear, mainly because of a lack of consensus on the expected progression in labour. We found that the adjusted median difference of duration of labour from 4 cm to delivery was 48 min longer in the Zhang group compared with the WHO group, and that the corresponding adjusted median differences were 40 min and 11 min in the first and second stages, respectively. The differences were statistically significant between the two study groups, although the clinical relevance can be questioned.

The length of labour may have been affected in different ways, and the use of synthetic oxytocin may partly explain the differences. More women in the WHO group received augmentation with synthetic oxytocin compared with the Zhang group (47.2% vs 41.7%), and it is known that synthetic oxytocin shortens the duration of labour (Bugg et al., 2013). EDA may also affect the duration of labour and is known to extend the second stage (Anim-Somuah et al., 2011; Grant et al., 2015). The rate of EDA was similar in the Zhang and WHO groups (48.2% vs 50.0%) and, therefore, probably has limited impact on the differences in labour duration.

In general, labour duration in the two study groups were in accordance with the previously reported contemporary results (Oladapo et al., 2018; Zhang et al., 2010a); however, some differences are worth noting. The unadjusted time duration according to the 95th percentile of the second stage reported in both study groups was considerably longer than the previously reported results (Abalos et al., 2018; Oladapo et al., 2018; Zhang et al., 2002). The women who delivered by ICS may have a different labour progression pattern and duration of labour compared with the women who had vaginal births. In contrast to the analyses in the previously reported studies (Oladapo et al., 2018; Zhang et al., 2010a), our analyses included all the participating women regardless of interventions and mode of delivery, representing a real-life clinical situation. Presenting labour duration by including all women in the survival analyses and censoring for ICS allow each woman to contribute to the duration of labour with their unique time-to-event. The women who adhered to Zhang's guideline were diagnosed with labour dystocia to a larger extent than the women who adhered to the WHO partograph (47.4% vs 45.7%), which might have affected the duration of labour. Furthermore, we do not know whether shorter or longer labours affected the women's labour experience. Since a shorter duration of labour was associated with

increased use of synthetic oxytocin, and using intravenous infusion line and monitoring of the foetus limit women's mobility, it would be important to make an informed decision on a shorter labour as opposed to more medical interventions.

As shown in Table 3, most median and 95th percentile time in hours to advance from one integer centimetre to the next were longer for women who followed Zhang's guideline than for the women who adhered to the WHO partograph. For those who delivered vaginally, the unadjusted median time difference was 30 min from 4 to 5 cm of cervical dilatation between the two study groups, whereas the 95th percentile differed by 90 min. This indicates the complexity of time limits in labour duration. Even for those 5% of women in the Zhang group who took six hours or more to reach from 4 to 5 cm, the labour resulted in a vaginal delivery. This illustrates the importance of assessing labour progression on an individual level rather than using a universal progression guideline. The differences in the unadjusted median hours decreased as labour advanced, and from 8 cm of cervical dilatation onwards the intervals were equal. The findings are in accordance with the previously reported duration in contemporary research (Oladapo et al., 2017, 2018; Shi et al., 2016; Zhang et al., 2010a) except for one Japanese study (Suzuki et al., 2010) that reported an even longer duration of labour progression from one integer centimetre to the next.

When comparing the 95th percentile for the women who delivered by ICS in the two study groups, the differences were most obvious in the intervals from 5 to 6 cm and from 8 to 9 cm. The 95th percentile to reach from 8 to 9 cm was almost two hours longer for the Zhang group compared with the WHO group, despite the fact that the duration in this interval is shorter according to Zhang's guideline. Overall, the women who delivered by ICS had longer intervals from one centimetre to the next centimetre throughout labour compared with those who delivered vaginally in both study groups.

Conclusion

We found a longer overall duration of labour and duration of first and second stages when adhering to Zhang's guideline compared with the WHO partograph. The results confirm there are wide individual variations in labour patterns, illustrating the importance of assessing labour progression on an individual basis. Our randomised trial makes an important contribution by presenting the duration and transition of the different phases and stages of labour according to two different guidelines. This highlights the complexity of assessing labour progression using a universal progression guideline, and this in sum can inform clinical practice.

Ethical approval

The study, patient information and informed consent details were approved on December 11, 2013 by the Regional Committee for Medical and Health Research Ethics: (2013/1862/REK) South-East and the Norwegian Social Science Data services (NSD). The ethical approval for the baseline characteristics of the drop-out women was also obtained from the Regional Committee for Medical and Health Research Ethics. The study protocol was published in BMC Pregnancy and Childbirth, and it was also approved and signed by the management of each birth care unit before the commencement of the trial.

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Clinical trial registry and registration number

The trial was registered at www.clinicaltrials.gov (NCT02221427) before the enrolment of the participants.

Declaration of Competing Interest

The authors declare no conflict of interest.

Acknowledgment

We acknowledge the contribution of the midwives, doctors and maternity unit staff in the birth care units of all the hospitals that participated in this project. We are grateful to all the women who participated and made the trial possible. SB, PØ and EB developed the research protocol. RD, KFF and ICO performed the analysis. RD wrote the first draft of the manuscript. All the authors contributed to the interpretation of the data and also commented on and approved the final version.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:[10.1016/j.midw.2019.102578](https://doi.org/10.1016/j.midw.2019.102578).

References

- Abalos, E., Oladapo, O.T., Chamillard, M., Diaz, V., Pasquale, J., Bonet, M., ..., Gulmezoglu, A.M., 2018. Duration of spontaneous labour in 'low-risk' women with 'normal' perinatal outcomes: a systematic review. *Eur. J. Obstet. Gynecol. Reprod. Biol.* 223, 123–132. doi:[10.1016/j.ejogrb.2018.02.026](https://doi.org/10.1016/j.ejogrb.2018.02.026).
- Anim-Somuah, M., Smyth, R.M., Jones, L., 2011. Epidural versus non-epidural or no analgesia in labour. *Cochrane Database Syst. Rev.* (12), CD000331 doi:[10.1002/14651858.CD000331.pub3](https://doi.org/10.1002/14651858.CD000331.pub3).
- Bernitz, S., Dalbye, R., Oian, P., Zhang, J., Eggebo, T.M., Blix, E., 2017. Study protocol: the Labor Progression Study, Laps - does the use of a dynamic progression guideline in labor reduce the rate of intrapartum cesarean sections in nulliparous women? a multicenter, cluster randomized trial in Norway. *BMC Pregnancy Childbirth* 17 (1), 370. doi:[10.1186/s12884-017-1553-8](https://doi.org/10.1186/s12884-017-1553-8).
- Bernitz, S., Dalbye, R., Zhang, J., Eggebo, T.M., Frøslie, K.F., Olsen, I.C., ..., Øian, P., 2019. The frequency of intrapartum cesarean section use with the WHO partograph versus Zhang's guideline in the Labour Progression Study (LaPS): a multicentre, cluster-randomised controlled trial. *The Lancet* 393 (10169), 340–348. doi:[10.1016/s0140-6736\(18\)31991-3](https://doi.org/10.1016/s0140-6736(18)31991-3).
- Bugg, G.J., Siddiqui, F., Thornton, J.G., 2013. Oxytocin versus no treatment or delayed treatment for slow progress in the first stage of spontaneous labour. *Cochrane Database Syst. Rev.* 6, Cd007123. doi:[10.1002/14651858.CD007123.pub3](https://doi.org/10.1002/14651858.CD007123.pub3).
- Caughey, A.B., 2015. The safe prevention of the primary cesarean. *Clin. Obstet. Gynecol.* 58 (2), 207–210. doi:[10.1097/GRF.0000000000000111](https://doi.org/10.1097/GRF.0000000000000111).
- Dallal, G. (2008). Randomization.com. Retrieved from <http://www.randomization.com>
- Friedman, E., 1954. The graphic analysis of labor. *Am. J. Obstet. Gynecol.* 68 (6), 1568–1575.
- Grant, E.N., Tao, W., Craig, M., McIntire, D., Leveno, K., 2015. Neuraxial analgesia effects on labour progression: facts, fallacies, uncertainties and the future. *BJOG* 122 (3), 288–293. doi:[10.1111/1471-0528.12966](https://doi.org/10.1111/1471-0528.12966).
- Hanley, G.E., Munro, S., Greyson, D., Gross, M.M., Hundley, V., Spiby, H., Janssen, P.A., 2016. Diagnosing onset of labor: a systematic review of definitions in the research literature. *BMC Pregnancy Childbirth* 16, 71. doi:[10.1186/s12884-016-0857-4](https://doi.org/10.1186/s12884-016-0857-4).
- Hernan, M.A., Hernandez-Diaz, S., Werler, M.M., Mitchell, A.A., 2002. Causal knowledge as a prerequisite for confounding evaluation: an application to birth defects epidemiology. *Am. J. Epidemiol.* 155 (2), 176–184.
- Neal, J.L., Lowe, N.K., Patrick, T.E., Cabbage, L.A., Corwin, E.J., 2010. What is the slowest-yet-normal cervical dilation rate among nulliparous women with spontaneous labor onset? *J. Obstet. Gynecol. Neonatal Nurs* 39 (4), 361–369. doi:[10.1111/j.1552-6909.2010.01154.x](https://doi.org/10.1111/j.1552-6909.2010.01154.x).
- Neal, J.L., Lowe, N.K., Schorn, M.N., Holley, S.L., Ryan, S.L., Buxton, M., Wilson-Liverman, A.M., 2015. Labor dystocia: a common approach to diagnosis. *J. Midwifery Womens Health* 60 (5), 499–509. doi:[10.1111/jmwh.12360](https://doi.org/10.1111/jmwh.12360).
- NICE guidelines. (2014, 2017). Intrapartum care. Clinical Guidelines, Intrapartum Care Retrieved from <https://www.nice.org.uk/guidance/cg190>.
- Norwegian Medical Association. (2014). Augmentation of labor. Retrieved from <http://www.nfог.org/files/guidelines/34%20NGF%20Obst%20Augmentation%20of%20labour%20Eggeb%20C3%B8.pdf>
- Oladapo, O.T., Diaz, V., Bonet, M., Abalos, E., Thwin, S.S., Souza, H., ..., Gulmezoglu, A.M., 2017. Cervical dilatation patterns of 'low-risk' women with spontaneous labour and normal perinatal outcomes: a systematic review. *BJOG* 125 (8), 944–954. doi:[10.1111/1471-0528.14930](https://doi.org/10.1111/1471-0528.14930).
- Oladapo, O.T., Souza, J.P., Fawole, B., Mugerwa, K., Perdon, G., Alves, D., ..., Gulmezoglu, A.M., 2018. Progression of the first stage of spontaneous labour: a prospective cohort study in two sub-Saharan African countries. *PLoS Med.* 15 (1), e1002492. doi:[10.1371/journal.pmed.1002492](https://doi.org/10.1371/journal.pmed.1002492).
- Philpott, R.H., Castle, W.M., 1972a. Cervicographs in the management of labour in primigravidae. I. The alert line for detecting abnormal labour. *J. Obstet. Gynaecol. Br Commonw.* 79 (7), 592–598.
- Philpott, R.H., Castle, W.M., 1972b. Cervicographs in the management of labour in primigravidae. II. The action line and treatment of abnormal labour. *J. Obstet. Gynaecol. Br Commonw.* 79 (7), 599–602.
- Robson, M., Murphy, M., Byrne, F., 2015. Quality assurance: the 10-Group classification system (Robson classification), induction of labor, and cesarean delivery. *Int. J. Gynaecol. Obstet.* 131 (Suppl 1), S23–S27. doi:[10.1016/j.ijgo.2015.04.026](https://doi.org/10.1016/j.ijgo.2015.04.026).
- Shi, Q., Tan, X.Q., Liu, X.R., Tian, X.B., Qi, H.B., 2016. Labour patterns in Chinese women in Chongqing. *BJOG* 123 (Suppl 3), 57–63. doi:[10.1111/1471-0528.14019](https://doi.org/10.1111/1471-0528.14019).
- Souza, J.P., Oladapo, O.T., Fawole, B., Mugerwa, K., Reis, R., Barbosa-Junior, F., ... Gulmezoglu, A.M., 2018. Cervical dilatation over time is a poor predictor of severe adverse birth outcomes: a diagnostic accuracy study. *BJOG* 125 (8), 991–1000. doi:[10.1111/1471-0528.15205](https://doi.org/10.1111/1471-0528.15205).
- Stedman, M.R., Lew, R.A., Losina, E., Gagnon, D.R., Solomon, D.H., Brookhart, M.A., 2012. A comparison of statistical approaches for physician-randomized trials with survival outcomes. *Contemp. Clin. Trials* 33 (1), 104–115. doi:[10.1016/j.cct.2011.08.008](https://doi.org/10.1016/j.cct.2011.08.008).
- Suzuki, R., Horiuchi, S., Ohtsu, H., 2010. Evaluation of the labor curve in nulliparous Japanese women. *Am. J. Obstet. Gynecol.* 203 (3). doi:[10.1016/j.ajog.2010.04.014](https://doi.org/10.1016/j.ajog.2010.04.014), 226 e221–226.
- Vahratian, A., Troendle, J.F., Siega-Riz, A.M., Zhang, J., 2006. Methodological challenges in studying labour progression in contemporary practice. *Paediatr Perinat Epidemiol* 20 (1), 72–78. doi:[10.1111/j.1365-3016.2006.00696.x](https://doi.org/10.1111/j.1365-3016.2006.00696.x).
- World Health Organization, 1994. World health organization partograph in management of labour. world health organization maternal health and safe motherhood programme. *Lancet* 343 (8910), 1399–1404.
- World Health Organization. (2000, 2007). Managing complications in pregnancy and childbirth: a guide for midwives and doctors. Retrieved from http://whqlibdoc.who.int/publications/2007/9241545879_eng.pdf
- World Health Organization. (2018). WHO recommendations: intrapartum care for a positive childbirth experience. Retrieved from <http://apps.who.int/iris/bitstream/handle/10665/260178/9789241550215-eng.pdf;jsessionid=F1F5397399F448885328491174AC61C6?sequence=1>
- Zhang, J., Landy, H.J., Branch, D.W., Burkman, R., Haberman, S., Gregory, K.D., ... Consortium on Safe, L., 2010a. Contemporary patterns of spontaneous labor with normal neonatal outcomes. *Obstet. Gynecol.* 116 (6), 1281–1287. doi:[10.1097/AOG.0b013e3181fdef6e](https://doi.org/10.1097/AOG.0b013e3181fdef6e).
- Zhang, J., Troendle, J., Mikolajczyk, R., Sundaram, R., Beaver, J., Fraser, W., 2010b. The natural history of the normal first stage of labor. *Obstet. Gynecol.* 115 (4), 705–710. doi:[10.1097/AOG.0b013e3181d55925](https://doi.org/10.1097/AOG.0b013e3181d55925).
- Zhang, J., Troendle, J.F., Yancey, M.K., 2002. Reassessing the labor curve in nulliparous women. *Am. J. Obstet. Gynecol.* 187 (4), 824–828.